R-Biopharm AG

RIDA qLine® autoBlot

User manual – version 1.0

R-Biopharm – for reliable diagnostics.

It is important to read this manual before using the instrument

Please read this manual carefully before using the instrument and make it accessible to all users. Failure to comply with the instructions in this manual will void the manufacturer's warranty and may pose a risk to the user.
Ensure all users are conversant with the instrument - contact R-Biopharm AG for any further instrument or training requirements if in any doubt before using the instrument.
Consult User Manual where symbol (left) is seen on the instrument

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User manual
RIDA qline® autoBlot
Art. Nr. ZG3101
Revision 1.0 (2017-12-14)

Contents

1 Intended use

For in-vitro Diagnostics. The RIDA qLine® autoBlot is a fully automated Analyzer for the processing of up to 36 RIDA qLine® Allergy membranes for the quantitative determination of specific IgE antibodies in human serum or citrate plasma in one run in combination with the software RIDA qLine® Soft.

2 Introduction

2.1 Purpose

The purpose of this document is to provide end-users with a complete overview of the RIDA qline® autoBlot (henceforth named as "autoBlot") instrument, to such an extent that once the document has been read, the reader will have an understanding of what the instrument does and how it can be operated to fully utilize its potential.

2.2 Product Overview

The RIDA qLine® autoBlot was designed for the automated processing of RIDA qLine® Allergy Lineblot assays using all appropriate matrices. With no exception, the instrument can only be used by trained personnel and only with liquids and substances appropriate for RIDA qLine® autoBlot. The standard deviations for pipetting volumes determined by R-Biopharm AG can only be achieved by using the pipetting tips recommended by R-Biopharm AG. Any use other than mentioned above does not apply to the intended use of the system and R-Biopharm AG shall not be liable for any damage resulting from such unintended use. An intended use also includes the compliance with any safety and environmental laws and regulations as well as the instructions in the manual to prevent any damage to the user and the environment. Any liability will also extinguish when no or inadequate maintenance of the system has been performed. In doubt, please contact R-Biopharm AG.

All steps like the detection of the samples by a barcode reader, pipetting of all reagents, washing the membranes, scanning of the membranes and transfer of the picture to the appropriate evaluation software of R-Biopharm AG are operated discretely.

Fig. 1 RIDA qLine® autoBlot

The autoBlot Processor is an instrument which supports 3 dimensional robotic movement on the X, Y and Z axes. It's comprised of a built-in CCD scanner, a barcode reader and a pressure sensor. Also built in to the instrument is a bespoke tilting and orbital shaker mechanism for agitating the membranes used on the instrument. The unit as a whole is controlled via an integrated touch-screen which is running a bespoke software controller and graphical user interface. The combination of all these features result in the ability to completely automate the processing of R-Biopharm RIDA qLine® allergy membranes, starting from sample handling and ending with images of the membranes once processing has completed.

The instrument is designed to be partnered with third-party interpretation software used on a standalone computer which resides somewhere on the same network as the instrument. By creating work-lists and passing them along to the instrument, the software can track the progress of a work-list and finally interpret the results when the scanning has completed.

The typical work-flow of the instrument would go as follows:

1. The user inserts randomly up to 36 barcoded sample tubes into the sample carousel
2. The barcodes are scanned and transmitted to our evaluation software RIDA qLine® Soft.
3. The RIDA qLine® Soft is collecting the requests for the scanned samples and creates a worklist which is send to the instrument. The worklist is automatically shown and activated on the screen of the autoBlot and can be started. In case the work-list would contain more than 36 membranes the software would generate sub work-lists by adding an underline and a consecutive number like test_1, test_2, and so on. The sub work-lists can be operated consecutively.
4. Following on-screen instructions, the user is told how to prepare the instrument.
5. When the instrument has been loaded as requested, a panel pre-scan will begin (optional). This scan ensures that the correct numbers of membranes are inserted, in the correct order. This validation process works by detecting the colour of each membrane. This option is currently deactivated as a full scan needs more than 10 minutes.
6. The actual processing protocol will start. The protocol includes the prewashing of the membranes, the transferring of samples from the carousel to the membranes, and the continued processing of the membranes, including the dispensing and aspiration of reagents using precision piston pumps. All samples and reagents are transferred using disposable plastic tips.
7. Once the protocol has come to a graceful finish, the image scanning will automatically begin to capture an image of all processed membranes. This image is saved on the instrument and is transferred automatically to our evaluation software RIDA qLine® Soft .
8. An optional, but recommended last step, would be to run an automated cleaning routine with the instrument. This is a simple process of washing out all the water lines with a cleaning solution, followed by a rinse with de-ionised water.

Glossary

Definitions	Meaning
RIDA qLine® autoBlot	The name of the instrument that this document is discussing
Instrument	Synonymous with "RIDA qLine® autoBlot".
User	The person who is using the RIDA qLine® autoBlot in its standard operation.
Operator	Synonymous with "User".

3 Technical Specifications

Instrument type:	Stand-alone bench top
Processing Capability:	1 to 36 samples per run
Processing Time:	Typically 3.5 hours for 36 samples
Temperature Control:	PID under software control
Processing Volumes:	10 µL to 1000 µL
Dispensing Mode & Accuracy:	Piston Pump: +0/-5% / Peristaltic pumps: +0/-10%
Software:	Embedded software
Bar codes	JAN/UPC/EAN incl. add on, Codabar NW-7, Code 11, Code 39, Code 93, Code 128, GS1-128 (EAN-128), GS1 DataBar (RSS), IATA, Industrial 2of5, Interleaved 2of5, ISBN-ISMN-ISSN, Matrix 2of5, MSI/Plessey, S-Code, Telepen, Tri-Optic, UK/Plessey Postal code: Chinese Post, Korean Postal Authority
Voltage & Frequency:	Electrical power source at AC 100 to 240 V AC 10A 50/60Hz
Fuses	5 A UL Approved – Ø 5 x 20 mm
Dimensions:	600(H) x 620(D) x 780(W) mm
Weight:	65 kg
Consumption value (energy)	150 W (max)
Acoustic noise level (dB)	~ 60 dB
Electromagnetic emissions	Class A 30 MHz to 1000 MHz
Radiated field immunity	10 V/m 80 MHz to 1000 MHz 3 V/m 1.4 GHz to 2 GHz 1 V/m 2 GHz to 2.7 GHz

4 Safety & General Information

4.1 Unpacking and installation

Caution! Heavy instrument

The instrument itself weighs 65 kg and the whole unopened container may weigh as much as 95 kg.

At least two able bodied persons are required to move the instrument from the container.

1. Upon receipt of the instrument, visually inspect the container for any transit damage. Any damage should be recorded prior to opening.
2. Ensure that the wooden container is placed in an upright position before attempting to open.
3. As the container may have sharp edges, it is highly recommended that appropriate gloves be worn for unpacking.
4. Remove the outer straps and lift off the main cover. When open, remove all accessories from the container. Lift the wooden outer shell upwards and place to one side.
5. To lift the instrument off the base, AT LEAST two able bodied persons are required. One person should be positioned at the front of the instrument, and another should be positioned at the back of the instrument. To remove the foam side cheek, lift one side of the instrument and have another person remove it from the raised side. Gently lower the instrument back down and repeat this for the other side. Remove any protective bubble wrap and the foam top protectors that remain.
6. Remove accessory box from inside of the instrument, and remove all drive securing tapes.
7. The outer shell can be collapsed flat and placed onto the base of the packaging and the lid replaced over it.
8. Inspect the instrument for any obvious signs of transit damage. Report any damage immediately to your local representative.
9. Check that the serial number on the instrument and the delivery note are the same.
10. Unpack accessory box and check that all accessories are present. The full list of accessories is listed in the table below.

Parts	Quantity
Touch screen & cables	1
Touch screen mounting arm	1
Touch screen screws & keys	1
Pack of 2 5A fuses (spares)	1
Reagent Bottle Holder	1
Wash Bottle Holder	1
Waste Bottle Holder	1
Priming Trough	1
Waste Tip Trough	1
Tip Rack Holder	1
Tray (Strip Holder)	1
Sample Carousel	1
Wash Bottle & Lid	1
Waste Bottle & Lid	1
Mains Lead	1
Packaging tape (spares)	1

11. Store all packing materials until completely satisfied that the instrument was delivered safely and that it is performing to specification.

4.2 Instrument Labelling

Please observe and respect all caution labels shown on instrument & consumables:

4.3 Detailed personal safety information

	Warning Avoid touching the instrument with wet hands, and **do not** attempt to disassemble the instrument. In either case electrical shock may result, and in both cases the warranty will be invalidated.
	Warning! The instrument will automatically stop when the Cover is opened. Never attempt to manipulate or run the instrument with the Cover opened
	It is recommended to wear eye protection, a laboratory coat and protective gloves when operating the instrument / handling reagents. If contact of any reagent occurs with skin or eyes, wash thoroughly with water

4.4 Environmental conditions

4.4.1 Bench space

Always place the instrument on a flat and solid surface while ensuring that there are no obstructions to the Touch Screen on the right-hand side of the instrument. The minimum bench space that required is a width of 1000 mm and a depth of 700 mm – The depth constraint is required to ensure there is no overhang on the front of the instrument.

The instrument should be placed no further than 1 meter away from an appropriate power source.

The door to the instrument swings upwards. When fully raised, the height from the base of the instrument to the extreme of the door is 1000 mm. Ensure the allocated bench location accounts for this.

4.4.2 Disconnection guidelines

In an emergency immediately turn the power off and unplug from power source.

The mains switch and mains lead connection is located on the right hand side panel of the instrument. Do not place the instrument too close to any object that might impair emergency disconnection in an emergency, particularly any object to the right side panel of the instrument.

4.4.3 Ventilation

The instrument should not be placed in line with a direct draft (such as an air vent) and a clearance of 100 mm should be afforded from any other obstruction (e.g. walls or other instruments).

4.4.4 General

The instrument should be kept free of dust, harsh solvents and acidic vapours. The instrument should not be exposed to vibrations, harsh sunlight or unduly large variations in temperature and humidity. Failure to abide could affect the correctness of the result.
The instrument is designed and intended for in-door use only: located on a flat surface within a typical laboratory environment, i.e.:

Altitude:	Up to 2000 m. For any altitude above 2000m it is recommended to calibrate the pumps for the environment.
Temperature:	Ambient temperature range: Between 5-40 ºC
Humidity:	Maximum relative humidity 80 % for temperatures up to 31 °C decreasing linearly to 50 % relative humidity at 40 °C
Mains voltage:	100 to 240 VAS – 10A 50/60Hz & fluctuations of up to ± 10 % in supply
Storage conditions:	from 5 ºC to 50 ºC

It’s advised to let the instrument to stand for 3 hours before applying power to avoid problems that might arise from condensation.

4.5 Initial setup

Once the instrument has been unpacked according to the statements in section 4.1, and placed on suitable bench as described in section 4.4.1, the initial set-up steps can be started.

4.5.1 Lubricate (grease) the probe o-ring

Fig. 2

Apply a small amount (approx 1 mm 'blob') of silicone grease to the o-ring.

Place a 1000 µL tip onto the tip-picking probe, rotate the tip on the probe twice over in order to spread the grease over the whole o-ring, and then remove the tip.

Thoroughly wipe the metal parts of the probes (and not the o-rings) clean with tissue, so that there is no grease left on the probes themselves.

