QOCA Portable ECG Monitoring Device User Manual

MODEL： ecg106a

Contents

SAFETY NOTICE

- Please read through the user guide carefully before using the device.
- The device is to be used for clinical assessment and personal reference only.
- The 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 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 device is low on battery power, it will automatically stop taking measurements.
- Avoid using devices that can affect the accuracy of the readings when the 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 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 device near open flames, excessive heat, or in an explosive environment
- Pay attention to ensure that the device is not swallowed by pets or children.
- Cardiac pacemakers or other electrical stimulators may affect the accuracy of the measurements of the 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 device.
- The 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 device to extreme temperatures, extremely moist environments, dust, or direct sunlight.
- The device should be cleaned before providing to another patient. Please follow the cleaning instruction in this manual. Do not clean the device with corrosive or abrasive cleaning agents.
- The device and its accessories should be disposed of properly. Disposal of the device and its accessories should comply with the relevant local regulations.
- The 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 device is replaced by an incorrect battery type.
- The expected service life of the device is 2 years.
- Do not use 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. The device is not suitable for use in an explosive environment.
- 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, device should be removed beforehand.
- Avoid using heavy electronic equipment or other sources of electromagnetic interference (such as electric blankets) when using the 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.

- Close the app after completing event record. Leaving the app open may cause the battery of device to deplete faster due to continuous BLE Connection
- The QOCA ecg App does not have any diagnostic function. Healthcare providers should inform the patiens NOT to take or change medication due to the result of event record before consulting to a healthcare professional.
- To avoid Bluetooth interference with pacemaker, for patients with a pacemaker, turn the Bluetooth off before apply on patient’s body.

Body patch precautions for use:

- The body patch is a single-use product, and the patch will become invalid after being attached once, please do not reuse it.
- Once the body patch bag is opened, wear the body patch as soon as possible. Please use immediately after opening the package.
- Do not use the body patch on patients with known skin allergies or family history of skin allergies
- Repeated use will result in failure to measure or incorrect ECG signals.
- The wear time of the body patch is 1 to 14 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.
- Please follow up below instrutions to clean skin and make sure the well attachment.
- Do not bathe or swim, and do not rinse the device with water directly when showering.
- 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.

- It is recommended to avoid water exposure or any activities that cause sweating within 24 hours of application.
- If the patch is removed early, the recorded ECG data can still be used as clinical evaluation and reference data.
- It is normal for the patch to appear dirty after wearing it for a period. Do not use corrosive and abrasive cleaners to clean and wipe the QOCA portable ECG measuring instrument and patch.

Other instruction:

- Please read the instructions carefully before using.
- When using the device, please keep as still as possible to obtain qualified ECG signals for professional reference.
- When it is necessary to use the patch for a long time, please observe the skin status and patch status at least every 24 hours. Please check whether any occurrence of allergies.
- When using device, do not use related medical electronic equipment such as "AED"

- Please stop the measurement immediately if you could not get the useful ECG data (Not everyone is suitable for device measurement)
- The device can only measure when the subject is still (such as sitting, lying down) or in a general exercise state. Any activity not permitted by the attending physician may affect the accuracy of the measurement.
- Do not use the device in an environment with high humidity. It can be used in the shower, but do not immerse it directly in water.
- Please recycle the device and patch according to the local regulations.
- Device may be affected the accuracy of ECG signal near the high-frequency communication equipment.
- The devicet is only suitable for adults, not for children under 20 kg.

PRODUCT REVIEW

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

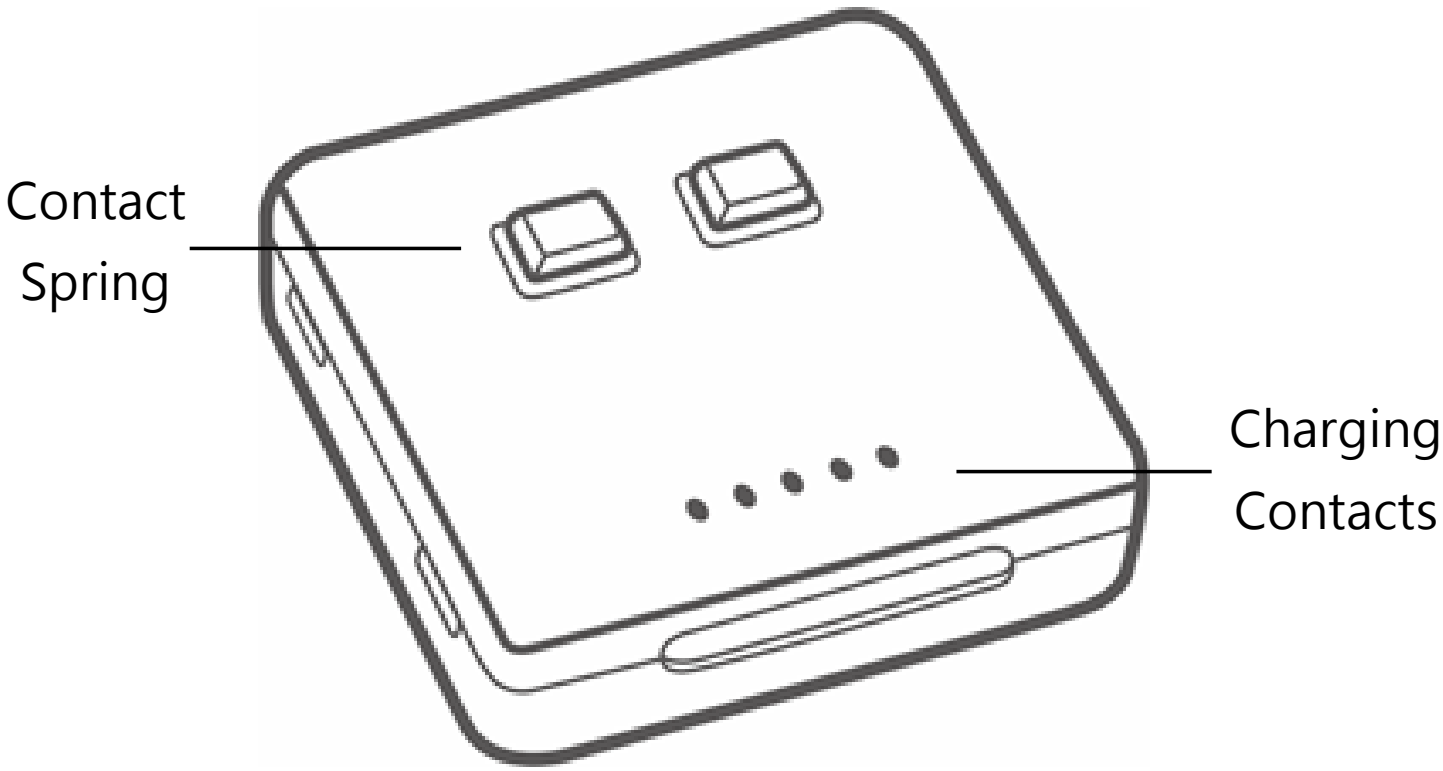
The product package includes the following items :

