



Quanta Computer

QOCA PORTABLE ECG MONITORING DEVICE User Manual

Model name : ecg102D

CIE418-01 Ver.: 3A



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SAFETY NOTES

- Please read through this user guide carefully before using QOCA PORTABLE ECG MONITORING DEVICE.
- The QOCA PORTABLE ECG MONITORING DEVICE is to be used for clinical assessment and personal reference only.
- The QOCA PORTABLE ECG MONITORING DEVICE consists entirely of sophisticated medical electrical parts. Maintenance can only be carried out by professional technicians. Unauthorized disassembly of the device by the user is not allowed.
- The QOCA PORTABLE ECG MONITORING DEVICE must be used with its specified accessories and electrodes. The use of accessories and electrodes from other brands can damage the device or cause inaccurate readings.
- Do not allow the connectors or contacts on the devices to come into contact with any kind of power source during use.
- Damaged or faulty accessories and electrodes should not be used.
- When the QOCA PORTABLE ECG MONITORING DEVICE is low on battery power, it will automatically stop taking measurements. Please exchange the new battery as soon as it shows a low battery state.

- Avoid using devices that can affect the accuracy of the readings when the QOCA PORTABLE ECG MONITORING DEVICE is taking measurements (e.g., using a blood pressure monitor will affect the ECG's pulse measurement).
- Avoid using other electronic devices when the QOCA PORTABLE ECG MONITORING DEVICE is taking measurements. If using another other electronic device is necessary, please check to ensure the ECG is continuing to take measurements normally. See The QOCA ECG App to see how to check if the device taking measurements normally.
- Do not use the QOCA PORTABLE ECG MONITORING DEVICE near open flames or in excessive heat.
- Pay attention to ensure that the QOCA PORTABLE ECG MONITORING DEVICE is not swallowed by pets or children.
- Cardiac pacemakers or other electrical stimulators may affect the accuracy of the measurements of the QOCA PORTABLE ECG MONITORING DEVICE.

- The conductive parts of the electrodes and associated connectors for type BF applied parts, which are parts that make conductive contact with the heart, including the neutral electrode, should not make contact with other conductive parts including the ground. Direct contact with other conductive parts may result in electric shock.
- Do not use high-frequency instruments or electrical medical equipment such as defibrillators when using the QOCA PORTABLE ECG MONITORING DEVICE.
- The QOCA PORTABLE ECG MONITORING DEVICE can only take measurements while the subject is stationary (e.g., while sitting). Any activities not permitted by the attending physician may affect the accuracy of the measurements.
- Do not expose QOCA PORTABLE ECG MONITORING DEVICE to extreme temperatures, extremely moist environments, dust, or direct sunlight.
- Do not clean the QOCA PORTABLE ECG MONITORING DEVICE with corrosive or abrasive cleaning agents.
- The QOCA PORTABLE ECG MONITORING DEVICE and its accessories should be disposed of properly. Disposal of the device and its accessories should comply with the relevant local regulations.

- The QOCA PORTABLE ECG MONITORING DEVICE has been tested and certified to international electro-magnetic compatibility (EMC) standards for medical equipment (EN 60601-1 and EN 60601-1-2). If abnormal behavior is observed due to EMC disturbances, please relocate the device accordingly.
- Battery Caution: There is a risk of explosion if the battery for the QOCA PORTABLE ECG MONITORING DEVICE is replaced by an incorrect battery type.
- The expected service life of the QOCA PORTABLE ECG MONITORING DEVICE is 2 years.
- Do not use QOCA PORTABLE ECG MONITORING DEVICE with MRI / X-ray room /AED equipment together.
- This device should not be used adjacent to or stacked with other equipment.
- Please do not use any other cables or accessories not approved by the manufacturer in this manual to avoid negative influence on electromagnetic compatibility.
- Due to electrostatic discharge (ESD) sparks may cause sparks. QOCA PORTABLE ECG MONITORING DEVICE is not suitable for use in an explosive environment.

