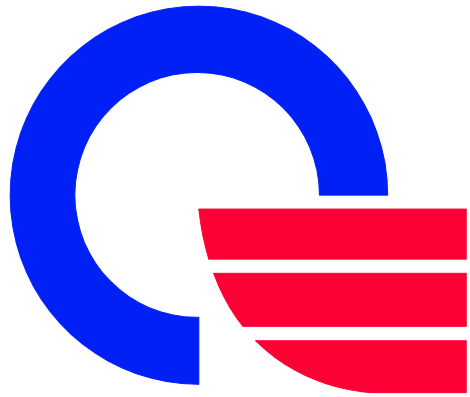


Quanta Computer

QOCA PORTABLE ECG MONITORING DEVICE
User Manual

Model name：ecg102D

CIE418-01 Ver.: 3A

TABLE OF CONTENTS

SAFETY NOTES

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

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

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

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

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

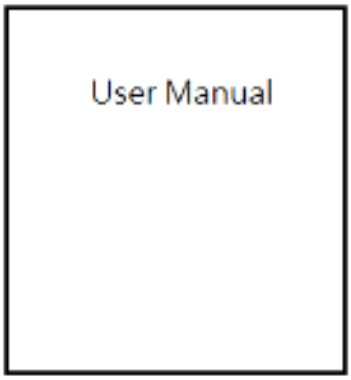
PRODUCT OVERVIEW

Indication for Use

The QOCA Portable ECG Monitoring Device is intended for use by trained medical personnel and trained adults to measure Electrocardiogram (ECG) and heart rate (HR) in hospitals, healthcare institutes, or home environments. The transmission, storage, and display of ECG and HR data are available with dedicated software.
The device is intended for use on adult patients who are not in critical condition.

Package Contents

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

	
ECG Sensor x 1	**User Manual x 1**

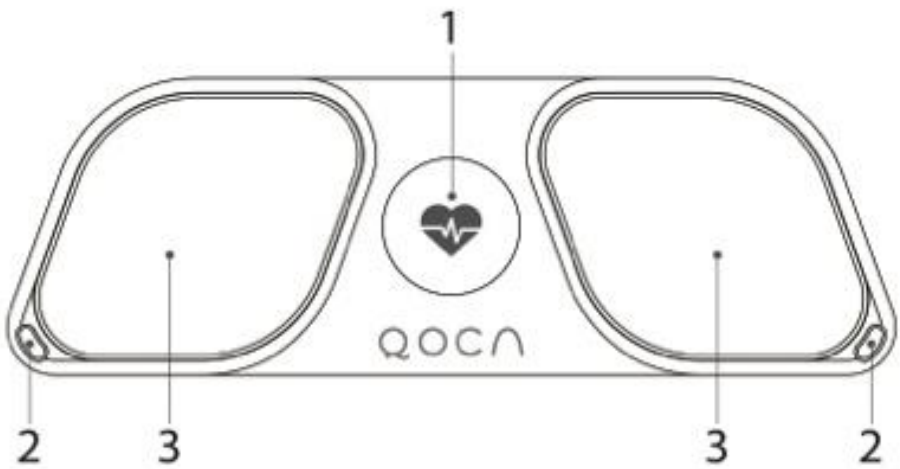
*Model name: ecg102D

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

Components

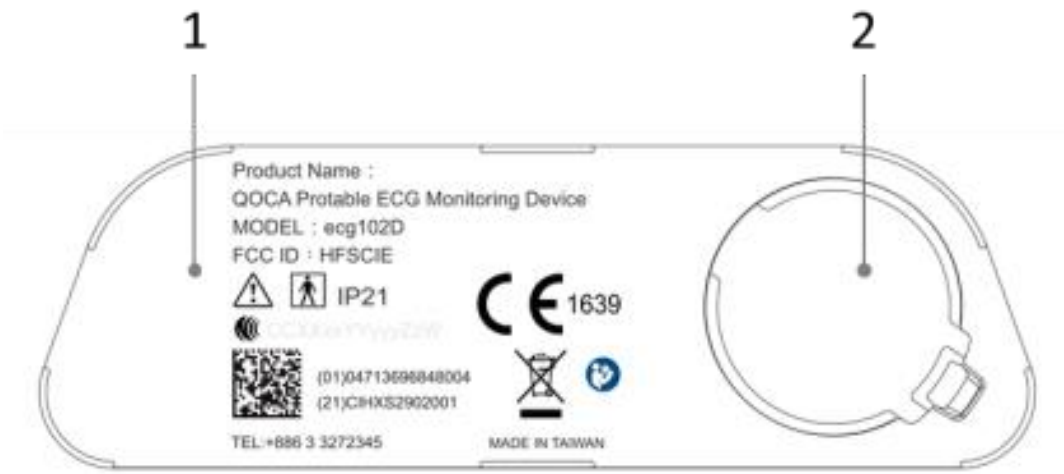
ECG Sensor

Front



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

Back



1	Label Area
2	Battery cover (Coin Battery CR2016)

Product Requirements

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

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

** Items not included in the product package.*

BEFORE YOU START

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

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

Installing the App

To install QOCA ECG app on your smartphone.

