

GYROLAB xPlore™ INSTRUMENT GUIDE

Original version

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1 Important user information

1.1 Gyrolab xPlore Instrument Guide

Gyrolab xPlore Instrument Guide is valid for Gyrolab xPlore with software Gyrolab Control 8.1 or higher, product no. P0014000. Gyrolab xPand and Gyrolab xP have their own Instrument Guides. Gyrolab xPlore is delivered with all the equipment and software needed for installation and running of the system.

In this document Gyrolab xPlore is referred to as Gyrolab.

NOTE: *The product model name of the instrument is Gyrolab™ xPS while the commercial name used in this guide is Gyrolab xPlore™*

1.2 Intended use

Gyrolab is a flexible instrument platform used for running Gyrolab CDs. CDs are designed for development and processing of miniaturized immunoassays for protein quantification. Products are for research use only. Not for use in diagnostic procedures.

1.3 Man-machine interface

The instrument is a bench model which is controlled by the operator by a user interface in a control software and by instrument buttons. In addition, there is loading and unloading of CDs and microplates.

1.4 Disclaimer

Do not use Gyrolab, or other products from Gyros Protein Technologies AB in any way other than described in this Instrument Guide, the Gyrolab User Guide or other documentation provided from Gyros Protein Technologies AB. The protection provided by the equipment may be reduced if other operations, outside the scope of the Gyrolab User Guide, are performed.

Gyros Protein Technologies AB will use reasonable efforts to include accurate and up-to-date information in this document, but Gyros Protein Technologies AB makes no warranties or representations of any kind as to its accuracy, currency or completeness. Gyros Protein Technologies AB disclaims all warranties, expressed or implied, including warranties of satisfactory quality or fitness for a particular purpose. Neither Gyros Protein Technologies AB nor any party involved in creating, producing or delivering this document shall be liable for any damages arising out of use of this document, or any errors or omissions in the content thereof.

1.5 Symbols

The following symbols are used throughout this Instrument Guide to draw attention to important usage and safety issues when working with Gyrolab.



WARNING: *Indicates a situation that could result in potential injury to operators of the equipment or those nearby. Situations highlighted with these precautionary symbols may also cause mechanical or electrical damage to Gyrolab.*

CAUTION: *Indicates an action or condition that could potentially damage equipment, data or materials. To disregard this caution may cause mechanical damage.*

NOTE: *Provides and highlights information for the user that will help ensure proper execution of an action or procedure.*

TIP: *Provides suggestions.*

1.6 User training

Gyros Protein Technologies AB provides user training for use of Gyrolab. Gyrolab should not be used by personnel which has not been given this training.

1.7 EU Declaration of Conformity

Gyrolab xPlore is in conformity with the EC directives and harmonized standards listed below. A copy of a signed version of EU Declaration of Conformity and Certificate of Conformance Gyrolab xPlore is shipped with the instrument.

We:

Manufacturer	Gyros Protein Technologies AB
Address	Uppsala Science Park Dag Hammarskjölds väg 54 SE-751 83 Uppsala Sweden
Telephone	+46 18 566300
Telefax	+46 18 566350
Web page	www.gyrosproteintechnologies.com

Declare under our sole responsibility that the product:

Type of equipment	Laboratory instrument for research use
Model	Gyrolab xPlore™
Article number	P0014000 rev. A4 and higher (from serial number XPS1001)

Is in conformity with applicable requirements of the:

Reference number	Title/subject
2006/42/EC	Machinery Directive

And is in conformity with applicable requirements of the:

Reference number	Title/subject
2014/30/EU	Electromagnetic Compatibility (EMC) Directive
2014/53/EU	Radio Equipment Directive (RED)

Reference number	Title/subject
2006/1907/EC	Registration, Evaluation, Authorisation and restriction of Chemicals (REACH)
2011/65/EU	Restriction of the use of certain hazardous substances (RoHS)
2012/19/EU	Waste electrical and electronic equipment (WEEE)
94/62/EC	Packaging and Packaging Waste Directive

The following harmonized standards have been applied, any amendments included:

Reference number	Title/subject
EN IEC 61326-1:2013	EMC Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use
EN ETSI 300 330-2, V2.1.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz
EN IEC 61010-1:2010	General safety requirements for electrical equipment for measurement, control and laboratory use
EN IEC 61010-2-081:2015	Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
EN IEC 60825-1:2014	Safety of laser products – Part 1: Equipment classification and requirements
EN IEC ISO 12100:2010	Safety of machinery. General principles for design. Risk assessment and risk reduction

Legal person authorized to draw up the technical file:

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 Director Instrument Development
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 Sweden
 Telephone: +46 18 566300
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1.8 FCC statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) This device must accept any interference received, including interference that may cause undesired operation.

The user is cautioned that any changes or modifications not expressly approved by Gyros Protein Technologies AB could void the user's authority to operate the equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

1.9 Regulatory requirements

Gyrolab software is designed to support compliance to 21 CFR Part 11. Gyrolab can be qualified into a GxP environment. Support in the GxP qualification process can be provided by Gyros Protein Technologies AB as an additional service.

Examples of regulatory features:

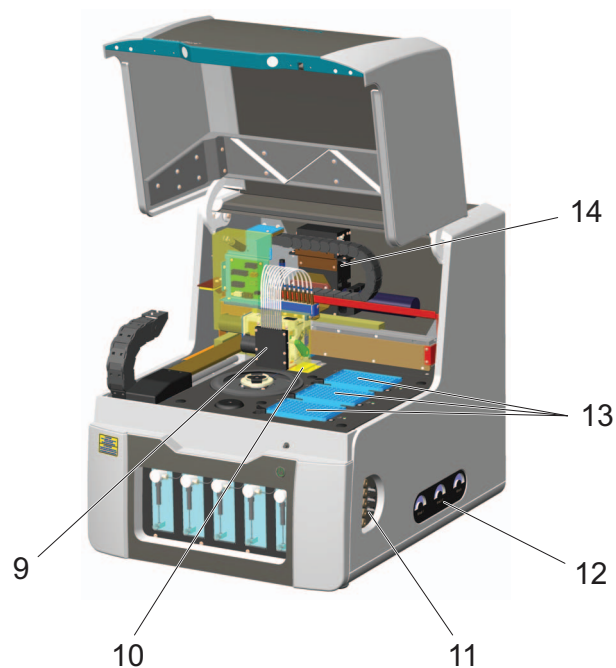
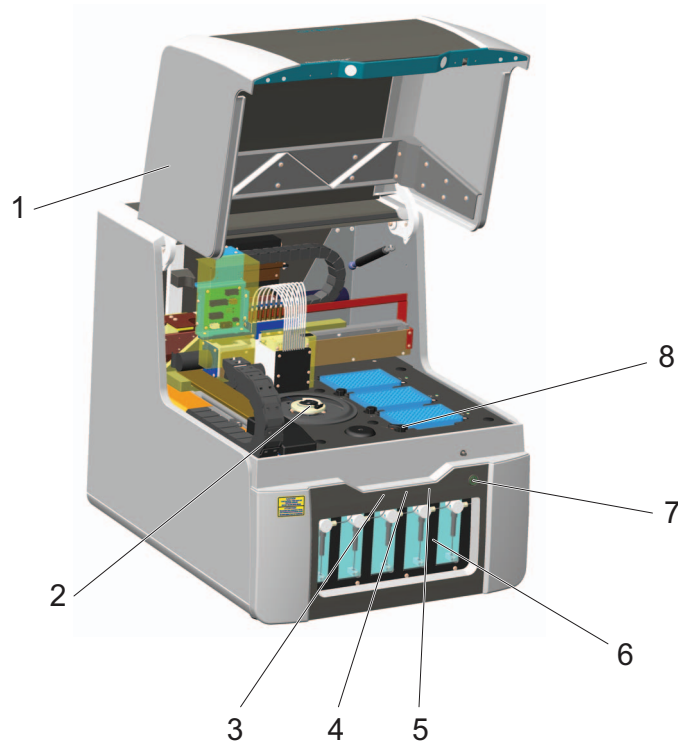
- Audit trail: all changes in the software and instrument settings are recorded.
- Accurate and complete electronic copies of records.
- Protection of records to ensure their accuracy and retrieval throughout the records' retention period.
- System access only by authorized individuals.
- Use of authority checks.
- Operational system checks enforcing correct data input and operational sequence of steps and events of experiments.

1.10 Trademarks and patents

Gyrolab and Rexxip are registered trademarks and Gyros, Gyrolab xPlore, Bioaffy and Gyros logo are trademarks of Gyros Protein Technologies Group. All other trademarks are the property of their respective owners. Products and technologies from Gyros Protein Technologies AB are covered by one or more patents and/or proprietary intellectual property rights. All infringements are prohibited and will be prosecuted. Please contact Gyros Protein Technologies AB for further details. Products are for research use only. Not for use in diagnostic procedures. © Gyros Protein Technologies AB 2024.

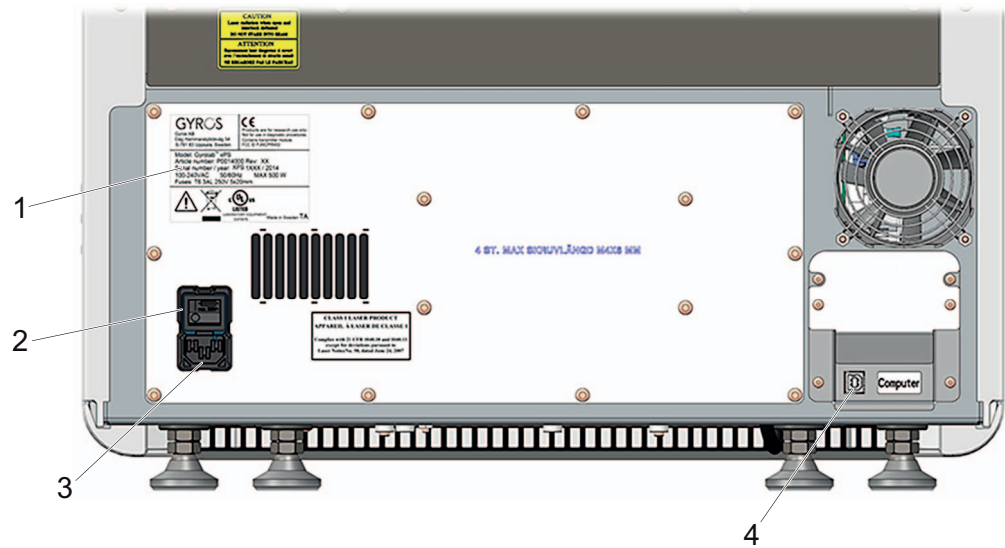
2 Gyrolab system description

2.1 Gyrolab instrument front view



No	Part
1.	Hatch
2.	CD loading position and spinning unit with protective casing
3.	Instrument Ready LED Green light indicates that the start-up sequence has finished and the instrument is ready for use.
4.	Instrument Run LED Green light indicates that the instrument is performing a Run.
5.	Instrument Alarm LED Red light indicates that the instrument is in alarm state.
6.	Syringe Pumps (for the needles)
7.	Power button
8.	Microplate locking lever
9.	Needle head
10.	Wash Stations
11.	Connecting panel for external tubing
12.	Peristaltic pumps (for Wash Stations and waste)
13.	Microplate positions (positions 1, 2 and 3)
14.	Fluorescence detector

2.2 Gyrolab instrument rear view



No	Part
1.	Instrument label
2.	Mains power switch (0 = Off, 1 = On)
3.	Mains power cable connection
4.	USB for instrument control

2.3 Gyrolab software

2.3.1 Gyrolab Manager software

- Gyrolab Manager

2.3.2 Gyrolab control software

- Gyrolab Control
- Gyrolab Administration Tool
- Gyrolab Set System Time
- Gyrolab Service Application (intended only for Gyros Protein Technologies AB service personnel)

2.3.3 Software for managing files and database

Results and Report files from one or more Run made with Gyrolab are stored in Gyrolab Result Database.

- Gyrolab Result Database Explorer
- Gyrolab Database Backup Manager

2.3.4 Analyzing software

- Gyrolab Evaluator

Gyrolab Evaluator is part of the base software package installed on all Gyrolab systems. It is designed to analyze data from Gyrolab Runs. Several evaluation functions and setting options are available to achieve optimal quantification results. For an introduction to Gyrolab Evaluator please refer to the Gyrolab User Guide.

2.3.5 LIMS integration of Gyrolab

Module for interfacing Laboratory Information Management Systems (LIMS).

2.4 Gyrolab user documentation

The following user documentation is available:

- Gyrolab xPlore Instrument Guide
- Gyrolab User Guide
- Gyrolab Quick Guide

3 Safety Information

This section describes safety precautions and the safety labels attached to Gyrolab. Built-in safety functions, emergency procedures, tools required for maintenance and disposal procedures are also described.

3.1 General precautions

Read this entire guide before using Gyrolab. Keep Gyrolab dry and clean. Do not operate Gyrolab in extreme climate (above 28 degrees Celcius, 82 degrees Fahrenheit, and 80% RH). Allow Gyrolab to reach ambient temperature to avoid condensation. Ensure that the waste container has sufficient capacity to collect all waste fluid from an entire Run.

CAUTION: Gyrolab must always be connected to an electrical supply. Any equipment connected to Gyrolab should meet the requirements of the EN 61 010-1 or similar international electrical safety standards.

CAUTION: Gyrolab is for indoor use only.

CAUTION: Gyrolab generates exhaust heat (up to maximum 1kW, on average 500W or lower depending on room temperature and if cooling of microplates is used). Make sure the room or area where Gyrolab is used is well ventilated.

