r-biopharm®

RIDA qLine® autoBlot

User Manual

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User manual
RIDA qLine® autoBlot

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CE

IVD

Inhalt

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

1 Introduction

1.1 Intended purpose

For in-vitro Diagnostics. The RIDA qLine® autoBlot is a fully automated Analyzer for the processing RIDA qLine® Allergy tests. The RIDA qLine® autoBlot may only be used in combination with RIDA qLine® Allergy tests that are approved for processing and analysis. The RIDA qLine® autoBlot must be used in combination with the RIDA qLine® Soft software. The product is intended for professional use.

1.2 Purpose oft the document

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 utilise its potential.

2 Product Overview

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 Charge-Coupled Device (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 strips used on the instrument. The unit as a whole is controlled via an integrated touchscreen 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 for detection of specific IgE in allergy diagnostic.

Starting from sample handling and ending with images of the panels once processing has completed.

The instrument is designed to be partnered with RIDA qLine® Soft for the band interpretation of RIDA qLine® Allergy tests 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:

i. A user sends 1 or more work-list from RIDA qLine® Soft to the instrument.

ii. The user walks over to the instrument and selects a work-list they wish to process. Following onscreen instructions, the user is told how to prepare the instrument.

iii. When the instrument has been loaded as requested, a panel pre-scan will begin. This scan ensures that the correct number of test kit panels are inserted, in the correct order. This process works by detecting the colour of each panel.

iv. When the pre-scan has verified the correctness of the panels, the sample tube verification begins. This is a process of ensuring all the correct sample tubes are loaded into the carousel. This is done by comparing detected barcodes with the ones specified in the work-list.

v. When the correctness of the samples have been verified, the actual processing protocol is triggered. The protocol includes the prewashing of the membranes, the transferring of samples from the carousel to the panels, and the continued processing of the panels, including the dispensing and aspiration of reagents using precision piston pumps. All samples and reagents are transferred using disposable plastic tips. All reagents are provided as part of a kit.

vi. Once the assay has been completed, the image scanning will automatically begin to capture an image of every panel. These images are saved on the instrument and are made available to RIDA qLine® Soft.

vii. An optional, but recommended last step, would be to run an automated cleaning routine with the instrument.

2.1 Glossary

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

3 Technical Specifications

Instrument type:	Standalone 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 mL to 1000 mL
Minimum required sample volume:	1000 mL
Dispensing Mode & Accuracy:	Piston Pump: +0/-5 % Peristaltic pumps: +0/-10 %
Software:	Pegasus software
Voltage & Frequency:	Electrical power source at AC 100 to 240 V AC 10A 50/60Hz
Fuses:	5A UL Approved – Ø5x20mm
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 3V/m 1.4 GHz to 2 GHz 1V/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 a third 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 apes.

7. Remove the X Rail Transit Clamp.

8. The outer shell can be collapsed flat and placed onto the base of the packaging and the lid replaced over it.

9. Inspect the instrument for any obvious signs of transit damage. Report any damage immediately to your local representative.

10. Check that the serial number on the instrument and the delivery note are the same.

11. Unpack accessory box and check that all accessories are present. The full list of accessories are listed in the table below.

4.2 Accessories provided with the instrument

Accessory Box A

Item	Description	Quantity
1	Wash Bottle Holder	1
2	Waste Bottle Holder	1
3	Wash Bottle & Lid	1
4	Waste Bottle & Lid	1
5	Reagent Bottle Holder	1

6	Priming Trough	**1**
7	Tip Rack Holder	**1**
8	Touchscreen Screws & Keys	**1**
9	5A Fuse	2
10	Instrument Mains Lead	1
11	Ethernet Cable	1
12	Spare Packing Tape Set	1

Accessory Box B

Item	Description	Quantity
13	1000 mL spare Nalgene Rect. Bottle* *Labelled “A. bidest”	**1**
14	Touchscreen, Mounting Arm, Cables	**1**
15	Waste Tip Trough	**1**
16	Tray (Strip Holder)	**1**
17	Sample Carousel	**1**

Software

Product	Art. No.
RIDA qLine® Soft	Z9995

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

4.3 Consumables required but not provided with the instrument

Consumables in addition to the RIDA qLine® Allergy tests are the disposable plastic tips (Tecan Genesis Compatible, 1000 µL non-filtered, non-sterile, clear tips. The instrument has been designed for use with a specific type of tip, 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.

The Carousel uses Sample Tubes which sizes range between:
Height: 75 - 102 mm
Diameter: 12 - 17 mm

The supplied RIDA qLine® Allergy reagents must be transferred into the glass bottles for the autoBlot before use. The tips and glass bottles for the reagents can be directly ordered from R-Biopharm, as well as the corresponding screw caps.

Product	Art. No.
RIDA qLine® Allergy	A6442, A6242, A6342, A6142, A6142EC2, A6142VIET, A6142PSMI, A6442UA1, A6242H, A6242PA, A6342UY, A6142UZ, A6442TZA, A6342MENA, A6442UZ, A6442BY, A6342KE, A6342BY, A6142HVEN, A6142UY, A6442UA2, A6242GR, A6342PH, A6242PH, A6142BY, A6242BY, A6242UY, A6142ZW2, A6142EAWU, A6242EAWU, A6342EAWU, A6442EAWU, AW2001, AW2002, AW2003, AW2004
RIDA qLine® autoBlot Screw cap bottle 20 mL	Z0011
RIDA qLine® autoBlot Screw cap for Z0011	Z0012
RIDA qLine® autoBlot Pipet tips	Z0013
RIDA qLine® QC-Kit (for RIDA qLine® Soft)	ZG1108

4.4 Instrument labeling

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

4.5 Detailed Personal Safety Information

Symbol	Description
	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.
	Warning! 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.

4.6 Environmental Conditions

4.6.1 Bench Space

Always place the instrument on a flat and solid surface while ensuring that there are no obstruction 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.

4.6.2 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.

4.6.3 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).

4.6.4 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
Temperature:	Ambient temperature range: Between 5 - 40 °C
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 V – 10A 50/60Hz & fluctuations of up to ± 10 % in supply
Storage conditions:	from 5 °C to 50 °C

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

4.7 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 **4.6.1**, the initial set-up steps can be started.

4.7.1 Lubricate (grease) the Probe O-Ring

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

Place a 1000 mL 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, 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.

