Quantum Blue® Reader
User Manual

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1 INTRODUCTION

Thank you for choosing the Quantum Blue® Reader. We are confident that this product will become an integral part of your daily work.

Rapid testing enables fast result reporting and thus provides a tool for health care professionals to support immediate decision making. Using the wealth of experience obtained from providing reflectometric detection technology with previous generations of the Quantum Blue® Reader to thousands of customers worldwide, the specialists at BÜHLMANN Laboratories AG have developed a new generation reader for mobile rapid test applications. The Quantum Blue® Reader is a highly sensitive, robust, and cost-effective measurement system for lateral flow tests. This flexible and reliable system, based on a ready-to-use concept, enables the users to easily run lateral flow tests.

This manual describes how to operate the Quantum Blue® Reader. Before using the device, it is essential that you read this user manual carefully.

2 GENERAL INFORMATION

2.1 Technical Assistance

At BÜHLMANN Laboratories AG, we pride ourselves on the quality and availability of our technical and scientific support. Our Customer Support Department is staffed by experienced scientists and engineers with extensive practical and theoretical expertise in the use of BÜHLMANN Laboratories AG products.

For technical and scientific assistance regarding the Quantum Blue® products, contact your local BÜHLMANN Laboratories AG distributor (see chapter 13 Technical and Scientific Support).

For up-to-date information about the lateral flow reader products of the Quantum Blue® Reader, visit https://www.buhlmannlabs.ch.

2.2 Policy Statement

It is the policy of BÜHLMANN Laboratories AG to improve products as new techniques and components become available. BÜHLMANN Laboratories AG reserves the right to change the specifications of products at any time.

2.3 Version Management

This document is the Quantum Blue® Reader User Manual VA3_IVDR_EN.

3 INTENDED USE OF THE QUANTUM BLUE® READER

The Quantum Blue® Reader is a rapid test reader for the *in vitro* detection and/or quantification of target analytes on lateral flow test cassettes.

The Quantum Blue® Reader is used only in combination with BÜHLMANN lateral flow tests.

4 SAFETY INFORMATION

The instructions and safety information in this user manual must be followed to ensure safe operation of the Quantum Blue® Reader. Please note that if the equipment is used in a manner not specified by BÜHLMANN Laboratories AG, the protection provided by the equipment may be impaired.

The following types of safety information appear throughout the Manual. Details are given in the format as shown below.

⚠ DANGER	The term DANGER is used to inform you about situations that could result in personal death or serious injury.
⚠ WARNING	The term WARNING is used to inform you about situations that could result in personal injury to other persons.
⚠ CAUTION	The term CAUTION is used to inform you about situations that could result in damage to the instrument or other equipment.
NOTICE	The term NOTICE is used to indicate information considered important but not hazard related (e.g. security messages, maintenance and cleaning guidelines).

NOTICE	The advice given in this manual is intended to supplement, not supersede, the normal safety requirements prevailing in the user's country.

4.1 Proper Use

The Quantum Blue® Reader must be operated by personnel familiar with BÜHLMANN Quantum Blue® assays and have the appropriate training.

As potentially infectious patient specimens will be measured with the Quantum Blue® Reader, BÜHLMANN recommends to use appropriate personal safety equipment such as gloves. Patient specimens should be handled in accordance with Good Laboratory Practice (GLP) using appropriate precautions. If, despite all precautionary measures, the Quantum Blue® Reader should come into contact with potentially infectious material, please follow the instructions provided in chapter 12.1 Cleaning.

⚠ WARNING	Improper use of the Quantum Blue® Reader may cause personal injuries or damage to the instrument. The Quantum Blue® Reader must be operated by qualified personnel that has received the appropriate training. All instrument-related interventions may only be performed by employees of BÜHLMANN Laboratories AG.

4.2 Electrical Safety

DANGER	Any defects which you discover on electrical components/sub-assemblies must be repaired without delay. Until this is done, the system, sub-assembly or item of equipment must not be used in its faulty condition. Call your local BÜHLMANN distributor.
CAUTION	Do not expose the reader to strong electromagnetic radiation. It is the responsibility of the user to ensure that a compatible electromagnetic environment is maintained for the instrument in order to guarantee appropriate performance. This device fulfills the emitted interference and emitted immunity requirements of the standard DIN EN 61326-2-6.

4.3 Environment

If the Quantum Blue® Reader is to be used in a working environment prone to dirt build-up, clean the device regularly. For cleaning, please follow the instructions provided in chapter 12.1 Cleaning.

4.4 Environmental Hazards

CAUTION	Do not expose the Quantum Blue® Reader to direct sunlight during operation.
CAUTION	Protect the reader from high humidity and contact with liquids.

4.5 Heat Hazard

CAUTION	Do not expose the reader to excessive heat.

4.6 Maintenance Safety

Perform the maintenance as described in chapter 12.2 Maintenance. BÜHLMANN Laboratories AG charges for repairs that are required due to incorrect handling.

4.7 Waste Disposal

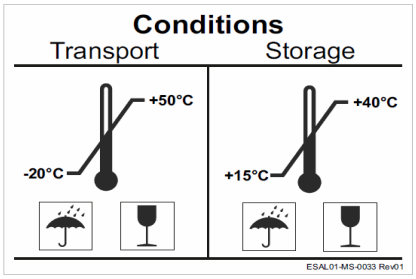
Waste of tests measured with the Quantum Blue® Reader may contain certain hazardous chemicals or contagious/bio-hazardous materials and must be collected and disposed properly in accordance with all national, state, and local health and safety regulations and laws.

4.8 Symbols on the Quantum Blue® Reader

The following symbols appear on the type plate at the rear of the Quantum Blue® Reader instrument.

Symbol	Description
	CE mark for Europe
	*In vitro* diagnostic mark, device is intended to be used as an *in vitro* diagnostic device
	Serial number
	Legal manufacturer
	Date of manufacture
	Waste Electrical and Electronic Equipment (WEEE)
	Catalog number
	Caution - consult instructions before use
IP10	IP Classification
UDI-DI	Unique Device Identifier

4.9 Symbols on the Package of the Quantum Blue® Reader

Symbol	Description
	Transport and Storage conditions
	Keep package dry!
	Handle package with care!
	Authorized representative in the European Union
	Importer in the European Union

5 FUNCTIONAL DESCRIPTION

5.1 Hardware

Figure 1

Figure 2

1	Touch display
2	Power button with LED
3	Drawer for lateral flow test cassette
4	Handle
5	Connector for power supply
6	Type Plate (for more information refer to chapter 4.8 Symbols on the Quantum Blue® Reader)
7	3 USB ports (type A)
8	Ethernet port (RJ-45)

The drawer can be completely ejected by pushing the button at the bottom of the device (indicated in Figure 3) while simultaneously pulling out the drawer. Beware, not to touch the white orientation point (indicated in Figure 4) on the upper right side of the drawer.


Figure 3

Figure 4

NOTICE	The drawer must be completely inserted into the instrument for instrument start-up and for performing measurements.

NOTICE	Do not switch drawers between different Quantum Blue® Reader instruments.

5.2 Delivered Content

- Quantum Blue® Reader
- Quick guides Fast Track Mode and Fail Safe Mode
- Instructions for the download of user manuals and additional software tools (eg. Quantum Blue® Connect Software)
- Power supply including international connection adapter
- Cleaning/ cotton swabs

6 UNPACKING AND SET-UP PROCEDURES

6.1 Unpacking of the Quantum Blue® Reader

Take out the Quantum Blue® Reader from its transport case, place it on a stable and leveled surface and check whether it contains all items as listed in chapter 5.2 Delivered Content.

Carefully examine the instrument to make sure that it has not been damaged during the shipment. In case of damage or if any parts are missing (refer to chapter 5.2 Delivered Content), contact immediately your local BÜHLMANN Laboratories AG distributor.

NOTICE	Please keep the original transport case. It is required when returning or shipping the device.

6.2 Setup and Connection of the Quantum Blue® Reader

6.2.1 AC Power Connection

The Quantum Blue® Reader may only be used with the power supply provided with the device.

Plug the power supply cable (low voltage end) into the connector at the rear of the device (pos. 5 in chapter 5.1 Hardware). Plug the power supply cable (mains end) into a power outlet. Make sure that the cable is plugged in properly on both sides.

⚠ CAUTION	Please make sure that the locally available mains voltage matches the voltage indicated on the type plate of the Quantum Blue® Reader.

7 INSTALLATION

7.1 Requirements

The location of the Quantum Blue® Reader should be preferably on a desk or any other stable and leveled surface with enough surrounding space in order to easily insert the test cassette or unplug the device. In case of emergency or under abnormal operating conditions the location should at any time provide enough space to allow the easy disconnection of the device.

The Quantum Blue® Reader is a highly sensitive and precise optical device. The result can be influenced by vibrations e.g. if the device is placed close to vibrating machines.

The device has an internal correction for normal levels of ambient light. Highly intense light falling into the test cassette drawer can cause serious interference with the measurement and must be avoided where possible.

NOTICE	The reader must not be exposed to direct sunlight during operation.

7.2 Hardware Installation / Accessories

Installation of power supply options and accessories:

- **External power supply**: connect external power supply to power port (pos. 5 in chapter 5.1 Hardware). A blue LED light in the power button will indicate the connection to a power supply.
- **Thermal printer:** The Quantum Blue® Reader can be connected to a **Dymo TM 450/550** label writer with **large address labels (101 x 54mm)** via USB.

⚠ CAUTION	Do not plug in the power supply of the DYMO printer into the Quantum Blue® Reader. This can cause permanent damage to the Quantum Blue® Reader.

- **External Barcode Reader:** An external barcode reader can be used to enter the user ID or sample ID instead of using the on-screen keyboard. Plug the USB cable of the barcode reader into a free USB port at the rear of the Quantum Blue® Reader (pos. 7 in chapter 5.1 Hardware).

The Quantum Blue® Reader was tested in combination with the barcode reader Model Zebra DS 2208. It is the sole responsibility of the user if alternative/other barcode reader models are used.

NOTICE	Please note that the thermal printer and external barcode reader are not included with Quantum Blue® Reader and would need to be ordered separately from a local supplier. BÜHLMANN does not supply the above described accessories.

7.3 Relocating the Quantum Blue® Reader

The Quantum Blue® Reader is a mobile instrument that can be relocated easily. Make sure that proper operating conditions are always met (see chapter 15 Technical Data).

NOTICE	Please don't relocate or move the instrument while a measurement is running.

8 GENERAL OPERATION

Disclaimer: The screenshots in this instruction for use are only for demonstration purposes and can vary depending on the selected reader language, used test method and lot number.

8.1 Powering the Quantum Blue® Reader On and Off

Switch on the device by pressing the power button (pos. 2 Figure 1, chapter 5.1 Hardware). The device will show a standard black screen and then switches to a boot screen. After successful initialization of all components, the home screen is visible.

Switch off by pressing the power button for at least 1 second. The Quantum Blue® Reader will ask for confirmation before shutting down.
Note that the blue LED will remain turned on even if the device is turned off.

8.2 Instrument Startup

During boot up, the internal self-check routine will be performed to check if the values from internal reference standards are within the defined tolerance range. If the measured values of the internal reference standards are outside of the tolerance range a warning message will be displayed. For additional information about this warning message, please see chapter 12.2 Maintenance.

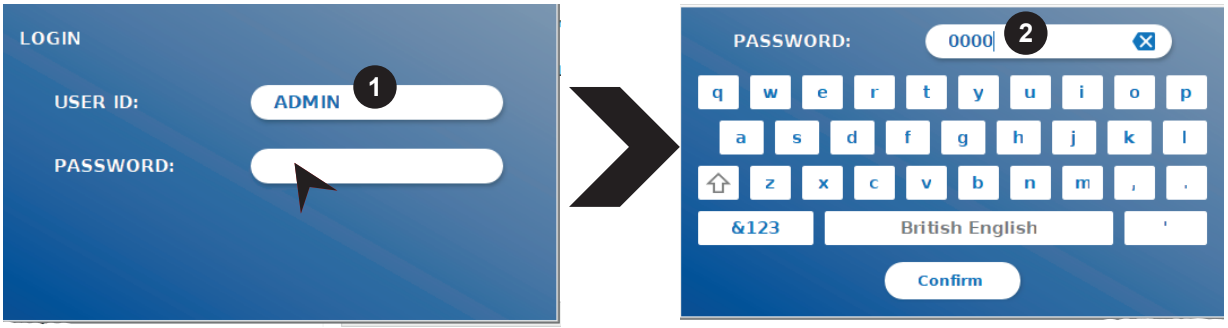
NOTICE	Please make sure, that the drawer is inserted completely.