CAUTION: Gyrolab must only be used according to procedures specified in this document or other Gyrolab user documentation to avoid exposure to hazardous laser radiation. There is a risk for exposure to a class 3B laser radiation source when the instrument hatch is open and interlocks are defeated. Any procedures involving removal of covers and defeating of interlocks, except procedures explicitly mentioned in this instruction, must be performed by Gyros Protein Technologies AB authorized staff only.

CAUTION: Gyrolab must be placed in a way that safeguards easy access to the instrument power plug, where it is inserted into a socket-outlet in the laboratory/building when the operator of the instrument is standing in front of the instrument.

CAUTION: If any leakage is detected from Gyrolab, immediately remove the instrument power plug and call for service.

CAUTION: Liquids with fire or explosion hazard must not be used with Gyrolab.

CAUTION: If Gyrolab is exposed to liquids that enter the instrument chassis, immediately remove the instrument power plug and call for service.

CAUTION: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

CAUTION: A small amount of aerosols are transferred from the Gyrolab system. It is commonly accepted that risks related to biosafety can be reduced but usually not completely eliminated. Users should perform risk assessments of their specific biological samples and processes considering that aerosols can be generated in a variety of laboratory procedures, such as, for example, centrifugation, homogenization, vortexing and pipetting, ultra sound treatment or by any liquid processing instruments. Samples should be handled according to corporate policies and laboratory SOPs. To minimize biosafety risks when operating Gyrolab in laboratory environments use the instrument in a laboratory environment with efficient air exchange.

3.2 Warnings

3.2.1 General



WARNING: Do not use Gyrolab, or other products from Gyros Protein Technologies AB in any way other than described in the Gyrolab User Guide or other documentation provided from Gyros Protein Technologies AB. The protection provided by the equipment may be reduced if other operations, outside the scope of the Gyrolab User Guide, are performed.



WARNING: To avoid any risk of injury, Gyrolab should be operated by trained personnel in accordance with the instructions provided.



WARNING: Always wear gloves when handling the Gyrolab CDs and when working on Gyrolab. Use of goggles and lab coat is recommended.



WARNING: Gyrolab must always be operated with the front cover in place to avoid the syringe pump pinching hazard.



WARNING: Watch out for moving parts during the loading/unloading of microplates and Gyrolab CDs.



WARNING: *There is a risk of injury from moving parts when the hatch is open.*



WARNING: *Wait for 30 seconds before opening the hatch when it is unlocked. The CD may still be spinning.*



WARNING: HEAVY OBJECT. *Gyrolab weighs approximately 80 kg. The customer is not allowed to physically relocate Gyrolab without prior written approval by Gyros Protein Technologies AB. Only authorized service personnel of Gyros Protein Technologies AB may perform such operations. Any unauthorized physical relocation of Gyrolab will void warranty of Gyros Protein Technologies AB equipment.*



WARNING: *Make sure that no objects such as liquid bottles or other lab equipment block easy access to the instrument power plug in emergency situations.*



WARNING: *Gyrolab must be connected to a grounded power outlet. Do not replace the mains power cable provided with the instrument unless it is provided by Gyros Protein Technologies AB.*



WARNING: *Gyrolab must not be used in a potentially explosive atmosphere.*



WARNING: *Gyrolab must not be installed in locations having an explosion or fire hazard.*

3.2.2 Chemical hazard and biohazard



WARNING: *Human or animal samples may contain hazardous infectious agents. Follow appropriate biosafety procedures when handling human or animal samples and equipment and containers which have been in direct contact. When running human or animal samples, the instrument shall have a "Biohazard" label. See Chapter 3.3 for more information on this label.*



WARNING: *It is the responsibility of the user to ensure that Gyrolab is free from viral and/or bacterial contamination.*



WARNING: The protective casing may be contaminated with sample material and/or reagents.



WARNING: Sodium azide (NaN_3) is very toxic. Handle with care.



WARNING: If hazardous chemicals are being used together with the instrument, forced ventilation shall be provided for the work area.

3.2.3 Maintenance



WARNING: Maintenance action not described in this manual must be performed by authorized personnel only.



WARNING: Sanitization of protective CD casing, Wash Stations, needles and Gyrolab shall be made frequently when biological samples are used.



WARNING: Turn the Gyrolab instrument off during cleaning except when operation of the instrument is required as part of the cleaning procedure.



WARNING: Gyrolab must be shut down before working with the Syringe Pumps. Shut down the instrument according to the procedure in Chapter 5.6.



3.3 Warning labels

Labels on the equipment warn the user of potentially hazardous conditions.

On the needle head:



WARNING! PINCHING HAZARD. No-one should be working near the needles when an operation is started from the Control software. Hatch should be closed during running.

WARNING! Moving parts. Read this Instrument Guide before operating Gyrolab.

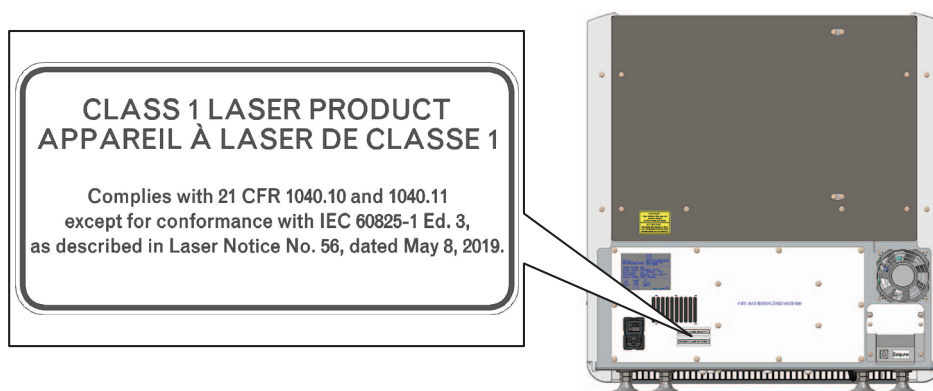
On the rear panel:



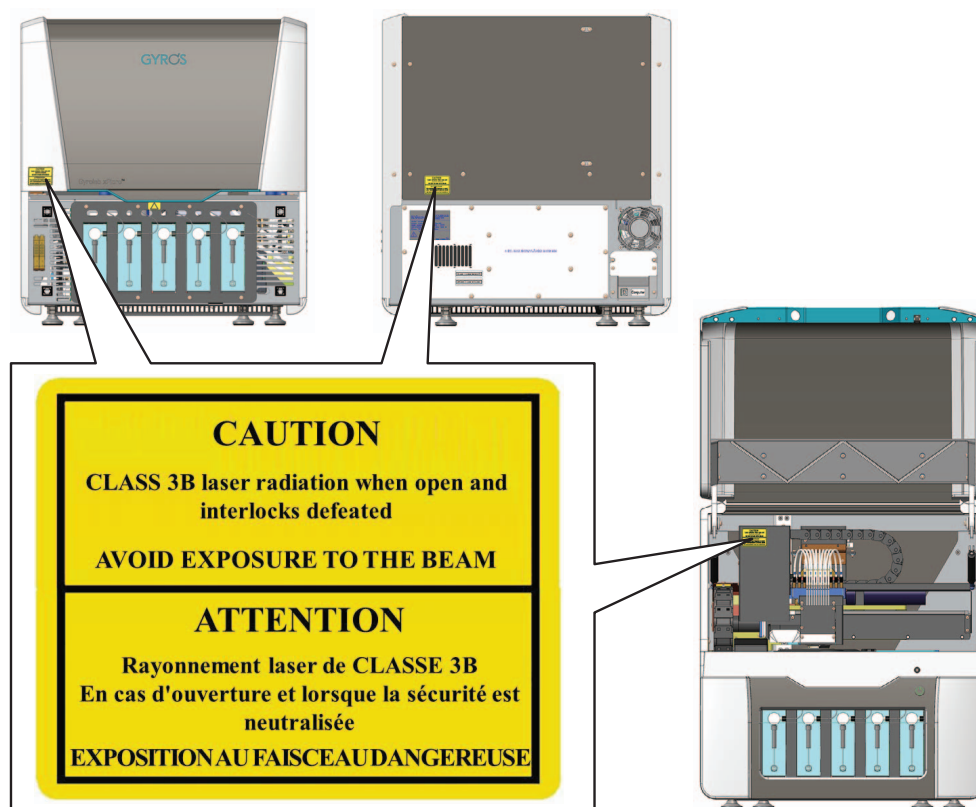
CAUTION! Read this Instrument Guide before connecting or disconnecting any cables to Gyrolab.

WARNING! NO SERVICEABLE PARTS INSIDE. Do not open. Service and maintenance should be performed by qualified personnel only.

On the instrument hatch, on the rear panel and inside the instrument:



CLASS 1 LASER PRODUCT



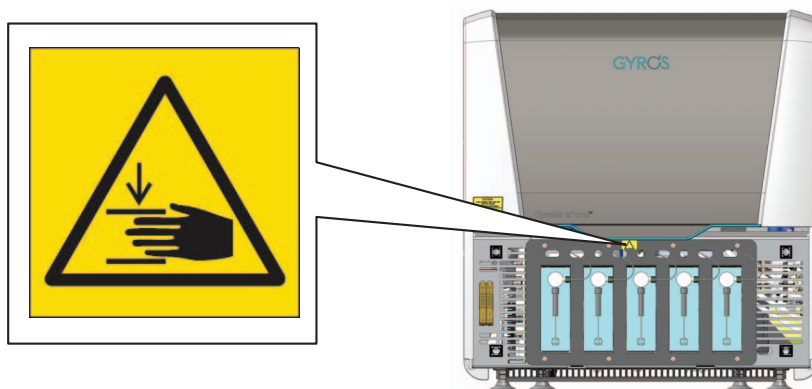
CAUTION – Class 3B laser radiation when open and interlocks defeated – AVOID EXPOSURE TO THE BEAM

On the front panel and on the waste container:

This label is placed on Gyrolab by the user when human or animal samples are run. The user is responsible for determining when there is a need for a Biohazard label on Gyrolab and if it can be removed. Biohazard labels are delivered with Gyrolab.



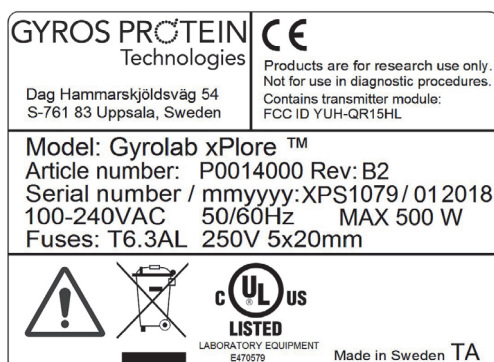
On the syringe pump mounting plate:



WARNING: PINCHING HAZARD. Gyrolab must always be operated with the plastic front cover in place to avoid the syringe pump pinching hazard.

WARNING: See Chapter 6.7 for syringe pump maintenance instructions.

3.4 Instrument label



Symbol	Description
	- CAUTION! Read the Gyrolab Instrument Guide before using the instrument. - WARNING! NO SERVICEABLE PARTS INSIDE. Do not open. Service and maintenance should be performed by qualified personnel only.

3.5 Built-in safety functions

- Gyrolab is verified to comply with EN 61 010-1 safety standard.
- Gyrolab has a built-in software-controlled interlock.
- Gyrolab has a built-in redundant electric hatch lock that prohibits the operator from opening the hatch during processing of CDs.



WARNING: *There is a risk of injury from moving parts when the hatch is open.*

- The CD spinner is equipped with a protective casing that catches micro particles or liquids that may spin off the Gyrolab CDs.

3.6 Emergency procedure

3.6.1 Emergency shutdown

In emergency situations, switch mains power off (0). The power switch is located at the rear of the instrument, see Chapter 2.2.

CAUTION: *If there is a risk of physical injury, unplug the instrument power plug.*

3.6.2 Power failure routine

In the event of power failure, any ongoing Run is interrupted in an undefined state. The results from any Run interrupted by failure of power should be discarded.

NOTE: *In case of power failure, the CD in the spinner may be damaged and should be removed. Do not re-use CDs after power failure.*

When power returns, the instrument is not re-started until the **Power** button is pressed.

3.6.3 Restart procedure

Step Action

1. Shut down Gyrolab and Gyrolab Control according to the procedure in Chapter 5.6.
2. If preparing for a Run, check that the waste container is in place and empty.
- 3.



WARNING: *Wait for 30 seconds before opening the hatch when it is unlocked. The CD may still be spinning.*

Open the hatch and remove all microplates and CDs.

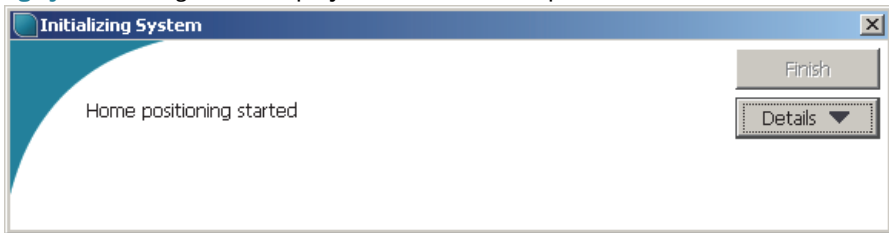
4. Turn on Gyrolab:
 - Plug the instrument power plug into the socket-outlet in the laboratory/building if it has been unplugged.
 - Switch on the mains power switch (I). The power switch is located on the Gyrolab instrument rear panel.
 - Push the **Power** button on the Gyrolab instrument front panel.
 - Check that the waste container is in place and empty.
5. Start the computer and log in.