4.5.2 Mount and connect the touchscreen

Fig. 3

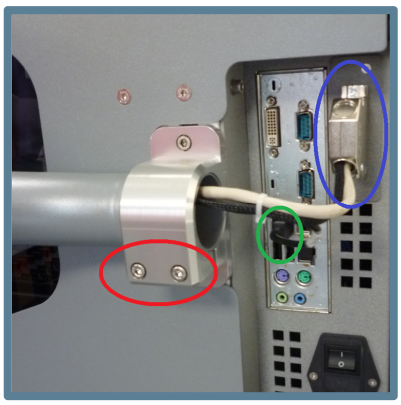


Fig. 4

To attach the support arm, and thus the touch screen to the instrument, 4 screws, 3 washers and two Allen keys must be retrieved from the accessory collection.

Using the longest M6x75 screw from the screw set (and appropriate M6 washer), secure the Touchscreen rear clamp to the arm. This is illustrated within the yellow circle. On the opposite side, locate the smallest M4 screw in position in order to limit the tilt movement of the Touchscreen.

It is recommended to obtain help from an assistant at this stage.

Manoeuvre the arm onto the bracket at the side of the instrument, ensure that the screen is aligned correctly, then tightly clamp the bracket by using the remaining 2x M5 screws (and appropriate M5 washers) provided in the screw set. This is illustrated within the red circle.

Ensure that the screen cannot move after clamping.

For anything to appear on the touch-screen, the DVI cable of the touch-screen must be attached to the 25-way connector at the side of the instrument. This connection is illustrated within the top-most blue circle in Figure 4

For touch-support to be enabled, the USB cable of the touch-screen must be attached to a USB port on the instrument's on-board computer. This connection is illustrated within the central green circle.

Once all of the above has been completed, connect the power supply to the touch-screen.

4.5.3 Powering the instrument

Fig. 5

4.5.4 System start and initialization check

Once the instrument has been powered and the on-board computer has loaded up, the main software application should automatically launch and begin an initialisation task. This is a task which happens every start-up to ensure that all the core components are fully functional and ready for use.

During the initialisation check, the instrument will move the drives to ensure everything is okay. For this movement to start and complete, ensure the door is closed throughout the initialisation process. The movement that should be witnessed goes as follows:

1. The Z axis will move to the home position; this consists of raising up if lowered.
2. The Y axis will move to its home position; this consists moving to the back of the instrument.
3. The X axis will move to its home position; this consists of moving to the left hand side.
4. The carousel drive will rotate to its home position; this consists of ensuring position 1 is in-front of the barcode reader.
5. The tray table will move to its home position; this consists of tilting the table.
6. The X and Y arm will move out to the tip waste trough, where the Z will perform an eject action, followed by a return home by all axes.

If the above is successful, the master controller checks will be ticked off and followed by quick camera and barcode reader checks. If all are successful, the screen should resemble what is shown in Figure 6. At this point, the application can be entered by pressing start.

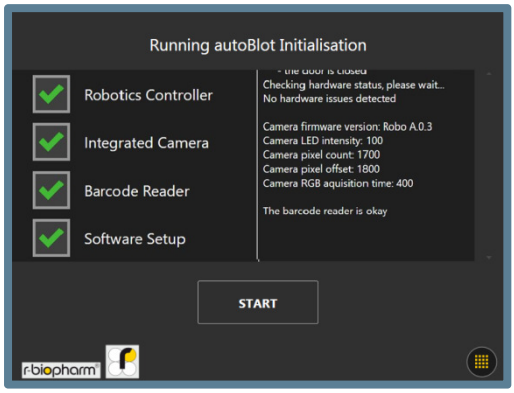


Fig. 6:

If anything goes wrong during initialisation, a cross will be put next to the component being initialised and a message will be shown telling the user to contact technical support. If anything goes wrong here during the first time set-up, please contact your service provider.

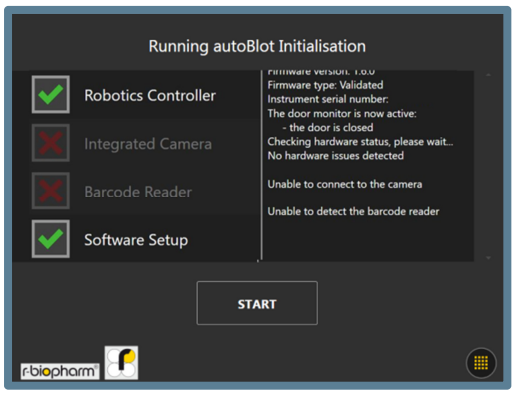


Fig. 7:

An example of a failure screen is shown here. Note you will not be allowed to enter the main application if any errors occur.

4.5.5 Critical errors

The robotic side of the instrument has its own error handler that is separate from the global software controller. This means that it has its own way of generating and displaying errors. Any time a robotics error is detected; the following screen will be shown that contains error sequences that are vital for ensuring that the service provider is able to diagnose the root of the problem. If this screen appears during initialisation, or any other process, contact your service provider straight away, giving details which include the numbers contained within the box. Each line denotes 1 sequence.

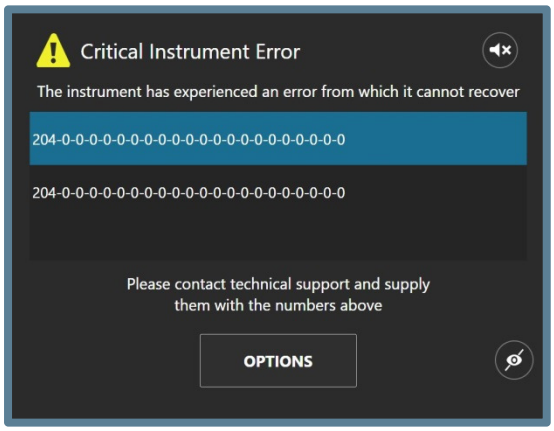


Fig. 8

5 System overview

5.1 RIDA qLine® autoBlot component guide

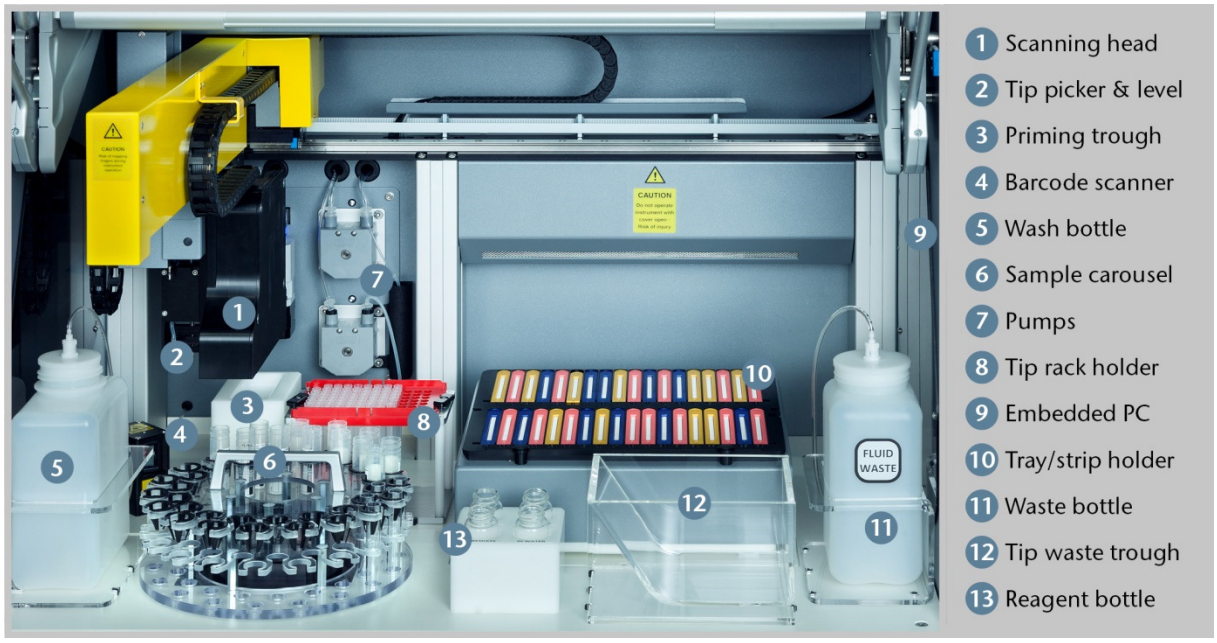


Fig. 9 Components of the RIDA qLine® autoBlot

5.2 Installation of accessories

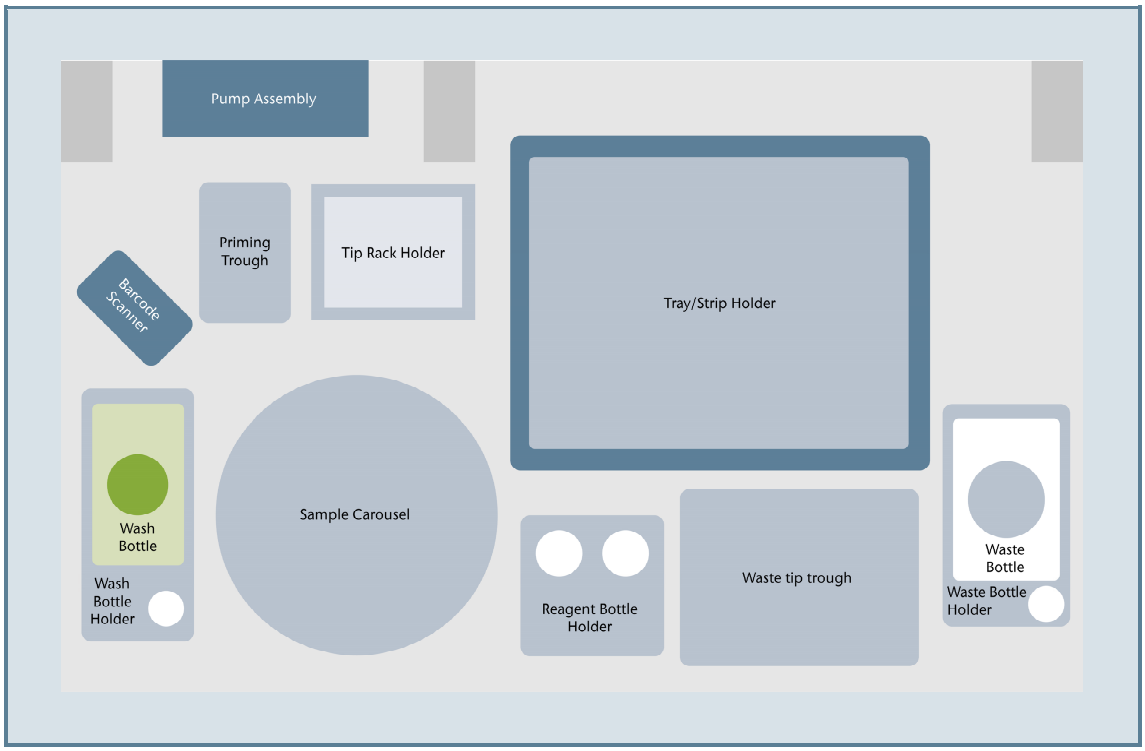


Fig. 10

The drawing above illustrates the positioning of all the accessories on the deck of the instrument. Further notes on the assembly and placement of the accessories can be found below.

