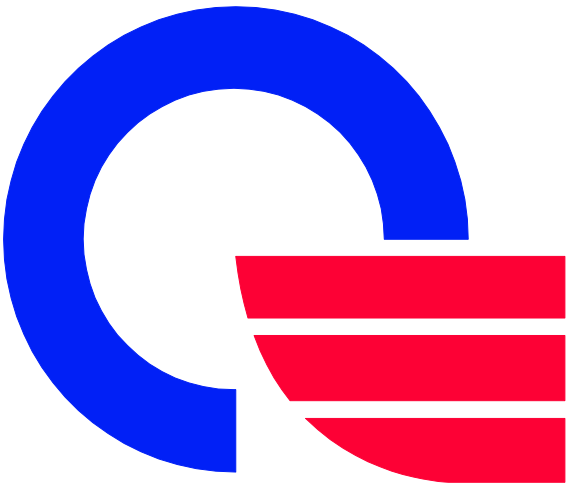


Quanta Computer

QOCA PORTABLE ECG MONITORING DEVICE
User Manual

CIH418-01 Ver.: 2B

TABLE OF CONTENTS

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 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 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 check to ensure the ECG is continuing to take measurements normally. See The QOCA ecg APP to see how to check if the device taking measurements normally.
- Do not use the QOCA PORTABLE ECG MONITORING DEVICE near open flames or in excessive heat.
- 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.
- 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 QOCA PORTABLE ECG MONITORING DEVICE is not swallowed by pets or children.
- Cardiac pacemakers or other electrical stimulators may affect the accuracy of the measurements of the QOCA PORTABLE ECG MONITORING DEVICE.
- The conductive parts of the electrodes and associated connectors for type BF applied parts, which are parts that make conductive contact with the heart, including the neutral electrode, should not make contact with other conductive parts including the ground. Direct contact with other conductive parts may result in electric shock.
- 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 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 QOCA PORTABLE ECG MONITORING DEVICE.
- The QOCA PORTABLE ECG MONITORING DEVICE can only take measurements while the subject is at rest (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.
- 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 ’s use is not intended for use with infants weighing less than 45lbs. (20 kg).
- The expected service life of the QOCA PORTABLE ECG MONITORING DEVICE is 2 years.
- People with sensitive skin or with known skin conditions should use the QOCA PORTABLE ECG MONITORING DEVICE with caution. If irritation such as redness, severe itching or allergic symptoms (i.e. hives) develop, instruct patients to remove the QOCA PORTABLE ECG MONITORING DEVICE immediately and have them contact their physician.
- Do not use ECG sensor on patients with known skin allergies or family history of skin allergies.
- 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.

PRODUCT OVERVIEW

Indication for Use

The QOCA WEARABLE ECG MONITORING DEVICE is intended for non-invasive measurement of Electrocardiogram (ECG) and heart rate (HR) of patients at rest in hospitals, healthcare institutes, and home environments. The QOCA WEARABLE ECG MONITORING DEVICE will process ECG signals and calculate HR on continuous, spot check, or event record mode. ECG and HR data will be transferred to a smartphone via Bluetooth and displayed on the smartphone screen via a dedicated application called QOCA ecg. The data can be further transferred to cloud server for storage.

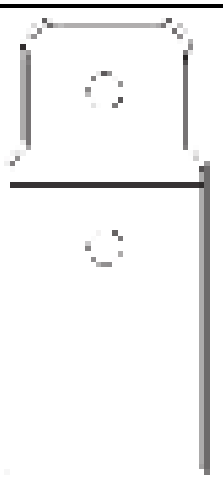
The device should be worn on the human body along with a body patch or a sensor holder with gel electrodes. The QOCA WEARABLE ECG MONITORING DEVICE is available to professional organizations such as home caregivers, clinics, or hospitals. It is not available to the general public. It should only be used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

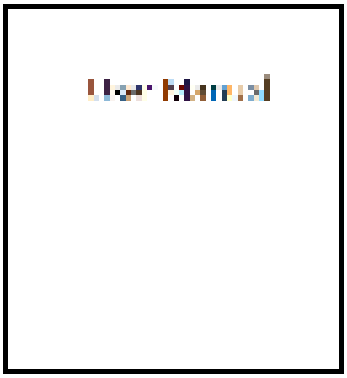
The device is intended for use on patients 20 years of age and older. The QOCA WEARABLE ECG MONITORING DEVICE is only available by prescription and be used by or under the instruction of medical personnel.