Step Action

6. Start Gyrolab Control:
 - Click **Start:All Programs:Gyros:Server**. A Gyrolab icon appears on the right side of the task bar.
 - Click **Start:All Programs:Gyros:Client**.
 - Enter required **Username** and **Password** in the **Login** dialog box and click **OK**.

Once logged in, the main screen will appear.
7. Initialize the system:

Close Gyrolab hatch if open. Click **Initialize System** on the Main menu. The **Initializing System** dialog box is displayed as initialization proceeds.


8. The system is now ready for use.

3.7 Tools required for Gyrolab maintenance

- Torx driver for maintenance of CD protective casing, P0004277.
- Flangeless nut extender tool, 5 ml plastic syringe with adapter (part of Degasser accessories P0030272).



3.8 Recycling of instrument

This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste (RoHS and WEEE).

Send Gyrolab instrument to Gyros Protein Technologies AB for decommissioning of equipment and recycling.

For EU customers:

As part of the Gyros Protein Technologies focus on improvements and caring for the environment, our approach is to share the WEEE-related costs. Please contact your Gyros Protein Technologies Field Service Engineer to discuss the following:

- Gyros Protein Technologies will pay for the costs of treatment, recycling and recovery of the WEEE to meet the targets set by the WEEE Regulations.
- Gyros Protein Technologies will pay for the costs of reporting to the Environment Agency to demonstrate compliance with all administrative requirements of the WEEE Regulations.
- Customers pay for transportation of your equipment to Gyros Protein Technologies or appointed recycler in Sweden.

3.9 Disposal procedures

Gyrolab CDs and microplates should be disposed of in accordance with federal, state and local environmental control regulations (RoHS and WEEE). The user is responsible for waste disposal and for providing suitable waste containers. Gyrolab packaging material shall be saved for potential return transport during the warranty period and disposed through combustion for energy recovery after that.

3.10 Sample and solvent hazards

3.10.1 Unknown samples

- Personal protective equipment should be worn when operating samples and solvents.
- Toxic and contagious samples should be handled according to internal risk assessment and local regulations.



WARNING: Human or animal samples may contain hazardous infectious agents. Follow appropriate biosafety procedures when handling human or animal samples and equipment and containers which have been in direct contact. When running human or animal samples, the instrument shall have a "Biohazard" label. See Chapter 3.3 for more information on this label.

3.10.2 Solvents and reagents

Material safety data sheets for the chemicals used with Gyrolab and Gyrolab CDs should be requested from the suppliers.

4 Installation and site requirements

NOTE: Gyros Protein Technologies AB is neither responsible for any problems caused by changes in the characteristics of computer hardware or computer operating systems after delivery, nor for problems in the interaction of the Gyrolab Control with other software not supplied and/or manufactured by Gyros Protein Technologies AB.

4.1 Location and environmental conditions

Consider the following when preparing a laboratory for Gyrolab:

4.1.1 Gyrolab instrument measurements

- Size (width x height x depth): 54 cm × 58 cm × 64 cm (21 in x 23 in x 25 in)
- Weight: approximately 80 kg (176 Lbs)

4.1.2 Gyrolab work area

- The bench space required to accommodate Gyrolab, external solutions and host computer:
Bench depth: 60 cm (24 in) with open space behind, 65 cm (26 in) with wall behind
Bench length: 125 cm (50 in)
Bench loading capacity approximately: 90 kg (200 Lbs)
Overhead clearance: 100 cm (40 in)
- The operator needs 100 cm (40 in) workspace from the Gyrolab workbench.

4.1.3 Other location and environmental conditions

- Gyrolab should be kept in a clean laboratory environment.
- Place Gyrolab in a vibration free location to minimize influence from vibrations, as this may have an adverse effect on performance.
- Ambient temperature range: +20°C to +28°C (68 to 82°F). Care should be taken to avoid heat sources such as direct sunlight and hot air exhaust from any other laboratory equipment.
- Ambient humidity range: 20% to 80% relative humidity (non-condensing).
- Gyrolab will produce small amounts of liquid waste. A waste tube (2 m long) will be supplied which can be directed to a waste reservoir or a drainage facility. Waste reservoir/drainage facility should be located below the instrument, prohibiting waste liquid to flow back into the instrument.
- If hazardous chemicals are being used together with the instrument, forced ventilation shall be provided for the work area.
- To minimize biosafety risks when operating Gyrolab in laboratory environments use the instrument in a laboratory environment with efficient air exchange.

4.1.4 IP class

IP20

4.2 System power



WARNING: The instrument shall be connected to a grounded power outlet.

Gyrolab must be connected to mains power. The mains power inlet is located at the rear of Gyrolab. The instrument power plug must be connected to a socket-outlet in the laboratory building and must not be provided with a locking device.

Gyrolab must be placed in a way that ensures easy access to the instrument power plug when the operator of the instrument is standing in front of the instrument.

4.2.1 Power supply requirements

- 100 – 240 VAC, +/- 10%. US and JP standard 15 A power outlet, Europe standard 10 A outlet
- 50/60 Hz
- 500 W

4.3 Instrument noise level

<70 db (Normal operating conditions with hatch closed).

4.4 Unpacking and installation

CAUTION: Personnel from Gyros Protein Technologies AB shall handle the unpacking procedure. Gyrolab is installed and checked by a Gyros Protein Technologies AB representative on delivery.

4.5 Moving and transportation

CAUTION: The customer is not allowed to physically relocate Gyrolab without prior written approval by Gyros Protein Technologies AB. Only authorized service personnel of Gyros Protein Technologies AB may perform such operations. Any unauthorized physical relocation of Gyrolab will void warranty of Gyros Protein Technologies AB equipment.

CAUTION: Gyrolab may require re-calibration after transport, contact Gyros Protein Technologies Service for assistance.

CAUTION: Please refer to local regulations regarding lifting of heavy objects. Make sure you have the knowledge of how to lift heavy objects prior to lifting the instrument.

During transportation of Gyrolab, the following conditions can be tolerated without damaging the equipment:

- Ambient temperature range: -15°C to +60°C (5 to 140°F).
- Ambient humidity range: 10% to 90% relative humidity (non-condensing).

5 Operation

Protein quantification by miniaturized immunoassay using Gyrolab xPlore and Gyrolab CDs.

5.1 Capture and detection reagent labeling

NOTE: For detailed operating instructions and recipes, see *Gyrolab User Guide*.

The reagent to be labeled must be in a buffer free of stabilizing proteins (e.g. BSA), ammonium ions, primary amines and sodium azide in order to obtain the best possible degree of labeling. Buffer exchange can be performed using Nanosep Centrifugal Devices with suitable cut off.

5.1.1 Labeling

For protocols for Biotin labeling of the capture reagent and for fluorophore labeling of the detection reagent, see *Gyrolab User Guide*.

5.1.2 Verify labeling

For all newly labeled reagents, determine the protein concentration and perform a titration run in Gyrolab to find the optimal concentration for the fluorophore labeled reagent to use in a Gyrolab Run. For a sandwich immunoassay using a biotin labeled IgG molecule as capturing reagent the typical assay run concentration is 0.1 mg/ml.

5.1.3 Storage

Store the biotin labeled capture reagent at +4°C (at -20°C for long-term storage). Aliquot if necessary.

For fluorophore labeled reagents, dilute to 1000 nM in a buffer containing 0.2% BSA, aliquot and store at +4°C (at -20°C for long-term storage) protected from light.

5.2 Turn on Gyrolab

Before turning the instrument on, make sure that the instrument power cord is connected to mains power.

Step Action

1. Switch on the instrument mains power switch (I) on the rear panel of the instrument if it is not already in the on position.
2. Push the **Power** button on the front panel of the instrument for 1 second. The button lights up.
3. Wait with any further actions until the **Ready** LED on the instrument front panel is lit. This may take several minutes.

5.3 Start and prime Gyrolab

NOTE: For detailed operating instructions and recipes, see the Gyrolab User Guide.

Step Action

1. Start Gyrolab Control:
 - Click **Start:All Programs:Gyros:Server**. A Gyrolab icon appears on the right side of the task bar. 
 - Click **Start:All Programs:Gyros:Client**.
 - Enter required **Username** and **Password** in the **Login** dialog box and click **OK**.

Once logged in, the main screen will appear.
2. Prepare Bioaffy Pump Liquid and wash solutions. Place solutions in flasks with correct tubing.
3. Click **Initialize System** in the Gyrolab Control main menu. The system initializes.
4. Click **Prime** in the Gyrolab Control main menu and prime the instrument (Syringe Pumps and Wash Station 1) once.

NOTE: If Gyrolab has been in Standby mode for more than two weeks: Prime the Syringe Pumps three times with Standby Solution and twice with Bioaffy Pump Liquid. Prime Wash Stations with wash solutions.
5. During prime, check syringes for air bubbles. Remove air bubbles if present.

NOTE: Air bubbles may affect the transferred volumes. Refer to Chapter 6.2.3 for instructions on how to remove air bubbles.
6. Ensure that enough Bioaffy Pump Liquid and wash solutions are available for the planned Run.

5.4 Load instrument and start Run

NOTE: For detailed operating instructions and recipes, please refer to *Gyrolab User Guide*.

For details about how to set Run conditions, create loading lists, prepare samples, reagents and CDs, please refer to the User Guide or Instructions for Use.

Step Action

1.
 - Create a Run Setup in Gyrolab Manager and queue it for execution.
 - In Gyrolab Control, select **Execute Run** > **Run Setup** in the main menu.
 - Choose to execute the Run Setup.

The following screen guides the user through the process of loading microplates and CDs into the instrument and connecting liquids. A green indicator is lit for each completed step.

Run Executions:

Run Setup	Method	Cooling	Execution...
test	Bioaffy 200 3-step C-A-D 1% PMT ...	No	Run 0

CDs: 1 x Gyrolab Bioaffy 200

Microplates

Run Setup	Type	Identity	Sector	Nr. of u...	Cooling	Available
test	MP96 PCR	#1MP-1			No	Not Loaded
test	MP96 PCR	#2MP-2			No	Not Loaded

CDs

Run Setup	Type	Identity	Segments	Status
test	Gyrolab Bioaffy 200			

1 CD is needed, 0 loaded

Wash Station Solutions

Solution	Wash Station
Bioaffy wash station solution 1	1

Pump Liquids

Liquid	Pump
Bioaffy pump liquid	1, 2, 3, 4, 5

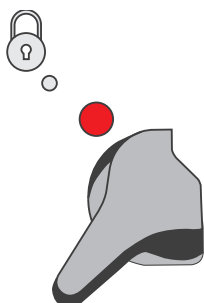
Buttons: Cancel, Start, Pause 1st 10 min

Step Action

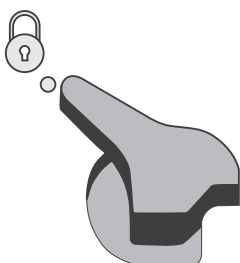
2. Load samples.
 - Open the instrument hatch if closed.
 - Centrifuge sample microplates (4000 × g for two minutes) to eliminate bubbles and ensure that samples are at the bottom of the wells.
 - Click **Load...** button in the **Samples** section of the screen. The **Microplate ID** dialog opens.
 - Enter microplate identity or read microplate bar code with bar code reader.*

NOTE: *The bar code reader is optional and not provided by Gyros or included with Gyrolab xPlore.*

- Place the sample microplate in the microplate position indicated by the lit green LED beside the microplate position in the instrument and click **Confirm**. The microplate locking lever must be opened by pulling it forward while inserting a microplate.



- Make sure that the microplate locking lever is in the locked position according to the following figure after microplate loading.

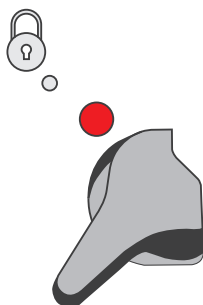


3. Repeat step 2 for additional sample microplates.
4. Confirm **Wash Station Solutions**.
 - Highlight **Wash Station Solution**.
 - Click the **Confirm** button.
5. Confirm **Pump Liquid**.
 - Highlight the **Bioaffy Pump Liquid**.
 - Click the **Confirm** button.

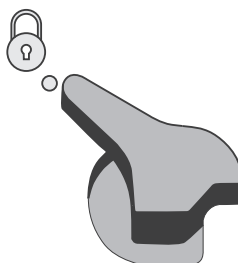
* Ensure the Bar Code Reader is configured so that **Enter** or **Carriage Return** is not added when scanning the identity of a MP

Step Action

6. Load reagents.
 - Click **Load...** button in the **Reagents** section of the screen. The **Define Reagent Microplate** dialog opens.
 - Verify correct placement of reagents (see Chapter Load instrument and start Run on page 27) and click **OK**.
 - The **Load Reagent Microplate** dialog opens.
 - Enter microplate identity or read microplate barcode with barcode reader.*
 - Place the reagent microplate in the microplate position indicated by the lit green LED beside the microplate position in the instrument and click **Confirm**. The microplate locking lever must be opened by pulling it forward while inserting a microplate.

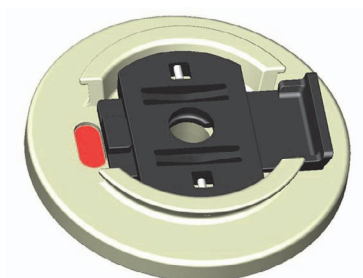


- Make sure that the microplate locking lever is in the locked position according to the following figure after microplate loading.

