



Quantum Blue® Reader

Manual

V06/May 2010

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Quantum Blue® Reader Manual
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BÜHLMANN Laboratories AG
Baselstrasse 55
CH-4124 Schönenbuch

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

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1. Introduction

1.1. General

Lateral Flow assays represent a well established, proven technology for a variety of 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 fulfil the requirements for new diagnostic tests. The Quantum Blue® Reader is ideal for field-based tests and many more applications.

1.2. Intended Use of the Device

The Quantum Blue® Reader is a Lateral Flow Reader to analyze colorimetric tests by reflectometry at the point of care (). The fast and precise scanning allows the detection of quantitative or qualitative results depending on the rapid test and/or the configuration of the device. The data are stored automatically and can be printed if required. All stored data include measuring time, date, user ID, patient ID, raw data, etc.

The mobile reader is powered by rechargeable batteries or with the external power supply. The Quantum Blue® Reader provides precise measurements for mobile use in the field or fixed use in the laboratory.

Note: For your own safety do not operate the device without a Test Cartridge inserted. Do not open the drawer (tray) while measurement is in progress. Only authorised persons are allowed to service or disassemble the reader.

1.3. Main Features of the Reader

- **Quantitative:** Excellent repeatability, long term stability and the powerful controller enable reliable quantification of lateral flow tests.
- **Highly sensitive:** The award winning confocal sensor used provides unmatched sensitivity.
- **Easy to use:** via a single button operation: Insert Test Cartridge and press ENTER button and everything else will be done by the reader (scanning, evaluating, displaying and storing results and date/time).
- **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 the last 100 test results. It can be operated with rechargeable batteries (3 x AA).
- **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 bar code reader or a portable printer can be connected to the Quantum Blue® Reader.

1.4. Safety Precautions

Battery power

The Quantum Blue® Reader can be powered by batteries without external power supply. The batteries must be periodically recharged. Connect the external power supply for at least 4 hours (complete charging time: 14 hours). Note: The batteries are recharged only when the reader is switched on.

Ambient temperature

The use of the Quantum Blue® Reader in environments prone to large changes in temperature can cause measurement values to deviate from real values.

Ambient light

The Quantum Blue® Reader is a highly sensitive and precise optical device. The device has internal correction for normal levels of ambient light, BUT highly intense light falling into the test strip port can cause serious interference with the measurement and must be avoided.

Vibration

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

Dirty 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. By more persistent stains, it is also possible to clean the surface with a cloth dipped in pure alcohol (isopropanol or ethanol). Avoid the use of aggressive solvents such as acetone.



Do not expose the Quantum Blue® Reader to direct sunlight.



Protect the reader from high humidity and extensive contact to liquids.



Do not expose the reader to extensive heat.



Do not expose the reader to strong electromagnetic radiation.

The **Quantum Blue®** Reader can be used under the following conditions:

Temperature range: +15°C to +40°C

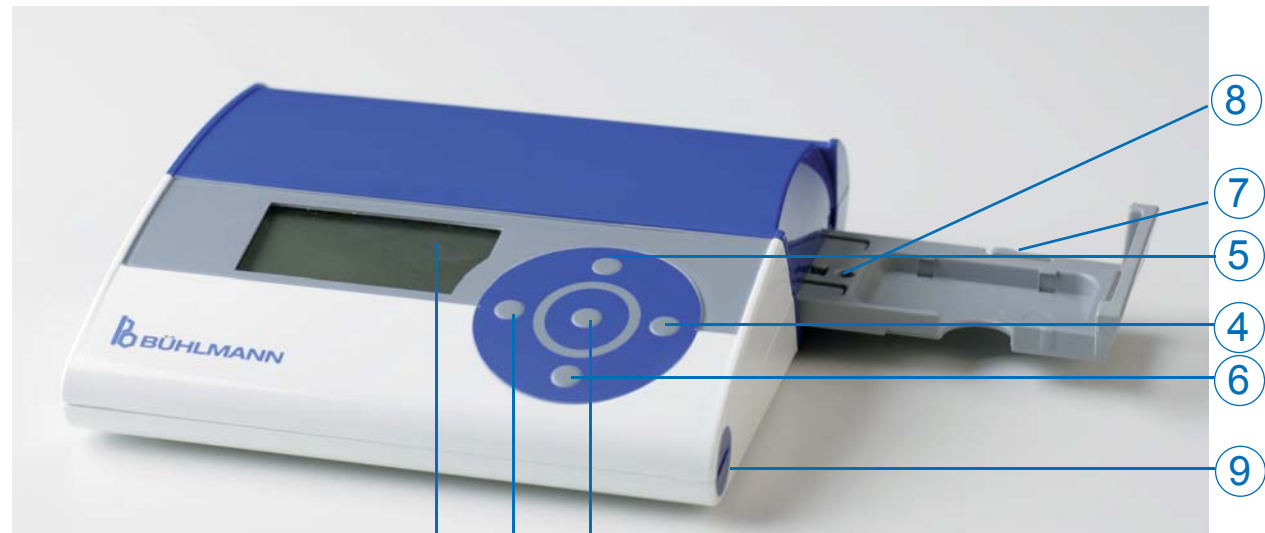
Relative humidity: ≤ 70 %

Air pressure: 300-1060 hPa

2. Getting to know the Reader

2.1. Overview

- 1) Display
- 2) ENTER and ON/OFF button
- 3) BACK button ◀
- 4) FORWARD button ▶
- 5) UP button ▲
- 6) DOWN button ▼
- 7) Test cartridge insertion port (Tray)
- 8) Calibration spot
- 9) Battery compartment
- 10) I/O ports for printer / RFID reader
- 11) USB port
- 12) Power jack



2.2. Contents of the Package

- Case
- Blue® Reader
- Batteries
- USB cable
- Power supply
- Set of power plugs
- CD-ROM with manuals, software and USB drivers
- RFID reader



Tag position of RFID reader (place RFID chip card here)

RFID chip card

Connecting Plug to the I/O port(s) of the Quantum Blue® Reader

2.3. Installation

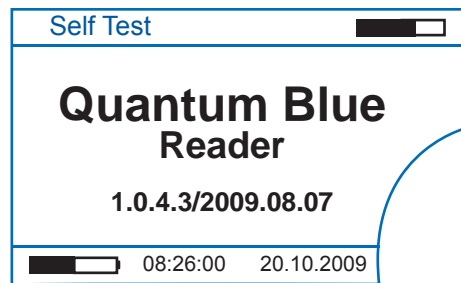
2.3.1. Power supply options

- a) Battery powered: Insert three rechargeable AA batteries in battery holder (see maintenance chapter 5.1)
- b) External power: connect external power supply to power jack.

2.3.2. Connecting RFID reader

Plug the connecting cable of the RFID reader into I/O port of the Quantum Blue® Reader, refer to page 6 of this manual. The RFID reader is now ready for use.

3. Operation

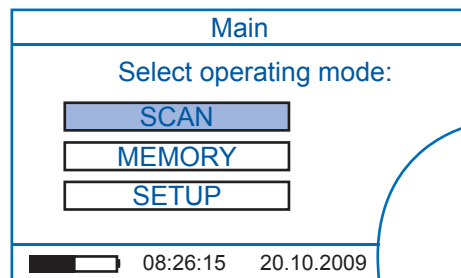


To switch ON press ENTER button for one second.

After switching on the reader, self test and calibration check will be performed automatically. After appearance of the main menu, the self test and calibration check was successful and the reader is ready to use.

To switch OFF press ENTER button for three seconds.

The reader can be switched off regardless of the position within the menu.



Choose operating mode with ▲▼ (up, down buttons)

Select operating mode with ENTER (central ENTER button)

Scan Mode: see chapter 3.2.

Memory Mode: see chapter 3.3.

Setup Mode: see chapter 3.4.

