

Quantum Dot
Immunofluorescence Analyzer

Mokosensor-Q100

Instructions for Use

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PLEASE READ THIS MANUAL CAREFULLY BEFORE USE

Precautions

Please read these instructions carefully before using the instrument.

Graphics, symbols, and abbreviations used on the instrument are as follows:

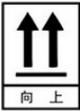
No.	Symbols	Description	Meaning
1		Caution and Danger	They are warning signs. Please refer to requirements in the instructions for use
2		Biohazard	To strengthen the protection and treatment
3		In Vitro diagnostic	In vitro diagnostic equipment.
4		Up	The shipping package should be kept upright during transportation.
5		Fragile	The shipping package contains fragile items and should be handled with care.
6		Keep dry	The shipping package should be kept dry.
7		Limit of stacking layers	It indicates the maximum number of layers that can be stacked with the same shipping package

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I. Overview

The quantum dot immunofluorescence analyzer (Model: Mokosensor-Q100) is microprocessor-based and compatible with the quantum dot fluorescence immunoassay kit to quantitatively or qualitatively test the content of the substance of interest in human specimen.

This manual describes the installation, operation, use, maintenance and related precautions of the quantum dot immunofluorescence analyzer (Model: Mokosensor-Q100). Please read this manual carefully before using this instrument.

II. Technical Specifications

2.1 Operating Conditions

- (1) Temperature: 5°C to 40°C/39.2°F to 104°F.
- (2) Humidity: Not greater than 80%.
- (3) Atmospheric pressure: 86.0 kPa to 106.0 kPa.
- (4) Power supply: 100~240VAC-50/60Hz.
- (5) Miscellaneous: Avoid dust, direct sunlight, splashing liquid, corrosive gas, vibration, and strong electromagnetic interference.

