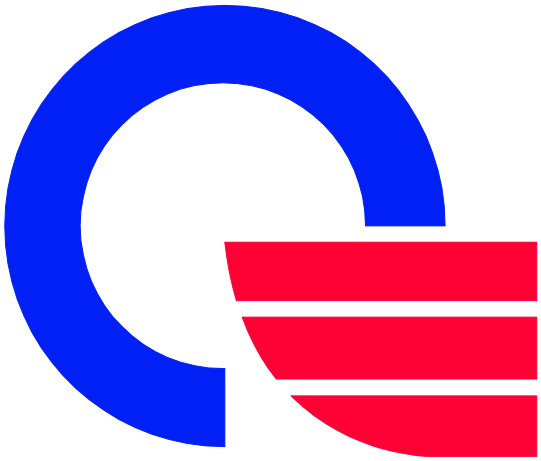


Quanta Computer

“QUANTA” PORTABLE ECG MONITORING DEVICE

User Manual

TABLE OF CONTENTS

SAFETY NOTES

- The “QUANTA” PORTABLE ECG MONITORING DEVICE is to be used for clinical assessment and personal reference only.
- The “QUANTA” 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 “QUANTA” 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. For more information, see Product Requirements.
- Do not allow the connectors or contacts on the device’s to come into contact with any kind of power source during use.
- Damaged or faulty accessories and electrodes should not be used.
- When the “QUANTA” PORTABLE ECG MONITORING DEVICE is low on battery power, it will automatically stop taking measurements and the corresponding indicator lights will blink. Please charge the sensor’s battery as soon as it shows a low battery state.
- Avoid using devices that can affect the accuracy of the readings when the “QUANTA” 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 “QUANTA” 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 Q-ECG App to see how to check if the device taking measurements normally.
- Do not use the “QUANTA” PORTABLE ECG MONITORING DEVICE near open flames, in excessive heat, extreme temperatures, moist, dust, or direct sunlight.
- When ambient temperature is 104°F – 113°F (40 – 45°C), do not use the “QUANTA” PORTABLE ECG MONITORING DEVICE because it may cause low-temperature burns.
- Users must purchase Sensor Holder、ECG electrodes or Body Patch separately when using the Sensor Holder or Body Patch. The specification can be found in ECG Electrode Information.
- Pay attention to ensure that the “QUANTA” 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 “QUANTA” 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.
- Please read through this user guide carefully before using “QUANTA” PORTABLE ECG MONITORING DEVICE.
- If “QUANTA” PORTABLE ECG MONITORING DEVICE must be used to take measurements over an extended period of time, please inspect the contact point of the electrodes at least once every 24 hours to make sure that the electrodes are in the right position and that there is no allergic reaction on the user’s skin.
- Do not use high-frequency instruments or electrical medical equipment such as defibrillators when using the “QUANTA” PORTABLE ECG MONITORING DEVICE.
- The “QUANTA” PORTABLE ECG MONITORING DEVICE can only take measurements while the subject is stationary (e.g., while sitting or lying down) or engaging in ordinary activity. Any activities not permitted by the attending physician may affect the accuracy of the measurements.
- Do not use “QUANTA” PORTABLE ECG MONITORING DEVICE in MRI or X-ray room.
- Do not clean the “QUANTA” PORTABLE ECG MONITORING DEVICE with corrosive or abrasive cleaning agents.
- The “QUANTA” 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 “QUANTA” 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 “QUANTA” PORTABLE ECG MONITORING DEVICE is replaced by an incorrect battery type.
- The “QUANTA” PORTABLE ECG MONITORING DEVICE ’s use is not intended for use with infants weighing less than 45lbs. (20 kg).
- The expected service life of the “QUANTA” PORTABLE ECG MONITORING DEVICE is 2 years.
- If you feel very itching or find redness when wearing the body patch, remove the body patch immediately.
- 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. “QUANTA” PORTABLE ECG MONITORING DEVICE is not suitable for use in an explosive environment.
- “QUANTA” 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, “QUANTA” 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 “QUANTA” PORTABLE ECG MONITORING DEVICE.
- When the ECG signal is always unstable, please contact the manufacturer.

PRODUCT OVERVIEW

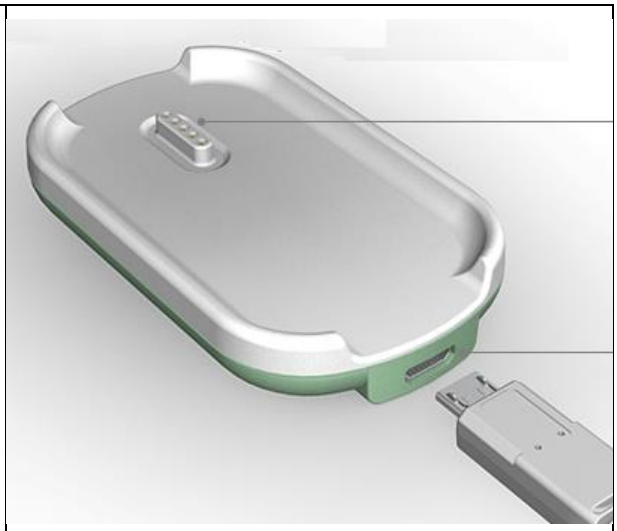
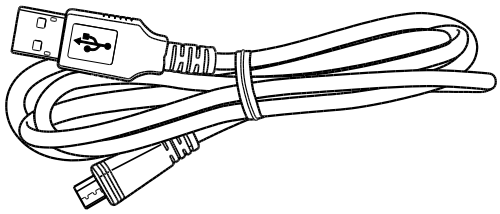
Indication for Use

The “QUANTA” PORTABLE ECG MONITORING DEVICE is intended for non-invasive measurement of a functional Electrocardiogram (ECG) and heart rate (HR) in hospitals, healthcare institutes, and home environments by trained medical professionals and trained adult. The “QUANTA” PORTABLE ECG MONITORING DEVICE will process ECG signals and calculate HR on continuous, spot check, or event record mode. Users can also add time tags to the ECG signals by pressing the button. ECG and HR data will be transferred to a smartphone via Bluetooth and displayed on the smartphone screen via a dedicated application called Q-ecg. The data can be further transferred to cloud server for storage.

The device should be worn on the human body along with a body patch or a sensor holder with gel electrodes. The “QUANTA” PORTABLE ECG MONITORING DEVICE is available to professional organizations such as home caregivers, clinics, or hospitals. It is not available to the general public. It should only be used by medical personnel or trained adult patients. Use by unauthorized users is not allowed.

