

RIDA qLine® Soft

User Manual





User Manual RIDA qLine® Soft

Z9995 Version 2022-03-10 Software Version 2.3

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Carefully read this manual before using the software and make this manual available to all users. Failure to observe the instructions in this manual will void the manufacturer's warranty and can pose a risk to users.

Make sure that all users are familiar with the software. When in doubt, contact R-Biopharm AG if you need additional software or training before using the software.

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1 Intended use

For *in vitro* diagnostic use. The RIDA qLine® Soft is a comprehensive program used for the automatic evaluation of scanned or photographed color intensities of a biochemical reaction in comparison to the background of the membrane. The RIDA qLine® Soft may be used only for the evaluation of RIDA qLine® Allergy tests in combination with the equipment specified by R-Biopharm AG.

The product is intended for professional use.

2 Function

Program for evaluating the data of RIDA qLine® Allergy. RIDA qLine® Allergy is a quantitative line blot system for determining specific IgE antibodies against up to 20 individual allergens on a nitrocellulose membrane as part of *in vitro* allergy diagnostic testing.

The program allows both manual entry and importing of requests from external computer systems, with compilation of the requests into worklists. For this purpose, an image of the manually processed strips (RIDA qLine® Scan (ZG1109)) or automatically processed strips (RIDA qLine® autoBlot (ZG3101)) is sent to RIDA qLine® Soft, where it is analyzed.

Based on the 5 standards that are present on every membrane, the program creates a standard curve for analysis of the test results. The validity criteria of the standard curve are met if all 5 standards are visible and detected by the software, the smallest standard reaches a defined minimum intensity in the software, and the intensity of standard 1 is < standard 2 < standard 3 < standard 5.

The positive control must reach RAST ≥ 4 to be valid.

After the measurement, the results are either printed out, saved as a PDF, or returned online to the laboratory computer system.

3 Symbols

Explanation of the safety information in the user manual

Symbol	Description
1	Warning! Follow the instructions to avoid the risk of injury.
	Warning! Follow the instructions to prevent software damage.
	General safety information Follow the instructions to ensure optimal software performance.

4 Requirements

4.1 System requirements

Operating system	Microsoft Windows 7 or higher (32/64 bit; latest service packs recommended)
Memory	Min. 1 GB
Free hard disk space	Enough memory for the database (min. 250 MB)
Screen resolution	800 x 600; recommended: 1280 x 1024
Access permission	Administration rights are required for the installation



4.2 Scope of delivery

4.2.1 Included in the scope of delivery

Product	Item no.
RIDA qLine® Soft	Z9995

4.2.2 Required accessories, not included with the software

Product	Item no.
RIDA qLine® Incubation Set	ZG2701

4.2.3 Required consumables, not included with the software

Product	Item no.
RIDA qLine® QC-Kit	ZG1108

5 Installation

5.1 RIDA qLine® Soft installation

The RIDA qLine® Soft installation routine installs the complete software on a computer and sets up the software for the registered user. The necessary software components are installed as well as the device drivers and additional software that are needed to operate the measuring equipment that will be used.

The installation routine requires local administration rights on the computer.

 Start the installation process by double-clicking the installation file (setup_qLineSoft_ XYZ.exe).

If an older version of RIDA qLine® Soft is already installed on your computer, the newer version can be installed over the existing version (the database remains unchanged). When RIDA qLine® Soft is being uninstalled, the database containing the patient data and measurement values remains unchanged.

2. Follow the instructions on the screen to complete the installation process.

The following installation types (drop-down menu) are predefined and thus simplify repetitive installation tasks. The appropriate installation components are predefined depending on the type of installation.



Software needs to be installed as specified by Microsoft. The software may be installed only in areas that are intended for such by Microsoft or protected accordingly by the IT department concerned.

Installation type	Description
Single workstation installation	Installs a typical single-workstation system. The program and the database are installed on the computer. Standard installation. Recommended for non-IT specialists.
Client installation	Only the program is installed. This type is particularly suitable if several computers in a network need to be equipped with RIDA qLine® Soft. Recommended only for IT specialists.