Part	Unit
QOCA Portable ECG Monitoring Device (model : ecg106a)	1
Body patch (model : ecg105-Pa)	1
Abrader disc	1

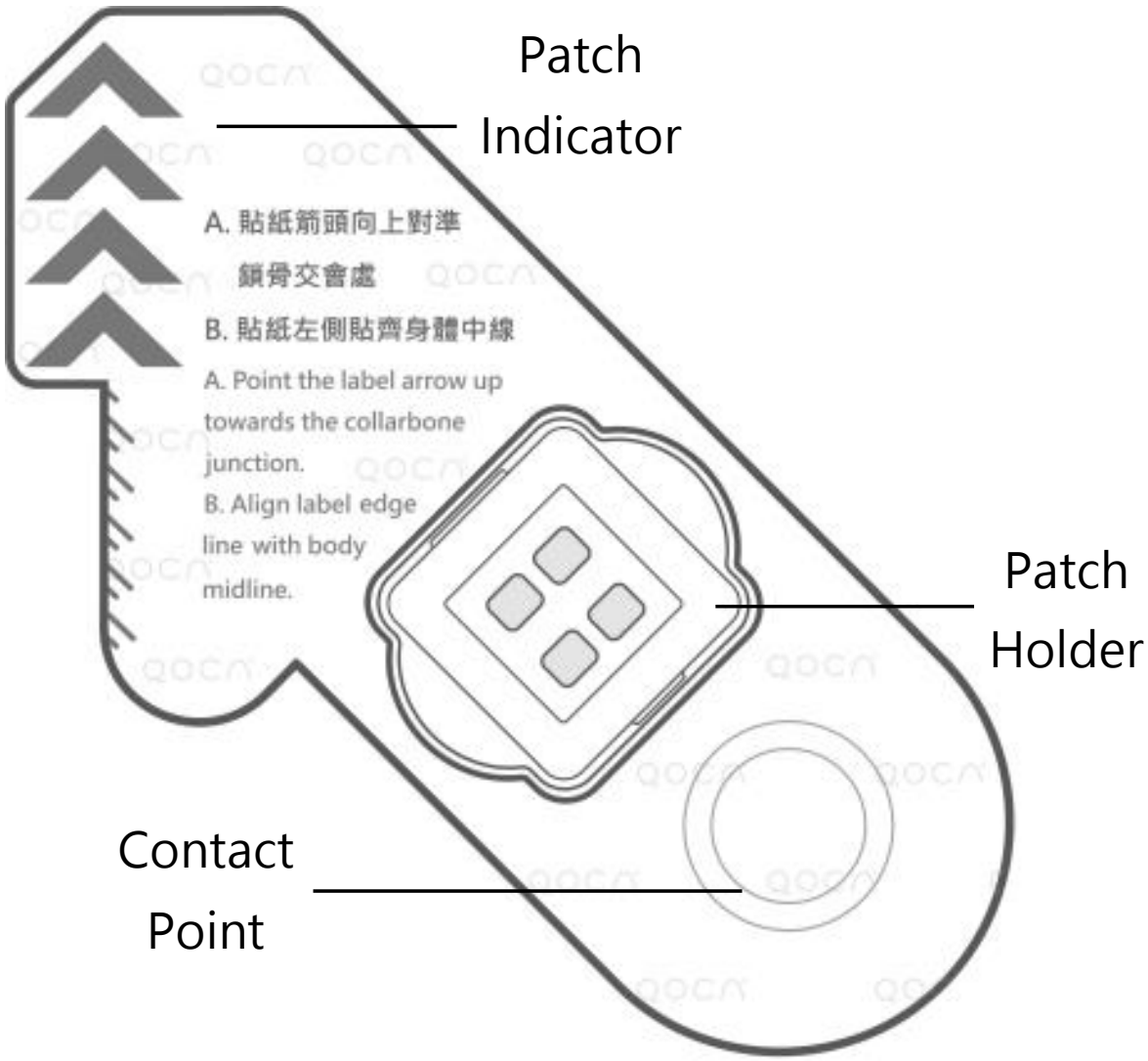
DEVICE Introduction (Model : ecg106a)

Top side

Bottom side



Body Patch (Model: ecg105-Pa)



Product Requirements

The following items are required

- QOCA Portable ECG Monitoring Device (Abbr. Device)
- Body Patch
- Smartphone
  - 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)
- QOCA ecg APP*
  (Please download the app from Google Play or Apple Store)

* Items not included in the product package

BEFORE YOU START

Before you start using the QOCA Portable ECG Monitoring Device you must:

1. Installed the QOCA ecg app on the smartphone
2. Enable bluetooth function on the smartphone

GETTING STARTED

Once you have completed the previous steps, you can begin using QOCA Portable ECG Monitoring Device by following these steps：

1. Launch the QOCA ecg App and choose sensor type to pair the sensor to your smartphone.
2. Wear the QOCA PORTABLE ECG MONITORING DEVICE

