RIDA qLine® Scan

User Manual

User Manual
RIDA qLine® Scan

Art. No. ZG1109:
Version 2022-04-08

Content

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

Warnings, Cautions and notes

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.

Labels

Symbol	Description
RIDA qLine® Scan	Product branding
IVD	In vitro diagnostic medical device
REF	Reference number
⚠	Caution
⊠ (WEEE)	WEEE Waste Electrical and Electronic Equipment
⊠ (WEEE)	WEEE Waste Electrical and Electronic Equipment
📖	Refer to user manual
🏭	Manufacturer
🏭	Date of manufacturing
LOT	RIDA qLine® Scan serial number
SN	RIDA qLine® Scan serial number
🌡	Acceptable storage temperature range
%	Acceptable storage humidity range

1 Safety instructions

- The device is intended for use by professional users only.
- The guidelines for work in medical laboratories must be observed.
- The operating instructions for the devices must be strictly observed.
- Please handle this equipment carefully at all times.
- Follow basic safety precautions to reduce the risk of injuries, fire and electrical shock.
- Read all information in this document attentively. Failures in understanding and following the instructions may result in damage to the product, injury to operating personnel and poor instrument performance.
- Electrostatic discharges can damage the device and affect the behavior and stability of laboratory equipment. Therefore, avoid any electrostatic charge.
- Pay attention to all WARNING, CAUTION and STOP statements in this publication.
- Never open the electrical compartment while the equipment is plugged into a power source.
- When using the RIDA qLine® Scan, Good Laboratory Practice (GLP) must be observed.
- Use a lab coat and pay attention to the safety standard procedures in you laboratory.
- Please be careful while working with infectious material and pay attention to the safety instructions thoroughly. Always wear gloves for your own safety. Proceed according to the safety instructions of your laboratory when infectious substances get in contact with your skin

⚠️ Warning:
If the RIDA qLine® Scan or corresponding pieces are damaged, the system cannot work correctly and therefore the warranty will no longer be valid!

⚠️ Warning:
Always pay attention to the safety instructions while working with infectious material

2 General information

2.1 Intended purpose

For *in-vitro* diagnostic use. The RIDA qLine® Scan reader creates scanned images of the RIDA qLine® Allergy test membranes. RIDA qLine® Soft must be used for operation in compliance with in-vitro diagnostic use and for further processing of the images. The product is intended for professional use.

2.2 Functions

RIDA qLine® Scan allows RIDA qLine® Allergy tests to be scanned after manual processing. The images are then quantitatively analyzed with RIDA qLine® Soft.

Instrument features:
- Generation of pictures within a few seconds
- Picture handover in Bitmap format
- Control through Imaging-Software with Twain-Interface
- Easy to use

⚠ Caution:
If the directions given in this manual are not followed, the system may not work correctly and it can be damaged!

⚠ Warning:
Warranty void if any changes or modifications are made to the product.

2.3 Device specifications and requirements

Fig. 1: Open Drawer

2.3.1 Specifications

Parameter	Specifications
General	weight 2.9 kg
Plastic contents	2 parts of body housing
Drawer	mechanical drawer
Power Supply	1 x external power supply Mod. 3A-183WP24
Input	100V – 240V 50-60 Hz, 0.6 A
Output	24V – 0.75 A
Dimensions	300 x 300 x 80 mm
Throughput	10 membranes within 20 seconds
Calibrating	Self calibrating

2.3.2 Requirements

Hardware minimum requirements:
• PC according DIN EN 60950
• USB 2.0 port (3.0 possible)

Software requirements:
• Microsoft Windows Version 7,8,10
• RIDA qLine® Soft

3 Start up

3.1 Introduction

This chapter describes how to install and start this device. This includes unpacking, accessories, the software installation and PC connections.

⚠ Note:
Make sure you do not drop the scanner, this could injure someone or damage the device.

3.2 Device and accessories

Accessories provided with the instrument:

Product	Accessory
RIDA qLine® Scan	• Power supply (100-240V Input and 24V, 0.75A Output) • USB cable, ca. 1.2 - 2 m • Instruction manual

Accessories required but not provided with the instrument:

Product	Art. No.
RIDA qLine® Soft	Z9995
RIDA qLine® Incubation Set	ZG2701

Product	Art. No.
RIDA qLine® QC-Kit **(for RIDA qLine® Soft)**	ZG1108
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

3.3 Unpacking and positioning of the device

Place the instrument on a flat, horizontal surface. Remove all indicated safeguarding and adhesive tape. Put no heavy objects onto the reader.