Package Contents

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

ecg103 product package

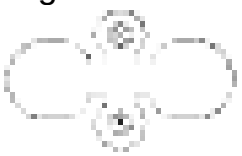
		
ecg103 ECG Sensor x 1	**Charger x 1**	**Protection bag x 1**

		
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 QOCA Portable ECG Monitoring Device.

		Product Package	
Part Name	**Model Number**	**ecg103-K1**	**ecg103-K2**
QOCA PORTABLE ECG MONITORING DEVICE	ecg103	✓	✓
Charger	ecg103-C1	✓	✓
USB Charging Cable	NA	✓	✓
Sensor Holder*	ecg103-P5 	✓	

Body Patch*	ecg103-P1 		✓

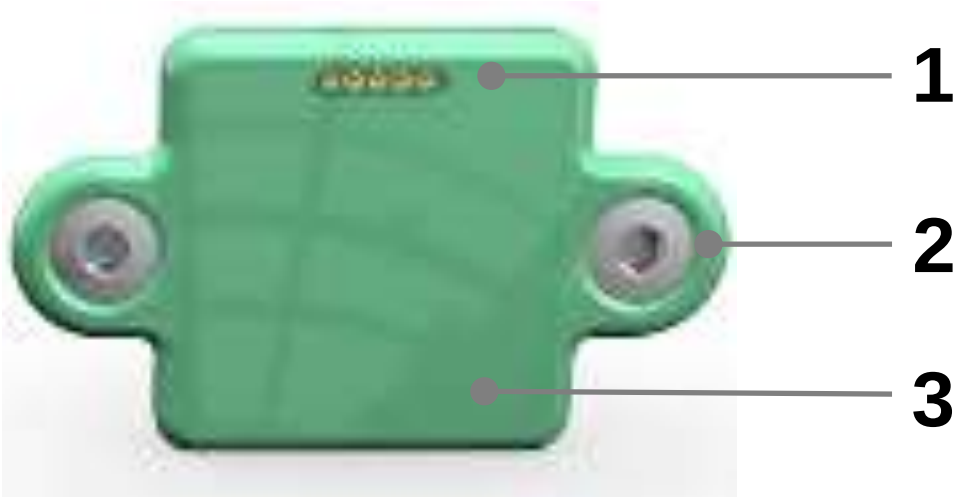
Components

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	Laser Printing Area

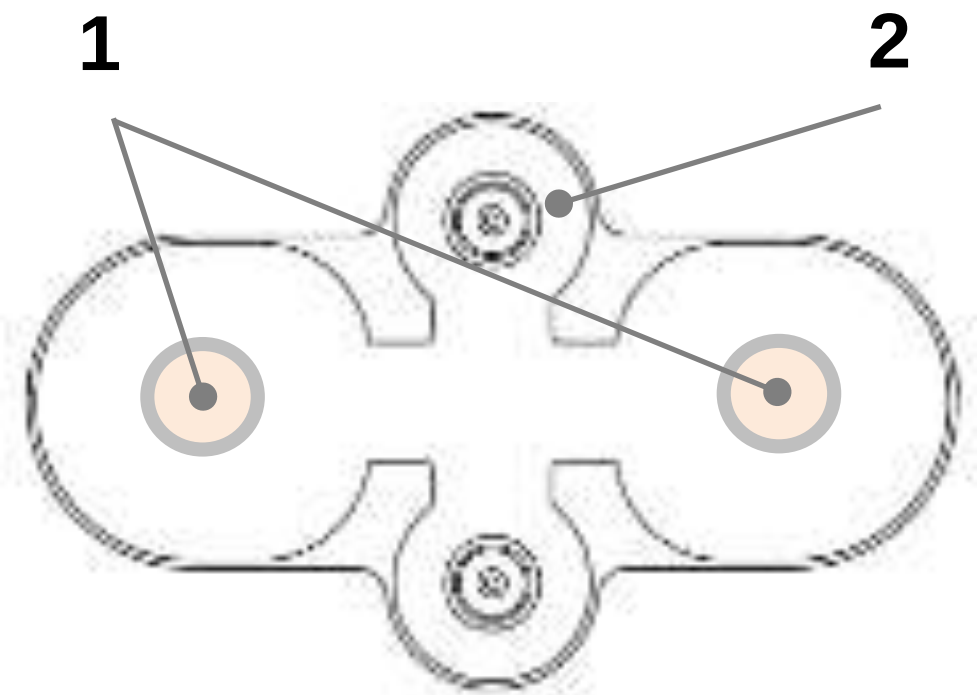
NOTE: Electrode button connector will support plug in/off test under 1000 times.

