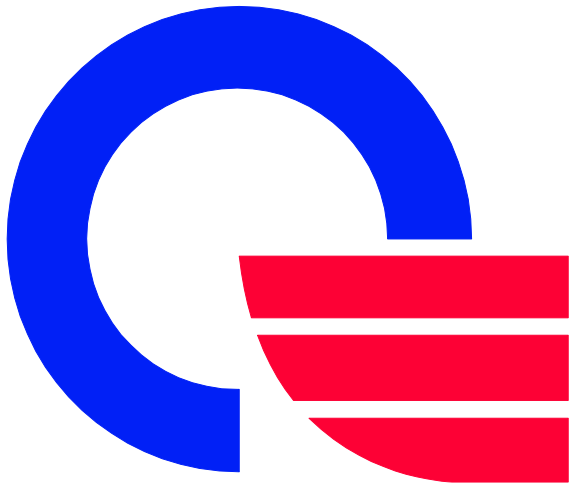

Quanta Computer

QOCA PORTABLE ECG MONITORING DEVICE
User Manual

CI9418-01 Ver.: 3A

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SAFETY NOTES

- 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 body patch. The use of accessories and body patch 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 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 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 make sure the QOCA PORTABLE ECG MONITORING DEVICE continues to take measurements normally. See The QOCA ecg APP to see how to do device test.
- Do not use the QOCA PORTABLE ECG MONITORING DEVICE near open flames or in excessive heat.
- When ambient temperature is 104°F – 113°F (40 – 45°C), do not use the QOCA PORTABLE ECG MONITORING DEVICE because it may cause low temperature burns.
- Pay attention to ensure that the QOCA PORTABLE ECG MONITORING DEVICE is not swallowed by pets or children.
- 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.

- Please read through this user guide carefully before using QOCA PORTABLE ECG MONITORING DEVICE.
- If QOCA PORTABLE ECG MONITORING DEVICE must be used to take measurements over an extended period of time, please inspect the contact point of the body patch at least once every 24 hours to make sure that the body patch is in the right position and that there is no allergic reaction on the user's skin.
- Do not use the QOCA Portable ECG Monitoring Device in combination with external cardiac defibrillators or high frequency surgical equipment near strong magnetic fields or devices such as MRI.
- The QOCA 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 expose QOCA PORTABLE ECG MONITORING DEVICE to extreme temperatures, extremely moist environments, dust, or direct sunlight.

- The ECG sensor should be cleaned before providing to another patient. Please follow the cleaning instruction in this manual. 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 QOCA PORTABLE ECG MONITORING DEVICE is NOT intended for use on patients weighing less than 45lbs (20 kg). It is intended for use on adult patients only.
- The expected service life of the QOCA 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.

- Do not use QOCA PORTABLE ECG MONITORING DEVICE in MRI or X-ray room.
- 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.
- The body patch is a single-use part.

- Tear open the body patch bag only when it is time to wear the body patch. Once the body patch bag is opened, wear the body patch as soon as possible.
- Re-use of the body patch will decrease its adhesion and cause incorrect ECG and heart rate measurement.
- Do not use the body patch if the user is allergic to hydrogel or tape adhesive.
- The body patch should be placed on patients by trained medical personnel.
- The wear time of the body patch is up to 5 days. The wear duration may decrease by improper placement or differ by individual skin condition and activity level. We suggest users avoid sweating to extend the wearing time.
- Before wearing the body patch, the applied skin area should be properly prepared by following the steps described in Wearing the ECG Sensor section.
- Do not submerge, bath, or swim with QOCA Portable ECG monitoring device and the body patch.
- Do not apply any lotion or skin care products on applied area.
- Remove the body patch with cautions and do not damage the skin. If the skin at the contact point develops a rash, blisters, reddening, or other irritation, please contact a medical professional or physician.

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.