8.3 First Log In

The Quantum Blue® Reader will have the user management mode turned on by default. To log in, use the default user which is pre-installed named “ADMIN” (1). The initial password is “0000” (2).

After the initial First Log In, the user has the possibility to change the administrator password and to define new users with either «Administrator» or «Lab User» rights . The so called user management can be configured in the menu under System/Settings/Admin Areas/User Management (see chapter 11.4.5 User Management).

Note: It is recommended that the newly set password contains at least 8 characters of these at least 1 in lower case, 1 in upper case and 1 digit. Add additional characters like @ or # to make the password more secure.



8.4 Hard Shutdown

To perform a hard shutdown, the power button needs to be pushed for at least 6 seconds until the device turns off. Afterwards, the device has to be restarted.

8.5 Menu Structure

Figure 5 shows the menu structure of the Quantum Blue® Reader. The grey shaded box indicates menus, which are available for administrators only. For more information on administrator settings refer to chapter 11.4.5 User Management.

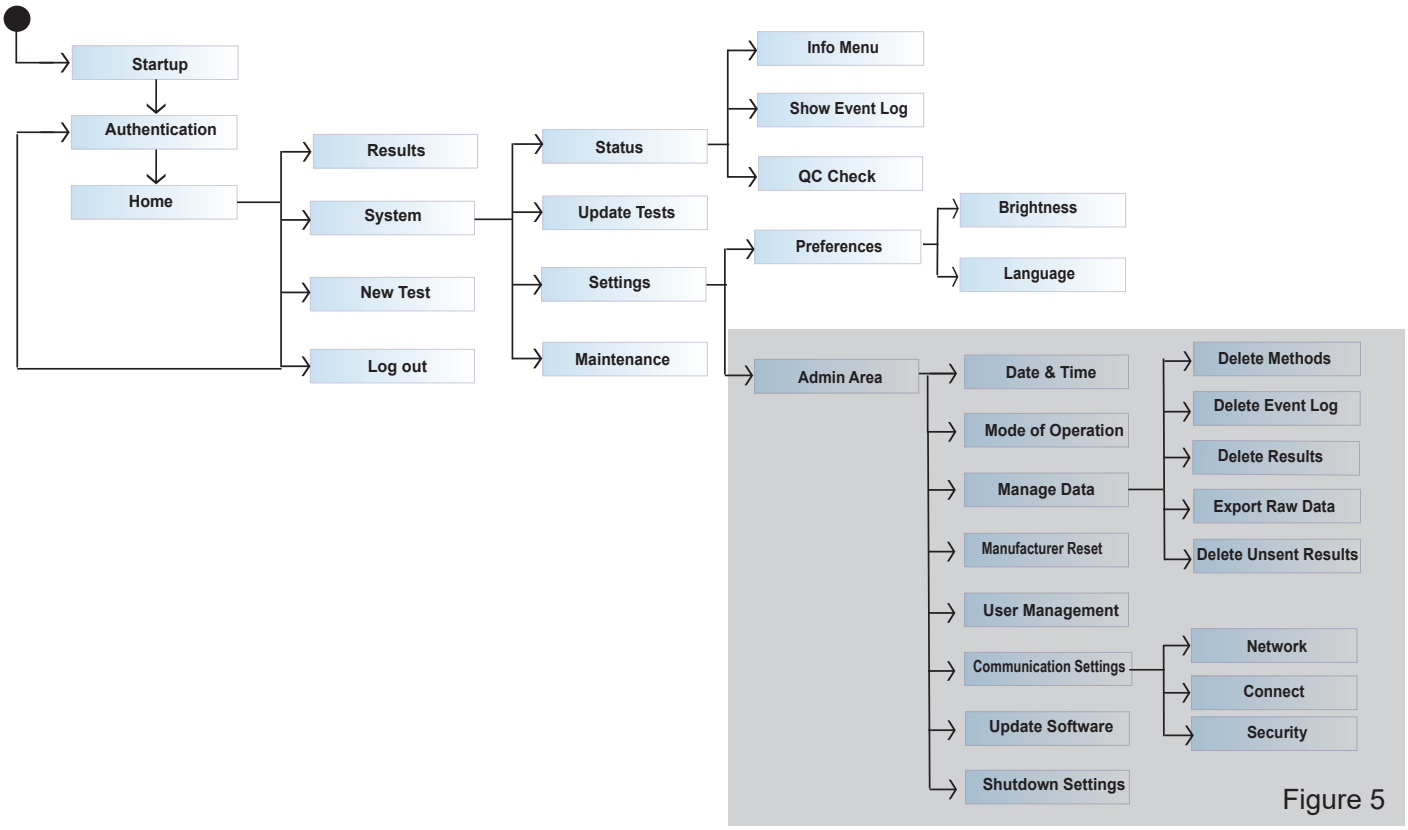
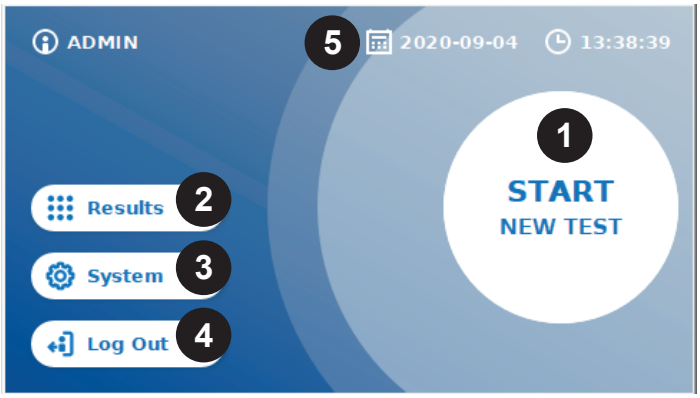


Figure 5

8.6 Home Screen

Once the system has started successfully, the home screen is visible. The home screen displays the three main menus: start a new test (1), result summary (2) and system settings (3), as well as the log out function (4) and the date and time (5).



1	Button to start a new measurement
2	Button to review results
3	Button to view status and change settings
4	Button to log off from device
5	Status Bar displaying Date/Time and status symbols if applicable

9 INSTRUMENT USAGE

9.1 The Two Modes of Operations

Two modes of operations are available on the Quantum Blue® Reader: Fail Safe Mode and Fast Track Mode.

NOTICE	The mode of operation can be configured by users with administrator rights in the menu under System/Settings/Admin Areas/Mode of Operation (see chapter 11 System and Settings).

The Fail Safe Mode (see chapter 9.2 Starting a Test in the Fail Safe Mode) is the default setting and will always require the reading of the barcode card. When starting the measurement, the Quantum Blue® Reader will first run the test-specific incubation time and then scan the test cassette.

In the Fast Track Mode (see chapter 9.3 Starting a Test in the Fast Track Mode) the desired test method can be selected from a list of already installed test methods on the Quantum Blue® Reader. The incubation time can be skipped and an external timer can be used instead of the internal timer included in the reader. A test method, with the same settings, can be repeated by pressing the **Repeat Test** button on the screen.

The Fail Safe Mode is intended to be used for individual tests, whereas the Fast Track Mode is intended to be used for running batches of tests.

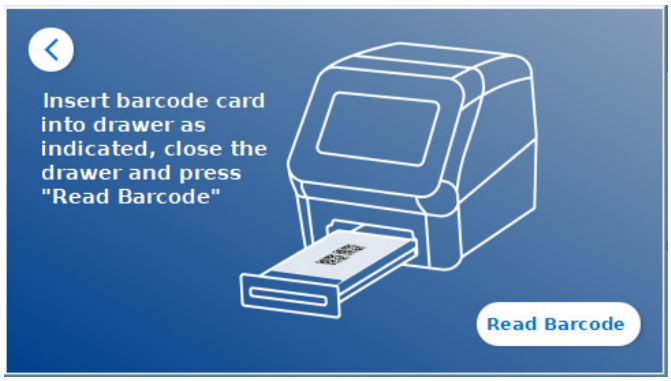
9.2 Starting a Test in the Fail Safe Mode

Please read the instructions below carefully before starting your measurement. Make sure to apply your sample at the appropriate time point to ensure the correct test-specific incubation time.

- To start a new run, press the **START NEW TEST** button on the home screen (1).

Step 1:

The workflow starts with a screen, prompting you to insert the test barcode card.



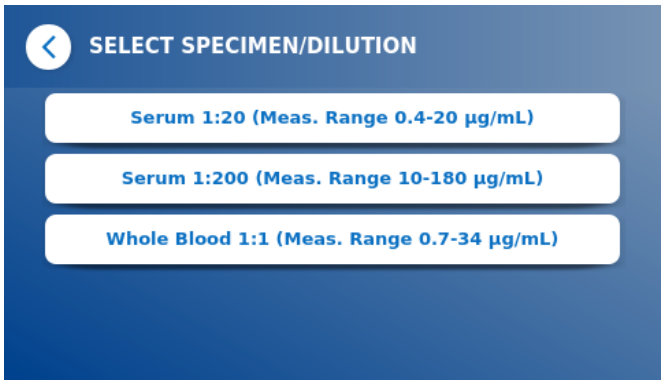
- Open the drawer located in front of the Quantum Blue® Reader and place the barcode card into the holder. Close the drawer and start the reading process by pressing **Read Barcode**.

Step 2:

- Remove your barcode card and press **Continue** when prompted by the instructions on the screen.

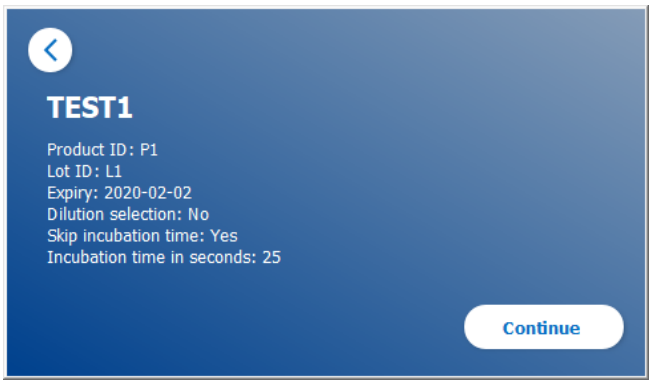
  Note: The reader has now loaded all method specific settings to perform the run such as test method, lot ID and calibration parameters.

Step 3:



- Some test methods may require a selection of the specimen type and/or the sample dilution. If prompted, choose your specimen type and/or appropriate sample dilution from the submenu.

Step 4:

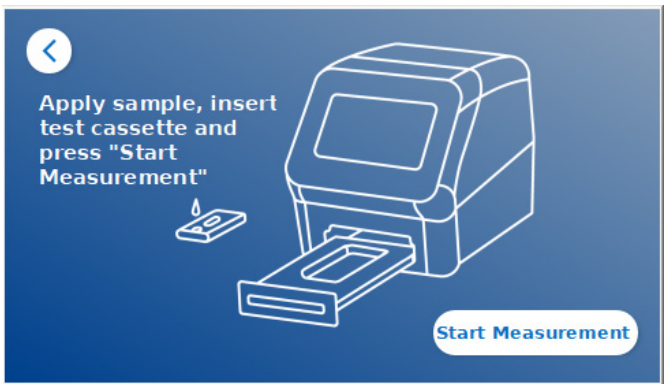


- A summary window appears on the screen displaying all test specific parameters (e.g. test method, product ID, Lot ID, expiration date, incubation time setting etc.)
- If the test settings are correct, press **Continue** to proceed to the sample entry screen.

Step 5:

- Enter the sample ID either via the screen keyboard, an external keyboard or via an external barcode scanner (see chapter 7.2 Hardware Installation/Accessories).
- The **Continue** button appears if at least 3 characters are entered. Press **Continue** to go to the last screen to start the measurement.

Step 6:

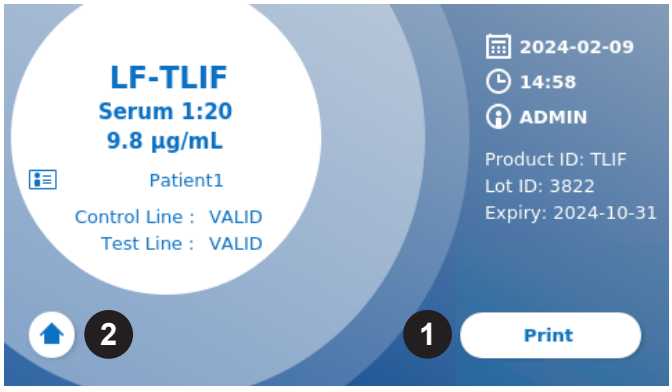


- Apply your sample onto the test cassette according to the test-specific instruction for use. Ensure that the test cassette is placed in the correct orientation (refer to the test cassette relief within the drawer).
- Close the drawer and immediately continue by pressing **Start Measurement**.
- The run will now start with the test-specific incubation time. Afterwards, the Quantum Blue® Reader will automatically proceed to measure the test cassette.