Charger

1	Charging Contacts
2	USB Charging Port

Body Patch

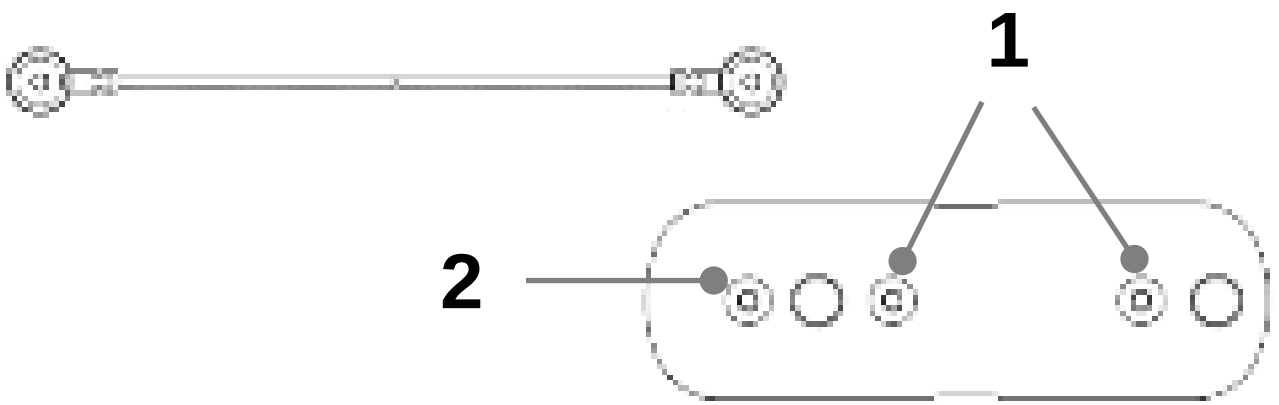
Front Exterior (with pocket closed)



1	Gel
2	Contact Point
Material	Made from Nonwoven

Sensor Holder & Cable

Front



1	Sensor Connectors
Material	Made from Polydefin Foam
2	Cable Connector

Back

1	Electrode Connectors

<u>IMPORTANT</u>: 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:

Charging indicator	LED on Sensor
Working temp	5 ~ 35ºC (Sensor working temp is 5 ~ 35ºC when it is charging)
Storage temp	-20 ~ 60ºC
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 QOCA 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 8.x or above and a display resolution of 1920x1080 or 2560x1440)
- The QOCA 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 8.x or above and a display resolution of 1920x1080 or 2560x1440)
- 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 Android 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. 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 green. 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.

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 ECG sensor via Bluetooth
2. Wear the QOCA PORTABLE ECG MONITORING DEVICE

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 “CIHXSXXXXXXX” 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 QOCA ecg APP fails, 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 with the sensor holder.