The program modules are installed by default, and a configuration can be selected which is then set up on the
computer.
The support for any measuring equipment that may be
required is not provided automatically, even if the
equipment is specified in the configuration.
This type is particularly suitable if several computers with a
predefined configuration need to be installed.
Recommended only for IT specialists.
Predominantly free installation and configuration.
Recommended only for IT specialists.
Installs updates for new software versions. Any additional
information on installation will be in the release notes.

The following installation components can be selected for installation. When installation types are selected, some components are marked by the type selection. The user can select or deselect any components. In this way, "User-defined installation" is selected as the installation type.

Installation components	Description
Install the RIDA qLine® Soft program	Installs all necessary program modules.
Activate LIS connection	This establishes a connection to the RLink LIS-ASTM program. Recommended only for IT specialists.
Set up RLink LIS-ASTM	The connection to LIS is set up. Attention: LIS interface RLink LIS-ASTM must be installed once in the network. Recommended only for IT specialists.

Install/update the database	Updates will be imported into the database.
Use existing configuration	An existing configuration is selected which is then used for the installation. With the "UseConfigPart=c:\xxx" command-line parameter, a directory containing the configuration files to be used can be transferred when the directory is accessed. Recommended only for IT specialists.

A setting can also be made as to whether RAST values should be displayed without decimal places (see 6.2.4).

The program is installed successfully if the home screen and then the program showing the Requests page appear when the program is started. The QC kit can be measured to check whether the installation was correct (Section 7.4).

5.2 RIDA qLine® Soft update

Updates will be available for new software versions as a stand-alone installation file for download. Additional information on installation will be sent with the release notes.

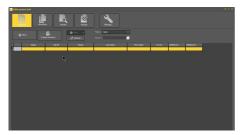
5.3 Starting the program

Double-click this symbol to start the program:





The program starts with the following window:



6 Preparation

6.1 Settings

The software version, database, and the paths of the Program, User, Common, Database, and Reports directories can be found under the Settings menu item in the About... tab. Furthermore, the Configuration tab can be used to set the appearance and language.

"Auric" and "Windows" can be selected for appearance.





Auric Windows

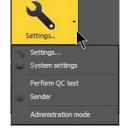
In the language selection option, you can choose between "Standard Windows language" and "User defined". If "Standard Windows language" is enabled, the program will start in the Windows language. If another language is to be selected, "User defined" must be activated. Click on the arrow to open a list with different languages. Select the language you want, press OK, and restart the program for the language setting to take effect.

Press OK to confirm the selection of the appearance and the language, and restart the software for the changes to take effect.



6.2 System settings

From the System settings submenu, the tests used for routine processing can be preselected. You must enter a password to access the System settings submenu.

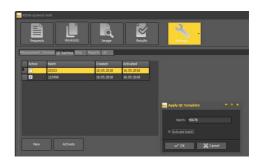


The default password is "qsoft".

To obtain permanent access to the system settings, you can also enter the password in the Administration mode. If you do this, you do not need to enter a password when making changes to the system settings. Furthermore, other functions can be selected in the Administration mode (e.g., importing exported measurements).

6.2.1 Creating and activating QC batches

Several QC kit batches can be incorporated and activated under the QC batches section. The batch of the currently activated

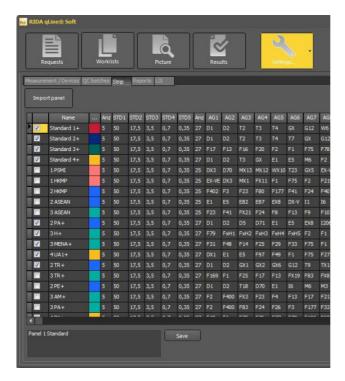




QC kit is displayed on the QC report. Insert the batch indicated on the RIDA qLine® QC-Kit label by clicking New, then click Activate batch, and press OK.

