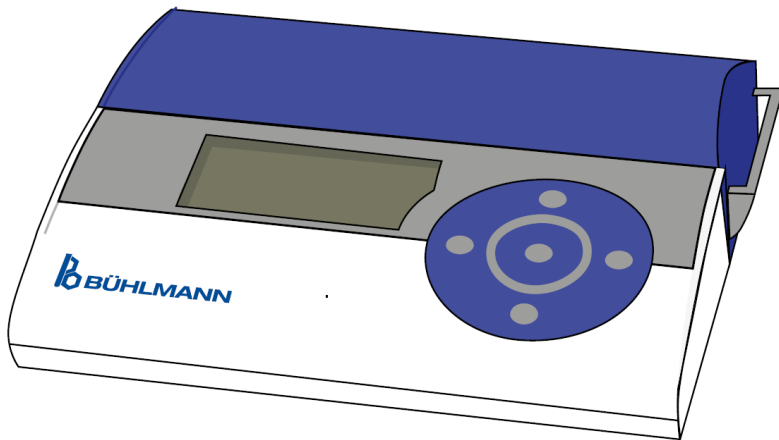


Quantum Blue® Reader

User Manual



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Quantum Blue® Reader User Manual

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1 Introduction

1.1 General

Lateral flow assays represent a well-established proven technology for a variety of near patient and field use applications. Although these simple diagnostic tests are established in many routine applications, this technology has not been widely applied when very sensitive, highly reproducible, quantitative results or electronic data documentation are required. The Quantum Blue® Reader now makes this possible, by combining the major advantages of traditional lateral flow assay with modern technologies to fulfill the requirements for new diagnostic tests.

1.2 Intended Use

The intended use of the Quantum Blue® Reader is to analyze colorimetric tests by reflectometry. The fast and precise scanning allows the detection of quantitative results depending on the rapid test and/or the configuration of the device. The data are stored automatically. All stored data include measuring time, date, user ID, patient ID, raw data, etc. This mobile reader is powered by rechargeable batteries or with the external power supply.

It should only be used according to the safety precautions outlined in chapter 2.



The Quantum Blue® Reader should only be used with specified tests by trained and qualified personnel. The reader has to be powered by the specified rechargeable batteries or by the specified external power supply. The data can be transferred to a PC via USB port only with the QB Soft software provided. The Quantum Blue® Reader may be used in a laboratory or in the field provided that all the environmental and operating conditions are met.

1.3 Main Features of the Quantum Blue® Reader

- Precision: Excellent repeatability, long term stability of the detector (optical system), and the powerful controller enable reliable quantification of lateral flow tests.
- High sensitivity: The award winning confocal sensor used provides unmatched sensitivity.
- Ease of use: Load the lot-specific test information by scanning the RFID card of the kit, insert the test cassette, press start button and everything else will be done by the reader (scanning, evaluating, displaying and storing of the results).
- Portable: The Quantum Blue® Reader provides all the necessary requirements of a portable reader: It is small, lightweight, can be operated as a stand-alone device and stores up to 80 test results. The reader can be operated by rechargeable batteries (3 x AA Ni-MH).
- Connectivity: Easy connection and transfer of data to a PC via USB is available, intuitive software allows quick and easy processing of data. Also, additional equipment such as a barcode reader and an external RFID-reader can be connected to the Quantum Blue® Reader.

2 Safety Information






This manual contains information about warnings and cautions that must be followed by the user to ensure safe operation of the Quantum Blue® Reader and to maintain the Quantum Blue® Reader in a safe condition. Please note: If the Quantum Blue® Reader is used in a manner not specified by BÜHLMANN Laboratories AG, the protection provided may be impaired.


WARNING 	The term WARNING is used to inform you about situations that could result in personal injury to you or other persons. Details about these circumstances are given in a box like this one.
CAUTION 	The term CAUTION is used to inform you about situations that could result in damage to the instrument or other equipment. Details about these circumstances are given in a box like this one.


Before using the Quantum Blue® Reader, it is essential to read this manual carefully and to pay particular attention to any advice it contains concerning hazards that may arise from the use of the Quantum Blue® Reader.

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


2.1 Proper Use


<p>CAUTION</p> 	<p>Improper use of the Quantum Blue® Reader may cause personal injuries or damage to the instrument. The Quantum Blue® Reader must only be operated by qualified personnel who have been appropriately trained.</p> <p>Servicing of the Quantum Blue® Reader must only be performed by Field Service Engineers trained by BÜHLMANN Laboratories AG.</p>
<p>CAUTION</p> 	<p>For your own safety do not operate the device without a test cassette inserted. Do not open the drawer while measurement is in progress. Only authorized persons are allowed to service or disassemble the reader.</p>
<p>CAUTION</p> 	<p>Do not expose the Quantum Blue® Reader to direct sunlight.</p>
<p>CAUTION</p> 	<p>Protect the Quantum Blue® Reader from high humidity and contact with liquids.</p>
<p>CAUTION</p> 	<p>Do not expose the Quantum Blue® Reader to excessive heat.</p>

<p>CAUTION</p> 	<p>Take note of the operating conditions of the Quantum Blue® Reader. Should the device come into contact with high humidity or temperatures other than +15°C - +40°C, let it stand overnight at proper operating conditions before turning it on.</p>
--	--

<p>CAUTION</p> 	<p>Metal surfaces can interfere with RFID reader function.</p>
--	--

2.2 Electrical Safety


<p>CAUTION</p> 	<p>Do not expose the Quantum Blue® Reader to strong electromagnetic radiation.</p>
--	--

<p>CAUTION</p> 	<p>Use the specified AA rechargeable batteries only!</p> <p>Do not use alkaline batteries!</p>
--	--


Note: Switch off the Quantum Blue® Reader when it is not in use.