Package Contents

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

	
ECG Sensor x 1	Charger x 1
	
USB Charging Cable x 1	User Manual x 1

Product Configurations

The following table lists the sensor related items included in the various packages available for the “QUANTA” PORTABLE ECG MONITORING DEVICE .

		Product Package	
Part Name	**Model Number**	**Q-ecg-wu2-K1**	**Q-ecg-wu2-K2**
“QUANTA” PORTABLE ECG MONITORING DEVICE	Q-ecg-wu2	✓	✓
Charger	Q-ecg-wu2-C1	✓	✓
USB Charging Cable	NA	✓	✓
Sensor Holder*	Q-ecg-wu2-P5 	✓	
Body Patch*	Q-ecg-wu2-P3 		✓

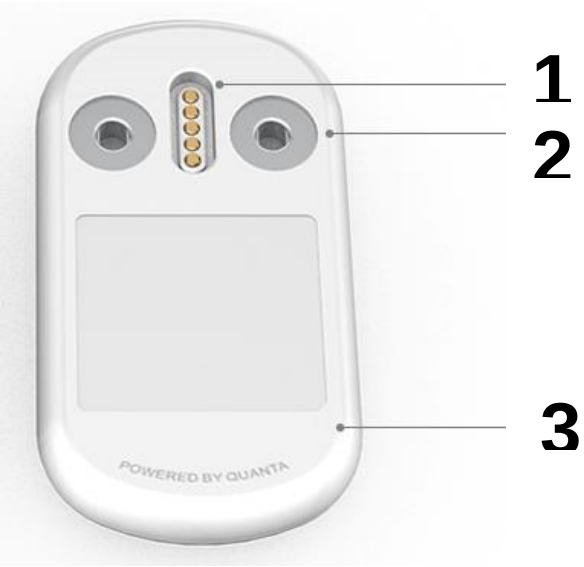
Components

Sensor

Front

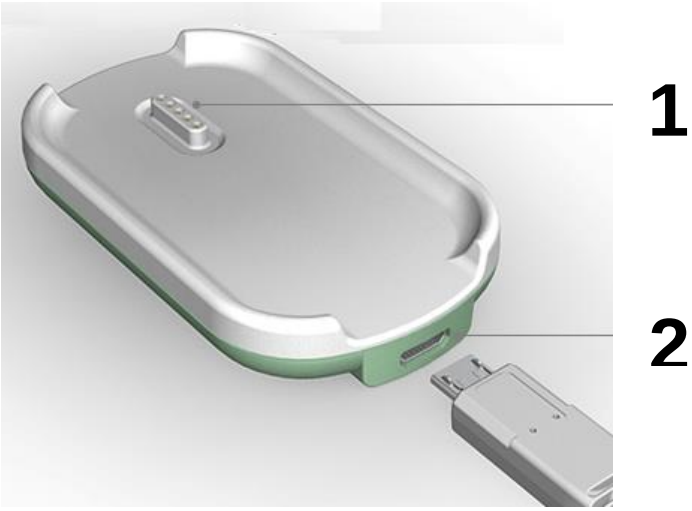
1	Power Button
2	Battery LED (see *LED Indicators* for more information)
3	Indicator LED (see *LED Indicators* for more information)

Back



1	Charging Contacts
2	Holder Connectors
3	Label Area

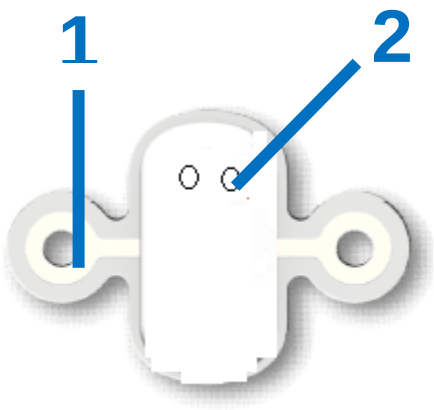
Charger



1	Charging Contacts
2	USB Charging Port

Body Patch

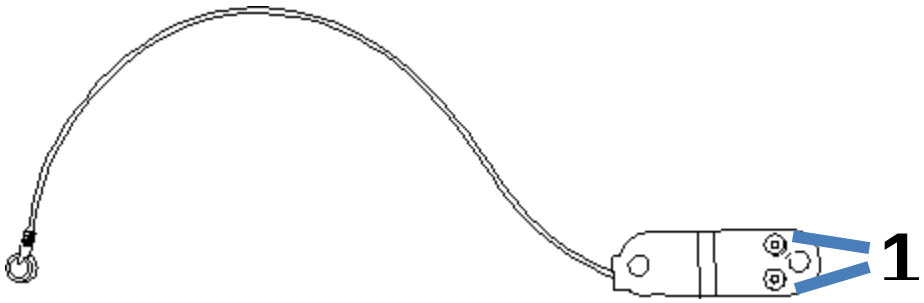
Front Exterior (with pocket closed)



1	Gel
2	Contact Point
Material	Made from Nonwoven
Length	124 mm

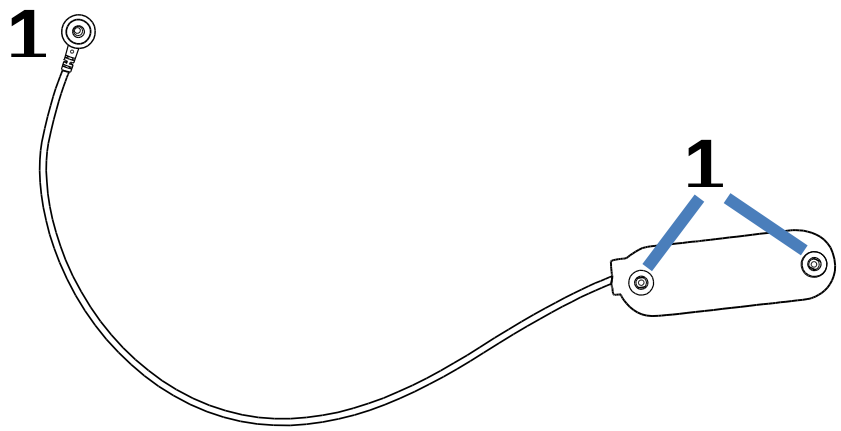
Sensor Holder & Cable

Front



1	Sensor Connectors
Material	Made from Polydefin Foam
Length	600 mm

Back



1	Electrode Connectors

IMPORTANT: If any damage to the wire shielding is found on the holder, replace immediately.

