Smart Wearable ECG Monitoring Device User Manual V 1.0

TABLE OF CONTENTS

SAFETY NOTES

- The Quanta Smart Wearable ECG Monitoring Device is to be used for clinical assessment and personal reference only. The Quanta Smart Wearable ECG Monitoring Device is not intended for diagnostic use.
- The Quanta Smart Wearable ECG Monitoring Device consists entirely of sophisticated medical electrical parts so maintenance can only be carried out by professional technicians. Unauthorized disassembly of the device by the user is not allowed.
- The Quanta Smart Wearable ECG Monitoring Device must be used with the specified "accessories" and "electrodes". The use of accessories and electrodes from other brands may lead to faulty readings. For more information, see *Product Requirements*.
- Do not allow the metal connectors to come into contact with any kind of power source during use.
- Damaged or faulty accessories and electrodes should not be used.
- When the Quanta Smart Wearable ECG Monitoring Device is low on power, it will automatically stop taking measurements and the corresponding indicator lights will blink. Please charge the sensor as soon as it shows a low battery state.
- When the Quanta Smart Wearable ECG Monitoring Device is taking measurements, please try and avoid using any instruments or devices that may affect the accuracy of the readings (e.g. the use of a blood pressure meter will affect the measurement of the pulse).
- When the Quanta Smart Wearable ECG Monitoring Device is taking measurements, please try and avoid using other electronic devices nearby. If it must be used with other electronic devices simultaneously, please check to make sure that the Quanta Smart Wearable ECG Monitoring Device is continuing to take measurements normally.
- The Quanta Smart Wearable ECG Monitoring Device-specific accessories are defined in this user guide. The use of accessories from other brands may damage the device.
- Do not use the Quanta Smart Wearable ECG Monitoring Device in a flammable environment.
- When the environment temperature is 45degC, the surface temperature of Quanta Smart Wearable ECG Monitoring Device will be 46degC.
- When ambient temperature is 40~45degC, do not use the Quanta Smart Wearable ECG Monitoring Device for more than 4 hours to avoid low-temperature burns.
- Users have to buy ECG electrodes themselves when using the direct wear patch. The specification for ECG electrodes can be found in *ECG Electrode Information*.

- Pay attention to ensure that the Quanta Smart Wearable ECG Monitoring Device is not swallowed by pets or children.
- Cardiac pacemakers or other electrical stimulators may affect the accuracy of the measurements for the Quanta Smart Wearable ECG Monitoring Device.
- The conductive parts of the electrodes and associated connectors for type CF applied parts, including the neutral electrode, should not make contact with other conductive parts including the ground.
- Please read through this user guide carefully before using the Quanta Smart Wearable ECG Monitoring Device.
- If the Quanta Smart Wearable 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 8 hours to make sure that the electrodes are in the right position and there is no allergic skin reaction on the user.
- Do not use high-frequency instruments or electrical medical equipment such as "defibrillators" when using the Quanta Smart Wearable ECG Monitoring Device.
- When the Quanta Smart Wearable ECG Monitoring Device is taking measurements and a stable reading cannot be taken then stop taking measurements right away as not everyone is suitable to sensor using the Quanta Smart Wearable ECG Monitoring Device.
- The Quanta Smart Wearable ECG Monitoring Device can only take measurements when the subject is stationary (e.g. while sitting or lying down) or engaging in ordinary activity. Any activities not permitted by the attending physician may affect the accuracy of the measurements.
- Do not use the Quanta Smart Wearable ECG Monitoring Device in an excessively humid environment and never submerge it directly under water.
- Do not expose the Quanta Wearable ECG Monitoring Device to extremely temperature, moist environment, dust or direct sun light.
- Do not clean or wipe the Quanta Smart Wearable ECG Monitoring Device with corrosive and abrasive cleaning agents.
- The disposal of the Quanta Smart Wearable ECG Monitoring Device and its accessories should comply with the relevant local regulations.
- The Quanta Smart Wearable 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).
- The Quanta Smart Wearable ECG Monitoring Device and its accessories should be disposed of properly.
- Battery Caution: There is a risk of explosion if the battery for the Quanta Smart Wearable ECG Monitoring Device is replaced by an incorrect type.
- The Quanta Smart Wearable ECG Monitoring Device's use is not intended for infants weighing less than 10 kg.