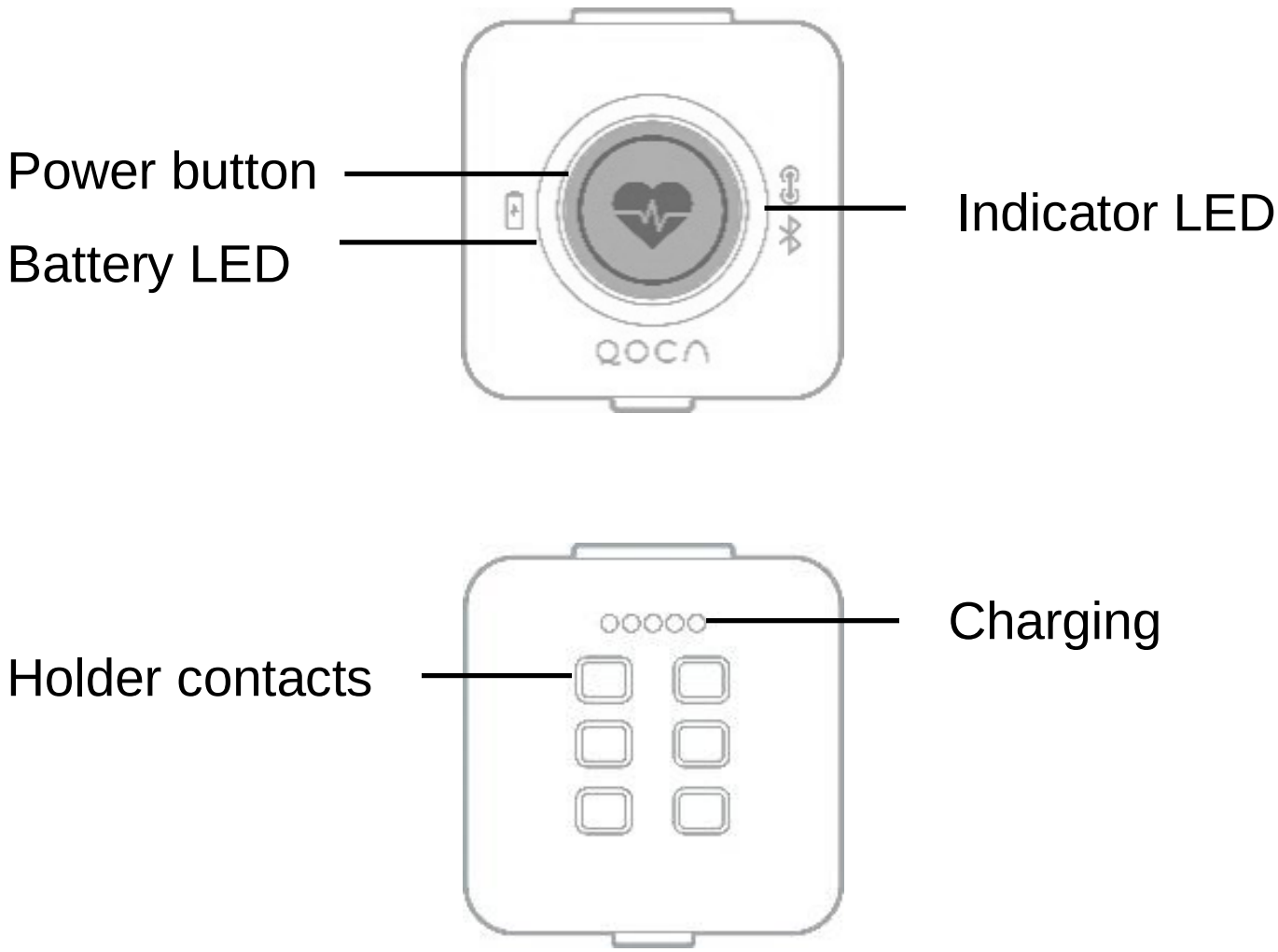
Package Contents

Component	Model	Quantity
Sensor	ecg901	1pc
Charger*	CR6P	1pc
USB charging cable*	NA	1pc
Body patch*	ecg901-P1	1 set
Main patch	ecg901-P1a	
Chest lead patch	ecg901-P1b	
Sensor cable	ecg901-P1c2 ecg901-P1c4 ecg901-P1c5	
Abrader disc*	NA	1pc

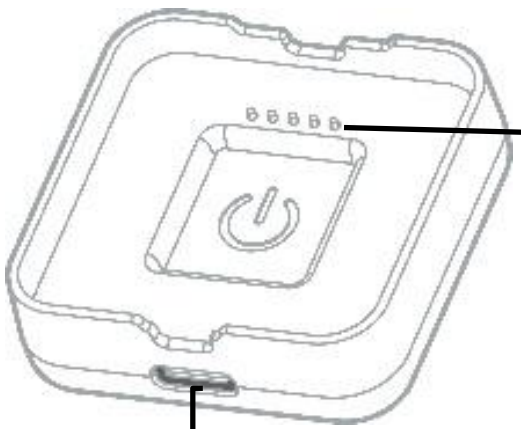
*The items marked with * are optional. Contact manufacturer for procurement.

Components

Sensor (ecg901)



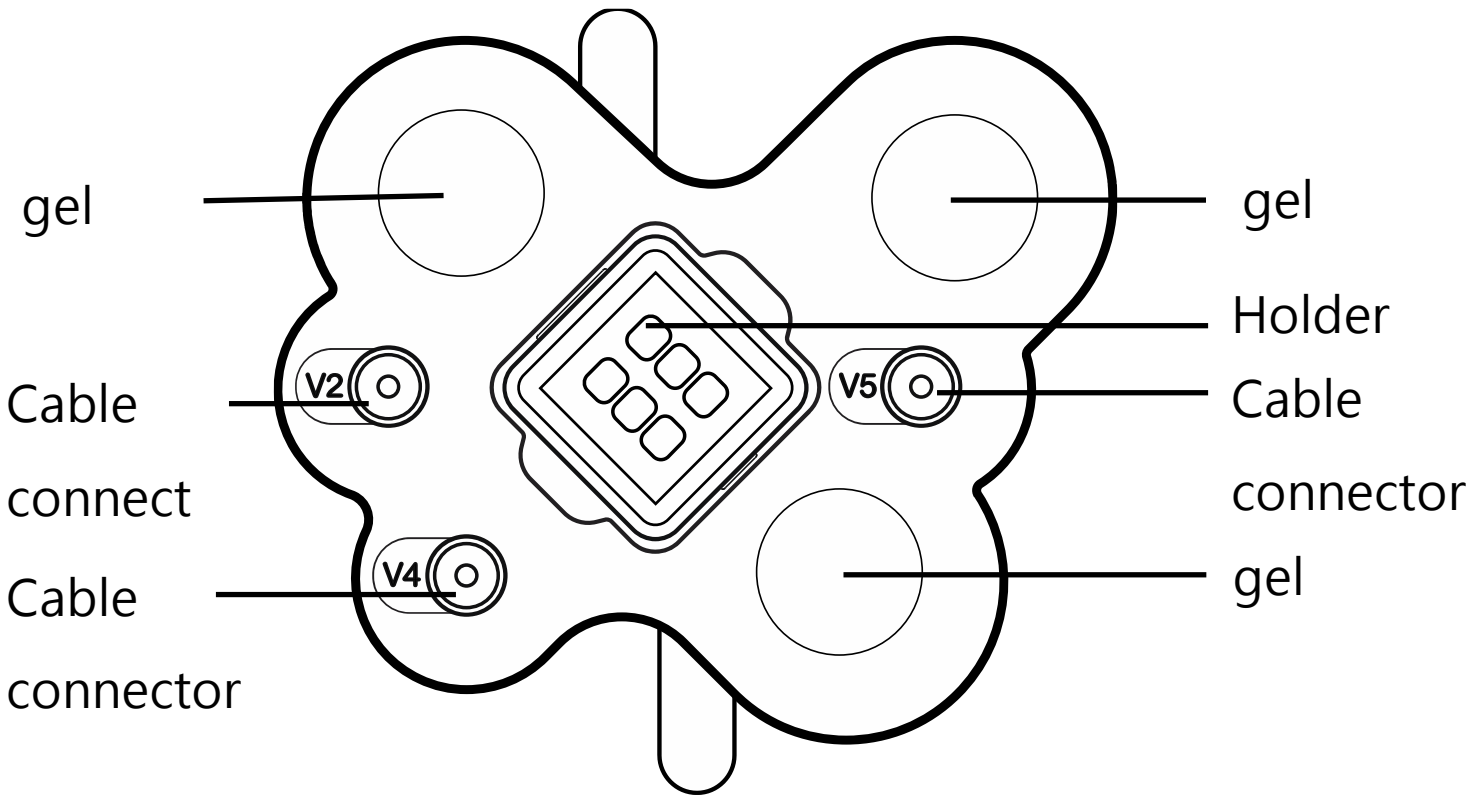
Charger(CR6P)