  The incubation and measurement can be aborted by pressing **(X)**.

Step 7:

After measurement, the result is automatically saved and displayed on the result summary screen:



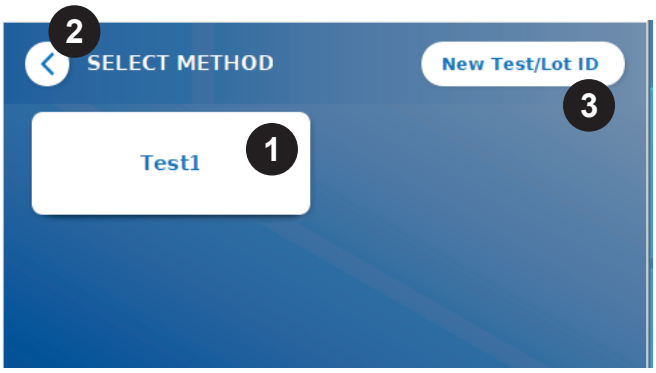
- You can either print the result (1) if a printer is connected, or you can return to the home screen (2).

9.3 Starting a Test in the Fast Track Mode

- To start a new run, press the **START NEW TEST** button on the home screen (1).

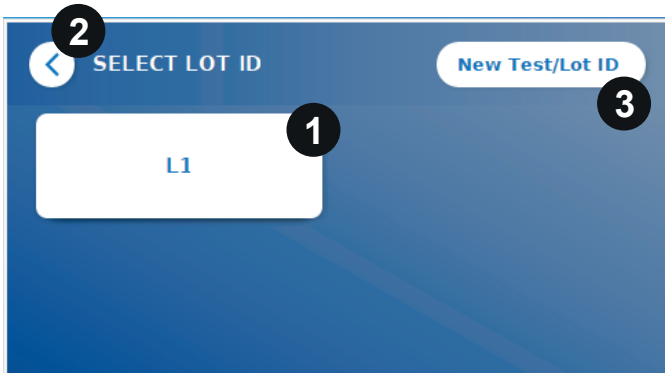
Step 1a:

The “Select Method” screen, shows all installed test methods that were previously uploaded to the reader.



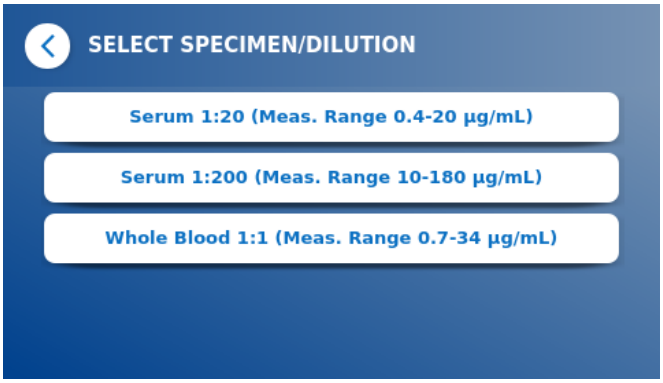
- You can select an already installed test method by pressing the corresponding button on the screen (1).
- If the desired test method is missing in the list or no test is installed so far, press **New Test / Lot ID** (3) to import a new test method from the barcode card (refer to Fail Safe Mode, step 2).
- To go one step back, tap the Go-Back button **(<)** (2). Press longer to return to the home screen.

Step 1b:



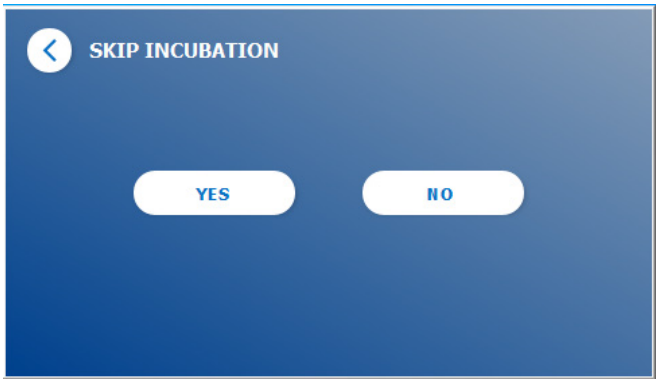
- If the desired test method is selected, you proceed to the LOT selection screen where the desired LOT ID for your test method can be chosen (1).
- If the LOT ID is missing, you can import the test method (3) with the correct lot ID by using the barcode card included in your test package (refer to Fail Safe Mode, step 2).
- To go one step back, tap the Go-Back button **(<)** (2). Press longer to return to the home screen.

Step 2:



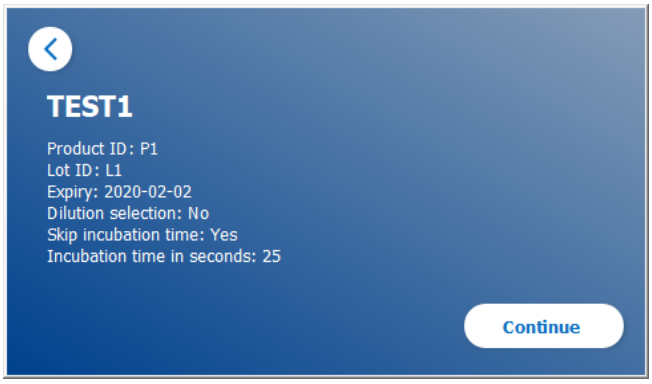
- Some test methods may require a selection of the specimen type and/or the sample dilution. If prompted, choose your specimen type and/or appropriate sample dilution from the submenu.

Step 3:



- On the SKIP INCUBATION screen, select whether the incubation time of your test cassette is done via an external timer (press **YES**) or whether the incubation time should be counted down by the reader (press **NO**).

Step 4:



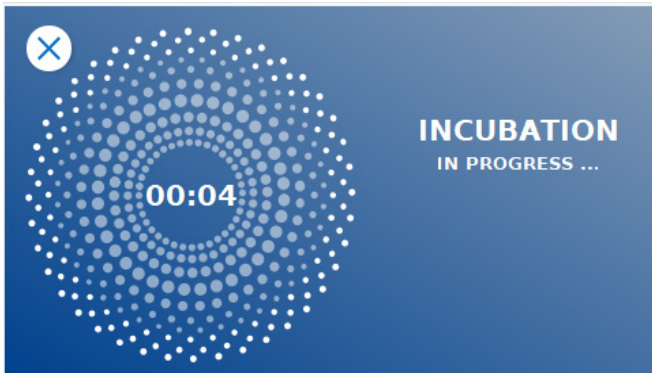
- A summary window appears on the screen displaying all test specific parameters (e.g. test method, product ID, Lot ID, expiration date, incubation time setting etc.)
- If the test settings are correct, press **Continue** to proceed to the sample entry screen.

Step 5:

- Enter the sample ID either via the screen keyboard, an external keyboard or via an external barcode scanner (see chapter 7.2 Hardware Installation/Accessories).
- The **Continue** button appears if at least 3 characters are entered. Press **Continue** to go to the last screen to start the measurement.

Step 6a:

If SKIP INCUBATION NO was selected (= incubation time is counted down by the reader):



- Apply your sample onto the test cassette according to the test-specific instruction for use. Ensure that the test cassette is placed in the correct orientation (refer to the test cassette relief within the drawer).
- Close the drawer and immediately continue by pressing **Start Measurement**.
- The run will now start with the test-specific incubation time. Afterwards, the Quantum Blue® Reader will automatically proceed to measure the test cassette.

  The incubation and measurement can be aborted by pressing **(X)**.

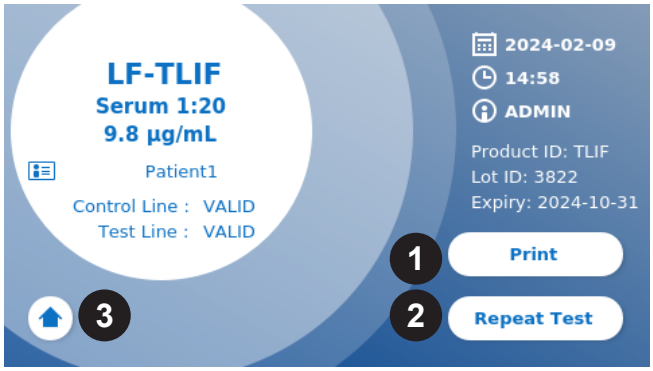
Step 6b:

If SKIP INCUBATION YES was selected (= an external timer is used to count down the incubation time):

- Apply your sample onto the test cassette according to the test-specific instruction for use. Set an external timer manually for the test-specific incubation time as indicated in the corresponding instruction for use.
- Open the drawer and place the test cassette into the holder. Ensure that the test cassette is placed in the correct orientation (refer to the test cassette relief within the drawer).
- Once the incubation time of the sample on the test cassette is completed, close the drawer and press **Start Measurement.**
- The test cassette will be measured by the Quantum Blue® Reader.

Step 7:

After measurement the result is automatically saved and displayed on the result summary screen:

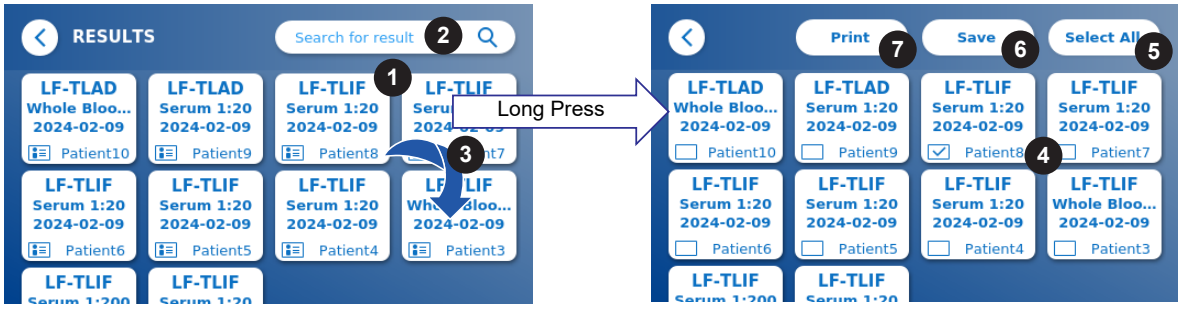


- You can print the result (1) if a printer is connected, or you can repeat the test using the same settings (2) or you can return to the home screen (3).

10 REVIEW RESULTS

By pressing the **Results** button, the result screen is displayed with an overview of the last acquired results.

The result screen shows all test results in a tile view. Different actions are available to view and search results (see table below).



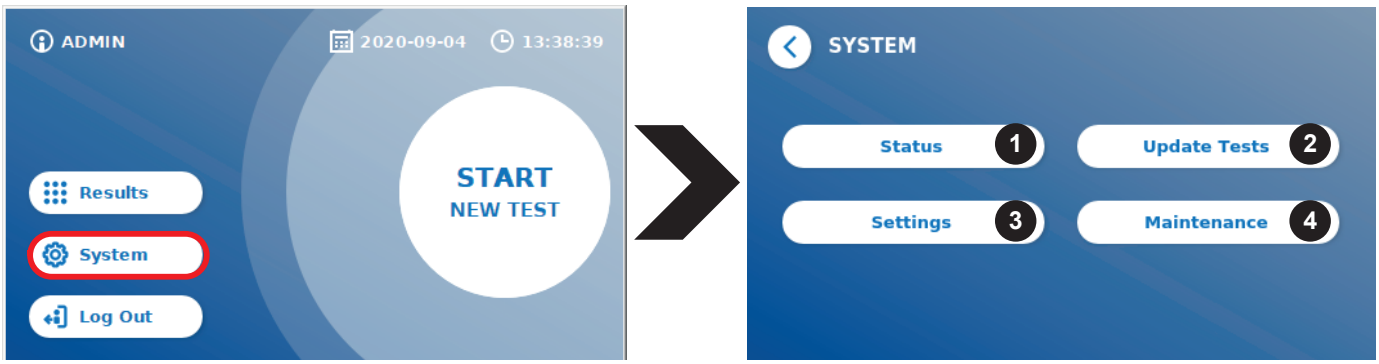
Number	Action
1	Tapping on a tile opens the single result view with all result details (see Step 7 Fail Safe and Fast Track Mode).
2	Enter test method name, date, or sample-/user-ID in the “Search for Result” field in order to search for specific test results.
3	Swipe over the result list to scroll down the list.