Note: Contact your BÜHLMANN Laboratories AG representative or your local distributor for replacement batteries.

2.3 Hazardous Substances

<p>WARNING</p> 	<p>The products used with this instrument may contain hazardous substances.</p> <p>When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate material safety data sheet (MSDS) of a given product.</p>
--	--

2.4 Infectious Substances

<p>WARNING</p> 	<p>Some samples measured in this instrument may contain infectious agents. Handle such samples with the greatest care and in accordance with the required safety regulations.</p> <p>Always wear safety glasses, 2 pairs of disposable gloves, and a suitable lab coat.</p> <p>The responsible body (e.g., laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe, and that the instrument operators are suitably trained and not exposed to hazardous levels of infectious agents.</p> <p>Venting for fumes and disposal of waste must be in accordance with all national, state, and local health and safety regulations and laws.</p>
--	--

2.5 Waste Disposal

Waste may contain certain hazardous chemicals, or contagious/bio hazardous materials and must be collected and properly disposed in accordance with national, state, and local health and safety regulations and laws.

For disposal of waste electrical and electronic equipment (WEEE compliance), see appendix.

2.6 Maintenance

Perform the maintenance procedures described in chapter 6.








2.7 Cleaning and Decontamination

The user is responsible for carrying out appropriate decontamination of the instrument (according to instructions provided under service and maintenance, cleaning section, chapter 6.4) if hazardous materials are spilled on or inside the test cassette holder.

Clean the outside of the reader with a mild detergent or a 70% alcohol solution (isopropanol or ethanol). Avoid the use of aggressive solvents such as acetone.

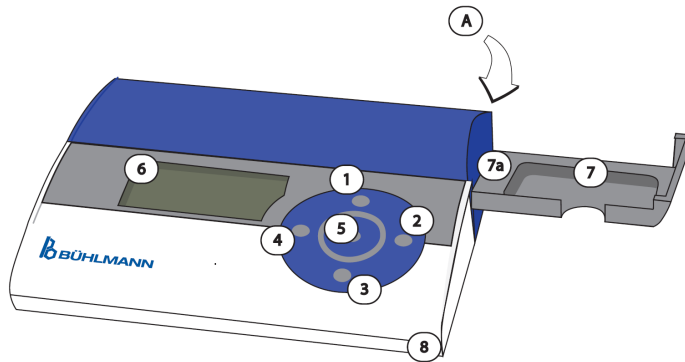
Note: Before using any cleaning or decontamination method, except those recommended in this user manual, check with your local BÜHLMANN Laboratories AG representative or with the BÜHLMANN Laboratories AG Customer Support to ensure that the equipment will not be damaged.

2.8 Symbols on the Quantum Blue® Reader

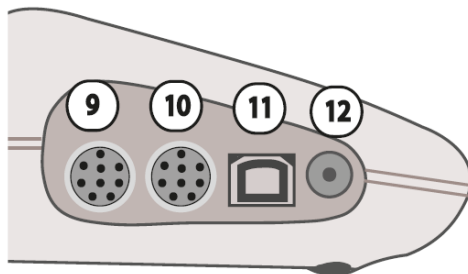
Symbol	Location	Description
	Type plate on the back of the instrument	CE mark for Europe
	Type plate on the back of the instrument	<i>In vitro</i> diagnostic (IVD) medical device
	Type plate on the back of the instrument	Serial number
	Type plate on the back of the instrument	Legal manufacturer
	Type plate on the back of the instrument	Production date
	Type plate on the back of the instrument	Waste electrical and electronic equipment (WEEE)
IP21	Type plate on the back of the instrument	Degree of Protection (IP= Ingress Protection)
	Type plate on the back of the instrument	Consult instructions for use (ie. this user manual)

3 General Description

3.1 Hardware



1	UP button
2	FORWARD button
3	DOWN button
4	BACK button
5	ENTER and ON/OFF button
6	Display
7	Test cassette holder (Drawer)
7a	with Calibration Spot
8	Battery compartment
A	Position for placement of RFID Chip Card



9	I/O port for barcode reader, USB extension, or external RFID reader (all optional)
10	I/O port for barcode reader, USB extension, or external RFID reader (all optional)
11	USB port for PC-connection
12	Power port

3.2 Software

QB Soft software for running and controlling the Quantum Blue® Reader, reading test results, printing test results, up/downloading test results, managing test methods and user rights via PC.

3.3 Contents of the Package

- Transportation case
- Quantum Blue® lateral flow reader
- CD-ROM with USB Drivers, Language Updaters, QB Soft Software and Manuals
- Batteries
- USB cable
- Power supply
- Adapter set for power supply

4 Installation

4.1 Requirements

4.1.1 Site

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

Note: Please avoid locations of metallic surface that may affect the RFID reader function.

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 used close to vibrating machines). The device must be used on a stable and leveled surface.

The Quantum Blue® Reader has an internal correction for normal levels of ambient light, but highly intense light falling into the insertion port of the test cassette (holder) can cause serious interference with the measurement and must be avoided.