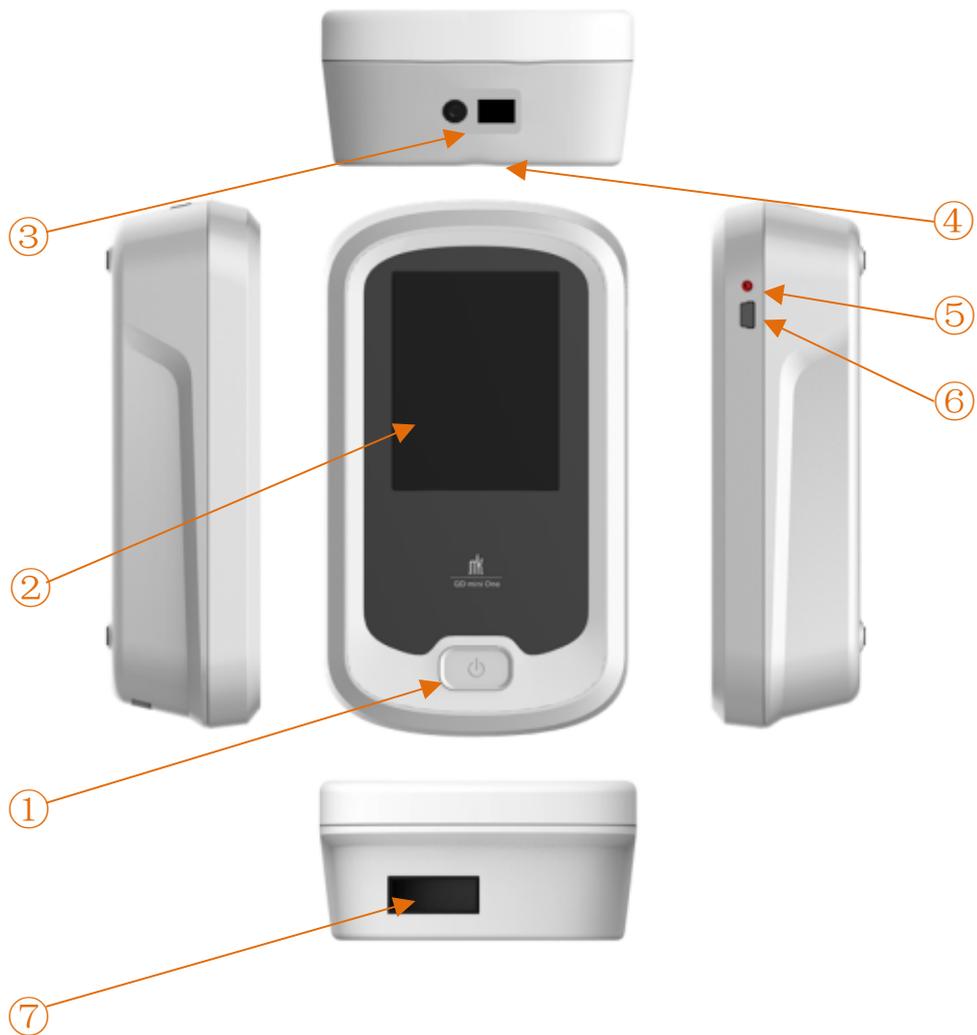
2.2 Shipping and Storage Conditions

- (1) Temperature: 5°C to 40°C/39.2°F to 104°F.
- (2) Humidity: Not greater than 80%.
- (3) Atmospheric pressure: 86.0 kPa to 106.0 kPa.
- (4) Handle with care: When shipping, use the original packaging material to prevent damage to the instrument. Avoid any violent impact, which will result in damage to the packaging and product.

2.3 Sketch of Appearance

Structure:

- ① Power switch.
- ② Touch-screen display.
- ③ Barcode scanner.
- ④ IC card reader, on the upper back side of the instrument.
- ⑤ Power indicator.
- ⑥ Power Port/USB Port.
- ⑦ Sample inlet.



2.4 Main Structural Components

The quantum dot immunofluorescence analyzer consists of a main unit, a power adapter, a power cable, and a Bluetooth printer (optional).

2.5 Technical Parameters

- (1) Power input: 44VA.
- (2) Dimensions (Length × Width × Height): 165mm × 90mm × 50mm.
- (3) Weight: The net weight of the main unit is approximately 250g.
- (4) Number of channels: 1.
- (5) Reproducibility: Coefficient of variability (CV) is not greater than 5%.
- (6) Variability: Inter-instrument variation is not greater than 5%.
- (7) Linearity: Linear correlation coefficient (r) is not less than 0.975.
- (8) Single test time: Not greater than 40s.

III. Installation and Use

3.1 Installation of Instrument

3.1.1 Unpack the box and check the contents against the packing list (Table 1). If any component is missing or damaged, please contact the supplier immediately.

3.1.2 Take out the Main Unit and place on a clean, flat and stable surface (no strong vibration).

Table 1 Packing List

No.	Description	Quantity
1	Main unit	1
2	Power adapter	1
3	Power cable	1
4	Instruction manual	1
5	Warranty card	1
6	Certificate of conformity	1
7	Bluetooth printer	Optional

3.1.3 Plug the power adapter into an appropriate outlet. Charge the instrument by connecting the power cable to the outlet socket on the right.

3.2 Installation Precautions

Grounding: when charging the instrument, the power cable must be plugged into a power outlet 100-240 VAC- 50 /60Hz, with proper grounding.

The instrument should be protected from dust and corrosives. Avoid vibration and strong electromagnetic interference. The instrument should be operated under the normal working environment & conditions specified above. Do not place the instrument against the wall and leave a > 20cm gap to ensure air circulation.

3.3 Switch on the Instrument

Press and hold the power switch for 3 seconds to turn on the instrument and display the main menu.

3.4 IC Scanning

Each reagent kit (e.g. SARS-CoV-2 IgG & IgM Quantum Dot immunoassay) contains an information card (IC), which stores batch-specific standard curve to ensure assay consistency by eliminating batch-to-batch variation.

When starting a new test (or a new batch of reagent of the same test), the corresponding IC card should be scanned as follow:

3.4.1 Click on the “**Reagent Info**” button on the menu.

3.4.2 Place IC card to the Q100’s scanning area (the upper back side of the instrument).

3.4.3. When the progress bar reaches 100% (or completed), click the “**Import**” button and then

“OK” in the pop-up window. Click on the button “Close” to return to the menu interface.

3.5 Test

3.5.1 Select test

On the menu interface, click the “Test” button to enter the testing interface.

Click the “Select” button to choose the test to be performed. Use the “▼” button to navigate. After confirming the information on the selected item, click on the button “OK” for testing.

Note

1. In the sample ID column, the defaulted sample ID automatically generated by the instrument can be used. Alternatively, you can create a sample ID by scanning the barcode on the sample collection tube. Click on the button “Scan” and the light beside the barcode scanner will be on. Scan the barcode on the sample collection tube to identify the sample ID. After a “beep” sound occurs, the barcode has been successfully identified and the sample ID will be displayed.
2. Insert the test cassette into the sample inlet. Noted that the testing items of the test cassette should be consistent with the selected test (Name and Batch).

3.5.2 Select Test method

On the testing interface (Fig. 1), click on either the “Test A” or “Test B” button to measure the test cassette as explained below. When the test is complete, the test results including testing items, results, and range will be automatically displayed on the testing interface.

Remove the test cassette when the test is complete.

