RR Mechatronics

Instructions for Use

RPI

MRN-184-EN Version 6 (05-01-2022)

Contents

Contents

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IVD CE Rx Only

Issued by the Support Department of RR Mechatronics

Document history overview

MRN-184-EN

Issue No	Date	Revised Section(s)	Changes	Authorised
6	jan. 2021	Disclaimer Safety	Modification claim Exposure limits / USB-port use	HSR
5	dec.2021	Calibration procedures Decommissioning	Metrology traceability addition Decommissioning only by FSE remark	HSR
4	nov. 2021	All	General update including software version 2.14 and changes due to wording intended use of RPI-Check	HSR
3	jun. 2021	All	General update and changed chapter sequence according FDA regulations	HSR
2	jan. 2021	All	General update	HSR
1	oct. 2020	All	General update	HSR

1

Introduction

Read this manual, especially the standard operation procedure and Safety instructions , before using the instrument.

1.1 - About this manual

This manual describes all necessary procedures and information required for the correct and successful use of the RPI, covering normal operation, user maintenance and troubleshooting. When instrument is mentioned, it is used for the complete instrument, the RPI including the AFS-24 unit.

This manual is applicable for the following RPI-models and concentrated reagents:

A0021587 RPI-ECO21 (120V), for DxH Concentrated ECO Diluent C67249 (Beckman-Coulter).

A0021595 RPI-ECO21 (230V), for DxH Concentrated ECO Diluent C67249 (Beckman-Coulter).

This manual does not describe specific service related issues, such as detailed technical information and repair procedures.

The manual found with your RPI is important for proper usage and maintenance in compliance with the manufacturer specifications.

Your RPI is delivered with these documents:

An "*Instruction for Use*" which describes all specifications, operations, user functions and user maintenance of the RPI.

A "*User manual AFS® 8, 16, 24*" which describes all specifications, operations, user functions and user maintenance of the AFS-24 (WPU).

It may be necessary to reference these documents for maintenance or other procedures with the RPI. It is recommended to store these documents in such way that they can be quickly located and where they will not be damaged.

Updates of this manual and RPI software will be published on our website, distributors will be informed about updates. Electronic versions of this manual and versions in available languages and future revisions are available on:

https://support.rrmechatronics.com

1.2 - Used symbols

This ATTENTION symbol is used to refer to instructions in this manual that need to be done carefully.

These symbols are used to indicate that proper safety equipment has to be used. Protective glasses and gloves must be worn

This UV RADIATION sticker is used to refer to a position on or inside the water system cabinet where exposure to UV light is possible

This ELECTRICAL GROUND sticker is used to refer to a position on the water system Cabinet or inside where an electrical ground connection is made.

This DANGER sticker is used to refer to a position on the water system Cabinet or inside of it that could be hazardous.

This symbol indicates useful information, not related to any specific danger.

1.3 - Installation

The instrument must be installed in a dry and dust-free location on a solid and stable surface.

Do not expose the instrument to excessive temperature fluctuation and direct sunlight.
Avoid shocks and vibrations. Ensure good ventilation and do not place the instrument directly in contact with other equipment.
Leave >1m space in front of the instrument to be able to move the instrument forwards to perform maintenance activities at the back side.

Avoid installation near devices causing interference e.g. radios, centrifuges, etc. Installation of the instrument in places where chemicals are stored or gas develops is not permitted.

1.4 - Disclaimer

Operate and maintain this instrument according to this manual and other instructions from the manufacturer. Failures and defects as result of unspecified use will void the product warranty. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

The instrument is not equipped with backup- or control systems to prevent production of incorrect reagent due to conditions such as:

- Uncalibrated measuring circuitry
- Instrument malfunction
- Poor quality of concentrated reagent
- Poor quality of feed water

The RPI (including WPU) is designed to stay connected to the main power supply and water supply at all times.
The quality of RPI's production has to be checked daily for use on the connected analyzers according local quality specifications.

Do not disconnect the RPI(s) prior to completion of the shut-down cycle.

The manufacturer disclaims any liability for any direct, indirect, incidental, special or consequential damages of any kind, arising from the use of incorrect prepared reagent.

Note:
This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. 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 in which case the user will be required to correct the interference at his own expense.

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Intended use RPI

The RPI is a general purpose instrument intended to dilute a concentrated reagent to a usable fluid for in vitro laboratory testing.

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Installation procedures and requirements

Users are not allowed to install and connect the instrument. The RPI must be unpacked, installed and checked by a trained engineer prior to first operation.

Installation procedures and requirements are described in the Installation manual.

3.1 - Feed water requirements

The provided feed water quality will affect the performance of the RPI and is required to be within the specifications mentioned below.

RR Mechatronics recommends that a Merck Millipore representative performs a water analysis prior to the installation of the RPI to ensure your water supply meets the requirements.

This representative can also arrange for mitigations if laboratory water quality does not meet specifications.

Requirements:	
Pressure:	1 – 6 bar
Flow rate:	> 5 L/min at 2 bar
Type:	Potable tap water
Temperature:	10 – 30 °C
Conductivity:	100 – 2000 µS/cm @ 25 °C
pH:	4- 10
Langelier Saturation Index (LSI):	< 0.3
Free total chlorine:	< 3 ppm

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Principles of operation

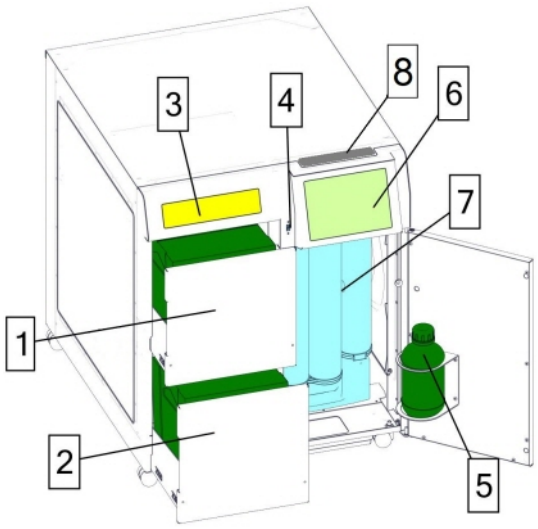
The RPI (Reagent Production Instrument) is an automated reagent preparation instrument. It produces a ready-to-use reagent out of a concentrated reagent and lab water to a predetermined target conductivity.

The instrument is a single unit, housing all necessary parts inside a closed frame. The frame is covered with easily removable, coated, sheet metal panels. The instrument is operated with a user interface with multi-authority levels.

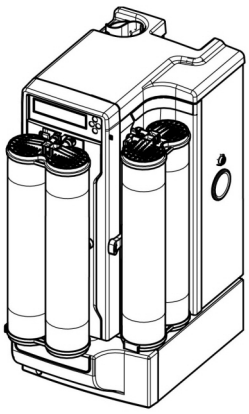
All external connectors are situated on the rear side of the instrument, including the ON/OFF switch.

All user serviceable and replaceable parts are accessible through the doors, drawers and panels.

The RPI and its modules are shown here.



The WPU (Water Purifying Unit) is shown here (See AFS manual for details).



1. Top concentrate cubitainer
2. Bottom concentrate cubitainer
3. Power indicator
4. USB connection
5. RPI Check
6. Touchscreen with Graphical User Interface
7. WPU (Water Purifying Unit, AFS® 24)
8. Sight glass for display WPU

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Performance characteristics and specifications

5.1 - Technical specifications

Instrument model	Model name RPI-ECO21	Catalogue number (REF) **A0021587 120V** **A0021595 230V**
Dilution method	Electrical Conductivity and Temperature measurement (EC-T)	
Concentration window	Upon request (indication 15 - 25x)	
Temperature compensation method	Reagent specific conductivity-temperature curve	
Reconstitution accuracy	< 1% (1SD)	
Conductivity production range	Upon request (indication 10 -20 mS/cm @25˚C)	
Production capacity	~20 L/hr peak (for 3 hours) <17 L/hr continuous (excluding lot-change and service)	
Number of concentrate cubitainers	2 x 10L, hot swappable	
Result monitoring method	RPI-Check	
Intended use	The RPI is a general purpose instrument intended to dilute a concentrated reagent to a usable fluid for in vitro laboratory testing.	

Traceability	
Concentrated reagent cubitainers	Near Field Communication (NFC)
RPI-Check	NFC
User interaction	4 access levels [to be entered in the Graphical User Interface(GUI)]

Internal Water Production Unit	
Water Purification Unit (WPU)	Merck Millipore AFS® 24
Feed Water quality requirements	See specification from AFS® 24 manual for details
Feed water temperature	10 - 30°C

Input water connection	1x John Guest PM Acetal fitting 8 mm
Produced water quality	Clinical laboratory reagent water, conductivity ≥ 1MΩ/cm
Installation requirement	Installation by Merck-Millipore Field Installation Engineer is required

Waste

RPI Waste connection	1x John Guest PM Acetal fitting 10mm (OD)
AFS-24 Waste connection	1x John Guest PM Acetal fitting 6 mm (OD)

Concentrate cubitainers

Cubitainer positions	2
Cubitainer orientation	Upright
Cubitainer volume	10L
Maximum Cubitainer dimensions	H 245 x W 245 x D 245 mm
Cubitainer detection & identification	NFC
Location RFID at cubitainer	Rear
Concentrate pick-up tube	To be determined with customer

Monitoring process:

Monitoring method	Control cycle using RPI-Check
RPI-Check temperature	Acclimated to environment temperature (>24 hours)
Frequency	≥1x per 24 hrs
Control process start	Manual start and time scheduled

Internal reagent storage:

Storage volume	10 liters
Storage temperature	Displayed in GUI and monitored (not controlled)

Reagent delivery port details:	
Number of output ports	4
Output port outer diameter	John Guest PM Acetal 6 mm (OD)
End point filtration	0.22 µm
Expected priming vacuum	~ 33 kPa (250 mmHg) by analyzer

User interface	
Human machine interface	Full color touch screen
Display specifications	154x90mm (7"), 1024x600 resolution, 85° viewing angle
User access levels	Operator / Lab manager / Lab technician / Field Service Engineer (FSE)
Languages	English, Dutch, French, Italian, German, Spanish

Intended use:	
Use environment	In-Vitro Diagnostic laboratories
Intended operators	Trained IVD lab personnel

Cubitainer switching	
Intra lot cubitainer switching	Uninterrupted production
Lot-to-lot cubitainer switching	When storage is empty, prime with new lot. Analyzers background cycles recommended.

Operational	
Maximum ready to use reagent storage time	To be determined by customer
Mobility	4 wheels

Sanitation	
Reconstitution rinse cycle	Timer initiated, once every 24 hrs.
Rinse medium	Clinical laboratory reagent water, resistivity≥ 1MΩ/cm

Deep cleanse cycle	Yearly maintenance+ incidentally
Deep cleanse medium	Chloride cleaning tablet
Exterior sanitation	Common lab practice

Maintenance

Preventive maintenance calls per year	1, by qualified field service engineer
Consumables replacement frequency	RPI: Every 3 months, WPU: Every 3 months
Consumables	RPI-Check / Progard / Q-gard / end point filters / peristaltic pump tubing and pickup tubes

Electrical requirements

Mains voltage	120 or 230V (± 10%), 50-60 Hz (± 3%)
Fuse EU (230V)	2x 3.15A T (Slow blow) Hollyland 31-50T-032H or equivalent according IEC 60127 (250V, temp range -55°C to + 125°C)
Fuse USA (120V)	2x 6.3 A T (Slow blow)Hollyland 31-50T-063H or equivalent according IEC 60127 (250V, temp range -55°C to + 125°C)
Power consumption	600 VA
Protection class	IP 20
Overvoltage category	II
Pollution degree	2

External connections

RS232 Serial connection	RJ11
Ethernet connection	TCP/IP
External light (24V)(option)	24V, < 2A
USB	2.0

Environment	
Sound level	Less than 62 dBA
Environment temperature	5-40 °C
Operating temperature	15.5 – 32 °C
Relative humidity	35-75% non-condensing
Operational altitude	0 – 2000 m AMSL
Indoor/outdoor use	Indoor use

Total dimensions	
Instrument size	L 775 x W 620 x H 750 mm
Empty weight	107 kg, including WPU

Chemical compatibility	
Wetted surface materials	PFA / HDPE / PP / PPS (40%GFR) / LLDPE / EPDM / AlO / ANSI-316 / Pyrex 3.3/ POM / Pt / Tygon

Data storage	
Storage medium	Onboard memory & data export storage (USB) (4 GB)
Stored data	Batch production information and reagent traceability information
Data on Cubitainer NFC tag	Reagent type, dilution target, origin, production date, lot number, ID, shelf life, remaining volume

Compliance	
Classification EU	IVD Class A
Classification USA	Class 1, 510 (k) Exempt
Compliant to	EU harmonized standards relevant to IVD Medical devices/ cMETus certified
Used materials	ROHS 2011/65/EU and 2015/863/EU

5.2 - User level description

The software has four access levels from basic functionality for the operator up to full access for the Field Service Engineer.

The four levels are:

1. *Operator:*
   - Basic functionality
2. *Supervisor:*
   - Basic functionality
   - Retrieve performance data
   - Environmental settings
3. *Technician:*
   - all previous
   - Basic maintenance
4. *Field Service Engineer:*
   (these functions are not described in this manual)
   - all previous
   - Replace failing / damaged modules
   - Perform yearly maintenance/Shutdown procedure

5.3 - Application

The instrument is used as part of an automated laboratory logistical system and can be connected to a maximum of 4 analyzers or similar reagent consuming instruments. These combined instruments are expected to have a continuous consumption of <17 L/hr / ~20 L/hr peak (for 3 hours).

The instrument will be standing on the laboratory floor.

The instrument has limited mobility (allowing service) due to its filled weight, the connected tubing and cables and its limited ground clearance.

The instrument will be used daily, typically during one or two shifts.

The instrument will operate in a conditioned laboratory environment, typically; 15-32˚C, Relative Humidity 35-75% (non-condensing) for temperatures up to 31 °C decreasing linearly to 50 % relative humidity at 40 °C.

The instrument is designed for an operational altitude of 0-2000 m AMSL.

5.4 - Output performance characteristics

The actual output capacity is strongly dependent on input water conditions and the dilution ratio of the used concentrated reagent.

- Reconstitution capacity: 20 L/hr
- Reconstituted reagent buffer volume: 10L
- Conductivity range: user specific (indication 10 -20 mS/cm @25˚C)

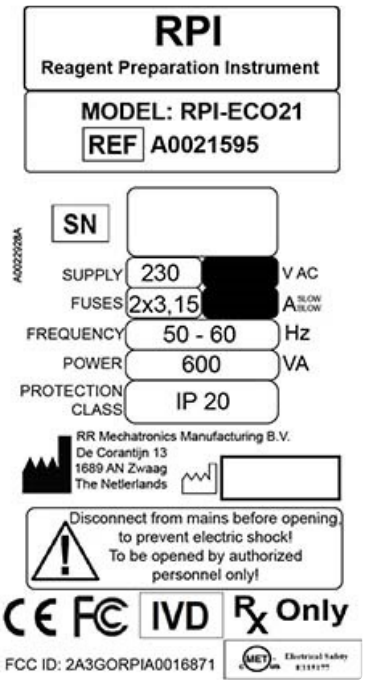
The exact conductivity is set in the software, depending on customer preferences.

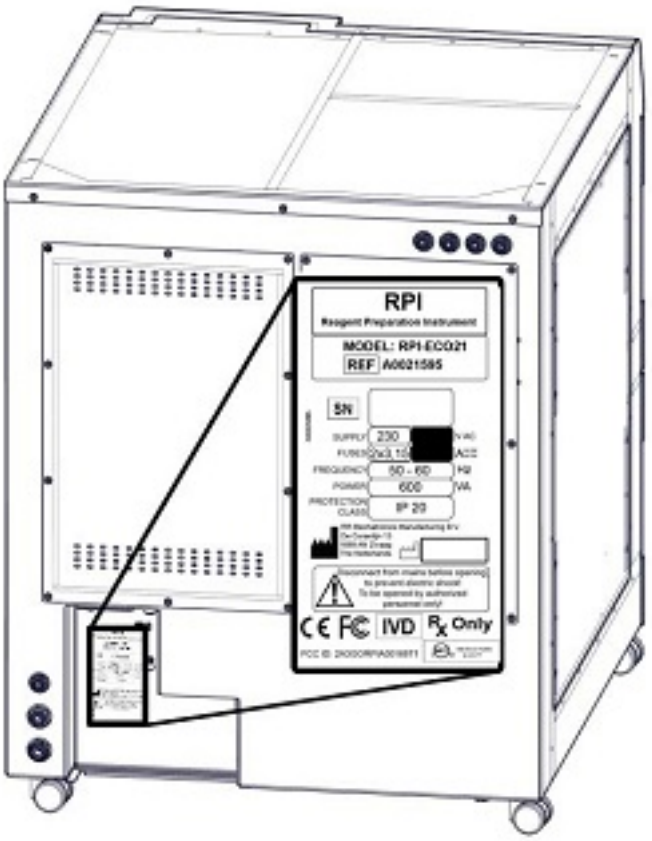
5.5 - Waste

A drain for waste disposal must be present at the proximity of the instrument, no further away than 4m and no elevation higher than 1m.

5.6 - Identification and Labelling

Example of type plate





This label indicates the voltage configuration / used fuses in which the instrument is delivered. The voltage cannot be changed.

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Standard operation procedures

6.1 - Check before starting up after inactive period

Normally, the RPI is running continuously but in case of starting up the instrument again:

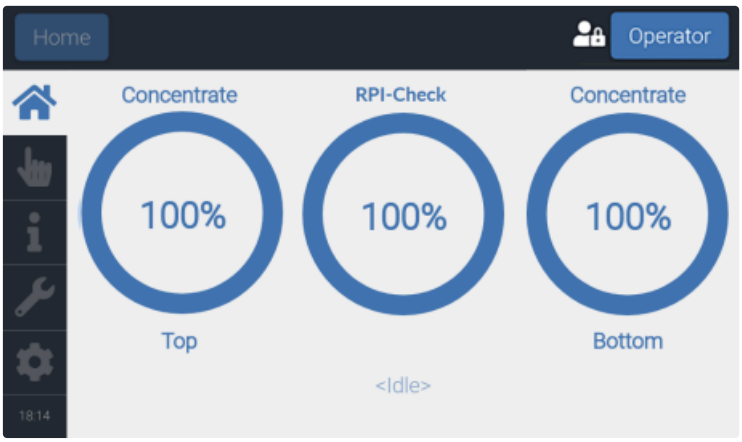
- check status of the concentrated reagents and RPI-Check
- check if action is required for the WPU (see AFS display)
- check water supply
- check General and lab settings (by the Lab Manager)
- check if End filter connections are correct (by the Lab Technician)

During startup the instrument is automatically checked and if all start conditions are met, the instrument is ready for production. If not, this will be indicated with a "is waiting for" message.