4.1.2 Environment

If you plan to use the Quantum Blue® Reader in a working environment prone to dirt build-up, you will need to clean the device regularly. For cleaning, use a damp cloth. For more persistent stains, it is also possible to clean the surface with a cloth dipped in a mild detergent or in a 70% alcohol solution (isopropanol or ethanol). Avoid the use of aggressive solvents such as acetone and the like.

4.1.3 Ambient Temperature

The use of the Quantum Blue® Reader in environments prone to large temperature changes can cause measurement values to deviate from real values. Please take the environmental conditions into account in case of trouble shooting (see chapter 7).

Note: Best storage condition for the Quantum® Blue Reader is at ambient temperature. Avoid storage of the Quantum Blue® Reader at low (-20 °C) or high (+50°C) temperatures.

4.1.4 Power Requirements

With an external power supply, the Quantum Blue® Reader operates at 100–240 V_{AC}, 0.5 A, and 50–60 Hz.

The Quantum Blue® Reader can also be powered by rechargeable batteries without an external power supply. The batteries must be periodically recharged connecting the external power supply for at least 4 hours (the complete charging time is 14 hours).

4.1.5 Power Supply Options

- Battery powered: Insert three rechargeable AA batteries (Ni-MH only) in the battery compartment (refer to chapters 3.1 and 6.1). It is recommended to regularly check the battery status on the display.
- External power: Connect external power supply to power port (refer to chapter 3.1).

4.1.6 Unpacking

Take out the Quantum Blue® Reader from its protective transportation case and place it on a stable and leveled surface.

4.1.7 Connecting Accessories (optional)

- External RFID or barcode reader: Connect the device to the related I/O Port (refer to chapter 3.1).

4.2 Language Setting

4.2.1 Overview

The default language of the Quantum Blue® Reader is English. The language can be changed by choosing one of the language updaters on the CD-ROM. Please note that only ONE language can be displayed at a time on the firmware of the Quantum Blue® Reader (refer to chapter 4.2.2 Installation Procedure).

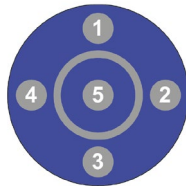
4.2.2 Installation Procedure

Connect the Quantum Blue® Reader to your PC. Open (double-click) the language updater of choice on the CD-ROM and follow the instructions on your PC screen. The firmware will be updated with the language of choice within less than a minute. Finish the updating process by pressing “Exit” in the updater menu and then “Finish” in the updater start menu. The Quantum Blue® Reader is now ready to be used with your language of choice.


For any further questions regarding installation procedure or language settings please contact BÜHLMANN Laboratories AG Customer Support.

5 Operation of the Quantum Blue® Reader

5.1 Basic Functions

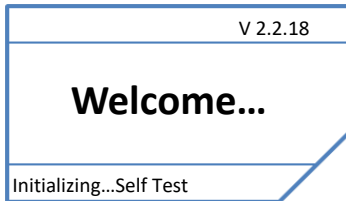


Key pad with buttons

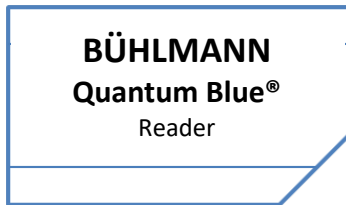
- a) Press ENTER button (5) for 2 seconds to turn on the Quantum Blue® Reader (see chapter 5.2).
- b) Select  on the upper right part on any screen in order to go back to the main menu using the buttons (1), (2), (3) and/or (4). Then press the ENTER button (5) and the main menu screen will be displayed (see chapter 5.3).
- c) A specific function (for example „Test Method“ or „Patient ID“) is selected using the ENTER button (5). Specific parameters (for example „CAL_0“ in the function „ Test Method “ or „User01“ in the function „User ID“) are selected using buttons (1) and/or (3) and then confirmed using the ENTER button (5). For the function „Patient ID“ toggle through the characters using buttons (2) and (4) and change characters using buttons (1) and (3).
- d) „N“ and „B“ on the lower part of the display menus mean: power supply fitted („N“); battery status („B“).
- e) Error and other messages from the reader (such as “Error RFID-2105” or “Initializing Memory”, etc.) are displayed on the lower part of the display menus where usually the battery status is displayed. In cases of error messages please refer to chapter 7 “Trouble Shooting”.
- f) Press ENTER button (5) for 3 seconds to switch off the Quantum Blue® Reader at any time and on any screen.

5.2 Start Manual Operation and Initialization of the Reader

To turn ON the Quantum Blue® Reader press the ENTER button (5) for 2 seconds.



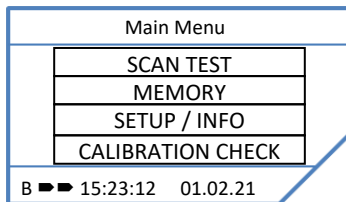
After turning on the reader the self test, the detector check, the initialization of the motor and memory, and the calibration check is performed automatically.



After a successful calibration check the reader turns automatically to the “Test Selection” screen (see chapter 5.4).

5.3 Main Menu

Select  on any screen to switch back to the main menu.



Choose operating mode with buttons (1) and (3). Select operating mode with ENTER button (5).