Accessory I.	Priming Trough	Position on the dimples in front of the pump assembly. There is only one way in which it can fit.
Accessory II	Sample Carousel	Align the protruding cylinders with the matching holes in the center ring of the carousel frame.
Accessory III.	Reagent Bottle Holder	Position on the dimples in front of the tray table. There is only one way in which it can fit.
Accessory IV	Tip Rack Holder	Position on the dimples to the right of the priming trough. There is only one way in which it can fit
Accessory V.	Waste Tip Trough	Position on the dimples to the right of the reagent bottle holder. There is only one way in which it can fit.
Accessory VI.	Waste Bottle Holder	Position on the dimples to the right of the tip waste trough. There is only one way in which it can fit.
Accessory VII.	Waste Bottle and Lid	Position the bottle into the holder and place the white lid onto the bottle. Connect the tubing from the waste pump.
Accessory VIII.	Wash Bottle Holder	Position on the dimples to the left of the carousel. There is only one way in which it can fit.
Accessory IX.	Wash Bottle and Lid	Position the bottle into the holder and place the green lid onto the bottle. Connect the tubing from the wash pump.
Accessory X	Tray	Place the membrane holder (also known as the tray) onto the table. There is only one way it can fit.

5.3 Instrument consumables

The only other consumables in addition to the diagnostic kit being used are the disposable plastic tips. The instrument has been designed for use with a specific type of tips, ones which will be provided by the distributor. **No attempt** should be made to try and use other forms of plastic tips. Failure to adhere to this advice may result in the failure of the instrument and will void any warranties provided.

6 System overview

Following a successful instrument initialization routine, the start button will have become available, as demonstrated in Figure 6. Upon pressing the start button, the first screen that will become visible is the main menu which has the work-lists tab automatically selected. The main menu is split into three main categories: Worklists, Imaging and Cleaning. Each tab represents a core process in the instrument's use. Anything worklist related can be found in the worklists tab, anything imaging related can be found in the imaging tab, and anything cleaning related can be found within the cleaning tab.

This section will cover the key areas that are required to get users familiar with each of the instrument software features, specifically where they are and what they do.

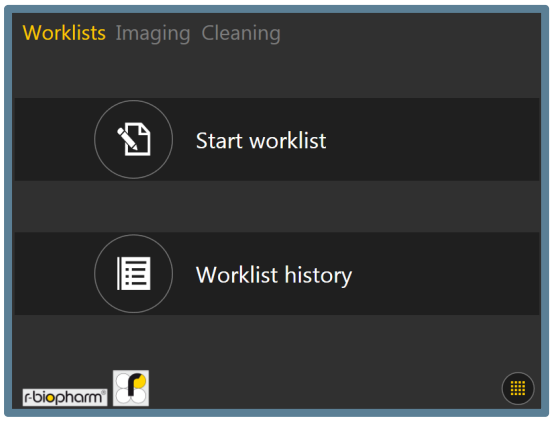


Fig. 11

6.1 System Menu

At any point while within the main menu, the system menu button can be found in the bottom right corner of the screen. This button opens a system menu, a menu which contains information about the system, as well as some important features.

Fig. 12

6.1.1 Information tab

Upon pressing the button, a new window will cover the old and show a screen that resembles what is show in the screen below. The first tab is called 'information' and primarily serves as a view for showing the instrument name, slogan and software version. The bottom row all contain power options: 'power off' turns the instrument off, 'restart instrument' turns the instrument off but immediately back on again, and 'restart application' closes the software application and re-launches it once more.

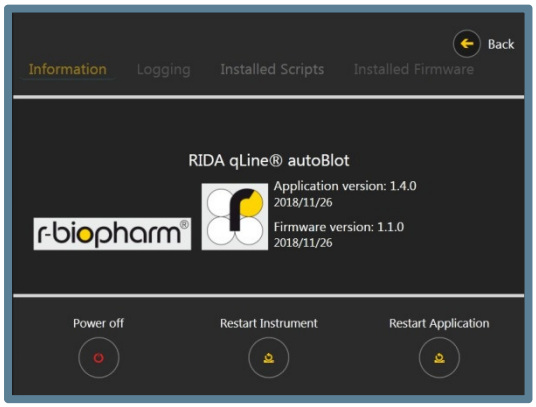


Fig. 13

A hidden feature on this screen is the ability to unlock a fourth **main menu** tab called Engineering. This is done by pressing down on the R-Biopharm branding logo for approximately 3 seconds, or until you see the message ‘engineering activated’ as shown in the following screen. The engineering tab can be deactivated by repeating the above steps until a similar ‘engineering has been deactivated’ message is shown.

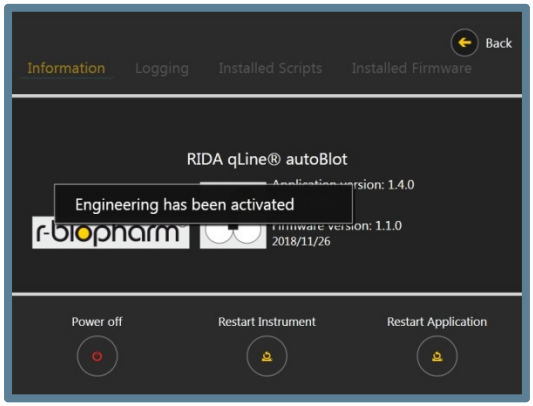


Fig. 14

If the back button is pressed while engineering is set to active, an additional entry will be found next to the ‘Cleaning’ tab, one called ‘Engineering’.

6.1.2 Logging tab

The logging tab can be found to the right of the information tab. This is a tab which provides a preview of the most recent events that were logged by the software, including the ability to copy all of the log files from the past 5 days to a USB device that may be connected to the instrument.

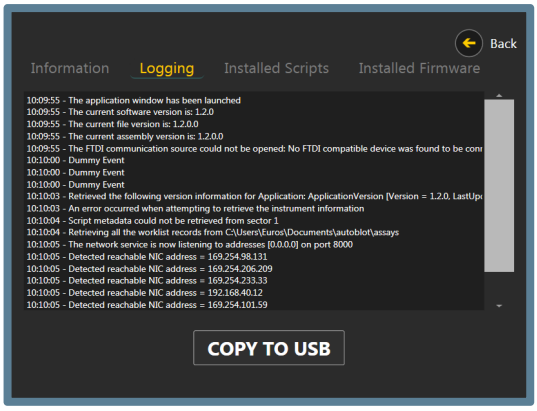


Fig. 15

If as a user you witness unusual behaviour that you would like to report to your service provider, the instrument logs should be copied using this tool and forwarded along with your report.

6.1.3 Installed scripts tab

The installed scripts tab can be found to the right of the logging tab (see Figure 16). This tab contains the names, version numbers and build dates of all the scripts that the software executes in-order to carry out the membrane processing protocols.

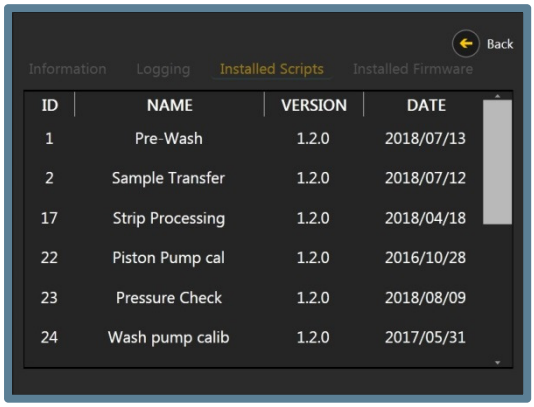


Fig. 16

6.1.4 Installed firmware tab

The installed firmware tab can be found to the right of the installed scripts tab. This tab contains the names, version numbers and build dates of all the firmware modules that are installed on the instrument. Firmware modules generally define how the robotics performs.

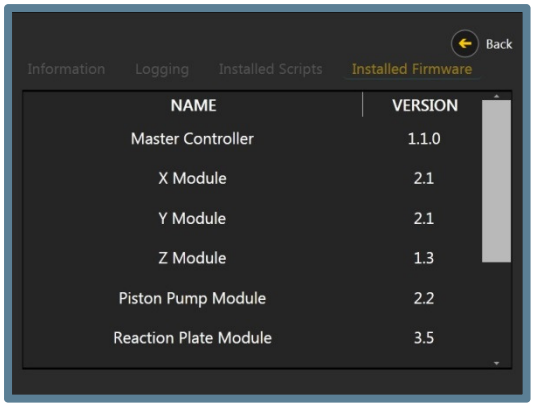


Fig. 17

6.2 Determining the IP address of the instrument

As the use of the instrument is heavily dependent on receiving work-lists from the third party software application, one of the first tasks a user should perform is determine the IP address of the instrument. This can be done by accessing one of the instrument's engineering tools.

6.2.1 Pre-requisites

Before the instrument can be used with a third party software, the instrument needs to be turned on with an RJ-45 Ethernet connector already inserted into the RJ-45 socket on the side of the instrument.

If the instrument has already entered the main menu before an RJ-45 cable is connected, the application will need to be restarted to register it.

6.2.2 Activating Engineering

Activate the engineering tab by following the steps outlined in section 6.1.1 upon activating engineering and closing the system menu, the following screen become visible. The ‘Advanced Tools’ option is password protected and not intended for normal users; therefore this tool should be left alone.

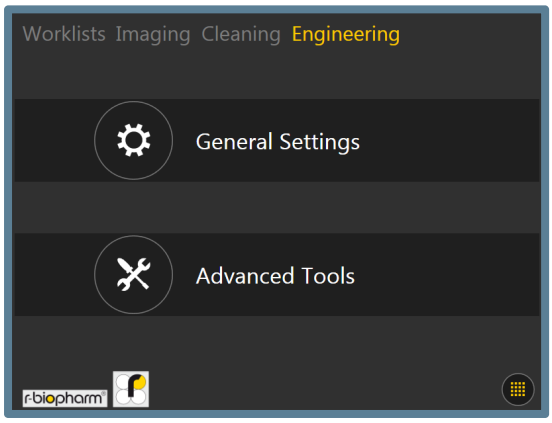


Fig. 18:

Selecting the ‘General Settings’ option will show all the engineering options which don’t require authentication. The screen below shows what should be seen upon clicking this option.

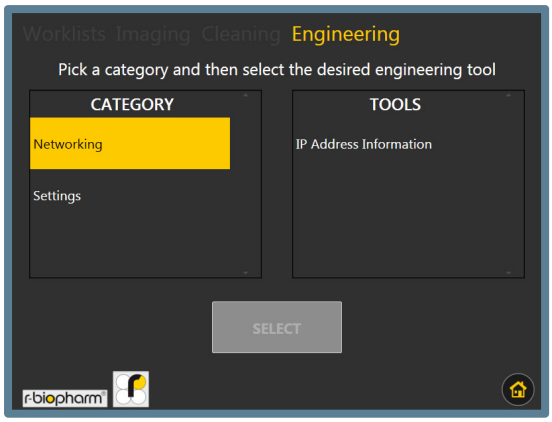


Fig. 19

6.2.3 Viewing the internet protocol (IP) address

In the engineering section, select the ‘Networking’ option from the ‘Category’ section, followed by the selection of the ‘IP Address Information’ option from the ‘Tool’ category. When both are highlighted yellow than press the select button. Completing the former should result in a screen similar to what is shown in the screen below.