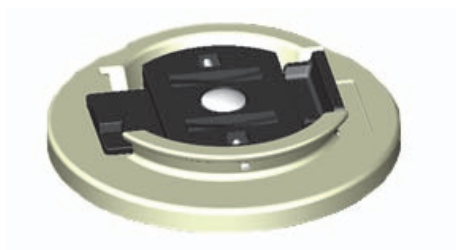


Step Action

7. Load CD.
 - Click **Load...** in the **CD Data** section of the screen. The **Load** dialog opens.
 - Place the CD on the CD position and lock the CD in place using the CD fastening device.
 - Make sure that the CD is placed with the "This side up" CD label text visible.
 - Make sure that the CD is centered on the spinner axis and that the CD fastening device is in its open position according to the following figure before it is applied.



- Apply the CD fastening device to the spinner center axis and make sure that it is pushed all the way down to the CD surface.
- Fasten the CD by pushing the black CD fastening device lever to the locked position according to the following figure. Make sure that the CD fastening device is pushed downwards while closing the lever.



CAUTION: It is vital to fasten the CD correctly. Incorrect fastening will provide inaccurate analysis results and may severely damage the instrument.

- Close the Gyrolab xPlore hatch.
 - Click the **Load** button on the computer screen.
8. When loading is complete all green "LED's" on the computer screen shall be lit.
 9. Click **Start** button to start the Run.
 - Pause an ongoing Run by clicking **Pause** button. Click **Resume** button to resume the Run.
 - Stop an ongoing Run by clicking **Abort**.

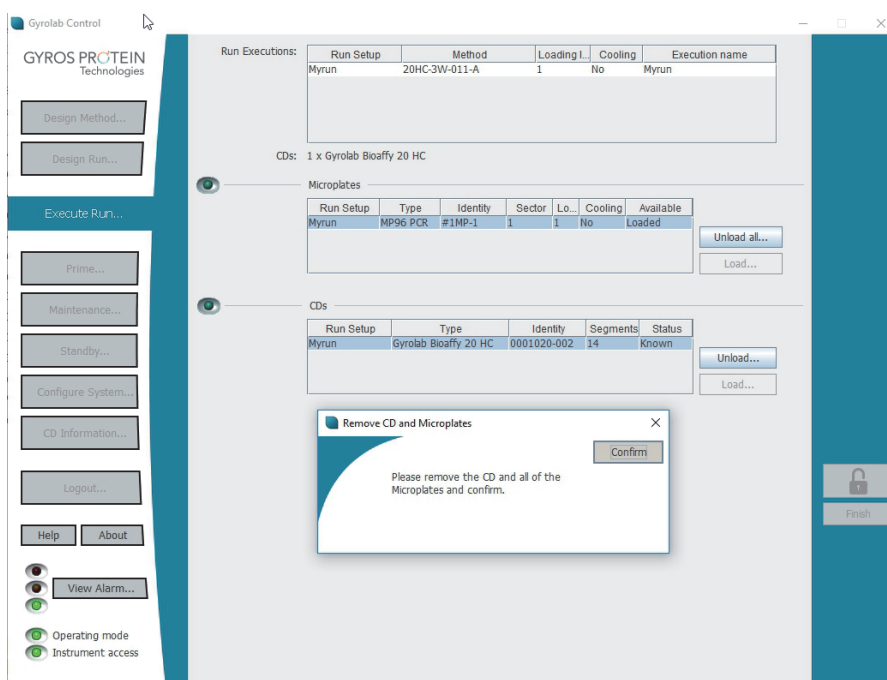
5.5 Finish Run and after Run procedures

NOTE: For detailed operating instructions and recipes, see *Gyrolab User Guide*.

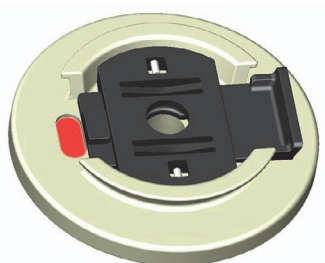
This section describes the workflow after using a Run Setup. For information on other types of runs, see the *Gyrolab User Guide*.

Step Action

1. Gyrolab stops automatically when the Run is completed. Click **Finish** button.
2. Open the Gyrolab hatch.
3. The unloading screen is shown.



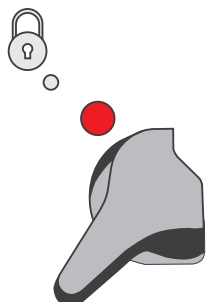
4. Remove the CDs:
 - Remove the CD by moving the CD fastening device lever to the open position according to the following figure and lift the CD by removing the CD fastening device from the CD position.



- Remove the CD from the CD fastening device by turning the CD fastening device clockwise while pulling it off from the CD.

Step Action

5. Remove all microplates. Remember to open the microplate locking lever while removing the plates from the instrument.



6. Click the **Confirm** button.
7. When unloading is complete and all green indicators are lit, click **Finish** button.
8. The **Gyrolab Control** dialog opens.
- Click **Yes** button to set the instrument in standby mode.
 - Click **No** button to start a new Run.
9. Remove the metal cooling microplate insert. Wipe microplate positions dry if cooling of microplate has been used.

5.6 Turn off Gyrolab

Before turning the instrument off for a longer period of time it is recommended to put the instrument in Standby mode, see Chapter 6.4.

The Gyrolab instrument can be turned off either by pushing the **Power** button on the instrument front panel or through the Gyrolab Server software.

5.6.1 Turn off Gyrolab by pushing the Power button

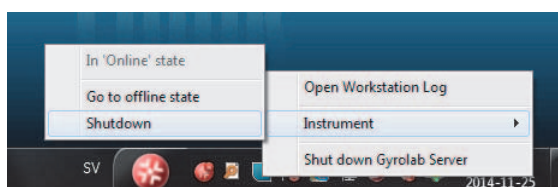
Step Action

1. Push and hold the **Power** button on the Gyrolab front panel. After 5 seconds, the three LEDs **Ready**, **Run** and **Alarm** will start blinking sequentially.
2. Release the **Power** button when the LEDs stop blinking.
3. The instrument power down sequence is completed when the light in the **Power** button on the instrument front panel has been turned off.
4. In case you need to switch off the instrument mains power for maintenance or service work on the instrument, switch off the mains power switch (0), located on the rear panel after the sequence in steps 1 to 3.

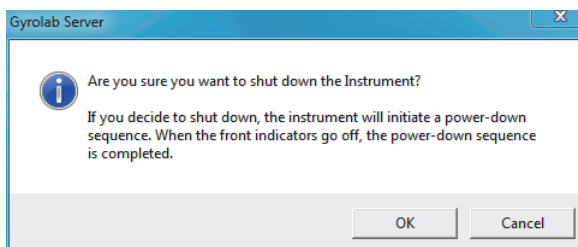
5.6.2 Turn off Gyrolab using the Gyrolab Server software

Step Action

1.  Right-click on the Gyrolab icon in the task bar in the bottom right corner of the computer screen and select **Instrument/Shutdown**.



2. A dialog will ask you to acknowledge instrument shutdown.



Click **OK**.

3. The instrument power down sequence is completed when the light in the **Power** button on the instrument front panel has been turned off.
4. In case you need to switch off the instrument mains power for maintenance or service work on the instrument, switch off the mains power switch (0), located on the rear panel after the sequence in steps 1 to 3.

6 Maintenance procedures



WARNING: Maintenance actions not described in this manual must be performed by authorized personnel only.



WARNING: Follow appropriate safety procedures when handling hazardous samples and equipment/containers which have been in direct contact with the samples. When running hazardous biological substances, the instrument must have a "Bio-hazard" label.



WARNING: Sanitization of protective CD casing, wash stations, needles and other surfaces in the instrument must be made according to internal risk assessment.



WARNING: Handle the needles with care. Use applicable personal protective equipment following local guidelines to prevent exposure to biohazards.



WARNING: The user must ensure that the instrument is free from hazardous biological or chemical agents before use. Clean and sanitize the instrument accordingly.



WARNING: The instrument must be shut down before cleaning, unless operation of the instrument is required as part of the cleaning procedure. Shut down the Gyrolab instrument according to the procedure in chapter 5.6.

CAUTION: Do not bend the needles. If a needle is bent contact Gyros Protein Technologies for assistance.

This chapter describes the regular maintenance procedures that is needed to keep the instrument in optimal condition. It includes the recommended maintenance schedule and instructions how to perform the procedures, or when to contact Gyros Protein Technologies.

For additional maintenance and support please contact your local Gyros Protein Technologies office.

6.1 Recommended maintenance schedule

Execute the maintenance tasks according to the table below to ensure optimal assay performance with the Gyrolab platform.

Perform a risk assessment to customize the maintenance schedule according to local laws and regulations, user-specific demands, and standard operating procedures.

Recommended frequency	Action	Chapter
Daily	Prime the instrument once before the first Run of the day (regular use).	6.2.1
Daily	Check Syringe Pumps for air bubbles during prime and remove air bubbles if present.	6.2.3
Daily	Put the instrument in standby for overnight storage or longer. If running over night put the workstation into standby the next day before prime.	6.4
Daily	Clean Wash Station with rinse bottle. • Daily when using both Wash Station 1 and 2 • Weekly when only using Wash Station 1	6.6.4
Weekly	Turn off/restart Gyrolab Control, the instrument and the computer.	5.6
Weekly	Clean surfaces in the instrument	6.6.3
Weekly	Prime with water to prevent salt buildup within the wash station.	6.6.4.3
Monthly	Perform a Gyrolab Functionality Check at regular intervals as confirmation of instrument functionality. For instrument in regular use Gyros Protein Technologies AB recommend that a functionality check is performed at least once a month or after every 20 CDs. Alternative frequency of Gyrolab Functionality Checking should be determined by the operator taking into account instrument usage and/or local regulations and Standard Operating Procedures. Always perform a Gyrolab Functionality Check if it is suspected that the instrument is malfunctioning.	6.5
Monthly	Clean protective casing at spinner position. Perform monthly or after 50 CDs.	6.6.2.3
Yearly	It is recommended to do a yearly Preventive Maintenance for calibration of the instrument and replacement of wear parts. Contact Gyros Protein Technologies AB for information.	1.7
Other	Change bottles for Wash Station solutions (two bottles) and Bioaffy Pump Liquid (one bottle) regularly in order to avoid accumulation of particles and bacterial growth.	6.3

Recommended frequency	Action	Chapter
Other	Sanitize Wash Station, needles, protective casing at spinner position and the instrument surfaces - Frequency based on risk assessment - Always before service	6.6.4, 6.6.2, 6.6.5, 6.6.3
Other	Perform extra priming if the instrument has not been used for two weeks or more.	6.2.2
Other	Perform extra priming with warm water if a wash station is suspected to be clogged.	6.6.4.4
Other	Always perform Needle Wash if a Run has been aborted or interrupted before completion	6.6.6
Other	Perform Needle Desorb when needle contamination is suspected.	6.6.7
Other	Inspect tubing, syringe seals and valves regularly and replace damaged components. The frequency of replacement will depend on the duty cycle, fluids used and instrument maintenance.	6.7.1, 6.7.2
Other	Change fuses when required.	6.8
Other	Always perform Sanitization of the instrument before service.	6.9
Other	The instrument may require instrument calibration after: - It has been moved - The site has been exposed to extensive vibrations (for example an earthquake) Contact Gyros Protein Technologies Service for assistance	1.7

6.2 Prime the Gyrolab instrument

In order to maintain optimal performance for the liquid handling processes in Gyrolab instruments, priming of the system should be performed regularly, according to the maintenance schedule or the risk assessment. When the instrument is primed the complete liquid volumes in the tubings are replaced with the solutions in the attached bottles.

The following components can be primed, either by themselves or all at once.

- Syringe Pumps, (5 pumps connected to 10 needles)
- Wash station 1
- Wash station 2

Wash station 1 and 2 are separate and can be connected to different solutions and primed separately.

Required tools/solutions

- Stand by Solution
- Bioaffy Pump Liquid
- Wash Station Solutions

NOTE: For recipes, refer to *Gyrolab User Guide*.

6.2.1 Priming

Gyrolab instrument priming requires 15–20 minutes.

Step Action

1. Click **Prime** on the main menu.

The screenshot displays the 'Syringe Pumps' and 'Wash Stations' configuration panels. The 'Syringe Pumps' panel has a table with columns: Syringe Pump, Connected Liquid, Number of Aligned Needles, Usage Type, and Select Syringe Pump. Below the table are fields for Standby Liquid, Prime Factor, and a Connect Liquid button. The 'Wash Stations' panel has a similar table with columns: Wash Station, Connected Solution, and Select Wash Station. Below it are fields for Standby Solution, Prime Factor, and a Connect Solution button. At the bottom are 'Select All' and 'Deselect All' buttons.

Syringe Pump	Connected Liquid	Number of Aligned Needles	Usage Type	Select Syringe Pump
Pump 1	Bioaffy pump liquid	2	Sample Transfer	☐
Pump 2	<None>	2	Sample Transfer	☐
Pump 3	<None>	2	Sample Transfer	☐
Pump 4	<None>	2	Sample Transfer	☐
Pump 5	<None>	2	Reagent Transfer	☐

Standby Liquid: Connect Liquid...

Prime Factor: %

Wash Station	Connected Solution	Select Wash Station
Wash Station 1	<None>	☐
Wash Station 2	<None>	☐

Standby Solution: Connect Solution...

Prime Factor: %

Select All Deselect All

2. If the pumps are to be primed:
Make sure that **Bioaffy Pump Liquid** is chosen as **Connected Liquid**:
 - Check the **Select Syringe Pump** boxes for **Pump 1–5** and click **Connect Liquid**.
 - Select **Bioaffy Pump Liquid** and click **Set**.