Body Patch (ecg901-P1)

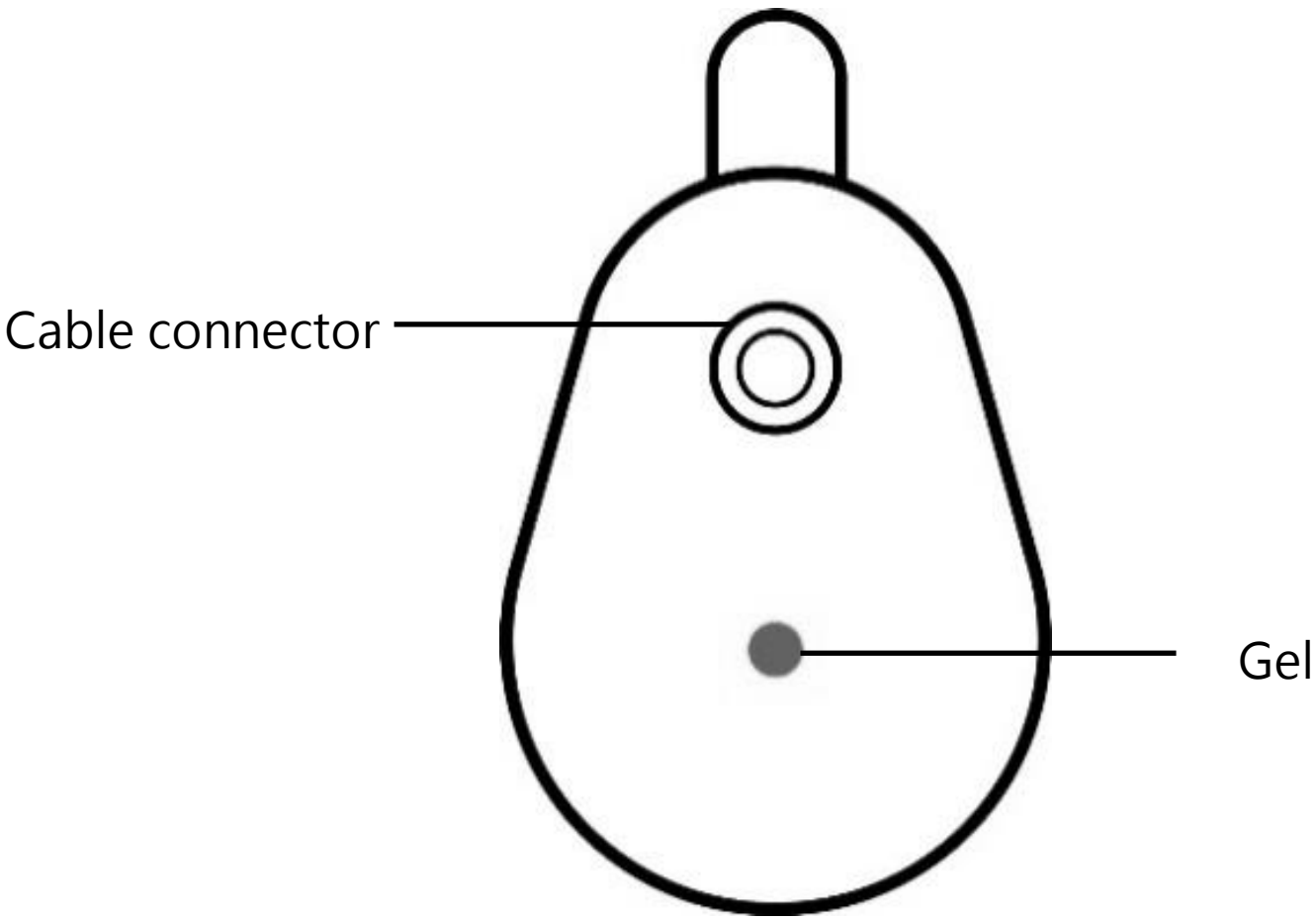
Main patch (ecg901-P1a)

Material：Nonwoven



Chest lead patch (ecg901-P1b)

Material：Nonwoven



Sensor cable (ecg901-P1c2/ ecg901-P1c4/ ecg901-P1c5)

Patch connector Patch connector

**Note: Please follow the table below to connect the right sensor cable to the chest leads.*

Lead	*V2*	*V4*	*V5*
Model	*ecg901-P1c2*	*ecg901-P1c4*	*ecg901-P1c5*
Connector color	*yellow*	*blue*	*orange*

Product Requirements

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

- The ECG Sensor
- The Body Patch
- Android Smartphone* with Android version 10 or above, BT5.0 or above, and a display resolution of 1920x1080 or above.
- iPhone* with iOS 13.0 (or above)
- The 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. Charge the battery on the Sensor
2. Install the QOCA ecg APP on your smartphone
3. Enable Bluetooth on your smartphone

Charging the Battery

To charge the battery:

1. Use an AC adapter conforming to standard IEC 60601-1 與 IEC 62368-1 class II) with a USB-C interface to connect the charger or connect the charger to PC by the provided USB-C cable. ***AC adaptor part is not included in the package. Please must use compatible AC adaptor***.
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 blue. This indicates that the battery is fully charged.