⚠️ Warning:
Please, pay attention to the temperature. During winter season, the instrument can be delivered very cold because of shipment. After positioning, wait until the instrument has reached the environmental temperature. Only then start the instrument.

Check all parts supplied according to the above-mentioned list. Compare the serial number of the instrument with the enclosed shipping documents. Please store all packaging material. It should be used for a return transport in case of damage or complaint. The instrument should be shipped in the original packing.

3.4 Environmental conditions

Place the instrument on a flat, horizontal surface with sufficient amount of space around it. Avoid setting up at places where it can fall down.

⚠️ Warning:
Please, pay attention that the pulled out drawer doesn't reach out over the working place. This might lead to injuries of the employees and can damage the instrument.

Avoid vibrations, strong electromagnetic waves (not computer), sources of heat and the exposure to direct sunlight.
Keep the workplace surrounding the instrument free of any aggressive liquids.

3.5 Environmental parameters

Operation temperature: 15 °C to 35 °C
Working height: 0 to 2.000 m above sea level
Relative humidity: 20 % - 80 %, no condensing

⚠️ Caution:
Before turning the instrument on, acclimatize the instrument at room temperature to let all condensed water evaporate from the inside.

3.6 Transport and storage conditions

Transport

Environmental temperature: -40 °C to 65 °C

Relative humidity: 0 % to 95 %

Storage

Environmental temperature: -20 °C to 30 °C

Relative humidity: 20 % to 30 %

It is recommended to choose the transport and storage conditions in the medium range of the conditions specified above. Before moving or transporting the device unplug it and use exclusively the original packaging for transport.

# 4 Installation and connection of RIDA qLine® Scan

4.1 Transportation lock

The device is locked for transportation. Please read the note attached to the device attentively. Turn the device upside down and proceed upon instruction.

> ⚠️ Caution:
> Before turning on the instrument, remove transportation lock.
> Using the device in a locked state might cause irreversible damage.
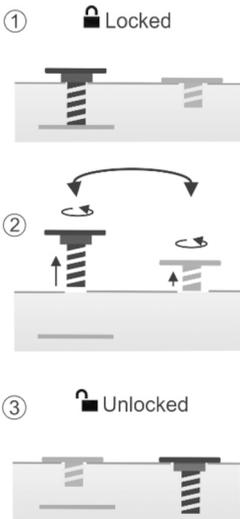
The device is delivered in a locked state.
The dark screw locks the scanning unit whereas the light colored screw seals a second opening.

In order to unlock the device, please unscrew both screws completely, remove the note slip and exchange the positions of the screws.
Please tighten both screws properly to keep the device free of dust.

After exchanging the screws, the device is unlocked and ready to use.

STOP

TRANSPORTATION LOCK

Exchange the screws at the rear before start and tighten them properly !

Please relock before any transport of device!

Fig. 2: How to remove the transportation lock

The device can be placed in an upright position and the drawer can be inserted completely now.

> ⚠️ Caution:
> Please tighten both screws properly to prevent any contaminations with dust.

4.2 Preparation

Please plug the supplied cables into the respective sockets at the rear of the scanner.

4.2.1 Connection

The RIDA qLine® Scan features two sockets at the rear.
1. Power Plug
2. USB Port

Connect the black power plug with socket at the rear of the scanner.
Use only the external power adapter provided with the instrument.

⚠️ Caution:
Only use the original power adapter of the RIDA qLine® Scan.

The plugs cannot be mixed up due to their different fit. The device has a power switch at the rear to turn it on. If the RIDA qLine® Scan is not in use it will automatically enter the standby mode after 15 minutes. An input signal of the software can reactivate the scanner.

4.3 Installation

> ⚠️ Note:
> Please install the RIDA qLine® Soft software first in order to install the driver of the RIDA qLine® Scan.
>
> Please disconnect the computer from the Internet in order to speed up the installation process of the driver

The Driver for RIDA qLine® Scan is integrated in RIDA qLine® Soft and will be installed during installation of RIDA qLine® Soft. When the driver installation is completed successfully please connect the RIDA qLine® Scan to the PC using the provided USB cable.