Scan Test mode: see chapter 5.4

Memory mode: see chapter 5.5

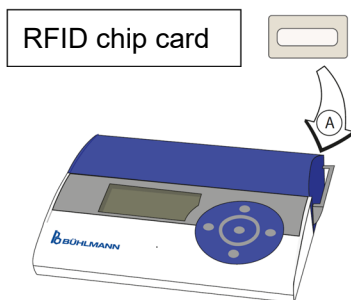
Setup / Info mode: see chapter 5.6

Calibration Check mode: see chapter 5.7

5.4 Scan Test Mode

After turning on, the Quantum Blue® Reader switches automatically to the “Test Selection” screen (see chapter 5.4.1) and is ready for the measurement of a test cassette. If “Method” and “Lot ID” correspond with the short name of the test method and lot number in the instruction for use and on the label of a selected test cassette, the measurement can be started immediately by pressing the ENTER button (5) (the default setting of the reader is on “START”).

If “Test Method” and/or “Lot ID” do not correspond with the short name of the test method and lot number in the instruction for use and on the label of a selected test cassette, hold the respective RFID chip card for a few seconds at position “A” on the Quantum Blue® Reader (see also chapter 3.1) and wait until the correct parameters are displayed. If the RFID chip card is not read correctly after some seconds, please hold the card a little further down the back of the unit. The precise position of “A” can vary slightly between different Quantum Blue® Readers. A test “Test Method” can also be selected manually (see chapter 5.4.1).



5.4.1 Select and enter Test Parameters

START	Test Selection	<input checked="" type="checkbox"/>
Test Method	CAL_0	
Lot ID	2105	
Patient ID	EXAMPLE11	
User ID	User01	
B ■■ 15:23:12 01.02.21		

Test Method: select with buttons (1) and (3), press ENTER button (5), select respective “Test Method” with buttons (1), and (3) and press ENTER button (5) to confirm.

Lot ID: can only be changed with RFID chip card (see above, chapter 5.4).

Patient ID: select with buttons (1) and (3), press ENTER button (5), select digits/characters with button (2) and (4), change digits/characters with button (1) and (3), and press ENTER button (5) to confirm.

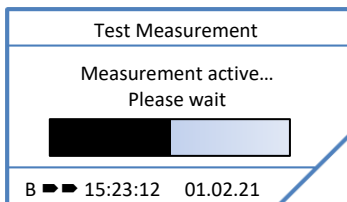
User ID: select with buttons (1) and (3), press ENTER button (5), select the user with buttons (1) and (3), and press ENTER button (5) to confirm.

Up to 10 users can be set/defined with the QB Soft software (see Quantum Blue® Reader QB Soft user manual).

5.4.2 Measuring Test Cassette

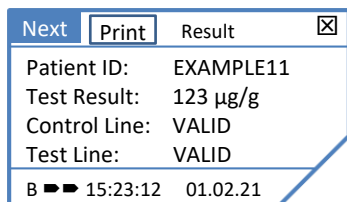
Test Incubation
Remaining incubation time:
0695
Cancel
B ■■ 15:23:12 01.02.21

Press “START” (using ENTER button (5)) on the “Test Selection” screen and the incubation time counts down (e.g. 720 seconds, if test method “CAL_720” was selected). This screen does not appear, if a test method without automatic incubation time was selected (e.g. “CAL_0”). The incubation timer can be cancelled by pressing the ENTER button (5).



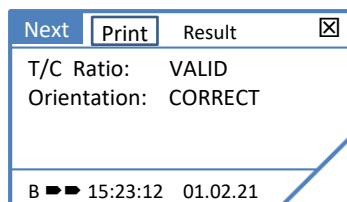
The test cassette is scanned either immediately or after finished incubation time count down.

5.4.3 Viewing Results



Note the test result. Detailed test data and results are saved automatically and can be viewed in the Memory mode (see chapter 5.5).

Navigate with buttons (1) and (3) between the screens.



Press “Next” (using ENTER button (5)) to return to the “Test Selection” screen and to measure the next test cassette.

Note: Printing of detailed test results is only possible via PC using QB Soft software.

Exporting raw data as an Excel file is possible via PC using QB Soft software (please refer to Quantum Blue® Reader QB Soft user manual).

5.5 Memory Mode

Detailed test data and test results can be viewed in the memory mode. Up to 80 data sets are stored. Select a data set with buttons (2) and (4). Navigate with buttons (1) and (3) between the 4 screens. If the limit of 80 stored data sets is reached, the oldest data set(s) are overwritten by the newest in chronological order.

Printing of detailed test results is only possible via PC using QB Soft software.

Print	Test No. 5/25	X
Test Method	CAL_0	
Product ID	LF-CAL	
Lot ID	2105	
Patient ID	EXAMPLE11	
B 15:23:12 01.02.21		

Test Method: short name of the product
(see instruction for use, IFU)

Product ID: code of the product (see IFU)

Lot ID: batch (lot) number of product

Patient ID: patient identification number

Print	Test No. 5/25	X
Date/Time	01.02.21 15:23:12	
User ID	XYZ	
Run No.	243	
Test Result	123 µg/g	
B 15:23:12 01.02.21		

Date/Time: date / time of measurement

User ID: operator

Run No.: total number of runs made with this reader

Test Result: displayed result (concentration of analyte measured)

Print	Test No. 5/25	X
Control Line:	VALID	
Test Line:	VALID	
T/C Ratio:	VALID	
Orientation:	CORRECT	
B ■ 15:23:12 01.02.21		

Control Line: assessment of control line
 Test Line: assessment of test line
 T/C Ratio: ratio between test and control line
 Orientation: position of test cassette
 Valid: The test result is acceptable.