TIP: The Prime Factor is set to 100%, by default. This value can be raised if required.
3. If Wash station 1 is to be primed:
Make sure that **Bioaffy Wash Station Solution 1** is chosen as **Connected Solution** for **Wash Station 1**:
 - Check the **Select Wash Station** box for **Wash Station 1** and click **Connect Solution**
 - Select **Bioaffy Wash Station Solution 1** and click **Set**.

TIP: The Prime Factor is set to 100%, by default. This value can be raised if required.

Step Action

4. If Wash station 2 is to be primed:
Make sure that **Bioaffy Wash Station Solution 2** is chosen as **Connected Solution** for **Wash Station 2**:
 - Check the Select Wash Station box for **Wash Station 2** and click **Connect Solution**
 - Select **Bioaffy Wash Station Solution 2** and click **Set**.
 Keep the tubing for Wash Station 2 in the Standby Solution bottle if it is not to be used.
5. Check the boxes for the components to be primed. Check **Select Syringe Pump** boxes for **Pump 1–5** and the **Select Wash Station** box for Wash station 1 and Wash station 2. The Prime view should look like:

Syringe pumps

Syringe Pump	Connected Liquid	Number of Aligned Needles	Usage Type	Select Syringe Pump
Pump 1	Bioaffy pump liquid	2	Sample transfer	☒
Pump 2	Bioaffy pump liquid	2	Sample transfer	☒
Pump 3	Bioaffy pump liquid	2	Sample transfer	☒
Pump 4	Bioaffy pump liquid	2	Sample transfer	☒
Pump 5	Bioaffy pump liquid	2	Reagent transfer	☒

Standby liquid: Connect liquid...

Prime factor: %

Wash stations

Wash Station	Connected Solution	Select Wash Station
Wash Station 1	Bioaffy wash station solution 1	☒
Wash Station 2	Standby solution	☐

Standby solution: Connect solution...

Prime factor: %

Select All Deselect All

6. Make sure that enough Syringe Pump liquid and **Wash station solutions** are available. Refer to chapter 6.3 for instructions on how to change solutions.

NOTE: *The required Wash solutions volumes varies depending on assay. Please refer to Gyrolab Kit Instructions For Use for recommended volumes.*
7. Check that the waste container is in place and that there is sufficient capacity for waste from a Priming.
8. Click **Prime**.
A warning message asking if there are sufficient liquids available for priming is displayed.

Step Action

9. Click **OK** to continue priming.
The Prime dialog describing the progress of the priming is displayed.
10. Check the syringes for air bubbles.
Refer to chapter 6.2.3 for instruction of how to remove air bubbles.
11. Click **Finish** when the priming is complete. Click **Close** to exit.

6.2.2 Extra priming

Extra priming should be performed if Gyrolab has been in standby mode for more than two weeks.

Extra priming should also be performed if the solution bottles have become empty and the system has run dry.

The complete liquid system, syringe pumps, wash station 1 and 2 are primed.

Step Action

1. Prime the Gyrolab instrument three times with Standby Solution in the Wash Station bottles and Pump liquid bottle.
2. Prime the Gyrolab instrument twice with Bioaffy Pump Liquid in the Pump liquid bottles and Wash Station Solution bottle.
3. Check syringes for air bubbles:
 - If there are no air bubbles the extra priming is completed.
 - If there are air bubbles present, continue with steps 4 and 5.
4. Remove air bubbles if present, refer to Chapter 6.2.3.
5. Prime the Gyrolab instrument twice with Bioaffy Pump Liquid in the Pump liquid bottles and Wash Station Solution bottle.

6.2.3 Remove air bubbles from Syringe Pumps

CAUTION: Prime the pumps with 20% ethanol or deionized water before removing the syringes to avoid rust damage.



WARNING: The Gyrolab instrument must be shut down before handling the Syringe Pumps. Shut down the Gyrolab instrument according to the procedure in Chapter 5.6

Air bubbles may affect the transferred volumes. For optimal liquid transfer performance no air bubbles should be present in the syringe pumps. If bubbles remain in the syringe pumps after repeated cycles of priming the syringes needs to be removed and manually cleaned, or they are damaged and needs to be replaced.

Required tools/solutions

- Ethanol 96%
- Deionized water

Step Action

1. Remove the Gyrolab xPlore front cover.
 - Open the hatch.
 - Pull the front cover gently towards the operator.

NOTE: *The front cover is connected to the instrument by a cable. Be careful not to pull the cable taut when the front cover is removed*

 - Press the unlocking lever on the cable connector and gently pull it out of the connector on the circuit board. This disconnects the cable connector from the circuit board on the inside of the front cover
2. Remove the syringe, refer to Chapter 6.7.1 for instructions.
3. Clean the syringe in ethanol (96%) by manually moving the piston up and down 5–10 times.
4. Rinse the syringe with deionized water by moving the piston up and down 5–10 times.
5. Fill the syringe with deionized water. Examine the syringe to ensure that no air bubbles are present inside the syringe chamber.
6. Install the syringe, refer to Chapter 6.7.1 for instructions.
7. Install the Gyrolab xPlore front cover.
 - Gently push the front cover cable connector to the connector on the circuit board on the in-side of the front cover.
 - Make sure that the instrument hatch is open.
 - Make sure that the cable to the front over is kept to the right of the syringe pumps.
 - Make sure that the drainage tubing is fed into the opening on the right of the black bottom bars behind the front cover
 - Push the front cover straight from the front into the four latches on the instrument chassis. This mounts the front cover. Continue to make sure that the cable and drainage tubing is in the correct position.
8. Switch on the instrument power. Turn on the Gyrolab instrument (Chapter 5.2).
9. Initialize system from Gyrolab Control.
10. Prime the system twice using **Prime** on the main menu (Chapter 6.2). Check for air bubbles during priming. If necessary, repeat priming several times.

TIP: *If cleaning with ethanol and priming have been repeated several times and there are still bubbles present, the syringe may be damaged. Refer to Chapter 6.7.1 for replacement instructions.*

6.3 Wash station and syringe pump liquids

CAUTION: *Make sure that the tubings reach the bottom of the bottles.*

There must be sufficient amounts of Wash Station solutions and Bioaffy Pump Liquid in the bottles for the Gyrolab instrument to ensure optimal performance.

The used bottles should be changed to clean bottles according to the maintenance schedule in order to avoid accumulation of contaminating particles and reduce risk for bacterial growth.

Required tools/solutions

- Bioaffy Pump Liquid, freshly made
- Wash Station Solutions, freshly made
- Clean bottles (DURAN®, borosilicate glass)
- Filtration equipment with 0.22 µm or 0.45 µm filter

NOTE: *For recipes, refer to Gyrolab User Guide.*

NOTE: *For information on the bottles, refer to Gyrolab User Guide.*

6.3.1 Refill wash station and syringe pump liquids

If the levels of Wash Station solution or Bioaffy Pump Liquid run low between the bottle changes, refill the bottles. Filter the solution through a 0.22 µm or 0.45 µm filter.

6.3.2 Change bottles for Wash Station Solution and Bioaffy Pump Liquid

Change the bottles for the Wash Stations and Syringes once a week.

Step Action

1. Remove the old bottles and replace them with clean bottles.
2. Filter the solution through a 0.22 µm or 0.45 µm filter and fill the bottles with solutions.
 - Wash Station Solutions in the wash station bottles
 - Bioaffy Pump Liquid in the syringe pump bottle
3. Make sure that the tubings reaches the bottom of the bottles.
4. Check the syringe pumps for air bubbles. Refer to Chapter 6.2.3 for instruction of how to remove air bubbles.

6.4 Standby mode

After the instrument is placed in standby mode the complete liquid handling system including Wash station and Syringe Pump is filled with Standby Solution.

Required tools/Solutions

- Stand by Solution

NOTE: For recipes, refer to *Gyrolab User Guide*.

Step Action

1. Prepare Standby Solution for Wash Stations and Syringe Pumps.
2. Ensure that enough Standby Solution is available for all Syringe Pumps and both Wash Stations.
3. Click **Standby** in the Gyrolab Control main menu to set the instrument in standby mode.

6.5 Gyrolab Functionality Check

Gyrolab Functionality Check should be performed regularly to verify instrument functionality. The Gyrolab Functionality Check requires a kit available from Gyros Protein Technologies AB.

For kit description and a guide for how to handle the results of the Gyrolab Functionality Check, refer to the Instruction For Use supplied with the kit.

NOTE:

Gyrolab Functionality Check takes approximately 20 minutes to complete.

Required tools/Solutions

- Bioaffy Wash Station Solution 1
- Bioaffy Pump Liquid
- Stand by Solution
- Gyrolab Functionality Check Kit (Product Number P0005002)

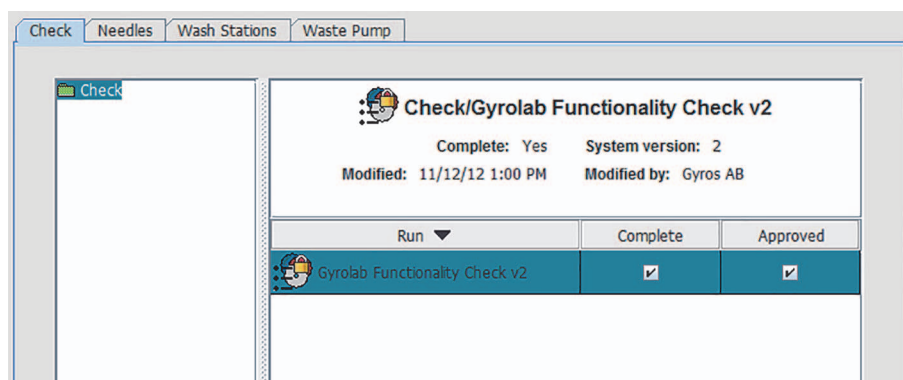
NOTE: For recipes, refer to *Gyrolab User Guide*.

Step Action

1. Fill Wash Station Solution bottle and Pump liquid bottle with Bioaffy Wash Station Solution 1 and Bioaffy Pump Liquid respectively.
2. Click **Maintenance** on the main menu. Select **Check** tab.

Step Action

3. Select **Gyrolab Functionality Check v2**, and click **OK**.



4. A start screen opens.

- Set desired **Detector response** range (refer to Gyrolab Functionality Check CD case).

In the **Report folder** and **Report file name** fields, location and name for report file copy are set. Report file is also saved in Gyrolab Result Database.

- To set default settings for **Report folder**:
 - Click **Use default settings** to put report file in C:\ProgramData\Gyros\Gyrolab\Results\Check
- To customize settings for **Report folder** and **Report file name**:
 - To edit **Report folder**, click **Browse**. Browse and click **Select** to set new folder in the **Select folder** dialog.
 - **Report file name** is not editable.
- Click **OK**.

Step Action

5. A loading screen opens.

CD type: Gyrolab Functionality Check CD

Execution name:

MP cooling: ☐ Enable cooling for sample and reagent MPs

CD data

Identity	Segments	CD Status

1 CD is needed, 0 loaded.

Start Structure...

Load... Unload...

Wash Station Solutions

Solution	Wash Station
Bioaffy wash station solution 1	1

Confirm Connect...

Pump Liquids

Liquid	Pump
Bioaffy pump liquid	1, 2, 3, 4, 5

Confirm Connect...

Reagents

Name	Identity	Available
MP96 PCR		Not Loaded

Load... Unload...

6. In the **CD data** panel:

- Click the **Load** button.
- Insert the CD from the Gyrolab Functionality Check Kit.
- Click the **Load** button in the **Load** dialog.
- Click the **Close** button in the **Load** dialog.

7. In the **Wash Station Solutions** panel, click the **Confirm** button to confirm that Bioaffy Wash Station Solution 1 is prepared and available in the Wash Station bottle.

8. In the **Pump Liquids** panel, click the **Confirm** button to confirm that Bioaffy pump liquid is prepared and available in the Pump Liquid bottle.