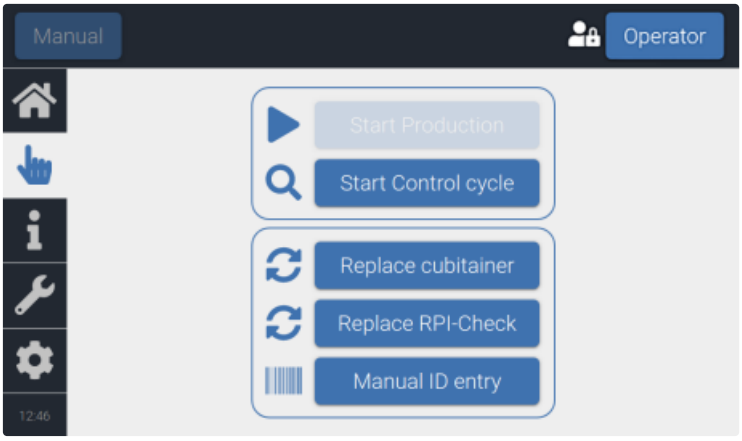
6.2 - Normal operation

Do not move the instrument during production (safety and quality reasons)

After login and checking the instrument:



Select "**Manual**" tab:



The operator can start production by pressing "**Start Production**". The instrument start producing ready-to-use reagent.

The main screen shows the consumption of the reagents.

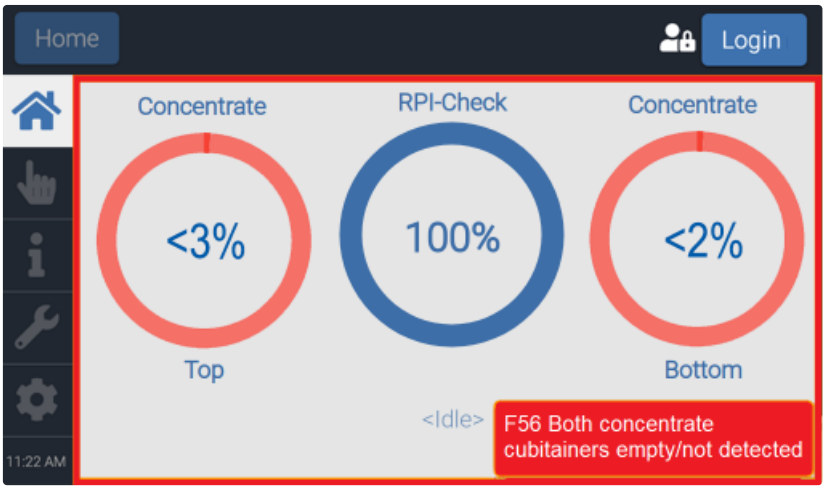
6.3 - Cubitainer Status

It is advised to replace the empty Cubitainer prior to the active Cubitainer reaching 50% of the fill level to ensure continuous production of ready-for-use reagent.

The color changes when a cubitainer has <20% concentrate reagent remaining.

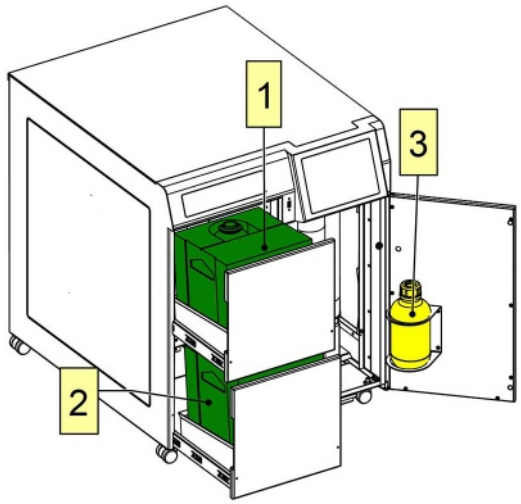
The color changes to red when a cubitainer is empty (<5%), production switches to other cubitainer and an audible and visual warning is given.

When both cubitainers are empty, an audible and visual warning is given and production stops until new cubitainers are placed.



6.4 - Replacement of the cubitainers and RPI-Check bottle

Wear protective clothing, gloves and safety glasses during replacement. Clean immediately in case of spilling or splashing.



Both cubitainers are positioned inside the RPI in designated drawers.

The upper position is indicated as the "Top" concentrate cubitainer (1).

The lower position is indicated as the "Bottom" concentrate cubitainer (2).

The RPI-Check bottle can be found inside the door at the right side of the instrument (3).

During normal operation it is possible to produce reagent until both cubitainers are empty.

After placing a new cubitainer, the data of this specific cubitainer is stored in the instrument: The ID of the cubitainer and the batch information of the reagent is logged for quality control purposes. This data is also visible in the software .

Always use concentrated reagent cubitainers that has been acclimatized for at least 24 hours to environment temperature.

6.4.1 - Placement of a new cubitainer

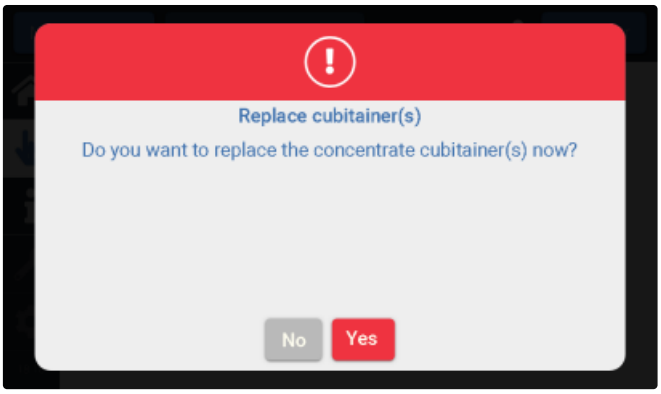
Always use concentrated reagent cubitainers that has been acclimatized for at least 24 hours to environment temperature.

1. Prior to use, inspect the cubitainer for any damage.

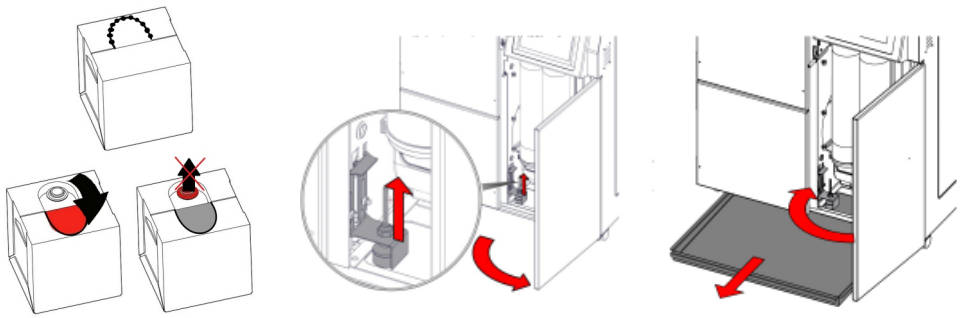
2. When the following screen appears, select '**Log in**' and enter credentials.

3. Select the '**Manual**' tab from the left side column of the screen.

4. Select '**Replace cubitainer**'. The following message appears:

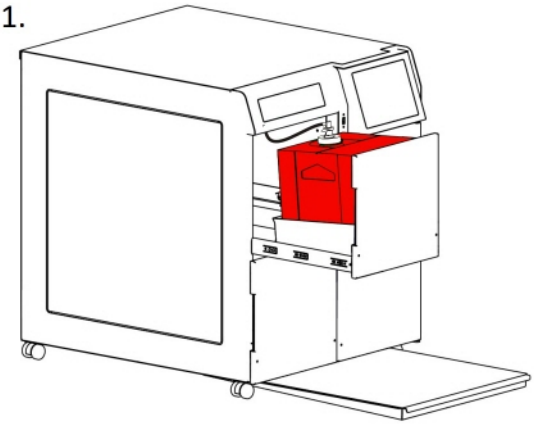


5. Prepare a new cubitainer, remove the cardboard cover to expose neck and cap. Do not extend the neck.
6. For replacement of top cubitainer: Open door, lift drip tray sensor and pull out the drip tray.



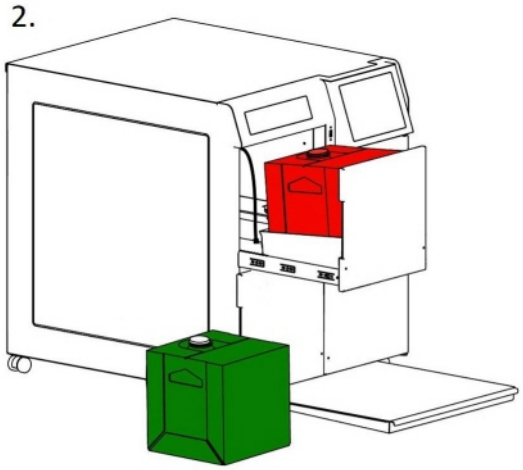
Replacement of top cubitainer

1.



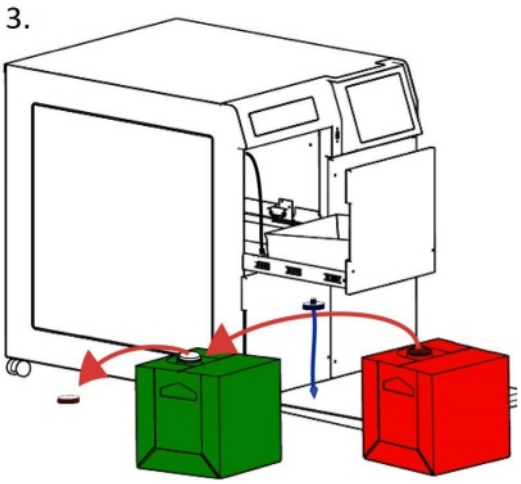
Open drawer

2.



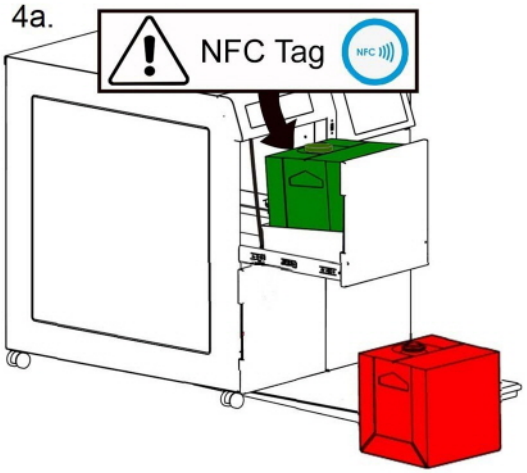
Place new cubitainer nearby and disconnect peristaltic pick-up tube cubitainer from old cubitainer.

3.

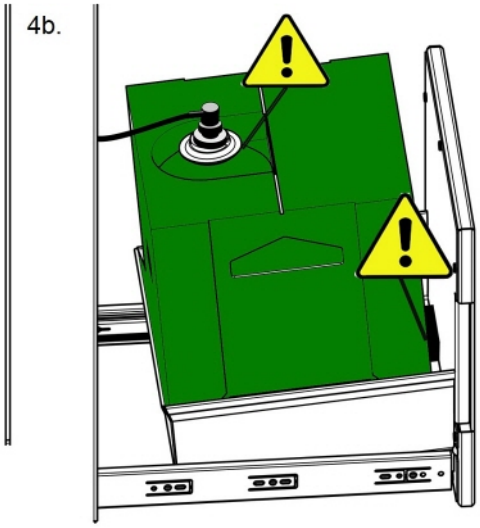


Remove old cubitainer, remove cap from new container, transfer pick-up tube from old to new container.

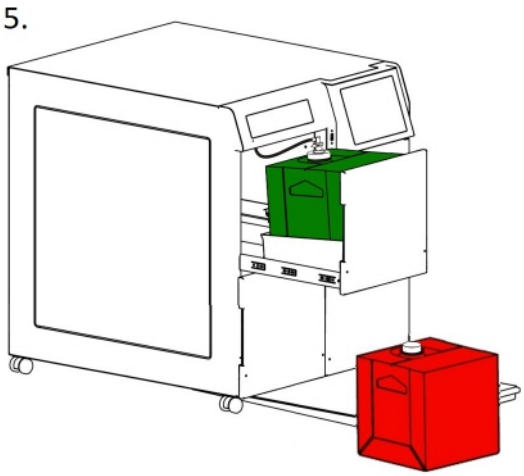
4a.



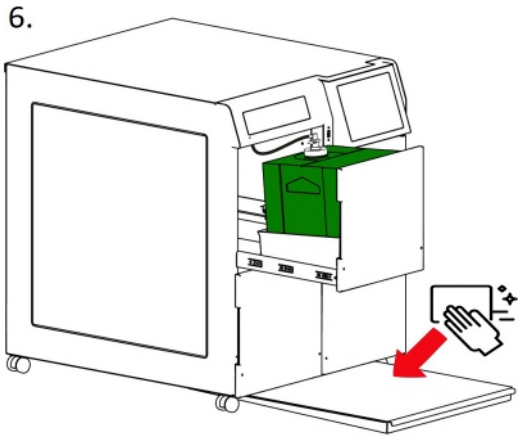
Place new cubitainer. Ensure the pick-up tube is clean and undamaged.



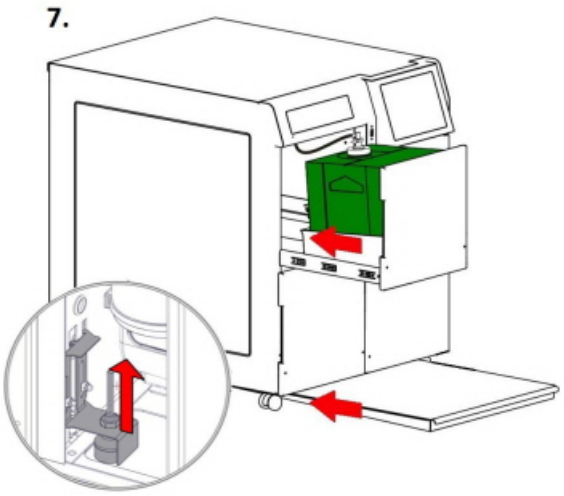
Ensure the cubitainer is placed correctly.
Place pickup tube on the new the container and connect peristaltic pump tube.



Place cap on the old cubitainer. Discard the old cubitainer according to local regulations.



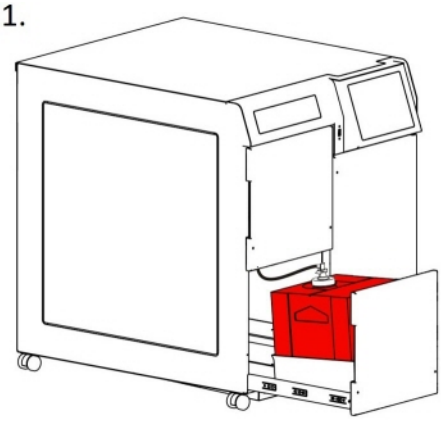
Wipe drip tray in case of leaking fluids.



Push drawer and drip tray in (mind the drip tray sensor).

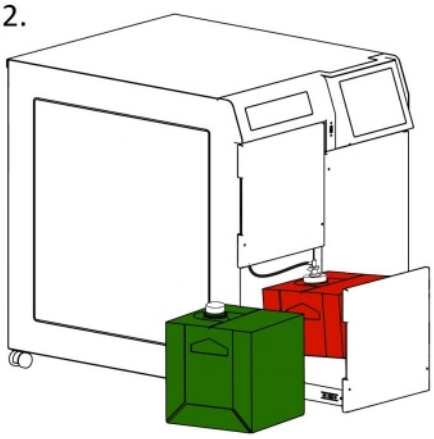
Replacement of bottom cubitainer

1.



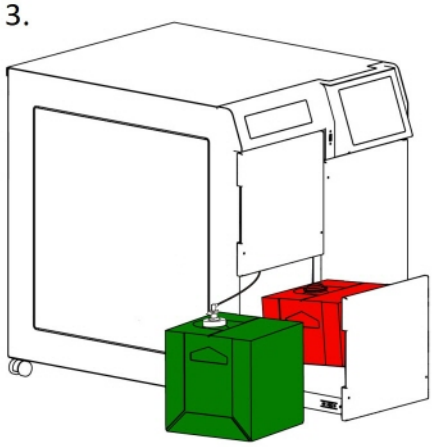
Open drawer.

2.



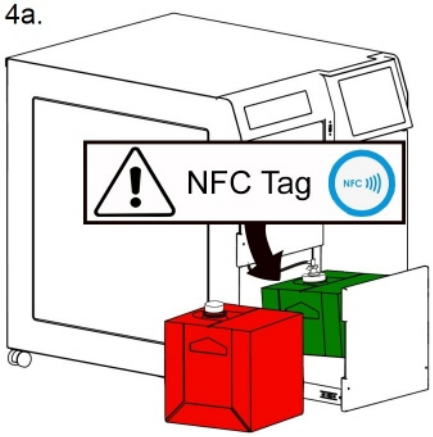
Place new cubitainer nearby.

3.



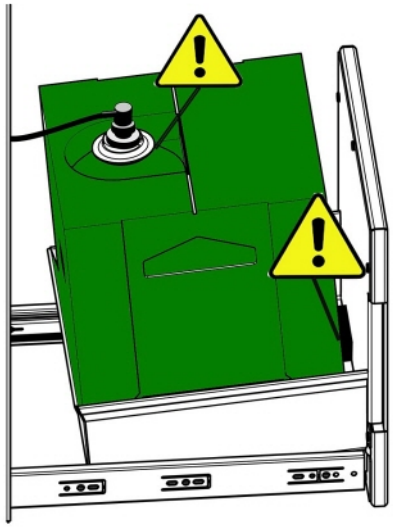
Exchange cap and pickup tube from both cubitainers.

4a.