3.2. Scan Mode

3.2.1. Enter Test Parameters

Scan Mode	
Enter test parameters	
TEST TYPE	CAL.720
USER ID	User 01
SAMPLE ID	1 2 3 4
NEXT	BACK

Select parameters with ▲▼
Change parameters with ENTER

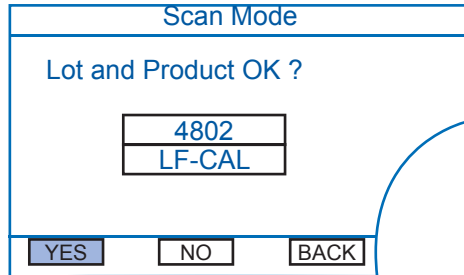
TEST TYPE:
Enter test type - Select with ▲▼
Press ENTER to confirm

USER ID:
Enter User ID - Select with ▲▼

20 strings can be defined and downloaded by the PC-Software LF Manage.
Default: USER 01 - USER 20
Press ENTER to confirm

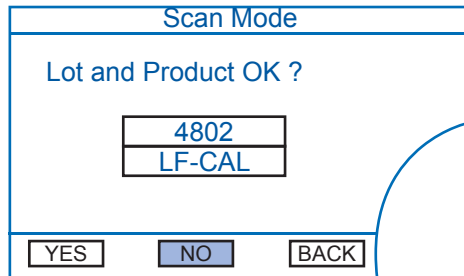
SAMPLE ID:
Enter Sample ID
Select digit with ◀▶
Change digit with ▲▼
Press ENTER to confirm

3.2.2. Check Lot and Product



Compare lot ID and product ID on the display with the details on the label of the test cartridge to be used.
If the information is identical, select YES and press ENTER. The Quantum Blue® Reader will proceed to the next step (chapter 3.2.3.).

3.2.2.1. How to enter Lot-specific coefficients by the RFID Reader



Compare lot ID and product ID on the display with those on the label of the test cartridge to be used.
If the information is NOT identical, select NO and press ENTER.



Attention: To activate the RFID reader, the Quantum Blue® Reader must be switched to „RFID“ in the Setup Mode (chapter 3.4.2.).



Put RFID chip card (RFID label) directly on the tag position of the RFID Reader.

Reading RFID data...

The lot and product-specific data will automatically be transferred into the firmware of the Quantum Blue® Reader.

If the reading process is correct, the Quantum Blue® Reader turns automatically to the next screen display as shown in chapter 3.2.3.

3.2.2.2. Entry of lot-specific coefficients manually

Scan Mode	
Lot and Product OK ?	
4802	LF-CAL
YES	NO
BACK	

Compare Lot ID and Product ID on the display with the details on the label of the test cartridge to be used. If the information is NOT identical, select NO and press ENTER.

Attention: To activate manual data entry, the Quantum Blue® Reader must be switched to „Manually“ in the Setup Mode (chapter 3.4.2).

Enter coefficients	
Batch-ID	4802
Prm 1	1.40
Prm 2	-0.46
Prm 3	0.013
NEXT	BACK

Enter the coefficients printed on the lot- and product-specific QC data sheet. If all the coefficients are entered correctly, select YES and press ENTER. The new Checksum will be calculated.

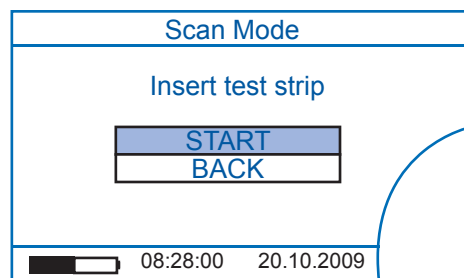
Compare the new Checksum with the QC data sheet.

Enter coefficients	
Prm 4	-1.25
Prm 5	0
Prm 6	0
NEXT	BACK

Enter coefficients	
Checksum OK ?	
657DC7B7	
YES	NO

Attention: Continue only if the Checksum is identical to the one on the QC data sheet.