Figure 1: probe o-ring

4.7.2 Mount and Connect the Touchscreen

Figure 2: touchscreen rear clamp mounting

Figure 3: touchscreen-to-instrument mounting

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 in Figure 2. 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.

Maneuver 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 in Figure 3. 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 25way connector at the side of the instrument. This connection is illustrated within the top-most **blue** circle in Figure 3.

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 in Figure 3.

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

4.7.3 Powering the Instrument

To power on the instrument, insert a mains lead into the side of the instrument while the switch state is set to off (as denoted by the marker) as shown in Figure 4.

Note that the instrument must be powered by an earthed mains supply, and it is recommended to power the instrument through an appropriate RCD device.

Once the cable has been connected on both ends, press the power switch until the | icon is down. Completing the former steps should have now resulted in the instrument being turned on.

Figure 4: The mains lead attached to the power inlet socket of the instrument

4.7.4 System Start-up and Initialisation 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 infront 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 5. At this point, the application can be entered by pressing start.

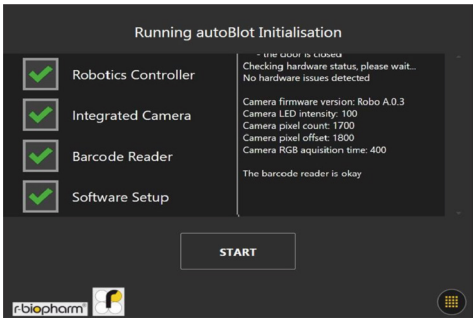


Figure 5: The interface that is shown after a fully successful instrument initialisation routine

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.

An example of a failure screen is shown in Figure 6. Note you will not be allowed to enter the main application if any errors occur.

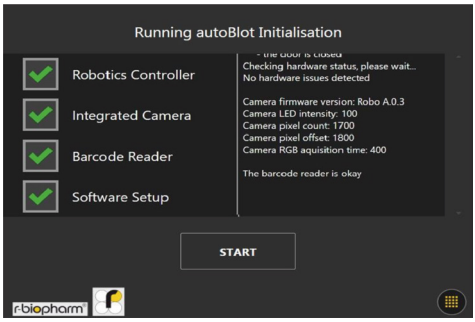


Figure 6: The interface that is shown when there are failures in the initialization routine

4.7.5 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, a screen as shown in Figure 7 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 initialization, 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.

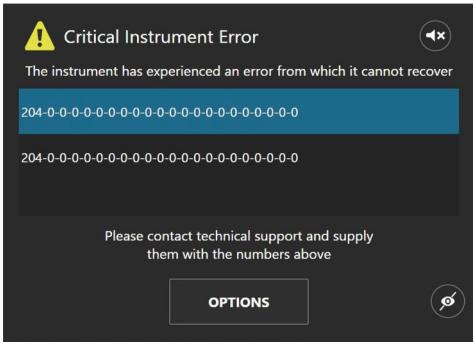


Figure 7: An example of the screen that is shown during an instrument error; this screen demonstrates two error code entries that were generated from the robotic controller

5 System Overview

5.1 AutoBlot Component Guide

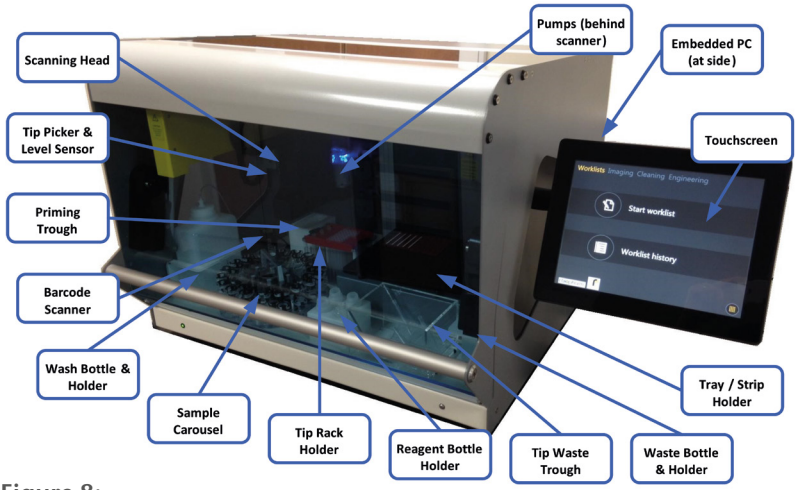


Figure 8:
A guide that details the components and locations which are vital to the instrument

5.2 Installation of Accessories

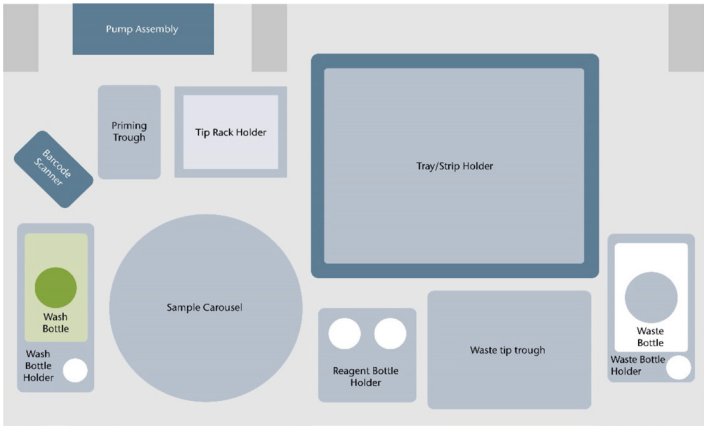


Figure 9: An illustration of the deck layout for the instrument

Figure 9 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 centre 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 strip holder (also known as the tray) onto the table. There is only one way it can fit.

Only use the liquid waste bottles supplied with the device

6 System Operation

Following a successful instrument initialisation routine, the start button will have become available, as demonstrated in Figure 5. Upon pressing the start button, the first screen that will become visible is the main menu which has the work-lists tab automatically selected (see Figure 10).

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.

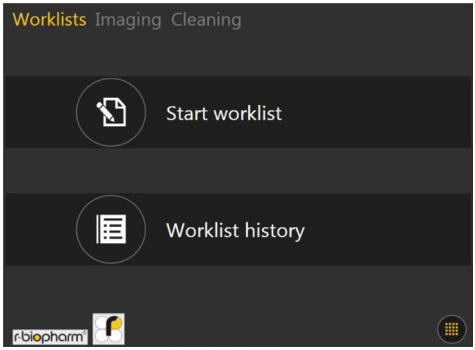


Figure 10: The main menu for the 'work-lists' category

6.1 The 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 (shown in Figure 10 and highlighted in Figure 11). This button opens a system menu, a menu which contains information about the system, as well as some important features.