Installing the App

To install the app, search for and download “QOCA ecg APP” on Google Play Store or Apple Store.

NOTE: In order to install the QOCA 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.

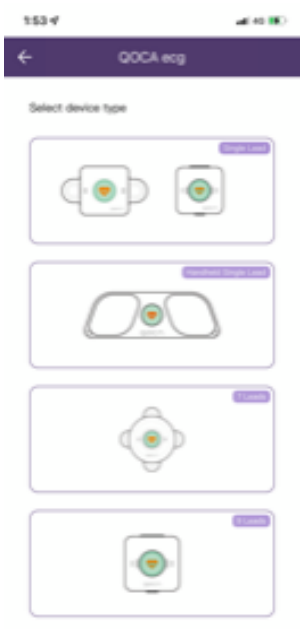
GETTING STARTED

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

1. Pair your smartphone to the QOCA PORTABLE ECG MONITORING DEVICE via Bluetooth
2. Wear the QOCA PORTABLE ECG MONITORING DEVICE

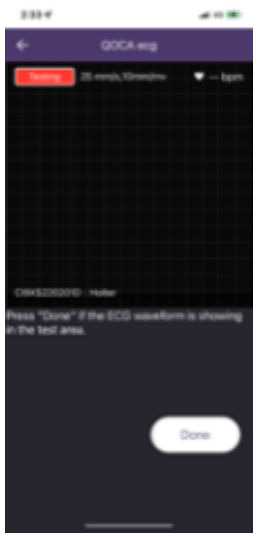
Pairing

Launch the QOCA ecg App and choose sensor type to pair the sensor to your smartphone:



1. After selecting CI9 (9-lead), it would show the nearby CI9 devices. Please select the name “CI9XSXXXXXXX” which is the same as serial number on the back of sensor.
2. After selecting the device number, the App will pop out message requesting to press power button on CI9 within 10 seconds (the LED on CI9 will flash blue in the meantime).

3. After pairing, the App will guide you to do device test. Click Complete when the test is done.



4. After test is done, the App will return to the page as illustrated below.

Note: At this moment the sensor is not yet applied to the body. Once your fingers are released from the sensor, the QOCA ecg app should pop up lead-off notification on the screen. This notification will go off once the sensor is worn on body.

Wearing the ECG Sensor

IMPORTANT:

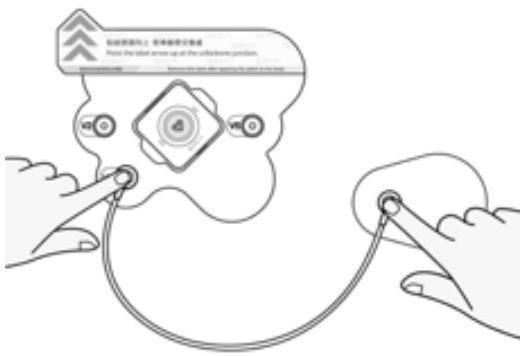
- *Tear open the body patch bag only when it is time to wear the body patch. Once the body patch bag is opened, wear the body patch as soon as possible.*
- *The body patch is a single-use part.*
- *Re-use of the body patch will decrease its adhesion and cause incorrect ECG and heart rate measurement.*
- *Do not use the body patch on non-intact skin.*
- *Do not use the body patch if the user is allergic to hydrogel or tape adhesive.*
- *The body patch should be placed on patients by trained medical personnel.*
- *The wear time of the body patch is up to 5 days. The wear duration may decrease by improper placement or differ by individual skin condition and activity level. We suggest users avoid sweating to extend the wearing time.*
- *Before wearing the body patch, the applied skin area should be properly prepared by following the steps described in Wearing the ECG Sensor section.*
- *Do not submerge, bath, or swim with QOCA Portable ECG monitoring device and the body patch.*

- *Do not apply any lotion or skin care products on applied area.*
- *Remove the body patch with cautions and do not damage the skin. If the skin at the contact point develops a rash, blisters, reddening, or other irritation, please contact a medical professional or physician.*

Step 1.

（1）. Install the sensor on the body patch before putting on body. The heart mark tip should point down right side.