Long press on a result tile opens a menu with additional actions:

Number	Action
4	Select results for export or printing.
5	Select or unselect all results.
6	Save selected results to a USB stick in csv format*.
7	Print selected results.

*In order to protect the data from manipulation/alteration, BÜHLMANN recommends to print out the collected data. Data integrity is only guaranteed on the device. A transfer is technically possible, but no liability is assumed.

11 SYSTEM AND SETTINGS



The system menu offers four main sections:

- **Status** (1) for the display of current reader information like software (SW) version, IP address or serial number.
- **Update test** menu (2)
- Change of device **settings** (3)
- **Maintenance** (4) of the Quantum Blue® Reader

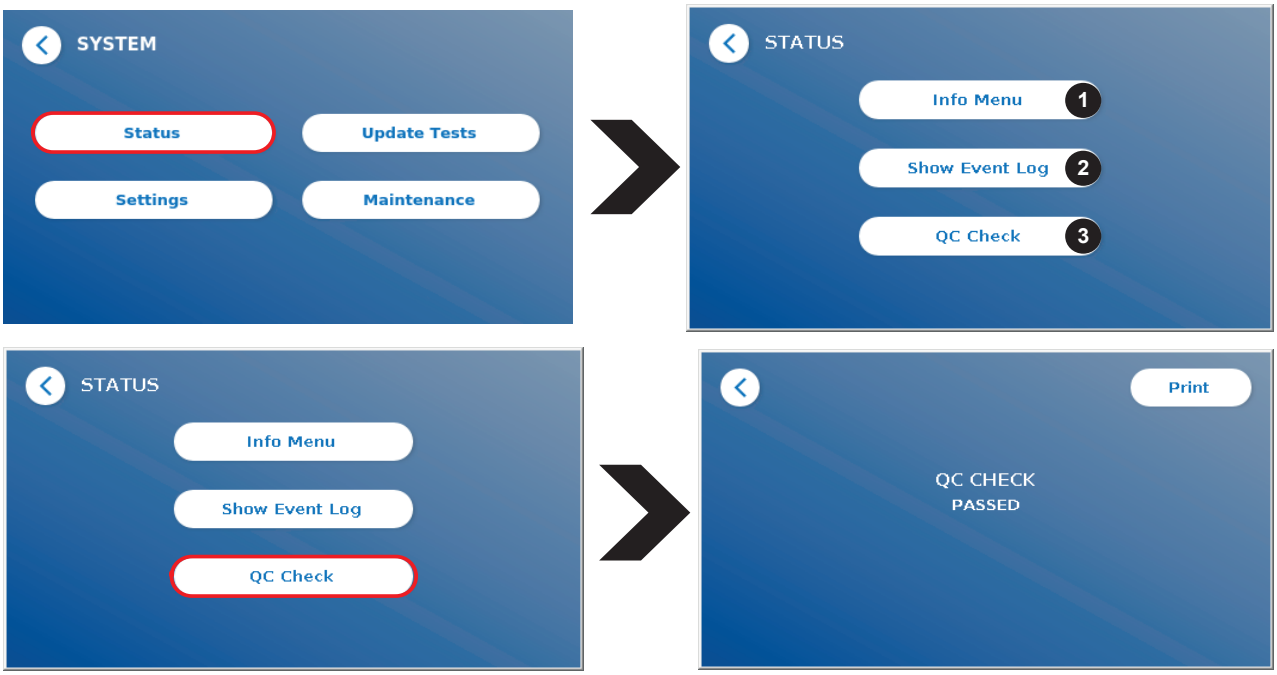
11.1 Status

Press System/ Status to enter a menu where you can access technical information about the Quantum Blue® Reader. There are two options available:

- **Info Menu** (1): displays IP address, device name, device ID, serial number, software ID, software version and operating system version
- **Show Event Log** (2): shows a chronological list of actions, which where performed on the Quantum Blue® Reader such as log in attempts, performed measurements and displayed error messages. This list can be exported on a USB stick.

Both menus can be left via the Go-Back button **(<)**

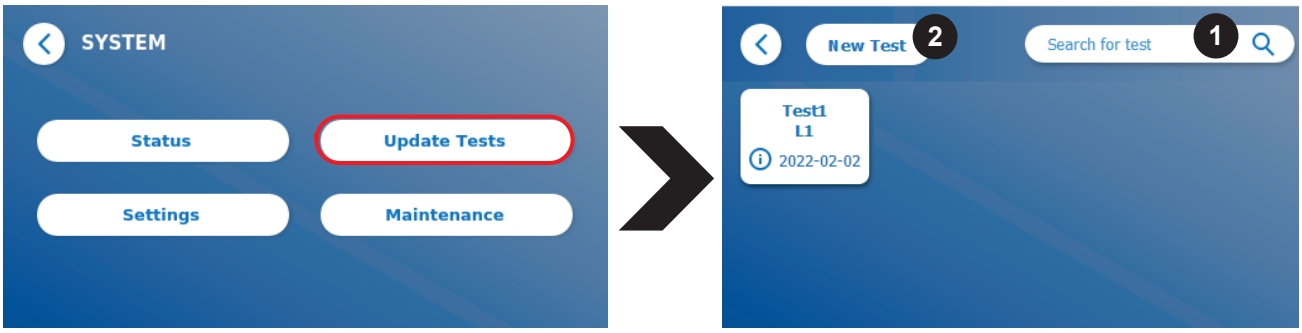
- **QC Check** (3): can be used to perform a verification test in addition to the self-check performed during startup of the instrument. In case the QC check fails, please refer to chapter 12.2 Maintenance and/or 12.3 Device Self-Check, for further information on follow-up measures.



11.2 Update Tests

Enter this menu, to update the Quantum Blue® Reader with new test methods.

NOTICE	Methods can be added by all users. The deletion of already installed methods is only possible by administrators.



The menu shows an overview of all installed test methods. It can be filtered for specific test methods by using the search field (1). To import a new test method, press **New Test** (2). The Quantum Blue® Reader prompts you to insert the barcode card into the drawer (purple arrow in Figure 6) provided with each BÜHLMANN lateral flow test kit in order to import a new test method. Ensure that the barcode card is positioned in the correct orientation in the drawer (Figure 7).

Figure 6

Figure 7

The import of a new method can take up to 1 min. In case you get an error message that your barcode card cannot be read, try the following actions:

- Re-position the barcode card
- Ensure that the barcode card is not bent
- Ensure that the area of the barcode is clean and undamaged
- Make sure that the barcode card was inserted in the correct orientation (Figure 7)
- In case your barcode card does not get read despite the above mentioned actions, please contact local BÜHLMANN Laboratories AG distributor for further help.

Important: *The Quantum Blue® Reader prevents importation of already installed test methods.*

11.3 Settings

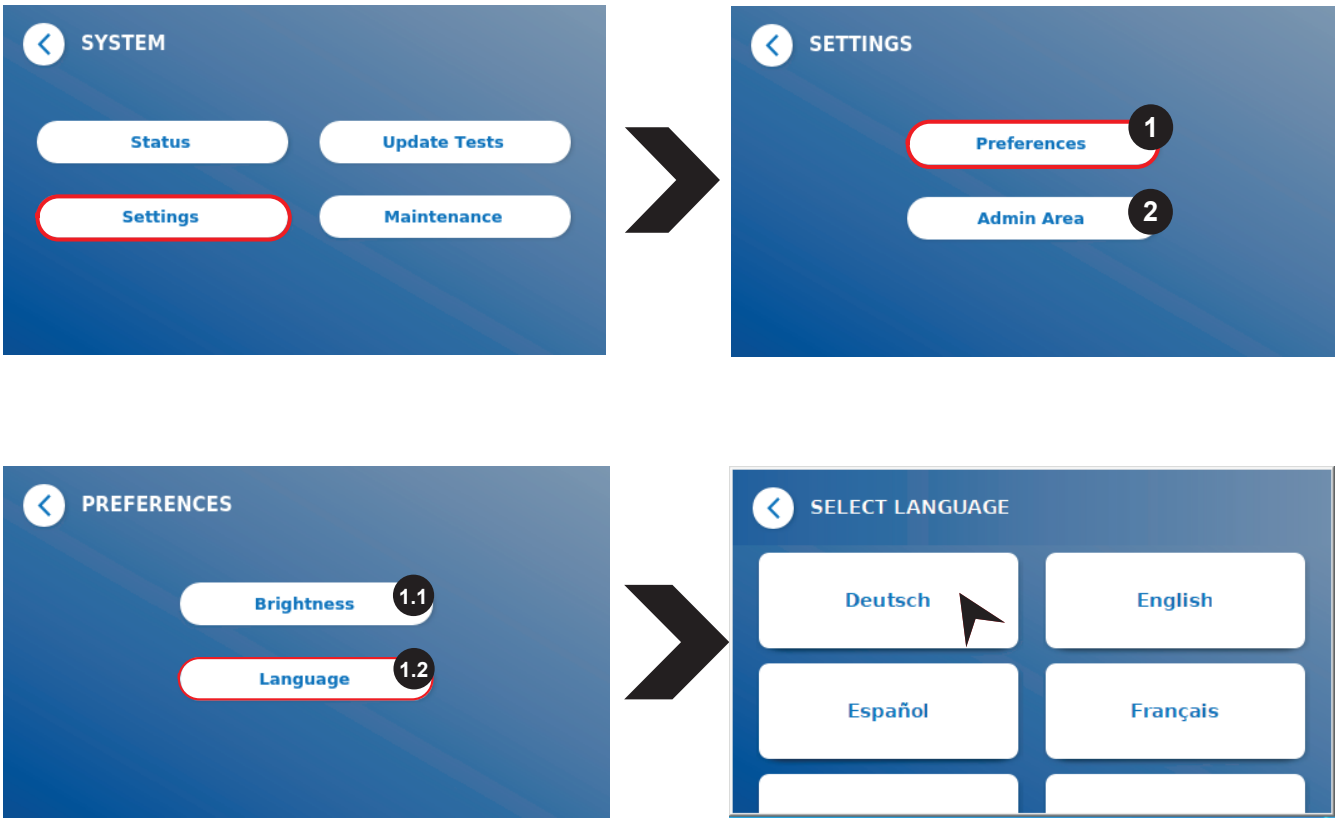
The setting menu consists of the following submenus:

- **Preferences (1),** which is accessible to all users
- **Admin Area (2),** which is only accessible to administrators

11.3.1 Preferences

Within the menu **Preferences**, the user can adjust the screen brightness (80% is the default setting) (1.1) and the reader language can be selected (1.2).

Apply the desired language by pressing the appropriate tile on the language selection screen.

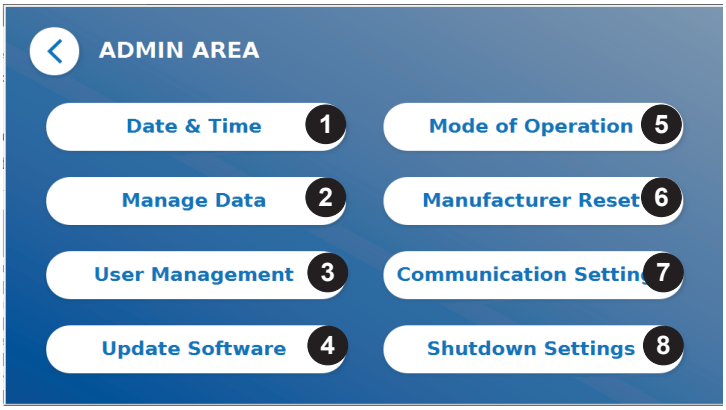


11.3.2 Admin Area

This menu can only be accessed by administrators when the user management is activated (refer to chapter 11.4.5 User Management).

