



Cedex Bio HT Analyzer Operator's Manual

Software Version 5.1

November 2020

How to Use the Cedex Bio HT Analyzer Guides



Before reading, please review the section "Revisions" for important information.

User Training Guide

Provides detailed step-by-step instructions for routine operation using the main applications of the Cedex Bio HT Analyzer, including instrument startup and shutdown.

Operator's Guide

Provides a detailed description of the Cedex Bio HT Analyzer, system components and all relevant software information not covered by the User Training Guide. For installation requirements, always refer to the Operator's Guide.

Revisions

Provides updates to the Cedex Bio HT Analyzer Guides, including new supplementary information and corrections to previous editions.

Revisions

J

Use this section of the manual as a repository for updates to the Cedex Bio HT Analyzer Operator's Manual. You can also use this section to insert your own notes about the system, so that all information about the system is in one place.

Revisions

This chapter contains amendments to the *Cedex Bio HT Analyzer* Operator's Manual and the *Cedex Bio HT Analyzer* User Training Guide.

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Changes in *Cedex Bio HT Analyzer* Guides 1.4

Manual	Manual Version	Software Version	Revision Chapter Version	Revision Date
<i>Cedex Bio HT Analyzer</i> Operator's Manual	1.4.1	5.1	1.0	November 2020
<i>Cedex Bio HT Analyzer</i> User Training Guide	1.3.1	5.1	1.0	November 2020

In order to ensure that the readers of the Cedex Bio HT Analyzer User Manual use the up-to-date content, Roche recommends to manually mark the affected passage in the original manual.

► **To update the *Cedex Bio HT Analyzer* User Guides**

- 1 In the current chapter *Revisions*, go to the first change.
- 2 Familiarize yourself with the items that changed.
- 3 Identify the page number affected in the original manual.
- 4 Go to the appropriate page in the original and manually mark the changes. For example cross out text that is no longer applicable or add a reference where to find new and changed content.



If you print these pages, Roche recommends printing them single-sided. This way you can easily insert them in the existing manual.

Structure of a change entry

The following illustration explains how changes are presented.

Cedex Bio HT Analyzer

A

Change 6

Safety statement about software and data security updated

B

C

Affected pages: 28-29

Software and data security

Revision: Safety statement about software and data security updated (several changes)

Unauthorized system access and data loss

External storage devices can transmit computer malware, which may be used to gain unauthorized access to data or cause unwanted changes to software.
The system is not protected against malicious software and hacker attacks.

- Physical access to the product and all attached IT infrastructure (including analyzer, computer systems, cables, network equipment, etc.) must be restricted at all times.
- A Roche-provided firewall is mandatory if the system is connected to a network to protect and separate Roche systems from other laboratory infrastructure.
- The laboratory network and any laboratory infrastructure must be secured against unauthorized access, malicious software, and cyber-attacks.
- All devices and services used in the customer lab infrastructure must be safe and secured against malicious software and unauthorized access.
- A secure network environment which is resilient to traffic redirection and eavesdropping must be installed.

Roche recommends the following precautions:

- Do not copy or install any software on the system unless it is part of the system

D

E

A

Change ID.

B

Change summary.

C

Pages that are affected in the manual.

D

An indication of the nature of the change immediately precedes the changed or new element(s).

E

Changed element(s).

Change 1

Changing password after initial installation

Affected page: Operator's Manual, page 10

Revision: New security statement added

For security reasons, the administrator should protect the access to the Cedex Bio HT Software with a new password after initial installation.

👁 For details, see Cedex Bio HT Analyzer Operator's Manual "Assigning and deleting user details".

Change 2

Warning statement added to inform about flammable refrigerant

Affected page: Operator's Manual, page 23

Cauterizing and toxic materials*Reagents and toxic chemicals*

Contact with cauterizing or toxic material may result in injury.

- Follow standard laboratory practices.
- Wear appropriate personal protective equipment.
- If cauterizing or toxic material is spilled, wipe it up immediately and apply a disinfectant.
- If cauterizing or toxic material comes into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant. Consult a physician.

Flammable materials**Revision:** New warning statement added*Flammable refrigerant*

There is a risk of fire or explosion due to the use of flammable refrigerant.

- All ventilation openings must be clear of obstructions.
- Do not use mechanical devices or other means to accelerate the defrosting process other than the ones recommended by the manufacturer.
- Do not damage the refrigerant circuit.
- Dispose of properly in accordance with federal or local regulations.

Change 3 Caution statement added to inform about sharps, rough edges, and/or moving parts

Affected page: Operator's Manual, page 25

Mechanical safety

*Personal injury and infection
due to sharps, rough edges,
and/or moving parts*

Revision: New caution statement added

Good Laboratory Practice can reduce the risk of injury. Be aware of your laboratory environment, well-prepared, and follow the instructions for use. Some areas of the instruments may have sharps, rough edges, and/or moving parts. Wear personal protective equipment to minimize the risk of injury from bodily contact with such parts, especially in less accessible areas, or while cleaning the instrument. Your personal protective equipment should be appropriate to the degree and type of potential hazard, e. g. suitable lab gloves, eye protection, lab coat, and footwear.

Change 4 Safety statement about software and data security updated

Affected pages: Operator's Manual, page 28-29

Software and data security

Revision: Safety statement about software and data security updated (several changes)*Unauthorized system access and data loss*

External storage devices can transmit computer malware, which may be used to gain unauthorized access to data or cause unwanted changes to software.

The system is not protected against malicious software and hacker attacks.

- Physical access to the product and all attached IT infrastructure (including analyzer, computer systems, cables, network equipment, etc.) must be restricted at all times.
- A Roche-provided firewall is mandatory if the system is connected to a network to protect and separate Roche systems from other laboratory infrastructure.
- The laboratory network and any laboratory infrastructure must be secured against unauthorized access, malicious software, and cyber-attacks.
- All devices and services used in the customer lab infrastructure must be safe and secured against malicious software and unauthorized access.
- A secure network environment which is resilient to traffic redirection and eavesdropping must be installed.

Roche recommends the following precautions:

- Do not copy or install any software on the system unless it is part of the system software or your Roche representative tells you to do so.
- If extra software is required, contact your Roche representative to ensure validation of the software in question.
- Do not use the USB ports to connect other storage devices unless your Roche representative or an operating instruction tells you to do so.
- Exercise care when you use external storage devices such as USB drives or DVDs. Do not connect to the system any external storage device that you use on public or home computers.
- Keep all external storage devices in a secure place, and make sure that only authorized personnel can access them.
- Back up your data regularly.

Cybersecurity and privacy awareness

- Perform regular security and privacy awareness trainings for the users to ensure that personal data is handled in a compliant way and in accordance with the privacy principles that are mandatory by customer regulations.
- Check your analyzer for suspicious activity and report any suspected compromise immediately to your local Roche representative.
- Update to latest software versions provided by Roche as soon as possible.
- Read and follow the recommendations and advices written in this chapter.

<i>Backup security</i>	The following precautions are mandatory: • Only use virus free external storage devices for backup purposes. • Transmit backup data to external storage devices via secure networks only. • Any data backup and data archive that has been exported from the analyzer must be physically securely stored and protected from any unauthorized access. • Data access to any data backup or data archive is permitted to authorized persons only. • Ensure that data backup and data archives are not taken from the safe and secure storage location.
<i>Data transfer and data entry on analyzer</i>	• Writing patient sensitive information in comment fields can violate patient health information protection laws. Do not write any patient sensitive information into comment fields, if these laws are applicable for your country. • Do not download from any host system (e.g. LIS, middleware) any patient sensitive data to the analyzer. • Data transfer using any host protocol (e.g. HL7, ASTM) is not encrypted; data is transferred as plain text and readable with IT tools like sniffers.
<i>Corrupt data due to a disclosed password</i>	The security of the system and its data depends on the password-protected access. If an unauthorized person discovers your user ID and password, they could compromise this security. • Always enter your password unobserved. • Do not write down your password anywhere, including in a contact form, in the address book, or in a file on the computer. • Do not disclose your password to anyone. Roche will never ask you for your password. • Do not use shared accounts. • If you ever disclose your password to anyone, change it immediately afterwards. • Contact your local Roche affiliate if you think your account has been compromised. • Use a personal user account for each user with appropriate user level. • Delete any unused user accounts from the analyzer (for example, when a user left).
<i>Corrupt data and unauthorized access due to faulty media converters</i>	Media converters may influence the signal quality and corrupt data. When using an RS232 to Ethernet media converter at the host interface, there is a possibility of unauthorized access to and modification of the data that are transmitted over the network. Roche shall not be held liable for possible data corruption associated with media converters.
<i>Unreliable data due to low quality connectors</i>	Using cable connections to the host that are not well shielded may lead to absence or instability of connection or to corrupt data. • Always use well shielded RS232 cables for host connection.
<i>Non-approved third-party software</i>	Installation of any third-party software that is not approved by Roche Diagnostics may result in incorrect behavior by the system. • Install only approved third-party software.

Unreliable validation due to unauthorized changes to the validation settings

The manufacturer shall not be held liable for any consequences resulting from subsequent, unauthorized modifications to the accepted validation settings included in the system at the customer's request.

- Ensure that only authorized personnel can change, if necessary, the validation settings.

Unreliable validation due to unauthorized changes to the validation and calculation rules

The manufacturer shall not be held liable for any consequences resulting from subsequent, unauthorized modifications to the accepted validation and calculation rules included in the system at the customer's request, as well as test results.

- Ensure that only authorized personnel can change, if necessary, the validation and calculation rules, and test results.

Change 5

Information added about two new safety labels on the system informing about flammable refrigerant

Affected page: Operator's Manual, page 30

**Biohazard**

Potentially biohazardous materials are used near this label.
Observe relevant good laboratory practices on safe usage.

Revision: Information about two new safety labels on the system added**Flammable**

There is a risk of fire or explosion near this label.

Flammable refrigerant in the cooling unit used.

Type of refrigerant R600a.

To be repaired only by trained service personnel. Do not puncture refrigerant tubing.

Consult Instruction Manual / Repair Manual / Owner's Guide before attempting to install or service this product. All safety precautions must be followed.

Dispose of properly in accordance with federal or local regulations.

"DANGER - Risk Of Fire Or Explosion. Flammable Refrigerant Used. To Be Repaired Only By Trained Service Personnel. Do Not Puncture Refrigerant Tubing", and, for C-UL, "DANGER - RISQUE DE FEU OU D'EXPLOSION. LE FRIGORIGÈNE EST INFLAMMABLE. CONFIER LES RÉPARATIONS À UN TECHNICIEN SPÉCIALISÉ. NE PAS PERFORER LA TUBULURE CONTENANT LE FRIGORIGÈNE"

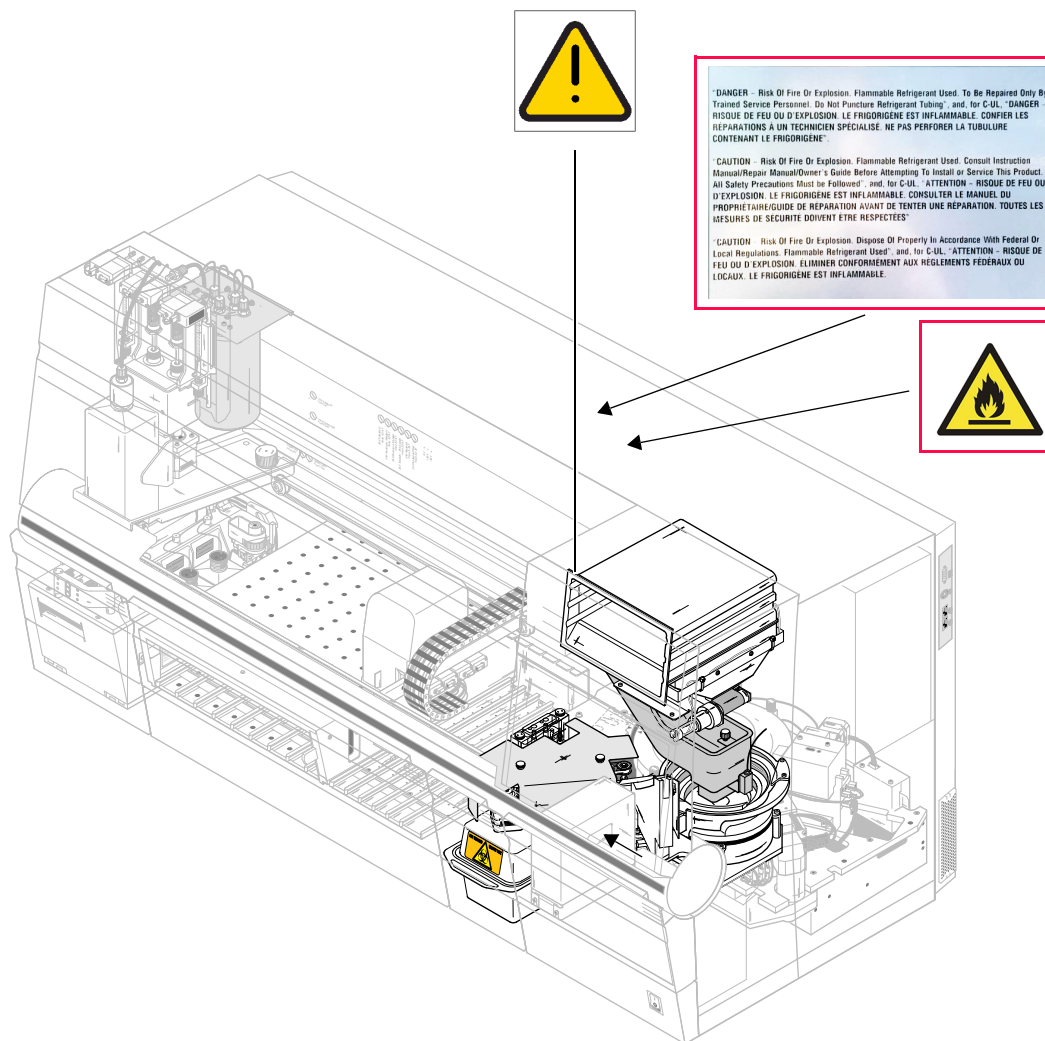
"CAUTION - Risk Of Fire Or Explosion. Flammable Refrigerant Used. Consult Instructions Manual/Repair Manual/Owner's Guide Before Attempting To Install or Service This Product. All Safety Precautions Must be Followed", and, for C-UL, "ATTENTION - RISQUE DE FEU OU D'EXPLOSION. LE FRIGORIGÈNE EST INFLAMMABLE. CONSULTER LE MANUEL DU PROPRIÉTAIRE/GUIDE DE RÉPARATION AVANT DE TENTER UNE RÉPARATION. TOUTES LES MESURES DE SÉCURITÉ DOIVENT ÊTRE RESPECTÉES"

"CAUTION - Risk Of Fire Or Explosion. Dispose Of Properly In Accordance With Federal Or Local Regulations. Flammable Refrigerant Used", and, for C-UL, "ATTENTION - RISQUE DE FEU OU D'EXPLOSION. ÉLIMINER CONFORMÉMENT AUX RÈGLEMENTS FÉDÉRAUX OU LOCAUX. LE FRIGORIGÈNE EST INFLAMMABLE."

Change 6

Label position of the two new safety labels added

Affected page: Operator's Manual, page 33

Revision: Indications of two new labels added**Figure 1**

Labels on cuvette feeder and on the back of the instrument

Change 7

The water purity must have a maximum microbiological content of 100 colony forming units per milliliter

Affected page: Operator’s Manual, page A-50

The water quality must fulfill the following requirements:

Purity	Revision: "type I NCCLS" removed Laboratory Reagent Grade, bidistilled or deionized water: >0.6MΩcm or <1.5 μS/cm <0.05 Silicate (mg/L, as SiO ₂) Revision: "10 colony forming units/mL" changed to "100 colony forming units/mL" Maximum microbiological content of 100 colony forming units/mL. Particulate matter (>0.2 μm) <500/L. Organic compound via activated carbon treatment.
Supply	From external reservoir or via direct connection to deionized water supply (optional).
Usage/Drainage	Approximately 2 L/h (0.53 US gallon/h) in operating mode
Minimum flow rate	0.2 L/min (0.053 US gallon/min)

Table A-27 Water quality requirements

Change 8

Information about water quality changed

Affected pages: several pages in the Operator's Manual

Revision: Information about water quality changed

In all relevant places in the Operator's Manual, the statement "Water must be reagent grade, type I." is replaced with "Use the water quality as specified in Table A-27 on page A-50."

Change 9Information about **Importing orders using Excel** added

Affected page: Operator's Manual, page B-59

Importing orders using Excel

Revision: New section "Importing orders using Excel" added

Use the **Import Orders from File** function to conveniently import order data using Excel files. To create an order import file, use the Excel template provided and adapt the template with the required order information.



- Use only the provided Excel template "OrderImport_ExampleTemp.xlsx" to create a new order import file.
- Ensure that you are using the correct Excel template for software version 5.1. Templates designed for software version 6.0 are not compatible with software version 5.1.

► **To prepare the order import file**

- 1 Copy the Excel template "OrderImport_ExampleTemp.xlsx" from the Cedex Bio HT Analyzer control unit to a separate computer that has Excel installed. The Excel template is located on the control unit on the C drive:
C:\Roche\Instrument\OrderImport

- 2 Open the template, add all sample and order information, and store the order import file using a meaningful name.

When using the template, carefully read the template instructions provided in the Excel file. Especially note the following:

- Do not change the column position or column number in the template.
 - Row 10 is the first row that can be used to enter data. Do not insert rows before row number 10.
 - There are mandatory and optional fields. Do not leave mandatory fields empty.
 - Use only unique sample IDs. Ensure that sample IDs entered into the template are not identical to any IDs on the order list.
 - Ensure that all selected test and profile IDs refer to tests and profiles installed on the system.
 - Order date is automatically set to the current date.
- 3 Copy the order import file to the Cedex Bio HT Analyzer control unit to:
C:\Roche\Instrument\OrderImport.

► **To load the order import file**

- 1 On the Cedex Bio HT Analyzer control unit, choose **Tools > Import Orders from File**.

A dialog box is displayed.

- 2 Load the order import Excel file that is located in C:\Roche\Instrument\OrderImport.



It is possible to store the Excel file in other locations, such as an USB drive, and load the file directly from the stored location.

The **Import Orders from File** dialog box is displayed, listing all orders from the Excel file.

- 3 Check that all orders are OK and click **Start**.

The orders are imported. Successfully imported orders are marked in green.

- 4 If rows could not be imported, a dialog box is displayed indicating which order rows not have been imported. Click **OK** to confirm the dialog box.



Software 5.1 does not provide information about why ordered rows were not accepted. Check carefully that all instructions have been followed. Ensure that the racks and rack positions chosen for the samples are empty, and that the racks are not loaded and locked on the instrument.

- 5 Create a new order import Excel file for the samples that not have been imported and repeat steps 1 to 3.

Change 10

Tip added to advise the user that the system must be in Standby state when creating a problem report

Affected page: Operator's Manual, page E-44

Creating a problem report

You can create a problem report on an external storage device. This report collates all the messages and other system information that the Roche representatives will need if you cannot solve a particular problem on your own. You should create the report (if possible) before contacting your Roche representative.

Revision: New tip added



It is essential that the problem report is only created when the system is in **Standby** state.

► **To create a problem report on an external storage device**

1 Click the **Messages** button on the navigation bar.

2 Click the **Options** tab.

3 Click **Problem Report**.

The **Create problem report** dialog box is displayed.

When the report is created, a message is displayed asking you whether you want to store the report on an external storage device.

4 On the **Create problem report** dialog box, click **Yes**.

A message is displayed asking you to insert an external storage device.

5 When you are asked to do so, insert an external storage device.

6 On the message dialog box, click **OK**.

7 On the **Save problem report** dialog box, navigate to the required folder and click **Save**.

When the report is stored on the external storage device, a message is displayed asking you to remove the external storage device.

8 When you are asked to do so, remove the storage device.

9 On the message dialog box, click **OK**.



Complementary information

- A copy of the problem report is automatically stored as a .zip file on the desktop, in the folder Problem Report. To access the desktop, press Windows + D.
 - You can also create a problem report from the message dialog box, for some types of messages.
 - Contact your Roche representative, and send the report to the address your are given.
 - If you turn off the main switch and turn on again, you may get a message prompting you to create a problem report before the system re-initializes. You can ignore this message.
-

Change 11

Tip added to advise the user that the system must be in Standby state when creating a problem report

Affected page: User Training Guide, page 41

Creating a problem report

When the system produces an error message that you cannot resolve, create a problem report. Send the report to the local Roche representative, along with a problem description, to help resolve the issue.

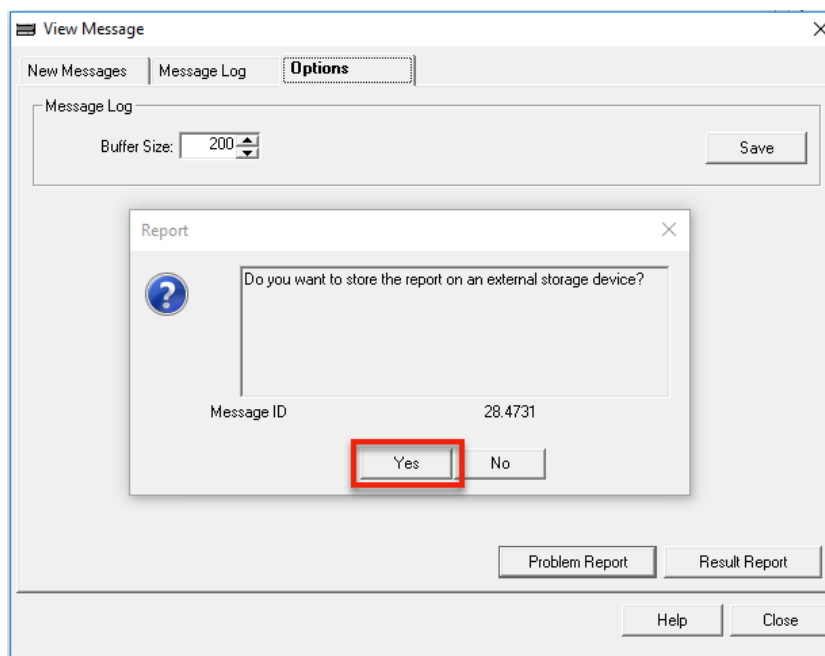
Revision: New tip added



It is essential that the problem report is only created when the system is in **Standby** state.

► **To create a problem report**

- 1 Click on Messages in the navigation bar. The **View Message** dialog box opens.
- 2 In the dialog box, select the **Options** tab.
- 3 Insert a USB stick at the USB port.
- 4 Click on the **Problem Report** button. A problem report is generated and a **Report** dialog box opens, asking whether you want to store the report on an external storage device.



5 Click on **Yes**.

The Report will automatically be saved on the external device you inserted beforehand.

6 Forward the PR.ZIP file copied to the USB stick to your local Roche representative.

Change 12

Language parameter

A system restart is required after changing the language of the software

Affected page: Operator's Manual, page G-42

Alert Sound Frequency Default: 2000 Hz**Revision:** Information added that a restart after a language change is required*Language* Default: **English**

Selected the language versions of the software from the list and restart the system to update all functionalities.

This function does not depend on the user access level.

Changes in Cedex Bio HT Analyzer Guides 1.4

Cedex Bio HT Analyzer

User Training Guide

Document information

Revision history

Version	Software version	Revision date	Changes
1.0	5.0	March 2015	First publication.
1.1	5.0	December 2016	Adjustment of regulations
1.3	5.1	March 2018	Updates to new SW version 5.1

Edition notice

The Cedex Bio HT Analyzer User Training Guide is for users of the Cedex Bio HT Analyzer running software version 5.1, together with the Cedex Bio HT Operator's Manual version 1.4 for software version 5.1.

Every effort has been made to ensure that all the information contained in the Cedex Bio HT Analyzer User Training Guide is correct at the time of printing. However, Roche Diagnostics GmbH reserves the right to make any changes necessary without notice as part of ongoing product development.

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Instrument approvals

The *Cedex Bio HT* analyzer meets the protection requirements laid down in:

- Directive 2014/30/EU of the European Parliament and Council of 26 February 2014 relating to electromagnetic compatibility (EMC).
- Directive 2014/35/EU of the European Parliament and Council of 26 February 2014 relating to electrical equipment designed for use within certain voltage limits.
- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Compliance is provided by means of the Declaration of Conformity.

Regulatory compliance is demonstrated by the following marks:



Complies with the provisions of the applicable EU directives. RoHS compliant from Serial No. 610001.



Issued by Underwriters Laboratories, Inc. (UL) for Canada and the US. 'Laboratory Equipment' is the product identifier as shown on the type plate.

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Preface

Intended use

The Cedex Bio HT Analyzer is a fully automated, computerized analyzer for professional use. It is intended for determination of a wide range of analytes in various aqueous solutions such as cell culture and fermentation media.

For use in quality control/manufacturing process only.

Preamble

Before setting up operation of the Cedex Bio HT Analyzer, it is important to read this User Training Guide and the Cedex Bio HT Operator's Manual thoroughly and completely. Non-observance of the instructions contained herein or performing an operation not stated in this User Training Guide could cause safety hazards.

Conventions used in this guide

Please refer to the preface of the latest version of the Cedex Bio HT Operator's Manual for symbols, user interface conventions, units, abbreviations and acronyms.

Warnings and precautions



General attention

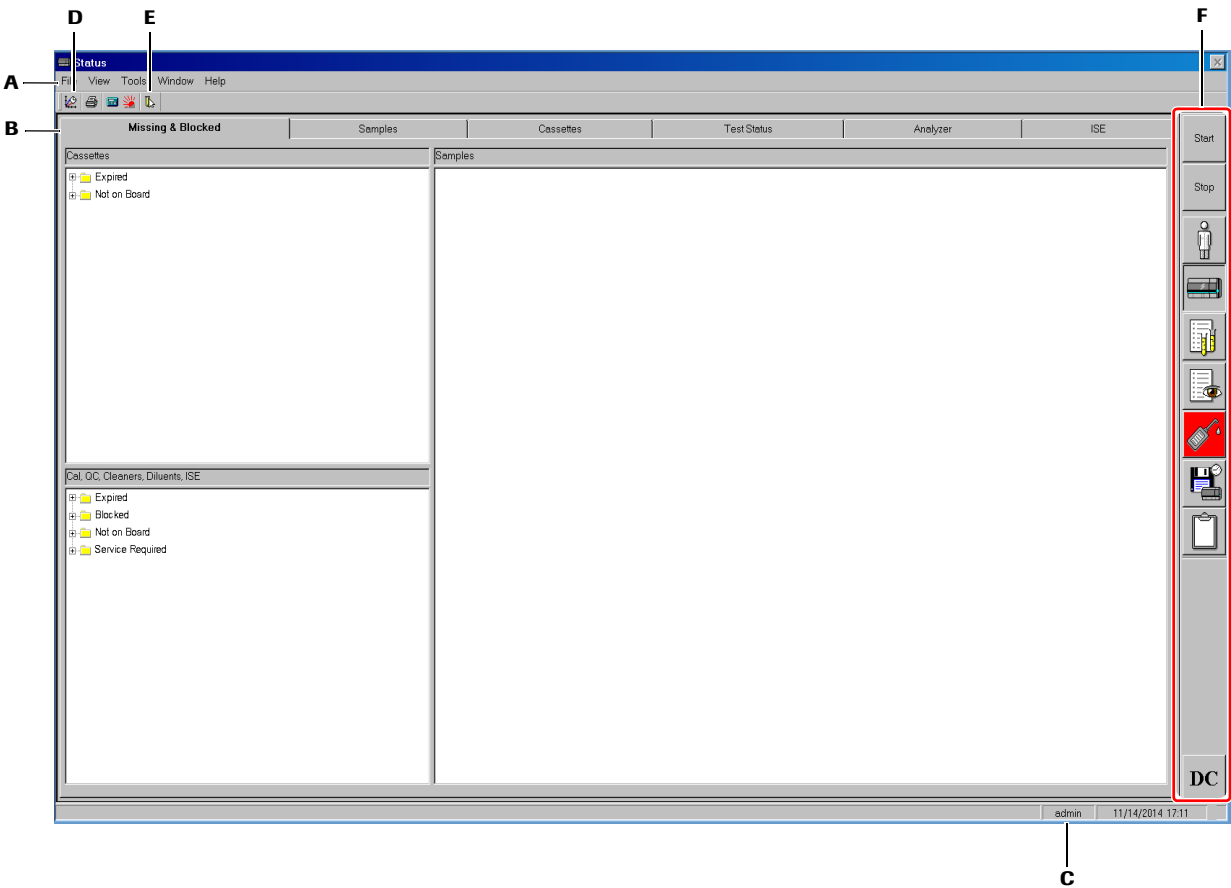
To avoid serious or fatal injury, read this publication and the Cedex Bio HT Operator's Manual thoroughly before you use the analyzer.

- Pay particular attention to all safety precautions.
- Always follow the instructions in this publication.
- Do not use the analyzer in a way that is not described in this publication.
- Keep this publication in a safe place to ensure that it is not damaged and remains available for use.
- This publication must always be easily accessible.

Before operating the system, read all safety messages carefully in the Chapter "Safety", located in the latest Cedex Bio HT Operator's Manual, for safety classifications, safety information, software virus warning, safety labels, and safety information for laser transmitters.

A Startup

Overview of user interface and button functions



- A

Menu bar
- B

Tabs (individual for each control menu)
- C

Logged in user
- D

Calibrations
- E

Place items
- F

Navigation bar

Figure 1 Overview of user interface

Button	Name	Function
	Start (F11)	- Start a run. - Wake up analyzer (sleep → standby).
	Stop (F12)	- Terminate a run. - Put analyzer in sleep mode (standby → sleep).
	Messages	- View messages. - Create problem report.
	Status	- Overview of system status and resources - Status of ISE unit.
	Orders	Order calibrations, controls, and analysis of samples.
	Results	View results of calibrations, controls, and analysis of samples.
	Service	Monitor and perform required maintenance procedures.
	System configuration	- Change system configuration. - Change calibrator and control lots.
	Memo Pad	Leave a message for colleagues.

Table 1 Main buttons and their functions

Preparing the Cedex Bio HT Analyzer for daily use

Follow the step-by-step instructions in this section to prepare the Cedex Bio HT Analyzer before starting to work with the instrument.

Logging on



The Cedex Bio HT Analyzer and control unit should be left on at all times. Therefore, it is generally not necessary to turn on the system before starting to work with it.

► To log on

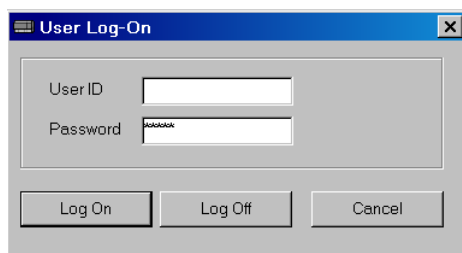
- 1 Press Shift + F3.

The **User Log-on** dialog box appears.

- 2 Enter your user ID and password.

The user ID and password defined by default are:

- **User ID:** admin (case sensitive)
- **Password:** ADMIN (case sensitive)



- 3 Click **Log On**. The logged in user is indicated in the bottom right-hand corner of the main user interface



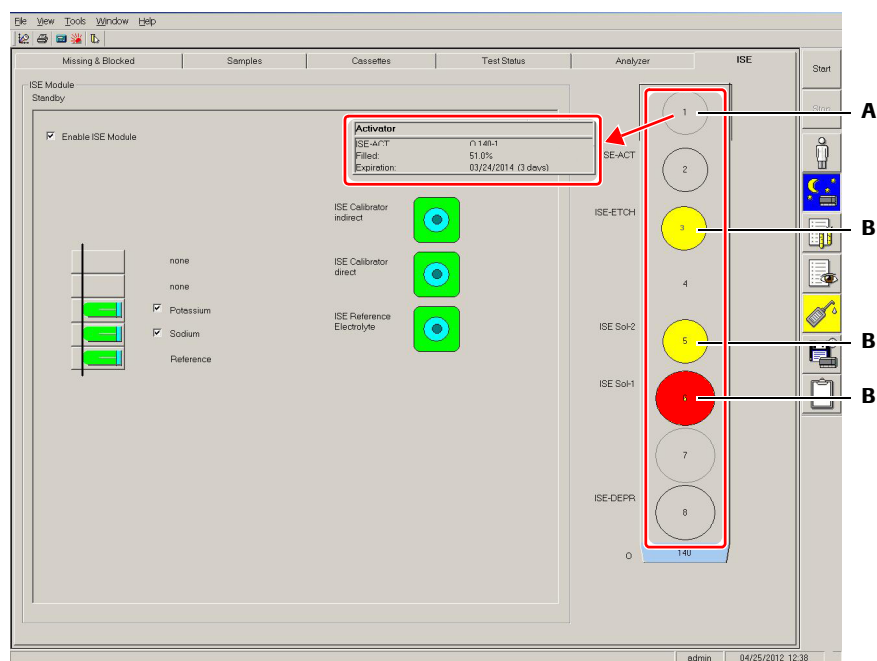
If you are not logged into the system, the buttons on the navigation bar on the right-hand side of the user interface will be greyed out, and you will not be able to work with the analyzer.



Checking and refilling reagents on the ISE rack

► To check and refill reagents on the ISE rack

- 1 Click on **Status** in the navigation bar and select the **ISE** tab.
- 2 Double-click on a circle (A) to display information on filling status and onboard stability.
- 3 Replace all reagents marked in yellow or red (B) on the **ISE rack** screen.



A Double-click on a reagent to display detailed information

B Replace reagents that are marked in yellow or red

Figure 2 Refilling reagents on ISE rack

■

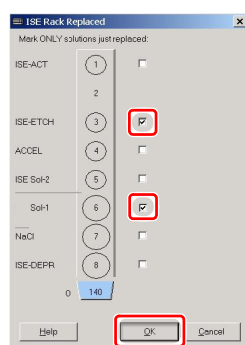
► **To replace a reagent on the ISE rack**

- 1 Remove the ISE rack.
- 2 Remove old reagent bottles and place new bottles in the assigned positions on the ISE rack.



Reagents are assigned to specific positions on the ISE rack. Ensure that the reagents are placed in the correct positions (see Figure 2 on page 11).

- 3 Re-insert the ISE rack.
- 4 The system automatically detects when the ISE rack has been re-inserted, and the **ISE Rack Replaced** dialog appears. In the dialog box, put a check mark next to the check box for all solutions that have been replaced, and confirm the replacement by clicking on **OK** in the bottom right-hand corner.

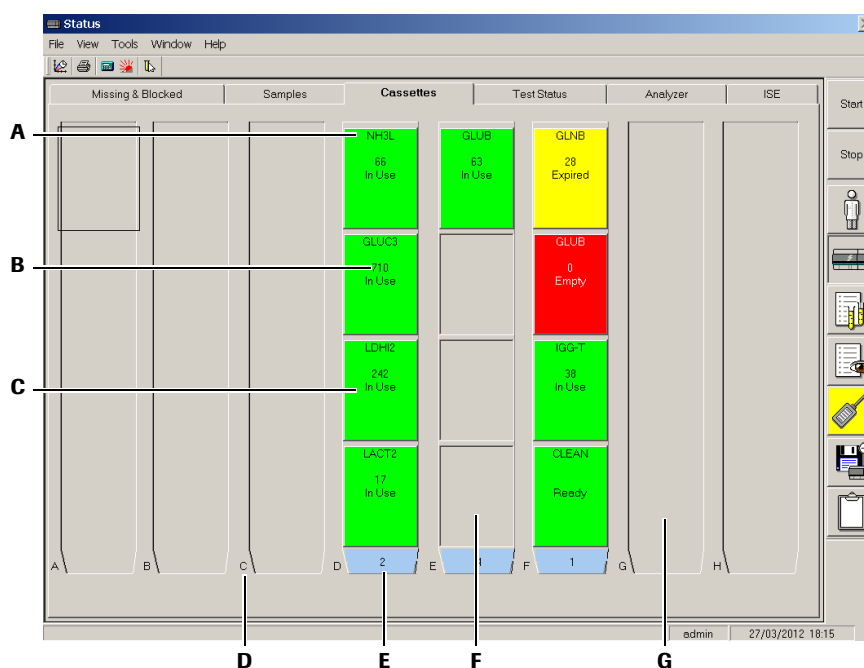


Checking and replacing test cassettes

► To check and replace a test cassette

- 1 Click on **Status** in the navigation bar and select the **Cassettes** tab.
- 2 Replace all test cassettes that are expired or close to empty, marked in yellow or red in the software.

👁 For details, see *To replace a test cassette* on page 13



- | | |
|---|-------------------------|
| A Cassette name | E Rack number |
| B Number of tests left in the cassette | F Empty position |
| C Cassette status | G Empty slot |
| D Slot ID | |

Figure 3 Checking and replacing test cassettes

- 3 Check all other cassettes and estimate whether the number of tests left will be enough for the working day. If not, add additional cassettes, and perform relevant calibrations and controls, if required.

👁 *To define a new calibrator lot on page 34*

To define a new control lot on page 36

To calibrate a cassette that is not yet in use on page 38

■

► To replace a test cassette

- 1 Remove the relevant cassette rack, and remove test cassettes that are marked in yellow or red in the software.
- 2 Place a new test cassette into the rack.
- 3 Re-insert the rack into the instrument. The analyzer will automatically detect which cassettes have been replaced and update the corresponding information in the **Cassettes** tab.

■

Checking the system and resources

The **System** button, located on the navigation bar, changes with regard to the icon displayed and background color, depending on the system status and whether any actions are required. The table below provides an overview of the icons and background colors that may be displayed, as well as required actions.

Perform all required actions indicated by the displayed icon.

👁 For more information about the actions described in Table 2, refer to the Cedex Bio HT Operator's Manual .

Status icon	Required action
 Operating	The system is in operating mode. No action required.
 Standby	The system is in standby mode. No action required.
 Cleaner	Check filling status of cleaner bottle and replace if necessary.
 Cuvettes	Check filling status of cuvette reservoir and replace if necessary.
 Water	Check filling status of external water reservoir and refill with water if necessary.
 Liquid waste	Empty the external waste reservoir.
 Cuvette waste	Replace the cuvette waste box.
 Temperature	Check temperature of analyzer, cassettes, and cleaner.
 ISE Unit	Check status of solutions on the ISE rack and electrodes. Refill ISE solutions or refer to the Cedex Bio HT Operator's Manual for further instructions.

Table 2 Status icons



Liquid waste from ISE measurements and calibrations is collected in the cuvette waste container. However, the instrument only counts sample measurements and used cuvettes. Check the filling status of the cuvette container regularly, even if the system does not indicate that the cuvette waste needs to be changed. If the ISE unit is not installed, this action is not necessary.

Performing service actions

The instrument automatically performs certain service actions at the beginning of the work day, at the Begin of Day (BOD) time, which is defined in the system configuration. These service actions are displayed in the **Service** window under the **Begin of Day** tab.

All other service actions that are due must be initiated by the user before starting to work with the instrument.



The instrument can only perform the Begin of Day actions if enough of the required solutions (e.g., Activator Bio) are available on the system, and the solutions are not expired. Therefore, it is essential to check resources on a daily basis.

► To perform a service action

- 1 Click on **Service** in the navigation bar and select the **Due** tab. The instrument will display maintenance actions that need to be performed.

Two types of service actions are shown in the **Due** tab:

- After the service action is initiated by the user, the action is automatically performed by the system without further user interference.
- Hands-on user intervention is required to perform the service action.

Table 3 Types of service actions

Service Action	Duration (min)	Type	Elapsed %
Electrode service	8	→	85345
Initiate ISE module	6	→	86246
Prime ISE calibrators	1	→	86245
Depressure probes	6	→	82346
Prime fluid system	1	→	82336
Clean probes and splash guard	5	→	12430
Clean ISE tower automatically	11	→	12430
Backup database	5	→	11792
Clean waste box fitting	1	→	2900
Clean ISE tower manually	6	→	2900
Replace ventilation filters	5	→	967
Replace external water reservoir filter	5	→	967
Replace chloride (Cl-) electrode	13	→	915
Replace lithium (Li+) electrode	13	→	886
Clean wash station	8	→	483
Clean instrument	16	→	483
Recalibrate	1	→	483
Replace ISE module tubing	38	→	483
Replace potassium (K+) electrode	13	→	483
Replace sodium (Na+) electrode	13	→	483
Replace reference (Ref) electrode	13	→	121

Selected Service Actions: 8 minute(s)

Buttons: Perform, Done, Print, DC

- 2 Ensure that the analyzer is in **Standby** mode. The mode is indicated by the icon displayed for the **System** button in the navigation bar (see Table 2 on page 14).
- 3 Select an action that is due and click on **Perform** in the bottom right-hand corner to initiate the action.
- 4 Perform the service actions according to the on-screen instructions. Refer to the Operator's Manual for further details, if necessary.
- 5 Repeat Steps 3 and 4 to complete all required service actions.



Performing the required calibrations and controls

Tests that do not have a valid calibration are blocked. To avoid this, calibrate all tests that do not have a valid calibration before beginning sample measurements.



Check the validity of each calibration with the applicable controls after calibration ("QC after calibration") to ensure accuracy of results.

Checking the calibration status of tests

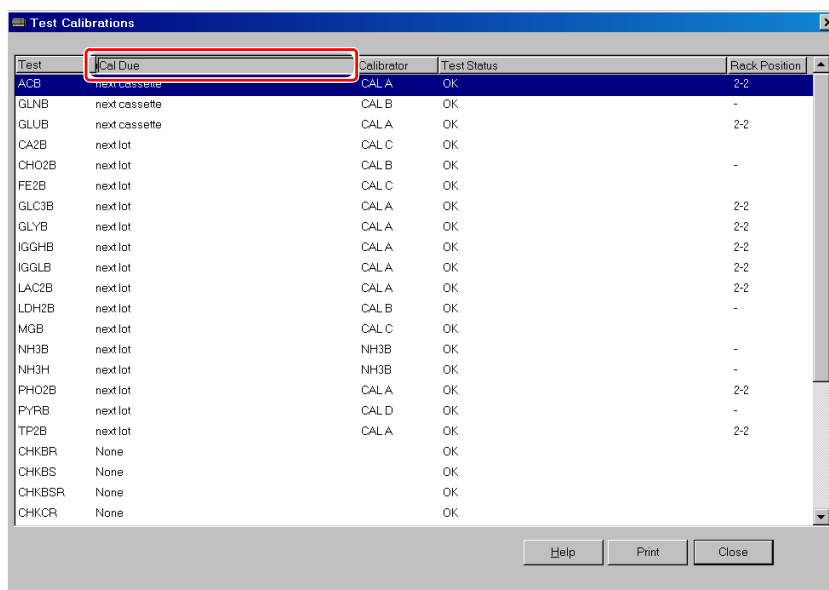
► To check the calibration status of a test

- 1 Click on the **Test Calibrations** icon.



The **Test Calibrations** dialog box opens.

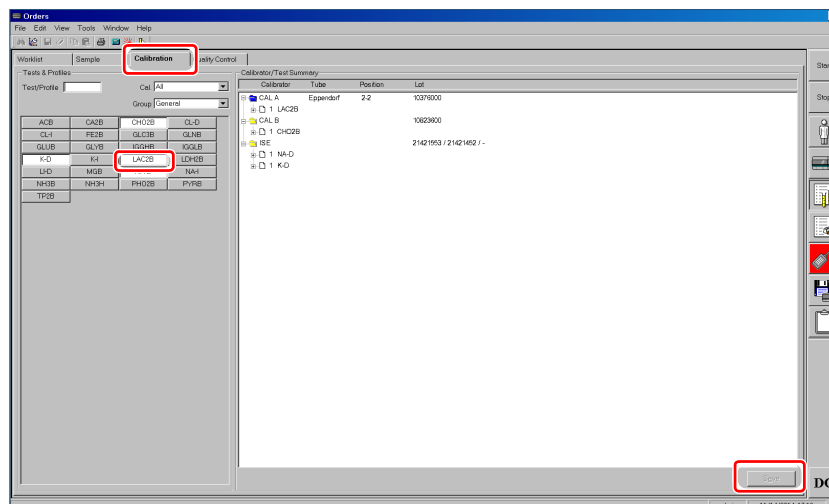
- 2 Click on the **Cal Due** column in the **Test Calibrations** dialog box to sort by due date and determine which tests need to be calibrated.



■

Ordering calibrations► **To order a calibration**

- 1 Click on **Orders** in the navigation bar and select the **Calibration** tab.
- 2 In the left-hand side of the **Calibration** dialog box, select all calibrations that need to be performed.



The right-hand side of the dialog box displays all calibrators that are required to perform the ordered calibrations.

- 3 Click on **Save**.

■

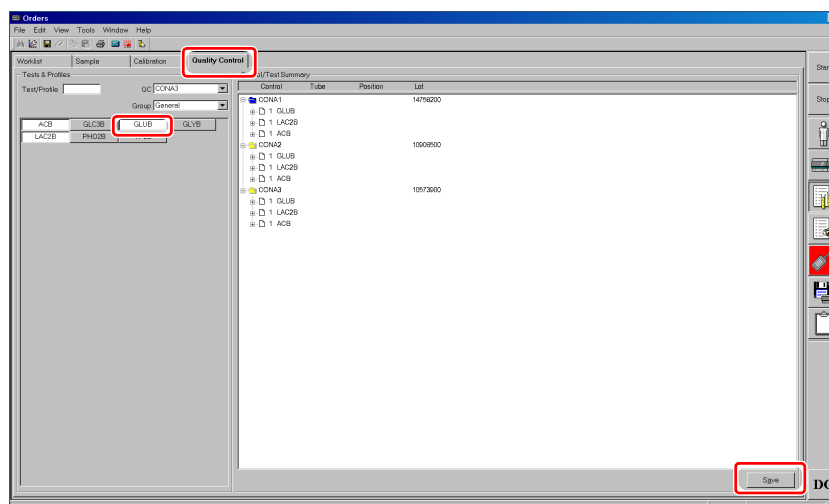
Ordering controls for tests



Roche highly recommends running controls for each test at least with each new calibration.

► **To order a control for a test**

- 1 Click on **Orders** in the navigation bar and select the **Quality Control** tab.



- 2 In the left-hand side of the **Orders** dialog box, select all controls that need to be performed.

The right-hand side of the dialog box displays all controls that are required to perform the ordered controls.

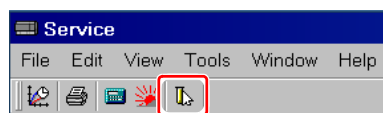
- 3 Click on **Save**.



Starting calibrations and controls

► To start the calibrations and controls

- 1 Click on the **Place Items** icon located under the main menu bar.



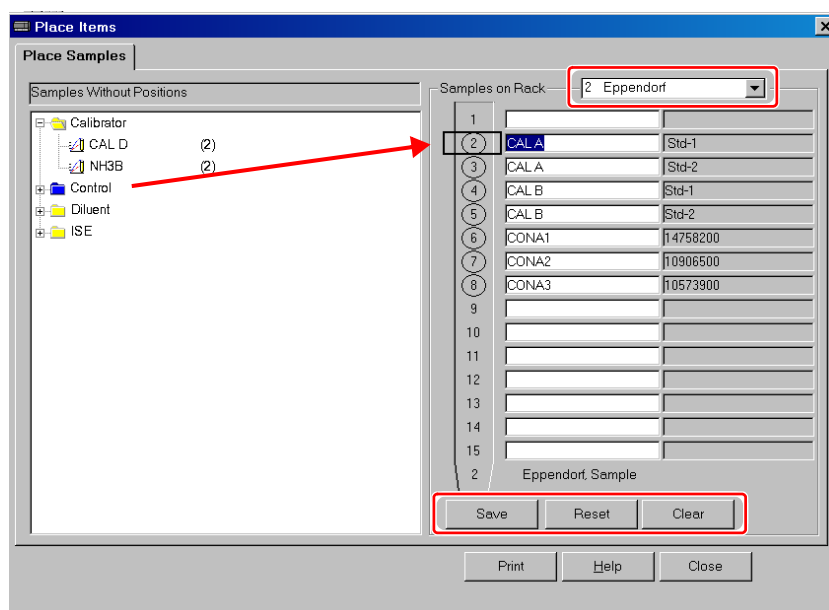
The **Place Items** dialog box opens.

- 2 In the **Place Items** dialog box, choose a sample rack from the drop-down menu on the right-hand side.



Racks that are on board cannot be modified and are marked with a lock symbol  in the drop-down menu.

- 3 Click on the **Clear** button in the bottom right-hand corner of the dialog box to remove all samples that are currently assigned to the rack.
- 4 On the left side of the dialog box, choose the required calibrators and controls and drag them to the desired positions in the **Samples on Rack** column.



- 5 Click on **Save** after all calibrators and controls have been added to the rack.



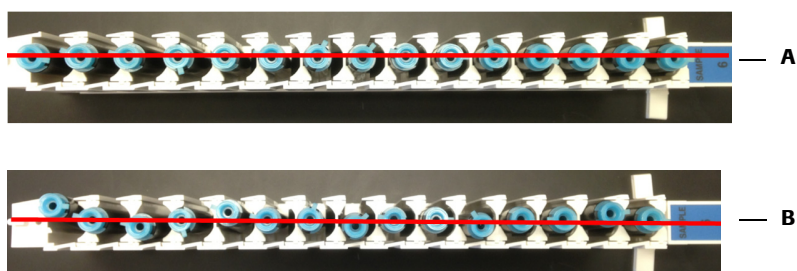
When choosing a calibrator for a two-point calibration (required for most tests), the system will automatically drag two cups on to the rack. The first one is for the calibrator; the second one is for water. Both calibrator and water must be placed in the indicated positions on the rack.

- 6 Prepare calibrators and controls in the appropriate sample cups, and place the cups on the rack at the assigned positions. Use adapter cups to hold the sample cups, if required.



- Ensure that the sample cup types match the pre-defined type for the sample rack. Only one type of sample cup can be used for a specific rack; it is not possible to mix different tube types on the same rack.
- Ensure that cups are aligned correctly. Misaligned cups may cause the probe to crash.

👁 For more information about pre-defined sample cups, see the Cedex Bio HT Operator's Manual.



A Good alignment

B Bad alignment, probe may crash

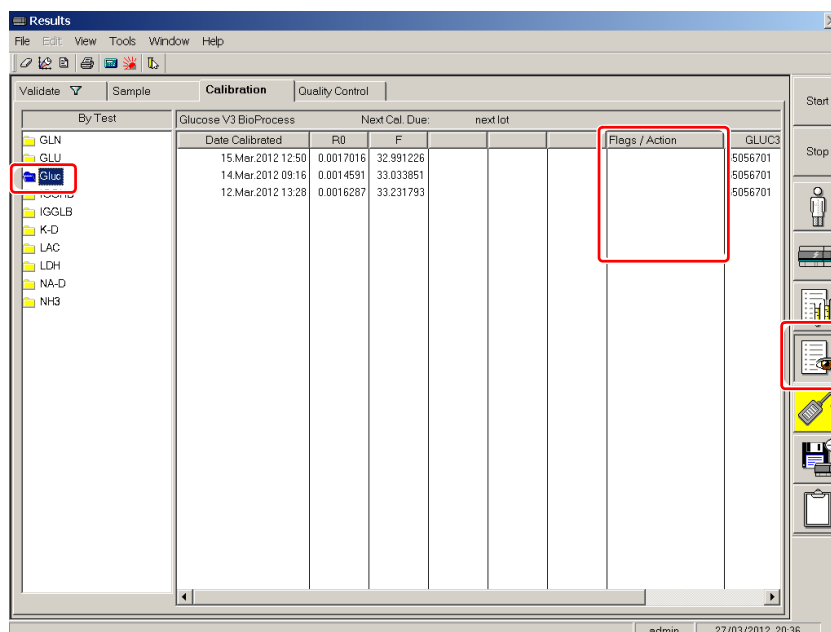
- 7 Insert the rack into the instrument.
- 8 Click on **Start** in the navigation bar.
- 9 Click on **Orders** in the navigation bar, and select the **Worklist** tab to check whether all calibrations and controls have been processed. Ensure that no orders are blocked.

■

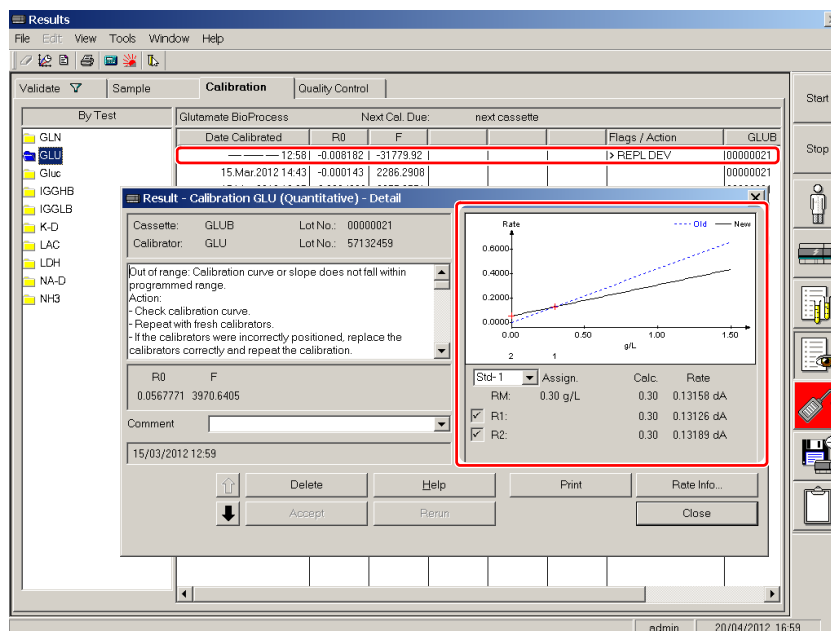
Reviewing calibration results

► To review calibration results

- 1 Click on **Results** in the navigation bar, and select the **Calibration** tab.
- 2 Select each test that received a new calibration.



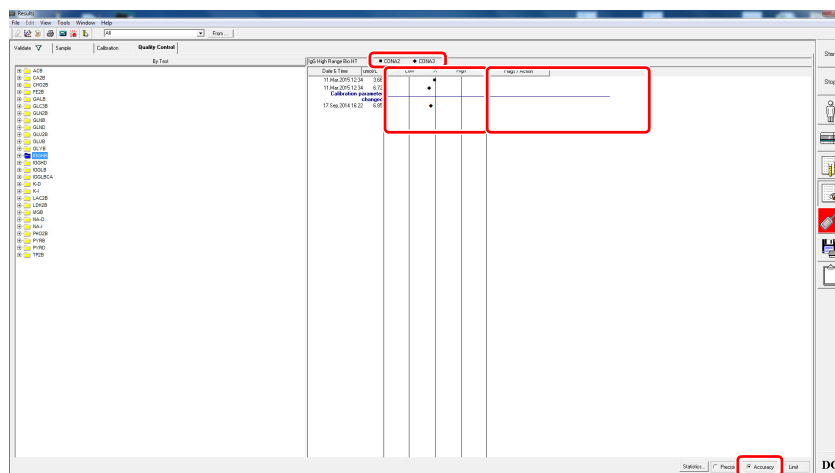
- 3 Verify that the calibration is not flagged.
- 4 Double-click on each calibration result to open and check the calibration curve.



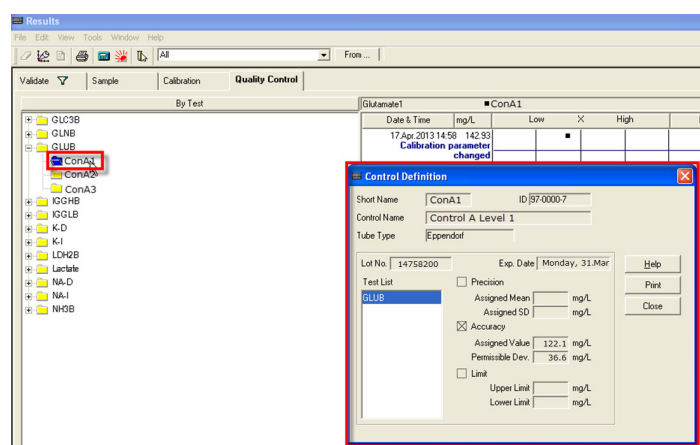
Reviewing control results

► To review control results

- 1 Click on **Results** in the navigation bar, and select the **Quality Control** tab.
- 2 Select a test on the left-hand side of the dialog box. All control results associated with that test are displayed on the right-hand side of the screen.



- 3 Select **Accuracy** in the lower right-hand side of the dialog box to display the accuracy results.
- 4 Ensure that the results are not flagged and are within the expected range for accuracy (i.e., within **Low** and **High** columns).
- 5 Select one of the controls displayed with a test on the left-hand side (e.g., ConA1) to see only the results for that control.
- 6 Double-click on a control to access a popup dialog box displaying control lot data.



After all required calibrations and controls have been performed, the Cedex Bio HT Analyzer is ready for sample measurements.

B Main applications

Performing sample measurements

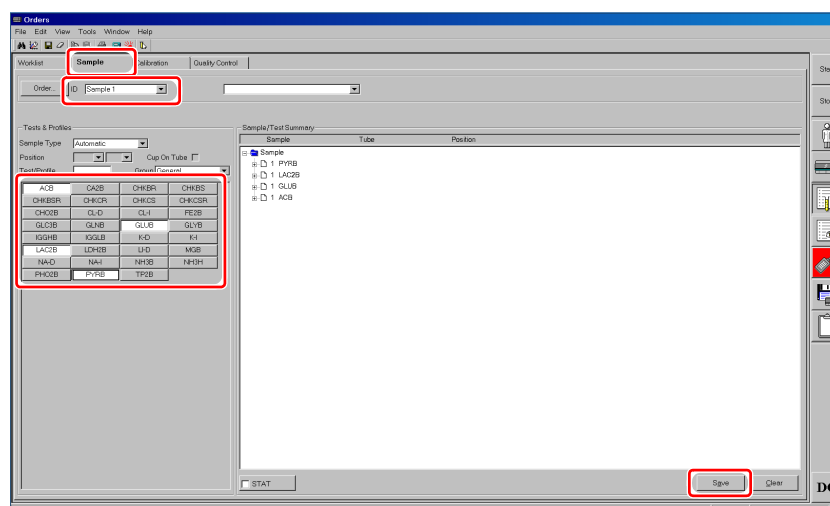
Creating orders

An order is a test or a series of tests that have been assigned to a particular sample to be measured.

► **To create an order**

- 1 Click on **Orders** in the navigation bar, and select the **Sample** tab.
- 2 Enter the sample name in the **Order ID** field.
- 3 Select the tests to be assigned to the sample and click on **Save**.
- 4 Alternatively, assign a profile containing a series of pre-selected tests to the sample, and click on **Save**.

👁 For details, see *Creating a test profile* on page 32.



- 5** Repeat Steps 1 to 3 to create orders for additional samples.



Assigning samples to racks

After orders for samples have been created, the samples to be measured need to be assigned to sample racks.

► To assign samples to a rack

- 1 Click on the **Place Items** icon.

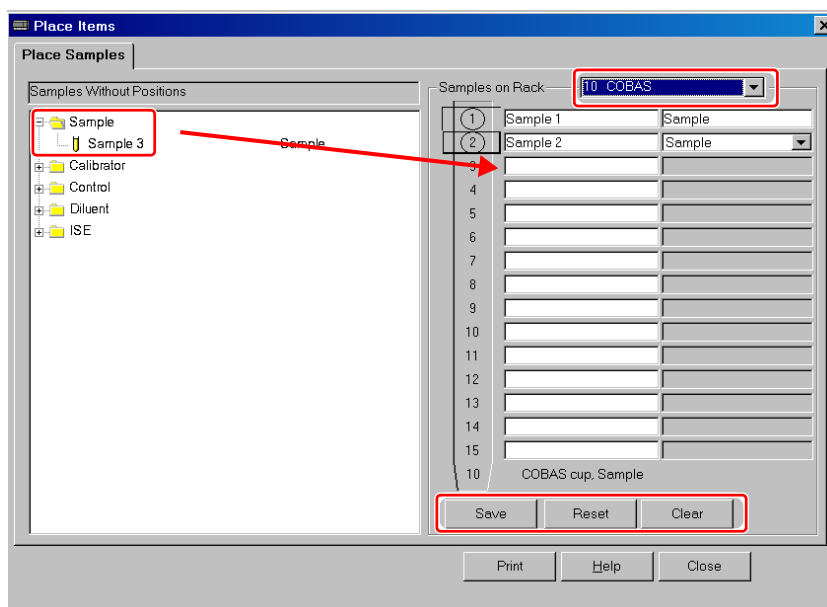


- 2 In the **Place Items** dialog box, located just under the main menu bar, choose a sample rack that is not on board from the drop-down menu on the right-hand side.



Racks that are on board cannot be modified and are marked with a lock symbol  in the drop-down menu.

- 3 Click on **Clear** to remove any old samples currently assigned to the rack.
- 4 Left-click on the samples to be measured, shown on the left-hand side of the dialog box, and drag them with the mouse to the sample rack column on the right-hand side of the dialog box.



- 5 Click on **Save**.

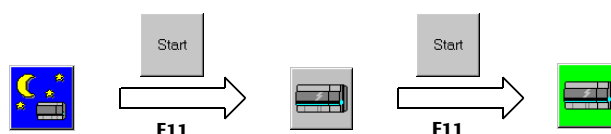


To change the position of a sample on the rack, left-click on the position number (1 to 15) for the relevant sample and drag it to a different position on the rack. The sample can also be removed from the **Samples on Rack** list by clicking on the circled number next to the sample to be removed and dragging it to the left-hand side of the dialog box.

Loading samples and starting the measurement process

► To load samples and start the measurement process

- 1 Prepare ordered samples in the appropriate sample cups, and place the cups on the rack at the assigned positions using adapter cups, if required. Ensure that the sample cup types match the defined type for the sample rack.
- 2 Insert the rack into the appropriate position on the analyzer.
- 3 If the analyzer is in standby mode, click on **Start** in the navigation bar to start the measurement process.
- 4 If the analyzer is in sleep mode, click on **Start** to wake up the analyzer. As soon as it is in standby mode, click on **Start** again to start the measurement process.



- 5 After the run is completed, click on **Orders** in the navigation bar, and select the **Worklist** tab. Check whether all orders have been processed, and ensure that no orders are blocked.



End of measurement: validating results

If configured accordingly, the system automatically validates any unflagged result after the end of the measurement. All flagged results must be manually validated.

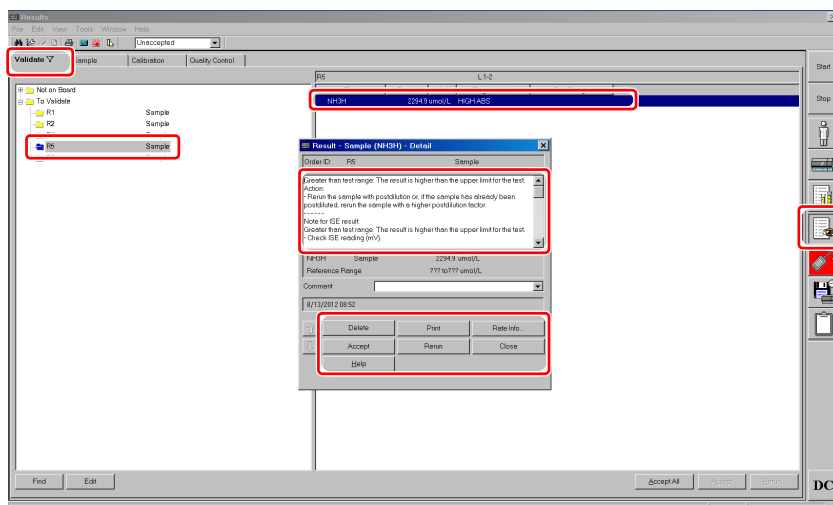


Results can be printed out. For more information about printing options, please refer to the Cedex Bio HT Operator's Manual.

► To manually validate results

- 1 Click on **Results** in the navigation bar, and select the **Validate** tab.
- 2 The left-hand side of the dialog box is structured with menus and sub-menus similar to the directories in Windows Explorer. Expand the **To Validate** folder in this section of the tab.
- 3 Select a result to be validated from the **To Validate** folder.

- 4 Double-click on the result in the list located on the right-hand side of the tab. The **Result Detail** dialog box is displayed.



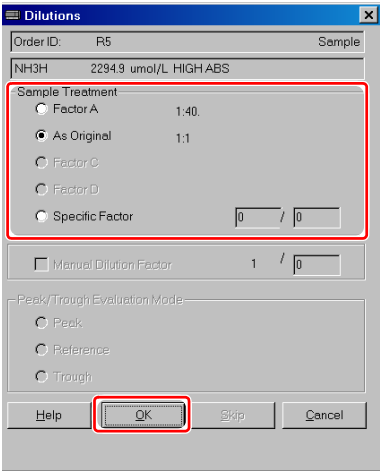
- 5 The upper left-hand corner of the **Result Detail** dialog box provides information about the flag and recommended actions. Multiple options for performing further actions or validating the result are shown on the bottom of the dialog box:
- **Accept** the result.
 - **Delete** the result.
 - **Rerun**: The test will be repeated. This action is described in more detail in the next section.
 - **Rate info**: See the raw data.
- 6 Choose the preferred action, and then click on **Close**.
- 7 Repeat Steps 3 to 6 for all other results that need to be manually validated.

■

Rerunning a measurement

► To rerun a measurement

- 1 Tests can be repeated via the **Rerun** option in the **Result Detail** dialog box.
When a rerun is ordered, the **Dilutions** dialog box automatically opens.



- 2 Choose one of the following options for the rerun:

Rerun mode	What the analyzer does	Dilution factor	Recommended when
Factor A	Test is repeated with diluted sample.	Pre-defined; specific for each test.	Analyte concentration is too high and result is flagged: >Test Rng or Antigen excess
As Original	Test is repeated (undiluted sample).	None	Flagged result
Specific Factor	Test is repeated with diluted sample.	User can define the dilution factor. ^(a)	Analyte concentration is too high and result is flagged: >Test Rng or Antigen excess
Manual Dilution Factor	User dilutes the sample manually before loading on the instrument.	User defines the dilution factor.	Not recommended due to high risk of dilution errors.

Table 4 Rerun modes

(a) Technically possible up to 1:100, but tests are validated only up to the dilution factor pre-defined for the **Factor A**.

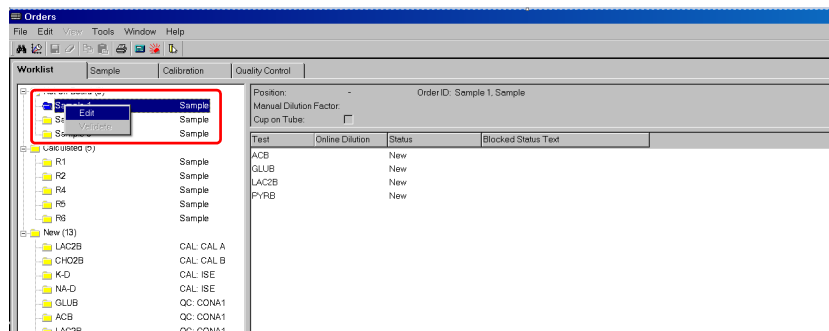
■

Additional measurement options

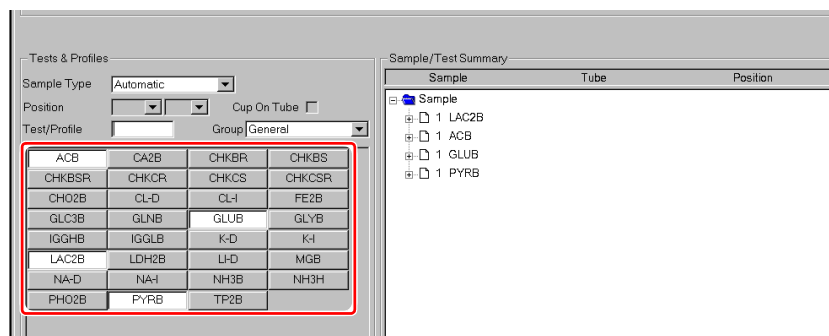
Editing or deleting tests and orders

► To change an order

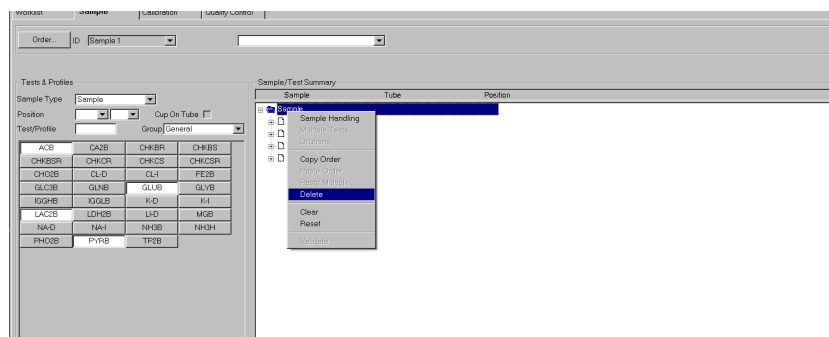
- 1 Click on **Orders** in the navigation bar, and select the **Worklist** tab.



- 2 In the left-hand side of the **Worklist** tab, right-click on the order to be changed and select the **Edit** option. The order is opened in the **Sample** tab.



- 3 In the **Test/Profile** field, use the mouse to add single or multiple tests to the order, or remove tests from the order, as described in *Creating orders* on page 23.
- 4 If desired, an order can be completely deleted by right-clicking on the sample name on the right-hand side of the screen and selecting the option **Delete**.



- 5 Click on **Save** in the lower right-hand corner of the screen to confirm the changes.

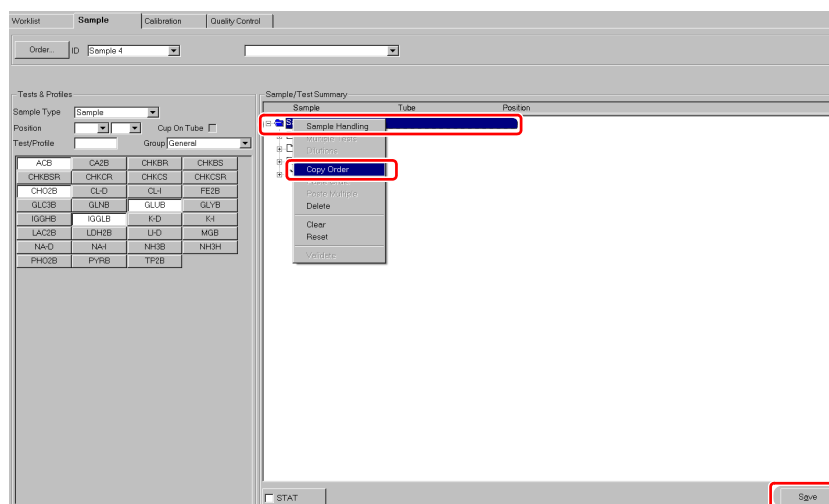
■

Creating multiple copies of an identical order

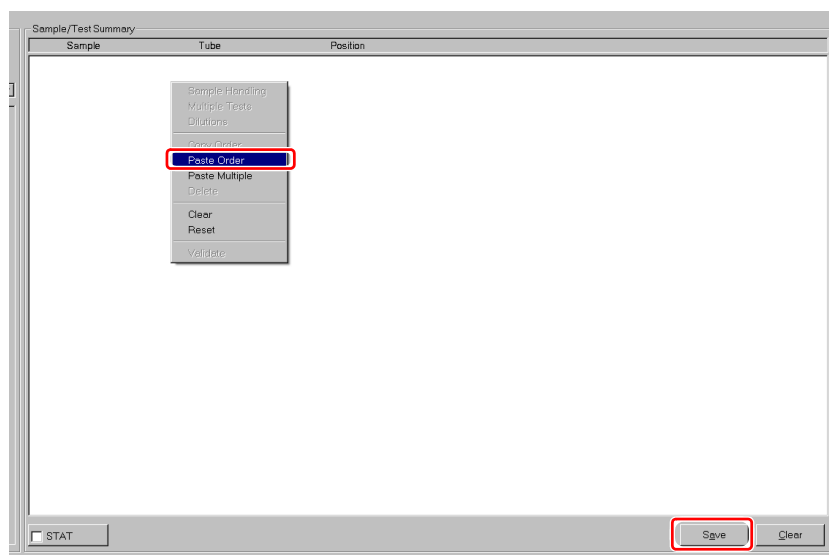
This option may be helpful when analyzing multiple samples that require the same test combination (e.g., glucose, glutamate prediluted 1:10, lactate prediluted 1:5).

► To create multiple copies of an identical order

- 1 Create an order as described in *Creating orders* on page 23.
- 2 Before saving the order, right-click on the sample and choose the option **Copy Order**.



- 3 Click on **Save** to save the order.
- 4 Enter the name of the next sample, as described in *Creating orders* on page 23.
- 5 Instead of selecting tests for this sample, right-click in the large window on the right-hand side and choose the option **Paste Order**.



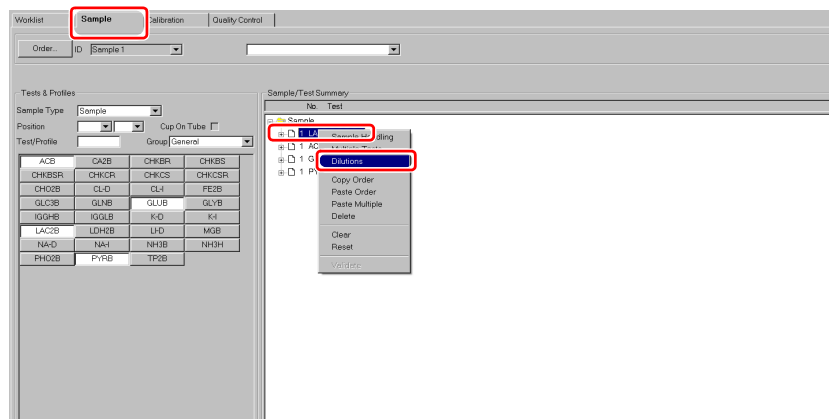
- 6 Click on **Save** to save the order with the copied tests.

■

Preparing tests for prediluted samples

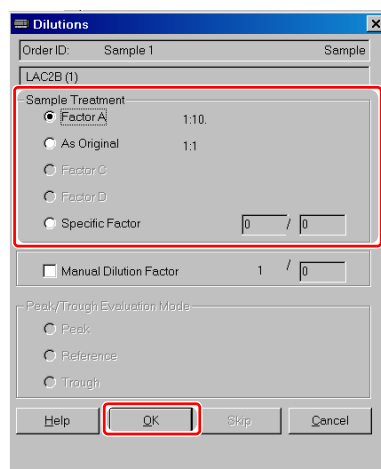
► To create an order for a prediluted sample

- 1 Create an order as described in *Creating orders* on page 23.
- 2 In the right-hand side of the **Sample** tab, right-click on the test that should use a prediluted sample and select the option **Dilutions**.



The **Dilutions** dialog box opens.

- 3 Choose **Factor A** or enter a **Specific Factor** in the designated field (see Table 4 on page 27).



- 4 Click on **OK** to confirm the selection.

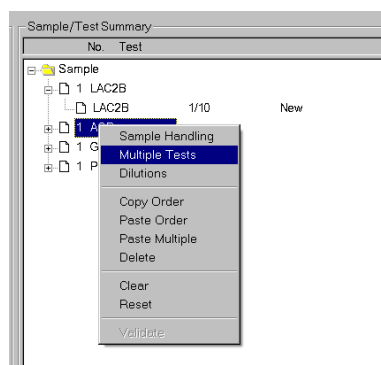


Setting up tests in replicate

Use the **Multiple Tests** function to determine the concentration of an analyte in a sample based on the results from replicate measurements for a particular test.

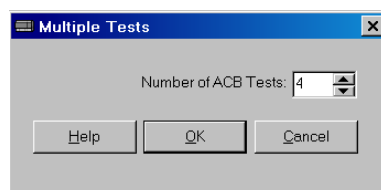
► To set up a test in replicate

- 1 Create an order as described in *Creating orders* on page 23.
- 2 Before saving the order, right-click on the test to be performed in replicate, and choose the option **Multiple Tests**.

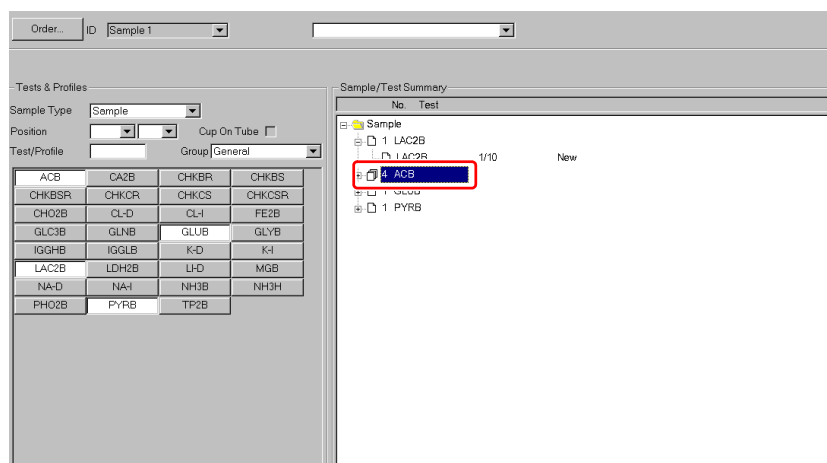


The **Multiple Tests** dialog box opens.

- 3 Select the number of replicates for the test in the dialog box.



- 4 Click on **OK** to confirm the selection. The number of replicates selected is displayed next to the test parameter. The number shown represents the total number of replicate measurements that will be performed.



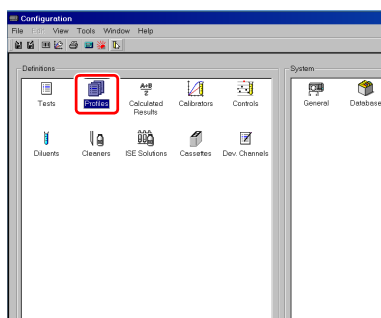
■

Creating a test profile

A test profile is a set of tests that are frequently ordered in combination. When ordering a test profile for a sample, all tests selected for the profile are performed.

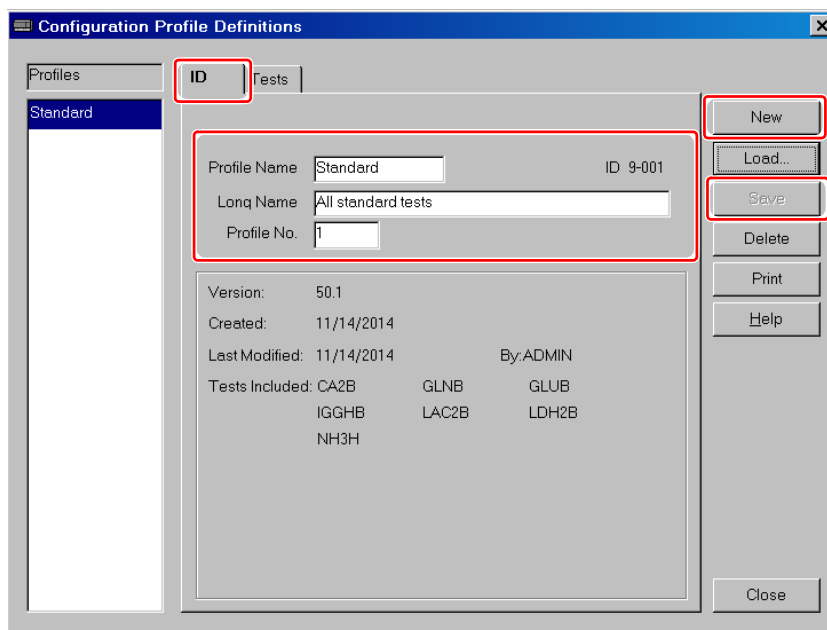
► To create a test profile

- 1 Click on **Configuration** in the navigation bar, and then double-click on the **Profiles** icon in the **Definitions** field.

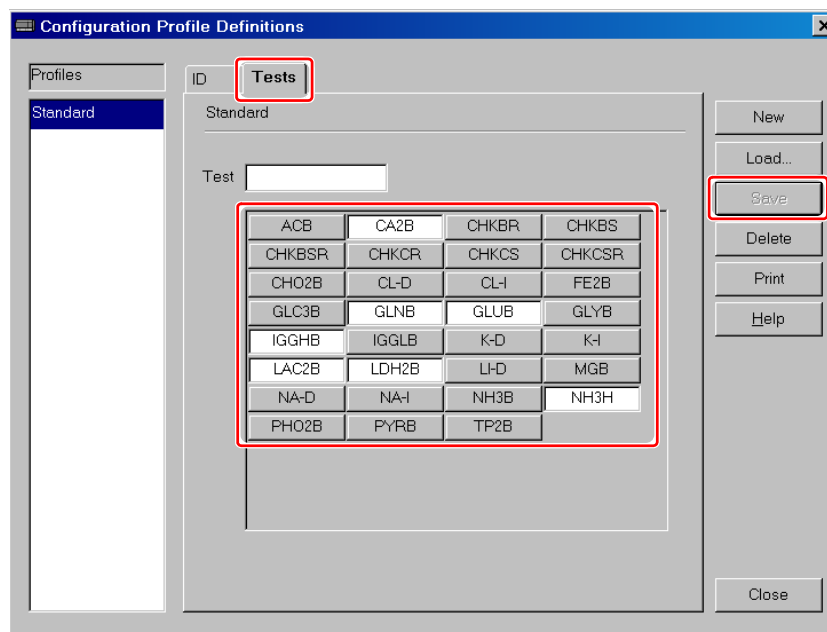


The **Configuration Profile Definitions** dialog box appears.

- 2 Select the **ID** tab in the dialog box, and then click on **New**.
- 3 Enter information for the following parameters:
 - **Profile Name**
 - **Long Name**
 - **Profile No.** (any unique number between 1 and 999)



- 4 Switch to the **Tests** tab, and select all tests to be included in the profile.



- 5 Click on **Save** on the right-hand side of the dialog box.



Defining new calibrator and control lots

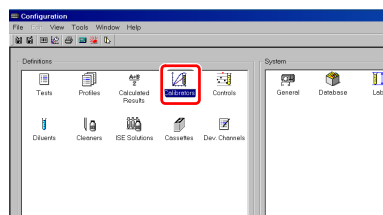
Defining new calibrator lots



The system must be in sleep or standby mode when making any configuration changes. All calibrations created with a particular calibrator must be validated before a new calibrator lot can be defined.

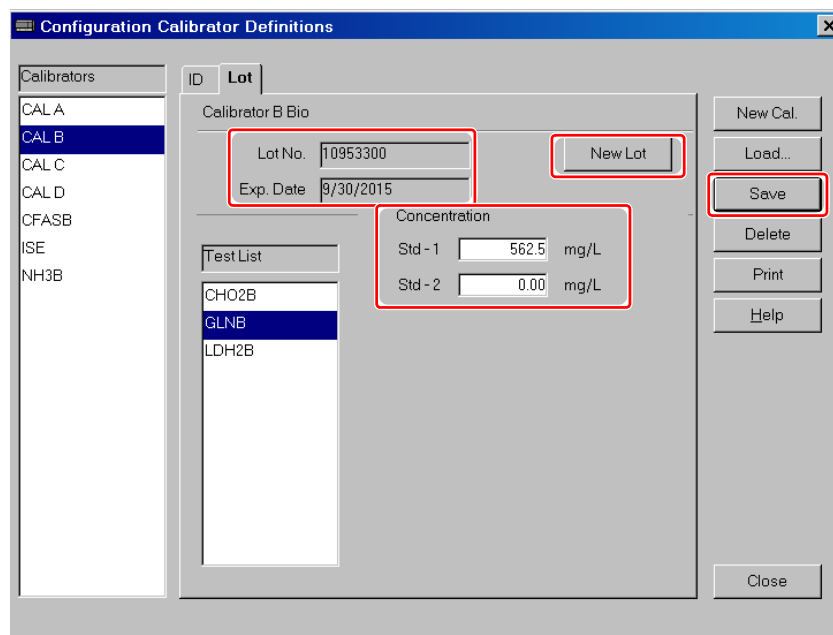
► To define a new calibrator lot

- 1 Click on **Configuration** in the navigation bar, and then double-click on the **Calibrators** icon in the **Definitions** field.



The **Configuration Calibrator Definitions** dialog box opens

- 2 In the **Configuration Calibrator Definitions** dialog box, choose the calibrator for which the new calibrator lot should be defined from the **Calibrators** list on the left-hand side of the dialog box.



- 3 Select the **Lot** tab, and click on the **New Lot** button.

- 4 Enter the relevant information for the new calibrator lot in the following fields:

- **Lot No.**
- **Exp. Date**



The format of the expiration date must be entered in the correct format (e.g., "mm/dd/yyyy"), as shown in the bottom right-hand corner of the screen.

- 5 Click on **Save** on the right-hand side of the dialog box.
- 6 Click on a test from the **Test List** field in the dialog box to highlight a test.
- 7 Type in the new values for the calibrator for the selected test, as follows:
- **Std-1:** Value taken from the Instructions for Use for the respective calibrator and test (see example in the figure below).

Enter values that correspond to the correct units (mmol/L or mg/L).



The units can be changed; refer to the Cedex Bio HT Operator's Manual for more information.

Analyte	Value	Unit
Cholesterol	0.403	mmol/L
	155.8	mg/L
Glutamine	3.848	mmol/L
	562.5	mg/L
LDH	322.7	U/L
NH ₃ (Ammonia)	4.872	mmol/L

- **Std-2:** 0 (water)



For tests that are calibrated with more than two calibration points (e.g. IgG), the system dilutes the calibrator on board. Therefore, water is not used as the zero point, and only the value for **Std-1** can be entered.

- 8 Click on **Save** on the right-hand side of the dialog box.
- 9 Repeat Steps 6 to 8 to enter lot-specific information for all other tests associated with the newly defined calibrator lot.



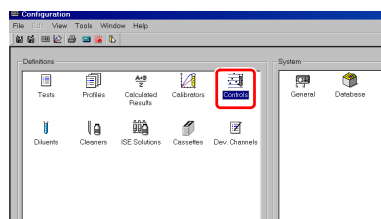
Defining new control lots



All control results must be accepted before new control lots can be defined.

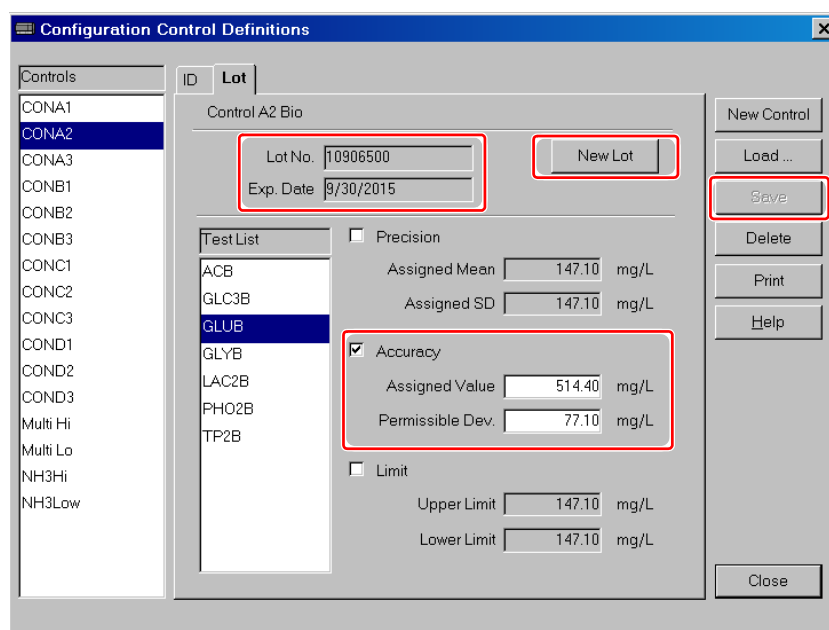
► **To define a new control lot**

- 1 Click on **Configuration** in the navigation bar, and then double-click on the **Controls** icon in the **Definitions** field.



The **Configuration Control Definitions** dialog box opens.

- 2 From the **Controls** list on the left-hand side of the dialog box, choose the control for which the new control lot should be defined.



- 3 Select the **Lot** tab, and click on **New Lot**.
- 4 Enter the relevant information for the new control lot in the **Lot No.** and **Exp. Date** fields.
 - **Lot No.**
 - **Exp. Date:** Dates must be entered in the correct format (e.g., mm/dd/yyyy), as shown in the bottom right-hand corner of the screen.
- 5 Click on the **Save** button located on the right-hand side of the dialog box.
- 6 Click on a test from the **Test List** field to highlight the test.

7 Place a check mark in the **Accuracy** check box.



In the **Accuracy** control mode, any control measurement outside the permissible deviation will be flagged (>ACC RNG) and should be repeated. The permissible deviation is defined based on the customer's own quality control criteria. Roche recommends starting with a three-fold of the value of the standard deviation, 1s, defined in the relevant lot-specific Instructions for Use for the control (see Figure 4, for example). However, each lab must determine the appropriate values according to local preferences or requirements.

8 Ensure that the check boxes for **Precision** and **Limit** are not checked.



The **Precision** and **Limit** control modes are not recommended. Please refer to the Cedex Bio HT Operator's Manual for more information.

9 Enter the relevant values in the **Accuracy** fields for each control. The values are found in the lot-specific Instructions for Use for the relevant control kit (see example shown in Figure 4 on page 37):

- **Assigned Value:** Lot-specific concentration value for the selected test.
- **Permissible Deviation:** For example, 3x the standard deviation (1 s) value for the selected test.

10 Click on the **Save** button, located on the right-hand side of the dialog box.

11 Repeat Steps 6 to 10 to enter lot-specific information for all other tests associated with the newly defined control lot.



Controls are not automatically assigned; they must be manually assigned to each test by the user. See the chapter *Assigning controls to tests* in the Cedex Bio HT Operator's Manual.

Print

Control B Level 1 Bio

for Cedex Bio and Cedex Bio HT Systems

REF 06 682 561 001 6 × 0.5 mL

Control code: CONB1, 401, 07-1106-3

CE Version 10
 Content version: July 2017
 Store at -15 to -25°C

Intended Use

This product is intended for quality control by monitoring accuracy and precision of quantitative assays using Cedex Bio and Cedex Bio HT Systems. Use this control as described in the Instructions for Use of the respective assay.

Storage and Stability

Store frozen at -15 to -25°C.
 Stable until expiration date printed on the label when stored at -15 to -25°C unopened in original vials and kept free of contamination.
 Open vial is stable for 1 day at +15 to +25°C.

Handling

After thawing, mix thoroughly (10 to 20 sec on a vortex mixer is recommended) and spin down for 10 to 20 sec in a microcentrifuge. The control is ready for use.

Trademarks

CEDEX is a trademark of Roche.

Changes to Previous Version

- New lot-specific data.

Lot-Specific Data

Lot No.: 28495000

Expiration Date: Aug 2018

Assigned concentration values:

Analyte	Value	1 s	Unit
Cholesterol	0.063 24.3	0.006 2.4	mmol/L mg/L
Glutamine	1.751 256.0	0.175 25.6	mmol/L mg/L
LDH	100.2	10.0	U/L
NH ₃ (Ammonia)	1.216	0.122	mmol/L

Figure 4 Example of Instructions for Use

Example Values for Glutamine from Control B Level 1 Bio from the Instructions for Use for Lot No. 28495000:

- Expiration Date: 08/31/2018 (format may differ, depending on the instrument)
- Assigned Value: 256.0 mg/L
- 1 s (for calculation of permissible deviation): 25.6 mg/L

Calculation of permissible deviation, based on 3x standard deviation (1 s) value:

$$SD = 25.6 \text{ mg/L} \rightarrow 3 \times 1s = 76.8 \text{ mg/L for permissible deviation}$$

Performing standby calibrations

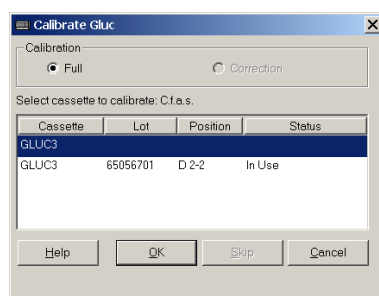
It may be helpful to create a standby calibration for test cassettes with a set calibration type (i.e., single cassettes that must be calibrated before use). A test cassette can be calibrated immediately after loading it on board ("standby calibration"), so that it can be used by the instrument as soon as the previous cassette is empty.



As with any other calibration, the standby calibration should be checked by quality control.

► To calibrate a cassette that is not yet in use

- 1 Before an old test cassette is empty, load the new test cassette on board, as described in section *To check and replace a test cassette* on page 13.
- 2 Click on **Orders** in the navigation bar, and select the **Calibration** tab.
- 3 Select the test that requires a standby calibration. Click on **Save** in the lower right-hand corner of the screen.
- 4 If more than one cassette of the same type is on board the instrument, the **Calibrate** dialog box will open.



- 5 Choose the cassette that is not in use and click on **OK** to create a standby calibration.



C Shutting down the system



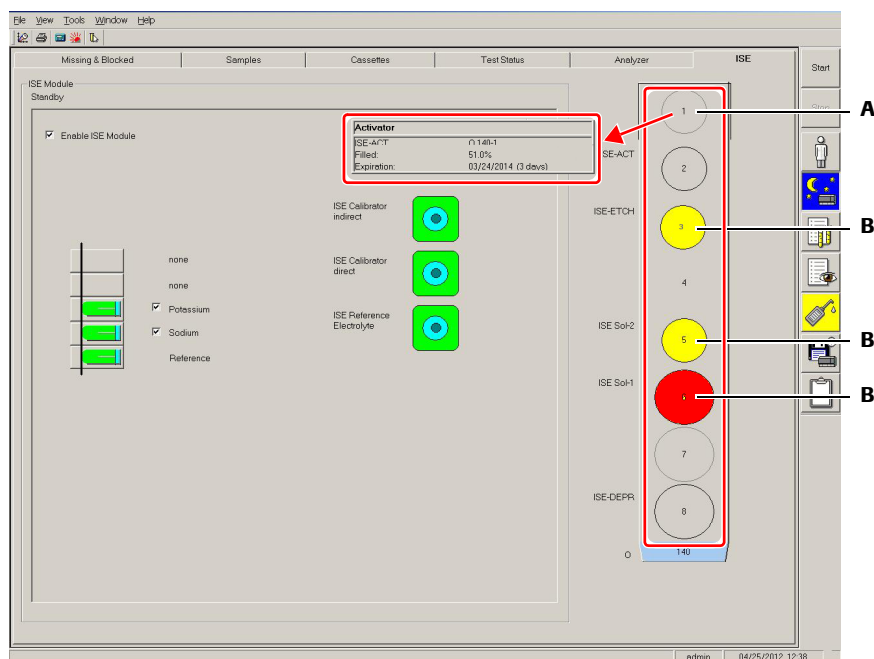
The Cedex Bio HT Analyzer and control unit should never be completely turned off during the night. Both the analyzer and the control unit must be left on in order for the system to perform Begin of Day activities in the morning and to perform the required continuous maintenance of the ISE module.

At the end of the working day, prepare the system for the break and for the Begin of Day activities the next day. Perform the following procedures:

Checking the solutions on the ISE rack

► To check the solutions on the ISE rack

- 1 Click on the **Status** button in the navigation bar, and then select the **ISE tab**.
- 2 Double-click on all of the solutions to check filling status and expiration date (A).
- 3 Replace any solution that will expire the next day to avoid exceeding the expiration date, so that the instrument can perform service actions during the Begin of Day (BOD) procedure the next morning.



A Double-click on a reagent to display detailed information

B Replace reagents that are marked in yellow or red

Figure 5 Checking reagents on ISE rack



The most critical component is the Activator Bio. Depending on the system configuration and the maintenance actions that will be due during the BOD on the next day, up to approximately 30% of Activator Bio may be consumed. Therefore, replace any remaining activator with a new bottle of Activator Bio as soon as the fill level is less than 30%. For more information, refer to the Instructions for Use for the Activator Bio.

- 4 Remove all sample racks. Test cassettes can be stored on board overnight in their cooled compartment.

- 5 Press Shift+F3 and click on log-off in the dialog box that opens to log off of the system.



Archiving results

The Cedex Bio HT Analyzer is not designed to store large quantities of results on the system. Therefore, results should be routinely archived and purged from the system.

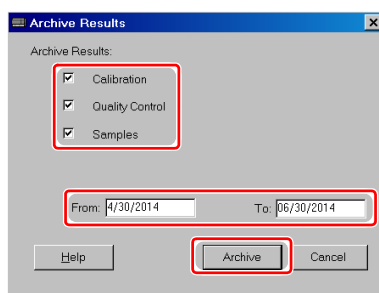
Archive results at the end of each working day. Roche recommends purging results manually at least once every two months.

- 👁 For detailed information about purging archived results, refer to the Cedex Bio HT Operator's Manual.

► To archive results

- 1 Select the **Archive Results** option from the **File** drop-down menu.

The **Archive Results** dialog box opens.



- 2 Select the type of results to be archived (i.e., **Calibrations**, **Controls**, and/or **Samples**).
- 3 Enter the date range of results to be archived (**From** and **To** fields). Dates must be entered in the correct format (e.g., mm/dd/yyyy), as shown in the bottom right-hand corner of the screen.
- 4 Click on **Archive** to start the procedure.
- 5 In the dialog box that opens, select the path to be used for storage of the archived data.
- 6 In the next dialog box, choose the following:
 - Select the file path to store the archived data.
 - Enter a file name for the file to be archived; the file will be archived as a .txt file.
- 7 Click on **Save** to confirm the information. The dialog box closes and the archive is automatically started.
- 8 Click on **OK** in the **Confirmation** dialog box to confirm successful completion of the archive and save the archive file.
- 9 The results can be transferred to other computers using a USB stick.



D Troubleshooting

Preparing samples, multicalibrators and controls

An essential prerequisite for consistent results is correct handling of samples, calibrators and controls prior to each measurement. Consider the following important points when handling all samples and reagents:

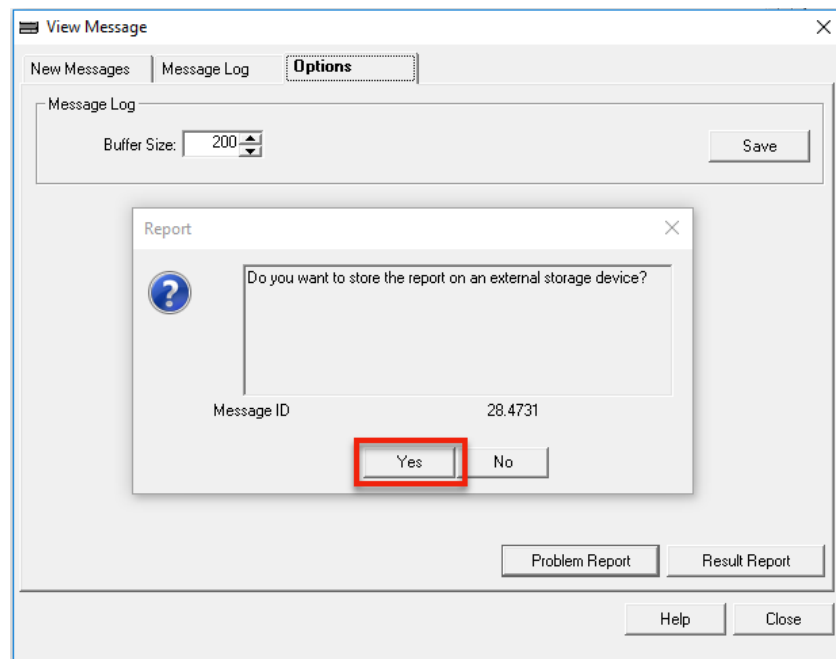
- It is essential to **avoid any foam** in samples, calibrators and controls before loading them on the instrument, in order not to disturb the liquid level detection system of the instrument. Foam can be removed by centrifugation.
- **Mix** calibrators and controls **thoroughly** before use (e.g., by vortexing or inverting several times) to ensure complete homogenization of the solution. Spin down in a microcentrifuge to remove any foam or bubbles.
- Both cellular and cell-free material can be used as sample material on the Cedex Bio HT Analyzer. However, remove cells from cell culture samples by centrifugation and only using the supernatant for the measurement. Otherwise, effects of cell metabolism on analyte concentrations in the medium may occur.

Creating a problem report

When the system produces an error message that you cannot resolve, create a problem report. Send the report to the local Roche representative, along with a problem description, to help resolve the issue.

► **To create a problem report**

- 1 Click on Messages in the navigation bar. The **View Message** dialog box opens.
- 2 In the dialog box, select the **Options** tab.
- 3 Insert a USB stick at the USB port.
- 4 Click on the **Problem Report** button. A problem report is generated and a **Report** dialog box opens, asking whether you want to store the report on an external storage device.



5 Click on Yes.

The Report will automatically be saved on the external device you inserted beforehand.

6 Forward the PR.ZIP file copied to the USB stick to your local Roche representative.



Common flags and recommended actions

The table below provides a selection of common flags and recommended actions. For a complete list of flags, as well as more detailed information about recommended actions, press F1 (Help) and select the Flags help topic or refer to the Operator's Manual.

Flag	Definition	Actions
>	Result was generated from a repeated run.	No action required.
V	The result was generated using a diluted sample. The dilution factor was automatically applied to the result calculation.	No action required.
>ACC RNG	Quality control result is outside accuracy range.	Repeat the quality control with a fresh control bottle. If flag persists, repeat calibration and control using fresh calibrator and control bottles.
<TEST RNG	Lower than test range. The result is lower than the lower limit of the test.	Check result for expected analyte concentration for the sample. - If the concentration is expected to be higher than the lower limit: Repeat the test. - If the concentration is expected to be lower than the lower limit: Accept the result.
>TEST RNG	Higher than test range. The result is higher than the upper limit of the test.	Rerun sample with post-dilution.
>AG EXCESS	Antigen excess. The sample contains an excess antigen and a valid result cannot be calculated.	Rerun the test with post-dilution.
>REPL DEV	Greater than replicate deviation. Deviation between replicate measurements of a calibration exceed programmed limit. One or more replicates are erroneous.	Check the calibrators for air bubbles and repeat the calibration. If flag persists, repeat calibration with fresh calibrator (open a new vial).

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Cedex Bio HT Analyzer (Version 5.1)

*Operator's Manual
Version 1.4*

Publication information

Revision history

Publication version	Software version	Revision date	Changes
1.0	5.0	May 2012	First release
1.0	5.0	September 2012	Updated laser information
1.1	5.0	April 2013	Remote access, diluent handling, 2nd LAN connector
1.2	5.0	September 2013	Hardware specifications, data handling via USB
1.3	5.0	December 2016	Revision chapter added.
1.4	5.1	March 2018	New control unit running Windows 10. Interlock feature. Fuse handling by Roche representatives only.

Edition notice

This publication is for users of the Cedex Bio HT Analyzer.

Every effort has been made to ensure that all the information contained in this publication is correct at the time of publishing. However, the manufacturer of this product may need to update the publication information as output of product surveillance activities, leading to a new version of this publication.

find information

The *User Assistance* contains all information about the product, including the following:

- Routine operation
- Maintenance
- Safety
- Troubleshooting information
- A software reference
- Configuration information
- Background information

The *Operators manual* focuses on routine operation and maintenance. The chapters are organized according to the normal operation workflow. It also contains important safety information. You must read the *Safety* chapter before operating the analyzer.

Intended use

The Cedex Bio HT Analyzer is a fully automated, computerized analyzer for professional use. It is intended for determination of a wide range of analytes in various aqueous solutions such as cell culture and fermentation media.

For use in quality control/manufacturing process only.

Training

Do not carry out operation tasks or maintenance actions unless you have received training from Roche Diagnostics. Leave tasks that are not described in the user documentation to trained Roche representatives.

Images

The screenshots and hardware images in this publication have been added exclusively for illustration purposes. Configurable and variable data in screenshots, such as tests, results, or path names visible therein must not be used for laboratory purposes.

Warranty Any customer modification to the system renders the warranty or service agreement null and void.

For conditions of warranty, contact your local sales representative or refer to your warranty contract partner.

Always leave software updates to a Roche representative, or perform such updates with their assistance.

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Feedback Every effort has been made to ensure that this publication fulfills the intended use. All feedback on any aspect of this publication is welcome and is considered during updates. Contact your Roche representative, should you have any such feedback.

Approvals The Cedex Bio HT Analyzer meets the requirements laid down in:
Directive 2014/30/EU of the European Parliament and Council of 26 February 2014 relating to electromagnetic compatibility (EMC).
Directive 2014/35/EU of the European Parliament and Council of 26 February 2014 relating to electrical equipment designed for use within certain voltage limits.
Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
RoHS (Restriction of Hazardous Substances) compliant from Serial No. 610001.
Compliance with the applicable directive(s) is provided by means of the Declaration of Conformity.
The following marks demonstrate compliance:



Complies with the provisions of the applicable EU directives.



Issued by Underwriters Laboratories, Inc. (UL) for Canada and the US. "Laboratory Equipment" is the product identifier as shown on the type plate.

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Preface

The Cedex Bio HT Analyzer is a fully automated, computerized analyzer for professional use. It is intended for determination of a wide range of analytes in various aqueous solutions such as cell culture and fermentation media. For use in quality control/manufacturing process only.

This manual refers specifically to the Cedex Bio HT Analyzer and software version 5.1 (Windows 10). It is intended for users of the analyzer and software.

About the Cedex Bio HT Analyzer

The Cedex Bio HT Analyzer is an advanced integrated system for monitoring of substrates and metabolites for process control of cell culturing and fermentation.

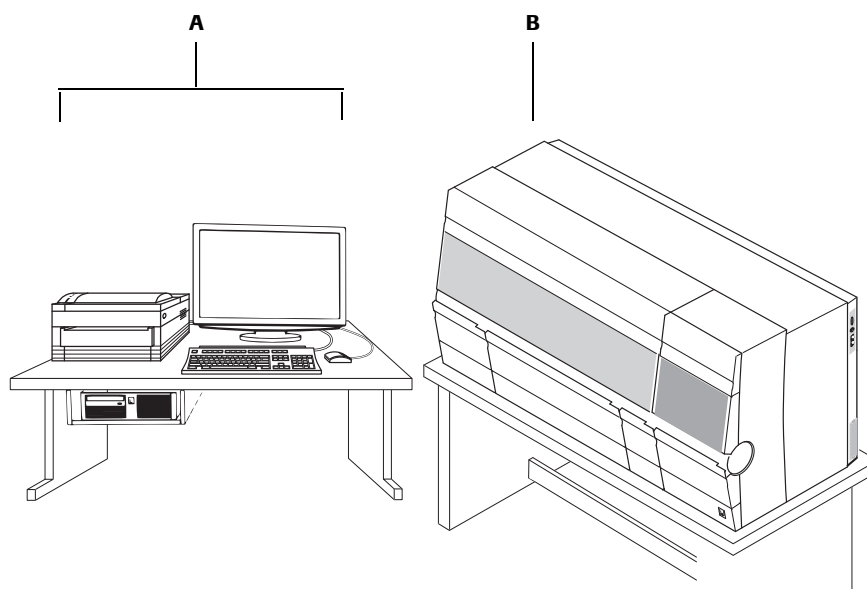
Testing of electrolytes, carbohydrates, amino acids, specific proteins and enzyme activities is consolidated into one system with a convenient reagent cassette design.

Robust robotics, an intuitive user interface and random sample access serve for optimized time management and streamlined workflows.

The Ion Selective Electrode (ISE) module allows the determination of sodium and potassium ions in parallel with absorbance measurements.

Reagent cassettes, samples, calibrators, and controls are identified by a barcode scanner.

The high performance, flexibility, and versatility of the Cedex Bio HT Analyzer make this system suitable as a routine analyzer as well as a dedicated instrument for specific tasks.



A Control unit
B Analyzer

Figure 1

How to use this manual



- Keep this Operator's Manual in a safe place to ensure that it is not damaged and remains available for use.
- This Operator's Manual should be easily accessible at all times.

To help you find information quickly, there is a table of contents at the beginning of the book and at the beginning of every chapter. In addition, a complete index can be found at the end.

This manual is designed to help you perform all of the tasks that are required as part of your work with the analyzer.

If you are a new user, the manual will also help you to understand general hardware principles, the user interface, the status of the analyzer and its modules. You should familiarize yourself with these areas before attempting to perform daily tasks.

You can also find information about how to use the analyzer in the in the online Help.

Content The manual is divided into the following parts:

- Part A - **System Description**: Contains general information about the analyzer, about the basic concepts of using the analyzer, the hardware, the software, and the online Help. It also includes technical specifications of the analyzer. The *Safety* chapter contains important safety information. You must read the *Safety* chapter before operating the analyzer.
- Part B - **Operation**: Starts with a workflow description for some typical laboratory setups, using step-by-step instructions. It then describes how to perform all the day-to-day tasks necessary to create orders, monitor the status of the analyzer, view results, and deal with some simple problems that do not require detailed analysis.
- Part C - **Flags**: Describes the flags that are generated for unaccepted results and gives recommended actions.
- Part D - **Service**: Describes how to start and perform service actions that are essential to maintain maximum productivity from this analyzer.
- Part E - **Troubleshooting**: Describes how to pinpoint potential problems and how to solve them.
- Part F - **ISE measurements**: Describes the principles of operation of the ISE module and contains specialized sections on ISE flags and troubleshooting, and ISE service actions.
- Part G - **Configuration**: Describes some of the most common configuration tasks for a fully operational system. Full details on all configuration procedures are given in the online Help.
- **Glossary** and **Index**: Provide reference and look-up material.

Where to find information

In addition to the Operator's Manual, the following documents are also provided to assist in finding desired information quickly:

<i>User Training Guide</i>	Provides detailed step-by-step instructions for routine operations using the main applications of the analyzer.
<i>Instructions for Use</i>	A detailed guide to the Cedex Bio HT reagents, including test definitions and performance data.

Symbols and abbreviations

Visual cues are used to help locate and interpret information in this Operator's Manual quickly. This section explains the formatting conventions used in this Operator's Manual.

Product names Except where the context clearly indicates otherwise, the following product names and abbreviations are used:

Product name	Descriptor
Cedex Bio HT Analyzer	analyzer

Symbols The following symbols are used:

Symbol	Used for
►	Start of procedure
•	List item
👁	Cross-reference
➔	Call-up (software reference)
💡	Tip, indicates additional information on correct use or useful tips
⚠	Safety alert
	Electrical and electronic equipment marked with this symbol are covered by the European directive WEEE. The symbol denotes that the equipment must not be disposed of in the municipal waste system.

The following symbols are used on labels on the analyzer:

Symbol	Used for
~	Indicates that the equipment is suitable for alternating current only; to identify relevant terminals.
	Global Trade Item Number

User interface conventions The following conventions are used throughout the user documentation:

User action	Meaning
Configuration > Tests > ID	1. Click Configuration in the navigation bar. 2. Double-click Tests in the Definitions group. 3. Click the ID tab.
Choose File > Print Report > BOD Report	1. Click File in the menu bar. 2. Select Print Report from the menu. 3. Select BOD Report from the next menu.
Shift + F3	Press the Shift key and hold it down; press and release the F3 function key; then release the Shift key.
Click	Press the left button on the mouse or the equivalent button on the system keyboard.
Click OK	Move the cursor to the OK button, and then press the left mouse button.

User action	Meaning
Click Status	Click the Status button on the navigation bar.
Click Print	Click the Print button in the current window or dialog box.
Right-click	Click the right mouse button (or equivalent on the keyboard).
Press	Press a key on the keyboard.
Double-click	Click the left mouse button (or equivalent on the keyboard) twice in rapid succession.
Open	Open the window or dialog box.
Close	Close the window or dialog box.

Units SI units (Système International d'Unités) are used throughout the manual, where appropriate. The following units are either non-SI or may be unfamiliar to some users:

Abbreviation	Unit
BTU	British thermal unit
cm	Centimeters
in	Inches
lb.	Pounds (weight)
MΩ	Megohm
psi	Pounds per square inch
VA	Volt-Amperes
VAC	Volts (alternating current)
μS	Microsiemens

Abbreviations and acronyms The following abbreviations and acronyms are used throughout the documentation.

Abbreviation	Meaning	Usage
abs.	absorbance	abs. measurement
BOD	Begin of day	BOD service action
CAL	calibrator	(legend on graphic)
DIL	diluent	(legend on graphic)
FP	Fluorescence polarization	FP photometer
ID	Identification (number)	Order ID, sample ID
in.	internal	in. water reservoir
ISE	Ion selective electrode	ISE module
LCD	Liquid crystal device	LCD monitor
LED	Light-emitting diode	LED status indicator
No.	number	Lot No.
QC	quality control	Verifies accuracy and precision of results
STAT	immediate order	Priority samples, tests and results
TAS	Test application software	Roche default test, calibration, control, and diluent definitions

What is new in publication version 1.4

<i>New layout and structure</i>	Resulting from customer feedback, we have updated the layout and the structure of this publication to help you find information easier and perform tasks quicker.
<i>Backward compatibility</i>	Some new features are not available if you run the latest software on hardware with serial number lower than 620001. You find appropriate indications in this publication. 👁 <i>Replacing the cleaner</i> on page B-18 👁 Clean internal water reservoir on page D-23 👁 For retransmitting results, see <i>Context menu</i> on page B-89 and <i>About the Result Output tab</i> on page G-67
<i>Safety</i>	The Safety chapter was adapted to the latest Roche standards for safety information in user documentation. 👁 <i>Safety</i> on page -17
<i>New operating system</i>	The analyzer now runs Windows 10.
<i>Control unit</i>	New control unit running Windows 10 operating system. There is no diskette drive any more, and the CD drive was replaced with a DVD drive. 👁 <i>Control unit</i> on page A-7 👁 <i>Computer systems</i> on page A-41
<i>HIF</i>	Possible to configure and choose either HIF or HIF Extended. HIF Extended is an extension of the HIF functionality that provides additional features for remote control and data transfer. Increased baud rate is selectable for HIF interface.
<i>Changes in application software</i>	Date/Time cannot be changed within the application. Additional Windows user level available. Sample name is available (field next to sample ID). Rerun does not delete result.
<i>Interlock function</i>	To prevent accidental access to the operating area, the main cover is now generally locked and can only be opened as part of performing guided procedures. A specific unlock function is provided for emergency cases. This function is available if you work with analyzer hardware with serial number 620001 or higher. 👁 <i>Unlocking the main cover</i> on page E-20
<i>Traceability</i>	For each test, a record is generated about exactly which calibrator, quality control, and reagents were used. These records can be collected in a file and exported to an external storage device by using the Export Traceability File function. 👁 <i>To back up the traceability file</i> on page B-102

Fuses The user can no longer change fuses. This is done by Roche representatives.
The fuse status is indicated by LEDs at the front of the analyzer, under the main cover.

👁 *Checking and replacing fuses* on page E-43

Unlock rack tool On analyzer hardware with serial number 620001 or higher, the unlock rack tool is now placed in front of the cuvette reservoir on the right side of the analyzer.

👁 *Unlock rack tool* on page A-28

Safety

This chapter contains important safety information.

In this chapter	Chapter 1
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Introduction



General attention

To avoid serious or fatal injury, read this publication thoroughly before you use the analyzer.

- Pay particular attention to all safety precautions.
- Always follow the instructions in this publication.
- Do not use the analyzer in a way that is not described in this publication.
- Keep this publication in a safe place to ensure that it is not damaged and remains available for use.

This publication must always be easily accessible.

Safety classifications

The safety precautions and important user notes are classified according to the ANSI Z535.6-2011 standard. Familiarize yourself with the following meanings and icons:



Safety alert symbol

- The safety alert symbol is used to alert you to potential physical injury hazards. To avoid possible injury or death, comply with all safety messages that follow this symbol.
-

These symbols and signal words are used for specific hazards:



Warning...

- ...indicates a hazardous situation that, if not avoided, could result in death or serious injury.
-



Caution...

- ...indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.
-

NOTICE

Notice...

- ...indicates a hazardous situation that, if not avoided, may result in damage to the system.
-

Important information that is not safety relevant is indicated with the following icon:



Tip...

- ...indicates additional information on correct use or useful tips.
-

Safety precautions



General attention

- To avoid serious or fatal injury, read and comply with the following safety precautions.

- 👁 *Operator qualification* on page 19
- 👁 *Installation and deinstallation* on page 19
- 👁 *Operating conditions* on page 20
- 👁 *Safe and proper use of the system* on page 21
- 👁 *Warning messages* on page 21
- 👁 *Caution messages* on page 25
- 👁 *Notice messages* on page 27
- 👁 *Software and data security* on page 28
- 👁 *Safety labels on the system* on page 30
- 👁 *Disposal* on page 36

Operator qualification

Insufficient knowledge and skills

As an operator, ensure that you know the relevant safety precaution guidelines and standards and the information and procedures contained in these instructions.

- Do not carry out operation and maintenance unless Roche Diagnostics has trained you to do so.
- Leave maintenance, installation, or service that is not described to trained Roche representatives.
- Carefully follow the procedures specified in the instructions for operation and maintenance.
- Follow standard laboratory practices, especially when you work with biohazardous material.

Installation and deinstallation

Errors in installation

Only trained Roche representatives may install the system.

- Leave installation that is not described to trained Roche representatives.

Damage in transit

- Do not attempt to relocate or transport the system.
- Leave relocation and transportation to Roche representatives.

Disposal

A biohazardous system may lead to infection.

- If you must dispose of the system, read the following information.
 - 👁 *Disposal* on page 36

Operating conditions

Unsuitable operating conditions

Operation outside of the specified ranges may lead to incorrect results or malfunction of the system.

- Use the system indoors only. Avoid operating conditions above average temperature in combination with high humidity. Condensation can build up, especially in the cassette area.
- Make sure that the system's ventilation openings remain unobstructed always.
- To maintain the operating conditions of the system, perform maintenance in accordance with the specified intervals.
- Keep the operating instructions undamaged and available for use. Operating instructions must be easily accessible for all users.

Power interruption

A power failure or momentary drop in voltage may damage the system or lead to data loss. The Cedex Bio HT Analyzer does *not* fully comply with IEC 61000-4-11.

- Operate only with an uninterruptible power supply (UPS). Make sure to connect both the analyzer and the control unit to the UPS.
- Ensure regular maintenance of the UPS.
- Perform regular backups of results.
- Do not switch off power while the control unit accesses the hard disk or storage device.



Roche does not recommend a specific type of UPS, but the following requirements should be met when choosing a UPS:

- Switch over time < 10 ms
- Runtime without external power > 15 min

For questions regarding the UPS contact your Roche representative.

Electromagnetic interference

Strong electromagnetic fields (originating from unshielded radio frequency sources) can interfere with proper operation and may lead to malfunction of the system and incorrect results.

This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference.

- Do not use this system near sources of strong electromagnetic fields because these fields can interfere with the proper operation.
- Evaluate the electromagnetic environment before you operate the system.
- Take measures to mitigate the interference.

Safe and proper use of the system

<i>Correct use</i>	Use the Cedex Bio HT Analyzer only to measure liquid samples with the provided reagents.
<i>Missing personal protective equipment</i>	Working without personal protective equipment means danger to life or health. - Wear appropriate personal protective equipment, including, but not limited to, the following items: - Eye protection with side shields - Fluid-resistant laboratory coat - Approved lab gloves - Face shield if there is a chance of splashing or splattering - Follow good laboratory practices and regularly change lab gloves to minimize the risk of infection and contamination (especially after contact with waste or sample material).
<i>Fatigue due to long hours of operation</i>	Looking at the monitor over an extended time may lead to eye strain or body fatigue. Take a break to relax, in accordance with your local regulations.
<i>Cleaning and maintenance</i>	Improper cleaning and maintenance can cause personal injuries and equipment damage. Always follow the cleaning and maintenance instructions contained in this publication.
<i>System not used for an extended period</i>	Follow the decommissioning procedure if available. - Set the power switch to OFF if you do not use the system for an extended period. - Remove and refrigerate any remaining reagents. - For further information, call your Roche representative.
<i>Non-approved parts</i>	Use of non-approved parts or devices may result in malfunction of the system and may render the warranty null and void. Use only parts and devices approved by Roche Diagnostics.