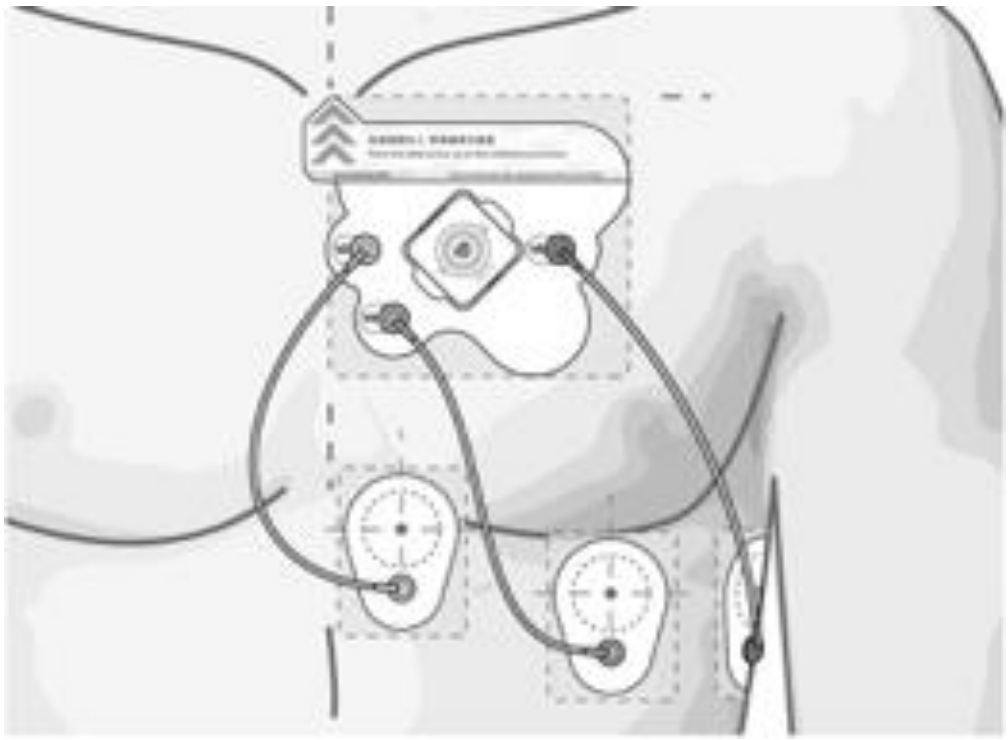
（2）. Connect main patch and chest lead patch with the sensor cable. V2(yellow)/V4(blue)/V5(orange)



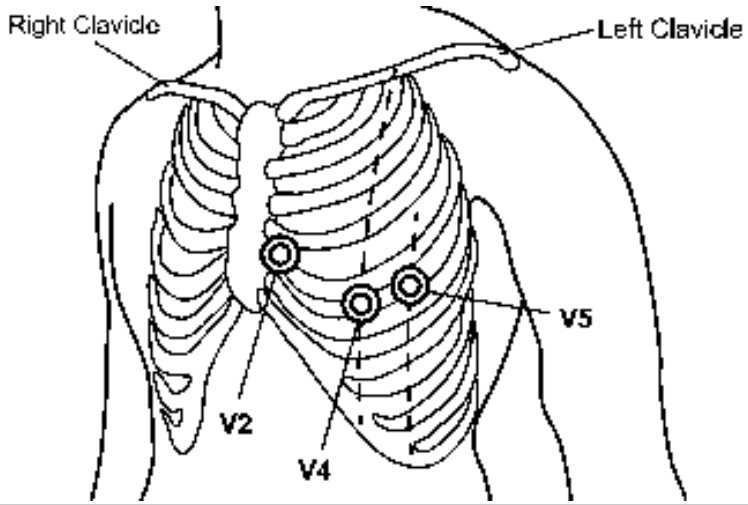
（3）. If the sensor is powered off, press the power button until the LEDs flashes green and then release the button (After powered on, the LED “⛓”will keep flashing orange until the patch is well attached to user body.

Step 2. Prepare the skin of applied area

（1）. Confirm the applied main patch area. A. Point the main patch label arrow up towards the collarbone junction. B. Make sure ECG heart mark tip point down right side.



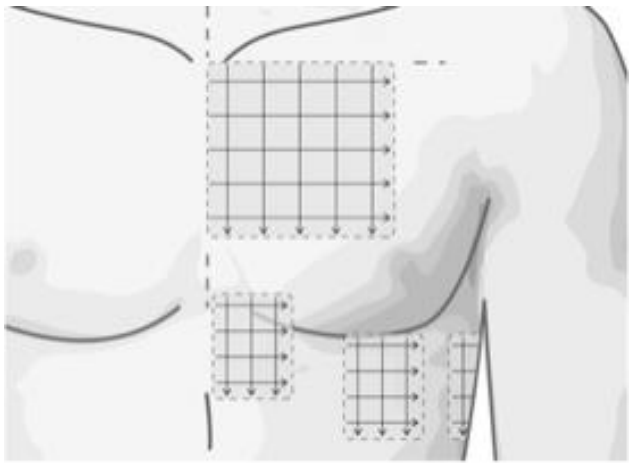
Confirm the applied chest lead area (V2/V4/V5 illustrated as follows.)



Chest Lead	location
V2	Fourth intercostal space at the left sternal border
V4	Fifth intercostal space in the midclavicular line
V5	Left anterior axillary line on the same horizontal plane as V4.

（2）. Remove body hair in the area of patch placement.

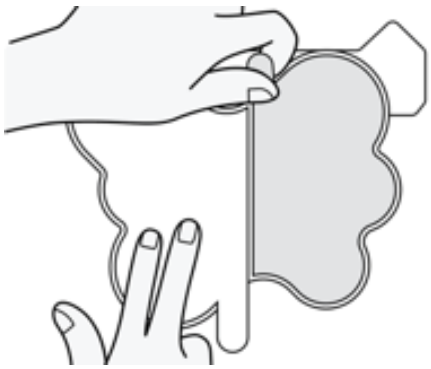
（3）. Use abrader disc to clean the skin first (horizontal by 10 times and vertical by 10 times) and alcohol pad cleaning. Allow site to dry.



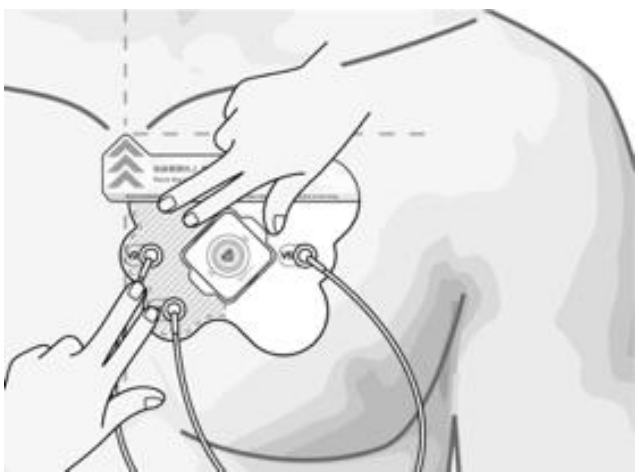
Note: If necessary, medical personnel may adjust chest lead area to fit different body shape or skin condition.