3.2.3. Insert Test Cartridge



Prepare and insert test cartridge (test strip) into the tray (see instruction for use of the corresponding test kit / product).

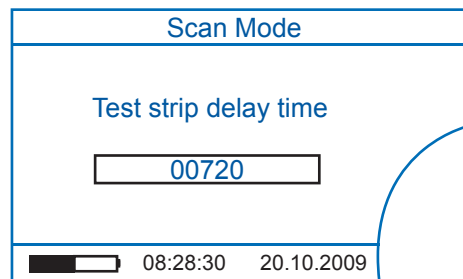
Press ENTER to start the timer function **immediately** after loading the sample (and optionally Chase Buffer) onto the loading port of the test cartridge.

Attention:

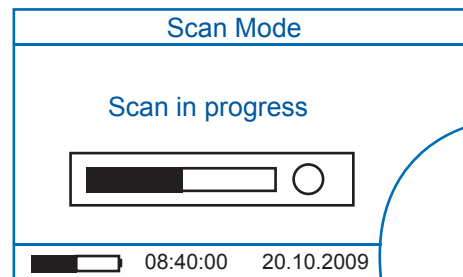
- Start the timer immediately after the sample has been loaded onto the test cartridge. The incubation time is then controlled by the instrument.
- To avoid mechanical wear do not press on the clamp on the backside (hatched arrow) while putting the test cartridge into the tray.
- To avoid contamination of the optical device of the Quantum Blue® Reader, close the tray only after sample solution has been soaked into the test cartridge.



3.2.4. Measuring the test cartridge

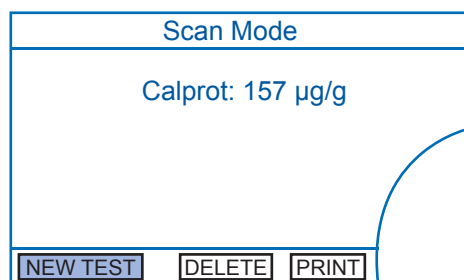


Remaining test time (in seconds) for test cartridge (test strip) incubation.



After termination of the incubation time the scanning of the test cartridge starts automatically.

3.2.5. Viewing the result



Note the test result and save it by selecting NEW TEST and pressing ENTER. The result will be saved automatically and can be viewed in the Memory Mode (see chapter 3.3)

New Test

Turns the Quantum Blue® Reader back to the main menu (chapter 3.1)

Delete

Delete data set.

Print

Print data set, if printer is connected and activated.

3.3. Memory Mode

Within the Memory Mode the stored data can be displayed.

◀ ▶ Select data set

▲ ▼ Display data set parameters

Memory Mode 1 / 100	
Run No.	708
Sample ID	0000
Test Type	Calprot
Result	157 µg/g
<input type="button" value="PRINT"/> <input type="button" value="DELETE"/> <input type="button" value="BACK"/>	

Run No. Total no. of runs ever made on the Quantum Blue® Reader
Sample ID Sample identification number
Test Type Test name
Result Displayed result (concentration)

Memory Mode 1 / 100	
Date	17.04.2009
Time	08:40:12
UserID	User 01
Product	LF-CAL
<input type="button" value="PRINT"/> <input type="button" value="DELETE"/> <input type="button" value="BACK"/>	

Date Date of measurement
Time Time of measurement
UserID Operator
Product Test code

Memory Mode		1 / 100
Lot	4802	
Concentr.	156.79	
T (mV)	824.89	
C (mV)	1310.36	
<input type="button" value="PRINT"/> <input type="button" value="DELETE"/> <input type="button" value="BACK"/>		

Lot Batch number (lot number) of the product
 Concentr. Calculated result
 T (mV) Value of test band in millivolt
 C (mV) Value of Control band in millivolt

Memory Mode		1 / 100
P1	1819.42	
<input type="button" value="PRINT"/> <input type="button" value="DELETE"/> <input type="button" value="BACK"/>		

P1 Background value of test cartridge

The data sets can be printed and deleted.