The following settings can be changed within this menu:

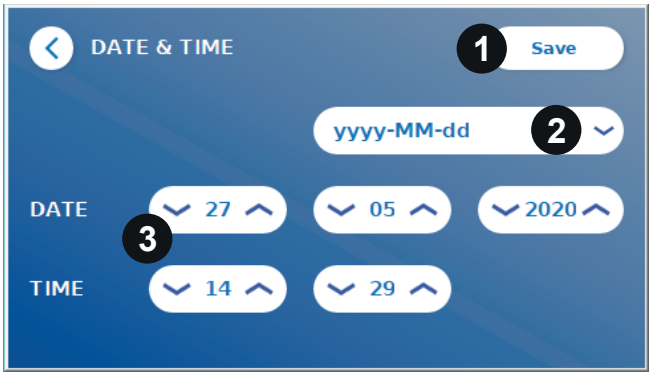
- **Date & Time** (1) settings of the Quantum Blue® Reader
- **Manage Data** (2) to delete installed test methods or results
- **User Management** (3) to add, administrate and delete users
- **Update Software** (4) to install an instrument software update
- **Mode of Operation** (5) to choose between the Fail Safe Mode and Fast Track Mode
- **Manufacturer Reset** (6) to delete all saved data and methods from the Quantum Blue® Reader
- **Communication Settings** (7) to configure network connections for data transfer
- **Shutdown Settings** (8) to configure the time interval for automated shutdown of the Quantum Blue® Reader



11.4 Menu Structure in the Admin Area

11.4.1 Date & Time

Enter this menu to change date, date format and time of the Quantum Blue® Reader.

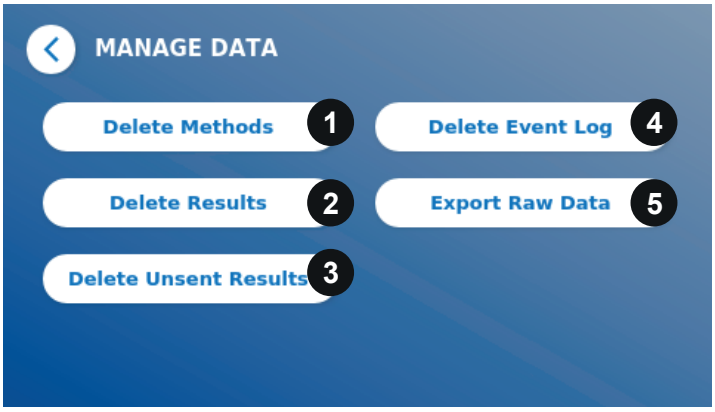


You can select between the following two date formats: yyyy-MM-dd and yyyyMMdd. Change values using the up and down arrows next to the date and time numbers (3). Save your selection by pressing **Save** (1).

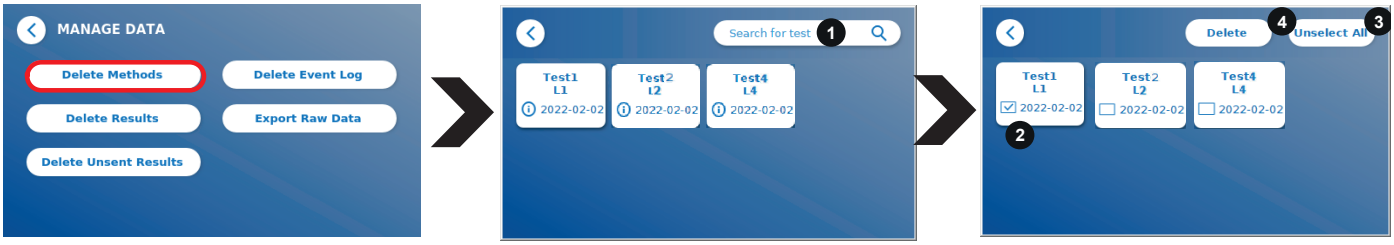
11.4.2 Manage Data

In this menu you can delete data or export the result data base. The following functions are available:

- **Delete Methods** (1)
- **Delete Results** (2)
- **Delete Unsent Results** (3)
- **Delete Event Log** (4)
- **Export Raw Data** (5)



An example of how to delete methods is shown below. **Delete Methods, Delete Results and Delete Unsent Results** submenus have a similar structure.

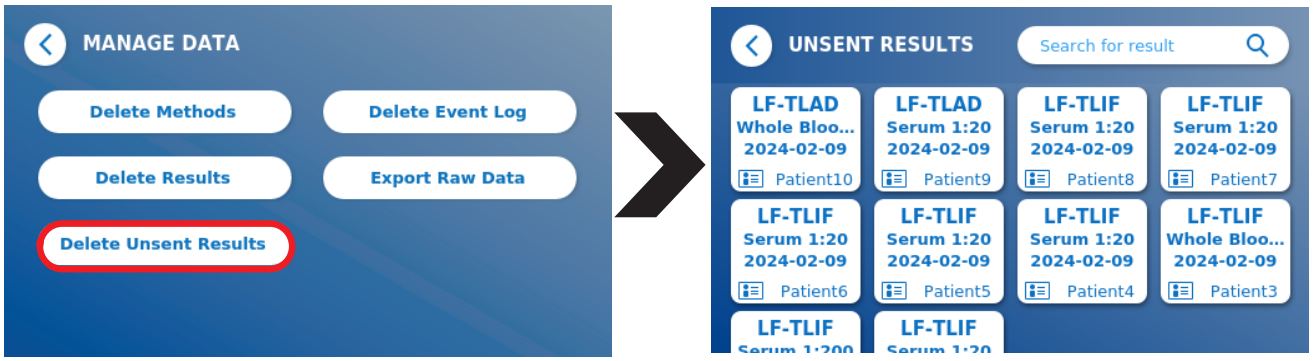


By pressing the **Delete Methods** submenu button, an overview of all installed test methods on the Quantum Blue® Reader is displayed. The text search function allows to search and filter for individual results or test methods (1).

By pressing on a test method tile, the selection mode will open and you can select individual (2) or all tiles (3). If at least one tile is marked, the Delete-button (4) will be activated and the selected tile(s) can be deleted.

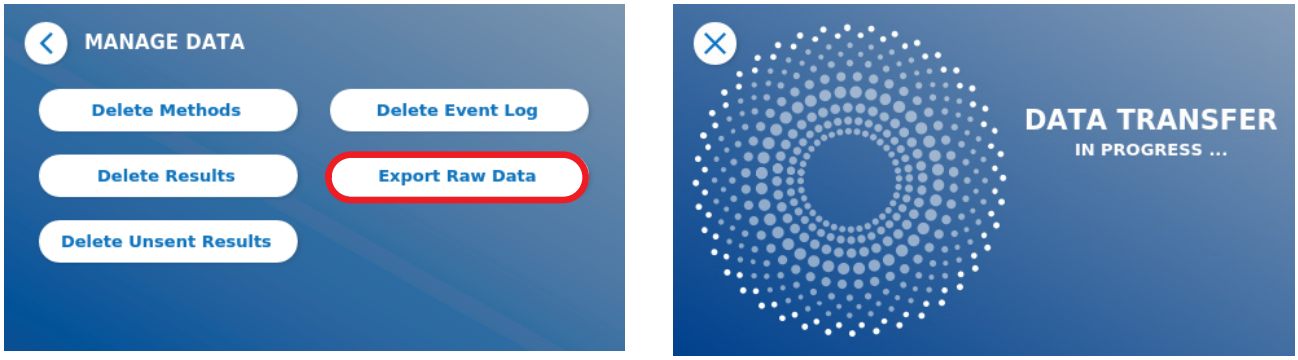
11.4.3 Delete Unsent Results

If the Quantum Blue® Reader is connected to an external computer and/or to a laboratory information system (for more information refer to the Quantum Blue® Connect Software manual), the submenu displays all unsent results. Results may not be sent due to a network interruption or server issue. Once the problem is resolved and the reader is reconnected to the server, the reader automatically transfers all remaining results to the server. If you do not want the results to be sent to the server, these results or a selection of them can be deleted under this submenu. Please note that deletion of results under this sub-menu only prevents the results from being sent to the server, the results themselves are still stored on the reader.



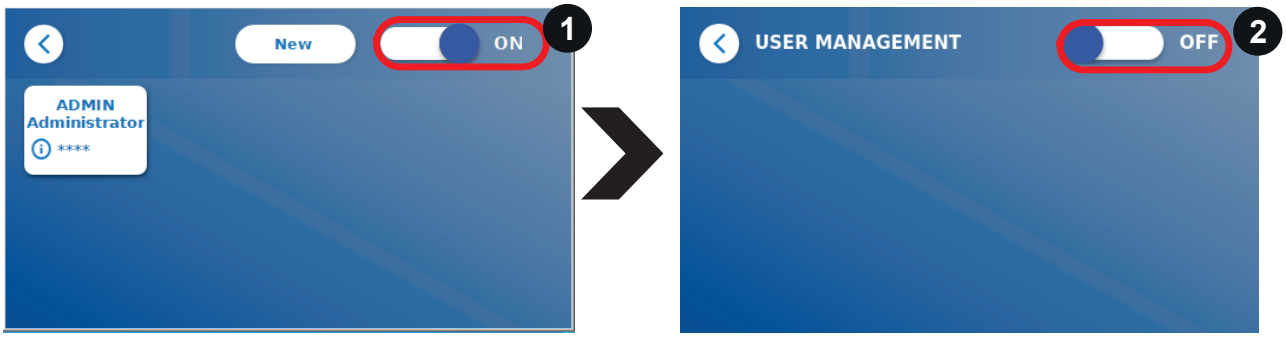
11.4.4 Export Raw Data

This menu allows the export of the whole result data base stored on the Quantum Blue® Reader to a USB stick. The raw data can help identify a root cause in case of trouble shootings. The file is encrypted and can only be decrypted by BÜHLMANN Laboratories AG. See also chapter 13 Technical and Scientific Support. The data transfer can take some time approximately up to 10 minutes.



11.4.5 User Management

The **User Management** is activated by default (1). It protects the reader against non-authorized access and use. If the **User Management** is turned off (2), no login credentials are required when turning on the device and the **Admin Area** is freely accessible. Be aware that if the **User Management** is off, generated results are not linked to the programmed users.

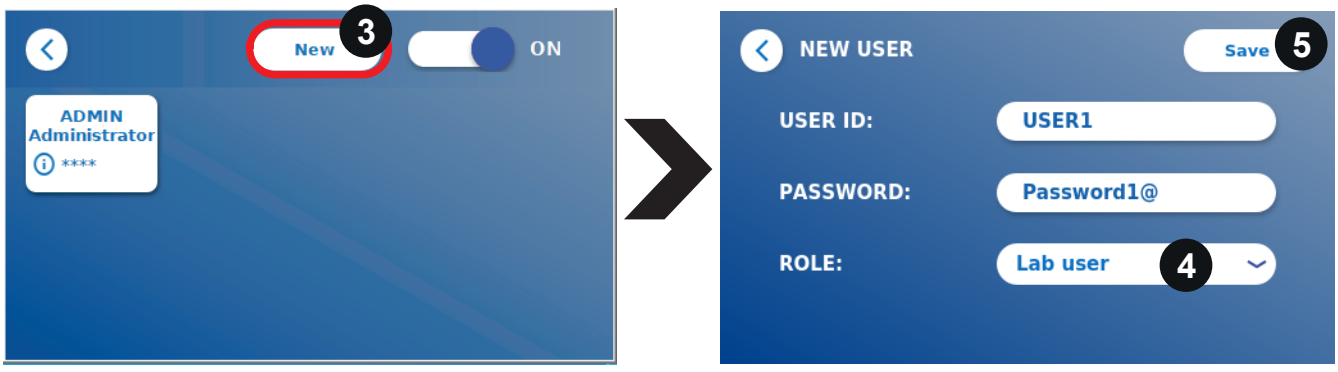


Two user roles are available:

1) **Administrator**, who can change settings and delete data in the Settings/Admin Area menu

2) **Lab user,** who can access all menus with the exception of the settings in the Admin Area.

Note: See chapter 8.5 Menu Structure for an overview of the graphical user interface structure and visualization of administrator menus.

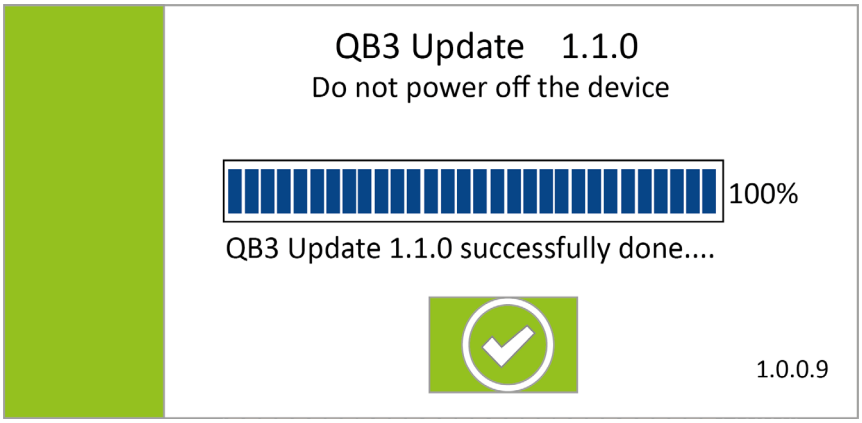


If the **User Management** is activated, administrators can create new user accounts (3), and define the role of the user (4). The new account is confirmed by pressing **Save** (5).