The plugs fit into the dedicated sockets only and you cannot mix them up. Please switch on the RIDA qLine® Scan. You will find the switch at the rear of the device. The small blue lamp on the right front side indicates that the reader is switched on.

Fig. 3: The device is ready to use as soon as the PC has identified the reader

> ⚠️ Note:
> If an older version was previously installed you must execute the program „SetRIDAqLineScanner.exe". This program is stored in the folder „C:\Program Files (x86)\R-Biopharm\qLine"

> ⚠️ Note:
> Please keep the manual of the RIDA qLine® Soft software at hand to support you working correctly with the reader. In this manual, you will find all the functions described in detail for controlling the RIDA qLine® Scan.

5 QC test using RIDA qLine® Soft

In order to check the perfect function of the RIDA qLine® Soft it is recommended to use the RIDA qLine® QC kit (ZG1108).

Start the RIDA qLine® Soft software on the connected PC.

To perform the QC test, click the down arrow in Settings menu item, and select Perform QC test.

Place 10 QC strips (Art. No. ZG1108) in the strip holder, included in the RIDA qLine® Incubation Set.
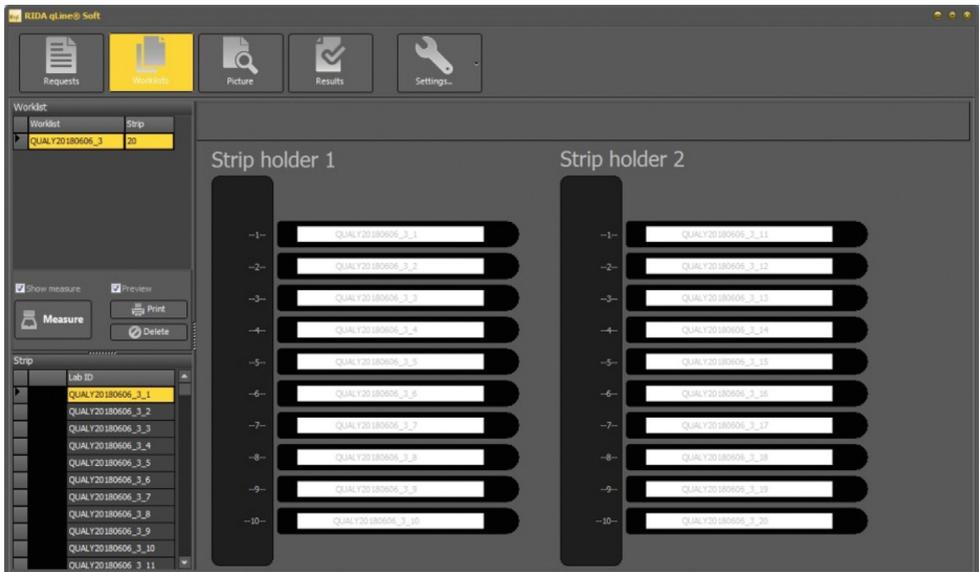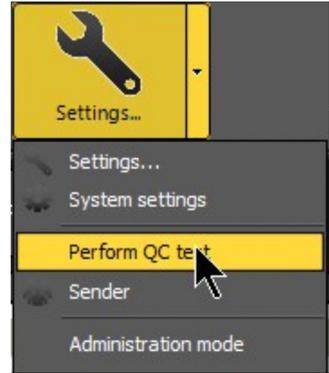
Insert it into the upper position (1) of the RIDA qLine® Scanner template. When using two strip holders, you must simultaneously insert them into the (1) and (2) position in the RIDA qLine® Scanner template.

Place the scanner template on the scanner, close the cover and click `Measure`.

You will be shown a QC report immediately after a successful measurement.
You can either print it, save it as a PDF, or simply close the preview.
All reports are automatically saved as PDF in this directory:
C:\R-Biopharm\Database\qLine\QCArchive.

This report consists of a total of either 11 or 21 pages: the first page of the report shows you an overview of the QC measurement, and subsequent pages show the results for each individual strip.

6 Image creation with RIDA qLine® Scan

6.1 Placing the test

Pull out the drawer at the front side of the
RIDA qLine® Scan.
Open the drawer until you see the complete pad
to place the strips (see Fig.4).

