

QOCA bioreader (Non-sterile)

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User manual

Model: QOCA bioreader

For in vitro diagnosis only

Before use, please read this user manual carefully and follow all instructions given.

MHC418-3A

【Intended Use】

This device is an in vitro diagnostic device performing quantitative analysis on enzymes in human blood by using a proper enzymatic chip detection kits, and suitable for the use in hospitals and medical laboratories by doctors or medical laboratory scientists.

【Description】

This device, utilizing EIS (electrochemical impedance spectroscopy), measures the data through a proper enzymatic chip detection kit and displays the results on the screen.

QOCA bioreader is easy to use. Simply drip the specimen on the reactive area of chip and then connect to QOCA bioreader. The device will display the quantitative results in 3-5 minutes.

This device, with built-in various enzyme concentration algorithms and corresponding detection chip kits, allows the user to measure the concentration of different enzymes.

QOCA bioreader is for in-room use only and not suitable for self-test.

Environmental pollution level: 2

【Cautions】

- Taking out the detection chip during test may damage QOCA bioreader.
- To prevent specimen, device and environmental contamination, please clean QOCA bioreader regularly. Please clean immediately when specimen splashes or after moving the specimen to QOCA bioreader. For details, please refer to the “Clean” section in this manual.
- Put QOCA bioreader on a stable surface to prevent dropping. Avoid other objects from falling on QOCA bioreader.
- QOCA bioreader may not be able to turn on successfully due to misuse (like dropping), out of battery or other factors. In a clinical environment requiring fail-safe, it is necessary to prepare backup batteries to minimize such risk.
- QOCA bioreader should only be used in an environment within the operating temperature or humidity range. When operating in an extreme environment, please balance QOCA bioreader under the operating conditions for a certain period of time before use.
- QOCA bioreader is not suitable for use in a hyperbaric oxygen environment.
- QOCA bioreader may be contaminated by blood from previous tests. Please take general protective measures when using QOCA bioreader to prevent attacks of bloodborne pathogens. General protective measures refer to the standard processes and actions, including wearing gloves and medical masks, to protect the user against attacks of bloodborne and human pathogens. The aforementioned measures are based on the following consumptions: blood, bodily fluid or tissue may contain infectious substances and should be handled as a biological hazard.
- Please use the correct chip kit and corresponding algorithm to ensure a correct result. Please read the user manual of chip kit carefully before testing.
- Do not modify the device or change software/hardware settings without a written permission of Manufacturer.

【Description of system】

QOCA bioreader system provides a kit necessary for enzymatic analysis. By using a QOCA bioreader, an enzymatic chip detection kit proper for the test item, a single-use specimen transfer dongle and USB-C/USB-C specimen transfer cable, medical staff can check the quantitative data displayed on the screen within 5 minutes.

■ Parts identification

QOCA bioreader		USB-C /USB-C cable	
Single-use specimen transfer dongle		USB-A / USB-C power cable	

■ Accessories

1. Single-use specimen transfer dongle
- 2.USB-C/USB-C cable
- 3.USB-A/USB-C power cable

■ Other accessories:

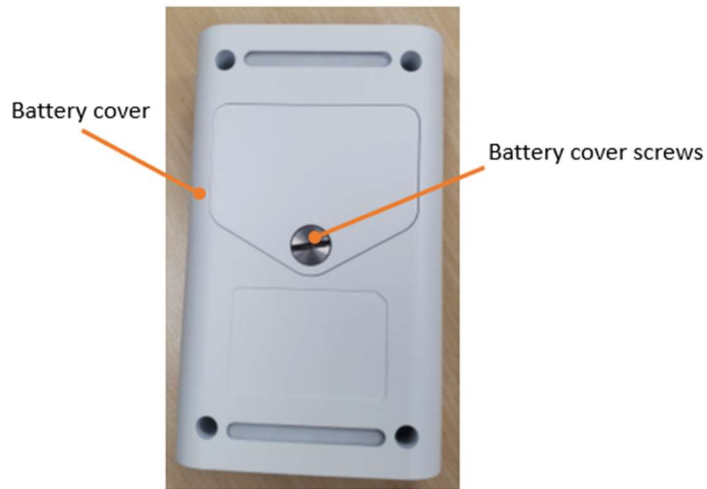
1. Certified proper enzymatic chip detection kit

■ Options:

1. 9V Alkaline battery
2. Single-use transfer dongle (20 pcs/pack)
3. AC/DC Adapter : SHENZHEN FUJIA APPLIANCE CO., LTD,
model: FJ-SW328U0502000N





*Options are sold separately by Manufacturer



■ Description of device





【Using the device】






■ First use and update specimen lot information.