◀ ▶ Select Data set and press ENTER

▲ ▼ Change between data set and options

Select options and press ENTER

PRINT

Print data set, if printer is connected and activated.

DELETE

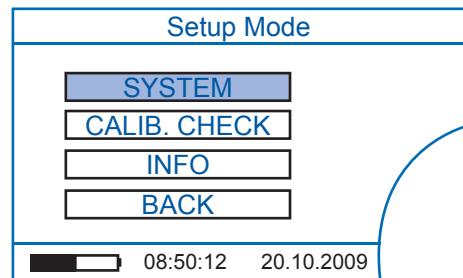
Delete data set.

BACK

Return to main menu.

3.4. Setup Mode

3.4.1. Setup Mode options



▲ ▼ Select Setup Mode options

SYSTEM
Setup device settings like
Date/time, language, power management, backlight, data transfer etc.

CALIBRATION CHECK
For additional calibration check of the Quantum Blue® Reader.

INFO
Shows the serial number of the Quantum Blue® Reader and its current firmware version.

3.4.2. Setup Mode - System Parameters

Setup Mode	
System parameters	
Date	17.04.2009
Time	08:54:46
Time format	24
▲▼ NEXT BACK	

Setup Mode	
System parameters	
Language	EN
Reader	RFID
▲▼ NEXT BACK	

Setup Mode	
System parameters	
Backlight	ON
Warning message	ON
PowerOff time	15 min
▲▼ NEXT BACK	

Select parameters with ▲▼◀▶
Change parameters with ENTER

DATE: Set date DD MM YYYY

TIME: Set time with HH:MM:SS

TIME FORMAT: Do not change time format. Leave it on 24 hours mode.

LANGUAGE: Set language of user interface (EN, DE, PT, ES, FR)

READER: Set the data transfer mode (Manually, RFID, Barcode*)

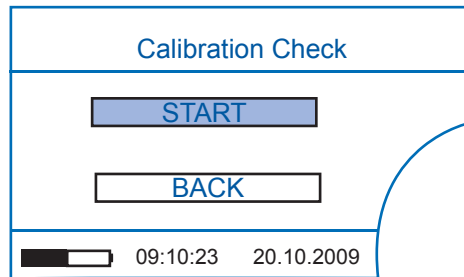
BACKLIGHT: Turn backlight ON/OFF

WARNING MESSAGE: Turn messages ON/OFF

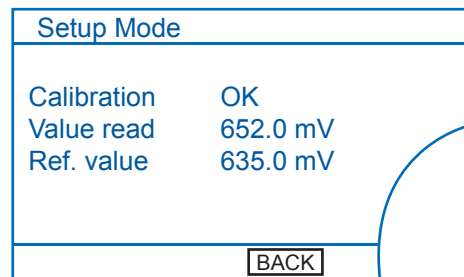
POWER OFF TIME: Automatic instrument turn off if no user interaction or no process is running.

* Barcode mode is not activated with the BÜHLMANN lateral flow assays.

3.4.3. Setup Mode - Calibration Check



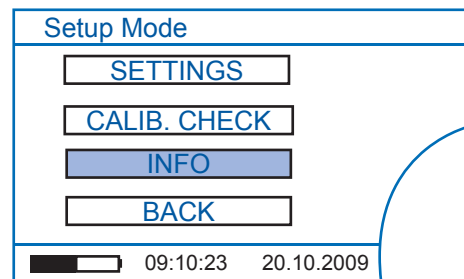
Select Start and press ENTER to perform calibration check.



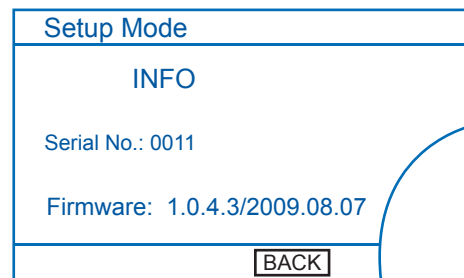
A difference within $\pm 10\%$ to the reference value is accepted by the firmware of the Quantum Blue® Reader.