6.2.2 Preselecting the panels

In the Strip tab, you can select panels that you routinely work with. Only those selected will appear when requests are entered or edited in the test selection. In the field below, you also have the option of adding comments on the respective panel. To do this, select the panel you want, enter your text in the field below the table, and click Save . The comment appears in the report under "Test/patient data."





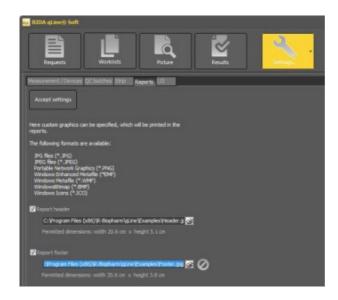
Important: The panels must be marked with a "+" after the panel name in order for the panels (strips) with CCD line and positive control to be evaluated.

6.2.3 Individual report design

You can individually design the report header and footer in the Reports tab by uploading individually designed images.

Allowed formats: .jpg, .jpeg, .png, .emf, .wmf, .bmp, .ico. Max. report header size: Width 20.6 cm x Height 5.1 cm Max. report footer size: Width 20.6 cm x Height 3.8 cm

Activate the report header and/or footer by checking the check box, and select the desired file from your hard drive or data carrier by clicking the small folder symbol in the report header and/or footer.



Confirm your selection by pressing Accept settings.



6.2.4 RAST values without decimal places

When selected, RAST classes will be exported only in whole numbers. This setting can be changed later.



Important: The numbers are NOT rounded. Example: A calculated RAST class of 2.9 becomes a RAST value of 2.

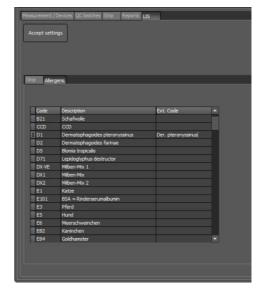
6.2.5 LIS – semantic mapping of allergens and strips

The semantic mapping of allergen and strip names can be carried out in this submenu. Semantic mapping is needed only if the name of the strip or allergen in the RIDA qLine® Soft is not identical to the name of the strip or an allergen in the external system.

For example, if allergen D1 is called "Dermatophagoides pteronyssinus" in RIDA qLine® Soft and "Derm. pteronyssinus" in the external system (e.g., LIS), then semantic mapping must take place.

The mapping takes place when you enter the target name in the "Ext. Code" column

either under "Strip" or under "Allergens." Confirm the changes by selecting "Accept settings."

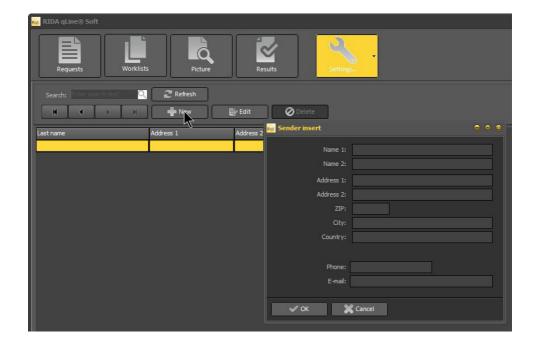


6.3 Creating senders

In Settings, click the down arrow, and select the Sender submenu item. In this submenu, it is possible to create all senders available during the initial set up of the program.

To create a sender, click New, enter all desired information for this sender, and confirm your entry by pressing OK.





Repeat these steps until all senders have been created.



Alternatively, you can also create senders in the Requests menu when entering new requests.

To do this, click the down arrow in the New... button and select Sender .



7 Using the program (workflow)

7.1 Requests and worklists

7.1.1 Entering requests and creating worklists (manual entry)

In order to enter new requests, click New... in the Requests menu item.



The following window opens for entering patient data, and the panel to be measured can be selected:

Enter the unique patient or lab number into the Lab ID: field. Click the down arrow in the Test: selection field. This opens up a table containing all panels selected in the System settings. Click on the desired panel.



