CE IVD

CLEO™ Q16

Rapid Real-time PCR System

Instruction for use

REF CL0016

For *in vitro* diagnostic use.
For professional use only.

wizbiosolutions
THE INNOVATION OF GENOMICS

Contents

General Information

Please carefully compare the contents of this delivery with the enclosed delivery note, the package insert, or the invoice. We recommend that you keep a copy of this document together with the instructions so that you can quickly access information about the date and scope of delivery in case of future queries, re-orders, or service work.

Please be sure to remove all small parts from the packaging material.

We wish to inform you that our devices are adjusted at the factory and can be used immediately after installation.

Before using the CLEO™ Q16 device for the first time, please read the user manual carefully. We recommend that it always be kept with the CLEO™ Q16 device.

Important Information

Before using the CLEO™ Q16 system, it is important to read this user manual to familiarize yourself with the instrument. Follow all instructions to ensure proper operation of the CLEO™ Q16 device. Do not use any consumables, accessories, or external equipment other than that specified. Safety warnings must be adhered to at all times to avoid risk in personal injury and/or damage to the instrument. If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired. The advice given in this manual is intended to supplement, not supersede, the normal safety requirements established in the user's country.

Intended Use

The CLEO™ Q16 system is intended for real-time fluorescence PCR experiments (Real-time PCR) and analyzes the experimental data. The instrument is operated in a laboratory with the corresponding reagents, to carry out rapid and accurate quantitative and qualitative detection of target nucleic acid sequences from human and animal samples (such as blood, oral swabs, nasopharyngeal swabs, body fluids, etc.) or other analytes, or to conduct melting curves, genotype analysis, etc.

The CLEO™ Q16 system is a compact 16-well qPCR instrument with a 4-channel fluorescence detection channel and analysis software. Analysis results are provided through a built-in Ct algorithm that analyzes PCR curve data.

CLEO™ Q16 system is intended for research or in vitro diagnostic use only.

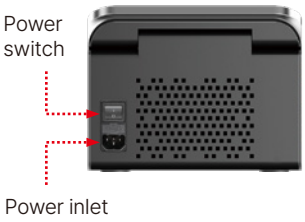
Components

The package of CLEO™ Q16 contains following componets.

- CLEO™ Q16 device ---------- 1
- Power cable ---------- 1
- Instruction for Use ---------- 1

CLEO™ Q16 Overview

<Front view>



<Back view>

CLEO™ Q16 Specifications

Model No.	CL0016
Test Capacity	16 Tests (8 tubes X 2)
Detection Channel	4 Channel (FAM, HEX, ROX, Cy5)
Repeatability of Fluorescent Intensity Detection	< 5% CV
Test ID and Sample ID Input	QR code scan
Operating System	Android OS
Input power	100 - 240 VAC (50/60 Hz)
Max. power	300 W
Operating environment	Indoor Use Only
Operating temperature range	10 °C to 30 °C (50 °F - 86 °F)
Storage temperature range	0 °C to 50 °C (32 °F - 122 °F)
Operating humidity range	20% - 80%
Storage humidity range	20% - 80%
Dimensions (L×W×H)	280 × 220 × 180 mm (11.0″ x 8.6″ x 7.0″)
Net weight	4.12 kg (145 oz)

Unpacking and Installation

The following items are packaged within the CLEO™ Q16 shipping container:

- CLEO™ Q16 device
- Power cable
- CLEO™ Q16 manual

1. Hardware installation

(1) Place the CLEO™ Q16 device on a flat surface.
Note : Plug the power cord into the power inlet on the back of the device.

(2) Plug the power cord into a wall outlet and turn on the power from the socket. Use the power switch on the back of the unit to 'turn on' the CLEO™ Q16 device.

(3) When the power of the device is connected normally, the display screen on the front of the device turns on and the software of the device works.

(4) To turn the instrument 'Off', use the power switch on the back of the instrument.

2. Updating software

- For the software update of CLEO™ Q16 device, you can check the software version of your CLEO™ Q16 device and update information in the device information of Setting.
- If the CLEO™ Q16 device is not connected to the Internet, you can find out the released updated version of the CLEO™ Q16 device on the webpage of wizbiosolutions, (www.wizbiosolution.com) and you can ask help for the software update with your Wizbiosolutions sales representative or contact our technical services.

3. For online software update

- Check the new software update information in the device information of the CLEO™ Q16 device setting menu.
  Note : Wi-Fi or LAN cable connection required
- When an updated software version is released, click the Update button to proceed with the software update.
  Note : Make sure that CLEO™ Q16 device keeps the power turn-on while the software update is in progress.
- Then CLEO™ Q16 device will start automatically software update, your CLEO™ Q16 device runs to the login screen in the updated version.

4. Upgrading firmware

- Some new releases of software can require a firmware upgrade. In that case, Wizbiosolutions will notify the user of the requirement to upgrade the firmware, separately.
- To achieve the firmware upgrade, the CLEO™ Q16 device must be connected to the PC via USB cable.
- Firmware upgrades cannot be achieved through Bluetooth.