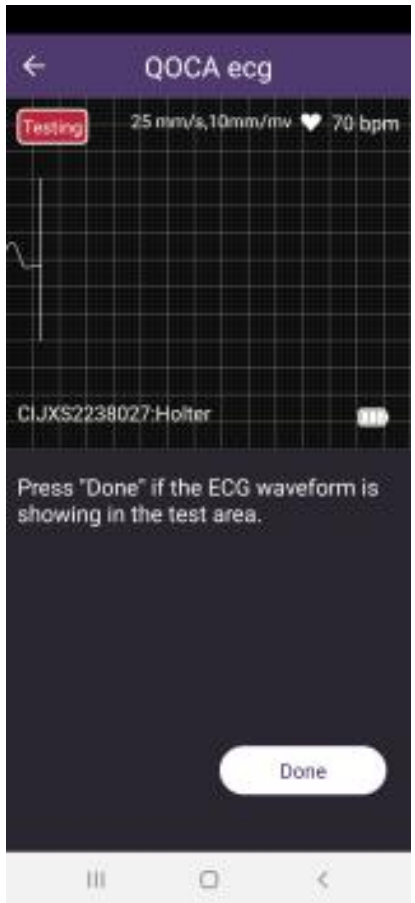
Device Pairing

Please enter the pairing process :

It would show the nearby BLE devices in pairing page. Please select the serial number CIK********* which is the same as serial number on the back of device.

Press the power button according to app instruction and confirm it.

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



Wearing the device (ecg106a)

Notice :

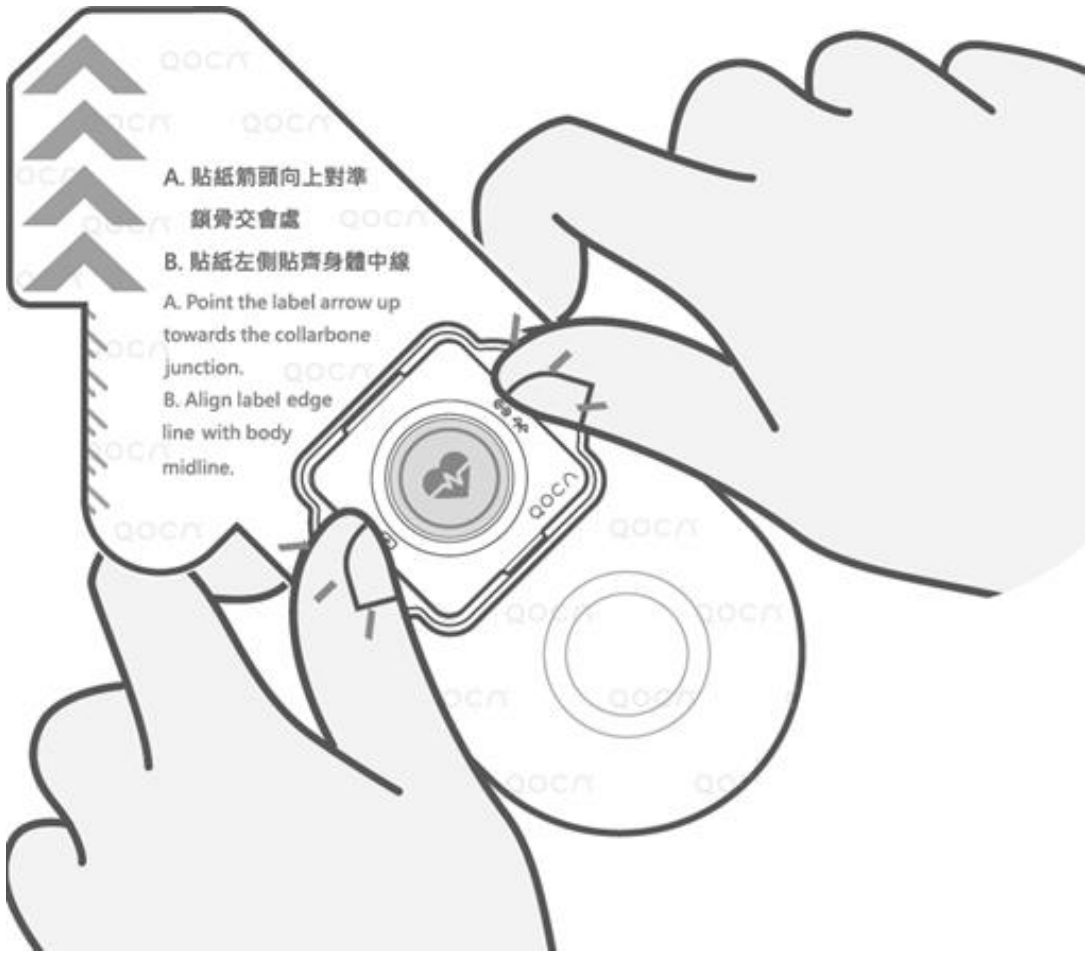
1. *The Body Patch is a single-use product, and the patch will become invalid after being attached once, please do not reuse it. Repeated use will result in failure to measure or incorrect ECG signals.*
2. *The sticking period is 1 to 14 days. If patch attachment is not correct or different skin type and daily activities of each person, the patch may fall off early. It is recommended to stay in a proper temperature environment to prolong the wearing time.*
3. *Please follow up below instrutions to clean skin and make sure the well attachment.*
4. *Do not bathe or swim, and do not rinse the device with water directly when showering.*
5. *Do not apply any lotion or skin care products on applied area.*
6. *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.*

7. *It is recommended to avoid water exposure or any activities that cause sweating within 24 hours of application.*