9. In the **Reagents** panel, click the **Load** button.

10. The **Define Reagent Microplate** dialog opens.

Define Reagent Microplate

1. Select microplate type.

MP96 PCR

2. Load reagents as defined by the selected MP type.

Reagent	Well
A1 Reagent solution 10 ul	A:1
A2 Reagent solution 10 ul	A:2
A3 Reagent solution 10 ul	A:3
A4 Reagent solution 10 ul	A:4
A5 Reagent solution 10 ul	A:5
A6 Reagent solution 10 ul	A:6
A7 Reagent solution 10 ul	A:7
A8 Reagent solution 10 ul	A:8
A9 Reagent solution 10 ul	A:9
A10 Reagent solution 10 ul	A:10
B1 Reagent solution 50 ul	B:1
B2 Reagent solution 50 ul	B:2
B3 Reagent solution 50 ul	B:3
B4 Reagent solution 50 ul	B:4
B5 Reagent solution 50 ul	B:5
B6 Reagent solution 50 ul	B:6
B7 Reagent solution 50 ul	B:7
B8 Reagent solution 50 ul	B:8

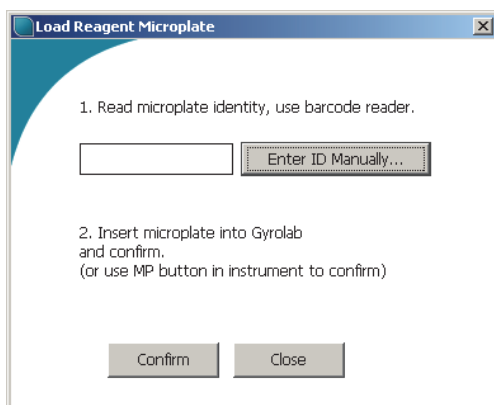
	1	2	3	4	5	6	7	8	9	10	11	12	
A													A
B													B
C													C
D													D
E													E
F													F
G													G
H													H

Select Deselect

OK Cancel

Step Action

11. Prepare the reagent microplate according to the **Define Reagent Microplate** dialog. Solutions are provided in the Gyrolab Functionality Check Kit.
12. Click **OK** in the **Define Reagent Microplate** dialog.
13. In the **Load Reagent Microplate** dialog:



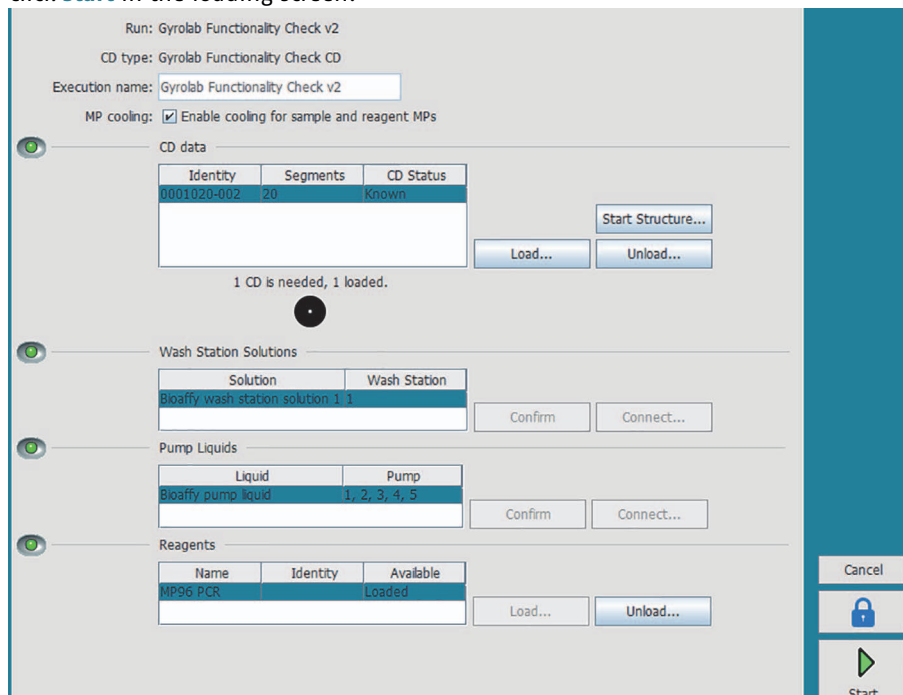
- Read microplate barcode with barcode reader, or click on **Enter ID Manually**, enter ID and click **OK**.*

NOTE: *The bar code reader is optional, and is not provided by Gyros Protein Technologies AB or included with Gyrolab.*

- Insert reagent microplate in the loading position.
- Click **Confirm** button.

The microplate ID will appear in the list on screen.

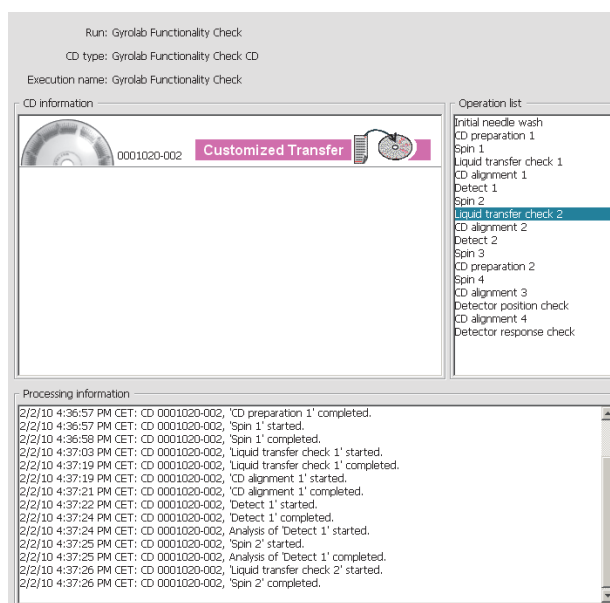
14. Click **Start** in the loading screen:



* Ensure the Bar Code Reader is configured so that **Enter** or **Carriage Return** is not added when scanning the identity of a MP.

Step Action

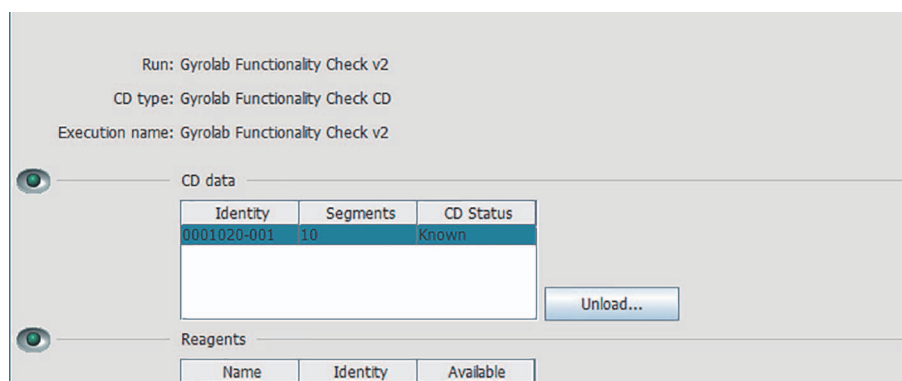
15. The Gyrolab Functionality Check Run starts. It is possible to view the progress.



It is not recommended to click **Pause** or **Abort** as it may cause incorrect check results.

16. When the Run is completed, click **Finish**.

17. The unload panel opens.



18. In the **CD data** panel:

- Click the **Unload** button.
- Remove the CD from the Gyrolab instrument.
- Click the **Confirm** button in the **Unload CD** dialog.

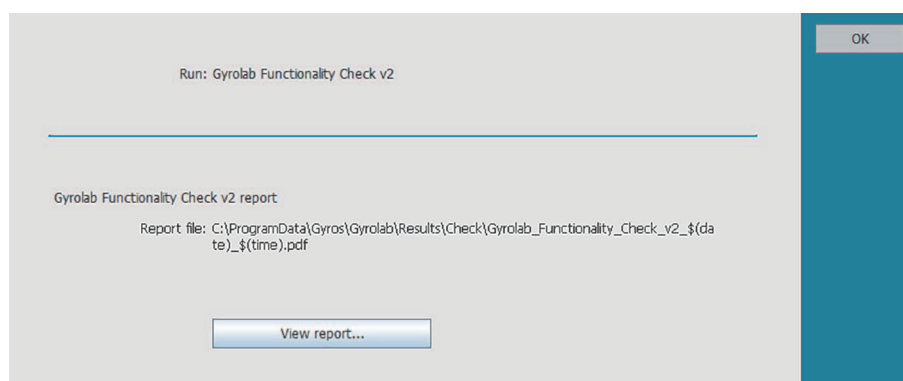
19. In the **Reagents** panel:

- Click the **Unload** button.
- Remove the microplate from the Gyrolab instrument.
- Click the **Confirm** button in the **Unload Microplate** dialog.

20. Click **Finish**.

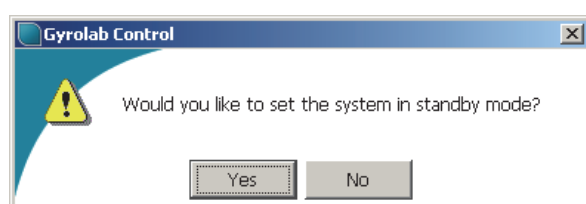
Step Action

21. The report screen opens.



- Click **View report** to open a pdf-copy of the Gyrolab Functionality Check report.
- Click **OK** to finish the Gyrolab Functionality Check Run.
- The report is also saved in the database and on disk for later reference.

22. The **Standby** dialog opens.



- If another Run is to be made during the day, click **No**.
- If it is the last Run of the day, click **Yes**.
The **Ensure enough standby solution is available** dialog opens. Check that appropriate solutions are available and click **OK**. Priming and Standby procedures will start.

6.6 Cleaning and sanitization

WARNING: Some ingredients used in solutions for cleaning and sanitization are considered environmentally hazardous waste and must be taken care of in conformity with national and local regulations.

CAUTION: Do not attempt to clean the optics. If there is reason to believe that the optics have been contaminated, contact Gyros Protein Technologies for assistance.

CAUTION: Do not disassemble anything in addition to what is described in this manual when cleaning the system. Do not use force.

CAUTION: Other solutions for cleaning and sanitization than those used in this chapter may have unintended effects. Contact Gyros Protein Technologies for assistance.

Cleaning and sanitization of the Gyrolab instrument exterior and interior surfaces including the liquid handling system is part of the maintenance routines.

- Cleaning removes the dust and wear of daily use. The cleaning processes removes contaminants, including proteins, from the liquid handling system.
- Sanitization inactivates contaminants and sanitizes the components when bio-hazardous components have been present.

Adapt the frequency of cleaning and sanitization according to the risk assessment and to local laws and regulations, user-specific demands, and standard operating procedures.

The solutions used in this chapter cover almost all sanitization needs.

NOTE: Chose appropriate disinfectant according to risk assessment. If suggested sanitization processes and solutions is not sufficient contact Gyros Protein Technologies for advice and for material compatibility.

6.6.1 Sanitization order

It is possible to sanitize the components separately according to the Maintenance schedule or when it is needed, or to sanitize the entire instrument at once. When the entire instrument is to be sanitized it is important to clean and sanitize the instrument in the correct order.

Sanitize the surfaces before cleaning them in order not to spread contaminants to other surfaces during the cleaning process.

Perform needle wash and needle desorb if it is necessary.

Action	Chapter
First remove, sanitize and clean the protective CD casing.	6.6.2
Then sanitize and clean the surfaces of the instrument.	6.6.3
Then sanitize and clean the liquid handling modules, including the wash station and sample transfer needles.	6.6.4, 6.6.5

6.6.2 Clean and sanitize the protective CD casing



WARNING: The protective casing may be contaminated with sample material and/or reagents. Handle according to reliable procedure for sanitization.

In the CD position the CD is surrounded by a protective casing to recover any liquids or micro particles that may leave the CD as it spins. The protective casing has been designed to avoid any liquid splashing on other parts of the Gyrolab instrument.

Required tools/solutions

- Torx driver T20, refer to chapter 3.7
- Appropriate disinfectant: 1% Virkon, 70% Ethanol or Contec ProChlor/ProKlean
- Soft brush
- Cleaning solution: Water with neutral detergent
- Water

NOTE: For recipes, refer to Gyrolab User Guide.

NOTE: Do not use a brush with a metal handle. It might scratch the inner edge of the casing, (3) in Figure 1.

6.6.2.1 Disassemble the protective CD casing

Step Action

1. Loosen the two screws, (1) in Figure 1, that hold the casing in place. The screws do not need to be removed.
NOTE: Ensure there is no CD in the spinning position before removing the protective casing. The protective casing is a single unit and should not be taken apart.
2. Turn the casing clockwise to the position where it can be lifted off (approximately 0.5 cm).
3. Pull out the casing. Be very careful not to touch the sensor head, (2) in Figure 1. If the sensors are damaged this may interfere with the system's ability to find the home position on the CD.

If sanitization is not required go to 6.6.2.3.

6.6.2.2 Sanitize the protective CD casing

Step Action

1. Place the protective CD casing in the disinfectant for 10 minutes.
2. Rinse the protective CD-casing in water.

6.6.2.3 Clean the protective CD casing

Step Action

1. Clean the casing manually with the soft brush, water with neutral detergent.
The upper inner surface is the most critical to keep clean.
2. Rinse the protective CD-casing in water.

6.6.2.4 Assemble the protective CD casing

Step Action

1. Dry the casing completely before putting it back in the Gyrolab instrument.
2. Put the casing back in place. Be very careful not to touch the sensor head, (2) in Figure 1.
3. Turn the casing counter-clockwise as far as possible.
NOTE: *Ensure that the protective casing is in its end position.*
4. Tighten the two screws, (1) in Figure 1, that hold the casing in place.

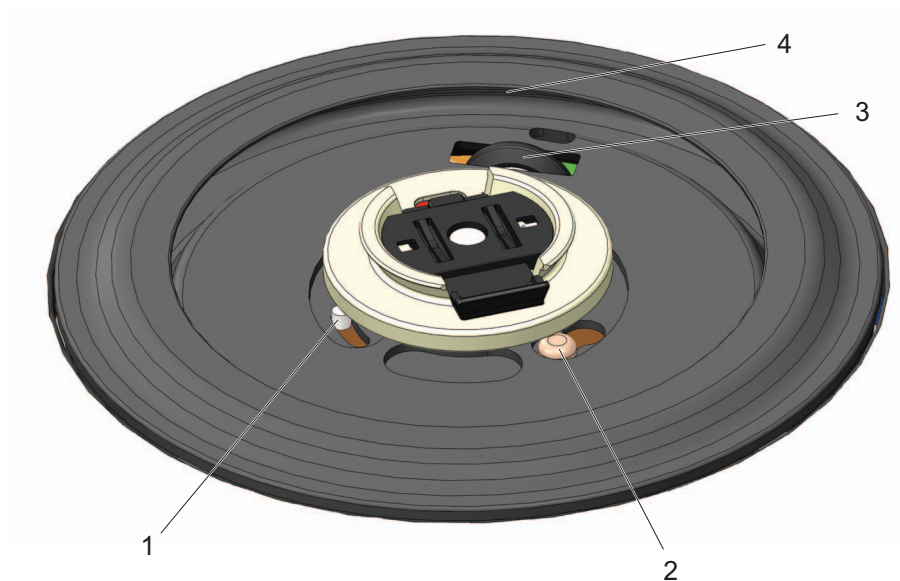


Figure 1: Protective casing for collecting waste.