If you need to print out the results, please connect to a Bluetooth printer and click on the button “Print” after the measurement.

Fig. 1

Note

1. After the sample is successfully identified and the correct item barcode is entered, the user can choose the button “Test A” or “Test B”, as needed.
2. **Test A:** make an instant measurement without incubation. If this test mode is used, the incubation takes place on bench rather than in the instrument.

Test B: make a measurement after the test cassette is incubated automatically in the instrument for a duration specified by the assay IC card.



3.6 Result Inquiry

On the main menu, click “History” to view all stored test results. Use “Prev” and “Next” to navigate the historical records.

Result inquiry instructions:

1. You can perform operations such as viewing, printing, and exporting after the searched results are displayed on the screen.
2. The test results can be transferred to a computer via USB connection and/or printed out by a connected Bluetooth printer.

3.7 System Settings

On the main menu interface, click the "**Config**" button to access system settings including Reagent, Record, History, Date Time, Language, and Screen Setting.

3.7.1 Reagent setting

Click "**Reagent**" then you can view the information of the standard curve that has been imported to the equipment, including reagent name, batch, expiration date, incubation time, etc.

1. You can inquire about the imported information of the standard curve on the reagent setting interface. Click "**Import**" to import a new standard curve.
2. Click the "**Delete**" button to delete the currently displayed standard curve.
3. Click "**Previous**" or "**Next**" to view the reagent standard curve that has been scanned into the instrument.

3.7.2 Record setting

Click "**History**" and then click "**Clear**" on the record setting interface to delete all test records.

3.7.3 Time setting

The displayed Date/time on the instrument can be adjusted in the time setting.

Click "**Date time**" and then,

1. Tap "empty box" next to "Date" displayed on the screen to enter the date setting page and adjust it to the desired date in the format of yyyy-mm-dd.
2. Tap "empty box" next to "Time" displayed on the screen to enter the time setting page and adjust it to the desired time in the inputting format of hh: mm: ss.
3. When the setting is complete, click on the button "**Apply**" to finish time adjustment.

3.7.4 Language setting

The system interface language includes both Chinese and English. After entering the language submenu, choose "Chinese" or "English" and wait for 1 to 2 seconds to finish the language setting.

3.7.5 Touchscreen calibration

This function is designed for the touch screen calibration.

1. After entering the calibrating interface, click on the crosshairs at the upper left, upper right, lower right, lower left, and center in a sequential manner.

2. After the calibration is successfully performed, it will automatically return to the system setting menu.

Note

1. Do not apply excessive force or click repeatedly during the screen calibration.
2. Avoid touching the rest of the screen when clicking on the crosshairs.

3.7.6 Factory setting

This function is only accessible to the Manufacturer for quality control and troubleshooting.

3.8 Turning Off Instrument

Press and hold the power switch for 3 seconds to safely turn off the instrument.

IV. Precautions and Requirements

4.1 Requirements for Electrical Safety

The product is designed in compliance with GB 4793.1-2007, (Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements), GB 4793.9-2013, (Safety requirements for electrical equipment for measurement, control and laboratory use — Part 9: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes), and YY 0648-2008, (Safety requirements for electrical equipment for measurement control and laboratory use — Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment).

4.2 EMC Requirements

The instrument is designed in accordance with GB/T 18268.1-2010, Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 1: General requirements and GB/T 18268.26-2010, Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 26: Particular requirements — In vitro diagnostic (IVD) medical equipment.

The instrument (or device) is designed and tested as Class A equipment in accordance with GB 4824. In a household environment, the equipment may cause radio interference therefore protective measures are necessary.

It is recommended to evaluate the electromagnetic environment before using this equipment. Do not use the equipment near a strong radiation source (e.g. an unshielded RF source), which may interfere with the normal operation of the instrument.

Note: It is the Manufacturer's responsibility to provide customers or users with EMC information of the equipment. It is the user's responsibility to provide an EMC environment to ensure proper function of the instrument.

4.3 Network Safety

4.3.1 Data interface

(1) USB: The USB2.0 protocol is used to transfer data from instrument to computer.

(2) Bluetooth: The Bluetooth 2.0 protocol is used to connect a printer to the instrument.

4.4 Precautions

4.4.1 Read this manual carefully before using the instrument.

4.4.2 Avoid splashing liquid on the instrument or immersing the instrument in liquid.

4.4.3 Turn off instrument after the test is finished or Turn off the instrument if not in use for a long time.

4.4.4 Do not plug/unplug the power supply with wet hands, which may cause an electric shock.

4.4.5 Do not use any damaged wires and cables, etc. Do not step on, twist or forcibly pull the wires and cables. Broken or damaged wires may cause fires.