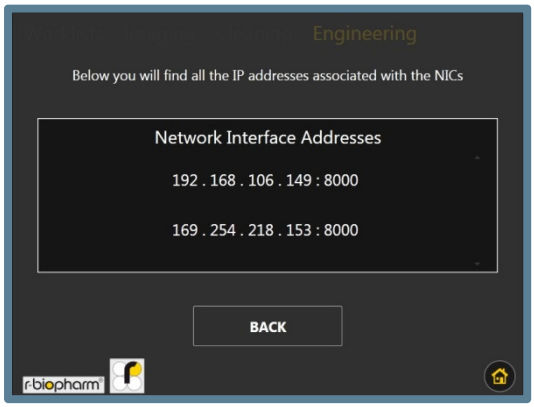


Fig. 20

The instrument comes with two RJ-45 Ethernet ports which mean there are two possible addresses that can be listened to. Each of the two IP addresses represent the IP address the instrument is listening to for messages. In this example, 192.168.106.149 is the IP address of the network that the instrument is connected to, and 169.254.206.209 is the local IP of the instrument (i.e. no connection on this port).

Note!
The upper IP address is allocated to the lower Ethernet port (LAN2) and the lower IP address is allocated to the upper Ethernet port (LAN1)

For users unfamiliar with the IP address ranges and need assistance determining which 1 of the 2 addresses represents their network, the following guidelines apply:
The addresses of private networks typically come in number ranges similar to some of the following:

- 10.0.0.0
- 172.16.0.0
- 192.168.0.0

The addresses of Ethernet ports which don't have a network connection will typically start with 168 or 169.

The port will always be 8000, this is donated by the value which follows the colon (:) character after the IP address. The IP address and port number should be recorded for later use.

6.3 Connecting to the instrument from third party software

Both the autoBlot and the RIDA qLine® Soft must be connected with the same network. The TCP/IP communication must be enabled in all parties. The connection is recommended to be done by an IT specialist.

During the installation of RIDA qLine® Soft the autoBlot support must be selected. In the following input mask the IP address, the port, the name of the device and the serial number must be entered.

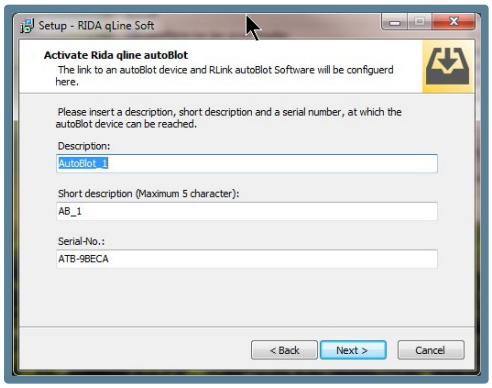


Fig. 21

If more than 1 autoBlot should be connected to the RIDA qLine® Soft the parameters of the other devices (in maximum 4) must be entered manually into the qsoft.ini-file. In order to find the qsoft.ini file please enter %appdata%\R-Biopharm\qsoft into the address bar of the windows explorer and confirm with the enter key.

Please open the qsoft.ini file by double click and go to the section as shown below:

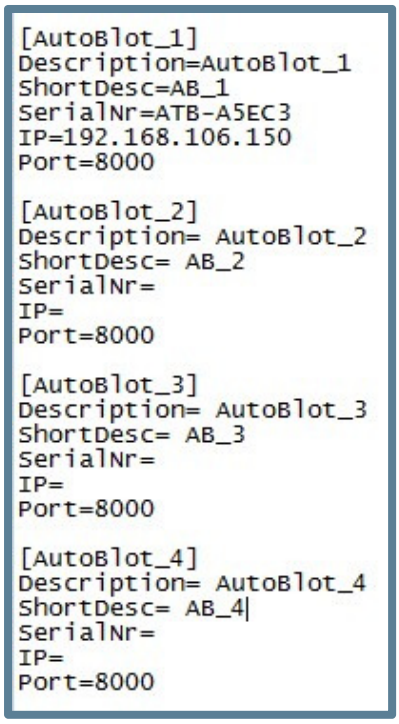


Fig. 22

For all connected machines the Description (name), the serial number and the IP address must be entered.

The software versions of all connected devices must be identical. In case a software update for the machine is available all connected machines must be updated with the software update and the software version must be entered into the qsoft.ini file. For that purpose please look for the section in the qsoft.ini file and enter the software version after the update. If the software version of the machine and the software version which is entered in the qsoft.ini is different, the connection of our RIDA qLine® Soft via the R-link software is not possible.

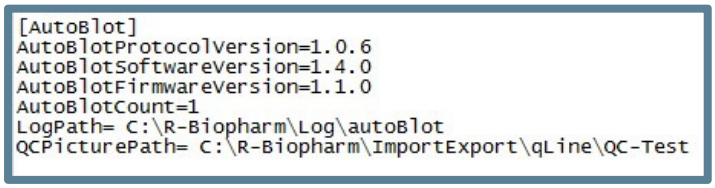


Fig. 23

The AutoBlotProtocolversion may not be changed. The AutoBlotSoftwareversion corresponds with the Application version and the AutoBlotFirmwareversion corresponds with the FirmwareVersion shown in the Information tab (see section 6.1.1)

6.4 Creating a worklist

In order to create a work-list the autoBlot must be connected with the evaluation software RIDA qLine® Soft.
To create a worklist, all samples to be tested must first be placed randomly in the carousel.

Warning

The sample tubes must be inserted into the carousel with the barcodes directed to the barcode scanner.
The minimum volume of the sample is 1 ml.

Now the barcodes of the samples must be scanned. Click on the button Start worklist

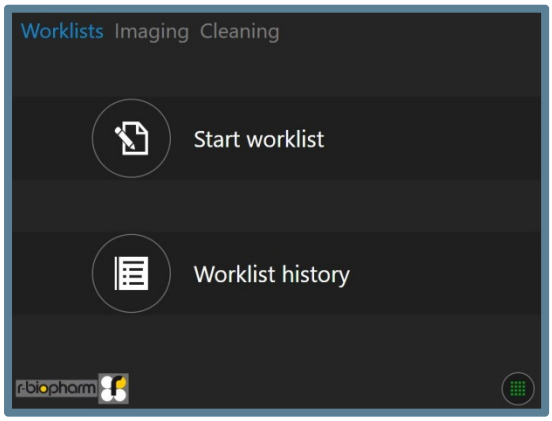


Fig. 24

and then Carousel → LIS

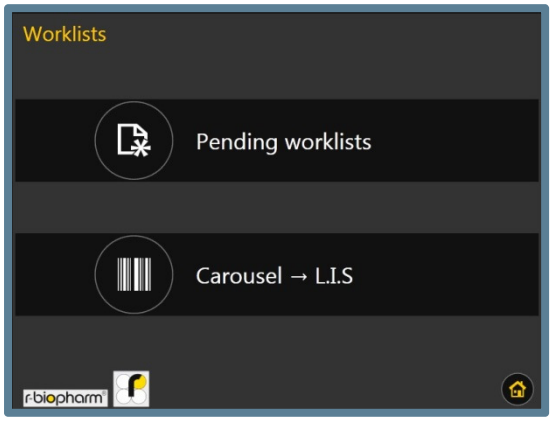


Fig. 25
and then SCAN CAROUSEL

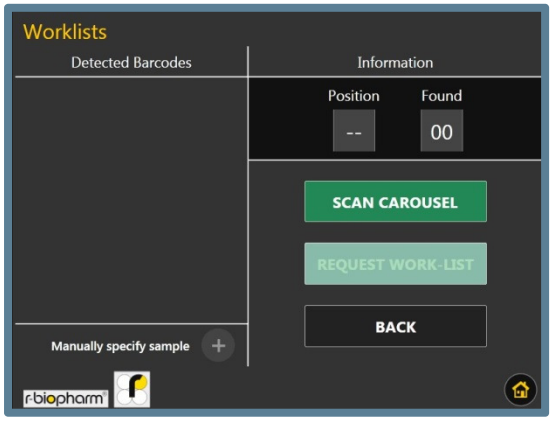


Fig.26
After the scanning process the numbers of recognized barcodes are displayed on the touchscreen.

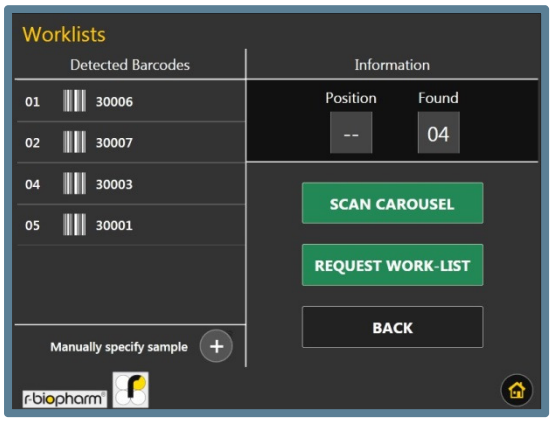


Fig. 27
In case the barcode of not all sample tubes are detected, the Lab ID and the position in the carousel of the not detected sample(s) could be entered manually.

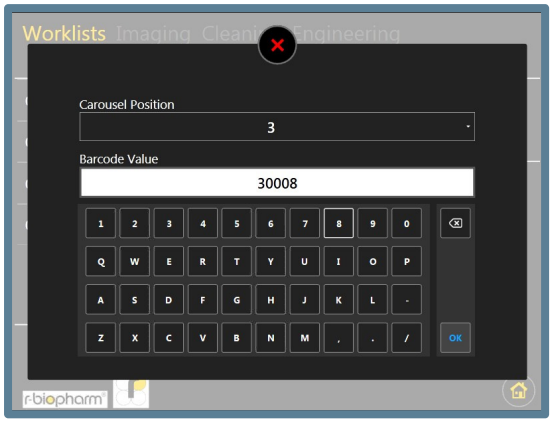


Fig. 28
If the RIDA qLine® Soft is connected with a LIS system it is possible to identify the samples for which no requests are existing. For that purpose select in the RIDA qLine® Soft under Requests the filter "LIS request". All samples for which no requests exist will be listed.

If there is no LIS connection select the filter "open". All samples are displayed for which a request exists. For all not displayed LabIDs no request exists.

If no request exist for one or more barcodes the work-list cannot be created, and an error message (Timeout) will be displayed.

If all requests are detected or inserted manually click on REQUEST WORK LIST in order to get the work-list.

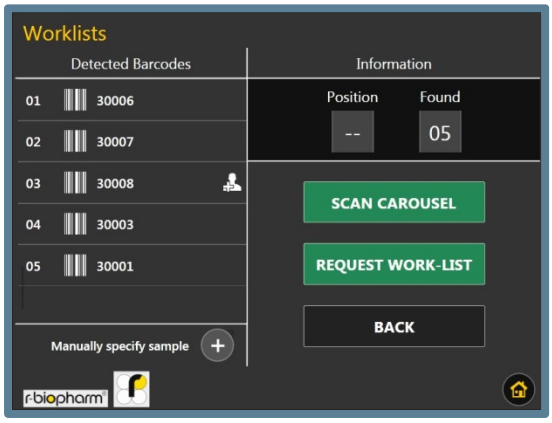


Fig. 29

The creation of the work-list is confirmed with the message "Worklist received".

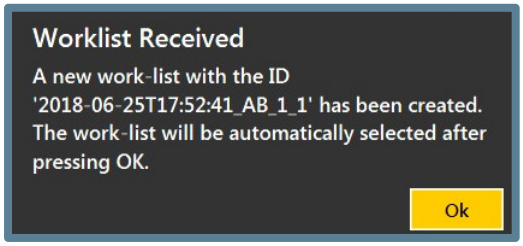


Fig. 30

After confirmation the processing of the work list starts (see 5.5). The software shows the reagents needed.