11.4.6 Update Software

You will be informed by your local BÜHLMANN Laboratories AG distributor about current software updates. Under this submenu, the instrument software version can be updated and/or additional languages can be added to the language selection section by plugging in an USB stick containing an instrument SW update or a language update.

Confirm the successfully completed update by pressing the tick symbol.



11.4.7 Mode of Operation

Choose here between the FastTrack or the FailSafe Mode (see chapter 9.1 The Two Modes of Operations).

11.4.8 Manufacturer reset

An orange warning screen (Figure 8) asking for confirmation to proceed will appear if you press the **Manufacturer Reset** button.

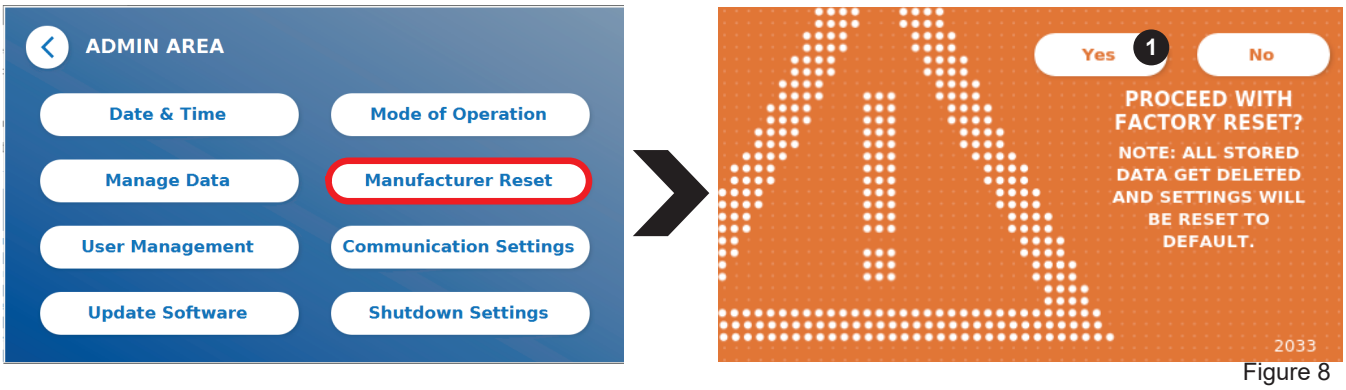


Figure 8

If you confirm to proceed by pressing **YES** (1), the following data will be adjusted/deleted from the Quantum Blue® Reader:

- Deletion of all measurement results, test methods and entries in the event log
- Deletion of all users, with the exception of the default administration user
- Deletion of all user IDs and passwords. Resetting to default „ADMIN“ user ID and “0000” password. User management is turned on.
- Resetting language to English and screen brightness to the default setting 80%
- Setting all communication settings to OFF and activation of default entries
- Setting mode of operation to Fail Safe Mode

NOTICE	Please note that the Quantum Blue® Reader will shut down and restart automatically when performing a manufacturer reset.

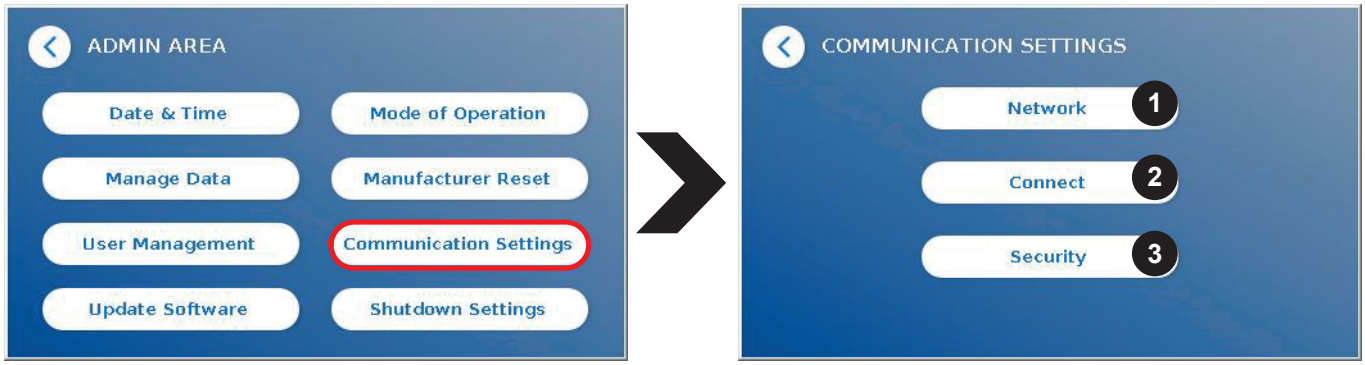
11.4.9 Communication Settings

In this menu, the administrator can manage network connections and is able to set up a connection to the Quantum Blue® Connect Software and, an external server/client solution to manage and view results from external devices.

The menu offers 3 submenus called

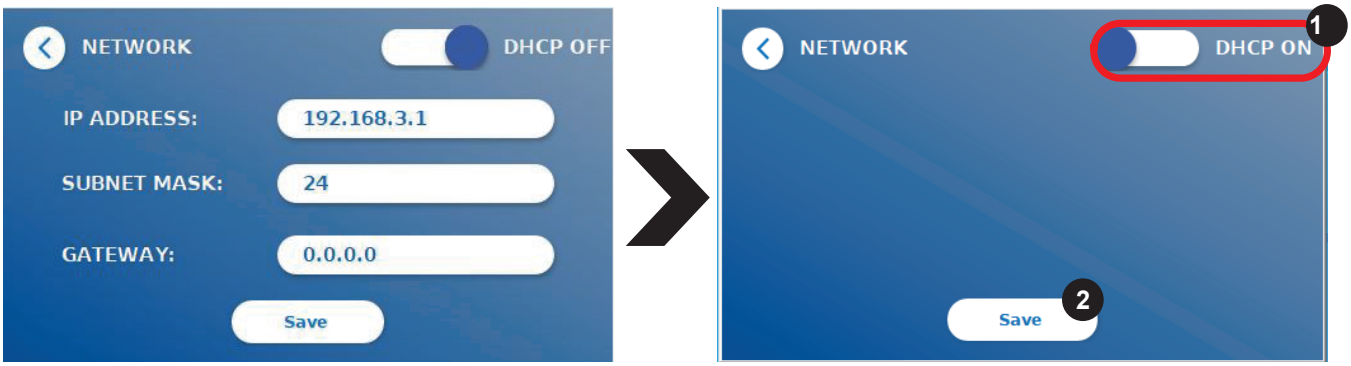
- **Network** (1)
- **Connect** (2)
- **Security** (3)

Aks your laboratoy IT-specialist in case you need support to set up the connections described in the following subchapters.



Submenu Network within communication settings

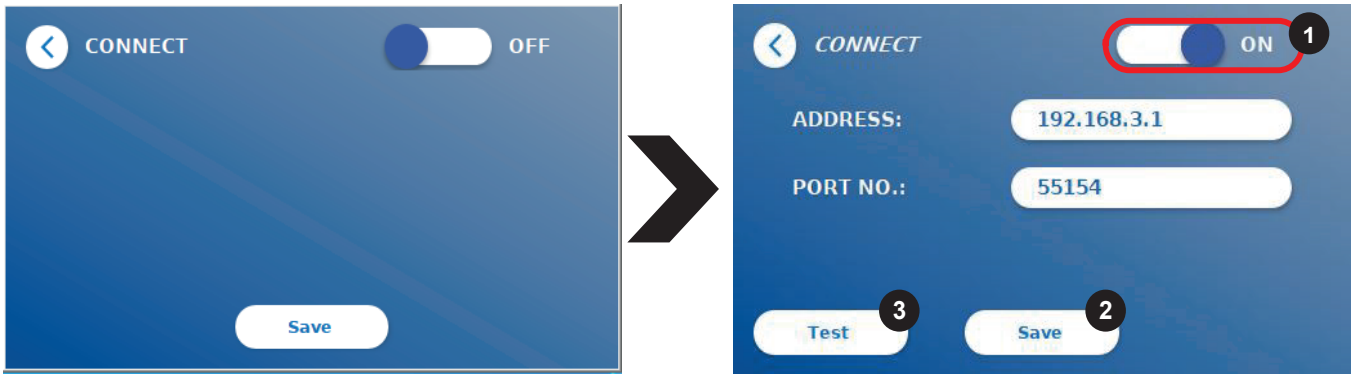
In this menu, the network properties of the reader can be configured such as its IP address, its subnet mask and the default gateway. Alternatively a DHCP (Dynamic host configuration protocol) can be turned on (1) and the Quantum Blue® Reader will receive its network configuration from a DHCP server.



Settings and changes are saved by pressing the **Save** button (2).

Submenu Connect within Communication Settings

For the reader to report results to the Quantum Blue® Connect Software, the **Connect** functionality needs to be turned on (1). The Connect server IP address and port number need to be entered and changes need to be saved (2).



By pressing **Test** (3), it can be tested if the connection to the Quantum Blue® Connect Software was successfully established. A success message (Figure 9) will appear on the reader display.

Figure 9

Submenu Security within Communication Settings

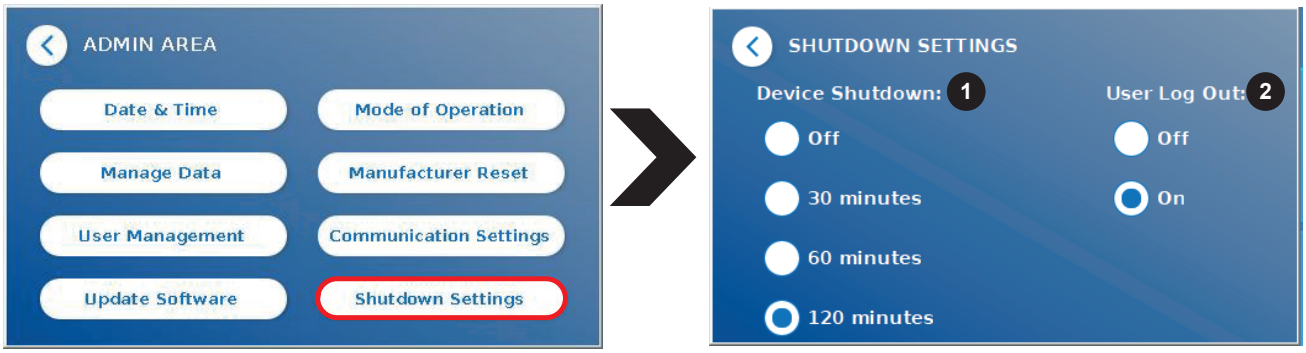
The settings under this menu are only accessible by BÜHLMANN Laboratories AG employees.

11.4.10 Shutdown Settings

An automated log off followed by an automated device shut down increases the security level of the Quantum Blue® Reader, preserves components like the display and saves energy.

You can select between three different time periods of Quantum Blue® Reader inactivity after which it will shut down automatically: 30, 60 or 120 minutes (1). Device shutdown can also be disabled (OFF) and the Quantum Blue® Reader won't shut down automatically as long as connected to a power supply.

If **User Log Out** is turned on (2), the user will automatically be logged out after 10 minutes of inactivity. This feature protects the reader from unauthorized use.



12 MAINTENANCE AND CLEANING

NOTICE	The safety information, maintenance and cleaning chapters must be read thoroughly and understood before starting maintenance and cleaning work.

12.1 Cleaning

In order to clean the Quantum Blue® Reader housing, use a damp cloth moistened with water or a mild detergent. If the dirt is persistent, rub the surface of the Quantum Blue® Reader with a cloth moistened with 70% alcohol solvent. Do not use aggressive cleaning agents such as acetone.