12-unit Charger (Charging 12 sensors at the same time)

Specification for Charger Dock:

Charging indicator	LED on Sensor
Working temp	5 ~ 35°C (Sensor working temp is 5 ~ 35°C when it is charging)
Storage temp	-20 ~ 60°C
Input	12V/2A
Size	241.3 mm * 166.4 mm * 66.25 mm

- *NOTE: 12-unit charger can only be used by trained person/adult.*

Product Requirements

In order to properly use the “QUANTA” PORTABLE ECG MONITORING DEVICE the following items are required:

For Body Patch:

- The ECG Sensor
- The Body Patch
- A Bluetooth-enabled Android Smartphone* (with Android version 5.x or above and a display resolution of 1920x1080 or 2560x1440) or iPhone (iOS 12 above)
- The ECG Sensor Q-ecg App*

** Items not included in the product package.*

For Sensor Holder & Cable

- The ECG Sensor
- The Sensor Holder & Cable
- 3 ECG Electrodes*

  NOTE: For more information on electrode specifications, see ECG Electrode Information.
- A Bluetooth-enabled Android Smartphone* (with Android version 5.x or above and a display resolution of 1920x1080 or 2560x1440) or iPhone (iOS 12 above)
- The ECG Sensor Q-ecg App*

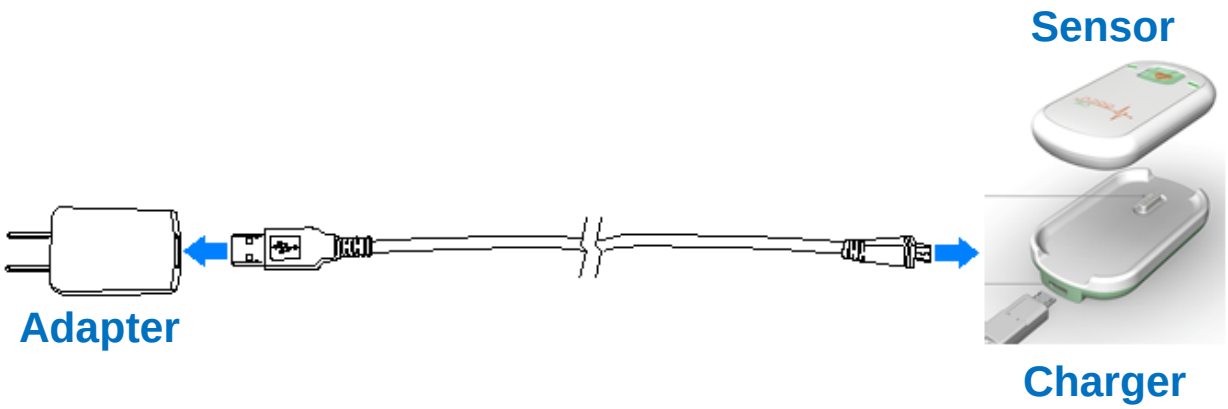
** Items not included in the product package.*

BEFORE YOU START

Before you start using the "QUANTA" PORTABLE ECG MONITORING DEVICE you must:

1. Charge the battery on the Sensor
2. Install the Q-ecg app on your smartphone
3. Enable Bluetooth on your smartphone

Charging the Battery



To charge the battery:

1. Plug the charger's AC adapter (with 5V/1A and conform to standard 60950) into a power source (i.e., wall outlet) and connect the charging cable. Connect the other end of the charging cable to the charger.
2. Place the sensor into the charger so that the sensor snaps into the charger and the charging contacts on both the sensor and charger make contact.
3. Allow the sensor to charge until the charging indicator light on the charger shows solid green. This indicates that the battery is fully charged.

Installing the App

To install the app, search for and download "Q-ecg" on Google Play Store or APP Store.

NOTE: In order to install the Q-ecg app your smartphone will need at least 5MB of storage capacity available.

Enabling Bluetooth

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

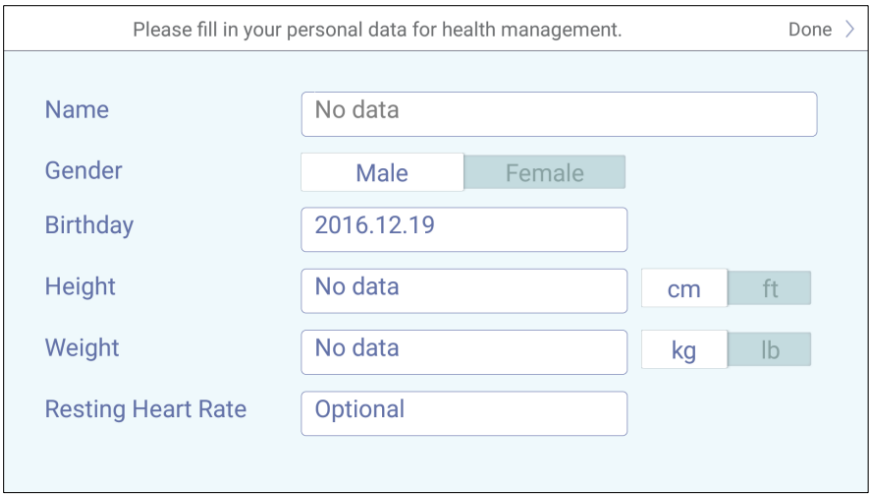
GETTING STARTED

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

1. Create a profile in the Q-ecg app
2. Pair your smartphone to the ECG sensor via Bluetooth
3. Wear the "QUANTA" PORTABLE ECG MONITORING DEVICE

Creating a Profile

The first time you launch the Q-ecg app you will need to create a profile. Fill in the following fields to create your profile:



- **Name**
- **Gender**
- **Birthday**
- **Height**
- **Weight**
- **[Optional] Resting Heart Rate**

  NOTE: When filling in your resting heart rate, you may ask a trained medical professional to measure your resting heart rate, or determine your resting heart rate by measuring your heart rate after at least 5 minutes of inactivity.

Once you have filled in your profile, tap **Done** to continue.

Pairing

After creating a profile, please enter the pairing page. To pair the sensor to your smartphone:

1. When enter the pairing page, it would show the nearby BLE devices. Please select the name “CIRXSXXXXXXX” which is the same as serial number on the back of sensor.
2. It takes a few seconds to do the pairing. Please wait for a while.
3. Wait until a message displays on your smartphone indicating that the pairing is complete.

NOTE: If pairing within the Q-ecg app fails (as shown below), please check the Bluetooth status on the smartphone.