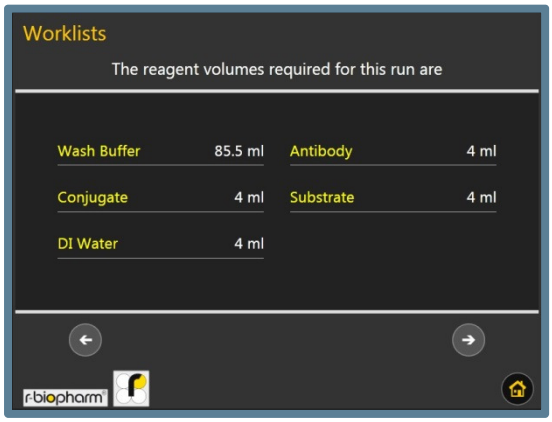


Fig. 31

Continue with the navigate forward button.

Fig. 32 navigate forward button

After pressing the navigate forward button the allocation of the strips onto the strip holder will be shown.

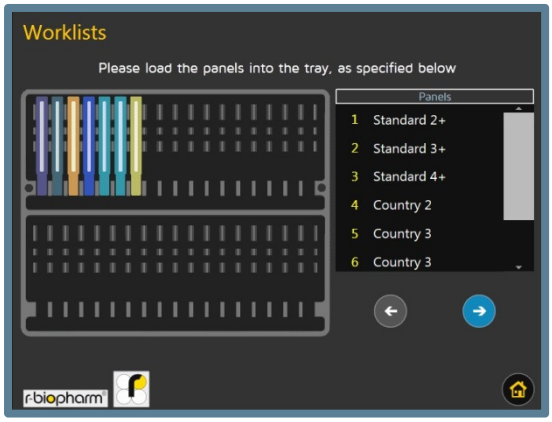


Fig. 33

By navigating ahead by pressing the navigate forward button (denoted by the right-pointing arrow), the user will be taken to a check-list which the user will need to complete; both by performing the specified actions and ticking off each item to confirm they have done the specified task. When all the tasks have been completed and ticked, a new navigate forward button will become enabled.

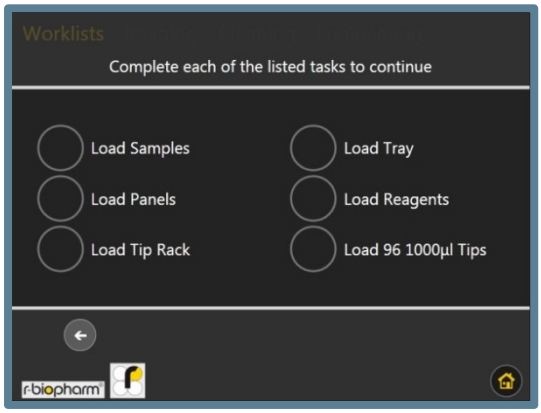


Fig. 34

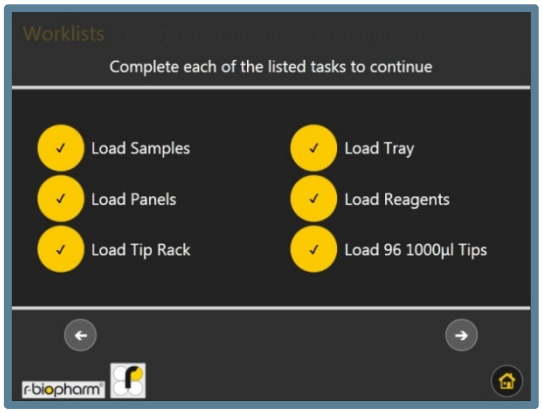


Fig. 35

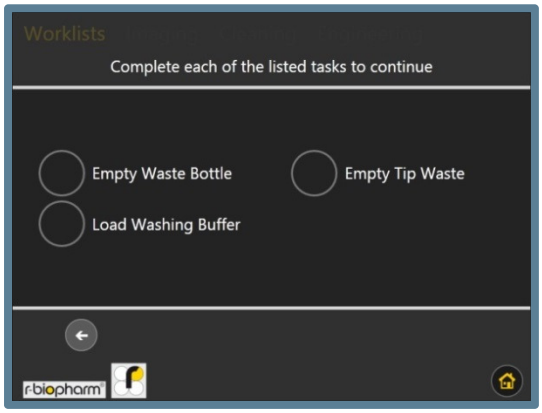


Fig. 36

Fig. 37

This is the core screen that will be visible while the instrument runs the protocol on the troughs and samples; starts with pre-washing and is then followed by sample transfer and strip processing.

If the number of strips to be tested after scanning the sample tubes is greater than 36 (maximum number of strips per run), the work list is divided into 1 or more sub-work lists. The first of the sub-work lists is displayed and is active. After processing the first sub-worklist, the next sub-worklist can be selected. For that purpose please return to ‘Start Worklist’ menu where a single entry should now be visible in a list called ‘Pending Worklists’.

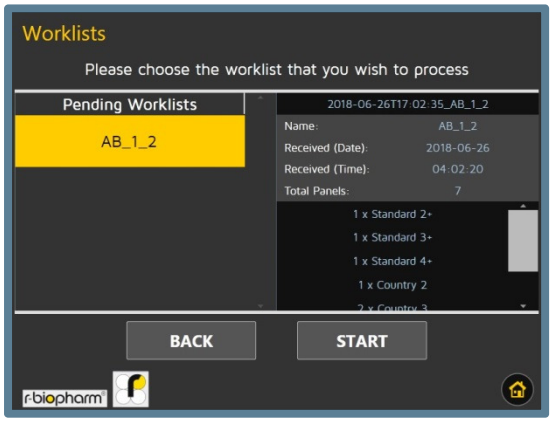


Fig. 38

Alternatively, a work list can be created in the RIDA qLine® Soft. For this, as in the RIDA qLine® Soft Manual point 6.1.1 described, the Lab IDs of the samples to be tested are entered. The samples should be placed in a carousel of the autoBlot after entry. When scanning the carousel as described above the samples are recognized and a worklist is created automatically in the RIDA qLine® Soft. The worklist is transmitted to the machine. It must be ensured that the samples and the work list are identical.

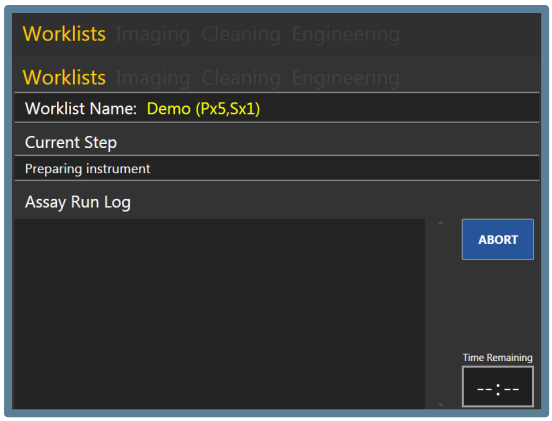


Fig. 39

6.5 Running a work-list

By highlighting a selected work-list and pressing start, the user will be taken into the first screen on the work-list set-up menu; here they will find out how much volume is required for each reagent. The user should take note of these values and take the necessary action.

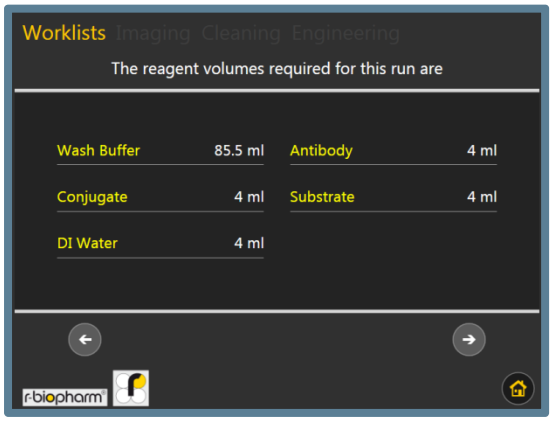


Fig. 40

After pressing the navigate forward button the allocation of the strips onto the strip holder will be shown.

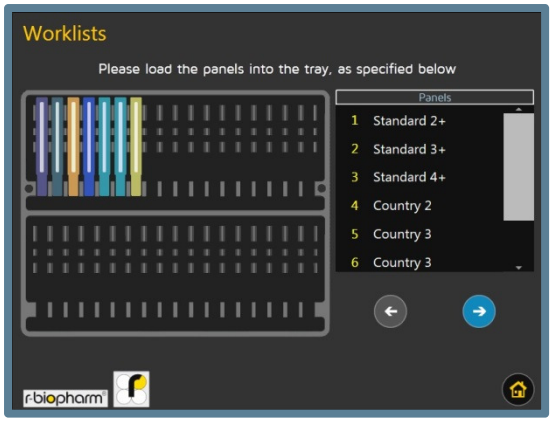


Fig. 41

By navigating ahead by pressing the navigate forward button (denoted by the right-pointing arrow), the user will be taken to a check-list which the user will need to complete; both by performing the specified actions and ticking off each item to confirm they have done the specified task. When all the tasks have been completed and ticked, a new navigate forward button will become enabled.

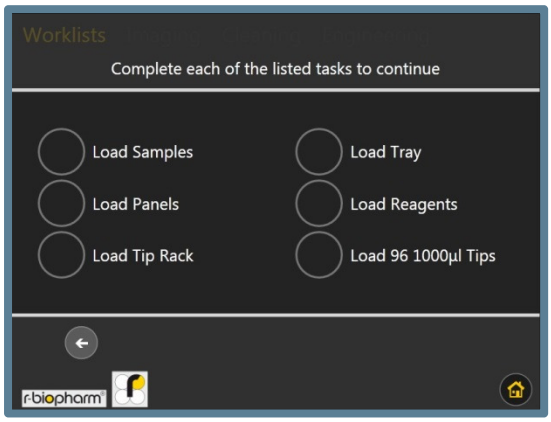


Fig. 42

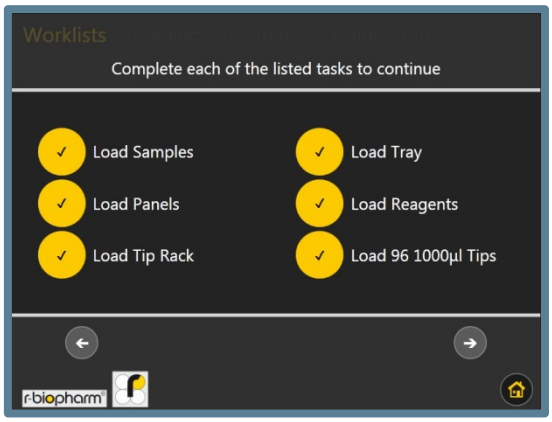


Fig.43

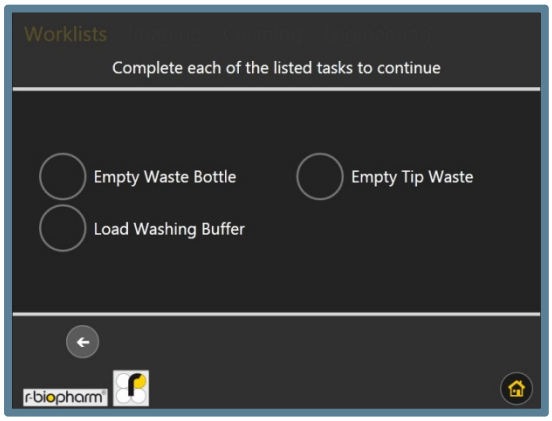


Fig. 44

Fig. 45

After confirming that everything is located correctly within the instrument, pressing navigate forward will immediately lead to the start of the run.