Position the strip holder including RIDA qLine® Allergy strips (RIDA qLine® Incubation Set) into the cavity of the pad (see Fig 5).

Fig. 4: RIDA qLine® Scan with opened drawer

⚠ Pay attention that the test membranes are positioned facing up.

Close the drawer as far as it will go. The drawer is completely held in place by a magnet.

Start the scan-process now using the software.
Open the drawer after scanning and remove
the strips.

Fig. 5: RIDA qLine® Scan with placed strip holder

7 Erroneous image acquisition

If any image does not reflect the visual perception, please check the correct proceeding upon the instructions and restart the image acquisition again. If you are not able to receive a correct image please contact the manufacturer.

⚠️ Warning:
After scanning please check, if the membranes were evaluated with good quality. Repeat the scan, if necessary.

8 Turn off the reader

At the rear of the device you can find a switch to turn the device on and off.

⚡ When you turn off the device, it is not disconnected from the power source.

The device is only disconnected from the power source completely if it is unplugged.

⚡ Please position the scanner in such a way that you can easily access the rear to disconnect the device from the power source.

9 Cleaning and maintanance

⚠️ Optimal results will be obtained when the device is operated virtually dust-free. Clean the drawer and the insert from time to time, depending on the level of contamination

9.1 Outside

Clean the device only with water and a mild detergent. For external cleaning, use a moist cloth and wipe the device evenly.

9.2 Inside

The cleaning of the interior is limited to the drawer area.

⚠️ Warning: Wear rubber gloves when cleaning the scanner.

Slight contaminations
Pull out the drawer and then wipe the drawer with a damp cloth carefully.

Heavy contaminations
In case of heavy contaminations of the drawer, pull it out completely. In order to pull out the drawer completely the clamps on the bottom side must be drawn outwards. Then the drawer can be pulled out completely.
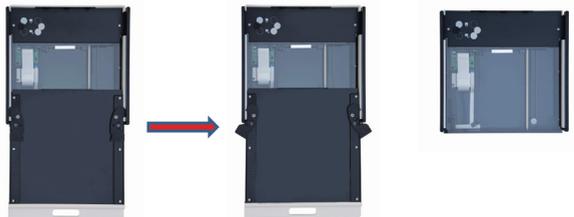

Fig. 6: Open the drawer completely

⚠️ Caution:
Never use acetone or concentrated alcohol to clean the plastic components in the device.

9.3 Cleaning of the glass sheet

⚠️ Before cleaning, take out the pad and the drawer completely.

⚠️ Warning:
Always ensure the disconnection of the device from the power grid by unplugging the reader.

To clean the RIDA qLine® Scan intensively, please unplug the device and pull the drawer out.

Position the device upside-down and wipe the glass plate with a lint-free cloth carefully. If it is necessary repeat this procedure until the glass sheet is clean (see picture).

Put the device back to its initial position carefully. Please place the drawer back into its guideways and close it completely. Finally reconnect the scanner to the power supply.
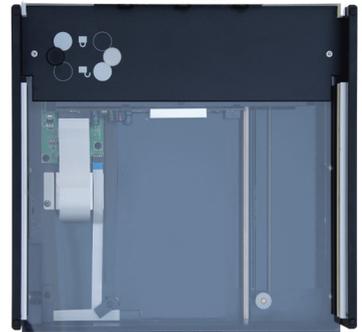

Fig. 7: Glass sheet

9.4 Maintenance

No further duties are required for the maintenance of the device and its accessories.

9.5 Return and repair

Relock the device for transportation (please also refer to 4.1) and use the original packaging. Only in doing so, transportation damages can be prevented.
The instrument can only be shipped in a locked state using the original packing.

10 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.

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

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.

Warning:
Always pay attention to your laboratory safety standards when working with infectious substances before disposing the device and its accessories.

11 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.

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12 Conformity IEC 61326-2-6 and RoHS3

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

In addition, the RIDA qLine® Scan fulfils the EMC protection requirements according to EN 61326-2-6. The RIDA qLine® Scan is compliant with the current RoHS Directive.

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13 Version Number

Version Number	Chapter and Description
Version 1 (2018-11-27)	Previous version
Version 2 (2022-04-08)	IVDR Adaptation: Labels 2.3.2 Requirements 10 Disposal 11 Corrective action/Notification to authorities 13 Version Number