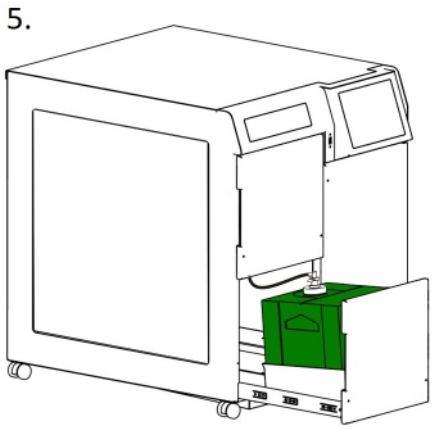
Place new cubitainer in the drawer. Ensure the pick-up tube is clean and undamaged. Remove spilled liquid immediately.

4b.



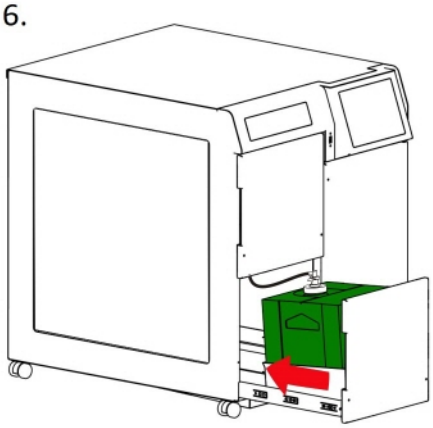
Ensure the cubitainer is placed and connected correctly.

5.



Discard the old cubitainer according to local regulations.

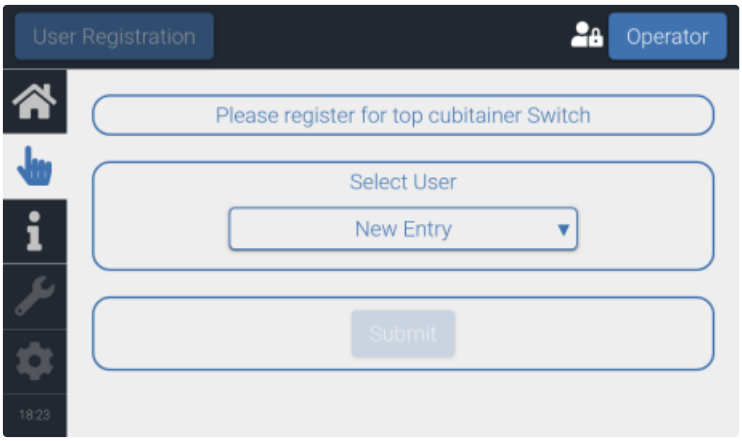
6.



Push drawer in

The GUI will indicate if the NFC tag was read correctly. If the NFC tag is not orientated in the correct way or not readable, the reagent information has to be entered manually, see Manual insert cubitainer ID .

Enter new or existing user information and press Submit.

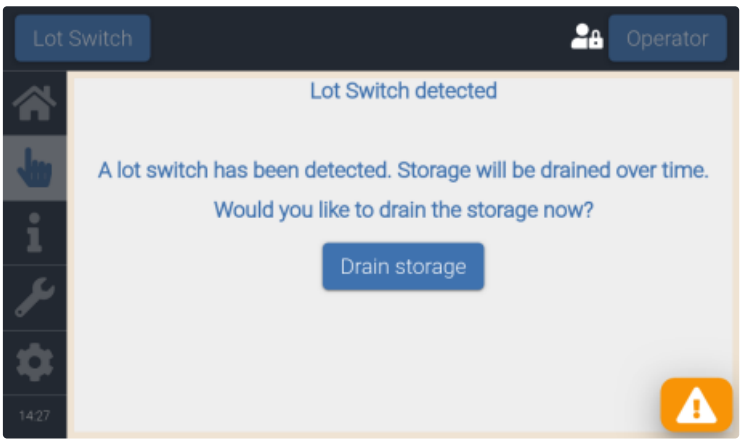


Note: After a lot switch, production can be low and F67 occurs. This will be automatically solved by the instrument (RPI).

6.4.2 - Concentrated reagent lot switch

When both concentrated reagent cubitainers have the same lot number, reagent production continues without interruption.

If a new lot is used, a visual and audible warning is given that availability will pause soon.



If no action is taken, all further steps are automatically performed, the remaining reagent will be used. Press Drain storage only to drain immediately and not use the remaining reagent.

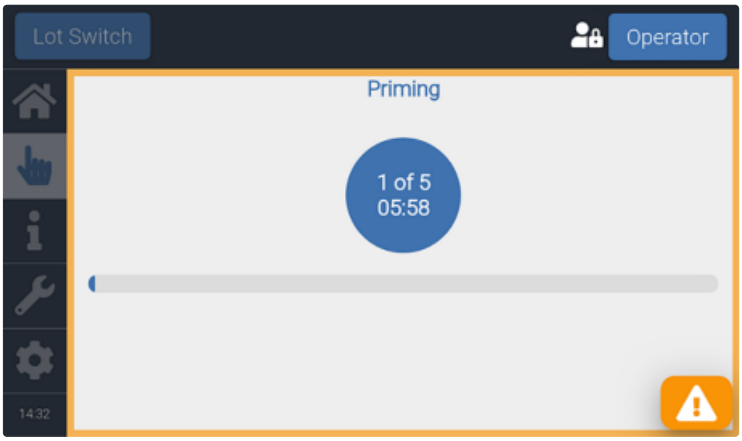
The automatic steps:

- Let analyzers deplete ready-for-use reagent storage
- Provide information to analyzers that ready-for-use reagent is unavailable when storage is almost empty
- Prime storage with new lot

- Produce 3 batches
- Provide a "Ready for production" message
- Add a new lot number

Press **Start Production** to start production from concentrated reagent with a new lot

Progress of the Prime storage step is shown on the screen:



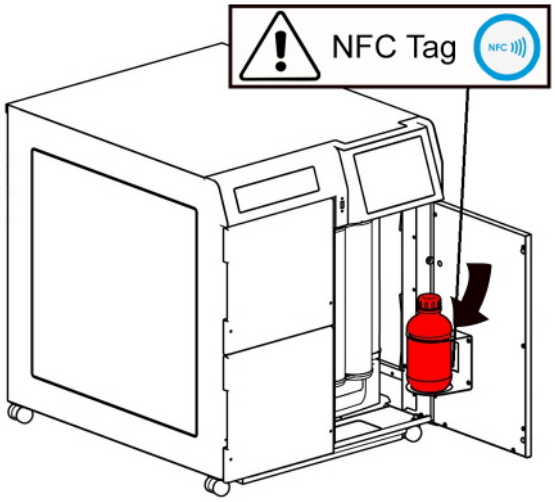
6.4.3 - Placement of a new RPI-Check bottle

It is shown on the screen if the RPI-Check bottle fluid has to be replaced:

Log in and select the '**Manual**" tab, press **Replace RPI-Check**:

1. Open the door.
2. Remove empty bottle from the instrument and replace with a new one. Always use a bottle that has been acclimatized to room temperature for at least 24 hours.
3. Place the bottle with the NFC-tag facing the NFC-reader to enable the RPI to read the NFC properly.
4. Close the door.

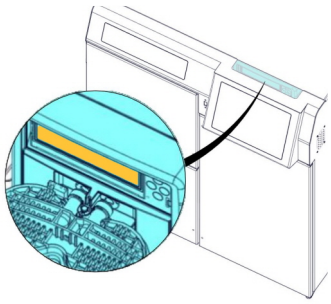
The NFC is automatically read to import batch information. If the NFC tag is not read correctly it can be manually entered.



6.5 - Checks during operation

Pay attention for the status of the cubitainers on the main screen. It is advisable to replace the empty cubitainer prior to the active one reaching it's 50% level.

Check the display of the WPU for possible signals of the condition of the filters (see display of the AFS, visible from the outside)



If optional external warning light is installed, the status of the instrument is indicated as:

Green: instrument in operation mode
Orange: warning, instrument needs attention
Red: error, instrument needs attention immediately

The quality of RPI's production has to be checked daily for use on the connected analyzers according local quality specifications.

7

Calibration procedures

The RPI is not calibrated but monitored with a control cycle.

7.1 - Control cycle

With the control cycle the measurement accuracy is validated. This cycle will take a maximum of 20 minutes and uses RPI-Check (conductivity range of 16.5-17.5 mS/cm @25˚C).

The accuracy of RPI-Check is guaranteed through RR Mechatronics measurement and quality control procedures, and based on a Certified Reference Material produced by the Danish National Metrology Institute.

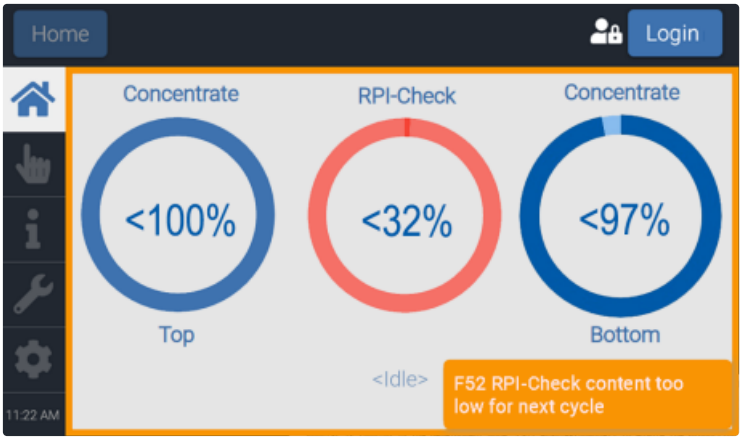
The assigned value as stored in the RFID tag has an uncertainty U(k=2) of 0.025 mS/cm.

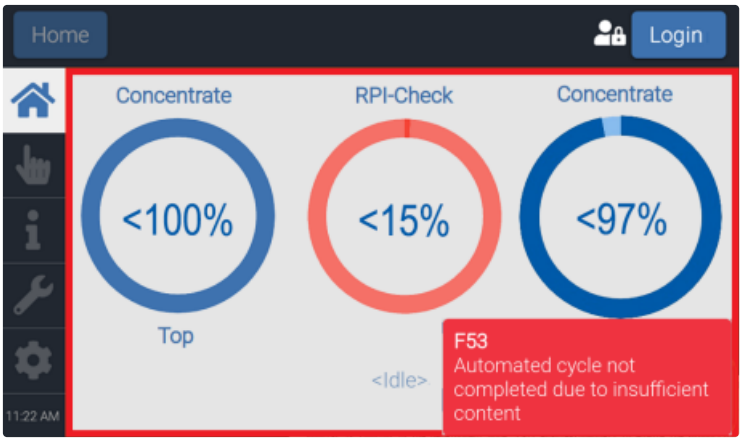
The RPI measures the conductivity of the RPI-Check and compares it to limits based on the conductivity value stored in the NFC-tag on the RPI-Check bottle. If the measured conductivity is within the limits, the control cycle is passed and the control cycle is finished. If the measured conductivity fails, the GUI will display an error. Production can only be started again after a successful control cycle.

Normally the control cycle is started automatically, but can be performed manually with "**Start Control cycle**"on the tab "**Manual**".

The home screen shows the filling level, indicating when the RPI-Check bottle must be replaced. At least 5 control cycles can be performed with one bottle. See the Maintenance chapter for further instructions.

When these messages occur, the RPI-Check bottle has to be replaced:


Home
Login
Concentrate
RPI-Check
Concentrate
<100%
<32%
<97%
Top
Bottom
<Idle>
F52 RPI-Check content too low for next cycle
11:22 AM

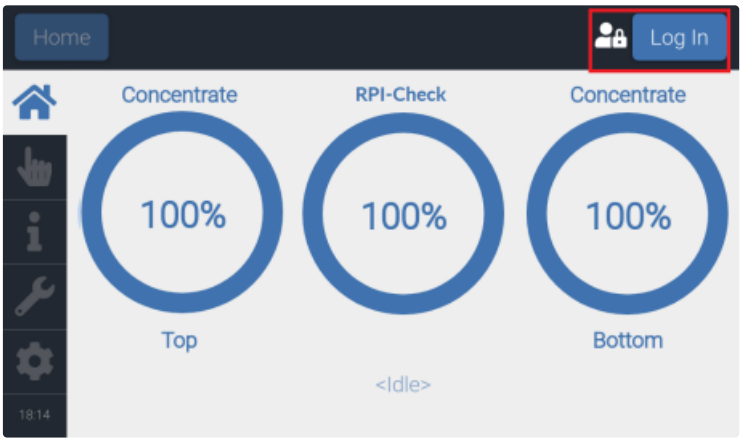

Home
Login
Concentrate
RPI-Check
Concentrate
<100%
<15%
<97%
Top
<Idle>
F53
Automated cycle not completed due to insufficient content
11:22 AM

8

User interface and software menu

The Graphical User Interface or GUI is featured on a touch operated screen located on the front of the instrument.

The following program description is valid for software from version 2.15 and up.



The user interface has four levels of access:

- **Operator**: with basic user functionality
- **Supervisor**: For the lab manager/supervisor, with full user functionality
- **Technician**: For the local technician, with some maintenance, setting and service functionality
- **FSE**: For the Field Service Engineer, restricted service functionality (functions are described in the Installation and Service manual)

8.1 - User Menu

The following tabs are available:

Home

Maintenance

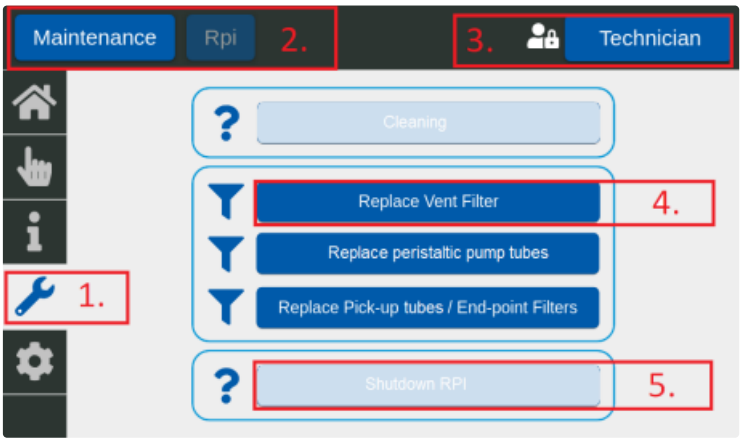
Manual

Settings

Information

Depending on the access level one or more functions are available.

On each screen is shown: active tab (1), menu level (2) and the active access level (3). Available functions are indicated in dark blue (4). Not activated functions, due to access level restrictions, are indicated in light blue (5).



8.2 - Access levels

The following functions are available for the user:

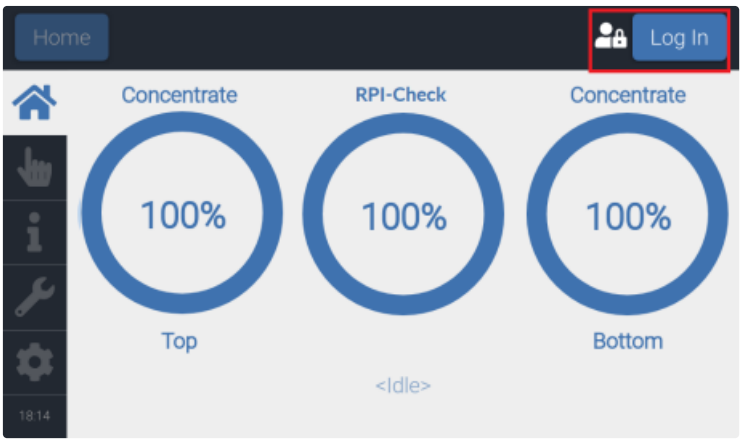
Tab		Function	Operator	Supervisor	Technician
Home		View status	x	x	x
		Concentrate/RPI-Check levels	x	x	x
Manual		Start/Stop Production	x	x	x
		Replace cubitainer/RPI-Check bottle	x	x	x
		Start Manual Control cycle	x	x	x
		Manual ID entry	x	x	x
Info		Performance data		x	x
		Instrument state		x	x
		Instrument information	x	x	x
Maintenance		WPU maintenance items			x
		RPI Maintenance items			x
Settings		General settings		x	x
		Audio settings		x	x
		Lab settings		x	x

All other functions are only available for the Field Service Engineer (see Service manual).

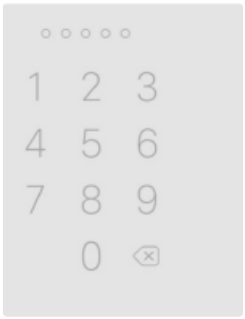
8.3 - Operator level

The lab operator has to login to be able to operate the touch screen.

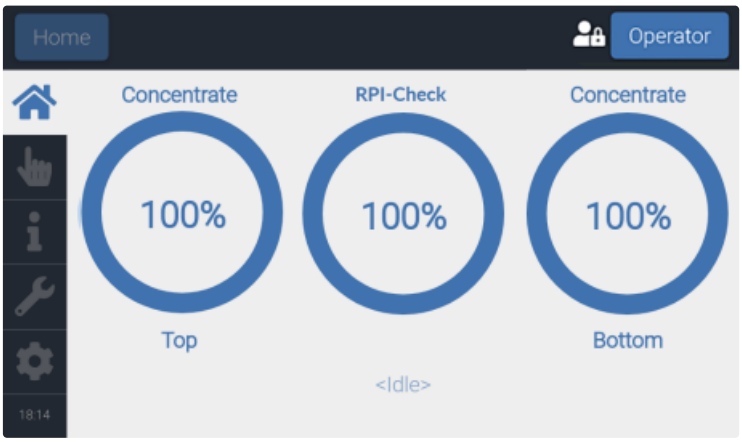
1. Select Log In



2. Enter the Lab employee credentials on the-screen keypad, to operate the graphical user interface:



3. The menu for the lab operator is visible:

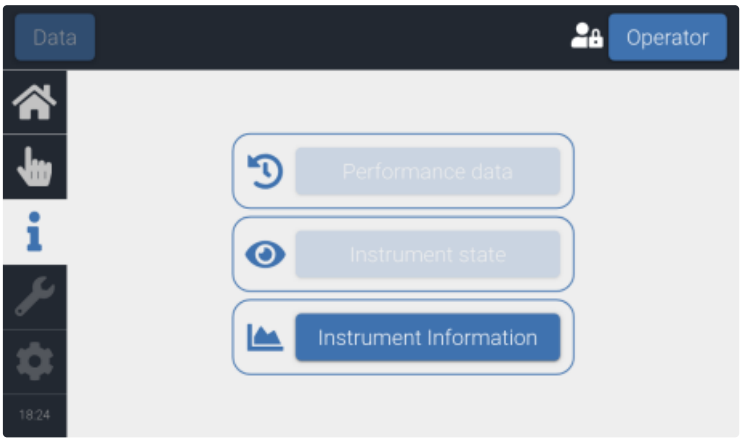


On the home screen, information for the available cubitainers is given, indicated which cubitainer is used and which container is the spare.