Wearing the ECG Sensor

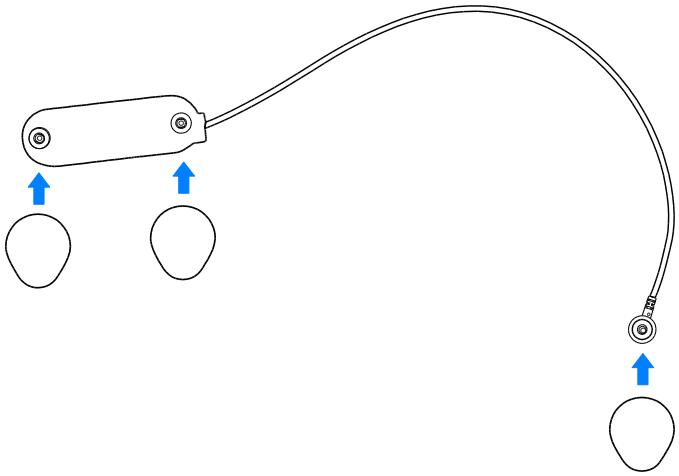
Depending on the model you have purchased, you may either wear the ECG sensor using the provided body patch, or wear the ECG sensor the sensor holder.

IMPORTANT: When wearing the ECG sensor directly you must use compatible electrodes (sold separately) for the device to work properly. For more information on electrode specifications see ECG Electrode Information.
IMPORTANT: If the skin at the contact point develops a rash, blisters, reddening, or other irritation, please contact a medical professional or physician.

Wearing the sensor holder

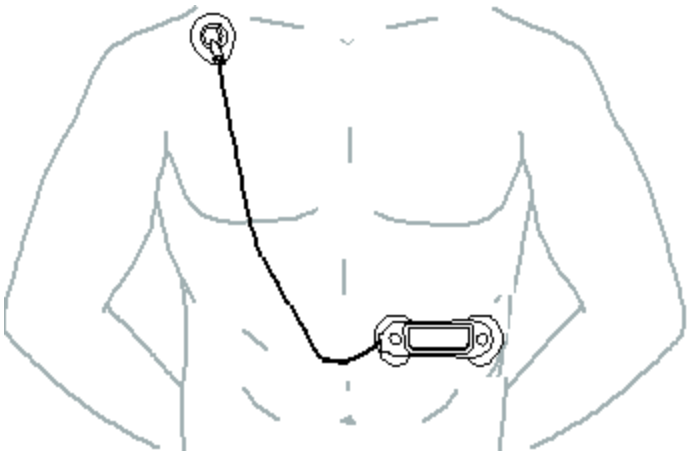
To wear the ECG sensor directly on your body, follow the directions below:

1. Attach an ECG electrode to each of the 3 connectors on the back of the sensor holder (see image below).
   NOTE: For more information on electrode specifications, see ECG Electrode Information*.*



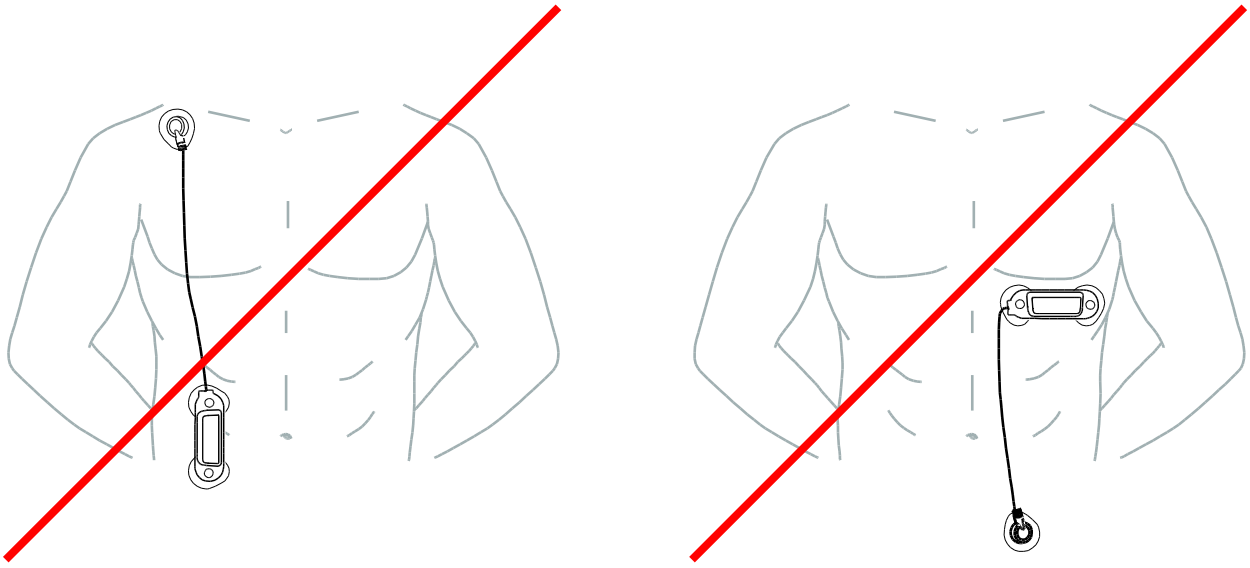
2. Attach the ECG sensor to the front of the sensor holder so that all four holder connectors on the sensor are properly clicked into the four sensor connectors on the holder (see image below).

   NOTE: Once connected, the status indicator on the sensor will light green then slowly flash indicating that the sensor is connected to the holder but that the holder has not properly made contact with a body.
3. Remove the paper backing on the contact side of each of the ECG electrodes.
4. Adhere the 2 electrodes located near the sensor under your left pectoral area (see image below).
   NOTE: The electrodes feature adhesive on the contact side to ensure secure contact with your body. If an electrode does not adhere securely, please replace it with a new electrode.
5. Adhere the electrode attached to the cable to the area under your right collarbone (see image below).



6. Once the ECG sensor is properly positioned on your body, wait half a minute then check the Q-ecg app to see if a real-time ECG reading is shown on the main screen on the app. If a real-time ECG is shown on the app, the ECG sensor has been properly worn.

<u>WARNING</u>: When wearing the ECG sensor directly on your body, ensure that all 3 electrodes are firmly adhered to your body. Ensure that no parts of the sensor holder are dangling (as shown below), which can lead to damage or cause the device to short-circuit if the electrodes comes into contact with the electrical contacts on another powered device.



Removing the ECG Sensor from the Holder

When removing the ECG sensor from the holder, always remove the sensor by holding the sensor and gently detaching it from the sensor holder, as shown below.
<u>WARNING</u>: Never remove the sensor by pulling the cable. This can damage the holder.