Step 3. Place body patch

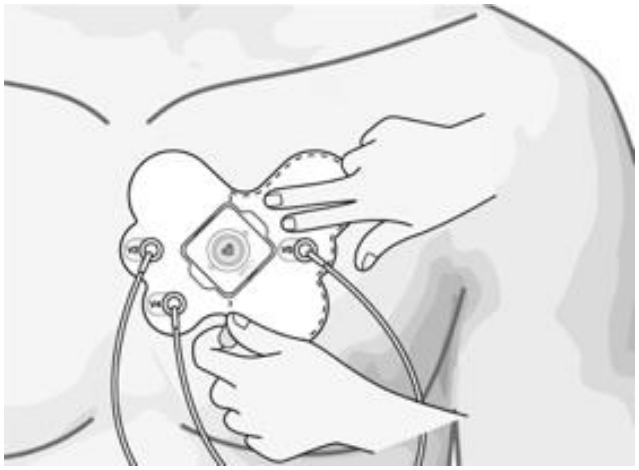
（1）. Remove the right release paper. Do not touch the stick area.



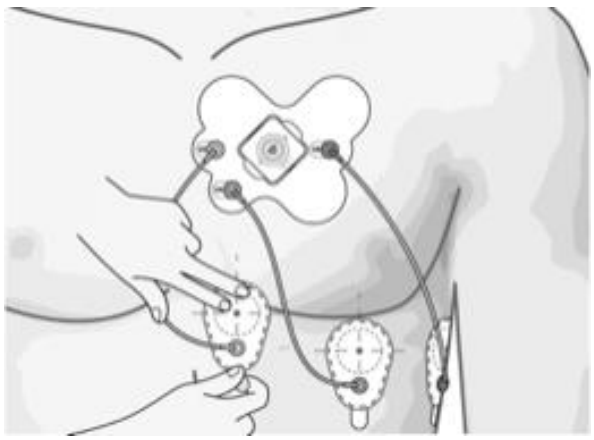
（2）. Point the main patch label arrow up towards the collarbone junction. User’s arms are placed on the side. Press the central area to stick the patch on body (avoid pressing the power button)



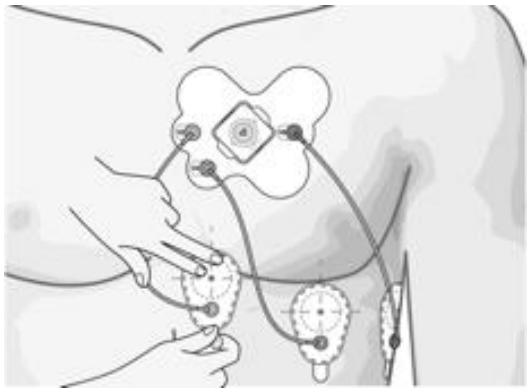
（3）. Remove the left release paper. Press the left area to stick the patch on body.



（4）. Remove the release paper of chest lead patch. Point the red positioning dot to the chest lead appointed by the physician.

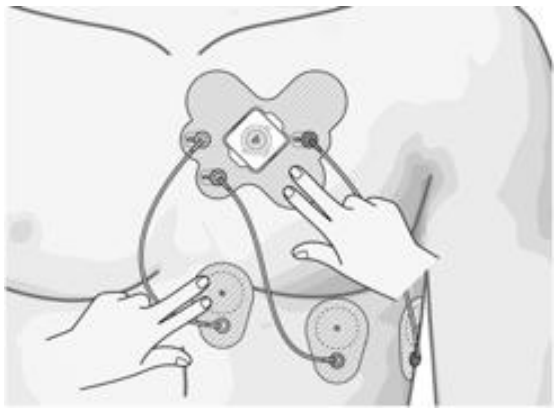


（5）. Press and stick the patch on chest lead area.



（6）. After completing the steps above, the event LED “” will flash blue 5 times and then distinguish.

Step 4. Hand pressure on both main and chest lead patch (especially on the connect point) for 30 seconds.

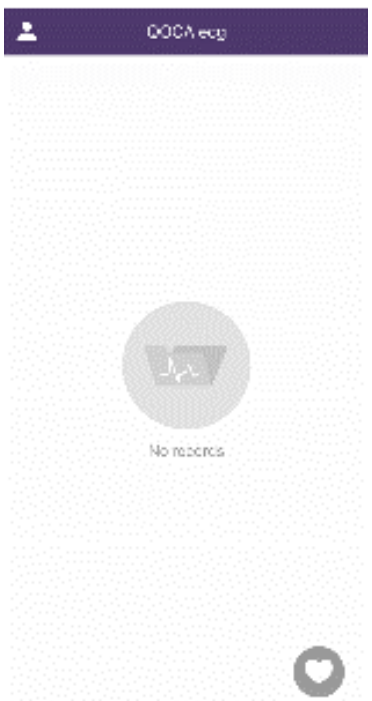


IMPORTANT: The Patch needs 24 hours to fully stick to your skin. It is recommended to avoid water exposure or any activities that cause sweating within 24 hours of application.