This screen shows if one the cubitainers is empty (<5%) and has to be replaced. If one cubitainer is empty and the other is <10% filled, a warning is given to replace the empty cubitainer. For the RPI-Check bottle the first warning (almost empty) is given if the level is <40% and an urgent replace warning if the level is <20%.

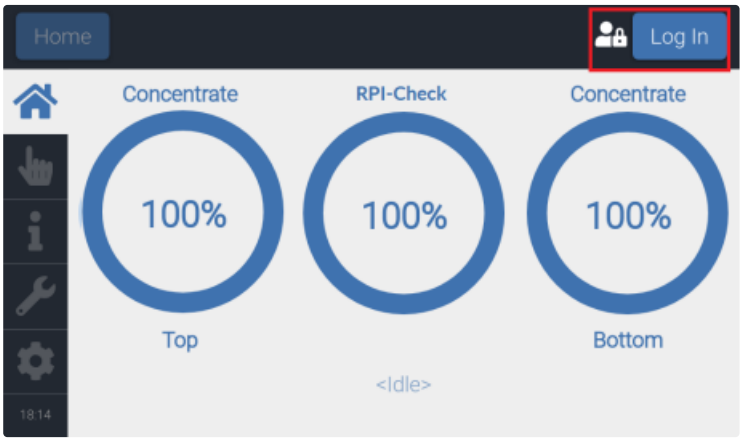
At the **Manual** tab, production can be started or stopped and actions performed, related to replacement of cubitainers or RPI-Check.

At the information tab only instrument information is visible.

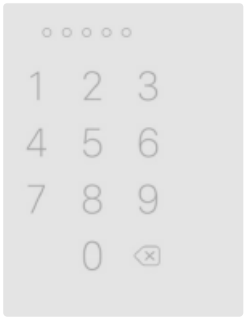


8.4 - Supervisor level

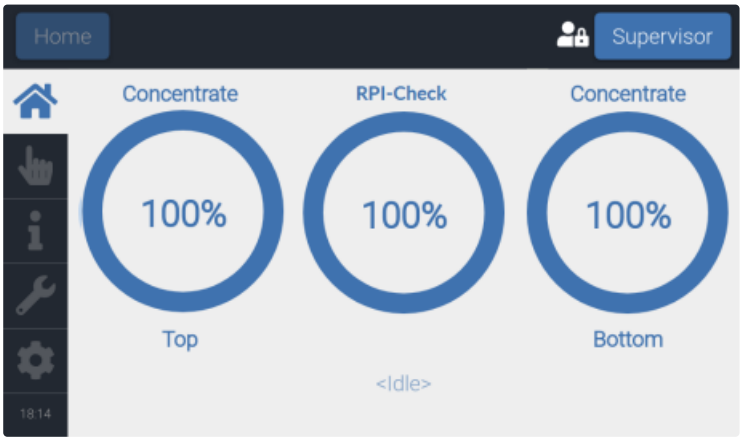
1. Select Log In



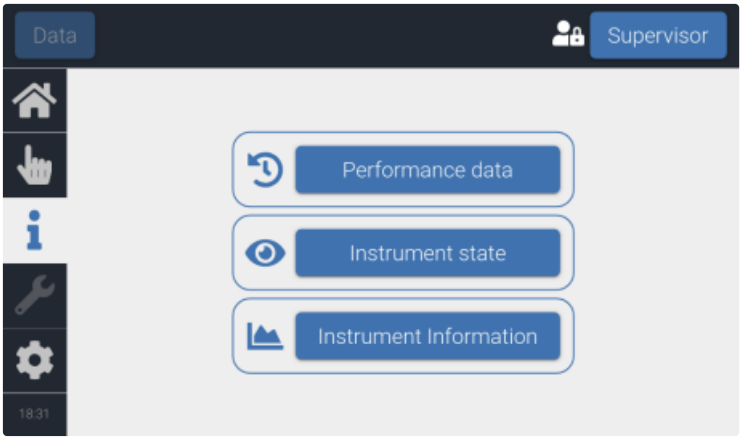
2. Enter the Supervisor credentials on the-screen keypad, to operate the graphical user interface:



3. The menu for the Supervisor is visible:



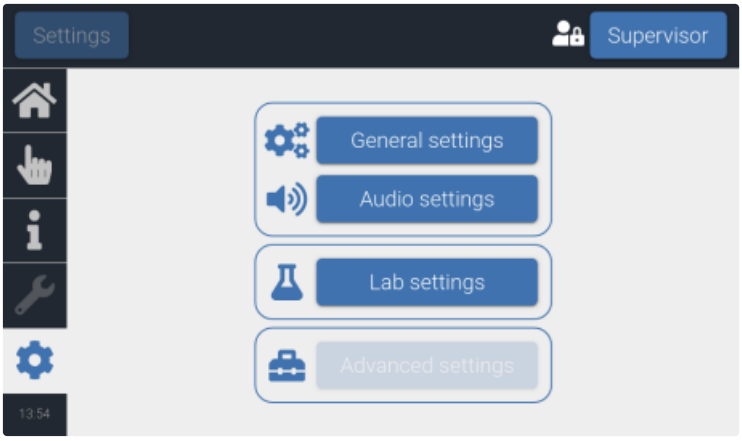
More screens are activated at Information tab



- Performance data
- Instrument state
- Instrument information

It is not possible to use items on the Maintenance tab

On tab Settings the following functions are activated:



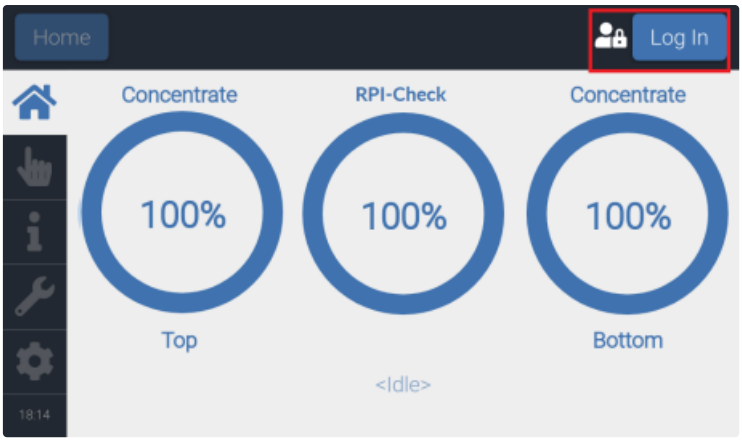
- General settings
- Audio settings
- Lab settings

8.5 - Technician level

The Lab technician is allowed to replace regular items in the instrument and can confirm these actions in the software to be able to start production again after the required replacement of parts. The Lab technician has to be trained by a qualified Field Service Engineer.

See chapter Maintenance screen for all functions which are available on Technician level.

8.6 - Home screen

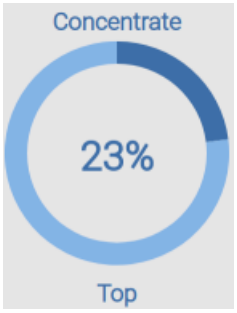


The Home screen provides relevant information for available cubitainers and indication of the status of the concentrated reagent cubitainers and RPI-Check.

The status can be indicated in three colors: blue=no action needed, orange=action needed, red=immediate action needed.

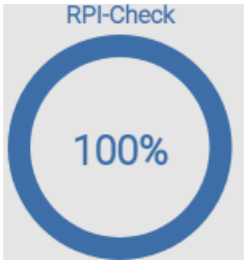
Overview:

<Idle>	The instrument is in idle mode, ready for starting production.
<Running Production>	The instrument is in production mode. Reagent concentrated is produced and reconstituted to analyzers.



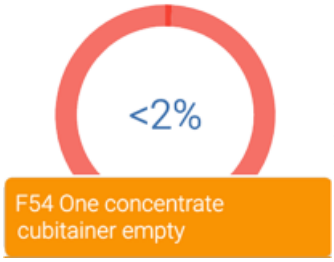
The status of the current used concentrated reagent.

The status of the concentrated reagent not currently in use.



The status of the RPI-Check.

Concentrated reagent or RPI-Check has to be replaced. Concentrated reagent level is almost empty (indicated if concentrate level is <10%). Production is switched to other cubitainer or control cycle cannot be performed.



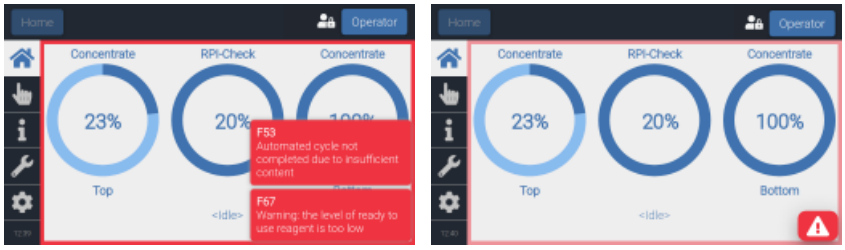
Concentrated reagent or RPI-Check has to be replaced immediately.
Concentrated reagent level is empty. (indicated if concentrate level is <5%).

By pressing on one of the circles more information is visible with specific data:

Top

Cubitainer ID	111111
Version	222222
Lot number	333333
Production date	2021-04-30
Reagent ID	Concentrate
Current volume (ml)	870
Initial volume (ml)	1000
Shelf Life (days)	10
Open life (days)	5
Date opened	2021-07-08

Warnings are indicated with an orange frame, errors are indicated with a red frame on the screen, including a message. This message can be minimized by pressing on the message or enlarged by pressing the warning sign. See the Error list for more information.



8.7 - Manual screen

Select Manual .

On this tab reagent production can be started or stopped or to start a Control cycle .

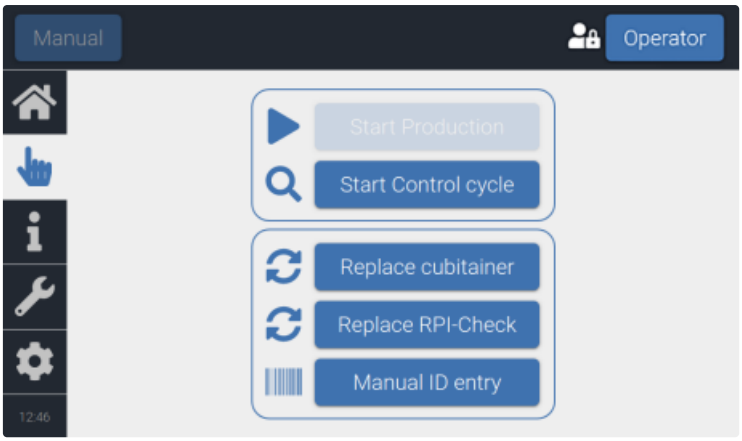
The other options are:

Replace cubitainer (and adding users)

Replace RPI-Check

Manual ID entry

If the button "**Start production**" is grey, it has been more than 24h since a control cycle has been performed.



During operation, production can be stopped, press "**Stop production**".

8.7.1 - Manual Control cycle

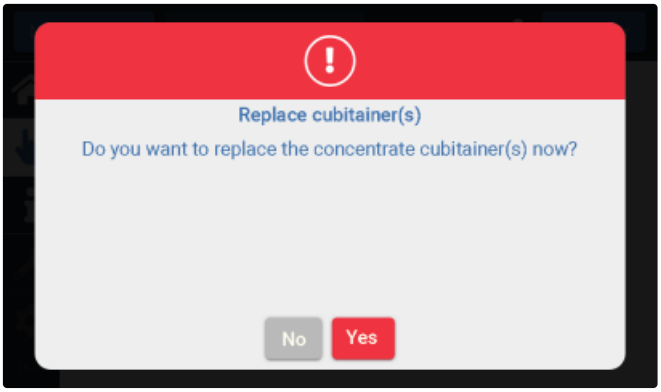
his option can be used if an additional control cycle has to be performed. A control cycle will take maximum 20 minutes. For this step the door has to be closed.

1. Select '**Log in**'
2. Enter credentials
3. Select tab '**Manual**'

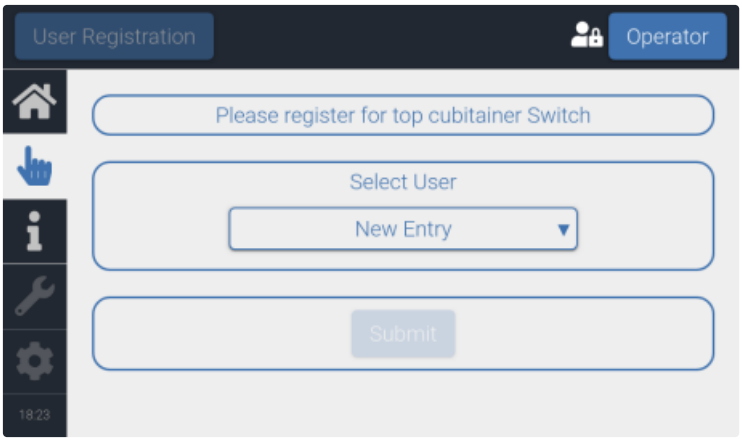
4. Select "**Start Control cycle**", initiating the control cycle.
The instrument will start the control cycle once the current process is finalized. Once the cycle is done, production is continued automatically.
5. Log out or otherwise log-out will occur automatically after 5 minutes of inactivity.

8.7.2 - Replace cubitainer function and adding users

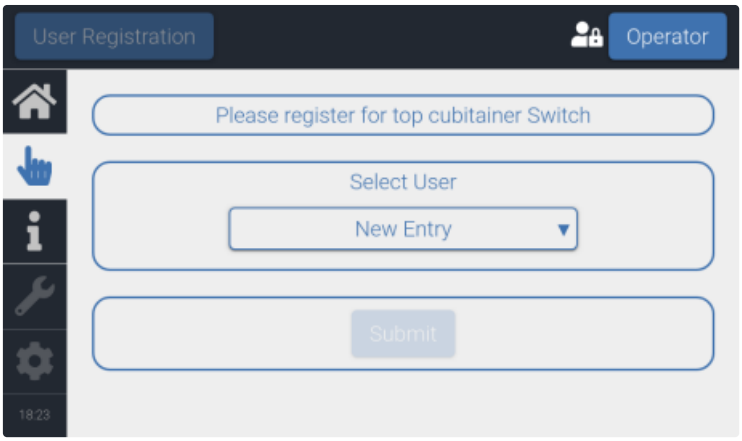
A new cubitainer has to be installed after a reagent warning or error message. After selecting **Replace cubitainer** the following message appears:



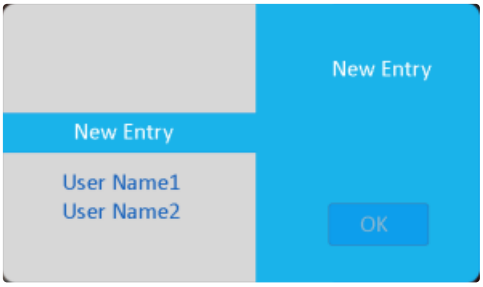
Press **Yes**, the following screen appears, enter new or existing user information.



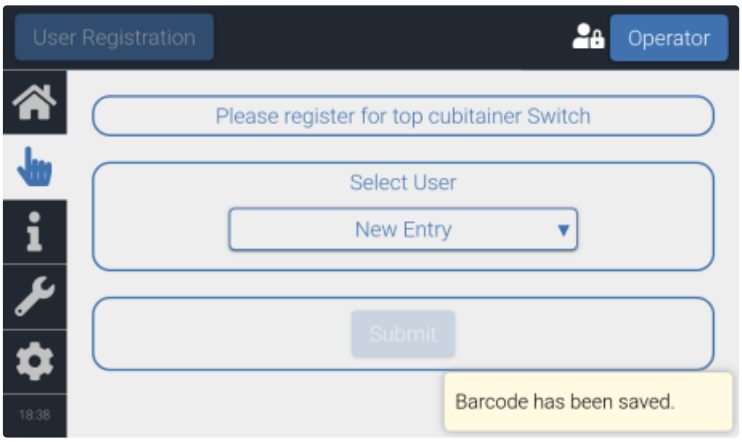
Click on "new entry" to add a new user. The following screen appears:



The next time, this user can be selected from the list.



Press **Submit** and it will be confirmed that all the concentrate information has been stored correctly:

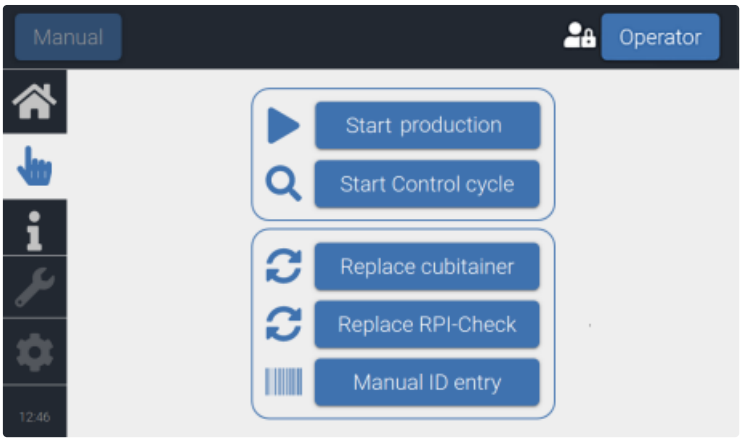


8.7.3 - Manual insert cubitainer ID

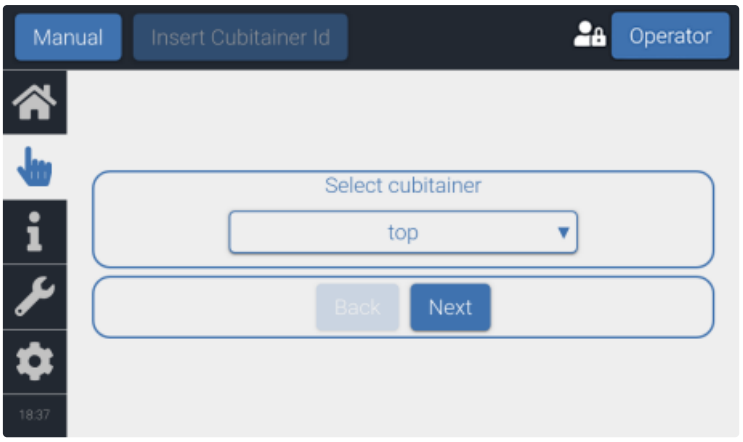
Disclaimer
This is not the recommended process.
"By manually entering the cubitainer ID the instrument is unable to determine and track the consumption from that cubitainer. The user accepts all performance and potential legal consequences that this action may have"

1. Select '**Log in**', in the right side of the screen.
2. Enter access level credentials.
3. Select **Manual** tab.

4. Select '**Manual ID entry**'.



5. Select applicable "top" or "bottom" concentrated reagent.



6. Enter applicable data, exactly as printed on the cubitainer label and press **Next**.

Manual entered data is marked in grey, the liquid level of a cubitainer with manual entered data is not tracked by the software, production is stopped in case of insufficient level of concentrated reagent. Press Submit to enter the data.