Wearing the body patch

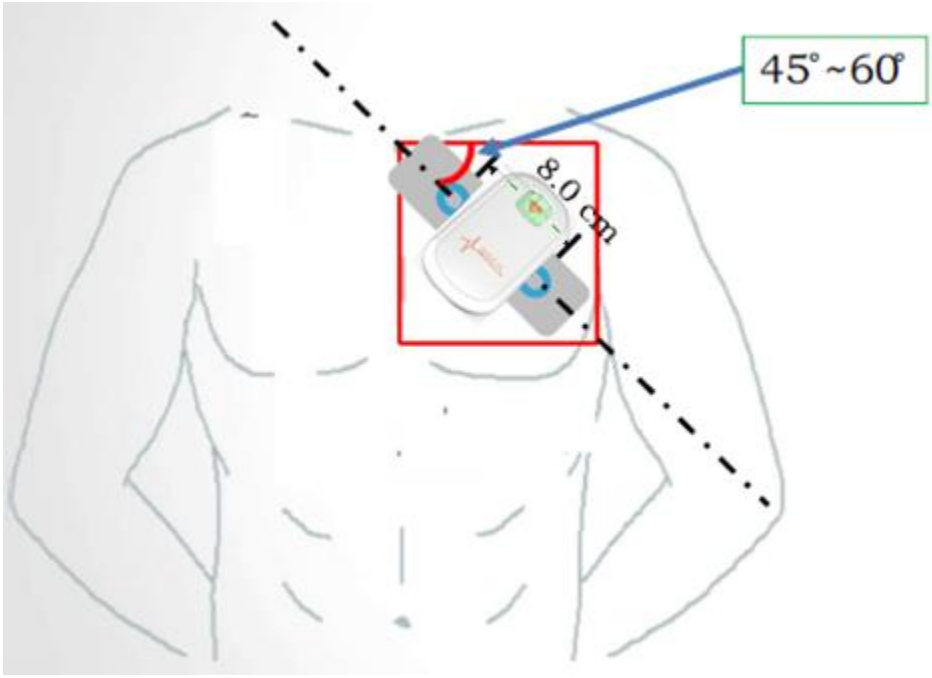
The following steps describe the body patch wearing process:

Step1. Attach the Device on the body patch before put on body.

Step2. Wipe with alcohol cotton on the left chest.

Step3. Left hand naturally put down.

Step4. Put body patch under clavicle with angle 45º ~ 60 º



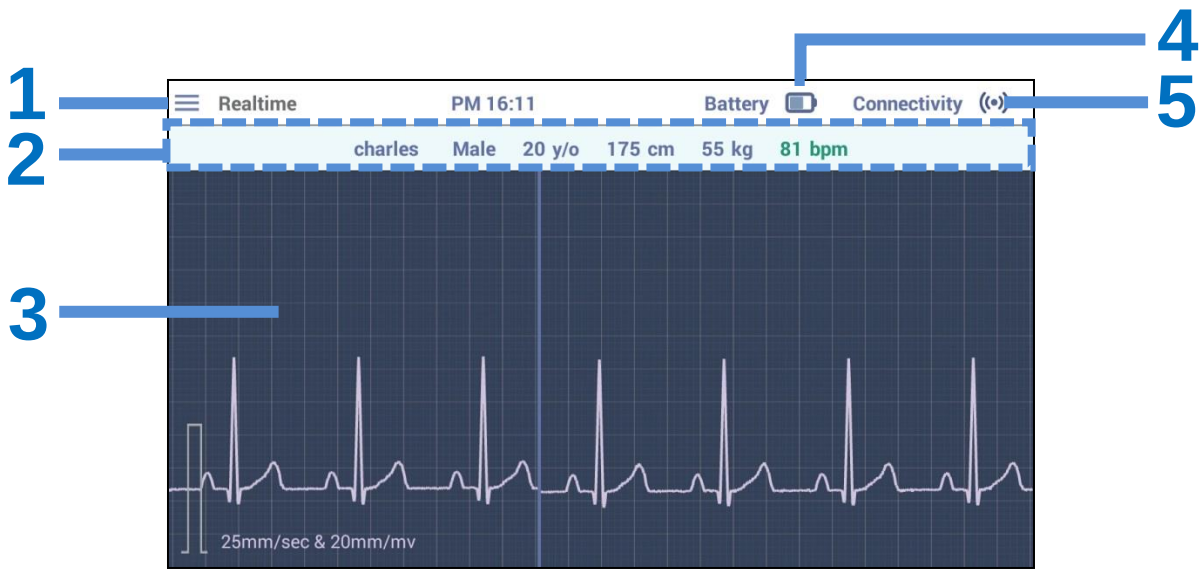
Step5. Hand pressure on the body patch (especially on the connect point) for 30 seconds.

IMPORTANT: The Patch needs 24 hours to fully stick to your skin, we recommend showering briefly with your back to the water, and avoid any activities that cause sweating during this period.

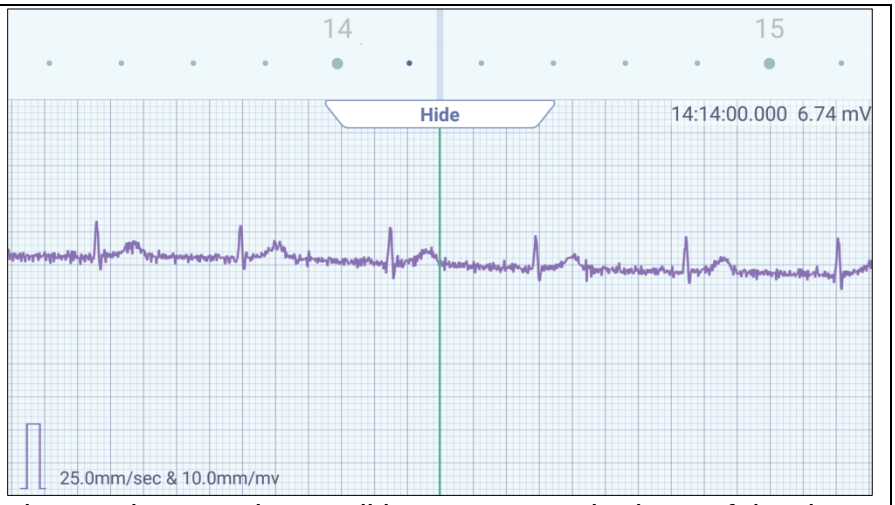
THE Q-ECG APP

Main Screen

Once you have successfully paired and worn the ECG sensor, the Q-ecg app's main screen will display on your mobile device. The main screen (shown below) displays a real-time ECG which should be shown to a medical professional for evaluation.