Warning messages



List of warning messages

Failure to observe warning messages may result in death or serious injury.

- Before operating the system, read the warning messages carefully

- 👁 *Electrical safety* on page 22
- 👁 *Biohazardous materials* on page 22
- 👁 *Cauterizing and toxic materials* on page 23
- 👁 *Incorrect results* on page 23
- 👁 *Labeling* on page 24

Electrical safety

Electric shock Removing the covers of electronic equipment can cause electric shock because there are high-voltage parts inside.

- Do not attempt to work on any electronic equipment.
- Do not remove any cover of the system except those covers specified in the instructions.
- Only Roche representatives may install, service, and repair the system.

Biohazardous materials

Infectious substances Contact with substances containing material of human origin may result in infection. All materials and mechanical components associated with substances containing material of human origin are potentially biohazardous.

- Follow standard laboratory practices, especially when working with biohazardous material.
- Keep all covers closed while the system is operating.
- Always switch off the system or go to maintenance mode, if available, before you work with an opened cover (for example, for cleaning or maintenance).
- Wear appropriate personal protective equipment.
- If any biohazardous material is spilled, wipe it up immediately and apply a disinfectant.
- If sample or waste comes into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant. Consult a physician.
- Take particular care when removing and cleaning up possible broken cuvettes and glass fragments.

Sharp objects Contact with probes or needles may result in infection.

- When you wipe probes or needles, use several layers of gauze and wipe from the top down.
- Take care not to puncture yourself.
- Take particular care when removing and cleaning up possible broken cuvettes and glass fragments.
- Wear appropriate personal protective equipment.
Take extra care when working with lab gloves, which can easily be pierced or cut, leading to infection. When cleaning near the needles, take care not to puncture yourself.

Infectious waste Contact with waste (liquid and/or solid) may result in infection. All materials and mechanical components associated with the waste systems are potentially biohazardous.

- Wear appropriate personal protective equipment. Take extra care when working with lab gloves. They can easily be pierced or cut, leading to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply a disinfectant.
- If waste comes into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant. Consult a physician.

Environmental harm The system generates liquid and/or solid waste. This waste contains concentrated reaction solutions and is potentially biohazardous. Improper disposal may contaminate the environment.

- Treat this waste as infectious waste.
- Dispose of waste in accordance with the local regulations.

Cauterizing and toxic materials

Reagents and toxic chemicals Contact with cauterizing or toxic material may result in injury.

- Follow standard laboratory practices.
- Wear appropriate personal protective equipment.
- If cauterizing or toxic material is spilled, wipe it up immediately and apply a disinfectant.
- If cauterizing or toxic material comes into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant. Consult a physician.

Incorrect results

Installation Incorrect system setup may lead to incorrect results.

- Leave installation that is not described to trained Roche representatives.

Poor accuracy and precision Poor accuracy and precision may lead to incorrect results.

- For proper use of the system, run QC tests and monitor the system during operation.
- Do not use reagents or consumables that have exceeded their expiry date, otherwise you may obtain inaccurate data.

Incorrect reagent volume Incorrect reagent handling may cause an undetectable loss of reagent.

- Always store reagents according to the specified storage conditions as stated in the Instructions for Use for the test.
- Do not reuse a reagent cassette whose reagent has spilled.
- Do not use a reagent cassette for different systems.

Incorrect reagent handling Incorrect reagent handling may lead to incorrect results.

- Always store and handle reagents as stated in the Instructions for Use for the test.
- Do not reuse a reagent cassette whose reagent has spilled.
- Do not use a reagent cassette for different systems.

Foam, clots, films, or bubbles Incorrect results may occur due to foam, clots, films, or bubbles in reagents or samples.

- Avoid the formation of foam, clots, and bubbles in all reagents, samples, calibrators, and controls.
- Follow the instructions given by the primary tube manufacturers.

<i>Contaminated samples</i>	Insoluble contaminants, bubbles, or films in samples may cause clogging or pipetting volume shortage, leading to incorrect results. • Make sure that the samples contain no insoluble contaminants, such as dust.
<i>Evaporation of samples or reagents</i>	Evaporation of samples or reagents may lead to incorrect or invalid results. • Sample material may evaporate if left open. Do not leave samples open for any length of time. • Do not use improperly stored reagents. Ensure that reagents are stored according to the Instructions for Use.
<i>Unsuitable calibrators, incorrect placing of calibrators</i>	Using unsuitable calibrators or not placing them on the correct position may lead to incorrect results. • Always use the calibrators defined in the test definitions. • Always place the calibrators on the position defined in the order.
<i>Carryover</i>	Traces of analytes or reagents may be carried over from one test to the next. • Take adequate measures (for example, extra wash cycles) to avoid extra testing and potentially incorrect results, especially with high-sensitive methods (e.g. heterogeneous immuno-assays).
<i>Condensation water</i>	In operating conditions of above average temperature and in combination with high humidity, condensation can build up especially in the cassette area. Water can spill on the cassettes and may lead to incorrect or invalid results. In operating conditions of above average temperature and in combination with high humidity, observe the following precautions: • Check every two hours if condensation has built up inside of the cassette area. Check also underneath the cassettes. • Wipe up any condensation water on the cassettes, the cassette racks, and in the cassette area. • Adjust the ambient conditions so that condensation water cannot build up.

Labeling

If a recall of a consumable is required you need to be able to identify your consumables exactly.

- If the label of the container that contains the consumables is no longer available you can still find the identification information on the sleeve that contains the consumables.

Caution messages



List of caution messages

Failure to observe caution messages may result in minor or moderate injury.

- Before operating the system, read the caution messages carefully
-

- 👁 *Operator qualification* on page 25
- 👁 *Mechanical safety* on page 25
- 👁 *Reagents and working solutions* on page 26
- 👁 *Maintenance* on page 26
- 👁 *Laser beam* on page 26

Operator qualification

Insufficient knowledge and skills

Incorrect use of the analyzer may delay the results and influence their quality.

- Do not carry out operation and maintenance unless Roche Diagnostics has trained you to do so.
- Leave maintenance, installation, or service that is not described to trained Roche representatives.
- Carefully follow the procedures specified in the instructions for operation and maintenance.
- Follow standard laboratory practices, especially when you work with biohazardous material.

Mechanical safety

Moving parts

Contact with moving parts may result in personal injury.

- Keep all covers closed and in place while the system is operating.
 - Always switch off the system or go to maintenance mode, if available, before you work with an opened cover (for example for cleaning or maintenance).
 - Do not touch any parts of the system except those parts specified. Keep away from moving parts during operation.
 - Be careful not to hit your head when the covers are open.
 - Pay attention to the covers during automatic movement, check for obstructions and keep out of reach.
 - During operation and maintenance, carefully follow the instructions.
- 👁 *Safety labels on the system* on page 30

Reagents and working solutions

- Skin inflammation or injury* Direct contact with reagents, detergents, cleaning solutions, or other working solutions may cause skin irritation, inflammation, or burns.
- When you handle reagents, exercise the precautions required for handling laboratory reagents.
 - Wear appropriate personal protective equipment.
 - Observe the instructions given in the Instructions for Use.
 - Observe the information given in Safety Data Sheets (available for Roche Diagnostics reagents and cleaning solutions).
 - If reagents, detergents, or other cleaning solutions come into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant. Consult a physician.

- Fire and burns* Flammable substances can be ignited by sparks or electric short circuits. Alcohol is a flammable substance.
- Keep all sources of ignition (such as sparks, flames, or heat) away from the system when you perform maintenance or checks that involve alcohol.
 - When you use alcohol on or around the system, use no more than 20 mL at a time.
 - Do not spray any liquid on the power supply parts.

- Spilled liquid* Any liquid spilled on the system may result in malfunction or damage.
- Do not place samples, reagents, or any other liquid on top of the analyzer. Liquid may run into the cooling unit and the electronics.
 - When you remove or replace consumables, do not spill any liquid on the system.
 - If liquid does spill on the system, wipe it up immediately and apply a disinfectant. Wear appropriate personal protective equipment. Dispose waste according to the local regulations.

Maintenance

- Cleaning and maintenance* Improper cleaning and maintenance can cause personal injuries and equipment damage.
- Always follow the cleaning and maintenance instructions contained in this publication.

Laser beam

- Blindness due to intense barcode scanner light* The intense light of a laser or LED barcode scanner may severely damage your eyes or result in exposure to hazardous radiation.
- Do not stare into the beam of a laser or LED barcode scanner.
 - Do not remove covers from barcode readers.
 - Do not perform any maintenance actions on barcode readers. If you experience problems with the barcode readers, contact your Roche representative.
 - Perform only the procedures described in operating instructions. Performing unauthorized procedures may result in exposure to hazardous radiation.

Notice messages

NOTICE

List of notice messages

Failure to observe notice messages may result in damage to the system.

- Before operating the system, read the notice messages carefully

👁 *Collision with moving parts* on page 27

👁 *Circuit breakers and fuses* on page 27

👁 *Spilled liquid* on page 27

👁 *Unreliable data due to low quality connectors* on page 27

Collision with moving parts

Contact with moving parts may bend the probes or needles or damage some other component. If the system detects a collision, an alarm is raised, stopping the operation immediately.

- Keep all covers closed and in place during operation.
- Do not touch any parts of the system except those parts specified. Keep away from moving parts during operation.

Circuit breakers and fuses

Improper use may result in damage to the system.

- If one of the circuit breakers or fuses blows, do not attempt to operate the system before contacting either your Roche representative or technical support.

Spilled liquid

Any liquid spilled on the system may result in malfunction or damage.

- Place samples, reagents, or any other liquid only at the intended positions. Do not place samples, reagents, or any other liquid on the covers or other surfaces of the system.
- When you remove or replace consumables, do not spill any liquid on the system.
- If liquid does spill on the system, wipe it up immediately and apply a disinfectant. Wear appropriate personal protective equipment. Dispose waste according to the local regulations.
- Do not place anything on top of the analyzer. Small objects may fall and spilled liquid may run into the cooling unit and the electronics.

Unreliable data due to low quality connectors

Using cable connections to the host that are not well shielded may lead to absence or instability of connection or to corrupt data.

- Always use well shielded RS232 cables for host connection.

Software and data security

- 👁 *Unauthorized system access and data loss on page 28*
- 👁 *Backup security on page 28*
- 👁 *Corrupt data due to a disclosed password on page 29*
- 👁 *Corrupt data and unauthorized access due to faulty media converters on page 29*
- 👁 *Unreliable data due to low quality connectors on page 29*
- 👁 *Non-approved third-party software on page 29*
- 👁 *Unreliable validation due to unauthorized changes to the validation settings on page 29*
- 👁 *Unreliable validation due to unauthorized changes to the validation and calculation rules on page 29*

Unauthorized system access and data loss

External storage devices can transmit computer malware, which may be used to gain unauthorized access to data or cause unwanted changes to software.

The system is not protected against malicious software and hacker attacks.

The operators are responsible for the IT security of their IT infrastructure and for protecting it against malicious software and hacker attacks. Failure to do so may result in data loss or may render the system unusable.

Roche recommends the following precautions:

- Allow physical access only to authorized personnel.
- Allow connection only to authorized external devices.
- Protect all external devices, make sure that you use appropriate security software.
- Protect access to all external devices, make sure that you use appropriate security equipment. Your Roche representative can recommend a suitable firewall.

If this product is connected to a local area network, this network must be protected against unauthorized access. Do not connect directly to other networks or the Internet.

- Do not copy or install any software on the system unless it is part of the system software or your Roche representative tells you to do so.
- If extra software is required, contact your Roche representative to ensure validation of the software in question.
- Do not use the USB ports to connect other storage devices unless your Roche representative or an operating instruction tells you to do so.
- Exercise care when you use external storage devices such as USB drives or DVDs. Do not connect to the system any external storage device that you use on public or home computers.
- Keep all external storage devices in a secure place, and make sure that only authorized personnel can access them.
- Back up your data regularly.

Backup security

Roche recommends the following precautions:

- Only use virus free external storage devices for backup purposes.
- Transmit backup data to external storage devices via secure networks only.
- Keep external storage devices that hold backup data in secure locations with strictly regulated access only.

<i>Corrupt data due to a disclosed password</i>	The security of the system and its data depends on the password-protected access. If an unauthorized person discovers your user ID and password, they could compromise this security. • Always enter your password unobserved. • Do not write down your password anywhere, including in a contact form, in the address book, or in a file on the computer. • Do not disclose your password to anyone. Roche will never ask you for your password. • Do not use shared accounts. • If you ever disclose your password to anyone, change it immediately afterwards. • Contact your local Roche affiliate if you think your account has been compromised.
<i>Corrupt data and unauthorized access due to faulty media converters</i>	Media converters may influence the signal quality and corrupt data. When using an RS232 to Ethernet media converter at the host interface, there is a possibility of unauthorized access to and modification of the data that are transmitted over the network. Roche shall not be held liable for possible data corruption associated with media converters.
<i>Unreliable data due to low quality connectors</i>	Using cable connections to the host that are not well shielded may lead to absence or instability of connection or to corrupt data. • Always use well shielded RS232 cables for host connection.
<i>Non-approved third-party software</i>	Installation of any third-party software that is not approved by Roche Diagnostics may result in incorrect behavior by the system. • Install only approved third-party software.
<i>Unreliable validation due to unauthorized changes to the validation settings</i>	The manufacturer shall not be held liable for any consequences resulting from subsequent, unauthorized modifications to the accepted validation settings included in the system at the customer's request. • Ensure that only authorized personnel can change, if necessary, the validation settings.
<i>Unreliable validation due to unauthorized changes to the validation and calculation rules</i>	The manufacturer shall not be held liable for any consequences resulting from subsequent, unauthorized modifications to the accepted validation and calculation rules included in the system at the customer's request, as well as test results. • Ensure that only authorized personnel can change, if necessary, the validation and calculation rules, and test results.

Safety labels on the system

The system has warning labels to draw your attention to areas of potential hazard. The following sections briefly describe the meaning of the safety labels at the locations where they are labeled on the system.

The safety labels on the analyzer comply with the following standards: ANSI Z535, IEC 61010-2-101, IEC 61010-1, IEC 60417, ISO 7000, or ISO 15223-1.



If the labels are damaged, they must be replaced by a Roche representative. For replacement labels, contact your local Roche representative.



General warning

Potential hazards located near this label may lead to death or serious injury. Refer to the user documentation for instructions on safe operation.



Laser transmitter

There is a danger of contact with laser light or severe damage to the eyes.

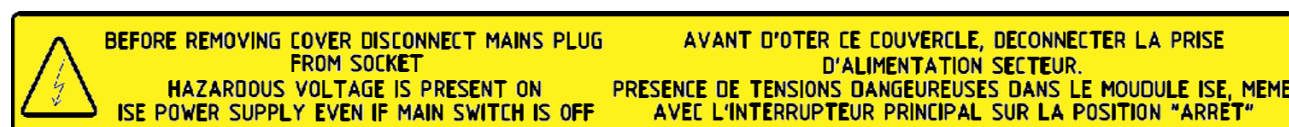
Do not stare into the laser transmitter.

👁 For details, see *Laser beam* on page 26.



Biohazard

Potentially biohazardous materials are used near this label. Observe relevant good laboratory practices on safe usage.

**Electric shock**

If you access a part of the system marked with this label, contact with electrical components may cause an electric shock.

Refer to the user documentation for instructions on safe operation.



The safety messages give more detailed information about potentially hazardous situations that may arise during daily operation, or when carrying out maintenance actions.

When working with the system, observe both the safety labels on the system and the safety messages in the user documentation.

When working with the system, observe both the safety labels on the system and the safety messages in the user documentation.

**Hot surface**

The area near this label may be hot.

To avoid burns, do not touch this area.

**Consult user documentation**

The item with this label has its own user documentation.

To ensure proper handling if the item with this label, consult its associated user documentation.

**Injury due to moving or rotating parts**

There is a risk of injury, body parts, hair and clothes can be caught or squeezed by moving parts even when the analyzer main power switch is off

Keep away from moving parts.

DO NOT INTERCHANGE OPENED REAGENT CASSETTES BETWEEN INSTRUMENTS
NE PAS ECHANGER DE CASSETTES DE REACTIF OUVERTES ENTRE INSTRUMENTS

Incorrect results

Each cassette has its own individual cassette number, which the system uses to identify it. Using a cassette already used on a different system may lead to incorrect results.

Do not use a reagent cassette for different systems. Each cassette rack with its cassettes may be used on one individual system only.

If more than one system is used in the same lab, be sure to dedicate each cassette rack with its cassettes to one single, individual system (e.g. by color coding).

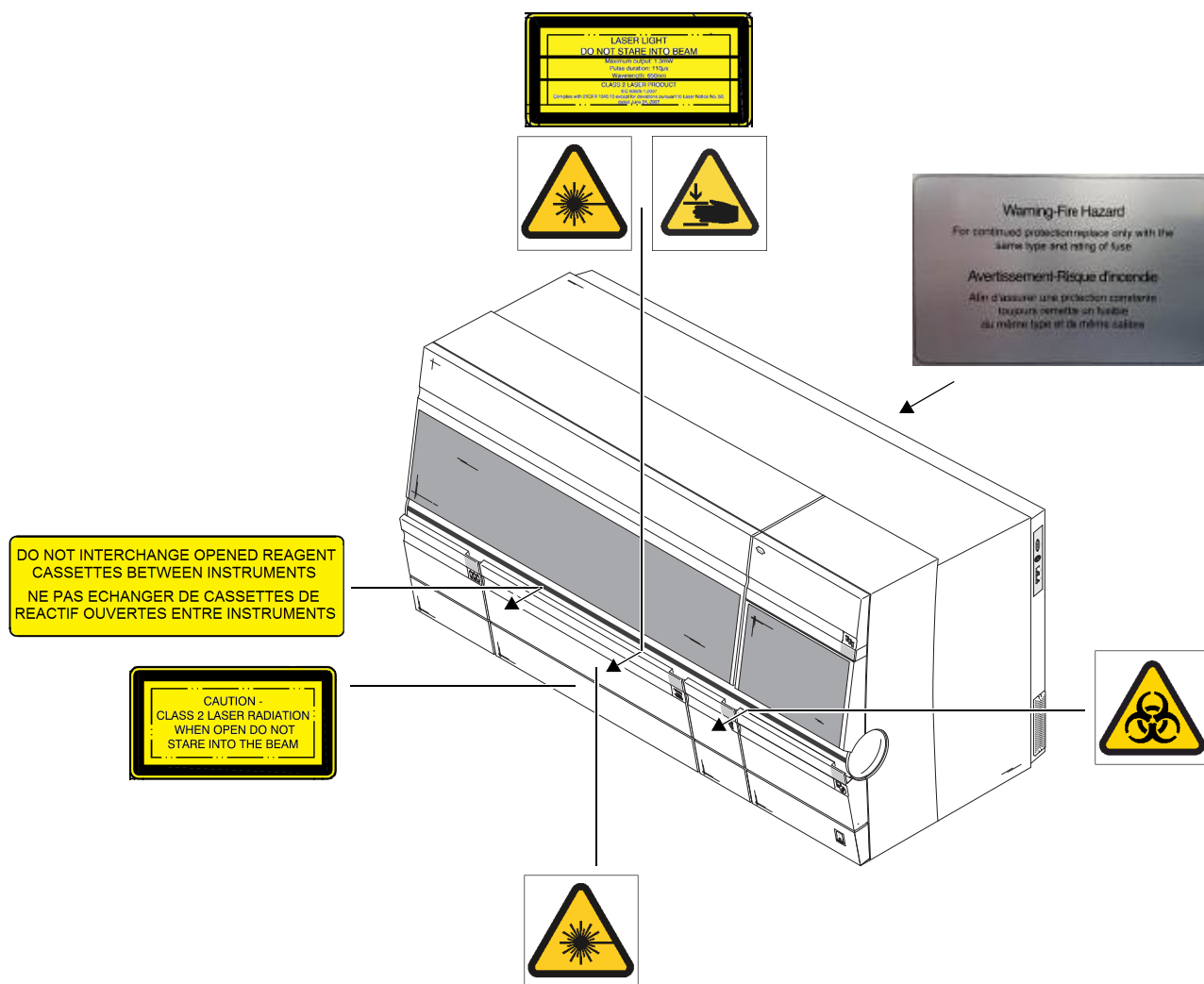


Figure 2 Labels on the inside and outside of covers and lids

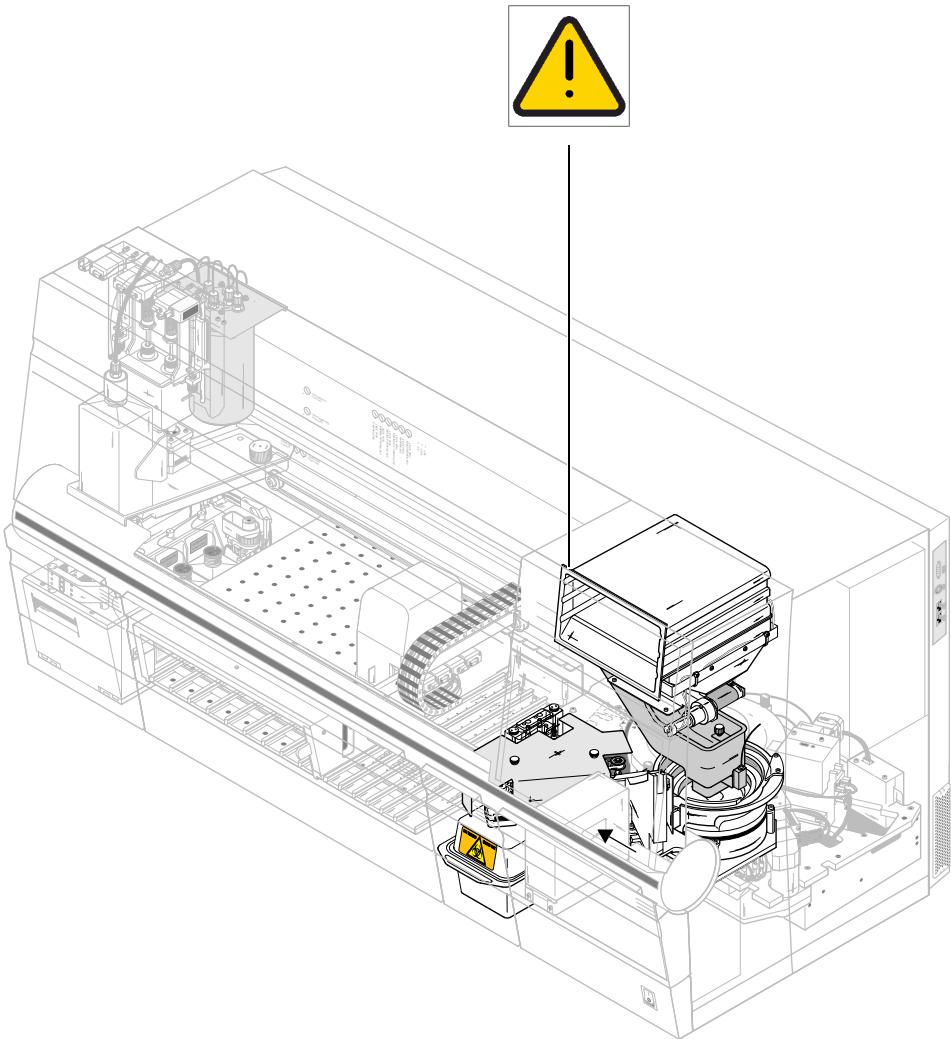


Figure 3 Labels on cuvette feeder

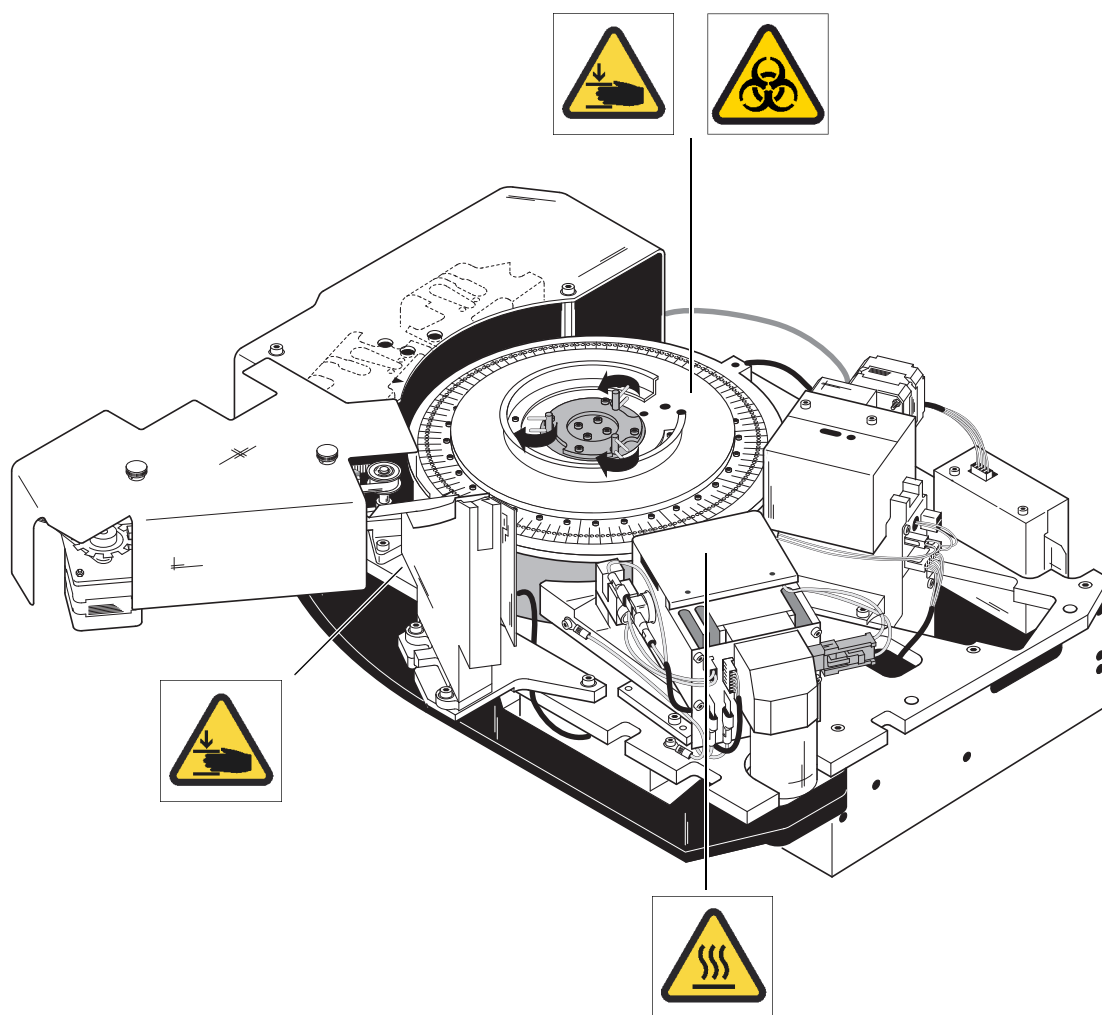


Figure 4 Labels on analyzer rotor and the photometer

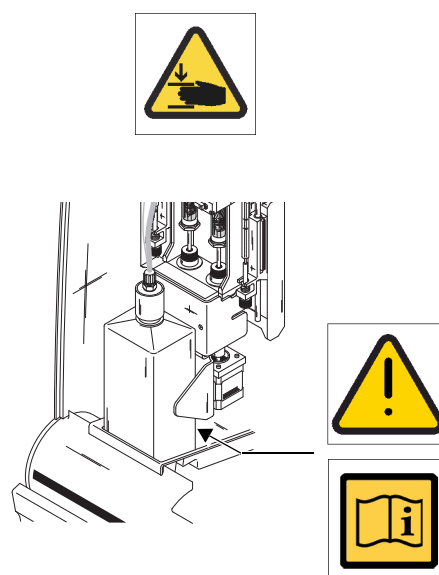


Figure 5 Labels on pipette module and cleaner bottle holder

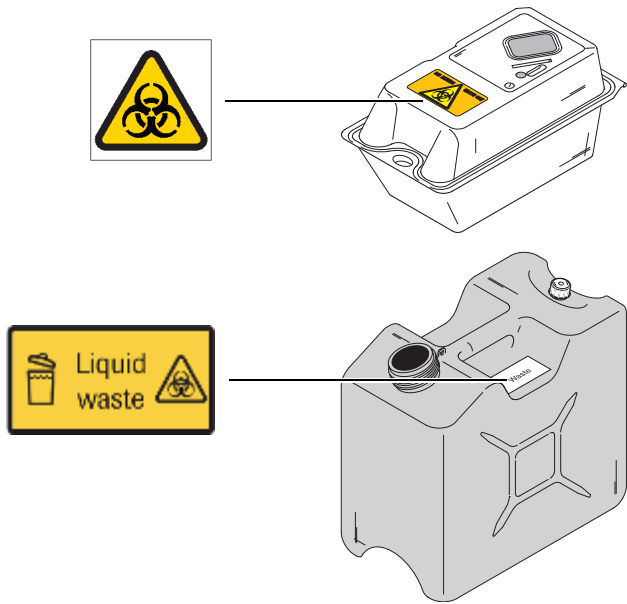


Figure 6 Labels on waste containers

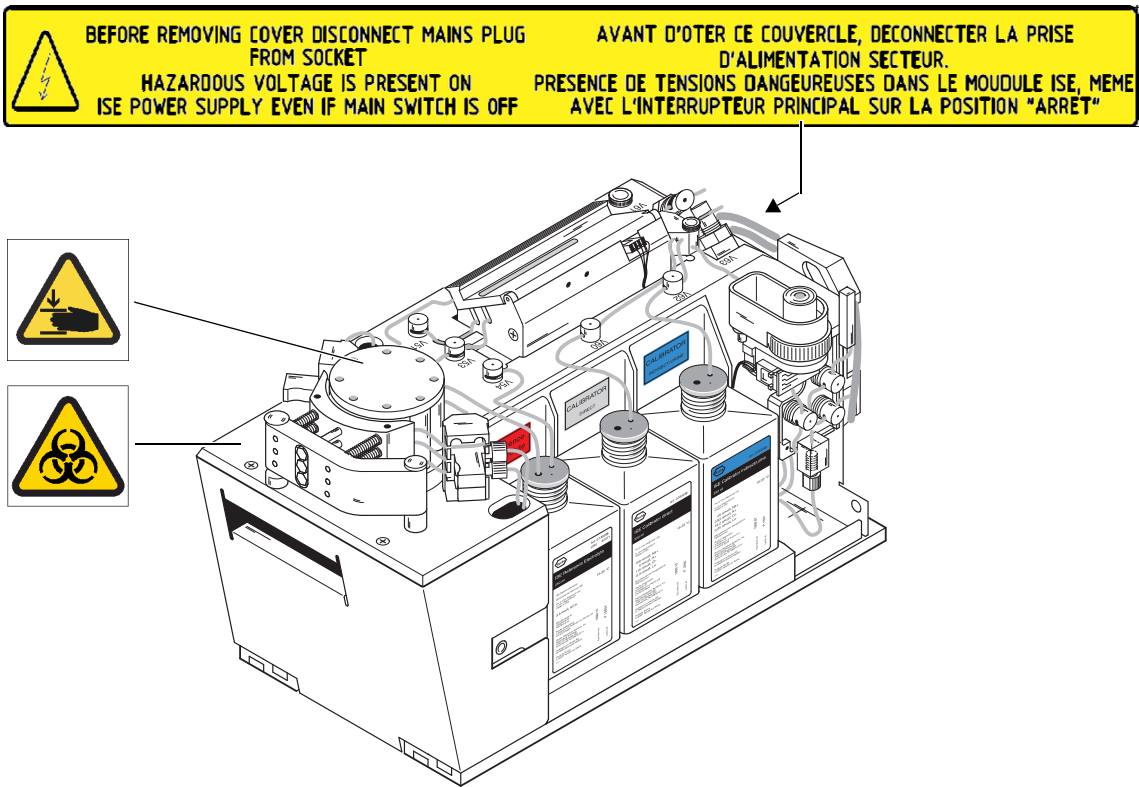


Figure 7 Labels on ISE module

Disposal

Infection by a biohazardous system

Treat the system as biohazardous waste.

- Decontamination (the combination of processes including cleaning, disinfection, and/or sterilization) is required before reuse, recycling, or disposal of the system.
- Dispose of the system according to the local regulations. For more information, contact your Roche representative.

Electrical components

Proper disposal of your old appliance prevents potential negative consequences for the environment and human health.

- Dispose of all electrical and electronic products separately from the municipal waste system.

Control unit components

Components of your Control Unit such as the computer, monitor, keyboard, etc. which are marked with the crossed-out wheeled bin symbol are covered by the European Directive on Waste Electrical and Electronic Equipment (WEEE).



For more information about disposal of your old product, please contact your city office, waste disposal service or your local Roche Support personnel.

- Dispose of these items via designated collection facilities appointed by government or local authorities.
- It is left to the responsible laboratory organization to determine whether control unit components are contaminated or not. If contaminated, treat them in the same way as the system.

System Description



2	<i>Overview</i>	A-3
3	<i>System description</i>	A-13
4	<i>User Interface</i>	A-53
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Overview

A quick look at the analyzer

This chapter provides an overview of the analyzer and its main features. It also provides an introduction to some of the key ideas that are developed later on in the manual

In this chapter

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 System status A-11

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 Waste disposal A-12

 Automatic start-up A-12

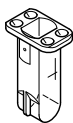
 Begin of Day A-12

Introduction

The Cedex Bio HT Analyzer is a random and continuous selective analyzer designed to operate from a table top. There are three separate measurement systems supporting four different measurement principles:

Measurement system	Measurement principle
Absorbance photometer	Absorbance photometry Turbidimetry
ISE (Ion-Selective Electrode) module	Ion selective potentiometry
FP photometer (not used)	Fluorescence polarimetry

Table A-1



Samples are automatically transferred from a sample tube or cup to the module where the measurements are made. All optical measurements use the same transparent plastic containers, called cuvettes.

The graphical user interface provides quick and easy access to sample, control, and calibration data, while continuously monitoring all system functions. Color-coded icons alert you to changes in the system status. Connection to a host system allows for automatic transfer of results to and from the analyzer.

What the system does

The system consists of the analyzer and the control unit.

The analyzer runs tests on samples, calibrators, and controls, and produces the results. The control unit analyses and further processes the results.

Here are just some of the actions the system performs automatically:

- Delivers the correct volumes of samples, reagents, and other solutions to the measuring modules.
- Reads the barcodes on reagent cassettes, samples (if barcoded), and other solutions.
- Performs washing and cleaning cycles to minimize carry-over between tests.
- Takes the physical measurements on which the results are based.
- Calculates and ensures the integrity of the result, generating flags for suspect ones.
- Keeps track of all samples, tests, and orders on the analyzer.
- Collates results into reports for printing or transmission to another computer system.
- Stores the results on each sample and test in a database.

A first look at a analyzer

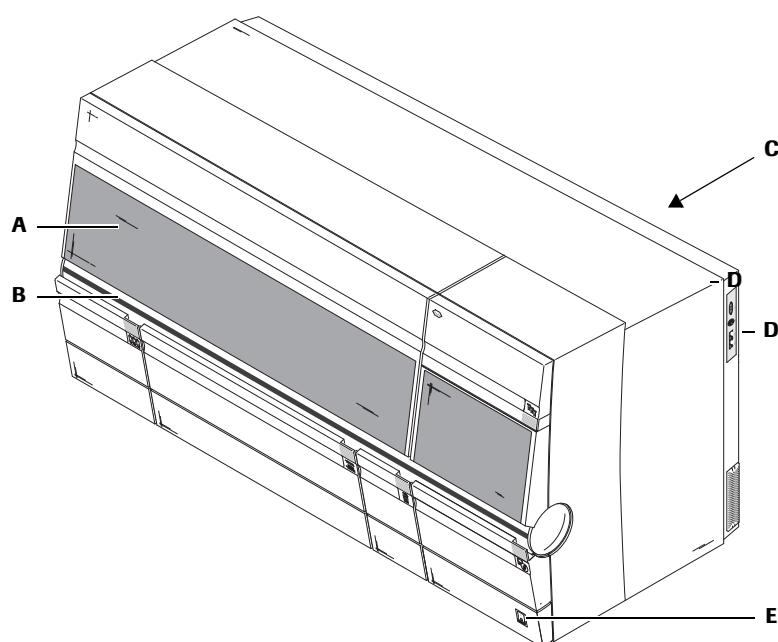
Analyzer

The analyzer carries out all test orders automatically and is equipped with measuring modules for absorbance photometry (Abs.), fluorescence polarization (FP) photometry, and optionally for ion-selective electrode (ISE) measurements.



FP photometry is not active on the Cedex Bio HT Analyzer and is not used for Cedex Bio HT tests.

Colored LEDs (light-emitting diodes) on the rack status indicator panel on the front of the analyzer tell you the current status of onboard cassette and sample racks.



- A** Main cover
- B** Status indicator panel
- C** External waste, water, and power connections (not shown)
- D** Data connectors (for connection to the control unit and the LAN)
- E** Main switch

Figure A-1

The system is designed to run continuously, 24 hours a day, if necessary. However, an On/Off switch (main switch) is provided if you need to switch off the power to the system in an emergency or for troubleshooting.

- 👁 *Switching on the system* on page B-5
- 👁 *Shutting down the system* on page B-10

External waste, water and power connections are made at the rear of the analyzer. The analyzer may be connected to the laboratory waste and water system or you can use external waste and water reservoirs.

Control unit

The control unit comprises the following elements:

- Printer (optional)
- Computer
- Keyboard
- Monitor
- Hand-held barcode scanner
- Mouse

User interface

You can control the user interface with the mouse and keyboard. The user interface is structured as a series of work areas; the main ones are **Status**, **Orders**, **Results**, and **Service**. Each work area contains two or more tabs. By clicking a tab, you can move around the work area.

You can display any test results on the monitor or print reports containing information on samples, orders, and results. Connection to a local printer is optional. This printer needs to be PCL 5 compliant, and can be connected using either LPT or a USB port.

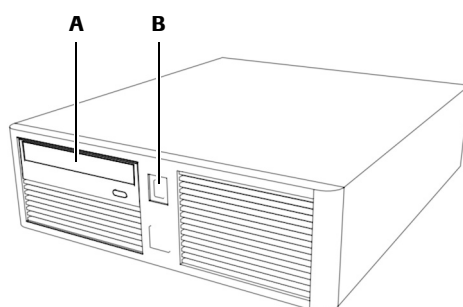
You can manually enter orders for tests on samples in the **Orders** work area. Alternatively, the system receives orders electronically from a host system, if your analyzer is connected to such a system.

System messages are displayed in the **Messages** work area, and you can communicate with other users by using the **Memo Pad**.

👁 Chapter 4 User Interface

Computer

The computer performs tasks in connection with order processing, data management, and user interface management. It makes it possible to simultaneously manage data and enter new orders.



- A** DVD drive.
Used for upgrades and data mirroring.
- B** USB ports.
Information can be saved on external storage device.

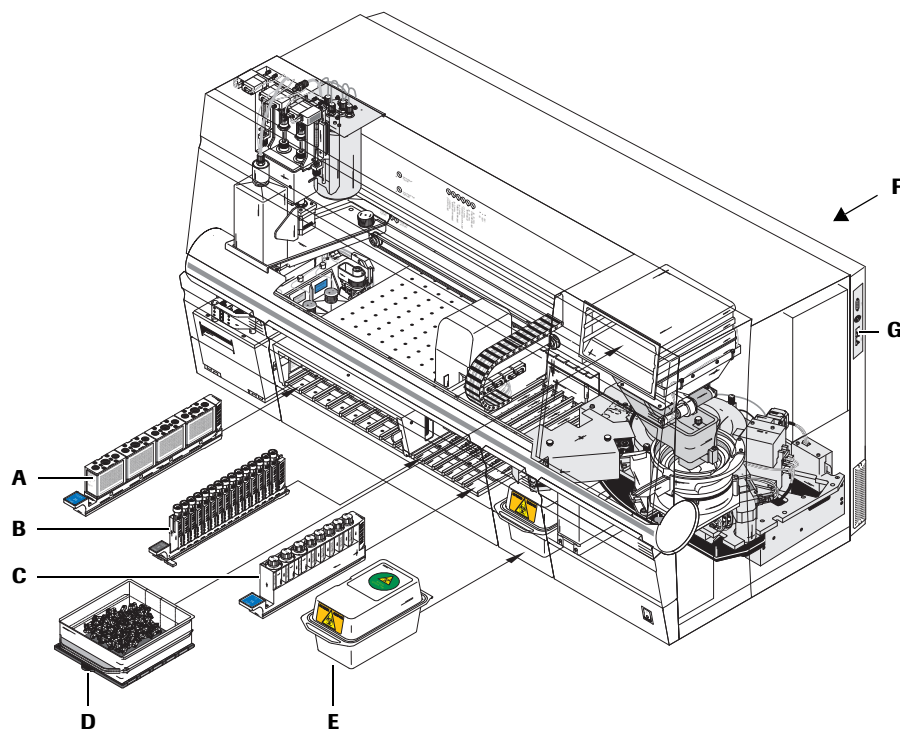
Figure A-2 Computer for the analyzer

Hand-held barcode scanner

You use the hand-held barcode scanner to read sample barcodes.

Overview of user tasks

The figure below shows some of the main access points for tasks you perform regularly.



- A** Cassette rack with reagent cassettes
- B** Sample rack with samples (or calibrators, controls, and diluents)
- C** ISE rack with ISE solutions and diluents
- D** Cuvette reservoir for new cuvettes
- E** Disposable cuvette waste box (autoclavable) for used cuvettes
- F** Connections to water and waste are made on the rear panel (not shown)
- G** Data connectors

Figure A-3

Here are some important user tasks:

- Perform service actions.
- Prepare resources.
- Replace consumables such as cleaners, cuvettes and dispose of used ones.
- Print reports, for example, the **Loadlist**.
- Load racks containing samples, reagents (cassettes), calibrators, controls, and diluents. Remove processed racks.
- Create orders and request calibrations and controls.
- Monitor the status of the analyzer: check resources and **Missing & Blocked** in the **Status** work area.
- Validate results.
- Troubleshoot problems.
- Remove waste, for example, used cuvettes or waste liquid.
- Delete results and orders.

Cleaning the analyzer externally

You can clean the analyzer externally with a cloth and a soap solution with mild disinfectant, or a solution of 70% ethanol.

Incorrect cleaning materials can damage the analyzer.

- Do not clean the analyzer while it is switched on.
- Do not use organic cleaning solvents (for example, petroleum, benzene, petrol or other solvents) because they can damage cuvettes, tubing, and other plastic materials.
- Do not use an alcohol solution with a concentration of greater than 70% alcohol, because this may damage transparent viewing windows.
- Do not use sodium hypochlorite solution because it causes corrosion on metal parts.

Service actions

You must perform all internal cleaning tasks according to the instructions given in the user documentation and provided online as part of the software assisted service actions. You review and perform service actions in the **Service** work area. The system prompts you when service actions are due.

Basic principles

This section provides a quick introduction to some of the key features of the analyzer and how you use it.

Sample handling

Samples can be placed in 5, 5.5, 7, 7.5 or 10 mL primary tubes. COBAS cups, Eppendorf, and Cup on Tube can be used for smaller volumes of samples.

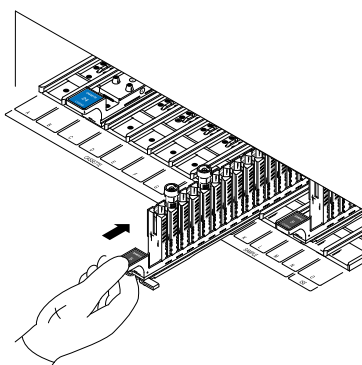


Figure A-4 Sample rack

Sample racks allow continuous access to samples as tests are completed and new samples arrive. Samples can be barcoded to allow the positive identification of samples by the system. You can add or remove the racks as necessary. When you insert a rack, the sample barcodes are read automatically.

The samples on the left most rack (rack in slot with lowest position letter) are measured first, followed by those on the rack next to it on the right.

STATs are automatically given priority to speed up the delivery of results, while the routine workflow remains uninterrupted.

Cassettes and reagents

All tests use the same reagent cassette design. A large number of reagent cassettes specifically tailored to the Cedex Bio HT Analyzer are available in an easy-to-use, easy-to-store design.

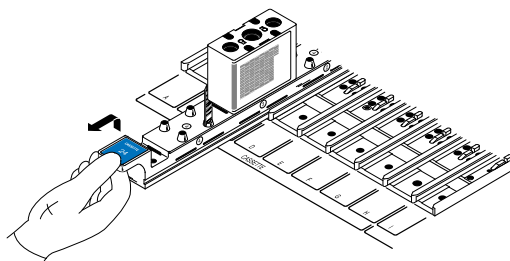


Figure A-5 Cassette rack

You put cassettes onto a cassette rack, which you can load or remove while the system is running. Cassette labels are barcoded for fast, accurate, and secure entry of reagent data, such as the number of tests, lot number, and expiry date.



- When handling multiple cassette racks, wait at least three seconds before you manually handle the next rack.
- When inserting a cassette rack, try to tilt the rack slightly clockwise (5-10°), so that the barcode is not read at an exactly 90° angle. This can help in case of barcode reading problems due to unwanted surface reflection from a glossy barcode label material.



WARNING

Incorrect results due to use of same cassette on multiple systems

Each cassette has its own individual cassette number, which the system uses to identify it. Using a cassette already used on a different system may lead to incorrect results.

- Do not use a reagent cassette for different systems. Each cassette rack with its cassettes may be used on one individual system only.
- If more than one system is used in the same lab, be sure to dedicate each cassette rack with its cassettes to one single, individual system (e.g. by color coding).

The list of onboard tests is continuously monitored; you are automatically notified when the supply is low. Color-coded cassette graphics tell you at a glance when you need to load new cassettes. Once you load a new cassette, the system automatically uses the new cassette as soon as the current one is used up. The system tracks the reagents available on board and forecasts if additional cassettes are required based on your workflow statistics. Test data is stored even after a cassette has been removed.

Calibrations and quality controls

Calibrators and quality controls use the same types of tubes and racks as samples. A refrigerated rack position improves the stability of onboard calibrators and controls.

The system can perform calibrations and controls automatically according to the specification in the test definition. Alternatively, you can request a calibration or control manually. The system tells you when calibrations or controls are required and when there is not enough calibrator or control material on board to complete the request.

You can use precision, accuracy, or limit controls. You can use up to six controls per test, and you can exclude suspect controls from the statistics.

Result handling

The system automatically generates flags for all results that do not meet the required specifications. For quality controls, you can apply rules to ensure reliable results. On-screen Levey-Jennings plots allow a quick review of results.

Accepting results

An auto-accept feature means that you can choose whether appropriate results are accepted automatically, for example, if they have no test or quality control flags and are within range. You can display all non-accepted results (for samples, calibrators, or controls) in the user interface. For each non-accepted result, you can choose to accept the result or rerun the measurement, for example with dilution.



Suspect results due to working with flagged calibrator or QC results

If you accept flagged calibration or quality control results, all results in tests that use those calibrations or controls will be suspect.

- Do not accept flagged calibrator or QC results.
-

System status

The system continually monitors its own status and informs you when resources are low. You can then take the required action to keep the system running. For example, when the supply of cuvettes is low, the icon and background color of the **Status** button on the navigation bar change.

The **Missing & Blocked** tab in the **Status** work area, and the **Worklist** tab in the **Orders** work area tell you which tests are blocked and what you have to do to remove the block. For example, if a test cannot run because a calibrator is not on board and a calibration is overdue, the system tells you. Once you have loaded the calibrator, the system can perform the calibration and then the test.

Maintenance, service, and troubleshooting

Essential maintenance activities (referred to as service actions) are automatically tracked by the system. The system prompts you when you need to perform a service action. Online wizards guide you through the service actions, and additional step-by-step information is available in the online Help and later in this manual. The system uses workload statistics to establish the interval between service actions rather than using a fixed number of days.

For each service action performed, the system automatically logs the user, date, time, and comments in accordance with standard good laboratory practice.

Context-sensitive online Help provides troubleshooting information on hardware and software. If you cannot solve a problem yourself, you can contact your Roche representative, who can (with your permission) dial into your system via the **connect 2** box or a cobas link gateway and control it remotely. You can then work together to resolve errors quickly and efficiently without waiting for an on-site service visit.

Waste disposal

The liquid waste from rinsing and cleaning operations is automatically removed from the analyzer. Waste system water is transferred either to an external container or to the laboratory waste system.

Sample and reagent waste is removed with the cuvette. Used cuvettes are automatically dropped into the cuvette waste box. You have to remove the waste box and dispose of it, according to your local procedures for dealing with hazardous waste. ISE waste is transferred directly to the cuvette waste box.

Automatic start-up

At the beginning of each day, the system goes through a series of automatic service actions. Typically, these actions are performed before the work day begins, so that the analyzer is ready to use when you start work.

Begin of Day

The time allocated for these service actions is called **Begin of Day (BOD)**, and the service actions are called the BOD service actions.

While these service actions are being performed, the system cannot run any tests. However, you can terminate BOD, if you need to run urgent (STAT) orders.

System description

Finding your way around the system and its hardware

This chapter gives an overview of the hardware and provides more detailed information about the main functional systems. Some of the features described are available only if your system is configured to support them.

In this chapter

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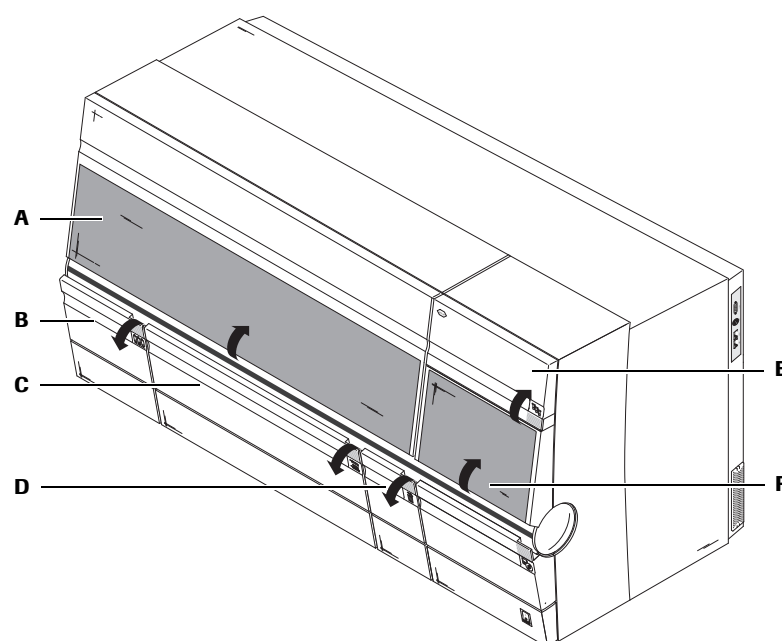
 Environmental conditions A-49

Panels and logos

You can open access panels when you need to work on the internal parts of the analyzer. Logos on the panels help you to find your way around.

To prevent accidental access to the operating area, the main cover is now generally locked and can only be opened as part of performing guided procedures. A specific unlock function is provided for emergency cases.

This function is available if you work with analyzer hardware with serial number 620001 or higher.



A Main front cover: gives access to the pipette module, cleaner reservoir, transfer arm and probes, initialization posts, and wash station. Always lift the cover as far as it will go when opening it.



B ISE access panel: open downwards to pull out the ISE module. See *Parts of the ISE module* on page F-6



C Rack access panel: open downwards to load or remove racks. See *Loading samples* on page B-12



D Cuvette waste panel: open downwards to remove and replace the cuvette waste box. See *Replacing the cuvette waste box* on page B-24



E Cuvette reservoir access panel: lift up to remove the cuvette reservoir when you need to add more cuvettes. See *Refilling the cuvette reservoir* on page B-20

F Service access panel: lift up to remove for example a stuck cuvette. When opening the panel make sure to secure the panel with the Locking Device Auxiliary Front Panel. When closing the panel again, first release the bracket and then close the panel slowly

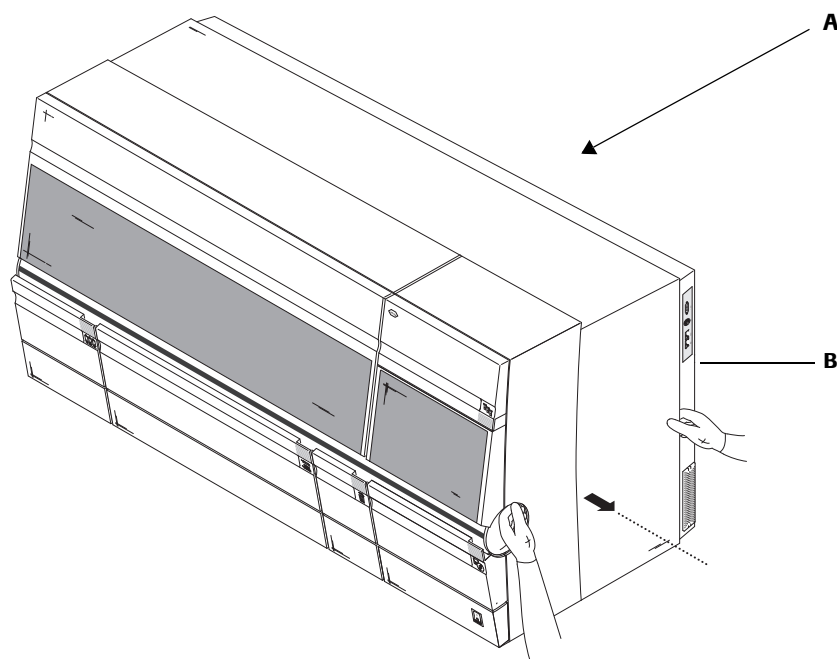
Figure A-6 Access panels

**Personal injury or malfunction due to inappropriate handling**

- Do not attempt to remove items from any of these locations without first referring to the appropriate section in this manual or to the appropriate topic in the online Help

Always close any access panels you have opened when you have finished working on that part of the analyzer.

The right side panel is detachable. You can remove it by pulling it as shown below. When you reinstall the side panel, make sure that it clicks securely into place.



- A** Rear panel (not shown)
Not detachable without a tool set. Does not provide access to any user-serviceable parts.
- B** Right side panel
Provides access to analyzer rotor, absorbance photometer, FP photometer, and cuvette transport system.

Figure A-7 Side access panels

External connectors

The external connectors are located at the back (water, waste, and power) and on the right side (data connectors) of the analyzer.

👁 *External connectors* on page E-40

Modules and main components

The figure below shows how the modules and components are arranged inside the analyzer.

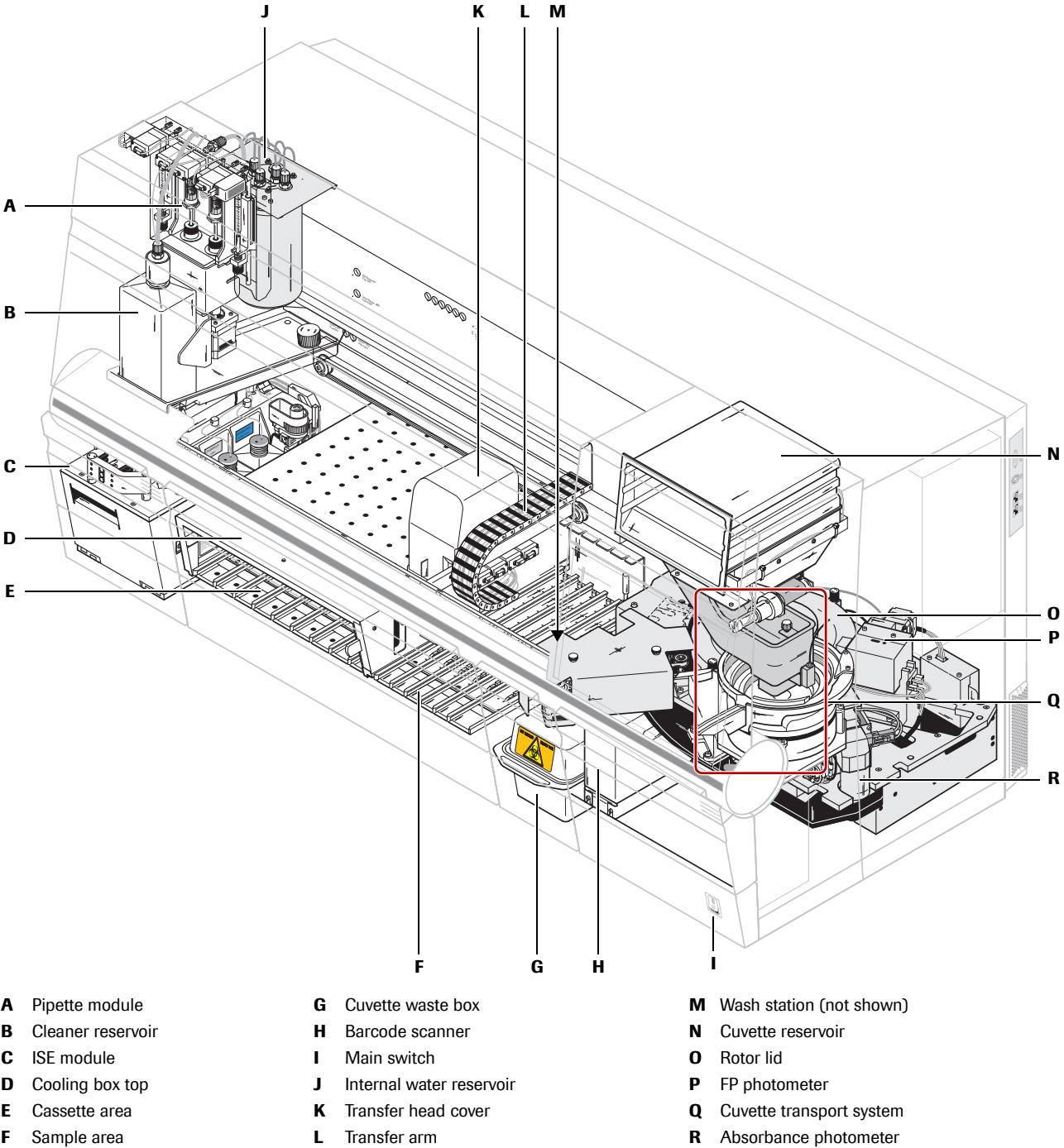


Figure A-8 Modules and main components

Functional systems

The analyzer comprises these functional systems:

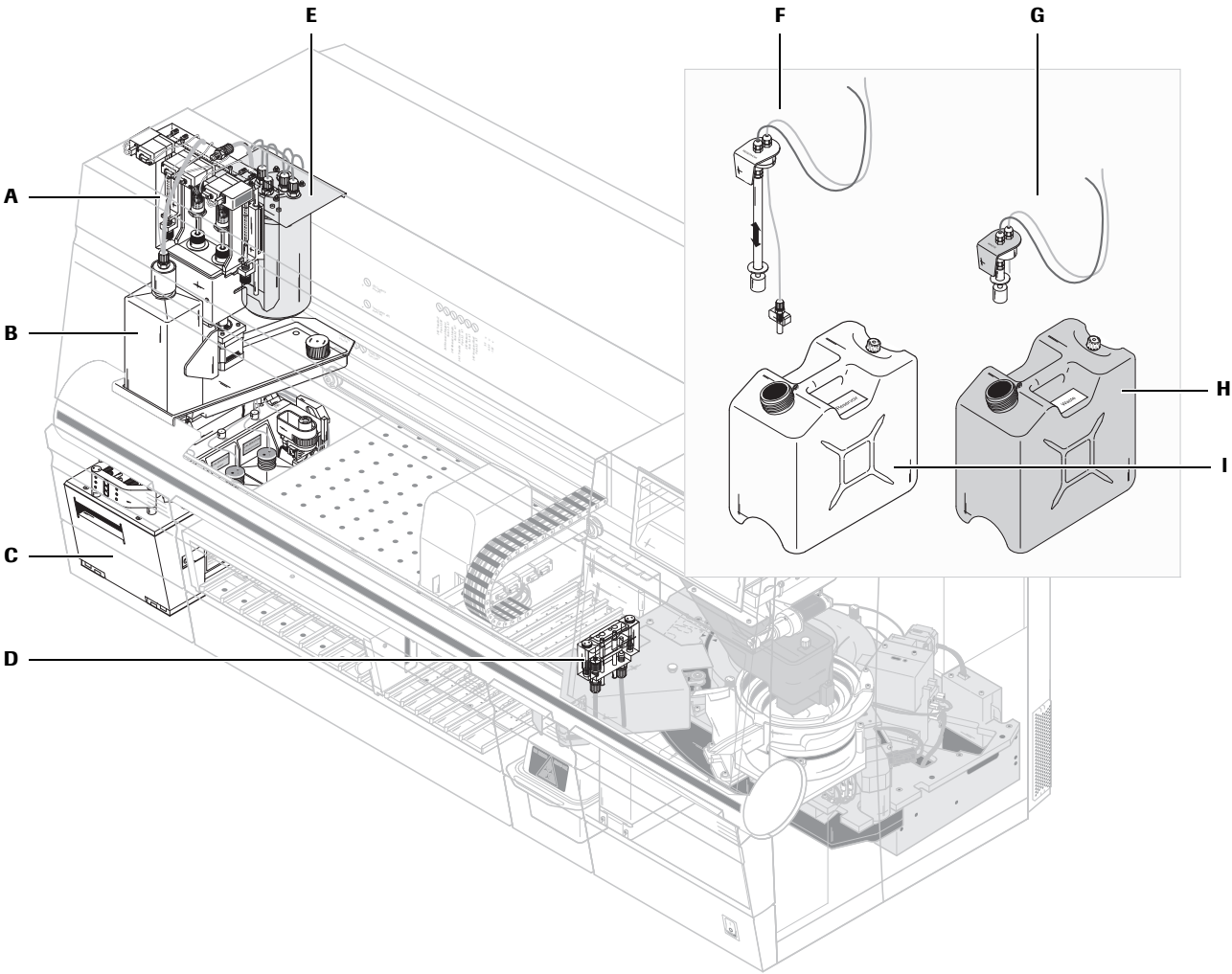
System	Function
Fluid system	Moves all the fluids used by the system, including water, samples, reagents, diluents, and cleaners.
Cuvette transport system	Provides a continuous supply of cuvettes, in the correct orientation, to the analyzer rotor; also includes the cuvette waste.
Rack system	Provides fixed slots into which different types of racks can be placed and accessed by the robotic transfer system. This also includes the racks and the barcode scanner.
Robotic transfer system	Pipettes samples, reagents, and other fluids from their containers into cuvettes for mixing so that measurements can be performed.
Analyzer module	Contains the absorbance and FP (not used) photometers, used for making measurements; also contains the workstations, which move the cuvettes for pipetting, mixing, and measuring.
ISE module	Provides the instrumentation for performing ion selective electrode (ISE) measurements.
Computer systems	The circuit boards on the analyzer control the analyzer. The computer records measurements and calculates the results. It also controls the database that is used to keep track of all samples, orders, and results, and it manages the user interface.

Table A-2

Fluid system

The fluid system consists of all the valves, pumps, tubing, pipettes, fluid sensors, water and waste reservoirs, the wash station.

The fluid system transports all fluids around the system, including samples, reagents, calibrators, controls, diluents, cleaners, system water, and waste. The fluid system delivers the correct amounts of fluids for the reactions, dilutions, and cleaning.



- | | | |
|----------------------------|---|--|
| A Pipette module | E Internal water reservoir | H External waste reservoir (yellow container) |
| B Cleaner reservoir | F External water reservoir connectors (sensor and fluid) | I External water reservoir (white container) |
| C ISE module | | |
| D Wash station | G External waste connectors (sensor and fluid) | |

Figure A-9 Main components of the fluid system

Pipette module

The pipette module contains two dosage pipettes and two wash pipettes. These are connected by tubing to the probes attached to the transfer arm. The pipettes control the pipetting action of the probes.

👁 *Robotic transfer system on page A-36*



Personal injury due to contact with moving parts

- Do not place your hands or fingers near the moving pipettes.

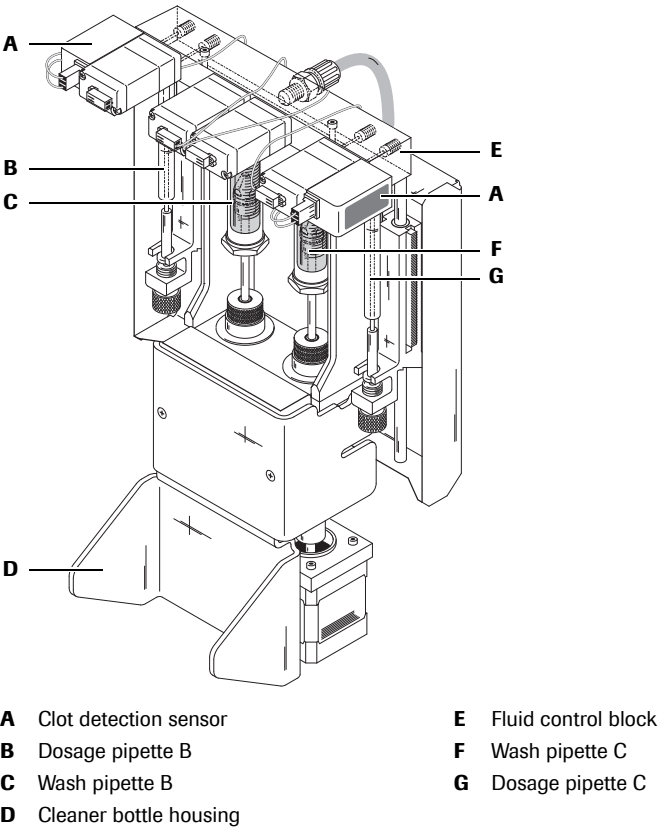


Figure A-10 Pipette module

The dosage pipettes control the pipetting of the required amounts of sample and reagent (or other fluid) through the probes. The wash pipettes supply water and cleaner to clean the probes in the wash station after every pipetting action and to prevent carry-over between tests.

There are several service actions you must perform related to the pipettes.

👁 *Chapter 14 Service actions*

Wash cycle After each pipetting action, the system automatically moves the probes over to the wash station and then starts a wash cycle. During this cycle, the probes and tubing are flushed with water and cleaner. There is one wash pipe for each probe.

Wash station The wash station is made of clear plastic. All waste water from the wash station is removed to the system waste. You must disassemble the wash station for routine cleaning, according to the service action schedule.

👁 **Clean wash station** on page D-28

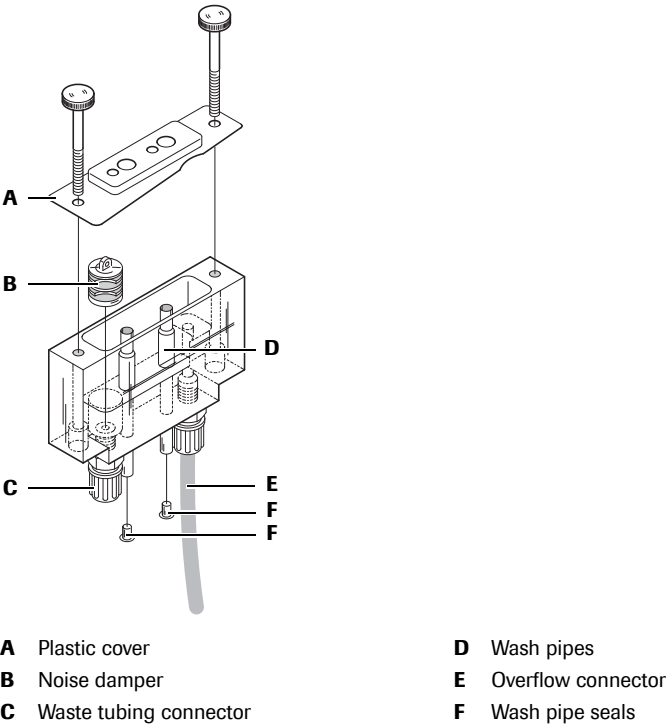


Figure A-11 Wash station (disassembled)

Water supply The analyzer can be connected to the laboratory water supply or to an external water reservoir. Water must be reagent grade, type 1.

The external water reservoir or laboratory supply feeds into an internal water reservoir located behind the pipette module.

If your system uses an external water reservoir, a sensor is connected so that the system can inform you when the water supply is nearly empty. You must clean the reservoir according to the service action schedule.

👁 **Clean external water reservoir and fluid waste reservoir** on page D-31

Internal water reservoir An internal water reservoir (1000 mL) feeds the wash pipettes and the ISE module with reagent grade, type 1 water.

Waste connection The analyzer can be connected directly to the laboratory waste system or to the supplied external waste container. This container has a level sensor, so the system informs you when the container is nearly full.

👁 **Clean external water reservoir and fluid waste reservoir** on page D-31

Pumps If the analyzer is connected to an external water reservoir, the water reservoir pump brings water to the internal water reservoir. (This pump is not required for analyzers connected to a pressurized supply.) A separate pump, the fluid waste pump, removes the liquid from the wash station.

The ISE module has its own pump.

<i>Water filters</i>	Water filters remove small particles from the water. The filters are located in the internal and external water reservoirs and between the water reservoir pump and the internal water reservoir. The service action tells you when you need to change the external water reservoir filter.
<i>Cleaners</i>	Probes and tubing are cleaned with water and cleaner. The cleaner reservoir contains 1000 mL of cleaner. The system informs you when you need to replace the cleaner. 👁 <i>Replacing the cleaner</i> on page B-18 Where specified in the test definition, special cleaner is also used to improve the effectiveness of probe cleaning if particular reagent combinations are in use. The special cleaner is supplied in cassettes which are placed on the cassette rack. 👁 For information about cleaner handling, see the corresponding Instructions for Use.
<i>Fluid waste</i>	Waste fluids from the probes and tubing are removed automatically to the fluid waste reservoir or directly to the laboratory's sanitary waste system, if connected. Fluid waste from the ISE module goes directly to the cuvette waste box. Fluid waste from the cuvettes is automatically discarded with the cuvette.
<i>Degasser unit</i>	The degasser is a unit containing special filters that remove dissolved gases from the fluid system. Excessive amounts of air in the fluid system can affect the accuracy of any results obtained.
<i>External water supply unit (optional)</i>	This option is required when connecting the laboratory water supply to the analyzer, thereby replacing the external water reservoir.
<i>ISE module</i>	The ISE module uses system water from the water reservoir. Fluid waste from the ISE module goes directly to the cuvette waste box. 👁 Chapter 17 <i>ISE module</i>
<i>Clot detection</i>	For each sample probe, one pressure sensor for clot detection is mounted at the rear of the pipetting module. They detect clots during aspiration of samples, during washing of probes, or when initializing the system. When a clot is detected, the probe is flushed, and a message is displayed. The run continues but no further pipetting is done from the sample cup that led to the clot detection or with the probe that is blocked. No results are printed for the sample cup associated with the clot. When an aspirated clot clogs the probe and the automatic washing steps cannot remove it, the system stops sampling and goes into Standby. 👁 To remove a clot, see <i>Clot error after sample/probe washing</i> on page E-33 Clot detection can be enabled and disabled for each test individually in Configuration > Tests > General.

Cuvette transport system

All photometric tests involving the absorbance photometer are performed in transparent containers called cuvettes. The cuvette transport system delivers new cuvettes to workstation In/Out, where they are fed into the analyzer rotor. The figure below shows the location of the cuvette transport system.

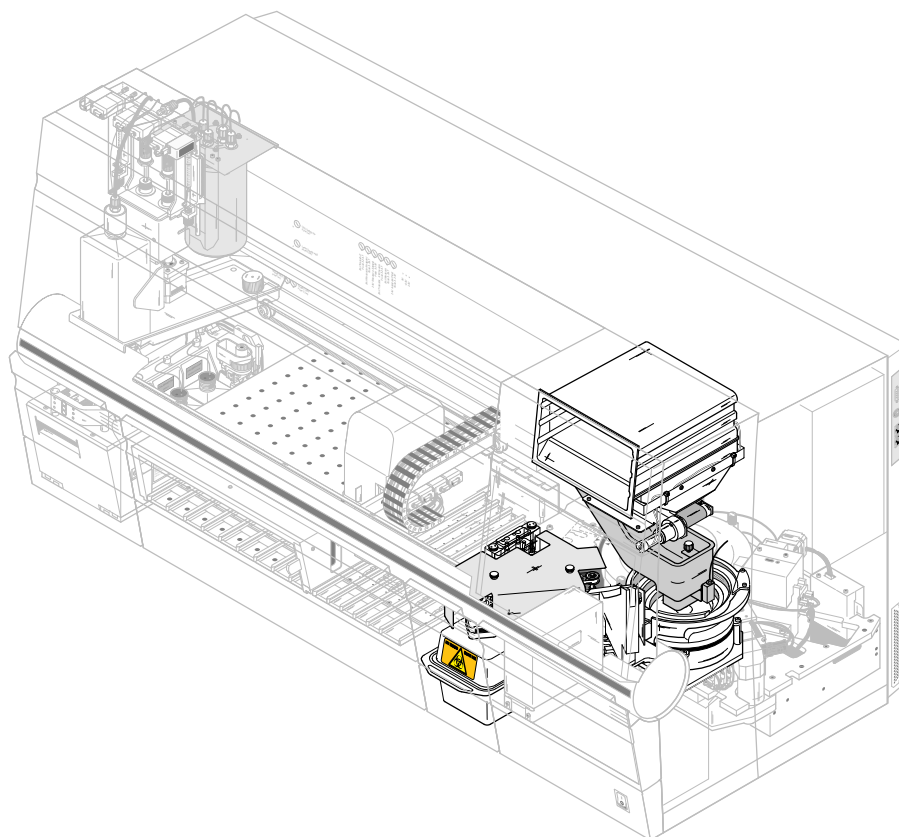


Figure A-12 Cuvette transport system

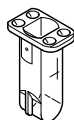


CAUTION

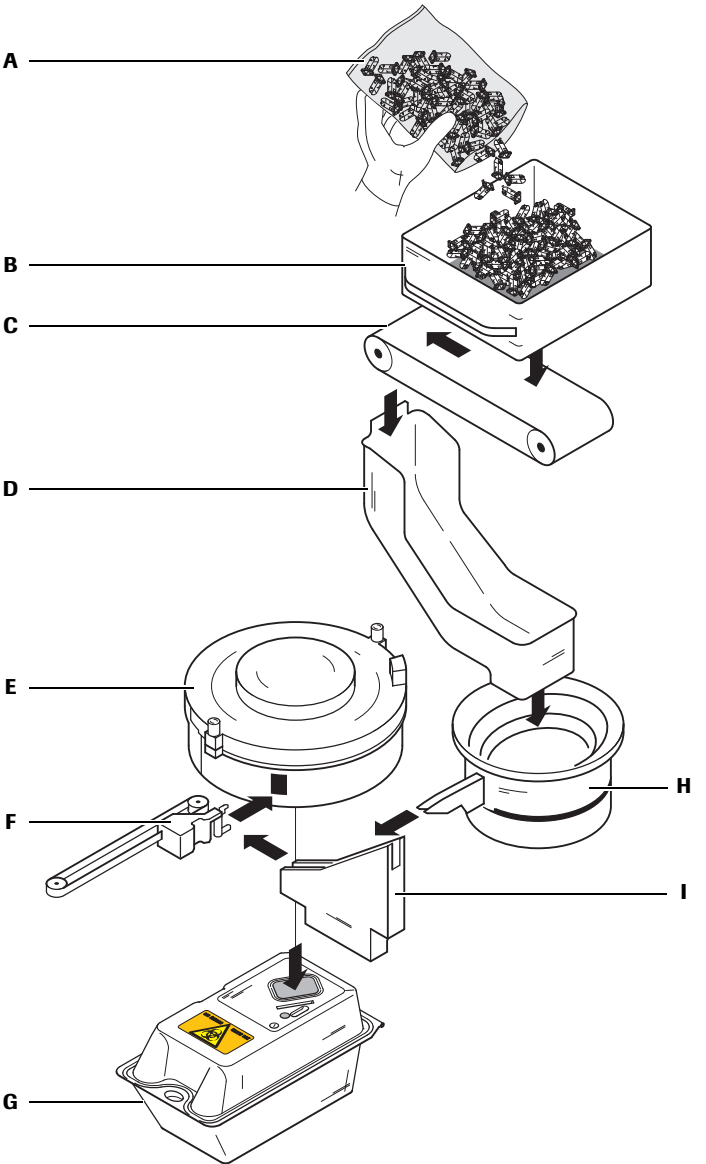
Personal injury due to contact with moving parts

- Do not place your hands or fingers near the moving parts in the cuvette transport system.

The figure below shows the movement of cuvettes through the transport system, starting at the cuvette reservoir and ending in the cuvette waste box.



- Cuvettes are made of optical quality acrylic plastic.
- The optical path length is 5.0 mm.
- Cuvettes are disposable. They are used only once, to guarantee optical consistency and to eliminate carry-over in the cuvette.
- For optical measurements, the minimum volume of liquid in a cuvette is 120 μL , the maximum is 245 μL .
- A cuvette pack contains approximately 1000 cuvettes.
- The system quality checks the cuvettes before use by reading an empty cuvette and comparing it with an acceptable absorbance range.



- | | |
|---------------------------------|-----------------------------------|
| A Pack of cuvettes | F Workstation In/Out |
| B Cuvette reservoir | G Cuvette waste box |
| C Cuvette conveyor belt | H Cuvette spiral feeder |
| D Cuvette feeder channel | I Cuvette buffer and slide |
| E Analyzer rotor | |

Figure A-13 Movement of cuvettes through the cuvette transport system

<i>Cuvette reservoir</i>	The cuvette reservoir feeds cuvettes onto the conveyor belt. You can pull out the cuvette reservoir and put the cuvettes in. You can add cuvettes while the analyzer is running.  <i>Refilling the cuvette reservoir on page B-20</i> The cuvette reservoir holds up to 1400 cuvettes. A light barrier detects when the supply of cuvettes is low, and the system warns you when you have to refill the cuvette reservoir with new cuvettes.
<i>Cuvette conveyor belt</i>	Cuvettes drop from the reservoir onto the conveyor belt, which transports them horizontally so that they can fall into the feeder channel below. The movement of the belt is controlled by the number of cuvettes in the cuvette spiral feeder. This ensures a controlled supply of cuvettes; the cuvette buffer is kept full or nearly full, without the spiral feeder overflowing.
<i>Cuvette feeder channel</i>	The cuvette feeder channel guides cuvettes to the spiral feeder below, as they drop from the conveyor.
<i>Cuvette spiral feeder</i>	The spiral feeder sorts the cuvettes into the correct orientation for feeding into the cuvette buffer.
<i>Cuvette buffer and slide</i>	The cuvette buffer holds up to 20 cuvettes aligned in a slide, which feeds cuvettes into workstation In/Out. The cuvette buffer acts as a storage area to ensure that cuvettes are always available for the workstation In/Out.
<i>Workstation In/Out</i>	Workstation In/Out feeds new cuvettes into the analyzer rotor. At the start of a measurement cycle, the workstation adds a new cuvette; at the end of the cycle, it removes the used cuvettes for disposal into the cuvette waste box.
<i>Cuvette waste box</i>	The cuvette waste box is a disposable plastic container that can hold 1000 used cuvettes. Fluid waste from the ISE module goes directly to the cuvette waste box. The box is automatically shaken to make room for newly discarded cuvettes. You can remove the waste box, seal it, and then autoclave it. A warning message tells you when the waste box is full and needs to be replaced.  <i>Replacing the cuvette waste box on page B-24</i>

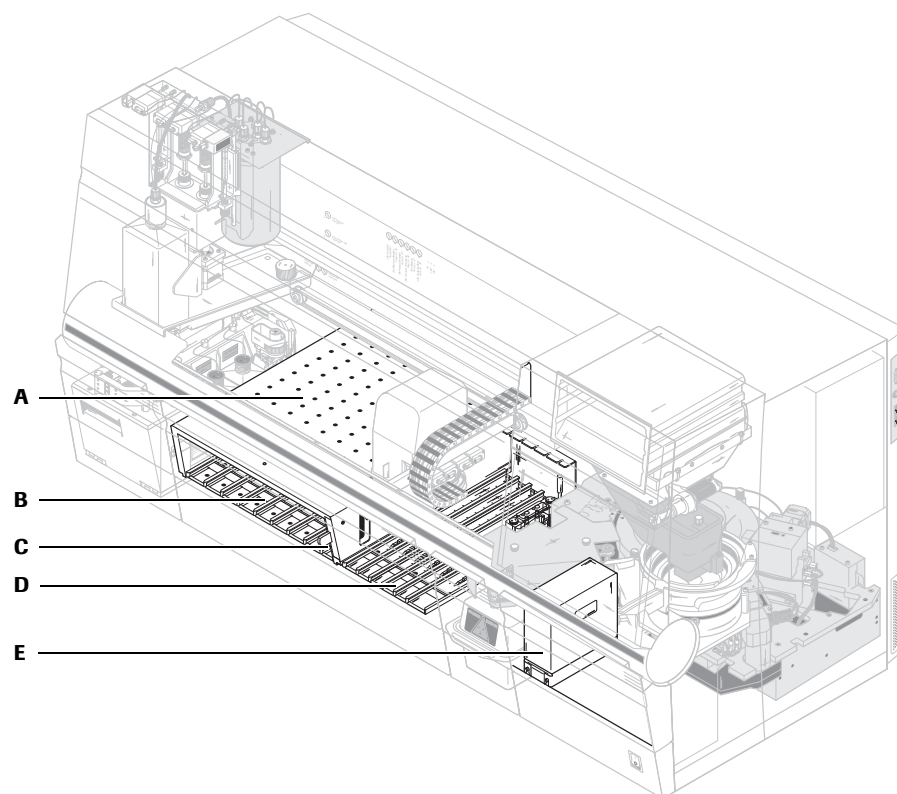
Rack system

The rack system allows you to physically place reagents (cassettes), samples, calibrators, controls, special diluents, and ISE solutions onto the analyzer. The rack system contains slots for three different types of racks:

- Cassette rack
- Sample rack
- ISE rack

These racks are all different sizes and fit into different sized slots on the system.

A barcode scanner automatically reads barcodes on any items loaded into the rack system.



- | | |
|------------------------------------|--------------------------|
| A Cassette area cooling box | D Sample area |
| B Cassette area | E Barcode scanner |
| C Cooled sample rack | |

Figure A-14 The rack system (racks not shown)

Rack areas and platforms

You access the rack area by opening the rack access panel (see logo, left). Inside, there are two rack areas:



Cassette area	Contains the cassette rack platform. This area is enclosed by the cooling box, and the temperature inside is maintained at 10-15 °C (50-59 °F.) The cassette rack platform has slots for eight cassette racks and one sample rack.
Sample area	Contains the sample rack platform. This area is not enclosed by a box; the temperature is approximately room temperature. The sample platform has five slots for sample racks and an additional dedicated slot for an ISE rack.

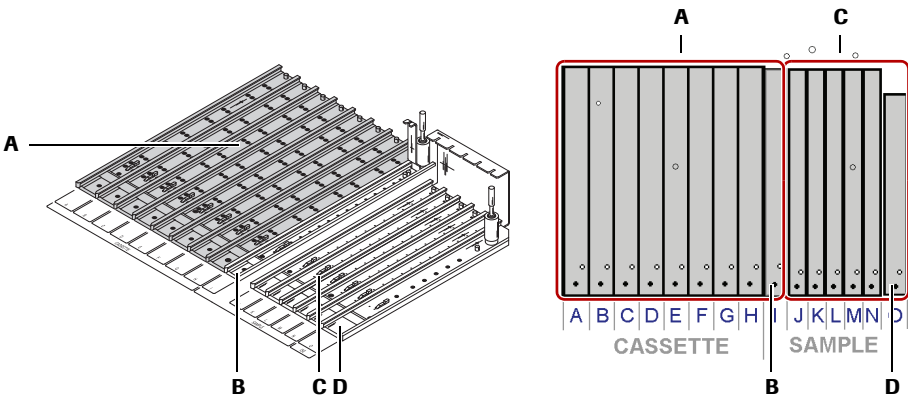


Condensation in the cassette area

Condensation can build up, especially in the cassette area.

- Avoid operating conditions above average temperature in combination with high humidity.
- Check every two hours for condensation buildup inside the cassette area.
- Wipe up any condensation water on the cassettes, the cassette racks, and in the cassette area

The figure below shows the rack platforms removed from the system (left) and a schematic layout of the rack platform from above (right).



- A** Cassette area (cooled to 10-15 °C (50-59 °F)).
Slots A through H are for cassette racks.
- B** Slot I in the cassette area (also cooled) is for sample racks—typically used for calibrators and controls.
- C** Sample area.
Slots I through N are for sample racks.
- D** Slot O is for the ISE rack.

Figure A-15 Rack platforms (callouts refer to both figures)

You can remove cassette platforms individually for routine cleaning as part of a service action.

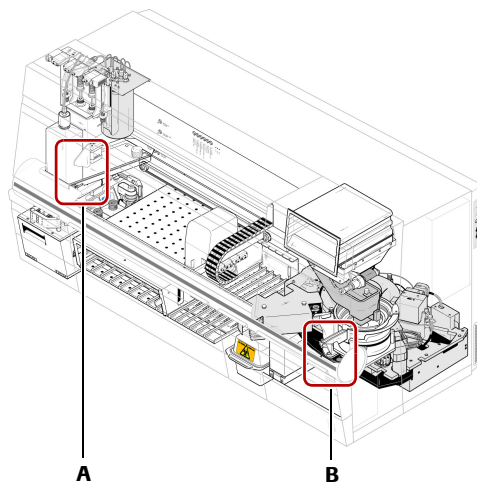
Clean instrument on page D-34

Unlock rack tool

The unlock rack tool is supplied with the analyzer.

On analyzer hardware with serial number 620001 or higher, the unlock rack tool is placed in front of the cuvette reservoir on the right side of the analyzer.

On analyzer hardware with serial number lower than 620001, the unlock rack tool is located on the right of the cleaner reservoir.



A Storage position on analyzer hardware with serial number lower than 620001 **B** Storage position on analyzer hardware with serial number 620001 or higher

Figure A-16 Storage location for unlock rack tool

You can use it to:

- Remove the rack platforms for cleaning.
 - 👁 **Clean instrument** on page D-34
- Manually release racks.

When the analyzer **is not** in operation, you can release the rack manually by using the unlock rack tool and pressing the release button shown in Figure A-19.

👁 *Unlocking the main cover* on page E-20



WARNING

Infection and injury due to contact with system mechanisms

Contact with the sampling mechanism or other mechanisms may lead to biohazardous contamination, resulting in personal injury and/or infection.

Pressing the release button while the analyzer is pipetting may damage your hands and the probes.

- Do not release racks manually when the analyzer is in operation.
-

Rack status indicators

The rack status panel (A) contains a set of small lights (LEDs—light-emitting diodes) that show the status of the rack immediately below the light.

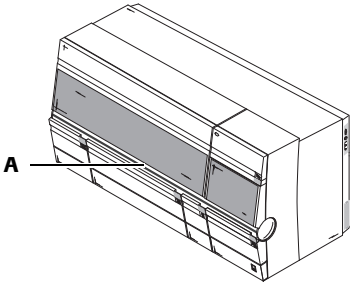


Figure A-17

The logo on each light tells you the type of rack (cassette, sample, or ISE). The color and whether the light is blinking or steady tells you the status of the rack.



Cassette rack



Sample rack



ISE rack

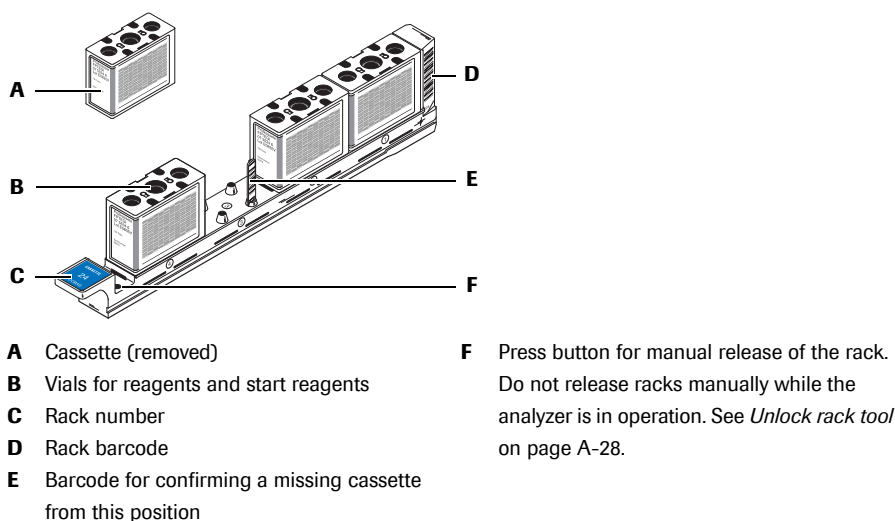
Figure A-18

The following table tells you the rack states and the user actions you can perform in each state:

If you see...	This means...	User action
No light	There is no rack in the slot.	You can insert a rack into the rack platform.
Green light steady	- The rack has been inserted correctly and is ready to be processed or... - The processing of the rack is completed.	You can remove the rack from the rack platform.
Green light blinking	- The rack is being loaded and rack identification is taking place or... - The rack is being removed.	You can still remove the rack from the platform.
Red light steady	The rack is locked because it is being processed. Pipetting is in process or about to begin.	You cannot remove the rack while the red light is displayed.
Orange light blinking	- The rack cannot be identified because it is not defined on the system or... - The barcode scanner could not read the barcode label. - The rack has not been properly inserted or... - The barcodes were not recognized or... - Another rack on board has the same code.	Remove the rack and define it in Configuration > Lab > Racks. Check the barcode label for damage. Remove and reinsert the rack. If blinking reoccurs, check the messages for the reason.

Table A-3

Cassettes and cassette racks

**Figure A-19** Cassette rack and cassettes

The reagents for a test are supplied in a single cassette. All cassettes have the same basic design.

Each cassette holds enough reagent for between 80 and 800 tests, depending on the test.

👁 For detailed information, see the test specific Instructions for Use.

**WARNING****Incorrect results due to use of same cassette on multiple systems**

Each cassette has its own individual cassette number, which the system uses to identify it. Using a cassette already used on a different system may lead to incorrect results.

- Do not use a reagent cassette for different systems. Each cassette rack with its cassettes may be used on one individual system only.
- If more than one system is used in the same lab, be sure to dedicate each cassette rack with its cassettes to one single, individual system (e.g. by color coding).

Cassette label The cassette name, lot number, expiry date, content of active ingredients, and other test specific information is written on the cassette label.

Cassette barcode The system automatically reads the following information from the barcode label:

- Article number
- Cassette number
- Expiry date
- Lot number

Cassette racks A cassette rack holds up to four cassettes. Each rack is identified by a number on the front tab of the rack and a barcode label on the side. The barcode scanner reads the cassette rack IDs as the rack is inserted into the rack platform.

Integrated cassette volume check (ICVC) The integrated cassette volume check (ICVC) function is activated by the cassette barcode labels of all reagent cassettes that have to be filled manually in order to prevent erroneous results caused by incorrect filling.

The cassette volume check is carried out once per reagent cassette when the cassette is placed for the first time on the analyzer. Each cassette vial is checked individually by

aspirating reagent at the expected filling level into a cuvette. Presence or absence of reagent is detected using the absorbance photometer.

If the integrated cassette volume check fails a message is displayed and the cassette access is denied.

The cassette volume check is enabled by default (**Configuration > General > System**). The current status of the cassette volume check (enabled or disabled) is listed in the BOD report.



This function is only used for a few tests where the reagent cassette has to be filled manually.

Sample racks

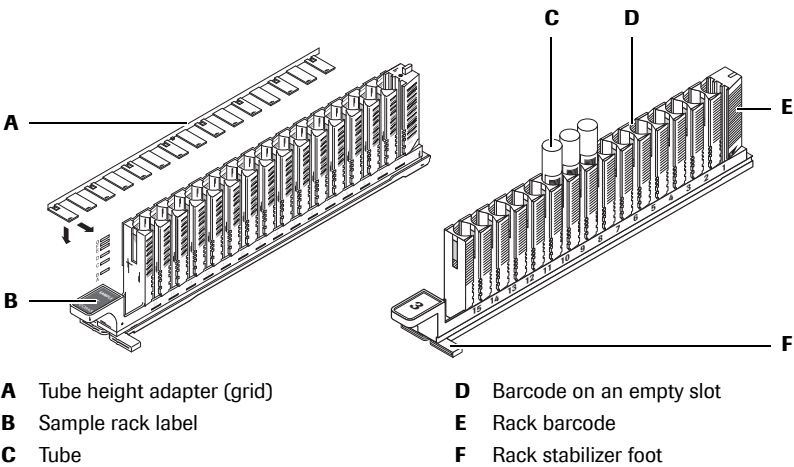


Figure A-20 Sample racks and tube height adapter

A sample rack has 15 positions for tubes containing samples, calibrators, controls, or diluents. For samples, both primary and secondary tubes can be used.



Analyzer damage due to using multiple tube types on a rack

Using multiple tube types on a rack may prevent the analyzer from recognizing the correct dimensions and lead to malfunction and analyzer damage.

- Ensure that the sample cup types match the predefined type for the sample rack.

Sample type specific racks are used when the barcodes on the samples do not contain sample information. This enables the system to identify the sample type.

Tube height adapter (grid)

You can adjust the height of the tubes in the rack by using a grid device. The correct grid position is given by the software and depends on the specific tube definition. You can check the correct grid position in **Configuration > Lab > Racks**.

Rack number and rack code Each rack has a number on the front tab of the rack and a barcode on the side. The barcode scanner reads the sample and sample rack barcodes as you insert the rack into the sample rack platform.

In the rack definition dialog box (**Configuration > Lab > Racks**), each rack is assigned the following parameters:

Rack number	A three-digit number corresponding to the number you see on the sample rack label.
Rack code	The number automatically read from the barcode label on the rack as it is inserted into the rack platform.
Rack name	A user-defined value that typically tells you the purpose of the rack. For example, a rack reserved for calibrators and control might be assigned a rack name of CAL-QC.
Tube type	Select the tube type for the specified rack.
Sample type	Select the sample type for the specified sample rack.
Barcode	If the box is selected, the barcode labels on the samples, tubes, and adapters are read.

Table A-4

ISE rack

You can assign these positions in **Configuration > Lab > Reserve Positions**. Slot O on the sample rack platform is reserved for the ISE rack.

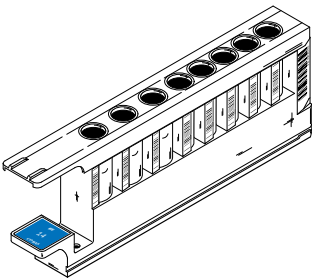


Figure A-21

👁 Chapter 17 ISE module

Tubes and cups

You can use several different types of tubes and cups on the system, although you must ensure that you use only types that have been predefined for your system. This is done for you at installation by a Roche representative.

The following table summarizes which type of containers you can (or must) use with each type of solution on the system:

Solution	Container(s)
Samples	Primary or secondary tubes or cups
Controls	Tubes or cups
Calibrators	Tubes or cups
Diluents	Bottles on the ISE rack or tubes on a sample rack Note: It is possible but not recommended to place NaCl Diluent 9% on a sample rack. Always place NaCl Diluent 9% in its original bottle or in a 25 mL dead volume optimized bottle on the ISE rack.
Cleaners	Cleaner cassettes on the cassette racks
ISE solutions	On the ISE module itself or in bottles on the ISE rack

Table A-5

Sample tubes and cups

The system can use both primary and secondary tubes. The following types of tubes are predefined:

- COBAS cup
- Eppendorf cup
- Sarstedt 5 mL
- Sarstedt 5.5 mL
- Sarstedt 7.5 mL
- Vacutainer 7 mL
- Vacutainer 10 mL

You can use other types of tubes, but these must be defined for your system in **Configuration > Lab > Sample Tubes**.

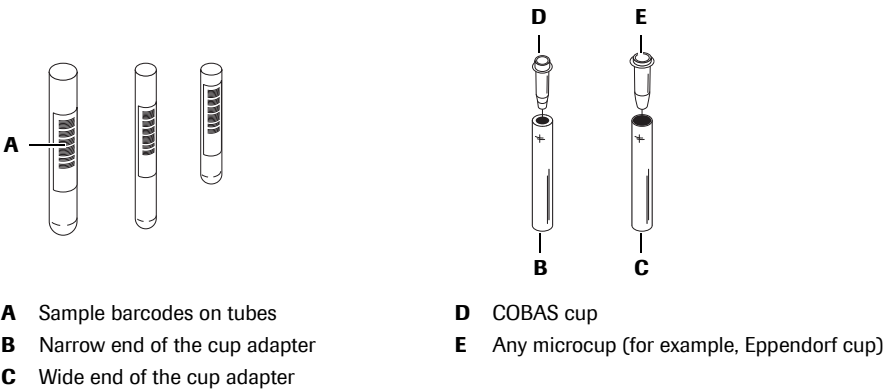


Figure A-22 Sample tubes and cups

Cup adapters

For smaller quantities of samples (or other solutions), you can use COBAS cups and Eppendorf cups.

You insert these cups into an adapter, using the narrow end for COBAS cups and the wide end for Eppendorf cups. You can attach a barcode on the side of the adapter. You then insert the adapter together with the cup into a free slot on the rack.

**WARNING****Incorrect results due to placing COBAS cups into the wide end of cup adapters**

Placing COBAS cups into the wide end of the cup adapter may damage or block the probe or lead to unreliable results due to level detection problems.

- Do not place COBAS cups into the wide end of cup adapters.

You can define *one* microcup as the Cup on Tube, that is the cup you will use on top of primary tubes.

NOTICE**Analyzer damage due to incorrect cup configuration**

Incorrect configuration of cups may lead to serious analyzer damage.

- Contact your Roche representative for support before you define the use of Cup on Tube.

Diluent handling

Accelerator is supplied in vials that are incompatible with the ISE rack. Therefore, to use Accelerator on the ISE rack, pour it into extra bottles prior to placement.

The following table lists possible placements of available diluents on the analyzer:

Diluent	Placement	Capped
NaCl Diluent 9%	ISE rack	Yes
Accelerator	ISE rack	No
ISE Deproteinizer	ISE rack	Yes
ISE Etcher	ISE rack	Yes
Activator Bio	ISE rack	No
ISE Solution 1	ISE rack	Yes
ISE Solution 2	ISE rack	Yes

Table A-6

The onboard stability of the diluents is monitored by the system software when the diluent is placed on the ISE rack. In contrast, on sample racks the onboard stability cannot be monitored by the system. In this case, it has to be monitored by the operator.

👁 For details about the onboard stability, refer to the corresponding Instructions for Use.

Barcode scanner

Barcodes contain machine-readable information in the form of black and white stripes. All cassettes are barcoded so that they are automatically recognized when you load them on board. You can attach barcodes to sample tubes and cup adapters to identify samples, calibrators, controls, and diluents.

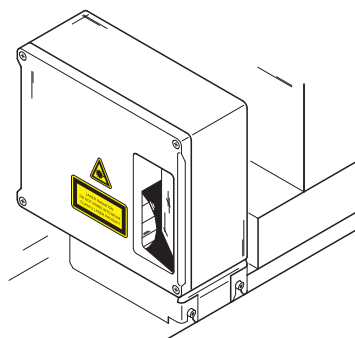


Figure A-23

The barcodes supported are:

- Code 2 of 5 Interleaved
- Codabar (code 2 of 7)
- Code 128
- Code 39 (3 of 9 interleaved)
- UPC (A, E)
- EAN

You can select the predefined barcodes you need and configure the specific barcode values in **Configuration > General > Barcode**, if you have the required user access level.

Barcode reading can individually be set for each rack group (**Configuration > Lab > Racks**).

Samples are automatically recognized when they are loaded, if the sample tubes have barcodes on them and either of the following is true:

- The barcode contains sample type information.
- The barcode does not contain sample type information, but the sample is assigned to a rack that is sample type specific.

For samples without barcode labels, you can use the **Automatically Assign Rack Positions** feature, and then accept the proposed assigned rack positions in the **Sample Handling** dialog box.

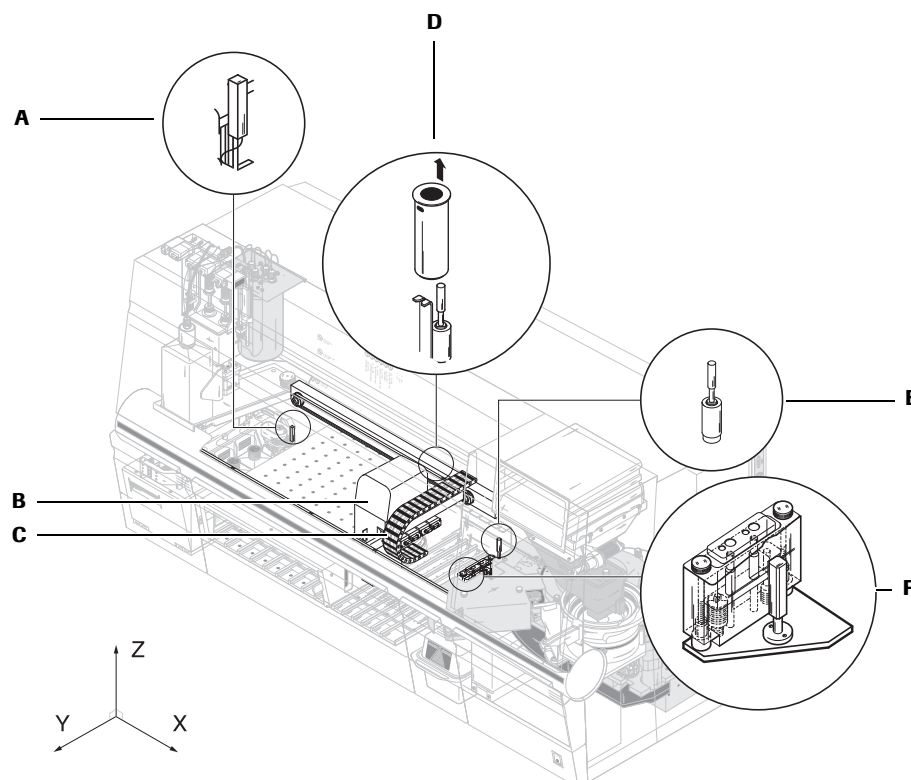
 *Loading samples on page B-12*



- Insert only one rack at a time. The barcode scanner reads across the whole rack area, and therefore a second rack could be obscured by the first. Wait at least three seconds before the next rack movement.
- When you insert a rack, the rack is blocked momentarily to allow the scanner to focus on the correct rack slot and rack barcode.
- Insert the rack in one clean motion; stopping halfway generates an orange blinking light on the status indicator.
- When removing a rack, remove it completely. If you leave the rack partially removed, other racks being inserted may not be seen properly by the scanner.

Robotic transfer system

The robotic transfer system automatically controls and moves the probes to the correct positions for all pipetting and cleaning actions. There is one transfer arm to which the two probes are attached. The transfer arm moves in a horizontal (X- and Y-axes) plane; the probes also move up and down (Z-axis). The figure below shows the parts and location of the transfer system, including the initialization posts.



- A** ISE initialization post
- B** Transfer head cover
- C** Transfer arm
- D** Cassette area initialization post and protective sleeve (not visible in the main system part of the picture)
- E** Sample area initialization post
- F** Wash station initialization post (not visible in the main system part of the picture)

Figure A-24 Transfer system and initialization posts

Coordinates System messages relating to the transfer arms often refer to a specific direction of movement. If you stand facing the analyzer, the direction axes are defined as follows:

- X-axis* Left-to-right motion
- Y-axis* Backwards-and-forwards motion
- Z-axis* Up-and-down motion

Probes

There are two probes named probe B and probe C. Their names are based on the workstation (B or C) where they pipette the required amounts of fluids into a cuvette.

The probes are thin hollow metal tubes attached to the transfer arm and directly connected by tubing to the pipettes in the fluid system. The dosage pipettes control the volumes of liquids pipetted.

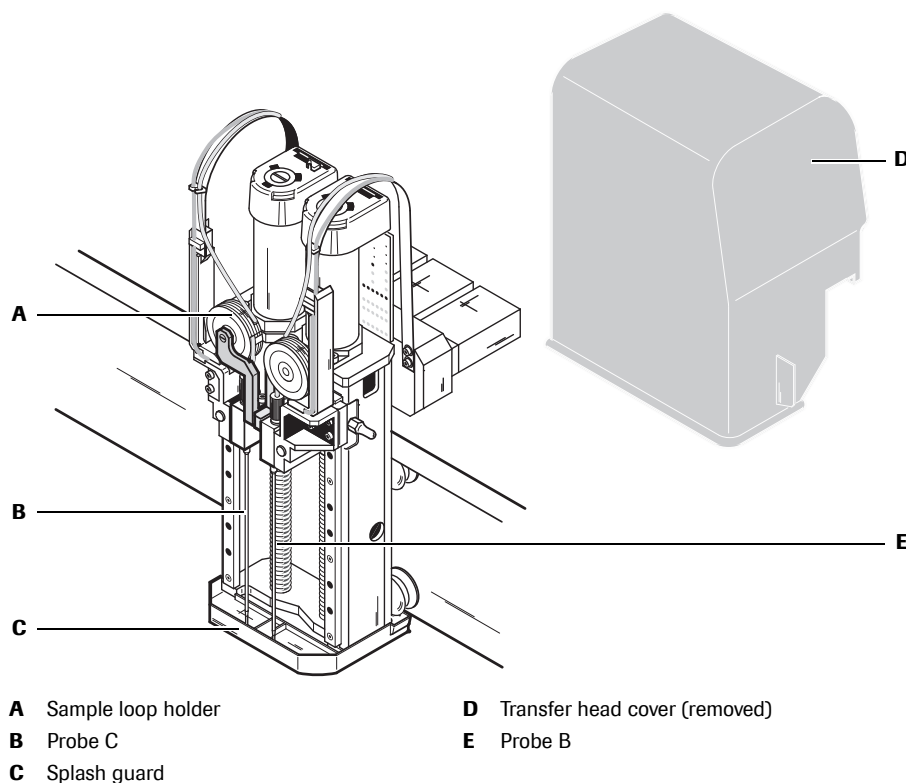


Figure A-25 Transfer head with the cover removed



Personal injury due to contact with moving parts

- Do not place your hands or fingers near the moving probes.

- Probe B*
- Pipettes reagent, sample or diluent.
 - The pipetting takes place at workstation B.
 - Is located nearest to you when you open the main front cover.

- Probe C*
- Pipettes reagent, sample, diluent and ISE sample.
 - The pipetting takes place at workstation C.
 - Is located furthest away from you when you open the main front cover.

Sample loops The sample loops are coils of tubing long enough to hold any liquid pipetted and to allow a complete change-over of fluid.

Splash guard The splash guard is a black plastic tray that prevents direct user access to the probes, thus protecting them from accidental damage. It also catches any drips of liquid on the outside of the probes, preventing contamination of other parts of the analyzer.

The system informs you when the splash guard needs cleaning as part of the service schedule.

👁 **Clean probes and splash guard** on page D-26

Initialization posts

The initialization posts are fixed surfaces that the analyzer uses as transfer reference points during initialization. There are four initialization posts:

- ISE module
- Cassette area
- Sample area
- Wash station

👁 Figure A-24

The positioning of the probes depends on the initialization posts; the posts must therefore be kept clean. In particular, you clean the posts as part of the service action Clean instrument and at other times if you see that they are not clean.

👁 **Clean instrument** on page D-34

Analyzer module

The analyzer module is the part of the analyzer where the reaction between the sample and the reagent(s) takes place and where the photometric measurements are made. The figure below shows the main external components of the analyzer module.

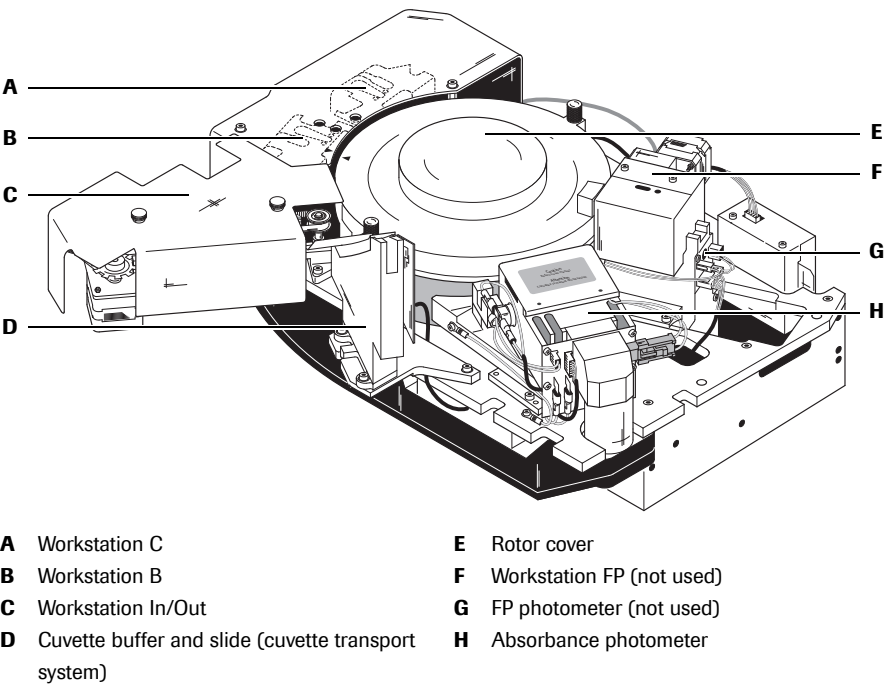


Figure A-26 Analyzer module with workstations and photometers



Personal injury due to contact with moving parts

- Do not place your hands or fingers inside the workstation In/Out module.
-



Personal injury due to contact with hot surfaces

The ABS lamp and its surrounding elements may be hot and cause burns when touched.

- Do not place your hands or fingers on the ABS lamp and its surrounding elements while they are hot.
-

Analyzer rotor

The analyzer rotor is a ring-like assembly that has slots into which cuvettes are loaded automatically from workstation In/Out. The rotor holds up to 71 cuvettes. As the rotor turns, it moves the cuvettes to the appropriate locations so that pipetting operations can be performed and photometric measurements can be made.

Typically, these operations occur in parallel, that is, pipetting can be carried out on one cuvette, while another is undergoing photometric measurements.



Personal injury due to contact with moving parts

- Do not place your hands or fingers near the rotating analyzer rotor.
-

Temperature

The temperature inside the analyzer is maintained at:

- yellow icon 37 °C ±0.2°C (98.6 °C ±0.36 °F)
- red icon 37 °C ±0.5 °C (98.6 °C ±0.9 °F)

If the temperature goes outside these limits, the system automatically informs you.

👁 **Analyzer tab** on page B-51

Cycle time

The cycle time of the analyzer rotor is 10.6 seconds. The whole operation of the system is based on this cycle time, with each measurement taking a whole number of cycles. A cycle begins with workstation In/Out loading a new cuvette onto the rotor. Afterwards the rotor turns in an anti-clockwise direction. At cycle 70, the cuvette is removed by workstation In/Out and dropped into the cuvette waste.

Workstations

The workstations handle the cuvettes, loading them onto the analyzer rotor and removing them temporarily for pipetting, mixing, and measuring.

Workstation In/Out

Workstation In/Out moves new cuvettes, one at a time, from the cuvette buffer slide and loads them onto the analyzer rotor. When all the measurements for a particular cuvette have been completed, workstation In/Out removes the used cuvette and drops it into the cuvette waste box.

Workstation B

Workstation B temporarily removes a single cuvette from the rotor so that the cuvette can be accessed by probe B, for reagent, sample, or diluent pipetting.

When the pipetting is finished, the cuvette is rotated elliptically in the workstation to mix the fluids. The cuvette is then put back onto the rotor to be moved around to one of the photometers for the measurement phase.

Workstation C Workstation C temporarily removes a single cuvette from the rotor so that the cuvette can be accessed by probe C, for reagent, sample, or diluent pipetting.

When the pipetting is finished, the cuvette is rotated elliptically in the workstation to mix the fluids. The cuvette is then put back onto the rotor to be moved around to one of the photometers for the measurement phase.

Workstation FP This workstation removes a single cuvette at a time from the rotor so that fluorescence polarization measurements can be made in the FP photometer. When the measurements are complete, the workstation returns the cuvette to the rotor.

At the absorbance photometer, the measurement is made with the cuvette still in the rotor.



The FP workstation is not used for Cedex Bio HT tests.

Photometers

There are two photometers: one for absorbance measurements and one for fluorescence polarization measurements (not used for Cedex Bio HT tests).

Absorbance photometer For each cuvette slot, the absorbance photometer measures light intensity at 12 different wavelengths. The light beam from the absorbance halogen lamp passes through the cuvette and then into a photo-diode array where the measurements are made.

The absorbance photometer makes both absorbance and turbidimetric measurements.

For absorbance measurements:

- Absorbance readings are linear in the range 0.0 through 2.0 absorbance with less than 1% deviation at a path length of 0.5 cm.
- The measurement system uses blank positions on the rotor to monitor the background signal for the electronic adjustment of drift.
- The measurements are taken without removing the cuvette from the analyzer rotor.

The life expectancy of the absorbance halogen lamp is 800 hours. The system informs you when you need to replace the lamp.

 **Replace Abs. halogen lamp** on page D-48

Wavelengths for the absorbance photometer

The absorbance photometer makes measurements at the following wavelengths:

• 340 nm	• 480 nm	• 552 nm	• 652 nm
• 378 nm	• 512 nm	• 583 nm	• 659 nm
• 409 nm	• 520 nm	• 629 nm	• 800 nm

Table A-7

All wavelengths are measured at the same time, but only one wavelength (for monochromatic measurements) or two wavelengths (for bichromatic measurements) are used.

Computer systems

The system contains two computer systems: one - the circuit boards in the analyzer - for controlling the automatic operations of the analyzer, the other - the computer of the control unit - for processing data and managing the user interface.

The control unit computer runs under Windows 10. This system includes:

- Monitor
- Standard US keyboard
- Mouse
- DVD drive (R/W)
- Two hard disks
- 2 serial interfaces
- Analog modem connector (no longer included for control unit model rp5810 and later)
- LAN connector
- USB Ports
- 2nd LAN connector



The 2nd LAN connector must only be used for Roche remote service connectivity. If a remote service connection is established over an unsecure network via an AXEDA client, the device must be installed behind either a Roche “connect 2” device or a cobas link gateway. The use of an AXEDA client is the only approved and supported remote service solution.



WARNING

Unauthorized system access and data loss

External storage devices can transmit computer malware, which may be used to gain unauthorized access to data or cause unwanted changes to software.

Connecting the LAN connectors to devices other than the ones stated in this publication could lead to unauthorized database access resulting in possible disclosure or modification of sensitive data.

- Only use the LAN connectors for purposes described in this publication. See *Data connectors* on page E-41.
- Follow the recommendations stated in *Software and data security* on page 28.

Processing data

Working data is stored in a database on the hard disk of the control unit computer. This includes sample and order information and results. Raw data, that is, the measurements taken by the analyzers, is stored only short term and is then deleted. The results calculated from the measurements are stored longer term.

Backups

The control unit computer maintains a backup of all current data. You can start this manually from the service action **Backup data** or you can configure this as a **Begin of Day** action. A backup can take more than 10 minutes to complete, during which time the analyzer cannot run any tests.

In addition, the computer has a USB Port and a DVD drive that can be used for:

- Loading updates to software and help.
- TAS (test application software) updates.

You can use an external storage device for archiving data for long term storage and retrieval.

Electronics

Control of the many automatic systems within the analyzer is performed by a set of electronic printed circuit boards (PCBs). These are located in a controller rack in a closed cabinet above the cassette and sample areas. The PCBs are protected by fuses, each of which must have the correct rating.

👁 *Checking and replacing fuses* on page E-43

System states

The current state of the system determines what actions you can perform. You can force some changes of state by pressing the function keys F11 and F12 or by clicking the **Start** and **Stop** buttons on the navigation bar; all other changes are automatic. The figure below shows some of the states and how the system moves between them. The boxes represent the states, and the arrows represent transitions between states. The icons represent the **Status** button on the navigation bar when the system is in that particular state.

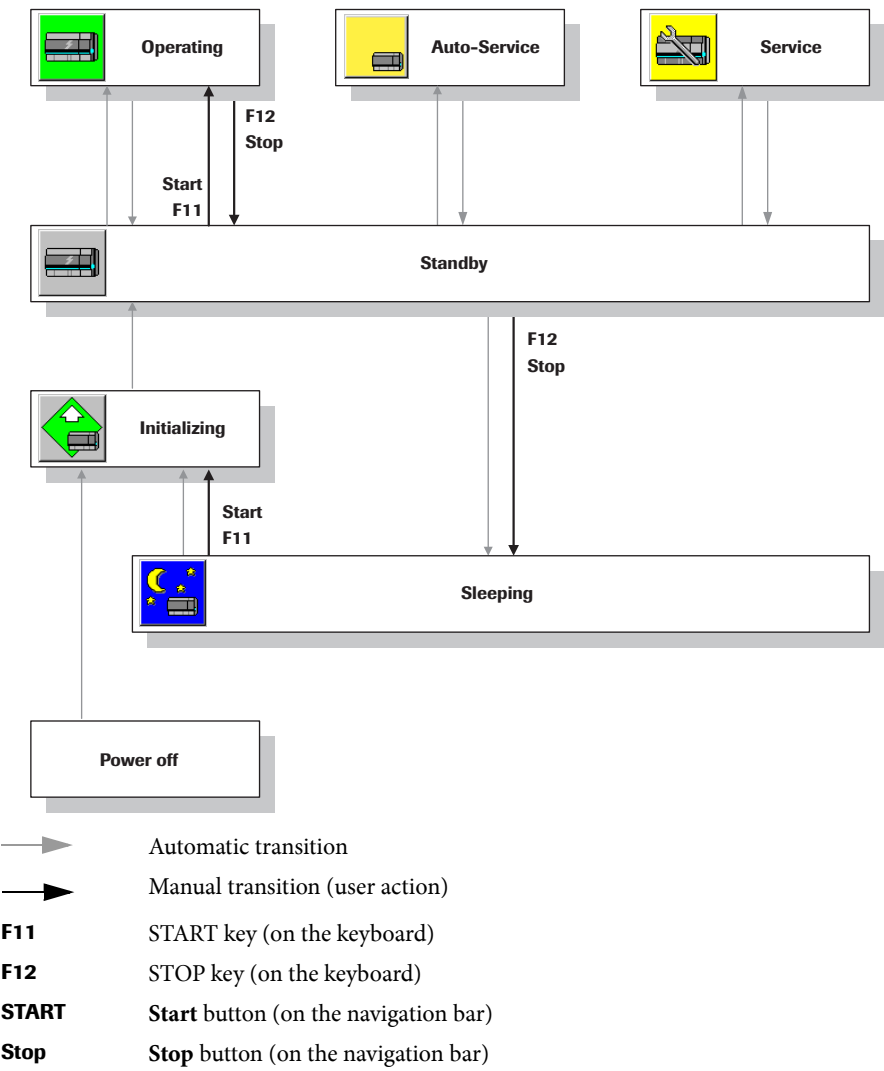


Figure A-27 System states (not all states are shown)

👁 Starting up and logging on to the system on page B-5

Transitions between states

The following table shows the icons on the **Status** button (and the predominant background color) for the main transitions between system states (state 1 to state 2).

State 1	State 2	Comments
Power off	Initializing	Turn the power on by using the main switch on the front of the analyzer.
		
	(green)	
Initializing	Standby	This transition is automatic, that is, when the system has finished initializing it goes into Standby . This takes a few minutes to complete.
		
(green)	(gray)	
Standby	Operating	This transition is automatic, if Autostart is enabled (Configuration > General > System). Alternatively, press F11 or click Start to start processing tests.
		