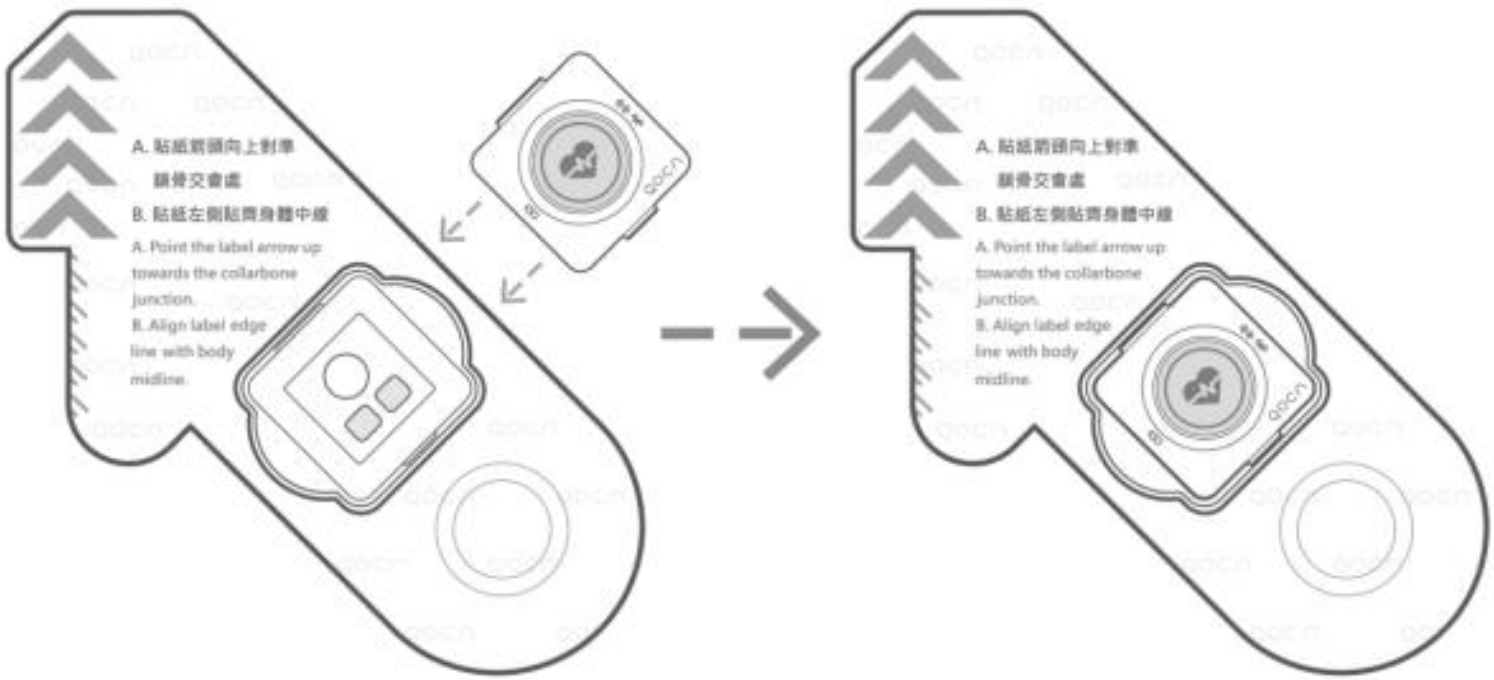
Body patch (Model: ecg105-P1 / ecg105-Pa)

Step1：

(1) After opening the packaging, please first remove the sensor and the isolation film from the patch holder, and then reattach it to the holder well.



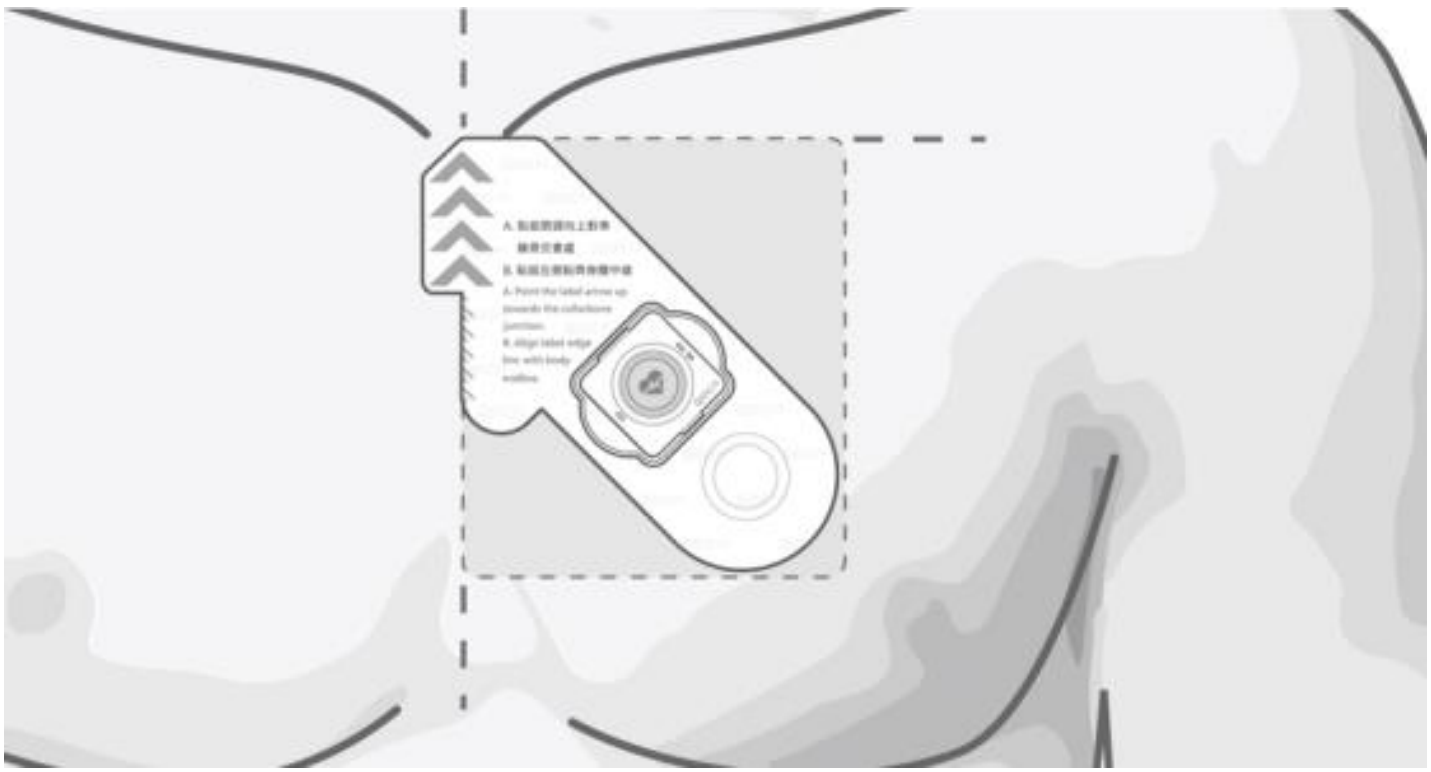
(2) Make sure correct device direction on patch holder.