<p>Step 1</p> <p>When you turn on the QOCA bioreader for the first time, you will see a prompt screen to update the lot number information of the specimen.</p> <p>* This screen only appears when using the QOCA bioreader for the first time.</p>	 <p>The image shows a smartphone screen with a dark background. At the top, the date and time are 2023/05/09 14:21. In the top right corner, there is a small 'iD' icon. The main text in the center reads 'Please Update Chip Lot Information For First Test.' in orange and white.</p>
<p>Step 2</p> <p>Use USB-A/USB-C power cable connect the QOCA bioreader and the computer. Open the AP of MHC Tool for lot number update.</p>	 <p>The image is a screenshot of a web browser window titled 'MHC tool ver.1.0 test build'. It features a 'QR Code' section with a QR code icon, a text input field, and a blue button labeled '清空欄位'. Below the input field, it says 'Please scan the qrcode and press Enter.' The browser window has standard navigation buttons (back, forward, refresh, home) and window controls (minimize, maximize, close).</p>
<p>Step 3</p> <p>Scan the lot number on the package with 2D barcode scanner.</p>	 <p>The image shows a close-up of a white QR code on a light-colored surface. A blue circle highlights the QR code, and a blue arrow points to it from the text 'Lot Number' written below. Below the QR code, the lot number 'AT23430001' is printed.</p>
<p>Step 4</p> <p>The QOCA bioreader will be ready for measurement after completing self-inspection.</p>	 <p>The image shows the QOCA bioreader's screen. At the top, the 'QOCA' logo is visible. Below it, the text 'Count 010' is displayed. The word 'READY' is shown in large, bold, blue letters. Underneath 'READY', it says 'Press button to start'. At the bottom of the screen, the date and time '2022/01/06 07:27' and the word 'bioreader' are visible.</p>





<p>Step 5</p> <p>Press the left button to enter the information screen and check the packaging batch number.</p>	
<p>Step 6</p> <p>When using test chips with different lot numbers, please repeat STEP 2 ~ STEP 4 to update the chip lot number information to ensure that the measurement information is complete.</p>	

■ Operation Process


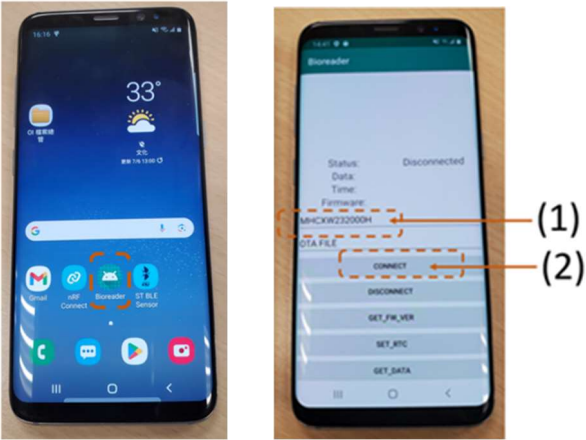

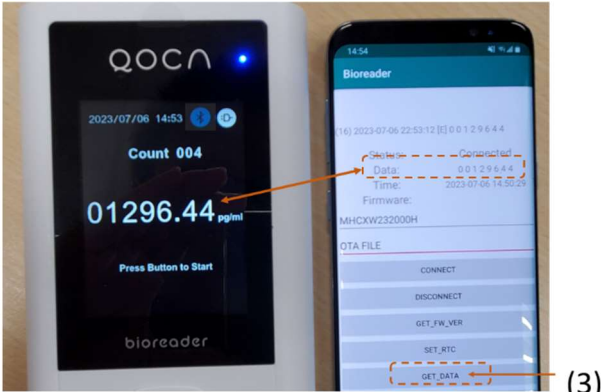
<p>Step 1</p> <p>Connect USB-A/USB-C power cable to the charger port on top of QOCA bioreader. QOCA bioreader will be ready for measurement after completing self-inspection.</p> <p>* When powered by a 9V Alkaline battery, please turn on QOCA bioreader by pressing the power button on top. QOCA bioreader will be ready for measurement after completing self-inspection.</p>	
<p>Step 2</p> <p>Connect USB-C/USB-C cable to QOCA bioreader and single-use specimen transfer dongle.</p> <p>*When using, please make sure that the words QOCA on the transfer dongle stand face up.</p>	

<p>Step 3</p> <p>Follow the user manual of test chip and drip the specimen on the specified area. After the reaction is completed, connect the test chip to a single-use transfer dongle.</p>	
<p>Step 4</p> <p>Press Middle-button to start "Measurement".</p>	
<p>Step 5</p> <p>The result will be displayed on the screen, including values and units.</p>	
<p>Step 6</p> <p>After the test, please remove the chip and transfer dongle, put them in a zipper bag and dispose as biological waste.</p>	
<p>Step 7</p> <p>After the test, the screen of QOCA bioreader will dim after idling for 1 minute and enter sleep mode. Press any button to wake the device. If QOCA bioreader will not be used for a long time, please disconnect USB-A/USB-C power cable.</p> <p>* When powered by a 9V Alkaline battery, please turn off QOCA bioreader by pressing the power button on top.</p>	