(gray)	(green)	
Operating	Standby	You can force the system into Standby by pressing F12 or clicking Stop . Alternatively, the system automatically goes into Standby either after a user specified period of inactivity or at a specific time.
		
(green)	(gray)	
Standby	Sleeping	You can force a system to go from Standby into Sleeping by pressing F12 or clicking Stop . Alternatively, the system automatically goes into Sleeping after user-specified period.
		
(gray)	(blue)	
Sleeping	Initializing	The system automatically initializes when a rack is inserted or when it is time for the Begin of Day actions. Alternatively, you can force the system from Sleeping into Initializing by pressing F11 or clicking Start .
		
(blue)	(green)	
Standby	Service	The Service icon is displayed when the system (or a user) is performing a service action. The system must be in Standby before you can start manual service actions.
		
(gray)	(green)	

Table A-8

State 1	State 2	Comments
Service	Standby	The system automatically goes to Standby when the service action is complete.
		
(green)	(gray)	
Standby	Auto-service	Auto-service means the system is automatically performing Begin of Day actions. If the system is in Operating , the Begin of Day service actions are not performed. When the system has returned to Standby , you have to start the BOD actions manually by clicking the Execute Begin of Day Action button on the tool bar. The system automatically goes into Standby after completing BOD actions.
		
(gray)	(green)	

Table A-8



The following parameters concerning system states are defined in **Configuration > General > System**:

- **End of Sequence**
- **Autostart**
- **Sleeping Mode**
- **BOD**

You can review these parameters, to alter them you must have the required user access level.

Technical specifications



These specifications are subject to change without notice.

General specifications

System principle

Random and continuous access, sample selective analyzer
Integration of four measuring principles with capacity of up to 36 tests on board
Separate analyzer and control unit

Table A-9 System principle

Measurement principles

Principle	Usage
Absorbance photometry	Enzymes, substrates
Turbidimetry	Specific proteins
Potentiometry	Na ⁺ , K ⁺ , Cl ⁻

Table A-10 Measurement principles

Throughput

Up to 400 tests per hour
Up to 260 tests per hour consolidated

Table A-11 Throughput

Urgent analyses (STAT interrupt)

STAT samples prioritized and performed immediately

Samples

Sample tubes and cups	Primary or secondary tubes: 16 x 100 mm, 13 x 100 mm, 16 x 75 mm, 13 x 75 mm Cups: Eppendorf cup 1.5 mL (dead volume 80 µL) COBAS Cup 0.6 mL (dead volume 80 µL) Cup on tube: Hitachi microcup 500 µL or Hitachi standard cup 1.5 mL on primary or secondary tubes 16 x 100 mm, 16 x 75 mm.
Sample volumes	Typically 2-10 µL per test ISE: 20 µL (indirect mode) 97 µL (direct mode)
Sample types	Sample
Sample loading capacity	Up to 90 samples on board

Table A-12 Samples

	Sample handling	Rack system for samples, calibrators and controls Up to six racks of 15 sample tubes on board LED icons indicating rack status Automatic predilution Postdilution with user-definable factors Offline dilution factors can be entered
	Sample barcode	Positive sample identification by barcode scanner. Codabar 2 of 7, Code 39, Interleaved 2 of 5, Code 128
Table A-12 Samples		
<i>Calibration</i>	Linear and nonlinear	Multiple standards with single- and two-point correction. Automatic dilution of multipoint standard curves.
	Stability	Typically: Each lot for enzymes, substrates, or proteins.
Table A-13 Calibration		
<i>Reagent cassettes</i>	Test capacity	Test dependent. Standardized cassettes for all tests.
	Cassette identification	Automatic barcode reading; each cassette uniquely coded for inventory control.
	Onboard storage capacity	32 cassettes
	Cassette storage temperature	10-15 °C (50-59 °F)
	Onboard stability	Typically 8-12 weeks
Table A-14 Reagent cassettes		
<i>Cuvettes</i>	Reaction volume	120-245 µL
	Path length	5 mm
	Composition	PMMA acrylic plastic
	Cuvette reservoir capacity	1000 disposable cuvettes, refilling possible during operation
	Waste container capacity	1000 cuvettes
Table A-15 Cuvettes		
<i>Photometry analyzer</i>	Cuvette capacity	71 cuvettes with automatic loading/unloading
	System cycle time	10.6 seconds
	Temperature control	Heated air bath 37 °C (99 °F)
Table A-16 Photometer analyzer		
<i>Absorbance module</i>	Spectrophotometer	Grating monochromator and diode array
	Light source	Halogen lamp, 100 W
	Wavelength range	340-800 nm, 12 wavelengths Mono- and bichromatic measurement
	Measuring range	0-2.0 A (for 5 mm path length)
Table A-17 Absorbance module		

ISE module

Measuring principle	Potentiometry
Measuring method	Direct (undiluted) Indirect (1:6 dilution).
Measuring cycle	53 seconds
Calibration interval	One-point calibration every sample measurement. Main calibration every 5 hours. If there is a temperature difference of 5 °C (9 °F) since the last calibration After certain service actions (Prime ISE calibrators, Electrode service, Replace electrode)
Electrode life span	Reference: 2 years Na ⁺ : 6 months K ⁺ : 6 months Cl ⁻ : Labeled orange: 3 months Cl ⁻ : Labeled purple: 14 days or 2000 counts
Measuring range	Na ⁺ : 20-250 mmol/L K ⁺ : 0.2-30 mmol/L Cl ⁻ : 20-250 mmol/L

Table A-18 ISE module*Pipetting system*

Type	XYZ robotic syringe
Automatic cleaning	All probe tips
Clot detection	Pressure sensor
Reproducibility	Sample/ reagent CV <1.5%
Level detection	Sample level Reagent level: initial photometric cassette check

Table A-19 Pipetting system*Laser sources (barcode scanner)*

IEC	Class 2 Laser Product in conformity to IEC 60825-1:2014 Max. output 1.1 mW, Pulse duration: 132 µs Emitted Wavelength: 650 nm
USA	Complies with 21 CFR 1040.10 2015

Table A-20 Laser sources (barcode scanner)*Software and data handling*

Computer	Intel Pentium 800MHz CPU or faster 512 MB RAM or more Hard disk and backup hard disk DVD drive for software updates Integrated network card USB Ports Internal modem (no longer included for control unit model rp5810 and later) US keyboard and Mouse (PS2) 19 inch flat screen monitor
Operating system	Windows 10 (English or Japanese)

Table A-21 Software and data handling

Software languages	Default: English Optional: French, German, Italian, Spanish Max. 5 languages concurrently available on one system
Online Help	Context sensitive
Printer	Standard laser printer (optional). The printer must be PCL 5 compliant.
Interfaces	Bidirectional RS 232 C interface for host connection; host query mode Bidirectional RS 232 C interface for Power Ctrl connection USB 2.0 connector for printer 2nd LAN port for remote service Parallel port (for printer) (no longer included for control unit model rp5810 and later)

Table A-21 Software and data handling

Plumbing requirements

Connection	Optional direct connection to deionized water supply.
Fluid waste disposal	Fluid waste disposal via direct connection to sanitary sewer system.

Table A-22 Plumbing requirements

Dimensions and weights

Tabletop analyzer	Width: 135 cm (53.1 in) Height: 75 cm (29.5 in) Height with open lid: 108 cm (42 in) Depth: 66 cm (26 in) Weight: 198 kg (436 lb)
Printer paper format	A4 (210 mm x 297 mm) US (8.5 in x 11 in)

Table A-23 Dimensions and weights

Environmental conditions

The location must comply with the following conditions:

Ambient room temperature	15-32 °C (59-89 °F)
Relative humidity (in operation)	30-80% (non condensing)
Maximum altitude	2000 m (6500 feet)
Pollution	Degree 2 (IEC 61010-1)

Table A-24 Ambient conditions

The power supply and the water supply must fulfill the following requirements.
Never operate the system if one of the environmental conditions is not fulfilled.

Item	
Line voltage	100-125 V / 200-240 V; +10%, -15%
Line frequency	50 or 60 Hz $\pm$ 5%
Current	4 A (230 V) or 8 A (115 V) (typical values, single phase)
Power consumption	Typical value 1200 VA
Thermal load	2400 BTU/h (2520 kJoules/h)
Insulation Coordination	Installation category II (IEC 61010-1)
Degree of Protection	IP20 (IEC 60529)

Table A-25 Power requirements analyzer

Item	
Line voltage	100-127 V 200-240 V
Line frequency	50 / 60 Hz
Current	2.7 A (220 V) or 5.4 A (115 V) (typical values, single phase)
Power consumption	200 VA
Thermal load	680 BTU/h (720 kJoules/h)

Table A-26 Power requirements computer

The water quality must fulfill the following requirements:

Purity	Laboratory Reagent Grade, type I NCCLS, bidistilled or deionized water: >0.6M Ω cm or <1.5 μ S/cm <0.05 Silicate (mg/L, as SiO ₂) Maximum microbiologic content of 10 colony forming units/mL. Particulate matter (>0.2 μ m) <500/L. Organic compound via activated carbon treatment.
Supply	From external reservoir or via direct connection to deionized water supply (optional).
Usage/Drainage	Approximately 2 L/h (0.53 US gallon/h) in operating mode
Minimum flow rate	0.2 L/min (0.053 US gallon/min)

Table A-27 Water quality requirements

Other environmental conditions

- Indoor use only
- Horizontal installation space
- Dust-free environment with adequate ventilation
- No direct sunlight
- No perceptible vibration
- No equipment generating electromagnetic waves in the near vicinity
- No machines discharging ultrahigh frequencies (e.g., electric discharger)

Waste handling

Cuvettes with samples and reagents are disposed into an enclosed container inside the analyzer. The container can be removed and disposed of by the user.

Table A-28 Waste handling

- 👁 For additional information on hazardous substances, refer to the instruction for use of respective reagent kit used on the relevant analyzer.

User Interface

An overview of the analyzer software

You control the day-to-day operation of the analyzer through the user interface. This chapter describes the main features of the user interface and how to move between the main work areas. It also provides some tips to help you work more efficiently.

In this chapter

Chapter **4**

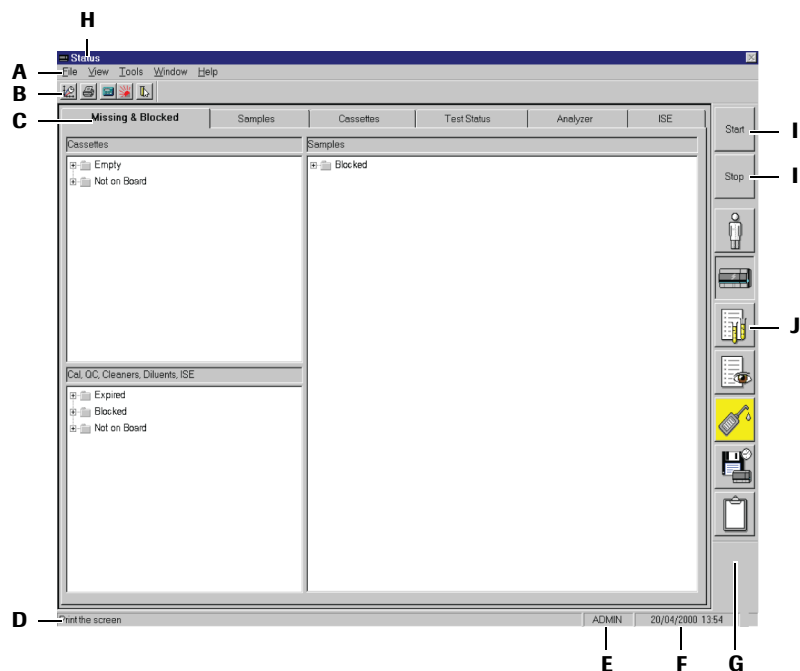
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A first look at the user interface

When you have logged on, the **Status** work area is displayed.

👁 *Logging onto the system on page B-8*

The following picture shows the main features of a work area:



- A** Menu bar
Click any item to display the corresponding menu.
- B** Toolbar
Click a button to run the corresponding command.
- C** Tab name
Change the tab displayed by clicking another tab, for example, **Cassettes**.
- D** Status bar
Short text for messages and expanded tool tips are displayed here.
- E** User ID
For the currently logged-on user.
- F** Date and time
Date and time (automatically updated) displayed in the current Windows format.
- G** Navigation bar
Click a navigation button to open the corresponding work area.
- H** Work area name
Name of the current work area.
- I** **Start** and **Stop** buttons
Start or restart a run; interrupt or stop sampling once the current actions are finished
- J** Navigation button
For example, click this button to open the **Orders** work area.

Figure A-28

Work areas

A work area is a window where you can perform a set of generally related tasks. You can open a work area by:

- Clicking one of the buttons on the navigation bar.
- Pressing the appropriate function key (see below).
- Using the Window menu from the menu bar.

Navigation button	Work area	What you can do...
	Messages Shift + F5	Display system messages. You can also review the message log for all the system messages, particularly those that have resulted from errors or problems.
	Status F5	Display the status of the system, including the status of samples, calibrators, quality controls, diluents, and cassettes. You can check the status of any test and find any missing or blocked items for the current worklist.
	Orders F6	Check the status of the orders, create new orders, and make requests for calibrations and quality controls. You can create and modify a set of details about an order (order demographics).
	Results F7	Review any results that have not been automatically accepted by the system. You can also review accepted results (result history) for samples, calibrations, and quality controls.
	Service F8	Review when scheduled service procedures, called service actions, are due and perform them, if necessary.
	Configuration Shift + F8	Set up system parameters that define how the system runs. For example, you can specify the quality controls you are going to use with a particular test. You cannot use these functions, unless you have the required user access level, which your system administrator defines for you.
	Memo pad Shift + F7	Leave messages on the system for other users. You can type in the text manually and indicate if the memo is urgent.

Table A-29

Menu bar

You can use the menu bar, which is available in the **Status**, **Orders**, **Results**, **Service**, and **Configuration** work areas, to move to (open) a different work area.

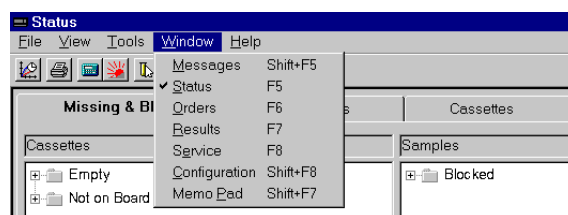
► To open a different work area from the menu bar

- 1 Click **Window** on the menu bar.

The **Window** menu is displayed.

The current work area is marked with ✓.

- 2 Click the required work area name.



Tabs

In the **Status**, **Orders**, **Results**, and **Service** work areas, the information is arranged in several tabs. The tabs of a work area contain different but related information.

► To open a different tab

- 1 Click a tab,
or
Press the Tab key until the work area tab has focus.
You see a dotted line around the tab.
- 2 Press the Right Arrow key to move left-to-right from tab to tab.
- 3 Press the Left Arrow key to move right-to-left.

Dialog boxes

Dialog boxes are secondary windows that are displayed on top of the main work area window. Typically, a dialog box requests or provides information that is supplementary to that in the main window.

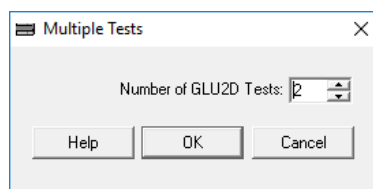


Figure A-29

You can access dialog boxes from within the work areas or through the menu bar. Some dialog boxes are shared by different work areas.

Working with the user interface

Command buttons

Click a command button to perform a particular function. For example, click **OK** to request the specified number of tests.

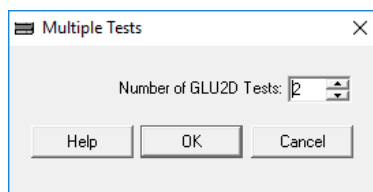
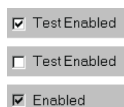


Figure A-30

Check boxes

- 1 Click once on a check box to select the suggested value.



- 2 Click again to clear the check box.

A grayed check box, with or without a tick, shows a preselected value, which you cannot change.

Typically, this means that the values have been set in other dialog boxes or have been preset on your system. It may also mean that you do not have sufficient user privileges to alter this box.



You can select more than one check box at the same time, in the same window.

Folders

- 1 Double-click a closed folder (A) to open it to show its contents.



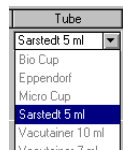
- 2 Double-click an open folder (B) to close it.



You can also single-click  to open the folder and single-click  to close it.

Drop down lists

- 1 Click the Down Arrow to expand a drop down list.



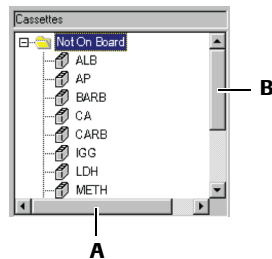
- 2 Select an item from the list.

Context menus

 Context menus (right mouse button) on page A-61

Scroll bars

Use the scroll bars when the list is longer than the available space.



Click and hold the scroll bar, and then move the mouse up or down on a vertical scroll bar (B) or left or right on a horizontal scroll bar (A).



You can use the Arrow keys and the Page Up and Page Down keys instead of the mouse.

Option buttons

- 1 Click the required option (A) to select it.



- 2 Clear the option, by selecting one of the other options.



Options in the same frame (the rectangular box around the options) are mutually exclusive. Options in other frames are treated separately.

Toolbars

Click a toolbar button to quickly start specific functions. The content of the toolbar (A) depends on which work area is displayed.



Figure A-31

This is what the toolbar buttons do:

Button	Function	Button	Function
	Archive Definitions: archive current definitions and system settings. You can then reload them in the event of a system failure.		Detail: display a Detail dialog box about the currently selected item.
	Load Definitions: load archived definitions.		Find: find an order ID.
	Calculator: open the calculator tool.		Paste: copy details from a previously saved order into the current order.
	Clear: clear the current order. If the order has not previously been saved, all details are lost.		Print: Print the current screen.
	Copy: copy details of the current order into memory so that you can retrieve them into another order later on.		Save: save the current order (Orders work area).
	Test Calibrations: Show the test calibrations.		Begin of Day: Start the Begin of Day actions manually.
	Place Items: Display the Place Items dialog box.		Barcode: Display the Barcode dialog box.

Table A-30



If a function is not currently available, the corresponding toolbar button is grayed out.

Tips and techniques

Here are a few suggestions that may help speed up your work.

Context menus (right mouse button)

Use the right mouse button to display a context menu (A) for the currently selected item. The context menu contains a list of frequently used commands relevant to the item you have selected.

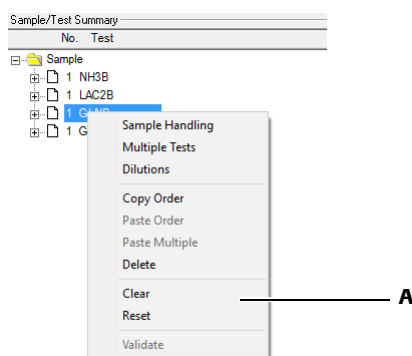


Figure A-32

This is almost always quicker than using the menu bar, because you do not have to search the menus.

► To display a context menu

- 1 Select the item you are interested in.
- 2 Place the cursor  over the item and click the right-hand mouse button.

The context menu is displayed.



Context menus are not available for all items, but they are useful for some key actions that you have to perform frequently, or simply to see what actions can be executed on the selected item.

Windows shortcut keys

You can often use the standard Windows functions cut, paste, and copy text, for example, in the **Memo Pad**. These functions have the same shortcut keys that you find on any PC:

Use Ctrl + C to copy, Ctrl + X to cut, and Ctrl + V to paste.

If you are not familiar with Windows, you use Ctrl + C, for example, as follows:

- 1 Select text or an item.
- 2 Press and hold down the Ctrl key.
- 3 Press and release the C key.
- 4 Release the Ctrl key.

The selected text or item is copied to the clipboard (part of Windows). You can retrieve it into another document later by using the **Paste** function.



- The Windows Paste function is not quite the same as the analyzer paste function, but the general idea is the same.
- There are two Ctrl keys, one each side of the space bar. They both perform the same function.
- The cut function copies text or an item to the clipboard and deletes the original.

Keyboard shortcuts

The function keys (A) are located on the top row of the keyboard.

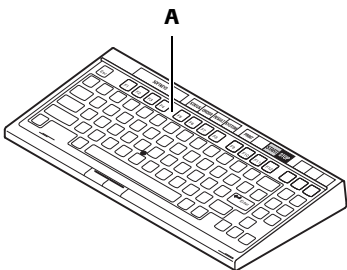


Figure A-33

Work areas on page A-56

The following keyboard shortcuts are available:

F1	Display Help for tab page or dialog box
F3	Find
F5	Status work area
F6	Orders work area
F7	Results work area
F8	Service work area
F9	Print
F10	Select menu bar
F11	Start
F12	Stop
Ctrl + A	Select All (Edit menu)
Ctrl + C	Copy (Edit menu)
Ctrl + V	Paste (Edit menu)
Ctrl + X	Cut (Edit menu)
Ctrl + Z	Undo (Edit menu)
Ctrl + Arrow	Flip through dialog box tabs
Shift + F3	Log on or off
Shift + F5	View Messages dialog box
Shift + F7	Memo Pad
Shift + F8	Configuration work area
Esc	Equivalent to clicking the Cancel or Close button in a dialog box

Table A-31 Keyboard shortcuts

Tab	Move focus to next object
Alt + F4	Shut down the system (equivalent to File menu > Shut Down)
Alt + Print Screen	Copy the current window, as a bitmap, to the clipboard
Print Screen	Copies the desktop, as a bitmap, to the clipboard

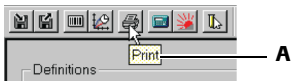
Table A-31 Keyboard shortcuts

Tool tips

Tool tips provide prompts to help you when you are not familiar with the user interface, or when you are using a feature for the first time.

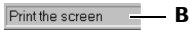
► **To view a tooltip**

- 1 Place the cursor over an item and hold it there for a couple of seconds.



The corresponding tooltip (A) is displayed.

- 2 Check the status bar (B) for an expansion of the tooltip.



If you are not familiar with the user interface, use the tooltip function to find out what each button in the navigation bar does.

Drag and drop

Use this technique, for example, to place items on a rack.

- 1 Move the cursor over the item you want to place.
- 2 Press the left mouse button and hold it down.
- 3 Move the mouse so that the item is dragged across the screen.
- 4 When your item reaches the required destination, release the mouse button.

Menu structure



Menu options are context-sensitive, that is, certain options are only available in certain situations. Therefore, some of the options displayed on the following figures may not be available on your system. For reasons of readability, the attempt was made to show as many options in active state as possible.

Status menus

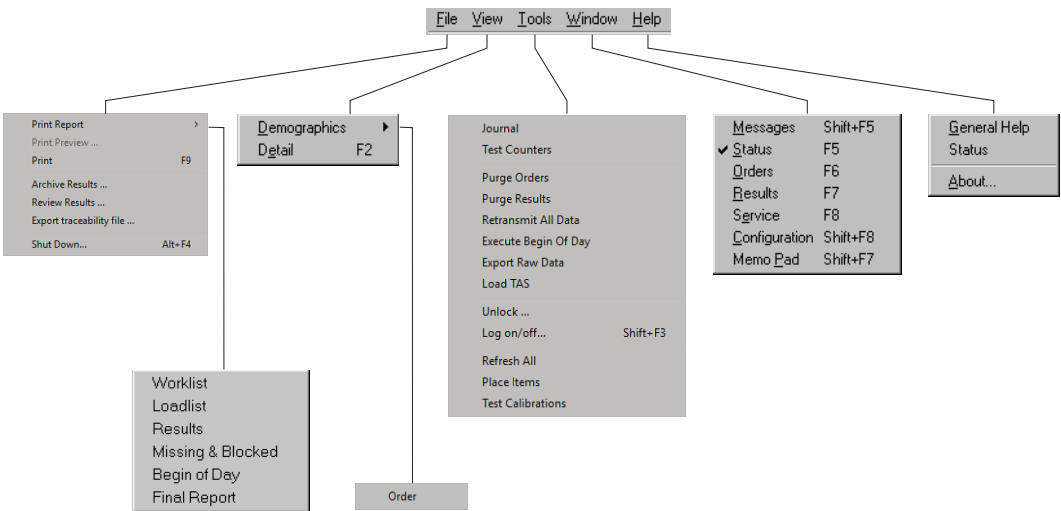


Figure A-34 Status menus

Orders menus

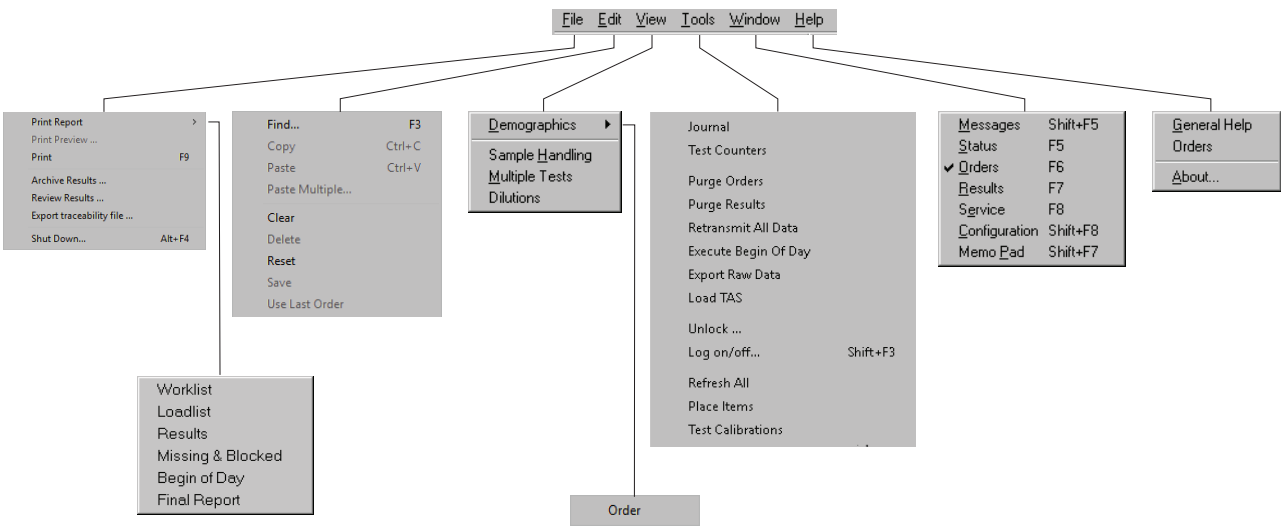


Figure A-35 Orders menus

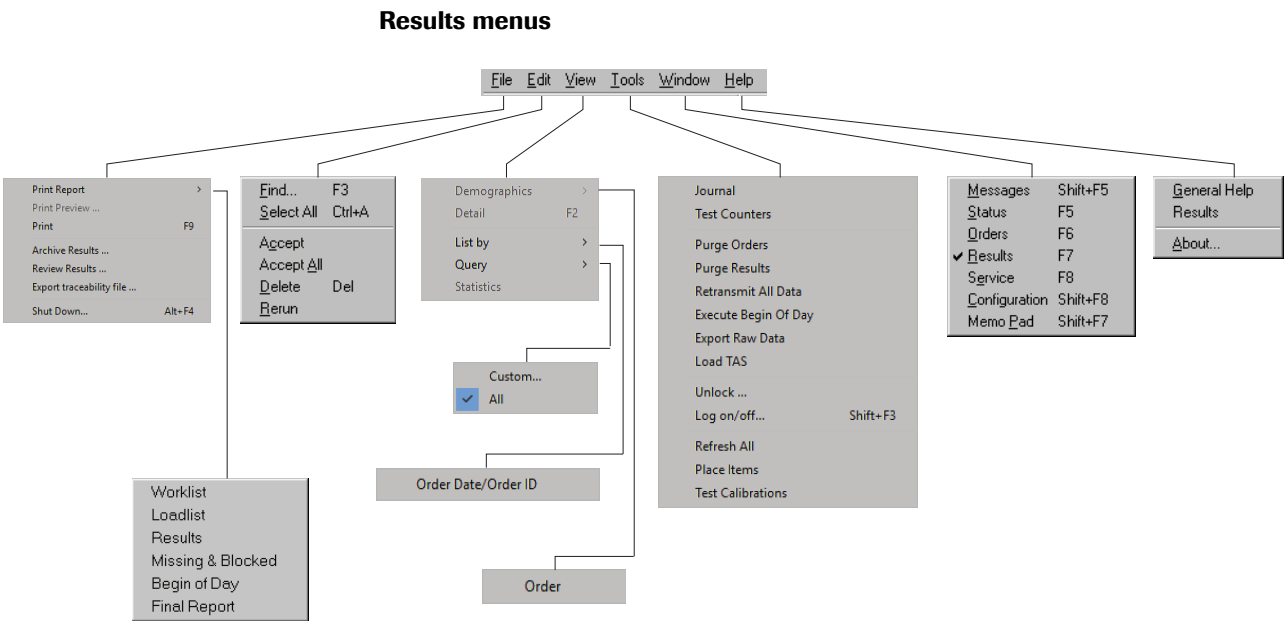


Figure A-36 Results menus

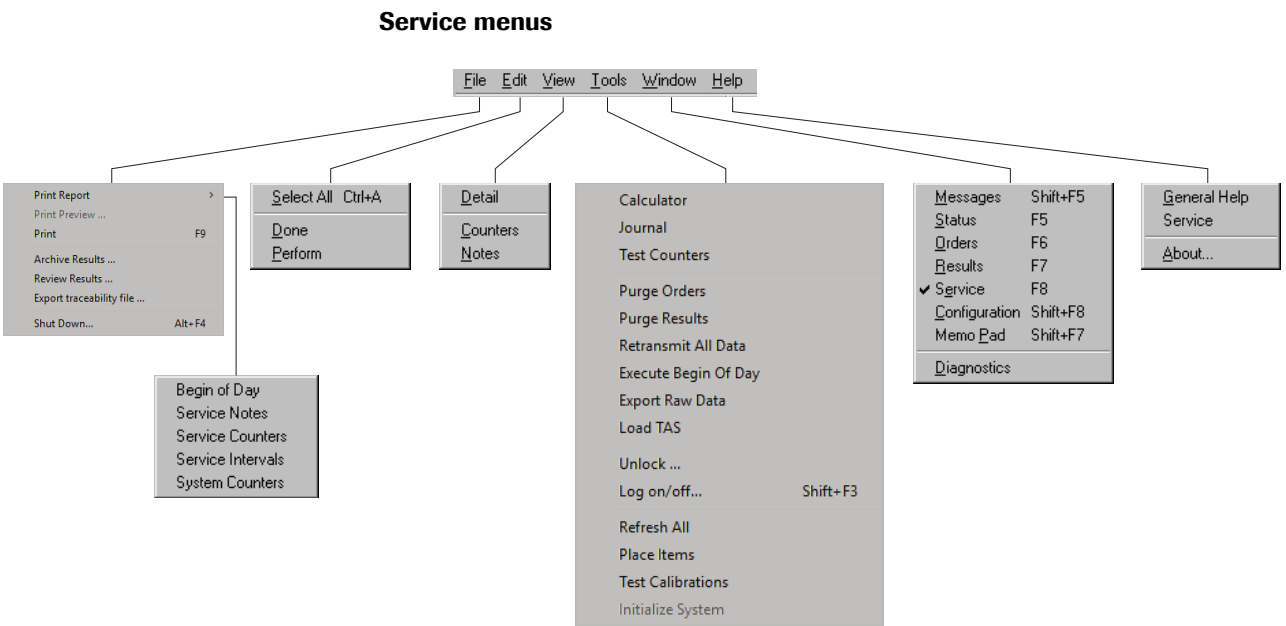


Figure A-37 Service menus

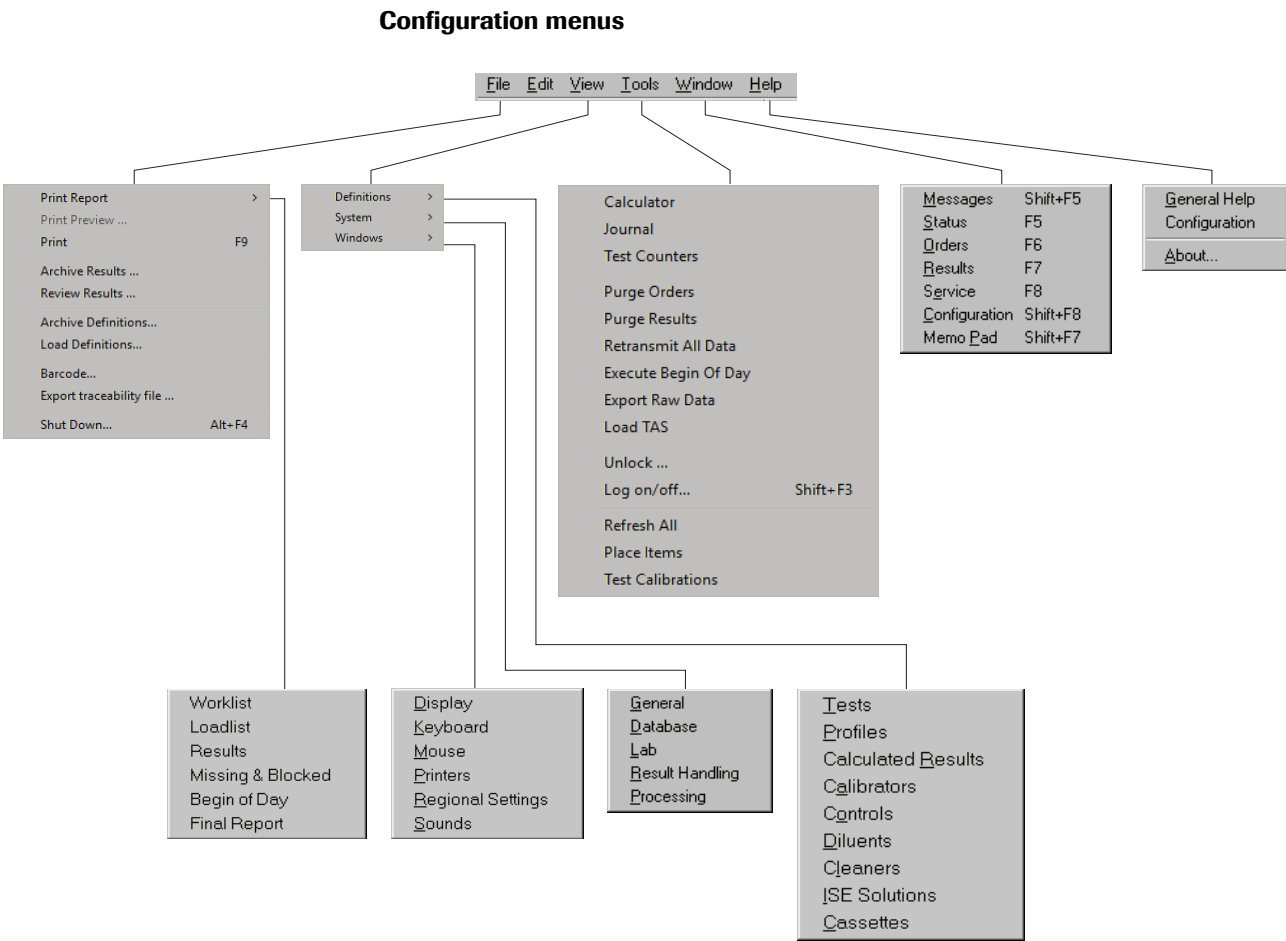


Figure A-38 Configuration menus

Workflows

Use the system efficiently

This chapter provides step by step instructions for the daily workflow. The daily routines are described for three typical laboratory setups: working without sample barcodes and without a host system, working with sample barcodes and *without* a host system, and working with sample barcodes and *with* a host system.

In this chapter

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Introduction

This chapter guides you through your working day. The optimized workflow makes sure that you get the most out of the analyzer features.

The workflow is divided into the following three sections:

Daily start-up	Prepare your system for the day.
Daily routine	Keep your system running for the routine work.
End of day	Prepare your system for the next day.

The Daily routine tasks are further divided into three procedures, reflecting the three main kinds of laboratory setup.

Sample barcode	Host	See subsection...
No	No	Daily routine (without sample barcode and without host) on page A-76.
Yes	No	Daily routine (with sample barcode and without host) on page A-81.
Yes	Yes	Daily routine (with sample barcode and with host) on page A-86.



To provide you with a clear overview of the procedures, the level of detail with which individual steps are described is kept low. More complex steps are described in detail later in the manual, and cross references are provided where appropriate. Alternatively, you can find detailed descriptions of the steps in the online Help.

Safety precautions



Follow these safety precautions at all times while using the analyzer.

- Never open the analyzer cover while the analyzer is running.
- Never remove a rack from the rack area if the rack status indicators are red.
- Never touch any moving parts.
- Never place any objects (bottles, samples, etc.) on top of the analyzer.
- Follow the analyzer messages (View Messages).
- Perform maintenance as required.
- Remove the side panels only when the power supply is disconnected.
- Use the Cedex Bio HT Analyzer only for determination of analytes in aqueous solutions.

Also, follow the general safety precautions described in *Safety* on page -17.

Working with a host computer

To allow efficient processing of the large quantities of test data generated by the analyzer, a host computer may be installed. This host computer, while optional, is recommended for most analyzer applications. Communication between the host system and the analyzer is provided by the Cedex Bio HT host interface.

The Cedex Bio HT host interface is hardware and software allowing communication between the analyzer control unit and the host computer.

Communication between the host and the analyzer's control unit works on a master-slave basis, where the host is the master. This allows the host to send orders to the analyzer via the control unit as well as to request results from the control unit. The control unit, being slave, never sends data to the host unless the host first requests it.

Features of the host interface include:

Orders	• Entry • Modification • Deletion • Host query
Results	• Single results • Collated results

Host software, including the host user interface, is not supplied by Roche and is thus customer specific. For information about the data display at your host or about the method of communication between host and control unit including data formats, please refer to the Host Interface Manual.

👁 For a description of routine operation using a host computer, see *Daily routine (with sample barcode and with host)* on page A-86

Assumptions

The analyzer can be set up in different ways to accommodate the way you work in your laboratory. The workflows outlined in this user documentation assumes that your system is configured and used in one of the following recommended ways.

Daily startup

<i>Cassettes</i>	Cassettes stay on board during the night.
<i>System shutdown</i>	The system is not shut down during the night.

Daily routine: Working without barcode and without host

Working without barcode and without host

<i>Sample barcode</i>	To work without barcode on sample tubes, clear the Use Barcode On Sample Cups check box in Configuration > General > Barcode .
<i>Rack position</i>	To automatically assign samples to rack positions, select the Automatically Assign Rack Positions check box in Configuration > Database > Automatic Actions. To reset rack position at Begin of Day, select the Reset Rack Positions at Begin of Day check box in Configuration > Database > Automatic Actions.

Rack configuration The rack configuration depends on the number of different tube types and sample types used in your laboratory.

Daily routine: Working with barcode and without host

Rack position The system identifies the samples by their barcode. Therefore, the function **Automatically Assign Rack Positions** is not used.

- Clear the **Automatically Assign Rack Positions** check box in **Configuration > Database > Automatic Actions**.
- Select the **Reset Rack Positions at Begin of Day** check box in **Configuration > Database > Automatic Actions**.

Sample barcode To work with barcode on sample tubes, select the **Use Barcode On Sample Cups** check box in **Configuration > General > Barcode**.

Rack configuration The rack configuration depends on the information coded in the sample barcode.

- If your sample barcode includes sample type information, you don't need to define the sample type. Define tube type only during rack definition.
- If your sample barcode does not include sample type information, define sample type and tube type during rack definition.

Daily routine: Working with barcode and with host

Rack position The system identifies the samples by their barcode. Therefore, the function **Automatically Assign Rack Positions** is not used.

- Clear the **Automatically Assign Rack Positions** check box in **Configuration > Database > Automatic Actions**.
- Select the **Reset Rack Positions at Begin of Day** check box in **Configuration > Database > Automatic Actions**.

Sample barcode To work with barcode on sample tubes, select the **Use Barcode On Sample Cups** check box in **Configuration > General > Barcode**.

Rack configuration The rack configuration depends on the information coded in the sample barcode.

- If your sample barcode includes sample type information, you don't need to define the sample type. Define tube type only during rack definition.
- If your sample barcode does not include sample type information, define sample type and tube type during rack definition.

Daily start-up

To prepare your system for the day, perform the following steps:

- | | |
|--|-------------|
| 1. Log on | 👁 page A-72 |
| 2. Check the Begin of Day report | 👁 page A-72 |
| 3. Load cleaner, diluents, and ISE solutions | 👁 page A-73 |
| 4. Load the cassettes. | 👁 page A-73 |
| 5. Check the resources | 👁 page A-74 |
| 6. Perform the necessary service actions | 👁 page A-75 |
| 7. Load calibrators and controls | 👁 page A-75 |

Logging on and checking the Memo Pad

► To log on

- 1 Press Shift + F3.
- 2 Type your user ID and password.
- 3 Click **Log On**.

👁 *Logging off the system* on page B-9

► To check the Memo Pad



- 1 Click **Memo Pad** on the navigation bar.
- 2 Check the **Memo Pad** for messages. A red icon points to an urgent message.

👁 *Checking the **Memo Pad*** on page B-28

Checking the Begin of Day report

The system performs preselected service actions and other automatic actions at the assigned **Begin of Day** (BOD) time. No user action is required.

The **Begin of Day** report summarizes all information about the last performed BOD. Use the report to plan your next steps, such as preparing calibrators and controls, loading cassettes, or performing service actions that are due.

► To check the Begin of Day report

- 1 Choose **File > Print Report > Begin of Day**.
- 2 Click **OK**.

The **Begin of Day** report is printed.

- 3 Check the **Begin of Day** report for the following items and plan your next steps accordingly.

- Service actions that need to be performed.
- Required calibrators, controls, cleaner, diluents, and ISE solutions. (Only cassettes required for tests remain on board.)
- Cassettes that need to be handled.



Complementary information

- To identify the required calibrators, check also the status of the calibration intervals on the **Test Calibrations** dialog box (**Tools > Test Calibrations**).
 - Prepare calibrators and controls now, so that they are ready for loading later on.
 - If no BOD was performed, choose **Tools > Execute Begin of Day** or click  to start BOD manually.
-

 For printing the report, see *Printing the Begin of Day report* on page B-30.

Loading diluents and ISE solutions

► To load diluents and ISE solutions

- 1 Check the printed **Begin of Day** report for diluent and ISE solutions to be loaded.
- 2 Load the diluents on their correct rack positions indicated in the **Begin of Day** report.
- 3 Insert the racks.



Complementary information

After loading or replacing ISE solutions on the ISE rack, the **ISE Rack Replaced** dialog box is displayed. On the dialog box select the ISE solutions that you have replaced.

Leave the check boxes cleared for ISE solutions you have not replaced.

 Replace ISE solutions on the ISE rack on page F-33

Loading cassettes



Incorrect results due to use of same cassette on multiple systems

Each cassette has its own individual cassette number, which the system uses to identify it. Using a cassette already used on a different system may lead to incorrect results.

- Do not use a reagent cassette for different systems. Each cassette rack with its cassettes may be used on one individual system only.
 - If more than one system is used in the same lab, be sure to dedicate each cassette rack with its cassettes to one single, individual system (e.g. by color coding).
-

► To load cassettes on board

- 1 Click the **Cassettes** tab in the **Status** work area to check what cassettes you need to load for the daily routine. Check the printed **Begin of Day** report for additional cassettes to be loaded.
- 2 Unwrap the cassettes.
- 3 Place the required cassettes on a cassette rack.

- 4 Insert the rack into a free slot in the cassette area.

 *Loading cassettes on page B-15*



Complementary information

The integrated cassette volume check (ICVC) function is activated by the reagent cassette barcode labels of all reagents that have to be filled manually in order to prevent erroneous results caused by incorrect filling of the reagent cassette.

If the integrated cassette volume check fails a message is displayed and the cassette access is denied. Use another cassette if the volume check fails.

Checking resources



You can check all system resources on the **Analyzer** tab of the **Status** work area.

The background color of the **Status** button tells you whether you need to take action or not.

Button	Background color	Take action...
	Red (Fatal error)	Immediately
	Yellow	Soon (when convenient)
	Green or gray	None
		

The icon on the **Status** button also changes, depending on the resource status. For example, if cuvettes are running low, you see the cuvette icon (on a yellow background).

Status button	Resource	User action
	Cleaner	Replace cleaner.
	Cuvettes	Add cuvettes to cuvette reservoir.
	Water	Check water supply connections. If supplied from an external reservoir, check the level.
	Cuvette Waste	Empty the cuvette waste reservoir.
	Waste Drain	If waste is put into an external reservoir, check the level.
	Temperature	Check all ventilation filters and passages. Check the fuses.
	ISE Solutions	Check the ISE tab in the Status work area for more information.

 *Checking resources on page B-17*

Performing service actions



Processing stop due to lack of disk space

The accumulated data gradually fills the available space on the hard disk. When there is no space left the system will be blocked.

- Perform database backup in regular intervals.

► To perform service actions

- 1 Check the printed **Begin of Day** report for service actions that need to be performed. Prepare all required tools and materials.
- 2 Click **Service** on the navigation bar.
- 3 Select the required service actions from the **Due** tab.
- 4 Click **Perform**.
- 5 Perform the service actions according to the on-screen instructions. Click **Help** for full details.



Complementary information

Should you choose to not perform the Backup database service action automatically at BOD (**Service > View Counters > Service Intervals**), then if the **Backup database** service action is due, perform it at the end of the day. This service action may take about 5 minutes.

👁 Chapter 14 *Service actions*

👁 Chapter 13 *Service action software*

Loading calibrators and controls

► To load calibrators and controls on board

- 1 Check the printed **Begin of Day** report for the preassigned rack numbers and positions of the required calibrators and controls.
- 2 Load the calibrators and controls on their correct rack positions.
- 3 Insert the rack into a free slot in the sample or cassette area.



Complementary information

- Calibrations are performed automatically together with the next ordered test.
- Automatic calibrations are only performed, if a test is requested during the day. If applicable, request a calibration manually in **Orders > Calibration**.
- The preferred slot for calibrators and controls is slot I, which is in the cooled cassette area.
- You must put multi-set calibrators in continuous positions on the same rack, starting with the highest concentration standard furthest away from you when you insert the rack.
- If barcodes for calibrators with several standards are used, label all standard cups with the same barcode.

👁 *Loading calibrators, controls, and diluents on page B-15*

Daily routine (without sample barcode and without host)

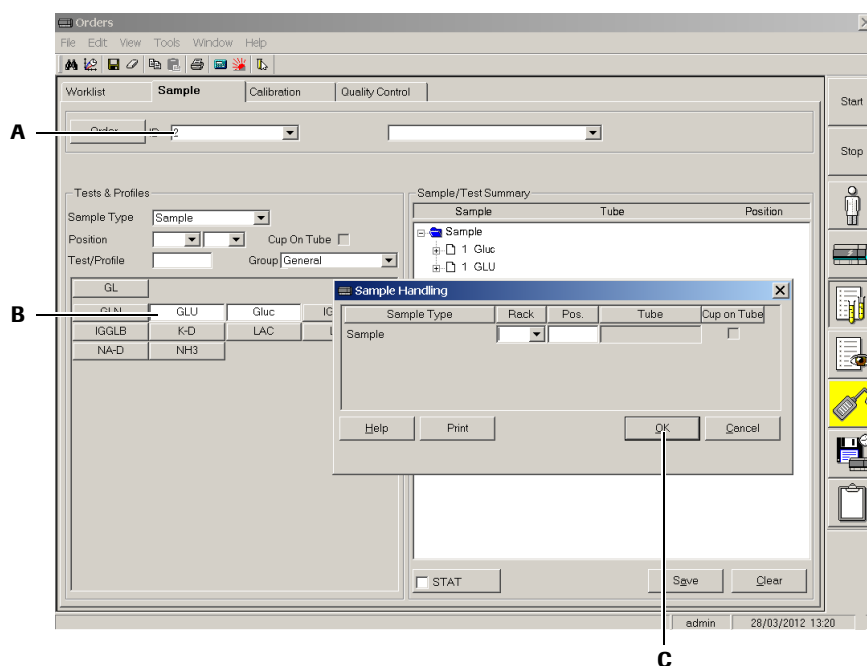
When working without sample barcodes and without a host, daily routine involves the following tasks:

1. Create the orders 👁 page A-76
2. Load samples 👁 page A-78
3. Start processing 👁 page A-78
4. Validate the results 👁 page A-78
5. Print the final report 👁 page A-81

Creating orders

Creating orders involves the following tasks:

1. Add order ID and demographics 👁 page A-77
2. Select tests and save the order 👁 page A-77
3. Confirm the rack positions 👁 page A-77



- A** Enter an order ID and if required a comment.
- B** Select tests and click **Save**.
- C** To confirm rack number and position for all sample types on the **Sample Handling** dialog box, click **OK**.

Figure A-39

👁 Creating an order on page B-69

► **To add the order ID**

- 1 Type an order number in the **Order ID** box and press Enter.

**Complementary information**

Type * (asterisk) in the Order ID box and press Enter to use the lookup function. The **Lookup** dialog box is displayed with a list of all order IDs stored on the system.

👁 *Specifying an order ID on page B-69*

► **To select tests and save the order**

- 1 Click the buttons for the required profiles and tests.
- 2 Click **STAT** for a high priority order.
- 3 Click **Save**.

**Complementary information**

- The samples are automatically assigned to appropriate rack positions. These positions can be modified, if required, on the **Sample Handling** dialog box, which is displayed after the order is saved.
- By default, the sample type **Automatic** is displayed. The **Position** boxes for rack number and position are disabled.
- Change the test group in the **Group** box to limit or expand the display of test and profile buttons. Select **General** to display all available test and profile buttons.

If you want...	Then do this...
To limit or expand the display of test and profile buttons in the Test & Profiles group	Select the appropriate group in the Test & Profiles group.
To delete a test from the Sample , Calibration , or QC tab	Right-click the test in the Test Summary group, and choose Delete from the context menu. Alternatively, click the test button.
To request a dilution for a sample test	Right-click the test in the Sample > Test Summary group, and choose Dilutions from the context menu. Select or type a factor in the Dilutions dialog box.
To add a sample test several times to an order	Right-click the test in the Sample > Test Summary group, and choose Multiple Tests from the context menu. Type the number of tests in the Multiple Tests dialog box.
To create multiple copies of an order	Right-click in the Sample > Test Summary group, and choose Copy Order from the context menu. Right-click again in the Test Summary group, and choose Paste Multiple from the context menu. Type the number of orders you wish to create, and accept or change the first order ID for the new orders.

► **To confirm rack positions**

- 1 Check the automatically assigned rack number and position for each sample type listed on the **Sample Handling** dialog box. Modify the position if required.
- 2 Select the **Cup on Tube** check box if the sample is placed in a secondary cup on a primary tube.
- 3 Click **OK**.



Complementary information

- The **Sample Handling** dialog box is displayed when you click **Save**.
 - When a sample type is used for the first time on a day, you must assign it manually to the appropriate rack position, using the **Sample Handling** dialog box. Afterwards, all other rack position assignments are done automatically by the system.
 - Enter the rack number and position for samples manually on the **Sample Handling** dialog box, if the function **Automatically Assign Rack Positions** is not used.
 - The **Cup on Tube** function on the **Sample Handling** dialog box is only available if the selected rack has the appropriate tube type assigned to it, the rack position is entered, and the rack is not on board.
-

👁 *Assigning samples to racks on page B-70*

👁 *Selecting **Cup on Tube** on page B-75*

Loading samples on board

► **To load samples on board**

- 1 Choose **File > Print Report > Loadlist** from the menu bar and click **OK** to print the loadlist.
- 2 Use the loadlist to place the sample tubes and cups on the correct rack position.
- 3 Insert the rack into one of the slots in the sample area.



Complementary information

- On the loadlist, the sample order is displayed, but whether a sample is a **Cup on Tube** sample is not indicated.
 - You can use only one tube type per rack.
 - If you use tubes that are not defined on your system, you may damage the probes.
 - Before you move a rack, wait until the status light above the rack is green.
-

👁 *Loading samples on page B-12*

Start processing

► **To start processing**

- If the system is in **Standby**, press F11 or click **Start** on the navigation bar.
 - If the system is in **Sleeping**, press F11 or click **Start** on the navigation bar.
- As soon as the system is in **Standby**, press F11 again.



Complementary information

If you work with **Auto Start (Configuration > General > System)**, the system starts processing automatically, as soon as you insert a rack, provided there are orders that need to be processed.

► **To check the workload**

- 1 Click **Orders** on the navigation bar and click the **Worklist** tab.
- 2 Check the **Worklist** for orders that are blocked or have no samples on board.

- 3 Take the appropriate actions to resolve the problem.
- 4 If you are sure all your scheduled orders are being processed properly and your first results are calculated, switch to the **Validate** tab in the **Results** work area for result validation.



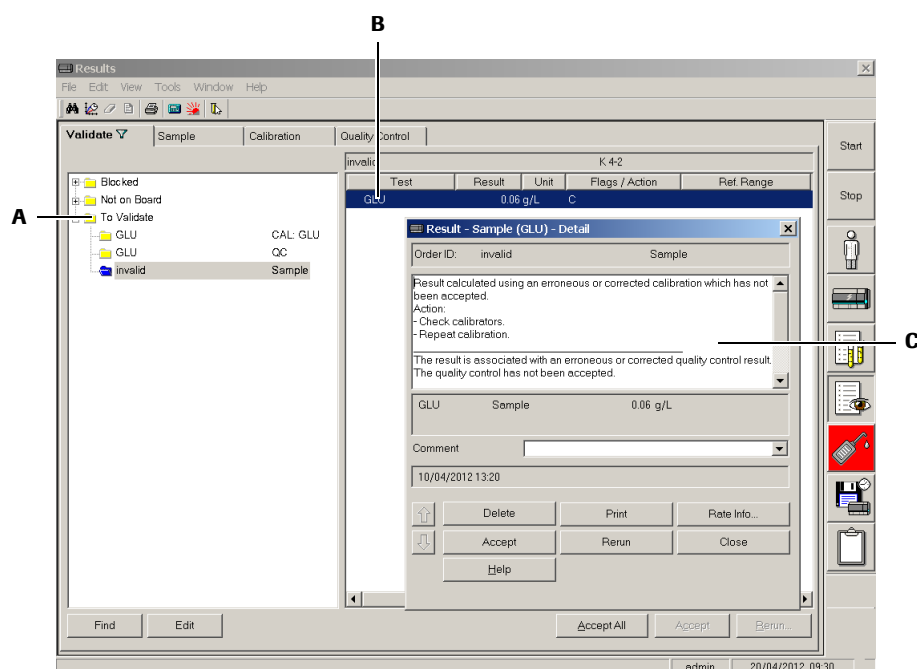
Complementary information

- Select a blocked test and press F1 to get Help.
- Select an order and click **Edit** to modify the order or click **Validate** to switch to the **Validate** tab in the **Results** work area for result validation.

👁 **Worklist tab** on page B-63

👁 *Printing the Worklist* on page B-34

Validating results



- A Check all results located in the **To Validate** folder on the Validate tab of the **Results** work area.
- B Double-click a result line in the list of results.
The **Result Detail** dialog box is displayed, where you get information about recommended actions for flagged results.
- C Perform the recommended actions for flagged results. Recommended actions include:
Rerun the test with dilution
Repeat the test
Check the required items as listed in the recommended actions of the **Results Detail** dialog box
Review test result details; accept the result

Figure A-40

👁 **Validate tab** on page B-90

👁 *Working with results* on page B-100

► **To rerun or repeat a test**

- 1 Click the **Validate** tab on the **Results** work area.
- 2 In the **To Validate** folder, select a sample, calibration, or control order.
- 3 Select the result in question from the **Results** list, and click **Rerun**.
The **Dilutions** dialog box is displayed if you have selected a test order.
- 4 Do one of the following:
 - Select a dilution factor to rerun the test order with dilution.
 - Select **As Original** to repeat the test order with the setting defined in the test definition.

👁 Requesting a dilution on page B-81

► **To review test result details**

- 1 Click the **Validate** tab on the **Results** work area.
- 2 In the **To Validate** folder, select a sample, calibration, or control order.
- 3 Double-click a result line in the list of results.
The **Result Detail** dialog box is displayed.
- 4 Click **Rate Info**.
The **Rate Info** dialog box is displayed.
- 5 Review the information to check the reason for the flag.

**Complementary information**

- Select an order and click **Edit** to switch to the **Orders** work area for editing.
- Right-click an order in the **Blocked** folder and choose **Detail** from the context menu to see the test status of the blocked order on the **Results - Detail - Test Orders** dialog box.

► **To accept a result**

- 1 Click the **Validate** tab on the **Results** work area.
- 2 In the **To Validate** folder, select a sample, calibration, or control order.
- 3 Select a result from the list of results and click **Accept**.

**Complementary information**

- Click **Accept All** to accept all the results of the selected order.
- Set the filter option of the **Validate** tab to **Unaccepted** to display only the unaccepted results of the selected order.

Printing the Final Report

► To print the Final Report

- 1 Choose **File > Print Report > Final Report** from the menu bar.
The **Print Result Query** dialog box is displayed.
- 2 Define the ranges for **Order ID** and **Order Date**.
- 3 Click **Print**.



Complementary information

Select **Final Report** in **Configuration > Database > Automatic Actions** to print the **Final Report** automatically as soon as the last result of an order is accepted.

👁 *Printing the Final Report* on page B-31

Daily routine (with sample barcode and without host)

When working with sample barcodes but without a host, daily routine involves the following tasks:

- | | |
|---------------------------|-------------|
| 1. Load samples | 👁 page A-81 |
| 2. Create orders | 👁 page A-82 |
| 3. Confirm orders | 👁 page A-83 |
| 4. Start processing | 👁 page A-83 |
| 5. Validate the results | 👁 page A-84 |
| 6. Print the final report | 👁 page A-86 |

Loading samples on board

► To load samples on board

- 1 Place the sample tubes and cups on the appropriate racks.
- 2 Insert the rack into one of the slots in the sample area.



Complementary information

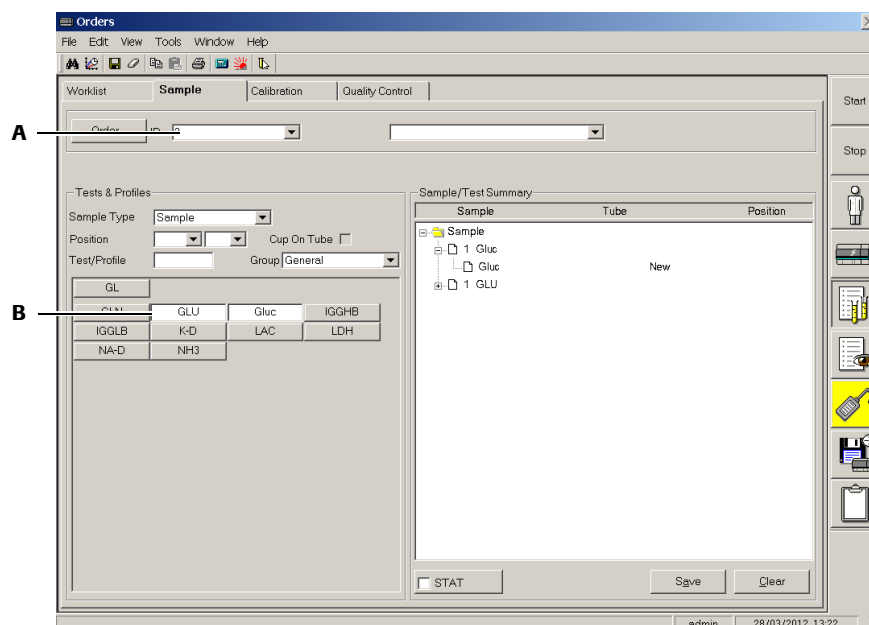
- You can use only one tube type per rack.
 - If you use tubes that are not defined on your system, you may damage the probes.
 - Before you move a rack, wait until the status light above the rack is green.
-

👁 *Loading samples* on page B-12

Creating orders

Creating orders involves the following tasks:

1. Select an order ID from the list and add demographics.  page A-82
2. Select tests and click **Save**.  page A-82



A Select an order ID from the list.

B Select tests and click **Save**.

Figure A-41

► To select the order ID



Complementary information

- The **Order ID** list lists all samples that are present on the system and have no orders assigned to them.
- Type * (asterisk) in the **Order ID** box and press Enter to use the lookup function. The **Lookup** dialog box is displayed with a list of all order IDs stored on the system.

 *Specifying an order ID on page B-69*

► To select tests and save the order

- 1 Click the buttons for the required profiles and tests.
- 2 Click **STAT** for a high priority order.
- 3 Click **Save**.



Complementary information

Change the test group in the **Group** box to limit or expand the display of test and profile buttons. Select **General** to display all available test and profile buttons.

 *Selecting tests for the order on page B-70*

If you want...	Then do this...
To limit or expand the display of test and profile buttons in the Test & Profiles group	Select the appropriate group in the Test & Profiles group.
To delete a test from the Sample , Calibration , or QC tab	Right-click the test in the Test Summary group, and choose Delete from the context menu. Alternatively, click the test button of the test.
To request a dilution for a sample test	Right-click the test in the Sample > Test Summary group, and choose Dilutions from the context menu. Select or type a factor in the Dilutions dialog box.
To add a sample test several times to an order	Right-click the test in the Sample > Test Summary group, and choose Multiple Tests from the context menu. Type the number of test in the Multiple Tests dialog box.
To create multiple copies of an order	Right-click in the Sample > Test Summary group, and choose Copy Order from the context menu. Right-click again in the Test Summary group, and choose Paste Multiple from the context menu. Type the number of orders you wish to create, and accept or change the first order ID for the new orders.

Confirming the orders

► To print the worklist

- 1 Choose **File > Print Report > Worklist** from the menu bar and click **OK** to print the worklist.
- 2 Review the printed worklist to confirm that all orders have been entered correctly.

👁 *Printing the Worklist on page B-34*

Start processing

► To start processing

- If the system is in **Standby**, press F11 or click **Start** on the navigation bar.
- If the system is in **Sleeping**, press F11 or click **Start** on the navigation bar.

As soon as the system is in **Standby**, press F11 again.



Complementary information

If you work with **Auto Start (Configuration > General > System)**, the system starts processing automatically, as soon as you insert a rack, provided there are orders that need to be processed.

► To check the worklist

- 1 Click **Orders** on the navigation bar and click the **Worklist** tab.
- 2 Check the **Worklist** for orders that are blocked or have no samples on board and for samples that have no orders assigned to them.
- 3 Take the appropriate actions to resolve the problem.

- If you are sure all your scheduled orders are being processed properly and your first results are calculated, switch to the **Validate** tab in the **Results** work area for result validation.



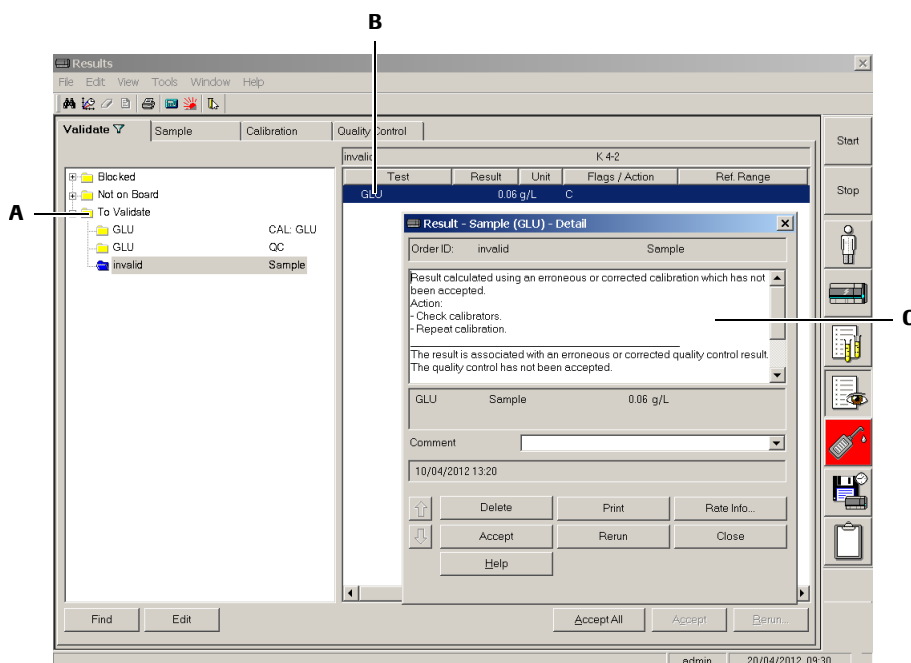
Complementary information

- Select a blocked test and press F1 to get Help.
- Select an order and click Edit to modify the order or click **Validate** to switch to the **Validate** tab in the **Results** work area for result validation.

Worklist tab on page B-63

Validating results

Validate results on the **Validate** tab of the **Results** work area.



- Check all results located in the **To Validate** folder on the **Validate** tab of the **Results** work area.
- Double-click a result line in the list of results.
The **Result Detail** dialog box is displayed, where you get information about recommended actions for flagged results.
- Perform the recommended actions for flagged results.
Recommended actions include:
Rerun the test with dilution.
Repeat the test.
Check the required items as listed in the recommended actions of the **Results Detail** dialog box.
Review test result details.
Accept the result.

Figure A-42

Validate tab on page B-90

About results on page B-86

► **To rerun or repeat a test**

- 1 Click the **Validate** tab on the **Results** work area.
- 2 In the **To Validate** folder, select a sample, calibration, or control order.
- 3 Select the result in question from the list of results and click **Rerun**.
The **Dilutions** dialog box is displayed if you have selected a test order.
- 4 Do one of the following:
 - Select a dilution factor to rerun the test order with dilution.
 - Select **As Original** to repeat the test order with the setting defined in the test definition.

👁 Requesting a dilution on page B-81

► **To review test result details**

- 1 Click the **Validate** tab on the **Results** work area.
- 2 In the **To Validate** folder, select a sample, calibration, or control order.
- 3 Double-click a result line in the list of results.
The **Result Detail** dialog box is displayed.
- 4 Click **Rate Info**.
The **Rate Info** dialog box is displayed.
- 5 Review the information to check the reason for the flag.

**Complementary information**

- Select an order and click **Edit** to switch to the **Orders** work area for editing.
- Right-click an order in the **Blocked** folder and choose **Detail** from the context menu to see the test status of the blocked order on the **Results - Detail - Test Orders** dialog box.

► **To accept a result**

- 1 Click the **Validate** tab on the **Results** work area.
- 2 In the **To Validate** folder, select a sample, calibration, or control order.
- 3 Select a result from the list of results and click **Accept**.

**Complementary information**

- Click **Accept All** to accept all the results of the selected order.
- Set the filter option of the **Validate** tab to Unaccepted to display only the unaccepted results of the selected order.

Printing the Final Report

► To print the Final Report

- 1 Choose **File > Print Report > Final Report** from the menu bar.
The **Print Result Query** dialog box is displayed.
- 2 Define the ranges for **Order ID** and **Order Date**.
- 3 Click **Print**.



Complementary information

Select **Final Report** in **Configuration > Database > Automatic Actions** to print the **Final Report** automatically as soon as the last result of an order is accepted.

👁 *Printing the Final Report* on page B-31

Daily routine (with sample barcode and with host)

When working with sample barcodes and with a host, daily routine involves the following tasks:

- | | |
|---|-------------|
| 1. Load samples | 👁 page A-86 |
| 2. Start processing | 👁 page A-87 |
| 3. Monitor scheduled orders | 👁 page A-88 |
| 4. Validate the results | 👁 page A-88 |
| 5. Create orders manually (if required) | 👁 page A-90 |

Loading samples on board

► To load samples on board

- 1 Place the sample tubes and cups on the appropriate racks.
- 2 Insert the rack into one of the slots in the sample area.



Complementary information

- You can use only one tube type per rack.
 - If you use tubes that are not defined on your system, you may damage the probes.
 - Before you move a rack, wait until the status light above the rack is green.
-

👁 *Loading samples* on page B-12

Start processing

► To start processing

- If the system is in **Standby**, press F11 or click **Start** on the navigation bar.
- If the system is in **Sleeping**, press F11 or click **Start** on the navigation bar.

As soon as the system is in **Standby**, press F11 again.



Complementary information

If you work with **Auto Start** (**Configuration > General > System**), the system starts processing automatically, as soon as you insert a rack, provided there are orders that need to be processed.

Monitoring scheduled orders

► To identify blocked tests or samples that are not on board

- 1 Check the **Validate** tab on the **Results** work area for orders that are blocked or have no samples on board.
- 2 Double-click a sample, calibration, or control order in the folders **Blocked** or **Not On Board**.

The **Results - Detail - Test Orders** dialog box is displayed.

- 3 On the **Results - Detail - Test Orders** dialog box, select a blocked test and press F1 to get Help.
- 4 Take the appropriate actions to resolve the problem.



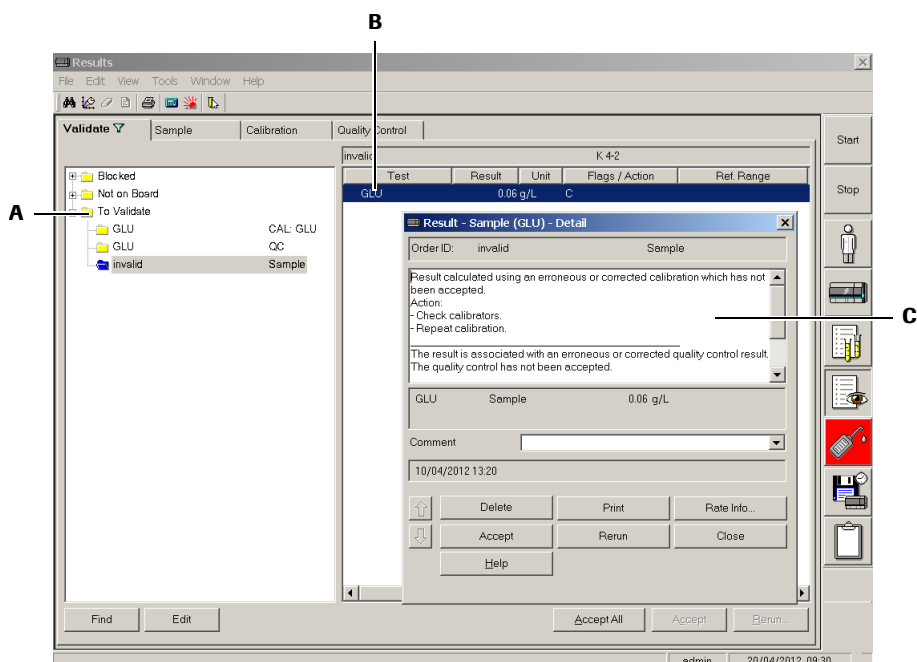
Complementary information

- The folders **Blocked** and **Not On Board** are only listed on the **Validate** tab if they contain at least one entry. If the folders are not displayed, no tests are blocked and all samples are on board.
- Right-click an order in the **Blocked** folder and choose **Detail** from the context menu to see the test status of the blocked order on the **Results - Detail - Test Orders** dialog box.
- Select an order and click **Edit** to switch to the **Orders** work area for editing.

👁 **Validate tab** on page B-90

Validating results

Validate results on the **Validate** tab of the **Results** work area.



- A** Check all results located in the **To Validate** folder on the **Validate** tab of the **Results** work area.
- B** Double-click a result line in the list of results.
The **Result Detail** dialog box is displayed, where you get information about recommended actions for flagged results.
- C** Perform the recommended actions for flagged results.
Recommended actions include:
Rerun the test with dilution.
Repeat the test.
Check the required items as listed in the recommended actions of the **Results Detail** dialog box.
Review test result details.
Accept the result.

Figure A-43

- 👁 **Validate tab** on page B-90
- 👁 **About results** on page B-86

► To rerun or repeat a test

- 1 Click the **Validate** tab on the **Results** work area.
- 2 In the **To Validate** folder, select a sample, calibration, or control order.
- 3 Select the result in question from the list of results and click **Rerun**.
The **Dilutions** dialog box is displayed if you have selected a test order.

- 4 Do one of the following:
 - Select a dilution factor to rerun the test order with dilution.
 - Select **As Original** to repeat the test order with the setting defined in the test definition

 *Requesting a dilution on page B-81*

► **To review test result details**

- 1 Click the **Validate** tab on the **Results** work area.
- 2 In the **To Validate** folder, select a sample, calibration, or control order.
- 3 Double-click a result line in the list of results.
The **Result Detail** dialog box is displayed.
- 4 Click **Rate Info**.
The **Rate Info** dialog box is displayed.
- 5 Review the information to check the reason for the flag.

► **To accept a result**

- 1 Click the **Validate** tab on the **Results** work area.
- 2 In the **To Validate** folder, select a sample, calibration, or control order.
- 3 Select a result from the list of results and click **Accept**.



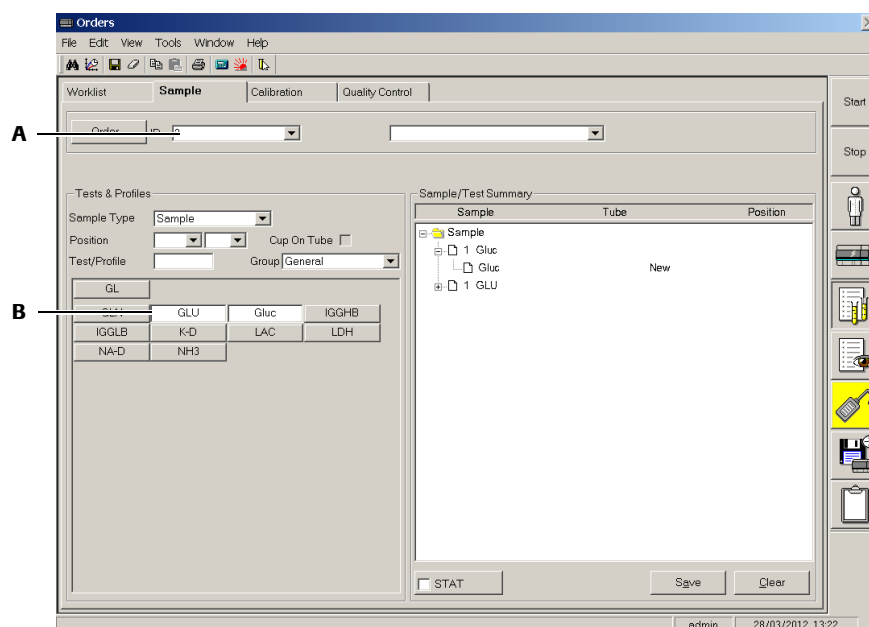
Complementary information

- Click **Accept All** to accept all the results of the selected order.
 - Set the filter option on the **Validate** tab to **Unaccepted** to display only the unaccepted results of the selected order.
-

Creating orders

If necessary, create orders manually in three steps:

1. To select the order ID on page A-90
2. To select tests and save the order on page A-90



- A** Add order ID on the **Sample** tab of the **Orders** work area.
- B** Select tests and click **Save**.

Figure A-44

👁 Creating an order on page B-69

► To select the order ID

- 1 Select the appropriate order ID from the **Order ID** list and press Enter.
- 2 Depending on the configuration of your system, add additional order information:
 - In the text box to the right of the order ID, type the text, or select a predefined text from the list, and press Enter.



Complementary information

- The **Order ID** list lists all samples that are present on the system and have no orders assigned to them.
- Type * (asterisk) in the **Order ID** box and press Enter to use the lookup function. The **Lookup** dialog box is displayed with a list of all order IDs stored on the system.

👁 Specifying an order ID on page B-69

► To select tests and save the order

- 1 Click the buttons for the required profiles and tests.
- 2 Click **STAT** for a high priority order.
- 3 Click **Save**.



Complementary information

Change the test group in the **Group** box to limit or expand the display of test and profile buttons. Select **General** to display all available test and profile buttons.

Selecting tests for the order on page B-70

If you want...	Then do this...
To limit or expand the display of test and profile buttons in the Test & Profiles group	Select the appropriate group in the Test & Profiles group.
To delete a test from the Sample, Calibration, or QC tab	Right-click the test in the Test Summary group, and choose Delete from the context menu.
To request a dilution for a sample test	Right-click the test in the Sample > Test Summary group, and choose Dilutions from the context menu. Select or type a factor in the Dilutions dialog box.
To add a sample test several times to an order	Right-click the test in the Sample > Test Summary group, and choose Multiple Tests from the context menu. Type the number of test in the Multiple Tests dialog box.
To create multiple copies of an order	Right-click in the Sample > Test Summary group, and choose Copy Order from the context menu. Right-click again in the Test Summary group, and choose Paste Multiple from the context menu. Type the number of orders you wish to create, and accept or change the first order ID for the new orders.

End of day

End of day activities include the following tasks:

- | | |
|---|-----------|
| 1. Remove the sample racks | page A-91 |
| 2. Delete result orders | page A-92 |
| 3. Complete the remaining service actions | page A-92 |
| 4. Log off | page A-93 |

Removing sample racks

► **To remove sample racks**

- 1 Open the rack access panel.
- 2 Remove all sample racks.

Deleting results and orders



Loss of data due to deleting the results of the day.

If you archive the results on the system, deleting the results of the day may lead to data loss.

- Do not delete the results of the day if you archive the results on the system.

► To delete selected results

- 1 Click **Results** on the navigation bar.
- 2 Click the **Sample** tab.
- 3 Right-click the date folder you want to delete and choose **Delete** from the context menu.
- 4 Click **Yes** to confirm the deletion.



Complementary information

To delete a single result, right-click a result in the **Results** list, and choose **Delete** from the context menu.

👁 *Purging results on page B-103*

► To purge orders

- 1 Choose **Tools > Purge Orders**.
- 2 Click **Yes** on the **Confirm Purge Orders** dialog box.



Complementary information

- Depending on the setup of your system, orders are deleted automatically at BOD time.
- If you archive the results in the **Results** work area you need to purge the results regularly. The analyzer is not designed to store large quantities of results on the system. As part of data management, you should periodically purge results manually. At least every 2 months is recommended.

👁 *Purging and deleting orders on page B-39*

Complete the remaining service actions

► To complete the remaining service actions

- 1 Click **Service** on the navigation bar.
- 2 Select the required service actions from the **Due** tab.
- 3 Click **Perform**.
- 4 Perform the service actions according to the on-screen instructions. Click **Help** for full details.

👁 *Chapter 14 Service actions*

👁 *Chapter 13 Service action software*

Logging off

► To log off

1 Double-click the user ID in the status bar.

2 Click **Log Off**.

👁 *Logging off and shutting down the system on page B-9*

👁 *Logging off the system on page B-9*

👁 *Shutting down the system on page B-10*

End of day

Operation



6	<i>Routine tasks</i>	<i>B-3</i>
7	<i>Status</i>	<i>B-41</i>
8	<i>Orders</i>	<i>B-57</i>
9	<i>Results</i>	<i>B-85</i>
10	<i>Calibration</i>	<i>B-107</i>
11	<i>Quality controls</i>	<i>B-127</i>

Routine tasks

Performing everyday tasks to keep the system running

This chapter describes the routine tasks that you need to perform to keep your analyzer running.

In this chapter

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General safety information

To avoid personal injury and damage to the equipment, do the following:

- Make sure you have read the safety precautions in Chapter 1 *Safety*.
 - Pay particular attention to all safety precautions.
 - Always follow the instructions in this publication.
-

Starting up and logging on to the system

Switching on the system

Always switch on the system components in the following order:

1. Monitor
2. Printer
3. Analyzer
4. Control unit

► **To switch on the monitor**

- 1 Follow your monitor instructions.

Switching on the printer

Standard printers go into **Standby** state as soon as they are connected to the mains power.

If there is an On/Off switch on your printer, switch on the printer and follow your printer instructions.

Switching on the analyzer

To turn on the analyzer, press the main switch (A).

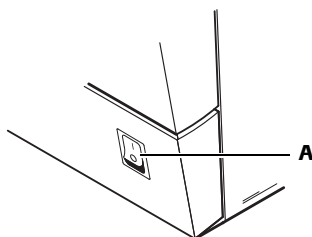
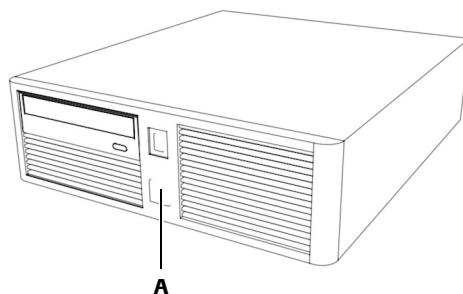


Figure B-1

Switching on the computer► **To switch on the computer**

- 1 Press the On/Off switch (A) of the computer. The green indicator lights up as soon as the computer starts up.



After completing the startup procedures, the user interface of the analyzer software is displayed. Startup may take a few minutes.

Starting the analyzer

The method of starting up the analyzer depends on its state when you start work. The **Status** button (A) on the navigation bar shows the analyzer state.

👁 System states on page A-43

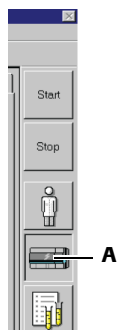


Figure B-2

► To start up the analyzer

Use the following table to decide which start-up procedure to use.

State	Button	Start-up procedure
Power off: analyzer is turned off.		Power on the analyzer then the computer. The system performs a full initialization.
Sleeping : analyzer has not been used for a while.	 Blue background	Press F11 on the keyboard or click Start on the navigation bar to start a partial analyzer initialization.
Standby : analyzer was started by an earlier user.	 Gray background	None. You are ready to log on.

Table B-1

Initialization

After starting up from power off:

1. The system goes through its Windows 10 start-up procedure.
2. The Windows Desktop is displayed.
3. The analyzer main window is displayed showing the **Status** work area.
4. The **Status** button on the navigation bar shows the system is initializing (flashing arrow).
5. The system goes into **Standby**.



Complementary information

- You must log on before you can access all the functions available to you.
- If you switch on after the **Begin of Day** (BOD) time has passed, all the BOD actions are run automatically before processing orders, provided you had not switched on the system previously that day.
- The system goes into **Standby** after a definable period of inactivity (default value is 10 minutes), or at a defined time. Then, after a defined interval (by default, **Sleeping Mode after** is set to 10 minutes), the system goes into **Sleeping**.
- You can configure the system to start processing automatically; otherwise, click **Start** or press F11 to start processing, and click **Stop** or press F12 to stop processing.
- Configure **Auto Start**, BOD time, **End of Sequence**, and **Sleeping state** in **Configuration > General > System**.

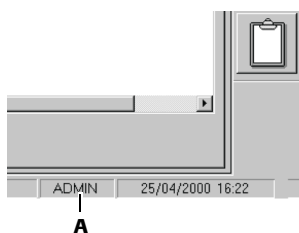
Logging onto the system

To log on, you must use the password and user ID that were created for you by your administrator. The software uses the ID of the person who is logged on to record their actions.

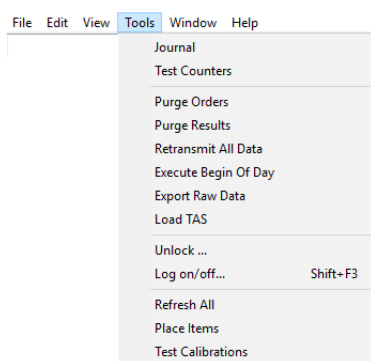
► To log on

1 Use one of the following methods to open the dialog box:

- Press Shift + F3.
- Double-click the user ID (A) in the status bar.



- Choose **Tools > Log on/off**, in any work area.



2 Type your user ID and password:



3 Click **Log On**.

The system activates the buttons on the navigation bar. You now have access to the system, depending on your user access level.



Complementary information

Your user access level determines the system features that are available to you. Contact your administrator if you do not have the privileges you require. The user privileges are defined in **Configuration > General > User access** and **Configuration > General > User level**.

What if?*My password is rejected*

Check whether you have typed your password and user ID correctly:

- Spaces are not allowed
- The password is case-sensitive, so make sure that you type it exactly as it is defined. For example, the following are different passwords: DOWNie, downie, DOWNIE.

*Another user is logged on*Ask the other user to log off, or click **Log Off** in the **User Log-On** dialog box. You can then log on.

Logging off and shutting down the system

For steps to be performed in connection with messages and troubleshooting, see

👁 *Putting the system into **Standby** on page E-11*👁 *Stopping and restarting the system on page E-12*

Logging off the system

Logging off leaves the system ready for the next user. When you log off, the system removes your user ID as the current user and replaces it with None.

► **To log off**

1 Use one of the following methods to open the **User Log On** dialog box:

- Double-click the user ID in the status bar.
- Choose **Tools > Log on/off**, in any work area.
- Press Shift + F3.

The **Log On/Off** dialog box is displayed:**2** Click **Log Off**.

Shutting down the system

If you perform a shutdown, the system waits for a convenient point in the processing, then closes all work areas and dialog boxes, closes down the operating system, and cuts the power.

► To shut down the system

- 1 Perform any necessary end-of-day tasks.

This step is not necessary if you shut down the system as part of a troubleshooting action.

- 2 Choose **File > Shut Down**.

Your are asked to confirm.

The control unit is switched off automatically.

- 3 Switch off the analyzer at the main switch.

- 4 Switch off the printer.

This step is only necessary if your printer has an On/Off switch.



Complementary information

- Once you initiate a shutdown, you cannot use the system for about 10 minutes.
 - After shutdown, certain maintenance procedures will be run automatically from a separate standby power supply.
 - The analyzer is designed to run continuously, so there is no need to switch it off every day, unless that is a requirement in your laboratory. The analyzer will switch off and re-initialize automatically every 7 days.
-

Shutting down the ISE module

The analyzer provides an ISE standby power supply unit. When the analyzer is switched off at the main switch, this standby power supply continues feeding the ISE module to perform continuous maintenance. This is necessary to prevent damage to the electrodes and the build up of blockages in the tubing.

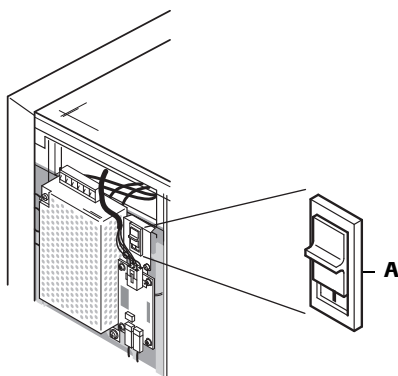
👁 *ISE Standby* on page F-11

NOTICE**Damage to the ISE module due to switching off the ISE standby power supply**

To prevent damage to the electrodes and the build up of blockages in the tubing, the ISE module performs continuous maintenance.

When the analyzer is switched off at the main switch, the standby power supply continues feeding the ISE module.

- Do not switch off the ISE standby power supply.
- If for some special reason, you need to switch off this power supply, make sure you use the Roche Diagnostic software and perform this task under the guidance of a Roche representative only.



A On/Off switch for the ISE standby power supply unit (left side of the analyzer).

Figure B-3

(Re)Starting and stopping a run

Start



The **Start** button serves to start or restart a run.

When the system is in the **Stopped**, **AutoService**, or **Operating** status, the text of the **Start** button changes to **Restart**.



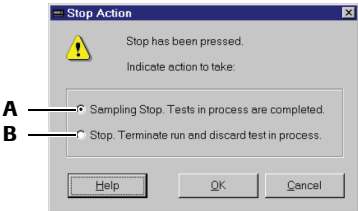
- Clicking **Restart** causes the system to perform a re-scheduling of all tasks. For example, clicking **Restart** after inserting a new rack into the system while in **Operating** status, causes the system to start pipetting on the sample rack that is positioned furthest to the left.
- In terms of system states, clicking **Start** changes the state from **Sleeping** to **Initializing** or from **Standby** to **Operating**.

Stop



The **Stop** button serves to interrupt sampling or to stop sampling once the current actions are finished.

When clicking **Stop**, the **Stop Action** dialog box is displayed, which offers the **Sampling Stop** and the **Stop** options:



- A** Stop pipetting samples but finish processing tests that are already in progress.
- B** Stop all system operations immediately. The system aborts all current activities. The system may need special attention before it can resume its normal operation.

Figure B-4



Complementary information

- In terms of system states, clicking **Stop** changes the state from **Operating** to **Standby** or from **Standby** to **Sleeping**.
- Tests that were interrupted are marked as blocked and displayed in the corresponding folders in the **Status** work area and in the **Worklist**.

Handling test materials

Loading samples

The following table gives information about loading samples, depending on whether the sample tubes have barcodes, and the information given by the barcode.

Barcode	Sample information	Comment
Yes	Yes	Load samples onto any rack defined for that tube type. Barcodes are read automatically.
Yes	No	Load samples onto any rack with the correct default sample type.
No	No	Use the Automatically Assign Rack Position function to automatically assign samples to rack positions. Then use the Sample Handling dialog box to confirm the position or change it. You can also use the Place Items function to manually assign samples to rack positions.

Table B-2



Use only tube and cup types that are defined on your system in **Configuration > Lab > Sample Tubes**.

**Incorrect results due to incorrect sample placement**

If you work without sample barcodes, the system assumes that the sample is placed in exactly the rack position as indicated in the order.

Placing a sample in a different position may lead to incorrect sample association.

- When working without sample barcodes, always make sure that you place the sample tube on the position indicated in the order.

► To load samples

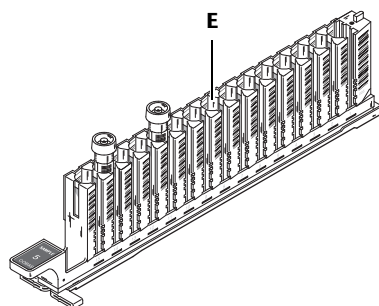
- 1 Load the samples in primary tubes, secondary tubes (A) or in cups (C) on adapters (D)



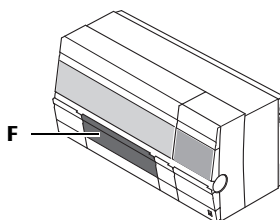
The tubes may have barcodes (B).

- 2 Place the sample tubes or cups into the rack (E).

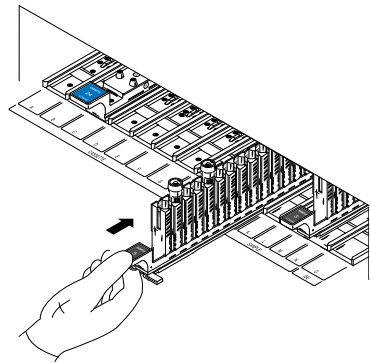
Ensure that barcodes, if used, face to the right when you insert the rack, and that the grid level corresponds with that defined for the tube type (**Configuration > Lab > Racks**).



- 3 Open the rack area access panel (F).



- 4 Insert the rack into one of the five slots (labeled J, K, L, M, or N) in the sample area.



- 5 Push the rack a short way (about 2 cm) into the slot until you feel the resistance of the stop pin.



Personal injury and infection due to contact with probe

In the case of a software error, it may be possible that the probe is lowered into the sample area even if there is no sample rack present.

- Do not place your hand or fingers inside the sample area.

- 6 Look at the rack status panel above the slot you are inserting the rack into. When the LED changes from red to green, push the rack all the way into the slot.

Red	Rack in use, do not remove.
Orange blinking	Rack has not been properly inserted.
Green	OK to use; processing complete.

Table B-3 Rack status panel (LEDs):

- 7 Close the rack access panel.
- 8 Use the worklist to check your sample placements.



Complementary information

- You must use only one tube type per rack.
- Racks must be defined for a particular tube type. To check this, use **Configuration > Lab > Racks**.
- If you use any other types of tubes than those defined on your system, you risk damaging the probes, which have to be replaced before you can continue.
- An orange blinking LED on the rack status display means the system could not identify the barcodes. Remove the rack from the analyzer, check the sample and rack barcodes and insert it again.
- The samples on the left most rack (rack in slot with lowest position letter) are measured first, followed by those on the rack next to it on the right.

Loading calibrators, controls, and diluents

You have to load the calibrators, controls, and diluents that the system needs to process the daily workload.

If calibrators and controls have barcodes, you can simply load them on board. The system identifies the locations of the calibrators and controls from the barcodes.

If you do not use barcodes, assign solutions to rack positions in **Configuration > Lab > Reserve Positions**. You can then print the assigned rack positions, or you can view them in the **Samples** tab in the **Status** work area.



Complementary information

- If you have a set of calibrator levels to load, you must have enough available positions on the rack for all the calibrator levels in the set. You must put multi-set calibrators in continuous positions on the same rack, starting with the highest concentration standard furthest away from you when you insert the rack.
 - Consider loading frequently used controls on a rack in slot I, in the cooled cassette area.
 - If barcodes for calibrators with several standards are used, label all standard cups with the same barcode
 - If you use any other types of tubes than those defined on your system, you risk damaging the probes, which may have to be replaced before you can continue.
-

Loading cassettes

Cassettes contain up to three reagents and are usually refrigerated, both before use, and on the analyzer.

If a cassette is reloaded on the analyzer (for example after storage in the fridge), in certain circumstances the cassette information may have been deleted from the database and the cassette can no longer be used. This is the case if one or more of the following conditions were met while the cassette was off board:

- The lot expiry date had passed
- Onboard stability had expired
- At least ten accepted calibration results exist for this cassette
- The cassette had not been used for 180 days



WARNING

Incorrect results due to use of same cassette on multiple systems

Each cassette has its own individual cassette number, which the system uses to identify it. Using a cassette already used on a different system may lead to incorrect results.

- Do not use a reagent cassette for different systems. Each cassette rack with its cassettes may be used on one individual system only.
 - If more than one system is used in the same lab, be sure to dedicate each cassette rack with its cassettes to one single, individual system (e.g. by color coding).
-



Personal injury due to contact with reagent

Contact with reagent may cause cauterization or poisoning.

- Follow standard laboratory practices.
 - Wear appropriate personal protective equipment.
 - If reagent is spilled, wipe it up immediately and apply a disinfectant.
 - If reagent comes into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant. Consult a physician.
-



Personal injury and infection due to contact with probe

In the case of a software error, it may be possible that the probe is lowered into the reagent area even if there is no sample rack present.

- Do not place your hand or fingers inside the reagent area.
-

What if?

I put the rack back in another slot

If you insert the rack into another slot, the system will identify the rack and the slot.

I cannot print the worklist or loadlist

Check whether the printer is connected (using either LPT or a USB port), switched on, and whether there is a supply of paper in the printer. Make sure you have the user access level for printing (**Configuration > General > User Level**).

If a new printer was installed for your system, ask your system administrator to check whether the appropriate Windows 10 printer driver is installed. (Other drivers will not work on Windows 10.) Ensure that the printer is also PCL 5 compliant.

I need to load multiple cassettes

You can load additional cassettes at any time.

The new cassette belongs to a different test lot

If you have used up the current lot, load a new cassette. The system will detect the difference in lot numbers and request a new calibration if necessary.

The system does not recognize the new cassette

Check whether the barcode is damaged, whether it is correctly positioned and whether the cassette is correctly inserted. If the problem persists, check the barcode scanner itself, making sure that the beam is not cut off in any way. Also, check whether you have loaded the cassette definition for the cassette in question.

On the **Cassettes** tab in the **Status** work area, the cassette is displayed in red, with the status **Unknown Fluid**.

The new cassette is past its expiry date

The system will detect this; the button turns yellow. Do not use expired cassettes.

Managing resources

Use the **Analyzer** tab in the **Status** work area to review the status of onboard resources. The color of each icon shows the status of the corresponding resource.

Checking resources

If you need to take some action to keep the system running efficiently, the background color and the picture on the **Status** button change: for example, if cuvettes are running low, you see the cuvette icon with a yellow background.

Background color	Take action
Red	Immediately
Yellow	Soon (when convenient)
Green or gray	None

Table B-4

If the analyzer icon is displayed, there are no resource problems.



Resource status

The **Status** button shows the resources that need to be replaced.

Status button	Resource	User action
	Cleaner	See <i>Replacing the cleaner</i> on page B-18.
	Cuvettes	See <i>Refilling the cuvette reservoir</i> on page B-20.
	Water	See <i>Refilling the external water reservoir</i> on page B-22.
	Cuvette waste	See <i>Replacing the cuvette waste box</i> on page B-24.
	Waste drain	See <i>Emptying the external waste reservoir</i> on page B-23.
	Temperature	See Replace ventilation filters on page D-46. See <i>Checking and replacing fuses</i> on page E-43.
	ISE solutions	Check the ISE tab in the Status work area for more information. See <i>Replace ISE solutions on the ISE rack</i> on page F-33. See <i>Replace bottles on ISE module</i> on page F-35.

Table B-5

Replacing the cleaner



If the cleaner is nearly used up, or if the cleaner temperature is between 36.6 °C (97.9 °F) and 37°C (98.6 °F) the system warns you by displaying the cleaner icon with a yellow background. The icon is displayed both on the navigation bar and in the **Analyzer** tab in the **Status** work area.

The system automatically detects that cleaner has been replaced and resets the icons to their normal states.

The replacement cleaner bottle must have a minimum volume of 250 mL.

If the system completely runs out of cleaner, or if the cleaner temperature exceeds 37.5 °C (99.5 °F), the icon turns red and the system stops.

Replacing the cleaner consists of the following steps:

1. Putting the analyzer into **Standby** state, if required.
 To put the analyzer into **Standby state** on page B-19
2. Replacing the cleaner bottle.
 To replace the cleaner bottle on page B-19



- The **Replace cleaner bottle** button and service action are only available if you work with analyzer hardware with serial number 620001 or higher.
- Roche recommends working with the **Replace cleaner bottle** button.
(If you prefer to use the service action **Replace cleaner bottle**, you can start it in the **Service** work area.)
- If you work with analyzer hardware with serial number lower than 620001, perform steps 4 through 9 in *To replace the cleaner bottle* on page B-19.

Duration 5 minutes

Tools and materials

- 1000 mL bottle of cleaner
- Paper tissues
- Protective gloves

Precautions Cleaner contains hydrogen chloride. Use standard laboratory safety procedures when using hydrogen chloride solution.



Skin inflammation or injury

Cleaner contains hydrogen chloride. Direct contact with cleaning solutions may cause skin irritation, inflammation, or burns.

- Wear appropriate protective equipment.



Collision with moving parts

Contact with moving parts may bend the probes or needles or damage some other component. If the system detects a collision, an alarm is raised, stopping the operation immediately

- Replace the cleaner bottle only while the system is in **Standby** status or while it is switched off.

Preconditions The analyzer must be in **Standby** state.

► **To put the analyzer into Standby state**

1 If the analyzer is in **Sleeping** state, click **Start**.

2 If the analyzer is in **Operating** state, click **Stop**.

- Choose the appropriate option:

Sampling Stop: Tests in progress are completed.

Stop: Processing is stopped immediately. (You will need to redefine all orders that are currently in progress.)

- Click **OK**.

► **To replace the cleaner bottle**

1 Make sure the analyzer is in **Standby** state.

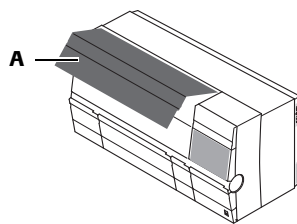
👁 See *To put the analyzer into Standby state* on page B-19

2 Choose **Status** button > **Analyzer** tab and click **Replace cleaner bottle** next to the cleaner status button.

The **Service Actions** dialog box is displayed.

3 Follow the instructions on the **Service Actions** dialog box.

4 Open the main cover (A), be sure to lift it as far as it will go.

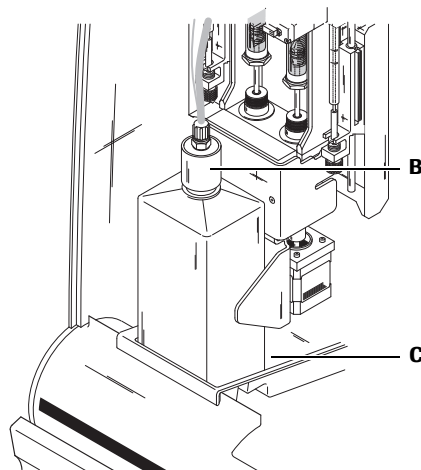


Personal injury due to self-closing main cover

If the main front cover is not opened completely it might close unintentionally by itself.

- Whenever you open the main front cover, be sure to open it as far as it will go.

5 Remove the cap (B) from the existing cleaner bottle and place the level detection sensor and tubing carefully to one side.



- 6 Discard the used cleaner bottle.
- 7 Remove the cap from the new cleaner bottle and place the bottle in the slot provided (C).
- 8 Reinsert the sensor and tubing. The cap (through which the tubing passes) should fit loosely on the top of the bottle.
- 9 Close the main cover.
- 10 On the service dialog box, click **Next**.
The robotic transfer is automatically initialized.
When the procedure is complete, the **Finish** button is displayed.
- 11 On the service dialog box, click **Finish**.

Refilling the cuvette reservoir



When the cuvette icon turns yellow (in **Status > Analyzer** or on the **Status** button) you must refill the cuvette reservoir before the system runs out of cuvettes. The number of cuvettes that are still available for use is displayed in the **Analyzer** tab in the **Status** work area. You can perform this task at any time while the system is running. When the icon is red, the system stops.

The cuvette reservoir can hold a maximum of 1400 cuvettes. Each pack contains approximately 1000 cuvettes.

Tools and materials

- New pack of cuvettes



WARNING

Incorrect results due to soiled cuvettes

Touching the surface of cuvettes may lead to soiling and affect result accuracy.

- Do not touch cuvettes.
- Make sure that the cuvette drawer slide is always clean and that you replace it properly when you have completed this task.



CAUTION

Personal injury due to contact with moving parts

- Do not place your hands or fingers inside the workstation In/Out module.



CAUTION

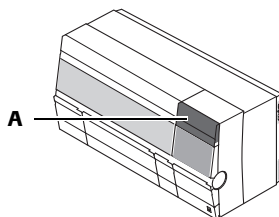
Personal injury due to contact with falling lid

A defective gas damper that may let drop the cuvette reservoir access panel when releasing the locking mechanism.

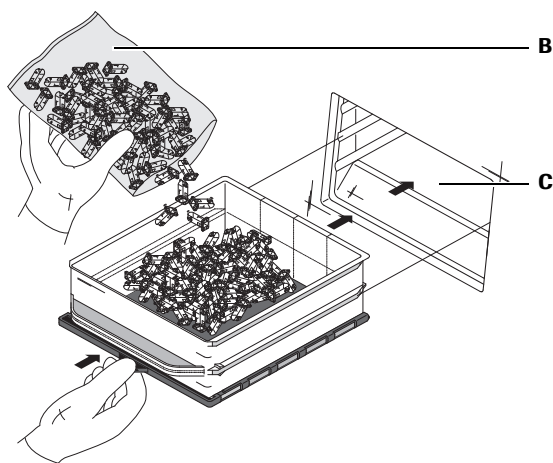
- Do not place your hands, fingers or head near the cuvette reservoir unless the cuvette reservoir access panel is securely opened or completely closed.

► **To refill the cuvette reservoir**

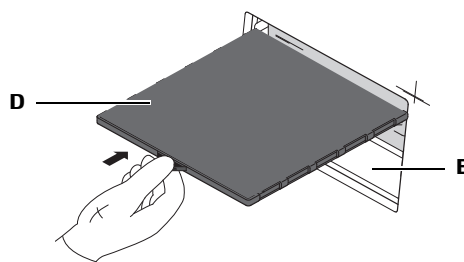
- 1 Open the cuvette reservoir access panel (A).



- 2 Remove the cuvette reservoir together with the covering slide.
Do not remove the slide from the reservoir.
- 3 Turn the cuvette reservoir upside down.
- 4 Open the cuvette pack (B) and, taking care not to touch the cuvettes, pour the cuvettes into the reservoir.



- 5 Reinsert the reservoir and the slide back into position (C).
- 6 Remove the slide, taking care not to spill any cuvettes.
- 7 Replace the slide (D) at the top of the reservoir (E).



The system automatically detects that the cuvette reservoir has been refilled.

Refilling the external water reservoir



You do not need to perform this task if your system is connected directly to a laboratory water supply. However, you will get a resource alert, if the laboratory water supply pressure drops below the required value.

When the water supply icon turns yellow (in **Status > Analyzer** or on the **Status** button), you must refill the external water reservoir. When the icon is red, the system stops.

The system cannot operate without a water supply, but you can disconnect it temporarily while the system runs from the internal water reservoir. When the internal water reservoir becomes empty, the system stops.

Location The external water reservoir is usually located underneath the analyzer. The reservoir is a 10 L white plastic reservoir, labeled "Reservoir".

Tools and materials

- 10 L of reagent grade, type 1 water
- 1000 mL beaker



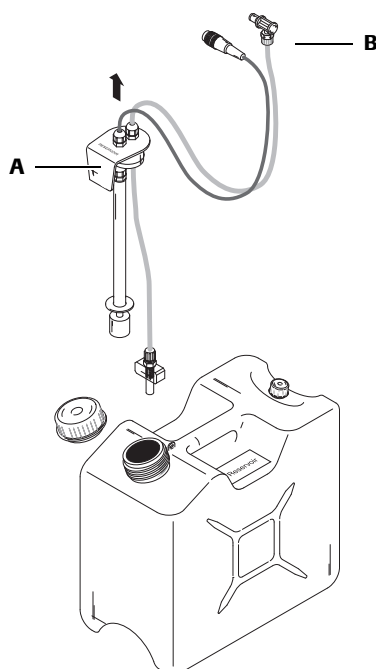
Incorrect results due to inappropriate water quality

Using water that does not meet the required purity standards can affect result accuracy and cause general maintenance problems.

- Always use water that meets the required purity standards.

► To refill the external water reservoir

- 1 Remove the tubing adapter (A) from the reservoir and put it temporarily into a clean empty 1000 mL beaker.



- 2 Refill the reservoir with reagent grade, type 1 water.

- 3 Insert the tubing adapter into the reservoir.



Complementary information

- The system can run off the internal water reservoir for a short time. If you perform this task promptly, you can avoid having the system shut down due to lack of water.
 - You do not have to disconnect the water reservoir (B) connectors from the rear of the analyzer.
-

Emptying the external waste reservoir



You do not need to perform this task if your system is connected directly to a laboratory waste system. However, you will get a resource alert, if the laboratory waste system becomes blocked.

If the waste drain icon turns yellow or red (in **Status > Analyzer** or on the **Status** button), you must empty the external waste reservoir.

Location The external waste reservoir is usually located underneath the analyzer. The reservoir is a 10 L yellow plastic container, labeled “Waste”.

Tools and materials

- Protective gloves
- Disinfectant
- 1000 mL beaker

Precautions Fluid waste is potentially infectious and must be handled using proper safety precautions.



WARNING

Infectious waste and potentially hazardous reagents

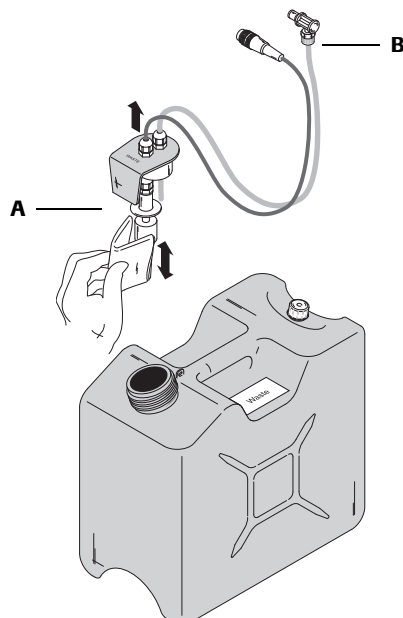
Contact with waste (liquid and/or solid) may result in infection. All materials and mechanical components associated with the waste systems are potentially biohazardous.

Direct contact with reagents, detergents, cleaning solutions, or other working solutions may cause skin irritation, inflammation, or burns.

- Wear appropriate protective equipment.
Take extra care when working with lab gloves, which can easily be pierced or cut, leading to infection.
 - If any biohazardous material is spilled, wipe it up immediately and apply a disinfectant.
 - If waste comes into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant. Consult a physician.
-

► **To empty the external waste reservoir**

- 1 Ensure that the system is in **Standby** or **Sleeping** state or that it is switched off.
- 2 Remove the tubing adapter (A) from the reservoir and place it temporarily in a clean 1000 mL beaker.



- 3 Dispose of the fluid waste according to the procedures established in your laboratory.
- 4 Rinse the waste reservoir with disinfectant and then water.
- 5 Replace the tubing adapter.
- 6 Restart the system, if necessary.



Complementary information

Step 2: You do not have to disconnect the electrical and waste connectors (B) from the rear of the analyzer.

Replacing the cuvette waste box



The cuvette waste box stores fluid waste from the ISE module, and up to 1000 used cuvettes.

When the yellow **Cuvette Waste Box** icon appears (in **Status > Analyzer** or on the **Status** button), you must replace the cuvette waste box as soon as possible, and confirm that you have done so. When the icon is red, the system stops.

The cuvette waste box can store up to 1000 cuvettes, and the **Cuvette Waste Box** icon turns yellow as soon as about 800 used cuvettes are in the box.



- Replace the cuvette waste box while the system is in **Standby**, and avoid replacing it while the box is being shaken.
- The filling status of the waste container is determined only by the cuvette counter. The waste volume is not monitored by the system. A regular check of the waste container level is recommended.

- Tools and materials*
- Protective gloves
 - Cuvette waste box

Precautions Cuvette waste is potentially infectious and must be handled using proper safety precautions.



WARNING

Infectious waste and potentially hazardous reagents

Contact with waste (liquid and/or solid) may result in infection. All materials and mechanical components associated with the waste systems are potentially biohazardous.

Direct contact with reagents, detergents, cleaning solutions, or other working solutions may cause skin irritation, inflammation, or burns.

- Wear appropriate protective equipment.
Take extra care when working with lab gloves, which can easily be pierced or cut, leading to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply a disinfectant.
- If waste comes into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant. Consult a physician.
- Never tilt the waste box. If you do so, there is a risk of spilling of contaminated waste if the waste box is not properly closed.
- Store the removed waste box in an autoclaves plastic bag or dispose the waste box immediately.
- Dispose of the old cuvette waste box and its contents according to your local regulations for the disposal of hazardous waste.



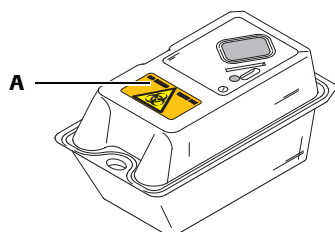
CAUTION

Personal injury due to contact with moving parts

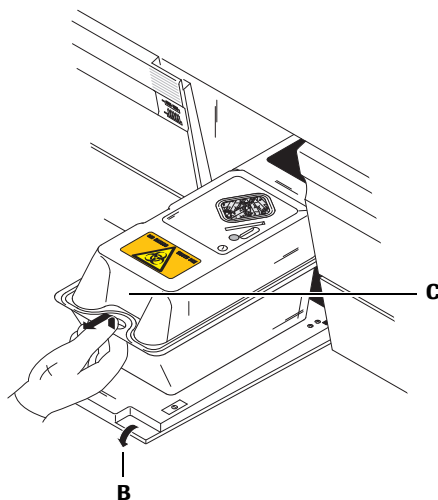
- Do not place your hands or fingers inside the workstation In/Out module.

► To replace the cuvette waste box

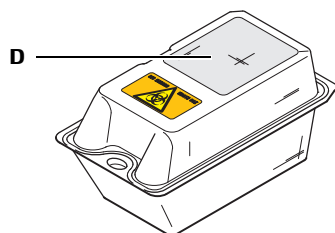
- 1 Wait until the system is in **Standby**.
- 2 Construct the new cuvette waste box according to the instructions inside the cuvette waste access panel (B). The cuvette waste box is supplied with a yellow biohazard sticker already in place (A).



- 3 Open the cuvette waste access panel (B).



- 4 Remove the full cuvette waste box (C), taking care not to spill any of the contents.
- 5 Put a rectangular sticker (D) over the holes in the top of the waste box.



- 6 Insert the new waste box, taking care to ensure that the lip around the middle of the box fits into the guide rails.
- 7 Close the cuvette waste access panel.
The system asks you whether the cuvette waste box is empty.
- 8 Click **Yes**, if the new box is empty.
- 9 Dispose of the old waste box and its contents according to your local regulations for the disposal of hazardous waste.

Checking due service actions

Service actions are tasks that keep the analyzer running properly. In some service actions all the steps are performed automatically; others have some steps that you must perform manually.

If the button color is...	Do this...
Grey	No action is required.
Yellow	Perform the due service action as soon as possible.
Red	Service action Database update is overdue. Take immediate action! As a first step, back up the database immediately. Then perform the due service action(s).

Table B-6



For details on service actions, see the individual service action.

► To perform due service actions

Check the **Service** button on the navigation bar. If its background is yellow:



- 1 Click **Service** on the navigation bar.
- 2 Select one or more service actions from the list.
- 3 Click **Perform**.
- 4 Perform the service actions according to the on-screen instructions.
Click **Help** for full details.



Should you have chosen to not perform the **Backup database** service action automatically at BOD (**Service > View Counters > Service Intervals**), then if the **Backup database** service action is due, perform it at the end of the day. This service action may take about 5 minutes.



Processing stop due to lack of disk space

The accumulated data gradually fills the available space on the hard disk. When there is no space left the system will be blocked.

- Perform database backup in regular intervals.

Checking the Memo Pad

The Memo Pad may contain messages from other users. You recognize the urgency of a message by the color of the icon on the **Memo Pad** navigation button:

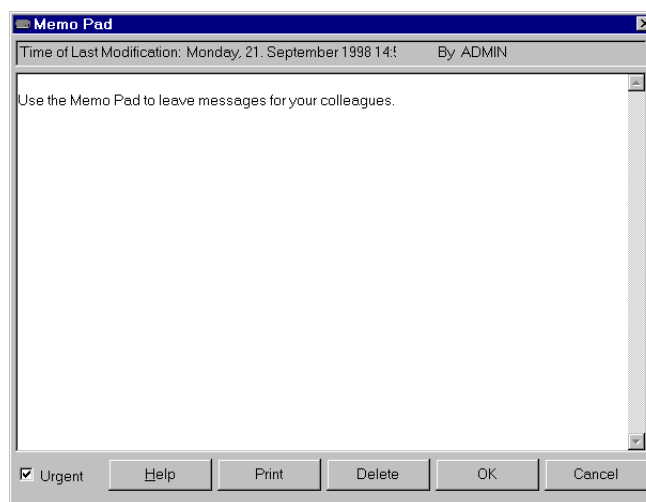
- For urgent messages, the icon text is displayed in white font on red background.
- For normal messages, the icon text is displayed in white font on blue background.
- If there are no messages the icon is displayed all white.



► To read the Memo Pad

- 1 Click **Memo Pad** on the navigation bar.

The **Memo Pad** dialog box is displayed.



► To leave a message for another user

- 1 Click **Memo Pad** on the navigation bar.

The **Memo Pad** dialog box is displayed.

- 2 Type your message.
- 3 Select the **Urgent** check box if the message is urgent.
- 4 Click **OK**.



Complementary information

The **Delete** button deletes all text on the dialog box. To delete selected text, use the **Delete** key on your keyboard.

Printing reports

The table below shows the reports that are available in each work area.

Report	Available in work area	Choose	See page
Begin of Day (BOD)	Status, Orders, Results, Service, and Configuration	File > Print Report > Begin of Day	 page B-30
Final Report	Status, Orders, Results, and Configuration	File > Print Report > Final Report	 page B-31  page B-32
Journal	Status, Orders, Results, and Configuration	Tools > Journal, then click Print	 page B-34
Loadlist	Status, Orders, Results and Configuration	File > Print Report > Loadlist	 page B-32
Missing & Blocked	Status, Orders, Results and Configuration	File > Print Report > Missing & Blocked	 page B-32
Quality Control	Results > Quality Control	File > Print QC Report	 page B-34
Results	Status, Orders, Results and Configuration	File > Print Report > Results	 page B-33
Service Counters	Service	File > Print Report > Service Counters	 page B-36
Service Intervals	Service	File > Print Report > Service Intervals	 page B-36
Service Notes	Service	File > Print Report > Service Notes	 page B-37
System Counters	Service	File > Print Report > System Counters	 page B-37
Test Counters	Status, Orders, Results and Configuration	Tools > Test Counters, then click Print	 page B-37
Worklist	Status, Orders, Results and Configuration	File > Print Report > Worklist	 page B-34

Table B-7

The reports are described in the following sections.



Complementary information

Your printing rights are defined in **Configuration > General > User Level**.

Printing the Begin of Day report

The **Begin of Day** report serves as a check list during daily start-up (see *Daily start-up* on page A-72). The report provides information on events that took place while the **Begin of Day** actions were performed, and it also lists actions that were not performed successfully and therefore may require user intervention.

The **Begin of Day** report is structured in the following way (only those headings are listed in the report for which there are entries):

- **Following Begin of Day actions were not completed:**

Service actions that are programmed to be performed automatically at BOD, but were not completed successfully.

- **Following service actions need to be performed:**

Service actions that are due. An Elapsed value of 100% means that the action is due now, a value smaller than 100% means it will be due soon, a value greater than 100% means that the action has been due for some time.

This list includes all service actions that are due.

- **Test with pending calibration or control requests:**

- **Tests with postponed calibration:**

- **Required Calibrators, Controls, Diluents, and ISE Solutions:**

The required calibrators, controls, diluents, and ISE solutions necessary to run the pending calibrator and control requests together with their status (for example **Blocked**) are displayed.

- **Following cassettes need to be handled:**

This information is identical with that displayed in the **Cassettes** group on the **Missing & Blocked** tab of the **Status** work area.

► To print a Begin of Day report

- 1 Choose **File > Print Report > Begin of Day** from the menu bar.
- 2 The **Print** dialog box is displayed.
- 3 Click **OK**.



Complementary information

Place all calibrators on the system before you print the BOD report. (The system updates the calibrator status of onboard calibrators only.)

Printing the Final Report

The **Final Report** lists order details and accepted test results for a single sample.

The header information of the **Final Report** is defined in **Configuration > Processing > Report Layout**. To specify the reporting order for tests, use **Configuration > Processing > Report Layout**, and click **Print Sequence**.

System-specific flags are not included in the report.

Test-specific ranges and limits shown on the report

- Reference ranges are given in numbers.
- For quantitative tests, results outside the defined reference range are presented the following way:
 - **H** (high) stands for **>RR** and **>Critical Range**
 - **L** (low) stands for **<RR** and **<Critical Range**
- For qualitative tests that depend on the direction of the reaction, the following abbreviation is used:
 - POS: The value is above the cutoff limit

(The cutoff limit is defined in Configuration > Tests > Evaluation.)

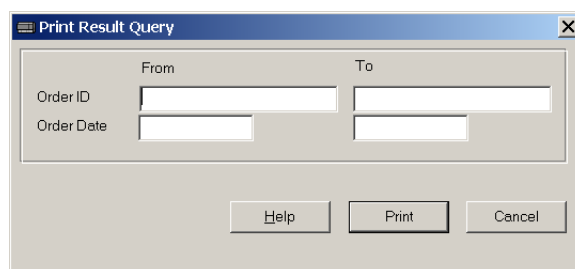
Calculated results (ratio)

You can print a calculated result together with the tests these results are based on. In **Configuration > Processing > Report Layout > Print Seq.**, you can define where in the report the calculated results should appear.

► To print a Final Report

- 1 Click **Status**, **Orders**, **Results**, or **Configuration** on the navigation bar.
- 2 Choose **File > Print Report > Final Report** from the menu bar.

The **Print Result Query** dialog box is displayed



The image shows a 'Print Result Query' dialog box with a title bar containing a menu icon and a close button. The dialog has two columns of input fields. The first column is labeled 'From' and contains two fields: 'Order ID' and 'Order Date'. The second column is labeled 'To' and also contains two fields: 'Order ID' and 'Order Date'. At the bottom of the dialog, there are three buttons: 'Help', 'Print', and 'Cancel'.

- 3 Type the values to define your selection.

If you do not provide any selection criteria, all available results will be included in the report.

- 4 Click **Print** to generate the report and print it.

Printing the Final Report automatically

You can choose to have the **Final Report** printed automatically, without any user intervention.