Figure 11:
The button icon which launches the system menu

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 Figure 12. 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.

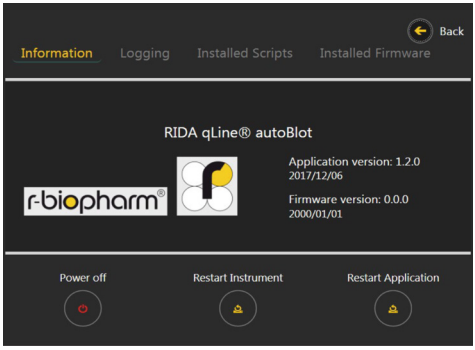


Figure 12: The instrument information tab of the system menu

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 branding logo for approximately 3 seconds, or until you see the message 'engineering activated' as shown in Figure 13.

The engineering tab can be deactivated by repeating the above steps until a similar 'engineering has been deactivated' message is shown.

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'.

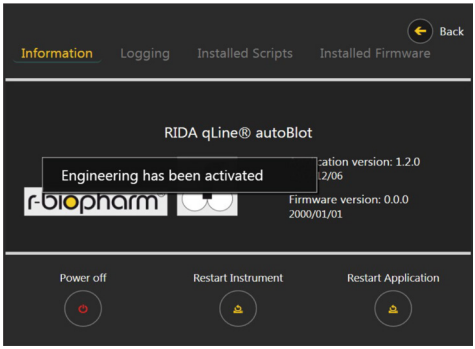


Figure 13: The message that is shown when the engineering tab has been activated

6.1.2 Logging Tab

The logging tab can be found to the right of the information tab (see Figure 14). This is a tab which provides a preview of the most recent events that were logged by t he 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.

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.

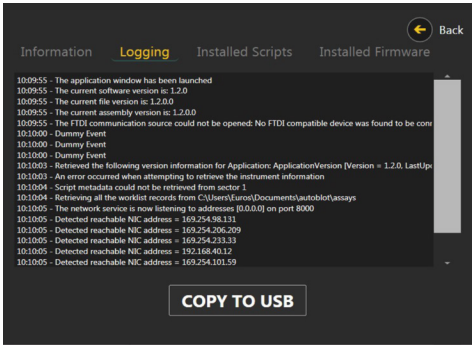


Figure 14: The logging tab of the system menu

6.1.3 Installed Scripts Tab

The installed scripts tab can be found to the right of the logging tab (see Figure 15). This tab contains the names, version numbers and build dates of all the scripts that the software executes in-order to carry out the strip processing protocols.

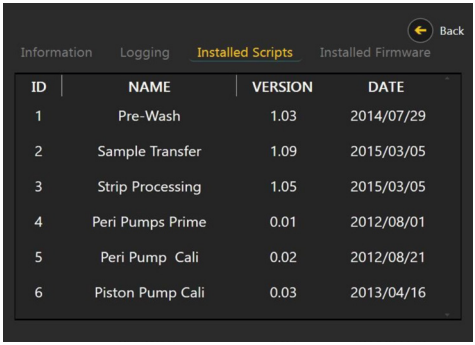


Figure 15: The installed scripts tab of the system menu

6.1.4 Installed Firmware Tab

The installed firmware tab can be found to the right of the installed scripts tab (see Figure 16).

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 perform.

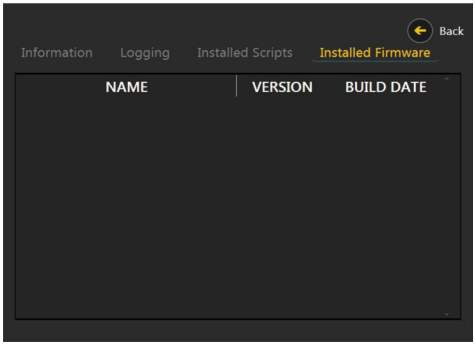


Figure 16: The installed firmware tab of the system menu, which contains 0 entries

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 RIDA qLine® Soft, 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 screen from Figure 17 should become visible. The 'Advanced Tools' option is password protected and not intended for normal users, therefore this tool should be left alone.

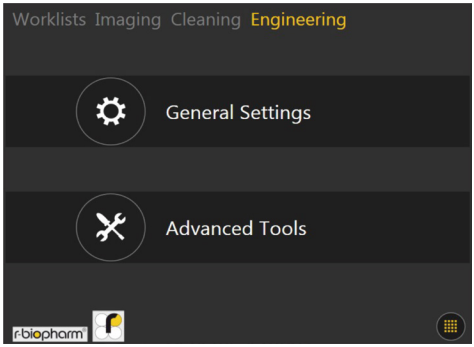


Figure 17: The engineering tab that is located within the main menu

Selecting the ‘General Settings’ option will show all the engineering options which don’t require authentication. Figure 18 shows what should be seen upon clicking this option.

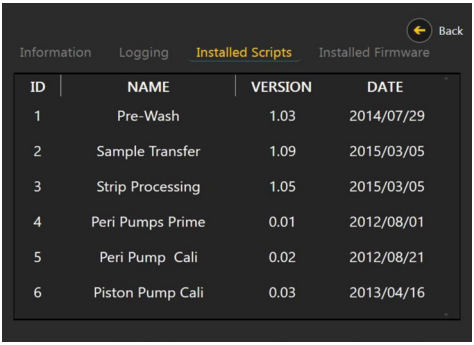


Figure 18: The engineering menu for the general instrument settings

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 blue, press the select button. Completing the former should result in a screen similar to what is shown in Figure 19.

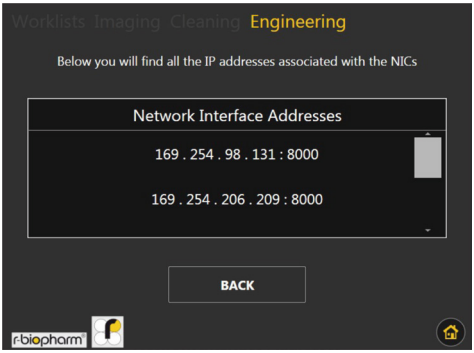


Figure 19: The screen that is shown after selecting the ‘IP Address Information’ tool from the engineering section

The instrument comes with two RJ-45 Ethernet ports which means there are two possible addresses that can be listened to. Each of the two IP addresses in Figure 19 represent the IP address the instrument is listening to for messages. In this example, 169.254.98.131 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).