- QOCA PORTABLE ECG MONITORING DEVICE does not support with the devices that apply high-frequency voltage to patients (such as electrosurgical equipment and some respiratory sensors); if such devices are used at the same time, it may cause adverse consequences. For procedures that require the use of high-frequency surgical equipment, QOCA PORTABLE ECG MONITORING DEVICE should be removed beforehand.
- Avoid using heavy electronic equipment or other sources of electromagnetic interference (such as electric blankets) when using the QOCA PORTABLE ECG MONITORING DEVICE.
- When the ECG signal is always unstable, please contact the manufacturer.
- In order to obtain good contact between the electrode pad and the skin, it is very important to prepare the skin for cleaning.
- Dry the skin to increase the capillary blood flow and remove the skin shavings and oil.

PRODUCT OVERVIEW



Indication for Use

The QOCA Portable ECG Monitoring Device is intended for use by trained medical personnel and trained adults to measure Electrocardiogram (ECG) and heart rate (HR) in hospitals, healthcare institutes, or home environments. The transmission, storage, and display of ECG and HR data are available with dedicated software.

The device is intended for use on adult patients who are not in critical condition.

Package Contents

After purchasing the QOCA PORTABLE ECG MONITORING DEVICE , please check the product package to ensure that the following items are included:

	
ECG Sensor x 1	User Manual x 1

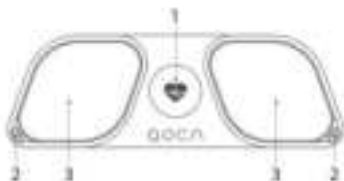
*Model name: ecg102D

*The package includes coin battery(CR2016) 1pcs for device test use

Components

ECG Sensor

Front



1	Indicator LED (LED flash blue light when user's fingers touch the two electrodes.)
2	Strap Holes
3	ECG Electrodes

Back



1	Label Area
2	Battery cover (Coin Battery CR2016)

Product Requirements

In order to properly use the QOCA PORTABLE ECG MONITORING DEVICE the following items are required:

- The ECG Sensor (Included coin battery CR2016)
- A Bluetooth-enabled Android Smartphone* (with Android version 8.x or above and a display resolution of 1560x720)
- QOCA ECG App*

** Items not included in the product package.*

BEFORE YOU START

Before you start using the QOCA PORTABLE ECG MONITORING DEVICE you must:

1. ECG Sensor requires a coin battery (CR2016)
2. Install the QOCA ECG app on your smartphone
3. Enable Bluetooth on your smartphone

Installing the App

To install QOCA ECG app on your smartphone.

NOTE: In order to install the QOCA ECG app your smartphone will need at least 15MB of storage capacity available.

Enabling Bluetooth

To enable Bluetooth, enter the Settings menu on your smartphone and enable Bluetooth.

GETTING STARTED

Once you have completed the steps described in *Before You Start*, you can begin using the QOCA PORTABLE ECG MONITORING DEVICE by following these steps:

1. Binding
2. Prepare to record ECG
3. Start to record ECG

Sensor binding

To pair the sensor and mobile phone, please select the "Upload Record" method of use. If pairing is not required, please select the "Personal use" method for direct measurement.

Upload Record :

- User account: Please fill in user account. Please contact the service staff for user account information
- Please follow the instructions of the app to complete the operation setting.
- The page will go into main screen when sensor binding.

Personal use :

- Please follow the instructions of the app to complete the operation setting.

- The page will go into main screen when sensor binding.



Main screen

If the measurement process cannot be completed, the screen will jump out of the measurement page and return to the operation instructions and display the prompt "Recording failed, please measure it again".

Prepare to record ECG

Before you start to record ECG you must:

1. Lay ECG sensor on a flat surface near your smartphone.
2. Launch QOCA ECG app and tap “+” button (lower-right corner) on the screen. It will enter Real-Time ECG page.



Note: Make sure Bluetooth of your smartphone is turned on.

Start to record ECG

Follow the on-screen instruction, you have to place your fingers from each hand on the two electrodes. Please put the device on the table before ECG recording. This will help the device to get more stable ECG waveform data.



After a while, app will start to record ECG and count down automatically. Please keep fingers attaching to the electrodes until the time counting is completed.



Note: It is critical to led fingers stable to avoid unwanted failure while recording ECG.

Note: The app will show “Recording complete” when you finished the measurement

Note: The app will show "Recording fail, please try it again" when the sensor has a "lead-off" condition.