6.6.3 Clean and sanitize surfaces in the Gyrolab instrument

The inside and the outside surfaces on the Gyrolab system needs to be cleaned and sanitized regularly according to the maintenance schedule or the risk assessment.

Required tools/solutions

- Appropriate disinfectant: 70% Ethanol or Contec ProChlor/ProKlean
- Lint-free tissues
- Water

NOTE: For recipes, refer to *Gyrolab User Guide*.

6.6.3.1 Sanitize the surfaces

Step Action

1. Wipe the inside and outside surfaces of the Gyrolab instrument with a lint free tissue soaked in disinfectant.
2. Wipe the LIF spinner unit with a fresh lint-free tissue soaked with 70% ethanol.
3. If Contec ProChlor/ProKlean was used, wipe off residues with water.
4. Dispose of the sanitization waste according to local regulations for biohazardous waste disposal.

6.6.3.2 Clean the surfaces

Step Action

1. Wipe the inside and outside surfaces of the Gyrolab instrument with a lint free tissue soaked in water.
2. Wipe the LIF spinner unit with a fresh lint-free tissue soaked in water
3. Dispose of the cleaning waste according to local regulations for biohazardous waste disposal.

6.6.4 Clean and sanitize the Wash Station

The Wash stations needs to be cleaned and sanitized to maintain optimal performance.

It is important to clean the wash stations to maintain the wash efficiency. Salt crystals from the wash buffer need to be removed regularly according to maintenance schedule.

Sanitize according to the risk assessment when hazardous components including bacterial and viral contamination is present.

6.6.4.1 Sanitize the wash stations

Required tools/solutions

- Wash Station Sanitize Solution
- Bioaffy Wash Station Solution 1
- Deionized water
- Lint-free tissue
- Appropriate disinfectant: 70% Ethanol or Contec ProChlor/ProKlean

NOTE: For recipes, refer to *Gyrolab User Guide*.

Step Action

1. Place the tubing from both Wash Station pumps into a bottle containing 1000 ml of **Wash Station Sanitize Solution 1**.
2. Prime Wash Stations 1 and 2, twice. Refer to Chapter 6.2.1
3. Rinse the outer tubing from both Wash Station pumps with water and then place the tubing into a bottle containing 1000 ml of **Bioaffy Wash Station Solution 1**.
4. Prime Wash Stations 1 and 2, twice.
5. Follow the cleaning process in Chapter 6.6.4.2.
Use a lint-free tissue soaked in disinfectant instead of deionized water.
6. If Contec ProChlor/ProKlean was used, wipe off residues with water.
7. Set the instrument in **Standby mode** unless a new Run is to be started. Refer to Chapter 6.4.

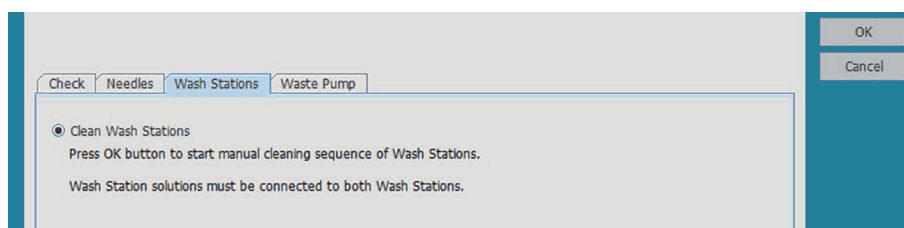
6.6.4.2 Clean the Wash stations

Required tools/solutions

- Rinse bottle
- Deionized water
- Lint-free tissue

Step Action

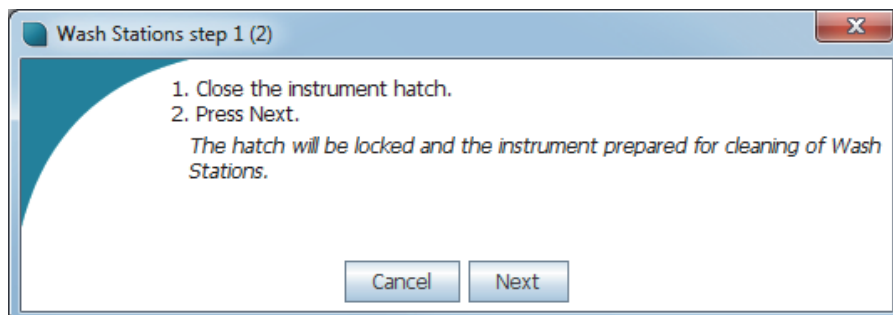
1. Select **Maintenance** in the main menu and then select the **Wash Station** tab.
The "Clean Wash Stations" option is pre-selected.



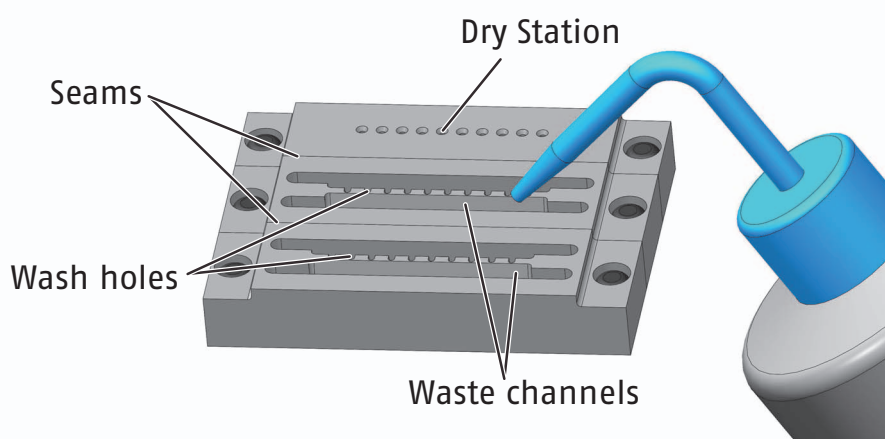
Step Action

2. Click **OK**.

The following dialogue appears:



3. Close the hatch and click **Next**.
The wash station waste pumps starts and the wash station can be rinsed manually.
4. Once notified, open the hatch.
5. Use the rinse bottle to carefully spray deionized water over the wash holes and the waste channels.



NOTE: Avoid spraying in the Dry Station or the seams.

6. Wipe the Wash Station surface with a lint-free tissue soaked in deionized water.
7. Continue spraying and wiping until the Wash Station is free from salt deposit.
8. To end the cleaning sequence; close the hatch and click **Finish**.

The Wash Stations will now be rinsed with the connected Wash Station Solutions for a short period of time. The instrument then needs to be initialized again.

NOTE: If you spray too much deionized water, some liquid might flow through the overflow system. It will then end up on the right side of the system close to the beige tubing. Sanitize with appropriate disinfectant, clean and wipe dry.

6.6.4.3 Prevent salt buildup in the wash stations

Required tools/solutions

- Water, room temperature, 2x 1000 ml

Step Action

1. Place the tubing from both Wash Station pumps into a bottle containing 1000 ml of room temperature water.
2. Prime Wash Stations 1 and 2, three times. (Or set the **Prime Factor** to 300%) Refer to Chapter 6.2.1

6.6.4.4 Clean a clogged wash station

Required tools/solutions

- Water, up to +50°C, 2x 1000 ml

Step Action

1. Place the tubing from both Wash Station pumps into a bottle containing 1000 ml of warm water.
2. Prime Wash Stations 1 and 2, six times. (Or set the **Prime Factor** to 600%) Refer to Chapter 6.2.1

6.6.5 Needle Sanitize

Needle Sanitize is used to inactivate bacterial and viral contamination. The needles are sanitized on the inside and outside with Sanitize Solution.

The Needle Sanitize method takes approximately 50 minutes to complete.

Required tools/solutions

- Microplate MP96 PCR
- Bioaffy Pump Liquid
- Bioaffy Wash Station Solution 1
- Needle Sanitize Solution

NOTE: For recipes, refer to *Gyrolab User Guide*.

Step Action

1. Click **Maintenance** on the main menu and select the **Needles** tab.

Step Action

2. Select the **Needle Sanitize** method. Click **OK**.

Maintenance/Needle sanitize v2

Complete: Yes Status: Approved
 System version: 9 Modified: 11/8/04 3:24 PM
 CD type: Maintenance Modified by: Gyros AB

Method	Approved	Complete
Needle desorb v3	☒	☒
Needle sanitize v2	☒	☒
Needle wash 1 solution v1	☒	☒
Needle wash 2 solutions v1	☒	☒

3. The following screen appears:

Maintenance method: Needle sanitize v2

Wash station solutions

Solution	Wash Station
Soaffy wash station solution 1.1	

Confirm Connect

Pump liquid

Liquid	Pump
Soaffy pump liquid	1, 2, 3, 4, 5

Confirm Connect...

Cleaning solutions

Name	Identity	Available
SP		Not Loaded

Load... Unload...

Cancel

Start

4. If the **Wash Station Solutions** and **Pump Liquid** are already connected (green indicators lit):

- Click **Confirm** for both **Wash Station Solutions** and **Pump Liquid**.

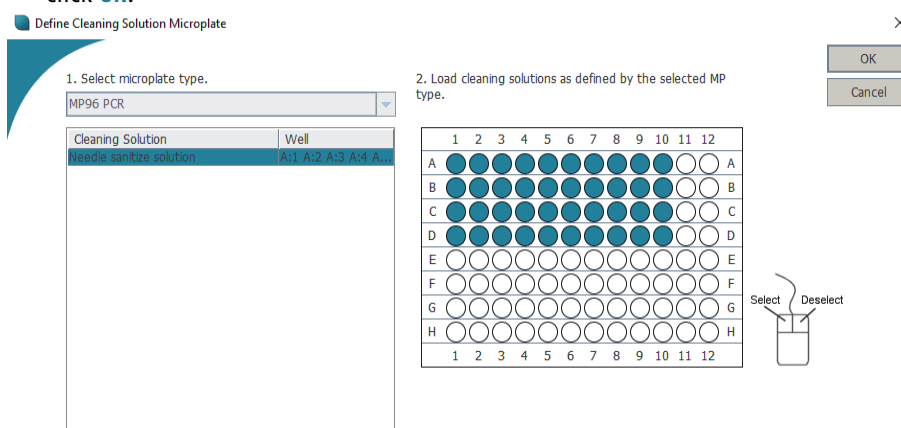
5. If the **Wash Station Solutions** and/or **Pump Liquid** are not connected:

- Click **Connect**.
- Then click **OK** on the **Connect Wash Station Solution** dialog and/or the **Connect Pump liquid** dialog.

NOTE: *If the Wash Station Solutions and/or Pump Liquid were not connected, the Needle Sanitize will begin with priming.*

Step Action

6.
 - Click **Load** in the **Cleaning solutions** section.
 - Add 100 µl Needle Sanitize Solution to each microplate well according to instructions in the **Define Cleaning Solution Microplate** dialog.
 - Click **OK**.



7.
 - Place the reagent microplate in the Gyrolab instrument.
 - Click **Confirm** on the Gyrolab Control screen.
8. All green indicators should now be lit.
Click **Start** in the lower right hand corner of the screen. A **Maintenance** dialog displays the progress of the wash cycle.
9. Click **Finish** when washing is complete.

6.6.6 Needle wash

The needle wash process thoroughly washes all needles with the Gyrolab wash solutions used in the Wash Stations.

Always perform a Needle wash if a Run has been aborted or interrupted before completion.

Needle wash 1 washes the needles with solution 1.

Needle wash 2 washes the needles with solution 1 and 2.

Required tools/solutions

- Bioaffy Pump Liquid
- Bioaffy Wash Station Solution 1
- Bioaffy Wash Station Solution 2

NOTE: For required solutions and recipes, refer to *Gyrolab User Guide*.

Step Action

1. Click **Maintenance** on the main menu and select the **Needles** tab.

Step Action

2. Select **Needle Wash** method. Click **OK**.

Maintenance/Needle wash 2 solutions v1

Complete: Yes Status: Approved
 System version: 9 Modified: 10/26/12 4:24 PM
 CD type: Maintenance Modified by: Gyros AB

Method	Approved	Complete
Needle desorb v3	☒	☒
Needle sanitize v2	☒	☒
Needle wash 1 solution v1	☒	☒
Needle wash 2 solutions v1	☒	☒

3. The following screen appears:

Maintenance method: Needle wash 2 solutions v1

Wash station solutions

Solution	Wash Station
Bioaffy wash station solution 1	1
Bioaffy wash station solution 2	2

Confirm Connect

Pump liquid

Liquid	Pump
Bioaffy pump liquid	1, 2, 3, 4, 5

Confirm Connect...

Cleaning solutions

Name	Identity	Available

Load... Unload...

Cancel
 Lock
 Start

4. If the **Wash Station Solutions** and **Pump Liquid** are already connected (green indicators lit):

- Click **Confirm** for both **Wash Station Solutions** and **Pump Liquid**.

5. If the **Wash Station Solutions** and/or **Pump Liquid** are not connected:

- Click **Connect**.
- Then click **OK** on the **Connect Wash Station Solution** dialog and/or the **Connect Pump liquid** dialog.

If the Wash Station Solutions and/or Pump Liquid were not connected, the Needle Sanitize will begin with priming.

6. Click **Start** in the lower right hand corner of the screen.

A Needle Wash Maintenance dialog displays the progress of the wash cycle.