► To have a report printed automatically

- 1 Click **Configuration** on the navigation bar.
- 2 Double-click **Database** in the **System** group.
- 3 Click the **Automatic Actions** tab.
- 4 Select **Final Report** from the **Automatic Printouts** list.
- 5 Click OK.
- 6 The **Final Report** will be printed as soon as:
 - All tests of the order are complete.
 - All results associated with the order are accepted.

Printing the Loadlist

The loadlist contains all orders known to the system. They are listed by their rack positions in ascending order, starting with the lowest rack position of the rack with the lowest rack number. The list shows all rack positions to which samples were assigned, either automatically by barcode reading or manually (see *Assigning samples to racks* on page B-70).

If you work with barcodes and without a host system, or if you work without barcodes, use this list to load the samples on the correct position on the sample racks.

► To print the load list

- 1 Click either **Status**, **Orders**, **Results**, or **Configuration** on the navigation bar.
- 2 Choose **File > Print Report > Loadlist** from the menu bar.

The **Print** dialog box is displayed.
- 3 Click OK.

Printing the Missing & Blocked report

The **Missing & Blocked** report allows you to produce a printout of the information stored on the **Missing & Blocked** tab in the **Status** work area.

The entries are listed under the headings

- **Cassettes**
- **Calibrators, Controls, ISE**
- **Samples**

► **To print a Missing & Blocked report**

- 1 Click either **Status**, **Orders**, **Results**, or **Configuration** on the navigation bar.
 - 2 Choose **File > Print Report > Missing & Blocked** from the menu bar.
The **Print** dialog box is displayed.
 - 3 Click **OK**.
- 👁 **Missing & Blocked tab** on page B-44

Printing results

There are two ways of printing results:

1. You can print a cumulative results report.
 - The Results report lists every result (accepted and unaccepted) on the system.
 - You can specify ranges for order IDs and order dates.
 - The results are listed by order ID in ascending order.
 - For each order creation date, a new page is started.
2. You can print the results of a single order.



► **To print the Results report**

- 1 Click **Results** on the navigation bar.
- 2 Choose **File > Print Report > Results** from the menu bar.
The **Print Result Query** dialog box is displayed.

- 3 Type the values to define your selection.
If you do not provide any selection criteria, all available results will be included in the report.
- 4 Click **Print** to generate the report and print it.



► **To print the Results of a single order**

- 1 Click **Results** on the navigation bar.
- 2 Right-click the order ID and choose **Print Preview** from the context menu.
- 3 Click **Print** in the **Report Preview** dialog box.

Printing the Worklist

The worklist contains all orders known to the system. They are listed by their order IDs in ascending order. It shows the orders that require completion, the tests ordered for each sample, and the status of each test.

If you work with barcodes and without a host system, or if you work without barcodes, use this list to get an overview on the orders and tests that need processing.

► To print the worklist

- 1 Click either **Status**, **Orders**, **Results**, or **Configuration** on the navigation bar.
- 2 Choose **File > Print Report > Worklist** from the menu bar.
- 3 The **Print** dialog box is displayed.
- 4 Click **OK**.

Printing the journal

The journal lists all results in chronological order of their associated test start time. Use this information to review the execution sequence of tests run on the system.



The flag listed in the Journal for a specific test is not necessarily the final flag for that test. The flag, if any, in the Journal is a temporary flag that was active when the pipetting took place. This flag is often overwritten or removed from the final result. To review flags for a result, see the **Sample**, **Calibration**, or **Quality Control** tabs in the **Results** work area.

► To print the journal

- 1 Click either **Status**, **Orders**, **Results**, **Configuration**, or **Service** on the navigation bar.
- 2 Choose **Tools > Journal** from the menu bar.
The **Journal** dialog box is displayed.
- 3 Select the items you wish to print, and click **Print**.

Printing Quality Control reports

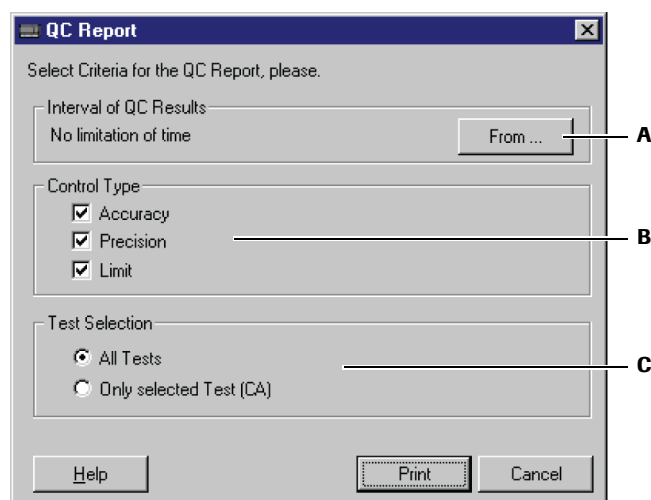
Use the **Quality Control** reports to review the quality control history of individual tests. You can select what results you want to include in the reports.

Content and layout of the report depend on the view type you selected in the folders list of the **Quality Control** tab.

- 👁 Selected features of a **Quality Control report** on page B-35
- 👁 To print a **Quality Control report from the By Test view** on page B-35
- 👁 To print a **Quality Control report from the Control view** on page B-36

Selected features of a **Quality Control** report

- A **Quality Control** report consists of several separate reports, one for each test and one for each control type.
- Each single report contains for one test the results of up to three controls of the same control type. Should there be more than three controls for the same control type, the report is split. The first report contains the results of the first three controls, the second report those of the next three, or the remaining controls.
- The page numbering in the printed **Quality Control** report refers to the single reports.
- As part of the printing process, you can specify the data you want to include in the report. Choose **File > Print QC Report** from the menu bar, and the **QC Report** dialog box is displayed. The following figure shows the **QC Report** dialog box with the **By Test** view selected:



- A** Set the period for which the QC report should be generated.
- B** Select the control types for which a report should be generated. These settings will remain active when this dialog is opened the next time. If you do not select any type, no report will be generated and printed. If multiple control types are selected, QC is printed more than once.
- C** Choose whether a report should be generated for the controls of the selected test only or of all tests. If you select **Only Selected Test**, the results of all controls of the test will be printed, irrespective of what level you selected on the **By Test** list of the **Quality Control** tab. The **Only Selected Test** option is only available while a test is selected in the folders list of the **Quality Control** tab.

Figure B-5



► To print a Quality Control report from the **By Test** view

- 1 Click **Results** on the navigation bar.
- 2 Click the **Quality Control** tab.
- 3 Click the column header to display the **By Test** View.
- 4 Select a test in the **By Test** column, if you want to print a report for a certain test.
- 5 Choose **File > Print QC Report** from the menu bar.
The **QC Report** dialog box is displayed.
- 6 Use **From** to set the period for which the QC report should be generated.
- 7 Select the control types for which a report should be generated.

- 8 Choose whether a report should be generated for the controls of the selected test only or of all tests.

- 9 Click **Print**.

The **Progress of QC Report** dialog box is displayed.

You can click **Cancel** to stop the report generation.



Complementary information

- The period you set for which the QC report should be generated, is valid for generating the report only. It does not affect the filter settings set in the **Results** work area.
 - Step 5: To simply print the statistics of the selected test, click **Statistics**, and then click **Print** in the **Results QC Statistics** dialog box.
-

► To print a Quality Control report from the Control view

- 1 Click the column header to display the **By Control** view, and proceed as when printing from the **By Test** view.

Printing service counters

The service notes report contains the information of the **Service Counters** dialog box (**Service > View > Counters**).



► To print the service counters

- 1 Click **Service** on the navigation bar.
- 2 Choose **File > Print Report > Service Counters** from the menu bar.

The **Print** dialog box is displayed.

- 3 Click **OK**.

👁 **Service Counters dialog box** on page D-14

Printing service intervals

The service intervals report contains the information of the **Service Intervals** tab on the **Service Counters** dialog box (**Service > View > Counters**).



► To print the service intervals

- 1 Click **Service** on the navigation bar.
- 2 Choose **File > Print Report > Service Counters** from the menu bar.

The **Print** dialog box is displayed.

- 3 Click **OK**.

👁 **Service Intervals tab** on page D-15

Printing service notes

The service notes report contains the information of the **Service Notes** dialog box (**Service > View > Notes**).

Added notes to service notes are printed immediately after the note they were added to. The original note is marked with the ¶ symbol.



► To print the service notes

- 1 Click **Service** on the navigation bar.
- 2 Choose **File > Print Report > Service Notes** from the menu bar.

The **Print** dialog box is displayed.

- 3 Click **OK**.

👁 *Service notes* on page D-11

Printing system counters

The system counters report contains the information of the **System Counters** tab on the **Service Counters** dialog box (**Service > View > Counters**).



► To print the system counters

- 1 Click **Service** on the navigation bar.
- 2 Choose **File > Print Report > System Counters** from the menu bar.

The **Print** dialog box is displayed.

- 3 Click **OK**.

👁 *System Counters tab* on page D-16

Printing test counters

The service notes report contains the information of the **Test Counters** dialog box (**Tools > Test Counters**).

► To print the test counters

- 1 Click either **Status**, **Orders**, **Results**, or **Configuration** on the navigation bar.
- 2 Choose **Tools > Test Counters** from the menu bar.

The **Test Counters** dialog box is displayed.

- 3 Use **From** to set the period for which the test counters should be printed.
- 4 Click **Print**.

The **Print** dialog box is displayed.

- 5 Click **OK**.

👁 *Test Counters dialog box* on page D-17

Purging and deleting information and items

Purging Eliminating unneeded information systematically.

Deleting Erasing orders and results without preconditions.

NOTICE

Database inconsistency due to deleting data from the D disk drive or from the Roche directory on the C drive

Deleting or modifying data on the D drive or the Roche directory on the C drive may lead to database inconsistencies.

- Do not delete or modify data from the D disk drive or from the Roche directory on the C drive.

Deleting raw data

Raw data are the numerical values of the physical measurements made by one of the measuring modules. Since each result comprises many measurements, the amount of raw data can become very large, very quickly. To prevent this from happening, you can choose either of two options:

- **Delete Raw Data after accepting results.**
- **Delete Raw Data after n days.**



► To delete raw data after accepting results

- 1 Click **Configuration** on the navigation bar.
- 2 Double-click **Database** in the **System** group.
- 3 Click the **Automatic Actions** tab.
- 4 Select the **Delete Raw Data after accepting results** check box.
- 5 Click **OK**.



► To automatically delete raw data after a certain period of time

- 1 Click **Configuration** on the navigation bar.
- 2 Double-click **Database** in the **System** group.
- 3 Click the **Automatic Actions** tab.
- 4 Select the **Delete Raw Data after** check box.
- 5 In the **Delete Raw Data after** box, type the number of days you want raw data to remain on the system.
- 6 Click **OK**.



Complementary information

- Type 0 (zero) to delete at the next **Begin of Day** all of today's raw data, that is all raw data generated between the time of the last and the next **Begin of Day** time.
- Type 1 to delete at **Begin of Day** all raw data that were generated more than 24 hours before **Begin of Day** time.

Purging and deleting orders

You can purge orders manually at any time, or delete them automatically at BOD. The main reason for purging orders is to free the order IDs for re-use.

Preconditions You can only purge an order when the system is in **Standby** or **Sleeping** state.

Orders are purged if "CANT":

- Order complete (C)
- Result accepted (A)
- Sample not on board (N)
- Result transmitted to the host, if you work with a host system (T)

👁 *To purge orders manually on page B-83*

👁 *To delete orders automatically at BOD on page B-83*

👁 *To delete a single order on page B-84*

Purging results

The analyzer is not designed to store safely large quantities of results on the system. As part of data management, you should periodically purge results manually. At least every 2 months is recommended.

The system should be in the **Standby** or **Sleeping** state when purging results.

When purging results, the following information is deleted:

- Results
- Calculated results that were derived from purgeable results
- Test orders
- Order IDs

If you archive the results in the results work area you need to purge the results regularly.



Complementary information

- Before you purge results, you should archive your current calibration, control, and sample results (**File > Archive Results**).
 - To delete a sample, use **Results > Sample**. Right-click the order ID, and choose **Delete**. In the **Confirm Delete** dialog box, click **Yes**.
-

👁 For details and procedures on purging results, see

Purging results on page B-103

Preconditions for purging results on page B-103

To purge results on page B-104

To delete a single result on page B-104

Archiving system information

To select what data you want to archive, click Configuration on the navigation bar and choose **File > Archive Definitions**.

Archiving the System Parameters

- What is stored?*
- General definitions
 - Database definitions
 - Processing definitions
 - Result Handling definitions

- What is not stored?*
- ISE definitions (**General > ISE**)
 - Lab definitions

Archiving the Complete Test Definitions

- What is stored?*
- Test definitions, including user-defined test definitions
 - Calibrator definitions
 - Control definitions
 - Diluent definitions
 - Cassette definitions
 - Cleaner definitions (only if the selected test is entered in the extra wash cycle table)

- What is not stored?*
- Profiles definitions
 - Calculated results (Ratios) definitions
 - The following calibrator definitions: lot number, expiry date, and values
 - The following control definitions: lot number, expiry date, and values

Status

Review the status of your analyzer



This chapter describes the **Status** work area and how to use it. It shows you how to review the status of samples, cassettes, tests, system resources, and the ISE module.

In this chapter

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About Status

The system continually monitors its status and displays this information in the **Status** work area. Much of the information is presented graphically, using the following color coding:

Color	Meaning
Green	OK.
Yellow	Caution, you need to do something soon.
Red	Critical, the system has stopped, and you must take corrective action immediately.

Table B-8

The exact meaning of each color depends on the tab.

System-wide alerts

If the system cannot function due to a resource shortage, an icon is displayed on the **Status** button on the navigation bar. The icon identifies the resource shortage; for example, when the cuvette supply is low, a cuvette icon is displayed. The background color of the icon shows whether the alert is a warning (yellow background) or a critical situation (red background). The **Analyzer** tab in the **Status** work area shows the status of all the resources and system temperatures.

Additional information relating to the ISE module is displayed in the **ISE** tab.

 *Checking resources on page B-17*

Missing and blocked

The system can perform a test only if all the items required for that test are loaded and all the items are current. The system automatically identifies any missing and blocked items:

Item status	Meaning
Not on Board	The item is not on board.
Blocked	The test (calibrator, control or sample) cannot run because a prerequisite has not been satisfied. For example, the system cannot run a test if the test cassette is not on board. The test is labeled Blocked until you load the required cassette.

Table B-9

Missing and blocked items are listed on the **Missing & Blocked** tab in the **Status** work area. By reviewing this information regularly, you can quickly identify the steps you need to take to maintain the throughput of tests on your system.

Status work area overview



To access the **Status** work area, click the **Status** button on the navigation bar, choose Window > **Status**, or click F7.

The **Status** work area has six tabs, each of which shows the state of a particular part of the system. The tabs in the **Status** work area are as follows:

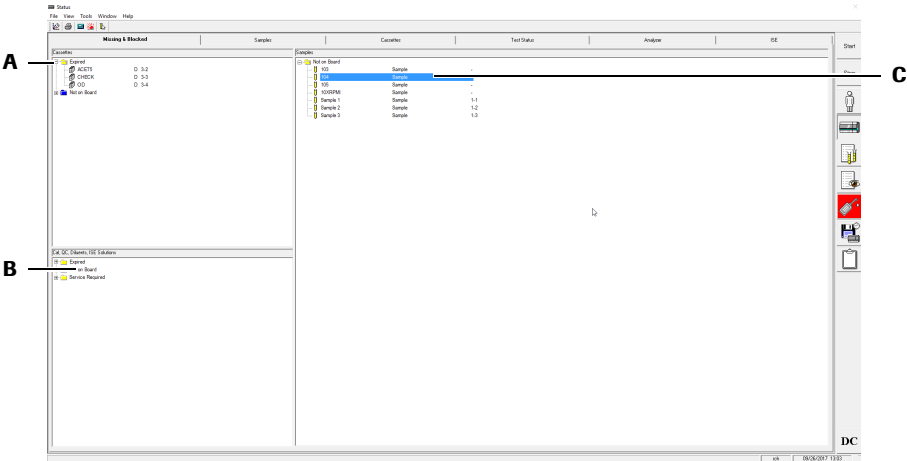
Tab	Function
Missing & Blocked	This tab gives information about: • Cassettes • Calibration, QC, diluents, ISE solutions • Samples When there is a problem with one of the solutions, for example, if a cassette is empty, or if an onboard sample has no associated order, the relevant information is displayed in this tab.
Samples	This tab gives a graphical representation of the sample racks on the system. The tube positions are color-coded so that you can easily check the status of the samples.
Cassettes	This tab gives a graphical representation of the cassette racks on the system. The cassette positions are color-coded so that you can easily check the status of the cassettes.
Test Status	This tab allows you to display cassette, calibration, quality control, and diluent information for a selected test.
Analyzer	This tab gives an overview of the state of the system. Bar graph indicators tell you about the state of sample processing, and color-coded icons tell you about system resources such as cuvettes and water supply, or the analyzer temperature.
ISE	This tab gives an overview of the state of the ISE module. Graphical representations of the electrodes, solutions on the ISE module and solutions on the ISE rack are color-coded so that you can quickly locate any blockages.

Table B-10

Missing & Blocked tab



Use the **Missing & Blocked** tab to see which samples, calibrations, or controls cannot be processed and why. For example, a sample may be listed as blocked because the cassette required to run a test on that sample is not on board.



- A Click to expand or contract the folder.
- B Folder name tells you why the item is blocked.
- C Double-click any line to display detail for that item.

Figure B-6



Complementary information

- The **Missing & Blocked** tab does not show items that are correctly loaded and ready to run, or items for which tests have already been run.
- To display the details for an item, do one of the following:
 - Double-click the item.
 - Right-click the item, then choose **Item Detail**.
 - Select an item and press Space.
- Press F1 to display Help for this tab.
- STAT orders are shown in bold.

Folders on the Missing & Blocked tab

The following table shows the meaning and action required for each folder on the **Missing & Blocked** tab.

Folder	Meaning	User action
Blocked	The test is blocked because an item is missing or not correctly defined. A test may be blocked because, for example, there is no relevant calibration.	Find the missing items (in other folders) and correct the problem. Details about the calibration for a test can be found in the Test Status tab.
Clot detected	A clot was detected in a probe or in the tubing.	Replace the affected items.
Empty	The item is on board, but it is empty.	Replace affected items.
Expired	The items listed have passed their expiry date. (For cassettes and diluents.)	Replace expired items.
Missing Information	The item is on board, but it is not correctly defined in the system. (For cassettes, diluents and cleaner.)	Use the Configuration work area to load the definition.
Not enough for worklist	The item is loaded, but there is not enough of it to run the tests in the current worklist. (For cassettes only.)	Replace or add more of the missing item. (For example, add additional cassettes.)
Not On Board	The item is not on board.	Load the missing item. For cleaner cassette and diluent tubes, the Not on Board status is generated only if there is actually an order for the test that needs the cleaner or the diluents.
Without Orders	The sample is loaded into the analyzer, but there is no order associated with the sample. (For samples only.)	Create an order for the sample or remove the sample.

Table B-11



Complementary information

- If a category has no entries, the corresponding folder is not listed.
- A sample on the system without an order is listed as **Without Order** on the **Missing & Blocked** tab.
- As long as the system is in **Standby**, the status of blocked cassettes remains **Blocked**, even if new cassettes were inserted. As soon as the system goes into **Operating** state, the status of the cassette is updated.

Samples tab



Use the **Samples** tab to review the status and positions of samples, calibrators, controls, and diluents loaded in slots I through N. You can display details for individual tube positions or for a whole rack.

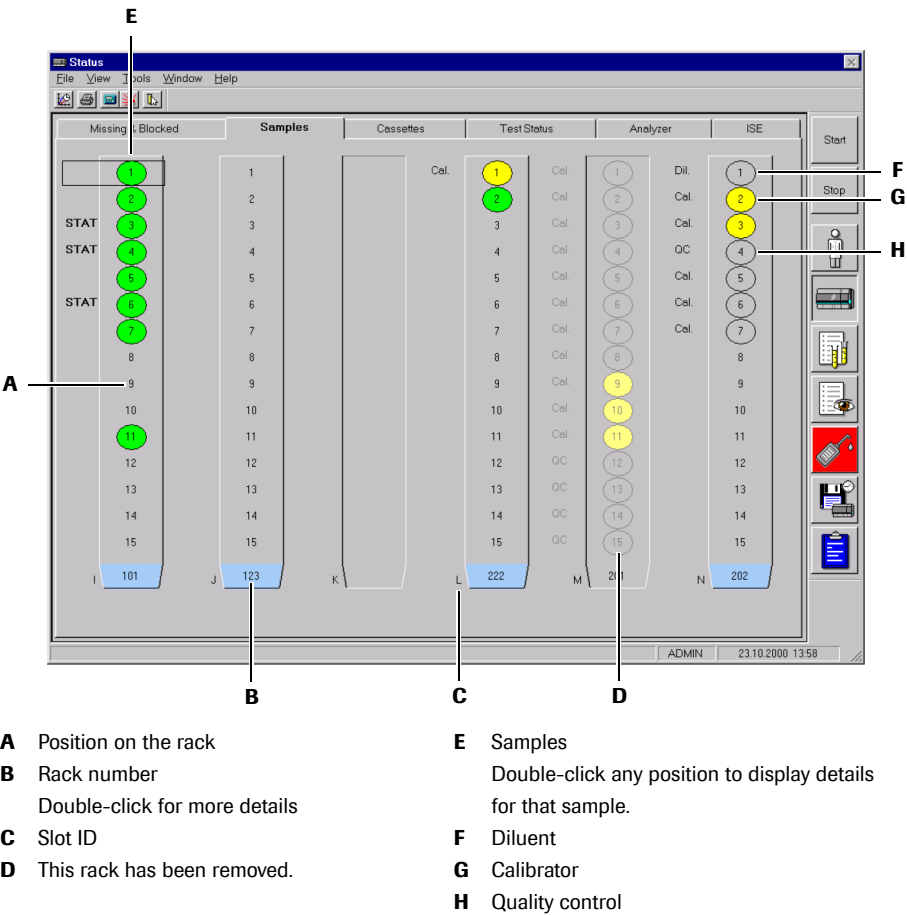


Figure B-7

Complementary information

- The color of the sample rack position tells you the status of the sample, calibrator, or control
 - *Color coding on sample rack positions on page B-47*
- To display the details for a rack position, do one of the following:
 - Double-click the rack position.
 - Right-click the rack position, then choose **Item Detail**.
 - Select a rack position and press Space (or press Enter to display details for the rack).
- To display the complete rack details, move the cursor over the rack number. When a small black arrow is displayed double click the rack number.
- Racks that have been removed from the system are shown as “grayed-out” (H).
 - *Loading samples on page B-12*
 - *Loading calibrators, controls, and diluents on page B-15*
- Press F1 to display Help for this tab.

Color coding on sample rack positions

The sample rack positions are color-coded. The following table shows the meaning of each of the colors.

Color	Meaning
None	Empty position (no cup or tube).
Gray	Ready.
Green	All tests have been calculated (but not necessarily validated).
Yellow	Cup or tube is blocked, because a reagent or diluent is missing.
Red	- Cup or tube is empty. - Sample is not known. - Position conflict between two samples. - No sample on this position (adapter is present, but not the cup). - Barcode cannot be read. - Clot detected.

Table B-12

Cassettes tab



Use the **Cassettes** tab to review the status of each cassette on board.



Figure B-8



Complementary information

- The slot IDs are identified by the letters A through H.
- Cassette barcodes are read automatically when you load them.
- To display the details for a cassette, do one of the following:
Double-click the cassette.
Right-click the cassette, then choose Item Detail.
Select the cassette and press Space.
- Use the same techniques to display details for the whole rack, but click the rack number.
- Racks that have been removed from the system are shown as “grayed-out” racks in the **Cassettes** tab.
 *Loading cassettes* on page B-15
- Press F1 to display Help for this tab.

Color coding on the Cassettes tab

The cassette graphics are color-coded. The following table shows the meaning of each of the colors and the action that should be taken by the user.

Color	Meaning	User action
Green	• Ready	None, the cassette is ready for use.
	• In Use	None.
Yellow	• Cal. expired	Replace the cassette. See <i>Loading cassettes</i> on page B-15.
	• Near Expiry or Expired	Replace the cassette. See <i>Loading cassettes</i> on page B-15.
	• Not enough for worklist or Cassette Tests Low	The number of ordered tests is bigger than the number of tests left in the cassette. The warning threshold defined for the cassette has been reached (Configuration > Cassettes > ID). Load additional cassettes. See <i>Loading cassettes</i> on page B-15.
Red	• Empty	Replace the cassette. See <i>Loading cassettes</i> on page B-15.
	• Unknown fluid (text shown on Details only)	Definition not loaded. See <i>About cassette definitions</i> on page G-33
	• Conflict with position... (text shown on Details only)	Conflict of positions between cassettes. Remove and re-insert the rack. See <i>Rack system</i> on page A-26.

Table B-13



Complementary information

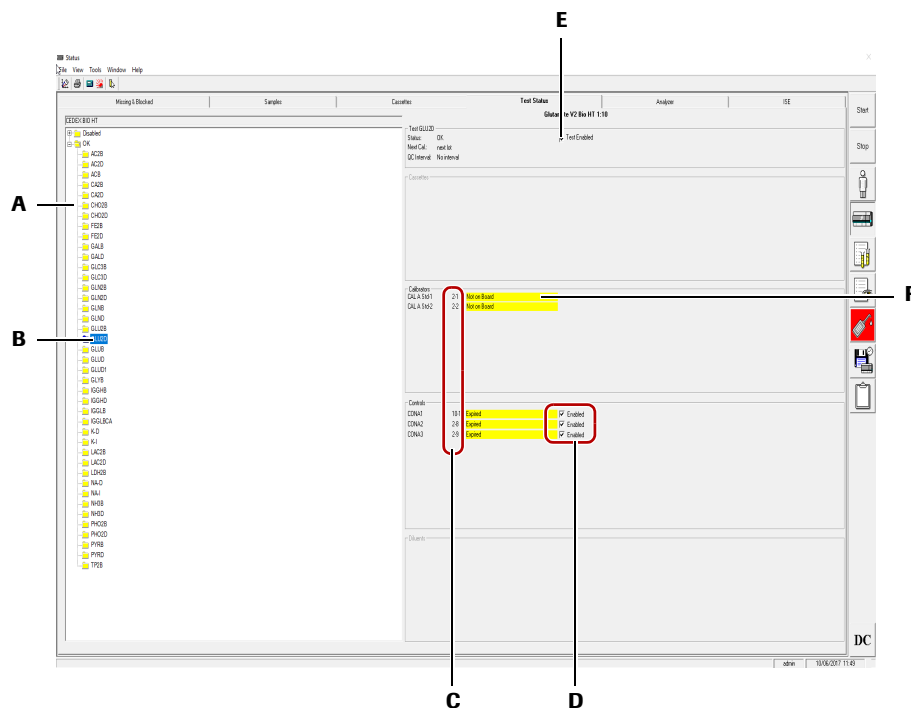
Cassettes whose barcode cannot be read are not displayed on the **Cassettes** tab. You see a blinking red LED. Check whether the label is damaged and reinsert the cassette. Make sure the definitions for the cassette are available on the system. You may have to replace the cassette with a new one.

Test Status tab



Use the **Test Status** tab to review detailed summary information about a test.

The tests are listed in folders based on the current test status: **Blocked**, **Disabled**, or **OK**. This tab also tells you when the next calibration for that test is due.



- A** Tests are grouped in folders, depending on their status.
- B** Selected test whose details are displayed on the right.
- C** Slot ID, rack number, and position on the rack.
- D** Select or clear check boxes to enable or disable individual controls for the selected test. The check boxes are selected by default.
- E** Enable or disable the selected test.
Tests may be automatically disabled (**Configuration > Result Handling**).
- F** Status message.
Red background: Take immediate action.
Yellow background: Warning, take action as soon as possible.

Figure B-9



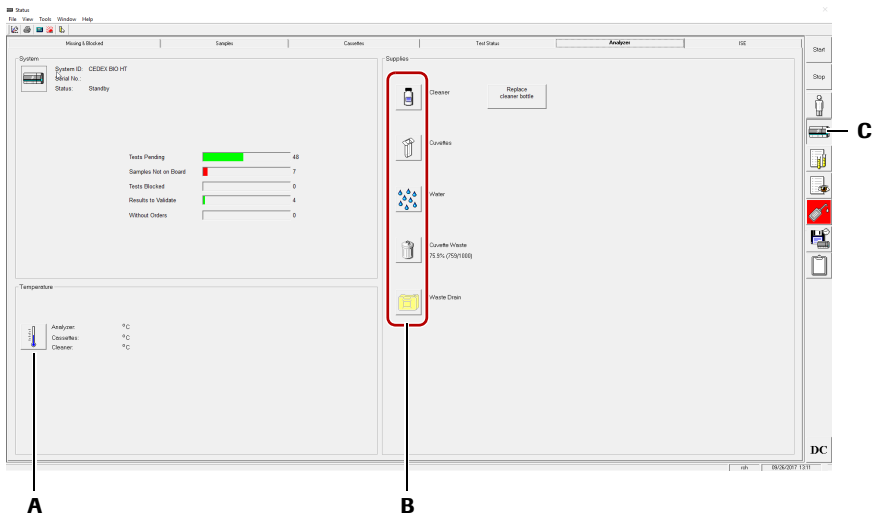
Complementary information

- Double-click on items in the **Cassettes**, **Calibrators**, **Controls**, and **Diluents** groups, to display details information on the item.
 - Clear the **Test Enabled** check box to disable a test. Calibrations and controls can be run on disabled tests, but samples cannot.
 - You can disable a control temporarily here (but you must re-enable it here also). Use the check box to the right of each control to enable or disable it.
 - **Next Cal** and **QC Interval**: These are values from the test definition.
 - All cassettes associated with the selected test are listed, even if they are not on board.
 - The **Calibration Postponed** status indicates that for the selected test the calibration was due, and that this calibration has been postponed.
 - The **Clot detected** status indicates that a clot was detected.
 - If you see, for example, a status of **Diluent not on board**, and you replace the diluent while the system is in **Standby**, the values for **Status** and **Next Cal.** in the **Test** group are not updated until the system is in **Operating**. The information in the **Diluents** group, however, is updated immediately. You may have to click **(Re)Start** on the navigation bar to get the system to **Operating** state.
 - The **Diluents** group is empty if no diluent is used for the selected test.
 - Press F1 to display Help for this tab.
-

Analyzer tab



Use the **Analyzer** tab to review the system, that is, the status of tests and orders, temperature, and resources.



- A** Shows the temperature of the analyzer, cassette area, and cleaner.
If the temperatures are not within the required limits, the system stops.
- B** Check the resource icons:
The **Cleaner** icon shows the status of the cleaner fluid bottle.
The **Cuvettes** icon shows the status of the cuvettes reservoir.
The **Water** icon shows the status of the water supply.
The **Cuvette Waste** icon shows the status of the cuvette waste box.
The **Waste Drain** icon shows the status of the waste drain or reservoir.
The icons are color-coded:
Red = Take action immediately
Yellow = Take action soon
Green or gray = No action needed
- C** The icon on the **Status** button changes depending on the system status (see *System states* on page A-43), and the resource status (see *Resource status* on page B-17).

Figure B-10



Complementary information

Press F1 to display Help for this tab.

Analyzer tab information

The **Analyzer** tab contains important information that you should review regularly and whenever the **Status** button on the navigation bar changes color.

System group

System ID and serial number

The system ID is user-defined in the **Configuration** work area. The serial number identifies your analyzer uniquely and is supplied with the analyzer.

Status icon The icon in the top left corner of the tab shows the current status of the analyzer.

 *System states* on page A-43

Bar graph indicators The bar graph indicators show the number of:

- Tests waiting to be run.
- Samples that are not on board.
- Blocked tests (for all, sample, control and calibration orders).
- Results requiring validation.
- Samples loaded that do not have an order associated with them.

Temperature group

The temperature of the analyzer (where all the photometric measurements are made), the cassette area and the cleaner is shown.

Supplies group

The icons change their background color when the supply is low (yellow), empty or full (red).

The cuvette waste container counts cuvettes; the count is restarted when you confirm that the cuvette waste container has been emptied.

The system detects when the fluid waste container (waste drain) is removed. When you reinstall the waste container, a message is displayed for you to confirm that you have emptied the container.



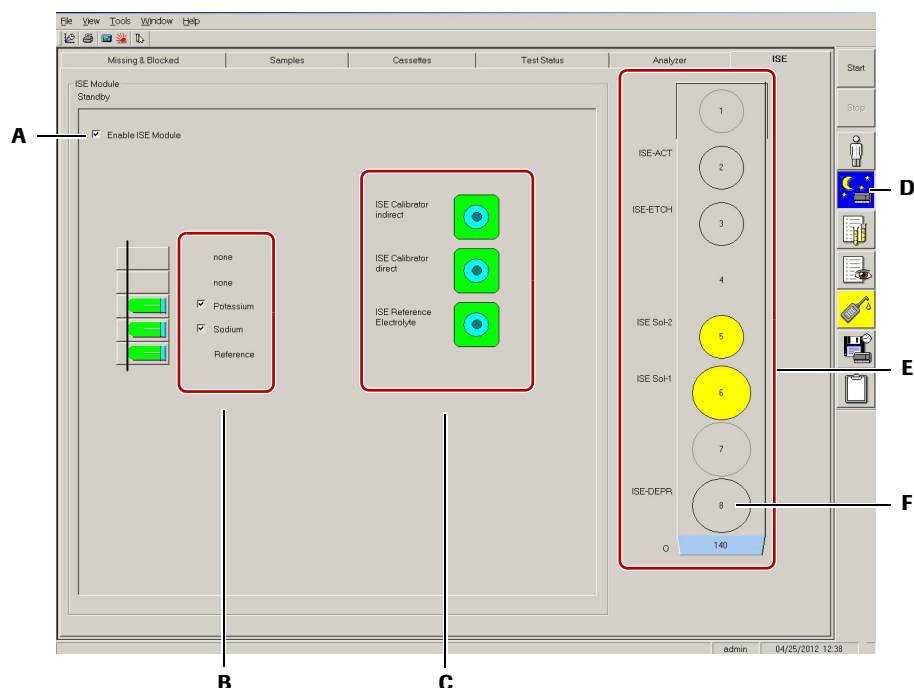
ISE fluid waste is not automatically monitored and needs to be checked manually

 *Checking resources* on page B-17

ISE tab



Use the **ISE** tab to review information about the ISE solutions on the ISE module, the ISE rack, and the installed electrodes.



- A** Select or clear this check box to enable or disable the ISE module.
- B** Select or clear these check boxes to enable or disable the ISE electrodes.
- C** Status of ISE solutions on the ISE module.
- D** The icon on the **Status** button changes depending on the status of the system.
- E** ISE rack status
- F** Double-click to display detailed status information about this item

Figure B-11



Complementary information

- If you do not have an ISE module, you must still place bottles of deproteinizer and activator on the ISE rack. You can use the other positions for diluents.
- The positions of the ISE solutions on the ISE rack are not fixed, but Roche recommends to use the predefined positions.
The ISE rack shows a lock symbol when it is on board. When it is locked, the positions cannot be changed. The rack must first be removed, and then the predefined positions can be changed using the **Configuration > Lab > Reserve Positions**.
- Replace ISE solutions on the ISE rack on page F-33
- All ISE solutions on the ISE rack should have caps except for the activator.
- If you pull out the ISE rack, a dialog box is displayed when you replace the rack. Use the dialog box to indicate the solutions you have replaced.
Leave the check boxes cleared for ISE solutions you have not replaced.
- Press F1 to display Help for this tab.
- After replacement and confirmation of the ISE solution and/or diluent bottle on the ISE rack, the appropriate bottle volume is assigned to the defined ISE rack position for the correct volume management.

Displaying item details



To display details for an item in the **Status** work area, do one of the following:

- Double-click the item.
- Right-click the item and choose Item Detail from the context menu.
- Select the item and press Space.

The corresponding details box is displayed.

The details box looks similar for the various items. The actual contents depends on the item for which detailed information is displayed.

The following are examples for detailed information.

Sample details

Double-click a rack position on the **Sample** tab or an item on the **Missing & Blocked** tab to display, for example, the following dialog box.

A — **Sample Blocked**

Order ID:	2
Sample	N 3-3
NH3	Reagent not on board

B **C**

A Status of this sample

B Slot ID, rack number, and position on the rack

C Reasons why this sample is blocked

Figure B-12

Rack details Double-click a rack number on the **Samples** tab to display the following dialog box.
To display the complete rack details, move the cursor over the rack number. When a small black arrow is displayed double click the rack number.

Sample Epp 2	
CAL A Std-1	Calibrator
CAL A Std-2	Calibrator
CAL B Std-1	Calibrator
CAL B Std-2	Calibrator
CONB1	Control
CONB2	Control
CONB3	Control
CONA2	Control
CONA3	Control
ConA2Sample	Sample
ConB2Sample	Sample
	Unknown fluid
	Unknown fluid
	Unknown fluid

- A Rack name (Defined in **Configuration > Lab > Racks**)
- B Order number, control name, or calibrator name
- C Sample type (or other solution)
- D STAT orders are shown in bold

Figure B-13

Cassette details Double-click a cassette graphic on the **Cassettes** tab to display the following dialog box.

Cassette In Use	
GLN2B	C 3-2
Tests Left:	137/200

Opened: 08/09/2017
Expiration: 11/01/2017 (22 days)
Lot No.: 25230400
Cassette No.: 485
Tests Req'd: 0

- A Status of this cassette
- B Cassette short name
- C Date this cassette was opened
- D Slot ID, rack number, and position on the rack
- E Number of tests remaining and total number of tests

Figure B-14



Complementary information

The details box for cleaner cassettes looks similar.

Selected tasks



► To review the status of tests on the system

- 1 Click **Status** on the navigation bar.
- 2 Click the **Test Status** tab.
- 3 Folders such as **OK**, **Blocked** and **Disabled** are displayed.
- 4 Click the test.

The information for the selected test is displayed on the right.



Complementary information

You can display detailed information on the selected test by double-clicking an entry in the **Cassettes**, **Calibrators**, **Controls**, or **Diluents** group. This displays the detail box for the item selected.

► To enable or disable a test

- 1 Click **Status** on the navigation bar.
- 2 Click the **Test Status** tab.
- 3 Click the test.

The information for the selected test is displayed on the right.

- 4 Select or clear the **Enable Test** check box to disable the test.



Complementary information

You cannot process a sample using a disabled test. You can, however, run calibrations and quality controls even if the test is disabled.

► To enable or disable the ISE module

- 1 Click **Status** on the navigation bar.
- 2 Click the **ISE** tab.
- 3 Select or clear the **Enable ISE Module** check box.



Complementary information

If you disable the ISE module, you must still place bottles of ISE Deproteinizer Bio HT and Activator Bio on the ISE rack (they are used for daily maintenance such as **Deproteinize Probe**.) You can use the other positions for diluents.

► To enable or disable ISE electrodes

- 1 Click **Status** on the navigation bar.
- 2 Click the **ISE** tab.
- 3 Select or clear the check box to the right of each electrode to enable or disable it.

► To replace ISE solutions on the ISE rack

- 👁 See Replace ISE solutions on the ISE rack on page F-33

Orders

Creating, modifying, and reviewing orders



This chapter describes the **Orders** work area and how to use it. It shows you how to request tests, calibrations, and quality controls.

In this chapter

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About orders

An order specifies the tests to be performed on a sample. An order also contains information about the sample and supplementary information about the order (order demographics). Order demographics include information about the order creation date and time.

You can create orders manually in the **Orders** work area, or your system may download orders automatically from the host system.

The way in which the sample and order information is presented, depends on how your system is configured.

Order IDs Each order must have an order ID, which may be alphanumeric (for example, AA-1234) or numeric (for example, 1234). Your system may be configured to increment order IDs automatically. This means that a new order ID is automatically displayed when you open the **Orders** work area (or save the previous order).

Order IDs are valid until they are deleted. Typically, the system is configured to delete processed orders automatically every morning, and with it the order IDs are deleted. You then can use the same order IDs the next day. You can purge orders only when the order has been processed, that is, when the results have been accepted and transmitted to the host, provided you work with a host system.

Racks and sample handling The way in which you place samples in racks depends on how the racks are configured on your system. Typically, you will define racks for a specific tube type (**Configuration > Lab > Racks**) and have tubes of one types on the same rack.

NOTICE **Analyzer damage due to using multiple tube types on a rack**

Using multiple tube types on a rack may prevent the analyzer from recognizing the correct dimensions and lead to malfunction and analyzer damage.

- Only use tubes of the same type on a rack.

If you use barcodes that contain sample type information, the process of placing samples is automatic: Load the samples onto a suitable sample rack and insert the rack into the rack platform. The system then reads the barcodes to uniquely identify each sample.

If you use barcodes that do not contain sample type information, define both tube type and sample type for a rack (**Configuration > Lab > Racks**).

Orders at a glance

Use the following table to locate specific tasks by work area and tab.

Work area	Tab	Tasks
Status 	Missing & Blocked	Review missing and blocked samples for the current worklist.
	Samples	Review samples on board; color shows the status. Double-click a rack position to display the details for the selected sample.
Orders 	Worklist	- Review the status of active orders and tests. - Access directly the areas where you perform the most frequent tasks on these items, such as editing and validating.
	Sample	- Create an order. - Add tests or profiles to an order. - Modify or delete an order. - Add or modify order information. - Assign samples to rack positions. - Request a dilution.
Results 	Validate	- Review unaccepted (flagged) results. - Accept results that have not been automatically accepted. - Rerun a test (for example, with dilution). - Review details and sample rate information for unaccepted results.
	Sample	- Review all results for an order whether accepted or not. - List results by order date and order ID. - Select results for specific orders, dates, and STAT or non-STAT samples. - Review statistics on a specific test.

Table B-14

Use the following table to locate specific tasks in the **Configuration** work area:

Icon	Tab	Tasks
General 	Barcode	Specify barcode use.
	Lab	- Specify tube parameters. - Specify Cup on Tube parameters.
	Racks	Specify rack configuration: define rack groups, rack numbers, and assign sample type and tube type.
	Reserve Positions	Preassign cup and tube positions for ISE solutions, diluents, calibrators and controls.
	Database	Specify Start Order ID, to enable automatic order numbering and automatic assigning of samples to rack positions.
	Automatic Actions	Specify Start Order ID, to enable automatic order numbering and automatic assigning of samples to rack positions.
	Demographics	Predefine the comments for up to three comment boxes in order demographics.

Table B-15

Orders work area



To access the **Orders** work area, click the **Orders** button on the navigation bar.
The **Orders** work area has the following four tabs:

Tab	Function
Worklist	This tab gives a clear and comprehensive overview of the active orders and tests, and provides easy access to the tasks you perform most frequently on these items, such as editing and validating.
Sample	This tab allows you to: • Request tests for a sample by creating an order. • Request dilutions. • Create multiple copies of an order. • Give an order STAT priority.
Calibration	This tab allows you to request calibrations for specific tests.
Quality Control	This tab allows you to request quality controls for specific tests.

Table B-16

Context menu

You can right-click a test, order, calibration, or control in any tab to display the context menu. It contains one or more of the following frequently used commands:

Menu item	Function
Clear	Clears the text boxes.
Copy	Copy to the clipboard text that was selected in a box.
Copy Order	Copy the details of the current order to the clipboard. Use with the Paste Order command to create multiple orders with the same content.
Cut	Cut selected text from a box.
Delete	Deletes the selected item.
Delete Order	Deletes the current order.
Detail	Gives detailed information for the selected item; for example, if you are on the Calibration tab for a test, the onboard cassettes are listed.
Dilutions	Request a dilution for the selected test.
Edit	On the Worklist tab, access the Sample tab to edit the item.
Multiple Tests	Request the same test multiple times for the order.
Paste	Paste previously selected text into a box.
Paste Order	Paste the details of an order into the current order. (You must have previously saved the details of another order and used Copy Order .)
Paste Multiple	Create multiple copies of an order. You copy tests from an existing order and then use the Paste Multiple dialog box to create a set of orders based on these tests.
Postpone Calibration	Override a system request for calibration and postpone it by a certain period of time or an event.
Reset	Resets the text boxes.
Sample Handling	Review the rack numbers and rack positions for the selected sample.
Select All	Selects all text in a box.
Undo	Revokes the last action.
Use Last Order	Re-displays the details of the last order you used.
Validate	On the Worklist tab, access the Validate tab on the Results work area to validate the result(s) of the selected item.

Table B-17

Worklist tab



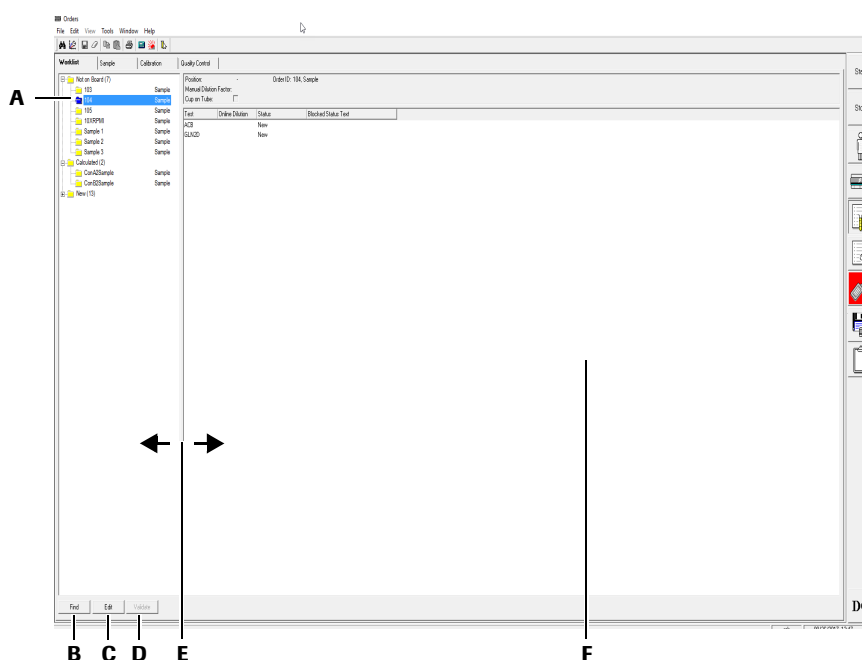
Use the **Worklist** tab to get a clear and comprehensive overview of the active orders and tests, and to gain easy access to the tasks you perform most frequently on these items, such as editing and validating.

The **Worklist** tab provides maximum support to users who work without barcodes and who are not connected to a host system.

The tab is divided into two horizontally adjustable areas:

- The area on the left, the **Orders** list, contains the folder view of the sample, calibration, and control orders.

The area on the right, the samples and tests list, displays detailed information on the item that is selected in the **Orders** list.



- A** Orders list, see section below.
- B** Click **Find** to search for a specific order ID.
- C** Click **Edit** to access the appropriate tab, where you can edit the order. This function is only available if there are related data on the system.
- D** Click **Validate** to access the **Validate** tab of the **Results** work area, where you can validate the results. This function is only available if the selected order has test results that need validating.
- E** Adjust the width of the **Order** list to display all information.
- F** The information displayed in the samples and tests list depends on the type of the selected order (sample, calibration, control), and on the folder the selected order is placed in. The samples and tests list provides a good overview of the status of the selected sample, calibration, or control order.

Figure B-15

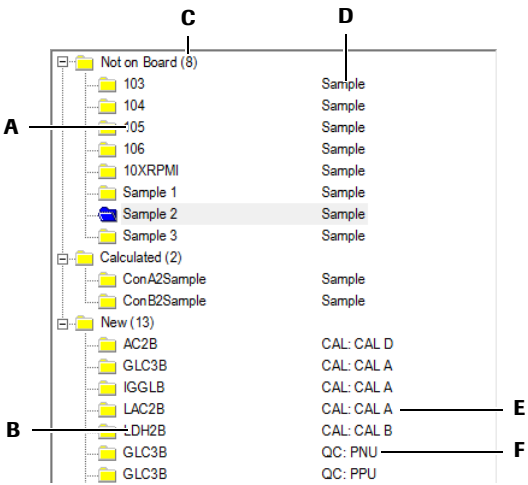


Complementary information

- Press F1 to display Help for this tab.

Orders list on the Worklist tab

This area contains the folder view of the sample, calibration, and control orders:



- A Order ID
- B Test name
- C Number of entries in the folder. This number is automatically updated. An increase of the number, for example, points to new entries.
- D Kind of order (calibration, quality control or sample type)
- E Calibrator name. With calibration orders, the calibrator name is displayed.
- F Control name. With quality control orders, the control name is displayed.

Figure B-16

The **Orders** list may contain the following folders and information:

Folder	Contents
Blocked	Orders with at least one test with the Blocked status.
Not On Board	Orders for which there are still tests to be performed, and for which the sample is not on board the system.
Without Orders	Samples without orders.
Calculated	Orders with calculated results.
New	Orders with tests that still need to be performed.
Running	Orders with tests that are currently being performed.

Table B-18



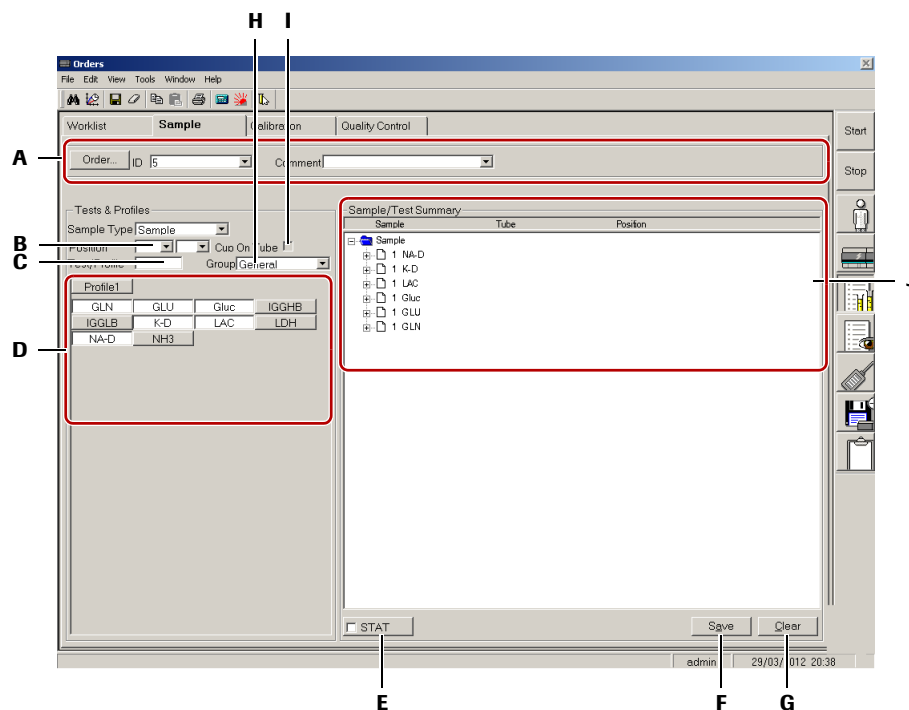
Complementary information

- Only folders that contain entries are displayed in the **Orders** list.
- STAT orders are displayed in bold print.
- To follow the logical job sequence, work through the entries in the list from top to bottom.

Sample tab



Use the **Sample** tab to create, modify, review, or delete an order for tests on one or more samples. You can select individual tests, or a profile containing several tests.



- A** Use the **Order** group to display or specify order details if you are creating a new order or modifying an existing one.
- B** To manually assign a sample to a rack position, first select a rack from the first drop-down list, and then select an available rack position from the second drop-down list.
- C** Type a test name, a profile name or a test number, and then press Enter. The specified tests are added to the **Sample/Test summary** group. Alternatively, you can use the test and profile buttons.
- D** Click one or more of the profile and test buttons to select the tests for the order you are creating. For tests only, you can remove a test from an order by clicking the corresponding button a second time. Use the scroll bars to display more tests, if necessary. Use the **Group** list to select a predefined group of tests, for example all **STAT** tests. Test groups are only available if they were previously defined in **Configuration > Definition > Test**).
- E** Select this check box to give the order STAT priority.
- F** Click **Save** to save the current order.
- G** Click **Clear** to clear the boxes in the tab.
- H** Select a test group to customize the type and number of test buttons displayed. Each test can belong to one or more groups, depending on the configuration of your system. When you specify the name of a group in the **Group** box, only buttons for tests that belong to that group are displayed.
- I** Select the **Cup on Tube** check box to indicate that you want to use the predefined secondary cup on top of the primary tube for the selected sample type. This option is only available if a sample type other than **Automatic** is selected.
- J** The **Sample/Test Summary** group lists the tests selected for the current order.

Figure B-17



Complementary information

- To request a dilution, in the **Sample / Test Summary** group, double-click a test name to open the **Dilutions** dialog box, or right-click a test name and choose **Dilutions** in the context menu.
 *Requesting a dilution* on page B-81
 - To review the results of completed orders, use the **Sample** tab in the **Results** work area.
 - To review flagged results, use the **Validate** tab in the **Results** work area.
 *Working with Orders* on page B-77
 - The system can handle up to 1000 test requests at any time. If you request more, the system will accept 1000 tests and issue a message.
 - Press F1 to display Help for this tab.
-

Calibration tab



Use the **Calibration** tab to create, modify, postpone, review, or delete calibration requests on one or more tests.

You can select individual tests, or a profile containing several tests. All pending calibrations, whether requested manually or scheduled automatically by the system, are listed.



- A** You can select a test or profile for the calibration request by typing its name here.
- B** In the **Configuration** work area, tests can be assigned to groups. You can use this feature to reduce the number of test buttons displayed at one time. Select another group if you do not see the required test.
- C** Click a profile button to request calibrations for all tests in the profile.
- D** Click test buttons to request a calibration for the test.
- E** Calibration already requested for this test.
- F** Click **Save** to save the calibration request.
- G** Select a calibrator to display only the tests that are associated with the calibrator.
- H** The **Calibrator/Test Summary** lists all current requests for calibrations.

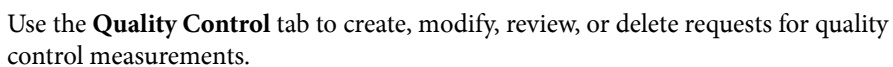
Figure B-18



Complementary information

- When you request a calibration for a test that has more than one cassette on board, the **Calibrate** dialog box is displayed. Select the cassette that you want to use.
- To postpone a calibration, right-click the test that now requires a calibration and choose **Postpone Calibration** from the context menu.
- To review completed calibrations, use the **Calibration** tab in the **Results** work area.
- To review flagged calibrations, use the **Validate** tab in the **Results** work area.
- Press F1 to display Help for this tab.

For more information, see Chapter 10 *Calibration*



- A** You can select a test or profile for the quality control request by typing in its name or number here.
- B** In the **Configuration** work area, tests can be assigned to groups. You can use this feature to reduce the number of test buttons displayed at one time. Select another group if you do not see the required test.
- C** Click a profile button to request controls for all tests in the profile.
- D** Click test buttons to request a control for the test.
- E** A control request has been made for this test.
- F** Click **Save** to save the quality control request.
- G** Click the **Place Item** button to place samples on the rack while defining orders for samples whose barcode could not be read, especially if you work with a host system.
- H** If you select a control here, only the tests that are associated with the control are displayed.
- I** The **Controls/Test Summary** lists all current requests for controls.

Figure B-19



- To review completed or flagged controls, use the **Quality Control** tab or the **Validate** tab respectively in the **Results** work area.
- Press F1 to display Help for this tab.

👁 For more information, see Chapter 11 *Quality controls*.

Creating an order

To run tests on samples, you must create an order with a unique order ID. The order specifies which tests are to be run and other optional information about the order and the sample.

You can create a new order, or you can add tests to an existing order.

When you create an order manually, you have to work through a series of substeps:

1. Specify an order ID (mandatory) and demographics.
 *Specifying an order ID* on page B-69
2. Select tests for the order and save.
 *Selecting tests for the order* on page B-70
3. If there are no barcodes on the tubes and you work without a host system, you must assign the samples to rack positions. This can be done either automatically or manually. (See *Assigning samples to racks* on page B-70.)

These and other step-by-step procedures related to the **Orders** work area are described in this section.

Some procedures may differ depending on the lab setup you are working with. The main criteria are whether or not you work with barcodes and whether or not you work with a host system.

The procedures describing the various steps of creating an order apply to working without barcodes and without host system, unless otherwise indicated.

For information on the procedures when working with a specific lab setup, see the Daily routine sections in Chapter 5 *Workflows*.

Some of the most common problems in connection with creating orders are dealt with in *What if?* on page B-76.

Specifying an order ID

You can enable the automatic order numbering facility in **Configuration > Database > Automatic Actions**. If it is enabled, the order ID increases automatically when you open the **Sample** tab in the **Orders** work area. This ensures that you always have a unique order ID. You can accept the order ID or type over it.

The automatic order numbering facility is not available for alphanumeric order IDs.



► To specify an order ID

- 1 Click **Orders** on the navigation bar.
- 2 Click the **Sample** tab.
- 3 Type a valid order ID in the ID box or use the proposed order ID.
- 4 Click the **Order** button.
The **Order Demographics** dialog box is displayed.
- 5 Add information as required.
- 6 Click **OK**.



Complementary information

- Step 3: A valid order ID has up to 15 alphanumeric characters.
 - Step 3: Users who work with barcodes first insert the sample rack into the system. All samples without test orders are then available in the **ID** drop-down list. Select an entry from this list.
 - Your system can be set up to automatically purge order IDs at BOD. You can then reuse order IDs each day.
 👁 *Purging and deleting orders on page B-83*
 - Step 5: Comments in the **Order Demographics** dialog box are defined in **Configuration > Database > Demographics**.
-

Selecting tests for the order

You can add tests one at a time, or you can select a test profile.

► **To add tests to an order**



In the **Sample** tab in the **Orders** work area:

- 1 Click the required profile buttons.
- 2 Click the required test buttons.
- 3 Click **Save**.



Complementary information

- The buttons for profiles are listed above those for individual tests.
 - Selected tests are shown in white and listed in the **Sample/Test Summary** group.
 - If a test belongs to two profiles and both profiles are selected, the test is only run once.
 - You can also select a test or profile by typing its name in the **Test/Profile** box.
-

Assigning samples to racks

In some cases, for example if you do not use barcodes, or when a sample barcode could not be read, you must assign each sample to a specific position on a rack. You can do this in two ways:

- Use the **Automatically Assign Rack Position** function to automatically assign samples to rack positions.

Roche recommends using this method if you work with non-barcoded samples.

👁 *Automatically assigning samples to rack positions on page B-71*

- Manually assign samples to racks, using either

👁 *To assign a sample manually on page B-72*

- **Sample Handling** dialog box

Use this method if you prefer to create an order and then specify all the sample positions for that order before moving on to the next order.

👁 *To assign a sample manually, using **Sample Handling** on page B-72*

- **Place Items** dialog box

Use this method if you want to assign all the samples on a rack at one go.

👁 *To assign a sample manually, using the **Place Items dialog box** on page B-73*

Automatically assigning samples to rack positions



► To create an order, using **Automatically Assign Rack Positions**

- 1 Define the order ID and demographics.

The sample type **Automatic** is displayed, and the **Position** boxes are disabled.

- 2 Select tests for the order.

- 3 Click **Save**.

The **Sample Handling** dialog box is displayed.

See **Sample Handling dialog box** on page B-74.

- 4 Confirm the automatically assigned rack number and position, or modify them, if required.



Complementary information

- To enable this function, use **Configuration > Database**, and select the **Automatically Assign Rack Positions** box on the **Automatic Actions** tab.
- Automatic rack position assignment *assigns positions of racks that are not on board the system*.
- You need to define manually the first position for each sample type. This is typically position 1 on the first rack allocated to the sample type in question. All further position assignment for samples of this type will be done automatically.
- Automatic rack position assignment works for samples, not for calibrations or controls.
- Automatic rack position assignment also works when **Paste Multiple** is used (**File > Copy**, then **File > Paste Multiple**). Note that the racks must not be on board, and that the **Sample Handling** dialog box is not opened automatically.
- Automatic rack position assignment continues as long as there are free positions on racks that are allocated to the sample and tube type of the kind required by your order.
- Roche recommends working with the **Reset Rack Positions at Begin of Day** function (**Configuration > Database**). This function resets each day the starting positions for automatic placement, as part of the **Begin of Day** actions.
- When working *with* barcodes, the **Automatically Assign Rack Position** function must be *disabled*. To disable this function, use **Configuration > Database**, and clear the **Automatically Assign Rack Positions** check box on the **Automatic Actions** tab.

Manually assigning samples to rack positions



► To assign a sample manually

- 1 From the **Sample Type** list, select a sample type other than **Automatic**.

If you select a sample type other than **Automatic**, drop-down lists assist you in assigning the sample to a rack position. These lists contain the available rack numbers and positions.

A **B**

Rack Name	Tube Type	Sample Type of Rack
3 SAMPLE	Sarstedt 2.0 mL	Sample
4 SAMPLE	Sarstedt 2.0 mL	Sample
5 SAMPLE	Sarstedt 2.0 mL	Sample
6 SAMPLE	Sarstedt 2.0 mL	Sample
101 CAL	COBAS cup	Sample
102 QC	COBAS cup	Sample

A There is a default tube type assigned to each rack.

B Sample types that are assigned to a rack are displayed.

- 2 Select a rack number from the first **Position** list.

Once a rack number is selected, you can display the available rack positions in the second list.

- 3 Select the rack position from the second **Position** list.

**Complementary information**

- A padlock symbol in front of an entry in the first **Position** list signifies that the rack is on board. With onboard racks, you are alerted by a message if you try to assign a sample to a position you cannot use.
- Use this method to create an order and then specify all the sample positions for that order before moving on to the next order.



► To assign a sample manually, using Sample Handling

- 1 Click **Orders** on the navigation bar.
- 2 Click the **Sample** tab.
- 3 Type the order ID in the **ID** box and press Tab.
- 4 Choose **View > Sample Handling**.
The **Sample Handling** dialog box is displayed.
👁 See **Sample Handling dialog box** on page B-74.
- 5 Specify the rack number and the position on the rack.
- 6 Click **OK**.
- 7 Put the samples in the correct positions on the rack and load the rack.

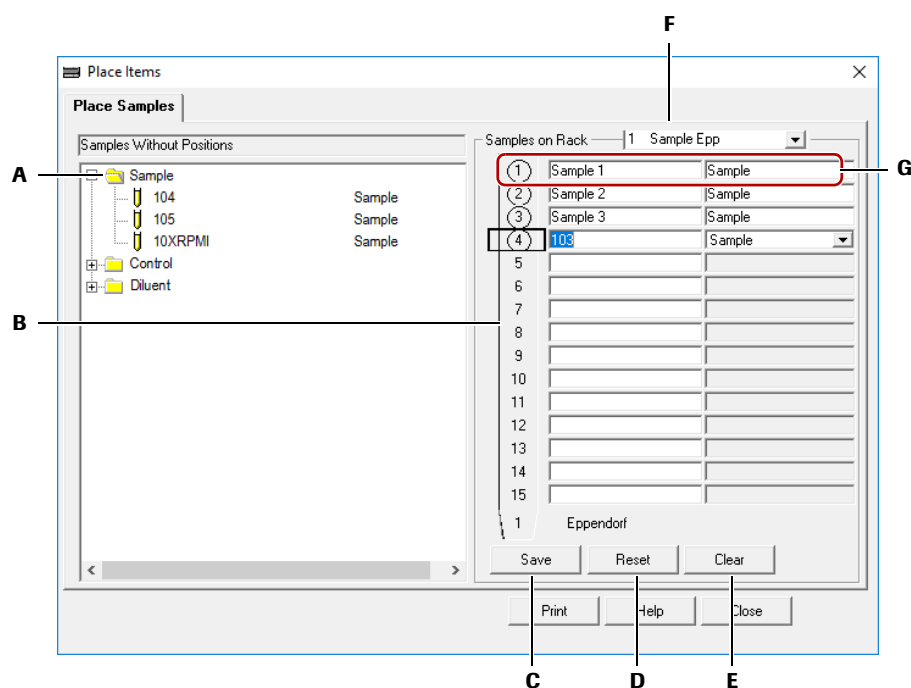
**Complementary information**

- Normally, you can assign positions only to racks that are not on board.
- Step 5: If the rack is not on board, you can overwrite rack positions.
- Step 5: If the rack position you want to use is not available, choose **Tools > Place Items**, and click **Clear** to clear previously assigned rack positions.



► **To assign a sample manually, using the Place Items dialog box**

- 1 Click **Place Items**  in the toolbar.
- 2 Select a rack from the list.
See F below.
- 3 Click  to expand the **Samples** folder.
See A below.
- 4 Drag and drop items from the Samples folder to the rack graphic. The positions you choose must correspond to the actual placement of the samples on the rack.
- 5 Repeat step 4 for any other samples.
- 6 Click **Save**.
- 7 Place the samples on the correct positions on the rack, and load the rack.



- A** The **Sample** folder containing samples to be placed on racks. Click to expand or to contract the folders.
- B** Rack placement graphic.
- C** Click **Save** to save the new assignments.
- D** Reset the assignments on this rack to what they were when (1) you opened this dialog box or (2) you last saved.
- E** Click **Clear** to clear all assignments on this rack.
- F** Rack identification list.
Click the arrow to display a list of available racks. The padlock symbol means the rack is on board.
- G** Order ID and sample type (or name for other solutions).

Figure B-20



Complementary information

- You can assign positions to both onboard and off-board racks.
- Step 2: Click **Clear** to clear previously assigned rack positions if necessary.
- Step 7: You can print out the sample positions by:
Clicking **Print** in the **Place Items** dialog box.
Choosing **File > Print Report > Loadlist**.

Sample Handling dialog box

The **Sample Handling** dialog box serves to assign samples to rack positions, and to confirm rack positions that were automatically assigned. It also serves to enable the **Cup on Tube** function.

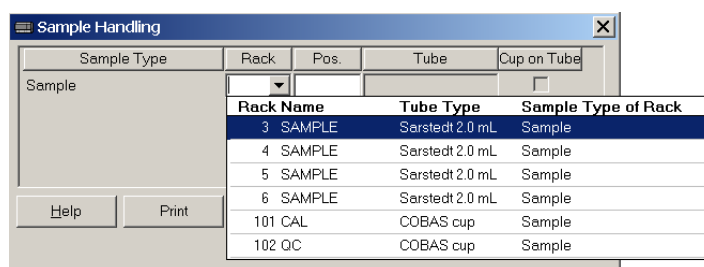


Figure B-21

You can display the **Sample Handling** dialog box at any time by right-clicking a sample or a test in the **Sample/Test Summary** group and then choosing **Sample Handling** from the context menu. You can also choose **View > Sample Handling** from the menu bar when an item is selected.

You cannot change the tube type in this dialog box.

If you do not work with barcodes, the **Sample Handling** dialog box is automatically displayed when you click **Save**. If you work with barcodes, the **Sample Handling** dialog box is not displayed when you click **Save**.



Complementary information

- While working with barcodes, you cannot change positions that were fully identified with order ID and sample type, as long as the associated rack is on board.
- You can overwrite positions of racks that are not on board the system without previously having cleared the position, for example on the **Place Items** dialog box.
- A padlock symbol in front of an entry in the **Rack** list signifies that the rack is on board. With onboard racks, you are alerted by a message if you try to assign a sample to a position that is not free.
- Assume you work with barcodes, and you have created an order while the rack was not on board, and then you insert the rack. If the system detects a discrepancy between the rack position you defined and the position read from the barcode, the **Sample Handling** dialog box is displayed. It contains the rack position read from the barcode.
- Changes in the system while the **Sample Handling** dialog box is displayed, such as inserting a rack, are not automatically reflected on the open **Sample Handling** dialog box. Close and re-display the **Sample Handling** dialog box to see the changes in the **Rack** and **Position** lists.
- You can print the **Sample Handling** dialog box.

Selecting Cup on Tube

You can define *one* cup - the **Cup on Tube** - as the secondary cup you want to use on top of primary tubes (**Configuration > System > Lab > Sample Tubes > Cup on Tube**).



NOTICE

You cannot enable **Cup on Tube** using the **Place Items** function.

Analyzer damage due to incorrect cup configuration

Incorrect configuration of cups may lead to serious analyzer damage.

- Contact your Roche representative for support before you define the use of Cup on Tube.

► **To enable Cup on Tube while working with barcodes**

- 1 Remove the sample rack from the system.
- 2 On the **Sample** tab of the **Orders** work area, type the **Order ID** (barcode number) and, if necessary, select the tests.
- 3 In the **Tests & Profiles** group, select the sample type from the **Sample Type** list.
- 4 In the **Tests & Profiles** group, select the **Cup On Tube** check box. This option is only available if the default tube type for the rack allows the use of cups on these tubes.
- 5 Click **Save**.
- 6 Re-insert the sample rack into the system.



Complementary information

When working with a host system, you first insert the sample rack into the system, and the host sends the orders. You then follow the standard procedure.

► **To enable Cup on Tube while working without barcodes**

The procedure for enabling **Cup on Tube** is basically the same as when working with barcodes. The difference is that you select the **Cup on Tube** check box on the **Sample Handling** dialog box rather than in the **Tests & Profiles** group.

- 1 Remove the sample rack from the system.
- 2 On the **Sample** tab of the **Orders** work area, create the sample order and, if necessary, select the tests.
- 3 On the **Sample Handling** dialog box, select the **Cup on Tube** check box, and click **OK**.
- 4 Re-insert the sample rack into the system.

NOTICE

Analyzer damage due to re-inserting the rack before enabling Cup On Tube

Re-inserting the rack before having selected and saved **Cup On Tube** may lead to serious damage to the probes.

- Be sure to have selected and saved **Cup On Tube** before re-inserting the rack.

What if?

<i>An order with the same order ID already exists</i>	Order IDs must be unique, so you have to specify an order ID that does not already exist. However, you can use the same order ID if the orders were made on separate days or if the order IDs have been purged.
<i>I can't find the test I need on the buttons</i>	Try selecting another group (Group box) or typing in the name of the test or profile (Test/Profile box). Alternatively, if the test is not installed, contact your system administrator to see if this test can be made available.
<i>I see predefined order IDs when I open the Samples tab</i>	The automatic order numbering facility is enabled. This means that each time you create an order, the number is automatically increased for the next order. You can manually type over the suggested order ID, if you prefer.

Working with Orders



When you have created an order, you can perform the following operations in the **Orders** work area:

- Look up orders. 👁 page B-77
- Review the tests in an order. 👁 page B-79
- Add tests to an existing order. 👁 page B-79
- Copy tests from one order to another. 👁 page B-80
- Make multiple copies of an order. 👁 page B-80
- Request a dilution. 👁 page B-81
- Delete tests. 👁 page B-83
- Delete orders. 👁 page B-83

These operations are described in the following sections.

Finding orders

You can choose between two methods of finding certain orders:

- With the **Lookup** function, you type the search criteria directly in boxes on the **Sample** tab.
- With the **Find** function, you first start the function by clicking  on the toolbar and then type your criteria in the **Find Orders** dialog box. This method offers more elaborate search criteria.

Specifying search criteria

You can use a wildcard (? or *) in your search, where ? represents a single character, and * represents one or more characters.

If you type	In this box	You find these values
*	Order ID	All values.
77*	Order ID	All values beginning with “77” including: 77, 775, 7756152, 773A21
77?	Order ID	All values beginning with 77, and which have three characters, including: 77, 775, 776, 77A, 77B
Glu*	Name	Gluc, Glut
Glu?l	Name	Gluc, Glut
5553*	Order ID	55531, 55532, 55534, 555311111012.
555?1	Order ID	55531, 55541, 55581

Table B-19



Complementary information

- You can only use the * wildcard at the end of a search string. For example, *77, 7*7 are not valid.
- You can specify only one wildcard in a string. For example, 77*? and 5??1 are not valid.

Lookup function

Use the **Lookup** function for a quick search for the tests of a certain order.

► To look up an existing order

- 1 Type "*" (asterisk) in the **Order ID** box, and press Enter.

The **Lookup** dialog box is displayed, containing a list with all order IDs stored on the system.

- 2 Select the desired entry and click **OK**.

The data for the selected order is displayed on the **Sample** tab.

Find function

With the **Find** function, you can search for orders by giving an order ID. You can also specify a range of dates within which the order was created.

Accessing the **Find** function

There are several methods of accessing the **Find** function:

- Click  on the toolbar.
- Click **Find** on the tab.
- Press F3 on the keyboard.

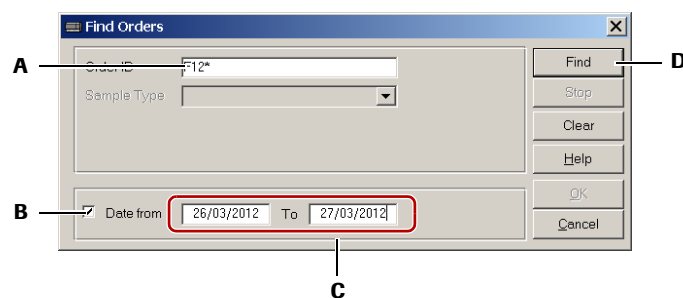
The **Find** function is available on the **Worklist** and **Sample** tabs of the **Orders** work area, and also on the **Validate** and **Sample** tabs of the **Results** work area.



► To find an existing order

- 1 Click **Orders** on the navigation bar.
- 2 Click the **Sample** tab.
- 3 Click  on the toolbar.

The **Find Orders** dialog box is displayed.



- A** Enter text and wildcards.
- B** Specify a date range for the order.
- C** Specify the start and end dates for the search period.
- D** Start the search, but leave the dialog box open.

- 4 Type your search criteria in the **Find Orders** dialog box.
- 5 Click **Find**.
The orders that match the search criteria are listed.
- 6 Double-click the order that you want to work with.

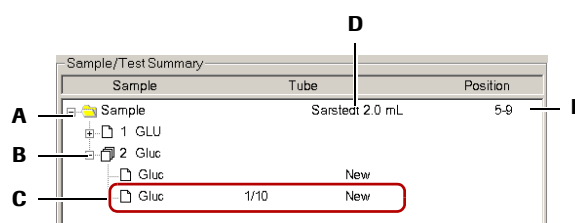


Complementary information

- The **Find** function is case-sensitive.
- If the search is not successful, remove or relax some of the search conditions.

Reviewing tests in an order

The **Sample/Test Summary** group displays the details of the tests selected for the current order. The tests are displayed in folders and are sorted by their short name; the folders are listed by sample type.



- A** Sample type is given by the folder name. Click to expand a folder, or to collapse it.
- B** A duplicate has been ordered for this test. You can order multiple tests so that you can run a variety of dilutions, for example. The **Multiple Tests** function is available for sample tests only.
- C** Single test ordered with dilution.
- D** Default tube type.
- E** Position of the sample on the rack.

Figure B-22



Complementary information

- Double-click a test line to open the **Dilutions** dialog box (to request dilutions).
 *Requesting a dilution* on page B-81
- Rack number information is available when:
 - The sample is on board and has been identified by its barcode.
 - The rack position for the sample has been manually assigned.
- Click **Save** to save any changes that you have made to the order.

Adding tests to an existing order

When you have created and saved an order, you can open it at a later stage and add more tests.



► To add tests to an existing order

- 1 Click **Orders** on the navigation bar.
- 2 Click the **Sample** tab.
- 3 Type the order ID in the **ID** box.
- 4 Press Tab.

The background in the **ID** box is grayed out so that you cannot alter the order ID.

- 5 Click the required profile buttons.
- 6 Click the required test button.

- 7 Click **Save** to save the order.



Complementary information

- You can add tests to a completed order.
-

Copying data from orders and tests

You can copy a set of tests from one order to another, or from one order to several others.



► **To copy tests from one order to another**

- Click **Orders** on the navigation bar.
- Click the **Sample** tab.
- Display an existing order that contains the tests to be copied.
- Right-click anywhere in the **Sample/Test Summary** and choose **Copy Order** from the context menu.
- Click **Save** to save the order.
- Click **Clear** to clear the text boxes.
- Type a new order ID in the **ID** box. This is the order to which the tests will be copied.
- Right-click anywhere in the **Sample/Test Summary** and choose **Paste Order** from the context menu.

The tests are displayed in the **Sample/Test Summary** group.

- Add order demographics as required.
- Click **Save**.



Complementary information

- You can modify the new order as required.
 - Step 4: You can also choose **Edit > Copy**.
 - Step 8: You can also choose **Edit > Paste**.
-



► **To create multiple copies of an order**

- Click **Orders** on the navigation bar.
- Click the **Sample** tab.
- Create an order containing the tests to be copied.
- Right-click anywhere in the **Sample/Test Summary** and choose **Copy Order** from the context menu.
- Click **Save** to save the order.
- Right-click anywhere in the **Sample/Test Summary** and choose **Paste Multiple** from the context menu.

The **Paste Multiple** dialog box is displayed.

- Type the number of orders that you want to create, and the order ID to start from.

8 Click OK.

A status dialog box shows how many orders are completed and how many remain.

**Complementary information**

- Step 4: You can also choose **Edit > Copy**.
- Step 6: You can also choose **Edit > Paste Multiple**.
- The order IDs that are created will be consecutive.
- The new order IDs must not conflict with any existing order ID, otherwise, the order request will fail.

Requesting a dilution

If a test result is out of range or a sample needs diluting before a test is run on it, you can request a test with one of the following types of dilution factor.

Dilution factor	Description
Factor	Select a predefined dilution or concentration factor. The system performs the dilution or concentration according to the factor you choose.
As Original	Use the original dilution.
Specific Factor	Select this option and type a dilution factor. The system performs the dilution according to the factor you specify.
Manual Dilution Factor	Select this option if you want to dilute the sample yourself. Type the dilution factor you are going to use. When you have performed the dilution, replace the sample tube (which now contains the diluted sample) in its original position on the same rack. All subsequent tests are performed on the diluted sample.

Table B-20

► **To request a test with a dilution factor**



- 1 Click **Orders** on the navigation bar.
- 2 Click the **Sample** tab
- 3 In the **Sample/Test Summary** group, right-click the test and choose **Dilutions** from the context menu.
The **Dilutions** dialog box is displayed.
- 4 Select the required option button for a predefined dilution factor, a specific factor, or a manual dilution.
- 5 Specify the dilution factor, if required.
- 6 Click **OK**.

- 7 Click **Save** in **Sample** tab (when you have specified all the tests for the current order).

- A** Select a predefined dilution factor for an automatic dilution.
- B** Use the original sample dilution.
- C** These factors have not been defined for this test.
- D** Select to specify a dilution factor for this test and sample.
Specify the values for an automatic dilution.
- E** Select this box if your sample has been diluted manually. Type the dilution factor.

Figure B-23



Complementary information

- For an automatic dilution, the diluent and sample are mixed automatically in a cuvette.
- It is technically possible to choose a dilution of up to 1:100 for the **Specific Factor**, however tests are validated only up to the dilution factor predefined for the **Factor A**.
- For a manual dilution, you mix the diluent and sample manually, then load the tube containing the diluted sample onto a rack.
- Do not use barcoded sample tubes for samples that require manual dilution. The barcode does not contain any information on the manual dilution factor.
- Roche recommends not to use manual dilution for ISE tests. The test range of all ISE tests (direct and indirect) covers all physiological ranges, and therefore, there is no need to measure electrolytes from off-line diluted samples.
- The sample is run using an automatic dilution factor if the result flag demands it. This depends on the configuration of your system, and overrides any dilution that you have requested.
- For some tests, dilution by the system is not allowed. In these cases, Roche has set **Automatic Dilutions to Disabled** in **Configuration > Test > Dilutions**. You cannot change this setting.
- Define dilution factors for a test in **Configuration > Tests > Dilutions**.

Deleting tests

You can delete tests from an order, or you can delete the whole order.



► To delete a test

- 1 Click **Orders** on the navigation bar.
- 2 Click the **Sample** tab.
- 3 Type the order ID in the **ID** box and press Tab.
- 4 In the **Sample/Test Summary** group, right-click the test to be deleted and choose **Delete** from the context menu.
- 5 Click **Save**.



Complementary information

- If the order has not yet been saved, click **Clear** to remove all tests.
- You cannot delete finished tests with results that have not been accepted yet.

Purging and deleting orders

You can purge orders manually at any time, or delete them automatically at BOD. The main reason for purging orders is to free the order IDs for re-use.

Purging orders removes the order ID from the **Orders** work area. This means that you can reuse the IDs after purging orders. In the **Results** work area, the order ID is still visible; the results are not removed. Each order ID is associated with a date and time so that you can always refer to a specific order by its ID, its date, and its time stamp. This ensures that each order is unique.

Preconditions

You can only purge an order or delete an order automatically at BOD when the system is in **Standby** or **Sleeping** state.

Orders are purged if "CANT":

- Order complete (C)
- Result accepted (A)
- Sample not on board (N)
- Result transmitted to the host, if you work with a host system (T)

► To purge orders manually

- 1 Choose **Tools > Purge Orders**.
- 2 Click **Yes** on the **Confirm Purge Orders** dialog box.

► To delete orders automatically at BOD

- 1 Click **Configuration** on the navigation bar.
- 2 Double-click **Database** in the **System** group.
- 3 Click the **Automatic Actions** tab.
- 4 In the **Delete Orders After** box, type the number of days after which the order should be deleted.
- 5 Click **OK**.



Complementary information

- Type 0 (zero) to delete at the next **Begin of Day** all of today's orders, that is, all orders defined between the time of the last and the next **Begin of Day** time.
 - Type 1 to delete at **Begin of Day** all orders that were created more than 24 hours before **Begin of Day** time.
-

**► To delete a single order**

- 1** Click **Orders** on the navigation bar.
- 2** Click the **Sample** tab.
- 3** Type the order ID in the **ID** box and press Tab.
- 4** Right-click anywhere in the **Sample** tab and choose **Delete Order** from the context menu.

The system prompts you to confirm the deletion.

- 5** Click OK.



Complementary information

- You cannot delete an order if the sample is on board.
 - Step 4: You can also choose **Edit > Delete**.
-

Results

Reviewing and validating results



This chapter describes the **Results** work area and how to use it. It shows you how to review results for samples, calibrations, and controls. You can also validate results and rerun tests.

You find more information on result handling in Chapter 10 *Calibration* and Chapter 11 *Quality controls*.

In this chapter

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About results

Result handling and the way that information is displayed in the **Results** work area is determined in the system configuration. The sections below give examples:

Result handling

You can specify what happens to flagged and unflagged results. The possible automatic actions following a flag are **None**, **Accept**, **Stop Test**, or **Rerun**; the options available depend on whether the result was for a sample, calibration, control, or calculated result.



When an automatic rerun is performed, the dilution is the same as that used for the last request.

Typically, the system is set up to automatically accept unflagged results. They are then displayed in the **Sample**, **Calibration**, and **Quality Control** tabs in the **Results** work area. Flagged results are usually displayed in the **Validate** tab in the **Results** work area so that you can review them, and either accept them manually, or rerun them

Flags and recommended actions on page C-5

Raw data

You can specify how long raw data are kept in the database in **Configuration > Database > Automatic Actions**. You can look at raw data values and a graph of the raw data over time in the **Results** work area.

To review rate information for a result on page B-99

Lab. units

If you want to use units that are different from the predefined standard units, you can specify laboratory units as part of the test definition (**Configuration > Tests > Laboratory**). Enter one of the appropriate conversion factors that are mentioned in the Instructions for Use.

Comparing results between analyzers

If you want to compare results from the analyzer with results from another analyzer or methodology, you can specify a factor and an offset value (in **Configuration > Tests > Laboratory**) to accommodate operational differences between the two analyzers or methodologies. The system applies the factor and offset to the results before displaying them in the **Results** work area.

Calculated Results

A calculated result is a mathematical relationship involving one or more test results, and optional numerical constants. You can define calculated results for tests (in **Configuration > Calculated Results**), and specify how to handle calculated result flags (in **Configuration > Result Handling > Calculated Results**). The system automatically calculates a calculated result if all the tests specified in the calculated result are requested in an order.



When tests are requested in duplicate, the calculated result is only calculated for the first run of the test.

Reference ranges

You can define a general reference and a critical range for each test in **Configuration > Tests > Evaluation**. If the test result falls outside the defined range, the settings in **Configuration > Result Handling** determine what happens next.

Automatic dilutions

You can specify up to four automatic dilution factors for each test (in **Configuration > Tests > Dilutions**). The automatic dilution factors are used only when **Automatic Dilutions** is set to **Sequential**.

Purging results Results are stored in a database on the hard disk. You can purge completed results to maintain disk space (**Tools > Purge Results**). If the analyzer is connected to a host, the results are considered to be completed when they have been transmitted. Without host connection, the results are considered to be completed when they have been accepted.

👁 *Purging results on page D-66*

Results at a glance

Use the following tables to locate specific tasks by work area and tab.

Work area	Tab	Tasks
Status 	Missing & Blocked	Review missing and blocked orders and requests that could not be run (no results).
	Samples	Review samples on board. The color shows the status. double-click a rack position to display the details of the selected sample.
	Analyzer	Review the number of pending or blocked tests and the number of results to validate.
Orders 	All tabs	No results are available in the Orders work area.
Results 	Validate	- Review unaccepted results for orders, calibrations, and controls. - Accept sample, calibration and control results that have not been automatically accepted. - Rerun tests as original or with dilution. - Rerun calibrations and controls as original. - Monitor controls over time. - Review rate information for unaccepted sample, calibration, and control results. - Find specific orders. - Display specific information by selecting filter options.

Table B-21

Work area	Tab	Tasks
	Sample	- Review all results (whether accepted or not) listed by order ID or date. - Find results of specific orders. - Display specific information by selecting filter options. - Review details for specific tests or orders.
	Calibration	- Review calibration curve parameters for a specific test. - Review calibration details in graphical form or as raw data.
	Quality Control	- Review QC results graphically by tests or controls. Use the From button to review only a selection of QC results. - Select the control mode (precision, accuracy, or limit). - Review statistics for each control mode. - Review details for QC results (including lot numbers). - Display specific information by selecting filter options.

Table B-21

Use the following table to locate specific tasks in the **Configuration** work area:

Icon	Tab	Tasks
	Laboratory	- Specify correlation factor and offset for each test. - Specify for each test lab units, and a conversion factor if necessary. - Specify quality controls for each test.
	Evaluation	Specify the result evaluation mode for each test (reference ranges, cut-off limits).
Database 	Automatic Actions	Specify the period after which result raw data is automatically deleted.
Result Handling 	All tabs	Turn result handling on or off.
	Calibration	Specify actions for flagged and non-flagged calibrations for each test class.
	Quality Control	Specify actions for flagged and non-flagged control results for each test class.
	Sample	Specify actions for flagged and non-flagged sample test results for each test class.
	Calculated Results	Specify actions for flagged and non-flagged calculated results.

Table B-22

Results work area overview



To access the **Results** work area, click Results on the navigation bar.

The **Results** work area has the following tabs:

Tab	Function
Validate	This tab lists orders, calibrations and controls that either require validation, are blocked, or are not on board. You can accept a result or rerun it. You can request a dilution for tests that you decide to rerun.
Sample	This tab lists all results of all orders.
Calibration	Use this tab to review the calibration results and the calibration history of a test.
Quality Control	Use this tab to review the quality control history of a test. Results for the quality controls are displayed graphically, allowing you to quickly locate those that are out of range.

Table B-23

Context menu

You can right-click a sample, order, calibration, control or result in any tab to display the context menu. It contains one or more of the following frequently used commands:

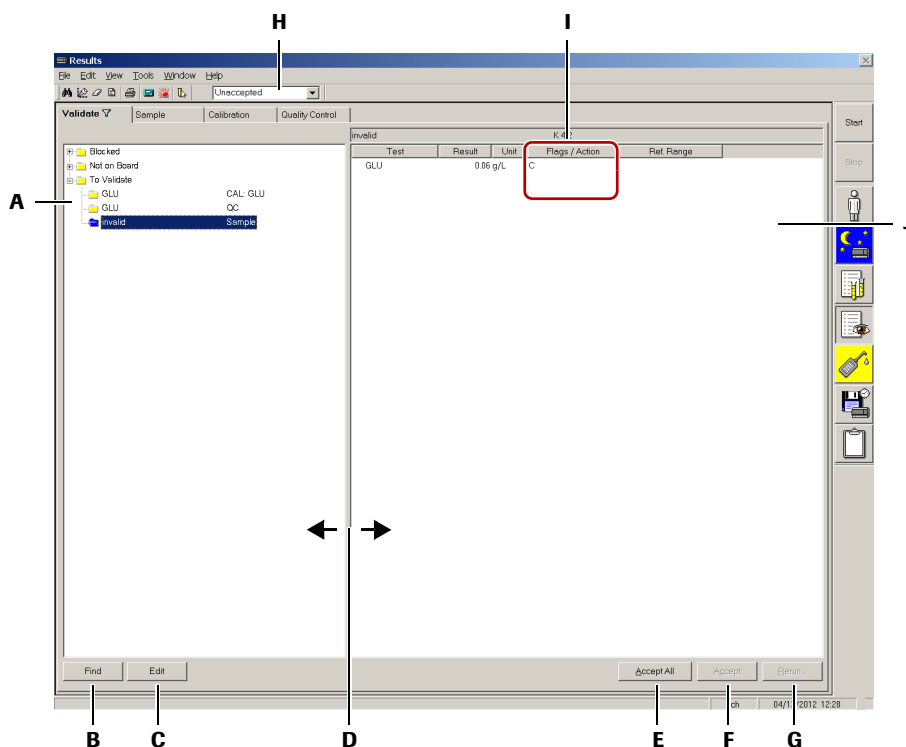
Context menu item	Function
Accept	Accepts the selected result.
Accept All	Accepts all the results in the list.
Delete	Deletes the selected item.
Detail	Displays detailed information for the selected item.
Demographics	Displays demographics for the selected order.
Edit	Displays the appropriate tab on the Orders work area.
Exclude from statistics	Excludes the selected control result from statistics. The result is grayed out in the Quality Control tab.
List by	Switches between the available column headings to determine how the list is sorted.
Print Preview	Displays the report on-screen for you to review or print.
Rerun	Reruns the selected item.
Retransmit	Sends the results to the host again. This option is only available if retransmitting is enabled (Configuration > System > Processing > Result Output).
Statistics	Displays statistical information for the selected result.
Test Status	Displays information on the status of the test for the selected calibration or control.

Table B-24

Validate tab



The **Validate** tab lists all results that have not been automatically accepted. You can accept the result or rerun it. Use the flag information to help you to make the decision.



- A** The **Validate** list shows orders, calibrations and controls whose results have not been accepted, are blocked, or are not on board. STAT orders are listed in bold type.
- B** Use **Find** to display the results of a particular order.
- C** Use **Edit** to modify a selected order. You are transferred to the appropriate tab in the **Orders** work area.
- D** To resize the columns, position your cursor here and click and drag the divider to the left or right.
- E** Accept all results currently displayed in the **Results** list.
- F** Accept the selected result(s).
- G** Rerun the selected test with dilutions. The **Dilutions** dialog box is displayed.
- H** The **Results** list shows results for the selected order, calibration, or control.
A paper clip at the beginning of the line indicates a comment in the detail dialog box.
An asterisk at the beginning of the line indicates an accepted test. You only see asterisks in the **Validate** tab if the option in the list on the toolbar is set to display all results rather than only the unaccepted ones.
- I** Flags are shown for each result. (Only the flags with the highest priority are displayed. Double-click the result line to display detailed information on all flags.)
The results line is grayed out and the **Flags/Action** column shows **Reactivated** if a rerun has been requested.
- J** From the list, select whether you want to display all results (**All**) or only the unaccepted results (**Unaccepted**)

Figure B-24



Complementary information

- The **Validate** tab can contain the following folders and information:
 - Blocked:** Orders with at least one test with the **Blocked** status
 - Not On Board:** Orders for which there are tests to be performed, and for which the sample is not on board the system.
 - To Validate:** Orders with results that need validating.
- Only folders that contain entries are displayed in the **Validate** list.
- To follow the logical job sequence, work through the entries in the list from top to bottom.
- Click a sample, calibration, or control order in the **Validate** list to display the corresponding results on the right side of the tab.
- Double-click any item in either of the lists to display more details for that item.
- Right-click an order and choose **Demographics > Order** to display the order demographics for the selected order.
- The reference range for the test is shown by the parentheses (---). The asterisk * shows the position of the result compared with the reference range:
 - *--(---)--- Result less than the reference range.
 - <--(---)--- Result much less than reference range.
 - (*-)--- Result inside the reference range.
 - (---)--> Result much greater than reference range.
 - (---)*- Result greater than the reference range.
- Press F1 to display Help for this tab.
- To display Help on a blocked test, select the test on the **Results - Detail** dialog box, and press F1.

Factors affecting the information you see here

The information displayed depends on how your system has been set up:

- The settings in **Configuration > Results Handling** determine which results are automatically accepted and which must be manually validated here. Typically, results without flags are accepted automatically; orders are listed only if they contain one or more flagged result.

Accepted orders are displayed in the **Sample** tab.

- The units displayed depend on the lab units defined for your system in **Configuration > Tests > Laboratory**.
- There are two options in the filter list on the toolbar:

Unaccepted: Only unaccepted results are displayed.

All: All results are displayed. Results that have been accepted are marked with an asterisk.

If you choose **Unaccepted**, the filter icon  is displayed on the tab label.

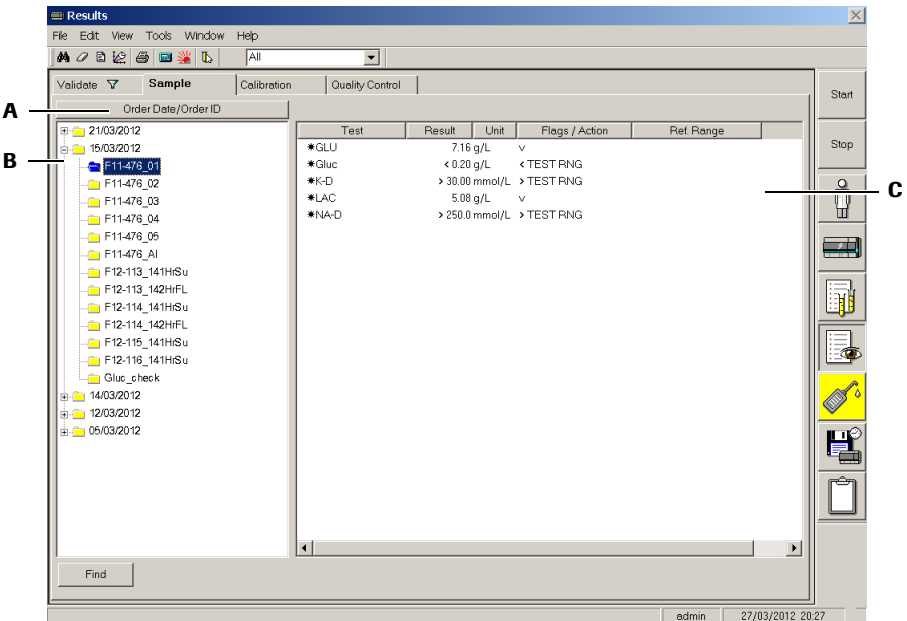
Sample tab



Use the **Sample** tab to review result information of all orders on the system. This includes accepted and unaccepted results.

The functions on this tab are similar to those on the **Validate** tab.

👁 **Validate tab** on page B-90



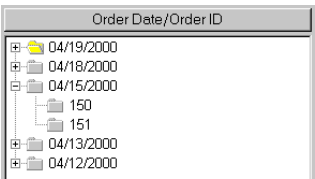
- A** Change the display in this column by clicking the column header.
- B** The orders list contains orders with unaccepted and accepted results.
- C** The results list contains all results for the selected order.

Figure B-25



Complementary information

- Click the column header at the top of the list to switch between views:
Order Date/Order ID



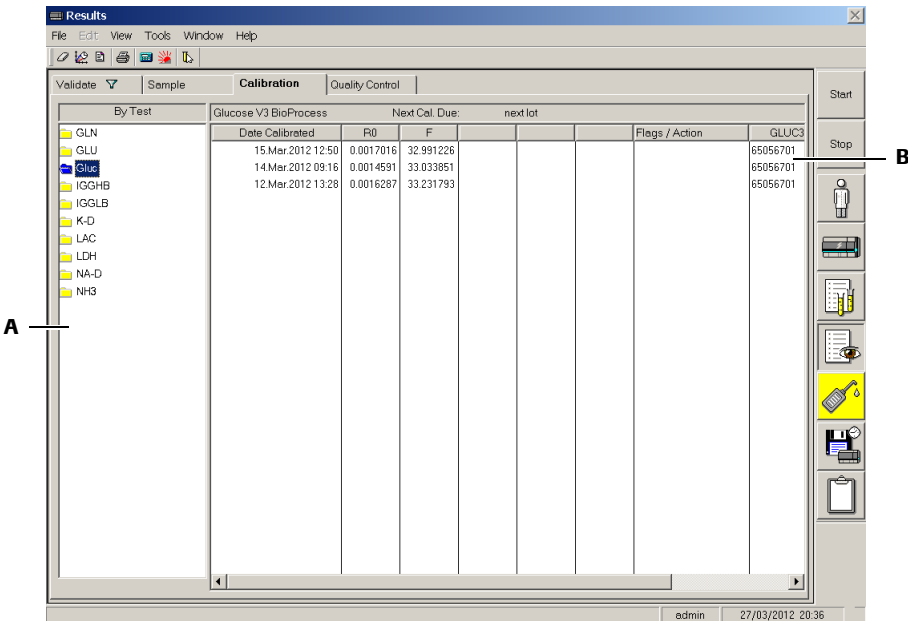
- The samples and orders list has a mnemonic search facility; click anywhere in the list and type the first few characters of the item you are trying to find.
- Select **All** or the user defined filter in the filter list on the toolbar to define what information is displayed on the tab.
- Press F1 to display Help for this tab.

Calibration tab



Use the calibration tab to review the calibration history of each test. The functions on this tab are similar to those on the **Validate** tab.

👁 **Validate tab** on page B-90



A The **Test** list shows all the tests on the system.

B The **Results** list shows the calibration history for the selected test.

Scroll right to display flags and actions, and test and calibrator lot numbers.

If a dotted line is displayed in the **Date Calibrated** column instead of the date, the calibration is running or is not accepted.

If a dotted line is displayed across all the columns, a new calibrator lot has been used.

Figure B-26



Complementary information

- The **Test** list has a mnemonic search facility; click anywhere in the **Test** list and type the first few characters of the test name to find a test.
- Press F1 to display Help for this tab.

👁 *Validating calibration results* on page B-121

👁 *Reviewing calibration history* on page B-123

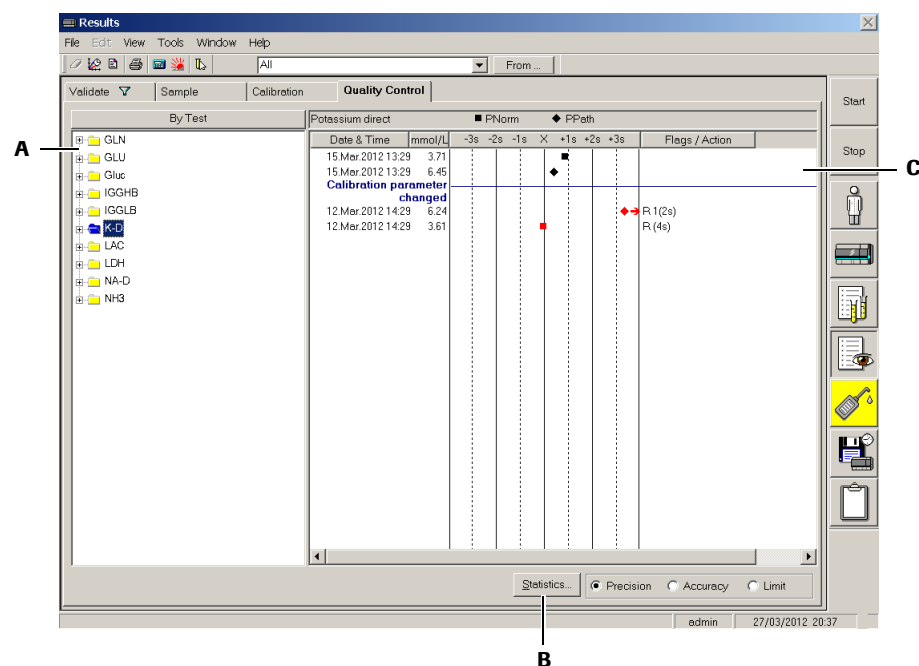
Quality Control tab



Use the **Quality Control** tab to review the quality control history of a test. The functions on this tab are similar to those on the **Validate** tab

👁 **.Validate tab** on page B-90

👁 **Understanding control results** on page B-142



A The **Test** list shows all the tests on the system and their associated controls.

B Use **Statistics** to display statistics for the selected test and its assigned controls. The statistics displayed depend on which control mode (**Accuracy**, **Precision**, or **Limit**) is selected. The **Results QC Statistics** dialog box shows the statistics for the selected test and control(s).

C The **Results** list shows control results for the selected test.

If a dotted line is displayed in the **Date & Time** column instead of the date, the control is running or is not accepted.

If a single control is selected and a dotted line is displayed across all columns, control lot values have been changed.

The results are displayed chronologically, and each time a calibration parameter has changed that was used for calculating a QC, this will be indicated by a separate line and with **Calibration parameter changed** displayed across all columns.

Figure B-27



Calibration parameter changes may be due to:

- A calibration event in the time interval between previous and subsequent QC measurement
- A change of reagent lot or reagent cassette between previous and subsequent QC measurement

In such a case, the change in calibration parameters would also be displayed in the QC report.



Complementary information

- Results are removed from the **Results** work area if you use a new control lot.
- Click the column header at the top of the **Test** list to switch between **By Test** or **By Control**. The option you choose determines how the list is sorted.
- The **Test** list has a search facility; click anywhere in the **Test** list and type the first few characters of the test name to find a test.
- Up to three controls can be displayed for one test. Each control is displayed using a unique symbol (a square, diamond, circle etc.). Flagged results are displayed in red.
- To show results for one control only, select the control.
- Position your cursor over a column heading in the **Date & Time** row (for example, X or 1s) to view the assigned limit and the standard deviations.
- Position your cursor over a result to display the control name and the Westgard rule (if flagged) or the result (if not flagged).
- Right-click a result and choose **Exclude from Statistics** to exclude the selected result from the statistical analysis.
- Select **All** or the last user defined period in the filter list on the toolbar to define what information is displayed on the tab.
To define a period, click **From** on the toolbar and use the **View of QC Results** dialog box to make the definitions.
- Press F1 to display Help for this tab.

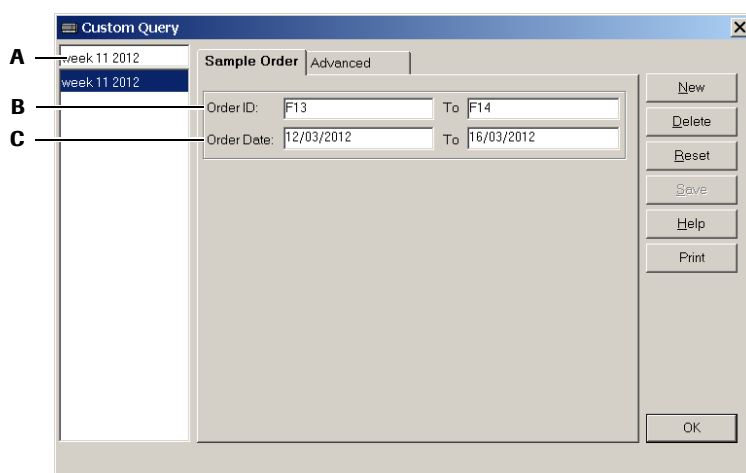
Selecting specific orders

Use the query function to filter orders displayed in the **Sample** result list according to the criteria you specify.



► To select specific orders using a query

- 1 Click **Results** on the navigation bar.
- 2 Click the **Sample** tab.
- 3 Choose **View > Query > Custom**.
A blank **Custom Query** dialog box is displayed.
- 4 Click **New** to display the text boxes.
- 5 Type the information in the boxes as required.
- 6 Click **Save**.
- 7 Click **OK** to run the query.



- A** Type the name of the query.
- B** Specify an order ID range. You can use the wildcards * and ?
- C** Specify date ranges. The date format is dd.mm.yyyy.

Figure B-28

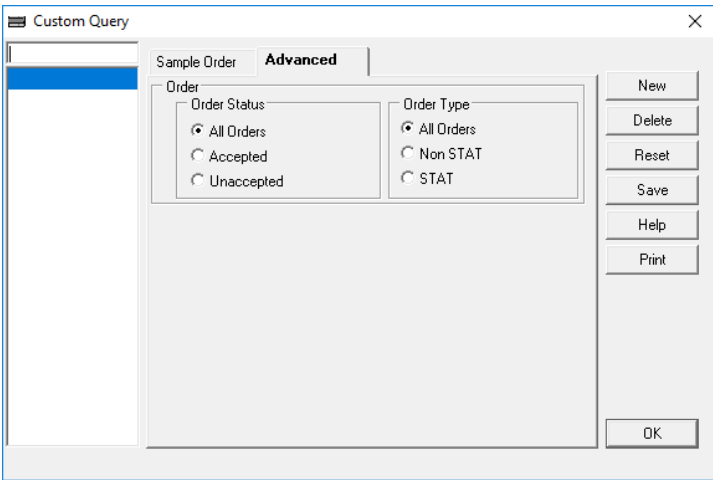
**Complementary information**

- Queries are valid only for the **Sample** tab in the **Results** work area.
- Where you can specify a range of values, you can specify none, a lower limit, an upper limit, or both a lower and an upper limit.
- You can use the wildcards ? (to represent a single character) and * (to represent one or more characters).
- If you do not want results to be filtered, select **All** in the filter list on the toolbar.
- You can run a previously defined query by selecting it in the filter list on the toolbar.

**► To refine a query**

- 1 Click **Results** on the navigation bar.
- 2 Click the **Sample** tab.
- 3 Choose **View > Query > Custom**.
A blank **Custom Query** dialog box is displayed.
- 4 Click **New** and complete the boxes as required.
- 5 Click the **Advanced** tab.
- 6 Specify the refinements that you wish to apply to the query by selecting the appropriate check boxes and options, for example, order status, order type, etc.
- 7 Click **Save**.

8 Click **OK** to run the query.



Displaying detailed information

You can double-click any item in the **Results** work area to get more detailed information. You can also access the same dialog boxes from the menu or by right-clicking the item.



► **To display detailed information for orders**

- 1 Click **Results** on the navigation bar.
- 2 Click the **Validate**, **Sample**, **Calibration**, or **Quality Control** tab.
- 3 Double-click an item in the list on the left side.

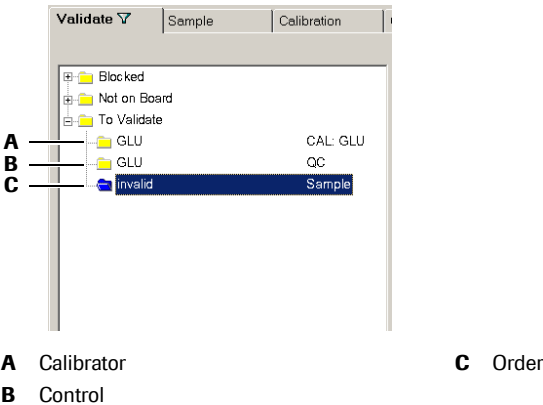


Figure B-29

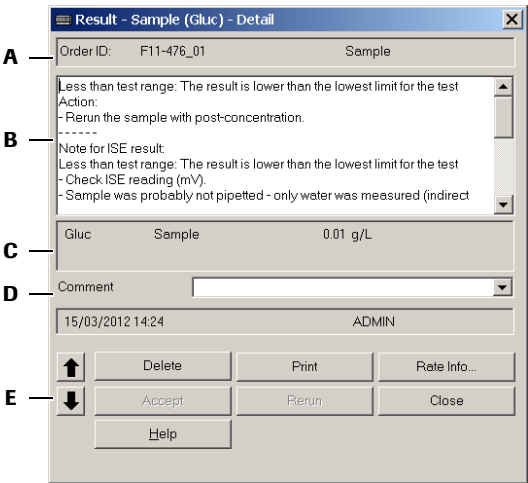
► **To display detailed information for individual results**



- 1 Click **Results** on the navigation bar.
- 2 Click the **Validate**, **Sample**, **Calibration**, or **Quality Control** tab.

- 3 Select an item in the list on the left side.
- 4 Double-click a result line in the **Results** list (on the right side).

The corresponding **Results - Detail** dialog box is displayed. The format of the dialog box is determined by the type of result that you are viewing. For example, when you double-click a sample, the **Sample - (Test) - Detail** dialog box is displayed:



- A Sample and order details.
- B Recommended user actions based on the flags generated.
- C Test name, result value and unit, and reference value(s).
- D You can type text into the **Comment** box, or select a predefined comment from the list.
- E For details on the buttons, see below.

Figure B-30

Buttons

Button name	Function
Delete	Delete this result.
Print	Print a screen shot of this dialog box to the current default printer.
Rate Info	Display rate information for this result.
Accept	Accept the result.
Rerun	Rerun the test. For samples: The rerun result is recorded in addition to the existing result. You can then accept the rerun result. The Reactivated status is added to this entry. For calibrations: The old result is removed from the dialog box. For controls: The old result is frozen and displayed in grey. The Deleted status is added to this entry.
Close	Close this dialog box. Any comments you have added while the dialog box was open, are saved automatically.
Help	Display Help topic for this dialog box.
Up/Down Arrow	Use the arrow buttons to review details of other tests in the same order.

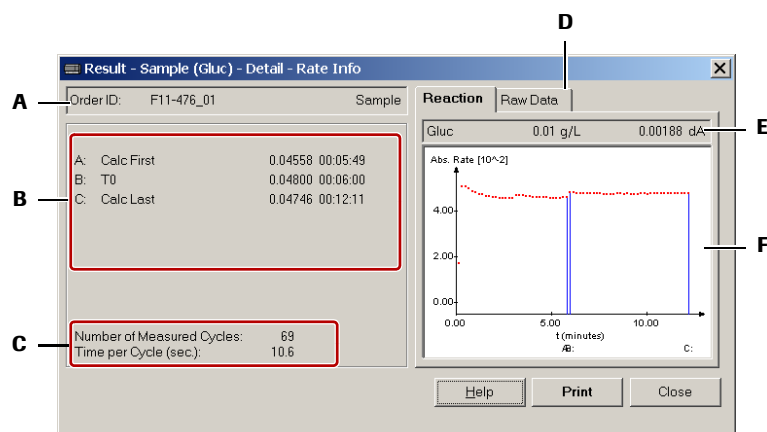
Table B-25



► **To review rate information for a result**

- 1 Click **Results** on the navigation bar.
- 2 Click any tab.
- 3 Select an item in the list to the left to display the results.
- 4 Double-click a result in the **Results** list.
The **Results - Detail** dialog box is displayed.
- 5 Click **Rate Info**.

The **Rate Info** dialog box is displayed. For example:



- A** Order details.
- B** The calculation parameters differ depending on the type of test.
- C** The number of measured cycles and the time per cycle (10.6 sec).
- D** Click the **Raw Data** tab to review the numerical raw data.
- E** Result and rate of the test.
- F** Graph of the raw data over time.

Figure B-31



Complementary information

Raw data is automatically deleted after a number of days (defined in **Configuration > Database > Automatic Actions**).

Working with results



You can perform the following tasks on the **Validate** and **Sample** tabs of the **Results** work area:

- Accept results
- Rerun results
- Delete test results
- Archive results

These tasks are described in the following sections.

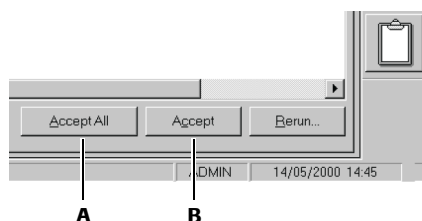
Accepting result or rerunning tests

When one or more results in an order are flagged, all the results for that order are displayed in the **Validate** tab, provided you have chosen **All** in the filter list on the toolbar to display all results. You can accept all of the results, or you can accept some and rerun others. Note that results are flagged to indicate a problem, and you should not accept them without careful consideration.



► To accept a result

- 1 Click **Results** on the navigation bar.
- 2 Click the **Validate** tab.
- 3 In the **To Validate** folder of the **Validate** list, select an order, calibration, or control.
- 4 Select a result and click **Accept**.



A Accept all results which are listed for the selected item.

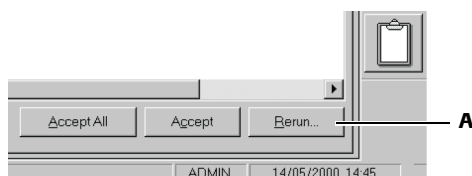
B Accept the selected (highlighted) results only.

Figure B-32



► **To rerun a test**

- 1 Click **Results** on the navigation bar.
- 2 Click the **Validate** tab.
- 3 In the **Validate** list, select an order, calibration, or control.
- 4 Select a result.
- 5 Click **Rerun**.



A Rerun the selected test.

Figure B-33



Complementary information

- When you click **Rerun**, the **Dilutions** dialog box is displayed.
 *Requesting a dilution* on page B-81
- Rerunning a calibration automatically reruns the corresponding controls, and any sample tests for this test, provided the results of the control and tests were not accepted.

Monitoring processes

When the same test has been performed several times for the same batch, you can use the monitoring and statistics facilities to compare the test results over time.

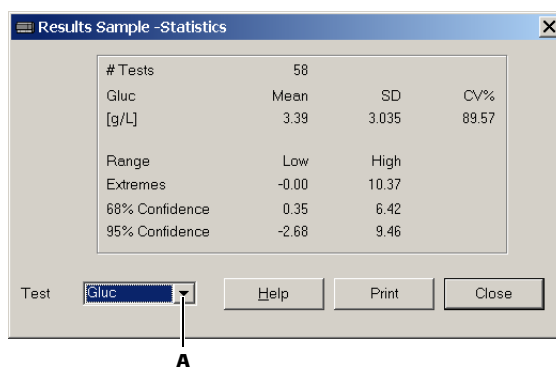


► **To show statistics for results of a batch**

- 1 Click **Results** on the navigation bar.
- 2 Click the **Sample** tab.
- 3 Select an item in the **Orders** list. The corresponding results are displayed in the **Results** list.

- 4 Right-click a result in the **Results** list and choose **Statistics**.

The **Results Sample - Statistics** dialog box is displayed.



- A** Select a different test from the list.

Figure B-34



Complementary information

- If the test selected was a rerun, only the last measured results are included in the statistics.

Deleting information from the Results work area

In the **Results** work area, you can delete test results, orders, samples, and data generated on a particular date. If your system is not set up to perform an automatic purge at BOD, you can manually delete results so that you can re-use order numbers.



Traceability

For each test, a record is generated about exactly which calibrator, quality control, and reagents were used. These records can be collected in a file and exported to an external storage device by using the **Export Traceability File** function.

To ensure reagent traceability, Roche recommends to back up the traceability file every time before you purge results.

► To back up the traceability file

- 1 Choose **File > Export Traceability File**.

A message is displayed asking you whether you want to store the file on an external storage device.

- 2 On the export dialog box, click **Yes**.

A message is displayed asking you to insert an external storage device.

- 3 When you are asked to do so, insert an external storage device.

- 4 On the message dialog box, click **OK**.

- 5 On the export dialog box, navigate to the required folder and click **Save**.

When the traceability file is stored on the external storage device, a message is displayed asking you to remove the external storage device.

- 6 When you are asked to do so, remove the storage device.

7 On the message dialog box, click **OK**.



A copy of the traceability file is automatically stored in the .csv format in C:\Roche\Instrument\Traceability.

Purging results

The analyzer is not designed to store large quantities of results on the system. As part of data management, you should periodically purge results manually. Roche recommends purging results at least every 2 months.

By default, results from sample tests, calibrations, and controls are kept indefinitely.

Purging removes completed results from the system. After purging, these results are no longer available on the system; you cannot retrieve them from the **Results** work area. When requesting statistics information, the statistics values are recalculated on the basis of the remaining test results.

Purging results manually can take considerable time. During this time, the system must remain in **Standby**; you should not attempt to insert a rack while a purge is in progress.

Preconditions for purging results

The system should be in the **Standby** or **Sleeping** state.

A sample test result is purged if "CANT":

- Order complete (C)
- Result accepted (A)
- Sample not on board (N)
- Result transferred to the host, if you work with a host system (T)

The associated order ID is purged as well, provided that

- There are no pending test orders associated with this ID.



Provided the above conditions are met, order IDs are deleted, even when tests were never performed for these orders, for example after inserting a rack with barcoded sample tubes and removing it again.

When purging results, the following information is deleted

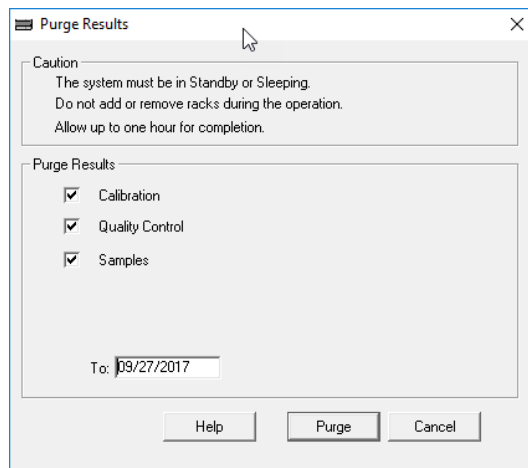
- Results
- Calculated results that were derived from purgeable results
- Test orders
- Order IDs



Before you purge results, you should archive your current calibration, control, and sample results (**File > Archive Results**).

► **To purge results**

- 1 Choose **Tools > Purge Results** on any work area.
- 2 The **Purge Results** dialog box is displayed.



- 3 Select or clear the **Calibration**, **Quality Control**, and **Samples** check boxes to choose the kind of test results you want to delete.
- 4 If you selected the **Samples** box, select the **Purge all samples...** box to delete in a further step all samples that will be without associated orders and results. The samples are deleted irrespective of the date specified on this dialog box.
- 5 In the **To** box, type the date up to which you want to delete the results. All results older than that date will be deleted.
- 6 Click **Purge**.

A status window is displayed while the results are being purged. The purging action may take quite some time, depending on the number of results that need to be deleted.

► **To delete a single result**

- 1 Click **Results** on the navigation bar.
- 2 On any of the tabs, right-click an item, and choose **Delete** from the context menu. The **Confirm Delete** dialog box is displayed. The text on this box tells you exactly what data will be deleted.
- 3 On the **Confirm Delete** dialog box, click **Yes**.

**Complementary information**

Depending on your user rights, this option may not be available to you.

Deleting orders► **To delete an order**

- 👁 For details on deleting orders, see *Purging and deleting orders* on page B-83.



- 1 Click **Results** on the navigation bar.
- 2 Click the **Validate** tab.

- 3 In the **Validate** list, right-click an order and choose **Delete** from the context menu.

The **Confirm Delete** dialog box is displayed. The text on this box tells you exactly what data will be deleted.

- 4 On the **Confirm Delete** dialog box, click **Yes** to delete the order, or **No** to cancel the deletion request.



Complementary information

- You cannot delete an order if a test belonging to that order is running, or if the sample is on board.
 - Deleting an order in this way deletes the sample information for this order, and all accepted results for this sample.
 - You can delete orders in the **Sample** tab in the **Results** work area.
-

**► To delete all orders for a specific date**

- 1 Click **Results** on the navigation bar.
- 2 Click the **Sample** tab.
- 3 Right-click the required date and choose **Delete** from the context menu.
The **Confirm Delete** dialog box is displayed.
- 4 On the **Confirm Delete** dialog box, click **Yes** to delete all the orders or **No** to cancel the deletion request.