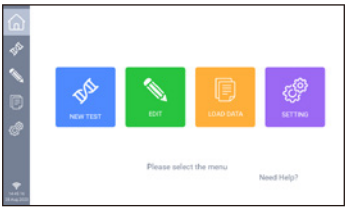
Menu Guide

- NEW TEST : Select the test item for diagnosis (WizDx™ kit use only)
- EDIT : Edit PCR settings by the user.
- LOAD DATA : View the test results.
- SETTING : Modify the setting menu of the device

Getting Started

1. Power on and Booting process

- Turn on the Power switch, the CLEO™ Q16 device booting logo will be displayed on the screen and check the status of the device as booting progresses.
- When device verification is complete, the main screen appears.



〈Main screen〉

2. New test

To proceed with a new test, select the <NEW TEST> to start a new test.

Note: The <NEW TEST> is only for the WizDx™ Kit. To use user settings, go to the <EDIT> menu on page 9.

3. Enter test information

1) Scan the QR code on the pouch of kit you want to test.
2) Once the QR code scanning is complete, check that the test name, Cat No, Lot No, and expiration date are entered correctly.
3) Once you have completed entering the test information, click the <CONFORM> to move to the next step.

Caution: If the expiration date of the kit has passed, a message will appear indicating that the test cannot be performed.

Note: If the QR code is damaged or the QR code cannot be recognized, please go to the <MANUAL INPUT> and directly enter the information required for testing.

〈QR code input〉

〈Test information input〉

4. Enter sample information

Sample information can be entered manually or through barcode.

<Manual input>

1) Select the number to be tested on the screen, moved to the sample information screen.
2) Enter sample information to be tested.
3) Once input is complete, click the <ENTER> to complete information input.

<Enter the Barcode>

1) Select <BARCODE> at the bottom of the menu.
2) Enter sample information by scanning the barcode or QR code attached to the sample tube.
3) Click the <NEXT> to continuously enter sample information.
4) Once input is complete, click the <ENTER> to complete information input.

5. Start the test

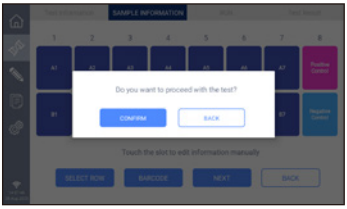
1) Insert the prepared PCR tube into the PCR tube slot of the device.
2) Close the lid of the device completely.
   Caution: The test will not proceed if the device lid is not completely closed.
3) When sample input is complete, touch the <NEXT>.
4) Click the <CONFORM> in the pop-up window to start the test.
5) When the test starts, the test progress is displayed on the monitor.

Note : At this time, check whether the test item is correct, and if the test item is selected incorrectly, press the <STOP> to stop the reaction immediately, then go to the <HOME> and start again from the new test process.

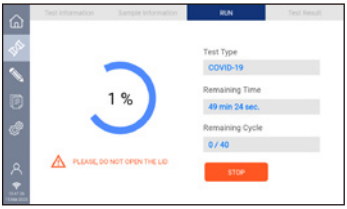
〈Sample information〉

〈Sample information〉

〈Barcode input〉



〈Test confirmation〉

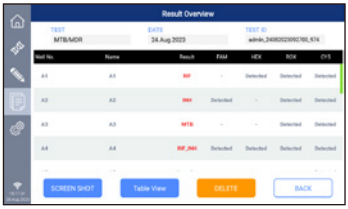


〈Test progress〉

6. Check the result

- When the test is complete, a warning sound will sound and a completion information pop-up window will appear. Click <OK> to move to the results screen.
- At this time, the test results are automatically saved.
- The result screen can be viewed in the form of <TABLE VIEW> and <LIST VIEW>.
- Click on each item on the results screen to see more detailed test results.

〈Result: Table view〉



〈Result: List view〉

〈Result details view〉

7. Remove PCR tube

Once all tests are complete, open the lid and remove the PCR tube from the tube slot.

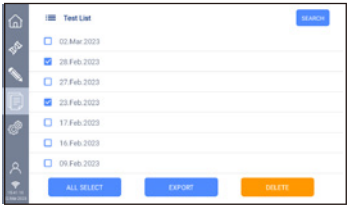
8. Additional testing

To perform additional tests or retests, go to the <HOME> and then <NEW TEST> step.

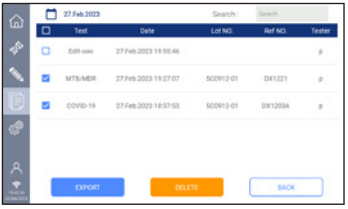
9. Data save and backup

Test results can be saved by selecting the entire date, or by specifying each detailed result separately.

1) Insert the USB memory into the USB port on the side of the device.
2) Click <Check results> on the main screen.
3) Go to the date or detailed list you want to save in the list, select the checkbox <☐> on the left, and then click <Export> at the bottom to save the data to USB memory.



〈Test list〉



〈Detailed test list〉

10. Power off

Turn off the power switch on the back of the device.