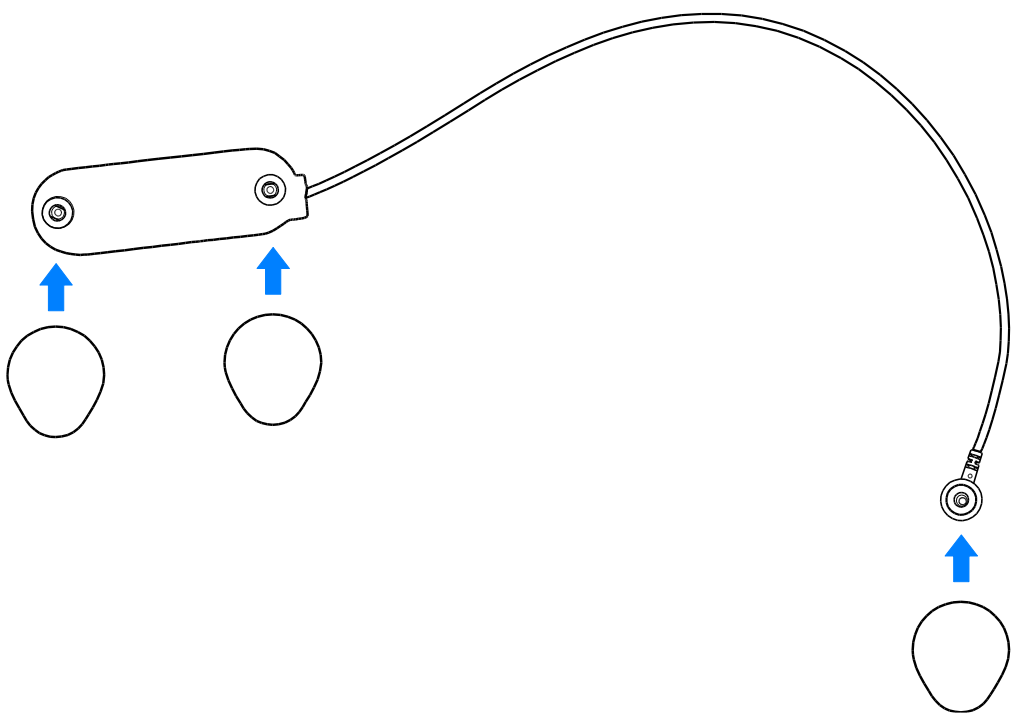
IMPORTANT: When wearing the ECG sensor directly you must use compatible electrodes (sold separately) for the device to work properly. For more information on electrode specifications see

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*
2. ECG Electrode Information.