Invalid: The test result is not acceptable and the test should be repeated.

Correct: The test cassette was inserted correctly and the test result is acceptable.

Incorrect: The test cassette was not correctly inserted. Turn the cassette through 180 °C, so that sample loading port directs to the right and scan it again.

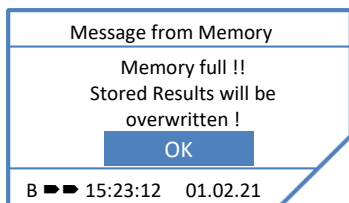
Print	Test No. 5/25	X
Control Line:	1401 mV	43
Test Line:	775 mV	51
T/C Ratio:	0.553	51
Orientation:	65 mV	47
B ■ 15:23:12 01.02.21		

Control Line: peak value (in millivolt, mV) and position (in mm) of control line.

Test Line: peak value (in mV) and position (in mm) of test line.

T/C Ratio: ratio between test and control line and position (in mm) of test line.

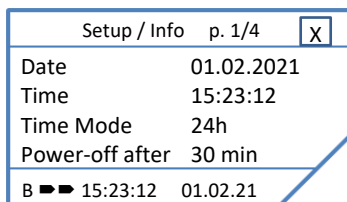
Orientation: If the peak value (in mV) reads " ~ " or below "200 mV", the test cassette was inserted correctly; if the peak value reads above "200 mV" the test cassette was inserted incorrectly, must be turned by 180° and scanned again.



If the limit of 80 stored data sets is reached, the message as shown on the left is displayed. If you want to keep the stored results, the data sets can be saved/stored using the QB Soft software (refer to the Quantum Blue® Reader QB Soft user manual for details). If the data sets are not saved and stored via QB Soft software, the oldest data set(s) are overwritten by the newest in chronological order. As shown on the left, the message is displayed until at least a part of the data sets is deleted using the QB Soft software and the memory capacity is restored.

5.6 Setup / Info Mode

Some system parameters such as date, time, data transfer mode, etc can be set and changed in the setup menu (2 screens, p. 1/4 and p. 2/4). Information about the Quantum Blue® Reader device and firmware version can be found on screen p. 3/4. Contact data of the manufacturer can be found on screen p. 4/4. Navigate with buttons (2) and (4) between the 4 screens. Select a system parameter with buttons (1) and (3), press ENTER button (5), select choice with buttons (1) and (3), and press ENTER button (5) to confirm selection.



Date:	set date DD.MM.YYYY
Time:	set time HH:MM:SS
Time Mode:	set 24h or 12am/pm (24h is recommended for optimal functionality)
Power-off after	(in battery mode only): automatic turn

off, if no user interaction or process is running. Set between 1 and 60 min.

Setup / Info p. 2/4		X
Background Light	On	
Data Transfer by	Rfid_intern	
Keyboard Signal	On	
B 15:23:12 01.02.21		

Background Light: set on/off

Data Transfer by*): choose

“Rfid_intern”,

“Rfid_extern”,

“Barcode”,

“Keyboard”,

“None”

Keyboard Signal: set on/off

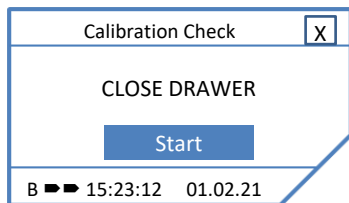
*) This Quantum Blue® Reader contains an internal RFID reader (therefore, default setting is “Rfid_intern”). An external RFID reader (“Rfid_extern”) can also be used, whereby the data transfer with a barcode reader (“Barcode”) or via key pad (“Keyboard”) is not supported by the current firmware version 2.2.18.

Setup / Info p. 3/4		X
Device	Quantum Blue®	
Device ID	ESLF35-MB-4501	
FW Vers.	V 2.2.18 2012.11.15	
Serial No.	1011	
B 15:23:12 01.02.21		

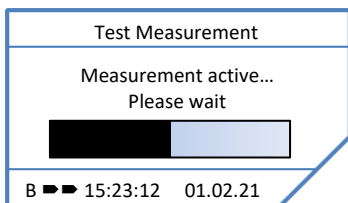
Setup / Info p. 4/4		X
BÜHLMANN Laboratories AG		
Schönenbuch/Switzerland		
www.buhlmannlabs.ch/		
contact/localdistributors		
B 15:23:12 01.02.21		

5.7 Calibration Check Mode

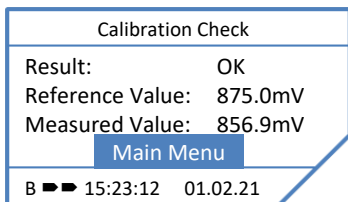
Each time the Quantum Blue® Reader is turned on, an automatic calibration check is made during initialization of the reader. A manual calibration check can be performed at each time during the reader operation in the calibration check mode.



Close the test cassette holder (drawer) and start calibration check by pressing the ENTER button (5).



The calibration spot (see no. 7a, chapter 3.1) is scanned.



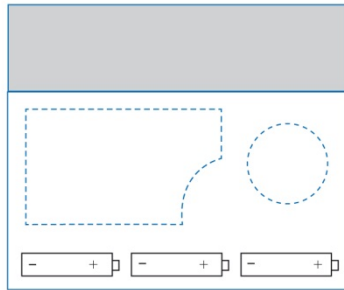
A certain deviation of the measured value to the reference value is accepted ("OK") by the firmware of the Quantum Blue® Reader.