If the calibration is out of tolerance, refer to trouble shooting guide (chapter 4).

3.4.4. Setup Mode - Info



Displays status of Quantum Blue® Reader.



4. Trouble Shooting

This section is intended for qualified users with installation and maintenance responsibilities. The instructions are intended to help users solve problems and fix errors in the proper operation of the Quantum Blue® Reader. Only problems specifically related to the use of the Quantum Blue® Reader and its specific solutions are described here:

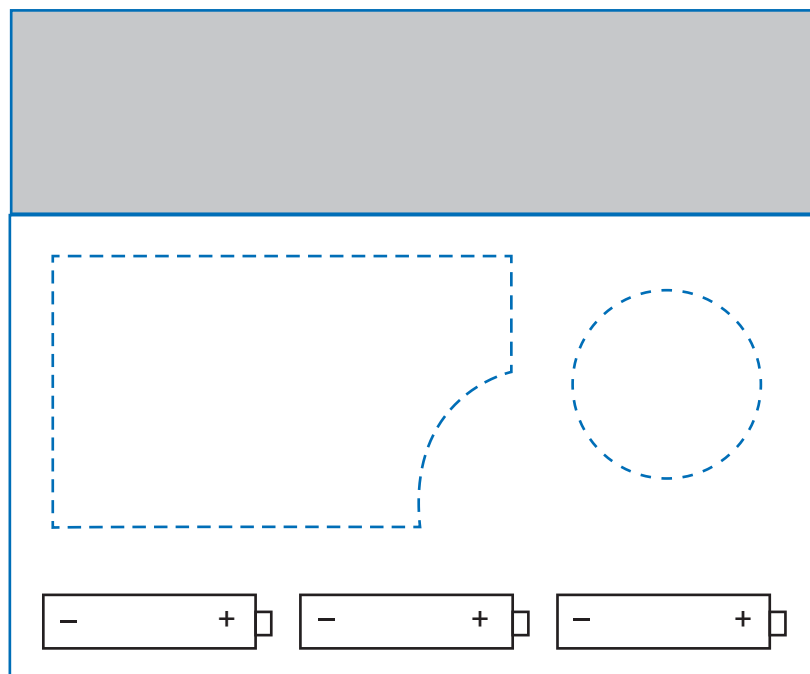
Problem	After switching on the Quantum Blue® Reader, the display remains blank
Cause	POWER ON Button was not pressed long enough.
Solution	Press the ENTER button on the keyboard for at least 2 seconds.
Cause	Batteries are empty.
Solution	Charge batteries by connecting the external power supply or exchange batteries. Batteries will be recharged only when the reader is switched ON.
Problem	Date and time are incorrect after switching on the reader
Cause	Date/time did not get saved.
Solution	Re-enter date and time in the SETUP mode.
Cause	The internal backup battery is empty.
Solution	Contact BÜHLMANN product support.
Problem	The power supply is plugged in, but the rechargeable batteries can not be recharged.
Cause	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	Turn on the Quantum Blue® Reader and check the external power supply unit.

Problem	Calibration is out of tolerance
Cause	Calibration spot is contaminated by dust or dirt.
Solution	Carefully clean the calibration spot (No. 8., page 6) with a soft tissue. Avoid any scratching of the surface. Repeat the calibration check.
Cause	Optical device is defective.
Solution	Contact BÜHLMANN product support.
Problem	RFID reader does not read correctly (different error messages)
Cause	RFID reader is not plugged into one of the I/O ports (No. 10, page 6).
Solution	Plug RFID reader into one of the I/O ports (No. 10, page.6).
Cause	RFID chip card is not correctly placed on the Tag of the RFID reader.
Solution	Move RFID chip card gently and slowly over the Tag of the RFID reader.
Cause	RFID reader displays the error message „ Product: Value read....“
Solution	Select the correct test type in the section“ Enter test parameters“ (see chapter 3.2.1)
Cause	RFID chip card is defective.
Solution	Enter the data set manually (see chapter 3.2.2.2.) and/or order a new RFID chip card for the same product and lot from BÜHLMANN AG or your local distributor.