No	Item	Description
1	Menu Button	Tap to access the app menu. For more information see *Menu.*
2	Profile Settings	Displays the profile settings that were entered during the profile creation process. For more information on changing profile settings, see *Quick* Search Scroll Bar The quick search scroll bar allows you to quickly scroll to a different point in the ECG history by swiping left or right on the scroll bar.

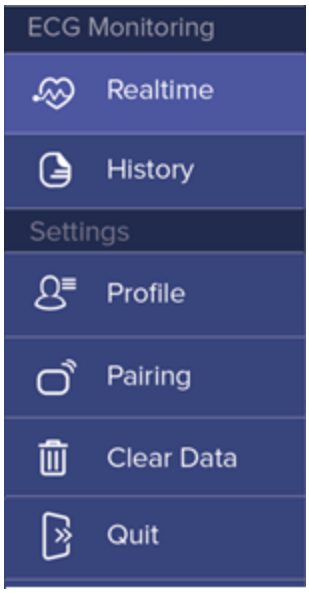
		 The numbers on the scroll bar represent the hour of the day shown, and each point on the scroll bar represents 10 minutes. Points on the scroll bar that are dark blue feature ECG readings. Tap **Hide** to return to the main toolbar for the History screen. Profile.
3	Real-Time ECG	Displays your real-time ECG in 5 second intervals.
4	Battery Status	Displays the current charge level of the battery.
5	Connection Status	Displays the connection status for the ECG sensor. If the ECG sensor becomes disconnected while in use, see *Pairing* for instructions on pairing your device.

NOTE: If the Bluetooth connection between the device and your smartphone is disconnected, the battery status icon will display a red question mark and the connectivity icon will display a red X, as seen in the image below.

NOTE: When using the Q-ecg app, the default "Back" button on your smartphone will become disabled. To exit the Q-ecg app, you must use the "Quit" button in the Q-ecg app's menu. For more information, see Quit.

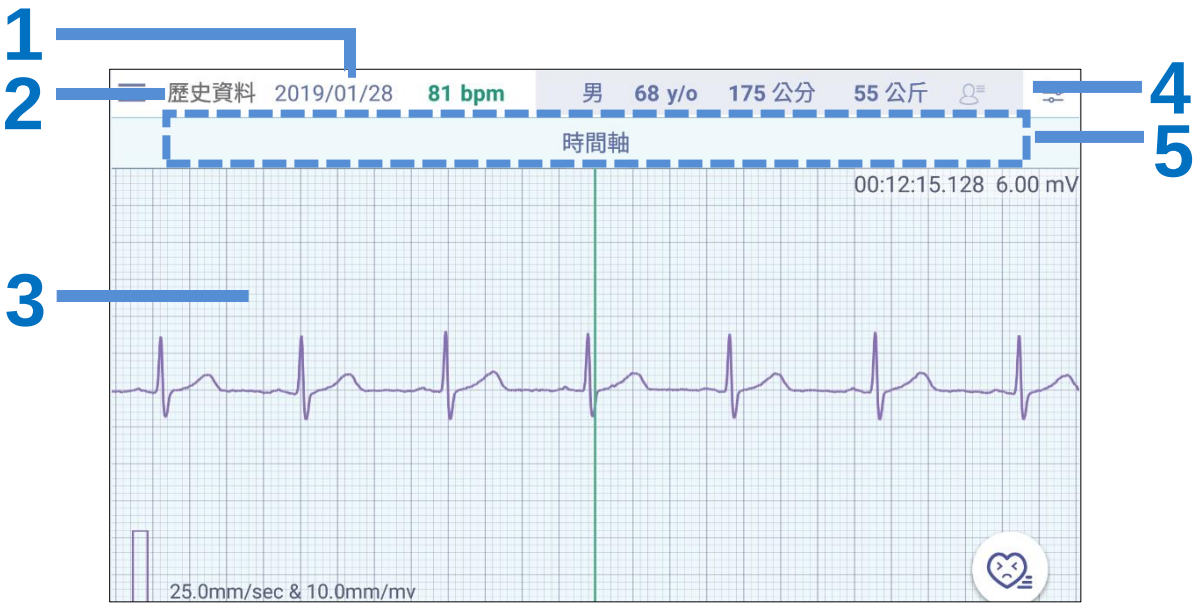
Menu

When you tap the menu button in the Q-ecg app's main screen, a menu will appear on the left side of the main screen. The menu allows you to view the real-time ECG reading, view ECG history, change profile settings, pair your ECG sensor to a smartphone, reset the Q-ecg app, or exit the Q-ecg app.


ECG Monitoring
Realtime
History
Settings
Profile
Pairing
Clear Data
Quit

History

Tap **History** in the Q-ecg app menu to view a scrollable and scalable ECG history. The following items can be found on the ECG history screen:

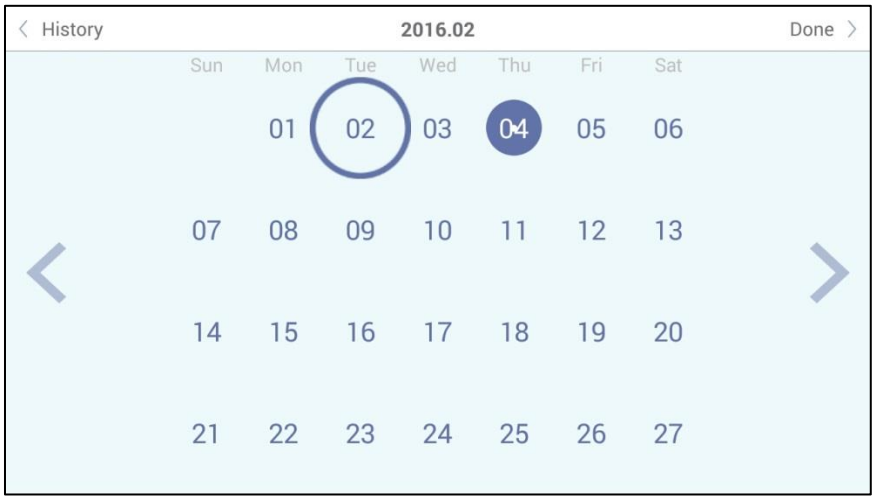


No	Item	Description
1	Date Button	Tap to view an ECG from a different date. For more information, see Date.
2	Menu Button	Tap to access the app menu.
3	ECG History	Tap to display your ECG history. Swipe left or right to move to forward or backward in your ECG history.
4	Display Options Button	Tap to adjust/rescale the view of the ECG history. For more information, see *Display Options*.
5	Quick Search Button	Tap to open the quick search scroll bar, see *Quick Search Scroll Bar*.