Deleting an empty orders folder**► To delete an empty folder**

- 1 Click **Results** on the navigation bar.
- 2 Click the **Sample** tab.
- 3 Right-click the folder in the **Orders** list, and choose **Delete** from the context menu.
The **Confirm Delete** dialog box is displayed.
- 4 On the **Confirm Delete** dialog box, click **Yes** to delete the order or **No** to cancel the deletion request.
- 5 Type 0 (zero) in the **Delete Orders after** box in **Configuration > Database > Automatic Actions**.

Archiving results



This is not a backup facility.

You can save results on the system for future reference. You cannot reload archived results onto the system; you can only review them.

► To archive results

- 1 Click **Results** on the navigation bar.
- 2 Choose **File > Archive**.
The **Archive Results** dialog box is displayed.
- 3 Select the type of results to archive and - optionally - a date range.
- 4 Click **Archive**.
The **Archive Result (File)** dialog box is displayed.
- 5 Select the F disk drive, and specify a folder, file type, and file name for the archive. You can also specify an external storage device.
Use the F drive if you want to review archived results on the analyzer. Use an external storage device to archive results externally.
- 6 Click **OK**.

Reviewing archived results

You can use the review facility to browse the archived results.

► To review archived results

- 1 Click **Results** on the navigation bar.
- 2 Choose **File > Review**.
The **Review (File)** dialog box is displayed.
- 3 Select the folder, file type, and filename from where the results should be read.
- 4 Click **OK**.
The **Review Results** dialog box is displayed.
- 5 Use **Find** to locate a specific test.
- 6 Click **Close**.

Calibration

Working with calibrators and calibration results

This chapter tells you how to load, set up, request, and analyze results for calibrators.

In this chapter	Chapter 10
About calibration	B-109
Calibrators, calibration points, and curve parameters	B-110
Calibrations at a glance	B-112
Reviewing the status of calibrators on board	B-113
What if?	B-113
Displaying the remaining calibration interval for tests	B-114
Viewing missing calibrators	B-115
Loading calibrators on board	B-116
Requesting calibrations	B-118
Postponing a calibration	B-120
Preconditions	B-120
Validating calibration results	B-121
Reviewing calibrations for validation	B-121
Reviewing calibration history	B-123

About calibration

Calibration is the process that establishes a relationship between (one or more) measured rates and the corresponding concentration of the calibrator. The measured rates are derived from analyzer measurements, for example absorbance values.

When calibrations are performed

Calibrations are performed at regular intervals (defined in **Configuration > Tests > General**) to compensate for changes over time in reagents and in the measurement systems. Calibrations also have to be performed when certain physical events occur. These include:

- A change in cassette (reagent) lot.
- An elapse of a defined interval.

Validating calibrations

Each new calibration has to be validated either automatically or manually. No further calibration can be performed until the previous calibration has been validated and the results have been accepted. If flags are generated, you must determine their cause, and decide whether to accept or rerun the calibration. If a calibration for a particular test is not valid, all the results obtained with that test should be checked.

Lot numbers

The exact compositions of calibrators and reagents vary between lots. Therefore, it is important to check the lot numbers each time you replace a cassette or a calibrator. If you do not update the lot numbers and values recorded on the analyzer, erroneous results can occur.

Calibration modes and calculations

Each calibration is assigned to a calibration mode by the manufacturer. Each mode represents a type of calibration curve and calibration curve parameter. From the calibration measurements, the system calculates the values of the appropriate parameters (called curve parameters) based on the calibration mode.

Calibrators, calibration points, and curve parameters

Linear calibrations Tests for most enzymes and substrates have linear calibration curves, which require only a two-point calibration.

For a linear calibration:

- A two-point calibration is used; one calibrator has a known amount of analyte, the other is water, which is the zero calibrator.
- There are two curve parameters to be determined, known as F and R_0 .
- The calibrators are placed next to each other on a sample rack. The calibrator with the highest concentration must be placed first (lower numerical position) on the rack.

Non-linear calibrations Tests for some specific proteins have non-linear calibrations.

For a non-linear calibration:

- Between four and six calibration points are used, depending on the calibration mode.
- There are four (K_C , R_0 , A, B) or five (K_C , R_0 , A, B, C) curve parameters, depending on the calibration mode.
- The calibrator is supplied as either a set of bottles or a single bottle from which the individual calibrators are made up automatically.

With a single calibrator and automatic dilution:

- There is only one calibrator to place on a rack.
- The system automatically makes up different dilutions of the calibrator to produce the required calibration points.

With a multi-calibrator set:

- Each calibrator has a different concentration of the analyte.
- The calibrators are placed in order on a rack with the calibrator with the highest concentration in the lowest numerical rack position.
- The software identifies individual calibrators as Std-1 (highest concentration), Std-2 (next highest concentration) and so on.
- All the calibrators in the set must be placed in adjacent slots on the same rack.

Calibration modes Possible calibration modes are shown in the following table:

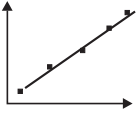
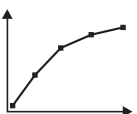
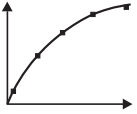
Calibration mode	Attributes
Linear regression 	Calibration curve: A straight line based on a calculated slope and offset. Number of calibration points: 0 - 6 Curve parameters: R_0, F - If no calibrators are used, both curve parameters, R_0 and F, are specified in the test definition file. - If one calibrator is used, one of the curve parameters, R_0 or F, is specified in the test definition file.
Linear interpolation 	Calibration curve: A straight line between adjacent points only. Number of calibration points: 3 - 6 Curve parameters: None
Logit/log 4 	Calibration curve: A curve characterized by the logit/log 4 formula, which has four calculated parameters. Number of calibration points: 5 - 6 Curve parameters: R_0, K_C, A, B
Logit/log 5 	Calibration curve: A curve characterized by the logit/log 5 formula, which has five calculated parameters. Number of calibration points: 5 - 6 Curve parameters: R_0, K_C, A, B, C
Spline 	Calibration curve: A curve characterized by the spline formula. Number of calibration points: 3 - 6 Curve parameters: None

Table B-26

Calibrations at a glance

Use the following table to locate specific tasks by work area and tab.

Work area	Tab	Tasks
Status 	Missing & Blocked	Review calibrators that cannot currently be used by the system, for example because they are not on board, expired, or some additional item such as a diluent is missing.
	Samples	- View calibrators on board; color shows the status. - Click a position to display the details for the selected calibrator.
	Test Status	Review test with calibrator, intervals, rack position.
Orders 	Calibration	- Review calibration. - Request a calibration. - Postpone a calibration. - Delete a calibration request. - Use Place Items or Sample Handling to manually assign calibrators to rack positions.
	Worklist	Review the status of pending calibration requests during operation.
Results 	Validate	- Review flagged calibrations. - Display the Calibration Definitions dialog and then Rate info. - Accept or rerun an unaccepted calibration. - Delete a calibration (if there are no dependent test results).
	Calibration	- Review calibrations by test. - Review curve parameters. - Review the calibration history. - Display the Details dialog to review data for individual calibrations, for replicates, and rate info. - Rerun or accept a calibration from the Details dialog.

Table B-27

Use the following table to locate specific tasks in the **Configuration** work area:

Icon	Tab	Tasks
Tests 	General	Specify calibrator, sample type, and interval for a calibration and whether replicates are to be run. Roche recommends to perform calibrations in duplicate.
	Calibrators	Specify a calibration lot number, expiry date, and the assigned values for a selected calibrator and test.
		

Table B-28

Reviewing the status of calibrators on board

You can check the status of the onboard calibrators, for example, to find out when they need replacing.



► To view the calibrators on board

- 1 Click **Status** on the navigation bar.
- 2 Click the **Samples** tab.

Samples, controls, and calibrators are displayed graphically. Cal indicates the presence of a calibrator.

- 3 Double-click a calibrator line to display details. For example:

Calibrator Expired	
GLN Std-2	101-8
Expiration:	30/09/2011 (-180 days)
Lot No.:	57132553

What if?

The calibrator is expired

Replace the expired calibrator with one that is not expired.

- 👁 To load calibrators (with barcodes) on page B-116
- 👁 To load calibrators (without barcodes) on page B-117

The calibrator is empty

Replace the calibrator. Make sure the lot number is the same as the previous calibrator.

If the calibrator is from a new lot, you need to update the lot number first.

- 👁 To load calibrators (with barcodes) on page B-116
- 👁 About calibrator definitions on page G-19

The calibrator is blocked

One or more of the calibrators are not available, or the test cassette is empty. Replace the cassette(s) as required.

- 👁 Blocked orders, tests, calibrations, or controls on page E-22

The calibrator is not on board

Load the required calibrator. Make sure the lot number of the calibrator you load is the same as that specified in the calibrator detail.

The calibrator definitions are missing

The system has detected a calibrator, but the calibrator definition is missing or incomplete.

- 👁 Loading and deleting calibrator definitions on page G-21

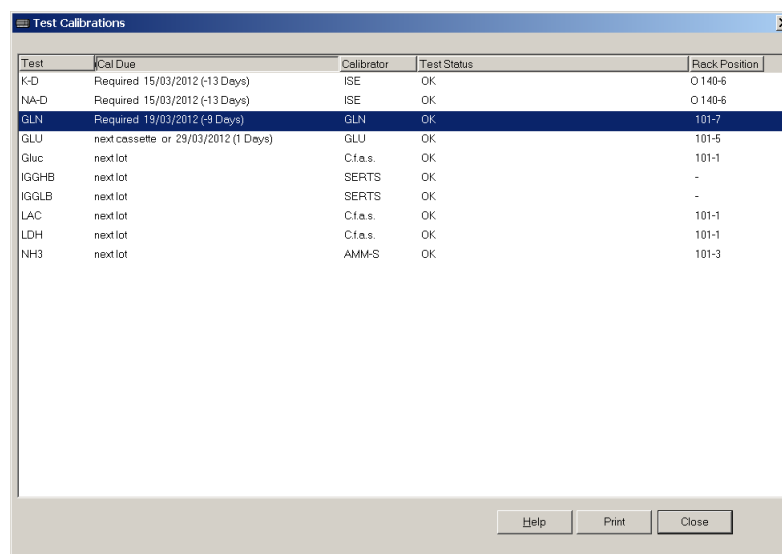
Displaying the remaining calibration interval for tests

Using the **Test Calibrations** function, you can display for all loaded tests, when the next calibration is due.

► To check when a calibration is due

- 1 Choose **Tools > Test Calibrations** on the menu bar.

The **Test Calibrations** dialog box is displayed.



Test	Cal Due	Calibrator	Test Status	Rack Position
K-D	Required 15/03/2012 (-13 Days)	ISE	OK	O 140-6
NA-D	Required 15/03/2012 (-13 Days)	ISE	OK	O 140-6
GLN	Required 19/03/2012 (-9 Days)	GLN	OK	101-7
GLU	next cassette or 29/03/2012 (1 Days)	GLU	OK	101-5
Gluc	next lot	C.t.a.s.	OK	101-1
IGGHB	next lot	SERTS	OK	-
IGGLB	next lot	SERTS	OK	-
LAC	next lot	C.t.a.s.	OK	101-1
LDH	next lot	C.t.a.s.	OK	101-1
NH3	next lot	AMM-S	OK	101-3



Complementary information

- This function is available from all work areas.
- You can click the **Test Calibrations** button on the toolbar instead of choosing **Tools > Test Calibrations**.
- Place all calibrators on the analyzer before you generate and print the list. (The system updates the calibrator status of onboard calibrators only.)
- Click a column header to sort the list.
- Click **Print** to print a report with the contents of the **Test Calibrations** dialog box.

Viewing rack positions for calibrators

Typically, calibrators have a preassigned rack position on a sample rack. (**Configuration > Lab > Reserve Positions**) You can also specify an *ad hoc* location for a particular calibrator, for example, if you are calibrating a test that does not need calibrating very often. The system may also use barcodes to identify calibrators.

► To view preassigned rack positions for calibrators

If the rack is on board:



- 1 Click **Status** on the navigation bar.
- 2 Click the **Sample** tab.
- 3 Double-click the rack number

The calibration name for each position is displayed.

👁 **Samples tab** on page B-46

If the rack is not on board:



- 1 Click **Configuration** on the navigation bar.
- 2 Double-click **Lab** in the **System** group.
- 3 Click the **Reserve Positions** tab.

👁 *To load calibrators (without barcodes)* on page B-117



Complementary information

You can also click **Place Items** in the toolbar and then select the rack.

Viewing missing calibrators

If a calibration is requested and one or more of the required calibrator(s) are not on board, the missing calibrators are listed in the **Missing & Blocked** tab in the **Status** work area.

► To view missing calibrators



- 1 Click **Status** on the navigation bar.
- 2 Click the **Missing & Blocked** tab.

- 3 Double-click the Not On Board folder in the **Cals, QCs, Diluents, and ISE Solutions** list:

		B
Cal, QC, Diluents, ISE Solutions		
Expired		
A	Not on Board	
	ACCEL	-
	CAL A Std-1	2-1
	CAL A Std-2	2-2
	CAL B Std-1	2-3
	CAL B Std-2	2-4
	CAL D Std-1	10-12
	CAL D Std-1	10-3
	CAL D Std-2	10-13
	CAL D Std-2	10-4
	CONB1	2-5
	CONB2	2-6
	CONB3	2-7

A Missing calibrators identified.

B Rack number and position.

Figure B-35



Complementary information

During operation, missing calibrators are also listed in the **Blocked** folder on the **Worklist** tab of the **Orders** work area.

Loading calibrators on board

There are two ways of loading calibrators, depending on whether the calibrator tube has a barcode or not.

► To load calibrators (with barcodes)

- 1 Prepare each calibrator according to the instructions on the lot specific Instructions for Use.
- 2 Remove the rack from its slot.
- 3 Transfer the calibrators to barcoded tubes on the rack.
- 4 Load the rack into an available slot.

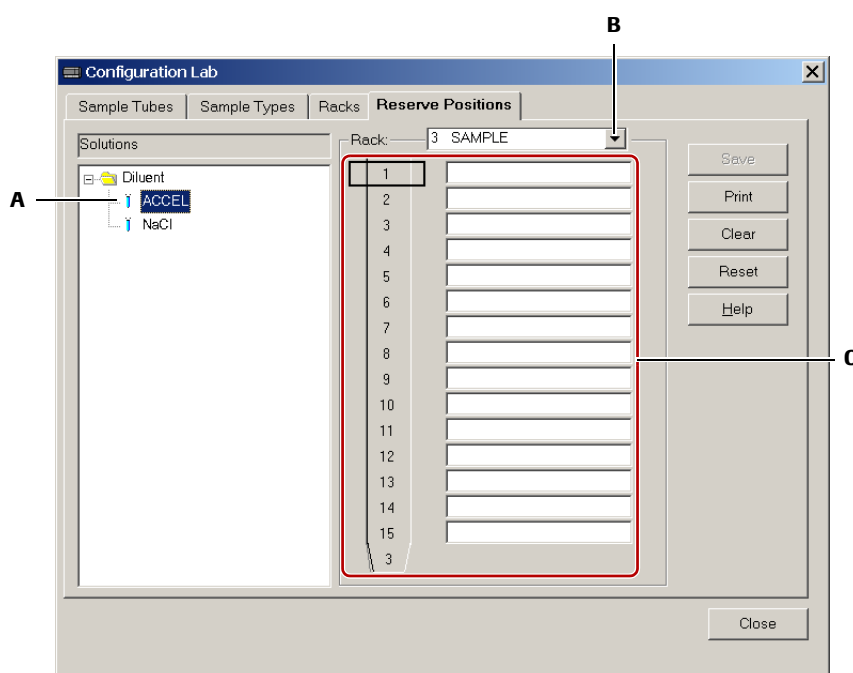


Complementary information

- When you load a multi-calibrator set:
All calibrators must have the same barcode.
Contact Roche for barcode specifications.
The calibrators must be placed consecutively on the rack, in descending concentration order. (Start by placing the most concentrated solution in the available rack position with the lowest number.)
- The barcode scanner identifies each calibrator as the rack is loaded. You do not need to use either the **Reserve Positions** function or the **Place Items** dialog box (if you are using barcodes).
- Use slot I, if available, for calibrators. This slot is in the cassette area, which is cooled. Alternatively, you can use any available slot because the system identifies the rack and its contents as it is loaded.

► **To load calibrators (without barcodes)**

- 1 Prepare each calibrator according to the instructions on the lot specific Instructions for Use.
- 2 Remove a sample rack (preferably the sample rack in the cooled cassette area).
- 3 Click **Configuration** on the navigation bar.
- 4 Double-click the **Lab** icon.
- 5 Click the **Reserve Positions** tab.
- 6 Select the rack from the list (see B, below).
- 7 Open the **Calibrator** folder.
- 8 Drag and drop the calibrator(s) into position on the **Rack** graphic.



- A** Calibrator to place, requires one tube. The number in parentheses shows the number of tubes required on the rack for this calibrator or calibrator set.
- B** Click here to choose the rack number and name of rack type.
- C** The rack is represented as a graphic, and the tubes that have reserved positions on the rack are listed.

- 9 Click **Save**.
- 10 Click **Close**.
- 11 Insert the sample rack.



Complementary information

- Step 8: For a multi-calibrator set, the system automatically reserves the required number of positions, in the correct order. You cannot reserve positions for the calibrators if there are not enough positions (without gaps) available.
- Step 8: The **Move calibrators** icon (that is displayed when you drag calibrators into position) shows the number of calibrators being moved.
- Click **Clear** to remove all the assignments from the rack.
- You can also use the **Place Items** dialog box to assign positions.

Requesting calibrations

Most calibrations are scheduled to run automatically, but you may need to request a calibration:

- If you start a new calibrator lot.
- If you change the test definition.
- If more than one cassette for the test are currently on board.
- If control measurements are outside the specified range.
- If all calibrations of the current lot are manually deleted.



Recommendations

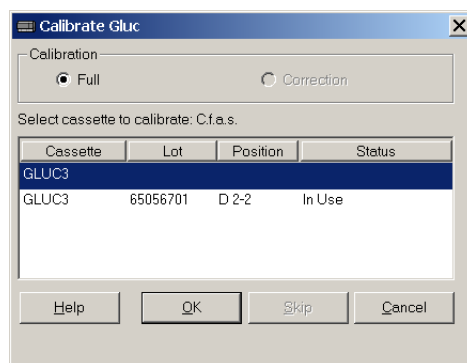
- You should run any related control measurements after a calibration. If the calibration and control are not flagged, you can accept the calibration, provided this is not configured to be done automatically anyway.
- You should not accept a flagged calibration without further investigation.



► To request a calibration

- 1 Click **Orders** on the navigation bar.
- 2 Click the **Calibration** tab.
- 3 In the **Tests & Profiles** group, click the buttons for the tests that you want to calibrate.

If more than one cassette for the test is currently on board, the **Calibrate** dialog box is displayed when you click a test button in the **Calibration** tab in the **Orders** work area.



Select the cassette you wish to use.

4 Click **Save**.

- A** You can select a test or profile for the calibration request by typing its name or number here.
- B** In the **Configuration** work area, tests can be assigned to groups. This feature can be used to reduce the number of tests displayed at one time in this tab. Select another group if you don't see the required test.
- C** Click profile buttons to request calibrations for all tests in the profile.
- D** Click test buttons to request a calibration for the test.
- E** Calibration already requested for this test.
- F** Click **Save** to save the calibration request.
- G** If you select a calibrator here, only the tests that are associated with the calibrator are displayed.
- H** The **Calibrator/Test Summary** lists all current requests for calibrations.

Figure B-36

**Complementary information**

- Only calibrators with current requests are displayed.
 - A full calibration means that all the calibrators defined for the test (up to a maximum of six) must be run. The calibrators must be placed in consecutive positions on the same rack.
 - When precalibrating a second cassette make sure that the corresponding controls are loaded on the analyzer. If precalibration is performed without having the corresponding controls loaded on the analyzer, subsequent QC will be performed using the first calibrated cassette.
 - Manual requests do not reset the automatic intervals until the calibration is accepted.
 - For an ISE Multi-test, selecting a calibration for any ISE test performs the calibration for all electrodes. No additional ISE tests are run until the calibration is accepted.
 - You cannot delete calibrations that are running.
- 👁 *Loading and deleting calibrator definitions on page G-21*
- Press F1 to display Help for this tab.

Postponing a calibration

When the system requests a calibration, you can overrule this request by postponing the calibration.

You can postpone a calibration by moving the due date or event for the calibration. The period by which you can postpone a calibration depends on the way the calibration interval is defined for the test:

Due date or event	Postponement period
Interval	Interval
Each new cassette	Until the next new cassette
Each new lot	Until the next new lot

Table B-29



Incorrect results due to changing calibration intervals

The analyzer is delivered with predefined calibration intervals for each test. The calibration intervals are carefully defined to guarantee reagent performance within the set onboard stability and shelf life of the reagents.

Any change may alter the reagent performance and, as a result, may lead to erroneous results.

- Do not change these default calibration intervals.

Preconditions

The following conditions must be met before you can postpone a calibration:

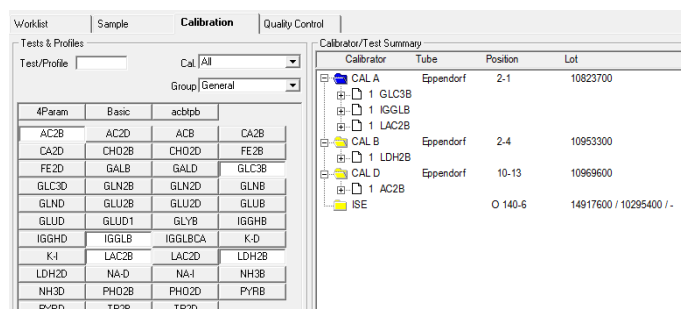
- A sample order exists for the test.
- An automatic calibration for the test is due now (the calibration interval has run out).
- When working with a host, an accepted and unflagged calibration must have been transmitted to the host.
- The test is blocked.

👁 *Folders on the **Missing & Blocked** tab on page B-45*

► **To postpone a calibration**

- 1 Click the **Calibration** tab on the **Orders** work area.
- 2 In the **Calibrator/Test Summary** group, right-click the test that now requires a calibration and choose **Postpone Calibration** from the context menu.

The calibration for the selected test is postponed by the period allowed for this test.



Complementary information

- In the **Calibrator/Test Summary** group, you can also choose **Edit > Postpone Calibration** instead of right-clicking the selection.
- You cannot postpone a calibration in advance. This function is only available while a test is due for calibration.
- You can postpone a calibration more than once.
- Sample and control results calculated with postponed calibrations are marked with “p”.
- Tests with postponed calibrations are listed in the BOD report.
- The fact that a calibration was postponed is recorded in the **View Message** dialog box (**Messages > New Messages**).
- If you select a calibrator in the **Calibrator/Test Summary** group instead of a test, the **Postpone Calibration** option is only available if the calibration can be postponed for all tests using this calibrator.

Validating calibration results

If any result in a calibration produces a flag, the whole calibration must be validated. Calibrations that run without creating flags are accepted automatically, provided the system is configured to do so (**Configuration > Result Handling > Calibration**).

If a calibration is flagged, you should not accept it without further investigation.

Reviewing calibrations for validation

Calibrations that require validation are displayed in the **Validate** tab in the **Results** work area. They are also listed in the **Worklist** of the **Orders** work area.

If a calibration is not accepted, any control or test results that depend on the calibration will be flagged and listed as well.



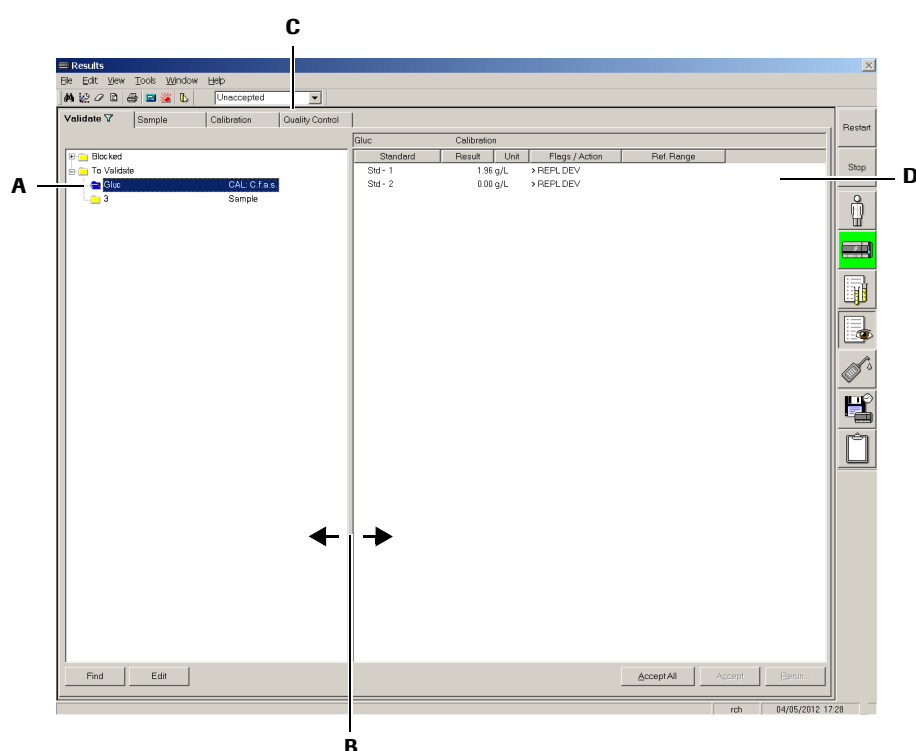
► **To review calibrations for validation**

- 1 Click **Results** on the navigation bar.
- 2 Click the **Validate** tab.
- 3 Select the required calibrator from the **Validate** list.
- 4 Resolve the action required from the flags generated.
- 5 Click the appropriate button:

Accept: Has the same effect as **Accept All**.

Accept All: Accept all the calibration results for the selected calibrator.

Rerun: Rerun the calibration. The current results are deleted. Any control or test that has not been accepted yet will be rerun automatically as well.



- A** The selected calibration.
- B** To resize the columns, position your cursor here and click and drag the divider. Move the divider to the right to reveal the sample type column.
- C** From the list, select whether you want to display all results (**All**) or only the unaccepted results (**Unaccepted**).
- D** These calibration points are flagged. Double-click for more information.
(The paper clip at the beginning of the line indicates that a comment has been entered in the **Details** dialog box.)

Figure B-37



Complementary information

- To view additional details about the calibration, double-click a calibration line.
 *Reviewing calibration history* on page B-123
 - Check to see if the flagged result occurs in more than one replicate.
 - For a flagged calibration, select the calibration, then perform these steps:
Follow the recommended action for each flag. See Chapter 12 *Result flags*.
Check the assigned lot number of the calibrator against the actual lot number on the lot specific Instructions for Use. If these are different, rerun the calibration with the correct calibrator lot.
Check the curve parameters against those of existing accepted calibrations for the same test.
To check individual calibration points, double-click one of the calibration lines to open the detail dialog.
 - Press F1 to display Help for this tab.
-



Recommendations

- You should run the control measurements after a calibration. If the calibration and controls are not flagged, you can accept the calibration, provided this is not configured to be done automatically anyway.
 - You should not accept a flagged calibration without further investigation.
-

Reviewing calibration history

The **Calibration** tab in the **Results** work area shows the calibration history of each test.

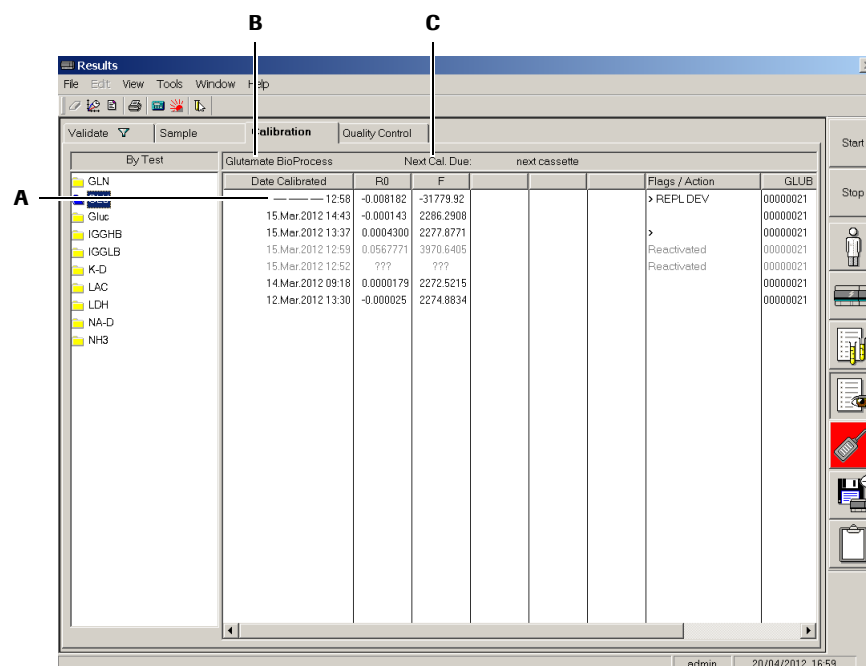
A calibration history lists the date and time, the curve parameters, and cassette lot numbers for the previous and current calibrations of a particular test.

Use the calibration history to review trends (for example, to see if the analyzer is running properly) or to examine a specific calibration in detail. You can display the calibration curve and raw data for each calibration, provided these results have not been deleted.



► **To review the calibration history**

- 1 Click **Results** on the navigation bar.
- 2 Click the **Calibration** tab.

3 Select a test from the **By Test** list.

A This calibration is not accepted (dashed line instead of the date).

B Test name.

C Shows when the next calibration is due.

Figure B-38



Complementary information

- Double-click a calibrator line to display the **Calibration Detail** dialog box.
- Double-click a test in the **By Test** list to show the **Test Status** dialog box.
- A paper clip at the beginning of a calibration line indicates a comment in the detail dialog box.
- Scroll to the right to display lot numbers of the calibrator and reagent.
- A horizontal dotted line shows a lot change of a calibrator.
- Press F1 to display Help for this tab.

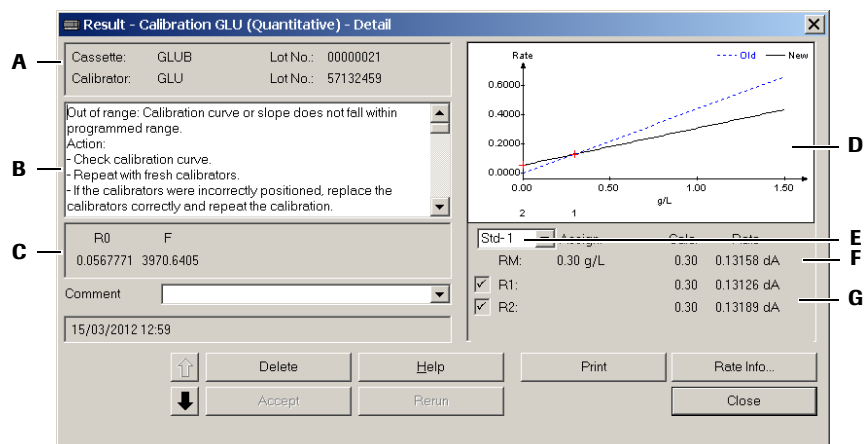
► To review calibration details



- 1 Click **Results** on the navigation bar.
- 2 Click the **Calibration** tab.
- 3 Select a test from the **By Test** list.

4 Double-click a calibration line.

The **Calibration Detail** dialog box is displayed.



A The cassette and calibrator names and their respective lot numbers.

B Recommended user actions based on the flags generated.

C Calibration curve parameters according to the calibration mode.

D Graph of the calibration.

Double-click the graph to expand it.

Drag the cursor along the line to see rate values for each point.

E Calibrator (standard) for which values are listed.

F Mean values for the selected calibrator.

G Replicate values. Select the appropriate check box.

Figure B-39

Buttons

Button name	Function
Delete	Delete this calibration. The calibration results will be lost.
Print	Print details of this calibration.
Rate Info	Display rate information for this calibration.
Rerun	Rerun the calibration. The existing calibration results are deleted.
Accept	Accept this calibration. The values from this calibration will be used from now on to calculate results for this test.
Help	Display Help for this dialog box.
Close	Close this dialog box.
Arrows	Use the arrow buttons to display values for a previous or following calibrator.

Table B-30

► To review rate information for a calibration

1 Click **Results** on the navigation bar.

2 Click the **Calibration** tab.

3 Select a test from the **By Test** list.

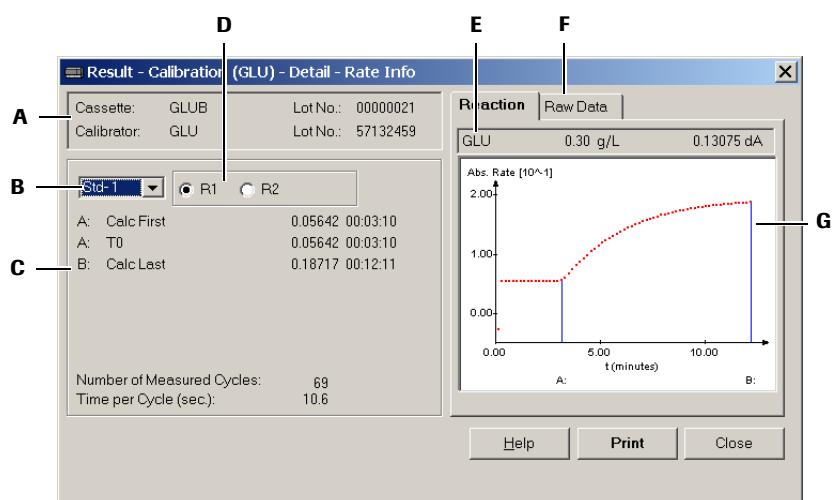
4 Double-click a calibrator line.

The **Calibration Detail** dialog box is displayed.



5 Click the **Rate Info** button.

The **Result Detail Rate Info** dialog box is displayed.



- A** The cassette and calibrator names and their respective lot numbers.
- B** The calibration standard to which this data applies.
- C** Measurement details. The parameters used and the calculation are test dependent.
- D** Select a replicate.
- E** Test name.
- F** Click the **Raw Data** tab to review the numerical raw data vs. cycle number for this calibration.
- G** Kinetic of the reaction; graph of the raw data over time.
Double-click the graph to expand it.
Drag the cursor along the line to see rate values for each point.

Figure B-40

Quality controls

Validating tests to ensure the integrity of your system

This chapter tells you how to load, set up, and request quality controls, and how to analyze quality control results.

In this chapter

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About controls

The analyzer's **Quality Control (QC)** function supports established control rules that can be customized to satisfy individual requirements.

It supports all test groups including routine chemistries, specific proteins and electrolytes. There are three control modes, each with its own set of rules.



Incorrect results due to failing to observe quality control requirements

Failing to observe the QC requirements may lead to incorrect results.

- Check the validity of each calibration with the applicable controls after calibration (QC after calibration) to ensure accuracy of results.
- Roche recommends starting with a three-fold of the value of the standard deviation, 1s, defined in the relevant lot-specific Instructions for Use for the control. However, each lab must determine the appropriate values according to local preferences or requirements.

Control modes

Three modes are recognized: accuracy, precision, and limit. Each is characterized by one or more rules; when the rule is broken, a flag is generated on the control result.

Control mode	Checks whether control results...	Rules and flags
Precision	Have violated rules according to the Shewhart procedure (commonly known as the Westgard rules). Depending on the rules violated, a systematic or random error may have been generated.	Westgard rules: R(1)2s, R10x, R(1)3s, R(2)2S, R(4s), R4(1s)
Accuracy	Are within a range defined by the assigned value of an assayed control and a permissible deviation. When control results are out of range, a systematic error may have been generated.	>ACC RNG (accuracy range exceeded)
Limit	Have exceeded either upper or lower limits.	>Up Limit, <Low Limit (upper or lower limit exceeded)

Table B-31

You can view a single control with any combination of the precision, accuracy and limit modes, if the appropriate definitions are made in the control definition.

Priority of quality control modes

The priority of quality control modes is:

1. Precision
2. Accuracy
3. Limit

Number of controls

Each test can have up to six controls at one time. Only the first three can be used as precision controls.

Controls and test definitions

The test definition defines which controls are used for a test and how often the control is run. You can modify the test definition in **Configuration > Tests > Control**.

Controls at a glance

- Control flags and test results* A control is valid for one test. A control result that meets all the rules for a particular test does not generate any flags and all test results can be automatically accepted, if this option is enabled.
- A control result that falls outside the defined limits generates a flag on that control result. This means that all the results for this test since the last unflagged control require validation. Typically this involves rerunning the control; otherwise, you may have to use other controls or recalibrate the test.
- Accepted control results are automatically removed from the **Validate** tab in the **Results** work area and put into the controls archive in the **Quality Control** tab in **Results**.
- Controls and calibrations* All controls depend on calibrations. If a calibration is flagged, the controls that depend on it are not accepted automatically; they are assigned an “unaccepted calibration” flag.
- Racks and controls* If the tubes containing your controls are barcoded, put them into the correct rack (with the barcode showing) and load the rack onto the analyzer.
- If your system is not configured to use barcodes, use one of these methods:
- Rack positions may have been previously defined for controls (using **Configuration > Lab > Reserve Positions**). Place the controls in the predefined positions and load the rack.
 - Use the **Place Items** (or **Sample Handling**) dialog box to assign rack positions to the controls. Place the controls in the defined positions and load the rack. The rack positions that you assign in this way are cleared at the next **Begin of Day**, provided the associated results were accepted and the racks are not on board.
- Control intervals* Controls are run automatically according to the control interval defined in **Configuration**. You can also request controls manually in the **Orders** work area.
- Printing control reports*  See *Printing Quality Control reports* on page B-34

Controls at a glance

Use the tables below to locate specific tasks by work area and tab.

Work area	Tab	Tasks
Status 	Missing & Blocked	• Review missing controls for the current work load.
	Samples	• View controls on board; color shows the status. • Click a position to display the details for the selected control.
	Test Status	• List tests with QC interval, controls and their rack positions, and whether the control was accepted.
Orders 	Worklist	• Review the status of pending control requests.

Table B-32

Work area	Tab	Tasks
Results 	Quality Control	- Review individual control requests. - Request a control. - Delete a control request.
	Validate	- Review flagged control results. - Display the Control Detail dialog and then Rate info. - Accept unaccepted control results or rerun the control. - Delete a control result (to exclude it from statistics).
	Quality Control	- Review controls by test, or by controls. - Review QC details dialog. - Specify a date range for a listed control. - Switch between Precision, Accuracy and Limit. - Review statistics for a selected control. - Exclude a single control result from statistics. - Monitor control values for a test over time. - Print Quality Control reports.

Table B-32

Use the following table to locate specific tasks in the **Configuration** work area:

Icon	Tab	Tasks
Tests 	Control	- Assign controls to tests. - Specify a control interval for a test and whether QC results are checked for this test.
Controls 	Lot	- Specify a control lot number and assigned values for a selected control and test. - Create a new non-Roche control definition.
Database 	QC Mode	Specify which QC rules are checked for all tests.
Result Handling 	Quality Control	Specify the automatic handling of flagged and unflagged quality control results.

Table B-33

Reviewing the status of controls on board

You can check the status of the controls on board, to find out if they need replacing, for example.



► To view the controls on board

- 1 Click **Status** on the navigation bar.
- 2 Click the **Samples** tab.

Samples, controls, and calibrators are displayed graphically. The legend **QC** indicates the presence of a control.

- 3 Double-click a control to display details about that control. For example:

Control	
PNorm	102-1
Expiration:	30/06/2013 (459 days)
Lot	160344



Complementary information

Double-click the rack number to display name and position of all controls on that rack.

What if?

<i>The control is expired</i>	Replace the expired control with one that is not expired. 👁 <i>Loading and deleting control definitions on page G-26</i>
<i>The control is empty</i>	Replace the control. Make sure that the lot number is the same as the previous control.
<i>The control is blocked</i>	One or more of the tests for this control is not available, for example, the test cassette is empty. Replace or load the cassette(s) as required.
<i>The control is not on board</i>	Load the required control. Make sure that the lot number of the control you load is the same as that specified in the control detail.
<i>The control definitions are missing</i>	The system has detected a control, but the control definition is missing or incomplete. 👁 <i>Loading and deleting control definitions on page G-26</i>

Viewing rack positions for controls

Typically, controls have preassigned rack positions on sample racks that you should use. You can also specify a location for a particular control, for example, if you intend to run control on a test that you do not run very often.



► To view rack positions for controls

- 1 Click **Status** on the navigation bar.
 - 2 Click the **Sample** tab.
- Or:
- Click  in the toolbar to open the **Place Items** dialog box.
- 3 Select a rack from the **Samples on Rack** list and check the positions.

 To load a control if rack positions have been predefined on page B-135



Complementary information

Use **Configuration > Lab > Reserve Positions** to check the reserved positions.

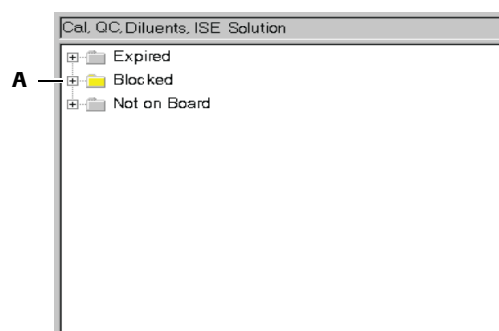
Viewing missing and blocked controls

If controls are requested and one or more of the required control(s) are not on board, the missing controls are listed on the **Missing & Blocked** tab in the **Status** work area, and also on the **Worklist** tab in the **Orders** work area.



► To view missing and blocked controls

- 1 Click **Status** on the navigation bar.
- 2 Click the **Missing & Blocked** tab.



- A** Click the plus sign to open the folder. Controls are listed with their last rack number and position.

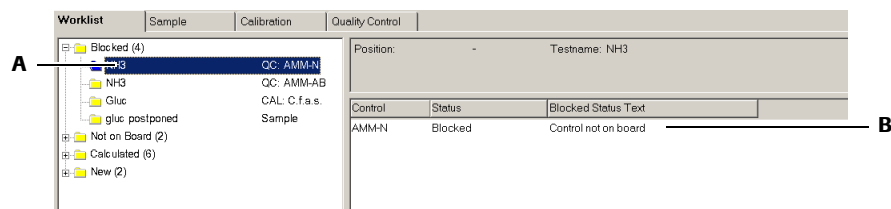
Figure B-41

Reviewing the status of controls on board

Alternatively:



- 1 Click **Orders** on the navigation bar.
- 2 Click the **Worklist** tab.



A Double-click the control to display information on the status of this control.

B The **Blocked Status Text** gives the reason why the control is blocked.

Figure B-42

Reviewing a control definition

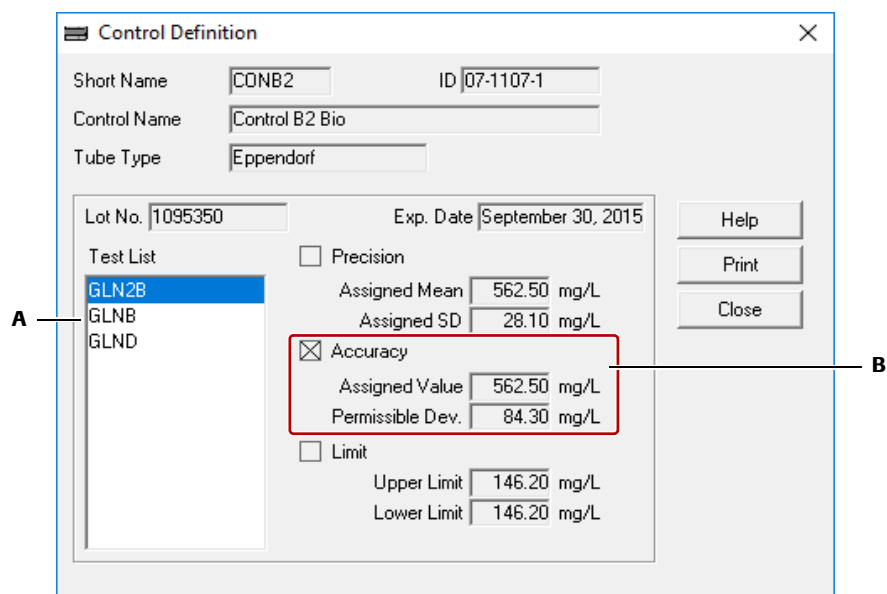
A control definition contains information about a control and the tests for which it is used.

► To review a control definition



- 1 Click **Results** on the navigation bar.
- 2 Click the **QC** tab.
- 3 Double-click a control name.

The **Control Definition** dialog box is displayed.



A List of tests that use the selected control.

B In this example, the **Accuracy** QC mode is selected, and the assigned values are entered.

Figure B-43

Loading controls on board

If the tubes containing your controls are barcoded, place them on a rack (with the barcode showing) and load the rack onto the analyzer.

If your system is not configured to use barcodes, follow one of the following procedures:

► To load a control if rack positions have been predefined

Rack positions may have been previously defined for controls using **Configuration > Lab > Reserve Positions**.



- 1 Click **Status** on the navigation bar.
- 2 Click the **Samples** tab.
- 3 Identify the rack and position of the control from the graphic.
- 4 Remove the rack from its slot.
- 5 Place the control in the specified position on the rack.
- 6 Load the rack into an available slot.



Complementary information

You can use **Place Items** to identify rack and position of the controls. You need to use this method if the rack is not on board when you start the procedure.

► To load a control if rack positions have not been predefined



- 1 Click **Orders** on the navigation bar.
- 2 Click the **Quality Control** tab.
- 3 Select **All** in the **QC** list.
- 4 Select the required control from the **Controls/Test Summary** list.
- 5 Choose **View > Sample Handling**.
- 6 Specify a value in the **Rack** column for the rack number.
- 7 Specify a value in the **Pos** column for the position on the rack.
- 8 Click **OK**.
- 9 Place the control on the rack.
- 10 Load the rack into an available slot.



Complementary information

You can use the **Place Items** dialog box instead of **Sample Handling** to assign controls to rack positions.

Requesting controls

Most controls are run automatically according to the intervals specified for the control in **Configuration > Tests > Control**. You can choose to run controls automatically after a calibration, and when a specified time period has elapsed or a number of tests have been run.

You can request a control manually at any time.



Recommendation

You should not accept a flagged control result without further investigation.

Requesting a control manually

You can request a control at any time in the **Orders** work area.



► To request a control manually

- 1 Click **Orders** on the navigation bar.
- 2 Click the **Quality Control** tab.
- 3 In the **Tests & Profiles** group, click the test for which you want to request a control.

- 4 Click **Save**.



Complementary information

- Step 3: In the **Control/Test Summary**, the name of the test is added to the folder of the required control. (White symbols indicate new tests, gray symbols point to tests with results.)
- Only controls with current requests are displayed in the **Control/Test Summary**.
- Controls for a test are run automatically depending on the test definition.

What if?

I can't see the test I want

- In the **Tests & Profiles** group, select **All** from the **QC** list, or ensure that the group you have selected contains the required test.
- Click the **Class/Group** button in **Configuration > Tests** to find out which tests are assigned to which groups.

Deleting a control request

If you find that you do not want to run a control, you can delete the request.



► To delete a control request

- 1 Click **Orders** on the navigation bar.
- 2 Click the **Quality Control** tab.
- 3 In the **Control/Test Summary**, click the plus sign to open a control folder.
- 4 Right-click the required test name, and choose **Delete** from the context menu.



Complementary information

Controls that are running are grayed out and you cannot delete them.

Reviewing and validating control results

If a control result falls outside the defined limits, a flag is created and you must validate the result. You should not accept a flagged control result without further investigation. Controls that run without creating flags are accepted automatically, provided the system is configured to do so (**Configuration > Result Handling > Quality Control**).

To review flagged control results, click the **Validate** tab in the **Results** work area.

To review control results that have been accepted either automatically or manually, click the **Quality Control** tab in the **Results** work area.

Reviewing controls for validation

Controls that require validation are displayed in the **Validate** tab in the **Results** work area.



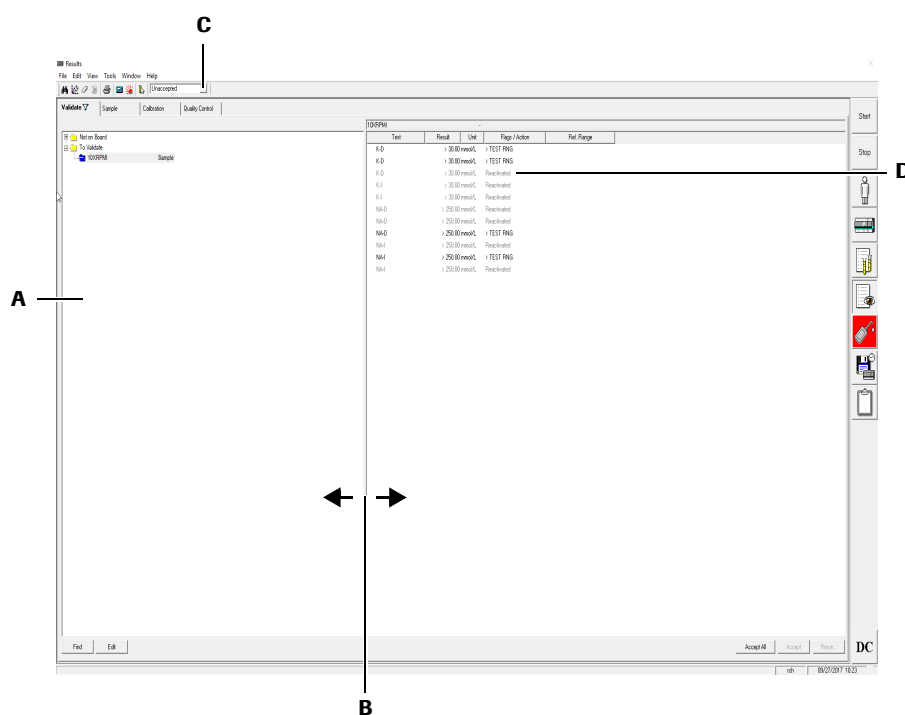
► To review controls for validation

- 1 Click **Results** on the navigation bar.
- 2 Click the **Validate** tab.
- 3 Select the required test from the **To Validate** folder.
- 4 Perform the actions required from the flags generated. (Double-click the control line to display details on the result.)
- 5 Click the appropriate button.

Accept: Accepts the selected control result.

Accept All: Accepts all control results for selected test.

Rerun: Rerun the control. The current results are deleted.



- A** The selected control.
- B** To resize the columns, position your cursor here and click and drag the divider.
- C** From the list, select whether you want to display all results (**All**) or only the unaccepted results (**Unaccepted**).
- D** This control is flagged. Double-click for more information.

Figure B-44



Complementary information

- Double-click the test name in the **Validate** list to view details about the control order.
- Double-click the control result to view additional details about the control.
- For a flagged control, select the control, then perform these steps:

Follow the recommended action for each flag.

Chapter 12 Result flags

Check the assigned lot number of the control against the actual lot number on the lot specific Instructions for Use. If these are different, rerun the control with the correct control lot.

- A paper clip at the beginning of the line indicates that a comment has been entered in the **Details** dialog box.)
- Press F1 to display Help for this tab.

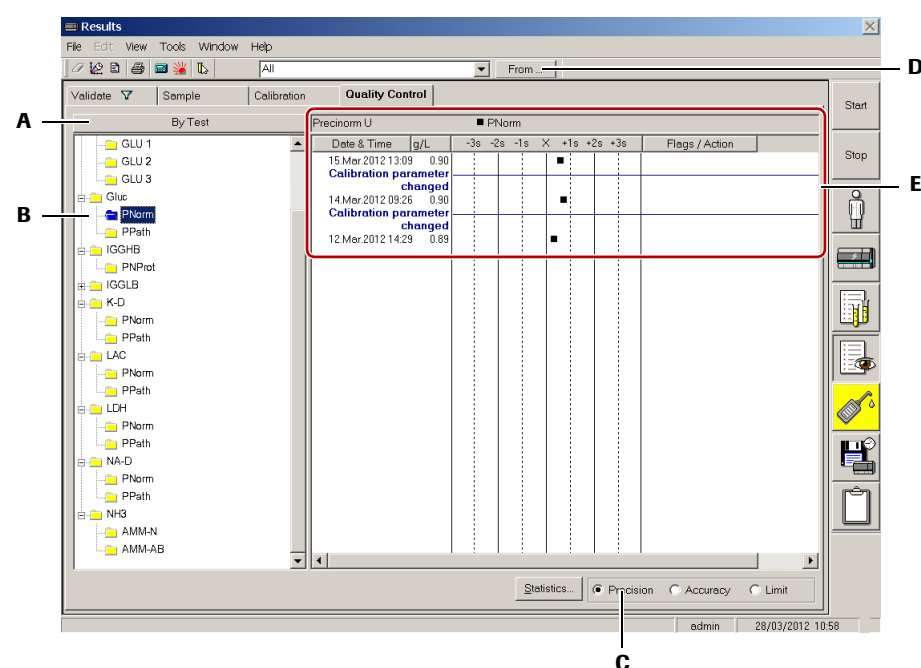
Reviewing control results

Use the **Quality Control** tab in the **Results** work area to review quality control results.



► To review control results

- 1 Click **Results** on the navigation bar.
- 2 Click the **Quality Control** tab.
- 3 Click the column header until it shows **By Test**.
- 4 Click the plus sign to open a test folder.
- 5 Use the **From** button on the toolbar to define a period to reduce the number of results displayed.



- A Click the column header to organize the information by controls or by tests.
- B The folder for the selected test. Each test can have up to six controls.
- C Select the **Precision**, **Accuracy**, or **Limit** QC mode. (The available options depend on the control definition for the selected test.)
- D Use **From** to specify or modify the date range. Only the results within the specified range are listed in the **Results** list.
- E Results are displayed in this area. Each control has a unique symbol.

Figure B-45

👁 Understanding control results on page B-142

Reviewing control statistics



► To review statistics for a specified control

- 1 Click **Results** on the navigation bar.
- 2 Click the **Quality Control** tab.
- 3 Select the **By Control** view.
- 4 Select the required control from the **By Control** list.
- 5 Click **Statistics**.
- 6 Select the required control mode using one of the option buttons.
The **Statistics** dialog displayed depends on the selected mode.



► To review statistics for the controls used by a test

- 1 Click **Results** on the navigation bar.
- 2 Click the **Quality Control** tab.
- 3 Select the **By Test** view.
- 4 Select the required test from the **By Test** list.
- 5 Click **Statistics**.
- 6 Select one of the control mode buttons.
The **Statistics** dialog displayed depends on the mode selected.

Precision controls

The **Statistics** dialog box shows the assigned and calculated values for the mean and standard deviation of selected results for each control.

The following example shows precision controls when a control is selected in the **By Control** list.

Results QC Statistics - Gluc							
Precision Control	Lot	Assigned Mean	Assigned SD	n	Calculated Mean	Calculated SD	Calculated CV%
PNorm	160344	0.87	0.04	3	0.90	0.01	1.02
PPath	163546	2.27	0.11	3	2.27	0.04	1.95

☒ Precision
 ☐ Accuracy
 ☐ Limit

Figure B-46

The following example shows precision controls when a test is selected in the **By Test** list

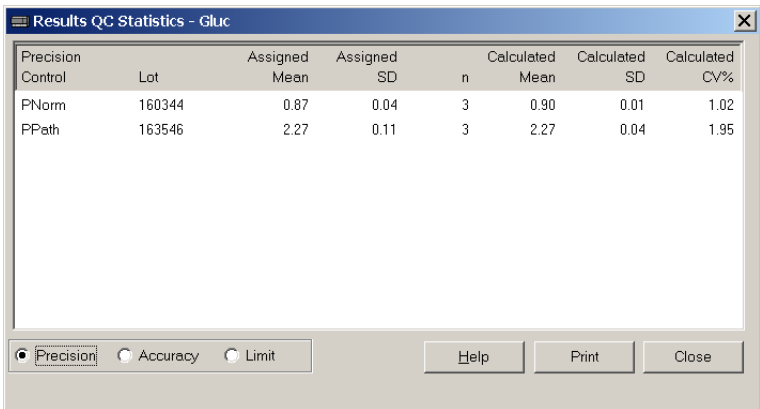


Figure B-47

Accuracy controls

The **Statistics** dialog box shows the assigned value, permissible deviation, the number of results in the statistic (n), the calculated mean, and the calculated bias for the selected results for each control.

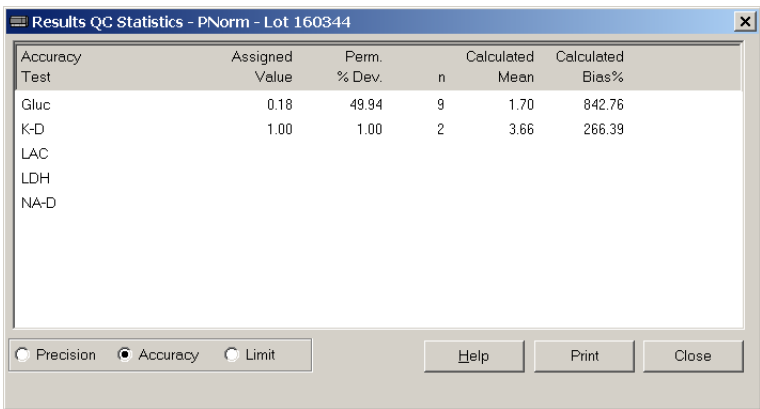


Figure B-48

Limit controls

The **Statistics** dialog box shows the predefined lower and upper limits, the number of results in the statistic, and the calculated mean.

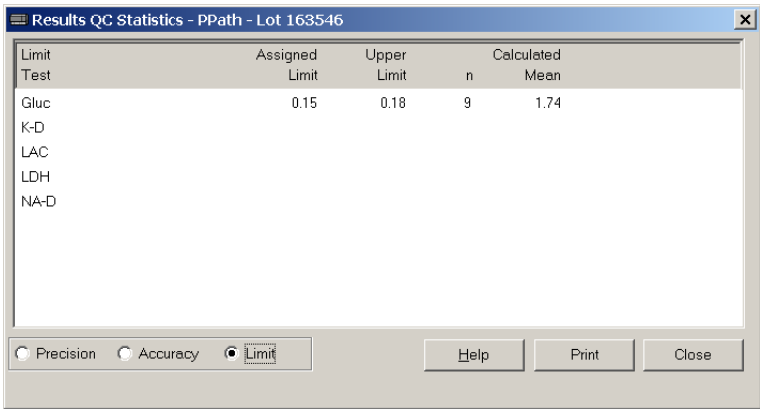
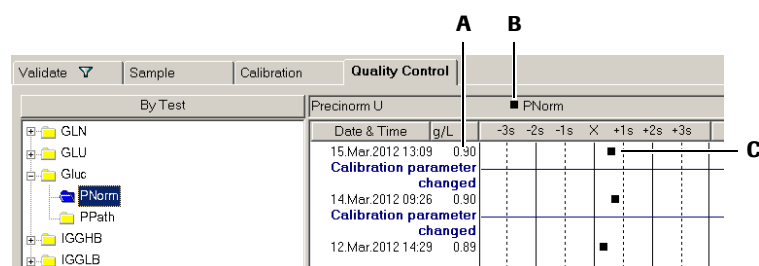


Figure B-49

Understanding control results

Each result for the selected test is displayed numerically and as a point on a graph. The type of graph depends on which QC mode (**Precision**, **Accuracy**, or **Limit**) is selected.



A Numerical control results

B Each control has its own symbol

C Graphical display of a result in terms of the mean and standard deviation (for precision controls)

Figure B-50

The graphical display above shows the results from a single precision control run over a period of time. Vertical lines show the relative positions of the mean and one, two, or three standard deviations on either side of the mean.



Complementary information

- The date for unaccepted controls is displayed as a dashed line.
- A paper clip at the beginning of the line indicates that a user comment has been entered in the detail dialog.
- A horizontal line indicates that the calibration environment has changed: The calibration parameter used for the calculation of the QC result has changed. The reagent lot or reagent cassette has changed between QC measurements.
- To view a different QC mode, select **Precision**, **Accuracy**, or **Limit** in this window.
- Position your cursor over a control symbol to display the control name and the Westgard rule (if flagged) or the result (if not flagged).

Multiple controls

Several controls can be displayed at the same time, depending on the test selected. Each control has its own unique symbol.

With multiple controls displayed, each graph is scaled to its own reference values. For example, for a precision control, the graphs are scaled to the respective mean and standard deviation for each control.



Complementary information

- Take care when making comparisons, because different controls have different scales.
- When you select a test, only the first three controls are displayed, even though up to six controls may have been run. (Only the first three results are used for statistics.)

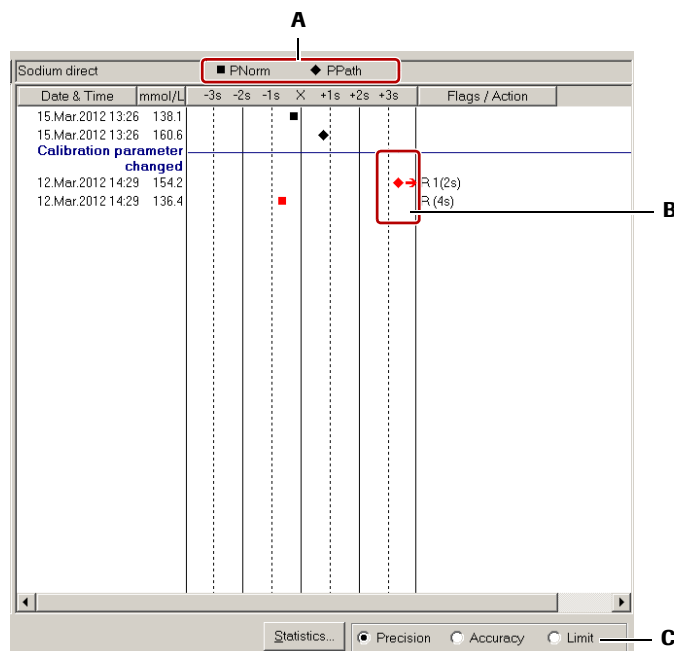
► To review precision controls

- 1 Click **Results** on the navigation bar.
- 2 Click the **Quality Control** tab.
- 3 Click the button at the top of the column until it shows **By Test**.
- 4 Click the plus sign to open a test folder.
- 5 Use the **From** button on the toolbar to define a period to reduce the number of results displayed.



6 Select the **Precision** option (if available for the selected control).

The results are displayed to the left of the graph; the graphical display looks like this:



A Legend showing the symbols for each control.

B Control point(s) outside 3 standard deviations.

C If a control mode is not available for this test, it is grayed out.

Figure B-51



Complementary information

- Red symbols represent flagged results.
- Gray entries represent results that either were excluded from the statistics or have the status **Deleted** (a rerun was ordered).

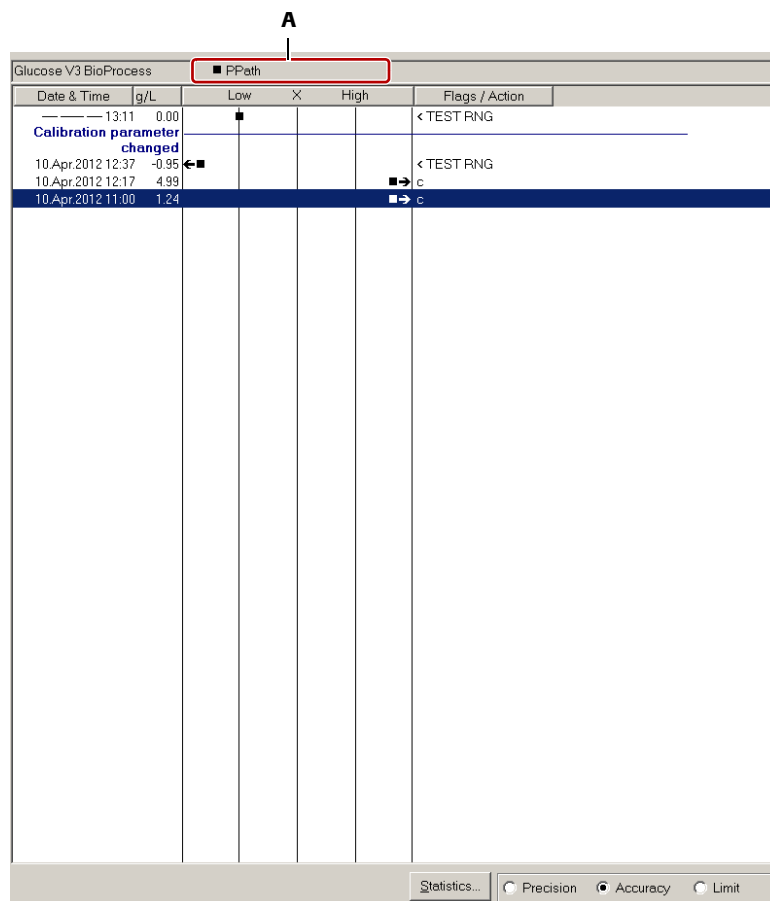


► To review accuracy controls

- 1 Click **Results** on the navigation bar.
- 2 Click the **Quality Control** tab.
- 3 Click the button at the top of the column until it shows **By Test**.
- 4 Click the plus sign to open a test folder.
- 5 Select a control.
- 6 Use the **From** button on the toolbar to define a period to reduce the number of displayed results.

7 Select the **Accuracy** option (if available for the selected control).

The results are displayed to the left of the graph; the graphical display looks like this:



A Legend showing the symbols for each control.

Figure B-52



Complementary information

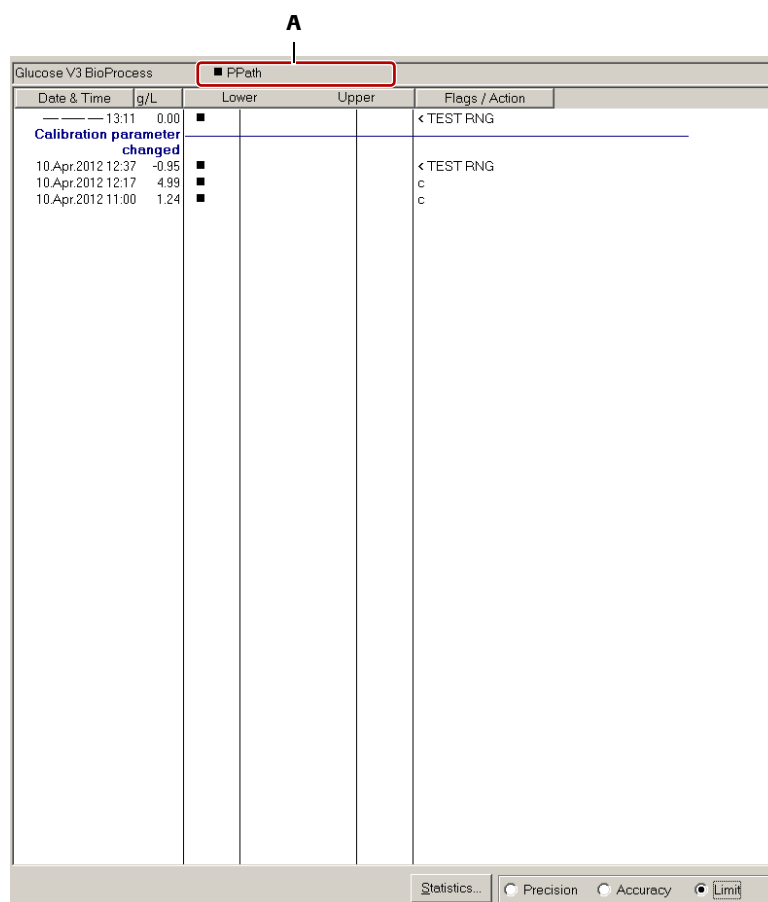
- Red symbols represent flagged results.
- Gray entries represent results that either were excluded from the statistics or have the status **Deleted** (a rerun was ordered).
- For accuracy controls the graph is scaled relative to the assigned value and the high and low values associated with the permissible deviation. Again, each control has its own symbol.



► **To review limit controls**

- 1 Click **Results** on the navigation bar.
- 2 Click the **Quality Control** tab.
- 3 Click the button at the top of the column until it shows **By Test**.
- 4 Click the plus sign to open a test folder.
- 5 Select a control.
- 6 Use the **From** button on the toolbar to define a period to reduce the number of displayed results.
- 7 Select the **Limit** option (if available for the selected control).

The results are displayed to the left of the graph; the graphical display looks like this:



A Legend showing the symbols for each control.

Figure B-53



Complementary information

- Red symbols represent flagged results.
- Gray entries represent results that either were excluded from the statistics or have the status **Deleted** (a rerun was ordered).

Flags

C

12 *Result flags* C-3

Result flags

Understanding flags on results

This chapter lists the flags that can be generated for the results of tests on samples, calibrations, or quality controls.

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About result flags

Flags are displayed and printed together with the results. They are also displayed with the results in the Results and Orders work areas.

Flag groups Flags are grouped according to the measurement method and the way the result is evaluated.

CAL	Flags from calibration measurement and result evaluation.
CNTL	Flags from quality control measurement and result evaluation.
RAT	Flags from calculated result (ratio) evaluation.
TEST	Flags from sample measurement and result evaluation.

Table C-1

Flag priority Within each of the flag groups, a priority level is assigned to each flag, and it is the flag with the highest priority (with the lowest priority number) that is displayed.

Flag display In the results lists on the tabs of the **Results** work area, only one flag is shown. To look at all generated flags, double-click the result, and the flags are explained in the **Details** dialog box.

👁 For details on individual ISE flags and recommended actions, see *Flags and user actions* on page F-41.

Flags and recommended actions

>ACC RNG

Meaning Accuracy range.
For an accuracy control, the result is outside the permitted range.

Recommended action

1. Check if the correct control material has been used.
2. Repeat with fresh control.

Attributes Priority: 53
Group: CNTL

>AG EXCESS

Meaning Antigen excess.
The sample contains an excess antigen and a valid result cannot be calculated.

Recommended action

1. Rerun the test with postdilution.
2. If the flag occurs after dilution, rerun the test using a higher dilution factor.

Attributes Priority: 29
Group: CAL, CNTL, TEST

AIR FLUID

👁 AIR FLUID on page F-43

AIR ISECAL

👁 AIR ISECAL on page F-44

C

<i>Meaning</i>	The result was calculated using an erroneous or corrected calibration which has been accepted.
<i>Recommended action</i>	• CNTL ◦ Repeat calibration. • RAT, TEST a) Review controls. b) Repeat calibration.
<i>Attributes</i>	Priority: 33 Group: CNTL, RAT, TEST

C

<i>Meaning</i>	Result calculated using an erroneous or corrected calibration which has not been accepted.
<i>Recommended action</i>	• CNTL a) Check that the correct calibrators have been used and that the calibrator cups are correctly positioned. b) Check that the correct assigned values are defined in Configuration > Calibrators > Lot. c) Repeat calibration. • RAT, TEST a) Check calibration. b) Repeat calibration.
<i>Attributes</i>	Priority: 32 Group: CNTL, RAT, TEST

CALC ERROR

<i>Meaning</i>	• CAL Calculation error. Nonlinear standard curve cannot be calculated due to calibration error. • CNTL Calculation error. Concentration could not be calculated. • RAT Calculation error. Result could not be calculated. • TEST Calculation error. Concentration could not be calculated.
<i>Recommended action</i>	• CAL a) Repeat calibration with fresh calibrators. b) If the calibrators were incorrectly positioned, replace the calibrators and repeat the calibration. • CNTL ◦ Repeat calibration and control. • RAT a) Check individual results that were used for the ratio calculation. b) Repeat all tests of that sample which are part of this ratio. • TEST ◦ Repeat sample.
<i>Attributes</i>	Priority: 24 Group: CAL, CNTL, RAT, TEST

<Critical Range

<i>Meaning</i>	The result is below the critical low value. Critical ranges are given in numbers. For quantitative tests, results below the defined critical range are presented on the final printout as L (low). For qualitative tests that depend on the direction of the reaction, POS is displayed if the value is above the cutoff limit. (The cutoff limit is defined in Configuration >Tests >Evaluation.)
<i>Recommended action</i>	Follow the laboratory procedure for critical value reporting.
<i>Attributes</i>	Priority: 56 Group: RAT, TEST

>Critical Range

Meaning The result is above the critical high value.

For quantitative tests, results above the defined critical range are presented on the final printout as **H (high)**.

For qualitative tests that depend on the direction of the reaction, **POS** is displayed if the value is above the cutoff limit.

(The cutoff limit is defined in **Configuration >Tests >Evaluation**.)

Recommended action Follow the laboratory procedure for critical value reporting.

Attributes Priority: 57
Group: RAT, TEST

CUR DIR

Meaning Curve direction.

The direction of the calibration curve is incorrect.

Recommended action

1. Check the detail of the calibration.
2. If the calibrators were incorrectly positioned, replace the calibrators correctly and rerun the calibration.

Attributes Priority: 19
Group: CAL

d

Meaning Deleted.

Std. Result (or replicate) has been deleted.

Recommended action

- Request a new measurement.

Attributes Priority: 40
Group: CAL

EP UNSTAB

<i>Meaning</i>	Endpoint unstable. The absorbance values near the endpoint show unacceptable fluctuation.
<i>Recommended action</i>	• CAL a) If only calibration is flagged, repeat with fresh calibrators. b) If flag is on controls and samples also, or repeats on calibration, replace reagent cassette. • CNTL a) If only one control is flagged, repeat with fresh control. b) If the flag is on control repeats and samples, replace reagent cassette. • TEST a) Rerun diluted. b) If only one sample, repeat with fresh sample. c) If flag is on more than one sample, or repeats, replace reagent cassette.
<i>Attributes</i>	Priority: 16 Group: CAL, CNTL, TEST

HIGH ABS

<i>Meaning</i>	High absorbance. The measured absorbance is greater than 2.0 A.
<i>Recommended action</i>	• CAL ◦ Repeat with fresh calibrator. • CNTL ◦ If a single control is flagged, rerun with fresh control. ◦ If more than one control is flagged, perform a calibration. • TEST ◦ If a single sample is flagged, rerun with dilution. ◦ If the problem persists, replace the reagent cassette.
<i>Attributes</i>	Priority: 1 Group: CAL, CNTL, TEST

HIGH ACT

Meaning High activity.
The Absorbance change during measurement exceeds the accepted limit, i.e. the reaction has taken off too fast. Possibility of substrate exhaustion.

Recommended action

- CAL
 - a) Check reaction curve in **Rate Info**
 - b) Check if correct calibrators placed on the calibrator rack.
 - c) Repeat with fresh calibrators.
- CNTL
 - a) Check reaction curve in **Rate Info**.
 - b) Check if correct control placed on the control rack.
 - c) Repeat with fresh control.
- TEST
 - a) Check reaction curve in **Rate Info**.
 - b) Rerun with dilution.

Attributes Priority: 17
Group: CAL, CNTL, TEST

HIGH BKG

Meaning High background noise.

Recommended action

- CAL
 - Repeat with fresh calibrators
- CNTL
 - a) Repeat with fresh control.
 - b) If the flag reappears, check that no fluorescence comes from the control.
- TEST
 - a) If single sample flagged, rerun with dilution.
 - b) If the flag reappears, Check that no fluorescence comes from the sample.

For some tests, you need to dilute the sample with zero calibrators or enclosed diluent.

Attributes Priority: 22
Group: CAL, CNTL, TEST

ISE UNSTAB

👁 ISE UNSTAB on page F-44

<KIN READ

<i>Meaning</i>	Not enough kinetic readings. Insufficient absorbance readings were found in the linear part of the reaction to be able to calculate a rate. Not enough readings in kinetic range for calc mode Kinetic or Kinsearch
<i>Recommended action</i>	• CAL a) Check Rate info - reaction plot. b) Repeat with fresh calibrator. c) If little reaction occurs, replace reagent cassette. • CNTL a) Check Rate info - reaction plot. b) Repeat with fresh control. c) If little reaction occurs, replace reagent cassette. • TEST a) Check Rate info - reaction plot. b) Repeat with dilution if necessary. c) If little reaction occurs, replace reagent cassette.
<i>Attributes</i>	Priority: 21 Group: CAL, CNTL, TEST

LOW ACT

Meaning Low activity.
The absorbance change during the measurement is lower than the defined limit.

Recommended action

- CAL
 - a) Check reaction curve in **Rate Info**.
 - b) Check if correct calibrator was used.
 - c) Repeat with fresh calibrators.
- CNTL
 - a) Check reaction curve in Rate Info.
 - b) Check if correct control was used.
 - c) Repeat with fresh control.
- TEST
 - a) Check reaction curve in Rate Info.
 - b) If the flag is for one sample: Check the sample tube or cup to ensure there is sufficient sample and that there are no bubbles, foam, or clots which could interfere with normal pipetting.
 - c) If the flag is displayed for multiple samples for the same test: Check the reagent pipetting system for clogged or bent needles and ensure the currently used reagent cassette (with status in use) is in place and contains sufficient reagent.

Attributes Priority: 18
Group: CAL, CNTL, TEST

<LOW LIM

Meaning Less than lower limit.
For a limit control, the result is lower than the defined lower limit.

Recommended action

1. Check that the correct control material has been used.
2. Rerun with fresh control.
3. If the flag reappears, check calibration, reagent cassette expiry and reaction curve

Attributes Priority: 55
Group: CNTL

LOW SIGNAL

<i>Meaning</i>	Low signal.
<i>Recommended action</i>	1. Repeat with fresh calibrators and diluent. 2. If the flag reappears, use new reagent cassette. 3. If the flag reappears, contact your Roche representative.
<i>Attributes</i>	Priority: 6 Group: CAL, CNTL, TEST

NO FLUID

👁 NO FLUID on page F-45

NO ISECAL

👁 NO ISECAL on page F-46

NON LINEAR

<i>Meaning</i>	Non-linear. The first and last parts of the reaction curve have different slopes.
<i>Recommended action</i>	• CAL a) Check reaction plot. b) Repeat with fresh calibrator. • CNTL a) Check reaction plot. b) Repeat with fresh control. • TEST a) Check reaction plot. b) Rerun with dilution or concentration if necessary.
<i>Attributes</i>	Priority: 20 Group: CAL, CNTL, TEST

NON MONO

<i>Meaning</i>	Curve not monotonic. No calibration curve could be calculated because the rates of the calibrators were non-monotonic.
<i>Recommended action</i>	1. Check the detail of the calibration. 2. If the calibrators were incorrectly positioned, replace the calibrators correctly and rerun the calibration.
<i>Attributes</i>	Priority: 25 Group: CAL

OUTLIERS

<i>Meaning</i>	Outliers. Air bubbles in the sample or electronic noise may be the cause.
<i>Recommended action</i>	1. Repeat with calibrators free of bubbles. 2. If the flag reappears, contact your Roche representative.
<i>Attributes</i>	Priority: 3 Group: CAL, CNTL, TEST

OUT OF RNG

	 For ISE calibration, see OUT OF RNG (ISE) on page F-46
	This is not a backup facility.
<i>Meaning</i>	Out of range. Calibration curve or slope does not fall within programmed range.
<i>Recommended action</i>	1. Check calibration curve. 2. If the calibrators were incorrectly positioned, place the calibrators correctly and repeat the calibration. 3. Repeat with fresh calibrators. 4. If flag reoccurs, replace reagent cassette.
<i>Attributes</i>	Priority: 26 Group: CAL

p

<i>Meaning</i>	Result calculated using a postponed calibration which has been accepted. <i>Note: Postponing a calibration may lead to erroneous results.</i>
<i>Recommended actions</i>	1. Review results. 2. Perform calibration if necessary.
<i>Attributes</i>	Priority: 35 Group: CNTL, RAT, TEST

P

<i>Meaning</i>	Result calculated using a postponed calibration which has not been accepted. <i>Note: Postponing a calibration may lead to erroneous results.</i>
<i>Recommended actions</i>	1. Check all results carefully. 2. Perform calibration if necessary.
<i>Attributes</i>	Priority: 34 Group: CNTL, RAT, TEST

POL ERR

<i>Meaning</i>	Polarization error.
<i>Recommended action</i>	1. Repeat the measurement. 2. If the flag reappears, contact your Roche representative.
<i>Attributes</i>	Priority: 5 Group: CAL, CNTL, TEST

POS (value)

<i>Meaning</i>	Positive. The sample result is greater than or equal to the cutoff value. (For semi-quantitative tests only.)
<i>Recommended action</i>	No action required.
<i>Attributes</i>	Priority: 66 Group: TEST

POSITIVE

<i>Meaning</i>	Positive. The sample result is greater than or equal to the cutoff value. (For qualitative tests only.)
<i>Recommended action</i>	No action required.
<i>Attributes</i>	Priority: 67 Group: TEST

q

<i>Meaning</i>	The sample result is associated with an erroneous or corrected quality control result. The quality control has been accepted.
<i>Recommended action</i>	1. Repeat the quality control measurement in order to obtain an unflagged control result. 2. Repeat the sample if necessary.
<i>Attributes</i>	Priority: 37 Group: RAT, TEST

Q

<i>Meaning</i>	The sample result is associated with an erroneous or corrected quality control result. The quality control has not been accepted.
<i>Recommended action</i>	1. Repeat the quality control measurement in order to obtain an unflagged control result. 2. Repeat the sample if necessary.
<i>Attributes</i>	Priority: 36 Group: RAT, TEST

r

Meaning Erroneous result.

The result is either erroneous or has been corrected (recalculated) and the result has been accepted.

One or more of the replicates either is erroneous or has been corrected (recalculated) and the result has been accepted.

Recommended action

- CAL
 - Repeat calibration after taking the appropriate action for the associated flag(s).
- CNTL
 - a) Check control performance.
 - b) Repeat control after taking the appropriate action for the associated flag(s).
- RAT
 - Repeat calibration and tests after taking the appropriate action for the associated flag(s).
- TEST
 - Repeat calibration and test after taking the appropriate action for the associated flag(s).

Attributes Priority: 39

Group: CAL, CNTL, RAT, TEST

R

<i>Meaning</i>	Erroneous result. - CAL, CNTL, TEST The result is either erroneous or has been corrected (recalculated) and the result has been accepted. - RAT Result calculated using erroneous sample results which have not been accepted.
<i>Recommended action</i>	- CAL - Check calibrator's reaction curve to establish the cause of the deviation. - Repeat calibration with fresh calibrators. - CNTL - Repeat test with fresh control. - RAT - Review controls. - Repeat calibration. - Repeat sample if necessary. - TEST - Check reaction curve to establish the cause of the deviation. - Repeat test.
<i>Attributes</i>	Priority: 38 Group: CAL, CNTL, RAT, TEST

R 1(2s)

<i>Meaning</i>	Westgard rule 1 violated. One quality control result deviated from the assigned mean (in either direction) by more than 2 standard deviations.
<i>Recommended action</i>	- Repeat with fresh control. - Check that the correct control material has been used. - If the flag reappears, check calibration, reagent cassette expiry and reaction curve.
<i>Attributes</i>	Priority: 44 Group: CNTL

R 1(3s)

Meaning Westgard rule 2 violated.
One quality control result deviated from the assigned mean (in either direction) by more than 3 standard deviations.

Recommended action

1. Repeat with fresh control.
2. Check that the correct control material has been used.
3. If the flag reappears, check calibration, reagent cassette expiry and reaction curve.

Attributes Priority: 45
Group: CNTL

R 2(2s)

Meaning Westgard rule 3 violated.
Two consecutive quality control results deviate from the assigned mean (in the same direction) by more than 2 standard deviations.

Recommended action

1. Repeat with fresh control.
2. Check that the correct control material has been used.
3. If the flag reappears, check calibration, reagent cassette expiry and reaction curve.

Attributes Priority: 46
Group: CNTL

R (4s)

Meaning Westgard rule 4 violated.
The difference between two consecutive quality control results is greater than 4 standard deviations.

Recommended action

1. Repeat with fresh control.
2. Check that the correct control material has been used.
3. If the flag reappears, check calibration, reagent cassette expiry and reaction curve.

Attributes Priority: 47
Group: CNTL

R 4(1s)

Meaning Westgard rule 5 violated.
Four consecutive quality control results deviate from the assigned mean by more than 1 standard deviation in the same direction.

Recommended action

1. Repeat with fresh control.
2. Check that the correct control material has been used.
3. If the flag reappears, check calibration, reagent cassette expiry and reaction curve.

Attributes Priority: 48
Group: CNTL

R7 ↓ Down Drift

Meaning Precision control rule violated.
There were 7 consecutive decreasing quality control results.

Recommended action

1. Repeat with fresh control.
2. Check that the correct control material has been used.
3. If the flag reappears, check calibration, reagent cassette expiry and reaction curve.



Check regularly that all Service actions were performed.

Attributes Priority: 49
Group: CNTL

R7 ↑ Up Drift

Meaning Precision control rule violated.
There were 7 consecutive increasing quality control results.

Recommended action

1. Repeat with fresh control.
2. Check that the correct control material has been used.
3. If the flag reappears, check calibration, reagent cassette expiry and reaction curve.



Check regularly that all Service actions were performed.

Attributes Priority: 50
Group: CNTL

R 7x

Meaning Precision control rule violated.
There were 7 consecutive quality control results falling on the same side of the assigned mean.

Recommended action

1. Repeat with fresh control.
2. Check that the correct control material has been used.
3. If the flag reappears, check calibration, reagent cassette expiry and reaction curve.

Attributes Priority: 51
Group: CNTL

R 10x

Meaning Westgard rule 6 violated.
There were 10 consecutive quality control results falling on the same side of the assigned mean.

Recommended action

1. Repeat with fresh control.
2. Check that the correct control material has been used.
3. If the flag reappears, check calibration, reagent cassette expiry and reaction curve.

Attributes Priority: 52
Group: CNTL

<REAG RNG

Meaning Less than reagent range.
The Absorbance value of the lowest calibrator is below the lower defined range

Recommended action

1. Check the calibration curve and reagent cassette expiry.
2. Repeat with fresh lowest calibrator.
3. If the flag reappears, replace reagent cassette (the reagent may be contaminated).

Attributes Priority: 14
Group: CAL

>REAG RNG

<i>Meaning</i>	Greater than reagent range. The absorbance value of the lowest calibrator is above the upper defined range.
<i>Recommended action</i>	1. Check the calibration curve and reagent cassette expiry. 2. Repeat with fresh lowest calibrator. 3. If the flag reappears, replace reagent cassette (the reagent may be contaminated).
<i>Attributes</i>	Priority: 15 Group: CAL

>REPL DEV

<i>Meaning</i>	Greater than replicate deviation. Deviation between replicates exceed programmed limit. One or more replicates are erroneous.
<i>Recommended action</i>	1. Check the calibrators for air bubbles and repeat the calibration. 2. If the flag reappears, repeat with fresh calibrators.
<i>Attributes</i>	Priority: 23 Group: CAL

<RR (value)

<i>Meaning</i>	Less than reference range. The result is lower than the low reference range limit. Reference ranges are given in numbers. For quantitative tests, results below the defined reference range are presented on the final printout as L (low) . For qualitative tests that depend on the direction of the reaction, POS is displayed if the value is above the cutoff limit. (The cutoff limit is defined in Configuration >Tests >Evaluation .)
<i>Recommended action</i>	No action required.
<i>Attributes</i>	Priority: 60 Group: RAT, TEST

>RR (value)

<i>Meaning</i>	Greater than reference range. The sample result is higher than the high reference range limit. Reference ranges are given in numbers. For quantitative tests, results above the defined reference range are presented on the final printout as H (high) . For qualitative tests that depend on the direction of the reaction, POS is displayed if the value is above the cutoff limit. (The cutoff limit is defined in Configuration >Tests >Evaluation.)
<i>Recommended action</i>	No action required.
<i>Attributes</i>	Priority: 61 Group: RAT, TEST

SEG FLUID

👁 SEG FLUID on page F-47

SEG ISECAL

👁 SEG ISECAL on page F-48

SOL 1 F DEV

👁 SOL 1 F DEV on page F-48

>STD DEV

<i>Meaning</i>	Greater than standard deviation. A point in the calibration fell outside the defined limits.
<i>Recommended action</i>	1. Check calibration curve. 2. Repeat with fresh calibrators. 3. If the calibrators were incorrectly positioned, replace the calibrators correctly.
<i>Attributes</i>	Priority: 27 Group: CAL

<TEST RNG

Meaning Less than test range.
The result is lower than the lowest limit for the test.

Recommended action

- CAL
 - Repeat calibration.
- CNTL
 - Repeat with fresh controls.
- TEST
 - Rerun the sample using a test that does not include a predilution factor if a sample predilution factor is defined for this application.

Attributes Priority: 30
Group: CAL, CNTL, TEST

>TEST RNG

Meaning Greater than test range.
The result is higher than the upper limit for the test.

Recommended action

- CAL
 - Repeat calibration.
- CNTL
 - Repeat with fresh controls.
- TEST
 - Rerun the sample with postdilution.
 - If the sample has already been postdiluted, rerun the sample with a higher postdilution factor.

Attributes Priority: 31
Group: CAL, CNTL, TEST

>UP LIM

Meaning Greater than upper limit.
For a limit control, the result is higher than the defined upper limit.

Recommended action

1. Rerun with fresh control.
2. Check that the correct control material has been used.
3. If the flag reappears, check calibration, reagent cassette expiry and reaction curve.

Attributes Priority: 54
Group: CNTL

>

<i>Meaning</i>	• For CAL and CNTL: Repeat The result was generated from a repeat. • For TEST: Rerun The result was generated from a rerun.
<i>Recommended action</i>	No action required.
<i>Attributes</i>	Priority: 43 Group: CAL, CNTL, TEST

V

<i>Meaning</i>	Diluted. The result was generated using a diluted sample and the dilution factor was automatically applied to the result calculation.
<i>Recommended action</i>	No action required.
<i>Attributes</i>	Priority: 41 Group: CNTL, TEST

^

<i>Meaning</i>	Concentrated. The result was generated using a concentrated sample and the concentration was automatically applied to the result calculation. Only applicable to tests defined to use predilution (usually specific proteins only).
<i>Recommended action</i>	No action required.
<i>Attributes</i>	Priority: 42 Group: CNTL, TEST

Flags and recommended actions

Service



13 *Service action software* D-3

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Service action software

Using the Service work area for preventative maintenance



Service actions are an essential part of your maintenance strategy. Completing service actions correctly and on time helps to ensure that your laboratory gets the maximum benefit from your analyzer.

This chapter describes the **Service** work area and the procedures that are used to track and initiate service actions. When you perform a service action, a set of online instructions is displayed to show you how to clean or replace parts of the analyzer.

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About service actions

Service actions are an essential part of your maintenance strategy. Completing service actions correctly and on time helps to ensure that your laboratory gets the maximum benefit from your analyzer.

When you perform a service action, a set of online instructions is displayed to show you how to clean or replace parts of the analyzer.

You must perform a number of service actions to ensure that your analyzer runs reliably.

Use the **Service** work area to track and perform service actions. When any service action is due, the **Service** icon on the navigation bar turns yellow. If the **Service** icon is red it means that the backup database service action is overdue.

Generally, the analyzer must be in **Standby** when you are performing service actions. The ISE service actions **Activate electrodes** and **Prime ISE calibrators** are exceptions to this.

 Chapter 18 ISE service actions

When are service actions due?

The due time for a service action is determined by the counters and timers that are maintained by the system. For example, with the default values, the **Clean probes and splash guard** service action is listed on the **Due** tab either

- after 3000 tests

or

- after 7 days.

The system uses the service interval (number of tests or number of days) that occurs soonest. Service intervals can be changed by your system administrator. When the service action has been performed, the counters and timers are reset.

When are service actions nearly due?

The system defines service actions to be “nearly due” by using a percentage of the service interval. For example, using 90% for the **Service Action Due at** calculation, the **Clean probes and splash guard** service action is listed on the **Due** tab either

- after 2700 tests have been done (90% of 3000)

or

- after 6.3 days have passed (90% of 7).

The percentage can be changed by your system administrator.

The **Begin of Day** tab lists only service actions that will be performed automatically at the next BOD.

Service work area overview



To access the **Service** work area, click the **Service** button on the navigation bar.
The **Service** work area has the following tabs:

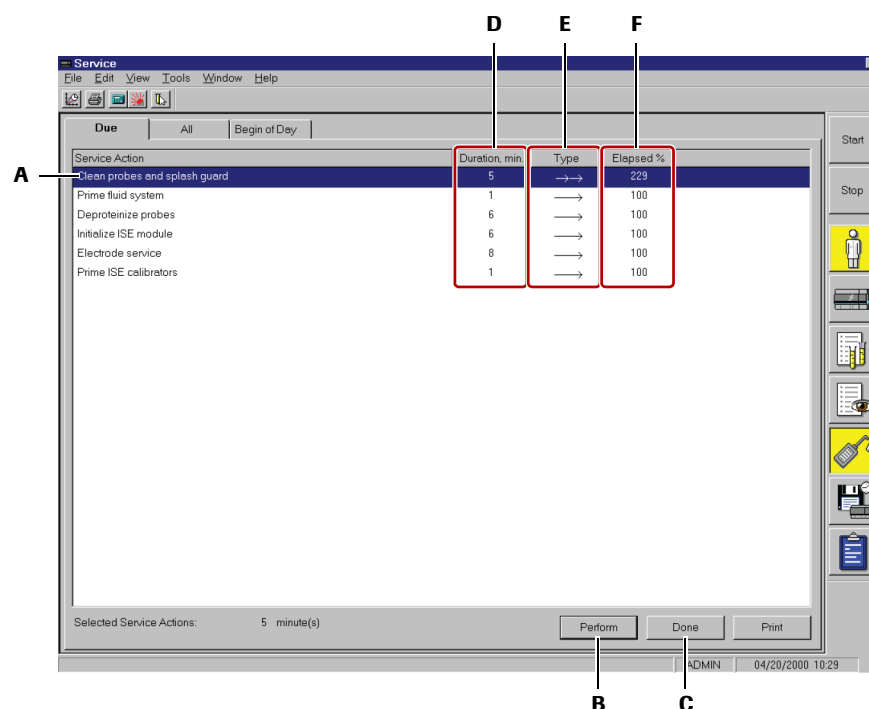
Tab	Function
Due	This tab lists service actions that are nearly due, due and overdue.
All	This tab lists all the service actions.
Begin of Day	This tab lists service actions that are to be automatically performed at the Begin of Day .

Table D-1

Due tab



The **Due** tab lists all due, nearly due, and overdue service actions. It tells you how long the service action will take to perform and whether it is partially or fully automatic.



- A** Overdue items are highlighted when you click the **Due** tab. The items that are not highlighted are almost due.
- B** Click **Perform** to perform the highlighted service action. The dialog box that lists the instructions for performing the service action is displayed.
- C** Click **Done** if you do not intend to perform the service action but wish to reset the counters to zero. The service action is removed from the **Due** tab.
- D** Shows the time it takes to perform the service action.
- E** Double arrows indicate a service action with user intervention.
Single arrows indicate an automatic service action without user intervention.
- F** Shows whether the service action is almost due (less than 100%), due (100%) or overdue (more than 100%).

Figure D-1



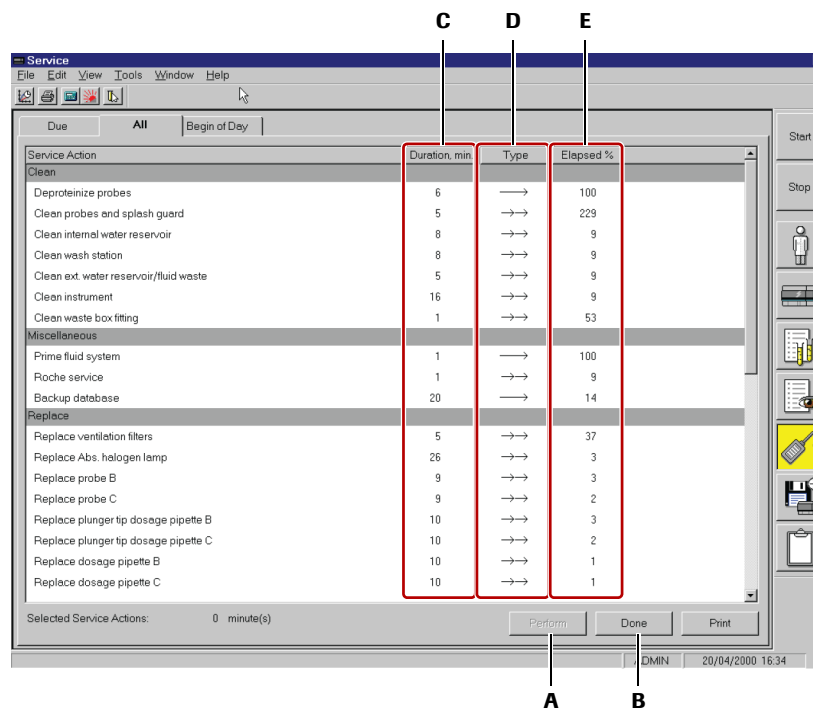
Complementary information

- Display the details for a particular service action by:
Double-clicking the item in the list.
Right-clicking the item, then choosing **Detail**.
- Choose **View > Notes** to see a list of user actions and service actions that have been performed. The paper clip indicates the presence of a **Service Note**.
👁 Service notes on page D-11
- Press F1 to display Help for this tab.

All tab



The **All** tab lists all of the service actions. It tells you how long the service action will take to perform, whether it is partially or fully automatic, and whether it is due.



- A** Click **Perform** to perform the highlighted service action. The dialog box that lists the instructions for performing the service action is displayed.
- B** Click **Done** if you do not intend to perform the service action but wish to reset the counters to zero. The service action is removed from the **Due** tab.
- C** Shows the time it takes to perform the service action in minutes.
- D** Double arrows indicate a service action with user intervention.
Single arrows indicate an automatic service action without user intervention.
- E** Shows whether the service action is almost due (less than 100%), due (100%) or overdue (more than 100%).

Figure D-2



Complementary information

- Display the details for a particular service action by:
Double-clicking the item in the list.
Right-clicking the item, then choosing **Detail**.
- Choose **View > Notes** to see a list of user actions and service actions that have been performed. The paper clip indicates the presence of a note.
 Service notes on page D-11
- Press F1 to display Help for this tab.

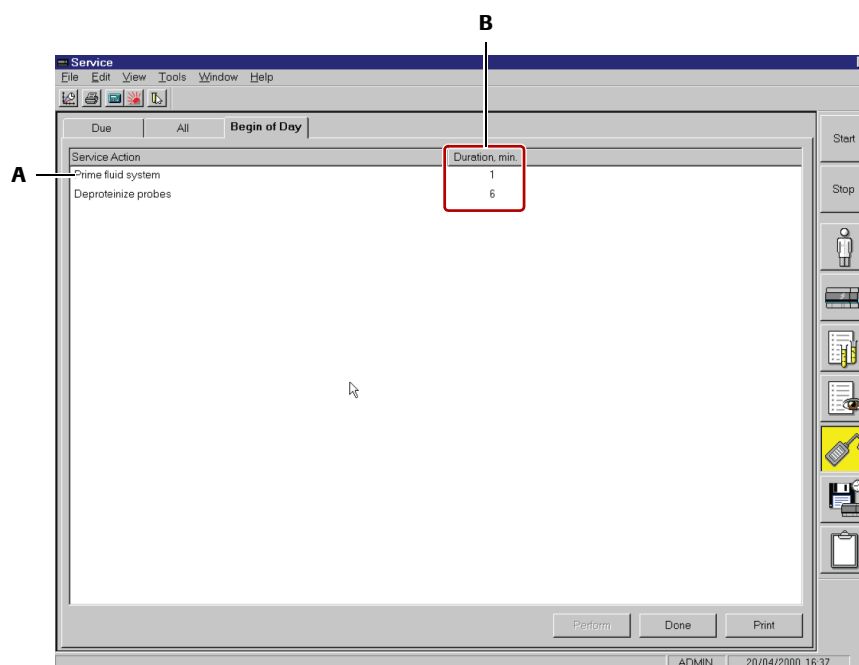
Begin of Day tab



Your system can be set up to perform the following service actions at the **Begin of Day**:

Service action	When is the service action listed on the BOD tab?
Deproteinize probes	Listed on the Begin of Day tab after a specified number of tests or number of days (whichever is the shortest time) has occurred.
Prime fluid system	Listed on the Begin of Day tab after the analyzer has been in Sleeping for a specified number of hours, or after a specified number of days (whichever is the shortest time).
Backup database	Listed on the Begin of Day tab after a specified number of tests or number of days (whichever is the shortest time) has occurred.
Initialize ISE module Activate electrodes Electrode service Prime ISE calibrators Clean ISE tower automatically Condition ISE tubing ISE Performance Check	ISE service actions: listed on the Begin of Day tab after a specified number of tests or number of days (whichever is the shortest time) has occurred.

Table D-2



- A** The service actions listed here will be performed at the next **Begin of Day**. They may be actions that are due at the next BOD, or actions that failed at the previous BOD.
- B** Shows the time it takes to perform the service action, in minutes.

Figure D-3



Complementary information

- You can perform the service actions displayed on the **Begin of Day** tab manually if necessary.
 - Display the details for a particular service action by:
Double-clicking the item in the list.
Right-clicking the item, then choosing **Detail**.
 - Choose **View > Notes** to see a list of user actions and service actions that have been performed. The paper clip indicates the presence of a note.
 *Service notes on page D-11*
 - Press F1 to display Help for this tab.
-

Performing a service action

You can perform a service action from any of the three tabs in the **Service** work area. A series of instruction dialog boxes are displayed to guide you through the steps.



To perform a service action, the analyzer must be in **Standby** status.

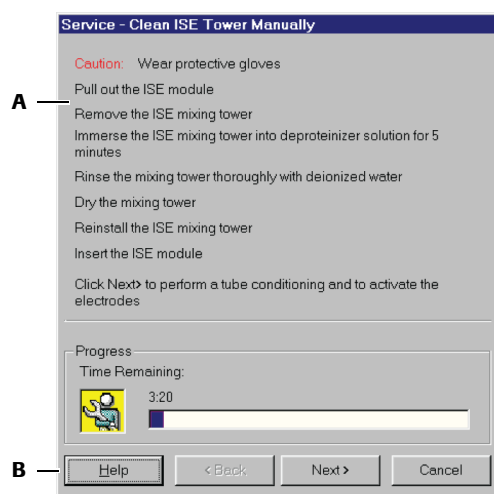


► **To perform a service action**

- 1 Click **Service** on the navigation bar.
- 2 Do one of the following:
 - Click the **Due** tab to display service actions that you must perform soon.
 - Click the **All** tab to display all service actions whether they are due or not.
 - Click the **Begin of Day** tab to display service actions that are performed automatically at the **Begin of Day**.
- 3 Select the service action to be performed and click **Perform**.

The service action dialog box is displayed. A typical example follows.

- 4 Follow the instructions listed on the dialog box.



- A** Lists the instructions for you and the actions that the system performs.
- B** Click **Next** to go to the next set of steps.
- Click **Finish** when you have completed the service action.
- Click **Cancel** to cancel the requested service action.
- Click **Help** for more information on the selected action.

Figure D-4



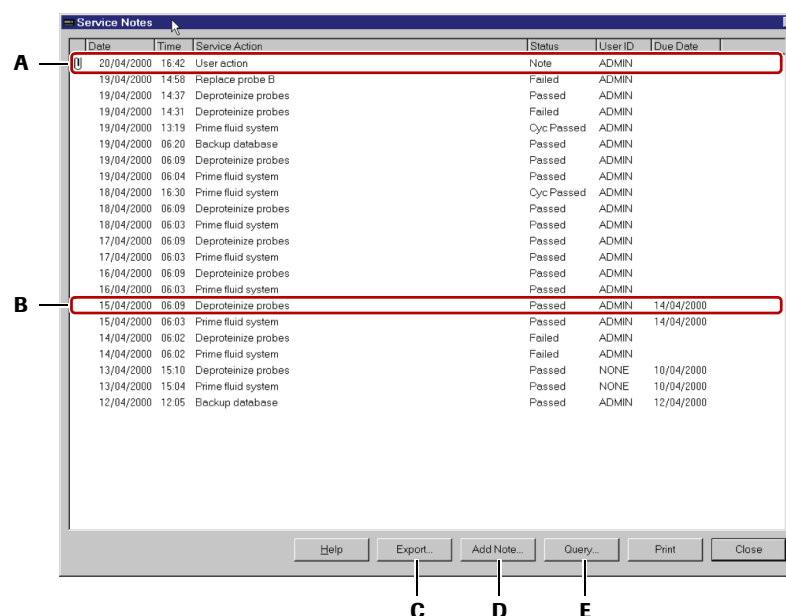
Complementary information

- For more detailed information about performing a service action:
Double-click the service action on the **Due**, **All** or **Begin of Day** tab.
Click **Help** on the dialog box.
- You may perform some service actions without using the Service action software. If you decide to do this, select the corresponding service action on the **All** tab, and click **Done**. The counters and timers will be reset to zero.
Examples of the service actions where this is possible are replacing ventilation filters or cleaning the fluid waste reservoir.

Service notes

Service actions that have been performed are listed on the **Service Notes** dialog box. User actions are included in the list. A paper clip indicates that a note has been attached to the service action or that the note was added by a user.

To open the **Service Notes** dialog box, choose **View > Notes** on the **Service** work area.



- A** User action not directly related to a particular service action. The paper clip indicates that the note was added by a user.
- B** Service action listed with the date and time it was performed, its status, and the user who performed it.
- C** Click to export notes.
- D** Click to add a service note to the selected service action. If no service action is selected, a user action is added to the list.
- E** Click this button to specify parameters that reduce the number of items displayed in the list.

Figure D-5



Complementary information

- The **Due date** column shows only **Begin of Day** service actions that were completed after the due date.
- Make the list more specific by clicking **Query**. The **Service Notes Query** dialog box is displayed. You can reduce the items in the list by specifying one or more of the following:
 - A type of service action
 - A time period
 - A user
- Check any service notes added by any user since the last work day. Double-click items with a paper clip next to them.
- Check any user actions, as these may contain information relevant to you.

Service action states

A service action has one of these states:

State	Meaning
Passed	The service action was completed successfully.
Aborted	The service action was canceled before completion.
Failed	The service action failed.
Manual	The service action was performed without the assistance of the service action software, and marked as performed by clicking Done on the All tab. This reset the counters to zero.
CycPassed	Some service actions can be performed while the analyzer is running. Is a service action displayed in the Due list and the system is in running mode, a successfully passed service action gets the state CycPassed . This state is also listed in the Service Notes .
Note	A user action that may contain comments. You type additional comments into the note.

Table D-3

Adding service notes and user actions

You can attach a note to a service action, either when you complete the service action or later, from the **Service Notes** dialog box. You can also make your own entries on the **Service Notes** dialog box; these are listed as **User Actions** and are not associated with a service action.



► To add a service note

- 1 Click **Service** on the navigation bar.
- 2 Choose **View > Notes**.
The **Service Notes** dialog box is displayed.
- 3 Select the service action to which you want to add the note.
- 4 Click **Add Note**.
- 5 Type your comments in the **Service - Add Note** dialog box.
- 6 Click **OK**.



► To add a user action

- 1 Click **Service** on the navigation bar.
- 2 Choose **View > Notes**.
The **Service Notes** dialog box is displayed.
- 3 Make sure that no service action is selected (highlighted).
- 4 Click **Add Note**.
- 5 Type your comments in the **Service - Add Note** dialog box.
- 6 Click **OK**.



Complementary information

To deselect a selected service action, press and hold down the Ctrl key, then click the selected service action.

Counters and timers

To keep track of the work that the analyzer does, the system maintains a set of counters and timers. These are used to determine when the different service actions become due. The **Service** work area tells you not only which service actions are due, but also when service actions are about to become due.

You can define both counters and timers for a service action. The system then uses whichever limit is reached first.

Performing a service action resets the counter and timer for that service action to zero.

An example of a counter

The system holds the following counters:

- The number of tests performed.
- A limit for the number of tests that a probe (for example) can do before it must be cleaned.



- The service action becomes due when the number of tests performed reaches the limit.
- The counter value "0" indicates that the service action never becomes due.

An example of a timer

The system holds the following timers:

- The number of days that have passed since a service action was last performed.
- A limit for the number of days that can pass before a probe (for example) must be cleaned.



The timer value "0" indicates that the service action never becomes due.

Counters, timers and due time

The system defines service actions to be due by using a percentage of the service interval. The permissible percentage range lies between 80% and 100%, and can be changed by your system administrator. (Select **View** > **Counters** in the **Service** work area, click the **Service Intervals** tab, and type the value in the **Service Action Due at** box.)

To change the percentage, you must have user access level 6. (**Configuration** > **General** > **User Level**)

Once a counter or timer reaches the defined percentage of the service interval, the service action is displayed in the **Due** tab of the **Service** work area.



The value "0" indicates that the service action never becomes due.

Service Counters dialog box



The **Service Counters** dialog box displays information about the counters and timers associated with service actions.

Choose **View > Counters** on the **Service** work area to open the **Service Counters** dialog box. There are three tabs:

- **Service Counters**
- **Service Intervals**
- **System Counters**

Service Counters tab

The **Service Counters** tab lists all the service actions with the counters and timers for each. The current status of each counter and timer is displayed along with the value that must be reached for the service action to become due. The service actions that are performed automatically at the **Begin of Day** are also shown here.

Choose **View > Counters > Service Counters** on the **Service** work area, to open the **Service Counters** tab.

	A	B	C	D	E
Service Action	Current	Due Unit	Current	Due Unit	BOB
Clean					
Decontaminate probes	0	600 tests	1	1 days	✓
Clean probes and splash guard	103	3000 tests	11	7 days	
Clean internal water reservoir	63577	0 tests	2001	0 days	
Clean wash station	103	0 tests	7	180 days	
Clean ext. water reservoir/fluid waste	306269	0 tests	2770	0 days	
Clean instrument	103	0 tests	7	180 days	
Clean waste bin fitting	27	2000 tests	21	30 days	
Miscellaneous					
Prime fluid system	19	4h idle	1	1 days	✓
Probe service	1484	15000 tests	137	180 days	
Backup database	0	0 tests	3	7 days	✓
Replace					
Replace ventilation filter	198	500h	21	90 days	
Replace Abx. hydrogen lamp	13	800h	7	0 days	
Replace probe B	8747	0 tests	517	0 days	
Replace probe C	44679	0 tests	1632	0 days	
Replace plunger tip dosage pipette B	119	0 tests	7	0 days	
Replace plunger tip dosage pipette C	406153	0 tests	2770	0 days	
Replace dosage pipette B	119	0 tests	7	0 days	
Replace dosage pipette C	406153	0 tests	2770	0 days	
Replace external water reservoir filter	103	0 tests	7	90 days	
ISE					
Initiate ISE module	0	0 tests	3	1 days	✓
Electrode service	0	4500 tests	5	1 days	✓
Activate electrodes	0	50 tests	5	0 days	
Prime ISE calibration	0	0 tests	4	1 days	✓
Clean ISE tower automatically	0	0 tests	5	7 days	✓
Clean ISE tower manually	10	0 tests	11	30 days	
Replace ISE module tubing	49	0 tests	113	180 days	
Replace chloride (Cl-) electrode	10	0 tests	7	90 days	
Replace lithium (Li+) electrode	10	0 tests	7	120 days	
Replace potassium (K+) electrode	10	0 tests	7	180 days	
Replace sodium (Na+) electrode	10	0 tests	7	180 days	
Replace reference (Ref) electrode	477	0 tests	392	720 days	
Condition ISE tubing	984	0 tests	335	0 days	
ISE Performance Check	0	0 tests	2770	0 days	

- A** The current number of tests or hours that have passed since the service action was last performed.
- B** The number of tests or hours that must have passed before the service action must be performed.
- C** The current number of days that have passed since the service action was last performed.
- D** The number of days that must pass before the service action must be performed.
- E** The check mark symbol shows which service actions are performed at the **Begin of Day**.

Figure D-6

Service Intervals tab



Service intervals are the values of the counters and timers that cause a service action to become due. You can change the values on this tab.

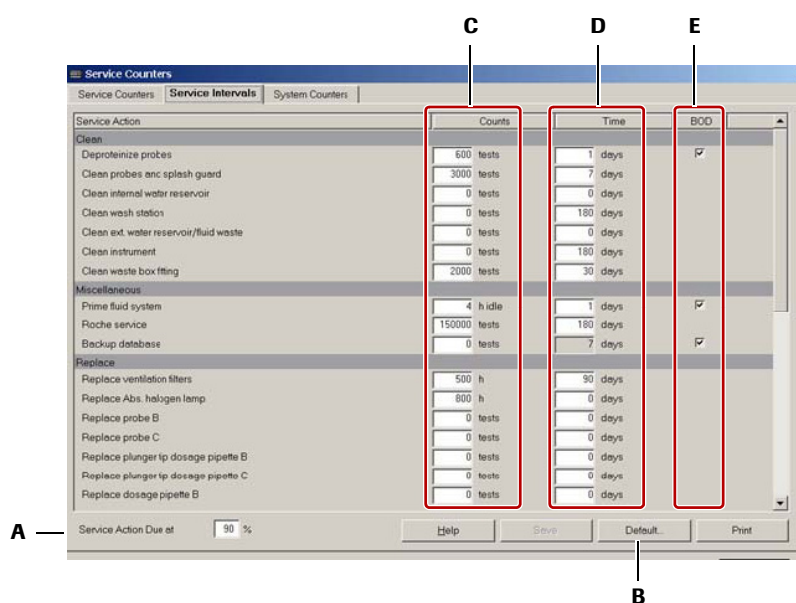
For the latest recommendations of values and counters, check with your Roche representative.

You normally must have user access level 6 to edit values on this tab.

Once a counter or timer reaches the defined percentage of the service interval, the service action is displayed in the **Due** tab of the **Service** work area. The permissible percentage range lies between 80% and 100%, and can be changed by your system administrator. (Select **View > Counters** in the **Service** work area, click the **Service Intervals** tab, and type the value in the **Service Action Due at** box.)

To change the percentage, you must have user access level 6.

Choose **View > Counters > Service Intervals** on the **Service** work area, to open the **Service Intervals** tab.



- A** Service actions are due when a percentage of the service interval is reached.
- B** Use this button to reset intervals to the Roche defined default values. It can apply to a single selected service action or to all service actions.
- C** Type the number of tests, cuvettes, hours, or hours idle that must occur before the service action becomes due.
- D** Type the number of days that must pass before the service action becomes due.
- E** Select the check box if you want the service action to be performed automatically at the **Begin of Day**. The service action becomes due when either the counter or the timer threshold value is reached.

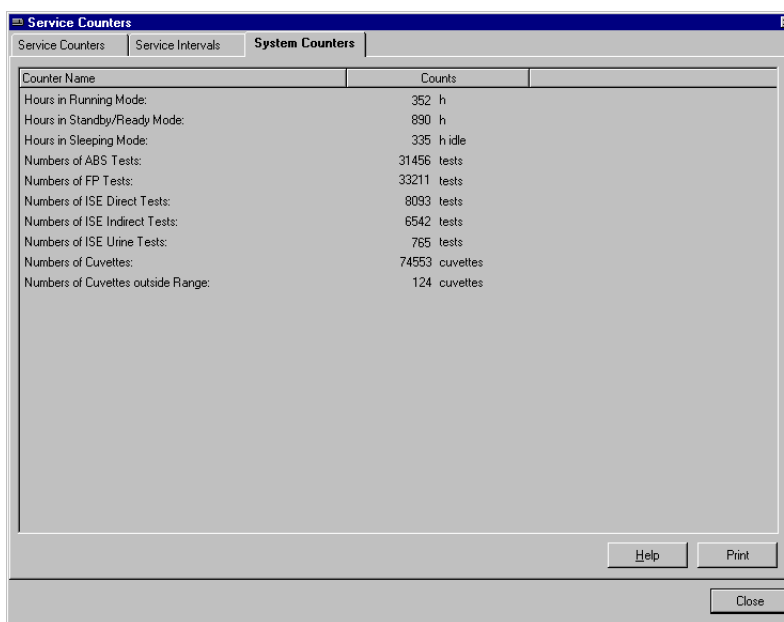
When they are due, selected service actions appear on the **Due** tab on the **Service** work area.

Figure D-7

System Counters tab

The **System Counters** tab displays the internal counters maintained by the system. The counters are updated automatically and all other counters are derived from them. These counters are always maintained, even through software updates. You cannot change any values on this dialog box.

Choose **View > Counters > System Counters** on the **Service** work area, to open the **System Counters** tab.



The screenshot shows a window titled "Service Counters" with three tabs: "Service Counters", "Service Intervals", and "System Counters". The "System Counters" tab is active. It contains a table with two columns: "Counter Name" and "Counts". The table lists various system counters and their current values. At the bottom right of the window are buttons for "Help", "Print", and "Close".

Counter Name	Counts
Hours in Running Mode:	352 h
Hours in Standby/Ready Mode:	890 h
Hours in Sleeping Mode:	335 h idle
Numbers of ABS Tests:	31456 tests
Numbers of FP Tests:	33211 tests
Numbers of ISE Direct Tests:	8093 tests
Numbers of ISE Indirect Tests:	6542 tests
Numbers of ISE Urine Tests:	765 tests
Numbers of Cuvettes:	74553 cuvettes
Numbers of Cuvettes outside Range:	124 cuvettes

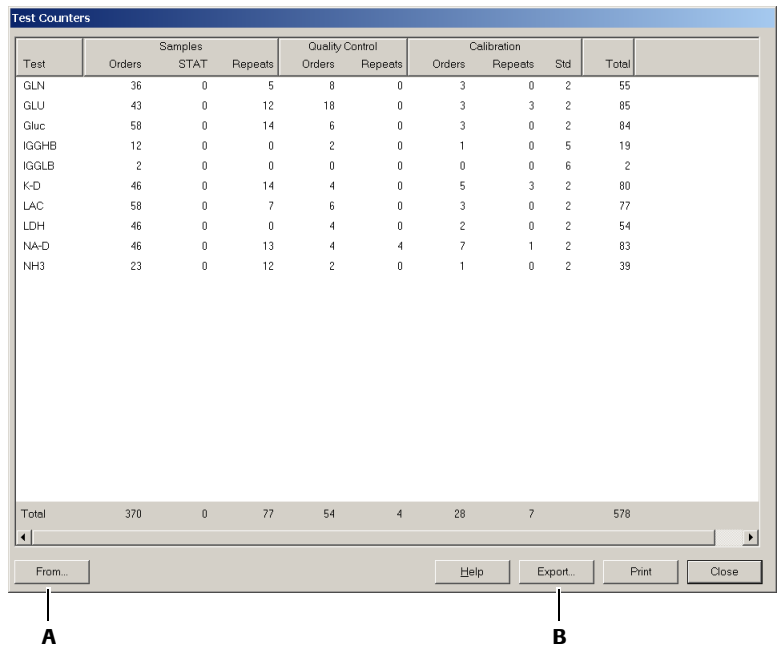
Figure D-8

Test Counters dialog box

For each test defined on your system, the **Service** work area maintains counts for orders, repeats, and the total.

These counters are always maintained, even through software updates; however, if you delete a test definition from the analyzer, the corresponding counters are also deleted.

To open the **Test Counters** dialog box, choose **Tools > Test Counters** on the **Service** work area.



- A** Click this button to show the counts for the last n days, a specific date range, or a specific month.
- B** You can export the data in this table into a spreadsheet (independent of the **Service** work area).

Figure D-9



Complementary information

To calculate the counters of a specific day, click **From** and enter the same date in both the **From** and **To** boxes on the **Test Counters Query** dialog box.

Service actions

Scheduled tasks for preventative maintenance



This chapter provides step-by-step procedures to guide you through the non-ISE service actions that require manual intervention. It lists the potential hazards and precautions in each case. General maintenance procedures are also described.

In this chapter

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General safety information

To avoid personal injury and damage to the equipment, do the following:

- Make sure you have read the safety precautions in Chapter 1 *Safety*.
 - 👁 *Safe and proper use of the system* on page 21
 - 👁 *Biohazardous materials* on page 22
 - 👁 *Mechanical safety* on page 25
 - 👁 *Reagents and working solutions* on page 26
 - Pay particular attention to all safety precautions.
 - Always follow the instructions in this publication.
-

**WARNING**

Incorrect results and malfunction due to not performing service actions when they are due

Your analyzer will not perform satisfactorily, if service actions are not performed when they are due.