(3) Power on the device (“⛓” indicator will flash orange light continouslly. When the patch is fully attached to the skin, the orange light will be off)

Step 2：Check the patch attachment area

(1) Align the patch arrow label upwards at the intersection of the clavicle. The dotted square area is the area where the skin must be cleaned.

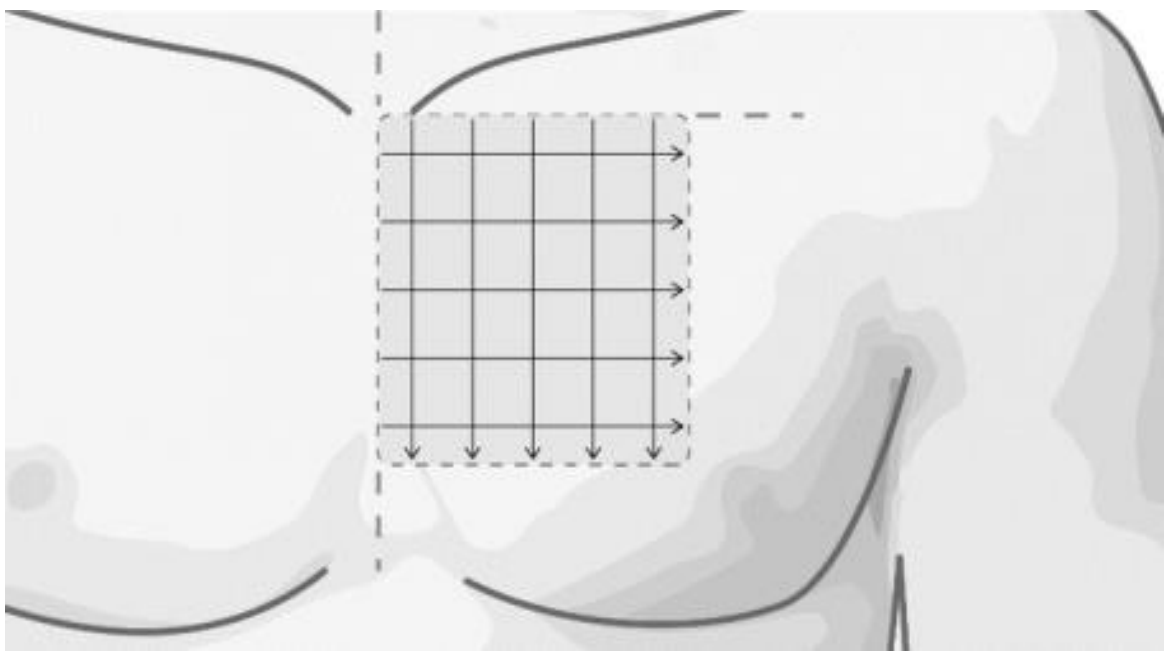


Step 3：Skin cleaning

(1) Remove the chest hair first. If there is no chest hair, this step can be skipped。

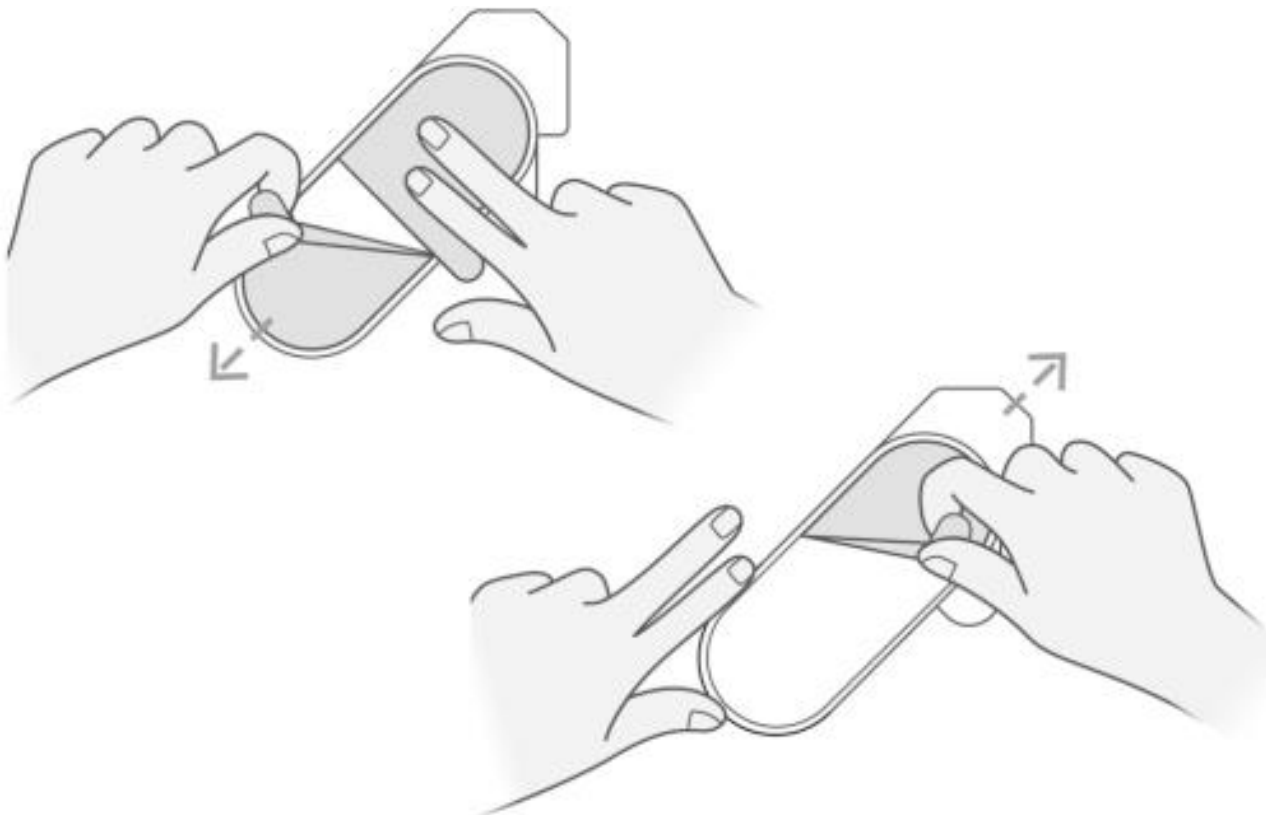
(2) Gently rub the skin with the exfoliating pad (Horizontal direction 10 times · Vertical direction 10 times)