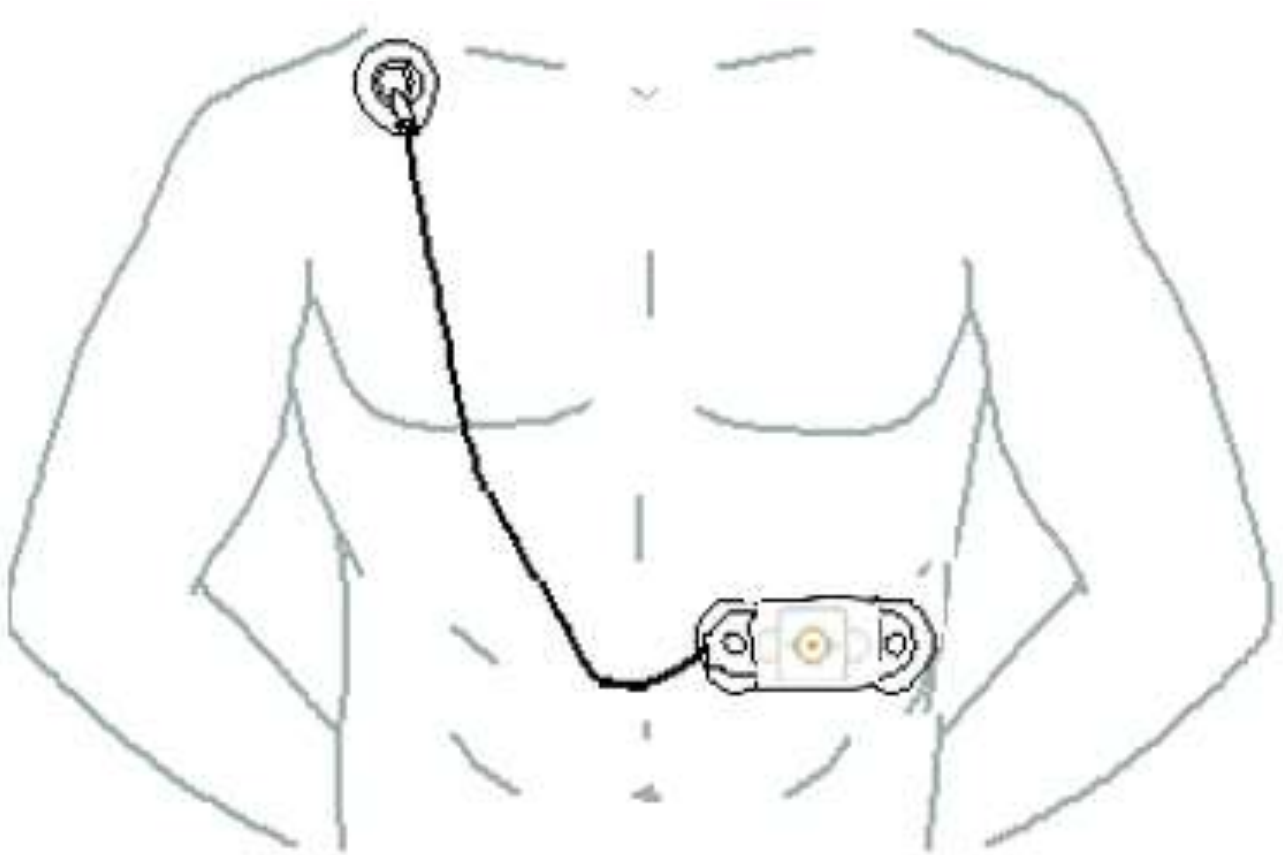


3. Attach the ECG sensor to the front of the sensor holder so that all four holder connectors on the sensor are properly clicked into the four sensor connectors on the holder (see image below).

<u>NOTE</u>: 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.

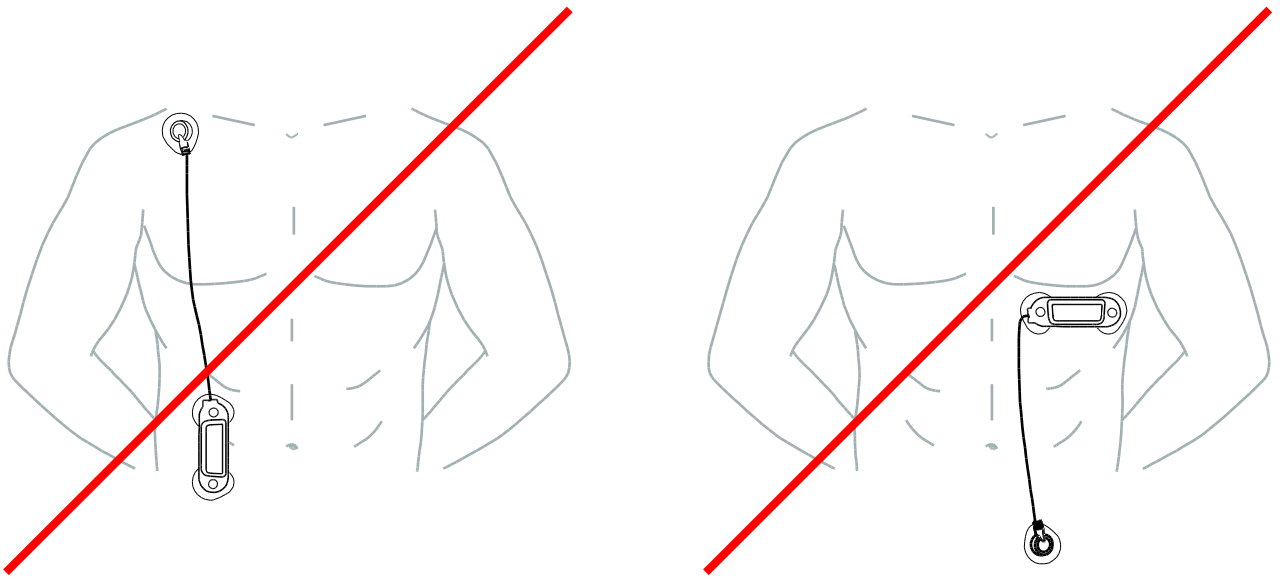
4. Remove the paper backing on the contact side of each of the ECG electrodes.
5. Adhere the 2 electrodes located near the sensor under your left pectoral area (see image below).
   <u>NOTE</u>: The electrodes feature adhesive on the contact side to ensure secure contact with your body. If an electrode does not adhere securely, please replace it with a new electrode.

6. Adhere the electrode attached to the cable to the area under your right collarbone (see image below).



7. Once the ECG sensor is properly positioned on your body, wait half a minute then check the QOCA 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:

A. Preparing the Skin

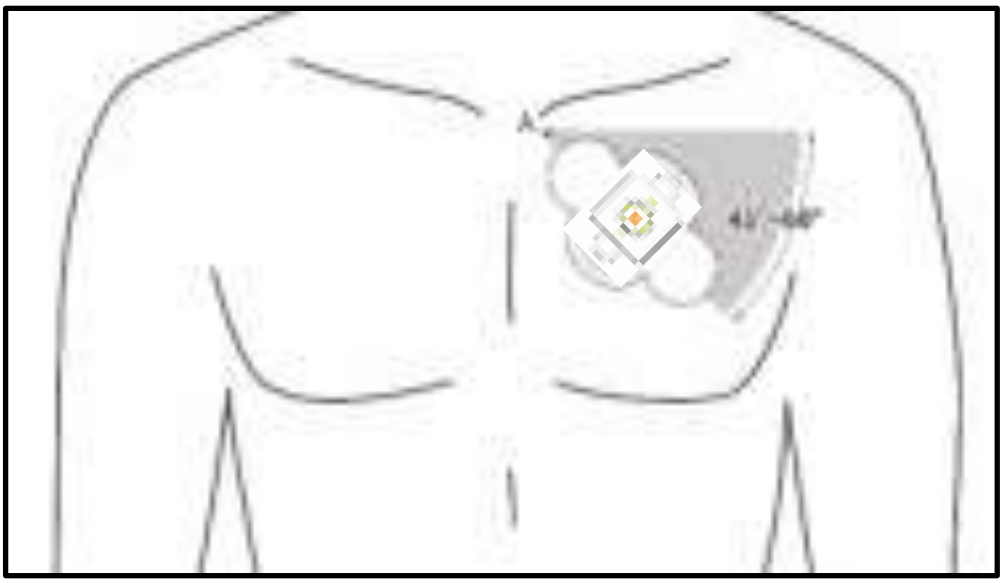
Step 1: Remove all hair over sternal area by shaving close to the skin. Do not merely clip hair. The prepared area should extend 2 inches past where the sensor will be placed.

Step 2: Use all prep pads provided in the box (Shown as below figure) to clean area shown. SCRUB the skin with the prep pads until they appear clean after use. Skin should be scrubbed well enough to be slightly reddened. Allow the skin to dry for 1 minute prior to applying.

B. Wearing the body patch

Step 3: The left hand is naturally placed downwards.

Step 4: Attach the ECG sensor on Body Patch. And adhere the body patch under clavicle near the center with angle 45º ~ 60 º as shown.



Step 5: Hand pressure on the body patch (especially on the connect point) for at least 30 seconds.

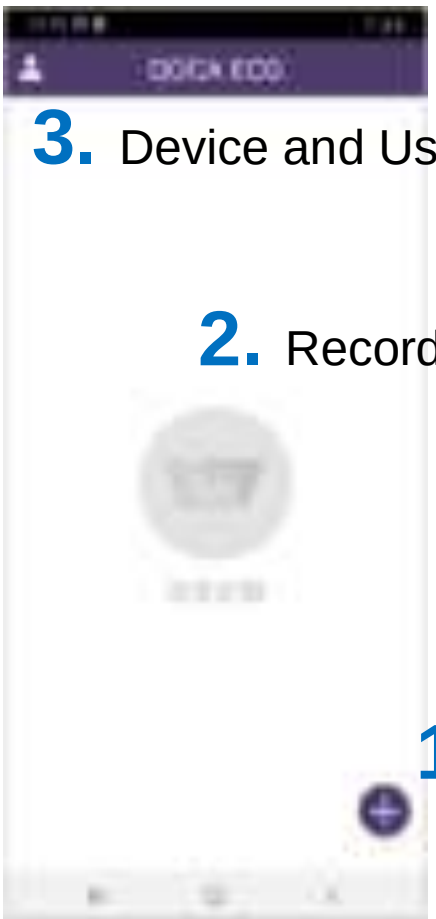
IMPORTANT: Able to engage in daily activities, do not do strenuous exercise, or swimming.

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. Skin exfoliation will help the contact of patch.

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 device. The main screen (as below figure) displays ECG records which should be shown to a medical professional for evaluation.



Take a Measurement

When you tap the + button in the QOCA ecg APP’s main screen, a measurement page will appear on the screen. It will show real time ECG waveform in the middle of screen.

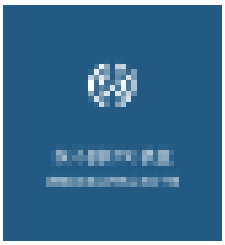
2. Real time ECG waveform

1. Measuring button

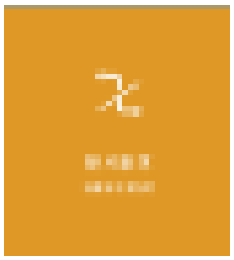
Once you tap the measuring button, it will start taking ECG measurement for 2 minutes. And you could see the countdown time bar is counting.