In case the entered cubitainer ID is not accepted by the instrument, repeat the process.

7. Log out or otherwise log-out will occur automatically after 5 minutes of inactivity.

8.7.4 - Manual insert RPI-Check ID

1. Select '**Log in**', in the right side of the screen.
2. Enter access level credentials.
3. Select **Manual** tab.
4. Select '**Manual ID entry**'. Follow the instructions on the screen, select RPI-Check.

5. Go to the customer portal of www.rrmechatronics.com to obtain an ID for RPI-Check.

Enter batch number and expiry date and an ID is generated.

This ID can be entered in the software as manual inserted ID for RPI-Check

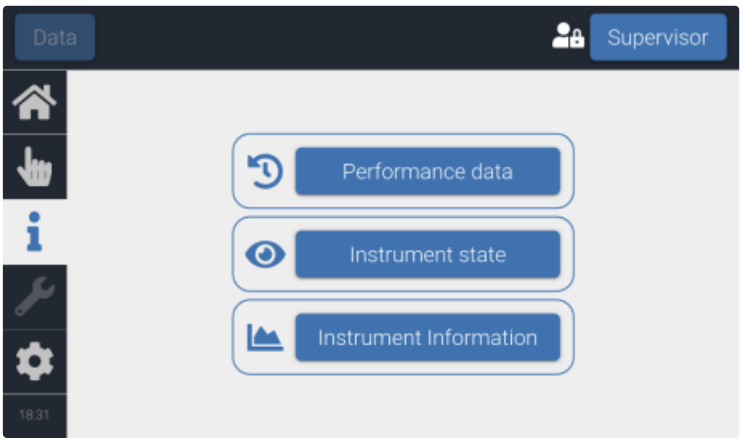
In case the entered RPI-Check ID is not accepted by the instrument, repeat the process.

6. Log out or otherwise log-out will occur automatically after 5 minutes of inactivity.

Disclaimer
"By manually entering the cubitainer ID the instrument is unable to determine and track the consumption from that cubitainer. The user accepts all performance and potential legal consequences that this action may have"

8.8 - Information screen

Select Information .



Three options are available:

Performance data

To retrieve data from a specific batch of concentrate, RPI-Check and traceabilty.

Instrument state

To see the status of the instrument.

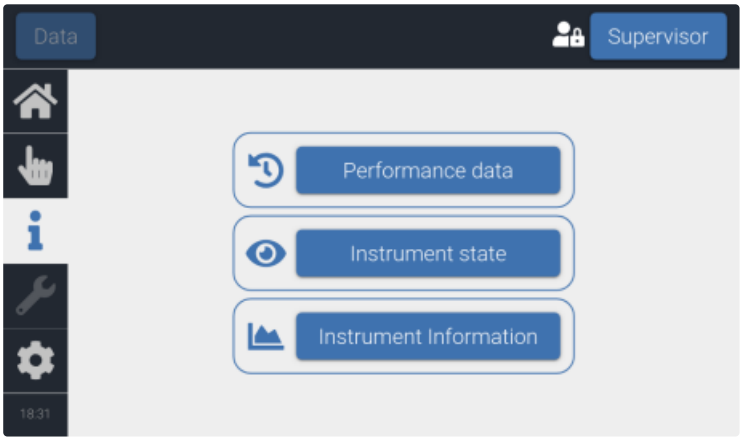
Instrument information

For general information about the instrument configuration.

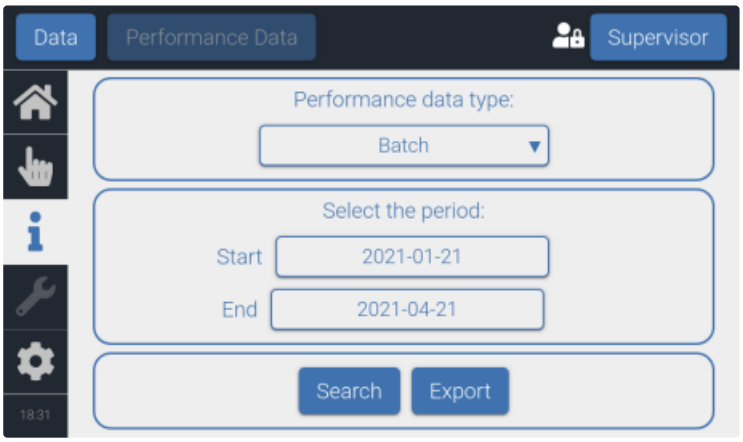
8.8.1 - Retrieve performance data

Use an empty, virus-free, USB stick, formatted with FAT32.

1. Select '**Login**'
2. Enter access level credentials
3. Select "Information"tab



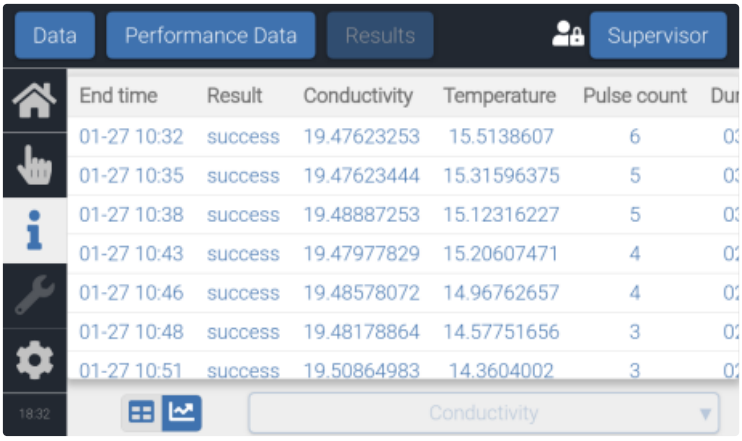
4. Select 'Performance Data'.



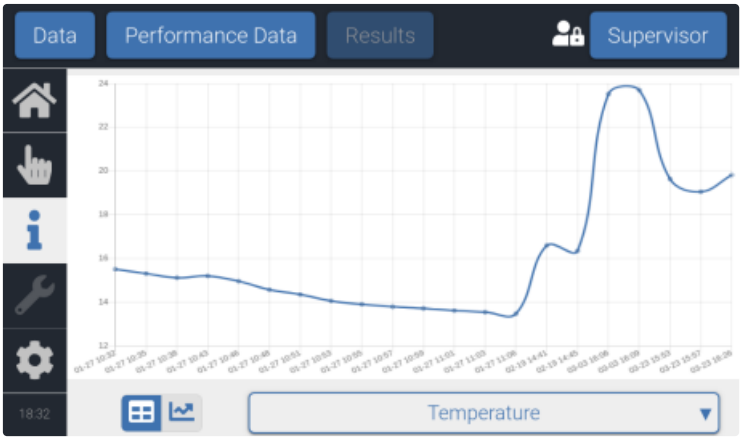
5. Data can be shown on screen with **Search**, data can be exported with **Export**.

Search option:

On screen can be seen: End time, Result, Conductivity, Temperature, Pulse count and Duration.



After using the table button: The available data is shown as a graph.



Export option:

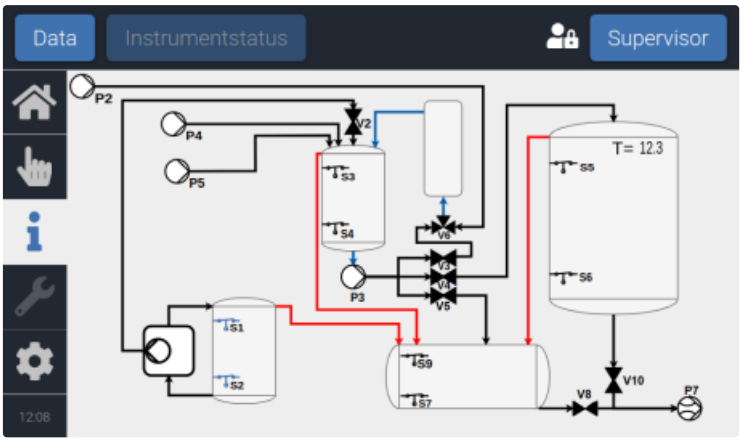
1. Select "**Performance Data**".
2. Insert an empty USB stick in the slot located at the front of the instrument, near the GUI screen.
3. Choose which data type has to be exported: batch data, control data or traceability data.
4. Select the period of which data is to be downloaded.
5. Press "**Export**" to copy the data (.CSV format) on the USB-stick.
6. After confirmation that the data is copied successfully, remove the USB stick.

The Batch.CSV contains the following data: Duration, batch id, temperature, conductivity, production total, date end, time end

The Control.CSV contains the following data: State, Timestamp, Initial cell constant , Calculated cell constant, Offset success, Gain success, Error information (3 columns).

The Traceability report contains the following data: Name and surname of the operator, Cubitainer id, data opened, Location (top, bottom, control), also manual entered information is included.

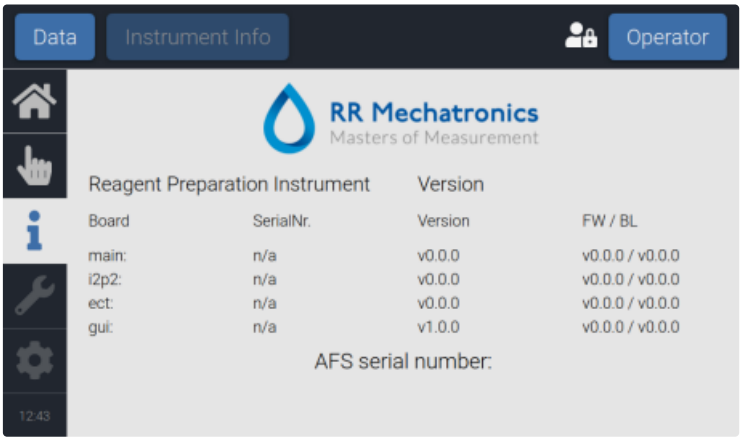
8.8.2 - Instrument state



This screen only indicates in which lines is an active water flow (in blue). The lines in black are not containing water at that moment.

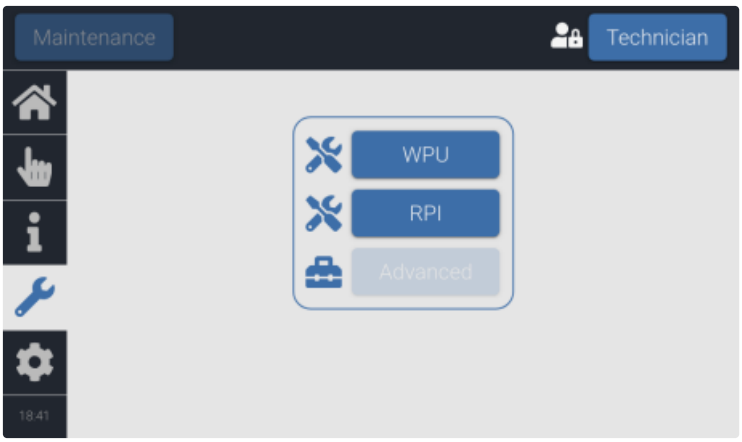
The overflow lines are only indicated in red, meaning an inactive water flow.

8.8.3 - Instrument information



On this screen general information, several software status and serial numbers are displayed.

8.9 - Maintenance screen

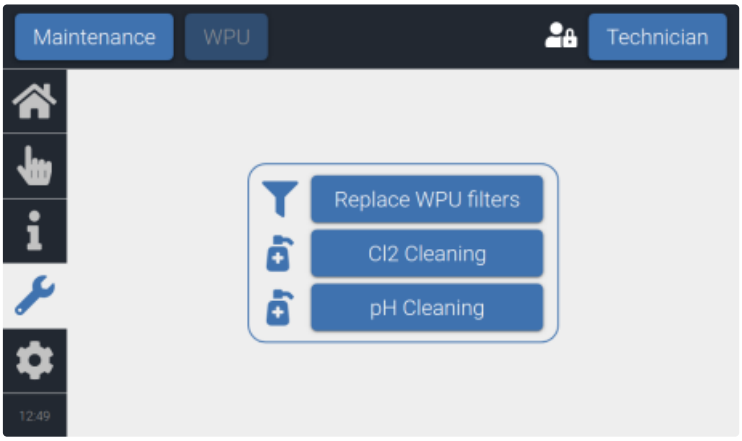


In the Maintenance screen, two options are available on Technician access level:

WPU , with maintenance functions for the WPU (filter replacement and cleaning).

RPI , with maintenance functions for the RPI (cleaning, replacement of standard parts and shut down).

8.9.1 - WPU maintenance



The filter packs in the WPU requires replacing or cleaning (Cl or pH). The WPU display provides an indicator for required actions. This display is visible through the sight glass.

Note: During these actions, production of ready-to-use reagent is paused.

See "*User manual AFS® 8, 16, 24*" for further instructions for the following items.

- **Replace WPU filters**
- **Cl2 Cleaning**
- **pH Cleaning**

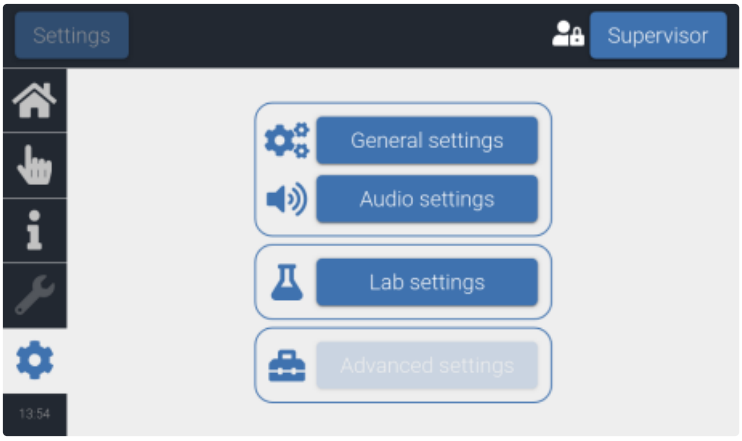
Confirm finishing the WPU Maintenance actions after they are performed. The RPI will go back to online.

8.9.2 - RPI maintenance

On the level Technician are options available for regular replacement items:

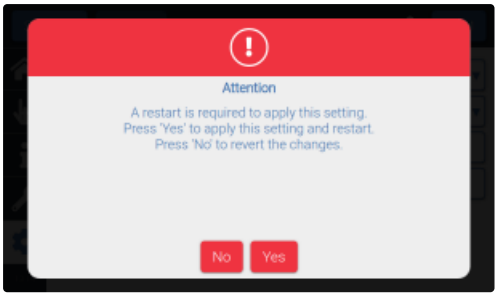
- Replace Vent filter
- Replace Peristaltic pump tubes
- Replace pick-up tubes / End point filters
  - *Note: During these actions, production of ready-to-use reagent is paused.*

8.10 - Settings



General settings:

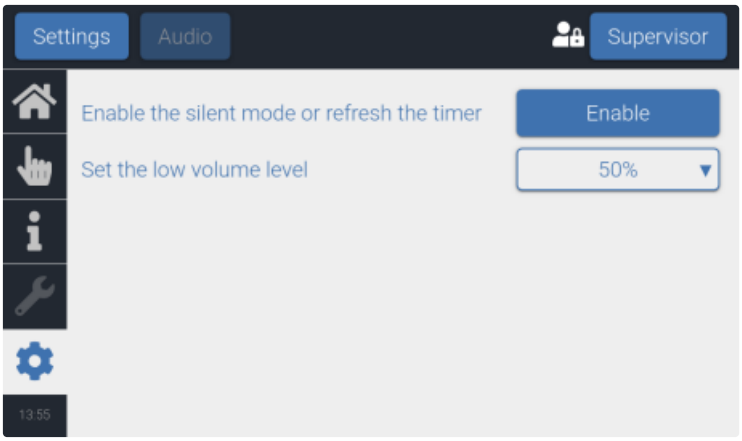
Change language: Select your language (if available)



Set the time zone, date and time with the next options. To apply Time and timezone settings a restart is required.

Note: Daylight saving time has to be set manually, the RPI is not connected with an external network.

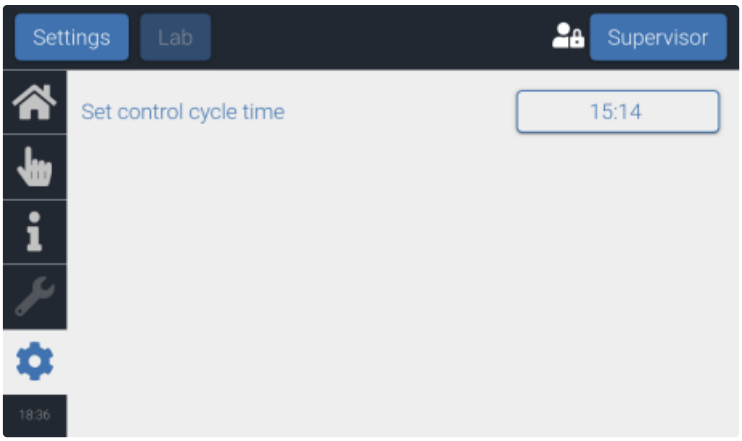
Audio settings:



After enabling the the silent mode, the timer can be refreshed for one hour.

With adjusting the sound volume., the normal sound level can be set. Only error messages signals will stay at the same level.

Lab settings:



Set control cycle time: For setting the time for the automatic control cycle.

9

Operational precautions, limitations and hazards

The RPI and the incorporated WPU should be operated according to the instructions in this manual and the manual of the WPU (AFS24). In particular, the hydraulic and electrical specifications should be followed and met. It is important to use this equipment as specified in this manual; using this equipment in a different manner may impair the safety precautions of the instrument.