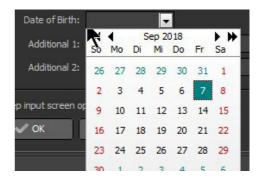
In the Sender field, you can select a sender if you created one or more senders beforehand, as described in Section 6.3.

Optionally, you can then enter patient data.

In order to enter the date of birth, click the down arrow in the Date of Birth field.

This opens up a calendar.

In the calendar, first click on the month and year to preselect the decade, year and month, or you can manually enter the date of birth.

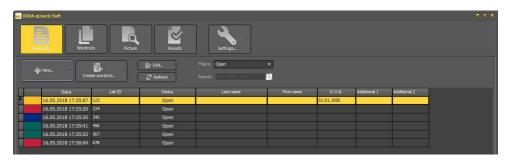


You can enter any additional information you want into the Additional 1: and Additional 2: fields.

Save the request by pressing OK. If the "Keep input screen open" option is activated, the input screen will remain open to enter the next request. If it is not activated, the input screen will be closed.



After all the requests have been entered, the window can be closed by pressing "Cancel". When all requests have been entered, create the worklist by selecting Create worklist.



In the following window, enter the name of the worklist.

If you would like to sort the worklist according to panels, activate the "Sorted by test" option. Otherwise, the requests will be sorted in the sequence in which they were entered.



If you only have one strip holder available, you should activate the

"Only 1 strip holder per worklist" option. If there are more than 10 requests, these will be divided into an appropriate number of worklists, each with a maximum of 10 requests. The worklists will now have the name that was entered and will also have underscore 1, underscore 2, and so on in the name (e.g., Test_1, Test_2, and so on).

Then the program automatically switches to the Worklists menu item where you can print, measure, or delete the worklists.

7.1.2 Importing requests (CSV)

If you do not want to enter the requests manually and would rather import them as a list, for example, from the lab computer, click the down arrow in the New... button, and select the "Import" function. This will open a Windows Explorer window in which you can select the storage location of the CSV file. The example file in the following directory can be used to structure the CSV file: C:\Program Files\R-Biopharm\qLine\Examples.



7.1.3 Importing requests and creating worklists (LIS)

If you want to create requests and worklists via a LIS, you must first establish a connection to your LIS (see interface description SAD Interfaces, or contact your local distributor or R-Biopharm AG directly for further information).

Once you have established a connection to your LIS and would like to create requests and worklists via the LIS, go to the Requests menu and click Worklist via LIS:





A "Record laboratory IDs" window opens. You can now manually enter all lab IDs by entering the ID into the Lab ID field and selecting Add to confirm, or you can scan the barcodes of the samples using a barcode scanner and select Add to confirm each step.

The name of the worklist is generated automatically (YYYYMMDDhhmmss). Only Add-on can be selected. For example, you may have 2 different workstations in the laboratory and need to distinguish between these worklists.



After you select OK to confirm, the data are sent to the LIS, and the LIS sends a worklist back to RIDA qLine® Soft.

Then the program automatically switches to the Worklists menu where you can print, measure, or delete a worklist.

7.1.4 View filter

With the help of the filter, you can have requests with different statuses displayed.



The following view options are available:

1. Open

This shows all requests that were entered but are not yet organized in a worklist.

2. Reset

This shows all requests that you have reset. The requests that were reset can be changed or remeasured (see 7.1.5 and 7.1.6). All reset requests are not taken into account during the creation of the worklist.

3. Processing

This shows all requests that are in a worklist but have not yet been measured.

4. Error

If the program does not recognize strips during the measurement, the strips have "Error" as the status. These can then be incorporated into the next worklist (see 7.1.5).

5. LIS request

All requests that were sent to the LIS but for which no requests were returned (occurs only if LIS <> RIDA gLine® Soft communication is incorrect).

6. All

This shows all requests regardless of their status.