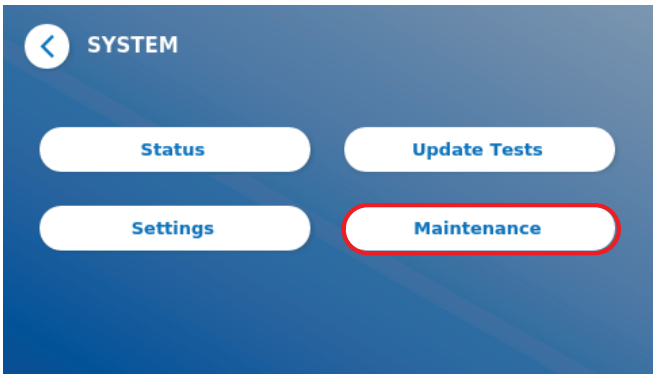
For more persistent stains and for disinfecting the instrument, it is possible to clean the surface with a cloth dipped in 1% bleach (1% active chlorine) followed by wiping with water. The procedure can be repeated 2-3 times. It is also possible to use 70% alcohol solvent to wipe off the remaining traces of bleach. Spillage of potentially infectious material should be wiped off immediately and materials used to clean spills, including gloves, should be disposed according to biohazard waste guidelines.

The test cassette holder should be cleaned using dust free swabs or appropriate cloths. Do not use objects that could damage or scratch the surface.

If the inside of the Quantum Blue® Reader is contaminated, contact your local BÜHLMANN Laboratories AG distributor directly (see chapter 13 Technical and Scientific Support).

12.2 Maintenance

In case the Quantum Blue® Reader displays a warning during self-check (refer to Figure 11 of chapter 12.3 Device Self-Check for more information), stating that the optical system has only partially met or not met the required values, the user can clean the internal reference material with dry swabs. In the **Maintenance** menu, a live view of the inside of the device is shown on the screen and the light inside the system is turned on (Figure 10C). The user can now clean the internal reference material and restart the Quantum Blue® Reader for another self-check.



Steps to clean:

- Turn on the Quantum Blue® Reader (Figure 10A)
- Ensure to have a lint free swab (recommended: Techspray, Super-Tip Foam Swab, Product 2306)
- Completely eject the drawer of the Quantum Blue® Reader (Figure 10B)
  (For more information on how to eject the drawer see chapter 5 Functional Description)
- Go to System/Maintenance → the live view starts (Figure 10C)
- Inspect the inside chamber of the Quantum Blue® Reader and carefully clean off dust and dirt particles from the internal reference material (indicated in Figure 10D).

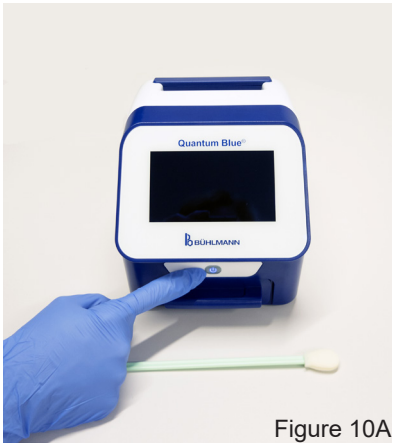


Figure 10A

Figure 10B

Figure 10C

Figure 10D

⚠ CAUTION	Make sure that you do not touch the camera or lights of the Quantum Blue® Reader which are located at the top side of the inside chamber.

NOTICE	The maintenance mode can only be exited by performing a hard shutdown - the power button needs to be pressed for at least 6 seconds until the device turns off. After restart, the Quantum Blue® Reader will perform a self-check and the home screen will be displayed.

12.3 Device Self-Check

The Quantum Blue® Reader is a highly sensitive optical device for qualitative and quantitative measurements. In order to check the status of the mechanical, electronic and optical components of the instrument, a self-check is performed every time the Quantum Blue® Reader is switched on.
In case of self-check failure, either a warning message stating to clean the internal reference materials is displayed (Figure 11, refer to chapter 12.2 Maintenance) or a warning message stating to directly call the service (Figure 12) is displayed on the screen of the Quantum Blue® Reader.

Figure 11

Figure 12

If the self-check was not successful, the Quantum Blue® Reader prevents further measurements. Results can still be reviewed and settings can be changed. The user is required to contact the local BÜHLMANN Laboratories AG distributor in such a case. Note that the measured signal may change due to the following reasons:

- Contamination of the optical parts
- Electromagnetic interferences
- Temperature/Humidity changes
- Mechanical movements
- Wrong drawer

NOTICE	Please make sure, that the drawer with the same serial number as the serial number of the Quantum Blue® Reader is inserted (see chapter 6 Unpacking and Set-Up Procedures).

13 TECHNICAL AND SCIENTIFIC SUPPORT

If technical or scientific support is required, please directly contact your local BÜHLMANN Laboratories AG distributor. Our local distributors will give you the initial assistance to find an immediate solution for your issue. If needed, our local distributor will escalate your questions or issues to the Customer Support Department at BÜHLMANN Laboratories AG.

In case you need to return the Quantum Blue® Reader, it must be decontaminated and free of pathogens and infectious materials in order to be handled safely in a non-biological safety laboratory (see chapter 12.1 Cleaning).

The Quantum Blue® Reader must be returned in the original package. If not available anymore, please inform your local BÜHLMANN Laboratories AG distributor.

NOTICE	The corresponding Quantum Blue® Reader is excluded from any warranty and further processing if the security seal label at the rear side of the Quantum Blue® Reader has been manipulated.

14 TROUBLESHOOTING AND MESSAGES

The following table lists information on error messages and potential mitigation measures.

Message on Graphical User Interface	Potential Root Cause	Possible user action
«Barcode not found. Check barcode on test card and retry» Err. 2001	No barcode card is in the drawer. Only one of the two method barcodes found. Barcode is unreadable due to e.g. dirt, damage, scratches, ...	Check that the barcode card in the drawer and try again (see also chapter 11.2 Update Tests).
«Invalid barcode/ method. Insert valid barcode and retry» Err. 2002	Protocol incorrect (e.g. test cassette instead of barcode card inserted into the drawer).	Check barcode card in the drawer and try again.
«Test expired. Check expiry date of test» Err. 2003	Expiry date of test is exceeded.	Check expiry date of test. Use a new test if expired.
«Test <-> cassette mismatch» Err. 2004 and Err. 2016	The chosen test method does not correspond to the barcode on the test cassette (Product ID and/or LotID).	Insert test cassette that corresponds to the chosen method within 30 seconds or choose correct test method and remeasure test cassette within 30 seconds.
«Test already exists» Err. 2012	A test method with the same Product ID and Lot ID is already installed on the Quantum Blue® Reader.	Delete existing method on device with same name and lot. If required, contact your admin user.
«No Cassette found» Err. 2006 and Err. 2010	No or non-BÜHLMANN test cassette is inserted.	Verify that you have the correct test cassette inserted. Try within 30 seconds.
«Wrong cassette orientation» Err. 2007 and Err. 2017	Incorrect test cassette orientation	Turn the cassette 180° and re-insert into the drawer within 30 seconds. Corresponding instructions will appear on the screen of the Quantum Blue® Reader. If 30 seconds are exceeded, take a new test cassette and apply the same sample again.
«Reader Initialization check failed. Call Service» /or «Device error. Restart Device» Err 1001 and Err. 1003	Self-check failure	Reboot device. Consult your local BÜHLMANN Laboratories AG distributor if error message persists (see chapter 12.3 Device Self-Check).
«System error. Text: xx Number: yy Mode: zz» Err. 2000	Potential Hardware or Software Error	Reboot device or consult your local BÜHLMANN Laboratories AG distributor if error message persists.
«Maintenance recommended» Err. 2011	Self-check values are close to limits of their target values.	Perform maintenance on the Quantum Blue® Reader by cleaning the internal reference material with swabs (see chapter 12.2 Maintenance).
«Drawer open during initialization. Close drawer and restart device to repeat initialization check» Err. 1004	The Drawer is open while initialization	Close the drawer, switch off and on to start a new test.

15 TECHNICAL DATA

BÜHLMANN Laboratories AG reserves the right to change specifications at any time.

15.1 Dimensions and Weight of the Instrument

Dimensions	H / W / D: 150 x 150 x 150 mm (6 x 6 x 6 inch)
Weight	Approx. 1.2 kg (2.6 lb)

15.2 Mechanical Data and Hardware Features

Graphical User Interface	Interactive 10.9 cm (4.3 inch) touchscreen
Noise	< 10 db(A)
Connections	3 x USB, 1x ethernet
Memory capacity	Up to 99 test methods and up to 300 test results
Operating conditions	+15 to +35 °C (59 to 95 °F), humidity < 70%, not condensing
Transport Conditions	-20 to +50°C
Storage Conditions	+15 to +40°C
IP-classification	IP10

15.3 Software Features

Instrument software (ISW)	The instrument software is the running and controlling unit of the Quantum Blue® Reader. It enables the reader to scan test cassettes, to analyze runs, and to display and store the results of runs.
Quantum Blue® Connect Software	The Quantum Blue® Connect Software is an optional component that can be used to manage and store data on external computers and to connect the Quantum Blue® Reader to Laboratory Information Systems or similar information systems.

15.4 Optics

Optical system	5 Mpix camera (8Bit)
Signal detection	Colorimetric
Colorimetric detection	Colloidal gold, colored latex beads, carbon particles, etc.
Measurement time	< 20 seconds
Surveillance	Internal reference check using solid standards

15.5 Power requirements of the instrument

External Power Supply	Input: 100–240 V AC, 0.5 A, 50-60 Hz; Output: +12 V DC / 1.67 A

15.6 Optional Accessories

External printer	Dymo TM 450/550 Label writer
Printer labels	Dymo large address labels (101mm x 54mm)
Barcode reader	Model Zebra DS 2208*
Cleaning Swabs	Techspray, Super-Tip Foam Swab, Product 2306
Others	Keyboard, mouse, to be connected via the USB ports

*The Quantum Blue® Reader was tested in combination with the barcode reader Model Zebra DS 2208.
It is the sole responsibility of the user if alternative/other barcode reader models are used.

15.7 Applicable Standards

CE conformity to CE	This Product is CE marked in accordance with the requirements of the applicable EU Directive and Regulation. Regulation on *in vitro* diagnostic medical devices	(EU) 2017/746
Electromagnetic compatibility (EMC) requirements	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment	DIN EN 61326-2-6:2013 + IEC 61326-2-6:2012
Safety requirements	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment	EN 61010-1:2010 + IEC 61010-1:2010 EN 61010-2 101:2017 + IEC 61010-2-101:2015
Restriction of Hazardous Substances (RoHS)	Based on the supplier statements for the used parts and to our current knowledge, the device can be declared RoHS complaint	dir. 2011/65/EU dir. 2015/863/EU
REACH	Based on the supplier statements for the used parts and to our current knowledge, the device can be declared REACH complaint	dir. 1907/2006/EC

16 WARRANTY AND OBLIGATIONS

For product and service inquiries, please contact:

BÜHLMANN Laboratories AG
Baselstrasse 55, 4124 Schönenbuch, Switzerland
Tel.: + 41 61 487 12 12
Fax: + 41 61 487 12 34
Email: support@buhlmannlabs.ch

Customer and product service are available during standard office times (Monday to Friday, 8 a.m. to 5 p.m. Central European Time (CET)).

16.1 Product Warranty

A manufacturers' warranty of twelve (12) months applies for all mechanical and electronic components and the operational reliability of the product.

In the case of used equipment, liability for defects and warranty shall be excluded.

The place of performance of the guarantee shall be BÜHLMANN, Schönenbuch. It shall be incumbent upon BÜHLMANN to decide whether the defective component or product are repaired or exchanged on site or in Schönenbuch. Products are supplied FOB to and from company site.

The guarantee shall not apply to any operating errors and damage attributable to improper handling, particularly to the use of third-party software, which has not been approved by BÜHLMANN for the device in question.

BÜHLMANN's liability shall in no case exceed the obligation to replace any defective component or product. These exclusions and limitations on damages shall apply regardless of how the loss or damage occurred (breach of contract, tort or otherwise).

BÜHLMANN shall not be liable for any losses caused through use of the Quantum Blue® Reader, its software or by analysis results generated by the customer and/or supplied to third parties.

NOTICE	Please not that the Quantum Blue® Reader is excluded from any warranty and further processing if the security seal label at the rear side of the Quantum Blue® Reader has been manipulated.

16.2 Obligations of the User

Except in case of damage or defect attributable to BÜHLMANN, the user shall not make any claims against BÜHLMANN for any damaged or defective products or components. The user shall carefully examine the condition of the products immediately upon receipt.

If instructions given by BÜHLMANN Laboratories AG with respect to storage, installation and handling of the products are not observed or if changes are made to the product, if components are replaced or if consumable items are used which do not comply with the original specifications, any warranty rights are forfeited unless the user is able to refute any assertion that only any of these circumstances has caused the deficiency.