- The expected service life of Quanta Smart Wearable ECG Monitoring Device is 3 years.
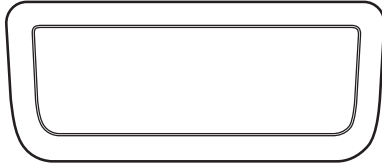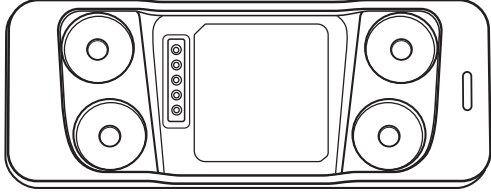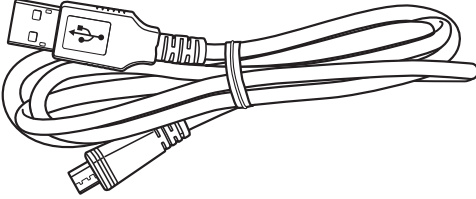
PRODUCT OVERVIEW
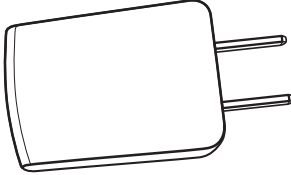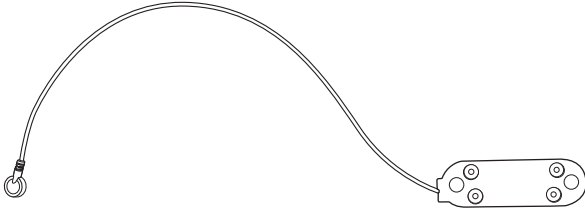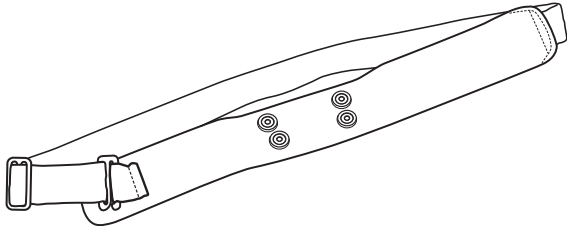
Indication for Use

The Quanta Smart Wearable ECG Monitoring Device is intended for use in the non-invasive measurement of a functional Electrocardiography (ECG) and heart rate (HR) in hospital, healthcare institute, and home environments by trained medical professionals and trained-adults. The Smart Wearable ECG Monitoring Device will process ECG signals and calculate HR. ECG and HR data will be transferred to a smartphone via Bluetooth, and further displayed on the smartphone screen via a dedicated app called Q-COR. The device should be worn on the human body along with a belt or a patch with gel electrodes. The Quanta Smart Wearable ECG Monitoring Device is sold to professional organizations such as home care givers, clinics, or hospitals rather than to the general public. It can only be installed by trained adults or medical personnel. Unauthorized installation by users is not allowed.

Package Contents

After purchasing the Smart Wearable ECG Monitoring Device please check the product package to ensure that the following items are included:

ECG Sensor x 1	**Charger x 1**
USB Charging Cable x 1	**5V/2A Adapter x 1**
Direct Wear Patch x 1 **(For Select Models)**	**Body Strap Patch x 1** **(For Select Models)**
Body Strap B1 x 1 **(For Select Models)**	**Body Strap B2 x 1** **(For Select Models)**
Pin x 1	**User Manual x 1**

Product Configurations

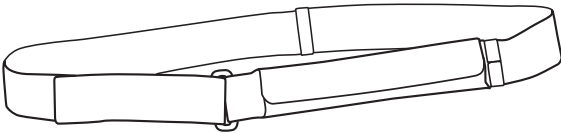The following is a table that lists the various product configurations for the Quanta Smart Wearable ECG Monitoring Device and the components included for each configuration.

Part Name	Model Number	Product Configuration		
		CI3SKU1	CI3SKU2	CI3SKU3
Smart Wearable ECG Sensor	CI3	V	V	V
Charger	CI3-C	V	V	V
Direct Wear Patch	CI3-P1	V		
Body Strap Patch	CI3-P2		V	
Body Strap B1	CI3-B1		V	
Body Strap B2	CI3-B2			V

Components

Sensor

Front
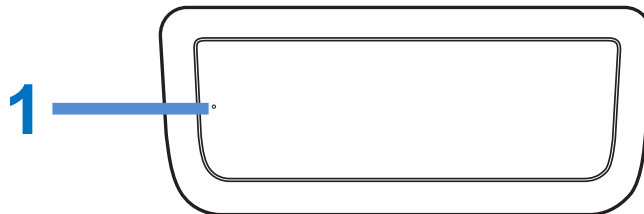
1	Status Indicator (see *LED Indicators* for more information)