7.1.5 Changing requests

Requests can be changed in different ways, depending on the status:

a) Open requests:

Mark the request you want to change and click the Edit... button or double-click the request. This reopens the input mask for requests, and you can change all entries. Confirm your changes by pressing OK.

b) Requests in process:

For requests that are in process, you can change only the patient data but not the lab ID or the test.

c) Reset requests:

See open requests.

d) Measured requests:

For measured requests, you can change only the patient data, but not the lab ID or the test.



7.1.6 Resetting, remeasuring, or deleting requests

In order to reset, remeasure, or delete one or several requests, you must select them. If you want to select several requests, click the first request, hold down the shift key, and click the last request.

Resetting requests

If you click the down arrow in the Edit... button, you can reset requests by selecting the "Reset" option (alternatively, you can select the option by right-clicking the selected request). However, these requests will not be taken into account when the worklist is created.



Remeasuring requests

Select the "Remeasure" option in the submenu shown above. The selected requests are then assigned the "open" status and will again be incorporated during the next creation of the worklist. This is possible for requests that have already been measured, documented, and reset. This option is not available if a LIS connection is active.



Attention: If requests that have already been measured or documented are remeasured, the previous measurement data will be lost.

Deleting requests

Requests can be completely deleted via the "Delete" option.



Attention: You can delete not just open requests, but also those that have been organized in worklists and requests that were already measured and documented; however, this also deletes all measured values and results.

This option not available if a LIS connection is active.

7.2 Managing and measuring worklists

After a worklist has been created, you can see the worklist(s) as well as the arrangement of the strips in the strip holder in this menu item.

Press Print to print the worklist for your own documentation since the worklist will not be stored after measuring.

If the "Preview" option is activated, you will first be shown a print preview. The list can be printed or saved as a PDF from this preview.

If the "Preview" option is not activated, the list is printed directly by the printer installed in the operating system with no preview.

Worker Step

| Commencer | Com



Select Delete to delete the worklist. The requests themselves are not deleted; instead they are displayed in the requests section with an "Open" status. Additional requests can now be added, or the requests can be edited.

7.2.1 Measuring the worklists

Select Measure to measure the worklist.

Once the measurement is completed, the image of the measured strip holder is displayed.



The following window will be displayed if one or several strips were not recognized:



7.2.2 Calculation method

The software assigns the measured intensities of the coloration of each standard to the appropriate IU/mL according to the following table. The standard curve is created by means of a point-to-point connection of the standards. The IU/mL and RAST classes of the allergens are evaluated by comparing the intensity of the coloration of the allergen band on the standard curve.

Intensity value of	IU/mL
STD5	50.00
STD4	17.50
STD3	3.50
STD2	0.70
STD1	0.35

Resulting in the following division of RAST classes:

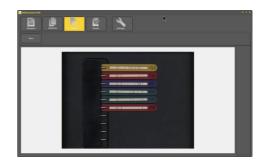
IU/mL	RAST class
< 0.35	0
0.35 - 0.69	1
0.70 - 3.49	2
3.50 - 17.49	3
17.50 - 49.99	4
50.00 - 99.90	5
> 100	6

7.2.3 Measurement image

The "Show measurement" option: If this option is activated, the program jumps to the **Picture** menu once the measurement is complete and displays an image of the measured strip holder and individual strips.

Select Save to save an image of the scan to a location of your choice.

To view the results and create reports, select the Results menu item.



7.3 Results

7.3.1 Results page display

The Results menu shows the measured strips in the table on the left.

The image of the highlighted panel and tray tab required for the positive identification of the correct strip are shown to the right.

d tray

on the control of the contro

Below the strip is a table containing the

allergen codes, a marking (x) of the allergens that could contain CCD, the intensity of the measured bands, quantitative information in IU, and RAST classes. For a quick overview, a horizontal bar chart is shown next to the table and has various color-coded RAST classes.



The most recent measurements are always displayed at the top of the list. By default, only the results of the last 4 weeks are shown. However, you can select any time frame for displaying the results of measurements.