IMPORTANT! Your RPI should be installed and operated in a clean and dry area. Please refer to the environment requirements.

General

- The RPI is not designed for domestic use.
- Use this instrument only as the stated intended use . The user is not protected in case of any other use (including use of not original or prescribed parts).
- When the instrument is not used (including overnight), the water supply must be closed to avoid water spillage accidents.
- Any serious incident that has occurred in relation to the instrument must be reported to the distributor and/or manufacturer and the competent local authorities.
- This device complies with the FCC RF exposure limits and has been evaluated in compliance with mobile exposure conditions. The equipment must be installed and operated with minimum distance of 20 cm of the human body.
- The USB-port on the outside of the instrument is only to be used for data export. All other (internal) USB-ports are only for use by the instrument, not for external devices.

Operation

- Read the instructions before operating the instrument. Observe all cautionary markings in the manual and on the instrument. Keep this manual for future reference.
- Do not spill fluids on to the instrument. This could cause a short-circuit. If this happens, turn the main switch OFF immediately and unplug the power cable. Contact your Service Representative.
- Do not place any objects on the instrument.
- The instrument panels may only be removed by trained personnel.
- If there is any doubt about proper instrument use and functionality, contact the distributor.
- Maintenance and repairs are only to be performed by trained Lab Technicians or a Field Service Engineer.
- If the RPI has to be shut off for a long period of time, at first the shut down cycle has to be performed by a trained Field Service Engineer. Contact your Service Representative.

Power Supply

- The power connection has to be accessible at any time, the power cord is functioning as disconnecting device.
- Should the instrument emit unusual smell or smoke, turn the main switch OFF immediately and unplug the power cable. Using the instrument further carries the risk of fire, electric shock or personal injury. Contact your Service Representative. Do not disconnect the power for any other reason.
- Do not touch the electric circuits inside the instrument particularly with wet hands, as there is a risk of electric shock.
- This instrument must be connected to a power outlet of the correct voltage. Please note that the instrument must be earthed. Use only the original delivered main power cord or exact equivalent with wire thickness of 3x1.0 mm2 (AWG 18) according local regulations.
- Avoid damage to the power cable. Do not place any appliances on the power cable or pull on the power cable.

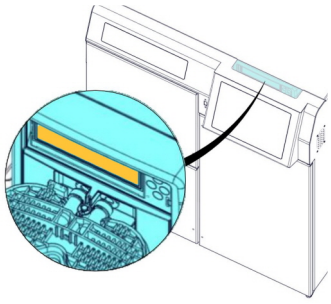
9.1 - Avoidance of infection

The internal fluid containers may never be opened by the user, but only by trained service personnel. During prolonged use of the RPI, harmful bacteria (f.e. legionella) may grow inside the containers. Before the containers are opened, the disinfection procedure must be performed (see section Maintenance-Cleaning for details).

10

Troubleshooting

In case of errors, the system will generate an error message on the GUI. Also, the (optional) status light will be changed from green to orange in the case of warning, or to red in the case of a production error. Warnings and errors of the WPU are displayed on the AFS-display (visible from the outside)

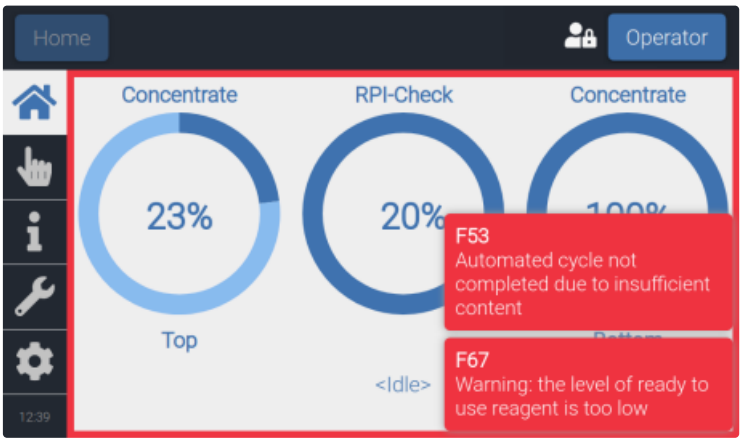


Occurring errors are indicated on the screens with red outlines and error codes with descriptions. These messages can be minimized if these errors can be solved later.

Indication messages are also displayed when there are multiple errors at the same time, errors originated by other errors, or action is needed but errors are active."

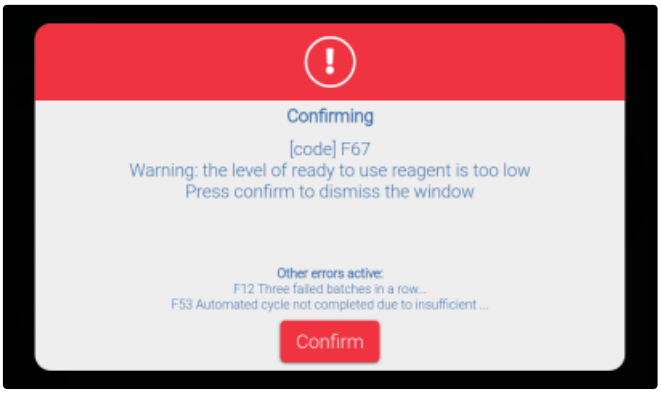
If errors can be resolved automatically it is indicated, Some errors are fatal, service is needed. See the Error list for more infomation.

If more errors are active it will be shown:



The error message(s) can be minimized:

If more errors are active, it will be indicated:



10.1 - No water

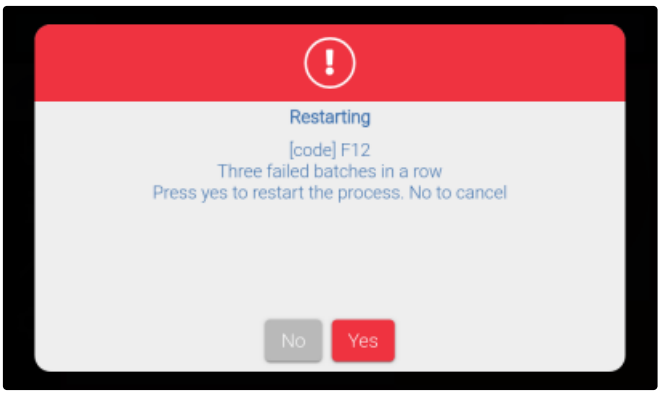
-Possible stop of water supply, check water connection/supply.

-WPU-error, check display of the WPU-unit, in case of no water, check tubing and water supply.

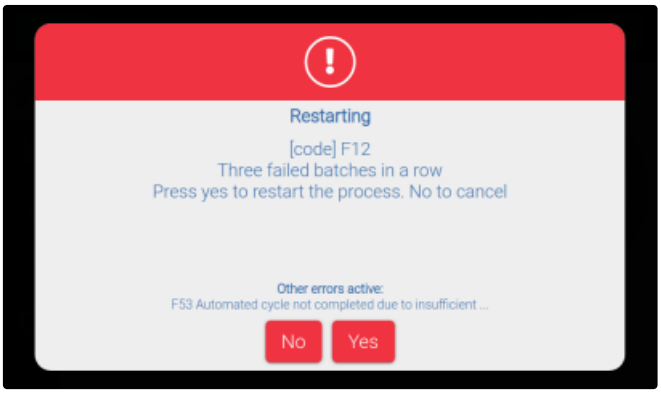
10.2 - Concentrated reagent information is not recognized

If after placing a new concentrated reagent cubitainer the data is not recognized (error F55), the instrument will not start production. This data has to be manually added in the cubitainers menu.

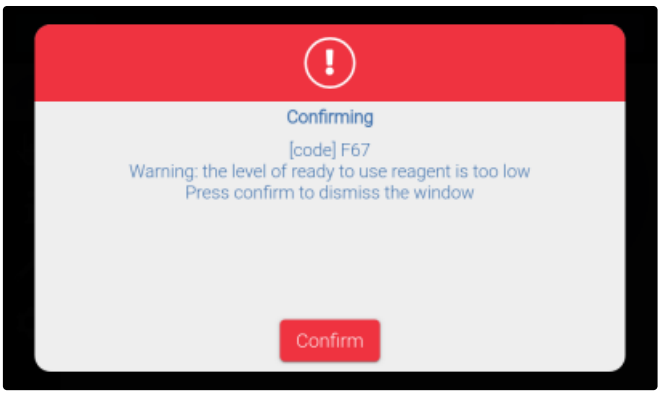
10.3 - Reagent errors



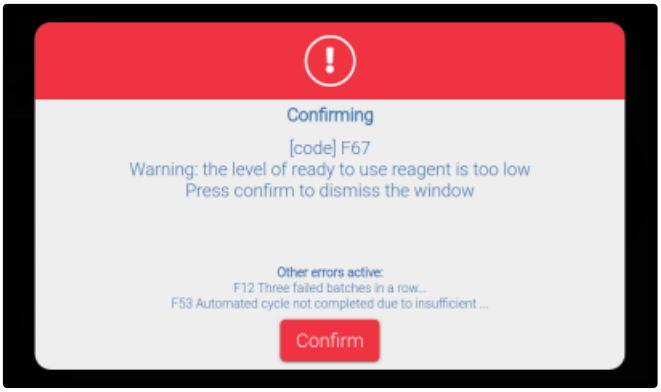
Check the cubitainer connection or replace the cubitainer if this error persists.



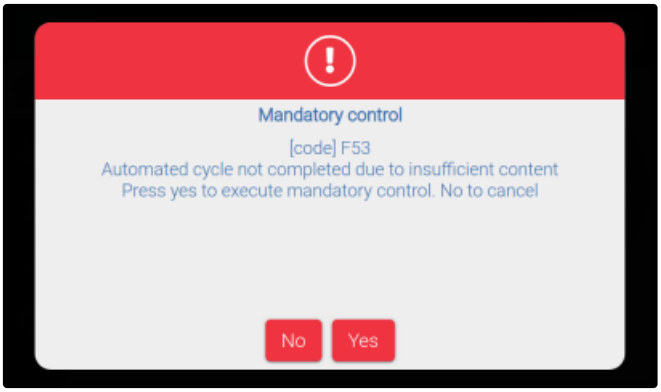
Press confirm to continue:



Press confirm and solve other errors if needed:



Press No to cancel or Yes to execute the control process:



10.4 - Control cycle does not start or fails

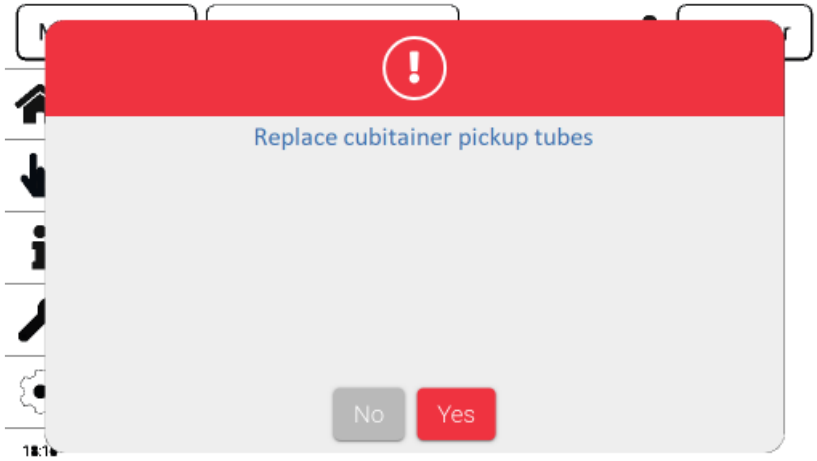
If the automatic control and manual control does not start:

- Check if the door is closed.
- DI-vessel is not filled (enough), check water supply and WPU-unit.
- Check/replace RPI-Check Peristaltic pump tube T30 .

11

Maintenance

Required maintenance items will be indicated by messages, which only can be removed after correct replacement and confirmation by a trained Lab Technician (quarterly maintenance) or Field Service Engineer (quarterly maintenance/yearly maintenance.



Inform the Lab Technician or your Field Service for performing maintenance as soon as possible. We recommend performing the maintenance in time to be sure the instrument will produce reagent as required. Delayed maintenance can result in poor quality, instrument failure and downtime.

Replacing Vent Filter, Peristaltic pump tubes, Pick-up tubes and End filters can be performed by the Lab Technician. It is advisable performing maintenance outside peak hours because production will be stopped during replacements.

The yearly maintenance and incidental replacement of other parts can only be performed by the Field Service Engineer.

If the instrument is in standby mode after maintenance and/or repair without any errors, the instrument can be used for production.

11.1 - Maintenance items & Maintenance schedule RPI

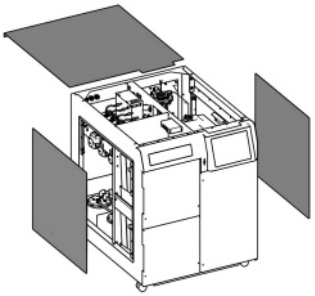
Item	Order nr.	Interval	Performed by
Concentrated Reagent	customer specific	If empty	Operator
RPI-Check	A0020487 (12 pcs)	If empty	Operator
Quarterly maintenance RPI (with parts from Quarterly Maintenance Kit A0020395):			
Replacement endpoint filters & tubing (4 pcs)	QLV0400013	3 months	Lab technician
Replacement RPI-Check tubing (1 pcs)	A0020834	3 months	Lab technician
Replacement concentrate tubing (2 pcs)	A0022758 (ECO)	3 months	Lab technician
Replace Concentrate pickup tubes (2 pcs)	A0022751 (ECO)	3 months	Lab technician
Vent filter	SQWLV040002	3 months	Lab technician
Maintenance of WPU unit:			
Replacement WPU filters	see AFS manual	5/6 months	Lab technician
Chlorine treatment of WPU	see AFS manual	upon instrument request~3 months	Lab technician
pH treatment of WPU	see AFS manual	upon instrument request~1 year	Lab technician
Yearly maintenance:			
Scheduled RPI maintenance with use of Yearly Maintenance Kit	with parts from A0020396	1 year	FSE
Scheduled WPU maintenance (AFS-24)	see AFS manual	1 year	Merck FSE

Chloride cleaning tablet	Merck ZWCL01F50 / Merck 5874316024 (US only) / Merck 5874316024C (Canada only)	1 year + on repairs	FSE
O-ring Vent filter	A0020832	1 year	FSE

Other parts:

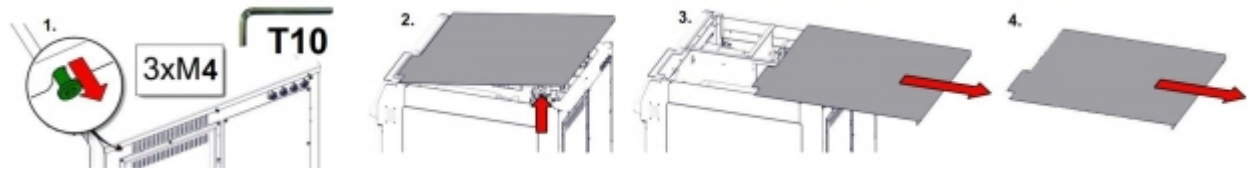
External tubing set	A0020393		
Concentrate tubing kit (Beckman Coulter)	A0019376	For replacing complete assembly consists of A0019806 Pick up tube A0019392 Peristaltic pump tube A0019520 Harness	

11.2 - Removing and replacing cover panels



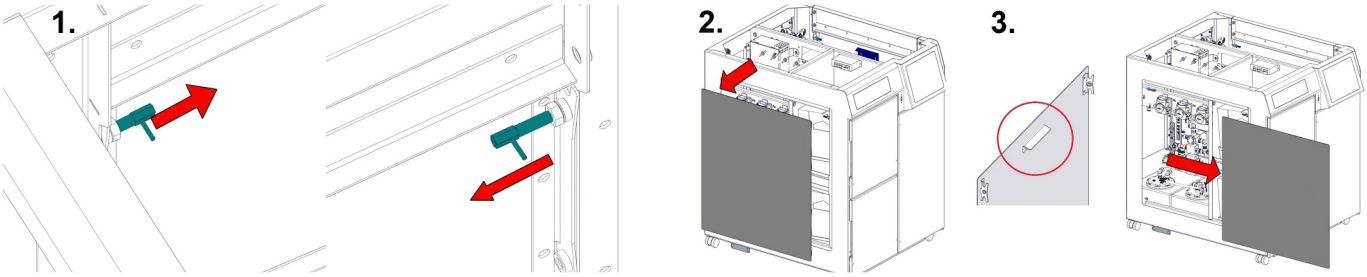
Remove top panel

1. Loosen the three M4 torx screws with torx key T10 (stored in plastic bag inside the door).
2. Lift the rear of the top cover approximately 5 cm.
3. Pull top cover to the rear.
   Now you can fully remove the top panel from RPI.
4. Place the top panel in a suitable location until it is placed back.



Remove side panels

1. Undo the latches from a side panel on the inside of the RPI.
2. Now gently push the side panel outwards.
3. Lift the side cover up out of the lower supports with use of the grip.
   Place the side cover in a suitable location until it is placed back.
4. Repeat Steps 1 to 4 for the other side panel.



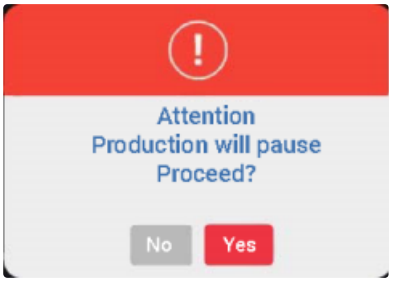
Reverse the steps to put the panels back.

11.3 - Replacing the Vent filter

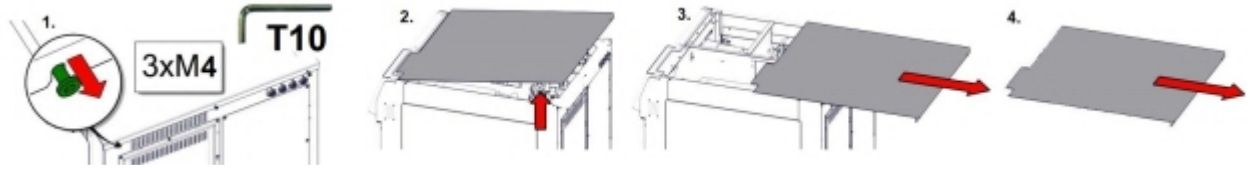
Only to be performed by a trained Lab Technician or FSE. Be aware of liquid spilling, use a cloth to prevent liquid dripping in the instrument.