If the difference of the measured value to the reference value is greater than this defined value, the result displayed is "NotOK". In such a case a scan of a test cassette is still possible, but a test measurement is not accepted and an "INVALID" result will be displayed on the result screen in the scan test mode (see chapter 5.4.3). Please refer to the troubleshooting guide (see chapter 7) for further information, if a calibration check reads "NotOK" or "No calibration".

6 Maintenance

This section is intended for qualified users who have had maintenance training. The instructions should provide the user with the necessary information for proper maintenance and care of the Quantum Blue® Reader.

6.1 Replacing the Batteries



To replace batteries: Open the cap of the battery compartment (no. 8 in chapter 3.1) with a flat tool (e.g. screw driver or coin), insert the batteries and make sure that the batteries are placed in the correct orientation (see drawing).

Note: Please remove batteries carefully. Do not shake the reader or hit it with force to replace batteries.

Manufacturer	Specified Battery Type	Capacity
Varta	Rechargeable Power Accu / 2700 mAh	2700 mAh
Sanyo	Twicell HR-3U-4BP	2700 mAh
Ansmann	Professional HR6 AA No. 5035212	2850 mAh
Panasonic	RECHARGE ACCU P6P/4B HR6 AA	2600 mAh
Duracell	Supreme HR6 Mignon AA No.75020290	2600 mAh
Energizer	Energizer NH15-AA 2500 mAh HR6 AA	2500 mAh

Note:

- Use specified AA rechargeable batteries only
- Use nickel-metal-hydride (Ni-MH) batteries only
- Never use alkaline batteries!

6.2 Charging the Batteries

The controlling of the charge process is carried out by the integrated microcontroller of the Quantum Blue® Reader. The Quantum Blue® Reader has to be switched on, if the batteries are to be recharged. If the Quantum Blue® Reader is switched off, the reader does not switch on the internal battery charger and is not ready for charging batteries.

6.3 Device Calibration

The Quantum Blue® Reader is a highly sensitive optical device for quantitative measurements. If the reader displays “NotOK” even after several calibration measurements and cleaning of the calibration spot (see no. 7a in chapter 3.1), the Quantum Blue® Reader requires a recalibration. In this case please contact your local BÜHLMANN Laboratories AG representative or the BÜHLMANN Laboratories AG Customer Support.

Please be note that the measured raw signal may change due to the following reasons:

- Extreme changes in ambient light levels
- Contamination of the optical parts
- Electronic interferences
- Extreme temperature changes
- Mechanical movements during measurement.

6.4 Cleaning

If you use the Quantum Blue® Reader in a working area that is subject to high levels of dirt, you should clean the reader regularly. Use a damp cloth to clean the device. If the dirt is persistent, you can also rub the surface of the device with a cloth that has been moistened with a mild detergent or a 70% alcohol solution (isopropanol or ethanol). Do not use aggressive cleaning agents such as acetone and the like. If the inside of the device is contaminated, please contact your local BÜHLMANN Laboratories AG representative or the BÜHLMANN Laboratories AG Customer Support.

6.5 Service Contact Information

For additional information and support please contact your local BÜHLMANN Laboratories AG representative or the manufacturer:

BÜHLMANN Laboratories AG

Baselstrasse 55, 4124 Schönenbuch, Switzerland

+41-61 487 12 12

support@buhlmannlabs.ch

www.buhlmannlabs.ch

7 Troubleshooting

This chapter describes some examples of possible failure causes.

If any malfunctions should occur during operation, please check the possible causes using the following table. For any further questions please contact your local BÜHLMANN Laboratories AG representative or the BÜHLMANN Laboratories AG Customer Support.

Problem A	The display remains blank after turning on the Quantum Blue® Reader.		
Cause A1	POWER ON button was not pressed long enough.	Solution A1	Press the ENTER button (5) on the key pad for more than 2 seconds.
Cause A2	Batteries are empty.	Solution A2	Charge batteries by connecting the external power supply and switch on the device or exchange batteries.
Cause A3	The "Software Upgrade" mode is activated.	Solution A3	Press the FORWARD button (2), the Quantum Blue® Reader switches into "Turn Off" mode. Now the reader can be turned on again.
Cause A4	The internal temperature sensor is malfunctioning.	Solution A4	Please contact your local BÜHLMANN Laboratories AG representative.
Problem B	The Quantum Blue® Reader is entirely blocked and none of the above solutions helped.		
Cause B	In most cases an internal software or firmware communication problem of unknown origin.	Solution B	Disconnect the Quantum Blue® Reader from electrical power, open the battery compartment (no. 7, chapter 3.1) and close it again. Turn the Quantum Blue® Reader on by pressing the ENTER button (5) for 2 seconds.