Once the time frame has been selected, you can use the filter to display the various results (see 7.4.4).

7.3.2 Diagram views

You can choose different views:

Line

The intensities of all lines, including the standards, are represented as peaks.



Bars

The intensities of all lines, including the standards, are shown as a bar chart.

Standard

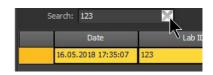
The standards are shown as a semi-log graph, with the intensity of the individual standards being displayed.

Bar + 3D

Next to the bar chart is a three-dimensional view of the lines on the allergen membrane.

7.3.3 Searching the results

To find all results for a lab ID, enter any search text into the search field in the Results menu. The system searches for this text in the "Lab ID," "Last name," "First name," "D.O.B.," "Additional 1," and "Additional 2" columns.



To stop the search, click the X.

7.3.4 View filter

Different filters are available to speed up finding results. First, select the time frame and the desired type of result in the view filter.

Filters: Measured & documented Type of the companies of the companie

a) Measured:

This shows all results that have been measured, but not yet documented (printed).

b) Documented:

This shows only documented (printed) results.

c) Measured & documented:

This shows all results.

d) Quality controls:

This shows the measurements of performed QC tests.



7.3.5 Positive control and CCD line

The check mark on the right side of the results screen indicates that the measurement is valid (the positive control is above the cutoff (RAST ≥ 4), and the standard 1 value is above the minimum).



If the CCD line and CCD-marked allergens are positive (RAST ≥ 1), you will see the following information on the right side of the screen: Positive results can originate from the CCD.



It is therefore recommended to treat the serum sample with RIDA® CCD Inhibitor (ZA0601) and repeat the test.

7.3.6 Printing the measurements

Select Print to generate the print preview of the highlighted result, where you can either print the report or save it as a PDF file.



To print several measurements, highlight all measurements that you want to print. To do this, use the mouse to click the first report that you want to print, press and hold the shift key, and left-click the last report; or left-click the first report that you want to print, hold down the left mouse button, drag the cursor down to the last report that you want to print, and then release the mouse button.

This will highlight all reports and display them in a document as print preview.

Date	Lab ID	Status
16.05.2018 17:36:04	678	Documented
16.05.2018 17:35:52	567	Measured
16.05.2018 17:35:41	456	Measured
16.05.2018 17:35:30	345	Measured
16.05.2018 17:35:20	234	Measured
16.05.2018 17:35:07	123	Measured

7.3.7 Exporting measurements as XML files

Individual measurements can be exported as an XML file. Select a result/measurement, and right-click the highlighted element.

- 1. If you select the "Export result" option in the window that opens, only the result data (Intens, Units, RAST) as well as the allergen code and the lab ID are exported.
- 2. If you select the "Export request" option in the window that opens, the individual images of the measurements are exported in addition to the result data (Intens, units, RAST) as well as the allergen code and the lab ID.

7.3.8 Exporting measurements via LIS

The results of all requests that were imported from the LIS in the Requests menu can also be exported back to the LIS. To do this, click LIS Export in the Results menu.

All the request results that were not imported from the LIS (manually entered requests or requests imported via CSV) will not be exported to the LIS.

7.3.9 Changing the measurements

If you would like change measurements, left-click the report you want to change to highlight it, and then right-click it. In the window that opens, select the Edit option.

This will open the request input screen where you can modify the patient data and sender. The lab ID and panel cannot be changed after measuring. You cannot change measurements when an LIS connection is activated.



System settings

Administration mode

7.3.10 Remeasuring

If you want to remeasure one or more strips, right-click the highlighted result in the table on the left, and select the Remeasure option from the window that opens. When asked whether to measure the marked test request again, answer with "Yes."

This request will then reappear in the Requests menu item as an open request, which will then be included when the next worklist is created.



Attention: The measured values of the previous measurement are erased when a strip is remeasured.