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 to RIDA qLine® Soft

6.3.1 Device settings for RIDA qLine® Soft

For use with RIDA qLine® Soft the data for RIDA qLine® autoBlot must be entered during the installation of RIDA qLine® Soft and RIDA qLine® autoBlot will be automatically selected as the device type in the program.

In addition to RIDA qLine® Soft, the RLink_AutoBlot.exe program will be copied into the directory C:\Program Files (x86)\R-Biopharm\qLine. It is recommended to create a shortcut to this file on the desktop since the RLink_autoBlot program does not start automatically, but is needed to connect to the RIDA qLine® autoBlot. The RIDA qLine® autoBlot must first be switched on, and then the RLink program must be started.

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 the input mask the IP address, the port, the name of the device and the serial number must be entered.

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 in Fig. 22:

```
[AutoBlot_1]
Description=AutoBlot_1
ShortDesc=AB_1
SerialNr=ATB-9BECA
IP=169.254.32.135
Port=8000

[AutoBlot_2]
Description= AutoBlot_2
ShortDesc= AB_2
SerialNr=
IP=
Port=8000

[AutoBlot_3]
Description= AutoBlot_3
ShortDesc= AB_3
SerialNr=
IP=
Port=8000

[AutoBlot_4]
Description= AutoBlot_4
ShortDesc= AB_4
SerialNr=
IP=
Port=8000
```

Fig. 22:
Connected machines

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.

```
[AutoBlot]
AutoBlotProtocolVersion=1.0.6
AutoBlotSoftwareVersion=1.4.0
AutoBlotFirmwareVersion=1.1.0
AutoBlotCount=1
LogPath= C:\R-Biopharm\Log\autoBlot
QCPicturePath= C:\R-Biopharm\ImportExport\qLine\QC-Test
```

Fig. 23: Autoblot protocolversion

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).

Make sure that the device is connected to the power supply during all update processes.

6.3.2 Full automatic processing

When the RIDA qLine® Allergy tests are processed fully automatically in RIDA qLine® autoBlot, the bar codes of the test tubes will be scanned and sent to the connected RIDA qLine® Soft program. When RIDA qLine® Soft is connected to the LIS, all requests will be retrieved from the LIS, and a worklist will be created automatically. This worklist will be sent automatically to RIDA qLine® autoBlot and displayed on the touchscreen.

If RIDA qLine® Soft is not connected to a LIS, the test requests of the specimens to be tested must be entered manually in RIDA qLine® Soft in advance. Once the specimens are scanned in the machine, a worklist is created, sent to the machine, and appears on the RIDA qLine® autoBlot screen.

The lab IDs that were entered in the program and the lab IDs on the test tubes must be identical. If the manually entered lab IDs are not identical to the scanned lab IDs, a worklist cannot be created.

7 Assay processing

7.1 Creating a Worklist

Upon connecting to the instrument and performing successful calibration scans, the environment is set for using the instrument for strip processing and analysis. From the **main menu** and within the **worklists** tab, the option called 'Start Worklist' takes the user to the menu from which they can select a work-list to run.

On a new instrument, the screen that the user will see is included in Figure 20, which states that there are no known work-lists for the user to choose from.

In order to populate this menu with work-lists, the user must first create new work-lists within RIDA qLine® Soft and then forward the details to the instrument. This section will cover how this can be achieved.

If the user returns to the 'Start Worklist' menu that was detailed at the beginning of this section, a single entry should now be visible in a list called 'Pending Worklists', as shown in Figure 21.

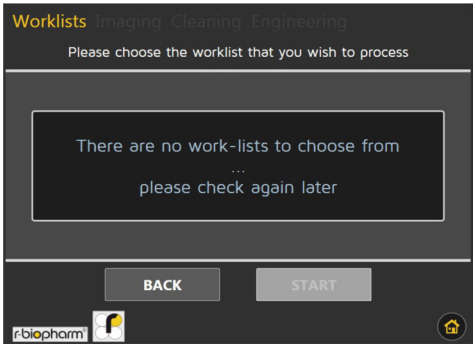


Figure 20: The work-list selection menu when no work-list entries have been sent

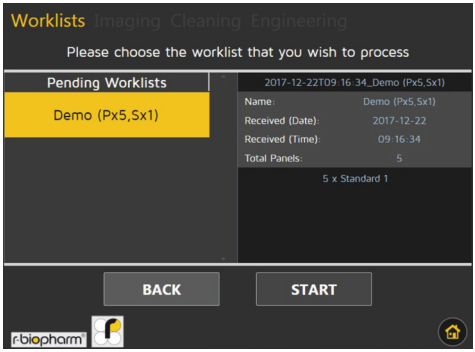


Figure 21: The 'start worklist' menu which contains a single entry that was received from the B4C software

7.2 Running a Work-list

If the user is able to see a screen similar to what is shown in Figure 21, then they are ready to start a worklist. 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, as shown in Figure 22.

Take note of these values Fill the required volume into the RIDA qLine® autoBlot Screw cap bottle 20 mL.

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 (see Figure 23); 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 (see Figure 24).

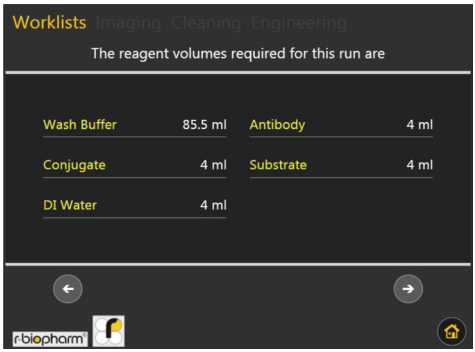


Figure 22: The screen that informs the user how much volume is required for each reagent that is required by the selected work-list