Date

When you tap the date button in the History screen, a calendar view will appear. Dates on which you recorded an ECG are circled. Tap on a circled date to view your ECG on days when an ECG data from that day.

NOTE: The Q-ecg app stores ECG data for up to 7 days.



Display Options

The ECG displayed on the Q-ecg app is displayed on a graph, on which the horizontal axis measures time (in seconds), and the vertical axis measures the electrical activity (in millivolts). Adjust the display options for the ECG history for a more detailed or a more general view of the ECG data. The following display options are available when viewing the ECG history:

- **Speed**: Using a lower speed option will shrink the ECG along the horizontal axis of the grid, and using a higher speed option will expand the ECG along the horizontal axis of the grid.

- **Sensitivity**: Using a lower sensitivity option will shrink the ECG along the vertical axis of the grid, and using a higher sensitivity option will expand the ECG along the vertical axis of the grid.

Quick Search Scroll Bar

The quick search scroll bar allows you to quickly scroll to a different point in the ECG history by swiping left or right on the scroll bar.

The numbers on the scroll bar represent the hour of the day shown, and each point on the scroll bar represents 10 minutes. Points on the scroll bar that are dark blue feature ECG readings.

Tap **Hide** to return to the main toolbar for the History screen.

Profile

Tap **Profile** in the Q-ecg app menu to change the profile settings used in the Q-ecg app. Follow the same instructions in *Creating a Profile* to change the profile settings.

Pairing

Tap **Pairing** in the Q-ecg app menu to pair/re-pair the ECG sensor to a smartphone. Follow the instructions in described in *Pairing* to pair the ECG sensor to a smartphone.

Setting

It is able to set ECG sensor in different mode. But this feature is not open for user, only for special group. Please contact us, if you need this function.

Clear Data

Tap **Clear Data** in the Q-ecg app to clear the profile settings, ECG history, and pairing information saved in the smartphone only. After clearing the data the user will need to pair the smartphone to the ECG sensor again by following the steps described in *Pairing*.

NOTE: If you upload ECG data to a smartphone with the double-sided Micro-USB cable and receive a system message stating the USB device is not recognized by the system, you will need to reset the sensor by tapping ***Reset Device****.*

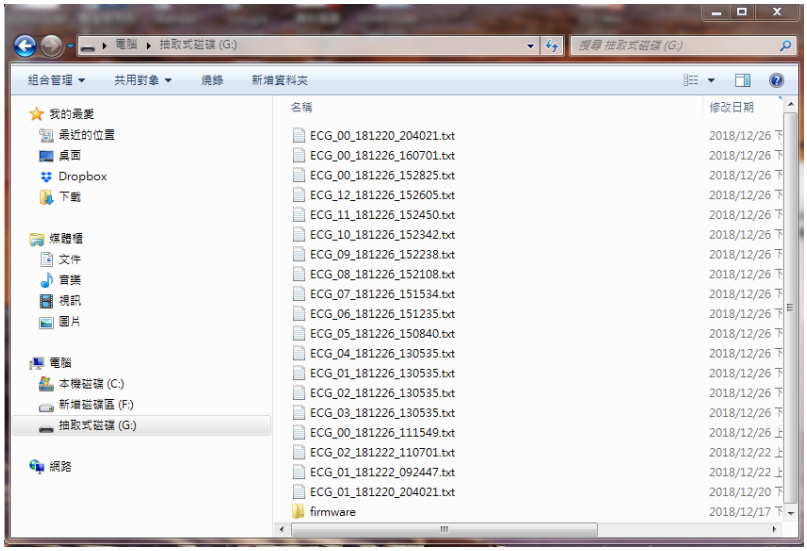
Quit

Tap **Quit** in the Q-ecg app to exit the app.

Measuring ECG when Bluetooth is Disconnected

The device is designed with embedded storage so that after initial setup is complete if the Bluetooth connection between the sensor and the smartphone is disconnected, the ECG data will still be stored in the device's embedded storage. In these situations once the Bluetooth connection is restored, the ECG data will be automatically transferred to your smartphone and displayed in the History screen. See *History* for more information.

You can also retrieve the ECG data stored in the device's embedded storage by physically connecting the sensor directly to the PC using the Micro-USB cable included in the package. Blow is ECG data stored in the device.



ADDITIONAL INFORMATION

LED Indicators

The following tables describe the indicators on both the sensor and charger:

Sensor Status Indicator

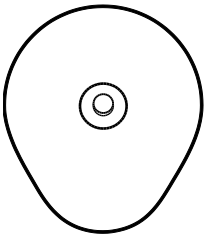
Event	Action	Behavior
Power on	Press power button	• Both Battery LED & Indicator LED flashing green 3 times
Power off	Long press power button for 10 seconds	• Solid blue light for both Battery LED and Indicator LED while press the button • After 5 seconds turn off lights
Lead off	User do not wear device	• Indicator LED flashing orange light
Event Recording	When it's lead on and press power button	• Indicator LED flashing blue light
Low battery	N/A	• Battery LED flashing orange light
Charging	Put on charger	• Battery LED flashing blue light
Fully charged	Put on charger	• Battery LED solid blue light
USB connected	Plug sensor to USB	• Indicator LED with solid blue light

Cleaning

The table below describes the appropriate cleaning methods for each item included with the "QUANTA" PORTABLE ECG MONITORING DEVICE :

Item	Cleaning Method
Sensor	Wipe with a dry cloth when it's dirty. And clean it every day if it is frequently used.
Charger	Wipe with a dry cloth when it's dirty. And clean it every day if it is frequently used.
Sensor holder	Carefully wipe with a dry cloth when it's dirty. And clean it every day if it is frequently used.