1. Countdown time bar

NOTE: When the Bluetooth is disconnected, it would show the BT disconnected message below.



NOTE: When the ECG sensor is worn inappropriately, it would show the lead off message below.



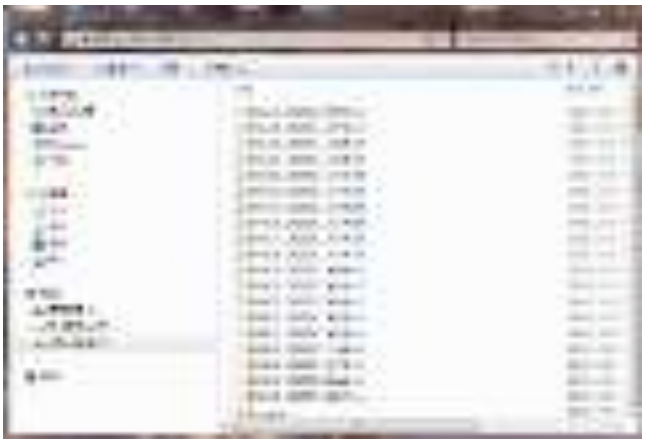
Check the Device and User Information

When you tap the Human figure button in the top-left corner of QOCA ecg APP's main screen, a device and user information page will appear on the screen. It will show the detailed user profile and device information.

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.

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 5 seconds	• Solid blue light for both Battery LED and Indicator LED while press the button • After 5 seconds turn off lights

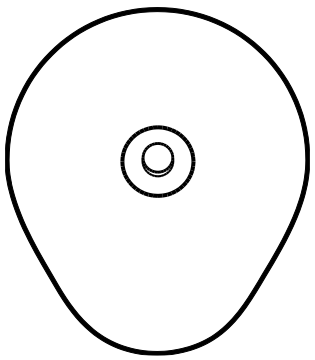
Lead off	User do not wear device	• Indicator LED flashing orange light
Event Recording	When it’s lead on and press power button	• Indicator LED flashing blue light
Low battery	N/A	• Battery LED flashing orange light
Charging	Put on charger	• Battery LED flashing blue light
Fully charged	Put on charger	• 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 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.
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 QOCA 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 MDD 93/42/EEC CE Marked
- FDA certified

Sensor Specifications

ECG Sensor	Continuous ECG data acquisition and calculation
	Measuring Lead: Lead 2 Frequency Response: Monitor 0.05 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 QOCA ecg APP will display "--".*
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 5.0: Transmit distance: 10 meters (open space) (2) Micro USB cable
USB	USB2.0
Battery	3.8V/340mAh
Battery Life	Storage mode: 14 Days or 5 Days @ 256Hz 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	IP26
Material flame retardant	PC+ABS, UL94V2
Weight	19 g for ecg103

Dimension	35(L) x 35(W) x 8.85(H) ±0.2 (mm) for ecg103

Charger Specifications

Input	5V/0.5A
Working Temperature	5 – 35°C
Storage Temperature	-20 – 60°C
Weight	22 ± 0.5 g
Dimension	42 mm (L) x 40.0 mm (W) x 12.0 mm (H) ±0.2 mm

Troubleshooting

1) **Cannot pair the QOCA PORTABLE ECG MONITORING DEVICE with the QOCA ecg APP.**
Refer to the notes listed in *Pairing*.