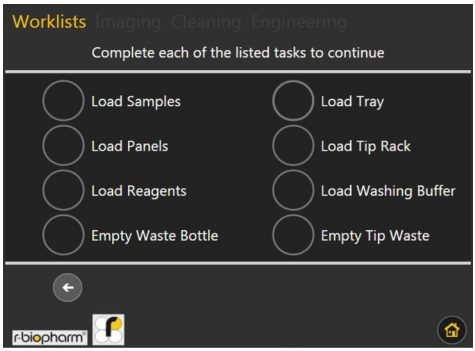


Figure 23: An in-complete check-list

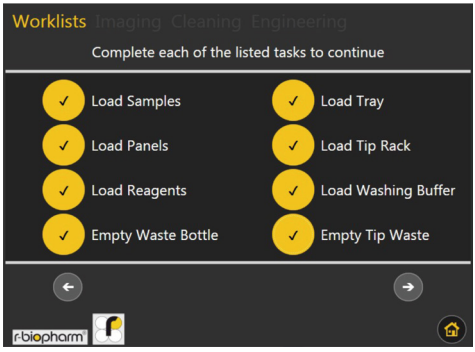


Figure 24: A completed check-list that results in the progression button becoming visible

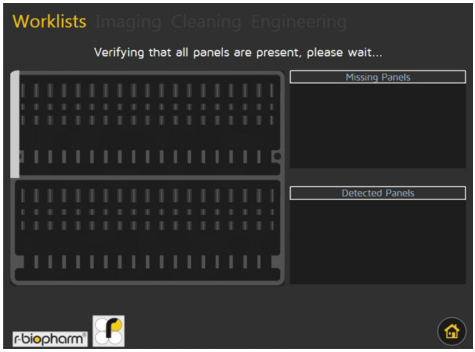


Figure 25: The pop-up that is shown if any of the expected panels are missing

After confirming that everything is located correctly within the instrument, pressing 'navigate forward' will immediately trigger the panel verification scan. This is a procedure where the on-board software verifies that all of the panels are present and in the correct order - see Figure 25. Whenever the verification fails, the user will be notified as to the cause. Following such an outcome, the user will be allowed to retry the verification routine by pressing the button that is shown in Figure 26.

A successful verification scan will automatically jump to the next menu, which is the sample verification routine.

Figure 26: The button that can be pressed to retry the panel verification routine

Following the completion of the panel verification, the user will be taken to the screen that is shown in Figure 27. In this screen, all the barcodes from the work-list will be listed on the left-hand side. As the instrument rotates the carousel checking for barcodes, the instrument will clear any detected entries from the 'missing' list. If the missing list

becomes empty, the verification passes and automatically navigates to the next screen. If the instrument scans the entire carousel but still has entries in the 'missing' list at the end, the sample verification will fail. This will result in the instrument sounding an alarm and showing an error pop-up.

When the user acknowledges the failed verification, the screen resets itself with an additional option to restart the scan after they have resolved the issues. These issues are usually that barcodes are missing, not pointing outwards towards the scanner, or are illegibly printed.

When the missing sample verification does not encounter any issues and all samples are detected, the main processing screen is entered (see Figure 28). 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.

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

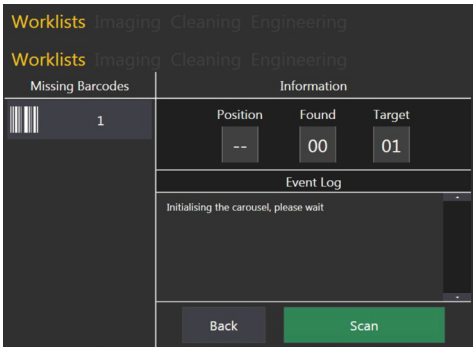


Figure 27: The screen that is shown while the instrument searches for known sample IDs within the carousel

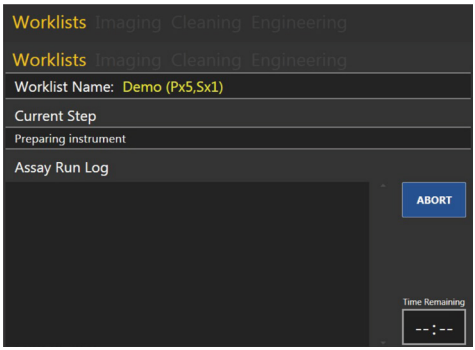


Figure 28: The initial view of the main work-list processing screen

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 that is seen in the bottom right corner of Figure 28 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' (Figure 30). Another tap will transform the control to show the 'Completion Time' (Figure 31). A third tap will return the control to show 'Time Remaining'.

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, pictured in Figure 32. 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

Figure 29: The time control when it has values to show, 3 hours and 7 minutes in this case

Figure 30: The time control when it's set to show the local time, currently 11 minutes past 11 (AM)

Figure 31: The time control when it's set to show the estimated local time at which the processing will finish

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.

Figure 32: The button which can trigger the cancellation of the entire work-list

When the strip processing completes, the imaging will automatically start. The screen that is active during the imaging is shown in Figure 33.

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.

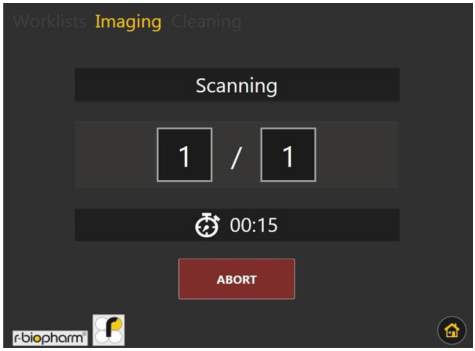


Figure 33: The screen that is shown during the scanning at the end of the work-list

When imaging completes, the data will be automatically saved on the instrument, ready for processing by the RIDA qLine® Soft.

7.3 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 is not resolved after the third attempt, the instrument will pause, sound an alarm and bring up a pop-up window as shown in Figure 34.

Figure 34: The options that become available in the transfer issue pop-up

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 Figure 34:

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**
   Restarts the sample transfer for the current trough (which includes another 3 attempts).

7.4 Obtaining Work-list Information Directly from the Instrument

The analysis of the work-list images can only be done from the RIDA qLine® Soft, 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 in Figure 35. 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.

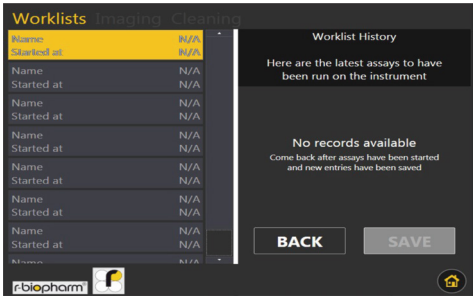


Figure 35: The work-list history screen that contains a single entry

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 included in Figure 36.