- Always perform service actions when they are due.
 - Do not perform any servicing except as explicitly described in this manual.
 - Always follow the service instructions contained in this publication.
-

Replace cleaner bottle

You can start this service action either from the **Service** work area as a standard service action or you can start it from the **Analyzer** tab in the **Status** work area.

👁 See *Replacing the cleaner* on page B-18



The **Replace Cleaner bottle** button is only available if you work with analyzer hardware with serial number 620001 or higher.

Deproteinize probes

This is an automatic service action that does not require manual intervention.

To maintain the efficiency of the analyzer, you must clean and deproteinize the probes regularly to prevent the build up of contaminants. By default, **Deproteinize probes** is a **Begin of Day** action, but you can initiate it at any time from the **Service** work area.

Duration 6 minutes

Interval Daily or after 600 tests

Tools and materials

- ISE deproteinizer on the ISE rack
- Activator Bio on the ISE rack



Complementary information

For general information about performing a service action, see Chapter 13 *Service action software*.

► To deproteinize probes

- 1 Select **Deproteinize probes** in the **Service** work area.
- 2 Click **Perform**.

The **Service Actions** dialog box is displayed; follow the online instructions.

- 3 Wash pipes are filled with deproteinizer (automatic step).
- 4 Probes and sample loops are filled with deproteinizer (automatic step).
- 5 Probes are positioned inside the wash pipes (automatic step).
- 6 Probes are moved up and down (automatic step).
- 7 Prime fluid system is performed (automatic step).
- 8 Probes are activated (automatic step).
- 9 Prime fluid system is performed (automatic step).

Clean internal water reservoir



This service action is only available if you work with analyzer hardware with serial number lower than 620001. With the latest hardware, this service action is no longer required to be performed by the user, it is done by your Roche representative.

You must clean the internal water reservoir to prevent the build up of contaminants which can affect the water quality, and therefore the quality of the results produced.

At the same time, you must also replace the liquid filters, which filter out particulate matter from the water supply.

Do not remove the internal water reservoir unless you are using the service action **Clean internal water reservoir**.

Duration 8 minutes

Interval Once every six months

Tools and materials

- 2 new liquid filters
- Protective gloves
- Reagent grade, type 1 water
- Paper tissues
- 0.6% sodium hypochlorite solution



Complementary information

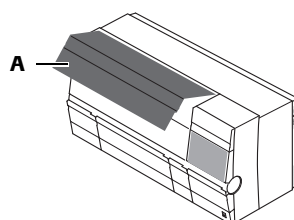
- Double-click the service action in the **Due**, **All**, or **Begin of Day** tab.
- Click **Help** in the dialog box.
- For general information about performing a service action, see Chapter 13 *Service action software*.

► To clean the internal water reservoir

- 1 Select **Clean internal water reservoir** in the **Service** work area.
- 2 Click **Perform**.

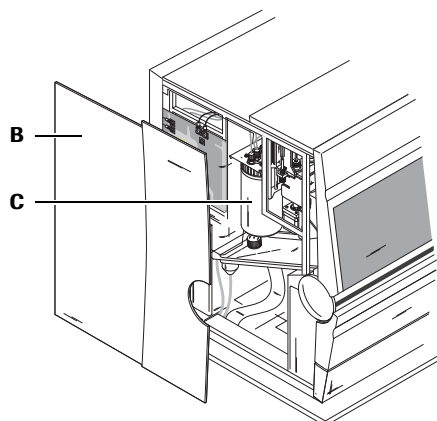
The **Service Actions** dialog box is displayed; follow the online instructions.

- 3 Open the main front cover (A).

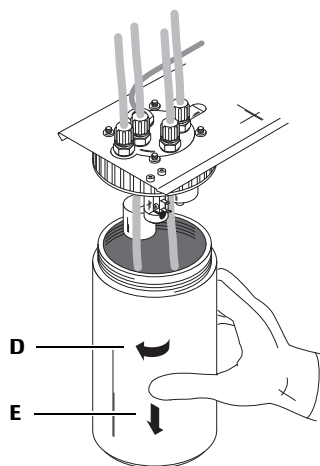


Clean internal water reservoir

- 4** Remove the left side panel (B) to access the internal water reservoir (C).

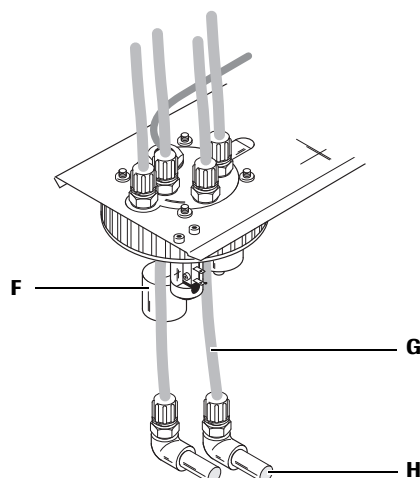


- 5** Unscrew the internal water reservoir (D and E).
The reservoir may be full; take care not to spill any water.

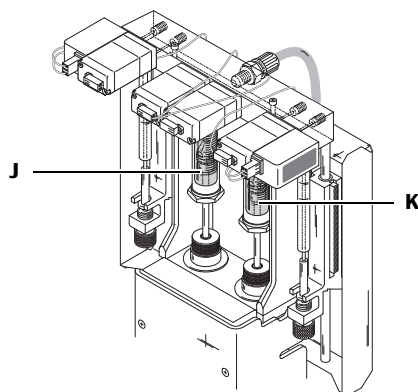


- 6** Empty the reservoir and clean it with 0.6% sodium hypochlorite solution.
7 Rinse the reservoir thoroughly with reagent grade, type 1 water four times.

- 8** Clean the internal water reservoir level switch (F) and the suction pipes (G) using a tissue moistened with ethyl alcohol.



- 9** Rinse thoroughly with water.
- 10** Replace the liquid filters (H) at the end of the suction pipes.
Wear clean protective gloves so that you do not contaminate the filters.
- 11** Reinstall the clean empty internal water reservoir.
- 12** Click **Next**.
- 13** The internal water reservoir is filled and the system is primed (automatic step).
- 14** Check the wash pipettes for air bubbles (J and K).



- 15** If necessary, perform another prime fluid system (until no air bubbles are visible).
👁 *Prime the fluid system* on page D-44
- 16** Reinstall the left side panel and close the main front cover.
- 17** Click **Finish**.

Clean probes and splash guard

You must clean the probes and splash guard regularly by hand to prevent any build up of deposits that may affect results.

The splash guard is a black plastic tray that prevents direct user access to the probes, thus protecting them from accidental damage. It also catches any drips of liquid on the outside of the probes, preventing contamination of other parts of the analyzer.

Duration 5 minutes

Interval Weekly or after 3000 tests

Tools and materials

- 70% ethanol solution
- Protective gloves
- Paper tissues
- Soap
- Wear protective gloves.



Complementary information

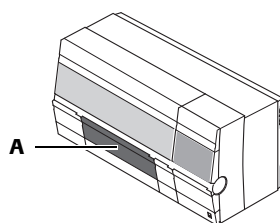
- Double-click the service action in the **Due**, **All**, or **Begin of Day** tab
 - Click **Help** in the dialog box
 - For general information about performing a service action, see Chapter 13 *Service action software*
-

► To clean probes and splash guard

- 1 Select **Clean probes and splash guard** in the **Service** work area.
- 2 Click **Perform**.

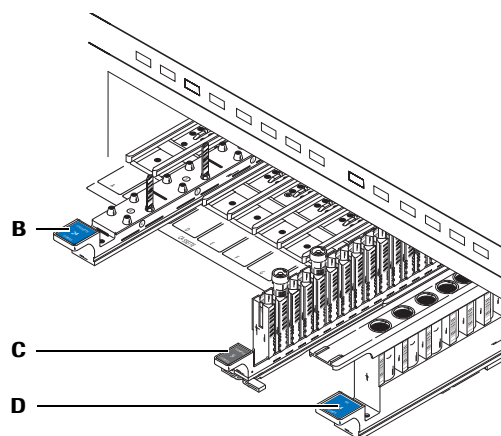
The **Service Actions** dialog box is displayed; follow the online instructions.

- 3 Open the rack access panel on the front of the analyzer (A).

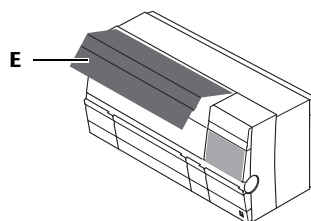


- 4** Remove all sample racks (C) and the ISE rack (D).

You do not have to remove the cassette racks (B).

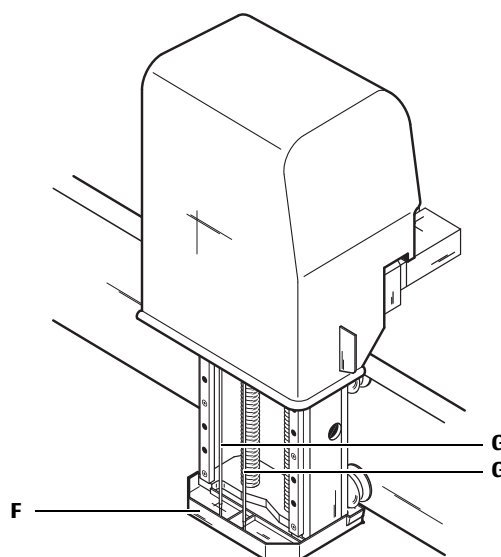


- 5** The transfer head is positioned in the sample area (automatic step).
- 6** Open the main front cover (E) to access the probes and splash guard.



- 7** Remove the splash guard (F).

Pull down the clip at the back of the splash guard to disengage it from the housing.



NOTICE

- 8 Clean both probes (G) with a tissue moistened with 70% ethanol.

Clean the probes from top to bottom.

Damage to probes

For proper functioning, the probes must be straight.

- Take care not to bend the probes.

- 9 Clean every part of the splash guard with soap and water.

- 10 Rinse and dry the splash guard.

- 11 Reinstall the splash guard.

- 12 Close the main cover.

- 13 Click **Next**.

- 14 The transfer system is initialized (automatic step).

- 15 Reinstall sample racks and the ISE rack.

- 16 Click **Next**.

- 17 Make any necessary notes and click **Finish**.

Clean wash station

You must clean the wash station and the inner part of the wash pipes to ensure that no foreign materials build up.

Duration 8 minutes

Interval Every six months

Tools and materials

- Wash pipe seals
- Paper tissues
- Cotton swabs
- Soap
- Protective gloves
- Tweezers

**Complementary information**

- Double-click the service action in the **Due**, **All**, or **Begin of Day** tab.
- Click **Help** in the dialog box.
- For general information about performing a service action, see Chapter 13 *Service action software*.

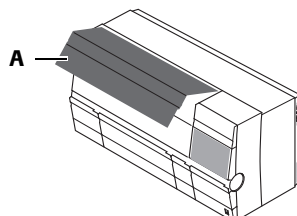
► **To clean the wash station**

1 Select **Clean wash station** in the **Service** work area.

2 Click **Perform**.

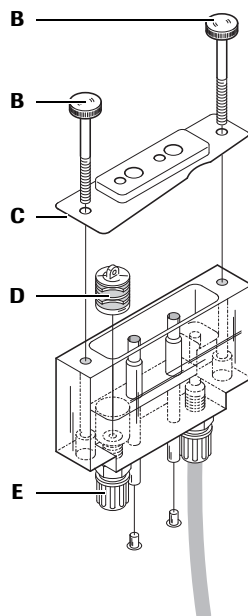
The **Service Actions** dialog box is displayed; follow the online instructions.

3 Open the main front cover (A).



4 Move the transfer head to one side so that you can access the wash station.

5 Remove the two screws on the wash station (B).



6 Remove the plastic cover (C).

Take note of the position of the cover so that you fit it correctly when reassembling the wash station.

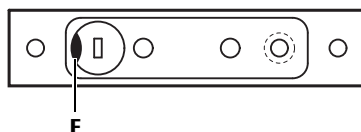
7 Lift the wash station, so that you can access the waste tubing connector (E).

8 Disconnect the waste tubing (not shown).

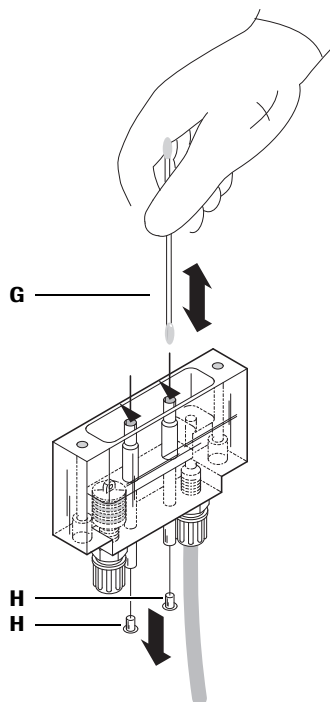
9 Use tweezers to remove the noise damper (D).

10 Rinse the noise damper with water.

- 11** Re-install the noise damper, making sure the notch faces outwards when you look at the wash station from above (F).



- 12** Clean the inner part of the wash pipes with cotton swabs (G).



- 13** Replace the wash pipe seals (H).
- 14** Rinse the wash station thoroughly using water.
- 15** Connect the waste tubing and reinstall the wash station.
- 16** When the wash station is in place, install the plastic cover (C).
The position of the cover must be with the wide end closest to you.
- 17** Close the main cover.
- 18** Click **Next**.
- 19** The transfer system is initialized (automatic step).
- 20** Click **Finish**.

Clean external water reservoir and fluid waste reservoir

You must clean the external water reservoir and fluid waste reservoir to prevent the build up of contaminants which can affect the water quality and therefore the quality of the results produced.

This service action is not required if your analyzer is directly connected to both a laboratory water supply and a laboratory fluid waste drain.

Duration 5 minutes

Interval Every three months

Tools and materials

- Liquid filters
- 0.6% sodium hypochlorite solution
- Clean beaker 1000 mL
- Reagent grade, type 1 water
- Paper tissues
- Protective gloves
- Ethyl alcohol



Complementary information

- Double-click the service action in the **Due**, **All**, or **Begin of Day** tab.
 - Click **Help** in the dialog box.
 - For general information about performing a service action, see Chapter 13 *Service action software*.
-

► **To clean the external water reservoir and the fluid waste reservoir**

- 1 Select **Clean external water reservoir / fluid waste reservoir** in the **Service work** area.

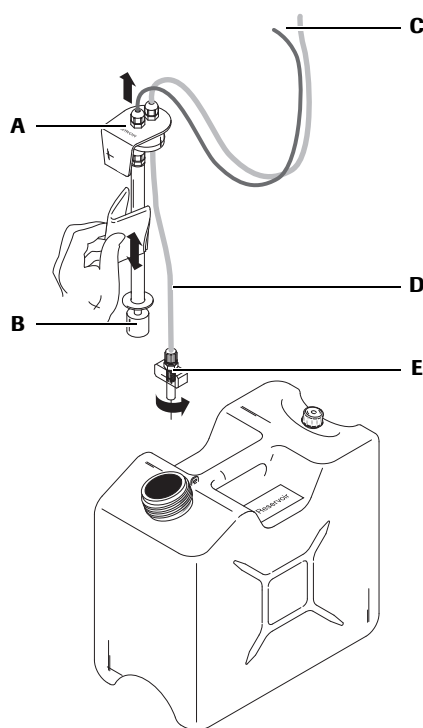
- 2 Click **Perform**.

The **Service Actions** dialog box is displayed; follow the online instructions.

- 3 Pull out the tubing adapter (A) from the external water reservoir.

Rest the adapter in a clean beaker to avoid contamination.

Do not disconnect the suction pipe or the level switch from the analyzer (C).

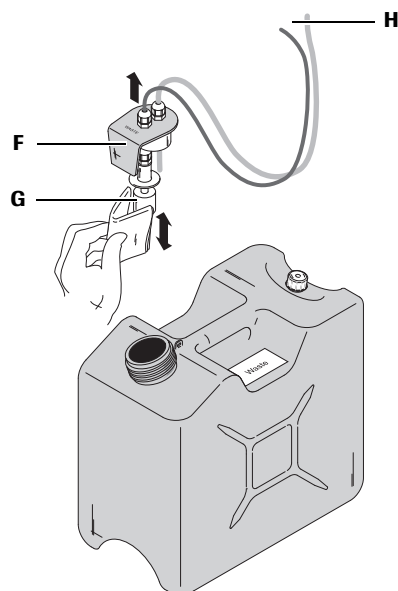


- 4 Empty the external water reservoir.
- 5 Pour 1000 mL of 0.6% sodium hypochlorite solution into the external water reservoir and shake vigorously.
- 6 Repeat steps 4 and 5.
- 7 Rinse with reagent grade, type 1 water four times.
- 8 Clean the level switch (B) and suction pipe (D) with a tissue moistened with ethyl alcohol.
- 9 Replace the liquid filter (E) on the external water reservoir suction assembly.
- 10 Fill the external water reservoir with reagent grade, type 1 water.
- 11 Reinstall the external water reservoir and insert the tubing adapter.

- 12** Pull out the tubing adapter (F) from the fluid waste reservoir.

Rest the adapter in a clean beaker to avoid contamination of the adapter and the work surfaces.

Do not disconnect the waste pipe or the level switch from the analyzer (H).



- 13** Empty the fluid waste reservoir according to your local requirements for the disposal of potentially hazardous waste.
- 14** Pour 1000 mL of 0.6% sodium hypochlorite solution into the fluid waste reservoir and shake vigorously.
- 15** Repeat steps 13 and 14.
- 16** Clean the level switch (G) with a tissue moistened with ethyl alcohol.
- 17** Reinstall the fluid waste reservoir and insert the tubing adapter.
- 18** Click **Finish**.

Clean instrument

You must clean the analyzer regularly to ensure that contaminants do not build up and affect the efficiency of the analyzer as a measurement system.

- Check the waste area for contamination and clean if necessary.
- The surface of the initialization posts must be clean so that the analyzer can perform an error-free initialization of the transfer arms.

Duration 16 minutes

Interval Every six months

Tools and materials

- 70% ethanol solution
- Non-abrasive soap
- Paper tissues
- Cuvette waste box
- Hex driver (3 mm), unlock rack tool
- Protective gloves



Complementary information

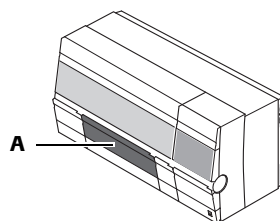
- Double-click the service action in the **Due**, **All**, or **Begin of Day** tab.
 - Click **Help** in the dialog box.
 - For general information about performing a service action, see Chapter 13 *Service action software*.
-

► To clean the analyzer

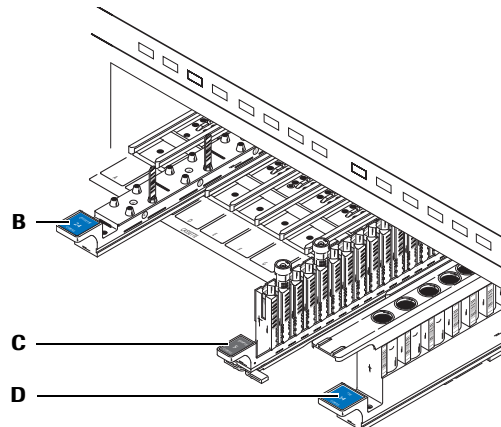
- 1 Select **Clean instrument** in the **Service** work area.
- 2 Click **Perform**.

The **Service Actions** dialog box is displayed; follow the online instructions.

- 3 Open the rack access panel on the front of the analyzer (A).

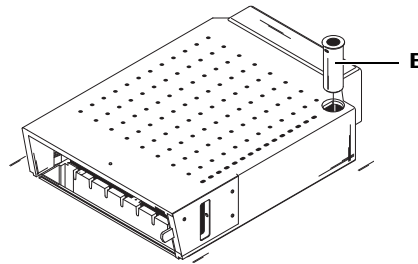


- 4 Remove cassette racks (B), sample racks (C), and the ISE rack (D).

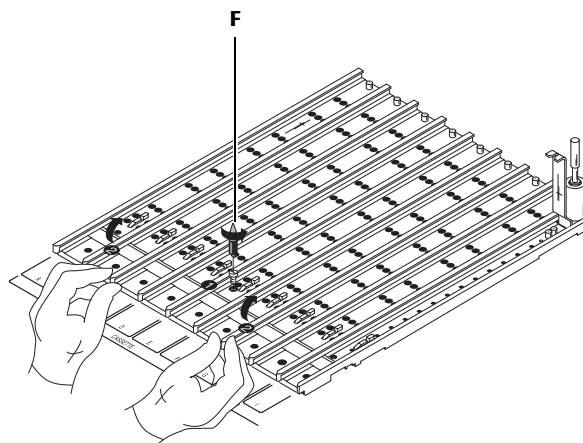


- 5 Open the main front cover.

- 6 Remove the cassette area initialization post insulator (E).

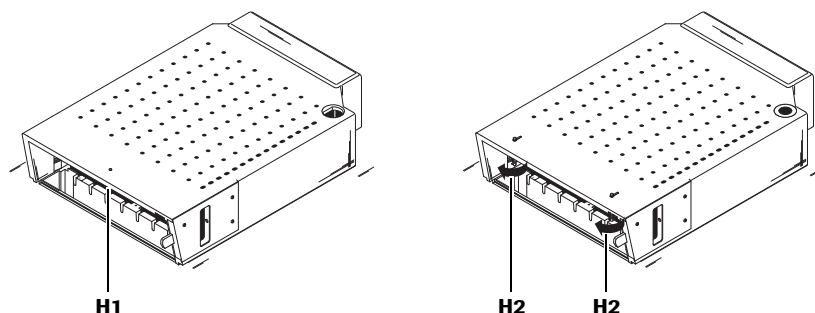


- 7 Use the unlock rack tool to remove the screw from the cassette rack platform (F).
Remove the platform.



8 Remove the cooling box top:

- a) Remove the screw (H1) under the front of the cooling box top, or turn the two spring loaded latches 180° (H2).



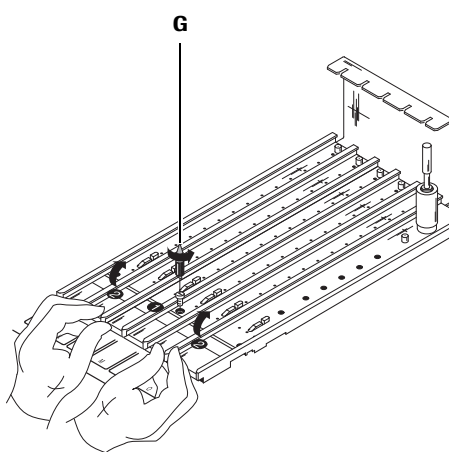
- b) Pull the cooling box top forward, through the open rack access panel.

9 Clean the cooling box top and the cassette rack platform with a tissue moistened with 70% ethanol.**10** Clean the cooling box base tray with a tissue moistened with 70% ethanol.**11** If you work with analyzer hardware with serial number 620001 or higher, proceed as follows with the sample rack platform:

- a) Access the sample rack platform from the top and, using a tissue moistened with 70% ethanol, clean the entire sample rack platform starting from the back of the instrument and towards the front of the instrument. Ensure that all debris is completely removed from the platform.
- b) Proceed with step 13.

12 If you work with analyzer hardware with serial number lower than 620001, proceed as follows:

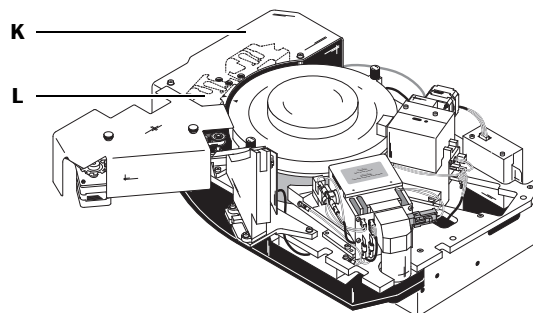
- a) Use the unlock rack tool to remove the screw from the sample rack platform (G).
- b) Remove the platform.



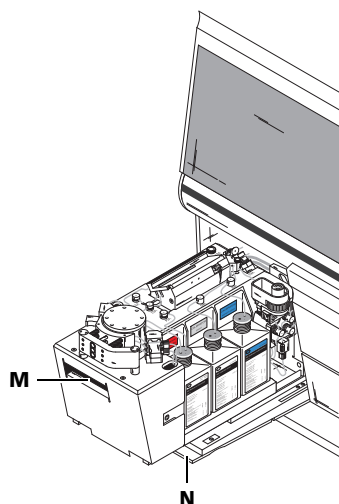
- c) Using a tissue moistened with 70% ethanol, clean the entire sample rack platform. Ensure that all debris is completely removed from the platform.
- d) Clean the sample rack base tray with tissue moistened with 70% Ethanol.

13 Reinstall the removed parts.

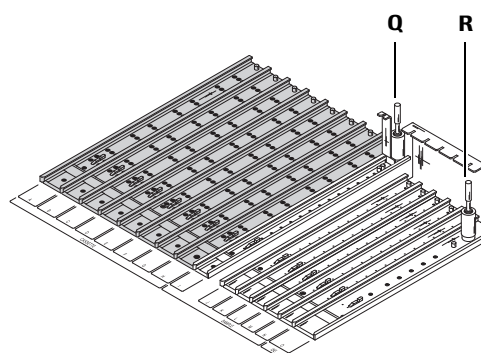
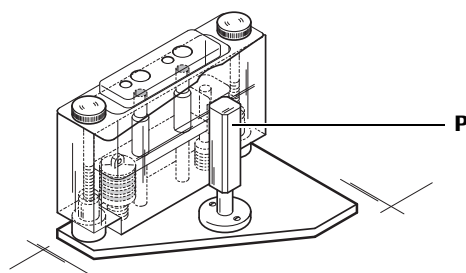
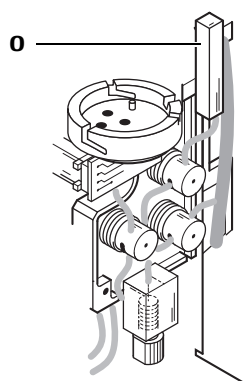
- 14** Remove the work station cover (K).



- 15** Clean the initialization surface of workstation B (L) with a tissue moistened with 70% ethanol.
- 16** Clean both the inside and the outside of the work station cover with 70% ethanol. Reinstall the cover.
- 17** Open the ISE access panel (M) and pull out the ISE module using the handle (N).



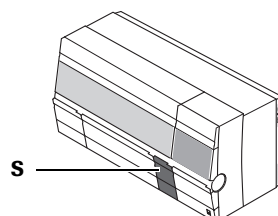
- 18** Use a tissue moistened with 70% ethanol to clean the initialization posts at the following locations:
- ISE module (O)
 - Wash station (P)
 - Cassette area (Q)
 - Sample area (R)



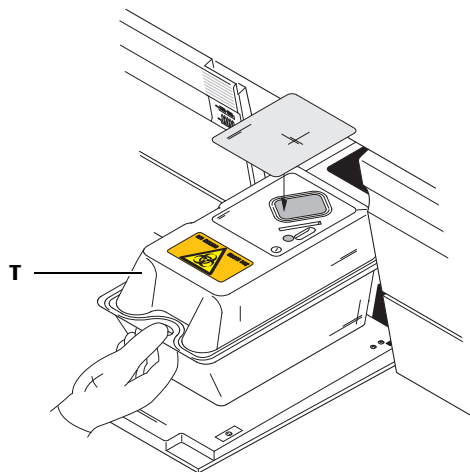
19 Reinstall the ISE module.

20 Clean the cooling box top and the cassette area initialization post insulator using 70% ethanol. Reinstall the cooling box top and the cassette area initialization post insulator.

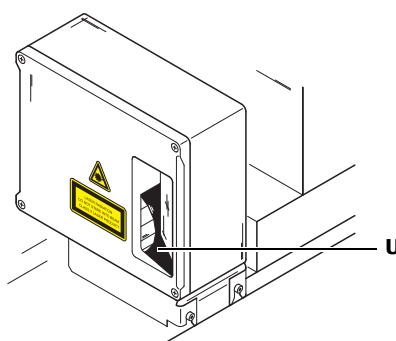
21 Open the cuvette waste access panel (S).



- 22** Remove the cuvette waste box (T). Make sure shaking is not performed while you remove the box. If disposal is required, put a rectangular sticker over the holes on the top of the waste box and dispose of it according to your local requirements for the disposal of potentially hazardous waste.



- 23** Remove the cuvette waste box tray and clean it with soap and water.
24 Clean the cuvette waste box tray with a tissue moistened with water.
25 Clean the cuvette waste box housing using 70% ethanol.
26 Reinsert the cuvette waste box tray.
27 Install a new cuvette waste box, if required.
28 Clean all the access panels and the main front cover with soap and water.
29 Clean the barcode scanner window (U) with a dry tissue.



- 30** Reinsert all the racks.
31 Close all covers.
32 Click **Next**.
33 The analyzer is fully initialized (automatic step).
34 Click **Finish**.

Clean the waste box fitting

Regular cleaning of the waste box fitting ensures proper functioning of the ISE module.

Duration 1 minute

Interval Every 30 days or after 2000 ISE tests are run.

Tools and materials

- Deionized water
- Protective gloves
- Paper tissue

► **To clean the waste box fitting**

1 Select **Clean waste box fitting** in the **Service** work area.

2 Click **Perform**.

The **Service Actions** dialog box is displayed. Follow the online instructions.

3 Remove the cuvette waste box. Make sure shaking is not performed while you remove the box.

4 Clean the Plexiglas protection of the waste box fitting with a paper tissue moistened with water.

5 Reinsert the cuvette waste box.

6 When all steps are complete, click **Finish** to reset the analyzer service counters.



Complementary information

- Double-click the service action in the **Due**, **All**, or **Begin of Day** tab.
 - Click **Help** in the dialog box.
 - For general information about performing a service action, see Chapter 13 *Service action software*.
-

Clean and lubricate the rotor

This action improves the cuvette positioning on the rotor. The positioning may affect the reproducibility of test results.



This service action is not listed in the **Service** work area of the system software.

Duration 15 minutes

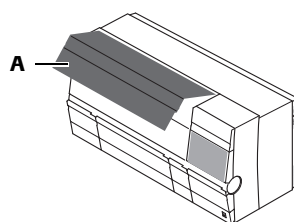
Interval When advised by Roche personnel or every 3 months.

Tools and materials

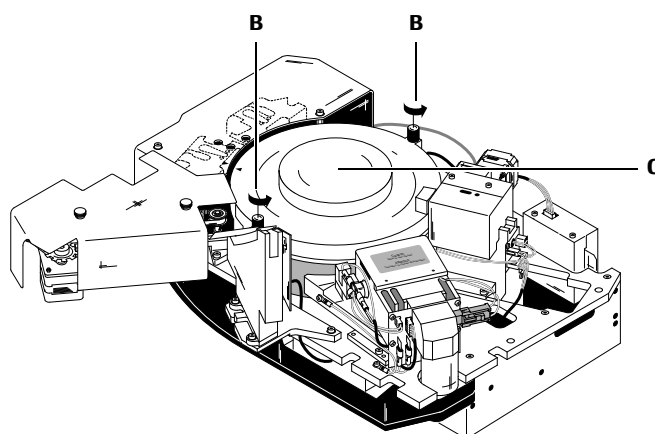
- Rotor Clean/Lube tool
(This tool is included in the Accessories Kit supplied with the analyzer.)

► To clean and lubricate the rotor

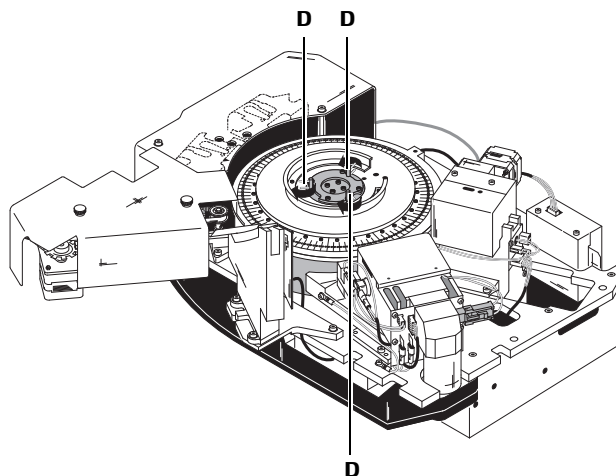
- 1 Perform a shutdown and switch off the analyzer at the main switch.
- 2 Open the main front cover (A) to access the transfer head.



- 3 Move the transfer head to the left to get access to the analyzer rotor cover.
- 4 Unscrew the two screws (B) of the analyzer rotor cover.
- 5 Remove the analyzer rotor cover (C).

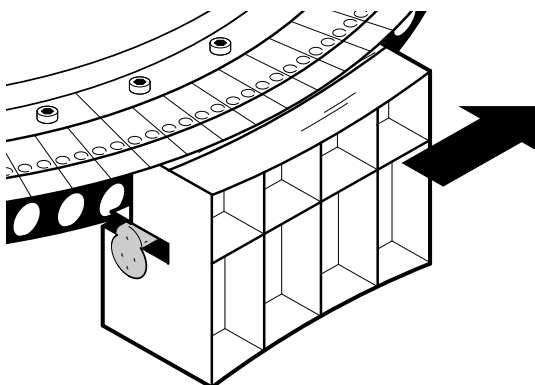


- 6 Lift & turn 90 degrees the three lever clips (D) on top of the rotor.



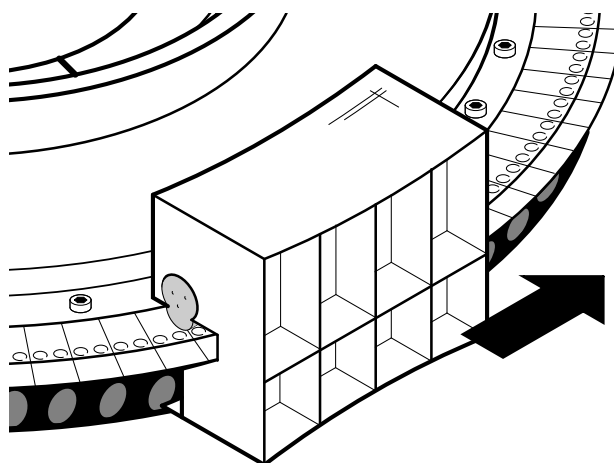
- 7 Carefully lift and remove the rotor.

- 8 Mount the Rotor Clean/Lube tool on the rotor as shown in the following figure.



- 9 Slide back and forth the tool along the periphery of the rotor until the rotor is clean.

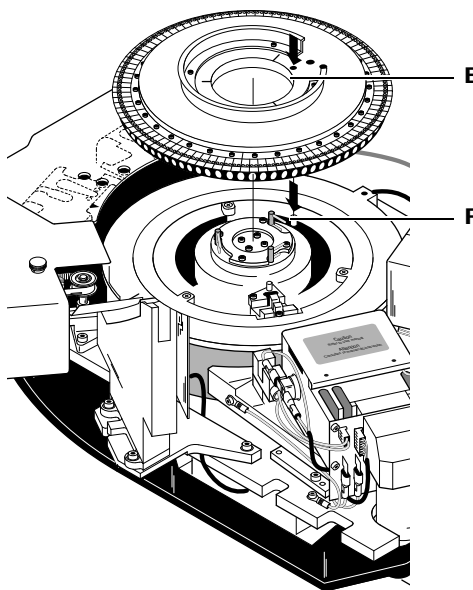
- 10 Remove the tool and mount it again upside down.



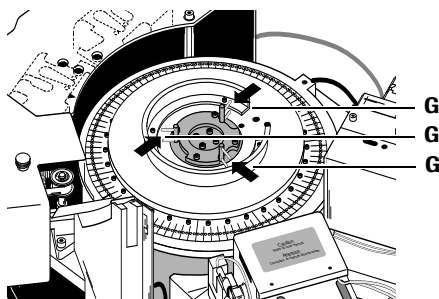
- 11 Slide back and forth the tool along the periphery of the rotor to lubricate the rotor balls.

12 Reinstall the rotor

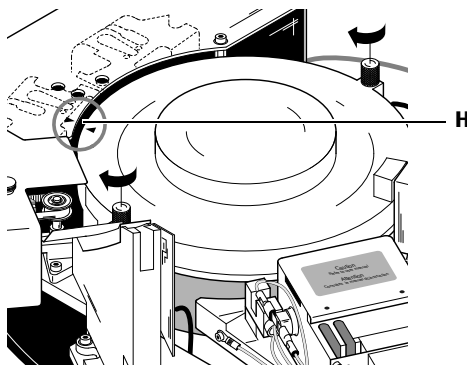
13 The positioning pin (E) must fit into the alignment hole (F) of the rotor.



14 Turn the three lever clips (G) 90 degrees to hold the rotor in position.



15 Reinstall the analyzer rotor cover. The white arrow (H) on the rotor cover must correspond with the white arrow on the workstation cover.



16 Close the main cover.

17 Restart the analyzer at the main switch and wait until initialization is completed.

Prime the fluid system

This is an automatic service action that does not require manual intervention.

Priming flushes the fluid system with water to ensure the paths in the fluid system (including pipettes, tubing, and probes) are filled with fluid and are free of air bubbles. If air bubbles are present in the fluid system, your test results will be inaccurate.

Priming the fluid system is an automatic step in several service actions. You can also prime the fluid system automatically as a **Begin of Day** action, or at any time by selecting the action from the **All** tab in the **Service** work area.

Duration 2 minutes

Interval Daily [BOD action] and if analyzer is in **Standby** or **Sleeping** for more than 4 hours



Complementary information

- Double-click the service action in the **Due**, **All**, or **Begin of Day** tab.
- Click **Help** in the dialog box.
- For general information about performing a service action, see Chapter 13 *Service action software*.

► To prime the fluid system

- 1 Select **Prime fluid system** in the **Service** work area.
- 2 Click **Perform**.

The **Service Actions** dialog box is displayed; follow the online instructions.

- 3 Probes are positioned outside the wash pipes (automatic step).
- 4 Five wash cycles with system cleaner are performed (automatic step).
- 5 Probes are positioned inside the wash pipes (automatic step).
- 6 One wash cycle with system cleaner is performed (automatic step).

Roche service

The whole analyzer must be regularly serviced by Roche representatives. This service action reminds you to contact your Roche representative and arrange a visit.

<i>Duration</i>	Not applicable
<i>Interval</i>	Between 4 and 8 months or after 150,000 tests
<i>Tools and materials</i>	None



Complementary information
For general information about performing a service action, see Chapter 13 *Service action software*.

Backup database

This is an automatic service action that does not require manual intervention.

You must back up the database regularly to ensure the integrity of data on the system in the (unlikely) case of disk failure. If a backup becomes overdue, the background on the **Service** button in the navigation bar turns red.

<i>Duration</i>	5 minutes
<i>Interval</i>	Weekly
<i>Tools and materials</i>	None



Complementary information
For general information about performing a service action, see Chapter 13 *Service action software*.

Replace ventilation filters

The ventilation filters remove particles from the air that is circulated through the analyzer. There are two filters, one each for the analyzer, and the sample area.

You need to replace these filters according to the service action schedule in order to ensure that clean air can circulate.

Duration 5 minutes

Interval 500 hours in **Running**, **Standby** or **Sleeping** state

Tools and materials

- Analyzer module ventilation filter
- Sample area ventilation filter



Complementary information

For general information about performing a service action, see Chapter 13 *Service action software*.

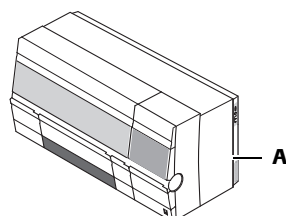
► To replace the ventilation filters

1 Select **Replace ventilation filters** in the **Service** work area.

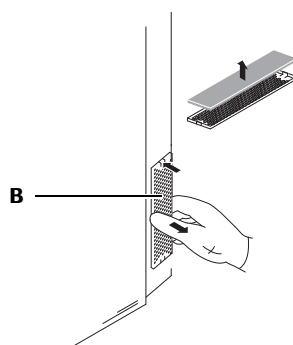
2 Click **Perform**.

The **Service Actions** dialog box is displayed; follow the online instructions.

3 Remove the filter covers at the right rear side of the analyzer (A).

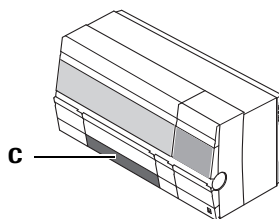


4 Replace the ventilation filter (B).

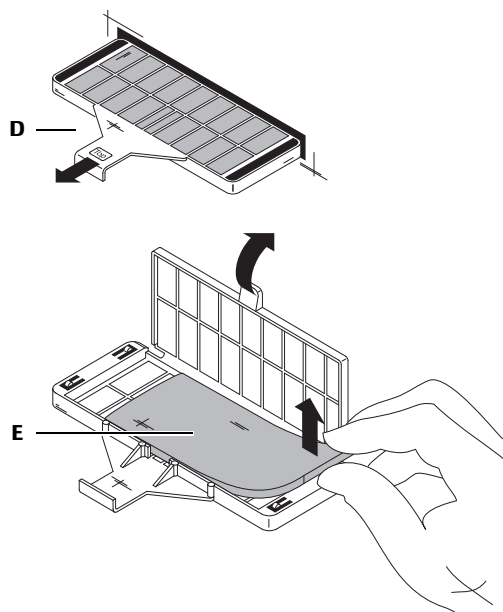


5 Reinstall the filter covers.

- 6** Remove the left bottom panel (C).



- 7** Pull out the sample area ventilation filter housing (D) and replace the filter (E).



- 8** Reinstall the filter housing.
9 Reinstall the left bottom panel.
10 Click **Finish**.

Replace Abs. halogen lamp

The absorbance photometer uses a halogen lamp as its light source. It is essential that this lamp maintains a constant intensity in successive absorbance measurements. You must replace the lamp according to the service action schedule.



Personal injury from broken glass

If the halogen lamp is damaged, broken glass may be present.

- Remove possible pieces of broken glass with a vacuum cleaner. Remove the rest of the halogen lamp carefully.
- While reconnecting the absorbance halogen lamp a small spark may be generated. This is not a malfunction and the energy of the system during this process is not enough to harm persons or damage the analyzer.

Duration 26 minutes

Interval After 800 hours in **Operating** or **Standby**

Tools and materials

- Paper tissues
- Absorbance photometer halogen lamp



Complementary information

- Double-click the service action in the **Due**, **All**, or **Begin of Day** tab.
- Click **Help** in the dialog box.
- For general information about performing a service action, see Chapter 13 *Service action software*.

► To replace the absorbance halogen lamp

1 Select **Replace Abs. halogen lamp** in the **Service** work area.

2 Click **Perform**.

The **Service Actions** dialog box is displayed; follow the online instructions.

3 The absorbance halogen lamp is switched off (automatic step).

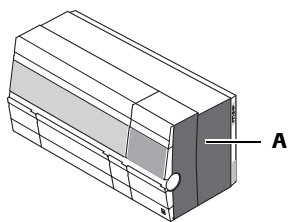


Burns due to hot absorbance halogen lamp and surrounding components

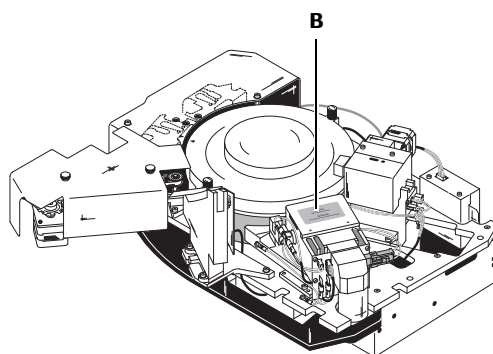
- Wait 2-3 minutes for the lamp and surrounding components to cool down.

4 Wait 2-3 minutes for the lamp to cool.

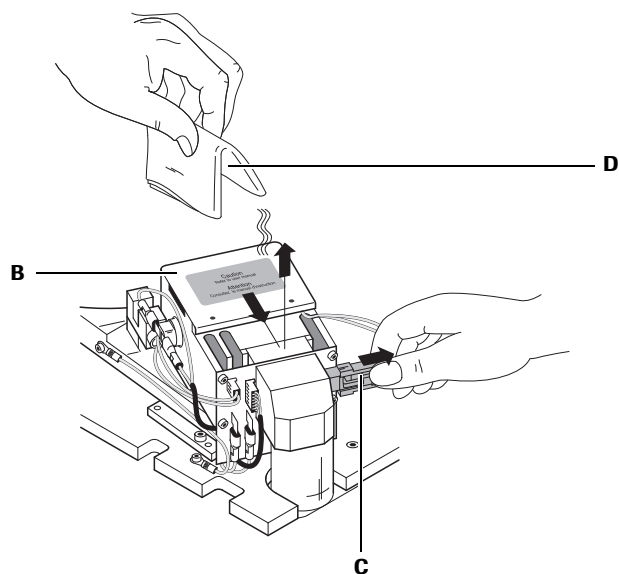
- 5 Remove the right side panel (A).



- 6 Remove the lamp cover (B).

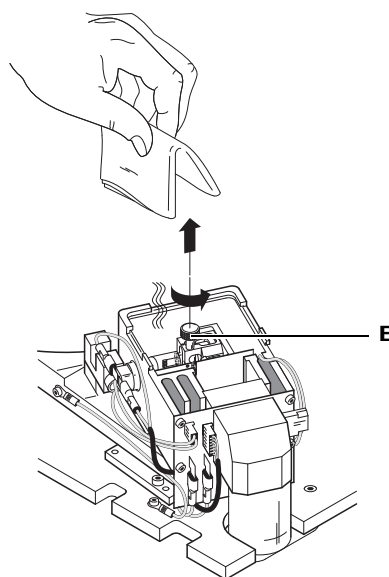


Use a dry cloth (D) to push the lamp cover (B) forward (towards the back of the analyzer) about 1 cm and then lift it out.



- 7 Disconnect the lamp cable (C) and release the cable from its restraint.

- 8 Release the lamp by unscrewing the securing bolt (E) on the lamp holder.



- 9 Remove the whole lamp by lifting it with the bolt (E).
10 Replace the old lamp with a new one, taking care not to touch the lamp itself.



WARNING

Incorrect results due to soiled absorbance halogen lamp

Touching the bulb surface reduces the life of the bulb and may affect the consistency of measurements made with the absorbance photometer.

Do not touch the bulb surface.

- 11 Screw the new lamp into position. Do not screw the lamp in too tightly.
12 Fit the cable into the restraint.
13 Reconnect the lamp cable.
14 Reinstall the lamp cover and click into place.
15 Reinstall the right side panel.
16 Click **Next**.
17 The absorbance photometer is initialized (automatic step).
18 A water/air calibration is performed (see below) (automatic step).
19 New water and air constants are automatically saved.
20 Click **Finish**.

Water/air calibration

The system measures absorbance for 50 empty cuvettes at each wavelength. The system fills the same cuvettes with water and measures the absorbance again at each wavelength. Mean values are stored in the database and used to adjust results.

Replace probe B (or C)

For continuing accuracy, you must replace one or both of the probes when this service action becomes due. This service action can also be performed as a troubleshooting measure to overcome poor pipetting accuracy.

There is a separate service action to replace either of the two probes (B and C). You can replace individual probes, or you can replace both probes at the same time. Probe B is the one closest to you when you open the main front cover.

Duration 9 minutes

Interval No interval. Status will be checked during Roche service visits.

Tools and materials

- Probe set
- Activator on the ISE rack
- Protective gloves
- QC material



WARNING

Incorrect results due to contamination

During probe replacement, the user moves the robotic head over the rack area, and when disconnecting the tube liquid may drop into ISE reagent or sample.

- To catch possible drippings, place an absorbent cloth under the probe.
- Avoid moving the robotic head over the ISE reagent rack.



WARNING

Infection due to contact with probes

Contact with contaminated probes may result in infection.

- Take care not to puncture yourself.
- Wear appropriate personal protective equipment. Take extra care when working with lab gloves, which can easily be pierced or cut, leading to infection. When cleaning near the needles, take care not to puncture yourself.



WARNING

Declining quality of probe and measurements

The efficiency of probes deteriorates with use. This may lead to decreased measurement quality.

- Replace the probes as recommended by your Roche representative.



Complementary information

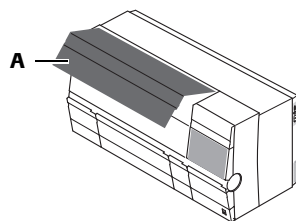
- Double-click the service action in the **Due**, **All**, or **Begin of Day** tab.
- Click **Help** in the dialog box.
- For general information about performing a service action, see Chapter 13 *Service action software*.

► To replace probe B (or C)

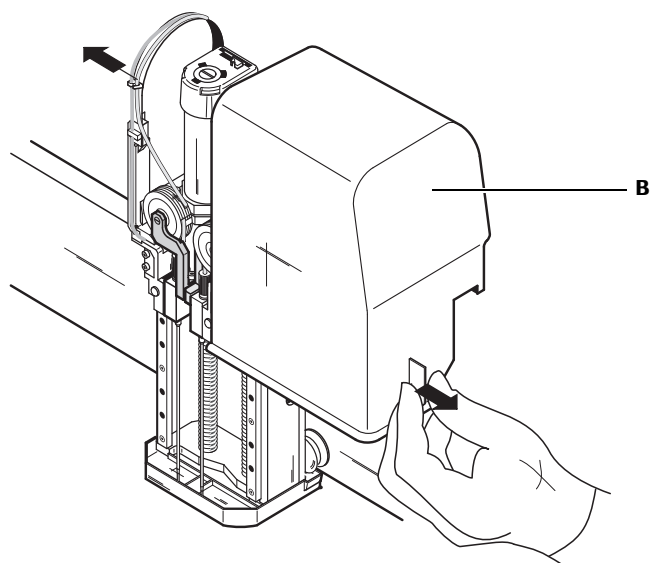
- 1 Select **Replace probe B (or C)** in the **Service** work area.
- 2 Click **Perform**.

The **Service Actions** dialog box is displayed; follow the online instructions.

- 3** Open the main front cover (A) to access the probes.

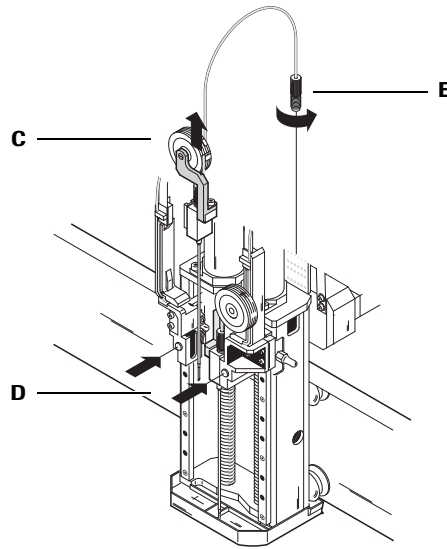


- 4** Move the transfer head to a position outside the ISE and sample rack area if this was not done automatically.
- 5** Remove the transfer head cover (B).



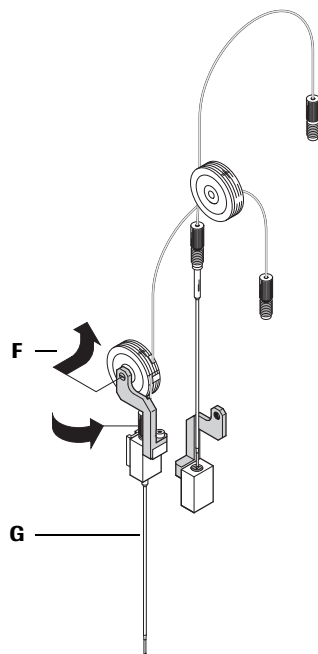
- 6** To catch possible drippings, place an absorbent cloth under the probe.
- 7** Disconnect the probe tubing from the transfer head fluid distributor (E).

- 8** Remove the probe and sample loop holder:
- Press and hold down the button (D).
 - Push the probe upwards (C) until it disengages from the housing.



*Replace probe B (or C)***9** Disassemble the probe and sample loop structure:

- a) Push the sample loop off the bracket (F).
- b) Unscrew the probe (G).
- c) Lift the probe out of the bracket.

**10** Reassemble the structure using a new probe and sample loop.

Make sure to hold the screw thread of the probe in line with the probe holder to avoid damaging the screw thread.

11 Install the new probe and sample loop on the transfer head.**12** Remove the absorbent cloth from under the probe.**13** Reinstall the transfer head cover.**14** Close the main cover.**15** Click **Next**.**16** The transfer system is initialized (automatic step).**17** The probes are activated and the fluid system is primed (automatic step).**18** Click **Finish**.

To ensure the pipetting accuracy, Roche recommends to perform a control measurement after performing the service action **Replace probe B (or C)**.

👁 See *To request a control manually* on page B-136.

Replace plunger tip dosage pipette B (or C)

The dosage pipettes deliver accurate quantities of liquid for each test performed. To ensure the continuing accuracy of pipetting operations, you must replace the dosage pipette plunger tips before they become worn, as determined by the service action schedule.

Duration 10 minutes

Interval No interval. Status will be checked during Roche service visits.

There is a separate service action to replace either of the two dosage pipette plunger tips (B and C). You can replace individual plunger tips, or you can replace both at the same time.

Tools and materials

- Teflon seal 250 µL
- Tip tool
- Scalpel
- Paper tissues
- Protective gloves
- QC material

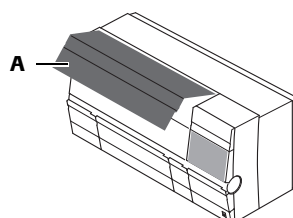


Complementary information

- Double-click the service action in the **Due**, **All**, or **Begin of Day** tab.
- Click **Help** in the dialog box.
- For general information about performing a service action, see Chapter 13 *Service action software*.

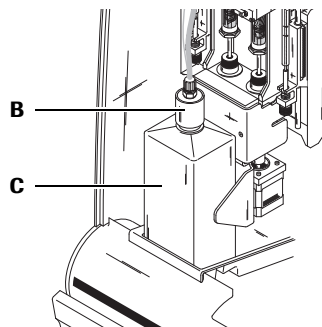
► To replace the dosage pipette plunger tip

- 1** Select **Replace plunger tip dosage pipette B (or C)** in the **Service** work area.
- 2** Click **Perform**.
The **Service Actions** dialog box is displayed; follow the online instructions.
- 3** The dosage pipettes are positioned (automatic step).
- 4** The probes are positioned inside the wash pipes (automatic step).
- 5** Open the main front cover (A) to access the pipettes.



Replace plunger tip dosage pipette B (or C)

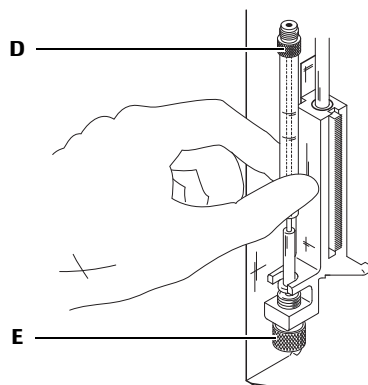
- 6 Remove the tubing (B) from the cleaner reservoir.



- 7 Remove the cleaner reservoir (C).

- 8 Loosen the dosage pipette locking bolt (E).

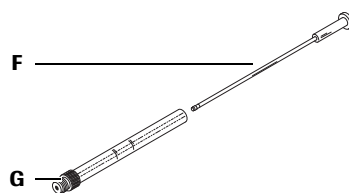
- 9 Unscrew the dosage pipette from the pipette fluid distributor (D).



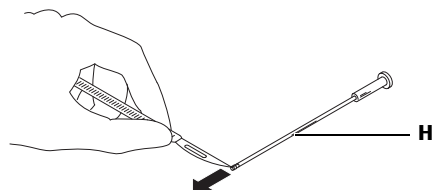
- 10 Pull the pipette forward to remove it from the module.

- 11 Pull out the piston (F).

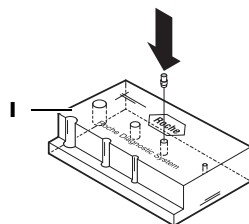
Make sure the seal cap is in place (G).



- 12 Cut and remove the plunger tip (H).



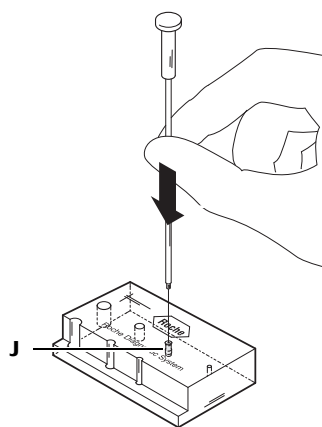
- 13** Insert the new tip into the tip tool (I).



- 14** Press the piston into the tip (J).

Ensure that tip is flush with the piston (L).

If it is not (K), you must repeat the procedure.

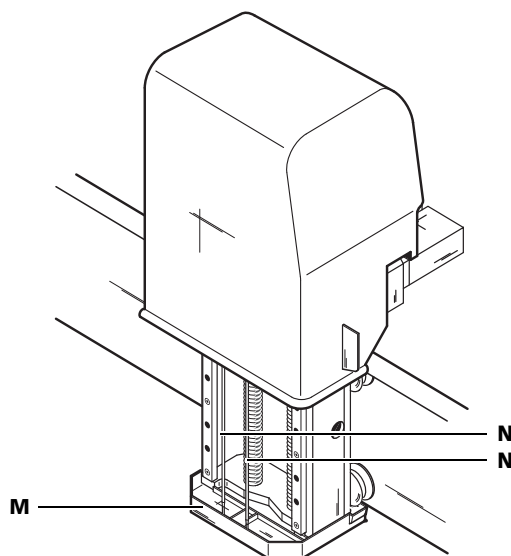


- 15** Insert the piston into the glass barrel and half-fill the pipette with water.

- 16** Reinstall the pipette.

Ensure that the seal cap (G) is correctly positioned.

- 17** Wipe away any drops of water from the pipette module, the probes (N), and the splash guard (M).



Replace plunger tip dosage pipette B (or C)

- 18** Reinstall the cleaner reservoir and the tubing.
- 19** Close the main cover.
- 20** Click **Next**.
- 21** The fluid system and the robotic transfer are automatically initialized (automatic step).
- 22** Open the main cover.
- 23** Check for air bubbles in the fluid system while the analyzer moves the pipettes.
- 24** Close the main cover.
 - If there are no air bubbles continue with step 25.
 - If air bubbles are still present in the fluid system, close the main cover and click the **Back** button to perform again the automatic initialization of the fluid system and the robotic transfer. Continue with step 22.
- 25** Click **Next**.
- 26** The pipette module is initialized and the fluid system is primed (automatic step).
- 27** Select the corresponding check boxes of all the actions that have been performed.
- 28** Click **Finish**.



To ensure the pipetting accuracy, Roche recommends to perform a control measurement after performing the service action **Replace plunger tip dosage pipette B (or C)**.

👁 See *To request a control manually* on page B-136.

Replace dosage pipette B (or C)

The dosage pipettes deliver accurate quantities of liquid for each test performed. To ensure the continuing accuracy of pipetting operations, you must replace the dosage pipettes before they become worn, as determined by the service action schedule.

Duration 10 minutes

Interval No interval. Status will be checked during Roche service visits.

There is a separate service action to replace either of the two dosage pipettes (B and C). You can replace individual pipettes, or you can replace both at the same time.

Tools and materials

- Pipette 250 µL
- Pipette seal cap
- Paper tissues
- Protective gloves
- QC material



Complementary information

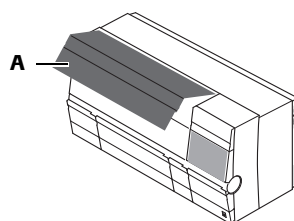
- Double-click the service action in the **Due**, **All**, or **Begin of Day** tab.
 - Click **Help** in the dialog box.
 - For general information about performing a service action, see Chapter 13 *Service action software*.
-

► To replace the dosage pipette(s)

- 1 Select **Replace dosage pipette B (or C)** in the **Service** work area.
- 2 Click **Perform**.

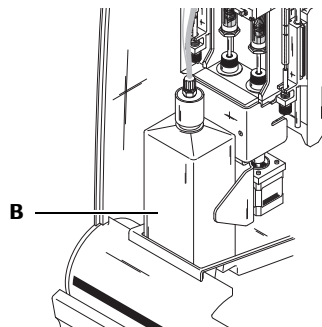
The **Service Actions** dialog box is displayed; follow the online instructions.

- 3 The dosage pipettes are positioned (automatic step).
- 4 The probes are positioned inside the wash pipes (automatic step).
- 5 Open the main front cover (A) to access the pipettes.

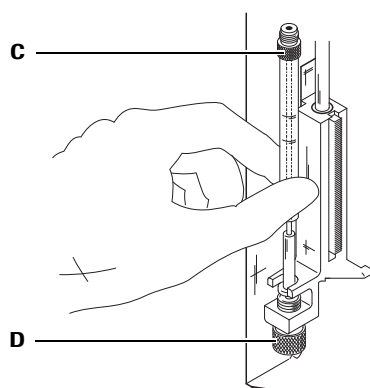


Replace dosage pipette B (or C)

- 6** Remove the cleaner reservoir (B).



- 7** Loosen the dosage pipette locking bolt (D).

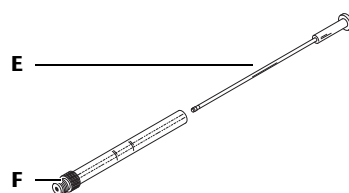


- 8** Unscrew the dosage pipette from the pipette fluid distributor (C).

- 9** Pull the pipette forward to remove it from the module.

- 10** Discard the used pipette according to your local requirements for the disposal of potentially hazardous waste.

- 11** Take the new pipette and pull out the piston (E).

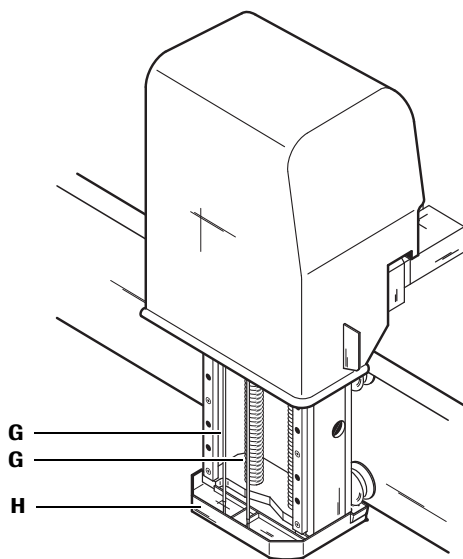


- 12** Insert the piston into the glass barrel and half-fill the pipette with water.

- 13** Install the pipette seal cap (F).

- 14** Reinstall the pipette.

- 15** Wipe away any drops of water from the pipette module, the probes (G), and the splash guard (H).



- 16** Reinstall the cleaner reservoir.
- 17** Close the main cover.
- 18** Click **Next**.
- 19** The fluid system and the robotic transfer are automatically initialized (automatic step).
- 20** Open the main cover.
- 21** Check for air bubbles in the fluid system while the analyzer moves the pipettes.
- 22** Close the main cover.
- If there are no air bubbles, continue with step 23.
 - If air bubbles are still present in the fluid system, close the main cover and click the **Back** button to perform again the automatic initialization of the fluid system and the robotic transfer. Continue with step 20.
- 23** Click **Next**.
- 24** The pipette module is initialized and the fluid system is primed (automatic step).
- 25** Select the corresponding check boxes of all the actions that have been performed.
- 26** Click **Finish**.



To ensure the pipetting accuracy, Roche recommends to perform a control measurement after performing the service action **Replace dosage pipette B (or C)**.

👁 See *To request a control manually* on page B-136.

Replace external water reservoir filter

The liquid filter on the external water reservoir removes particulate matter from the water supply. You must replace this filter according to the service action schedule, or earlier (if, for example, the water pressure is too low or the water throughput is insufficient).

Duration 5 minutes

Interval Every three months

Tools and materials Liquid filter



Complementary information

- Double-click the service action in the **Due**, **All**, or **Begin of Day** tab.
 - Click **Help** in the dialog box.
 - For general information about performing a service action, see Chapter 13 *Service action software*.
-

► To replace the external water reservoir filter

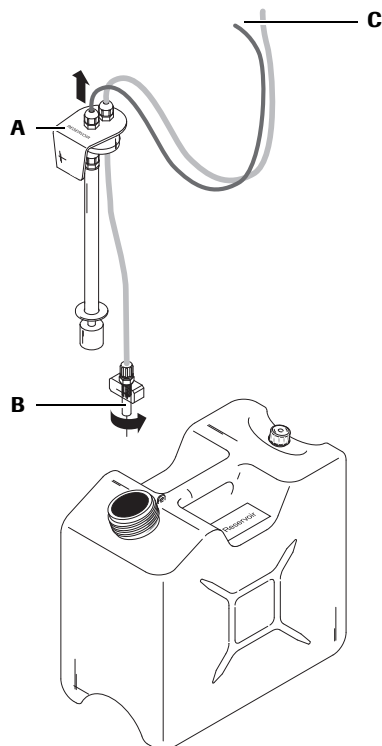
- 1 Select **Replace external water reservoir filter** in the **Service** work area.
- 2 Click **Perform**.

The **Service Actions** dialog box is displayed; follow the online instructions.

- 3** Pull out the tubing adapter (A) from the external water reservoir.

Rest the adapter in a clean beaker to avoid contamination of the adapter and of any work surfaces.

Do not disconnect the suction pipe or the level switch from the analyzer (C).



- 4** Replace the liquid filter (B).
- 5** Reinstall the tubing adapter.
- 6** Click **Finish**.

Managing data

The system generates a large amount of data that is stored on local disks. You must manage this data so that there is always enough space for the system to continue processing. The system stores most of its data in tables in an onboard database. The amount of data that can be stored in these tables is limited; also, even if the tables are not full, the system needs disk space for its own working data, for example, the system logs.

- 👁 *Database storage on page D-64*
- 👁 *Non-database storage on page D-71*
- 👁 *Backing up your data on page D-71*
- 👁 *Database messages on page D-71*
- 👁 *Where to save your data on page D-72*
- 👁 *Transmitting data to the host on page D-73*

Database storage

Users have no direct control over the operation of the database, other than to define configuration parameters for the system. The space for the database tables is allocated dynamically and is reclaimed automatically when no longer required.

The performance of the database is essential to the performance of the system. The system issues messages to warn you if table space in the database is running out, or if performance is likely to be impaired. Follow the recommendations in the messages for dealing with these problems.

The following types of data are stored in the database:

- **Orders** - Orders are created by users or downloaded from the host system. These data are stored in the onboard database until it is deleted manually or purged.
- **Results** - The data from calculated test, calibration, and control results.
- **Raw data** - Data from the physical measurements made by one of the measuring modules when the system processes test orders, calibrations, and controls.
- **Definitions** - Database tables containing the current parameters for all test and related definitions on the system.
- **Message log** - This log contains the most recent messages.
- **Journal** - Results listed in the order in which they were pipetted.

- 👁 *Purging and deleting orders on page D-65*
- 👁 *Purging results on page D-66*
- 👁 *Archiving results on page D-67*
- 👁 *Reviewing archived results on page D-68*
- 👁 *Exporting raw data on page D-68*
- 👁 *Deleting raw data on page D-69*
- 👁 *Definitions on page D-70*
- 👁 *Message log on page D-70*
- 👁 *Journal on page D-70*

Purging and deleting orders

After they have been processed, orders are kept on the system for a user-configurable time period. Orders older than this are automatically purged at the next BOD. You can set the time period in **Configuration > Database > Automatic Actions (Delete Orders after)**. For example, if you specify **Delete Orders after** as two days, all orders older than two days will be deleted at the next BOD.

Purging orders removes the order ID from the **Orders** work area. This means that you can reuse an order ID after purging orders. In the **Results** work area, the order ID is still visible; the results are not removed. Each order ID is associated with a date and time so that you can always refer to a specific order by its number, its date, and its time stamp. This ensures that each order is unique.

Preconditions You can only purge an order when the system is in **Standby** or **Sleeping** state.

You can only purge an order if "CANT":

- Order complete (C)
- Result accepted (A)
- Sample not on board (N)
- Result transferred to the host, if you work with a host system (T)

► To purge orders manually

- 1 Choose **Tools > Purge Orders**.
- 2 Click **Yes** on the **Confirm Purge Orders** dialog box.

► To delete orders automatically at BOD

- 1 Click **Configuration** on the navigation bar.
- 2 Double-click **Database** in the **System** group.
- 3 Click the **Automatic Actions** tab.
- 4 In the **Delete Orders After** box, type the number of days after which the order should be deleted.
- 5 Click **OK**.



Complementary information

- Type 0 (zero) to delete at the next **Begin of Day** all of today's orders, that is all orders defined between the time of the last and the next **Begin of Day** time.
 - Type 1 to delete at **Begin of Day** all orders that were created more than 24 hours before **Begin of Day** time.
-

► To delete a single order

- 1 Click **Orders** on the navigation bar.
- 2 Click the **Sample** tab.
- 3 Type the order ID in the **Order ID** box and press Enter.
- 4 Choose **Edit > Delete**.

Purging results

Purging results The analyzer is not designed to store safely large quantities of results on the system. As part of data management, you should periodically purge results manually. At least every 2 months is recommended.

By default, results from sample tests, calibrations, and controls are kept on the system indefinitely.

Purging removes completed results from the system. After purging, these results are no longer available on the system; you cannot retrieve them from the **Results** work area; any statistics that were calculated using the results are recalculated using the remaining results, when requested.

Purging results manually can take a considerable time. During this time, the system must remain in **Standby**; you should not attempt to insert a rack while a purge is in progress.

Preconditions The system must be in **Standby** or **Sleeping** state.

A sample test result is purged if "CANT":

- Order complete (C)
- Result accepted (A)
- Sample not on board (N)
- Result transferred to the host, if you work with a host system (T)

The associated order ID is purged as well, provided that there are no pending test orders associated with this ID.



Complementary information

- Provided the above conditions are met, order IDs are deleted, even if tests were never performed for these orders, for example after inserting a rack with barcoded sample tubes and removing it again.
- Purge regularly, typically every two months.

Precaution Before you purge results, you should archive your current calibration, control, and sample results (**File > Archive Results**).

What information is deleted? When purging results, the following information is deleted:

- Results
- Calculated results that were derived from purgeable results
- Test orders
- Order IDs

What information is not deleted? To make sure that the relevant calibration results are always available while processing orders (as long as the cassette is not empty), the following calibration results are kept when purging calibration results:

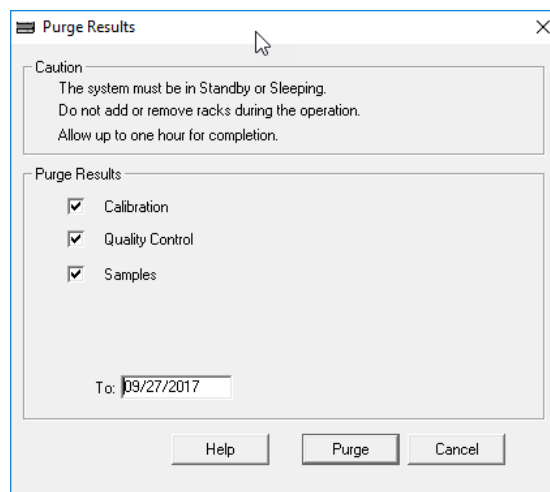
- The most recent calibration result for each test, even if it falls within the specified date range.
- Additional results are kept, depending on the calibration interval:

If calibration is due with each new cassette, a calibration result is kept for each started cassette.

If calibration is due when a new lot is started, one calibration result is kept for all cassettes of that lot.

► To purge results

- 1 Choose **Tools > Purge Results** on any work area.
- 2 The **Purge Results** dialog box is displayed.



- 3 Select or clear the **Calibration**, **Quality Control**, and **Samples** check box to choose the kind of test results you want to delete.
- 4 In the **To** box, type the date up to which you want to delete the results. All results older than that date will be deleted.
- 5 Click **Purge**.

A status window is displayed while the results are being purged. The purging action may take quite some time, depending on the number of results that need to be deleted.

Click **Stop** to stop purging results. Note, however, that any results that were deleted before you pressed **Stop** are lost and cannot be restored.

► To delete a single result

- 1 Click **Results** on the navigation bar.
- 2 On any of the tabs, right-click an item, and choose **Delete** from the context menu. The **Confirm Delete** dialog box is displayed. The text on this box tells you exactly what data will be deleted.
- 3 On the **Confirm Delete** dialog box, click **Yes**.



Complementary information

Depending on your user rights, this option may not be available to you.

Archiving results



You can save results on the system for future reference. If you archive results in this way, you cannot reload them onto the system; you can only review them.

This is not a backup facility.

► To archive results

- 1 Click **Results** on the navigation bar.
- 2 Choose **File > Archive**.
The **Archive Results** dialog box is displayed.
- 3 Select the type of results to archive and optionally a date range.
- 4 Click **Archive**.
The **Archive Result (File)** dialog box is displayed.
- 5 Select the F disk drive, and specify a file name, file type, and a folder for the archive.
- 6 Click **OK**.

Reviewing archived results

You can use the review facility to browse the archived results.

► To review archived results

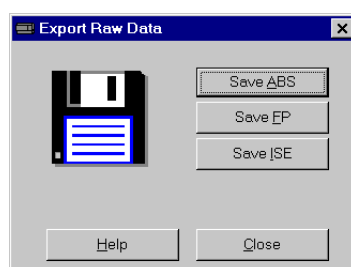
- 1 Click **Results** on the navigation bar.
- 2 Choose **File > Review**.
The **Review (File)** dialog box is displayed.
- 3 Select the folder, file type, and filename from where the results should be read.
- 4 Click **OK**.
The **Review Results** dialog box is displayed.
- 5 Use **Find** to locate a specific test.
- 6 Click **Close**.

Exporting raw data

Most of the time, you do not need raw data to assess sample results. If you do need to keep raw data for a long time, you can export the data to an external storage device. You can select which measuring module you want to save raw data for and also the format for the saved data.

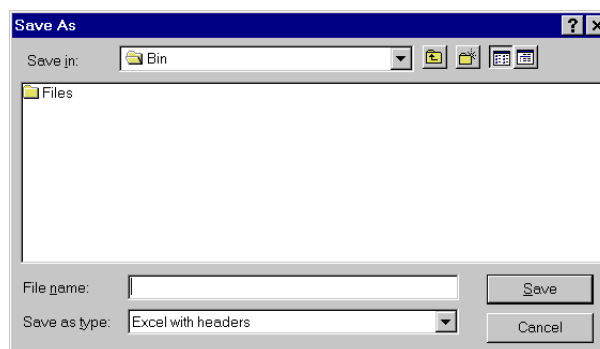
► To export raw data

- 1 Click **Configuration** on the navigation bar.
- 2 Choose **Tools > Export Raw Data**.
The **Export Raw Data** dialog box is displayed.



- 3 Select the measuring module.

The **Save As** dialog box is displayed.



- 4 Select the target directory, and type the file name.
- 5 Select the file format from the **Save As type** list.
- 6 Click **Save**.



Complementary information

- Exporting raw data does not delete the raw data from the database.
- Step 3: If you need to save raw data for more than one measuring module, you must export the data separately for each measuring module.

Deleting raw data

Raw data are the numerical values of the physical measurements made by one of the measuring modules. Since each result comprises many measurements, the amount of raw data can become very large, very quickly. To prevent this from happening, you can choose either of two options:

- Delete Raw Data after accepting results.
- Delete Raw Data after n days.

► To delete raw data after accepting results

- 1 Click **Configuration** on the navigation bar.
- 2 Double-click **Database** in the **System** group.
- 3 Click the **Automatic Actions** tab.
- 4 Select the **Delete Raw Data after accepting results** check box.
- 5 Click **OK**.

► To automatically delete raw data after a certain period of time

- 1 Click **Configuration** on the navigation bar.
- 2 Double-click **Database** in the **System** group.
- 3 Click the **Automatic Actions** tab.
- 4 Select the **Delete Raw Data after** check box.
- 5 In the **Delete Raw Data after** box, type the number of days you want raw data to remain on the system.



6 Click OK.

Complementary information

- Type 0 (zero) to delete at the next **Begin of Day** all of today's raw data, that is all raw data generated between the time of the last and the next **Begin of Day** time.
 - Type 1 to delete at **Begin of Day** all raw data that were generated more than 24 hours before **Begin of Day** time.
-

Definitions

The system automatically reserves enough space for test and related definitions in the database. When the system is set up, archive the definitions so that you can reload them quickly in the unlikely event of a damaged disk.

When you archive or load definitions, the data are stored in text files on an external storage device.

Archiving and reloading definitions on page G-38

Message log

The message log contains messages generated by the system. You can access this log by clicking Messages on the navigation bar, and then clicking the **Message Log** tab. By default, 200 messages are stored, but you can change this number to a maximum of 2000 messages (View **Messages** > **Options**).

The oldest messages are automatically deleted when the system needs space for new messages.

► To define the period during which message log information is kept

- 1 Click **Messages** on the navigation bar.
- 2 Click the **Options** tab.
- 3 In the **Buffer Size** box, type the number of messages that should be kept in the message log.

Journal

The journal lists the results chronologically according to their test start time. The data in the journal older than a specified number of days are automatically deleted during BOD processing.

Use this information to review the execution sequence of tests run on the system.

► To define the period during which journal information is kept

- 1 Click **Configuration** on the navigation bar.
- 2 Double-click **Database**.
- 3 Click the **Automatic Actions** tab.
- 4 In the **Delete Journal after** box, type the number of days for which log entries should be kept in the journal.

Flags in the journal

Take care when evaluating results that are flagged in the journal. The flag listed in the **Journal** for a specific test is not necessarily the final flag for that test. The flag in the **Journal** is a temporary flag that was active when the pipetting took place. This flag is often overwritten or removed from the final result. To review flags for a result, use the **Sample**, **Calibration**, or **Quality Control** tabs in the **Results** work area.

Non-database storage

Some data are stored on disk, and are not part of the database:

- **Archived definitions** - Data files containing the parameters (but not necessarily the current ones) for all test and related definitions on the system.
- **System logs** - Data files used by the system to store data so that, for example, the system can restart after an electrical, mechanical, or database failure. Generally not accessible to users.
- **Backup data** - Data files used to restore the system after a disk failure. These data are stored on drive D.

Backing up your data

The system automatically backs up the database as a BOD service action. The backup data is stored on disk D. You can also request this service action manually, in the **Service** work area.

The purpose of the backup is to ensure that you can reload all system data - including all definitions and results up to the last backup - if disk drive C were to fail. The system can then be restarted as it was at the last backup.

 **Backup database** on page D-45

Database messages

If you see the message 3731, part of the database allocation for a particular resource is at least 80% full. The most likely causes are that the system is:

- Storing too many orders
- Storing too many results
- Keeping raw data too long

Failure to deal with this message promptly can lead to poor system performance. In extreme cases, the system may stop.

Message 3731 may reappear during the next BOD action if remedial action is not taken before the BOD.

Recommended actions

► If you see message 3731

- 1 Purge orders (**Tools > Purge Orders**), if you have not already done this as part of your daily startup.
- 2 Purge results (**Tools > Purge Results**).
- 3 Delete any unwanted unaccepted results.
- 4 Reduce the time period over which raw data is kept (**Configuration > Database > Automatic Actions**). Specify a value of less than six days; consider specifying one day, and exporting the raw data to drive F.
- 5 You can also consider reducing the time that journal data is kept (**Configuration > Database > Automatic Actions**) and reducing the size of the message log (**View Messages > Options**).
- 6 If the problem reoccurs after completing steps 1 through 5, contact your Roche representative.

Where to save your data

The disk drives are organized as follows:

Drive	Contains...
A	Archived or exported data, updates, external storage device.
USB drive	Archived or exported data, updates.
B	Not used.
C	Programs and system data.
D	Backup data.
E	DVD-ROM.
F	User data, including archive data.

Table D-4



Complementary information

- Use drive F for all your own archive data. You can save any definitions, results, and raw data still on the system for future reference.
- Do not store any of your own data on drives C and D, otherwise your system may run out of disk space.

Transmitting data to the host

In normal operation, for systems that are enabled for host communication, accepted results are automatically sent to the host. After this the results are labeled internally as “completed”.

Retransmitting all results

If you need to retransmit results to the host, choose **Tools > Retransmit All Data** from the menu bar. This command retransmits all results on the system, even if you are only interested in one or two.



- This option is only available if **Retransmit All Data** is enabled in **Configuration > Processing > Result Output**.
- Transmitting all data to the host takes considerable time, depending on the size of the database.
- You cannot interrupt or abort this action, the system might be blocked for a longer period of time.

Retransmitting selected results

You can select one or more individual results, results for a specific order, or for a specific date to be transmitted to the host.

► To retransmit selected results

- 1 Use **Configuration > Processing > Result Output** to select **Host Interface Transmission** for the kind of result you want to transmit.
- 2 Select the required results in the **Results** work area.
- 3 Choose **Tools > Transmit Selected Data** from the menu bar.

Example: Transmit specific sample results

- 1 Use **Configuration > Processing > Result Output**.
- 2 Check that **Sample** is enabled.
- 3 In the **Results** work area, click the **Sample** tab.
- 4 Select the required folder.
- 5 Click the plus sign to open the folder.
- 6 Select the required results.
- 7 Choose **Tools > Retransmit Selected Data** from the menu bar.
The **Confirm Retransmit Data** message is displayed.
- 8 Click **Yes**.
A **Retransmit to Host** message is displayed.
- 9 Check that the required data were sent.
- 10 Click **OK**.



Complementary information

- Step 7: The command is shaded unless your selection contains one or more results.
- Do not change any host interface settings unless you are sure they are incorrect.

Troubleshooting

E

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Messages

General problem-solving techniques

This chapter explains how to identify and interpret messages, and suggests ways of reacting to these messages.

In this chapter

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About messages

Messages inform you about errors or other events that have occurred on the system. The icon displayed on the message dialog box reflects the severity of the problem:

Symbol	Meaning
	Information message: Often a prompt to ask you if you really want to do something.
	Warning: Alerts you to some condition or consequence, but the system as a whole can keep running. Some messages of these types may mean one or more measurement modules may not be able to run tests.
	Critical error: The system cannot continue. You must fix the problem and then restart the system.

Table E-1

All messages that generate a dialog box are listed on the **New Messages** tab on the **View Message** dialog box.

► To react to a message

- 1 On the message dialog box, click  to turn off the audible alarm, if necessary.
- 2 Read the message and take appropriate action.
- 3 Click **Help** for additional information, if available.
- 4 Click **Options** if you want to create and save a problem report.

👁 *Creating a problem report on page E-44*

- 5 Click **Close** when you have read the message.

- 6 Confirm the message.

👁 *Confirming messages on page E-9*



Complementary information

- If you need to refer to the message again after confirmation, use the **Message Log** tab. See **Message Log tab** on page E-7.
- All messages that generate a dialog box are listed on the **New Messages** tab on the **View Message** dialog box. Double-click a message for more details.

► To get Help on a particular message

👁 *Reacting to a hardware message on page E-32*

Messages button

👁 *Reacting to a hardware message on page E-32*

The background color of the **Messages** button shown on the navigation bar indicates whether there are messages waiting to be viewed. The background color also indicates the severity of the message.

Button	Background	Meaning
	Gray	The messages that are occurring need no action from the user.
	Yellow	Warning messages waiting to be dealt with. You should deal with these messages promptly, to ensure that a critical situation does not develop.
	Red flashing (Running messenger)	Error or critical messages waiting to be dealt with. You should deal with the causes of these messages immediately.

Table E-2

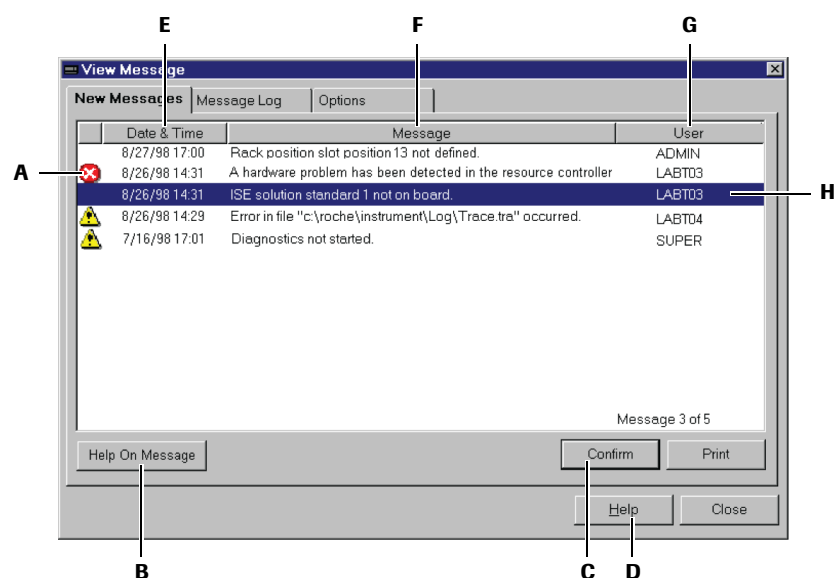
*Clearing the **Messages** button*

You can clear the red and yellow versions of the **Messages** button by confirming all warning, error, and critical messages.

👁 *Confirming messages on page E-9*

New Messages tab

Use the **New Messages** tab on the **View Message** dialog box to review all currently unconfirmed messages (listed by time).



- A** Icon showing the severity of the message (if any).
- B** Click to get Help on the selected message (if available).
- C** Click to confirm the selected message.
- D** Click for Help on this dialog box (this does not give Help on the selected message).
- E** The date and time when the message was created.
- F** Short message text.
- G** Name of the user logged-on at the time the message was created.
- H** The selected message. Double-click to display details on this message.

Figure E-1

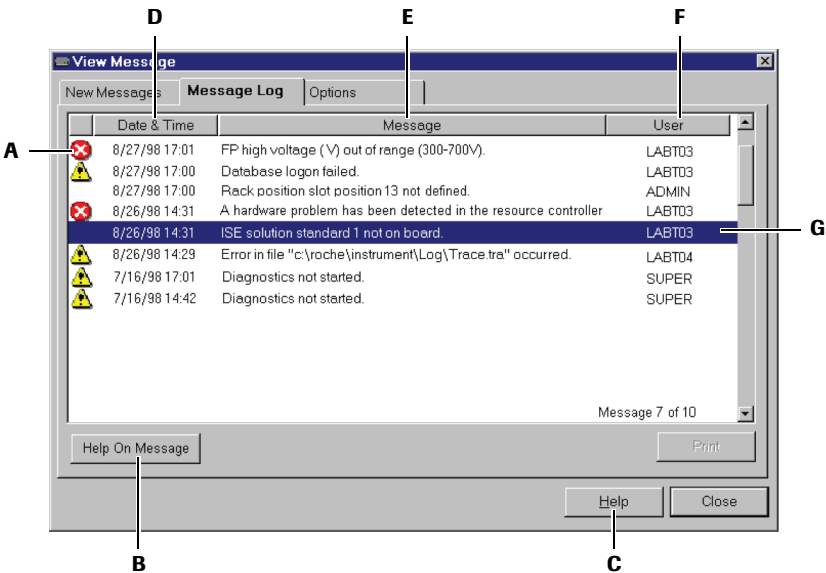


Complementary information

- You click **Confirm** to inform the system that you have fixed the problem in the message.
- If you have not fixed the problem, the system will either not restart, or the same message will reappear again, if the same conditions are met.
- Confirmed messages are automatically transferred to the message log.

Message Log tab

Use the **Message Log** tab on the **View Message** dialog box to review messages that you (or other users) have already confirmed as resolved. Double-click any message to display the **Message Detail** dialog box.



- A Icon showing the severity of the message if any.
- B Click to get Help on the selected message (if available).
- C Click for Help on this dialog box (this does not give Help on the selected message).
- D The date and time when the message was created.
- E Short message text.
- F Name of the user logged-on at the time the message was created.
- G The selected message. Double-click to display details on this message.

Figure E-2



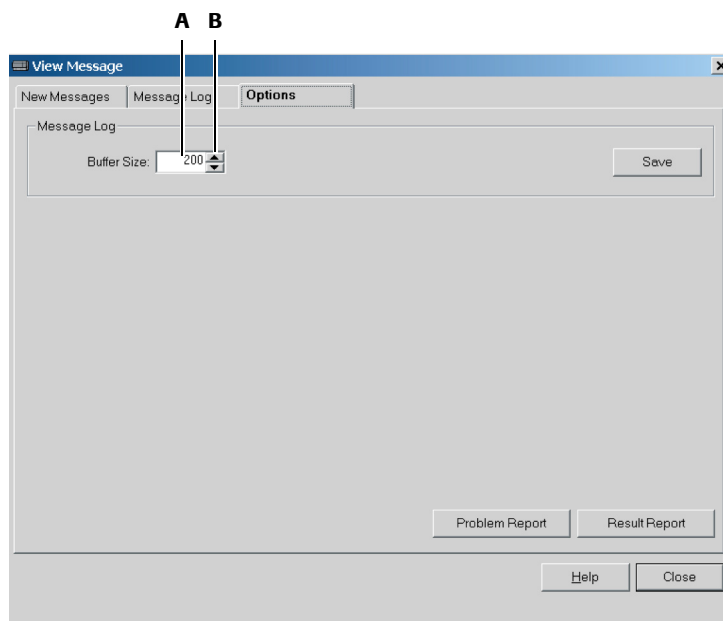
Complementary information

- The message log contains only confirmed messages.
- By default, 200 messages are stored, but you can change this number to a maximum of 2000 messages (**View Messages > Options**).
- The oldest messages are automatically deleted when the system needs space for new messages.

Options tab

Use the **Options** tab to specify the maximum number of messages stored in the message log. Type a number in the **Buffer Size** text box and click **Save**.

You can increase or decrease the size of message log buffer as required. A buffer size of 100 means that a maximum of 100 messages are stored in the log. The system saves the most recent messages and, if the log is full, deletes the oldest messages to make way for the more recent ones.



A Specifies the number of messages in the message log.

B Click to change the size of the message log.

Figure E-3



Complementary information

The **Options** tab is also used to save the **Problem Report** and **Result Report** for troubleshooting purpose.

Working with messages

You can confirm messages, display or print details on a message, review confirmed messages, or display Help on a message.

Confirming messages

A shortened form of each message is stored on the **New Messages** tab on the **View Message** dialog box. When you confirm a message, it is automatically removed from the **New Messages** tab and transferred to the **Message Log** tab. The system can carry on running even if there are unconfirmed messages.

Recommendation Do not confirm a message until you are sure that you have resolved the problem that caused it to appear in the first place.

The running man on the **Messages** button remains until you confirm:

1. The message that caused it to be displayed.
2. All subsequent messages that could have caused a running man to be displayed.



► To confirm a message

- 1 Click **Messages** on the navigation bar.
The **View Message** dialog box is displayed.
- 2 Click the **New Messages** tab.
- 3 When you have fixed the problem, select the message and click **Confirm**.
The selected message is automatically transferred to the message log.



Complementary information

- Double-click a message to get more information.
 - Follow any Help or instructions contained in the message to remove the cause or causes of the message (if you have not already fixed the problem from the original message dialog box).
 - If you need to refer to the message again, use the message log.
-

Displaying message details

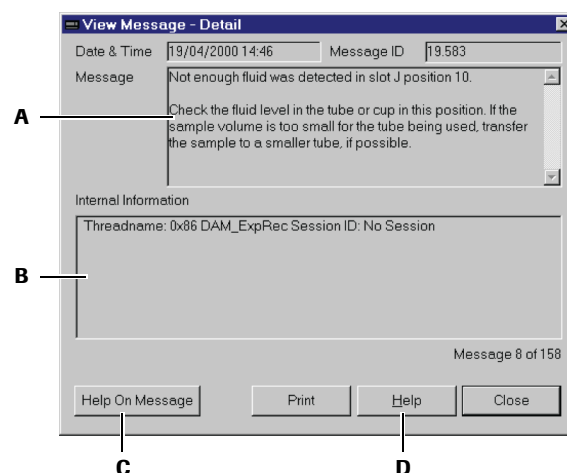


► To display message details

- 1 Click **Messages** on the navigation bar.
- 2 Click either the **New Messages** or **Message Log** tab.

- 3 Double-click a message.

The **View Message - Detail** dialog box is displayed.



- A Long text of the message.
- B Service and diagnostics information.
- C Click for Help on this message.
- D Click for Help on the dialog box (not message Help).

Figure E-4

Printing messages

You can print a list of messages from either the **New Messages** tab or the **Message Log** tab.



► To print a list of new messages

- 1 Click **Messages** on the navigation bar.
The **View Message** dialog box is displayed.
- 2 Click the **New Messages** tab.
- 3 Click **Print**.

Complementary information

This procedure prints only non-confirmed messages (for problems that have not yet been resolved).

► To print the message log

- 1 Click **Messages** on the navigation bar.
The **View Message** dialog box is displayed.
- 2 Click the **Message Log** tab.
- 3 Click **Print**.



Complementary information

The message log contains messages that have been confirmed (and therefore have been automatically removed from the list on the **New Messages** tab).

Putting the system into Standby

How you do this depends on the state the system is already in. The **Status** button on the navigation bar tells you what the system state is.

**Standby****Operating****Sleeping****Service actions****Initializing****Table E-3**

► **To put the system into Standby if it is in Operating state**

- 1 Click **Stop**.
- 2 In the **Stop Action** dialog box, click **Sampling Stop**.
- 3 Click **OK**.

► **To put the system into Standby if it is in Sleeping state**

- 1 Click **Start**.
- 2 The system performs a partial initialization and then goes into **Standby**.

► **To put the system into Standby if it is performing BOD actions or service actions**

- 1 Wait until the BOD actions or service actions have finished. The system returns to **Standby** automatically.



You cannot use **Stop** to force the system into **Standby** when it is performing BOD actions or service actions.

► **To put the system into Standby if it is Initializing**

- 1 Wait until initialization is complete.

Stopping and restarting the system

You sometimes need to stop the system while troubleshooting.

There are two levels of stopping:

1. Stop and continue processing
2. Shut down and restart the system.

Which method is appropriate depends not only on what you need to do in terms of corrective action, but also what the system is doing (the system state) and how your throughput will be affected.

Check the messages and online Help to see which method is recommended for a particular case.

The procedure for a complete shutdown and restart of the system consists of the following steps:

1. Stop processing
2. Shut down the system
3. Restart the system
4. Initialize the system
5. Restart processing

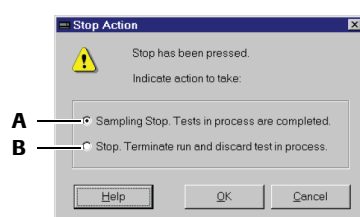
Stop processing



If the system is in the **Operating** state (for example, when it is processing tests) Click **Stop** on the navigation bar to interrupt sampling immediately or stop sampling as soon as the current actions are finished.

The precise function of the buttons depends on the current system status.

When clicking **Stop**, the **Stop Action** dialog box is displayed, which offers the **Sampling Stop** and **Stop** options:



- A** Stop pipetting samples but finish processing tests that are already in progress.
- B** Stop all system operations immediately. The system aborts all current activities. The system may need special attention before it can resume its normal operation.

Figure E-5



Complementary information

- If the system is already in **Standby** when you click **Stop**, it goes into **Sleeping**.
 - If you stop the run immediately, all the partially-run tests are stopped. In practice, this means you lose all the reagent, control, calibrator, and sample material for any tests that have been started but not yet completed.
 - The background color of the **Status** button tells you what the current system state is; green means **Operating** (unless there is a resource alert).
See *System states* on page A-43
 - You can also use F12 to stop the processing.
-

Restart processing

The **Start** button serves to start or restart a run.

When the system is in the **Stopped**, **AutoService**, or **Operating** status, the text of the **Start** button changes to **Restart**.

Complementary information

- Clicking **Restart** causes the system to perform a re-scheduling of all sample orders. For example, clicking **Restart** after inserting a new rack into the system while in **Operating** status, causes the system to start pipetting on the sample rack that is positioned furthest to the left.
 - You can also use F11 to start or restart the processing.
-

Re-initializing

When the system is in **Standby**, you can re-initialize, if necessary. Sometimes you will be asked to do this in the recommended actions for a particular message. You would also need to do this if your troubleshooting procedure caused you to knock (or move) an initialization post, for example.

► **To re-initialize the system**

- 1 Click **Stop** on the navigation bar to put the system into **Standby** state.
- 2 Click **Service** on the navigation bar.
- 3 Choose **Tools > Initialize System**.
System initialization takes a few minutes to complete.
- 4 Click **Restart**, if necessary.



Complementary information

- The system must be in **Standby** or **Fatal Error** state when you initialize.
 - The dialog box displayed after you click **Restart** is not listed here.
See *Stop processing* on page E-12.
In all messages and recommended actions in the Help, your reaction to this dialog box is assumed.
 - Step 4: This step is not required if **Auto Start** is enabled (in **Configuration > General > System**).
-

Shutting down the system

Shutting down the system means that the analyzer program is closed down and the analyzer and computer are switched off.

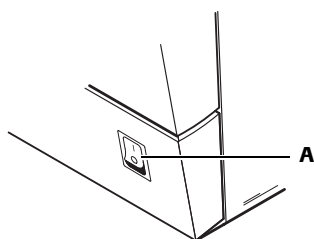
► To shut down the system

- 1 Choose **File > Shut Down**.

Your are asked to confirm.

The computer is switched off automatically.

- 2 Switch off the analyzer at the main switch (A).



After shutdown:

- All tests and procedures in progress are stopped.
- The analyzer main window is closed.



Complementary information

- You can also perform a shutdown by pressing **Alt + F4**.
- After shutdown, certain maintenance procedures will be run automatically from a separate standby power supply.

Restarting the system after shutdown

You should perform a restart only after the screen has become dark.

► To restart the system

- 1 Switch on the analyzer at the main switch.

- 2 Switch on the computer.

The system undergoes the complete startup procedure. The analyzer program is automatically restarted. Log on (**Shift + F3**) when the **Log On** dialog box is displayed.



Complementary information

- After restarting the following happens:
The operating system is automatically restarted. You do not have to log on.
The analyzer program is automatically started.
The system is re-initialized.
- When you log on, type in your user ID and password as usual. You must rerun tests that were in progress when the system was stopped.

Troubleshooting

General problem-solving techniques

This chapter explains how to identify and fix problems that can affect the running of the analyzer. It explains how to view and respond to system-generated messages and how to troubleshoot problems that do not generate messages. A description of how to check fuses is also included.

If you encounter any problems that you cannot resolve, information about contacting your Roche representative also-provided.

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Introduction

Effective troubleshooting on a analyzer requires a good understanding of all basic operating procedures for the analyzer and the system software. However, you can avoid most common problems if you observe the recommended procedures at all times and if the operating environment is effectively controlled.

For new users in particular, there are the usual familiarization problems including:

- Connecting various parts of the computer system, if necessary.
- Locating the main switch and function keys.
- Starting up the program and logging on.
- Finding your way around the user interface.

All the information you need is available either in the User Manual or in the online Help.

👁 For details on flags, error messages, and recommended actions for ISE related problems, see *Flags and user actions* on page F-41 and *General ISE troubleshooting* on page F-49.

Information about problems

The user interface keeps you informed about the status of the analyzer as a whole, and about particular hardware, software, and chemistry problems as they arise. It does this through:

- Messages displayed on the screen.
- **Status** work area.
- Buttons on the navigation bar.
- Flags on results from samples, calibrations, and controls.

You can also often see that something is wrong before any results are produced. A dripping probe for example, will affect the generated results.

Preventative maintenance

The most common sources of problems are related to service actions and water purity:

- For service actions, the main problem is a failure to keep to the maintenance schedules as defined by the service actions. Ensuring that the analyzer is correctly maintained is the most effective thing that you can do to reduce problems.
- Poor water quality can cause problems over a long period of time and can be difficult to troubleshoot especially if the water quality varies from day to day.

👁 *System water quality is unsuitable* on page E-31

Unlocking the main cover



This function is available if you work with analyzer hardware with serial number 620001 or higher.

During operation, the main cover is normally locked and cannot be opened. The main cover is automatically locked and unlocked as part of the various testing and service actions. In exceptional circumstances, for example when racks are jammed, you can use the **Unlock** function to allow access to the area where intervention is required even if the analyzer is in a state when the main cover normally is locked.

► To unlock the main cover

- 1 Choose **Tools > Unlock**.
- 2 If the analyzer is in **Operating** state, a message is displayed, informing you that the analyzer must be in **Standby** state to perform unlock.
 - a) On the message dialog box, click **OK**.
 - b) Perform the appropriate stop action.

Sampling Stop: Tests in progress are completed.

Stop: Processing is stopped immediately. (You will need to redefine all orders that are currently in progress.)

👁 See *Stop* on page B-12.
 - c) When the analyzer is in **Standby** state, continue with step 1.
- 3 Wait until, on the **Unlock Action** dialog box, you are informed that the main cover is unlocked.
- 4 When the emergency intervention on the analyzer is complete, click **Next** on the **Unlock Action** dialog box.

The main cover is locked again.

Start-up problems

This section lists potential problems arising from start-up or system initialization.

Computer mains power connector is not plugged in

- Recommended action*
1. Insert the plug into the socket.
 2. Switch on the analyzer
 3. Switch on the computer.

Analyzer main power cord is not plugged in

- Recommended action*
1. Switch off the analyzer.
 2. Insert the plug into the socket.
 3. Shut down the computer.
 4. The computer is switched off automatically.
 5. Switch on the analyzer.
 6. Switch on the computer.

Laboratory power supply has been interrupted

- Recommended action*
1. Check other electrical power sources and inform your in-house service personnel.
 2. When the power is re-established, the system will restart automatically; wait until the system is initialized.

System cannot initialize due to a fault in one or more of the analyzer modules

- Recommended action*
1. Check the displayed message(s) and take the necessary action.
 2. If the initialization is incomplete and no error is shown, contact your Roche representative.

System remains inactive in Operating state

- Recommended action*
- Check all the resources on the **Samples, Cassettes, Analyzer, and ISE** tabs of the **Status** work area.

Blocked orders, tests, calibrations, or controls

The following main conditions must be fulfilled before you can successfully run any test on the analyzer:

- All required reagents, diluents, calibrators, controls, and the cleaner, are on board and have enough volume to run the test.
- The last calibration and control results are accepted (for calibration and control tests).
- The sample is on board and has enough volume to run the test.
- The test and the measurement modules are enabled.
- The analyzer and the measurement modules are in an error-free state.

If any of these conditions are not fulfilled, the test will be blocked and the cause must be eliminated.

► To check the cause of blocked orders, tests, calibrations, or controls

- 1 Click **Orders** on the navigation bar.
- 2 Click the **Worklist** tab.
- 3 Open the **Blocked** folder and select a blocked order.
Detailed information of the selected order is displayed in the area on the right.
- 4 Make a note of the **Blocked Status Text** and look up the corresponding recommended actions in the list below.



Complementary information

- Double-click a blocked order in **Results > Validate** to see the **Blocked Status Text**.
- To get help on a blocked item, select the **Blocked Status Text** and press F1.

Cassettes and cleaner

Not on board

- Reagent not on board
- Cleaner not on board

Recommended action

1. Place the required reagent or cleaner cassette in a cassette rack.
2. Insert the cassette rack into the cassette area.

Empty

- Reagent is empty
- Cleaner empty

Recommended action

1. Locate the rack position of the empty reagent or cleaner cassette in **Status > Cassettes**.
2. Remove the cassette rack from the cassette area.
3. Replace the empty cassette with a new one.
4. Re-insert the cassette rack into the cassette area.

Not Enough for Worklist

The cassette is loaded, but there is not enough material to run all the tests in the current worklist.

Recommended action Place an additional cassette of the same kind on a rack.

Calibrators, controls, and diluents**Not on board**

- No calibrator on board
- Control not on board
- Diluent not on board

Recommended action 1. Load the required calibrators, controls, or diluents on their correct rack positions.
2. Insert the rack into a free slot in the sample or cassette area.

**Complementary information**

To check the correct calibrator, control, or diluent position, do one of the following:

- Open the **Not on Board** folder in **Status > Missing & Blocked**, to see the missing calibrators, controls, or diluents and their correct rack positions.
- Click a test folder in **Status > Test Status**, to see the calibrator, control, or diluent information of the selected test.
- If you see, for example, a status of Diluent not on board, and you replace the diluent while the system is in **Standby**, the values for **Status** and **Next Cal.** in the **Test** group are not updated until the system is in **Operating** status. The information in the **Diluents** group, however, is updated immediately. You may have to click **(Re)Start** on the navigation bar to get the system to **Operating** state.

Empty

- Calibrator empty
- Control empty
- Diluent is empty

Recommended action 1. Open the Empty folder in **Status > Missing & Blocked**, to see the empty calibrators, controls, diluents, and their correct rack positions.
2. Remove the required rack from the analyzer.
3. Refill the empty calibrator, control, diluent, and cups or tubes.
4. Re-insert the rack into a free slot in the sample or cassette area.

Not accepted

- Last calibration is not accepted
- Last control not accepted

The last calibration or control result was not accepted and a further calibration or control request has been made, either by the system (as a result of a cassette change, for example), or by the user. (Note that you can only request a further calibration or control once the calibration or control results are accepted, you may request a rerun, though.)

- Recommended action*
1. Accept the last calibration or control results in the **Validate** tab in the **Results** work area.
 2. If the last calibration or control result was not accepted because it was flagged, follow the recommended action for the displayed flag.



Accepting flagged calibrations without taking appropriate action will cause all subsequent sample results also to be flagged.

No definition

- No calibration definition available
- No control definition available

Recommended action Install the required calibration or control definitions. See online Help for details.

Samples

No fluid

No fluid level was detected in a tube or cup.

Possible reasons are:

- The tube or cup is empty.
- The tube or cup is overfilled.
- Wrong tube definition.

Recommended action Do one of the following:

- Refill the sample tube or cup.
- Remove some sample from the tube or cup.
- Check the parameters **Trigger Point** and **Lower Sample Margin** in **Configuration > Lab > Sample Tubes**.

Unknown fluid

No sample type was detected.

Possible reasons are:

- The sample type is not known.
- Position conflict between two samples.
- The barcode on the tube could not be read.

Recommended action Do one of the following:

- Assign the sample to a position on the rack
- Remove the rack and assign the sample to a new position on the rack.
 - 👁 *Assigning samples to racks* on page B-70
- Remove the clot.
 - 👁 "Clot error after pipetting from sample cup" on page -33
 - 👁 *Clotted transfer* on page E-33
 - 👁 *Clot error after sample/probe washing* on page E-33
 - 👁 *Sample prime clot error* on page E-34

- Manually enter the barcode information:
If you work with a host system:
 - a) Remove the rack and identify the missing information.
 - b) Re-insert the rack after identifying the tubes whose barcode could not be read.
 - c) Use the **Place Items** dialog box to define the orders and tests, and for assigning the samples to rack positions.
 If you work without a host system:
 - a) Remove the rack and identify the missing information.
 - b) On the **Sample** tab of the **Orders** work area, create the orders and tests that were not read from the barcode
 - c) Assign the samples to the rack positions.
 - d) Re-insert the rack into the system.

Tests

Disabled

Test is disabled.

Possible reasons are:

- Test was manually disabled.
- Test was automatically disabled due to a flagged calibration or quality control result. This is the case if the flag action is set to **Stop Test** in **Configuration > Result Handling**.

Recommended action

1. Open **Status > Test Status**.
2. Select the required test.
3. Select **Test Enabled**.



Complementary information

Check if the rules defined in **Configuration > Result Handling** apply to the workflow in your laboratory and change the result handling if applicable. See the online Help for details.

Aborted

Test was aborted either by stopping the run and selecting **STOP. Terminate Run and discard tests in progress** or by switching off the analyzer.

Recommended action

Restart the run.

ISE

Not on board

- Activator Bio not on board
- ISE Deproteinizer not on board
- ISE Etcher not on board
- No ISE solution available

Recommended action

1. Open the Not on Board folder in **Status > Missing & Blocked**, to see the solutions that are not on board and their correct rack positions.
2. Remove the ISE rack from the analyzer.
3. Load the required Activator Bio, ISE Deproteinizer, ISE Etcher, or ISE solutions on their correct ISE rack positions.
4. Re-insert the ISE rack into slot O.

The **ISE Rack Replaced** dialog box is displayed.

5. On the dialog box select the ISE solutions that you have replaced.



Leave the check boxes cleared for ISE solutions you have not replaced.

Empty

- Activator Bio is empty
- ISE Deproteinizer is empty
- ISE Etcher is empty
- ISE solution is empty

Recommended action

1. Open the Empty folder in **Status > Missing & Blocked**, to see the empty Activator Bio, ISE Deproteinizer, ISE Etcher, or ISE solution and their correct rack positions.
2. Remove the ISE rack from the analyzer.
3. Refill the empty Activator Bio, ISE Deproteinizer, ISE Etcher, or ISE solution.
4. Re-insert the ISE rack into slot O.

The **ISE Rack Replaced** dialog box is displayed.

5. On the dialog box select the ISE solutions that you have replaced.



Leave the check boxes cleared for ISE solutions you have not replaced.

Not ready

The ISE module is not initialized.

Possible reasons are:

- The last ISE initialization was not successfully completed.
- Not all required solutions are available, for example Activator Bio or Solution 1.
- The ISE module was recently enabled but no ISE initialization was performed.

Recommended action

- Make sure all solutions are on board.
- Perform the service action **Initialize ISE module** in **Service > All**.

Disabled

The ISE module was disabled manually.

Recommended action

1. Open **Status > ISE**.
2. Select **Enable ISE Module** to enable the ISE measurements.



The analyzer must be in **Standby** for enabling the ISE module.

No electrode

The ISE electrode is not defined or it is disabled.

Recommended action

1. Open **Configuration > General > ISE**.
2. Select the required electrode setting.
3. Click **OK**.
4. Open **Status > ISE**.
5. Select **Potassium** or **Sodium** to enable the required electrodes.

Error

Hardware error in the ISE module.

Recommended action

1. Check for new hardware error messages in **View Message > New Messages**.
2. Select the message and click **Help on Message** to open the online Help.
3. Follow the recommended actions of the selected message.

Hardware errors

Abs. error

Hardware error in the absorbance photometer module.

- Recommended action*
1. Check for new hardware error messages in **View Message > New Messages**.
 2. Select the message and click **Help on Message** to open the online Help.
 3. Follow the recommended actions of the selected message.

Fatal error

The system has a fatal hardware error. The robotic transfer system, the ISE module and the analyzer including absorbance photometer are not working due to a serious hardware problem. No measurement of tests is possible.

- Recommended action*
1. Check the status of the system in **Status > Analyzer**.
 2. Shut down and restart the system.
 3. If the problem reoccurs, contact your Roche representative.

Results

This section lists those problems that may occur when results are obtained from the analyzer.

Quality control results out of range

Quality control results are obtained but they are outside the expected range for the test.

Possible problems include:

- Control or a diluent in the wrong position  page E-29
- Control material has deteriorated  page E-29
- Lot-specific assigned values are not correct  page E-29
- Pipetting error  page E-29
- Reagent in the cassette has deteriorated  page E-30

Control or a diluent in the wrong position

- Recommended action*
1. Use **Status > Missing & Blocked** to check which items are missing.
 2. Use **Status > Samples** to check the current positions of all onboard controls and diluents.
 3. Replace the controls or diluents in their correct positions as required.

Control material has deteriorated

- Recommended action*
1. Use **Status > Samples** to check the current positions of all onboard controls.
 2. Replace the controls with fresh or freshly-prepared material in the correct rack positions.

Lot-specific assigned values are not correct

- Recommended action*
- Check the values in **Configuration > Controls > Lot**.

Pipetting error

The volume of fluid delivered by the dosage pipettes is incorrect.

- Recommended action*
-  See *Leakage* on page E-34
 -  See *Air bubbles in one or more pipettes* on page E-35
 -  See *Dripping pipettes* on page E-36
 -  See *Dripping probes* on page E-36

Reagent in the cassette has deteriorated

- Recommended action*
1. Check the cassette expiry date in **Status > Cassettes**.
If the cassette has reached its expiry date, replace it with a new cassette when the rack is released.
 2. Check the results of the last calibration or control.
If the results deviate significantly from the previous calibration or control, order a new calibration or control.
If the results are still wrong, check the calibrator or the control material. If these are OK, replace the reagent cassette.
 3. Check when the next calibration is due (**Status > Test Status**).
If the due time is some time away and the last calibration was performed some time back, order a new calibration.

Test results not reproducible

Results are obtained but are frequently flagged. In particular, when a particular test is rerun, the results are not consistent with earlier values.

Possible problems include:

- Air bubbles or foam on the surface of the sample  page E-30
- Clots or particles in the sample  page E-30
- Probes not clean  page E-31
- Leaking tubing or connections  page E-31
- Evaporation or deterioration of the sample  page E-31
- System water quality is unsuitable  page E-31
- Wash station is defective  page E-31

Air bubbles or foam on the surface of the sample

- Recommended action*
1. Carefully remove air bubbles or foam from the surface of the sample.
 2. When transferring samples to secondary cups, pipette the sample carefully to avoid the introduction of air bubbles or foam.
 3. Insert sample racks carefully to avoid disturbing the samples.

Clots or particles in the sample

- Recommended action*
1. Re-centrifuge the sample, if necessary.
 2. Alternatively, transfer some sample, free of clots or particles, into a secondary cup.

Probes not clean

- Recommended action*
1. Perform the service action **Deproteinize Probes**.
 2. Perform the service action **Clean Probes Manually**.
 3. If this does not work, replace the probes.

Leaking tubing or connections

Recommended action Leaking tubing or connections in the fluid system may lead to pipetting errors.

- 👁 See *Leakage* on page E-34
- 👁 See *Air bubbles in one or more pipettes* on page E-35
- 👁 See *Dripping pipettes* on page E-36
- 👁 See *Dripping probes* on page E-36

Evaporation or deterioration of the sample

- Recommended action*
1. Use fresh material, if possible.
 2. If the sample is in a secondary cup, transfer a new aliquot to a new cup from the original primary sample.

System water quality is unsuitable

- Recommended action*
1. Check the quality of the input water according to the instructions provided by the manufacturer of the deionized water supply system.
 2. You must use reagent grade, type 1 water or equivalent.
 3. If the water quality is not within specification, take the necessary action as recommended by the manufacturer of the deionized water supply system.

Wash station is defective

- Recommended action*
1. Check for leakage on the bench under the wash station.
 2. Check that the waste connector is properly connected and that the tubing is not clogged.
 3. If any leaks persist, contact your Roche representative.
 - 👁 *Leakage* on page E-34
 - 👁 *Air bubbles in one or more pipettes* on page E-35
 - 👁 *Dripping pipettes* on page E-36
 - 👁 *Dripping probes* on page E-36

Test results low or drifting

Results are obtained, but the values obtained are lower than expected.

Results are obtained, but the values show a consistent trend to drift (either up or down) from their expected values.

Pipetting incorrect sample or reagent volumes

1. Perform the service action **Deproteinize Probes**.
2. Perform the service action **Clean Probes Manually**.
3. Perform a **Check Test**.

4. If this is unsuccessful:
 - a) Replace the probes.
 - b) Check the pipettes and pistons.
 - c) Check for leaks.
 - 👁 *Leakage* on page E-34
 - 👁 *Air bubbles in one or more pipettes* on page E-35
 - 👁 *Dripping pipettes* on page E-36
 - 👁 *Dripping probes* on page E-36

Sample has deteriorated

Sample has deteriorated, for example, due to instability of the analyte.

Recommended action

1. Use fresh material, if possible.
2. If the sample is in a secondary cup, transfer a new aliquot to a new cup from the original primary sample.

Hardware

This section lists problems associated with hardware functions, particularly regarding the cuvettes and the fluid system.

Reacting to a hardware message

► To react to a hardware message

- 1 Read the message and follow the instructions in the Help text to this message.
- 2 If this does not solve the problem click **Stop**.
The **Stop Actions** dialog box is displayed.
 - a) If you can continue processing orders, select **Sampling Stop**.
 - b) If you cannot continue processing orders, select **Stop**.
- 3 Perform the **Initialize System** service action.
- 4 If this does not solve the problem, perform a system shutdown and restart the system.
- 5 If this does not solve the problem, contact your Roche representative.

- 👁 *To react to a message* on page E-4
- 👁 *(Re)Starting and stopping a run* on page B-11
- 👁 *Re-initializing* on page E-13
- 👁 *Shutting down the system* on page B-10
- 👁 *Switching on the system* on page B-5
- 👁 **Roche service** on page D-45

Cuvettes

Cuvettes must meet stringent optical specifications before they can be used on the analyzer. Defective cuvettes are discarded automatically.

System discards a large number of unused cuvettes

- Recommended action*
1. Remove several cuvettes from the reservoir.
 2. Check whether they are cloudy, scratched, or dirty. If so, empty the cuvette reservoir manually and refill with new cuvettes.
 3. If this is unsuccessful, open the analyzer cover and carefully remove some cuvettes from the cuvette buffer slide with tweezers. If these cuvettes are scratched or dirty, contact your Roche representative.

Clot error after pipetting from sample cup

Pressure sensors are fitted to detect clots during aspiration of samples, during washing of probes, or when initializing the system. When a clot is detected a message is displayed.

The tube or cup indicated may contain clotted sample material. There will be no further pipetting from this cup.

- Recommended action*
- Make sure no clots are contained in the sample cup. Depending on the kind of specimen, centrifuging or filtering may solve the problem.

No sample pipetting possible due to previous sample cup clot error

- Recommended action*
- Remove the clot physically from the sample.

Clotted transfer

Pressure sensors are fitted to detect clots during aspiration of samples, during washing of probes, or when initializing the system. When a clot is detected a message is displayed.

Clot detection for the transfer arm. Attempting to resume operation.

- Recommended action*
1. Look for other messages which may indicate the source of the clot.
 2. If the next wash operation succeeds the system will continue to operate normally.

Clot error after sample/probe washing

Pressure sensors are fitted to detect clots during aspiration of samples, during washing of probes, or when initializing the system. When a clot is detected a message is displayed.

Extensive clots have been detected in a sample probe which could not be removed automatically. The system will be stopped and some scheduled tests may need to be repeated.

- Recommended action*
1. Look for other messages which may indicate the source of the clot.
 2. Wait until the system is in **Standby**.
 3. Apply the cleaning procedure for the sample probe.
 4. Check the onboard samples for clots.
- 👁 **Clean probes and splash guard** on page D-26



If **Clean probes and splash guard** does not solve the problem perform **Replace Probe B (or C)**.

👁 **Replace probe B (or C)** on page D-51

Sample prime clot error

Pressure sensors are fitted to detect clots during aspiration of samples, during washing of probes, or when initializing the system. When a clot is detected a message is displayed.

Extensive clots have been detected in a sample probe which could not be removed automatically. Therefore the system will not start measuring.

- Recommended action*
1. Look for other messages which may indicate the source of the clot.
 2. Wait until the system is in **Standby**.
 3. Apply the cleaning procedure for the sample probe.
👁 **Clean probes and splash guard** on page D-26
 4. Check the onboard samples for clots.

Leakage

Fluid leaks can sometimes occur, especially when service actions (for example, **Replace Dosage Pipette Plunger Tip**) are not properly completed.

Leaking pipettes

- Recommended action*
1. Check that the pipette is firmly screwed into place and tighten, if necessary (do not over-tighten any connections).
 2. If the leak is from the barrel of the pipette, replace the pipette or piston.

Leaking tubing or tubing connections

- Recommended action*
1. Check that the tubing connectors are firmly screwed into place and tighten, if necessary (do not over-tighten any connections).
 2. Check the external water and external waste tubes and ensure they are properly connected and not damaged.
 3. Turn off the external water supply and reconnect or replace the water tubes, if necessary.
 4. If the leakage is from the internal fluid system (on the analyzer), perform a shutdown and switch off the system, then contact your Roche representative.

Air bubbles in one or more pipettes

Air bubbles are a sign that the fluid system (most likely a pipette) is leaking or that the cleaner is running low or the water supply is not properly connected.