7.4 QC test

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

When using manual processing, place 10 QC strips (item no. ZG1108) into the holder. For automated processing, make sure that 20 positions have QC strips.

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 PDFs in this directory:

<u>C:\R-Biopharm\Database\qLine\QCArchive.</u> The report has a total of either 11 or 21 pages: The first page of the report gives you an overview of the QC measurement. The other pages show the results of each individual strip.

Note: If you have results that are outside the tolerance range, follow the information in the instructions for use of the QC kit.

8 Troubleshooting

There are no tests or the number of tests available is too few.

The list of all available test panels can be found under System settings/Test strips. You will also find QC strips in addition to the current test panels. Future test panels can be imported via an update that will be provided by R-Biopharm AG.

When a test request is being processed, the desired test strips are not available, or unnecessary panels are displayed.

Under System settings/Test strips, you can select the tests strips to be displayed when test requests are created. To do this, simply check or uncheck the first column of the tests you want.

There are no data displayed on the printout of results.

There are no allergen translations for the language selected. Please contact R-Biopharm AG to receive the latest Panel test updates.



9 Where to find what

Where are the reports saved?

Default: C:\R-Biopharm\Reports\qLine

Can be specified in the user configuration file under [Reports]\Path

Where is the database installed?

Default: C:\R-Biopharm\Database\qLine

Can be specified in the user configuration file under [Database]\Db

Where can I find the QC reports?

Default: C:\R-Biopharm\Database\qLine

If another directory is specified for the database, the QC reports will always be stored in the QCArchive directory within the database directory.

Where are the following programs installed?

qSoft.exe

Win7: C:\Program Files (x86)\R-Biopharm\qLine

Open: WinMenu/R-Biopharm RIDA qLine/RIDA qLine Soft desktop icon

Client Installation Program (setup_qLineSoft_1.1.3_Client.exe)

Win7: C:\Program Files (x86)\R-Biopharm\qLine\Install

Open: WinMenu/R-Biopharm RIDA qLine \RIDA qLine Soft client installation

TeamViewer.exe

Win7: C:\Program Files (x86)\R-Biopharm\qLine\Install
Open: WinMenu/R-Biopharm RIDA qLine\TeamViewer

Where are the configuration files?

Standard configuration

Win7: C:\ProgramData\R-Biopharm\qSoft

Configuration for registered users

Win7: C:\Users_actual_user_\AppData\Roaming\R-Biopharm\qSoft

The configuration directories are not displayed in Explorer.

Win7

If the menu bar is not displayed in Explorer, execute the Organize\Layout\Menu bar command. The menu bar will be displayed. In the menu bar, open Extras\Folder options... and select the View page. In the Advanced settings list, select the Show hidden files, folders, and drives option, and close the dialog box by clicking OK. The configuration directories will be displayed.

10 Uninstalling

RIDA qLine® Soft can be uninstalled from the system menu. All files that were installed when the program was installed will be deleted:

- All files in the installation directory
- All reports in the report directory
- Configuration files that are shared by all users
- Configuration files for registered users

The following files will not be deleted:

- The database
- All files that were copied to the aforementioned directories
- Log files created by the programs



Attention: Sometimes, the directories will not be completely deleted. Delete the files manually as needed.



11 Troubleshooting/information on reporting to authorities

For users in the European Union: Report all serious adverse events associated with the product to R-Biopharm AG and the appropriate national authorities.

12 Symbols used in the software

Symbol	Description	
RIDA qLine® Soft	Product designation	
IVD	For <i>in vitro</i> diagnostic use	
REF	Item number	
LOT	Version number	
i	Follow instructions for use	
	Manufacturer	
~~	Date of manufacture	
UDI	Unique device identifier	

13 Version history

Version number	Chapter and description	
Version 2018-06-28	Previous version	
Version 2022-03-10	IVDR amendment:	
	4.2.2 Required accessories, not included with the software	
	11 Troubleshooting/information on reporting to authorities	
	12 Symbols used in the software	
	13 Version history	