The vent filter (SQWLV040002) must be replaced every 3 months. This is indicated before the due date and the message will be shown until replacement has been done.

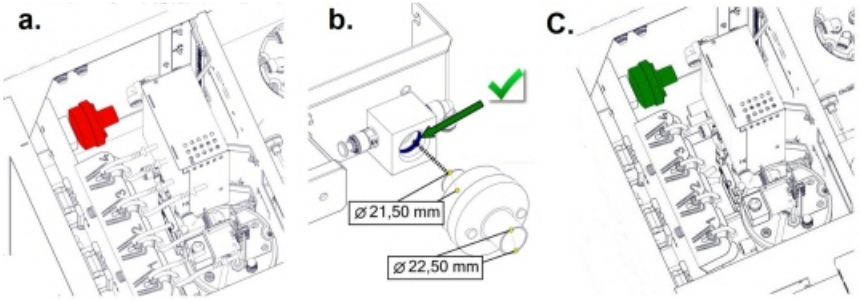
1. Enter software and log in with the applicable credentials.
2. Go to **Maintenance** and select **'RPI"**
3. Press **Replace vent filter**, the following message is given:



4. Press **YES** to confirm and start actual replacement.
5. Press **YES** after the message "Instrument will be offline."
6. Remove the top panel by loosening (with Torx T10) the three M4 bolts at the back, lifting up and fully removing from the instrument.



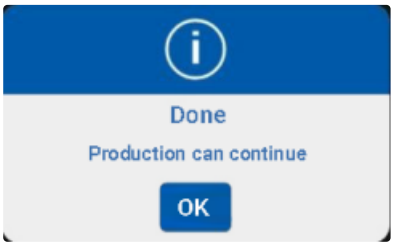
a.Unscrew the old filter,
b.Check O-ring
c.Replace it with a new filter.



If no other actions is needed:

7. Place top panel and fasten with the three bolts.

8. Confirm that replacement is correctly performed.



Production is started again.

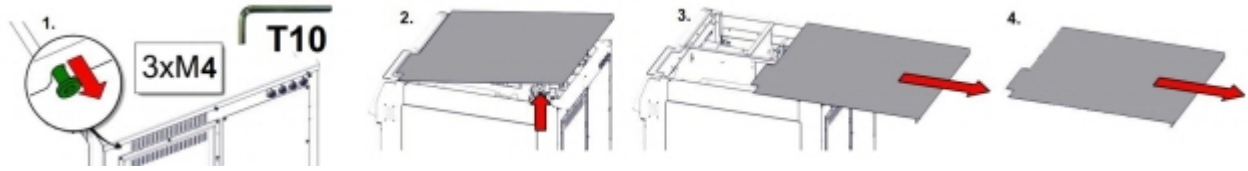
9. Log out or otherwise log-out will occur automatically after 5 minutes of inactivity.
10. Dispose of removed parts according to local regulations.

11.4 - Replacing peristaltic pump tubes

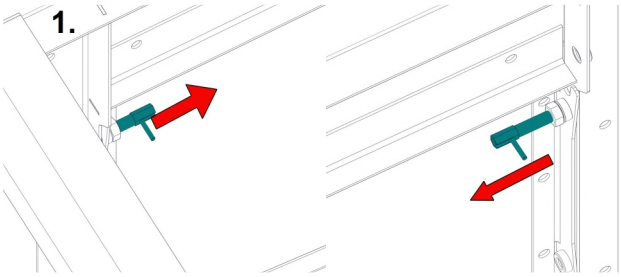
Only to be performed by a trained Lab Technician or FSE. Be aware of liquid spilling, use a cloth to prevent liquid dripping in the instrument.

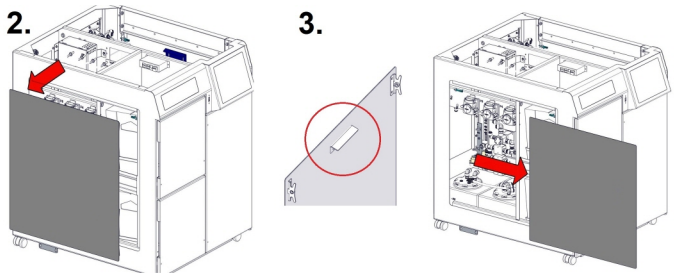
The peristaltic pump tubes T28 and T29 have to replaced every 3 months.

1. Remove the top panel by loosening the three M4 bolts(with Torx T10) at the back, lifting up and fully removing from the instrument.

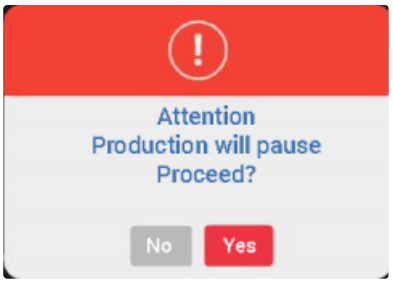


2. Undo the latches from the side panel on the inside of the RPI (1) and remove side panel (2) with use of the handle inside the panel, remove side panel completely (3).



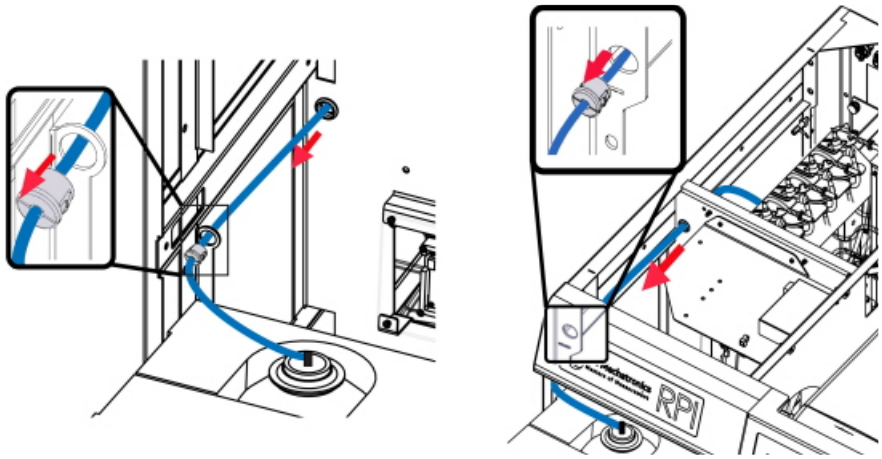


3. Enter software and log in with the applicable credentials.
4. Go to **Maintenance** and select **"RPI"**
5. Press **Replace peristaltic pump tubes**, the following message is given.

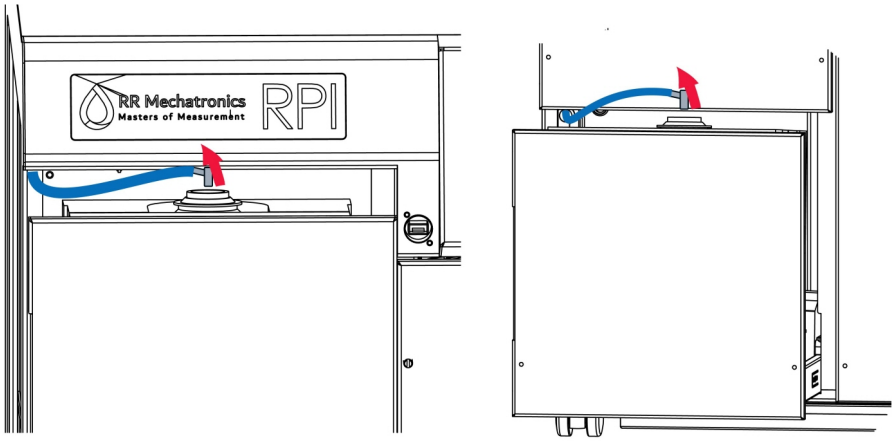


6. Press **YES** to confirm and start actual replacement.
7. Press **YES** after the message "Instrument will be offline."

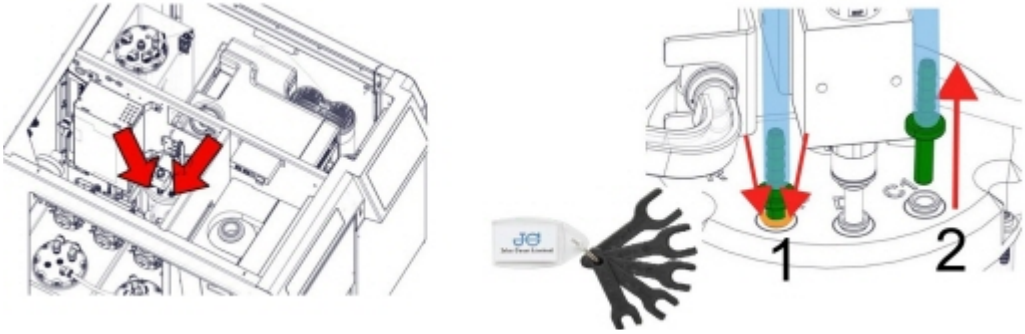
8. Remove the strain relief from the frame.



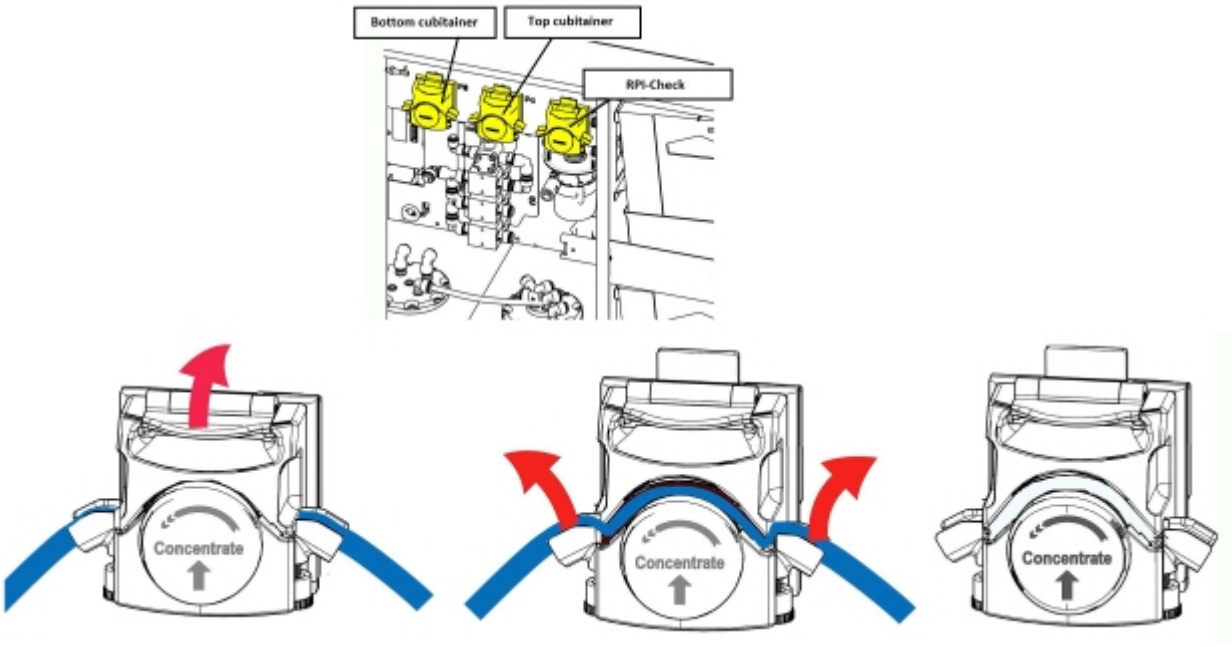
9. Disconnect the pump tubes from the cubitainers.



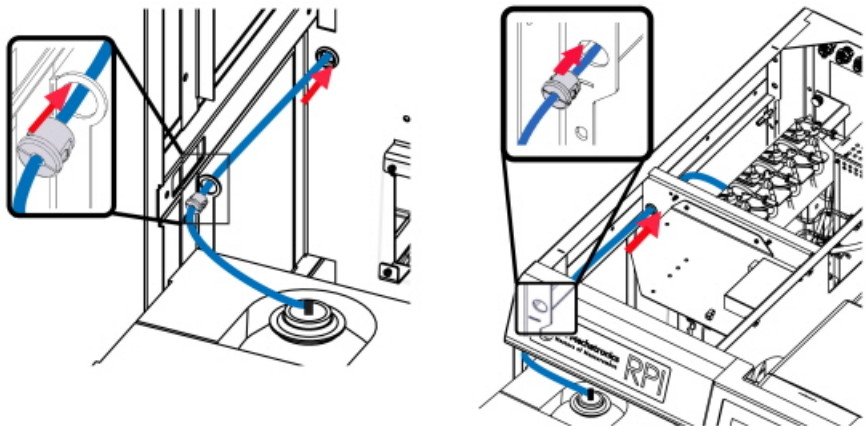
10. Disconnect the pump tubes from the mix vessel. Use the John Guest connection tool to remove the tube coupling.



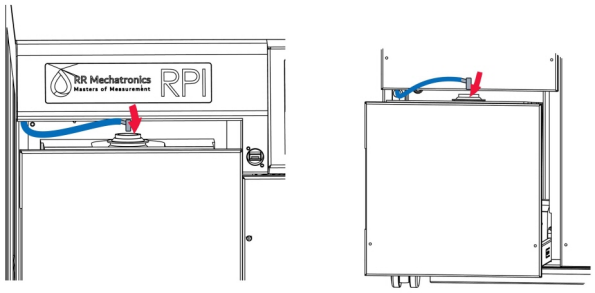
11. Remove the old tubes from the pumps.
    Lift the lever to open the clamp system, remove old tube



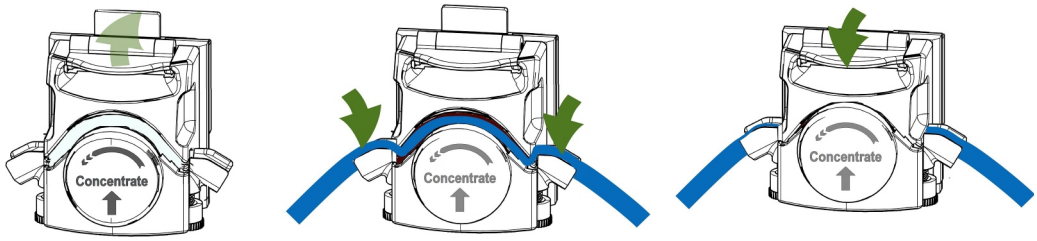
12. Guide the new pump tubes to the holes, push the strain relief in the hole.



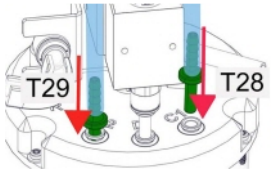
13. Connect the pump tubes with the "quick connect" to the cubitainers and close the drawers.



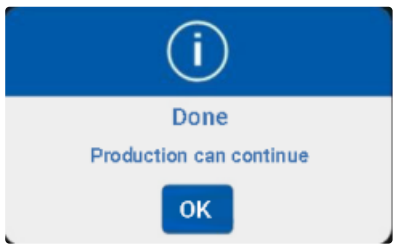
14. Mount new tube in the pumps, close the clamp system again.



15. Connect the new pump tubes to the mix vessel. C1 for top cubitainer (T28), C2 for bottom container (T29).



16. After replacement of the peristaltic pump tubes: confirm the replacement, the instrument primes tubing and rinses the mix vessel.
17. Monitor for leaks prior to replace the panels.
18. Replace the left panel and top panel (if no other maintenance action is needed).
19. Confirm that replacement is correctly performed.



Production will resume.

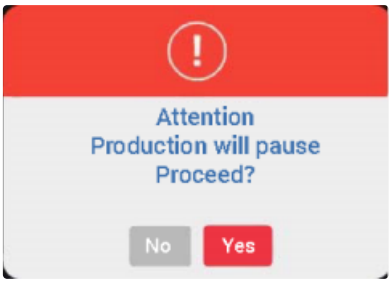
20. Dispose of removed parts according to local regulations.

11.5 - Replacing Pickup tubes/End point filters

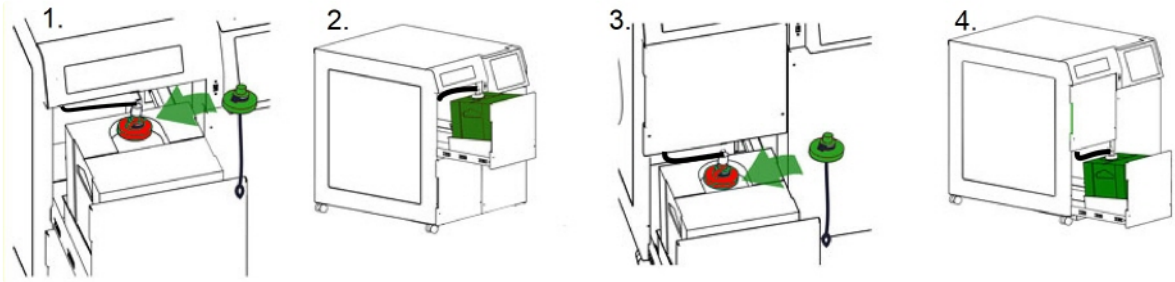
Only to be performed by a trained Lab Technician or FSE. Be aware of liquid spilling, use a cloth to prevent liquid dripping in the instrument.

Replacing Pickup tubes:

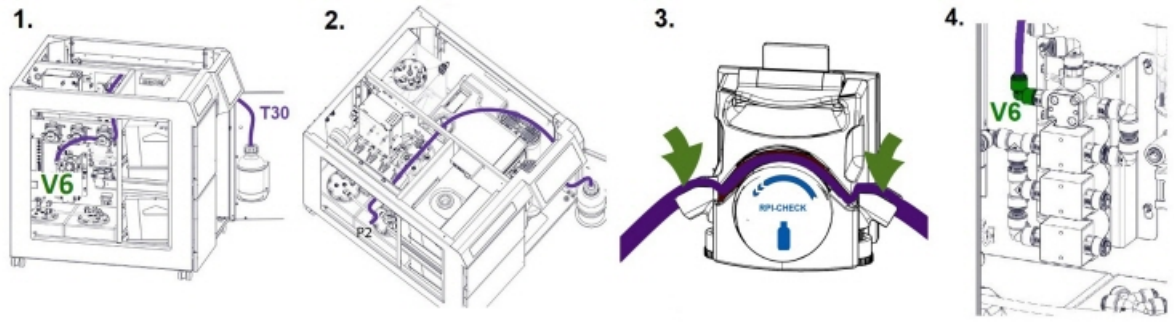
1. Enter software and log in with the applicable credentials.
2. Go to **Maintenance** and select **"RPI".**
3. Press **Replace Pickup tubes/End filter**, the following message is given.