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

Enabling Bluetooth

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

GETTING STARTED

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

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

Sensor binding

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

Upload Record :

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

Personal use :

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

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

Main screen

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

Prepare to record ECG

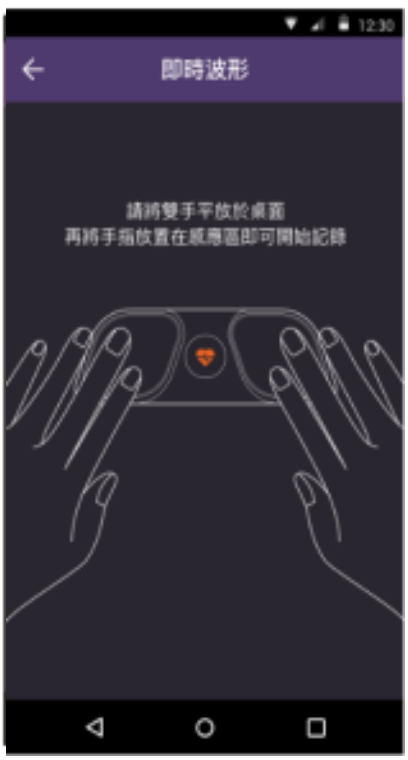
Before you start to record ECG you must:

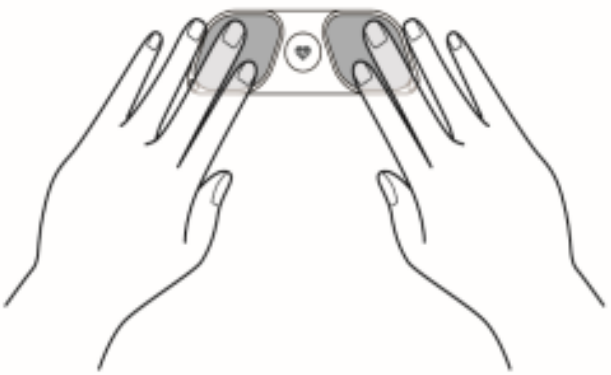
1. Lay ECG sensor on a flat surface near your smartphone.
2. Launch QOCA ECG app and tap “+” button (lower-right corner) on the screen. It will enter Real-Time ECG page.

<u>Note</u>: Make sure Bluetooth of your smartphone is turned on.

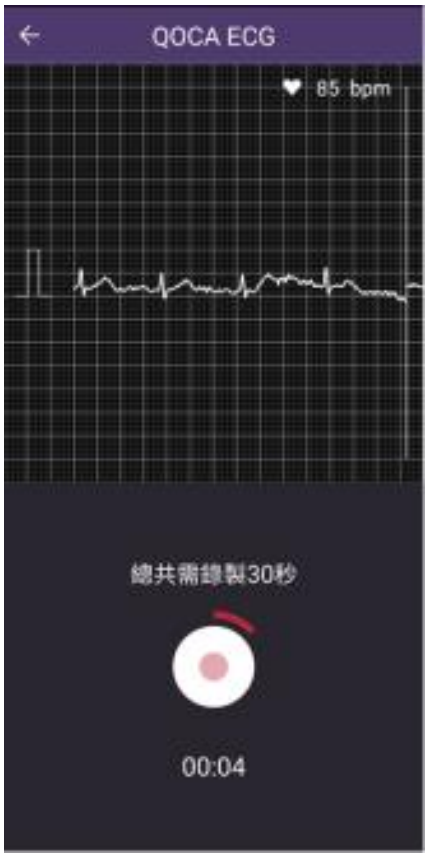
Start to record ECG

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





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



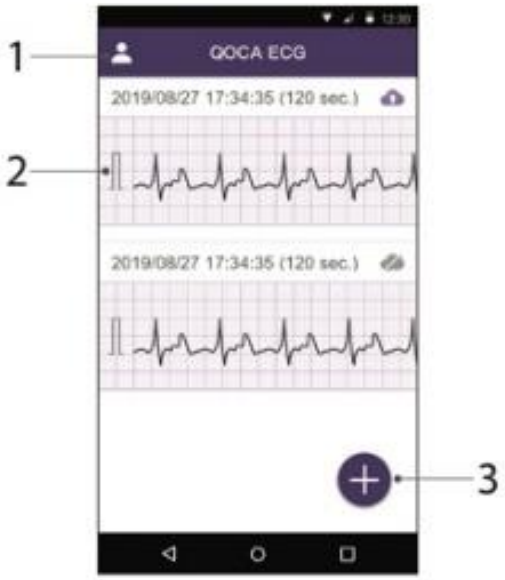
<u>Note</u>: It is critical to led fingers stable to avoid unwanted failure while recording ECG.
<u>Note</u>: The app will show “Recording complete” when you finished the measurement