Edit

PCR settings by user

1. How to set up PCR

1) Enter the test name.
2) Select PCR settings.
   (Reverse Transcription, 2-Step/3-Step/Nested-PCR, etc.)
3) Set the PCR cycle.
   (temperature, time, number of cycles, etc.)
4) Go to <THERSHOLD Settings>.
5) Set the Theshold value for each fluorescence.
6) Save the PCR setting conditions.
7) When you press the <RUN>, a pop-up window will appear confirming whether the test is in progress. At this time, after confirming that the test settings are correct, click the <CONFIRM> to move to the sample information input step.
8) The next step is go to <4. Enter sample information> step.

〈PCR confirmation〉

2. Edit Menu Guide

- Test name: Enter the test name
- PCR settings: Setting up Reverse Transcription, 2-Step/3-Step, Nested-PCR, etc.
- THRESHOLD setting: Set the threshold value for each fluorescence channel.

〈PCR setting〉

〈THRESHOLD setting〉

Device Safety Precautions

- Read this manual carefully before using the device and follow all recommended safety precautions to avoid personal injury or damage to the device.
- Check the rated voltage before use. If the rated voltage is not followed, the device may be damaged.
- Do not insert anything other than permitted test tubes into the device. It may cause device failure or incorrect test results.
- To avoid contamination of the device with biohazard materials, do not open test tubes during or after process steps.
- Keep the device dry, dust free and well ventilated on all sides. Do not place near heat sources.
- Unplug the device before cleaning.
- Do not force the device to open or attempt repairs. The device may be damaged. If you have any questions, please contact customer support.
- When the device is not in use, turn it off by unplugging it from the wall outlet.
- When not in use for a long period of time, cover the device with a cloth to protect it from dust.
- Any significant incidents related to the device should be notified to the competent authorities and manufacturers.
- If a cybersecurity threat is detected when connecting to a LAN, WiFi network, or USB to your device, stop using the product and contact your Wisbiosolution or service representative.

Cleaning & Maintenance

- Power off the device before cleaning. Do not use or fill wells with caustic cleaning solutions.
- If a foreign object enters the test tube slot, gently wipe it with a cotton swab moistened with alcohol. Then open the device cover and let it dry completely before use.
- Never turn over if foreign objects get inside. It may cause equipment failure.

Warranty

The free warranty period for this product is 1 year from the date of purchase. If a defect occurs in the device during the free warranty period, Wizbiosolution Inc. will repair or replace the product free of charge. However, defects arising from the following matters are excluded from the scope of the free warranty.

- Improper use or misuse
- Unauthorized repairs/replacements or modifications.
- Damage caused by disaster
- Corrosion caused by inappropriate solvents or samples.

Troubleshooting

Error type	Possible cause	Comments and suggestions
The CLEO™ Q16 device does not start	The CLEO™ Q16 device is not connected to the power outlet.	Check that the CLEO™ Q16 device is connected to the main power.
	The power switch at the back of the CLEO™ Q16 device is not powered ON.	Power ON using the power switch at the back of CLEO™ Q16 device.
	The CLEO™ Q16 device is in standby mode.	Press the ON/OFF button to take the CLEO™ Q16 device out of standby mode.
The touchscreen does not respond	The CLEO™ Q16 device is in standby mode (status indicator is blue).	Press the ON/OFF button on the Operational Module.
	Hardware failure	Contact Wizbiosolutions Technical Services
Barcode reader does not scan	Sample ID Barcode feature is not enabled.	Contact a Laboratory Supervisor or instrument Administrator to configure the Barcode feature on the CLEO™ Q16 device.
	Barcode reader has a hardware or software problem.	Contact Wizbiosolutions Technical Services
Lid does not open	Mechanical failure.	Contact Wizbiosolutions Technical Services
The Run Test button is not active	The cover is not completely closed.	Open the cover and close it by pressing firmly.
	Mechanical failure.	Contact Wizbiosolutions Technical Services
Assay does not run	The user does not have rights to run the test.	Contact a Laboratory Supervisor or instrument Administrator.
	There is a problem with the program.	Contact Wizbiosolutions Technical Services
Result upload status is “Error”	Connectivity with the host has been lost.	Contact a Laboratory Supervisor or instrument Administrator to check connection details and test connectivity.
	Message rejected from host	The host rejected the message for some reason (assay not recognized, semantic issues, etc.). Contact Wizbiosolutions Technical Services.

Symbols Glossary

Symbol	Meaning	Symbol	Meaning
CE	CE Marking	REF	Catalog number.
IVD	For *In Vitro* Diagnostics Use.	SN	Serial number.
	Caution	EC REP	Authorized EC Representative in the European Community
	Date of manufacture	RoHS COMPLIANT	Restriction of Hazardous Substances in Electrical and Electronic Equipment
	Manufacturer		Waste stream disposal status
	Consult instruction for use	UDI	Unique Device Identification
	Keep dry		Temperature limit
	Fragile, handle with care		Protective earth (ground)

Technical Support

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