4.4.6 Do not use any wires and cables other than the ones supplied with the instrument. Use of wires and cables with lower capacitance may cause fires.

4.4.7 The outlet socket must be grounded. Otherwise, an electric shock might occur in case of leakage.

4.4.8 After use, the remaining testing samples and their attachments shall be disposed according to national regulations and the requirements of local environmental organizations.

4.4.9 Wear lab coat and medical protective gloves when working with the instrument and test cassettes.

4.4.10 To handle potentially contaminated human fluid samples, the operator must wear laboratory coat and protective gloves to avoid splashing, spilling of infectious fluid, and its possible contact with any exposed part of the human body.

4.4.11 Do not use turpentine, benzene and other chemical reagents to remove the stains from the instrument. Wipe clean with a piece of soft or damp cloth. Remove severe stains (if any) using detergent or 75% alcohol.

4.4.12 If a malfunction occurs, switch off power supply immediately, unplug power adapter, and contact the dealer or the Manufacturer. Do not disassemble the instrument without authorization. Do not switch on defective products to avoid further damage to the instrument and to avoid danger to the operator if it is not troubleshot by the Manufacturer.

4.4.13 Turn off the power switch and unplug the power cord as soon as the operator smell a burning or other odor.

4.4.14 If necessary, connect a Bluetooth printer for printing.

4.4.15 The normal service life of the instrument is 5 years if operated under the specified environment and operating conditions. The user shall bear all the consequences resulting from the instrument operation beyond its service life.

V. Maintenance

5.1 Maintenance

Do not place the quantum dot fluorescence immunoassay analyzer in an environment with strong magnetic field interference and make sure that the environment is well ventilated to ensure its stability and accuracy.

Wear protective medical gloves when cleaning or disinfecting the instrument.

Note

1. Maintenance and check shall be performed by the Manufacturer and its agent or other qualified technicians.
2. For replacement, use components and parts supplied by the Manufacturer and its authorized agent.

5.2 Cleaning

5.2.1 Wipe to remove any residual liquid from the surface of the instrument using a piece of dry and

clean cloth.

5.2.2 Clean the outer surface of the instrument using a piece of disposable cloth with a small amount of water or mild detergent.

Warning

Make sure to switch off the power supply before cleaning.

5.3 Disinfection

Clean the sample inlet and the surface of the instrument using a piece of disposable cloth with 75% ethanol or 1% pentanediol.

Note: The cloth should be damp instead of wet.

VI. Troubleshooting and Service

6.1 Troubleshooting

No.	Problem	Solution
1	Sudden black screen during use	1. Connect to the power supply. Then, turn on the instrument after it has been charged for 3 minutes.
		2. After charging, press and hold the power key for 15 seconds, and then press it again for 3 seconds.
		3. Contact your dealer or the Manufacturer.
2	IC card cannot be scanned	1. Unplug the power cable and scan the card again.
		2. Flip the IC card and then scan, or try to adjust the scanning angle.
		3. Use a different IC card of the same batch if there is any.

		4. Contact your dealer or the Manufacturer.
3	Invalid results	1. Ensure the reagent information is correctly imported and match with batch number of the reagent pouch.
		2. Check the reagent manual to confirm that the operation is correct.
		3. Check the instrument manual to confirm that the operation is correct.
		4. Contact your dealer or the Manufacturer.
4	Screen responding slowly	1. Restart the equipment
		2. Enter the system setting and perform screen calibration according to the section 3.7.5 of this manual.
		3. Contact your dealer or the Manufacturer.
5	Barcode cannot be scanned.	1. Adjust the distance between the barcode scanner and the barcode.
		2. Replace the barcode
		3. Contact your dealer or the Manufacturer.

6.2 Service

6.2.1 The instrument has a one-year warranty excluding defects due to misuse. Beyond the warranty period, the Manufacturer will be responsible for repair at reasonable costs.

6.2.2 Do not disassemble the instrument unless directed by the Manufacturer. Violations will void the warranty and the repair therefrom shall be at the user's expense

6.2.3 The user may contact the Manufacturer's technical service department when ordering the components and parts or servicing the instrument.

Company information:

Name: Quantum Dot Immunofluorescence Analyzer

Model: Mokosensor-Q100

Manufacturing date: See the nameplate on the product.

Production license number: Su Shi Yao Jian Xie Sheng Chan Xu No. 20130089

Number of Registration Certificate/Number of Product Technical Requirements: Su Xie Zhu Zhun No. 20182400006

Registrant/Manufacturer Name: Mei Ning Kang Cheng China Biotechnology R&D Center INC.

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