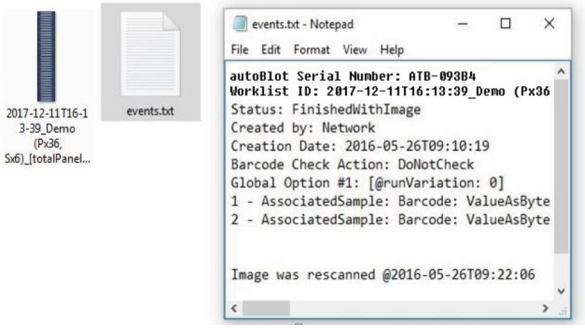


Figure 36: An example of files that are saved when using the Worklist History tool

7.5 Standalone 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, as shown in Figure 37. The -/+ controls increment and decrement the amount of panels/troughs will be scanned should the user press 'START SCAN'.
After pressing 'START SCAN', the screen from Figure 38 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.

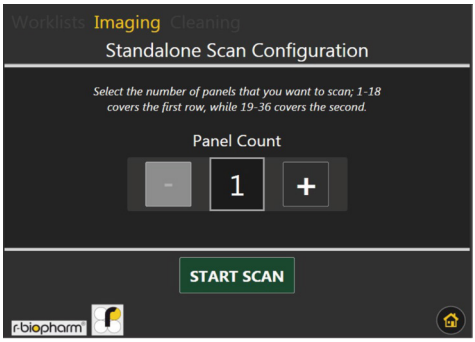


Figure 37: The configuration screen for the standalone scan option

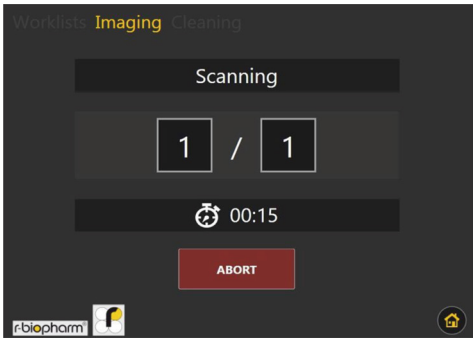


Figure 38: The screen that is shown during the standalone scan procedure

7.6 Accessing Stored Images

Images which are captured using the feature described in section 7.5 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.

Figure 39 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.

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.

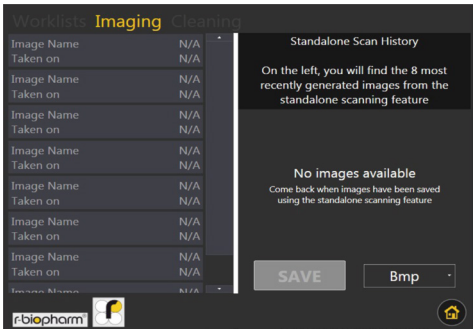


Figure 39: The screen that shows the latest standalone scan entries

8 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.

Immediately after pressing start, a pop-up will appear asking the user to load cleaning solution into the wash bottle as shown in Figure 41. At this point, the user is expected to perform the following:

1. Remove the wash bottle from the instrument

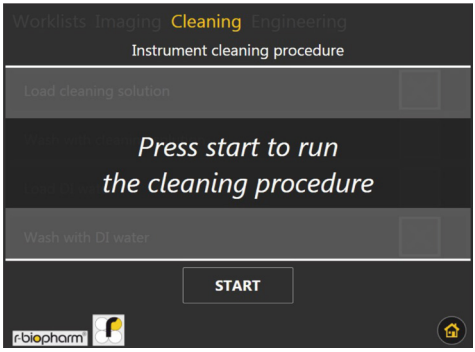


Figure 40: The first screen that is shown after selecting the 'Standard cleaning procedure' option

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, as shown in Figure 42.

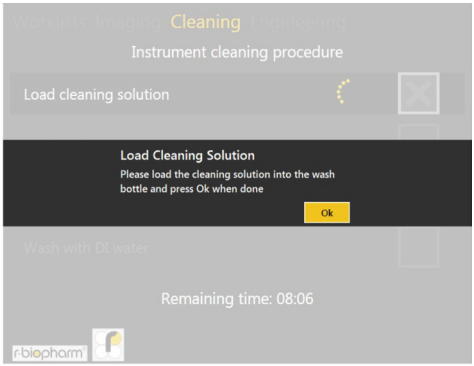


Figure 41: The pop-up asking the user to load a cleaning solution

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

1. Remove the wash bottle from the instrument.

2. Discard any remaining cleaning solution and rinse the wash bottle with de-ionised water.

3. Fill the wash bottle with de-ionised water and securely fasten the caps.

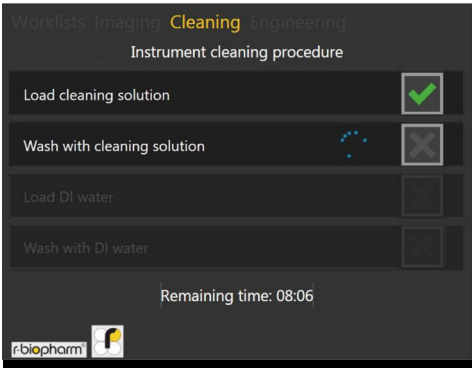


Figure 42: The screen that is shown while the cleaning solution is being used

4. Place the wash bottle back in the instrument and close the door.

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 44.

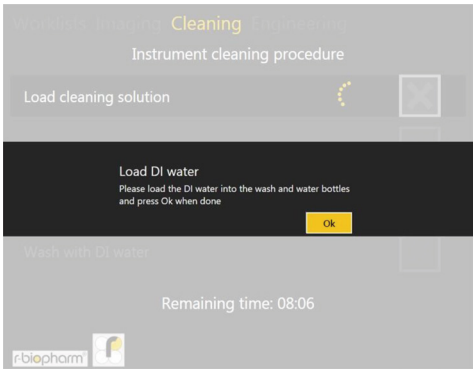


Figure 43: The pop-up asking the user to load the DI water

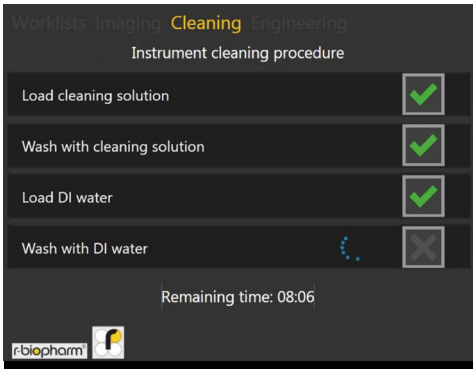


Figure 44: The screen that is shown while

When finished, the screen that is shown in Figure 40 will re-appear. From here, the user may return to the **main menu**, or if so inclined, re-run the cleaning.