(3) Wipe the skin with an alcohol pad and water. Waiting for the dry skin before using the patch.

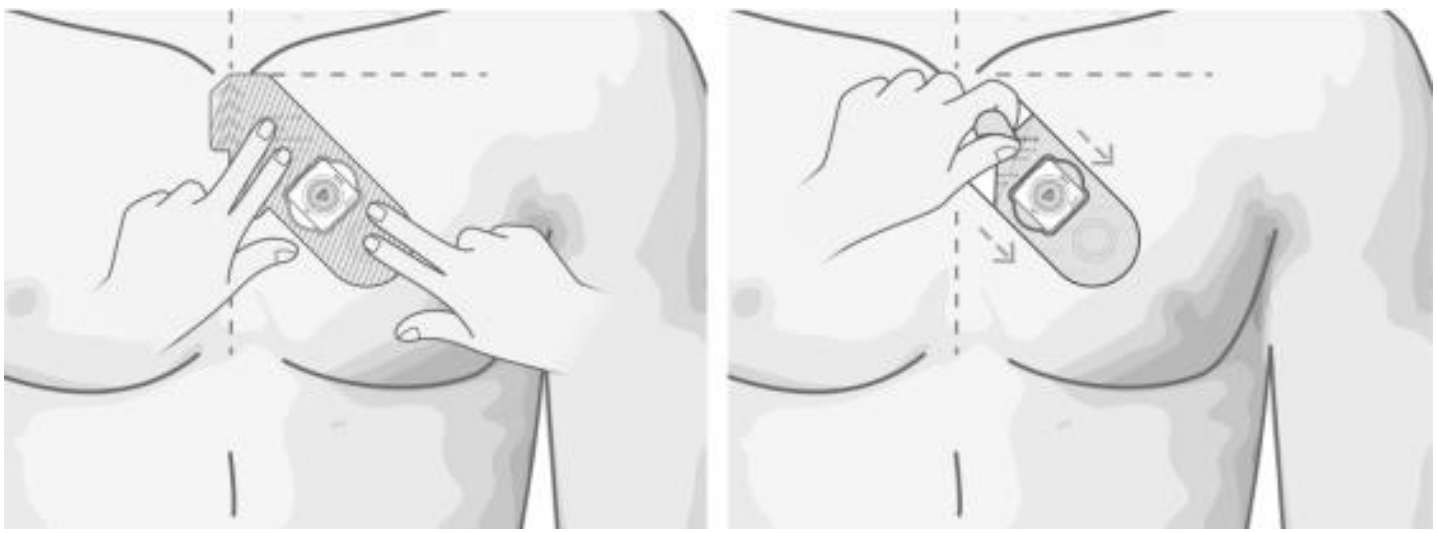


Step 4：Body patch attachment

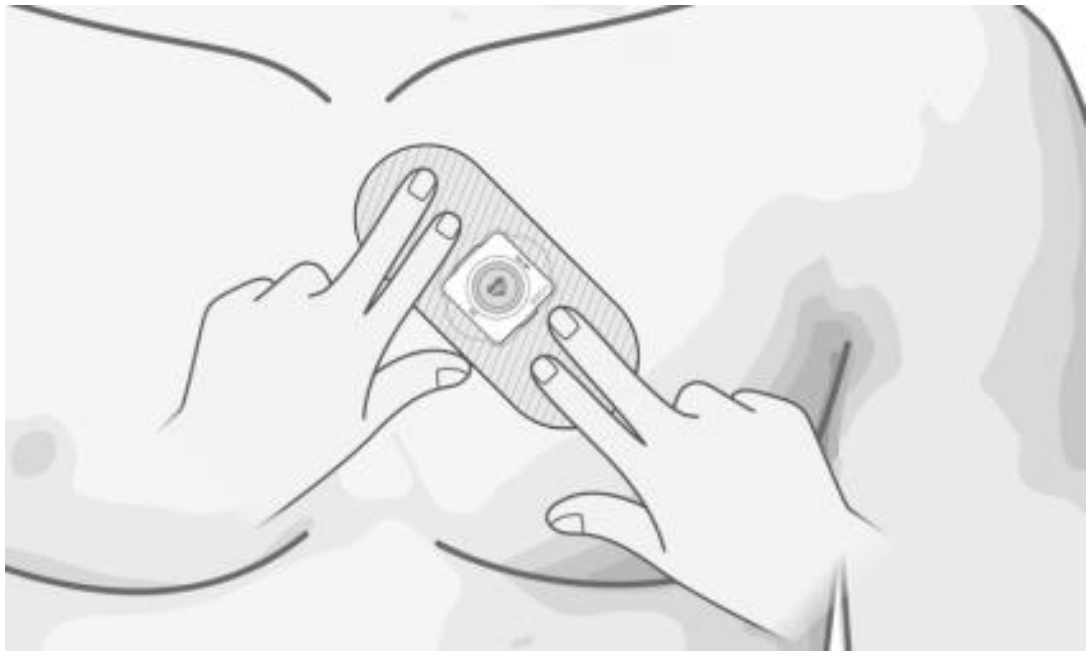
(1) Remove the release paper first



(2) Align the instruction label arrow up over the clavicle junction. Then hold your chest up and inhale, place your hands naturally, press the patch area, make the patch stick to the skin initially, and then tear off the instruction label