THE QOCA ECG APP

Main Screen

Main screen is the list of ECG recordings. The following items can be found on the screen:



No	Item	Description
1	Profile Icon	Tap profile icon to enter profile page.
2	ECG Recording	Each ECG recording is displayed first 3 seconds. You can tap to enter History page to review ECG recording.

3	“+” Button	Tap “+” button to enter Real-Time ECG page.
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Real-Time ECG

The screen displays Real-Time ECG while the app receives signals from ECG sensor. The following items can be found on the screen:



No	Item	Description
1	On-screen Instruction	Instruct user how to record ECG.
2	Heartbeat	Real-time heartbeat,
3	ECG	Real-time ECG
4	Timer	Timer, Circular process bar

History

The complete ECG is displayed on history page.



Profile (Upload record)

The screenshot shows a web form titled 'Profile (Upload record)'. It contains two main sections: 'Profile' and 'Device'. The 'Profile' section has fields for 'Name', 'Patient ID', 'Date of Birth', and 'Gender'. The 'Device' section has fields for 'Device ID', 'Measurement mode', 'Firmware version', 'Software version', 'Device testing', 'Data clean', and 'Waveform Enhanced'.

No	Item	Description
1	Profile	User name, Patient ID, Date of Birth, Gender
2	Device	Device ID, Measurement mode, Firmware version, Software version, Device testing, Data clean, Waveform Enhanced

Profile (Personnel use)



No	Item	Description
2	Device	Device ID, Measurement mode, Firmware version, Software version, Device testing, Data clean, Waveform Enhanced

Specifications

Sensor Specifications

ECG Sensor	Continuous ECG data acquisition and calculation
	Measuring Lead: Lead 2 Frequency Response: Monitor 0.5 to 40 Hz (-3db) Heart rate measurement range*: 30 – 240 bpm** Heart rate accuracy: ± 3 bpm or $\pm 3\%$ whichever is greater Differential Input Impedance: $> 10M\Omega$ Common Mode Rejection Ratio: > 70 dB Sampling rate: default at 256Hz <i>*Heart rate is calculated based on the R-R interval of the ECG.</i> <i>** If the heart rate falls out of the 30 – 240 bpm range, the QOCA ecg app will display "--".</i>
Lead-off Detection	Detect when the sensor gets loosened from holder or body patch

Data Transmission	Bluetooth BLE 5.0: Transmit distance: 1 meters (open space)
Battery	CR2016
Working Temperature / Humidity	5 – 45°C, 10% – 95% non-condensing
Storage Temperature / Humidity	-20 – 60°C, 20% – 95% non-condensing
Enclosure Rating	IP21
Weight	17g
Dimension	92.7 x 31.0 x 4.0 ± 0.2 (mm)

Bluetooth Specifications

Operating Frequencies	2402~2480MHz
Channel Spacing	2MHz
Channel number	40
Operating Voltage	1.8V
Modulation	GFSK
Antenna Gain	PCB Antenna, Peak Gain: : 0.46 dBi
Rated Power (EIRP)	7.01 dBm

Device cleaning

1. Please clean the device with dry cloth when it is dirty or wet.

Troubleshooting

- 1) Cannot bind the device with the QOCA ecg app

If the ECG monitor cannot be binded with the mobile phone, please refer to the instructions and recheck it again.

- 2) If the light of the love icon does not light up in blue. Please check whether the battery is power. Open the battery cover, replace the new battery and use it again.

- 3) Connection problem

- Check whether the Bluetooth function of the mobile phone is normally turned on
- Please restart the QOCA ecg application
- Check if the product battery is power enough

- 4) If ECG waveform is unstable, noise or no signal can be measured during measurement, please try the following steps:

- Use an alcohol wipe or dry cloth to wipe the surface of the metal electrode
- Please clean it, if your finger may be dirty or water-stained.

- Use water lotion if the surface of your fingers is too dry
 - Please use the sensor on a flat table. Relax your hand muscles during measurement and keep your hands and fingers stable during measurement. Moving the finger will cause signal instability and noise during the measuring. Please press the metal electrode normally with your fingers, do not squeeze it hard.
 - During the measurement, please do not place the sensor location higher than the heart or lower than the navel.
- 5) Before measurement, please eliminate the following situations. Phone is charging, transmitting data and using headphones.
- 6) Check if the product battery has enough power
- 7) In order to collect stable data, please do not place the sensor device location higher than the body's heart.