This is the core screen that will be visible while the instrument runs the protocol on the troughs and samples; starts with pre-washing and is then followed by sample transfer and strip processing.

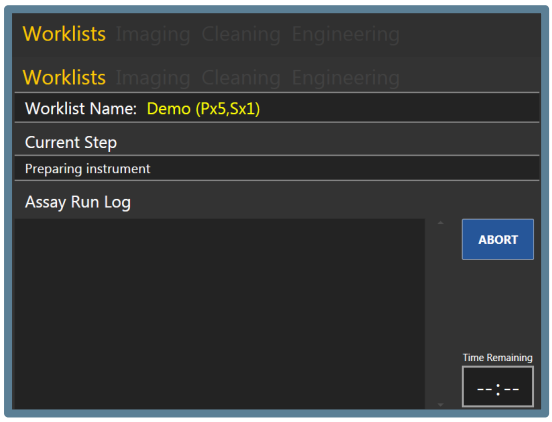


Fig. 46

The processing screen has the following properties: the name of the work-list, the name of the current work-list step, a log of all the past events that have happened since the start of the processing, a button to abort the work-list and a time control which can be used to determine the remaining time, as well as the current time and what time the processing will complete.

If there are no issues with the work-list, instrument or samples, then the user should not need to interact with this screen at all.

At the start of the protocol, from pre-washing to sample transfer, the time remaining control will not show any values, except for --:--. This indicates that no estimated time is available. Once sample transfer completes however, this control will be populated by the estimated amount of minutes and hours until the panel processing is complete.
Tapping on the time control box will cause the control to transform. While ‘Time Remaining’ is shown, a single tap will transform the control to show ‘Current Time’. Another tap will transform the control to show the ‘Completion Time’. A third tap will return the control to show ‘Time Remaining’.

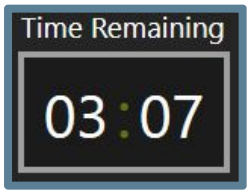


Fig. 47

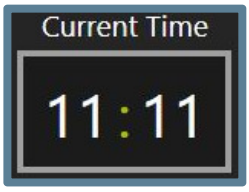


Fig. 48

Fig. 49

The time control should be accurate to within 10 minutes of the actual completion time.

The other interactable control on the processing screen is the abort button. Pressing this button will trigger a confirmation pop-up, which when confirmed, will begin the aborting procedure for a work-list. This involves getting rid of any tips that are being carried and parking the robotics. At the end, the user scanning will not take place and the work-list will be invalidated. This feature should only be used if the user has made a drastic mistake in the work-list and would like to start it from scratch later on.

Fig. 50

When the strip processing completes, the imaging will automatically start. The screen below is active during the imaging. The value on the left shows the current trough being scanned while the number of the right shows the total number of troughs that need to be scanned. In a work-list of 2 troughs, the number of trough images being taken is 2.

When imaging completes, the data will be automatically saved on the instrument, ready for processing by the third-party software.

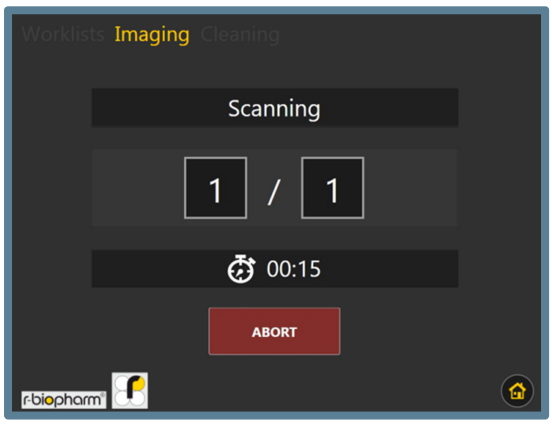


Fig. 51

6.5.1 Transfer exception handling

Thus far, it has been assumed that the processing of the samples has not experienced any issues. A summary of the potential issues that could arise during the sample transfer phase are listed below:

1. The barcode of the sample being transferred does not match the barcode that was detected during sample verification
2. The sample could not be found from within the sample tube
3. The tip being used to pick up and transfer the sample has a blockage

When any of the situations listed above arise, the instrument will retry the transfer 2 additional times (making a total of 3 attempts), each time using a new tip. If the initial issue isn't resolved after the third attempt, the instrument will pause, sound an alarm and bring up a pop-up window as shown in Figure 46.

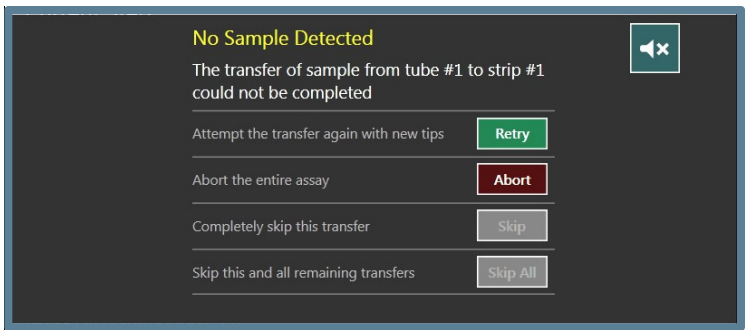


Fig. 52:

If the transfer issue states [TipBlocked], the user should check the condition of the tips being used. Fresh tips should always be used on each run. If the user can find no fault with the tips, they should check the target sample tube for clots or any other debris that might result in a blocked tip.

If the transfer issue states [SampleNotFound], the instrument is unable to detect any meniscus. In this scenario, the user's first action should be to ensure that there are tips in the tip rack. If tips are available, the user should ensure there is enough sample volume in the sample tube for the instrument to pick up. If inspection results in no issues being detected, the user should verify that tips of the correct specification are being used.

If the transfer issue states [BarcodeIncorrect], it means the instrument has rotated the carousel to the position that it found the target sample tube in from the verification run, but somehow the barcode no longer matches what is expected. In this situation, the user should open the door and remove the carousel. While the user has access to the carousel, they should ensure that the barcode points fully outwards and is not smudged or damaged in any way; a fresh sticker should be placed if damage is found. When done, the user should put the carousel back inside the instrument and close the door.

Whenever any of the above situations arise, the user is given 4 options as shown in the figure above.

1. Abort
   Abort the whole work-list. This is the same as aborting from the main processing screen.
2. Skip
   Skips the sample transfer for the current trough; this relies on the user manually doing the transfer before pressing skip.
3. Skip All
   Skips the sample transfer of all remaining troughs; this relies on the user manually doing the transfers before pressing skip.
4. Retry

6.6 Obtaining work-list information directly from the instrument

The analysis of the work-list images can only be done from the third-party software, but a copy of the images and event logs from the last 8 work-lists can always be accessed via the instrument. From the **main menu**, under the 'Worklists' category, there is a 'Worklist History' option which takes the user to the screen shown below. From this screen, the user can select a previously run work-list and export

the logs and images (if available) to a selected USB device. Entries can be deleted by pressing and holding down on the name of the work-list that should be deleted.

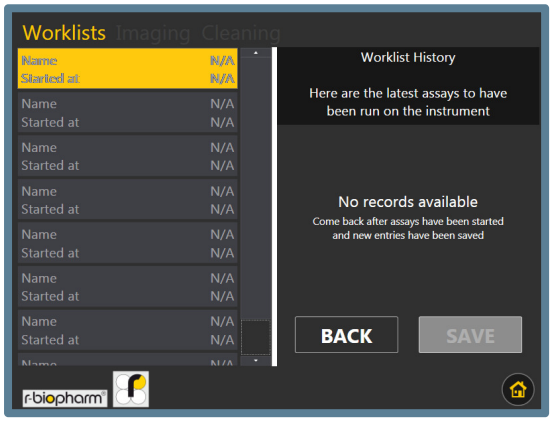


Fig. 53

When users save work-list history data to a USB device, folders are created with the following structure:
DEVICE\\AutoBlot_Assay_Records\\DATE\TIME\\WorklistName\\

An example of the data that is saved is shown here:

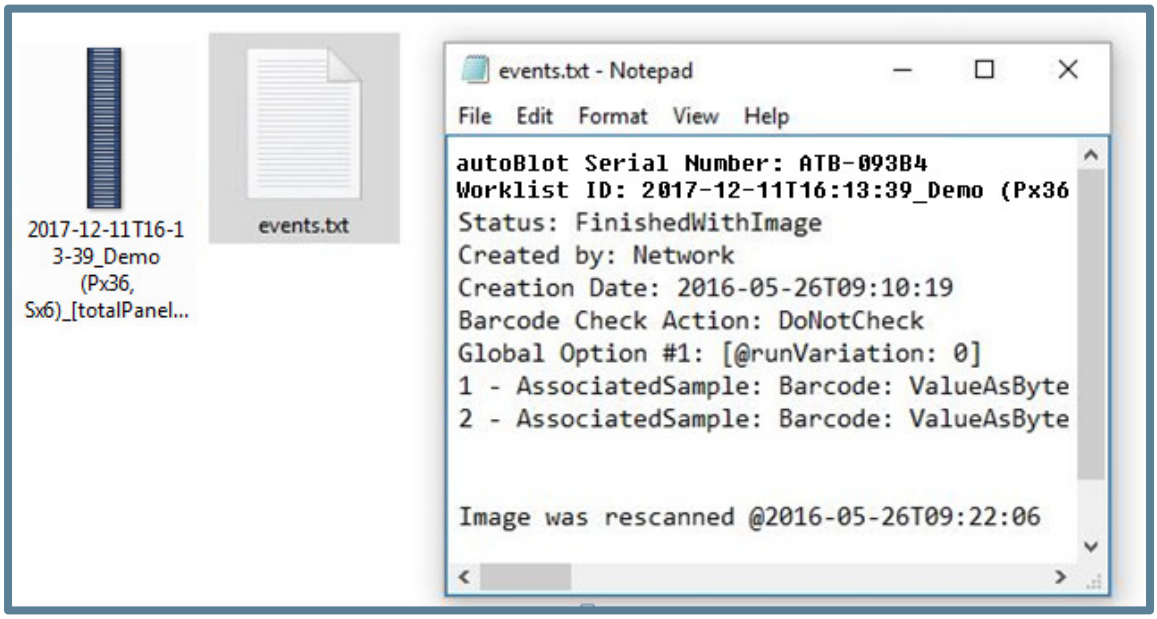


Fig. 54

6.7 Stand-alone Imaging

The premise of the instrument revolves around obtaining images following the completion of a work-list, but it's noted that sometimes users may want to perform a scan that isn't directly tied to a work-list. This can be achieved by navigating to the 'Imaging' category within the **main menu** and selecting 'Standalone Scan'. The first screen the user will encounter within this option is the scan configuration menu. The -/+ controls increment and decrement the amount of panels/troughs will be scanned should the user press 'START SCAN'.