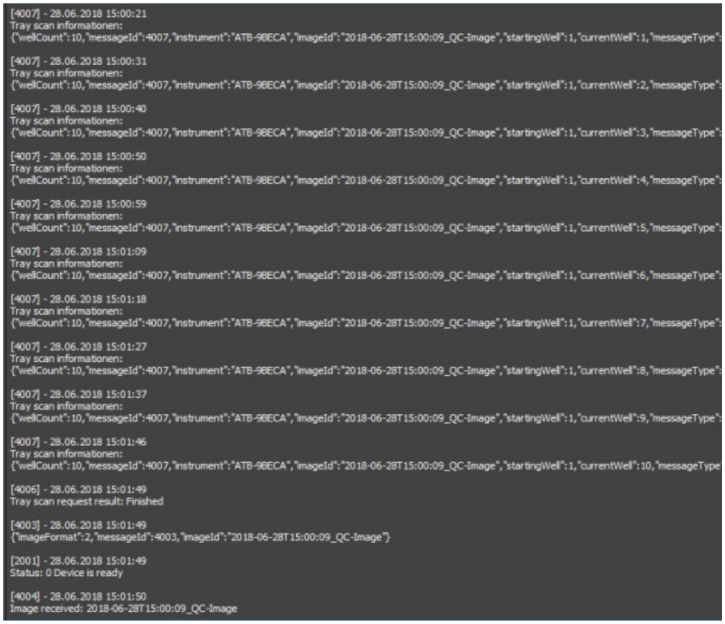
9 QC test using RIDA qLine® Soft

Place 10 strips of the RIDA qLine® QC-Kit (ZG1108) in positions 1 to 10 of the RIDA qLine® autoBlot strip holder. The autoBlot analyzer must be switched on.

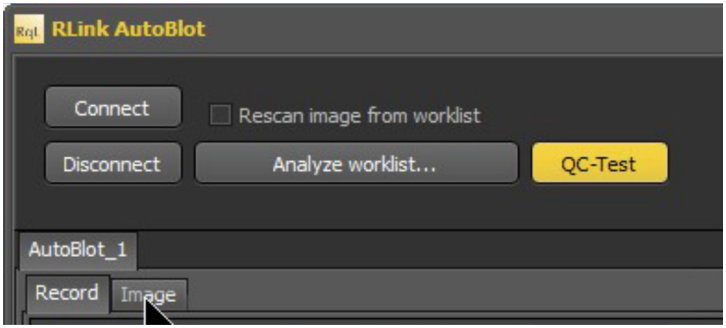
Next start the RIDA qLine® Soft program, and run RLink_AutoBlot.exe.

Open the RLink_AutoBlot program, and click QC test.

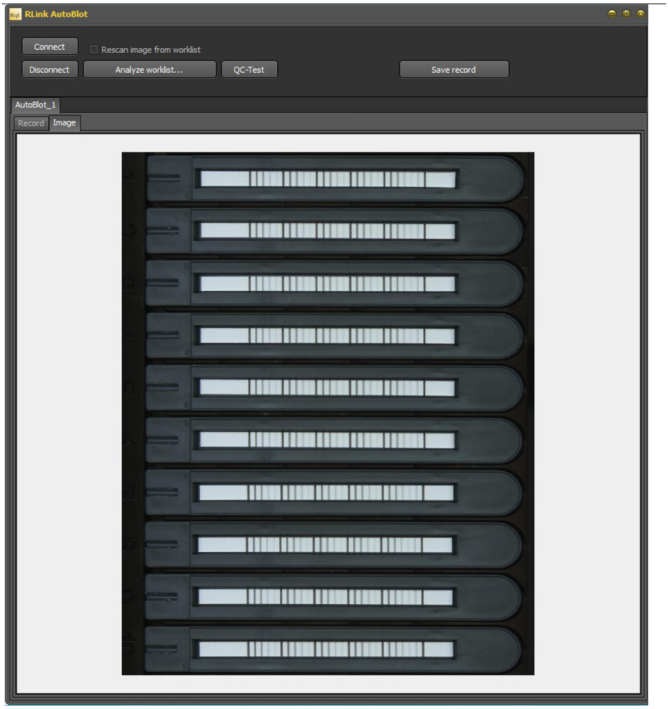
Measurement of the QC strips will start automatically. Measuring will take several seconds. After the measurement, the following image will be displayed in the RLink_ AutoBlot program:



Next click “Image”.



The scanned QC strips will be displayed for you.



Next, open RIDA qLine® Soft and start the QC measurement.

10 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, as shown in Figure 45. 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.

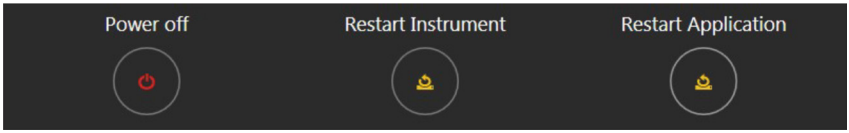


Figure 45: The power options that can be found within the system menu

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

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 strips 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 reinsert into the instrument.

10. Close the instrument door.

11 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.

11.1 Simple Troubleshooting

11.1.1 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.

11.1.2 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.

11.1.3 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.

11.1.4 Initialisation

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

(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 arm on 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.

11.1.5 Critical Error Messages

If critical instrument error messages, keep arising during initialization 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.

12 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**.

13 Disposal

All reagents and materials must be disposed of properly and responsibly after use. Instruments must be disposed of properly and responsibly at the end of their life cycle. Please observe the applicable national regulations for disposal.

Electrical and Electronic Equipment (WEEE) Directive of the European Union (EU).

Products placed on the market in EU countries must be marked with a crossed-out wheeled garbage can (or in individual cases the packaging).

The WEEE directive defines that customers and end users in countries of the European Union (EU) must not dispose of electronic and electrical equipment as well as electronic and electrical accessories in household waste. Within the EU, please contact the local representative or customer service of your equipment supplier who can provide you with information on WEEE disposal/collection.