(3) Finally, please press the entire patch area continuously for 30 seconds to make the special sensing patch really stick to the skin



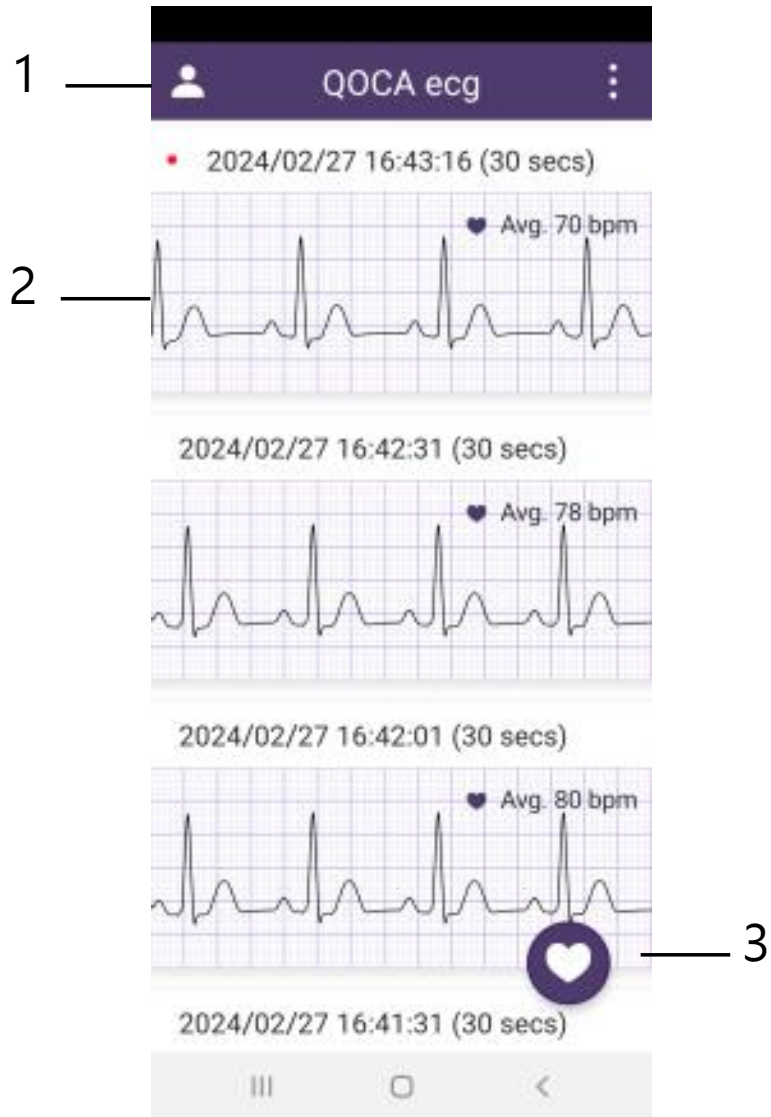
Patch remove notice:

If you need to remove the patch, you need to press the skin surface with one hand, and slowly and carefully tear off the patch with the other hand to avoid damage to the skin caused by tearing off the patch too quickly. If you experience unbearable itching, rash, redness and swelling, please consult a medical professional as soon as possible after removing the patch on your body.

QOCA ECG APP

Main page

Show the ecg wave information：



Main page information:

1	Information	Device information
2	Event Record History	Select item to review event record history data
3	 button	Press  button to trigger event record function at Holter mode

Setting Information

Select informaion icon on main page：

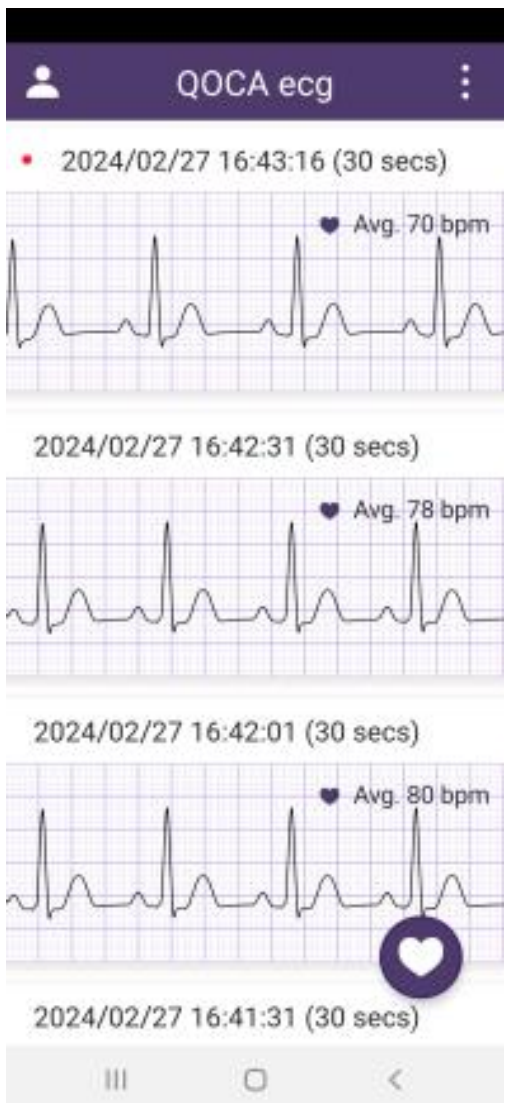
1	User account	Show your user account name
2	S/N	Paired device serial number
3	Measurement mode	Select Measurement mode
4	Recording duration	Default setting 30 seconds
5	Filter type	Enhanced or Original type
6	Battery level	Show current battery level
7	FW version	Device FW version
8	SW version	QOCA ecg App SW version
9	Device test	Device waveform connectivity test

10	Device replace	Replace and repairing new device
11	Erase all records and settings	QOCA ecg app will erase all records, settings and device pairing
12	About	Other information

Event record history page

Please select the ECG record button to trigger event record.