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

THE QOCA ECG APP

Main Screen

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



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

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

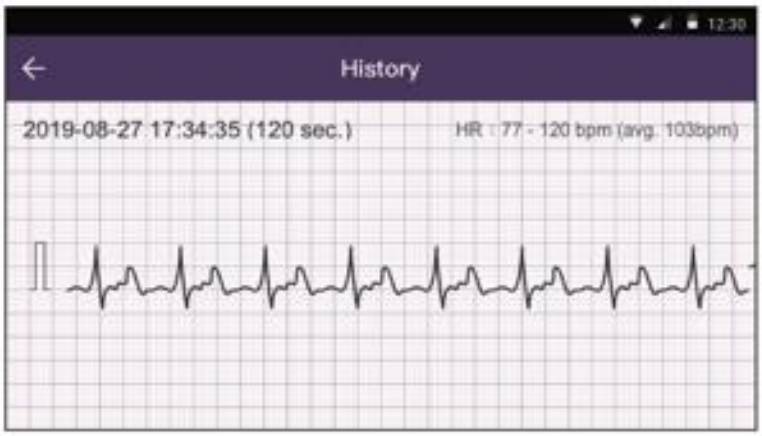
Real-Time ECG

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

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

History

The complete ECG is displayed on history page.



Profile (Upload record)

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

Profile (Personnel use)

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

Specifications

Sensor Specifications

ECG Sensor	Continuous ECG data acquisition and calculation
	Measuring Lead: Lead 2 Frequency Response: Monitor 0.5 to 40 Hz (-3db) Heart rate measurement range*: 30 – 240 bpm** Heart rate accuracy: ± 3 bpm or ±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 "--".*
Lead-off Detection	Detect when the sensor gets loosened from holder or body patch

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

Bluetooth Specifications

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

Device cleaning

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

Troubleshooting

1) Cannot bind the device with the QOCA ecg app

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

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

3) Connection problem

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

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

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

- Use water lotion if the surface of your fingers is too dry
- Please use the sensor on a flat table. Relax your hand muscles during measurement and keep your hands and fingers stable during measurement. Moving the finger will cause signal instability and noise during the measuring. Please press the metal electrode normally with your fingers, do not squeeze it hard.
- During the measurement, please do not place the sensor location higher than the heart or lower than the navel.

5) Before measurement, please eliminate the following situations. Phone is charging, transmitting data and using headphones.

6) Check if the product battery has enough power

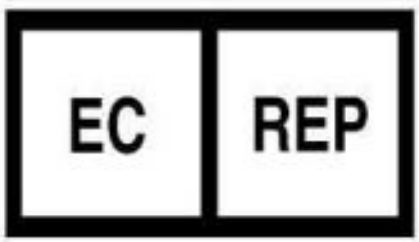
7) In order to collect stable data, please do not place the sensor device location higher than the body's heart.

Customer Support

For additional technical information, contact Quanta Customer Support Department.

Quanta Computer Inc.(QCI)
Address:
No. 188, Wenhua 2nd Rd.,
Guishan Dist., Taoyuan City 333, Taiwan
TEL: +886-3-327-2345
FAX: +886-3-318-4207
Email: MedicalService@quantatw.com

EU Representative



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

Federal Communications Commission (FCC) Statement

The FCC ID is HFSCIE

15.21
You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

15.19
This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
1) This device may not cause interference and
2) This device must accept any interference, including interference that may cause undesired operation of the device.

15.105(b)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may

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

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

FCC RF Radiation Exposure Statement:

1) This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter. For body worn operation, this device has been tested and meets FCC RF exposure guidelines. When used with an accessory that contains metal may not ensure compliance with FCC RF exposure guidelines

Regulatory Marks

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

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

Article 12

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

Article 14

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

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

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 sensor is classified as electrical or electronic equipment requiring proper disposal (WEEE Directive)
	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.

IP21	Protected against vertically dripping water

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 ecg102D is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the ecg102D 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 ecg102D 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 ecg102D 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 ecg102D is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the ecg102D should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance (for home and professional healthcare environment)**
Electrostatic discharge(ESD) IEC 61000-4-2	Contact: ± 8 kV Air ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	Contact: ± 8 kV Air ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	Not applicable Not applicable	Mains power quality should be that of a typical home and professional healthcare environment.
Surge IEC 61000-4-5	± 0.5kV, ±1kV line(s) to line(s) ± 0.5kV, ±1kV,± 2kV 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 Not applicable 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 ecg102D requires continued operation during power mains interruptions, it is recommended that the ecg102D 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 and 60 Hz	The ecg102D 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 ecg102D is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the ecg102D 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 Not applicable	**Portable and mobile RF communications equipment should be used no closer to any part of the ecg102D** 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.			

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

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

Recommended separation distance between portable and mobile RF communications equipment and the ecg102D			
The ecg102D 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 ecg102D can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ecg102D 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	N/A	0,12	0,23
0,1	N/A	0,38	0,73
1	N/A	1,2	2,3
10	N/A	3,8	7,3
100	N/A	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 ecg102D is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the ecg102D 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.