7. Click **Finish** when the washing is complete.

6.6.7 Needle Desorb

WARNING: Some ingredients used in solutions for cleaning and sanitization are considered environmentally hazardous waste and must be taken care of in conformity with national and local regulations.

Needle desorb is used to remove contaminants from the needles. The needles are cleaned on the inside and outside with Needle Desorb Solutions.

The Needle desorb method takes approximately 20 minutes to complete.

Needles can be washed with up to four different Needle desorb solutions within one Needle desorb run, see suggested needle desorb solutions in the table.

	Number of Needle desorb solutions	Needle desorb solutions
First choice	1	Gyrolab Wash Buffer, pH 11
Second choice	2	1. 0.5% Dodecylsulfate sodium salt (SDS) 2. 50 mM glycine, pH 9.5
Third choice	1	1.5 M NaCl in 20% ethanol

Required tools/solutions

- Microplate MP96 PCR
- Needle Desorb Solutions
- Bioaffy Pump Liquid
- Wash station solution
- Bioaffy Wash Station Solution 1
- Bioaffy Wash Station Solution 2

NOTE: For recipes, refer to *Gyrolab User Guide*.

Step Action

1. Prepare 100 ml of each required **Needle Desorb Solution**.
2. Prepare 1000 ml of **Wash Station Solution 1** and **Wash Station Solution 2**.
3. Click **Maintenance** on the main menu and select **Needles** tab.

Step Action

4. Select the **Needle Desorb** method. Click **OK**.

Maintenance/Needle desorb v3

Complete: Yes Status: Approved
 System version: 9 Modified: 11/19/10 10:35 AM
 CD type: Maintenance Modified by: Gyros AB

Method	Approved	Complete
Needle desorb v3	☒	☒
Needle sanitize v2	☒	☒
Needle wash 1 solution v1	☒	☒
Needle wash 2 solutions v1	☒	☒

5. Connect the wash solutions to the wash stations and syringe pumps.

Connect the syringe pumps to **Bioaffy Pump Liquid**.

Connect Wash Station 1 to **Bioaffy Wash Station Solution 1**.

Connect Wash Station 2 to **Bioaffy Wash Station Solution 2**.

6. If the **Wash Station Solutions** and **Pump Liquid** are already connected (green indicators lit):

Click **Confirm** for both **Wash Station Solutions** and **Pump Liquid**.

Maintenance method: Needle desorb v3

Wash station solutions

Solution	Wash Station
Bioaffy wash station solution 1	1
Bioaffy wash station solution 2	2

Confirm Connect

Pump liquid

Liquid	Pump
Bioaffy pump liquid	1, 2, 3, 4, 5

Confirm Connect...

Cleaning solutions

Name	Identity	Available
MP		Not Loaded

Load... Unload...

Cancel
 Lock
 Start

7. If the **Wash Station Solutions** and/or **Pump Liquid** are not connected:

- Click **Connect**.
- Then click **OK** on the **Connect Wash Station Solution** dialog and/or the **Connect Pump liquid** dialog.

If the Wash Station Solutions and/or Pump Liquid were not connected, the Needle Sanitize will begin with priming.

8. Click **Load** in the **Cleaning solutions** section.

The **Define Reagent Microplate** dialog is displayed..

Step Action

9. Prepare the microplate.

The **Cleaning Solution Microplate** dialog displays the names and number of wells required per Needle Desorb Solution as well as the position in the microplate.

Wells 1–10 are used, two rows for each desorb solution. 100 µl of solution should be added into each well.

For **Cleaning Solution** in the table in the **Cleaning Solution Microplate** dialog:

Define Cleaning Solution Microplate

1. Select microplate type.
MP96 PCR

2. Load cleaning solutions as defined by the selected MP type.

Cleaning Solution	Well
Needle desorb solution 1	A:1 A:2 A:3 A:4 A:...
Needle desorb solution 2	C:1 C:2 C:3 C:4 C:...
Needle desorb solution 3	E:1 E:2 E:3 E:4 E:...
Needle desorb solution 4	G:1 G:2 G:3 G:4 G:...

Microplate layout (Columns 1-12, Rows A-H):

	1	2	3	4	5	6	7	8	9	10	11	12	
A	●	●	●	●	○	○	○	○	○	○	○	○	A
B	●	●	●	●	○	○	○	○	○	○	○	○	B
C	○	○	○	○	○	○	○	○	○	○	○	○	C
D	○	○	○	○	○	○	○	○	○	○	○	○	D
E	○	○	○	○	○	○	○	○	○	○	○	○	E
F	○	○	○	○	○	○	○	○	○	○	○	○	F
G	○	○	○	○	○	○	○	○	○	○	○	○	G
H	○	○	○	○	○	○	○	○	○	○	○	○	H

Legend: ● Select, ○ Deselect

Buttons: OK, Cancel

- If one Needle desorb solution is used, **Needle desorb solution 1, 2, 3 and 4** represents the same solution.
- If two different Needle desorb solutions are used, then **Needle desorb solution 1 and 2** represents the first solution and **Needle desorb solution 3 and 4** represent the second solution.

10. Click **OK** in the **Define Cleaning Solution Microplate** dialog.

- Load the reagent microplate in the Gyrolab instrument.
- Click **Confirm**

11. All green indicators should now be lit.

- Click **Start** in the lower right hand corner of the screen.
- A **Needle Wash Maintenance** dialog displays the progress of the method.

12. Click **Finish** when washing is complete and unload the microplate.

6.7 Maintain Syringe Pumps and external tubing

CAUTION: Do not allow the pumps to run dry.

Inspect the Syringe Pumps regularly. Tubing, syringe seals and valves require periodic maintenance. If they become worn, the following symptoms may occur:

- Poor precision and accuracy
- Variable or moving air gap
- Leakage
- Air bubbles in syringes

If a problem with one of the components above is suspected, please consult your local Gyros Protein Technologies AB service representative.

The following components may be replaced by the Gyrolab user:

- Glass syringe, refer to Chapter 6.7.1.
- External tubing, refer to Chapter 6.7.2.

Replacement of the following components requires the assistance of a Gyros Protein Technologies AB trained engineer:

- Internal tubing
- Valves

NOTE: *The frequency of replacement will depend on the duty cycle, fluids used and Gyrolab instrument maintenance.*

6.7.1 Replacing a syringe

Required tools/solutions

- New syringe
- Degassed, deionized water

Step Action

1. Start Gyrolab instrument priming.
2.
 - Click **Abort** as the syringes are moving downwards (during Gyrolab instrument priming) and wait for the system to come to a stop.
 - Click **Finish** and then **Close**.
 - Turn off Gyrolab according to Chapter 5.6. Switch off the Gyrolab instrument. The power switch is located at the rear of the Gyrolab instrument.
3. Remove front cover according to the instruction in Chapter 6.7.1 step 1.
4. Loosen the plunger locking screw at the bottom, (1) in Figure 2.
5. Manually lower the plunger drive by firmly pushing down the plunger holder assembly, (2) in Figure 2.
6. Remove the syringe from the valve by unscrewing the syringe at the top nut, (3) in Figure 2.

Step Action

7. Clean the new syringe according to the instructions given in Chapter 6.7.1.
8. Fill the syringe chamber with degassed, deionized water.
NOTE: *Examine the syringe to ensure that no air bubbles are present inside the syringe chamber.*
 Install the new syringe into the valve by tightening the syringe at the top nut, (3) in Figure 2 until the touch-off point is reached. Tighten 1/8 to 1/4 turn.
9. Adjust syringe body inclination so that the plunger goes straight into the plunger holder hole without bending in.
 It may be necessary to loosen the screws for the valve and rotate the valve body to achieve best fit.
 Grab the syringe glass barrel or the valve body and align the syringe so that the plunger fitting is just above the hole in the plunger holder in both sideways and in-out directions. Tighten the valve screws when satisfactory alignment is achieved.
NOTE: *Great care is needed during this adjustment!*
10. Raise the plunger holder, (2) in Figure 2, so that the syringe fits completely into the holder.
11. Tighten the plunger locking screw, (1) in Figure 2.
12. Mount the front cover according to instruction in Chapter 6.7.1 step 7.
13. Turn on the instrument according to Chapter 5.2.
14. Initialize the system from Gyrolab Control by clicking **Initialize** on the Main menu.
15.
 - Prime the system twice using **Prime** on the main menu (Chapter 6.2). Check for air bubbles during priming. If necessary, repeat priming several times.
 - Check for air bubbles during priming.

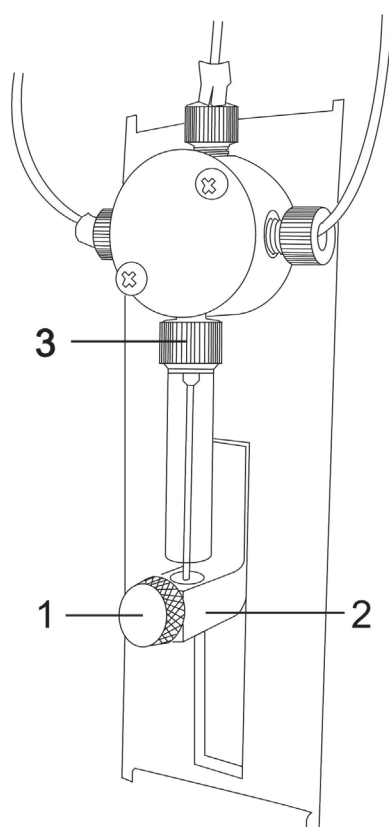


Figure 2: Syringe Pump with the plunger holder in the upper position.

No Part

1. Plunger locking screw
2. Plunger holder
3. Top nut

NOTE: *Ensure the Plunger locking screw (1) is securely tightened.*

6.7.2 Replacing external tubing

There are two types of external tubing that can be replaced by the user:

- **External tubing for the Syringe Pumps**
The Syringe Pump tubing assembly consists of 5 pieces of PEEK tubing that connect to a specially designed cap for the priming bottle, as well as fittings and filters.
- **External tubing for the Wash Stations and the waste container**
The wash tubing assembly for the Wash Stations consists of tubing, filters, cap, and bottle. The waste tubing assembly consists of tubing, cap, and bottle.

All external tubing is connected to the right-hand side of the Gyrolab instrument.



Figure 3: Connecting panel for external tubing

Required tools/Solutions

- Bioaffy Wash Station Solution 1
- Flangeless nut extender tool, refer to chapter 3.7
- Torx driver T20, refer to chapter 3.7

NOTE: For recipes, refer to *Gyrolab User Guide*.

6.7.2.1 Replace external tubing for the Syringe Pumps

Step Action

1. Turn off Gyrolab according to Chapter 5.6. Switch off the Gyrolab instrument. The power switch is located on the rear of the Gyrolab instrument.
2. Loosen the plastic fittings (1–5 in Figure 3) and remove the tubing assembly.
3. Put the new tubing assembly in the bottle filled with Bioaffy Pump Liquid and connect them to a 5 ml plastic syringe via the syringe adapter (both items enclosed with Gyrolab) to one of the tubes in the buffer.
4. Draw gently until liquid appears in the syringe. The liquid can be either Standby Solution or Bioaffy Pump Liquid.
5. Disconnect the syringe and the syringe adapter.

Step Action

6. Connect the tube to Gyrolab inlets (1–5 in Figure 3). First finger tighten the fitting and then tighten an additional $\frac{1}{4}$ to $\frac{1}{2}$ turn using the flangeless nut extender tool.
7. Turn on the Gyrolab instrument (see Chapter 5.2).
8. Prime the Gyrolab instrument two times.
Check for leaks. If air is visible in the syringes, repeat prime until all air is dissolved.

6.7.2.2 Replace external tubing for Wash Station and waste

Step Action

1. Turn off Gyrolab according to Chapter 5.6. Switch off the Gyrolab instrument. The power switch is located on the rear of the Gyrolab instrument.
2. To remove the tubing assembly, use a screwdriver to push the tubing from the panel.
3. To install new tubing assembly, push the tubing onto the fitting on the panel.
4. Turn on the Gyrolab instrument (Chapter 5.2).
5.
 - Prime the system using **Prime** on the main menu.
 - Repeat the priming 4 to 5 times to ensure that no air bubbles remain in the system.

NOTE: *Insert all tubing into the appropriate bottles and ensure that there is sufficient solution in the bottles before restarting the pumps.*

NOTE: *Ensure the liquid level covers the external filters.*

6.8 Change fuses

Required tools/solutions

- A flat blade screwdriver
- T6.3 AL, 250 V, 5×20 mm fuse

Step Action

1. Turn off Gyrolab according to Chapter 5.6. Switch off the Gyrolab instrument. The power switch is located on the rear of the Gyrolab instrument.
2. Remove the power cord. It is connected to the instrument on the rear of Gyrolab instrument below the power switch.
3. Carefully eject the fuse holder using the screwdriver at the position indicated by the arrows.



4. Replace the fuse (T6.3 AL, 250 V, 5×20 mm).
5. Remount the fuse holder.
6. Plug in the power cord.

6.9 Preparations before Service visit

The Gyrolab instrument must be sanitized before service. If hazardous material has been used in the system; clean and sanitize the instrument according to the risk assessment performed. Observe that it is up to the user to ensure that no hazardous material remains.

Required tools and solutions

- Decontamination Clearance Certificate

NOTE: *The Decontamination Clearance Certificate is available in the instrument binder, or from Gyros service personnel.*

Step Action

1. Sanitize and clean the entire instrument. Refer to chapter 6.6, especially chapter 6.6.1.
2. Complete the Decontamination Clearance Certificate.
Make sure to have the completed certificate at hand when Gyros service personnel arrives.

7 Troubleshooting

For troubleshooting, refer to Gyrolab User Guide.

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