The ECG history data could be reviewed as follow.



Event record

Press  button on main page. The measurement period will be set up in the detailed information page · You could also press the device button to start the event record during measurement period. The ECG data will be saved. The ECG data could be checked on history page.

INFORMATION

LED Indicators

Event	Action	LED behavior
Power on	Long press over 1 second	Both battery and indicator LED flashing green light, then off
Power off	Long press over 5 second	Both battery and indicator LED with solid blue light, then off
Lead off		Indicator LED flashing orange light
Low battery		Battery LED flashing orange light
Event recording	Press power button at power on status	Both battery and indicator LED flashing blue light

Fully disk		Both battery and indicator LED with solid orange light
Disk error		Both battery and indicator LED with solid purple light
USB connection	Connect device and computer	Indicator LED with solid blue light
Paring	App trigger paring mode	Indicator LED flashing blue light
Turn off device bluetooth	1. Only in lead off, press button 3 times consecutively 2. Bluetooth on/off changing indication 3. Check if Bluetooth is turned off	1. Both LED flash blue color while press the button 2. The indication LED flash Green color 5 times

		3. Both LED flash Green color while press the button
Turn on device bluetooth	1. Only in lead off, press the button 3 times consecutively 2. Bluetooth on/off changing indication 3. Check if Bluetooth is turned off	1. Both LED flash Green color while press the button 2. The indication LED flash Blue color 5 times 3. Both LED flash Blue color while press the button

ECG Data transmision

Place the device on Charger. Connecting Charger and computer（OS system Windows 7 / macOS 10.10 or above）with type C cable for ECG data download.

Cleaning and Conservation

Cleaning：

- Before cleaning, please power off the device
- Please wipe the device with a cloth. You could use cloth with water, neutral detergent, or alcohol. Please clean after each use
- Do not immerse the device directly in water or any liquid for cleaning

Conservation：

- Do not place in direct sunlight or high temperature and humidity. The suitable storage environment is -20 ~ 60 celsius degree/Humidity 10% ~ 95% non-condensing
- Do not drop on the ground and avoid collision
- Do not disassemble the device
- No regular calibration request

Specifications

Model	ecg106a
QOCA Portable ECG Monitoring Device	Channel：Single Lead Heart Rate：30~240 bpm Frequency Response： 0.05~40Hz HR Accuracy：±3 or ±3 % Sampling Rate：256Hz Differential Range：±5 mv Resolution：12 bits Input Impedance：>10M Ohm CMRR：> 70 dB
HR measurement	Waveform RR interval caculation
Pace detection	Support (Bluetooth function off)
Connectivity	BT BLE 5.0 ; Transmit distance : 10 meters Open space
Battery Type	Non-rechargeable coin battery 500 mAh, 3.0V
Battery Life	Up to 14 Day (Holter mode)

Working Temperature / Humidity	5 – 45℃, 10% – 95% (non-condensing)
Storage Temperature / Humidity	-20 – 60℃, 10% – 95% (non-condensing)
Atmospheric Pressure Range	800 hPa to 1013 hPa
Altitude	2,000 m
IP Rating	Device IP26
Weight	Device：13.6 ±0.5g
Dimension	Device：30.7 x 30.7 x 9.4 ±0.5 (mm)

Troubleshooting

1. If the device cannot be paired with smartphone, please refer to the instructions in device pairing process.
2. The indicator LED will flash orange light when the patch does not attach skin properly or the device is not fully buckled with patch well. Please follow up patch wearing steps.
3. If there is always a straight line or no waveform during the testing process, please follow up the patch wearing steps and recheck patch status.
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 patch or sensor falls off, please contact medical personnel for treatment.

Note: If the problem is still persisted, please contact the manufacturer or hospital for further supports. Do not disassemble the product by yourself.

Regulatory Marks

	Type applied part
	MR unsafe An item that is known to pose hazards in all MRI environments.
	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 that the sensor is classified as electrical or electronic equipment requiring proper disposal (WEEE Directive)
	Indicates the need for the user to consult the instructions for use.
IP	Ingress Protection Rating

Customer Support

For additional technical information, Manufacturer 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

Website: https://www.qoca.net

Federal Communications Commission (FCC) Statement

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.

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 ecg106 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the ecg106 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 ecg106 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 ecg106 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	

Manufacturer's declaration-electromagnetic immunity			
The ecg106 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the ecg106 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	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable Not applicable	Mains power quality should be that of a typical home and professional 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	Not applicable 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; 250/300 cycle	Voltage dips: Not applicable Voltage interruptions: Not applicable	Mains power quality should be that of a typical home and professional healthcare environment. If the user of the ecg106 requires continued operation during power mains interruptions, it is recommended that the ecg106 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 60 Hz	The ecg106 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 ecg106 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the ecg106 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 80 % AM at 1 kHz	Not applicable	**Portable and mobile RF communications equipment should be used no closer to any part of the** ecg106 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	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:** $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 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: 
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 ecg106

The ecg106 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 ecg106 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ecg106 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 ecg106 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the ecg106 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, 4, 25; UMTS	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.

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

The ecg106 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the ecg106 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 on photo below	CW	3	8
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 HEALTHCARE ENVIRONMENT.
(b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
(c) r.m.s., before modulation is applied.

Version 3A