THE QOCA ECG APP

Main Screen

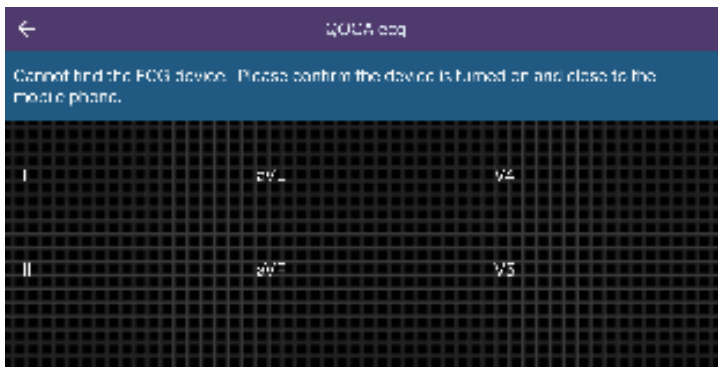
Once you have successfully launched and worn the ECG sensor, the QOCA ecg APP's main screen will display on your mobile phone. The main screen (shown below) displays ECG records which should be shown to a medical professional for evaluation.



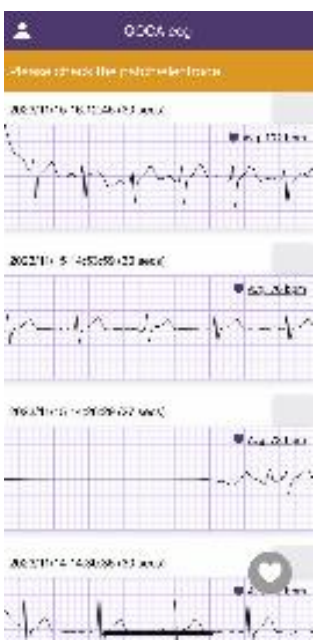
Main screen without records

Main screen with records

<u>NOTE</u>: When the Bluetooth is disconnected, it would show the BT disconnected message in blue box below.



<u>NOTE</u>: When the ECG sensor is worn inappropriately, it would show the lead off message in orange box below.



Event record

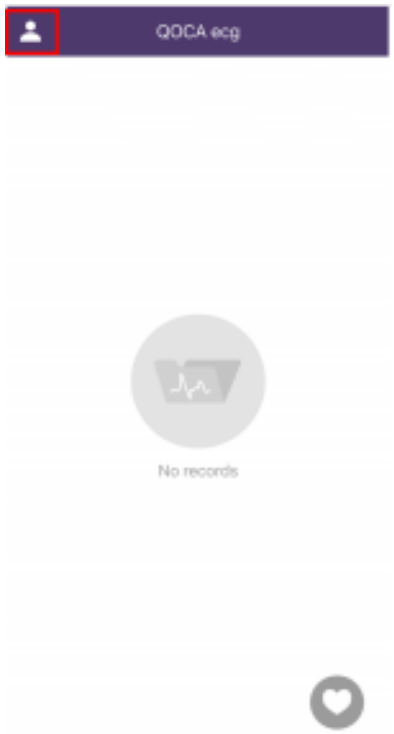
The ECG data is automatically saved in the embedded storage in the sensor. When you feel a symptom, you can press the button on the sensor or the heart button on the main screen to record this event. The recorded event will be saved in the sensor as well as in the QOCA ecg app. You can find the recorded event in the main screen.

The ECG data will also be stored in the sensor's embedded storage for back up.

Note: The data saved in QOCA ecg app will be erased after 14 days to preserve smart phone's storage usage.

Check the Device Information

Tap the user icon on the left top side of the main screen to check device information and access other settings.



Chest lead : V2/V4/V5 are set and cannot be changed.

Event duration: Options include 30 seconds/1 min/2 mins/5 mins (default setting is 30 secs)

Device Test: You can see real-time waveform with this option, but the waveform will not be saved to App.

Replace ECG device: You can change ECG device by using this option.

Erase all records and settings: You can unpair the sensor from the mobile phone by using this option. All data will be erased from the App.

Note: To preserve battery energy, turn off the App after completing event record or setting changes.

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 keep flashing and then extinguish when power on is done. Indicator LED will flash orange until the device is lead-on.
Power off	Long press power button for 5 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 & battery LEDs flashing blue light
Low battery	N/A	• Battery LED flashing orange light
Charging	Put on charger	• Battery LED flashing orange light
Fully charged	Put on charger	• Battery LED solid green 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 QOCA 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.

Specifications

Sensor Specifications

Item	Spec
ECG Sensor	Continuous ECG data acquisition and
	Measuring Lead: lead I, II, III, aVR, aVL, aVF, V2, V4, V5
	Frequency Response: Monitor 0.05 to
	Heart rate measurement range*: 30 –
	Heart rate accuracy: ± 3 bpm or ±3%
	Differential Input Impedance: > 10MΩ
	Common Mode Rejection Ratio: > 70
	Sampling rate: 256Hz
	**Heart rate is calculated based on the*
	*** If the heart rate falls out of the 30 –*
Pacemaker detection	Amplitude：2mV to 200mV Width: 0.1ms to 2ms Rise Time: <100us
Data Transmission	Bluetooth BLE 5.0: Transmit distance: 10 meters (open space)
Battery	3.8V/530mAh
Battery Life	Up to 5 days @ 256 Hz sampling rate,
Battery charging	3 hours

Working Temperature / Humidity	5 – 45ºC, 10% – 95% non-condensing
Storage & transportation Temperature / Humidity	-20 – 60ºC, 10% – 95% non-condensing
Atmospheric	800 hPa to 1013 hPa
Altitude	2000m
Enclosure	IP26
Material flame	PC+ABS, UL94V2
Weight	19.7± 0.5 g
Dimension	37.9 x37.9 x 9.7 ±0.2 mm

Charger Specifications

Item	Spec
Input	5V/0.5A
Working Temperature/humidity	5 – 35°C, 10% – 95% non-condensing
Storage & transportation Temperature/humidity	-20 – 60°C, 10% – 95% non-condensing
Enclosure Rating	IP21
Weight	17± 0.5 g
Dimension	41.1 x 41.1 x 13.45 ±0.2 mm

Body Patch Specifications

Dimension	134.72 x 112.23 ±0.2 mm 50.8 x 69.5 ±0.2 mm
Weight	43.3g
Storage & transportation Temperature/humidity	1 – 30°C, 10% – 95% non-condensing

Troubleshooting

1) Make sure the Bluetooth function of your mobile phone is enabled. If the problem is not resolved, contact manufacturer for assistance.