Problem C	Date and time are incorrect after turning on the Quantum Blue® Reader.		
Cause C1	Date/Time did not get saved.	Solution C1	Re-enter date and time in the "Setup/Info" mode (see chapter 5.6).
Cause C2	The internal backup battery is empty.	Solution C2	Please contact your local BÜHLMANN Laboratories AG representative.
Problem D	The power supply is plugged in, but the rechargeable batteries cannot be recharged.		
Cause D	The controlling of the charge process is carried out by the integrated microcontroller of the reader. If the Quantum Blue® Reader is turned off, the reader is not ready for use and does not switch on the internal battery charger.	Solution D	Turn on the Quantum Blue® Reader and check the external power supply unit.
Problem E	Calibration is out of tolerance ("NotOK" or "No calibration").		
Cause E1	An error during the initialization or during the operation of the Quantum Blue® Reader may have occurred.	Solution E1	Switch off and re-start the Quantum Blue® Reader. If the problem persists, refer to the next causes/solutions.
Cause E2	Calibration Spot (no. 7a, chapter 3.1) is contaminated by dust or dirt.	Solution E2	Carefully clean the Calibration Spot (no. 7a, chapter 3.1) with a soft tissue. Avoid any scratching of the surface. Please do not use alcohol or any detergent to clean. Repeat the calibration check.
Cause E3	Optical device is contaminated or defective.	Solution E3	Please contact your local BÜHLMANN Laboratories AG representative.
Problem F	RFID Chip Card is not recognized or read.		

Cause F1	The internal RFID reader is not activated.	Solution F1	Activate the internal RFID reader in the "Setup/Info" mode by selecting "Rfid_intern" (see chapter 5.6).
Cause F2	RFID Chip Card is not correctly placed on the Quantum Blue® Reader.	Solution F2	Hold RFID Chip Card in the correct position on the Quantum Blue® Reader (see chapter 3.1, "A") and/or move it gently and slowly around position "A".
Cause F3	RFID Chip Card is defective.	Solution F3	Please order a new RFID Chip Card for the same product and lot from your local BÜHLMANN Laboratories AG representative
Problem G	RFID Chip Card is not read correctly and/or the Quantum Blue® Reader displays an error message (e.g. "Error RFID -2105" or "Error RFID -10706").		
Cause G1	The RFID Chip Card was not placed long enough at position "A" on the Quantum Blue® Reader.	Solution G1	The RFID Chip Card must be placed at least 3 seconds in position "A" on the Quantum Blue® Reader (see chapter 3.1, "A") until a short "confirmation beep" sounded. If the error message persists, please note its error code and contact your local BÜHLMANN Laboratories AG representative. <i>Note: position "A" is located at the rear in the right-hand corner of the Quantum Blue® Reader.</i>
Cause G2	The RFID Chip Card used does not contain the correct information for the respective test "Test Method" to be measured.	Solution G2	Select the correct "Test Method" in the "Test Selection" menu for the respective test to be measured.

Cause G3	The RFID Chip Card used does not contain the correct information for the respective test "Test Method" to be measured.	Solution G3	Use the correct RFID Chip Card for a respective test "Test Method" to be measured.
Cause G4	The Quantum Blue® Reader displays an error message different from „Error RFID -2105“.	Solution G4	Switch the Quantum Blue® Reader off, hold the RFID chip card at least 3 seconds at position "A" on the Quantum Blue® Reader (see chapter 3.1, "A") until a short "confirmation beep" sounded. If the error message persists, please note its error code and contact your local BÜHLMANN Laboratories AG representative.
Cause G5	RFID chip card is defective.	Solution G5	Please contact your local BÜHLMANN Laboratories AG representative.
Cause G6	In the rare cases, in which an external RFID Reader is used, it may not be plugged into one of the I/O ports (no. 9/10, chapter 3.1).	Solution G6	Plug RFID reader correctly into one of the I/O ports (no. 9/10, chapter 3.1).
Cause G7	The Quantum Blue® Reader displays an unknown error message.	Solution G7	Switch the Quantum Blue® Reader off and on again and place the RFID Chip Card correctly and for at least 3 seconds in position "A" on the reader (see chapter 3.1, "A") until a short "confirmation beep" sounded. If the error message persists, please note its error code and contact your local BÜHLMANN Laboratories AG representative.

Problem H	The Quantum Blue® Reader is blocked or displays an error message on any page.		
Cause H1	Battery power is low or batteries are empty.	Solution H1	Switch off the Quantum Blue® Reader, plug in the external power supply and turn on the reader again. Charge batteries by connecting the external power supply or exchange batteries.
Cause H2	Unknown errors.	Solution H2	Switch off the Quantum Blue® Reader and turn it on again. If the error message persists, please note the error message code (eg. "Error -10001") and contact your local BÜHLMANN Laboratories AG representative.
Problem I	The Quantum Blue® Reader displays an "INVALID" test result.		
Cause I1	The Control Line on the measured test cassette is too weak or absent.	Solution I1	Re-test the test sample again using a fresh test cassette.
Cause I2	The test cassette is not correctly placed in the test cassette holder (no. 7, chapter 3.1).	Solution I2	Turn the test cassette 180°, place it back into the test cassette holder (no. 7, chapter 3.1) so that the loading port of the test cassette is to the right, and scan the test cassette again.
Cause I3	The calibration of the Quantum Blue® Reader is out of range ("NotOK").	Solution I3	See above "Calibration is out of tolerance".
Problem J	The Quantum Blue® Reader displays "Memory full!! Stored Results will be overwritten!"		
Cause J	The memory capacity of the reader is reached.	Solution J	Please refer to chapter 5.5