Defects, incorrect deliveries, quantities, or transport damage are to be notified without delay by the user in writing or by fax (in case of defects which can be identified immediately) to the BÜHLMANN distributor or to BÜHLMANN directly, otherwise within two weeks of receipt of the products at the place of destination, by clearly describing the defect; in this respect, it is necessary that the user properly fulfils his obligations of investigation and notification.

16.3 Waste Electrical and Electronic Equipment (WEEE)

This section provides information about disposal of waste electrical and electronic equipment by users in the European Union.

The European Directive 2012/19/EU on WEEE requires proper disposal of electrical and electronic equipment when it reaches its end of life. The crossed-out wheeled bin symbol (see below) indicates that this product must not be disposed off with other waste; it must be taken to an approved treatment facility or to a designated collection point for recycling, according to local legislation. The separate collection and recycling of waste electronic equipment at the time of disposal helps to conserve natural resources and ensures that the product is recycled in a manner that protects human health and the environment.

BÜHLMANN Laboratories AG accepts its responsibility in accordance with the specific WEEE recycling requirements and, where a replacement product is being supplied by BÜHLMANN Laboratories AG, provides free recycling of its WEEE-marked electronic equipment in Europe. If a replacement product is not being purchased from BÜHLMANN Laboratories AG, recycling can be provided upon request at additional cost. To recycle electronic equipment, contact your local BÜHLMANN Laboratories AG distributor for the required return form. Once the form is submitted, you will be contacted by BÜHLMANN Laboratories AG either to request follow-up information for scheduling collection of the electronic waste or to provide you with an individual quote.

17 DECLARATION OF CONFORMITY

BÜHLMANN Laboratories AG
Baselstrasse 55
4124 Schönenbuch
Switzerland

Phone +41 61 487 12 12
Fax +41 61 487 12 34
info@buhlmannlabs.ch
www.buhlmannlabs.ch

EU-KONFORMITÄTSERKLÄRUNG / EU DECLARATION OF CONFORMITY
DÉCLARATION DE CONFORMITÉ UE / DICHIARAZIONE DI CONFORMITÀ UE
DECLARACIÓN UE DE CONFORMIDAD / DECLARAÇÃO UE DE CONFORMIDADE

DE: Wir, BÜHLMANN Laboratories AG, erklären in alleiniger Verantwortung, dass das unten angegebene Produkt den Bestimmungen der IVD-Verordnung (EU) 2017/746 für *In-vitro*-Diagnostika entspricht und in Einklang mit anderen relevanten Rechtsvorschriften der Union, gemeinsamen Spezifikationen (GS)[i] und anderen normativen Dokumenten steht.

EN: We, BÜHLMANN Laboratories AG, declare under sole responsibility that the device specified below meets the provision of the IVD Regulation (EU) 2017/746 for *in vitro* diagnostic medical devices and is in conformity with other relevant Union legislations, common specifications (CS)[i] and other normative documents.

FR : Nous, BÜHLMANN Laboratories AG, déclarons sous notre seule responsabilité que le produit spécifié ci-dessous est conforme aux dispositions du règlement IVD (UE) 2017/746 pour les dispositifs médicaux de diagnostic *in vitro* et qu'il est conforme aux autres législations pertinentes de l'Union, des spécifications communes[i] et autres documents normatifs.

IT: Noi, BÜHLMANN Laboratories AG, dichiariamo sotto la nostra esclusiva responsabilità che il prodotto specificato di seguito è conforme alle disposizioni del regolamento IVD (UE) 2017/746 per i dispositivi medico-diagnostici *in vitro* ed è conforme ad altre leggi dell'Unione pertinenti, specifiche comuni (SC)[i] e altri documenti normativi.

ES: Nosotros, BÜHLMANN Laboratories AG, declaramos bajo nuestra exclusiva responsabilidad que el producto especificado a continuación cumple con las disposiciones del Reglamento IVD (UE) 2017/746 para productos sanitarios de diagnóstico *in vitro* y conforme con otra legislación pertinente de la Unión, especificaciones comunes[i] y otros documentos normativos.

PT: Nós, BÜHLMANN Laboratories AG, declaramos sob a nossa exclusiva responsabilidade que o produto especificado abaixo cumpre as disposições do Regulamento IVD (UE) 2017/746 para dispositivos médicos de diagnóstico *in vitro* e está em conformidade com outra legislação relevante da União, especificações comuns[i] e outros documentos normativos.

Name und Adresse des Herstellers Name and address of manufacturer Nom et adresse du fabricant Nome e indirizzo del produttore Nombre y localización del fabricante Nome e localização do fabricante	BÜHLMANN Laboratories AG, Baselstrasse 55, 4124 Schönenbuch, Switzerland	Name und Adresse des EU-Bevollmächtigter Name and address of EU authorised representative Nom et adresse du mandataire de l'UE Nome e indirizzo del mandatario dell'UE Nombre y localización del representante autorizado de la UE Nome e localização do mandatário da UE	BÜHLMANN Germany GmbH Marie-Curie-Straße 8, 79539 Lörrach, Germany
Einmalige Registrierungsnummer (SRN) Single registration number (SRN) Numéro d'enregistrement unique Numero di registrazione unico Número de registro único (SRN) Número único de registo	CH-MF-000026305	Einmalige Registrierungsnummer (SRN) Single registration number (SRN) Numéro d'enregistrement unique Numero di registrazione unico Número de registro único (SRN) Número único de registo	DE-AR-000024782
Produktname/ Katalognummer Product name/ Catalogue number Nom du produit/ Numéro de catalogue Nome del prodotto/ Numero di catalogo Nombre del producto/ Número de catálogo Nome do produto/ Número de catálogo	Quantum Blue® Reader/ BI-POCTR-ABS (Serienummer grosser als 3000 serial numbers above 3000 numéros de série supérieurs à 3000 numeri di serie superiori a 3000 números de serie superiores a 3000 números de série acima de 3000)	Basis UDI-DI Basic UDI-DI IUD-ID de base UDI-DI di base UDI-DI básico UDI-DI básico	++EBUHBIPOCTRABS2K
Zweckbestimmung Intended purpose Destination prévue Destinazione d'uso Uso previsto Utilização prevista	Der Quantum Blue® Reader ist ein Schnelltest-Lesegerät zum in vitro Nachweis und/oder zur Quantifizierung von Analysemethoden auf Lateral Flow Testkassetten. Der Quantum Blue® Reader wird ausschließlich in Kombination mit BÜHLMANN Lateral Flow Tests verwendet. The Quantum Blue® Reader is a rapid test reader for the in vitro detection and/or quantification of target analytes on lateral flow test cassettes. The Quantum Blue® Reader is used only in combination with BÜHLMANN lateral flow tests. Le Quantum Blue® Reader est un lecteur de test rapide pour la détection et/ou la quantification in vitro d'analytes cibles sur des cassettes test à flux latéral. Le Quantum Blue® Reader est uniquement utilisé en association avec les tests par dosage à flux latéral BÜHLMANN. Quantum Blue® Reader è un lettore di test rapidi per la rilevazione e/o quantificazione in vitro di analiti target su cassette di test a flusso laterale. Quantum Blue® Reader è utilizzato esclusivamente in abbinamento ai test a flusso laterale BÜHLMANN. El Quantum Blue® Reader es un lector de pruebas rápidas para la detección y/o cuantificación in vitro de analitos de interés en cartuchos para pruebas de flujo lateral. El Quantum Blue® Reader se utiliza sólo en combinación con las pruebas de flujo lateral de BÜHLMANN. O Quantum Blue® Reader é um leitor de teste rápido para a detecção e ou quantificação in vitro de analitos de interesse em cassetes de teste de fluxo lateral. O Quantum Blue® Reader somente é usado em combinação com testes de fluxo lateral BÜHLMANN.		

DECLARATION OF CONFORMITY

BÜHLMANN Laboratories AG
Baselstrasse 55
4124 Schönenbuch
Switzerland

Phone +41 61 487 12 12
Fax +41 61 487 12 34
info@buhlmannlabs.ch
www.buhlmannlabs.ch

Risikoklasse gemäss Anhang VIII der EU Verordnung 2017/746 Risk class in accordance to Annex VIII of the EU Regulation 2017/746 Classe de risque selon l'annexe VIII du Règlement (UE) 2017/746 Classe di rischio secondo l'allegato VIII del Regolamento (UE) 2017/746 Clase de riesgo de acuerdo con el anexo VIII del Reglamento (UE) 2017/746 Classe de risco de acordo com o anexo VIII do Regulamento (UE) 2017/746	Klasse A gemäss Klassifizierungsregel 5b Class A according to classification rule 5b Classe A selon du règle de classification 5b Classe A secondo la regola di classificazione 5b Clase A según la norma de clasificación 5b Classe A de acordo com a regra de classificação 5b		i) Weitere relevante (Unions) Rechtsvorschriften und GS i) Other relevant (Union) legislations and CS i) D'autres actes législatifs de l'Union pertinents et spécifications communes i) Altre leggi (dell'Unione) pertinenti e SC i) Otra legislación pertinente de la Unión y especificaciones comunes i) Outra legislação relevante da União e especificações comuns	DIN EN 61326-2-6:2013 + IEC 61326-2-6:2012 EN 61010-1:2010 + IEC 61010-1:2010 EN 61010-2 101:2017 + IEC 61010-2-101:2015 dir. 2011/65/EU dir. 2015/863/EU dir. 1907/2006/EC
Konformitätsbewertungsverfahren gemäss EU Verordnung 2017/746 Conformity assessment procedure according to EU Regulation 2017/746 Procédure d'évaluation de la conformité au Règlement (UE) 2017/746 Procedura di valutazione della conformità secondo del Regolamento (UE) 2017/746 Procedimiento de evaluación de la conformidad según el Reglamento (UE) 2017/746 Procedimento de avaliação da conformidade de acordo do Regulamento (UE) 2017/746	Klasse A gemäss Anhang IV Class A according to Annex IV Classe A selon l'annexe IV Classe A secondo l'allegato IV Clase A según el anexo IV Classe A de acordo com o anexo IV			
Konformitätsbewertungsstelle (0123) Notified body (0123) L'organisme notifié (0123) Organismo di valutazione della conformità (0123) Organismo notificado (0123) Organismo notificado (0123)	Nicht Anwendbar Not Applicable Non applicable Non applicabile No aplicable Não Aplicável		Qualitätsmanagement System Zertifikatsnummer Quality management system certificate number Numéro de certificat du système du management de la qualité Numero del certificato del sistema di gestione della qualità Número de certificado del sistema de gestión de la calidad Número do certificado do sistema de gestão de qualidade	Nicht Anwendbar Not Applicable Non applicable Non applicabile No aplicable Não Aplicável
Ort und Datum Place and date Lieu et date Località e data Lugar y fecha Local e data	Schönenbuch, 2022-09-05		Unterschrift des Herstellers Signature of manufacturer Signature du fabricant Firma del produttore Signatura del fabbricante Assinatura do fabricante	Fabio Perretta *Fabio Perretta* Quality Management Representative

CHANGELOG

Date	Version	Change
2024-06-06	VA3	Introduction of a disclaimer in chapter *“8 General Operation”* Introduction of a password recommendation in chapter *“8.3 First Log In”* Update to screenshots in chapters *“9.2 Starting a Test in the Fail Safe Mode”* (step 3 and 7), *“9.3 Starting a Test in the Fast Track Mode”* (step 2 and 7), *“10 Review Results”*, *“11.4.3 Delete Unsent Results”* and *“11.4.5 User Management”* Update to chapters *“7.2 Hardware Installation / Accessories”,* and *“15.6 Optional Accessories”* with introduction of new thermal printer Update to chapters *“9.2 Starting a Test in the Fail Safe Mode”* (step 5), *“9.3 Starting a Test in the Fast Track Mode”* (step 5) and *“15.6 Optional Accessories”* with introduction of keyboard/mouse connection and usage options Update of the Declaration of Conformity in chapter *“17 Declaration of Conformity”*

INCIDENT REPORTING IN EU MEMBER STATES

If any serious incident in relation to this device has occured, please report without delay to the manufacturer and competent authority of your Member State.

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Quantum Blue® Reader User Manual

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BÜHLMANN products are subject to the quality standards within the quality management system according to ISO 13485.

CE

BÜHLMANN Laboratories AG
Baselstrasse 55
4124 Schönenbuch
Switzerland

Phone +41 61 487 12 12
Fax orders +41 61 487 12 99
info@buhlmannlabs.ch
www.buhlmannlabs.ch