Customer Support

For additional technical information, contact Quanta Customer Support Department.



Quanta Computer Inc.(QCI)

Address:

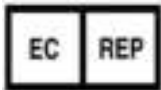
No. 188, Wenhua 2nd Rd.,
Guishan Dist., Taoyuan City 333, Taiwan

TEL: +886-3-327-2345

FAX: +886-3-318-4207

Email: MedicalService@quantatw.com

EU Representative



EU Representative: MedNet EC-REP GmbH

Address: Borkstrasse 10, 48163 Münster, Germany

Federal Communications Commission (FCC) Statement

The FCC ID is HFSCIE

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.

15.19

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- 1) This device may not cause interference and
- 2) This device must accept any interference, including interference that may cause undesired operation of the device.

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.

FCC RF Radiation Exposure Statement:

1) This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter. For body worn 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

Regulatory Marks

The QOCA PORTABLE ECG MONITORING DEVICE conforms to the following regulatory requirements.

Administrative Regulations on Low Power Radio Waves Radiated Devices (930322)





Article 12






Without permission granted by the NCC, any company, enterprise, or user is not allowed to change frequency, enhance transmitting power or alter original characteristic as well as performance to an approved low power radio-frequency devices.

Article 14

The low power radio-frequency devices shall not influence aircraft security and interfere with legal communications. If found, the user shall cease operation immediately until no interference is achieved. The said legal communications means radio communications is operated in compliance with the Telecommunications Act. The low power radio-frequency devices must be susceptible with

the interference from legal communications or ISM radio wave radiated devices.

	<p>CE Mark: Indicates that the body sensor has been certified and conforms to EC Directive 93/42/EEC on medical devices.</p>
	<p>Type applied part</p>
	<p>Indicates that the sensor is classified as electrical or electronic equipment requiring proper disposal (WEEE Directive)</p>
	<p>Indicates the manufacturer's catalogue number</p> <p>Attention: Catalogue number may also be referred to as the reference number or reorder number.</p>

	<p>Indicates the manufacture's serial number.</p>
	<p>Indicates the manufacturer's name and address</p>
	<p>To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.</p>
	<p>Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself</p>
	<p>Indicates the need for the user to consult the instructions for use.</p>

IP21	Protected against vertically dripping water
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Supplier's Declaration

The QOCA PORTABLE ECG MONITORING DEVICE conforms to the international EN 60601-1 and EN 60601-1-2 standards for electromagnetic compatibility with medical electrical devices and systems.

Manufacturer's declaration-electromagnetic emissions:-		
The <u>ecg1320</u> is intended for use in the electromagnetic environment (for home and professional healthcare) specified below:- The customer or the user of the <u>ecg1320</u> should assure that it is used in such an environment .-		
Emission test:-	Compliance:-	Electromagnetic environment-guidance :- (for home and professional healthcare environment):-
RF emissions CISPR 11:-	Group 1:-	The <u>ecg1320</u> uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment .-
RF emissions CISPR 11:-	Class B:-	The <u>ecg1320</u> is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes .-
Harmonic emissions :- IEC 61000-3-2:-	:- Not applicable:-	
Voltage fluctuations:- flicker emissions IEC 61000-3-3:-	:- Not applicable:-	

ME Equipment that intentionally receive RF energy shall include: frequency and/or band and bandwidth of receiving section

ME Equipment that include transmitters shall include frequency and/or band, modulation, and ERP

Recommended separation distance between portable and mobile RF communications equipment and the FCC/ICES			
The FCC/ICES is intended for use in an electromagnetic environment (for home and professional healthcare) in which calculated RF disturbance are controlled. The customer or the user of the FCC/ICES can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FCC/ICES as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter		
	150 kHz to 30 MHz at 1.2m	30 MHz to 100 MHz at 1.2m	100 MHz to 2.7 GHz at 1.2m
0.01	N/A	0.12	0.23
0.1	N/A	0.30	0.73
1	N/A	1.0	2.3
10	N/A	3.0	7.3
100	N/A	10	25
For transmitters rated at a maximum output power (varied above), the recommended separation distance (in meters [m]) can be estimated using this equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer.			
NOTE1: At 30 MHz and 100 MHz, the separation distance for the higher frequency range applies.			
NOTE2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