Pipette not correctly installed

- Recommended action*
1. Reinstall the pipette or the piston ensuring no air bubbles are trapped.
 2. Check for air bubbles appearing after reinstallation.
 3. If air bubbles reappear, call your Roche representative.
- 👁 **Replace plunger tip dosage pipette B (or C)** on page D-55

Water supply or cleaner not properly connected

- Recommended action*
1. In **Status > Analyzer**, check whether the cleaner is running low. If necessary, replace the cleaner.
 2. Check the connections to the cleaner and water supply.
 3. Perform the service action **Prime the fluid system**.
- 👁 *Replacing the cleaner* on page B-18
- 👁 *Waste, water, and power connectors* on page E-40
- 👁 *Prime the fluid system* on page D-44

Dripping pipettes

If a visual inspection shows that either of the pipettes is leaking, you must take immediate action.

Pipette not correctly installed

- Recommended action*
- Reinstall the pipette.
- 👁 **Replace plunger tip dosage pipette B (or C)** on page D-55

Piston worn out

- Recommended action*
1. Replace piston or pipette.
 2. If the piston only is replaced and drips reappear after replacement, replace the complete pipette.
- 👁 **Replace plunger tip dosage pipette B (or C)** on page D-55

Dripping probes

If a visual inspection shows that either of the probes is leaking, you must take immediate action.

Loose tubing connections

- Recommended action*
1. Check that the tubing connectors are firmly screwed into place and tighten, if necessary (do not over-tighten any connections).
 2. Replace the complete probe and tubing assembly, if necessary.
- 👁 **Replace probe B (or C)** on page D-51

Damaged tubing or probe

- Recommended action*
- Replace the complete probe and tubing assembly, if necessary.
- 👁 **Replace probe B (or C)** on page D-51

Valve is defective

A Hardware Warning message may be displayed (but not necessarily) stating that a valve is defective.

- Recommended action*
- Contact your Roche representative.

Damaged probes

- Recommended action*
1. Check the probes visually for damage and replace, if necessary.
 2. Check whether there is any physical obstruction that might have damaged the probe, if so, remove the obstruction.
- 👁 **Replace probe B (or C)** on page D-51

Due service actions not performed

Due service actions (related to pipettes and probes) were not performed on schedule.

- Use **Service** > **All** and perform all due service actions.

Temperature control

If the ambient temperature exceeds 30 °C (86 °F), the refrigerant pressure becomes too high and the cooling system generates a hardware error.

Recommended action

1. Switch off the analyzer at the main switch.
2. Ensure that at least one cassette slot is empty (to improve the air circulation inside the cooling box).
3. Switch on the main switch.
4. Allow the system to start up and complete its initialization.
5. Run the system with at least one spare cassette rack slot for about ten minutes. After this, you can use all the slots for cassette racks.
6. If this does not fix the problem, contact your Roche representative.

Condensation water

In operating conditions above average temperature in combination with high humidity, condensation can build up especially in the cassette area. Water can spill on the cassettes and may lead to incorrect or invalid results.

In operating conditions above average temperature in combination with high humidity, observe the following precautions:

- Check every two hours if condensation has built up inside of the cassette area. Check also underneath the cassettes
- Wipe up any condensation water on the cassettes, the cassette racks, and in the cassette area.

Software error messages

The process <process name> is no longer responding

Recommended action

1. Click **Shutdown** in the message dialog box.
The analyzer software is shut down and restarted.
2. Create a problem report.
 *Creating a problem report* on page E-44

Control unit accessories

This section lists problems that may be associated with the control unit, including connection problems, and other basic problems with the computer, monitor, printer, and barcode scanner.

Connections

Cables detached or damaged

- Recommended action*
1. Ensure that all the required connections are made.
 *Connections check list* on page E-41
 2. If any cables are damaged, contact your Roche representative.

Computer

- Recommended action*
1. Switch off the computer.
 2. Insert the plugs in the correct sockets, press them in firmly.
 3. Switch on the computer.

Monitor

Screen is partially or completely black

- Recommended action*
1. Check that the monitor is plugged into the laboratory mains and that it is connected to the computer.
 2. Check that the monitor is switched on.
 3. Move the mouse or press a key to deactivate the screen saver.
 4. If this does not fix the problem, contact your Roche representative.

Screen is dim or dark

- Recommended action*
- Check the screen brightness and contrast selections on the monitor, using the buttons on the screen.

Printer

Printer connections and printer indicators OK, but still no printout

- Recommended action*
1. Check the printer settings in Windows 10.
 2. Check that the printer driver, currently used as the default, corresponds to the printer actually connected. (This printer needs to be PCL 5 compliant.) Modify the printer settings, if necessary.
 3. Switch the printer off and back on again to re-initialize.
 4. If printing is still not possible, shut down the system. Restart and wait until the system is initialized.
 - 👁 *Shutting down the system* on page E-14
 - Restart processing* on page E-13
 5. If the problem reoccurs, contact your Roche representative.

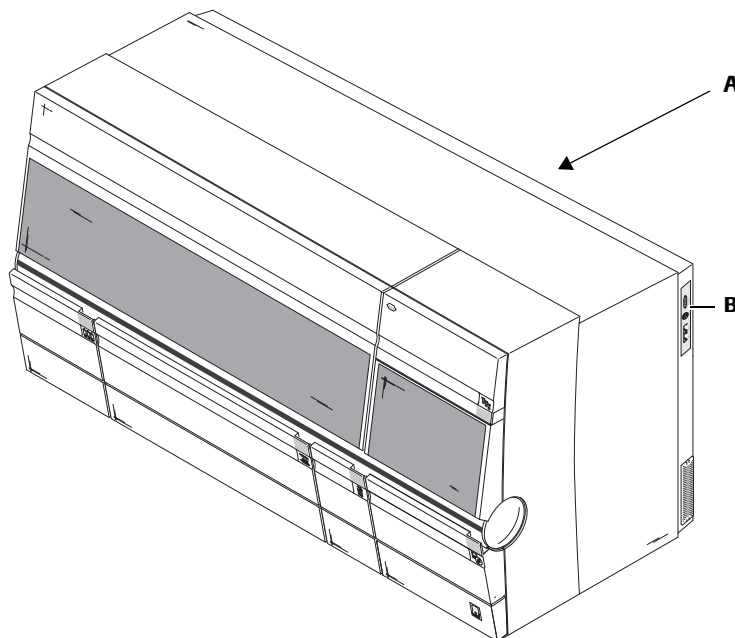
Barcode scanner

Barcode scanner cannot read the barcodes

- Recommended action*
1. Check that the barcode scanner window is free of grease and dirt.
 2. Clean the barcode scanner window, if necessary.
 3. Check whether the barcode setup, including the reading of the installation barcodes, was properly completed.
 4. Check whether the printing quality of the barcode labels is sufficient.
 5. Check whether there is condensation on the barcode labels.

External connectors

The connectors that you may need to check are located either at the back of the analyzer (A) or on the right side near the back (B) as shown below.

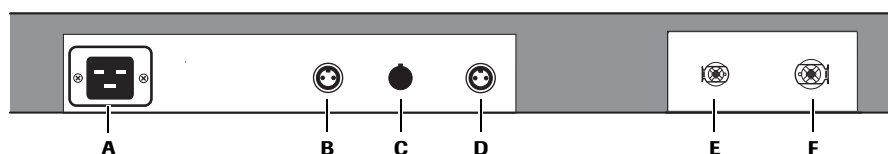


- A** Waste, water, and power connectors (not visible here)
B Data connectors

Figure E-6

Waste, water, and power connectors

The waste, water, and power connectors are located at the back of analyzer.



- | | |
|---------------------------------------|---------------------------------------|
| A Mains input connector | D Waste reservoir level sensor |
| B Water reservoir level sensor | E Water reservoir connector |
| C Not used | F Waste reservoir connector |

Figure E-7

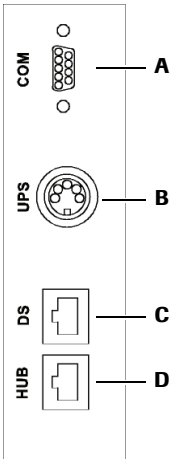


Complementary information

- Do not touch mains cables, if your hands are wet.
- Do not attempt to connect or disconnect either of the mains cables, if the analyzer is switched on.
- If any power connector becomes worn or frayed, it must be replaced immediately with an approved cable. Contact your Roche representative.
- You must connect the waste sensor, if you are using a separate waste container (that is, the analyzer is not connected to the main laboratory waste system).
- You must connect the water sensor, if you are using an external water reservoir.

Data connectors

These connectors are located on the right-hand side of the analyzer near the back.



- | | |
|---|--|
| A COM: Serial communications connector | C DS: LAN Direct connection to computer |
| B UPS: Auxiliary connector (not used) | D HUB: Not used |

Figure E-8



Serial ports, if used, are configured by your Roche representative.

Connections check list

Use this list if you need to check that your system is properly connected.

Mains connections

Recommended action

- Check that the power cable of the computer is plugged in at both ends.
- Check that the power cable of the analyzer is plugged in at both ends.
- Check that the power cable of the monitor is plugged in at both ends.

Connections between computer and analyzer

- Recommended action*
- Check that the connection from the COM connector on the computer is made to the COM connector on the analyzer.
 - Check that the connection from the DS connector on the computer is made to the DS connector on the analyzer.

Host connections

- Recommended action*
- If you work with a host system, check that the communication connection from the COM1 connector on the computer is made to the host computer.

Modem connection

- Recommended action*
- Check that the modem on the computer (Line) is not connected to the telephone socket. Do *not* use this connection for remote diagnostics.

2nd LAN connection

- Recommended action*
- This port can be used for remote diagnostics.



The 2nd LAN connector must only be used for Roche remote service connectivity. If a remote service connection is established over an unsecure network via a remote service client, the device must be installed behind either a Roche "connect 2" device or a cobas link gateway.



Unauthorized system access and data loss

Connecting the LAN connectors to devices other than the ones stated in this publication could lead to unauthorized database access resulting in possible disclosure or modification of sensitive data.

- Follow the recommendations stated in *Software and data security* on page 28.

Monitor connections

- Recommended action*
- Check that the connection from the 15 pin VGA connector on the computer is made to the monitor.
 - Check that the monitor power cable is plugged in at both ends.

Printer connections (optional)

- Recommended action*
- Ensure that the printer is PCL 5 compliant.
 - Check that the printer cable is connected to the control unit.
 - Check that the printer power cable is properly connected at both ends.

Hand-held barcode scanner connection (optional)

- Recommended action*
- Check that the hand-held barcode scanner is connected to an USB port.

Water supply

- Recommended action*
- Check that the water supply is connected. The analyzer will not initialize properly if a water supply is not connected.
 - Check that the water sensor is connected, if you are getting your water supply from a water container. (The water sensor must be inside the water container.)

Waste outlets

- Recommended action*
- Check that the waste outlet is connected to a suitable waste container or to a waste drain.
 - Check that the waste level sensor is connected, if your waste is going to a waste container. (The waste level sensor itself must be inside the waste container.)

Checking and replacing fuses

A set of fuses protects the analyzer from excessive electrical currents. If a fuse blows, a message is displayed to inform you that you need to replace that fuse.

You can check the status of the fuses by their LEDs.

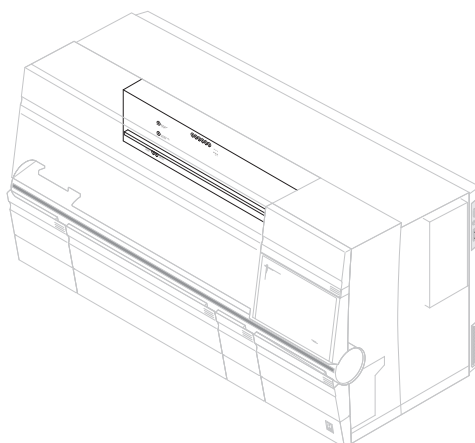


Figure E-9 Fuse LEDs

A green LED indicates that the fuse is working, if the LED is not lit, the fuse needs replacing.



- If the main cover is locked, use the unlock function first (**Tools > Unlock**).
- If a fuse needs replacing, contact your Roche representative.

Contacting Roche Service

Roche Service can help you solve many problems that you are unable to solve for yourself. However, before you contact your Roche representative:

1. Check this chapter to see if your particular problem is described. If it is, follow the recommended procedures.
2. Search the online Help for the information you require. You can perform a full text search to help you find this information.
3. If this fails, contact your system administrator for further advice.
4. If you still cannot solve the problem, make a note of any special conditions that you think might be relevant.
5. Create a problem report. (See *Creating a problem report* on page E-44.)
6. Contact your Roche representative.

In the first instance, contact the Roche remote diagnostics support service. This service allows a Roche representative to log on and control the system remotely. (See *Remote diagnostics* on page E-45.) For this level of support, a **connect 2** box or a cobas link gateway must be connected to the 2nd LAN port.

Creating a problem report

You can create a problem report on an external storage device. This report collates all the messages and other system information that the Roche representatives will need if you cannot solve a particular problem on your own. You should create the report (if possible) before contacting your Roche representative.

► To create a problem report on an external storage device

- 1 Click the **Messages** button on the navigation bar.
- 2 Click the **Options** tab.
- 3 Click **Problem Report**.

The **Create problem report** dialog box is displayed.

When the report is created, a message is displayed asking you whether you want to store the report on an external storage device.

- 4 On the **Create problem report** dialog box, click **Yes**.

A message is displayed asking you to insert an external storage device.

- 5 When you are asked to do so, insert an external storage device.
- 6 On the message dialog box, click **OK**.
- 7 On the **Save problem report** dialog box, navigate to the required folder and click **Save**.

When the report is stored on the external storage device, a message is displayed asking you to remove the external storage device.

- 8 When you are asked to do so, remove the storage device.
- 9 On the message dialog box, click **OK**.



Complementary information

- A copy of the problem report is automatically stored as a .zip file on the desktop, in the folder Problem Report. To access the desktop, press Windows + D.
 - You can also create a problem report from the message dialog box, for some types of messages.
 - Contact your Roche representative, and send the report to the address you are given.
 - If you turn off the main switch and turn on again, you may get a message prompting you to create a problem report before the system re-initializes. You can ignore this message.
-

Remote diagnostics

Use the Roche remote diagnostics support service whenever you have a problem that you cannot resolve.

This service allows a Roche representative to log on and control the system remotely. For this level of support, a **connect 2** box or a cobas link gateway must be connected to the 2nd LAN port.

► **To enable a remote diagnostic session**

- 1 Check that a **connect 2** box is connected to the 2nd LAN port.

👁 *Data connectors* on page E-41

👁 *Connections check list* on page E-41

- 2 Ensure that both the analyzer and the computer are on. You do not have to be logged on; the Roche representative will automatically log on using a remote service client.
- 3 The Roche representative can now access your system remotely.

Customer confidentiality

When a Roche representative logs on to your system remotely, sample results, records of calibrations, controls, and service actions are available to them.

Make a note of the following information

When you report a problem to Roche Service, please have the following information available:

- Analyzer serial number
- Maintenance information (see service notes in the **Service** work area)
- System software version
- TAS version of the test in question
- TAS version installed on the system
- Description of the problem
- Description of the last operations (carried out immediately before the problem arose)
- Time when the problem occurred

Problems with chemistry

For chemistry troubleshooting, you should also have the following additional information available:

Item	Lot number
Cassette	
Calibrator	
Control	
Diluent	

Table E-4

You may also need the following:

- ☐ The last calibration and control results
- ☐ A printout of the cassette status
- ☐ A printout of the raw data of the specific test(s)

ISE measurements

F

17	<i>ISE module</i>	<i>F-3</i>
18	<i>ISE service actions</i>	<i>F-15</i>
19	<i>ISE flags and troubleshooting</i>	<i>F-39</i>

ISE module

An overview of the ISE module

This chapter provides a description and general overview of the analyzer ISE module. It describes the main components of the ISE module and how it operates. It also describes in general terms how to make ISE measurements and is supported by an ISE solutions summary.

In this chapter

Chapter **17**

Overview F-5

 Measuring modes F-5

 Parts of the ISE module F-6

 ISE rack F-8

How the ISE module works F-8

 Principles of operation F-9

 Calibrations F-10

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 ISE Standby F-11

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Overview

The ISE module is a measurement system for electrolytes that runs independently of the absorbance photometry system. The ISE module uses the same samples, racks, and tubes that are used for photometric measurements, and the samples are transferred using probe C. The ISE module also uses specific solutions, some of which are kept in bottles on the ISE rack, the others on the ISE module itself.

Measuring modes

The analyzer Ion-Selective Electrode (ISE) module makes quantitative determinations of the following electrolytes:

- Sodium
- Potassium
- Chloride (optionally)

There are three measuring modes:

Measuring mode	Description
Direct mode	The sample, control, and standard solutions are used undiluted.
Indirect mode	The sample, control, and standard solutions are diluted with system water.

Table F-1

The dilutions and the mixing are performed automatically in the ISE tower.

The tests available in each mode are as follows:

	ISE Direct	ISE Indirect
Sodium	Yes	Yes
Potassium	Yes	Yes
Chloride	Yes	Yes

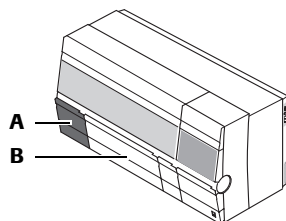
Table F-2

ISE measurements

ISE measurements and photometric measurements are carried out at the same time and are independent of each other (ISE measurements do not use cuvettes, the analyzer rotor, or photometers). In addition, all requested ISE measurements on a specific sample (or calibrator) are performed in parallel, that is, measurements are made at each electrode at the same time.

Parts of the ISE module

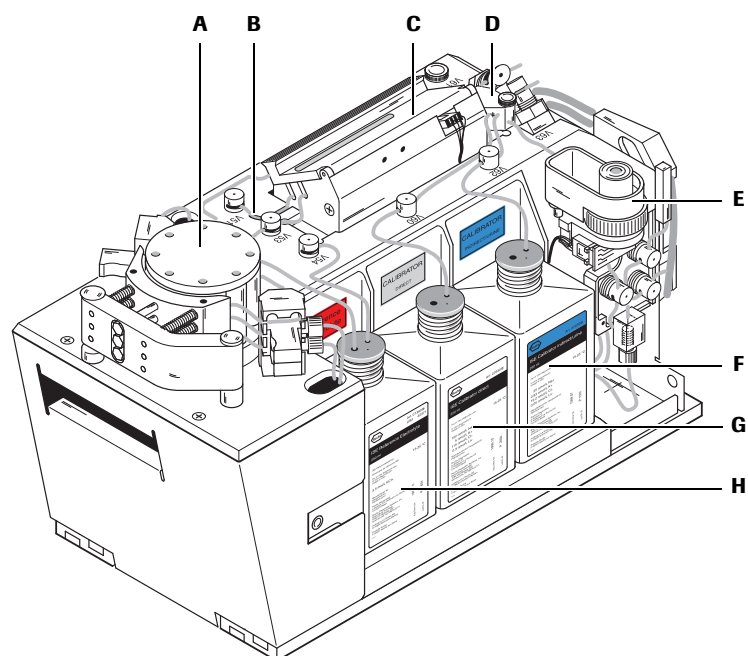
The ISE module is located behind the ISE access panel. The ISE rack (see page F-8) is on the sample rack platform.



- A** ISE access panel
B ISE rack accessed through the rack area panel

Figure F-1

The following figure shows the main parts of the ISE module:



- | | | |
|----------------------------|-------------------------------------|---|
| A Peristaltic pump | D Distribution block | G Calibrator Direct Bio HT |
| B ISE module tubing | E ISE tower | H ISE Reference Electrolyte Bio HT |
| C Electrode block | F Calibrator Indirect Bio HT | |

Figure F-2

The main parts of the ISE module are as follows:

ISE module part	Description
Electrode block	A metal block that contains the electrodes shielding them from electromagnetic interference.
Peristaltic pump	A fluid pump that draws the solutions through the electrode block and then into the sample waste.
ISE tower	A hollow, transparent cylinder with multiple inlets and outlets for air and solutions. When the ISE tower is blocked, the user can remove and clean it. In the ISE tower, samples and diluents for indirect measurements are mixed using an air stream. (Undiluted samples are not mixed.)
Tubing (not shown)	Tubing is used to connect the ISE module with the water and waste system. Tubing is also used for sample waste, ISE Reference Electrolyte Bio HT, and ISE calibrators, which are contained in bottles on the ISE module.
Sample transfer arm (not shown)	The sample transfer arm uses probe C to pipette samples into the ISE tower. If required, samples may be diluted automatically.
Valves (not shown)	A set of valves controls the flow of liquids through the tubing.
Sensors	A pair of sensors detects the presence of liquid or air and enables the correct placing of segments for measurement and cleaning.
ISE distribution block	A transparent plastic block used for liquid and air distribution within the ISE module.

Table F-3



CAUTION

Injury due to moving or rotating parts

There is a risk of injury, body parts, hair and clothes can be caught or squeezed by moving parts of the ISE peristaltic pump even when the analyzer main power switch is off

- Keep away from moving parts.

ISE solutions on the module

The following ISE solutions are stored in bottles that are located on the ISE module itself:

- ISE Reference Electrolyte Bio HT
- Calibrator Direct Bio HT
- Calibrator Indirect Bio HT

👁 *Replace bottles on ISE module on page F-35*

ISE rack

The ISE module uses a special rack called the ISE rack which is always loaded into slot O to the right of the sample platform.

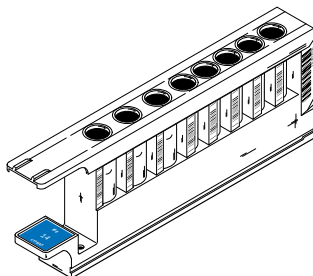


Figure F-3

The ISE rack contains the ISE solutions essential for its operation. You must place each solution in its correct position as defined in **Configuration > System > Lab > Reserve Positions**. The Activator Bio and ISE Deproteinizer in particular, need to be placed in the correct positions as the service action **Clean > Deproteinize probes** cannot be performed.

You are recommended not to change the default configuration unless this is essential. In this manual, all references to the ISE rack assume the default configuration.

👁 *ISE solutions summary* on page F-13

You can review the status of solutions on the ISE rack by clicking the **ISE** tab in the **Status** work area.

👁 *Replace ISE solutions on the ISE rack* on page F-33

The ISE rack must contain ISE Deproteinizer and Activator Bio. You can also use the ISE rack for solutions such as diluents.

How the ISE module works

The electrolyte module uses flow-through ion-selective electrodes and a reference electrode with an open liquid junction. Each electrode has a membrane or capillary that is sensitive to a particular type of ion.

Principles of operation

1. The sample is pipetted from the sample tube (located on a sample rack) into the ISE tower. Depending on the pipetting mode, the sample is diluted with system water. Mixing is performed with four air jets arranged in a circle. These jets blow air into the tower to produce a homogeneous mixture.
2. The other ISE solutions (ISE solution 1-2, ISE Deproteinizer, ISE Etcher, and Activator Bio) are pipetted from the ISE rack into the ISE tower by the sample probe C, when required.
3. The sample is divided into segments with the aid of a special arrangement of valves. The first (shorter) segments are used for cleaning, followed by a longer segment, on which the measurements are made.
4. The sample is passed to the ion-selective electrodes by the action of the peristaltic pump.
5. The exact positioning of segments is ensured by fluid sensor 2 in the measuring channel.
6. In the meantime, the ISE tower is washed with distilled water and dried.
7. ISE Reference Electrolyte Bio HT is passed through the reference electrode and into the measuring channel downstream of the electrodes. The ISE Reference Electrolyte Bio HT completes the electrical circuits for each electrode so that measurements can be made. When the measurements are made, the sample and ISE Reference Electrolyte Bio HT are stationary.
8. A one-point calibration is performed after each sample measurement using the relevant calibrator, which is located on the right side of the ISE module.
9. The electrolyte concentration of the sample is calculated.
10. The measuring channel is cleaned before the next measurement.

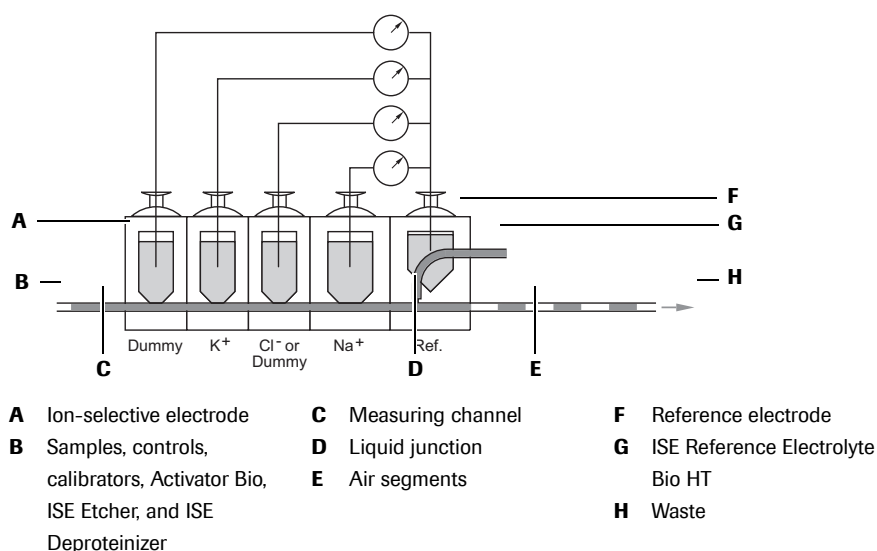


Figure F-4 Principal parts of the ISE measurement system

Calibrations

The ISE module requires frequent calibration to ensure the reliability of the test results obtained. All the required calibrations are performed automatically, although you can request a main calibration at any time.

Main calibration

Sodium, potassium, and chloride, are calibrated with a two-point calibration (duration 126 seconds) using ISE solutions 1 and 2. The time interval for main calibrations is five hours.

The following events trigger a main calibration:

- Calibration interval of 5 h exceeded (automatically ordered by analyzer)
- Rerun (manually done)
- ISE temperature difference $>5^{\circ}\text{C}$ ($>9^{\circ}\text{F}$) (automatically ordered by analyzer)

Some service actions trigger a main calibration when they are complete:

- **Electrode service**
- **Replace electrode**
- **Prime ISE calibrators**

One-point calibration

The ISE module automatically performs a one-point calibration with the corresponding ISE calibrator, depending on the measuring mode. For example, in direct mode, the Calibrator Direct Bio HT is used for the one-point calibration.

One-point calibrations are performed within the ISE cycle of 53 seconds.

Measuring modes

All ISE measurements are made in one of three measuring modes:

- Measuring direct
- Measuring indirect

In addition, the electrodes are calibrated at regular intervals and recalibrated after each measurement.



You cannot switch between measuring modes manually; this is always automatic.

STAT orders

ISE STAT samples are pipetted before routine samples.

Electrode service

Electrode Service is a service action that is automatically performed at **Begin of Day** (BOD) and during each electrode replacement. While **Electrode service** is taking place, the ISE module cannot carry out any tests.

An Electrode service contains the following steps:

- The electrodes are cleaned with ISE Deproteinizer to prevent protein build up on the electrodes and in the tubing.
- The surface of the sodium electrode is conditioned by etching.
- Electrodes are activated with Activator Bio. The Activator Bio is pipetted into the ISE tower and drawn through the measuring channel.

👁 Chapter 18 *ISE service actions*

ISE Standby

If there is no measurement after three minutes, the ISE module switches to **Standby** state. Calibrator Direct Bio HT is pumped into the measuring channel and transported slowly through the system every three minutes. Calibrator Direct Bio HT, and ISE Reference Electrolyte Bio HT are primed through the ISE module at fixed intervals (every two hours).

ISE Standby helps to prevent the following problems:

- Backflow of ISE Reference Electrolyte Bio HT into the measuring channel, which can damage the electrodes because of the high ion concentration of the ISE Reference Electrolyte Bio HT.
- Crystallization of salts in the tubing (blockage).
- Deviation from resting potential

ISE service actions

The service of the ISE module is supported by online service software. The software guides you through the service procedures to be performed at fixed time intervals or at other times depending on the work load. User defined service actions can be defined to be performed automatically by the system during the **Begin of Day** (BOD) procedure.

👁 Chapter 18 *ISE service actions*

👁 *Technical specifications* on page A-46

Making ISE measurements

The ISE module is a fully integrated part of the analyzer. You make requests for orders and place samples in the same way that you do for other types of tests. However, you must ensure that the ISE solutions and auxiliary reagents are in their correct positions.



WARNING

Incorrect results due to incorrect reagent handling

Incorrect reagent handling may cause an undetectable loss of reagent and lead to incorrect results.

- Always store and handle reagents as stated in the Instructions for Use for the test.
- Do not use containers from which reagent has spilled.
- Do not use a reagent container on different systems.

► To make ISE measurements

- 1 Check the positions of solutions and reagents on the ISE rack.
 - a) If necessary, remove the ISE rack. Wait until the ISE-rack LED on the rack status panel is green before removing the rack.
 - b) Confirm visually that the ISE solutions and auxiliary reagents (diluent) are in their correct positions on the ISE rack.

👁 *ISE solutions summary* on page F-13

- 2 Ensure that all the bottle caps (except for the Activator Bio, which has no cap) are closed firmly.

👁 *Replace bottles on ISE module* on page F-35

- 3 Check that the ISE calibrators and ISE Reference Electrolyte Bio HT are in their correct positions.

NOTICE

Damage to electrodes due to inappropriate use of ISE Reference Electrolyte Bio HT

Using the ISE Reference Electrolyte Bio HT as a calibrator or a sample will damage the electrodes. The ISE Reference Electrolyte Bio HT is automatically used with the reference electrode (and only the reference electrode) to make the electrical circuit with the measuring electrodes.

- Do not use the ISE Reference Electrolyte Bio HT as a calibrator or a sample.

👁 *Replace bottles on ISE module* on page F-35

- 4 Create an order.

Create an order for ISE tests in the **Orders** work area in the same way as other tests are ordered.

ISE tests are multi-tests, in that all ordered ISE tests for one sample are performed simultaneously with one sample pipetting.

👁 *Creating an order* on page B-69

- 5 Load samples.

Place your sample in any convenient position on a sample rack, just as you would with any other test (barcoded samples) or use the **Place Items** dialog box (**Tools** > **Place Items**).

👁 *Loading samples* on page B-12

6 Check results.

The results are displayed in the same way as any other results.

👁 Working with results on page B-100

ISE solutions summary

Solution	Cap	Location	Position	Usage
ISE Solution 1	Yes	ISE rack	6	Two-point calibration of sodium, chloride, and potassium and for the three-point calibration of lithium. Also used for the initialization of the ISE module.
ISE Solution 2	Yes	ISE rack	5	Two-point calibration of sodium, chloride, and potassium and for the three-point calibration of lithium.
Calibrator Direct Bio HT		ISE module		One-point calibration after each ISE direct measurement, which is performed once every ISE cycle when the module is in ISE direct mode. Also used during ISE standby and for servicing purposes.
Calibrator Indirect Bio HT		ISE module		One-point indirect ISE calibration, which is performed once every ISE cycle.
ISE Reference Electrolyte Bio HT		ISE module		Used in all ISE measurements of sodium, potassium, and chloride.
ISE Etcher	Yes	ISE rack	2	A cleaning solution intended for use with the ISE module for cleaning the sodium electrode during ISE service.
ISE Deproteinizer	Yes	ISE rack	8	A cleaning solution intended for use with the ISE module for cleaning the probes during BOD, the ion-selective electrodes, ISE tower, and tubing during ISE service.
Activator Bio	No	ISE rack	1	Activates the electrodes in ISE service actions and is also used for the initialization of the ISE module and for BOD.

Table F-4 ISE solutions summary



WARNING

Incorrect results

Using a non approved activator may lead to clots and incorrect results.

Failing to confirm the change of bottles on the ISE rack leads to incorrect filling level information and consequently to incorrect onboard intervals for special activator handling.

- Roche recommends to use the Activator Bio for Cedex Bio HT Analyzer systems as ISE Activator.
- Use only the original bottles of Activator Bio or the appropriate 11 mL plastic bottles of the Activator Bottle Set Bio HT.

For further details, refer to the Instructions for Use for the Activator Bio for Cedex Bio HT Analyzer systems.

- Place the solutions in the predefined positions on the ISE rack. The positions are defined in **Configuration > Lab > Reserve Positions**. Confirm the change of bottles on the ISE rack.

👁 ISE solutions summary on page F-13

Technical specifications

👁 *Technical specifications on page A-46*

ISE service actions

Maintenance tasks for the ISE module



This chapter describes the service actions and maintenance tasks for the ISE module. It provides step-by-step procedures to guide you through the service actions. It lists the potential hazards and precautions in each case.

In this chapter

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Clean ISE tower automatically	F-22
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Replace ISE tower	F-36
ISE Performance Check	F-37



General safety information

To avoid personal injury and damage to the equipment, do the following:

- Make sure you have read the safety precautions in Chapter 1 *Safety*.
 - 👁 *Safe and proper use of the system* on page 21
 - 👁 *Biohazardous materials* on page 22
 - 👁 *Mechanical safety* on page 25
 - 👁 *Reagents and working solutions* on page 26
- Pay particular attention to all safety precautions.
- Always follow the instructions in this publication.
- Make sure you read all the notes in the Instructions for Use and observe the warning labels on the bottles of ISE solutions.



Incorrect results and malfunction due to not performing service actions when they are due

Your analyzer will not perform satisfactorily, if service actions are not performed when they are due.

- Always perform service actions when they are due.
 - Do not perform any servicing except as explicitly described in this manual.
 - Always follow the service instructions contained in this publication.
-

About ISE service actions

ISE service actions work in the same way as the non-ISE service actions and are listed in the **Service** work area where you start them in the same way. ISE service actions also use the same type of service action dialog boxes, to help guide you through the steps you need to take.

Some of the service actions do not need manual interaction. From those you can choose a set to run automatically at the beginning of day (BOD)

👁 Chapter 13 *Service action software*

You can click **Help** in the **Service Actions** dialog box for online information for each service action.

Initialize ISE module



This is an automatic service action that does not require manual intervention.

The ISE module must be initialized at regular intervals to ensure proper transportation of fluids through the ISE module tubing.

The ISE module is automatically initialized during the Service action **Replace ISE module tubing**.

Duration 6 minutes

Interval Daily (can be assigned to BOD)

Begin of Day Yes

System state **Standby**

Tools and materials

- Activator Bio
- Calibrator Direct Bio HT
- ISE Reference Electrolyte Bio HT
- ISE Solution 1

► To initialize the ISE module

- 1** Select **Initialize ISE module** in the **Service** work area.
- 2** Click **Perform**.
- 3** Fluid system is initialized, if necessary [automatic step].
- 4** Transfer arm is initialized, if necessary [automatic step].
- 5** ISE Solution 1 is pipetted into the tower [automatic step].
- 6** ISE Solution 1 is transported to the fluid sensors [automatic step].
- 7** Probe C pipettes Activator Bio into the ISE tower [automatic step].
- 8** The pipetted Activator Bio is drawn into the electrode block [automatic step].
- 9** Steps 7 and 8 are repeated five times.
- 10** The ISE tower is washed and dried [automatic step].
- 11** Calibrator Direct Bio HT is pumped into the measuring channel.

Electrode service



This is an automatic service action that does not require manual intervention.

The electrodes must be cleaned regularly to prevent the build up of deposits to maintain the efficiency of the analyzer. This service action includes etching, deproteinizing and tubing conditioning steps.

Duration 8 minutes

Interval

- Daily, or
- Every 3 days if less than 50 samples per day are processed

Begin of Day Yes

System state **Standby**

Tools and materials

- Activator Bio
- Calibrator Direct Bio HT
- ISE Deproteinizer
- ISE Etcher
- ISE Reference Electrolyte Bio HT

► To service electrodes

- 1 Select **Electrode service** in the **Service** work area.
- 2 Click **Perform**.
- 3 Fluid system is initialized, if necessary [automatic step].
- 4 Transfer arm is initialized, if necessary [automatic step].
- 5 ISE module is initialized, if necessary [automatic step].
- 6 Electrodes are deproteinized [automatic step].
- 7 Electrodes are etched [automatic step].
- 8 ISE module tubing is conditioned twice with Activator Bio [automatic step].
- 9 Electrodes are rinsed with ISE calibrator [automatic step].
- 10 Electrodes are activated twice with Activator Bio [automatic step].
- 11 Calibrator Direct Bio HT is pumped into the measuring channel and transported slowly through the system every three minutes.



A calibration is run before any new samples or controls are processed [automatic step].

Activate electrodes



This is an automatic service action that does not require manual intervention.

The electrode surfaces must be activated with Activator Bio so that the correct potentials are measured. After the initial activation, the electrodes require periodic reactivation with Activator Bio, which occurs during the automated daily maintenance procedure, for optimal function.

Duration 3 minutes

Interval

- After every 50 measurements, or
- Daily if less than 50 samples per day are processed

Begin of Day Yes

System state **Standby** or **Operating**. You can perform this service action at the same time as absorbance measurements are made.

Tools and materials

- Activator Bio
- Calibrator Direct Bio HT
- ISE Reference Electrolyte Bio HT

► To activate electrodes

- 1 Select **Activate electrodes** in the **Service** work area.
- 2 Click **Perform**.
- 3 Fluid system is initialized, if necessary [automatic step].
- 4 Transfer arm is initialized, if necessary [automatic step].
- 5 ISE module is initialized, if necessary [automatic step].
- 6 Probe C pipettes Activator Bio into the ISE tower [automatic step].
- 7 The pipetted Activator Bio is drawn into the electrode block [automatic step].
 - If the ISE module is in **Standby**, the Activator Bio remains in the electrode block for 1 minute [automatic step].
 - If the ISE module is in **Operating**, the Activator Bio remains in the electrode block for 40 seconds [automatic step].
- 8 Steps 6 and 7 are repeated twice [automatic step], if the ISE module is in **Standby**. If the ISE module is in **Operating**, steps 6 and 7 are repeated three times.
- 9 Calibrator Direct Bio HT is pumped into the measuring channel.

Prime ISE calibrators



This is an automatic service action that does not require manual intervention.

You must prime the ISE calibrators when you replace a bottle containing ISE calibrator or ISE Reference Electrolyte Bio HT. This ensures that no traces of a previous calibrator are left in the tubing and therefore prevents drift in the results.



WARNING

Incorrect results because Prime ISE calibrators was not performed

Results produced with fresh calibrator bottles are not reliable unless you perform the service action **Prime ISE calibrators**

- Always perform the service action **Prime ISE calibrators** after replacing the ISE calibrator.
- Always perform the service action **Prime ISE calibrators** after replacing the ISE Reference Electrolyte Bio HT.

Duration 1 minute

Interval Daily

Begin of Day Yes

System state You can perform this procedure at the same time as absorbance measurements are made (**Operating**).

Tools and materials

- Calibrator Direct Bio HT
- Calibrator Indirect Bio HT
- ISE Reference Electrolyte Bio HT

► **To prime ISE calibrators**

- 1 Select **Prime ISE calibrators** in the **Service** work area.
- 2 Click **Perform**.
- 3 Fluid system is initialized, if necessary [automatic step].
- 4 Transfer arm is initialized, if necessary [automatic step].
- 5 ISE module is initialized, if necessary [automatic step].
- 6 Calibrator Direct Bio HT, Calibrator Indirect Bio HT, and ISE Reference Electrolyte Bio HT are pumped through the ISE module tubing [automatic step].
- 7 Calibrator Direct Bio HT is pumped into the measuring channel.



A calibration is run before any new samples or controls are processed [automatic step].

Clean ISE tower automatically



This is an automatic service action that does not require manual intervention.

The ISE tower must be cleaned regularly to ensure the proper functioning of the ISE module.

Duration 11 minutes

Interval

- Weekly
- Daily if more than 50 samples are processed per day

Begin of Day Yes

System state Standby

Tools and materials

- Activator Bio
- Calibrator Direct Bio HT
- ISE Deproteinizer
- ISE Reference Electrolyte Bio HT

► To clean the ISE tower automatically

- 1 Select **Clean ISE tower** automatically in the **Service** work area.
- 2 Click **Perform**.
The **Service Actions** dialog box is displayed; follow the online prompts as required.
- 3 Transfer arm is initialized, if necessary [automatic step].
- 4 Fluid system is initialized, if necessary [automatic step].
- 5 ISE module is initialized, if necessary [automatic step].
- 6 ISE Deproteinizer is pipetted into the ISE tower [automatic step].
- 7 The pipetted ISE Deproteinizer is drawn through the tubing [automatic step].
- 8 Steps 6 and 7 are repeated three times.
- 9 The ISE tower and tubing are rinsed with system water [automatic step].
- 10 ISE module tubing is conditioned twice with Activator Bio [automatic step].
- 11 Electrodes are rinsed with Calibrator Direct Bio HT [automatic step].
- 12 Electrodes are activated twice with Activator Bio [automatic step].
- 13 Calibrator Direct Bio HT is pumped into the measuring channel.

Clean ISE tower manually

You must clean the ISE tower manually to ensure the proper functioning of the ISE module. The tower must be exchanged if it is blocked.

Duration 6 minutes

Interval Every 30 days

Begin of Day No

System state **Standby**

- Tools and materials*
- Activator Bio
 - Calibrator Direct Bio HT
 - ISE Deproteinizer
 - ISE Reference Electrolyte Bio HT
 - Cotton swab
 - Deionized water
 - Protective gloves
 - Small glass beaker

NOTICE

Damage to analyzer

If you remove the ISE module when there are any ISE tests, calibrations, or service procedures running or pending, you may damage the analyzer.

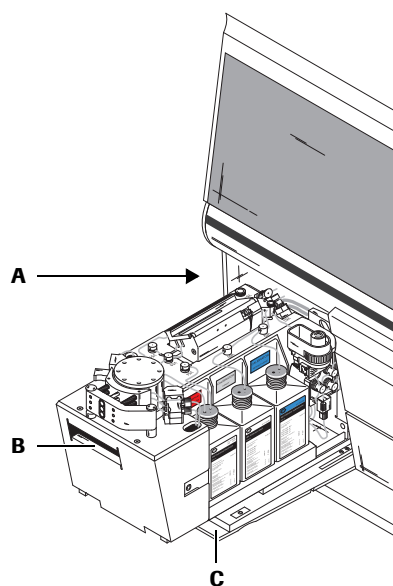
- Do not perform this procedure if there are any ISE tests, calibrations, or service procedures running or pending.

► **To clean the ISE tower manually**

- 1 Select **Clean ISE tower manually** in the **Service** work area.
- 2 Click **Perform**.

The **Service Actions** dialog box is displayed. Follow the online prompts as required.

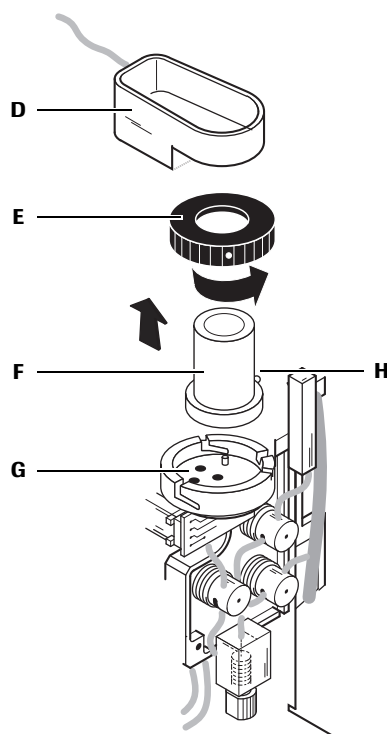
- 3 Open the ISE access panel (C).



- 4 Pull out the ISE module using the handle (B).

You have to pull quite hard because the ISE module is lodged firmly inside its housing.

- 5 Pull the module out until the spring catch (A - attached to the rear of the module) is engaged.
- 6 Remove the ISE overflow collector (D) by pulling it upwards and rotating it from side to side as you do so.



- 7 Carefully remove the tubing from the base of the ISE tower (H).

- 8** Remove the locking bolt (E) from the base of the ISE tower by rotating it counter-clockwise one quarter of a turn and lifting it over the ISE tower (F).
- 9** Remove the ISE tower (F).
(You can exchange the ISE tower at this point, if it is badly blocked.)
- 10** Clean the inside of the ISE tower with a cotton swab to remove any visible clots.
- 11** Soak the ISE tower in ISE Deproteinizer for about 5 minutes. (Extend the soaking time to 30 minutes if there are any clots in the ISE tower.)
- 12** Rinse the ISE tower in deionized water and leave to dry.
- 13** Reinstall the ISE tower.
Ensure that all three sealing rings (G) between the ISE tower and the mounting are positioned correctly.
- 14** Reinstall the tubing.
Ensure that the tubing is placed in the corresponding tubing guide.
- 15** Reinstall the locking bolt and the overflow collector.
- 16** Release the spring catch and slide the ISE module back until it clicks into place.
- 17** Click next.
- 18** ISE tower, ISE tubing, and electrodes are activated twice with Activator Bio [automatic step].
- 19** Calibrator Direct Bio HT is pumped into the measuring channel.
- 20** When all steps are complete, click **Finish** in the **Service** work area.



Complementary information

- You must connect the tubing to the ISE tower correctly otherwise it may be damaged during initialization.
 - If you replace one or more sealing rings, you must ensure that the replacements are exactly the same type as the originals.
-

Replace ISE module tubing

The tubing must be replaced according to the ISE service action schedule. This ensures proper functioning of the ISE module.

Duration 38 minutes

Interval Every 180 days

Begin of Day No

System state **Standby**

Tools and materials

- Activator Bio
- Calibrator Direct Bio HT
- Calibrator Indirect Bio HT
- ISE module tubing set
- ISE Reference Electrolyte Bio HT
- ISE Solution 1
- Protective gloves

NOTICE**ISE module malfunction due to incorrect tube lengths**

Using incorrect length of tubing will ultimately result in a malfunction of the ISE module.

- Use the correct length of tubing as indicated in the tubing set.
 - Use the service action **Replace ISE module tubing** in the **Service** program. Otherwise no ISE initialization is carried out.
-

NOTICE**ISE module malfunction due to damaged tubing**

Forcing tubes on metal fittings may damage the tubes.

- When replacing the tubes make sure not to damage them on the metal fittings.
-

► **To replace ISE module tubing**

1 Select **Replace ISE module tubing** in the **Service** work area.

2 Click **Perform**.

The **Service Actions** dialog box is displayed; follow the online prompts as required.

3 Transfer arm is initialized, if necessary [automatic step].

4 Fluid system is initialized, if necessary [automatic step].

5 ISE module is initialized, if necessary [automatic step].

6 Preparing ISE module for tube replacement [automatic step].

7 Refer to the cover of the tubing set to identify the correct tubing locations on the ISE module.

8 Replace the tubing.

9 ISE calibrators are primed [automatic step].

10 ISE module tubing is conditioned twelve times with Activator Bio [automatic step].

11 ISE module is initialized [automatic step].

12 ISE wash time is detected four times with Activator Bio.

13 Calibrator Direct Bio HT is pumped into the measuring channel.

14 When all steps are complete, click **Finish** in the **Service** work area.

Replace electrode

You must replace electrodes when their expiry date is exceeded or when the ISE results deteriorate despite regular service.

There are up to four ion-selective electrodes and a reference electrode on the ISE module. The replacement procedure is the same for each.



During replacing electrodes on the ISE module, the system performs automatically the **Electrode service** service action. This insures the proper functioning of the electrodes.



Injury due to moving or rotating parts

There is a risk of injury, body parts, hair and clothes can be caught or squeezed by moving parts of the ISE peristaltic pump even when the analyzer main power switch is off

- Keep away from moving parts.

Duration 13 minutes per electrode

- Interval*
- Every 90 days for orange labeled chloride electrodes
 - Every 14 days or 2000 counts for purple labeled chloride electrodes (Gen.2 electrodes)
 - Every 120 days for lithium
 - Every 180 days for sodium and potassium
 - Every 720 days for the reference electrode

Begin of Day No

System state **Standby**

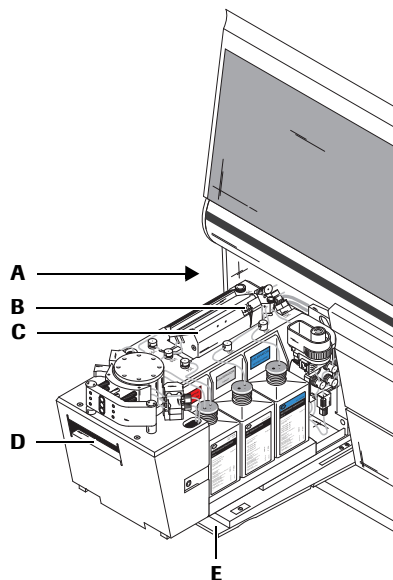
- Tools and materials*
- Activator Bio
 - ISE Deproteinizer
 - ISE Etcher
 - Calibrator Direct Bio HT
 - Calibrator Indirect Bio HT
 - ISE Reference Electrolyte Bio HT
 - Chloride electrode (optional)
 - Lithium electrode (optional)
 - Potassium electrode
 - Reference electrode
 - Sodium electrode
 - Protective gloves

► To replace an electrode

- 1 Select **Replace electrode** in the **Service** work area.
- 2 Click **Perform**.

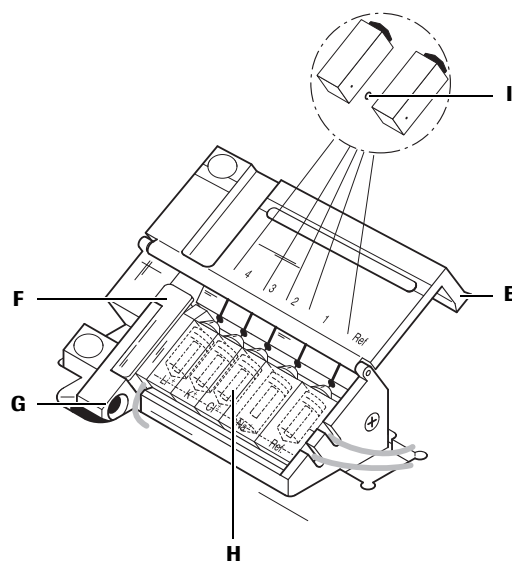
The **Service Actions** dialog box is displayed; follow the online prompts as required.

- 3 The electrodes are rinsed with Calibrator Direct Bio HT to remove any sample residue [automatic step].
- 4 Air is drawn through the ISE tower, tubing, and measuring channel to empty them completely [automatic step].
- 5 ISE Reference Electrolyte Bio HT is drawn through the bypass [automatic step].
- 6 Open the ISE access panel (E).



- 7 Pull out the ISE module using the handle (D).
You have to pull quite hard because the ISE module is lodged firmly inside its housing.
Pull the module out until the spring catch ((A) attached to the rear of the module) is engaged.
- 8 Remove the connector from fluid sensor 2 (B).
- 9 Open the electrode block cover (C).

- 10** Remove the black cover for fluid sensor 2 (G).



- 11** Remove fluid sensor 2 (F).
- 12** Note the positions of the electrodes. You must replace them in the same positions.
- 13** Remove all the electrodes.
- 14** Shorten both tygon tubings of the new reference electrode to a maximum length of 5 cm.
- 15** Replace electrodes as required.
- Make sure that the electrodes (H) are reinstalled in their original positions.
- Ensure that the electrodes and the electrode block are dry.
- 16** Take care not to lose the sealing O-rings (I):
- Between the electrodes.
 - Between the fluid sensor and the adjacent electrode.
- You must use the correct type of sealing O-ring otherwise the ISE module will not run reliably.
- 17** Reinstall fluid sensor 2 (F) and its cover (G).
- 18** Close the electrode block cover (E).
- 19** Reinstall the connector to fluid sensor 2 (B)
- 20** Release the spring catch and slide the ISE module back until it clicks into place.
- 21** Click **Next**.
- 22** ISE calibrators are primed [automatic step].
- 23** The ISE module is checked for leakage [automatic step].
- If a leak is found, a message is displayed and you must check that all the connections in the ISE module are secure.

24 The following steps are performed automatically:

- Fluid system is initialized, if necessary [automatic step].
- Transfer arm is initialized, if necessary [automatic step].
- ISE module is initialized, if necessary [automatic step].
- Electrodes are deproteinized [automatic step].
- Electrodes are etched [automatic step].
- ISE module tubing is conditioned twice with Activator Bio [automatic step].
- Electrodes are rinsed with ISE calibrator [automatic step].
- Electrodes are activated twice with Activator Bio [automatic step].
- Calibrator Direct Bio HT is pumped into the measuring channel.

25 When prompted:

- a) Indicate which electrode you have replaced.
- b) Click **Next**.
- c) Specify the lot number of the new electrode.

26 When all steps are complete, click **Finish** in the **Service** work area.

A calibration is run before any new samples or controls are processed [automatic step].

Condition ISE tubing



This is an automatic service action that does not require manual intervention.

When ISE module tubing has been replaced, it must then be conditioned to ensure the ISE module runs correctly.

Duration 3 minutes

Interval None

Begin of Day No

System state **Standby**

Tools and materials

- Activator Bio
- Calibrator Direct Bio HT
- ISE Reference Electrolyte Bio HT

► **To condition tubing**

- 1** Select **Condition ISE** tubing in the **Service** work area.
- 2** Click **Perform**.
- 3** Probe C pipettes Activator Bio into the ISE tower [automatic step].
- 4** ISE module tubing is filled with Activator Bio [automatic step].
- 5** Activator Bio is transported to the fluid waste [automatic step].
- 6** Steps 3, 4, and 5 are repeated twelve times.
- 7** Calibrator Direct Bio HT is pumped into the measuring channel.

Replace ISE solutions on the ISE rack



This is a general procedure, not a service action.

The **ISE** tab in the **Status** work area gives information about the status of the solutions on the ISE rack. They must be replaced before the bottle is empty, or when the maximum number of days of the onboard stability is reached.

Tools and materials

- Activator Bio
- ISE Deproteinizer
- ISE Etcher
- ISE Solutions 1, 2
- Protective gloves



WARNING

Incorrect results

Using a non approved activator may lead to clots and incorrect results.

Failing to confirm the change of bottles on the ISE rack leads to incorrect filling level information and consequently to incorrect onboard intervals for special activator handling.

- Roche recommends to use the Activator Bio for Cedex Bio HT Analyzer systems as ISE Activator.
- Use only the original bottles of Activator Bio or the appropriate 11 mL plastic bottles of the Activator Bottle Set Bio HT.

For further details, refer to the Instructions for Use for the Activator Bio for Cedex Bio HT Analyzer systems.

- Place the solutions in the predefined positions on the ISE rack. The positions are defined in **Configuration > Lab > Reserve Positions**. Confirm the change of bottles on the ISE rack.

 *ISE solutions summary* on page F-13



WARNING

Incorrect results due to expired solutions

Data obtained using solutions whose expiry date or online stability has elapsed is not reliable.

- Do not use reagents, calibrators, or controls that have exceeded their expiry dates.
 - Do not use reagents, calibrators, or controls whose onboard stability has elapsed.
-

NOTICE

Damage to the analyzer

Failing to uncapped the Activator Bio and Accelerator bottles on the ISE rack may lead to malfunction and probe damage.

- With the exception of the Activator Bio and the Accelerator, bottles on the ISE rack must be capped.
-

► To replace ISE Solutions on the ISE rack

- 1 Open the rack access panel on the front of the analyzer.
- 2 Remove the ISE rack.
- 3 Open the rack cover.
- 4 Replace the solutions, as required.

Replace ISE solutions on the ISE rack

- 5 Close the rack cover.
- 6 Reinstall the ISE rack.
- 7 You are prompted to indicate the solution(s) you have replaced. Click the corresponding button(s).

Position of ISE solutions on the rack

The default positions are as follows:

Rack position	Solution
1	Activator Bio Remove the cap from this bottle before placing it on the ISE rack. Do not use this solution after its expiry date.
2	ISE Etcher Do not use this solution after its expiry date.
4	Accelerator Remove the cap from this bottle before placing it on the ISE rack. Do not use this solution after its expiry date.
5	ISE Solution 2 (Sol-2) Do not use this solution after its expiry date.
6	ISE Solution 1 (Sol-1) Do not use this solution after its expiry date.
7	NaCl Diluent 9% Do not use this solution after its expiry date.
8	ISE Deproteinizer Do not use this solution after its expiry date.

Table F-5



Complementary information

- Use the **ISE** tab in the **Status** work area to check the defined positions of the ISE solutions in your system.

After placing the ISE Rack back on board, a window is displayed to confirm replaced bottles:

- When you click the button to indicate the ISE Solutions that you have replaced, the counters are reset to zero.
- The amount of remaining ISE Etcher, 9% NaCl Diluent, and ISE Deproteinizer is calculated from the number of pipette actions that have been performed.
- The remaining amount of Activator Bio, Accelerator, and ISE Solution 1 and 2 is determined by level detection.
- After replacement and confirmation of the ISE solution and/or diluent bottle on the ISE rack, the appropriate bottle volume is assigned to the defined ISE rack position for the correct volume management.
- The positions of the ISE solutions can be changed. The ISE rack shows a lock symbol  when it is on board. When it is locked, the positions cannot be changed. The rack must first be removed, and then the predefined positions can be changed using **Configuration > Lab > Reserve Positions**.

Replace bottles on ISE module



This is a general procedure, not a service action.

The **ISE** tab in the **Status** work area gives information about the status of the solutions on the ISE module. They must be replaced before the bottle is empty.

The ISE module must be in **Standby**, but the analyzer can be running non-ISE tests.



WARNING

Incorrect results due to remnants of calibrator in tubing

Calibrator of the previous bottle left in the tubing may cause drift in the results.

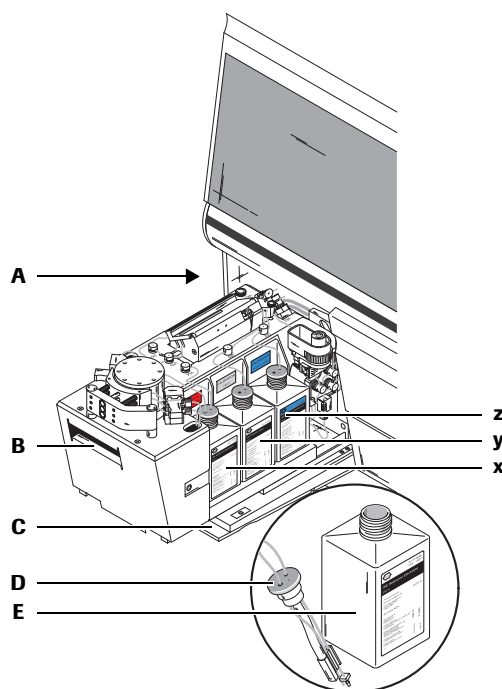
Always perform the service action **Prime ISE calibrators** after replacing solutions on the ISE module.

Tools and materials

- Calibrator Direct Bio HT
- Calibrator Indirect Bio HT
- ISE Reference Electrolyte Bio HT
- Protective gloves

► To replace ISE Calibrators/Reference electrolyte on the ISE module

- 1 Wait until the system is in **Standby**.
- 2 Open the ISE access panel (C).



- 3 Pull out the ISE module using the handle (B).

Pull the module out until the spring catch (A - attached to the rear of the module) is engaged.

- 4 Open a new bottle.
- 5 Remove the empty bottle (E) from the ISE module.

- 6 Remove the floater (D) from the empty bottle.
- 7 Insert the floater into the new bottle.
- 8 Place the new bottle in the assigned position on the ISE module.
- 9 Repeat steps 4 through 8 for all empty bottles.
- 10 Release the spring catch and slide the ISE module back until it clicks into place.
- 11 Perform the service action **Prime ISE calibrators**.



Complementary information

Place the solutions in their correct positions (x, y, or z) on the ISE module. The positions are color-coded to match the color on the corresponding bottle label:

Solution	Color of position and bottle label	Position on ISE module
ISE Reference Electrolyte Bio HT	Red	x
Calibrator Direct Bio HT	Gray	y
Calibrator Indirect Bio HT	Blue	z

Table F-6 Color coding of ISE solutions

Replace ISE tower



This is a general procedure, not a service action.

The ISE module cannot operate if the ISE tower is blocked. Flags or messages will be generated if you need to clean or replace the ISE tower.

You can replace the ISE tower if cleaning it manually does not have the required effect.

► To replace the ISE tower

- 1 Perform the service action **Clean ISE tower manually**.
- 2 Exchange the existing ISE tower with a replacement at the appropriate step.

ISE Performance Check



This is a general procedure, not a service action.

This procedure needs to be performed on request for ISE troubleshooting.

It checks the performance of each electrode by measuring 10 times Calibrator Direct Bio HT and Calibrator Indirect Bio HT respectively.

Duration 10 minutes

Interval None

Begin of Day No

System state **Standby**

Tools and materials

- Calibrator Direct Bio HT
- Calibrator Indirect Bio HT
- ISE Reference Electrolyte Bio HT

► To check the ISE performance

1 Select **ISE Performance Check** in the **Service** work area.

2 Click **Perform**.

The **Service Actions** dialog box is displayed; follow the online prompts as required.

3 Calibrator Direct Bio HT is transported to the electrode block and remains there for 45 seconds [automatic step].

4 Subsequently Calibrator Direct Bio HT is transported again to the electrode block and the first measuring starts [automatic step].

5 Step 4 is repeated ten times.

6 Calibrator Indirect Bio HT is transported to the electrode block and remains there for 45 seconds [automatic step].

7 Subsequently Calibrator Indirect Bio HT is transported again to the electrode block and the first measuring starts [automatic step].

8 Step 7 is repeated ten times.

9 Click **Next**.

10 Click **Show Values**.

11 The measured values, **Mean**, **Min**, **Max**, the **Standard Deviation** (SD) and the **Coefficient of Variation** (CV) for all electrodes in the respective modes are displayed.

12 Click **Print**.

13 Click **Cancel**.



Send the printout of the measured values to your Roche representative.

ISE flags and troubleshooting

Solving problems with the ISE module

This chapter describes some of the common problems that you may get with the ISE module and the actions you should take to overcome them. It describes the result flags that may be generated with ISE measurements and also provides guidance for general troubleshooting procedures.

To avoid problems, always follow the service schedules defined for your system.

If you have any problems that you cannot resolve, contact your Roche representative.

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About ISE flags

This section describes all the ISE flags generated by the analyzer, their associated error messages, and the corresponding user actions.

ISE flags, like other flags, are automatically generated with results when the system detects a problem or a potential problem. When a flag is generated, it is displayed together with the result in the **Results** work area. When you print a result, the flag is also printed.

Flags and error messages

Some ISE flags trigger error messages if they appear in a consecutive sequence. A flag counter monitors the number of consecutive flags and triggers an error message if the counter limit is reached. Each flag has its own counter and counter limit as listed in *Flags and user actions* on page F-41.

If a single ISE measurement does not generate a particular flag, the flag counter is reset to zero.

With a single flag, repeat the measurement or the calibration. An error message indicates a more persistent error requiring further action, for example, performing service actions.

Flag priority

If the conditions in the ISE module are such that multiple flags could be generated for a single ISE measurement, only the flag with the highest priority is displayed (or printed) with the result. The lower the number, the higher the priority. The priority of each flag is given in the flag description. All other flags with lower priority are shown in the result details.



Results without flags are automatically within the reference range and can be considered to be error-free.

Flags and result handling

When a flag occurs, processing is dependent upon result handling, which is defined in **Configuration > Result Handling > Results**. You can check the details held in result handling to review what your system does when it generates specific flags.



The system action can be different for calibrations, controls, and samples.

Flags and user actions

The action you need to take in response to a flag for an ISE measurement depends on whether:

- Only a single flag was generated.
- The flag was repeated and the error message for that flag was displayed.

Both cases are described in the flag descriptions.



Where a flag description gives a list of recommended actions, work through each step in turn until you have solved the problem. Proceed to the next step only after you have completed the previous one.

List of flags The following table lists the flags in alphabetical order:

Flag	Priority	Counter limit	Message ID	See page
AIR FLUID	11	5	14.3248.08.023.xxx	F-43
AIR ISECAL	12	5	14.3248.08.030.xxx	F-44
ISE UNSTAB	13	5	14.3248.08.031.xxx through 14.3248.08.038.xxx 14.3248.08.018.xxx (leakage)	F-44
NO FLUID	7	3	14.3248.08.010.xxx 14.3248.08.011.xxx	F-45
NO ISECAL	8	3	14.3248.08.027.xxx	F-46
OUT OF RNG	26	None	None	F-46
SEG FLUID	9	3	14.3248.08.012.xxx	F-47
SEG ISECAL	10	3	14.3248.08.028.xxx	F-48
SOL 1 F DEV	28	None	None	F-48
< TEST RNG	30	None	None	F-49
>TEST RNG	31	None	None	F-49

Table F-7



The following flags do not generate messages:

OUT OF RNG, SOL 1 F DEV, <TEST RNG, and >TEST RNG.

Messages number format

When a repeated flag generates a message, the message number has the format: aa.bbbb.cc.ddd.xxx as shown in the table above. You can uniquely identify a message by the second (cc) and the third (ddd) groups of digits.

For example, in the message 14.3248.08.012.xxx, the digits 08.012 identify the message; xxx means “don’t care”, that is, these digits are not significant.

If a message box is displayed, you can get detailed information by clicking **Help**.

Terminology

The following terminology is used in the flag descriptions that follow:

FLUID

Any liquid (sample, control, calibrator, or other solution) that is introduced into the ISE tower.

ISECAL

Calibrator Direct Bio HT or Calibrator Indirect Bio HT.

SEG

A segment of fluid that is drawn past the fluid sensor and, therefore, past the electrodes. Fluid segments are separated by air segments.

Flags and service actions

Some user actions for flags include performing service actions.

👁 Chapter 14 *Service actions* and Chapter 18 *ISE service actions*

Flag descriptions

AIR FLUID

<i>Meaning</i>	The length of the fluid segment was too short.
<i>Message ID</i>	14.3248.0814.3248.08.023.xxx
<i>Possible cause</i>	The sample segment was too short because: • Air bubbles are present. • The ISE tower is clogged. • The dosing from the sample probe is inaccurate. • The ISE module tubing is leaking or blocked, or it is not conditioned. • Mixing is too vigorous (for the indirect mode).
<i>Recommended actions</i>	If only one result is flagged: 1. Repeat the measurement. 2. Check the sample tubes and ISE solution bottles for foaming. If the error message is displayed: 1. Perform the service action Activate electrodes. 2. Replace the ISE tower (use the service action Clean ISE tower manually). 3. Perform the service action Deproteinize probes. 4. Check the ISE module tubing for leaks or blockages. 5. Replace the ISE module tubing (Use the service action Replace ISE module tubing). 6. Contact your Roche representative.

AIR ISECAL

<i>Meaning</i>	The length of the calibrator segment was too short.
<i>Message ID</i>	14.3248.08.030.xxx
<i>Possible cause</i>	The calibrator segment was too short because: • Air bubbles are present. • The ISE distribution block is leaking or blocked. • The ISE module tubing is leaking or blocked.
<i>Recommended actions</i>	If only one result is flagged: 1. Repeat the measurement. 2. Ensure that the ISE Calibrators on the ISE module are available and check the level of liquid; replace if necessary. 3. Check the ISE module tubing and the ISE distribution block for leaks or blockages. If the error message is displayed: 1. Perform the service action Prime ISE calibrators. 2. Check the ISE module tubing and the ISE distribution block for leaks or blockages. 3. Contact your Roche representative.

ISE UNSTAB

Meaning, cause, and action depend on the message ID, which are divided into two groups:

- 14.3248.08.031.xxx through 14.3248.08.038.xxx
- 14.3248.08.018.xxx (leakage)

<i>Meaning</i>	The signal from the electrode(s) was not stable during the measurement.
<i>Message IDs</i>	14.3248.08.031.xxx through 14.3248.08.038.xxx
<i>Possible cause</i>	The ISE measurements (mV Values) are unstable because: • There are air bubbles in the measuring segment. • The concentration of electrolyte in the sample is too low (for example, dialyzed samples). • The pH of the sample is too low (for example, pH < 5.5). • One or more O-rings are missing or damaged. • The electrodes have not been serviced. • The expiry date of the electrode has passed or the electrode is damaged. • The ISE Reference Electrolyte Bio HT tubing is blocked or leaking. • The floater of the ISE Reference Electrolyte Bio HT bottle is blocked. • The preamplifier is not working properly.

<i>Recommended actions</i>	If only one result is flagged: 1. Repeat the measurement. 2. Repeat the measurement with a suitable sample (where pH > 5.5 and correct electrolyte concentration) to establish that the ISE module is OK. 3. Check the position and condition of the O-rings and replace if necessary. If the error message is displayed: 1. Perform the service action Activate electrodes. 2. Perform the service action Electrode service. 3. Replace expired electrodes and perform the service action Electrode service. 4. Check the ISE Reference Electrolyte Bio HT tubing for leaks or blockages. 5. Check the floater of the ISE Reference Electrolyte Bio HT bottle for blockages. 6. Contact your Roche representative.
<i>Meaning</i>	A fluid leakage in the electrode block was detected
<i>Message ID</i>	14.3248.08.018.xxx (leakage)
<i>Possible cause</i>	The ISE measurements (mV Values) are unstable because: • One or more O-rings are missing or damaged. • The electrodes and/or the electrode block are not dry.
<i>Recommended actions</i>	1. Press F12 (Stop). 2. In the Stopping dialog box, select Stop when in-progress test have completed, then click OK. 3. Remove electrodes and clean and dry the electrode block. 4. Dry electrodes. 5. Check the position and condition of the O-rings and replace if necessary. 6. Re-install the electrodes. 7. Contact your Roche representative if the message reappears.

NO FLUID

<i>Meaning</i>	No fluid was detected at one of the fluid sensors (1 or 2).
<i>Message IDs</i>	14.3248.08.010.xxx 14.3248.08.011.xxx
<i>Possible cause</i>	The fluid sensors could not detect any liquid because: • The liquid was not pipetted. • The ISE tower is clogged. • The ISE module tubing is blocked. • Fluid sensor 1 or 2 is defective.

Flag descriptions

<i>Recommended actions</i>	If only one result is flagged: 1. Repeat the measurement. 2. Check the sample tubes for clots. 3. Ensure ISE solution bottles on the ISE rack are available and check the level of liquid; replace if necessary. If the error message is displayed: 1. Replace ISE tower (use the service action Clean ISE tower manually). 2. Check ISE module tubing for leaks or blockages. 3. Contact your Roche representative.
----------------------------	---

NO ISECAL

<i>Meaning</i>	No calibrator was detected at fluid sensor 2.
<i>Message ID</i>	14.3248.08.027.xxx
<i>Possible cause</i>	Fluid sensor 2 could not detect a calibrator because: • One or more calibrator bottles are not available. • The ISE module tubing is leaking or blocked. • The ISE distribution block is leaking or blocked. • Fluid sensor 2 is defective.
<i>Recommended actions</i>	If only one result is flagged: 1. Repeat the measurement. 2. Ensure that the ISE Calibrators on the ISE module are available and check the level of liquid; replace if necessary. If the error message is displayed: 1. Perform the service action Prime ISE calibrators. 2. Check the ISE module tubing and the ISE distribution block for leaks or blockages. 3. Contact your Roche representative.

OUT OF RNG (ISE)

<i>Meaning</i>	The electrode slopes were out of range.
<i>Message ID</i>	None
<i>Possible cause</i>	Electrode slope out of range. This flag appears with calibrations because: • There are problems with the ISE solutions on the ISE rack. • There are problems with the electrodes or an improperly serviced ISE module. • The ISE Reference Electrolyte Bio HT tubing is blocked or leaking. • The floater of the ISE Reference Electrolyte Bio HT bottle is blocked. • The dosing from the sample probe is not accurate. • The preamplifier is not working properly.

<i>Recommended actions</i>	If only one calibration is flagged: 1. Repeat the calibration. 2. Repeat the calibration with fresh ISE solutions 1, 2, and 3, and check visually the correct flow of all ISE solutions and the ISE Reference Electrolyte Bio HT. If successive calibrations are flagged: 1. Repeat the calibration with fresh ISE solutions 1, 2, and 3, and check visually the correct flow of all ISE solutions and the ISE Reference Electrolyte Bio HT. 2. Check whether the electrode expiry date has passed. Replace the electrodes, if necessary. 3. Perform the service action Electrode service. 4. Perform the service action Deproteinize probes. 5. Check ISE Reference Electrolyte Bio HT tubing for leaks or blockages. 6. Check the floater of the ISE Reference Electrolyte Bio HT bottle for leaks or blockages. 7. If the slopes of all electrodes are zero, replace the reference electrode. 8. Contact your Roche representative.
----------------------------	--

SEG FLUID

<i>Meaning</i>	The end of the fluid segment was not detected.
<i>Message ID</i>	14.3248.08.012.xxx
<i>Possible cause</i>	The end of the sample segment was not detected. It takes too long for a sample segment to reach the electrodes because: • The ISE tower is clogged. • The ISE module tubing is leaking or blocked.
<i>Recommended actions</i>	If only one result is flagged: 1. Repeat the measurement. If the error message is displayed: 1. Perform the service action Activate electrodes. 2. Replace the ISE tower (use the service action Clean ISE tower manually). 3. Check the ISE module tubing for leaks or blockages. 4. Replace the ISE module tubing, if necessary (Use the service action Replace ISE module tubing). 5. Contact your Roche representative.

SEG ISECAL

<i>Meaning</i>	The end of the calibrator segment was not detected.
<i>Message ID</i>	14.3248.08.028.xxx
<i>Possible cause</i>	The end of the calibrator segment was not detected. It takes too long for a calibrator segment to reach the electrodes because: • The ISE module tubing is leaking or blocked. • The ISE distribution block is leaking or blocked.
<i>Recommended actions</i>	If only one result is flagged: 1. Repeat the measurement. 2. Ensure that the ISE Calibrators on the ISE module are available and check the level of liquid; replace if necessary. If the error message is displayed: 1. Perform the service action Prime ISE calibrators. 2. Check ISE module tubing and ISE distribution block for leaks or blockages. 3. Contact your Roche representative.

SOL 1 F DEV

<i>Meaning</i>	Solution 1 factor is not within the permissible range.
<i>Message ID</i>	None
<i>Possible cause</i>	Deviation of Sol 1 Factor. This flag occurs with calibrations because: • The dosing from the sample probe is not accurate. • The ISE tower is blocked. • There may be problems with the ISE module tubing, the electrodes, or an improperly serviced ISE module. • Contaminated calibrator or bottle placed in wrong position.
<i>Recommended actions</i>	If only one calibration is flagged: 1. Repeat the calibration. If successive calibrations are flagged: 1. Check whether the calibrators are in the correct positions. 2. Perform the service action Activate electrodes. 3. Replace the ISE tower (use the service action Clean ISE tower manually). 4. Perform the service action Prime ISE calibrators. 5. Check whether the electrode expiry date has passed. Replace the expired electrode, if necessary, and perform the service action Electrode service. 6. Check the ISE module tubing for leaks or blockages. 7. Contact your Roche representative.

<TEST RNG

<i>Meaning</i>	The measured value is below the test range.
<i>Message ID</i>	None
<i>Possible cause</i>	The actual concentration in the sample is below the test range
<i>Recommended action</i>	Check the ISE reading (mV).

>TEST RNG

<i>Meaning</i>	The measured value is above the test range.
<i>Message ID</i>	None
<i>Possible cause</i>	The actual concentration in the sample exceeds the test range.
<i>Recommended action</i>	Check the ISE reading (mV).

General ISE troubleshooting

This section identifies some common problems that do not necessarily generate flags or messages.

Poor accuracy

Results are reproducible but do not match the known values.

ISE tower clogged or dirty

<i>Recommended action</i>	- If the ISE tower is clogged, replace it. - If the ISE tower is dirty, perform the service action Clean ISE tower automatically or Clean ISE tower manually. - If this does not fix the problem, perform the service action Replace ISE tower. You may have to perform the service action Clean ISE tower automatically more frequently. If so, reduce the service interval in the Service work area.
---------------------------	--

ISE solutions, calibrators, or electrodes expired

<i>Recommended action</i>	Check the expiry date of all ISE solutions, calibrators, and electrodes.
---------------------------	--

Probes clogged or dirty

<i>Recommended action</i>	- Perform the service action Deproteinize probes. - Perform the service action Replace probe C, if necessary.
---------------------------	--

Begin of Day actions not properly performed

- Recommended action*
1. Perform the service action **Electrode service**.
 2. Perform the service action **Deproteinize probes**.

Mixing, washing, or drying in the ISE tower not completed properly

- Recommended action*
1. Perform the service action **Clean ISE tower automatically** or **Clean ISE tower manually**.
 2. Contact your Roche representative.

ISE Reference Electrolyte Bio HT not present or flow not sufficient

- Recommended action*
1. Check whether there is enough ISE Reference Electrolyte Bio HT in the bottle.
 2. Check the ISE Reference Electrolyte Bio HT flow through the reference electrode.
The ISE Reference Electrolyte Bio HT flow should look like a bead chain. If it does not, check the ISE Reference Electrolyte Bio HT tubing and the floater, for blockage (salt deposits) or leaks.
 3. Remove any blockages and replace the tubing, if necessary.
 4. Replace the ISE module tubing, then perform the service actions: **Condition ISE module tubing** and **Prime ISE calibrators**.

Results not reproducible

Results are obtained, but different measurements give different results.

ISE tower clogged or dirty

- Recommended action*
1. If the ISE tower is clogged, replace it.
 2. If the ISE tower is dirty, perform the service action **Clean ISE tower automatically** or **Clean ISE tower manually**.
 3. If this does not fix the problem, perform the service action **Replace ISE tower**.
- You may have to perform the service action **Clean ISE tower automatically** more frequently. If so, reduce the service interval in the **Service** work area.

All electrodes:

- Recommended action*
1. Perform the service action **Electrode service**.
 2. Calibrate and rerun the tests.

Clogged or dirty sample probes

- Recommended action*
1. Perform the service action **Deproteinize probes**.
 2. Replace probes, if necessary.

Mixing, washing, or drying in the ISE tower not completed properly

- Recommended action*
1. Perform the service action **Clean ISE tower automatically** or **Clean ISE tower manually**.
 2. Contact your Roche representative.

Electrode slope out of range for sodium, potassium, or chloride

- Recommended action*
1. Repeat the calibration, with fresh ISE solutions 1, 2, and 3.
 2. Perform the service action **Electrodes service**.
 3. Repeat the calibration.
 4. Replace the ISE tower (use the service action **Clean ISE tower manually**).
 5. Check the expiry date of the electrodes. Perform the service action **Replace electrode**, if necessary.

All slopes out of range

The measured slopes are outside acceptable limits.

ISE solutions expired

- Recommended action*
- Check the expiry date of all ISE solutions and replace those which have expired.

ISE tower clogged or dirty

- Recommended action*
1. If the ISE tower is clogged, replace it.
 2. If the ISE tower is dirty, perform the service action **Clean ISE tower automatically** or **Clean ISE tower manually**.
 3. If this does not fix the problem, perform the service action **Replace ISE tower**.
- You may have to perform the service action **Clean ISE tower automatically** more frequently. If so, reduce the service interval in the **Service** work area.

Probes clogged or dirty

- Recommended action*
1. Perform the service action **Deproteinize probes**.
 2. Perform the service action **Replace probe C**, if necessary.

ISE Reference Electrolyte Bio HT or reference electrode expired

- Recommended action*
- Check the expiry and replacement dates of the ISE Reference Electrolyte Bio HT and the reference electrode, and replace if necessary.

ISE Reference Electrolyte Bio HT not present or flow not sufficient

- Recommended action*
1. Check whether there is enough ISE Reference Electrolyte Bio HT in the bottle.
 2. Check the ISE Reference Electrolyte Bio HT flow through the reference electrode.
The ISE Reference Electrolyte Bio HT flow should look like a bead chain. If it does not, check the ISE Reference Electrolyte Bio HT tubing and the floater, for blockage (salt deposits) or leaks.
 3. Remove any blockages and replace the tubing, if necessary.
 4. Replace the ISE module tubing, then perform the service actions **Condition ISE module tubing** and **Prime ISE calibrators**.

ISE module not used for one or more days

- Recommended action* Perform the service action **Activate electrodes** several times.

Configuration

G

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Configuration

Modifying your system configuration

This chapter provides an overview of common configuration procedures for the analyzer.

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Configuration overview

Configuration allows you to access the database and make modifications to support a wide range of system functionality requirements. The procedures in the **Definitions** group explain how, for example, you can modify test definitions, profile, calculated result, calibrator, and control details. The procedures in the **Systems** group explain how, for example, to specify tubes and racks, define the way results are handled and modified.

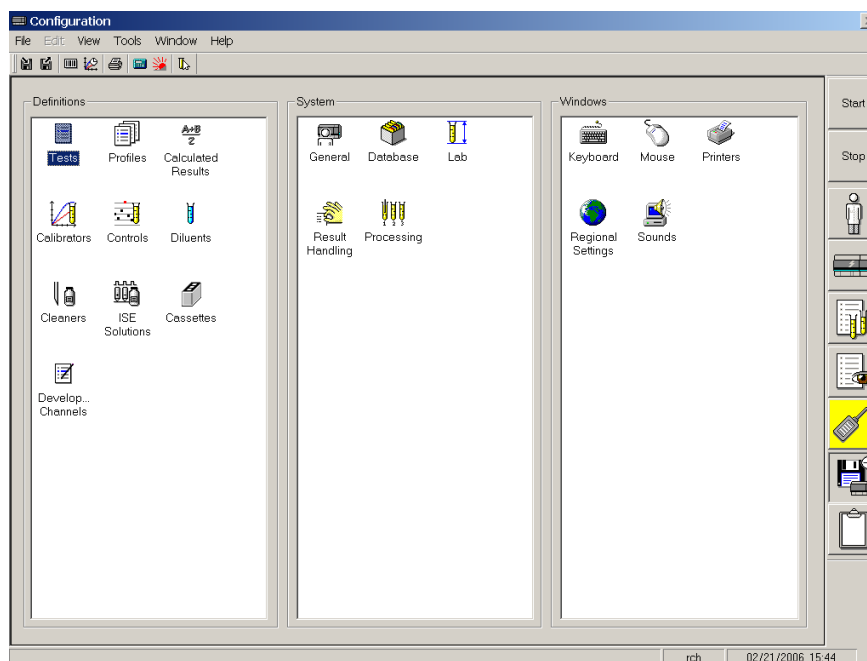


Figure G-1

The tasks included are designed to help you become familiar with the following definitions:

Definition tasks

- **Tests**
- **Profiles**
- **Calculated Results**
- **Calibrators**
- **Controls**
- **Diluents**
- **Cleaners**
- **ISE Solutions**
- **Cassettes**

- System definition tasks*
- **General**
 - **Database**
 - **Lab**
 - **Result Handling**
 - **Processing**

Configuration comprises three groups: **Definitions**, **System**, and **Windows**. Only those tasks primarily associated with the **Definitions** and **System** groups have been included in this manual.

Windows definitions tasks The **Windows** group can only be configured by a Roche representative. Please contact your local Roche representative for more information.

About the Definitions group

Generally, definitions are loaded during the installation process where default values are set by a Roche representative. You can subsequently create new definitions or modify existing ones using the dialogs in the **Configuration Definitions** group. You can do so only if you have the appropriate user access level.

Definitions group functions are as follows:

<i>Tests</i>	A test definition contains all the information the system needs in order to run a test including the names of the calibrators, controls, cleaner, and diluents. Click the Tests icon to review, load, modify, or delete test definitions.
<i>Test Group, Sequence, and Class</i>	You can define groups of tests for use in Orders and the sequence of the test buttons displayed. You can also define test classes for result handling purposes. From the Test Definitions dialog box, click the Class/Group button to define and modify test groups, sequence and classes
<i>Profiles</i>	A test profile is a named group of tests. In orders, tests are added to an order by clicking a button (which may have the profile name on it) which adds all the tests in the profile to the order. Click the Profiles icon to review, create, modify, or delete test profile definitions.
<i>Calculated results</i>	A calculated result is the arithmetical combination of two or more test results to produce a new value. A calculated result definition contains information about the formula and the tests to be used in the calculation. Click the Calculated Results icon to review, create, modify, or delete a calculated result definition.
<i>Calibrators</i>	A calibrator definition contains a list of all tests that are to be calibrated using a specific calibrator. It also contains details for individual calibration points. Click the Calibrators icon to review, create, modify, load, or delete a calibration definition.
<i>Controls</i>	A control definition contains a list of all the tests for which the control is to be used and, for each test, what type of control (precision, accuracy, or limit) it is. Click the Controls icon to review, create, modify, load, or delete a control definition.
<i>Diluents</i>	A diluent definition provides information about a diluent and the tests for which it is used. Click the Diluents icon to review, load, or delete a diluent definition.

Cleaner A cleaner definition provides information about the cleaner and the cleaner cassette used for extra wash cycles, and it provides a list of cassette and lot numbers that have been used for this type of cassette.

Click the **Cleaners** icon to review or delete a cleaner definition.

To view the loaded **Extra Wash Cycle** list or to define customized extra wash cycles, choose **Configuration > Processing > Extra Wash Cycles** tab.

ISE solutions ISE solutions are solutions used to perform deproteinizing, etching, and activating operations on the ISE module.

Click the **ISE Solutions** icon to review, load or delete the existing definitions.

Cassettes A cassette definition provides information about a cassette including the test(s) for which the cassette is used, and a list of cassette and lot numbers that have been used for this type of cassette.

Click the **Cassettes** icon to review, load, or delete a cassette definition.

About test definitions

You use the **Configuration Test Definitions** dialog box to load, review and modify test definitions. The dialog box lists all the currently installed tests on the left. When you select a test, the details are automatically listed on the right.

What is a test definition? A test definition contains all the information the system needs to run tests, including:

- Basic test information, such as names and number
- The default sample type
- Calibrator name and calibration intervals
- Controls and control intervals
- Correlation factors and laboratory units
- Result evaluation and reference ranges

► To use the Configuration Test Definitions dialog box



- 1 Click **Configuration** on the navigation bar.
- 2 Double-click the **Tests** icon in the **Definitions** group.

Loading and modifying test definitions

When loading test definitions, all required files are loaded. You are informed before existing files are overwritten.

- 👁 To install and load test definitions on page G-9
- 👁 To view and modify basic test definitions on page G-9
- 👁 To modify default sample type and calibration details on page G-10
- 👁 To modify dilutions and/or concentrations on page G-10
- 👁 To modify control parameters and the interval sequence on page G-11
- 👁 To modify correlation and default unit parameters on page G-12
- 👁 To modify reference and critical ranges on page G-12
- 👁 To delete a test definition on page G-13

Installing and loading test definitions

► To install and load test definitions

- 1 In the **Definition** group, double-click **Tests**.
- 2 Click **Load...** to open the **Load** dialog box.
- 3 Specify the path where the source files are located. (Default path: "C:/Roche/Instrument/TAS")
- 4 Click **OK**.
- 5 Select the tests to be installed.
The **Load Complete Test Definitions** dialog box is displayed.
- 6 Select the **Keep Old Lab Settings** check box to ensure that user defined parameters are preserved. (This box is selected by default.)
- 7 Click **Load**.
- 8 The **Load** definitions in progress window is displayed. Do not click **Stop**.
- 9 Click **Cancel** to return to the **ID** tab. The newly installed tests are listed in the installed tests panel.



Complementary information

- The analyzer must be in **Standby** or **Sleeping** state.
 - The relevant cassette, calibrator and diluent definition are loaded automatically.
-

Viewing and modify basic test definitions

► To view and modify basic test definitions

- 1 Click the **ID** tab.
- 2 Select a test from the **Installed Tests** list. Basic test details are displayed on the right.
- 3 Modify the **Short Name**, **Long Name** and **Test No** if required.
- 4 Click **Save**.



Complementary information

- The analyzer must be in **Standby** or **Sleeping** state.
 - **Short Name** is maximum eight alphanumeric characters. It affects the display of the test name in the user interface, for examples test buttons, test names in the orders and results work areas and all print reports except the final report.
 - **Long Name** is maximum 30 alphanumeric characters. The long name affects the display of the test name in the final report only.
 - **Test No** is a number in the range of 1 through 999.
 - The **Short Name**, **Long Name**, and **Test Number** are mandatory and must be unique for tests, profiles, and calculated results.
 - The ID is assigned by Roche and cannot be changed.
-

Modifying default sample type and calibration details

► To modify default sample type and calibration details

- 1 Click the **General** tab.
- 2 Select the required test from the **Installed Tests** list.
- 3 Modify the **Default Sample Type** by selecting an alternative from the list.
Use **Configuration > Lab > Sample Types** to define the list.
- 4 Modify the **Calibration** details:
 - a) Select one of the **Replicate** options. (No replicates for ISE.)
 - b) For the **Main Interval**, select the type of calibration interval and type the number of days required for the interval.
 - c) Select the **Clot Detection** box to enable the clot detection feature. It is selected by default.
- 5 Click **Save**.



Complementary information

The calibrator required for each test is automatically added when the test is entered.



WARNING

Incorrect results due to inappropriate calibration intervals

The system is delivered with predefined calibration intervals for each test. The calibration intervals are carefully defined to guarantee reagent performance within the set onboard stability and shelf life of the reagents. Any change may alter the reagent performance and, as a result, may lead to incorrect results.

- Roche recommends not to change the default calibration intervals.

Modifying dilutions and/or concentrations

► To modify dilutions and/or concentrations

- 1 Click the **Dilutions** tab.
- 2 Select the required test from the **Installed Tests** list.
- 3 Select **Automatic Dilutions > Off** if no automatic dilutions are required.
Automatic Dilutions > Sequential should be selected to allow post actions as and when required.
- 4 Select the dilution and type the dilution or concentration factor required for the test.
- 5 Click **Save**.



Complementary information

- The default post-handling factors are specific to each test and should not be modified.
- NaCl Diluent 9% can only be used in a ready to use 25 mL NaCl Diluent 9% bottle, which is placed on the ISE rack. You can no longer use a 10 mL bottle with NaCl Diluent 9% on the ISE-rack.

When defining and handling diluents, make sure you take into account the stability value of each diluent:

Diluent	Period of stability
NaCl Diluent 9% ^(a)	28 days
Accelerator	7 days
ISE Reference Electrolyte Bio HT	8 weeks
ISE Deproteinizer	4 weeks
ISE Etcher	8 weeks
Calibrator Direct Bio HT	8 weeks
Calibrator Indirect Bio HT	8 weeks
ISE Solution 1	2 weeks
ISE Solution 2	2 weeks

Table G-1 Diluent stability

(a) NaCl Diluent 9% can only be used in the ready-to-use 25 mL NaCl bottles placed on the ISE rack. It is no longer possible to use NaCl Diluent 9% in a 10 mL bottle and place it on the ISE rack.

Modifying control parameters and the interval sequence

► To modify control parameters and the interval sequence

- 1 Click the **Control** tab.
- 2 Select the required test from the **Installed Tests** list.
- 3 Select the **QC Treatment** check box to ensure that each control is checked according to **Precision**, **Accuracy**, and **Limit** rules.
- 4 Select the **Interval** check box to perform controls automatically.
- 5 Select **Tests** and type the number of tests that constitute one interval, or select **Hours** and type the number of hours that constitute one interval.
- 6 For each control you have selected, you can select the **After Cal** check box if you want the control to be run automatically after every calibration.
- 7 You can also select an interval sequence (one through six) for each control. If more than one control is defined, select consecutive **Interval Sequence** numbers.
- 8 Click **Save**.



Complementary information

- Controls, unlike calibrators, are not automatically installed with each test and should be selected as required.
- If **QC Treatment** is not selected, sample results will not be flagged with the **q** flag if the QC result violates a rule.
- For details on controls, see Chapter 11 *Quality controls*.



Control intervals can be based upon the number of tests run, time (number of hours), or after calibration.

Prior to defining this table, the laboratory must decide whether it prefers to request controls manually or to work with automated control intervals.

- To manually request controls, clear the **Interval** check box.
- To automate control intervals, select and define the **Interval** check box after a specified number of tests or after a specified number of hours.
- If you define one control only, select the check box **Interval Sequence 1**.
- If you define more than one control, select consecutive **Interval Sequence** numbers. For example: Control 1: select **Interval Sequence 1**, Control 2: select **Interval Sequence 2** and so on.

👁 For further information on how to assign controls to tests and how to define intervals for quality control, see *About control definitions* on page G-25

Modifying correlation and default unit parameters

► To modify correlation and default unit parameters

- 1 Click the **Laboratory** tab.
- 2 Select the required test from the **Installed Tests** list.
- 3 Modify the **Correlation Factor** and **Offset** as required.
- 4 Change the **Lab Unit** from the default if required. Modify the **Lab Unit Factor**.
- 5 Select the number of decimal places to be displayed in the reported result.
- 6 Click **Save**.



When you enter and save the **Lab Unit Factor**, entry fields for calibrator values and control values are displayed in the new lab units. Therefore enter these values as lab units and not as standard units.

If you entered calibration and controls values as standard units before entering and saving the lab unit factor, then these values are automatically converted to the new lab units.

If a hand-held barcode scanner is used for entering lot values, these values are automatically converted and displayed in lab units.

Modifying reference and critical ranges

► To modify reference and critical ranges

- 1 Click the **Evaluation** tab.
- 2 Select a test from the **Installed Tests** list.
- 3 In the **Result Evaluation Mode** box, select **None**, **Reference**, or **Cutoff**.
- 4 Modify the appropriate reference or critical ranges, or the cutoff limit as required.
- 5 Click **Save**.

Deleting test definitions

Preconditions

- Remove the associated calibrator and control racks.
- Make sure there are no orders pending for this test.
- Make sure all results associated with this test are accepted.

► To delete a test definition

- 1 From any tab, select one or more tests from the installed test list and click **Delete**.
- 2 Click **Yes** to confirm the deletion in the **Confirm Delete** dialog box.



Complementary information

- If a test is deleted, the calibration and quality control values for this test application are deleted as well.
 - If you decide not to delete a selected test after pressing the **Delete** key, you can click **No** or **Cancel** in the **Confirm Delete** dialog box.
 - If results exist for the selected test definition, another **Confirm Delete** dialog box appears to allow you to confirm the deletion of results associated with the test.
-

Creating and modifying test groups, sequences, and classes

Test groups are used in **Orders** to reduce the number of test buttons displayed. Test sequences arrange the way test buttons are displayed in **Orders**, and test classes are used in **Result Handling**.

Profiles are not affected by these definitions.

You may not have the necessary user access level to create and modify test groups, sequences, and classes. Ask your system manager for assistance.

To define and modify test groups, sequence and classes, click the **Class/Group** button from the **Configuration Test Definitions** dialog box.

👁 To create a new test group on page G-14

👁 To modify a test group on page G-14

👁 To modify a test sequence on page G-14

👁 To create a new test class on page G-15

👁 To modify a test class on page G-15

► To create a new test group

- 1 Click **Class/Group**.
- 2 Click the **Test Groups** tab
- 3 Click **New**.
- 4 Type a **Group Name** for the new group.
- 5 Select tests to be included in the new group from the **Installed Tests** list. Click **Add** to add them to the **Tests in Group** list.
- 6 Click **Save**.



Complementary information

- **Group Name** is up to nine alphanumeric characters and must be unique.
- Use **Remove** to remove a test from the **Test in Group** list and return it to the **Installed Tests** list.

► To modify a test group

- 1 Click **Class/Group**.
- 2 Click the **Test Groups** tab
- 3 Select a **Group Name** from the **Test Groups** list.
- 4 Use **Add** to move installed tests to the **Tests in Group** list.
- 5 Use **Remove** to move **Tests in Group** tests to the **Installed Tests** list.

► To modify a test sequence

- 1 Click **Class/Group**.
- 2 Click the **Test Sequences** tab.
- 3 Select the sequence in which test buttons in **Orders** are to be displayed.
- 4 Click **Save**.



Complementary information

- Sequence can be arranged in alphabetical order by **Test Class**, or you can select your own sequence (**Custom**).
 - The **Move** buttons are active only if you select **Custom**.
 - **Test Sequence** defines the display of the test buttons on the **Sample** tab of the **Order** work area.
-

► To create a new test class

- 1 Click **Class/Group**.
- 2 Click the **Test Classes** tab.
- 3 Click **New**.
- 4 Type a **Class Name** for the new test class.
- 5 Select tests to be included in the new class from the **Available Tests** list. Click **Add** to add them to the **Tests in Class** list.
- 6 Click **Save**.



Complementary information

- Each test appears in one test class only.
 - Roche defined test classes are displayed in blue, user defined test classes are displayed in black.
 - **Class Name** is up to nine alphanumeric characters.
 - The **Available Tests** list shows all tests that are not yet assigned to a class.
 - Use **Remove** to remove a test from the **Tests in Class** list and return it to the **Available Tests** list.
 - Test classes are used for result handling.
-

► To modify a test class

- 1 Click **Class/Group**.
- 2 Click the **Test Classes** tab.
- 3 Select a **Class Name** from the **Test Classes** list.
- 4 Use **Add** to move available tests to the **Tests in Class** list.
- 5 Use **Remove** move **Tests in Class** to the **Available Tests** list.
- 6 Click **Save**.



Complementary information

Roche defined test classes are displayed in blue, user defined test classes are displayed in black.

About profile definitions

You use the **Configuration Profile Definitions** dialog box to create new profile definitions, or modify or delete existing ones.

What is a profile?

You use profiles in the **Orders** work area to request groups of tests quickly, without having to select individual tests.



► To use the Configuration Profile Definitions dialog box

- 1 Click **Configuration** on the navigation bar.
- 2 Double-click the **Profiles** icon in the **Definitions** group.

Creating and modifying profile definitions

- 👁 To load a Roche profile on page G-16
- 👁 To create a customer defined profile on page G-16
- 👁 To view and modify profile definitions on page G-17
- 👁 To delete a profile definition on page G-17

► To load a Roche profile

- 1 Click **Load**.
- 2 Specify the path where the source files are located. The default path is "C:/Roche/Instrument/TAS".
- 3 Select the profile to be installed.
- 4 Perform the following steps for each profile:
 - Click the **ID** tab.
 - Modify the short name of the profile, if required.
The short name can have up to eight alphanumeric characters.
 - Modify the long name of the profile, if required.
The long name can have up to 30 alphanumeric characters.

► To create a customer defined profile

- 1 Click the **ID** tab.
- 2 Click **New**.
- 3 Type the **Profile Name**.
- 4 Type the **Short Name**.
- 5 Type the **Long Name**.
- 6 Type a profile number in the range of 910-930. This number must be unique among the test, profile and calculated results (ratio) numbers.
- 7 Click the **Tests** tab and click one or more test buttons to select the tests for the profile.
- 8 Click **Save**.
- 9 Click **Close**.

► **To view and modify profile definitions**

- 1 Click the **ID** tab.
- 2 Choose a profile from the list.
- 3 Modify the **Profile Name** or **Profile No** as required.
- 4 Click the **Tests** tab to modify the tests to be included in this profile.
- 5 Click one or more test buttons to select tests for the profile.
- 6 Click **Save**.

► **To delete a profile definition**

- 1 From any tab, select one or more profiles from the list.
- 2 Press the Delete key or click **Delete**.
- 3 Click **Yes** in the **Confirm Delete** dialog box.



Complementary information

If you decide not to delete a selected profile after pressing the **Delete** key, you can click **No** or **Cancel** in the **Confirm Delete** dialog box.

About calculated result definitions

You use the **Configuration Calculated Result Definitions** dialog box to add calculated result definitions, or modify or delete existing definitions.

What is a calculated result?

A calculated result is a mathematical relationship involving one or more test results and, optionally, numerical constants. The system automatically calculates a calculated result if all the tests specified in the calculated result definitions are requested in an order. Calculated results use the results from 1 to 4 tests in a mathematical formula to obtain another value, which can then be checked against a reference range and flagged.

$$\frac{A+B}{2}$$

► **To use the Configuration Calculated Result Definitions dialog box**

- 1 Click **Configuration** on the navigation bar.
- 2 Double-click the **Calculated Results** icon in the **Definitions** group.

Creating and modifying calculated result definitions

- 👁 *To load a Roche calculated result on page G-17*
- 👁 *To create a customer defined calculated result on page G-18*
- 👁 *To view and modify calculated result definitions on page G-19*
- 👁 *To delete a calculated result definition on page G-19*

You can create and modify calculated result definitions using the different tabs in the dialog box.

► **To load a Roche calculated result**

- 1 Click **Load**.
- 2 Specify the path where the source files are located. The default path is "C:/Roche/Instrument/TAS".

3 Perform the following steps for each calculated result:

- Click the **ID** tab.
- Modify the short name of the calculated result, if required. The short name can have up to eight alphanumeric characters.

Be aware that the short name affects the calculated result name in the user interface.
- Modify the long name of the calculated result, if required. The long name can have up to 30 alphanumeric characters.
- Click the **Laboratory** tab.
- Enter the correlation factor and the correlation offset if correlating two different methods.
- Enter the unit of the calculated result (ratio) and the factor and offset if the lab units are different from the specified units, if required.
- Enter the number of decimal places of the result.
- Click the **Evaluation** tab.
- Enter a general range and critical range, if required.
- Click **Add** and enter specific reference ranges.

► To create a customer defined calculated result

- 1** Click the **ID** tab.
- 2** Click **New**.
- 3** Type in the **Short Name**.
- 4** Type in the **Long Name**.
- 5** Type in the **Calc. Result No**.

The range for **Calc. Result No** is 910-930. This number must be unique among the test, profile and calculated results (ratio) numbers.

These definitions are mandatory.

- 6** Select the **Common Cuvette** box.

This is necessary to make sure that the calculated result is correct. For example, when using predilution, it is necessary that all tests required for a calculated result are prediluted from the same cuvette. The **Common Cuvette** box is selected by default.

- 7** Define formula, calculated result unit, and reference ranges for the new calculated result definition as required.
- 8** Click **Save**.



Complementary information

- **Short Name** consists of up to eight alphanumeric characters.
 - **Long Name** consists of up to 30 alphanumeric characters.
 - The calculated result number is in the range of 1 through 999, and is unique for tests, profiles, and calculated results.
 - Calculated result numbers 910-930 are for customer defined calculated results.
 - When creating formulas, up to four tests (A - D) and up to four factors (w - z) can be defined.
 - You can use the standard mathematical operations "+", "-", "*", and "/", as well as the brackets "(" and ")". The syntax is checked by the system when you click **Save**.
 - There are predefined Roche calculated results available for loading.
-

► To view and modify calculated result definitions

- 1 Click the **ID** tab.
- 2 Choose a calculated result from the list.
- 3 Modify the **Short Name**, **Long Name** or **Calc. Result No.** as required.
- 4 Select or clear the **Common Cuvette** box.
- 5 To modify a formula, calculated result units, and / or reference ranges for the calculated result definition, click the **Formula**, **Laboratory**, or **Evaluation** tab and modify the values as required.
- 6 Click **Save**.



Complementary information

Step 4: This step is only possible for customer calculated results, not for Roche calculated results.

► To delete a calculated result definition

- 1 From any tab, choose a calculated result from the list.
- 2 Press the Delete key or click **Delete**.
- 3 Click **Yes** in the **Confirm Delete** dialog box.



Complementary information

If you decide not to delete a selected calculated result after pressing the Delete key, you can click **No** or **Cancel** in the **Confirm delete** dialog box.

About calibrator definitions

Once tests have been loaded, the corresponding calibrators are automatically installed in the **Calibrators** list. The **Configuration Calibrator Definitions** dialog box is used to update lot numbers and values for existing calibrators or to create a user defined calibrator.

- 👁 *Specifying a calibration interval on page G-20*
- 👁 *Loading and deleting calibrator definitions on page G-21*
- 👁 *Specifying values for a new calibrator lot on page G-23*

Specifying a calibration interval

The calibration intervals for each test are defined in the test definition. You can reduce and extend the calibration interval of a test.



WARNING

Incorrect results due to changing calibration intervals

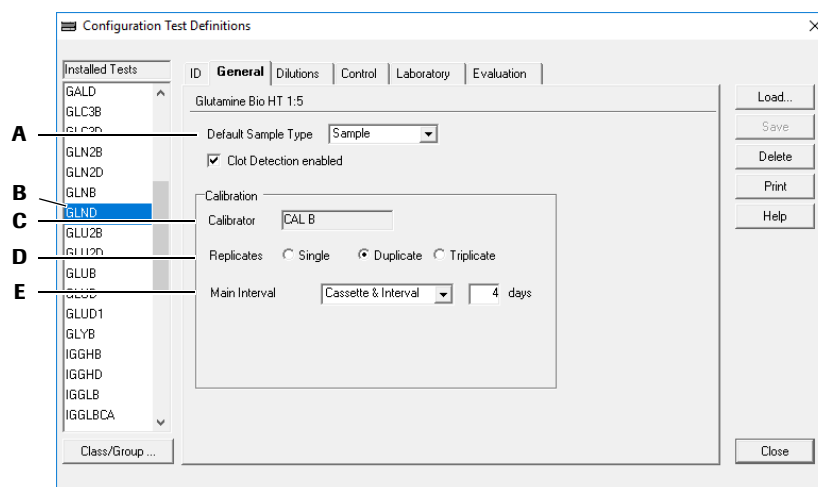
The analyzer is delivered with predefined calibration intervals for each test. The calibration intervals are carefully defined to guarantee reagent performance within the set onboard stability and shelf life of the reagents.

Any change may alter the reagent performance and, as a result, may lead to erroneous results.

- Do not change these default calibration intervals.

► To specify a calibration interval

- Click **Configuration** on the navigation bar.
- Double-click **Tests** in the **Definitions** group.
- Click the **General** tab.
- Select the required test from the **Installed Tests** list.
- Complete the **Calibration** text boxes as required.
- Click **Save**.



- A Sample type.
- B Selected test.
- C Roche calibrator.
- D If you select **Duplicate** or **Triplicate**, a mean value is calculated for each standard.
- E Specify the interval type if necessary.

Figure G-2



Complementary information

- Change the **Sample Type** only if necessary.
- You can only use the predefined Roche calibrators. This parameter can not be changed.
- The system must be in **Standby** or **Sleeping** state.
- You must have the required user access level to perform this procedure.
- You cannot modify a calibration interval if there is one or more unaccepted calibration curve for this calibrator or if there are unaccepted sample and QC results obtained on the basis of this calibrator.
- You cannot modify the calibration interval of ISE tests at all.
- The options for specifying a calibration interval are:
None: No calibration interval.
Interval: Calibration at time interval only.
Cass-Lot & Interval: Calibrate at each new cassette lot or specified interval, whichever comes sooner.
Cassette & Interval: Calibrate at each new cassette or specified interval, whichever comes sooner.

Loading and deleting calibrator definitions

If you get an update to a calibrator definition (for example, from a new test application software (TAS)), use this procedure to load the new calibrator definition.

Preconditions

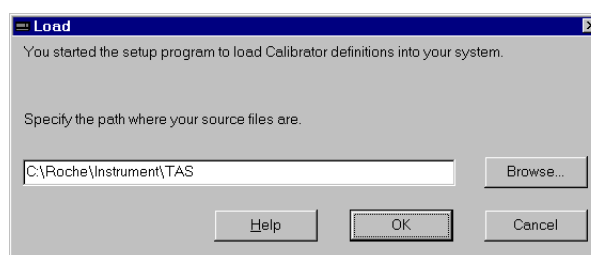
- You have sufficient user access privileges.
- The system is in **Standby** or **Sleeping** state.
- The rack containing the calibrator is *not* on board.
- There are no calibration results that were obtained on the basis of this calibrator.



► To load a new calibrator definition

- 1 Click **Configuration** on the navigation bar.
- 2 Double-click **Calibrators** in the **Definitions** group.
- 3 Click **Load**.

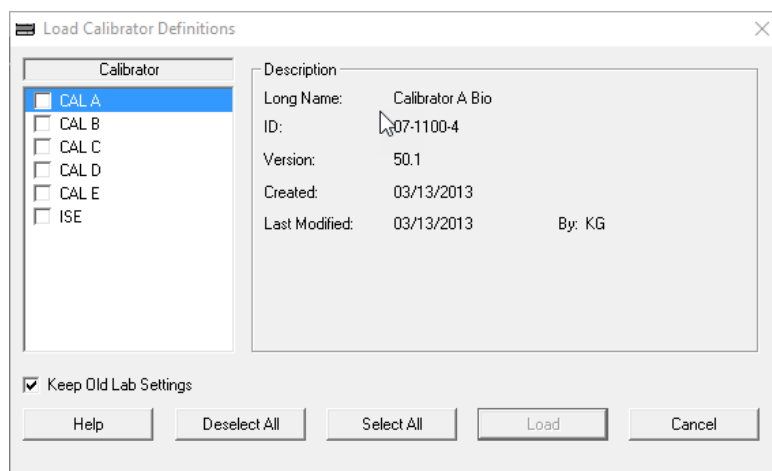
The **Load** dialog box is displayed.



- 4 Click **Browse** and choose the drive and directory where the required calibrator definition is located. By default, the "C:\Roche\Instrument\TAS" path is selected. Alternatively, type the complete path.

5 Click **OK**.

The **Load Calibrator Definitions** dialog box is displayed.



6 Select the calibrators that you require.

7 Click **Load**.

A progress indicator is displayed.

8 When the calibrators have been loaded, click **Cancel** to close the **Load Calibrator Definitions** dialog box.

To manually update lot specific calibrator values on page G-23

9 Select a calibrator from the **Calibrator** list10 Click the **Lot** tab to review existing lot information or to create a new lot.11 Click **Save**.12 Click **Close**.**Complementary information**

- You may be asked to update calibrator definitions from the test application software (TAS) from time to time.
- Update the assigned values for a new calibrator lot from the data given on the lot specific Instructions for Use.

► **To delete a calibrator definition**

- 1 Click **Configuration** on the navigation bar.
- 2 Double-click **Calibrators** in the **Definitions** group.
- 3 Click the **ID** tab.
- 4 Select a calibrator from the list.
- 5 Click **Delete**.
- 6 Click **Yes** in the **Confirm Delete** dialog box.

**Complementary information**

If you decide not to delete a selected calibrator after pressing the **Delete** key, you can click **No** or **Cancel** in the **Confirm Delete** dialog box.

Specifying values for a new calibrator lot

When you change calibrator lots you have to specify the lot number and expiry date, and the assigned values of the new lot.

The procedure to update calibrator lot numbers and values depends on whether you scan the barcode or enter it manually.



► To manually update lot specific calibrator values

- 1 Click **Configuration** on the navigation bar.
- 2 Double-click **Calibrators** in the **Definitions** group.
- 3 Select the required calibrator from the **Calibrators** list.
- 4 Click the **Lot** tab.

- 5 Click **New Lot**.
- 6 Type new values for the **Lot No** (Lot Number) and **Exp. Date** (Expiry Date), taking the values from the calibrator lot specific Instructions for Use.
- 7 Click **Save**.
- 8 Select a test from the **Test List**.
- 9 Type new values for each calibrator in the set (Std-1, Std-2, and so on), also taking these values from the calibrator lot specific Instructions for Use.
- 10 Click **Save**.



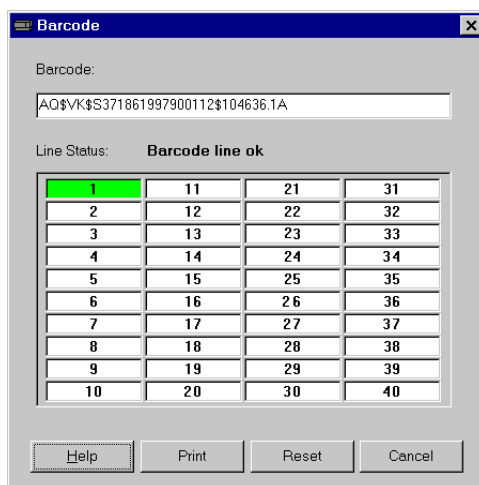
Complementary information

- The system must be in **Standby** or **Sleeping** state.
- You must have the required user access level to perform this procedure.
- Results obtained using calibration curves on the basis of the previous lot values of this calibrator are not changed.
- Std-1 is the standard with the highest concentration.
- When updating the lot numbers for the ISE solutions, enter both the lot number and expiry date of the solutions. You can enter the lot definitions for all three solutions individually.

► To update lot specific calibrator values using the hand-held barcode scanner

- 1 Click **Configuration** on the navigation bar.
- 2 Choose **File > Barcode** from the menu bar or click  from the toolbar.
The **Barcode** dialog box is displayed.
- 3 Run the hand-held barcode scanner over the first barcode line of the calibrator information sheet.

After reading the first line of barcode, the information is displayed on the **Barcode** dialog box.



Barcode:

AQ\$VK\$S371861997900112\$104636.1A

Line Status: **Barcode line ok**

1	11	21	31
2	12	22	32
3	13	23	33
4	14	24	34
5	15	25	35
6	16	26	36
7	17	27	37
8	18	28	38
9	19	29	39
10	20	30	40

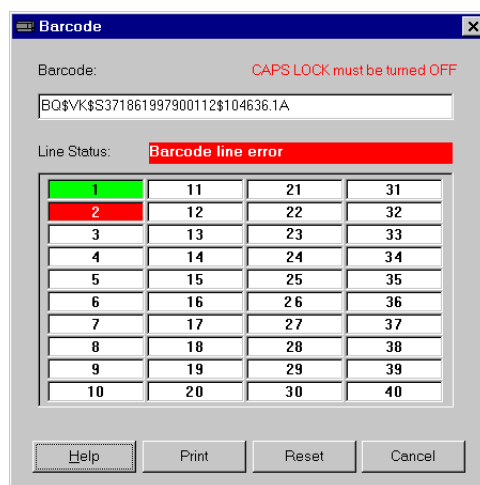
Buttons: Help, Print, Reset, Cancel

The numbered boxes represent the barcode lines.

- 4 Read the rest of the barcode lines of the calibrator information sheet.

5 Watch the **Barcode** dialog box.

Correctly read lines are represented by green boxes, lines with reading errors by red boxes and a message on the **Line Status** box of the **Barcode** dialog box.



- Using the hand-held barcode scanner, re-read the barcode lines that are represented by a red box in the **Line Status** group of the **Barcode** dialog box.
- Click **Reset** to delete all lines and restart the whole reading process.

6 When all lines are read correctly (all boxes are green), the **Barcode** dialog box closes automatically, and a message is displayed, informing you of the successful conclusion of the reading process.



Complementary information

- To read and edit the read lot information, use **Configuration > Calibrators > Lot**.
- Make sure Caps Lock on your keyboard is switched off.
- If you work with laboratory units other than the Roche standard units, the values read from the barcode sheet are automatically converted to your laboratory units, provided you specified the **Lab Unit Factor (Configuration > Tests > Laboratory)**.

About control definitions

You use the **Configuration Control Definitions** dialog box to load control definitions, create a user defined control, or update the lot number and values for an existing control definition and enter values.

- 👁 *Loading and deleting control definitions on page G-26*
- 👁 *Loading a non-Roche control on page G-27*
- 👁 *Assigning controls to tests on page G-28*
- 👁 *Specifying control intervals on page G-29*
- 👁 *Turning control rules on and off on page G-32*
- 👁 *Updating lot specific values for a control on page G-30*

Loading and deleting control definitions

If you receive an update to a control definition, use this procedure to load the new control definition.

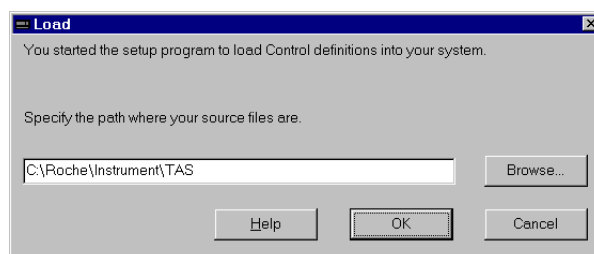
1. Load the control definition.
2. Assign the control to tests.
3. Update the lot information and values manually.

► To load a new control definition



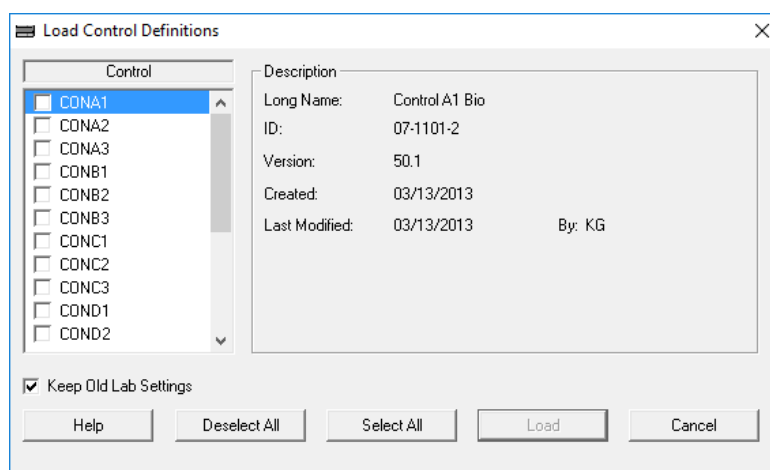
- 1 Click **Configuration** on the navigation bar.
- 2 Double-click **Controls** in the **Definitions** group.
- 3 Click **Load**.

The **Load** dialog box is displayed.



- 4 Click **Browse** and choose the drive and directory where the required control definition is located. By default, the "C:\Roche\Instrument\TAS" path is selected. Alternatively, type the complete path.
- 5 Click **OK**.

The **Load Control Definitions** dialog box is displayed.



- 6 Select the required controls.
 - 7 Click **Load**.
- A progress indicator is displayed.
- 8 When the controls have been loaded, click **Cancel** to close the **Load Control Definitions** dialog box.

- 9 Select the control from the **Control** list.
- 10 Click the **Lot** tab to review existing lot information or to create a new lot.
- 11 Click **Save**.
- 12 Click **Close**.



Complementary information

- You must have the correct user access level to load controls.
 - The system must be in **Sleeping** or **Standby** state.
 - Use the **New Control** button to create a control definition manually.
 - Roche controls have IDs with the format 07-xxxx-xx. You cannot change this ID.
-

► **To delete a control definition**



- 1 Click **Configuration** on the navigation bar.
- 2 Double-click **Controls** in the **Definitions** group.
- 3 Click the **ID** tab.
- 4 Select a control from the list.
- 5 Click **Delete**.
- 6 Click **Yes** in the **Confirm Delete** dialog box.



Complementary information

- If you decide not to delete a selected control after pressing the **Delete** key, you can click **No** or **Cancel** in the **Confirm Delete** dialog box.
 - You can press the Delete key instead of clicking Delete.
-

Preconditions

- You have sufficient user access privileges.
- The system is in Standby or **Sleeping** state.
- The rack containing the control is *not* on board.
- The control is no longer assigned to a test. You first need to assign a new control to the test or define that no control is required (**Configuration** > **Tests** > **Control**). Assigning a new control automatically deletes control results that were obtained on the basis of the previous control.

Loading a non-Roche control

If you want to use a non-Roche control, you have to set it up and assign it to tests in this sequence:

1. Create a control definition.
2. Assign the control to tests; for each test, specify an interval sequence.

► For the tests to which the control is assigned, specify the precision, accuracy, and limit values. **To define a non-Roche control**



- 1 Click **Configuration** on the navigation bar.
- 2 Double-click **Controls** in the **Definitions** group.
- 3 Click the **ID** tab.
- 4 Click **New Control** to clear the text boxes.

- 5 Type a short name, ID, and long name.
- 6 Click **Save**.
- 7 Click the **Lot** tab.
- 8 Click **New Lot**.
- 9 Type a lot number and expiry date.
- 10 Click **Save**.



Complementary information

- Step 5: Type the ID in the format 97-nnnn-n, where *n* is a number between 0 and 9.
- Step 10: When you click Save, an empty **Test** list is displayed. Tests are listed here when you have assigned the non-Roche control to tests.
- To determine the statistical values required, you have to run the control as a sample enough times for statistical accuracy.

Assigning controls to tests

When you have loaded a control definition, it can be assigned to the associated tests.



The following procedure applies to both Roche and non Roche controls.



► To assign a control to a test

- 1 Click **Configuration** on the navigation bar.
- 2 Double-click **Tests** in the **Definitions** group.
- 3 Select the required test from the **Installed Tests** list.
- 4 Click the **Control** tab.
- 5 Select the required control.