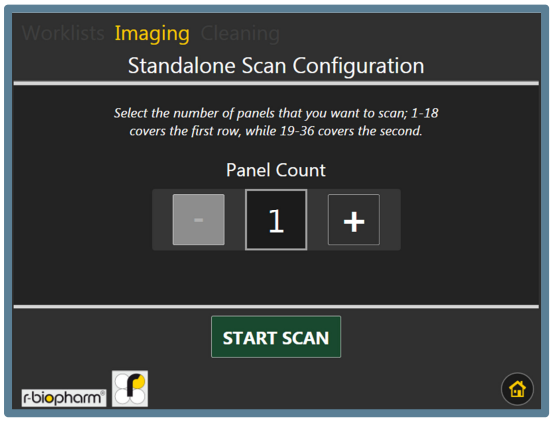


Fig. 55

After pressing START SCAN, the screen below will become active. This screen will inform the user of the progress of the scan, along with an estimated time before the procedure finishes. If the user wishes to cancel the scan and discard all associated data, pressing the ABORT button once will park the instrument and return the user to the **main menu**. If the user doesn't abort the scan, the images will be saved on the instrument for retrieval at any time.

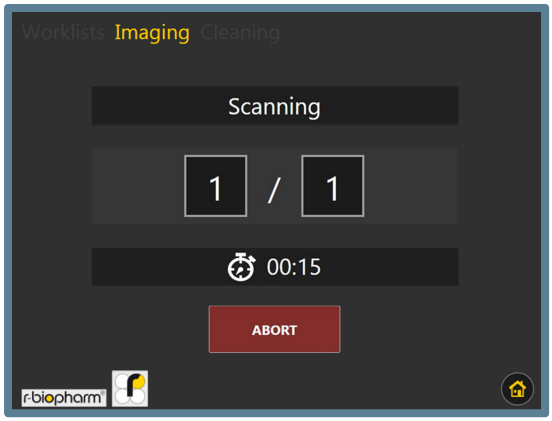


Fig. 56

6.8 Accessing stored Images

Images which are captured using the feature described in section 6.7 are stored on the instrument, but only up to a maximum of 8 entries. To access these images, the user can navigate to the 'Imaging' category of the **main menu** and select the Saved Images option.

The screen below shows the screen that contains the latest stored images. By selecting an entry, meta-data are shown on the right-hand side, as well as options to save the image to a USB device in either .JPEG, .PNG or .BMP format.

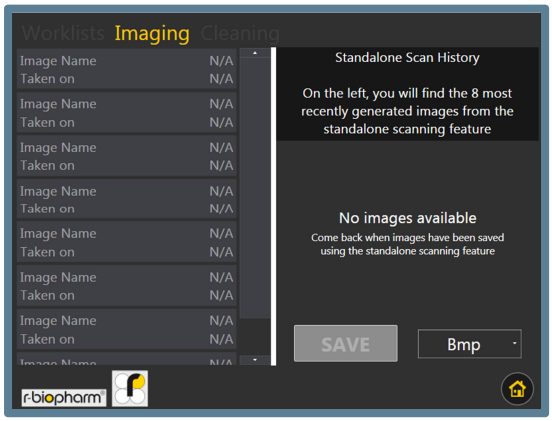


Fig. 57

Similarly to the other features within the instrument software, entries from this list can be deleted by pressing and holding down on a selected entry. Holding down for long enough will bring up a pop-up that asks if the user would like to delete the selected entry.

6.9 QC-test

For performing a QC test the RIDA qLine® QC Kit (ZG1108) is needed. The procedure is described in detail in the manual of the RIDA qLine® Soft.

6.10 Automated cleaning routine

Within the ‘Cleaning’ category of the **main menu**, there exists a button labelled ‘Standard cleaning procedure’ which allows the user to initiate the washing and rinsing of the reagent and waste lines.

Fig. 58

Immediately after pressing start, a pop-up will appear asking the user to load cleaning solution into the wash bottle.

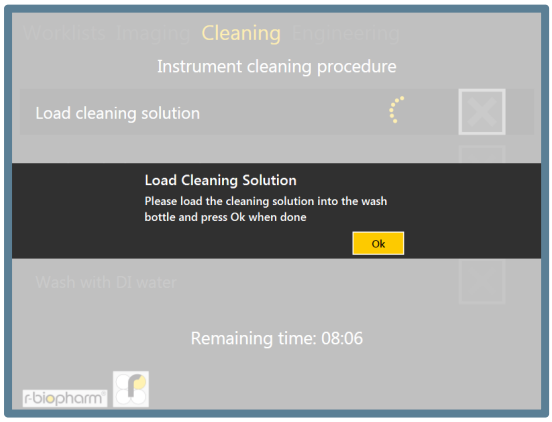


Fig. 59

At this point, the user is expected to perform the following:

1. Remove the wash bottle from the instrument
2. Load a cleaning solution (e.g. 4 % bleach or 4 % SDS) into the wash bottle and fastening the caps back on correctly.
3. Place the wash bottle back inside the instrument and close the door
4. Press OK on the pop-up

Once the pop-up has been closed, the instrument will start to prime the lines of the wash pump with the cleaning solution, followed by a short soaking period; the task is reflected on screen.

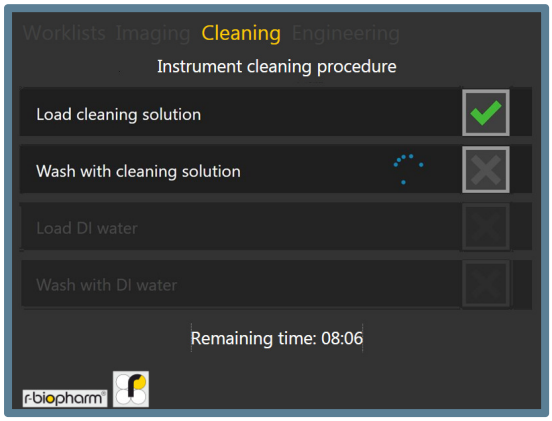


Fig. 60

Once the instrument has finished soaking the lines, a new pop-up will appear that asks the user to load DI water into the wash bottle as shown in Figure 55. At this point, the user is expected to perform the following:

1. Remove the wash bottle from the instrument and discard any remaining cleaning solution
2. Fill the wash bottle with de-ionised water and securely fasten the caps
3. Place the wash bottle back in the instrument and close the door

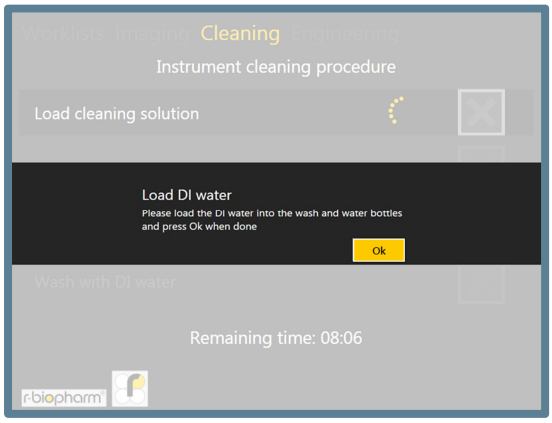


Fig. 61

Once the pop-up is closed, the instrument will once more flush and soak, while also back-priming the DI water in the system; the task is reflected on screen, as shown in Figure 62.

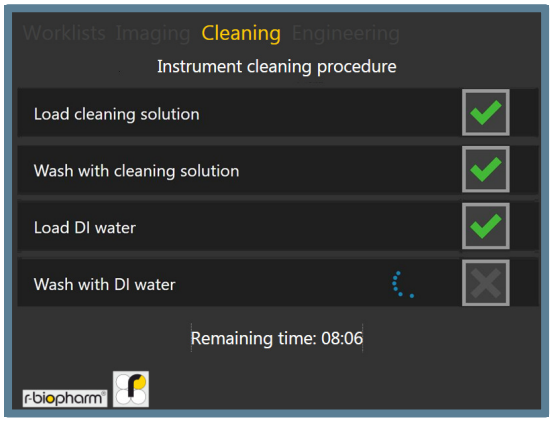


Fig. 62

When finished, the screen that is shown above will re-appear. From here, the user may return to the **main menu**, or if so inclined, re-run the cleaning.

7 Instrument shutdown

This section describes the procedure that must be followed when the user wishes to shut down the instrument. The user is strongly advised to follow this routine during every shutdown.

If the user is ready to shut down the instrument, the first step to take should be to power down the instrument. By navigating to the **main menu**, the **system menu** button will become available; the user should navigate to the system menu and access the 'Information' tab. At the bottom of this screen, the power options for the instrument can be found. To shut down the instrument, the user should press the Power Off option and confirm their selection when the pop-up appears.

If done correctly, the touch-screen should show a 'Shutting down…' message. Once the touch-screen has turned off, the mains power inlet should be switched off.

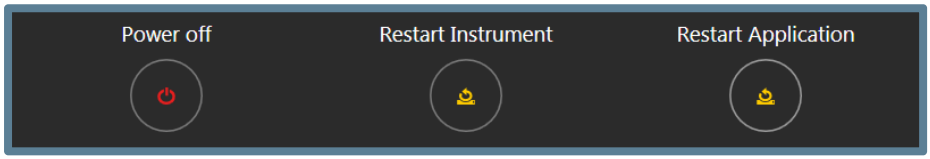


Fig. 63

When the instrument has been completely powered down, the following steps should be carried out to the instrument and its accessories:

Step	To-do
1	Remove the Wash and Reagent bottles from their respective holders. Cap the bottles if required for future use and return to the fridge.
2	Remove the Waste Bottle and dispose of waste in accordance with country, federal, state and local regulations.
3	Carefully remove the Sample Carousel from the instrument. Treat samples depending on subsequent use: cap if required again or discard in accordance with country, federal, state and local regulations
4	Remove the Tip Waste Trough and empty the contents into general hazardous waste.
5	Remove the Priming Trough and empty the contents into general hazardous waste.
6	Remove the Tip Rack from the deck.
7	Remove the Strip Holder from the tray. Remove membranes and store or discard as required.
8	Wipe down the interior with microsol or alcohol wipes
9	Clean the Sample Carousel, Tip Rack and Strip Holder with microsol or alcohol wipes and re-insert into the instrument.
10	Close the instrument door.

8 Troubleshooting

For any difficulties that are experienced with the instrument, consult the guidelines below for possible resolutions. If the guidelines do not resolve the issue, informing qualified service engineers of the steps that have already been taken via this section will help return the instrument to full working order as quickly as possible

8.1 Simple troubleshooting

8.1.1 Visual inspection

A good visual inspection of the instrument prior to switching it on can sometimes reveal problems or potential problems. Performing the following simple checks will help determine the condition of the instrument.
Check for any signs of obvious damage. With the instrument switched OFF, raise the main cover, and inspect the base of the instrument for any spillages or obstructions that will prevent the accessories from resting flat on the instruments base. Remove all the accessories from the base and clean with a lint free cloth

8.1.2 Mechanics

Ensuring that the tip picking/ejection system is in the HOME position, move the X and Y axes by hand to ensure that there are no obstructions. If obstructions are encountered, look for mechanical obstructions, such as loose screws.

Ensure that the aspirating needles are clean and in good condition. Gently clean each tip with an alcohol wipe. The needles should be straight, if for some reason they have been bent, then a qualified engineer should replace them.

Ensure that the carousel and holder are clean, and when the instrument is off, there is no undue friction when turning the carousel.

8.1.3 Fluidics

Check for any damage to the tubing, and ensure that there are no kinks visible along the 'Y' and 'X' axes, which could affect the sample processing. Pay particular attention to the connections at the tip picking/ejection mechanism.