Gateway mode information

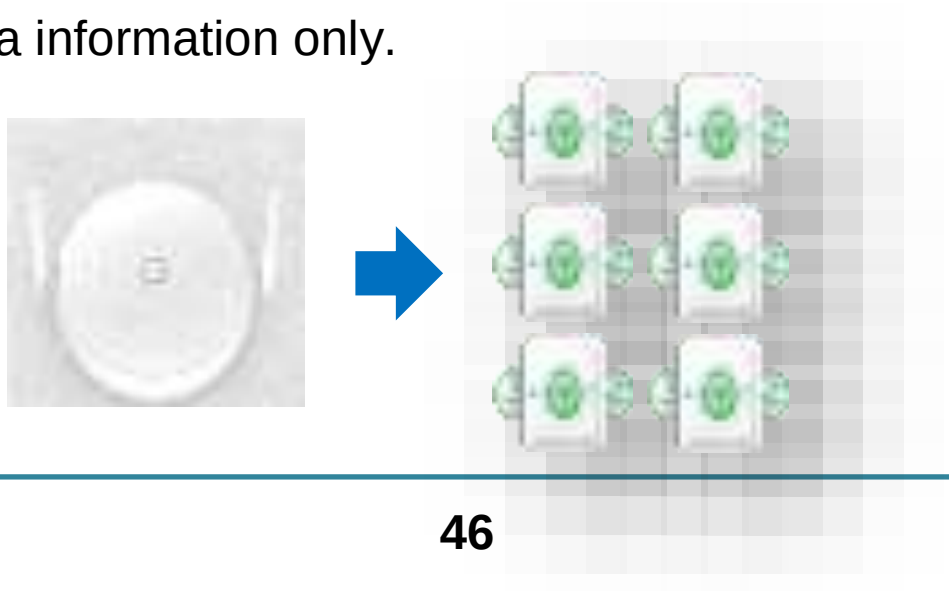
When using QOCA PORTABLE ECG MONITORING DEVICE, the data needs to be transmitted from many

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 6 sets) to connect gateway data transmission together, or any gateway device that meeting the following specifications:

Gateway Compatible Specifications

Blue tooth	BT 4.2 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.

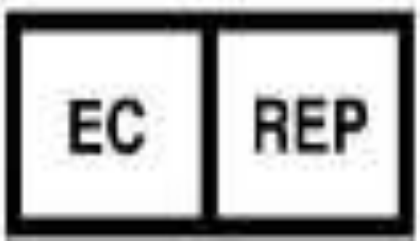


Customer Support

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: MedicalService@quantatw.com

EU Representative



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

Label Information:

Federal Communications Commission (FCC) Statement

The FCC ID is HFSCIH

15.21

You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

15.19

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

1) This device may not cause interference and

2) This device must accept any interference, including interference that may cause undesired operation of the device.

15.105(b)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates uses and can radiate radio frequency energy and, if not installed and used in

accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

FCC RF Radiation Exposure Statement:

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

For body worn operation, this device has been tested and meets FCC RF exposure guidelines. When used with an accessory that contains metal may not ensure compliance with FCC RF exposure guidelines

Regulatory Marks

The QOCA PORTABLE ECG MONITORING DEVICE conforms to the following regulatory requirements.
Administrative Regulations on Low Power Radio Waves Radiated Devices (930322)

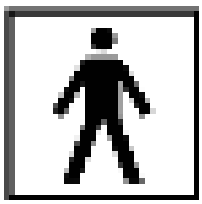
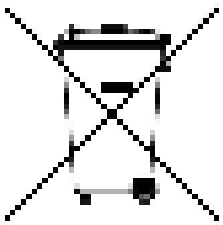
Article 12

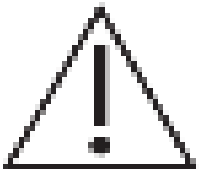
Without permission granted by the NCC, any company, enterprise, or user is not allowed to change frequency, enhance transmitting power or alter original characteristic as well as performance to an approved low power radio-frequency devices.

Article 14

The low power radio-frequency devices shall not influence aircraft security and interfere with legal communications. If found, the user shall cease operation immediately until no interference is achieved.

The said legal communications means radio communications is operated in compliance with the Telecommunications Act. The low power radio-frequency devices must be susceptible with the interference from legal communications or ISM radio wave radiated devices.

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 ecg103 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the ecg103 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 ecg103 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 ecg103 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	

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: -1.52 dBi
Rated Power (ERP)	-0.66 dBm

Manufacturer's declaration-electromagnetic immunity The ecg103 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the ecg103 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	± 0.5kV, ±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 ecg103 requires continued operation during power mains interruptions, it is recommended that the ecg103 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 ecg103 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 ecg103 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the ecg103 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 0,15 MHz and 80 MHz	**Portable and mobile RF communications equipment should be used no closer to any part of the** ecg103 including cables, than the recommended separation distance calculated from the equation

Radiated RF IEC 61000-4-3	radio bands between 0,15 MHz and 80 MHz 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	applicable to the frequency of the transmitter. **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 ecg103

The ecg103 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 ecg103 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ecg103 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 emissions		
The ecg103 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the ecg103 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 ecg103 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 ecg103 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	