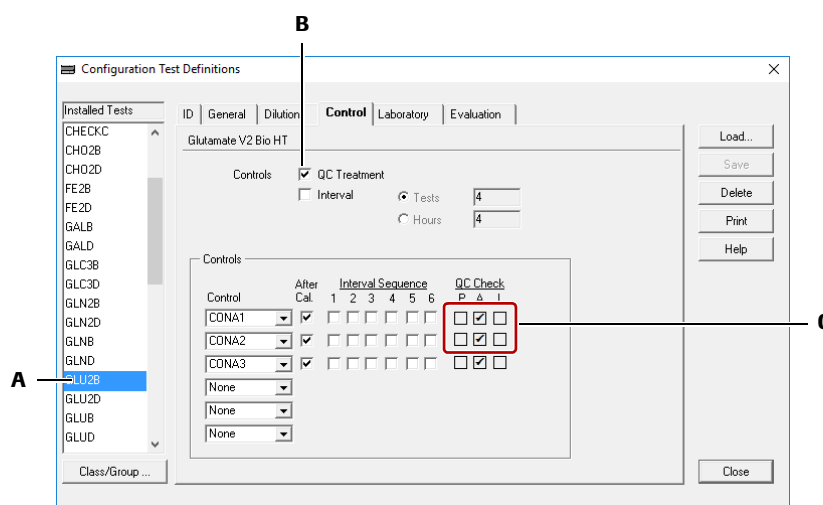
Control	After Cal.	Interval Sequence						QC Check		
		1	2	3	4	5	6	P	A	L
CDNA1	☒	☐	☐	☐	☐	☐	☐	☒	☒	☐
CDNA2	☒	☐	☐	☐	☐	☐	☐	☒	☒	☐
CDNA3	☒	☐	☐	☐	☐	☐	☐	☒	☒	☐
None	☐									
None	☐									
None	☐									

- A** No control defined. Click here to list all the controls, then select the one you want to assign.
- B** Click here to list all the controls, then select the one you want to assign.

- 6 Select the **QC treatment** check box to enable the QC rules and ranges for this test. The control results are automatically listed in the **Results** work area as they are calculated.

If you clear this check box, QC rules and ranges are not checked.

👁 *Specifying control intervals on page G-29*



- A** The selected test.
- B** Specifies whether control results are checked for QC rules and ranges.
- C** Shows which QC modes are enabled.

Figure G-3

Specifying control intervals



► To specify a control interval

- 1 Click **Configuration** on the navigation bar.
- 2 Double-click **Tests** in the **Definitions** group.
- 3 Click the **Control** tab.
- 4 Select the **Interval** box.
- 5 Select either **Tests** and type the number of tests, or select **Hours** and type the number of hours.
- 6 Select **After Cal**, if you want a control to be run automatically after each calibration.
- 7 Select an interval sequence. If more than one control is defined, select consecutive **Interval Sequence** numbers.
- 8 Click **Save**.

A This control is automatically run after each calibration.

B This control is run after two intervals (8 tests).

C An interval can be defined as a number of tests or a number of hours.

Figure G-4



Complementary information

- A control can be run automatically after each calibration. You can set additional control intervals based on time (Hours), or on the number of tests run.
- The interval is reset after the control is run.
- The **QC Check** columns tell you which QC modes are on for each control. These are defined in **Configuration > Controls > Lot**.

Updating lot specific values for a control



► To manually update lot specific control values

- 1 Click **Configuration** on the navigation bar.
- 2 Double-click **Controls** in the **Definitions** group.
- 3 Select the required control from the **Controls** list.
- 4 Click the **Lot** tab.
Tests to which the control is assigned are listed here, provided a lot exists.
- 5 Click **New Lot**.
- 6 Type new values for the **Lot No.** (lot number) and **Exp. Date** (expiry date).
- 7 Click **Save**.
- 8 For each test, select the control mode and type the values for this mode.
- 9 Click **Save**.



Complementary information

- The lot number is up to ten characters.
- The format of the expiry date must be the same as that for the date in the bottom right-hand corner of the screen.
- When you have saved the lot number and expiry date, the tests that use the control are displayed in the **Test** list. Enter and save new control values for each test.

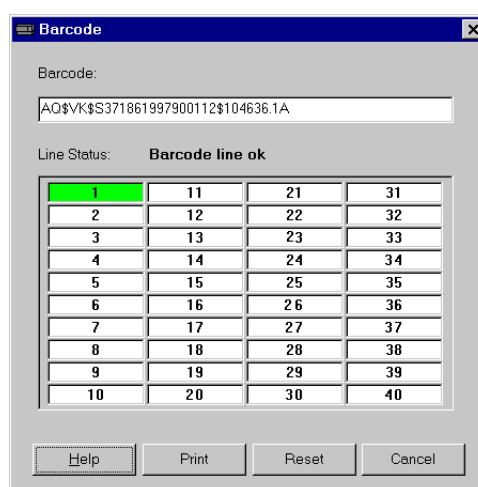
► **To update lot specific control values using the hand-held barcode scanner**

- 1 Click **Configuration** on the navigation bar.
- 2 Choose **File > Barcode** from the menu bar or click  in the toolbar.
The **Barcode** dialog box is displayed.
- 3 Scan the barcode of the lot specific control value sheet.



The controls load as accuracy controls.

After reading the first line of barcode, the information is displayed on the **Barcode** dialog box.



Barcode:

AQ\$VK\$S371861997900112\$104636.1A

Line Status: **Barcode line ok**

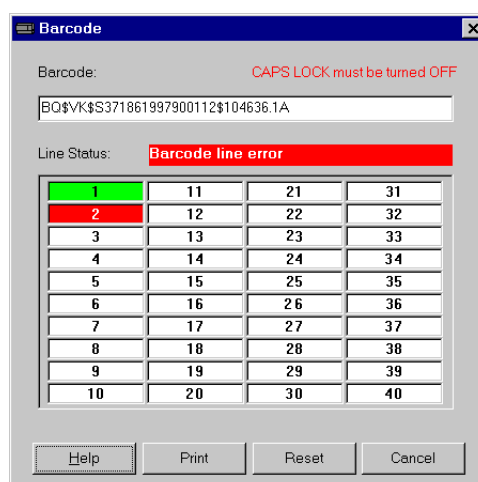
1	11	21	31
2	12	22	32
3	13	23	33
4	14	24	34
5	15	25	35
6	16	26	36
7	17	27	37
8	18	28	38
9	19	29	39
10	20	30	40

Help Print Reset Cancel

The numbered boxes represent the barcode lines.

- 4 Read the rest of the barcode lines of the lot specific control value sheet.
- 5 Watch the **Barcode** dialog box.

Correctly read lines are represented by green boxes, lines with reading errors by red boxes and a message on the **Line Status** box of the **Barcode** dialog box.



Barcode:

BQ\$VK\$S371861997900112\$104636.1A

Line Status: **Barcode line error**

1	11	21	31
2	12	22	32
3	13	23	33
4	14	24	34
5	15	25	35
6	16	26	36
7	17	27	37
8	18	28	38
9	19	29	39
10	20	30	40

Help Print Reset Cancel

- Using the hand-held barcode scanner, re-read the barcode lines that are represented by a red box in the **Line Status** group of the **Barcode** dialog box.
- Click **Reset** to delete all lines and restart the whole reading process.

- 6 When all lines are read correctly (all boxes are green), the **Barcode** dialog box closes automatically, and a message is displayed, informing you of the successful conclusion of the reading process.



Complementary information

- To read and edit the read lot information, use **Configuration > Controls > Lot**.
 - If you work with laboratory units other than the Roche standard units, the values read from the barcode sheet are automatically converted to your laboratory units, provided you specified the **Lab Unit Factor (Configuration > Tests > Laboratory)**.
 - Some controls have more than 40 barcode lines. In this case, read in the first 40 barcode lines. After reading 40 barcodes, a text appears telling the user to close the window or to continue reading the rest of the barcodes.
 - During barcode reading, never click on any message in the **Barcode** dialog box. The dialog box closes automatically when all lines are read.
-

Turning control rules on and off

If you need to run controls without using the control rules, you can turn off control rules in the test definition.



► **To turn control rules off for a specific test**

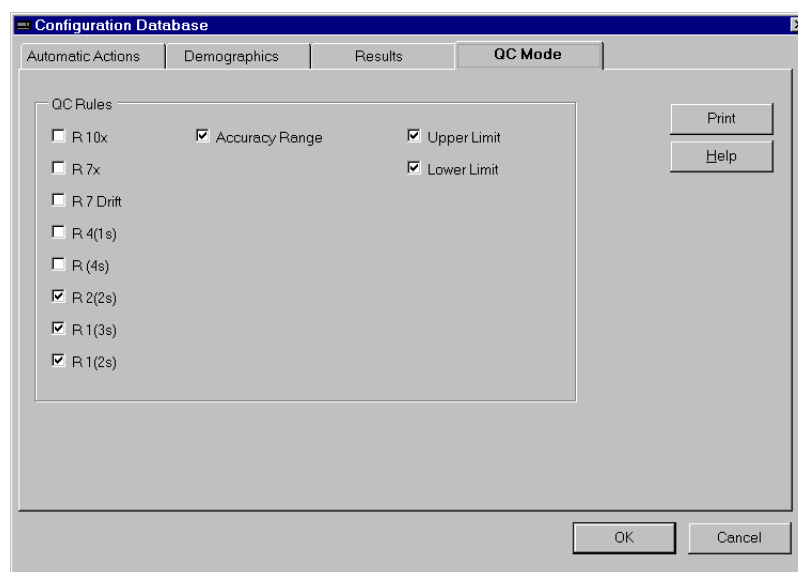
- 1 Click **Configuration** on the navigation bar.
- 2 Double-click **Tests** in the **Definitions** group.
- 3 Select the required test from the **Installed Tests** list.
- 4 Click the **Control** tab.
- 5 Clear the **QC treatment** box.
- 6 Click **Save**.



► **To specify which QC rules are checked**

- 1 Click **Configuration** on the navigation bar.
- 2 Double-click **Database** in the **System** group.

3 Click the **QC Mode** tab.



4 Select the check box for each rule, as required.

5 Click one of the following:

- **OK**, to save your changes for all the tabs in this dialog box
- **Cancel**, to close the dialog box without making any changes



Complementary information

- This dialog applies to the system as a whole. That is, if a rule is checked in this dialog, it is potentially available for any control on a test, if configured.
- If you clear the check box for a rule, that rule is not available for any control on any test on the analyzer.

About cassette definitions

You can use the **Configuration Cassette** dialog box to define warning levels for each cassette or view the cassette history.



► To display the Configuration Cassette Definitions dialog box

- 1 Click **Configuration** on the navigation bar.
- 2 Double-click the **Cassettes** icon in the **Definitions** group.

Viewing and modifying cassette definitions

► To modify the warning level

- 1 Click the **ID** tab.
- 2 Select a cassette from the list to display the information on the right.
- 3 Modify the warning level.



- 4 Click **Save**.

Complementary information

- You cannot change any of the cassette details, apart from the warning level.
 - **Warning Level** is used to generate a “tests low” warning message in **Status**. The entry is the percentage of tests remaining in the cassette.
-

► **To view the cassette history**

- 1 Click the **History** tab.
- 2 Select a cassette from the list to display the information on the right.



Complementary information

The **Cassette History** gives a list of the cassettes known to the system.

About cleaner definitions

You can use the **Configuration Cleaner** dialog box to view existing definitions, the cleaner history, and to load a new cleaner definition.



► **To use the Configuration Cleaner Definitions dialog box:**

- 1 Click **Configuration** on the navigation bar.
- 2 Double-click the **Cleaners** icon in the **Definitions** group.

► **To load cleaner definitions**

- 1 Click **Load**.
- 2 Specify the path where the source file is located (default path: "C:/Roche/Instrument/TAS").
- 3 Select the cleaner definition **Clean**.

► **To view cleaner definitions**

- 1 Click the **ID** tab.
- 2 Select a cleaner from the list to display the information on the right.
- 3 Click **Close**.



Complementary information

- You cannot change cleaner details.
 - The basic cleaner definition is used for the EWC extra wash cycle to avoid reagent carry-over.
-

► **To view the cleaner history**

- 1 Click the **History** tab.
- 2 Select a cleaner from the list to display the information on the right.
- 3 Click **Close**.

About diluent definitions

Diluent definitions are automatically installed with the associated test.

You can use the **Configuration Diluent** dialog box to view existing definitions, the dilution history, and to load a new diluent definition.



► **To use the Configuration Diluent Definitions dialog box:**

- 1 Click **Configuration** on the navigation bar.
- 2 Double-click the **Diluents** icon in the **Definitions** group.

► **To view diluent definitions**

- 1 Click the **ID** tab.
- 2 Select a diluent from the list to display the information on the right.
- 3 Click **Close**.



Complementary information

- You cannot change diluent details.
 - You can assign permanent rack positions to diluents in **Configuration > Lab > Reserve Positions**, or assign temporary placements using the **Place Samples** dialog box. Diluents can also be identified by barcode.
-

Loading ISE solutions

If you have loaded ISE tests, Activator, ISE Etcher and ISE Deproteinizer are automatically read from the ISE solutions list.

If you did not load ISE tests proceed as follows:

► **To load ISE solutions**

- 1 Click **Load** and specify the path (default: C:/Roche/Instrument/TAS).
- 2 Select the activator and deproteinizer.

Loading test application software

Test application software (TAS), such as test definition, profiles, calculated results, calibrators, controls, diluents, cleaners, ISE solutions, reagent definitions (cassettes) and extra wash cycle (EWC) definitions are delivered as file, which can be loaded to an external storage device.

Overview Loading TAS files comprises the following steps:

1. Perform the **Load TAS** function.
2. Insert the external storage device that contains the TAS files.
3. Remove the external storage device.

Adding a test (including calibration and QC) comprises the following tasks:

1. Load latest TAS (if applicable).

Tools > Load TAS

2. Load Roche controls.

Configuration > Definitions > Controls

3. Load test definitions.

Configuration > Definitions > Tests

4. Configure test definition, assign controls to tests.

Configuration > Definitions > Tests > Controls tab

5. Enter calibrator values.

Configuration > Definitions > Calibrators

6. Load quality control values.

Configuration > Definition > Controls

7. Load extra wash cycle (if required)

Configuration > System > Processing > EWC

8. Load Roche profiles or define non-Roche profiles.

Configuration > Definition > Profiles

9. Load Roche calculated results or define non-Roche calculated result.

Configuration > Definition > Calculated Result

10. Check the placement of diluents on the ISE rack.

Configuration > System > Lab > Reserve Position tab

11. Define new cassette rack (if required)

Configuration > System > Lab > Racks

12. Define a calibration and QC rack (if required)

Configuration > System > Lab > Racks

13. Assign calibrators and QC solutions to the calibrator racks and QC racks respectively.

Configuration > System > Lab > Reserve Position

Precondition You need user access level 6



- TAS files (Test Application Software update files) are usually sent as .zip files.
- TAS files are typically named "ickvxxxxvx".

► **To load a TAS using an external storage device**

1 Make sure the analyzer is in **Standby** state.

2 Choose **Tools > Load TAS**.

The **Load TAS** dialog box is displayed, asking you to insert the external storage device.

3 Insert the external storage device.

4 In the **Load TAS** dialog box, click **Yes**.

5 In the **Load TAS** dialog box, select the *ickv*.exe file.

You may first have to navigate to the directory where it is stored.

6 Click **Open**.

The analyzer automatically generates a backup of the existing TAS files and then replaces the existing files by the new ones.

When the TAS files are successfully loaded, a message is displayed, asking you to remove the external storage device.

7 When you are asked to do so, remove the external storage device.

8 In the **Load TAS** dialog box, click **OK**.

Archiving and reloading definitions

It is important to archive definitions regularly so that, in the unlikely event of a system failure, the archived definitions can be used to reload the system setup quickly and safely.

► To archive definitions and system parameters

- 1 In the **Configuration** work area, choose **File > Archive Definitions** from the menu bar, or click  on the toolbar.

The **Archive Definitions** dialog box is displayed.

- 2 Select one set of definitions from the list.

- 3 Click **OK**.

The corresponding **Archive** dialog box is displayed.

- 4 Select the item(s) to be archived.

- 5 Click **Archive**.

The **Archive Destination** dialog box is displayed.

- 6 Specify the path for the location of the archive.

- 7 Click **OK**.

- 8 The Archive in progress dialog is displayed where you may be prompted to confirm the action.



Complementary information

- Archived definitions are stored in text files.
 - You can archive only one set of definitions at a time.
 - Archive data to drive F or use an external storage device.
 - You must have read/write permission for each set of items you wish to archive.
-

 For more information about what is stored and what is not stored in the archives, refer to *Archiving system information* on page B-40

► To load definitions and system parameters from the archive

- 1 In the **Configuration** work area, choose **File > Load Definitions** from the menu bar or click  on the toolbar.

The **Load Definitions** dialog box is displayed.

- 2 Select the definition to be loaded.

- 3 Click **OK**.

- 4 Specify the path name of the archive from where the definitions are to be loaded.

- 5 Click **OK**.

- 6 Select the item to be loaded.

- 7 Click **Load**.

- 8 Click **Cancel** to complete the process.

About the System group

Generally, the **System** group is used to modify analyzer system settings that have been loaded during the installation process by a Roche representative. You can subsequently modify settings using the dialogs in the **System** group. You can make modifications only if you have the appropriate user access level.

Use the **System** group to configure general system settings and database setup. You can also specify tubes and racks, define how results are handled and modify processing options.

General Click the **General** icon to configure general details including user access and levels, host interface, system details, barcode specification, ISE settings.

Database Click the **Database** icon to configure the database for automatic actions, order demographics, result comments, and activation of QC rules.

Lab Click the **Lab** icon to specify sample tubes and types, assign tubes to racks, and define racks for calibrators, controls, diluents, and ISE solutions.

Result Handling Click the **Result Handling** icon to specify how flagged and unflagged results are automatically handled for samples, controls, calibrations, and calculated results.

Processing Click the **Processing** icon to specify processing options for report layouts, results uploaded to the host, the test processing sequence, and extra wash cycles for specific tests.

About user access

You use the **Configuration General** dialog box to add new users, modify user details and define user access levels.

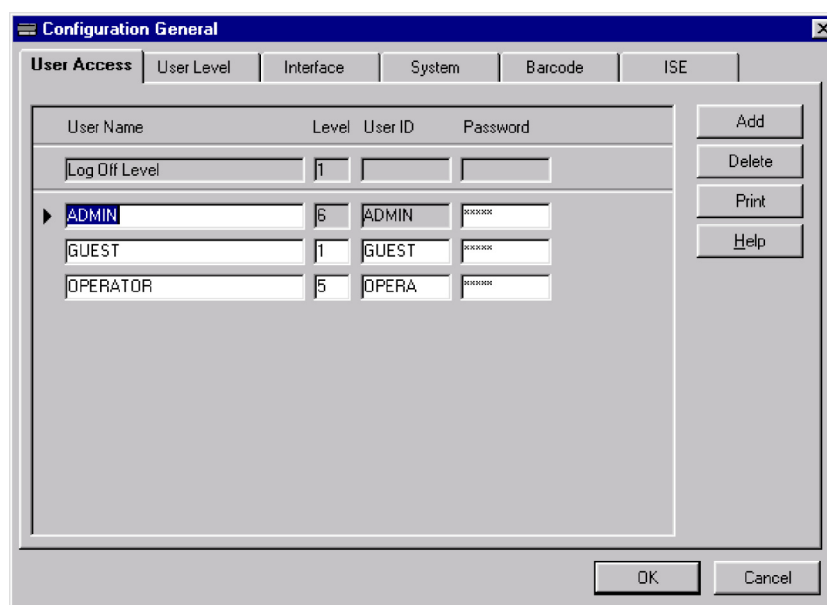


Figure G-5



Maintaining data security, integrity, and confidentiality

To maintain data security, integrity, and confidentiality, Roche recommends to always assign the lowest user level to a user that allows the user to perform the allocated tasks. For example, do not assign Administrator level to all users.



► To use the Configuration General dialog box:

- 1 Click **Configuration** on the navigation bar.
- 2 Double-click the **General** icon in the **System** group.

About user groups

By default, three user groups are defined:

Administrator

Administrators can perform the functions that are required for routine operation. In addition, they can configure most of the settings and parameters. The default access level is 6. This means that the administrator has access to all menus and functions. The default user ID and password is ADMIN.

Operator

Operators can perform all functions that are required for routine operation. The default log level is 5. The operator can access a limited number of menus and functions. The default user ID is OPERA, the default password is opera.

Guest

Guests can view information, but they cannot make entries or changes. The default log level is 1. The guest can access menus and functions for inspection only. The default user ID and password are GUEST.

Assigning and deleting user details

► To assign a user level to a user

- 1 Click **General**
- 2 Click the **User Access** tab.
- 3 Click **Add**. A new information box is displayed indicated by an arrow.
- 4 Type the user name, level, user ID, and password.
- 5 Click **OK**.



Complementary information

- **User name** is up to 16 alphanumeric characters.
- **Levels** are 1 (lowest) to 6 (highest); 1 is the default.
- **User ID** is up to six alphanumeric characters and must be unique.
- **Password** is up to six alphanumeric characters. The password is case-sensitive.
- Default password, user level and access rights to menus can be changed on this tab and in the **User Level** tab, provided you have access level 6.

► **To delete a user**

- 1 Double-click **General**
- 2 Click the **User Access** tab.
- 3 Select the required user and click **Delete**.
- 4 Click **OK** to confirm the new settings and close the dialog box.

Assigning user levels to functions

► **To assign user levels**

- 1 Click the **User Level** tab.
- 2 Select the user levels to be assigned to each function by clicking in the appropriate check boxes. Selecting a function for a specific user level automatically assigns this function to all higher user levels.
- 3 Click **OK** to accept the new settings and close the dialog box.



Complementary information

- Click **Default** to return all the settings to the original pattern set by Roche.
- There are six definable user levels that govern functionality for menus, buttons, and modifiable data. Generally, users with high user levels will find greater flexibility in using the system with more buttons, menus, and boxes enabled.

About system definitions

Use **Configuration > System > General > System**.

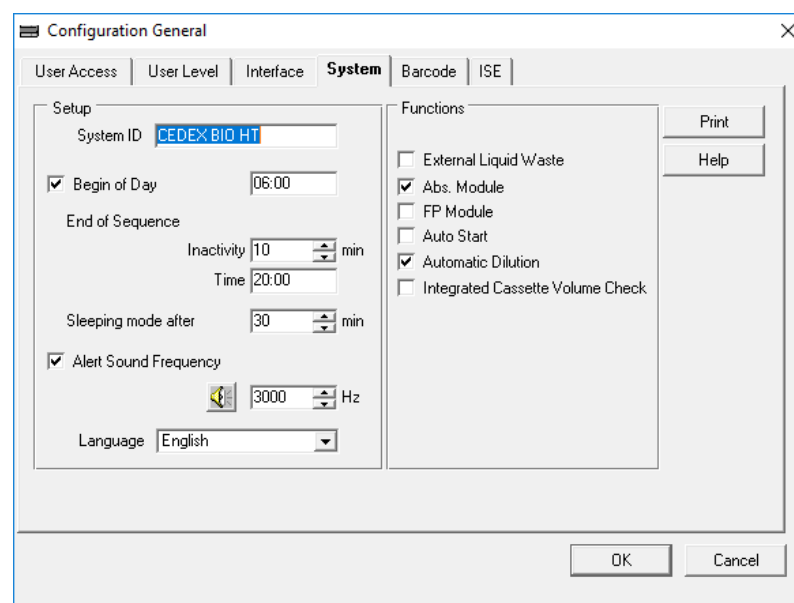


Figure G-6

System ID Default: **Cedex Bio HT**

This text box is used as the system identifier in host communication and is printed in the footer of most printouts.

Begin of Day Defaults: Check box selected, the time is set to 6:00.

Begin of Day (BOD) is the time a new work day is started. The system wakes up if in **Sleeping** state and performs the scheduled BOD service actions.

To postpone BOD actions clear the **Begin of Day** check box.

The system will not carry out the BOD actions on the next day at the defined BOD time. However, BOD actions will be performed again automatically on all subsequent days.

End of Sequence **End of Sequence** specifies the time when the system goes from **Operating** state into **Standby** state.

Default for **Inactivity**: 10 minutes. Type a value in the range of 10 to 60 minutes.

Default for **Time**: 20:00



- The laboratory must analyze its workflow in order to choose the appropriate **End of Sequence** time. Roche recommends setting the time of Inactivity outside the usual working period in order to avoid the problem of having the system still in **Operating** state at the defined BOD time. This would prevent the BOD service actions from being executed, which should be avoided.
- The life span of the absorbance photometer lamp and fans decrease if the system remains in **Operating** state.
- If the analyzer is in **Operating** state at BOD time, the BOD service actions will not start.

Sleeping Mode After Default: 10 minutes

The system goes from **Standby** state to **Sleeping** state after the defined time set. When the system is in **Sleeping** state, it takes up to 4 minutes to bring the system back into **Standby** state (absorbance photometer lamp warm-up phase).

Type values in the range of 10 - 60 minutes.

Alert Sound Frequency Default: 2000 Hz

Language Default: **English**

Selected the language versions of the software from the list.

This function does not depend on the user access level, and a system restart is not necessary following a language change.

External Liquid Waste Default: Check box not selected.

Select this parameter if the waste tube goes directly to an external drain and the supplied liquid (yellow) waste container is not used.



CAUTION

Infectious waste

Contact with waste may result in infection.

If this check box is activated, the fluid sensor in the yellow waste container is disabled.

If you are NOT working with an external liquid waste installation and this check box is disabled the yellow container can overflow and contaminate the environment.

- Do not activate the check box if you are NOT working with an external liquid waste installation.

Abs. Module	Default: Check box selected. This parameter activates the absorbance photometer module. If not selected, the analyzer never runs absorbance tests even if the Start button is clicked. The cuvette check remains active.
FP Module	Default: Check box is not selected.
	The FP module is not used for Cedex Bio HT tests.
Auto Start	Default: Check box not selected. If Auto Start is activated, after initialization, the analyzer performs all necessary BOD actions and then automatically goes into Operating state, provided there are orders to be processed. The analyzer also goes into Operating state as soon as a rack is inserted. The analyzer starts processing as soon as: • A sample rack is inserted, provided an order, test, calibration, control, sample, reagent set are defined, available, or loaded. • A test request is created manually. • A test request is received from the host.
Automatic Dilution	Default: Check box selected. This parameter activates or deactivates the overall automatic postaction capability (dilution and concentration). Even if activated, dilutions for individual tests must also be activated using the Sequential option in Configuration > Definitions > Tests > Dilutions. If the Automatic Dilution box is not selected, no rerun, and no postdilution will be performed.
Integrated Cassette Volume Check	Default: Check box selected. The ICVC function is activated by the reagent cassette barcode labels of all reagents that have to be filled manually in order to prevent erroneous results caused by incorrect filling of the cassette.
	The ICVC function can only be enabled or disabled by a Roche Service representative.

About barcode definitions

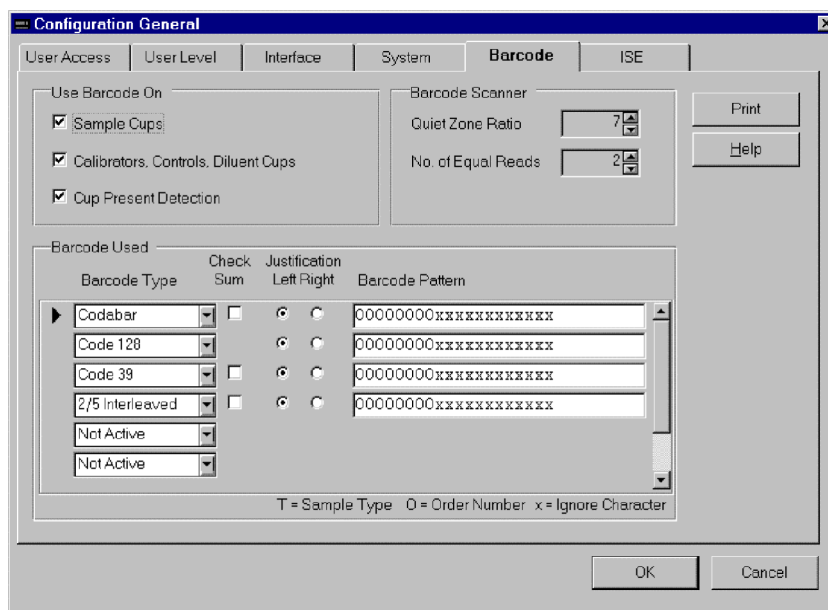


Figure G-7

Use Barcode On Default: All boxes selected.

These parameters activate or deactivate the usage of barcodes on sample tubes and calibrator, control and diluent cups.

- When using non-barcode samples, first deselect **Use Barcode on Sample Cups** before selecting **Auto Assign Rack Position** in **Configuration > System > Database > Automatic Actions**.
- If **Cup Present Detection** is deactivated, the system does not check for any presence of tubes or cups on the rack.
- **Cup Present Detection** does not work for empty adapters that are placed on the rack.

Barcode Scanner Barcode Scanner settings can be changed by a Roche representative only.

Barcode Used By default, the following barcode types are defined:

- Codabar (Code 2 of 7; Code 2/7)
- Code 39 (Code 3 of 9)
- Code 2 of 5 Interleaved
- Code 128
- UPC (A, E)
- EAN



To avoid conflicts with different barcodes, set the barcodes that are not needed to **Not Active**.

Barcode Pattern Default: six-digit order number plus twelve ignore characters (x)

The **Justification (Left/Right)** now works correctly. Therefore, leading or trailing ‘x’ patterns (**Ignore Character**) are no longer necessary for correct alignment.

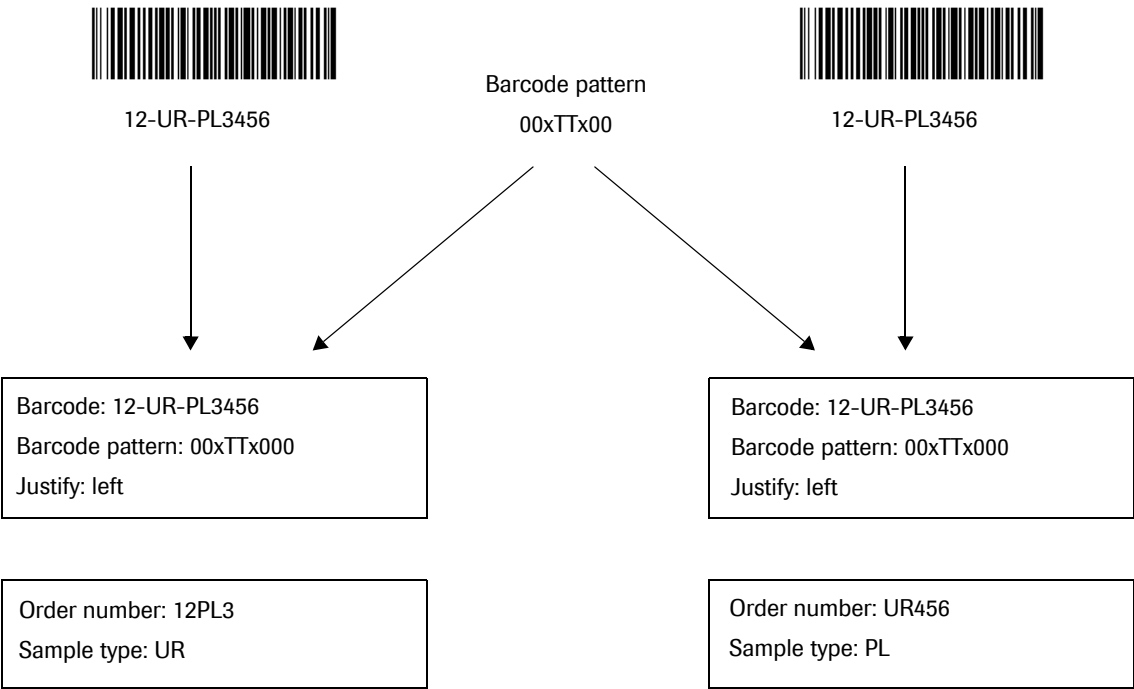


Table G-2 Example of barcode pattern

About ISE definitions

The screenshot shows the 'Configuration General' dialog box with the 'ISE' tab selected. The 'Electrode Assignment' section has a 'Setting' dropdown set to 'Na K -- --', and four electrode slots: '1st Electrode' (Sodium), '2nd Electrode' (Potassium), '3rd Electrode' (none), and '4th Electrode' (none). The 'Activation Factors' section has 'Direct' set to 1, 'Indirect' set to 1, and 'Counter Total' set to 50. The 'Main Calibration' section has 'Delta Temp.' set to 5.0 °C. Buttons for 'Print', 'Help', 'OK', and 'Cancel' are visible.

Figure G-8

Setting Default: Na, K

Select the electrode combination in use on your system.

Main Calibration Default Delta Temp: 5.0 °C (9 °F)

The **Main Calibration** compensates for any temperature drifts on the ISE module. If the temperature of the ISE module differs more than the setting predefined in **Delta Temp.** between the time a main calibration was performed and the next ISE measurement, an ISE main calibration is performed before the next sample is pipetted. A main calibration is also performed even if the main calibration interval (5 hours) is not due.



Roche strongly recommends not to change the **Delta Temperature**.

Activation Factors Defaults:

- **Direct:** 0
- **Indirect:** 1
- **Counter Total:** 50

The **Activation Factors** specify the number of tests before an electrode activation is automatically performed by the system.

The default counter for **Activation Factors** is preset to 1 count and 50 (tests) for **Counter Total**. This means that the service action **Activate Electrodes** is automatically performed once 50 ISE tests are measured.

If more than 50 ISE samples per day are measured, reduce **Counter Total** to 30 (tests) or less.



- Roche strongly recommends not to extend this interval.
- The counter that is visible in **Service > Service Counters > Service Intervals > ISE** is set here (not in the **Service** work area).

👁 See **Service Intervals** *tab* on page D-15

About automatic actions

Use **Configuration > System > Database > Automatic Actions**.

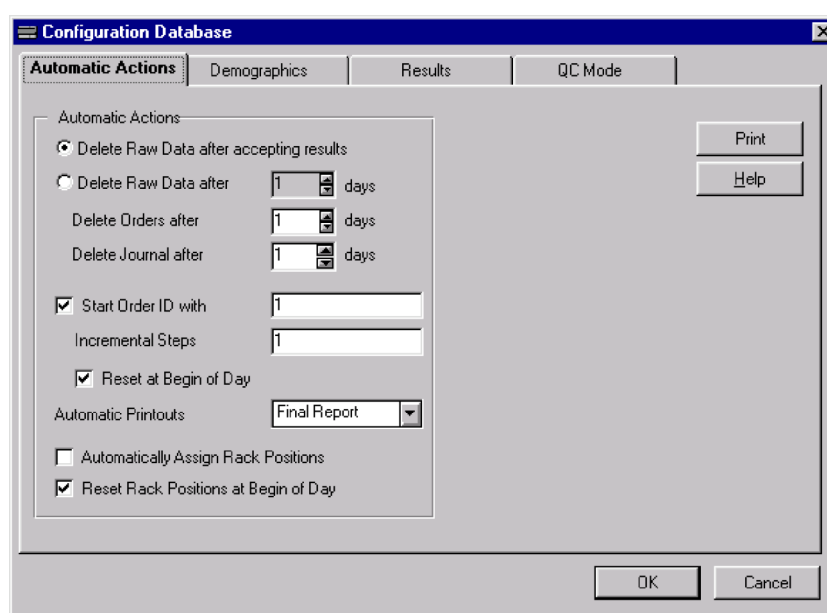


Figure G-9

Delete Raw Data after accepting results

Defaults:

- The check box **Delete Raw Data after accepting results** is selected.
- The check box **Delete Raw Data after n days** is not selected.

Sets the period during which raw data should be available for accepted results. You can either delete raw data immediately after accepting results or after the selected number of days at BOD time.

Example:

- Type “0” to delete all raw data from the previous day.
- Type “1” to delete all raw data created more than 24 hours ago.

Delete Orders after n days

Default: Delete after 1 day.

Deletes automatically all completed (accepted and transmitted) and unprocessed (new) test orders at BOD time. Once all test orders of a sample are deleted, the order ID in the **Orders** work area is deleted as well. Not accepted and transmitted test orders remain in the database.



Remove all sample racks from the system, otherwise orders cannot be deleted.

Example:

- Type “0” to delete all orders from the previous day.
- Type “1” to delete all orders created more than 24 hours ago.

Delete Journal after n days

Default: Delete after 1 day.

Deletes all result lines in the journal at BOD.

Example:

- Type “0” to delete all result lines from the previous day.
- Type “1” to delete all result lines generated more than 24 hours ago.

Start Order ID with

Defaults: Check box selected, **Order ID: 1**

Select this parameter to turn on automatic order numbering. Enter the start order ID for automatic numbering.

If this option is selected, define the increment and also the order ID reset at Begin of Day.

Incremental Steps

Default: 1

Reset at Begin of Day

Default: Check box selected.

Automatic Printout

Default: **Final Report**

Select if the **Final Report** should be printed automatically.

Automatically Assign Rack Positions

Default: Check box not selected.

Select the check box to allow automatic assignment of samples to rack positions.

This function can be activated only if no barcodes are used on sample cups. You cannot use **Automatically Assign Rack Position** if **Use Barcode on Sample Cups** is selected in **Configuration > System > General > Barcode**.

Reset Rack Positions at Begin of Day

Default: Check box selected.

If the check box is selected, all sample rack positions are cleared at the beginning of each day.



- Remove all sample racks from the system, otherwise sample rack positions cannot be cleared.
- Roche strongly recommends activating this function in order to prevent any possible confusion in rack position assignments.

About demographics definitions

Use **Configuration > System > Database > Demographics** to set the database parameters.

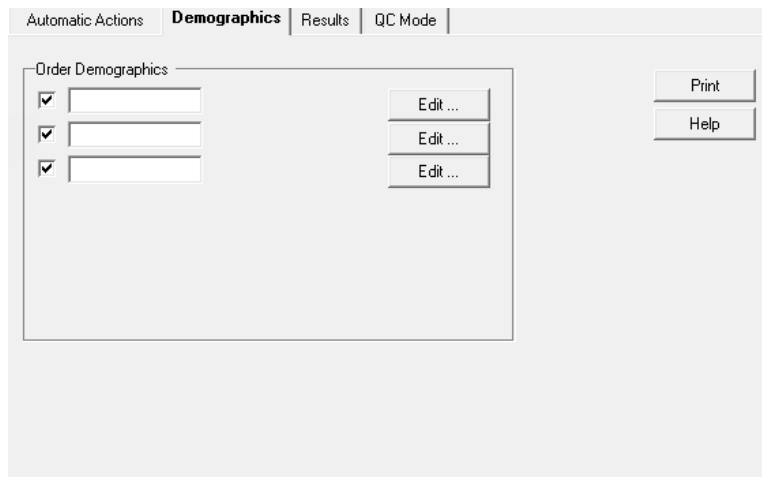


Figure G-10

- Define whether order demographics should be used.

About result definitions

Use **Configuration > System > Database > Results** to define result comments (for example turbid).

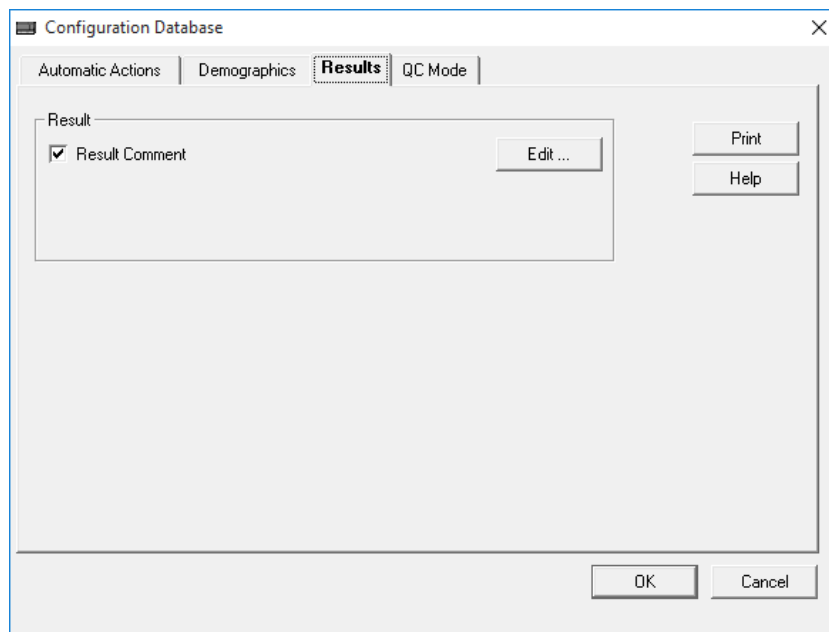


Figure G-11

About QC mode definitions

Use **Configuration > System > Database > QC Mode** to define the quality control rules.

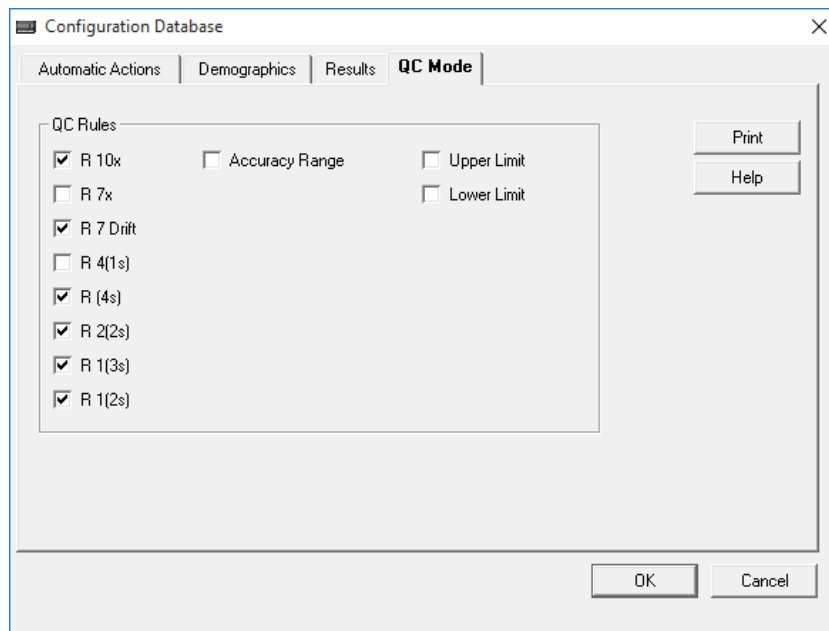


Figure G-12

Activate one or several of

- Westgard rules
- RiliBÄK precision rules
- Accuracy rules



- This dialog applies to the system as a whole. That is, if a rule is checked in this dialog, it is potentially available for any control on a test, if configured.
- If you clear the check box for a rule, that rule is not available for any control on any test on the analyzer.

About lab definitions

Use **Configuration > System > Lab** to define the following:

- Sample tubes used
- Sample types
- Rack configuration
- Assign permanent rack positions for calibrators, controls and diluents



Cedex Bio HT Analyzer users should consult their Roche representative for assistance if they intend to change the proposed tube settings, or if they use a tube type that is not listed in the **Defined Sample Tubes** list

About defining tube types

Use **Configuration > System > Lab > Sample Tubes**.

The **Defined Sample Tubes** list shows in alphabetical order all tube types defined by Roche and the user.

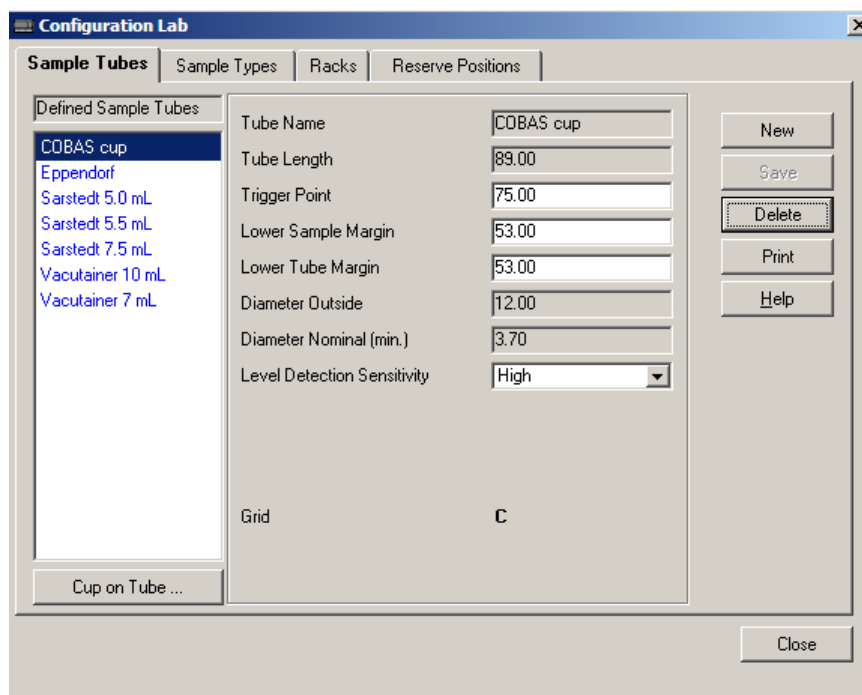


Figure G-13

The sample tubes that are predefined by Roche are displayed in blue and cannot be deleted. The **Tube Length** and the **Outside** and **Nominal Diameters** cannot be changed for any Roche sample tubes.

Tube name	COBAS cup	Eppendorf	Sarstedt 5.0 mL	Sarstedt 5.5 mL	Sarstedt 7.5 mL	Vacutainer 7 mL	Vacutainer 10 mL
ID Number of Tube / Cup	-	-	04.1934	03.1397	01.1728	-	368430
Tube Length	89 ^(a)	85 ^(a)	90	75	93	100	100
Trigger Point	75	73	85	70	88	85	95
Lower Sample Margin	53	41	10	10	15	5	5
Lower Tube Margin	53	41	10	10	15	5	5
Diameter Outside	12	12	13	15	15	13	16
Diameter Nominal (min.)	3.7	3.9	11	13	13	10.5	13
Level Detection Sensitivity	High	High	Middle	Middle	Middle	Middle	Low
Use default Cup on Tube	no	no	no	yes	yes	no	no
Grid	C	C	B	E	B	A	A

Table G-3 Overview of all predefined Roche sample tubes

(a) This value is chosen to allow this tubes to be inserted in slot I (cold position).



The grid settings of the selected tube may change if **Use Cup on Tube** is selected.

See *Defining additional tubes* on page G-52 for more detailed information

Dead volume for COBAS Cup and Eppendorf is ~80µL. No other recommendation can be given for the dead volumes, because it may vary from analyzer to analyzer.

Additional types of tubes and cups can be used on the system. They must be defined here. The permission to modify or add tube types depends on the user access level.

Defining additional tubes

Sample tubes can only be added or modified in **Standby**. No orders or results should be pending and no racks should be on board.

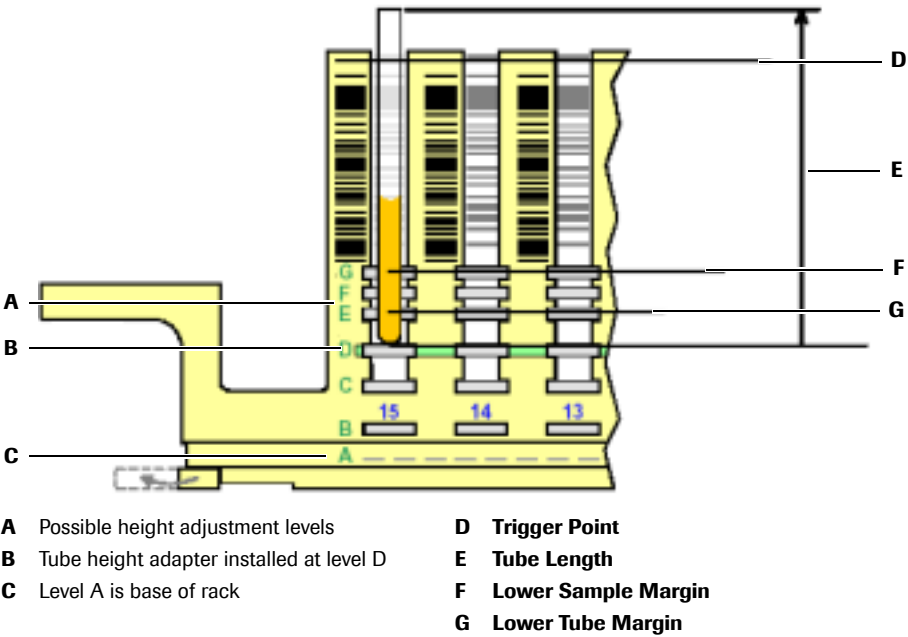


Figure G-14

► To define additional tube types

- 1 Click **New**.
The fields are cleared to allow a new tube type to be defined.
- 2 Enter the **Tube Name** of the sample tube to be defined.
- 3 Enter the **Tube Length** of the sample tube in the range of 20 mm to 108 mm.
The tube length defines the position of the sample rack grid device. See the following table:

Grid Position	A	B	C	D	E	F	G
Tube Length [mm]	108 - 99	98 - 90	89 - 83	82 - 76	75 - 72	71 - 68	67 - 20

Table G-4 Tube lengths

The selected grid position is displayed at the bottom of the screen.

Sample tubes with a maximum length of 108 mm can be used on sample area slots *J* to *O*. Use only sample tubes having a maximum length of 101 mm on cooled slot *I*.

For small sample cups (tube length less than 45 mm), Roche recommends using a *cup adapter*. For Eppendorf cups and COBAS Cups, use the Roche cup adapter. For other sample cups, use an appropriate sample tube as a cup adapter. In this

case, you might have to modify the level detection sensitivity. In addition, the total length of adapter plus sample cup must be defined.

4 Define the Trigger Point.

The **Trigger Point** indicates the height when level detection is activated. This measurement is made from the grid. The input range is 1 mm to <**Tube Length**> in mm.

5 Define the Lower Sample Margin.

The **Lower Sample Margin** indicates the maximum distance the sample probe will travel for samples. This measurement is made from the grid. Specify the **Lower Sample Margin** in the range of 1 mm to <**Trigger Point** - 1 mm>

6 Define the Lower Tube Margin.

The **Lower Tube Margin** indicates the maximum distance the sample probe will travel for calibrators, controls and diluents. This measurement is made from the grid. The **Lower Tube Margin** must be specified in the range of 1 mm to <**Trigger Point** - 1 mm> AND be less than the **Lower Sample Margin**.

7 Enter the outer diameter (mm) of the sample tube in the range of 11 mm to 18 mm.

8 Define the Diameter Nominal.

Enter the minimum inner diameter (mm) of the sample cup, measured at the height of the **Lower Cup Margin**.

The value must be in the range of 5 mm to < **Diameter Outside** - 1 mm>.

9 Adjust the Level Detection Sensitivity. Select from the list **Low**, **Middle**, **High**, or **Very High**.

Defining use of Cup on Tube

You can define *one* microcup as the Cup on Tube, that is the cup you will use on top of primary tubes.

Configuration > System > Lab > Sample Tubes > Cup on Tube

NOTICE

Analyzer damage due to incorrect cup configuration

Incorrect configuration of cups may lead to serious analyzer damage.

- Contact your Roche representative for support before you define the use of Cup on Tube.

Performing final checks

The final checks of the defined sample tube settings should be performed by a Roche representative.

Use the Check Solution Sample for these final checks:

Checking the lower sample and tube margin

- Fill the check sample solution to below the defined **Lower Margin** and order <CHKCS> twice.

The probe should not touch the bottom of the sample tube or cup and the following error message should be displayed: **No fluid detected: slot x position y**.

Checking the level detection sensitivity

1. Fill the check sample solution to above the defined **Lower Margin** and below the defined **Trigger Point**. Order <CHKCS> at least 30 times.

The error message **No fluid detected: slot x position y** should not be displayed, and no outlier should occur.

2. Check if the accuracy and precision of <CHKCS> are within the ranges specified. If necessary recheck with the next step of level detection sensitivity (one step up or down depending on sample tube dimensions).

Checking the trigger point

- Fill the check sample solution to above the defined **Trigger Point** and order <CHKCS> twice.

The following error message should be displayed: **No fluid detected: slot x position y**.

The probe should move down to the **Lower Sample or Tube Margin**, but it should not touch the bottom of the sample tube or cup.

Defining sample types



Sample types can only be added or modified if all results have been accepted or transmitted, and the samples of this sample type are not on board.

► To add a Sample Type

- 1 Open the **Sample Types** tab in **Configuration > System > Lab**.

The **Defined Sample Types** list shows in alphabetical order all sample types defined by Roche and the user. Selecting a **Defined Sample Type** displays associated information to the right.

Configuration Lab

Sample Tubes | **Sample Types** | Racks | Reserve Positions

Defined Sample Types

Sample	Sample Type Name: Sample	Sample Type Short Name: SAM
--------	--------------------------	-----------------------------

New
Save
Delete
Print
Help

Close

The following sample type is predefined:

- Sample

This sample type is displayed in blue and cannot be deleted. The **Sample Type Name** cannot be changed for any Roche sample types. However, additional sample types can be defined. The ability to modify or add sample types depends on the user access level.

- 2 To define an additional sample type, click **New**.

The cursor is positioned in the **Sample Type Name** input field.

- 3 Enter the **Sample Type Name**.

The name can have up to 10 alphanumeric characters and must be unique. It must contain at least one letter.

- 4 Enter the **Short Name**.

The short name consists of one to three alphanumeric characters. Avoid leading spaces!

The **Sample Type Short Name** is used in the Host Interface protocol (HIF) and barcode labels.

- 5 Click **Save** to save the newly defined or modified sample type.
- 6 Click **Delete** to delete the sample type configuration, if required.
- 7 Click **Print** to print the complete sample type configuration, if required.

About defining racks

- Prerequisites*
- The ability to modify or add sample racks depends on the user access level.
 - A rack can only be deleted or modified if it is not on board.

► To define a rack

- 1 Click **Configuration > System > Lab > Racks**.

All racks used on the system are defined here: ISE rack, cassette racks, calibrator racks, QC racks, and sample racks.

The **Defined Racks** list shows in alphabetical order all racks defined by Roche and the user. Selecting a **Defined Rack** displays associated information to the right.

Two types of racks are predefined by Roche:

- **ISE** (used for the ISE rack)
- **Cassette** (used for all cassette racks)

These racks are displayed in blue and cannot be deleted and the **Rack Name** cannot be changed.

- 2 Deselect the **Barcode** box if you work with nonbarcoded samples.
- 3 To define additional sample racks, click **New**.

Defining ISE racks

► To define an ISE rack

- 1 Select the **ISE** rack on the **Defined Racks** list.

The default **Rack Number** is 140 and the default **Rack Code** is 140.

- 2 Enter a rack number in the range of 1 to 999 corresponding to the **ISE Rack Code**, for example 140

The screenshot shows the 'Configuration Lab' window with the 'Racks' tab selected. On the left, a list of 'Defined Racks' includes 'ISE', 'Cassette', 'CAL/QC', and 'Sample Epp', with 'ISE' highlighted. The main area contains a 'Rack Name' field with 'ISE' entered. Below this is a table with columns 'Rack Number', 'Rack Code', and 'Barcode'. The first row has '140' in the 'Rack Number' and 'Rack Code' fields, and a checked checkbox in the 'Barcode' field. To the right of the table are buttons for 'New', 'Save', 'Delete', 'Print', and 'Help'. At the bottom of the main area are 'Add' and 'Delete' buttons. A 'Close' button is located at the bottom right of the window.

Rack Number	Rack Code	Barcode
140	140	☒

The ISE rack is labeled ISE on the front tab of the rack.

- 3 Enter the rack number in the range of 1 to 999, for example 140.
- 4 Enter the rack barcode in the range of 1 to 999, for example 140.

Rack codes must be unique.

The **Rack Code** is the barcode identification number of the rack used to identify the ISE rack.

- 5 Select the **Barcode** box to ensure that the barcode labels on the bottles on the ISE rack are read. By default this box is not checked.

Defining cassette racks

► To define a cassette rack

- 1 Select the Cassette rack on the Defined Racks list.
- 2 Click Add.

The screenshot shows the 'Configuration Lab' window with the 'Racks' tab selected. On the left, the 'Defined Racks' list contains 'ISE', 'Cassette' (highlighted), 'CAL/QC', and 'Sample Epp'. The main area shows 'Rack Name' set to 'Cassette'. Below this is a table with columns 'Rack Number' and 'Rack Code'. The table currently has 7 rows with values 1-7 and 101-107 respectively. An 'Add' button is at the bottom right of the table. To the right of the main area are buttons for 'New', 'Save', 'Delete', 'Print', and 'Help'. A 'Close' button is at the bottom right of the window.

Rack Number	Rack Code
1	101
2	102
3	103
4	104
5	105
6	106
7	107

Add inserts a new line, allowing you to enter the **Rack Number** and the **Rack Code** of the new cassette rack.

- 3 Enter the cassette rack number in the range of 1 to 999.

The **Rack Number** is the label number on the front tab of the rack.

- 4 Enter the rack barcode in the range of 1 to 999.

The **Rack Code** is the barcode identification number of the rack used to identify the cassette rack. It must be unique.

Defining sample racks



- Only one type of sample tube or sample cup can be used on each sample rack.
- Do not mix different tube types on the same sample rack!

► **To define a sample rack**

- 1 To define sample racks, click New.

The fields are cleared, allowing you to define a new sample rack type. The cursor is positioned in the **Rack Name** input field.

- 2 Enter the **Rack Name**.

The name can have up to 10 alphanumeric characters and must be unique. No special characters like +, -, /, * are allowed.

- 3 Select a **Tube Type** from the list of defined sample tubes (see **Configuration > System > Lab > Sample Tubes**).
- 4 Define the sample type.
 - Keep the **Sample Type** field blank to define the sample rack as a **Tube Type** specific rack.
 - Select a sample type from the list of defined sample types (see **Configuration > System > Lab > Sample Types**) to define the sample rack as a **Sample Type** specific rack. This sample type can only be used on this rack without confirmation.
- 5 The **Grid** is automatically assigned, based on the tube length of the selected tube type. The grid position cannot be changed manually.
- 6 Once the sample rack is defined, select the sample rack on the **Defined Racks** list.
- 7 Click **Add**.

A new line is inserted, allowing you to enter the **Rack Number** and **Rack Code** of the new sample rack.
- 8 Enter the **Rack Number** in the range of 1 to 999.

The rack number is the label number on the front tab of the rack.
- 9 Enter the **Rack Code** in the range of 1 to 999.

The **Rack Code** is the barcode identification number of the rack used to identify the rack. It must be unique.

10 Select Barcode.

If **Barcode** is checked, the barcodes on the sample tubes will be read. By default, the box is checked.

The “empty position barcode” at the back and front of the racks is always read, regardless of the Barcode setting.



Assigning racks

Use **Reserve Positions** for the **permanent** rack assignment of calibrators, controls, diluents, and ISE solutions.

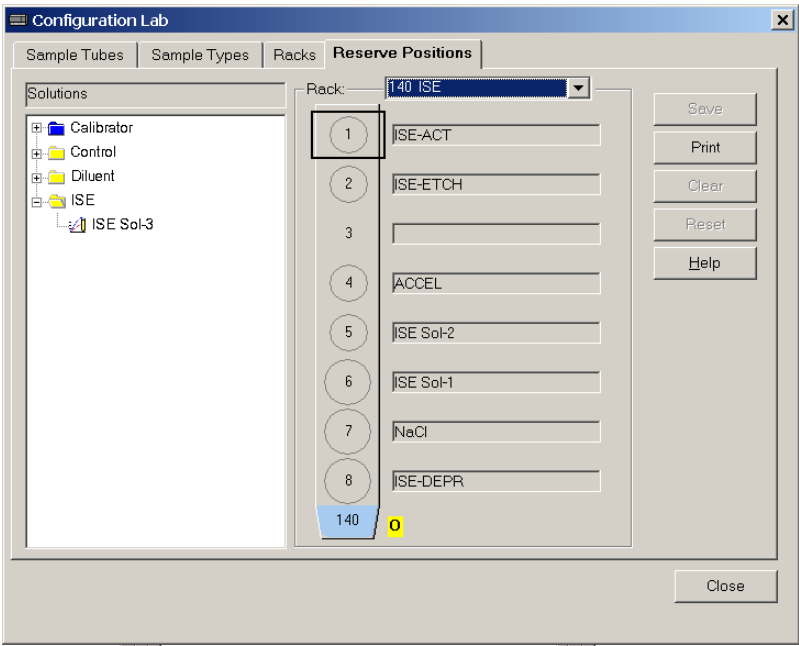


Figure G-15

► To assign calibrators, controls, or any other liquid to a rack

- 1 Select a rack from the **Rack** list. Selecting a rack will display its current position on the right.

Calibrators, controls, diluents and ISE solutions are listed in folders on the left.

- 2 Open a folder and drag and drop an item onto the rack.

Multiple positioning is possible for diluents. Consequently, these two folders are always displayed on the left.

Rack Position	Solution	Level Detection	Cap used
1	Activator Bio	Yes	No
2	ISE Etcher	No (checked with sensor1)	Yes
4	Accelerator	Yes	No
5	ISE Solution 2	Yes	Yes
6	ISE Solution 1	Yes	Yes
7	NaCl Diluent 9%	No	Yes
8	ISE Deproteinizer	No (checked with sensor1)	Yes

Table G-5 Recommended positions on the ISE rack for ISE solutions

Volume management is performed with all diluents. This software calculation mode is based on volume information and calculates the correct immersion depth of the sample probe if a new bottle is placed on a specific position of the ISE rack. It delivers information in percent about the filling status of bottles.

NaCl Diluent 9% can only be used in the ready to use 25 mL NaCl Diluent 9% bottles placed on the ISE-rack.

About result handling

To enable automatic result handling, click in the **Result Handling** check box on the top left of the **Configuration Result Handling** dialog box. If the **Result Handling** check box is not checked, no automatic handling of flagged results will occur.

In the **Result Handling Table** (**Configuration > System > Result Handling**), there are four tabs:

- **Calibration**
- **Quality Control**
- **Samples**
- **Calculated Results.**

The configuration of result handling depends on which type of result is to be handled automatically.

In general, the options for the **First Action** are as follows:

None	The analyzer will not automatically accept the results. No postactions are performed.
Accept	The analyzer will automatically accept the results. If this action is defined for any flag, then the flagged result is accepted and no postactions are performed.
Repeat	The analyzer performs the postactions which are configured in the test definitions.
Stop Test	The analyzer disables the test(s) on which the flag occurred.

If the option **Repeat** is selected, the box **End Action** automatically is displayed. Here it is possible to define a second action (**End Action**). For example, a flagged result can be accepted as the end action if as a result of the first action the test was rerun and the flag still appears.

About the Calibration tab

Configuration > System > Result Handling > Calibration

There are only 2 categories in this tab:

- **No Flag**
- **Any Flag.**

For each category, there are 3 possibilities for handling the results:

- **None**
- **Accept**
- **Stop Test**

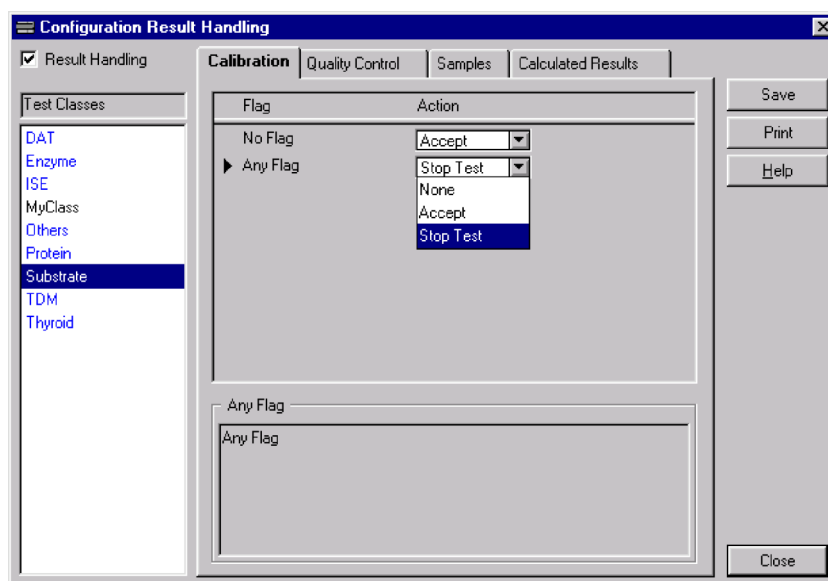


Figure G-16

No Flag Normally the first action for **No Flag** is Accept. If the customer wishes to manually validate and accept calibration results, define this as **None**.

Any Flag If **Any Flag** is generated for any calibration result, the action defined here will be performed. It is not flag specific.

- If **None** is defined, the system will continue to process samples following a flagged calibration, and these results will also be flagged.
- With ISE tests, the test is blocked in the same way as with the **Stop Test** action.
- If **Stop Test** is defined, the test will be disabled and no further samples will be processed.



- Reactivation of tests is done in **Status > Test Status**: Select the **Test Enabled** check box.
- Reactivation is also performed after a repeated calibration has been accepted.

About the Quality Control tab

Use **Configuration > System > Result Handling > Quality Control**

On this tab all the QC-specific flags (for example R1(2s)) are displayed individually. For each category or flag, there are 4 possibilities for handling the results:

- **None**
- **Accept**
- **Repeat**
- **Stop Test**

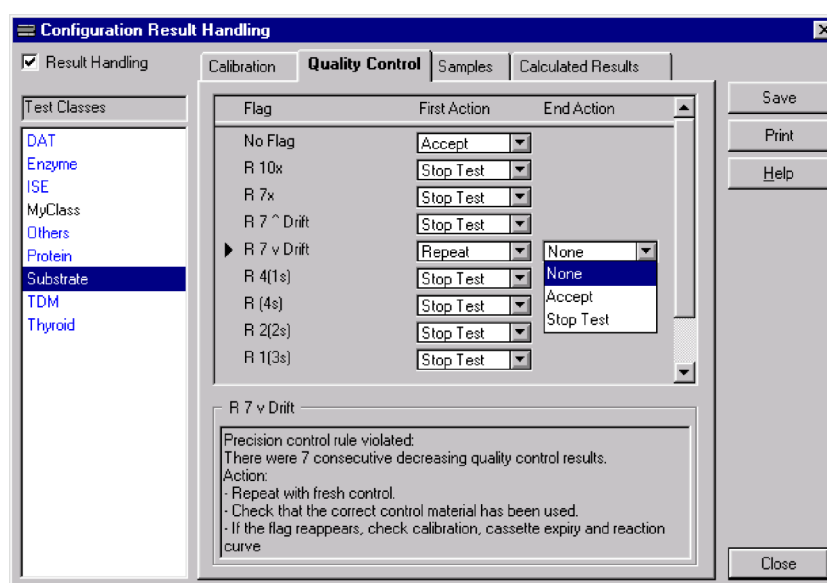


Figure G-17

No Flag Normally the first action for **No Flag** is **Accept**. If the customer wishes to validate and accept quality control results manually, define this as **None**.

Any Flag If any flag other than a QC specific flag is generated for a quality control result, the defined **First Action** is performed. This is not flag specific.

If **None** is defined, the system will continue to process samples following a flagged quality control result, and these results will also be flagged.

QC specific flags Here, the different **First Actions** for specific QC flags can be defined individually. The actions defined for **Any Flag** take priority over those defined for QC specific flags.

- If **None** is defined, the system will continue to process samples following a flagged quality control result, and these results will also be flagged.
- If **Repeat** is defined, the quality control order will be repeated. The order will be repeated **As Original**.
- If **Stop Test** is defined, the test will be disabled and no further samples will be processed



- Reactivation of tests is done in **Status > Test Status**: Check the **Test Enabled** check box.
- Reactivation is also performed after a repeated control has been accepted.

For each flag, a description of the flag and a recommended action is displayed at the bottom of the dialog box. The actions that need to be taken when a certain flag appears can be defined according to the customers needs.



It is possible to define **Repeat** for the **No Flag** category. Do not select this option! If you do, all samples will be repeated, irrespective of whether they are flagged or not.

About the Samples tab

Use **Configuration > System > Result Handling. > Samples**

All sample-related flags are listed on this tab, as well as the **No Flag** option. There are three possibilities for handling unflagged or flagged samples:

- **None**
- **Accept**
- **Repeat**

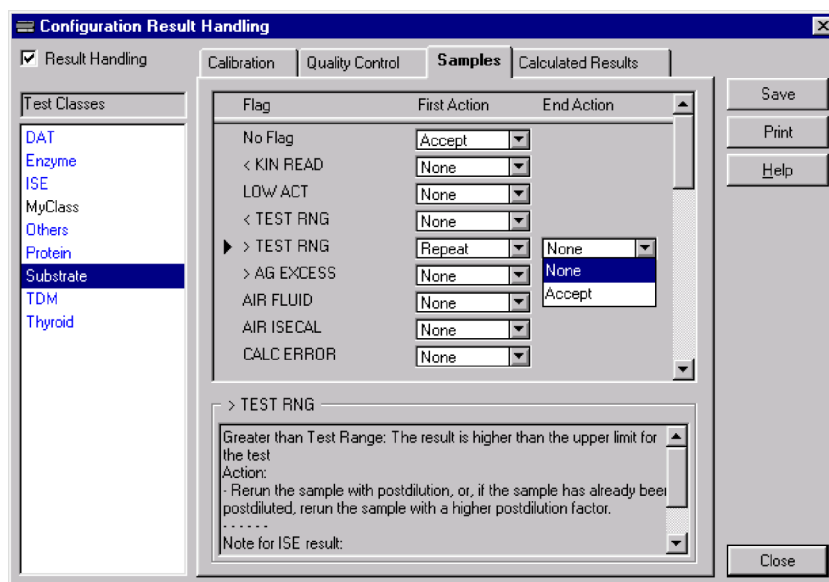


Figure G-18

As before, the **First Action** for **No Flag** is normally **Accept**, unless the customer wishes to validate and accept unflagged results manually.

For flags where the **First Action Repeat** is defined, the next action will depend on the test definitions.

For each flag, a description of the flag and a recommended action is displayed at the bottom of the dialog box. The actions that need to be taken when a certain flag appears can be defined according to the customers needs.



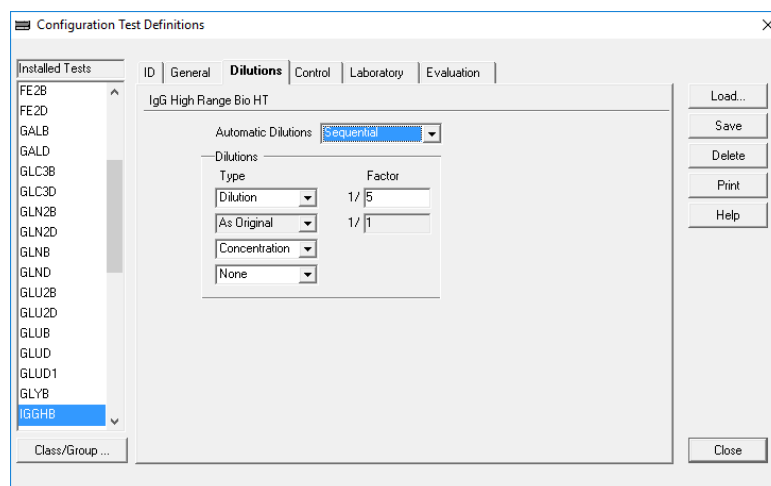
It is possible to define **Repeat** for the **No Flag** category. Do not select this option! If you do, all samples will be repeated, irrespective of whether they are flagged or not.

Defining postactions to be performed for automatic result handling

Postactions are defined for each test individually.

► To define a postaction

- 1 In **Configuration > Definitions > Tests**, select the test for which postactions are to be defined or modified.
- 2 Click the **Dilutions** tab.



- 3 For postactions to be performed, select **Sequential** from the **Automatic Dilutions** dialog box.

If **Off** is selected, no automatic postactions will be performed.

There are four possible postactions, one of which is always **As Original**. For the other postactions, one or more postdilutions can be defined. If there is a Roche recommended postaction, this is already defined by default.



Not all postactions can be performed on all tests. For example, postconcentration is not an option for Cedex Bio HT tests. If you select an inappropriate postaction type or factor for a test, a message is displayed, informing that the selected action is not possible.

About the Calculated Results tab

Use **Configuration > System > Result Handling > Calculated Results**

For Calculated Results (ratio), only results that are marked with the following flags can be handled automatically:

- No Flag
- >RR
- <RR
- >Critical Range
- <Critical Range

There are only two possible actions:

- None
- Accept.

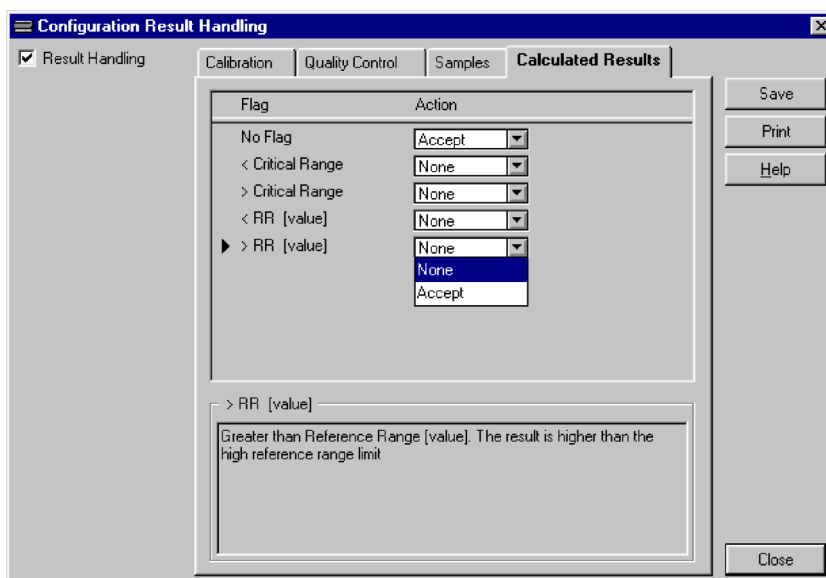


Figure G-19

If a calculated result was calculated using a flagged test result, that corresponding test will automatically be rerun according to the result handling settings for samples and the postactions defined for the individual test.



Except for calculated results, result handling can be defined according to the test class (including user defined test classes). This allows different **First** and **End Actions** to be used for different tests according to the customers requirements.

About the Result Output tab

Use **Configuration > System > Processing > Result Output**.

Use the **Result Output** tab to review the current settings that determine which results are sent to the host computer, and whether or not the **Sample Type** is transmitted to the host.



Do not change these settings without first contacting your Roche representative.

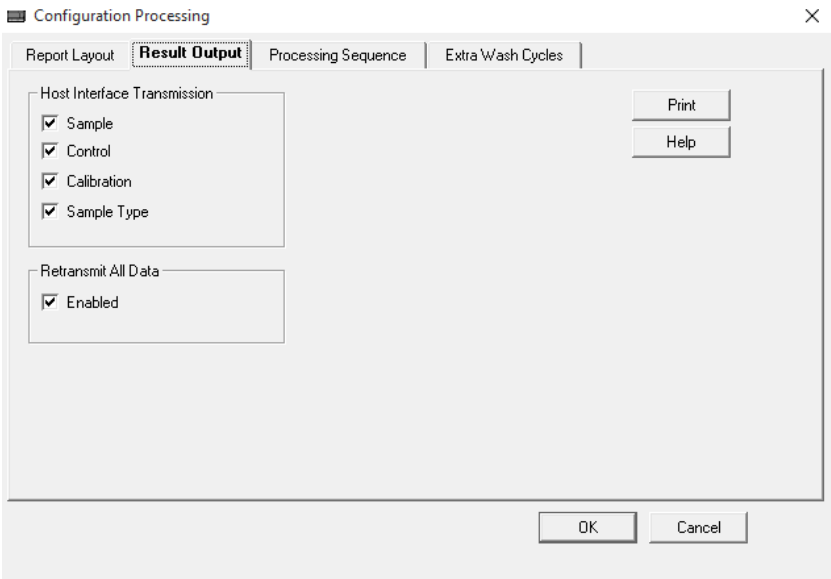


Figure G-20

For details, see the Cedex Bio HT Analyzer Host Interface Manual.



This function is available if you work with analyzer hardware with serial number 620001 or higher.

Retransmit All Data

Default: Check box cleared.

If **Retransmit All Data** is active, you can retransmit results to the host by choosing **Tools > Retransmit All Data** from the menu bar. This command retransmits all results on the system, even if you are only interested in one or two.

About the Processing Print Sequence dialog box

Click **Print Sequence** in **Configuration > System > Processing > Report Layout**. The **Processing Print Sequence** dialog box is displayed.

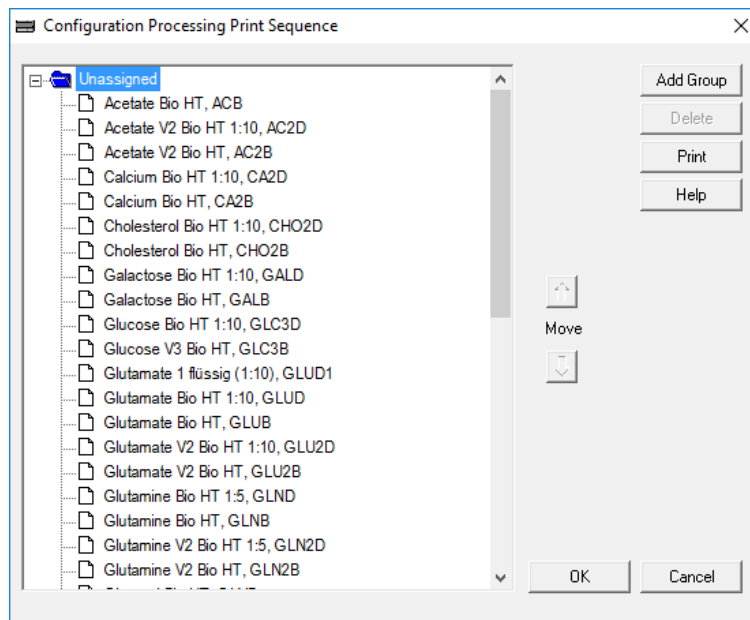


Figure G-21

As tests are loaded, the print sequence is sorted in alphabetical order within the unassigned test group.

Calculated results (Ratios) are included in the print sequence list.

Add Group Adds a test group to the print sequence list.

Move Moves the selected test up or down.

Tests can be moved to a test group using drag and drop or by selecting the **Move Up** and **Move Down** buttons.

About the Processing Sequence tab

Click the **Processing Sequence** tab in **Configuration > System > Processing**.

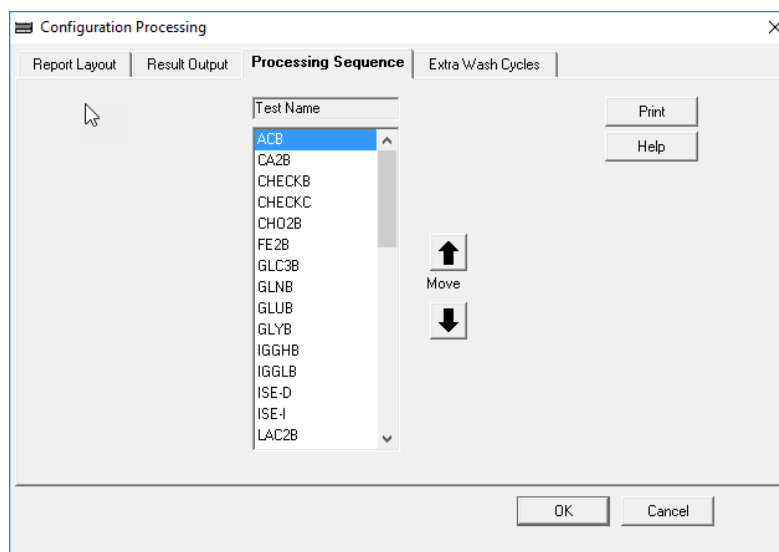


Figure G-22

The **Processing Sequence** defines the pipetting sequence **within** each sample order (tube).

Typical examples:

- Move high priority tests to the top of the list.
- Move long tests (for example Fructosamine, ASTPL) to the top of the list.

The setting of the processing sequence does not significantly influence test throughput.

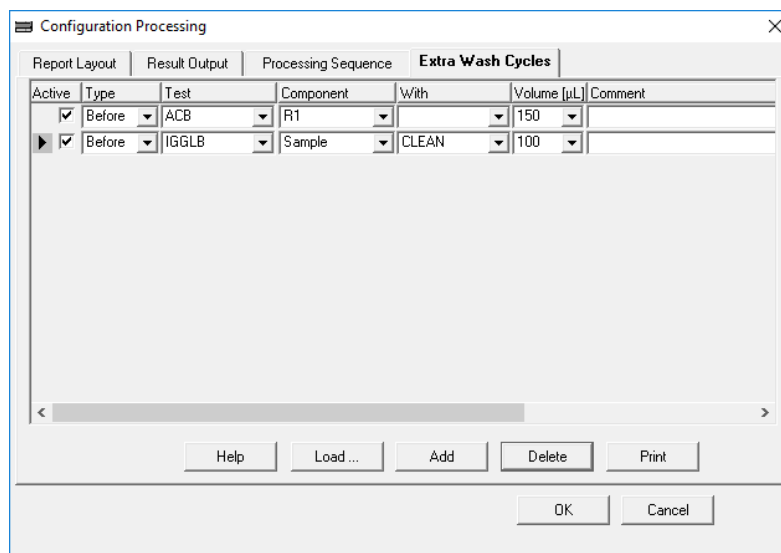
Each time tests are loaded, they are added to the bottom of the list.

Move Moves the selected test up or down the test list.

Defining extra wash cycles

► To define an extra wash cycle

- 1 Click the **Extra Wash Cycles** tab in **Configuration > System > Processing**.



- 2 Click **Load** to load the actual **Extra Wash Cycle (EWC)** table.
- 3 Specify the path from where the wash cycles should be loaded. Default: "C:/Roche/Instrument/TAS".
- 4 Select the extra wash cycle file.
- 5 Once the **Extra Wash Cycle (EWC)** table is loaded, you can switch off an extra wash cycle by clearing the **Active** check box, provided the test/reagent combination is not in use on the system.
- 6 Click **Add** to define an additional EWC.
- 7 Define the type, affected test, component, cleaner, and cleaner volume.

The actual **Extra Wash Cycle (EWC)** settings are shown in **Configuration > System > Processing > Extra Wash Cycles**.



Whenever new tests are added to the current test list, the **Extra Wash Cycle** is automatically loaded.



Carry-over and incorrect results due to inadequate wash procedures

Extra wash cycles are used to improve the effectiveness of probe cleaning. They are only needed for special combinations of reagents and samples.

- Roche strongly recommends that you do not change the predefined **Extra Wash Cycle (EWC)** settings

About the Windows group

The **Windows** group can only be configured by a Roche representative. Please contact your local Roche representative for more information.

Glossary

H

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Glossary

A

Absorbance photometer Device used to make absorbance photometry measurements. It consists of a halogen light source, optical groupings, monochromator (diffraction grating), preamplifier, filters and diode array. (See Absorbance Photometry)

Absorbance photometry A measurement technique for determining concentrations of substances in body fluids. Substances, or substances bound to reagents absorb specific wavelengths of light. The amount of absorbance is used to calculate the concentration in a solution.

Accept The accept function is used to validate results manually or automatically.

Accuracy control Is run to detect systematic result errors. (See also Precontrol, Precision Control, and Quality Control)

Activate electrodes ISE service action used to activate electrode surfaces so that the correct potentials are measured.

Activator Activator Bio for Cedex Bio HT Analyzer systems is used to coat ISE electrodes, tubing and sample probes after cleaning procedures.

Analyte The constituent in the sample that is to be determined.

Analyzer See Photometry analyzer

Analyzer rotor Disk that holds cuvettes, temperates them and carries them to the appropriate workstations.

Antigen excess check This check detects samples having excess antigen and thus avoids underestimation of the analyte.

Archive Storage of data on samples, orders, and results in Results work area.

Assigned mean The mean of an analyte in a control material or sample pool assigned by the user in order to establish a precision control.

Assigned standard deviation Deviation determined for a sample during precontrol and assigned for use of materials as precision controls.

Assigned value The assigned value reflects the quantity or activity of an analyte contained in an accuracy control sample. This value is established by the control manufacturer and is supplied with the lot specific Instructions for Use.

Auto start Automatic analyzer start function. Analyzer measurements start automatically following order entry or sample rack insertion.

B

Backup Saving of data onto external storage device. If such data is again required, but no longer available from main storage (hard disk), it can be restored (see Restore) from a backup copy.

Barcode An alphanumeric code used to identify a newly loaded cassette, identify samples, and read in calibration and control lot data from the lot specific Instructions for Use.

Barcode scanner A device which reads barcodes on tubes, racks, and reagent cassettes using a rotating mirror to scan a laser beam across the barcode. A sensor detects the dark and light reflections from the barcode, changing them into electrical pulses which are interpreted by software.

Begin of Day (BOD) The time when the analyzer starts its **Begin of Day** action (see **Begin of Day** action). This time can be specified in the Configuration work area.

Begin of Day action The software enables the user to define a specific time as the **Begin of Day** (for example 6:00 a.m.). At this time the system automatically carries out service actions and other procedures.

Begin of Day report A report that is automatically generated after the **Begin of Day**. The report lists service actions that have failed.

Bottle A glass or plastic container having a lid and used for liquids. Some bottles may be used directly on systems. Others have to be used on specific racks (e.g. ISE rack).

C

Calculated result (Ratio) Result calculated on the basis of two to four test results from the same sample.

Calibration The procedure to standardize each application with material of known concentration. Calibration establishes calibration curve parameters. (See Calibration Curve Parameter)

Calibration curve A plot of known concentrations of calibrators against their signals established during calibration.

Calibration curve parameters A series of factors or constants used to mathematically describe the characteristics of a calibration curve. The calibration curve parameters are used to calculate enzyme activity or analyte concentration based on the measured rate values. Cedex Bio HT curve parameters are labeled R0, Kc, A, B, etc.

Calibration mode A mathematical model to describe the relation between a signal and a concentration in the calibration curve (see Calibration Curve).

Calibrator Solution with known amounts of added analytes. They are used in different concentrations to adjust a measurement procedure.

Carry-over The phenomenon by which part of an analyte or reagent of a previous pipetting is inadvertently present in the current analysis.

Cassette area The cooled area where cassettes are loaded into the analyzer.

Cassette number A unique number that identifies a particular cassette.

Cedex Bio HT Registered name for the complete system consisting of analyzer, control unit, and software.

Cleaner The solution used to wash the interior and exterior of probes to prevent carry-over.

Clot detection Detects clots during aspiration and dispensing of samples, during washing of probes, or when initializing the system. When a clot is detected a message is displayed.

Coefficient of variation (CV) Statistical measurement used to evaluate imprecision. Ratio of the standard deviation to the mean of a set of replicate measurements ($CV\% = SD \times 100/\text{mean}$).

Consumables All materials used during operation that must be replaced regularly. These include cuvettes, cleaner, water, calibrators, controls, cassettes, ISE solutions, etc.

Control (QC) Material used to check accuracy and precision of a system.

Cup A small container used for samples as well as for calibrator and control material. Preferred vessel if only small amount of fluid is available. Only specific cups can be used on the analyzer.

Cup on tube A dead volume optimized configuration of samples having limited fluid quantities. The fluid can be transferred into a smaller cup that is placed onto a primary tube using the original barcode data of that tube.

Cuvette Disposable plastic containers into which sample, reagents, diluent, and water is pipetted, where the reaction and sample predilution takes place.

D

Daily start-up Procedures which ensure optimum working conditions such as checking/ loading calibrators and controls, emptying the waste container, or replacing depleted reagents. Daily Start-up includes the **Begin of Day** (BOD) actions (see **Begin of Day** action).

Control unit Part of the analyzer consisting of computer, monitor and optionally a printer.

Dead volume Volume remaining in a cup or tube after the last correct pipetting of maximum possible sample pipetting volume.

Degasser A module that removes gas bubbles from the fluid system and helps to improve both accuracy and precision in systems where dissolved gases cause problems.

Demographics Information about an order.

Determination The process of quantifying the concentration of analytes.

Deviation Difference between the assigned value and an actual value of a control sample.

Diluent A liquid used to dilute samples (for example physiological salt solution) or to affect an analytical reaction.

Direct mode (ISE) ISE measurements made on an undiluted sample.

F

Flag Generated by software, printed with results and also displayed with individual results in the Results work areas. Indicates that the limit of an internal check was exceeded or not reached.

Fluid system Consists of all tubing, pumps, valves, filters, and other devices that support sample, reagent, diluent, and cleaner dispensing.

Fluorescence polarization (FP) A measurement method where a sample is irradiated with light of a specified (excitation) wavelength. Fluorophores in the reaction mixture (for example fluorescein-labeled reagents) emit light at a second wavelength (fluorescence) and the emitted light is detected at 90° to the excitation beam. A filter mechanism is used to determine the parallel and perpendicular components (polarization) of the emitted light, and thus the concentration of e.g., the analyte in the sample.

FP photometer (Not used for Bio HT tests) Device used to make Fluorescence Polarization measurements. It consists of a blue LED light source (See Light Emitting Diode), optics, shutter, dc motor driving a two-position polarization filter, photomultiplier (light amplification) tube and associated high voltage electronics. (See Fluorescence Polarization)

Function keys Keys (F1 to F12) along the top of the keyboard used to enter specific commands.

G

Grid See Tube Height Adapter

H

Host computer External computer of the customer's Laboratory Information System communicating with the analyzer. Allows rapid processing of the large quantities of data generated. Communication between the Host and the analyzer is provided by the Cedex Bio HT Host Interface. (See Host Interface)

Host interface Hardware and software allowing bidirectional communication between the analyzer control unit and the Host Computer. The hardware is an RS-232 serial interface. (See Host Computer)

Roche Diagnostics

I

Identification number (ID) Number used to uniquely identify samples, cassettes, tests, calibrators, controls, and diluents.

Indirect mode (ISE) ISE measurements made on a diluted sample.

Initialization Status while the system performs any kind of initialization (e.g. of the fluid system or the transfer arms) - after power up or before being operative.

Integrated cassette volume check (ICVC) The ICVC function is activated by the reagent cassette barcode labels of all reagents which have to be filled manually in order to prevent erroneous results caused by incorrect filling of the cassettes.

ISE Ion-selective electrode.

ISE module The ISE module is an electro-mechanical device used to determine ionic concentrations in undiluted and diluted samples using electrodes selective to different ions. The ISE module is one of the two measurement areas of the analyzer, the Photometry Analyzer being the other.

ISE rack Contains fluids (Activator Bio, ISE Solutions 1, 2, ISE Deproteinizer, ISE Etcher) needed to perform ISE main calibration and maintenance actions. Diluents necessary for other tests can also be placed on the ISE rack.

J

Journal The journal lists the results chronologically according to their test start time. Use this information to review the execution sequence of tests run on the system.

L

Level detection The automatic determination of the level of fluid by the probes. Level detection establishes whether there is enough fluid to perform the incipient pipetting operation.

Light emitting diode (LED) Solid state lamp available in different colors. For the analyzer, LEDs are used for the warning light and rack status indicators on the front of the analyzer, the fuse indicators, etc.

Log off Quit access to the system - no current user is recorded.

Log on - Rack number

Log on Gain access to the system by entering a user name and, if required, a password. The given user name is taken as current user and may be printed on records.

Lot Consumables produced from the same materials in the same production run and subjected to the same quality control procedures.

M

Memo pad Electronic note pad used to leave messages or supplementary information for the next user.

Message Message icons on the user interface informing the user that intervention is required. An alarm sounds when an urgent message appears.

Navigation bar The column of buttons used for quick access to the work areas.

O

Online Help System in which the user can call up information in a context-sensitive manner and search for any given term. Just click the **Help** button or press F1 to access online Help.

Operating Status while the system is performing pipetting, measurement, and calculation activities.

Order An entry in the Orders work area to run a sample measurement.

Order demographics Customizable information for orders.

Order ID Unique identifier for an order. Can only be used once on a given day. The sample order identification refers to a number of sample tubes (one or more specimen types) of a given sample collected for a panel of different tests.

P

Password Log on identification allowing user access to the analyzer software.

Permissible deviation The maximum acceptable deviation of the control results from the assigned value of the accuracy controls.

Photometry analyzer Consists of workstations, the rotor, and the Absorbance (ABS) Photometer.

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Postaction Definable pipetting action that can be either dilution or concentration. It is triggered by appearance of several flags (e.g. >test range, antigen excess).

Postpone calibration Overruling of a due calibration by the user. All results of a test with a postponed calibration are flagged.

Power up The analyzer is designed to be left switched on. For maintenance or long breaks the system may have to be switched off (shutdown) and on (power up) again.

Precision control Precision controls are run to detect random errors (see also Accuracy Control, Precontrol, and Quality Control).

Precontrol Before a control material can be included as a precision control (see Precision Control), it should be evaluated by the laboratory. The results from the precontrol period, the assigned mean, and the standard deviation are used to automatically establish a precision control.

Primary wavelength Main wavelength for signal detection in bichromatic (ABS) measurements. (See Absorbance Photometry)

Profile Set of tests frequently ordered in combination.

Purge Command to clear all completed orders and results from the work areas.

Q

Quality control (QC) A tool which verifies accuracy and precision of results. analyzer quality control encompasses the functions of accuracy control, precision control, and limit control.

Quality control rules A set of statistical rules that help to identify problems with the analyzer.

Query Command to find and display the entries in the work areas according to customized search criteria.

R

Rack Carrier holding containers used on specific systems.

Rack number A number that identifies a particular rack. This number is assigned when the rack is defined to the system.

Rack status display Consists of a set of lights that show the status of the racks. The icon on each light indicates the type of rack. The color and whether the light is flashing or steady indicates the rack status.

Random access analysis Ability to run analyses flexibly in any order, as opposed to in batches.

Rate Absorbance difference between first and last measurement cycle (ΔA) or change in absorbance per minute ($\Delta A/\text{min}$).

Ratio See Calculated Result

Reference wavelength Second wavelength in bichromatic (ABS) measurements which corrects for interfering constituents in the sample. (See Absorbance Photometry)

Repeat Command to perform a test, calibration, or control order as in the original run.

Replicates Multiple repeated measurements of the same sample, calibrator, or control.

Report A collated set of data related to the running of the analyzer (for example test results, resource requirements, or service actions performed). Reports are automatically generated and printed on request.

Rerun Command to perform the same test with a concentrated or diluted sample either by decreasing the diluent or by increasing the sample volume.

Restore Command to reload data from an external storage device to the control unit hard disk. (See Backup)

Rotor See Analyzer Rotor

S

Sample area The area on the analyzer where sample racks and the ISE rack are located.

Sample cup See Cup

Sample tube See Tube

Scroll bars Thin rectangles normally found along the right side and bottom of windows. The bars have arrows at each end and a single rectangular box in them. Clicking on the arrows moves the contents of the window in the same direction. The box of the scroll bar can be moved with the mouse to provide the same effect as clicking on the arrows.

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Service action A service procedure that must be performed to keep the analyzer running correctly.

Shutdown Command to switch off the software and analyzer for longer breaks or if severe errors occur.

Sleeping Status while the system is in energy conservation mode.

Standard deviation (SD) The square root of the average of the squares of the deviations from the mean.

Standby Status when the system does not perform any measurement activities - but only a limited initialization / preparation time is required.

STAT Abbreviation for Short Turnaround Time. Emergency order automatically given the highest priority.

Status bar An area at the bottom of the main window where information and the current date and time are displayed.

Stop Button to achieve one of the following:
 -Stop pipetting samples but finish processing already scheduled activities without interruption or loss.
 -Stop all system operations immediately. The system aborts all current activities. The system may need special attention before it can resume its normal operation.

T

Test class A category of related tests which are handled in the same way.

Test group A set of tests that are displayed in the Orders work area. A test can belong to more than one test group.

Toolbar A bar positioned below the menu bar containing a series of shortcut buttons.

Tube Vessel for samples and Cal/QC/Dil fluids used on all kind of racks within the system. It is a primary vessel and may or may not have a barcode label for positive sample identification. A sample tube contains sample of one specific specimen (sample) type.

Tube height adapter (grid) Device to adjust the height of tubes or cups on aluminum cup adapters.

U

User access Access allowed to different users of the software. Each level has its own password and its own group of operational permissions.

User interface Link between the system and the user. The sum of screen displays supported by the analyzer software.

V

Volume management An internal software calculation mode. It is based on volume information to find the correct immersion depth of the sample probe if a new bottle is placed on a specific position of the ISE rack. Delivers information in percent about the filling status of bottles.

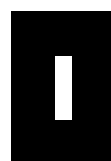
W

Waste The fluids (samples, cleaning solutions, etc.) and solid materials (cuvettes) discarded by the analyzer.

Waste container The waste container collects used cuvettes and potentially infectious fluids. Both the waste container and contents must be disposed of according to the local legal requirements associated with high level waste.

Work area Main areas of the user interface such as **Results** and **Orders** work areas.

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Revisions

J

Use this section of the manual as a repository for updates to the Cedex Bio HT Analyzer Operator's Manual. You can also use this section to insert your own notes about the system, so that all information about the system is in one place.

Revisions

This chapter contains amendments to the *Cedex Bio HT Analyzer* Operator's Manual and the *Cedex Bio HT Analyzer* User Training Guide.

In this chapter

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Change 2: Warning statement added to inform about flammable refrigerant ...	J-8
Change 3: Caution statement added to inform about sharps, rough edges, and/or moving parts	J-9
Change 4: Safety statement about software and data security updated	J-10
Change 5: Information added about two new safety labels on the system informing about flammable refrigerant	J-13
Change 6: Label position of the two new safety labels added	J-14
Change 7: The water purity must have a maximum microbiological content of 100 colony forming units per mililiter	J-15
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A system restart is required after changing the language of the software	J-23

Changes in *Cedex Bio HT Analyzer* Guides 1.4

Manual	Manual Version	Software Version	Revision Chapter Version	Revision Date
<i>Cedex Bio HT Analyzer</i> Operator's Manual	1.4.1	5.1	1.0	November 2020
<i>Cedex Bio HT Analyzer</i> User Training Guide	1.3.1	5.1	1.0	November 2020

In order to ensure that the readers of the Cedex Bio HT Analyzer User Manual use the up-to-date content, Roche recommends to manually mark the affected passage in the original manual.

► **To update the *Cedex Bio HT Analyzer* User Guides**

- 1 In the current chapter *Revisions*, go to the first change.
- 2 Familiarize yourself with the items that changed.
- 3 Identify the page number affected in the original manual.
- 4 Go to the appropriate page in the original and manually mark the changes. For example cross out text that is no longer applicable or add a reference where to find new and changed content.



If you print these pages, Roche recommends printing them single-sided. This way you can easily insert them in the existing manual.

Structure of a change entry

The following illustration explains how changes are presented.

Cedex Bio HT Analyzer

A

Change 6

Safety statement about software and data security updated

B

C

Affected pages: 28-29

Software and data security

Revision: Safety statement about software and data security updated (several changes)

Unauthorized system access and data loss

External storage devices can transmit computer malware, which may be used to gain unauthorized access to data or cause unwanted changes to software.
The system is not protected against malicious software and hacker attacks.

- Physical access to the product and all attached IT infrastructure (including analyzer, computer systems, cables, network equipment, etc.) must be restricted at all times.
- A Roche-provided firewall is mandatory if the system is connected to a network to protect and separate Roche systems from other laboratory infrastructure.
- The laboratory network and any laboratory infrastructure must be secured against unauthorized access, malicious software, and cyber-attacks.
- All devices and services used in the customer lab infrastructure must be safe and secured against malicious software and unauthorized access.
- A secure network environment which is resilient to traffic redirection and eavesdropping must be installed.

Roche recommends the following precautions:

- Do not copy or install any software on the system unless it is part of the system

D

E

A

Change ID.

B

Change summary.

C

Pages that are affected in the manual.

D

An indication of the nature of the change immediately precedes the changed or new element(s).

E

Changed element(s).

Change 1

Changing password after initial installation

Affected page: Operator's Manual, page 10

Revision: New security statement added

For security reasons, the administrator should protect the access to the Cedex Bio HT Software with a new password after initial installation.

👁 For details, see Cedex Bio HT Analyzer Operator's Manual "Assigning and deleting user details".

Change 2

Warning statement added to inform about flammable refrigerant

Affected page: Operator's Manual, page 23

Cauterizing and toxic materials*Reagents and toxic chemicals*

Contact with cauterizing or toxic material may result in injury.

- Follow standard laboratory practices.
- Wear appropriate personal protective equipment.
- If cauterizing or toxic material is spilled, wipe it up immediately and apply a disinfectant.
- If cauterizing or toxic material comes into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant. Consult a physician.

Flammable materials**Revision:** New warning statement added*Flammable refrigerant*

There is a risk of fire or explosion due to the use of flammable refrigerant.

- All ventilation openings must be clear of obstructions.
- Do not use mechanical devices or other means to accelerate the defrosting process other than the ones recommended by the manufacturer.
- Do not damage the refrigerant circuit.
- Dispose of properly in accordance with federal or local regulations.

Change 3 Caution statement added to inform about sharps, rough edges, and/or moving parts

Affected page: Operator's Manual, page 25

Mechanical safety

*Personal injury and infection
due to sharps, rough edges,
and/or moving parts*

Revision: New caution statement added

Good Laboratory Practice can reduce the risk of injury. Be aware of your laboratory environment, well-prepared, and follow the instructions for use. Some areas of the instruments may have sharps, rough edges, and/or moving parts. Wear personal protective equipment to minimize the risk of injury from bodily contact with such parts, especially in less accessible areas, or while cleaning the instrument. Your personal protective equipment should be appropriate to the degree and type of potential hazard, e. g. suitable lab gloves, eye protection, lab coat, and footwear.

Change 4 Safety statement about software and data security updated

Affected pages: Operator's Manual, page 28-29

Software and data security

Revision: Safety statement about software and data security updated (several changes)*Unauthorized system access and data loss*

External storage devices can transmit computer malware, which may be used to gain unauthorized access to data or cause unwanted changes to software.

The system is not protected against malicious software and hacker attacks.

- Physical access to the product and all attached IT infrastructure (including analyzer, computer systems, cables, network equipment, etc.) must be restricted at all times.
- A Roche-provided firewall is mandatory if the system is connected to a network to protect and separate Roche systems from other laboratory infrastructure.
- The laboratory network and any laboratory infrastructure must be secured against unauthorized access, malicious software, and cyber-attacks.
- All devices and services used in the customer lab infrastructure must be safe and secured against malicious software and unauthorized access.
- A secure network environment which is resilient to traffic redirection and eavesdropping must be installed.

Roche recommends the following precautions:

- Do not copy or install any software on the system unless it is part of the system software or your Roche representative tells you to do so.
- If extra software is required, contact your Roche representative to ensure validation of the software in question.
- Do not use the USB ports to connect other storage devices unless your Roche representative or an operating instruction tells you to do so.
- Exercise care when you use external storage devices such as USB drives or DVDs. Do not connect to the system any external storage device that you use on public or home computers.
- Keep all external storage devices in a secure place, and make sure that only authorized personnel can access them.
- Back up your data regularly.

Cybersecurity and privacy awareness

- Perform regular security and privacy awareness trainings for the users to ensure that personal data is handled in a compliant way and in accordance with the privacy principles that are mandatory by customer regulations.
- Check your analyzer for suspicious activity and report any suspected compromise immediately to your local Roche representative.
- Update to latest software versions provided by Roche as soon as possible.
- Read and follow the recommendations and advices written in this chapter.

<i>Backup security</i>	The following precautions are mandatory: • Only use virus free external storage devices for backup purposes. • Transmit backup data to external storage devices via secure networks only. • Any data backup and data archive that has been exported from the analyzer must be physically securely stored and protected from any unauthorized access. • Data access to any data backup or data archive is permitted to authorized persons only. • Ensure that data backup and data archives are not taken from the safe and secure storage location.
<i>Data transfer and data entry on analyzer</i>	• Writing patient sensitive information in comment fields can violate patient health information protection laws. Do not write any patient sensitive information into comment fields, if these laws are applicable for your country. • Do not download from any host system (e.g. LIS, middleware) any patient sensitive data to the analyzer. • Data transfer using any host protocol (e.g. HL7, ASTM) is not encrypted; data is transferred as plain text and readable with IT tools like sniffers.
<i>Corrupt data due to a disclosed password</i>	The security of the system and its data depends on the password-protected access. If an unauthorized person discovers your user ID and password, they could compromise this security. • Always enter your password unobserved. • Do not write down your password anywhere, including in a contact form, in the address book, or in a file on the computer. • Do not disclose your password to anyone. Roche will never ask you for your password. • Do not use shared accounts. • If you ever disclose your password to anyone, change it immediately afterwards. • Contact your local Roche affiliate if you think your account has been compromised. • Use a personal user account for each user with appropriate user level. • Delete any unused user accounts from the analyzer (for example, when a user left).
<i>Corrupt data and unauthorized access due to faulty media converters</i>	Media converters may influence the signal quality and corrupt data. When using an RS232 to Ethernet media converter at the host interface, there is a possibility of unauthorized access to and modification of the data that are transmitted over the network. Roche shall not be held liable for possible data corruption associated with media converters.
<i>Unreliable data due to low quality connectors</i>	Using cable connections to the host that are not well shielded may lead to absence or instability of connection or to corrupt data. • Always use well shielded RS232 cables for host connection.
<i>Non-approved third-party software</i>	Installation of any third-party software that is not approved by Roche Diagnostics may result in incorrect behavior by the system. • Install only approved third-party software.

Unreliable validation due to unauthorized changes to the validation settings

The manufacturer shall not be held liable for any consequences resulting from subsequent, unauthorized modifications to the accepted validation settings included in the system at the customer's request.

- Ensure that only authorized personnel can change, if necessary, the validation settings.

Unreliable validation due to unauthorized changes to the validation and calculation rules

The manufacturer shall not be held liable for any consequences resulting from subsequent, unauthorized modifications to the accepted validation and calculation rules included in the system at the customer's request, as well as test results.

- Ensure that only authorized personnel can change, if necessary, the validation and calculation rules, and test results.

Change 5

Information added about two new safety labels on the system informing about flammable refrigerant

Affected page: Operator's Manual, page 30

**Biohazard**

Potentially biohazardous materials are used near this label.
Observe relevant good laboratory practices on safe usage.

Revision: Information about two new safety labels on the system added**Flammable**

There is a risk of fire or explosion near this label.

Flammable refrigerant in the cooling unit used.

Type of refrigerant R600a.

To be repaired only by trained service personnel. Do not puncture refrigerant tubing.

Consult Instruction Manual / Repair Manual / Owner's Guide before attempting to install or service this product. All safety precautions must be followed.

Dispose of properly in accordance with federal or local regulations.

"DANGER - Risk Of Fire Or Explosion. Flammable Refrigerant Used. To Be Repaired Only By Trained Service Personnel. Do Not Puncture Refrigerant Tubing", and, for C-UL, "DANGER - RISQUE DE FEU OU D'EXPLOSION. LE FRIGORIGÈNE EST INFLAMMABLE. CONFIER LES RÉPARATIONS À UN TECHNICIEN SPÉCIALISÉ. NE PAS PERFORER LA TUBULURE CONTENANT LE FRIGORIGÈNE"

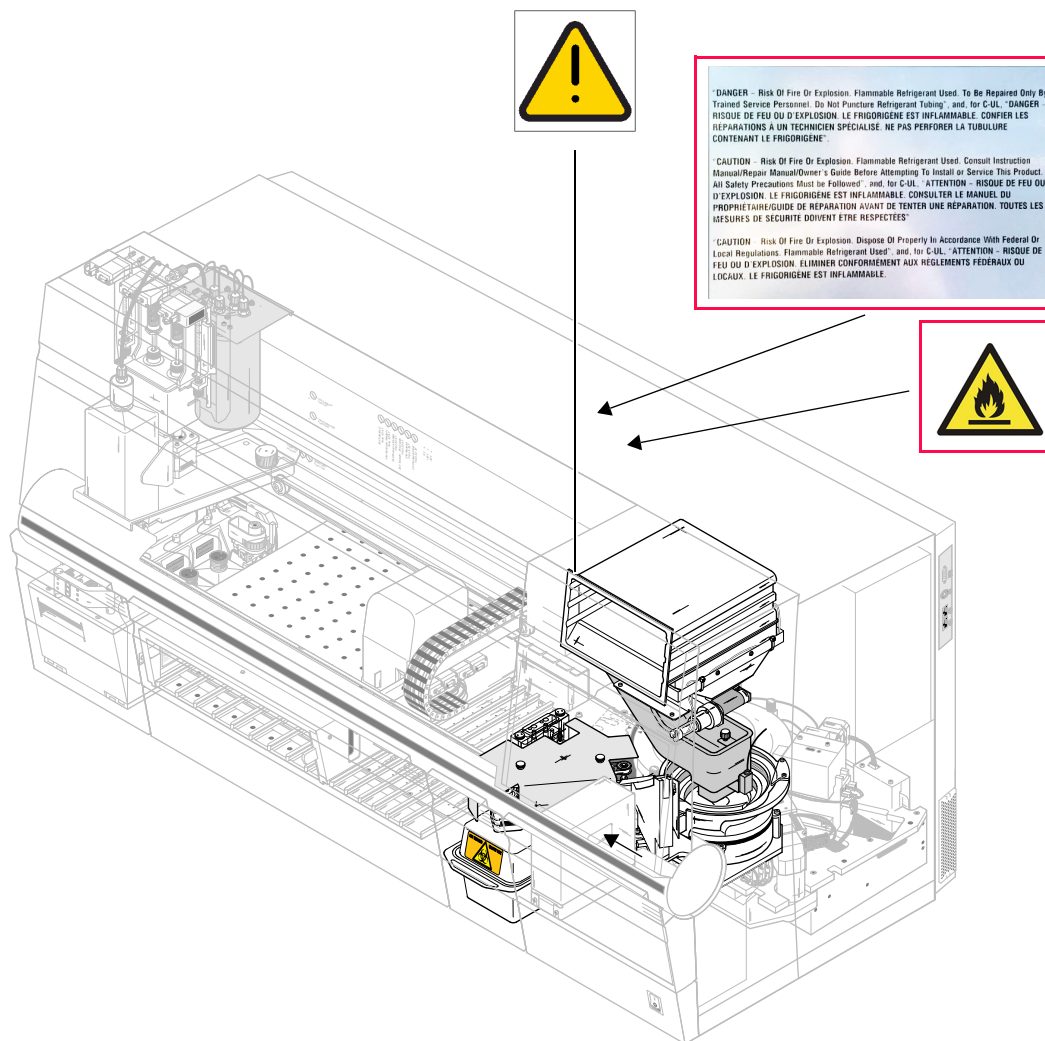
"CAUTION - Risk Of Fire Or Explosion. Flammable Refrigerant Used. Consult Instructions Manual/Repair Manual/Owner's Guide Before Attempting To Install or Service This Product. All Safety Precautions Must be Followed", and, for C-UL, "ATTENTION - RISQUE DE FEU OU D'EXPLOSION. LE FRIGORIGÈNE EST INFLAMMABLE. CONSULTER LE MANUEL DU PROPRIÉTAIRE/GUIDE DE RÉPARATION AVANT DE TENTER UNE RÉPARATION. TOUTES LES MESURES DE SÉCURITÉ DOIVENT ÊTRE RESPECTÉES"

"CAUTION - Risk Of Fire Or Explosion. Dispose Of Properly In Accordance With Federal Or Local Regulations. Flammable Refrigerant Used", and, for C-UL, "ATTENTION - RISQUE DE FEU OU D'EXPLOSION. ÉLIMINER CONFORMÉMENT AUX RÈGLEMENTS FÉDÉRAUX OU LOCAUX. LE FRIGORIGÈNE EST INFLAMMABLE."

Change 6

Label position of the two new safety labels added

Affected page: Operator's Manual, page 33

Revision: Indications of two new labels added**Figure 1**

Labels on cuvette feeder and on the back of the instrument

Change 7

The water purity must have a maximum microbiological content of 100 colony forming units per milliliter

Affected page: Operator’s Manual, page A-50

The water quality must fulfill the following requirements:

Purity	Revision: "type I NCCLS" removed Laboratory Reagent Grade, bidistilled or deionized water: >0.6MΩcm or <1.5 μS/cm <0.05 Silicate (mg/L, as SiO ₂) Revision: "10 colony forming units/mL" changed to "100 colony forming units/mL" Maximum microbiological content of 100 colony forming units/mL. Particulate matter (>0.2 μm) <500/L. Organic compound via activated carbon treatment.
Supply	From external reservoir or via direct connection to deionized water supply (optional).
Usage/Drainage	Approximately 2 L/h (0.53 US gallon/h) in operating mode
Minimum flow rate	0.2 L/min (0.053 US gallon/min)

Table A-27 Water quality requirements

Change 8

Information about water quality changed

Affected pages: several pages in the Operator's Manual

Revision: Information about water quality changed

In all relevant places in the Operator's Manual, the statement "Water must be reagent grade, type I." is replaced with "Use the water quality as specified in Table A-27 on page A-50."

Change 9Information about **Importing orders using Excel** added

Affected page: Operator's Manual, page B-59

Importing orders using Excel

Revision: New section "Importing orders using Excel" added

Use the **Import Orders from File** function to conveniently import order data using Excel files. To create an order import file, use the Excel template provided and adapt the template with the required order information.



- Use only the provided Excel template "OrderImport_ExampleTemp.xlsx" to create a new order import file.
- Ensure that you are using the correct Excel template for software version 5.1. Templates designed for software version 6.0 are not compatible with software version 5.1.

► **To prepare the order import file**

- 1 Copy the Excel template "OrderImport_ExampleTemp.xlsx" from the Cedex Bio HT Analyzer control unit to a separate computer that has Excel installed. The Excel template is located on the control unit on the C drive:
C:\Roche\Instrument\OrderImport

- 2 Open the template, add all sample and order information, and store the order import file using a meaningful name.

When using the template, carefully read the template instructions provided in the Excel file. Especially note the following:

- Do not change the column position or column number in the template.
 - Row 10 is the first row that can be used to enter data. Do not insert rows before row number 10.
 - There are mandatory and optional fields. Do not leave mandatory fields empty.
 - Use only unique sample IDs. Ensure that sample IDs entered into the template are not identical to any IDs on the order list.
 - Ensure that all selected test and profile IDs refer to tests and profiles installed on the system.
 - Order date is automatically set to the current date.
- 3 Copy the order import file to the Cedex Bio HT Analyzer control unit to:
C:\Roche\Instrument\OrderImport.

► **To load the order import file**

- 1** On the Cedex Bio HT Analyzer control unit, choose **Tools > Import Orders from File**.

A dialog box is displayed.

- 2** Load the order import Excel file that is located in C:\Roche\Instrument\OrderImport.



It is possible to store the Excel file in other locations, such as an USB drive, and load the file directly from the stored location.

The **Import Orders from File** dialog box is displayed, listing all orders from the Excel file.

- 3** Check that all orders are OK and click **Start**.

The orders are imported. Successfully imported orders are marked in green.

- 4** If rows could not be imported, a dialog box is displayed indicating which order rows not have been imported. Click **OK** to confirm the dialog box.



Software 5.1 does not provide information about why ordered rows were not accepted. Check carefully that all instructions have been followed. Ensure that the racks and rack positions chosen for the samples are empty, and that the racks are not loaded and locked on the instrument.

- 5** Create a new order import Excel file for the samples that not have been imported and repeat steps 1 to 3.

Change 10

Tip added to advise the user that the system must be in Standby state when creating a problem report

Affected page: Operator's Manual, page E-44

Creating a problem report

You can create a problem report on an external storage device. This report collates all the messages and other system information that the Roche representatives will need if you cannot solve a particular problem on your own. You should create the report (if possible) before contacting your Roche representative.

Revision: New tip added



It is essential that the problem report is only created when the system is in **Standby** state.

► **To create a problem report on an external storage device**

1 Click the **Messages** button on the navigation bar.

2 Click the **Options** tab.

3 Click **Problem Report**.

The **Create problem report** dialog box is displayed.

When the report is created, a message is displayed asking you whether you want to store the report on an external storage device.

4 On the **Create problem report** dialog box, click **Yes**.

A message is displayed asking you to insert an external storage device.

5 When you are asked to do so, insert an external storage device.

6 On the message dialog box, click **OK**.

7 On the **Save problem report** dialog box, navigate to the required folder and click **Save**.

When the report is stored on the external storage device, a message is displayed asking you to remove the external storage device.

8 When you are asked to do so, remove the storage device.

9 On the message dialog box, click **OK**.



Complementary information

- A copy of the problem report is automatically stored as a .zip file on the desktop, in the folder Problem Report. To access the desktop, press Windows + D.
 - You can also create a problem report from the message dialog box, for some types of messages.
 - Contact your Roche representative, and send the report to the address your are given.
 - If you turn off the main switch and turn on again, you may get a message prompting you to create a problem report before the system re-initializes. You can ignore this message.
-

Change 11

Tip added to advise the user that the system must be in Standby state when creating a problem report

Affected page: User Training Guide, page 41

Creating a problem report

When the system produces an error message that you cannot resolve, create a problem report. Send the report to the local Roche representative, along with a problem description, to help resolve the issue.

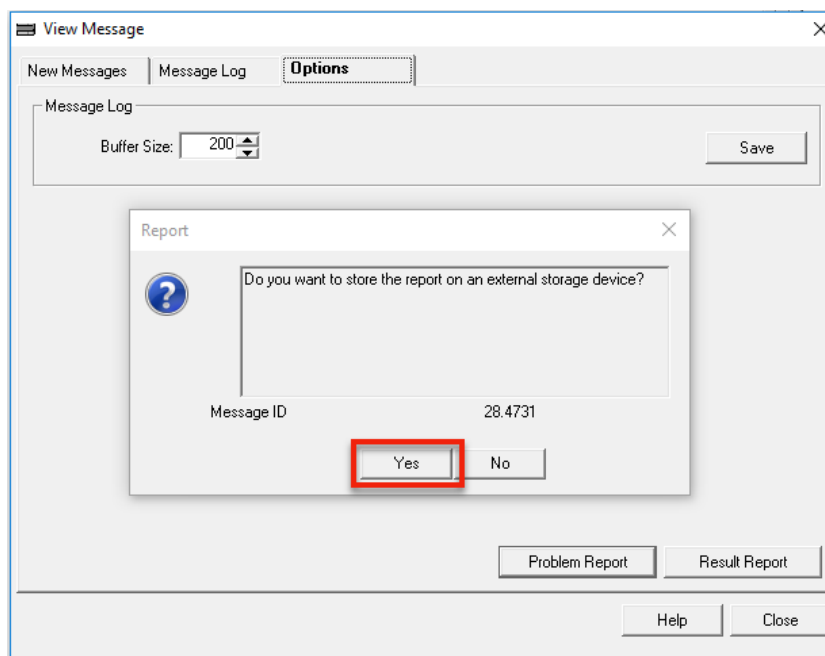
Revision: New tip added



It is essential that the problem report is only created when the system is in **Standby** state.

► **To create a problem report**

- 1 Click on Messages in the navigation bar. The **View Message** dialog box opens.
- 2 In the dialog box, select the **Options** tab.
- 3 Insert a USB stick at the USB port.
- 4 Click on the **Problem Report** button. A problem report is generated and a **Report** dialog box opens, asking whether you want to store the report on an external storage device.



5 Click on **Yes**.

The Report will automatically be saved on the external device you inserted beforehand.

6 Forward the PR.ZIP file copied to the USB stick to your local Roche representative.

Change 12

Language parameter

A system restart is required after changing the language of the software

Affected page: Operator's Manual, page G-42

Alert Sound Frequency Default: 2000 Hz**Revision:** Information added that a restart after a language change is required*Language* Default: **English**

Selected the language versions of the software from the list and restart the system to update all functionalities.

This function does not depend on the user access level.

Changes in Cedex Bio HT Analyzer Guides 1.4