5. Maintenance Notes

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

5.1. Replacing the Batteries



Manufacturer	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 2500mAh HR6 AA	2500 mAh

← To replace batteries, open cap of the battery compartment (No. 9 on page 6) with a flat instrument. Make sure that the batteries are placed in the correct direction (see drawing).

Take the following into consideration regarding the use of rechargeable batteries:

- Use AA rechargeable batteries.
- Use Nickel-Metal-Hydrate (NiMH) batteries only, which offer greater durability.

5.2. Charging the Batteries

The controlling of the charge process is carried out by the integrated microcontroller of the measuring device. If the Quantum Blue® Reader is turned off, the device is not ready for use and does not switch on the internal battery charger.

5.3. Calibration of the Quantum Blue® Reader

The Quantum Blue® Reader is a highly sensitive optical device for quantitative measurements. The reader requires calibrating against a physical standard in the calibration spot (see No. 8., page 6) which is done automatically. A difference within $\pm 10\%$ to the reference value is accepted by the firmware of the reader. During long-time use or after some thousand measurements the measured signal intensity may change due to the following reasons:

- Changes in ambient light levels
- Contamination of the optical parts
- Electronic interferences and temperature changes
- Mechanical movements

5.4. Updating Quantum Blue® Reader firmware

The program to replace the firmware of the Quantum Blue® Reader will be sent with the update image itself and a user manual „How to update...“ by BÜHLMANN AG or your local distributor.

5.5 Disposal of the Quantum Blue® Reader

The Quantum Blue® Reader is an electronic device and must be disposed according to the local regulations.

6. Technical Specifications

Voltage	Batteries: 3 x AA rechargeable batteries Power plug: +12V to +24V / 1,25A
Power adapter	
Voltage range	100-240 V AC
Frequency range	50-60 Hz
Current rating	0,5 A
Storage conditions	
Temperature	-20°C to +70°C
Rel. humidity (non-condensing)	≤ 70 %
Air pressure	300 - 1060 hPa
Operating conditions	
Temperature	+15°C to +40°C
Rel. humidity (non-condensing)	≤ 70 %
Air pressure	300 - 1060 hPa
Protection category	IP21
Physical data	
Housing material	ABS
Dimensions HxWxD	46mm x 178mm x 165mm
Weight	620 g
Interface	USB
Input	+5V to +24V level
Output	5V level

7. Warranty and Customer Services

For product and service inquiries, please contact:

BÜHLMANN Laboratories AG
Baselstrasse 55
CH-4124 Schönenbuch/Basel
Phone : +41 61 487 12 12
Fax : +41 61 487 12 34
Email : info@buhlmannlabs.ch
www.buhlmannlabs.ch

Customer and product service are available at standard office times (Monday to Friday, 8 a.m. to 12 a.m. and from 2 p.m. to 5 p.m.).

7.1. Warranty

A 24-month manufacturer warranty shall apply for hardware and software products. In the case of used equipment, liability for defects and warranty shall be excluded.

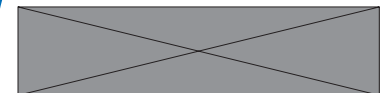
The place of fulfilment of this warranty shall be the company site stated above. Products are supplied FOB to and from company site.

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

7.2 Obligations of the User

If instructions given by BÜHLMANN 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 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.



BÜHLMANN Laboratories AG

Baselstrasse 55
CH-4124 Schönenbuch/Basel
Switzerland

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



Quantum Blue® Reader

BÜHLMANN products are subject to the quality standards within the quality management system according to ISO 9001 and ISO 13485.

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