2) If battery LED does not flash orange when QOCA PROTABLE ECG MONITORING DEVICE is placed on the charger for charging, check if the charger is well connected to the power source or pick up the device and put it back to charger again.

3) If the indicator LED flashed orange after the QOCA PORTABLE ECG MONITORING DEVICE is worn on the body, follow the steps below to resolve the problem. (1)Make sure the device is well installed on the holder of the body patch. (2)Press the gel and connector area to

enhance the adhesive force. (3)If the indicator LED continue to flash orange for 5 minutes, remove the body patch and prepare the skin again.

4) If the device cannot connect to QOCA ecg App, make sure the Bluetooth of the smart phone is enabled. If there is still no connection, restart the App or the device to build up the connection again.

5) If the indicator LED turns solid orange, that means the internal storage is full. Contact your medical personnel for assistance.

Gateway mode information

When using QOCA PORTABLE ECG MONITORING DEVICE, the data needs to be transmitted from many different ECG-sensors to server at the same time. The Gateway part is not included in the package. You must use compatible gateway device for the multi-ECG-sensors to work properly. System setting will allow ECG-sensors (not over 2 sets) to connect gateway data transmission together, or any gateway device that meeting the following specifications:

Gateway Compatible Specifications

Blue tooth	BT 4.2 or above
WIFI	2.4GHz/5GHz 802.11 a/b/g/n/ac

Storage	4GB
Ethernet	10/100/1000M
Connectivity	Up to 6 ECG sensor devices

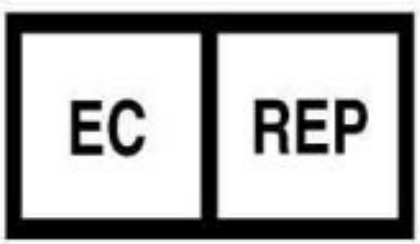
The gateway mode is designed to collect multi-ECG-sensors data information only.

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: QOCA@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 HFSCI9

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 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.

CE 1639	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.
IP26	Protected against solid objects down to 12mm. Protection against low pressure jets of water, limited ingress permitted.

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 ecg901 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the ecg901 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 ecg901 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 ecg901 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	

Bluetooth Technical Specification:

Technical Specification	Value
Operating Frequencies	2402~2480MHz
Channel Spacing	2MHz
Channel number	40
Operating Voltage	1.8V
Modulation	GFSK
Antenna Gain	FPC Antenna, Peak Gain: -1.74 dBi
Rated Power (EIRP)	4.03dBm

Manufacturer's declaration-electromagnetic immunity

The ecg901 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the ecg901 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	± 2kV for power supply lines	± 2kV for power supply lines	Mains power quality should be that of a typical

IEC 61000-4-4	± 1kV for input/ output lines	Not applicable	home healthcare environment.
Surge IEC 61000-4-5	± 0.5 kV, ±1 kV line(s) to line(s) ± 0.5 kV, ±1 kV, ± 2 kV line(s) to earth	± 0.5 kV, ±1 kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical home and professional 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; 300 cycles	Voltage dips: 0 % *U*T; 0,5 cycle 0 % *U*T; 1 cycle 70 % *U*T; 30 cycles Voltage interruptions: 0 % *U*T; 300 cycles	Mains power quality should be that of a typical home and professional healthcare environment. If the user of the ecg901 requires continued operation during power mains interruptions, it is recommended that the ecg901 be powered from an uninterruptible power supply or a battery.

	0 % U_T; 250/300 cycle		
Power frequency(50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 60 Hz	The ecg901 power frequency magnetic fields should be at levels characteristic of a typical location in a typical home and professional healthcare environment.

NOTE UT is the a.c. mains voltage prior to application of the test level.

Manufacturer's declaration-electromagnetic immunity			
The ecg901 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the ecg901 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	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between	**Portable and mobile RF communications equipment should be used no closer to any part of the** ecg901 including cables, than the recommended

	radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	0,15 MHz and 80 MHz 80 % AM at 1 kHz	separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	80 % AM at 1 kHz 10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	**Recommended separation distance:** d = 1,2 √*P* d = 1,2 √*P* 80MHz to 800 MHz d = 2,3 √*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: 

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 ecg901
The ecg901 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 ecg901 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ecg901 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.

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The ecg901 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the ecg901 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 professio
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	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, TE	Pulse modulation b) 18 Hz	2	0,3	28	28
870							

930		TRA 800					
1 720	1,700 – 1,990	GSM 1800; CDMA 1900; GSM 19	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	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							

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

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

The ecg901 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the ecg901 should assure that it is used in such an environment.

Frequencies	Test Level [A/m]	Point / Window	Modulation	Dwell time [s]	Compliance LEVEL [A/m] (for home and professional healthcare)
30 kHz (a)	8	All points	CW	3	8

		on photo below			
134,2 kHz	65	All points on photo below	Pulse modulation (b) 2,1 kHz	3	65 (c)
13,56 MHz	7,5	All points on photo below	Pulse modulation (b) 50 kHz	3	7,5 (c)

Note:
(a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME AND PROFESSIONAL HEALTHCARE ENVIRONMENT.
(b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
(c) r.m.s., before modulation is applied.