Packaging Disposal:

Please dispose of all packaging in accordance with local recycling regulations.

14 Corrective action/Notification to authorities

For users in the European Union: Serious incidents occurring in the context of the product must be reported to R-Biopharm AG and the responsible national authority.

15 Technical Support

For all technical support and assistance, contact:

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

+49 (0) 61 51 - 8102-0
info@r-biopharm.de
www.r-biopharm.com

Only by R-Biopharm AG or associated trained service personnel may authorized 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.

16 Conformity IEC 61326-2-6 and RoHS3

The CE marking of the RIDA qLine® autoBlot confirms that the RIDA qLine® autoBlot is compliant with Regulation (EU) 2017/746 (“In Vitro Diagnostic Medical Devices”).

In addition, the RIDA qLine® autoBlot is compliant with the current RoHS Directive and meets the standard IEC 61326-2-6.

17 Limited Warranty

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

SERIAL No. .....

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 authorized by R-Biopharm AG, or (5) theft, vandalism, fire, water or other peril. Product may not be returned without proper authorization 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.

18 Version Number

Version Number	Chapter and Description
Version 1.0 (2017-12-14)	Previous version
Version 2.0 (2022-03-30)	IVDR Adaptation: 4.2 Accessories provided with the instrument 4.3 Consumables required but not provided with the instrument 6.3 Connecting to the instrument to RIDA qLine® Soft 13 Disposal 14 Corrective action/Notification to authorities 18 Version Number 19.1 Symbols used in manual & on instrument

19 Appendix

19.1 Appendix II: Synopsis of Symbols used in manual & on instrument

Special notes in these operating instructions are highlighted by symbols

Symbol	Description
	Warning! Follow the instructions to avoid the risk of injury.
	Warning! Follow the instructions to avoid damage to the device.
	Warning! Possibility of electric shock!
	General safety instructions! Follow the instructions to achieve optimum device performance.

Symbol	Colour	Publication	Description	Placement
	Symbol & Outline: Black	IEC 60417 – 5032	Alternating Current	Instrument Serial Label
	Symbol & Outline: Black	IEC 60417 – 5007	On (Supply)	Inlet Filter
	Symbol & Outline: Black	IEC 60417 – 5008	Off (Supply)	Inlet Filter
	Background: White Symbol & Outline: Black	IEC 7000 – 0434A	Caution, Risk of Danger	On Caution Labels
	Background: White/Yellow Symbol & Outline: Black	ISO 7010-W004	Warning: Laser Beam	On Caution Labels
	Symbol & Outline: Black	N/A	In vitro diagnostic medical device	Instrument Serial Label
	Symbol & Outline: Black	ISO 7000-2498	Serial Number	Instrument Box Label
	Symbol & Outline: Black	ISO 7000-2493	Catalogue Number	Instrument Serial Label
	Symbol & Outline: Black	ISO 7000-3082	Manufacturer, Date of production	Instrument Serial Label
	Symbol & Outline: Black	ISO 7000 / IEC 60417	Date of manufacturing	Instrument Label
	Symbol & Outline: Black	IEC 60417-6414	WEEE Waste Electrical and Electronic Equipment	Instrument Serial Label User Manual
	Symbol & Outline: Black	ISO 7000-1641	Consult Instructions for Use	Instrument Serial Label User Manual
	Symbol & Outline: Black	ISO 7000 / IEC 60417	Acceptable storage temperature range	Instrument Box Label
	Symbol & Outline: Black	ISO 7000/ IEC 60417	Acceptable storage humidity range	Instrument Box Label

19.2 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
	Indicates that nearby values represent a duration	Home Screen (All Tabs)
	Shutdown the instrument	During imaging
	Restart – application or instrument	System Menu
	Return to previous screen	System Menu
	Navigate to the next screen	Global
	Show the engineering password as plain-text	Global
	Hide the engineering password with '*'	Advanced Engineering

19.3 Appendix III – Cyber Security Statements

Network Security

1. The INSTRUMENT supports the exchange of electronic data over a wired medium, pecifically over an Ethernet connection. The supported use case is that a laboratory configured computer is connected to the instrument using CAT5-CAT7 Ethernet cables. Validated software that implements the communication protocol will be installed on the laboratory configured computer and exchange messages with the control software installed within the INSTRUMENT.

2. R-Biopharm AG anticipates that laboratories have network technicians who configure the buildings to only have specific internet access points. As such, it's our recommendation that the INSTRUMENT never be connected to the internet where it could potentially be exposed to viruses – although no part of the INSTRUMENT operating system or control software is configured to download anything from remote sources. Following this recommendation, the INSTRUMENT does not therefore come with any pre-installed ANTI-VIRUS software. It's left up to the specific laboratory technicians to install their own licensed software. It should be noted that it's not recommended to connect the instrument to an internet access point, as a local-area connection (LAN) is the only expected use. Since networks themselves can be a point of vulnerability to viruses, the INSTRUMENT control software comes with a firewall implementation that should block the transfer of rogue software over the network.

User Access Controls

1. Access to an INSTRUMENT is first and foremost restricted behind access to a laboratory, where it is standard practice to have restricted personnel policies. After this point, access to the instrument software to be allowed to initiate a test is unrestricted.

2. Specially trained service engineers are provided with passwords and knowledge on how to access specialist tools that allow them to change the instrument configuration. These tools typically involve calibration routines to ensure the instrument is running with optimum performance.

3. Customers are advised not allow the connection of additional input peripherals such as keyboards and mice without from users other than service engineers.

Maintenance of Cyber Security

1. The maintenance of cybersecurity is managed through software updates.

    Updates to CONTROL SOFTWARE

When defects are found within the CONTROL SOFTWARE, Bee Robotics record them on an internal tracking system with the intention of resolving in the next release. When a release becomes available, R-Biopharm contact the customer with the update files and release notes indicating the defects or flaws that were found, along with a severity rating for each defect. After this point, it's the client's prerogative as to whether or not they apply the updates.

19.4 Appendix IV – RIDA qLine® autoBlot INSTALLATION CHECKLIST

Instrument serial number: .....

Customer name:	
Address:	
Telephone number:	
Fax number:	
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 initialize correctly? ☐ Yes ☐ No
(refer to 3.5.4 in User Manual)

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

19.5 Appendix V – RIDA qLine® 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: .....

Telephone number: .....

19.6 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

2022-03-30 – Version 2.0

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