4. Press **YES** to confirm and start actual replacement.
5. Press **YES** after the message "Instrument will be offline."
5. Replace Pick-up tubes of both concentrated reagent cubitainers.

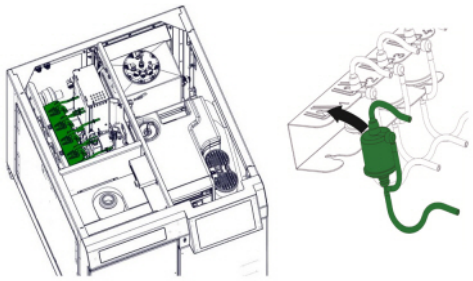


6. Replace T30 from RPI-Check bottle to V6 connection.

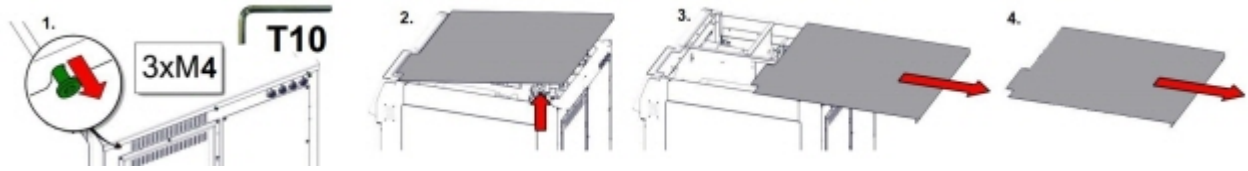


Replacing Endpoint filters and tubing (4xA0017999):

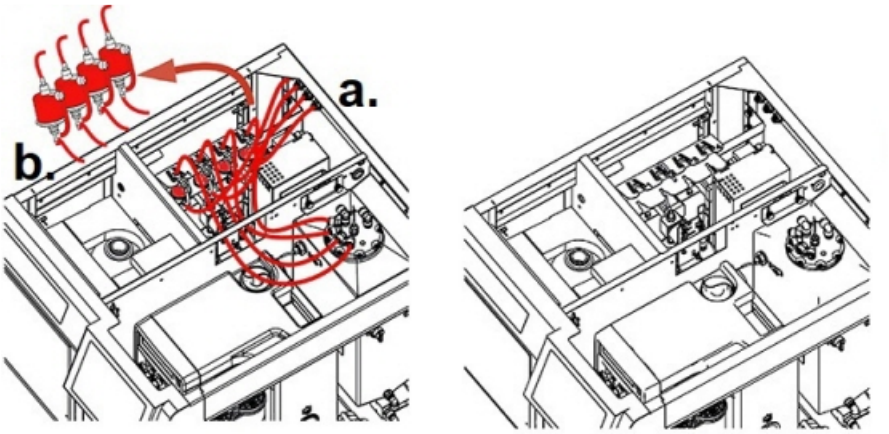
The end point filter module is positioned at the left upper side.



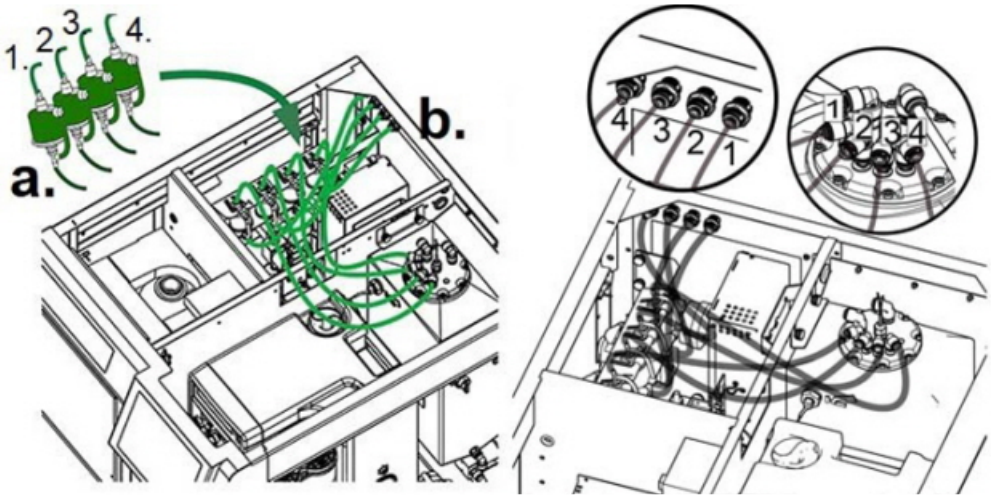
1. Ensure connected analyzers are placed in an operational mode where reagent consumption will not occur.
2. *If not done yet: R*emove the top panel by loosening the three M4 bolts(with Torx T10) at the back, lifting up and fully removing from the instrument.



3. Detach the end filter tubing, take care of leaking fluids and remove the old filters.

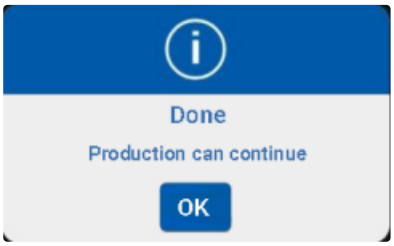


4. Place new A0017999 End point filter assemblies (filters+tubing), connect tubes according the numbers.



5. Place and fasten the top panel and place side panels (if still open) if no other maintenance action is needed.
6. Connected analyzers can resume consumption.

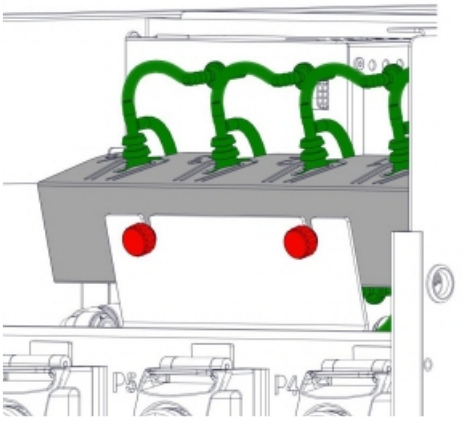
7. Confirm that replacement is correctly performed.

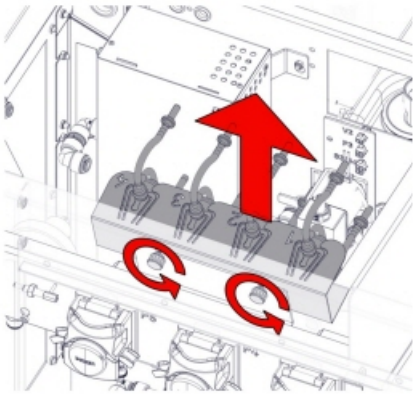


Production will resume.

8. Log out or otherwise log-out will occur automatically after 5 minutes of inactivity.
9. Dispose of removed parts according to local regulations.

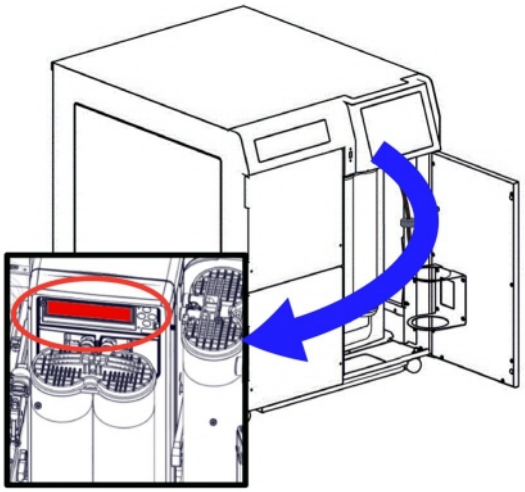
Note: Optional can the complete end filter assembly be demounted after removing the old tubing by loosening the knurled knobs.





11.6 - Maintenance WPU

Needed actions are shown on the screen of the WPU.



For maintenance of the WPU: See AFS24 User manual (Merck). Remove top and right side panel first.

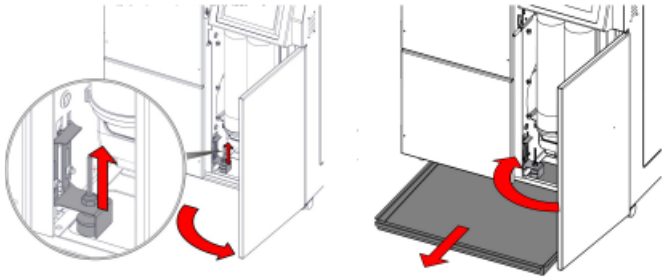
11.7 - Cleaning

The concentrate and reagent tubing are automatically rinsed before each control cycle. As needed a manual rinse cycle can be performed by the Field Service Engineer.

Annually, Service will perform additional internal cleaning during the PM visit.

11.7.1 - Cleaning of the drawers and casing

Remove spilled liquid inside the drawers and drip tray immediately. Lift the drip tray sensor before pulling out the drip tray.



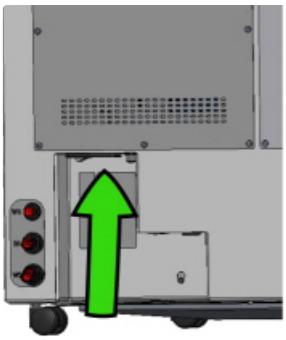
The outer casing of the instrument and the inside of the drawers can be cleaned with any standard (non-abrasive) cleaning agent or soap solution and a microfiber cloth.

The LCD screen and the light box can be cleaned with a clean soft cloth, slightly damped. Do not use organic solvents.

11.8 - Replacing main fuses

The instrument is delivered for 230VAC or 120VAC. Place only the applicable fuses, the voltage rate may not be changed (see Type-plate). The main power entrance is located on the rear side. Move the instrument in a way to reach the main power connection easily.

Order numbers: A0020825 230V (2x3,15 A) / A0023712 (2x6,3 A)



1. Switch power off
2. Disconnect the power plug
3. Pull the fuse holder out from the main power entrance module with use of a screwdriver or other flat tool.

Replace both fuses with the appropriate type, as indicated on the type label and in the Technical specifications .

Push the fuse holder back into the power entrance module.

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Error list

Description	Possible cause(s)	How to solve?
F01 Mix vessel will not fill (process error)	Issue with WPU Instrument failure	LT: Check WPU, drain mix vessel, restart process, if not solved: Fatal error, call for service
F02 Mix vessel will not fill (hardware error)	Issue with WPU Instrument failure	LT: Check WPU, drain mix vessel, restart process, if not solved: Call for service
F03 Mix vessel will not empty	Instrument failure	Call for service
F05 Internal test ECT unit timeout	Issue with the ECT module	Call for service
F06 Air bubbles detected in control process	Bubbles being pumped RPI-Check bottle is (almost) empty RPI-Check tubing/pickup is broken	Replace RPI-Check bottle Check pick up tube If not solved: Call for service
F07 Temperature is out of range	Temperature too high or low	Wait for temperature change
F08 Cell constant out of range	ECT unit issue	Perform Control cycle with another RPI-Check Check RPI-Check tubing Download and send control data to FSE for further analysis
F09 Fluid left in mix vessel (above low float)	DI valve leaking lower float suddenly broken	Call for service
F10 Temperature lab water out of range	Temperature of DI out of range	Check AFS inlet temperature. If not solved, call for service
F11 ECT module is not stable	ECT Sensor error	Restart Control cycle If not solved, call for service

F12 Three failed batches in a row	Wrong estimation of cubitainer contents Peristaltic pump broken Cubitainer pickup tube broken/ bend	Try other cubitainer Re-attach pickup tube Check peristaltic pump tubing on pinching
F13 Wrong order floats in storage vessel	Float switch(es) broken Not correctly connected	Call for service
F14 Wrong order floats in lab water vessel	Float switch(es) broken Not correctly connected	Call for service
F15 Power to wpu on, but it takes too long for vessel to be filled until lower float	WPU not producing No water supply to AFS	Check water supply AFS
F16 Wrong order floats in mix vessel	Float switch(es) broken Not correctly connected	Call for service
F17 Wrong order floats in overflow vessel	Float switch(es) broken Not correctly connected	Call for service
F18 Leak detection triggered	Leak Accidental spilling of e.g. RPI-Check fluid	Check vessels and tubes and replace leaking pick-up tubes.
F19 Waste pump not active and overflow upper float triggered	Float switch(es) broken Waste pump broken	Call for service
F20 ECT configuration is missing or damaged	Electronics malfunction	Call for service

F21 ECT Internal test failed	Electronics malfunction	Call for service
F22 ECT electrical amplification malfuction	Electronics malfunction	Call for service
F23 Suspect WPU is not producing lab water	Electronics malfunction AFS	Call for service
F24 Draining does not cause fluid level to decrease	Pump is broken Valve is broken Floats stuck	Call for service
F25 Internal communication failure	Electronics/Cable failure	Call for service

F26 CAN address error	Wiring incorrect or electronics failure	Call for service
F27 ECT measurement precision too low	ECT error	Call for service
F28 ECT module doesn't have valid control data	Fluid bottle is empty ECT module issue	(re)start Control cycle Place RPI-Check bottle Call for service
F29 No conductivity detected after starting control cycle	Pickup tube/Peristaltic pump tube issue	Replace the peristaltic tubing Restart the control cycle

F50 Temperature of 1x reagent in the storage vessel out of range	External temperature too high or too low	Automatic Drain storage and wait for restart production
F51 NFC tag for RPI-Check not successfully read and door is closed	No RPI-Check bottle installed NFC tag damaged Control orientation incorrect	Place new bottle or move control bottle
F52 RPI-Check content too low for next cycle	After control cycle, too little RPI-Check for next control cycle	Place new control bottle
F53 Automated cycle not completed due to insufficient content	Not sufficient RPI-Check when starting control cycle	Place new control bottle and start control cycle

F54 One concentrate cubitainer empty	Placement of new cubitainer is advised	Place new cubitainer
F55 One concentrate cubitainer not detected	No cubitainer installed NFC tag damaged Cubitainer orientation incorrect	Reposition cubitainer If still not read: Add NFC tag manually
F56 Both concentrate cubitainers empty/not detected	Production is on hold	Place two new cubitainers

F57 Open life one concentrate cubitainer expired	Open life of the concentrate RPI-Check is expired	Check cubitainers and bottle, replace applicable
F58 Open life both concentrate cubitainers expired	Open life of the concentrate RPI-Check is expired	Check cubitainers and bottle, replace applicable

F59 RPI-Check bottle open life expired	Open life expiration is detected	Replace RPI-Check bottle
F60 When starting control, open life expired	After start of control step shelf life expiration is detected	Replace RPI-Check bottle
F61 Shelf life one concentrate cubitainer expired	Shelf life expiration is detected	Replace cubitainer
F62 Shelf life both concentrate cubitainers expired	Shelf life expiration is detected	Replace cubitainers
F63 RPI-Check bottle shelf life expired	Shelf life expiration is detected	Replace RPI-Check bottle
F64 When starting control, shelf life expired	Shelf life expiration is detected	Replace RPI-Check bottle

F65 Door opened without logging in. Please close the door, or log in by pressing confirm	Unauthorized action	Close door/drawer or log in
F66 Internal communication error	Menu not found	Navigate to other menu Retry action that caused the error
F67 Warning: the level of ready to use reagent is too low	Low level of production. Risk of air bubbles. Will occur after lot switch.	In case of recurrence: Replace filters of WPU Call for Service

F68 Warning: cubitainer tag could not be read	Damaged NFC tag or NFC reader failure	Enter barcode manually
F69 Warning: The instrument is not configured for this type of cubitainer	Not supported type of cubitainer placed	Replace cubitainer with correct producer ID
F70 Warning: Entered barcode information is not valid	Mistyping or incomplete enter barcode	Enter correct barcode
F71 Database failure	System error	Call for service

F72 Error: Expiration date of manual barcode has already passed	Placed concentrate is out of date	Replace cubitainer with correct expiration date
F73 An unexpected error has occurred in the tagreader	NFC reader failure	Call for service
F74 Tag is write protected and cannot be used	Unusable tag on place cubitainer	Replace cubitainer with a writable tag
F75 Maintenance: Cleaning procedure is required		Call for service
F76 Maintenance: Replace the cubitainer pickup tubes		LT: Replace Cubitainer pickup tubes
F77 Maintenance: Replace the peristaltic pump tubes.		LT: Replace the peristaltic pump tubes.
F78 Maintenance: Replace the endpoint filters		LT: Replace endpoint filters
F79 Maintenance: Replace the vent filter		LT: Replace vent filter
F80 Maintenance: Annual maintenance is required		Annual maintenance is due, please contact your service engineer

13

System temporarily out of use

Als het instrument niet gebruikt wordt (inclusief 's nachts) dient de watertoevoer afgesloten te worden om incidenten met waterverspilling te voorkomen. Activeer de "LAb gesloten"modus van de WPU-eenheid.

If the RPI is shut off for a long period of time: Call for service, this can only be performed by a Field Service Engineer.

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Decommissioning and disposal

Only to be performed by a trained FSE.

In case of permanent removal of the instrument

1. Remove all data from the memory.
2. Perform a complete shut of procedure to remove all fluids from the instrument.
3. Remove the battery from the touch screen unit.
4. Dispose of the instrument and its parts according national or local regulations.

15

Glossary of Terms

Cell constant: A cell constant converts the measured conductivity value of a fluid with known conductivity (= a control fluid) into the known conductivity value of that control fluid.

Cl2 cleaning: Cleaning of the inside of the membranes of the AFS-24 with chlorine

CLRW: Clinical Laboratory Reagent Water

ECT: Electronic Conductivity and Temperature

End point filter: 0.22 µm filters positioned between the reagent buffer tank and the distribution ports on the back of the instrument

GUI: Graphical User Interface

IVD is short for **In Vitro Diagnostic.** This kind of diagnostic is performed on biological samples in a test tube, or more generally in a controlled environment outside a living organism. *In vitro* means *in glass* in Latin.

MRN is short for **Master Registration Number**. It is used as an identification number for any manual for Mechatronics products.

MSDS is short for **Material Safety Data Sheet**. In this type of MSDS all kind of important data can be found on reagents.

Progard: Pre filter pack positioned on the side of the Water Purification Unit

RPI: Reagent Preparation Instrument

WPU: Water Purification Unit (AFS-24 Merck)

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