If no problems are encountered during visual inspection, the instrument can be switched on. If problems are encountered during visual inspection, these must be rectified prior to switching the instrument on; otherwise further damage may be done to the instrument.

8.1.4 Initialisation

The following initialisation sequence of events should occur when the instrument is switched on:

Step	To-do
1	The aspirating needles should move upwards to its 'HOME' position.
2	The arm should move towards the back of the instrument to its 'HOME' position.
3	The X-axis should move left to its 'HOME' position.
4	The tray holder should move outwards.
5	The green light (LED) at the front left hand side of the instrument should be ON.
6	The Touch Screen Display to the right of the instrument should be ON.

If the instrument fails to perform any or all of these tasks, then there is a fault, which needs to be rectified.

Please contact your local representative or R-Biopharm AG for further help.

8.1.5 Critical error messages

If critical instrument error messages, as described in section 4.5.5, keep arising during initialisation or at any other step with the instrument, the code sequence for each entry should be recorded and sent to your local representative for further inspection. If possible, it's recommended to also retrieve the logs for the instrument using the procedure that is described in section 6.1.2, and forward those with the error report.

9 Maintenance

9.1 Cleaning the instrument

The cleaning of the instrument should be performed regularly using proprietary decontaminants followed by water and appropriate detergent. Only the deck and outside of the instrument should be cleaned, together with running the appropriate cleaning cycles to keep the tubing clean. No attempt should be made to remove instrument panels in order to clean the inside of the instrument, as there is a risk of injury and risk of damage to the instrument.
Protective gloves should always be worn when cleaning the instrument.
Appropriate detergents should be used to clean the surrounding surfaces.
A cloth, dampened in detergent should be used to wipe all areas in and around the base and the reagent area. Use the same technique to wash all parts that may come in contact with any accidental spillage.
The instrument will automatically clean all the lines with Buffer during the assay. Clean all the reagent

troughs at the end of each run, and ensure that the Waste Bottle is emptied and the tip-collecting basket also emptied and cleaned.
It is the responsibility of the user not to use decontamination or cleaning agents that could cause hazard as a result of the reaction with parts of the equipment or with material contained in it. If in any doubt about the compatibility of decontamination or cleaning agents, please contact your local agent, or:

R-Biopharm AG
An der neuen Bergstraße 17
64297 Darmstadt, Germany
Phone: +49 (0) 61 51 - 8102-0
Fax: +49 (0) 61 51 - 8102-40
E-mail: *info@r-biopharm.de*
www.r-biopharm.com

Overview of the cleaning procedures:

9.1.1 Daily cleaning

Evening – routine
After completion of the daily routine, the "Cleaning" routine should be selected. This is a system rinse with DI-water to remove the wash buffer from the system and prevent clogging of the washing unit by salt crystals. The device prompts you to load a cleaning solution, please use exclusive DI-water for the entire rinse.

9.1.2 Weekly cleaning

Reagent / buffer management, disinfection

- Once a week, the washbuffer- and wastetank should be emptied and rinsed with DI-water.
- After one week, all refilled reagents and the used glassware should be replaced.

9.1.3 As required

Cleaning the System

- If necessary, **the ”Cleaning” routine can be done by using 70% Ethanol**, then repeat the “Cleaning” routine with DI-water.

Cleaning surfaces

- To clean the surfaces (Orbital Shaker, Floor Surface, all removable parts) **use non-greasy surface cleaners.**

9.2 Maintenance and calibration of the pumps

The general maintenance and the calibration of the pumps is described in detail in the autoBlot Service manual.

Only by R-Biopharm AG or associated trained service personnel may authorised repairs and servicing be carried out.

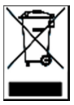
For further details of instrument or to arrange for training to be given on the instrument, contact R-Biopharm AG at the above address.

9 Disposal

Warning

Dispose of any unused reagents and waste in accordance with country, federal, state and local regulations.

Instrument Disposal:



As part of the WEEE EU directives, this instrument should be returned to the manufacturer for dismantling at the end of its life.

Packaging Disposal:

Please dispose of all packaging in accordance with local recycling regulations

10 Technical support

For all technical support and assistance, contact:

R-Biopharm AG
An der neuen Bergstraße 17
64297 Darmstadt, Germany
Phone: +49 (0) 61 51 - 8102-0
Fax: +49 (0) 61 51 - 8102-40
E-mail: *info@r-biopharm.de*

Only by R-Biopharm AG or associated trained service personnel may authorised repairs and servicing be carried out.

For further details of instrument or to arrange for training to be given on the instrument, contact R-Biopharm AG at the address above.

11 Limited warranty

Please note the serial number of the instrument (found on the back) below for future reference:

Instrument serial number:

Warranty Statement

R-Biopharm AG warrants that each product described herein will be free from defects in materials and workmanship for a period of one year from the date of delivery. R-Biopharm AG agrees, as its sole

responsibility under this limited warranty, and upon prompt notice of the defect, to repair or replace any product found to be defective within the warranty period.

The limited warranty is not applicable to: (1) abnormal wear and tear (2) abuse, unreasonable use, improper installation, mistreatment, or neglect (3) damage caused by equipment or system with which the product is used (4) damage caused by modification or repair not made or authorised by R-Biopharm AG, or (5) theft, vandalism, fire, water or other peril. Product may not be returned without proper authorisation from R-Biopharm AG; cost of transportation, removal, or reinstallation of the equipment will be paid by the purchaser. This warranty and the remedies set forth herein are exclusive and in lieu of all other express or implied (including any implied warranties or merchantability or fitness for a general purpose), and no other representations or claims shall be binding on or obligate R-Biopharm AG in any way. In no event will R-Biopharm AG be liable for any special, incidental, or consequential damages resulting from use or malfunction of this product or the equipment or system with which it is used, loss of revenue, or cost of replacement of goods.

12 Appendix

12.1 Appendix II: Synopsis of symbols used in manual an on instrument

Symbol	Colour	Publication	Description	Placement
	Symbol & Outline: Black	IEC 60417 – 5032	Alternating Current	Instrument Serial Label
	Symbol & Outline: White	IEC 60417 – 5007	On (Supply)	Inlet Filter
	Symbol & Outline: White	IEC 60417 – 5008	Off (Supply)	Inlet Filter
	Background: Yellow Symbol & Outline: Black	IEC 60417 – 5007	Caution, Risk of Danger	On Caution Labels

12.2 Touchscreen icons

Icon	Function	Location
	View, select then run a work-list	Home Screen (Worklist Tab)
	Access the work-list history menu	Home Screen (Worklist Tab)
	Initiate the standalone imaging	Home Screen (Imaging Tab)
	View latest standalone images	Home Screen (Imaging Tab)
	Initiate the automated cleaning procedure	Home Screen (Cleaning Tab)
	Access the general engineering settings	Home Screen (Engineering Tab)
	Access the advanced engineering settings	Home Screen (Engineering Tab)
	Open the System Menu	Bottom Right Corner of the Home Screen (All Tabs)
	Indicates that nearby values represent a duration	During imaging
	Shutdown the instrument	System Menu
	Restart – application or instrument	System Menu
	Return to previous screen	Global
	Navigate to the next screen	Global
	Show the engineering password as plain-text	Advanced Engineering
	Hide the engineering password with '*'	Advanced Engineering

12.3 Appendix II: autoBlot installation checklist

Instrument serial number:	

Customer name::	
Address:	
Phone:	
Fax: :	
E-mail address:	

Did the instrument arrive in good condition?	Yes	☐	No	☐

If no, provide details:

Were the following accessories present?

1 x Touch Screen, Mounting Arm & Attached Cables	
1 x Touch Screen Screws & Keys	
1 x Spare fuses 5A (pack of 2)	
1 x Reagent Bottle Holder	
1 x Wash Bottle Holder	
1 x Waste Bottle Holder	
1 x Priming Trough	
1 x Waste Tip Trough	
1 x Tip Rack Holder	
1 x Tray (Strip Holder)	
1 x Sample Carousel	
1 x Wash Bottle & Lid	
1 x Waste Bottle & Lid	
1 x Mains Lead	
1 x User Manual	
1 x Set of spare packaging tape	

Did the instrument initialise correctly? (refer to 4.5.4 in User Manual)	Yes	☐	No	☐

If no, provide details:

Any other comments:

Representative Name:	
Representative Address:	

Representative Signature:		Date:	
Customer Signature:		Date:	
Customer Print Name:		Position:	

Customer to retain original copy.

Distributor must send copy to:

R-Biopharm AG
An der neuen Bergstraße 17
64297 Darmstadt, Germany

12.4 Appendix IV - autoBlot- Decontamination certificate

Institute Name

Make of Instrument

Model Number

Tick:

☐ This equipment has not been used in an invasive procedure or been in contact with blood, other body fluids or pathological samples. It has been cleaned in preparation for inspection, service or repair.

or

☐ This equipment has been cleaned and decontaminated.
The decontamination method is outlined below:

or

☐ This equipment could not be decontaminated.
The nature of risks and safety precautions to be adopted are as follows:

Signed: Date:

Position Held:

Full Official Address:

Phone :

12.5 Assay protocol

This test is a nitrocellulose membrane-based enzyme immunoassay (immunoblot assay) for the quantitative detection of allergen-specific IgE antibodies in human serum and plasma (citrat).

Test procedure:

The test procedure is designed for 36 membranes in the RIDA qLine® autoBlot

1	Allow the Membranes, reagents and patient sera to come to room temperature (20 - 25 °C). Shake reagents before use.
2	Transfer the 5 ml of wash buffer concentrate Wash 25x of 4 kits to the wash buffer reservoir of the RIDA qLine® autoBlot and fill it up to 500 ml with distilled water (= wash buffer). All incubation steps should be performed at room temperature (20 - 25 °C)
3	400 µl of wash buffer are dispensed onto the membranes and incubated for 1 minute while shaking. After the incubation the wash buffer is aspirated whereat the membranes are tilted backwards
4	400 µl of patient's serum is dispensed onto the membranes and incubated for 30 minutes on the shaker. After incubation the serum is aspirated whereat the membranes are tilted backwards
5	400 µl of wash buffer are dispensed onto the membranes and for 1 minute while shaking. This step is **repeated for a total of 3 times**
6	400 µl of Antibody are dispensed to the membranes each and incubated on the orbital shaker for 45 minutes. After incubation the antibody is aspirated whereat the membranes are tilted backwards.
7	The washing is performed as described in item 5
8	400 µl of Conjugate are dispensed to the membranes each and incubated on the orbital shaker for 20 minutes
9	The washing is performed as described in item 5. But the washing step is **repeated as much as 7 times**.
10	400 µl of Substrate are dispensed to the membranes each and incubated on the orbital shaker for 15 minutes. After incubation the substrate is aspirated whereat the membranes are tilted backwards
11	400 µl of wash buffer are dispensed to the membranes each and incubated on the orbital shaker for 1 minute. Thereafter the wash buffer is aspirated whereat the membranes are tilted backwards
12	400 µl of distilled water are dispensed to the membranes each and incubated on the orbital shaker for 1 minute. Thereafter the water is aspirated whereat the membranes are tilted backwards
13	The membranes are dried by an integral fan for 10 minutes.
14	As a last step a picture is taken from all membranes by the integral scanner and send to the RIDA qLine® Soft for evaluation

The results are expressed in IU/ml and in 7 RAST classes