■ Reset process

<p>Step 1</p> <p>To delete data, press Right-button to enter RESET screen.</p>	
<p>Step 2</p> <p>Gently press the power-button and RESET will be displayed on the screen. Long-press the power-button for 3 seconds and release if you are sure to delete the data. If not, press Left- or Right-button to exit Delete process.</p>	
<p>Step 3</p> <p>Deleting data.</p>	
<p>Step 4</p> <p>After the data is cleared, it will return to the initial settings. At this time, you need to log in the chip lot number again to continue use.</p> <p>*please reference “First use and update specimen lot information”</p>	

■ BLE Connection

<p>Step 1</p> <p>When QOCA bioreader is turn on and ready .</p>	
<p>Step 2</p> <ol style="list-style-type: none"> 1)Turn on the BLE connection AP(Bioreader) of the mobile phone. 2)Enter the QOCA bioreader serial number at the position of (1) . 3)Press the CONNECT's button at the position (2). 	
<p>Step 3</p> <ol style="list-style-type: none"> 1)When the connection is successful ,the BLE symbol will appear on the QOCA bioreader. 2)The status of the BLE connection AP will display "Connected". 3)QOCA bioreader can start measuring now. 	
<p>Step 4</p> <ol style="list-style-type: none"> 1)When the QOCA bioreader measurement is completed, Press the Get_Data button at the position (3). 2)BLE connection AP will get test results from QOCA bioreader. 	

【Specifications】

Dimensions	L 13.6 * W 8.3 * H 3.4 (cm)
Weight	195 ± 5g (battery excluded)
Operating temperature	5 ~ 40℃
Operating humidity	10 ~ 80% RH
Transportation/storage temperature	-5 ~ 50℃
Transportation/storage humidity	10 ~ 85% RH
IP rating	IP 22
Power supply	DC 5V / 500mA or 9V Alkaline battery
Altitude	Under 2,000m (813 ~ 1013 hPa)
Technologies	Electrochemical impedance spectroscopy (E.I.S)
Product service life	3 years

【Replacement Battery】

- Flip over QOCA bioreader (the display facing the table)
- Use a flathead screwdriver or coin to remove screws of battery cover.
- Take out the old battery from the chamber and replace with a 9V Alkaline battery.
- Place the battery into the chamber.
- Put back the cover and secure with screws.

【Clean】

After use, spray 75% alcohol or 5% bleach on a lint-free cloth and clean the enclosure gently.

【Electromagnetic Interference】

QOCA bioreader is compliant with the radiation interference and anti-interference requirements in IEC 61326-2-6.



Please do not use the device near a strong magnetic field to ensure normal operations.

【Disposal of the system】

Please observe the local rules and regulations when disposing of the system or its components.

【Maintenance】

- Please store and use the device within the specified temperature and humidity range.
- Keep QOCA bioreader out of direct sunlight or extreme environments.

【Troubleshooting】

■ Unexpected result













When the results cannot accurately reflect the patient's condition, please retest with a new chip detection kit and specimen. If the result is still suspicious, please refer to Manufacturer section.

Problem	Cause	Action
The device won't turn on	The device is out of battery, rechargeable battery is completely discharged or the switch is broken.	Replace primary battery or charge rechargeable battery before use. If the device still won't turn on, please contact your sales representative.
No display	The device is out of battery or rechargeable battery is completely discharged.	Replace primary battery or charge rechargeable battery before use. Power by connecting to USB-C port on top of the device. If the issue persists, please contact your sales representative.
Low battery	The device is out of battery or rechargeable battery is completely discharged.	Replace primary battery or charge rechargeable battery before use.
Failure of continuous testing	USB-C connector is worn out	Replace with the same type of USB-C cable from Manufacturer.
Cannot measure	Damaged buttons	Please contact your sales representative.
Incorrect date/time	Real-time clock (RTC) out of battery	Please contact your sales representative.

【Repair】

Do not try to repair by yourself. Please contact your sales representative for repair.

【Symbols】

Symbol	Description
	Please read this manual carefully before use
	Manufacturer name and address
	Manufacture date
	Storage temperature range
	Lot No.
	Serial No.
	In vitro diagnostic device
	Model
	Do not use repeatedly
	Warning
	IP rating
	Humidity limitation

【Disclaimer】

Please use the original accessories and follow the specifications and regulations provided by the manufacturer. The Company is not liable for any direct or indirect damage resulting from the misuse of device.

【FCC Statement】

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

- 1) this device may not cause harmful interference and
- 2) this device must accept any interference received, including interference that may cause undesired operation.

Federal Communications Commission (FCC) Statement

15.105(b)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

15.21

You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

FCC RF Radiation Exposure Statement:

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. For portable operation, this device has been tested and meets FCC RF exposure guidelines. When used with an accessory that contains metal may not ensure compliance with FCC RF exposure guidelines.

【Manufacturer】

For further assistance, please feel free to contact the Quanta Customer Service



Medical device supplier: Quanta Computer Inc.

Hwa Ya Medical Devices Fab 2

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Taiwan

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