ECG Electrode Information



When using the Sensor Holder for the "QUANTA" PORTABLE ECG MONITORING DEVICE, you must use compatible electrodes (sold separately) for the ECG sensor to work properly. Suggested electrodes include Kendall Ag/AgCl electrodes, or any electrodes that meeting the following specifications:

- **Adapter:** Stud
- **Biocompatibility:**
  ISO 10993 approved
  Latex free
- CE Mark according to MDD93/42/EEC CE Marked
- FDA certified

Specifications

Sensor Specifications

ECG Sensor	Continuous ECG data acquisition and calculation
	Measuring Lead: Lead 2 Frequency Response: Monitor 0.1 to 40 Hz (-3db) Heart rate measurement range*: 30 – 240 bpm** Heart rate accuracy: ± 3 bpm or ±3% whichever is greater Differential Input Impedance: > 10MΩ Common Mode Rejection Ratio: > 70 dB Sampling rate: default at 256Hz **Heart rate is calculated based on the R-R interval of the ECG.* *** If the heart rate falls out of the 30 – 240 bpm range, the Q-ecg app will display "--".*
Activity Detection	Activity Status detection by G-sensor G-sensor (3 axis): ±8g G-sensor sampling rate: 52Hz G-sensor accuracy: ±0.0156g
Energy Expenditure	Calculated from HR and activity data
Lead-off Detection	Detect when the sensor gets loosened from holder or body

	patch
Data Transmission	(1) Bluetooth BLE 4.2: Transmit distance: 10 meters (open space) (2) Micro USB cable
USB	USB2.0
Battery	3.7V/600mAh
Battery Life	Storage mode: 14 Days @ 250 Hz sample rate
Working Temperature / Humidity	5 – 45^{0}C, 10% – 95% non-condensing
Storage Temperature / Humidity	-20 – 60^{0}C, 10% – 95% non-condensing
Atmospheric Pressure Range	800 hPa to 1013 hPA
Altitude	2000m
Enclosure Rating	IPX6
Weight	28.8 ± 0.5 g
Dimension	68 mm (L) x 37.3 mm (W) x 10.8 mm (H) ±0.2 mm

Charger Specifications

Input	5V/0.5A
Working Temperature	5 – 35°C
Storage Temperature	-20 – 60°C
Weight	23 ± 0.5 g
Dimension	72.8 mm (L) x 42.1 mm (W) x 12.5 mm (H) ±0.2 mm

Troubleshooting

1) **Cannot pair the "QUANTA" PORTABLE ECG MONITORING DEVICE with the Q-ecg app.**
   Refer to the notes listed in *Pairing*.

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: MedicalSales@quantatw.com

EU Representative

EC REP

EU Representative: MedNet GmbH
Address: Borkstrasse 10, 48163 Münster, Germany

Label Information:

SN: CIRXW17100AF

In the serial number on the product label, the 6th and 7th character starting from the left represents the year of manufacture, while the 8th and 9th character represents the week of manufacture. In the example shown the "17" represents a manufacture year of 2017 and the "10" represents the 10th week of 2017.

Federal Communications Commission (FCC) Statement

The FCC ID is HFSCIR.

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.

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 "QUANTA" 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.

CE 0120	CE Mark: Indicates that the body sensor has been certified and conforms to EC Directive 93/42/EEC on medical devices.
	Type applied part
	Indicates that the body sensor is classified as electrical or electronic equipment requiring proper disposal (WEEE Directive)
REF	Indicates the manufacturer's catalogue number **Attention: Catalogue number may also be referred to as the reference number or reorder number.**
SN	Indicates the manufacture's serial number.
	Indicates the manufacturer's name and address
	To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.
	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
	Indicates the need for the user to consult the instructions for use.

Supplier's Declaration

The Quanta "QUANTA" 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 Q-ecg-wu2 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the Q-ecg-wu2 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 Q-ecg-wu2 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 Q-ecg-wu2 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	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Compliance	

Manufacturer's declaration-electromagnetic immunity The Q-ecg-wu2 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the Q-ecg-wu2 should assure that it is used in such an environment.			
Immunity test	**IEC 60601** **test level**	**Compliance level**	**Electromagnetic environment-guidance (for home and professional healthcare environment)**
Electrostatic discharge(ESD) IEC 61000-4-2	Contact:±8 kV Air±2 kV,±4 kV,±8 kV,±15 kV	Contact:±8 kV Air±2 kV,±4 kV,±8 kV,±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines Not applicable	Mains power quality should be that of a typical home healthcare environment.
Surge IEC 61000-4-5	± 0.5kV, ±1kV line(s) to line(s) ± 0.5kV, ±1kV,± 2kV line(s) to earth	± 0.5kV, ±1kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical home healthcare environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % U_T; 0,5 cycle 0 % U_T; 1 cycle 70 % U_T; 25/30 cycles Voltage interruptions: 0 % U_T; 250/300 cycle	Voltage dips: 0 % U_T; 0,5 cycle 0 % U_T; 1 cycle 70 % U_T; 25 cycles Voltage interruptions: 0 % U_T; 250 cycle	Mains power quality should be that of a typical home healthcare environment. If the user of the Q-ecg-wu2 requires continued operation during power mains interruptions, it is recommended that the Q-ecg-wu2 be powered from an uninterruptible power supply or a battery.
Power frequency(50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz	The Q-ecg-wu2 power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Manufacturer's declaration-electromagnetic immunity			
The Q-ecg-wu2 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the Q-ecg-wu2 should assure that it is used in such and environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance (for home and professional healthcare environment)**
Conducted RF IEC 61000-4-6	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz	**Portable and mobile RF communications** **equipment should be used no closer to any part of the** Q-ecg-wu2 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ 80MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800MHz to 2,7 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	80 % AM at 1 kHz 10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	80 % AM at 1 kHz 10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	
NOTE1 At 80 MHz and 800 MHz, 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.			

Recommended separation distance between portable and mobile RF communications equipment and the Q-ecg-wu2			
The Q-ecg-wu2 is intended for use in an electromagnetic environment (for home and professional healthcare) in which radiated RF disturbances are controlled. The customer or the user of the Q-ecg-wu2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Q-ecg-wu2 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** **m**		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1,2\sqrt{P}$	**800 MHz to 2,7 GHz** $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the 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 80 MHz and 800 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.			

Bluetooth Technical Specification:

Technical Specification	Value
Operating Frequencies	2402~2480MHz
Channel Spacing	2MHz
Channel number	40
Operating Voltage	3.3V
Modulation	GFSK
Antenna Gain	FPC Antenna, Peak Gain: 1.87 dBi
Rated Power (ERP)	3.76 dBm

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The Q-ecg-wu2 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the Q-ecg-wu2 should assure that it is used in such an environment.

Test frequency (MHz)	**Band** [a] (MHz)	**Service** [a]	**Modulation** [b]	**Maximum power** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)	**Compliance LEVEL** (V/m) (for home and professional healthcare)
385	380 –390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28	28
870							
930							
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3	Pulse modulation b) 217 Hz	2	0,3	28	28
1 845							
1 970							
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9
5 500							
5 785							

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.