8 Technical Data

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

8.1 Environmental Conditions

8.1.1 Operating Conditions

External Power Supply	Input: 100 – 240V _{AC} , 0.5A, 50 – 60Hz Output: 12V _{DC} , 1.25A
Quantum Blue® Reader	Nominal input: 12V _{DC} , 1.25A
Batteries	3x 1.2V _{DC} AA Ni-MH rechargeable batteries (see chapter 6.1 for details)
RFID reader frequency	13.56 MHz
RFID reader maximum field strength	≤ 42 dBμA/m (≤ 94 dBμV/m) @ 10 m EN 300 330-1 compliant
Equipment Class	III
Air Temperature	+15°C to +40°C (ambient temperature)
Relative Humidity	≤ 70% (non-condensing)
Altitude	Up to 2000 m (6500ft.)
Air Pressure	700 – 1060 hPa
Place of Operation	For indoor use only
Pollution Degree	2
Ingress Protection	IP21

8.1.2 Transportation Conditions

Air Temperature	–20°C to +50°C
Relative Humidity	≤ 70%
Air Pressure	300 – 1060 hPa

8.1.3 Storage Conditions


Air Temperature	<u>-20°C</u> to +50°C
Relative Humidity	≤ 70%
Air Pressure	300 – 1060 hPa

8.1.4 Dimensions and Weight

Dimensions	Height: 46 mm Width: 178 mm Depth: 165 mm
Weight	Approx. 620 g

8.2 Shipment Instructions

The transportation case containing the Quantum Blue® reader device has to be placed in a shipping container/ delivery box for shipment.

CAUTION 	Do not ship the Quantum Blue® Reader without safe packaging.
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Note: the transportation case itself does not provide sufficiently robust packaging for forward shipment!

Do ship the Quantum Blue® Reader(s) safely packed in a shipment container/ delivery box.

The packing shall comply with all relevant standards and laws, both in the country of origin and in the country of destination, and shall protect the device against external influences, such as dust, dirt, rain, high air humidity, condensed water and consequent corrosion damages.

9 Warranty and Customer Services

For product and service inquiries, please contact:

BÜHLMANN Laboratories AG

Baselstrasse 55

4124 Schönenbuch, Switzerland

Phone: +41 61 487 12 12

Fax: +41 61 487 12 34

Email: support@buhlmannlabs.ch

www.buhlmannlabs.ch

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

9.1 Warranty

A 12-month manufacturer warranty shall apply for hardware and software products. In the case of used equipment, liability for defects and warranty shall be excluded.

The place of fulfilment of this warranty shall be the company site stated above. Products are supplied FOB to and from company site.

If customer or business partner notifies BÜHLMANN Laboratories AG that the products are defective, BÜHLMANN Laboratories AG may require return of the defective products to BÜHLMANN Laboratories AG for repair (rework or replacement) at the expense and option of BÜHLMANN Laboratories AG.

9.2 Obligations of the User

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 parts are replaced or if consumable items are used which do not comply with the original specifications, any warranty rights are forfeited unless the customer or business partner 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 customer or business partner of BÜHLMANN Laboratories AG in writing or by fax (in case of defects which can be identified immediately), 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 customer or business partner properly fulfils his obligations of investigation and notification.

Appendix

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 2002/96/EC 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 representative 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.

Declaration of Conformity




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KONFORMITÄTSERKLÄRUNG DECLARATION OF CONFORMITY

Wir erklären in alleiniger Verantwortung, dass das nachfolgend genannte Produkt auf welches sich diese Erklärung bezieht, die notwendigen Gesundheits- und Sicherheitsanforderungen erfüllt und in Einklang mit den relevanten Abschnitten der zutreffenden EG-Richtlinien und anderen normativen Weisungen steht. Wenn Änderungen an dem Produkt vorgenommen werden, auf welches sich die vorliegende Konformitätserklärung bezieht, verliert diese Erklärung ihre Gültigkeit.

We declare under sole responsibility that the following device to which this declaration relates, meets the essential health and safety requirements and is in conformity with the relevant sections of applicable EC standards and other normative documents. If changes are made to the product which is covered by this declaration of conformity, the declaration of conformity is no longer valid.

Produkte-Typ <i>Device type</i>	Medizinprodukt zur In-vitro Diagnostik <i>In Vitro Diagnostic Medical Device</i>
Produktgruppe/name <i>Product group/name</i>	Quantum Blue® Reader
Katalognummer <i>Catalog number</i>	BI-POCTR-ABS
EG-Richtlinien <i>EC Directives</i>	98/79/EC
Klassifizierung nach der Richtlinie über In-vitro-Diagnostika 98/79/EG <i>classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC</i>	„sonstige Produkte“ <i>„Other devices“</i>
Konformitätsbewertungsverfahren <i>Conformity Assessment procedure</i>	Gemäss Anhang III <i>According to annex III</i>
Datum <i>Date</i>	25.01.2021
Unterschrift des Herstellers <i>Signature of Manufacturer</i>	

Dipl. Ing. FH F. Perretta
Head Quality Management

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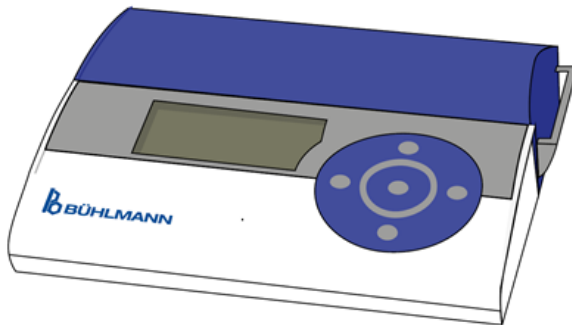
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BÜHLMANN products are subject to the quality standards within the quality management system according to ISO 13485.