Back
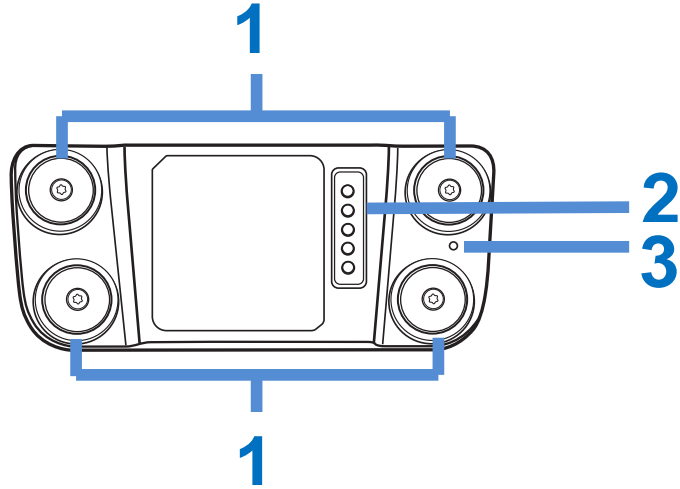
1	Patch Connectors
2	Charging Contacts
3	Bluetooth Pairing Button

Charger
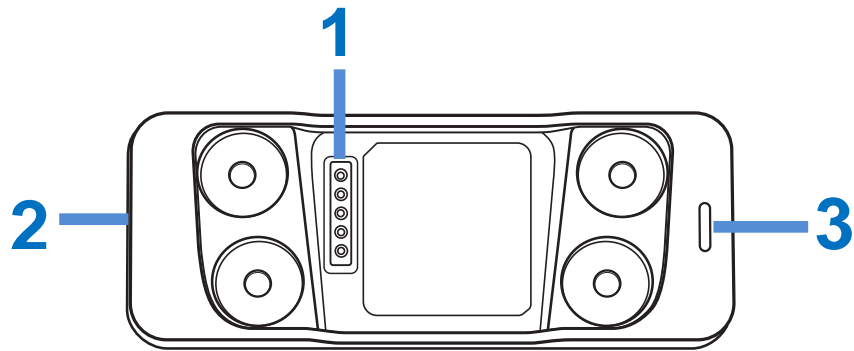
1	Charging Contacts
2	USB Charging Port
3	Charging Indicator (see *LED Indicators* for more information)

Body Strap Patch

Front
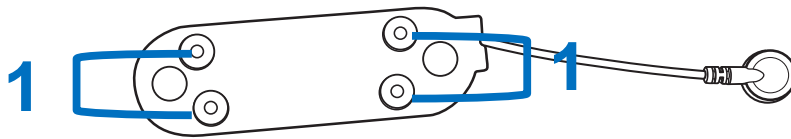
1	Sensor Connectors
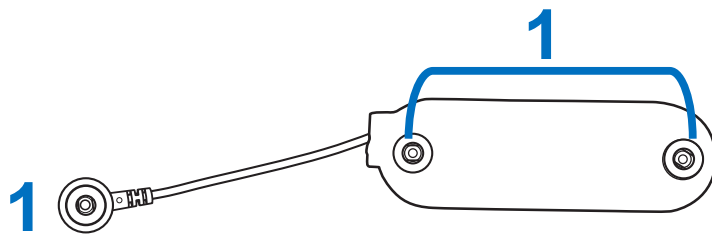
Back

1	Electrode Connectors

IMPORTANT: If any wear or damage to the wire shielding is found on the patch during use, replace immediately.

Direct Wear Patch

Front
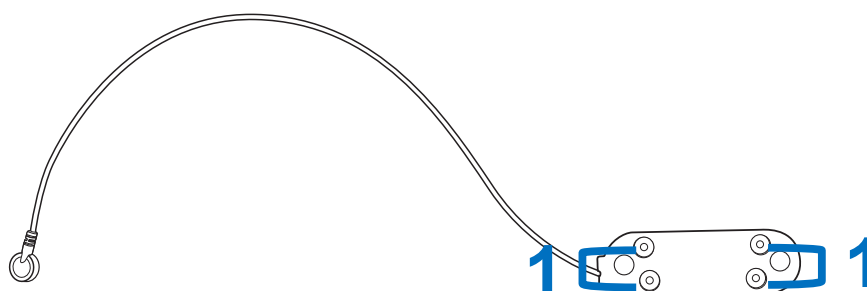
1	Sensor Connectors
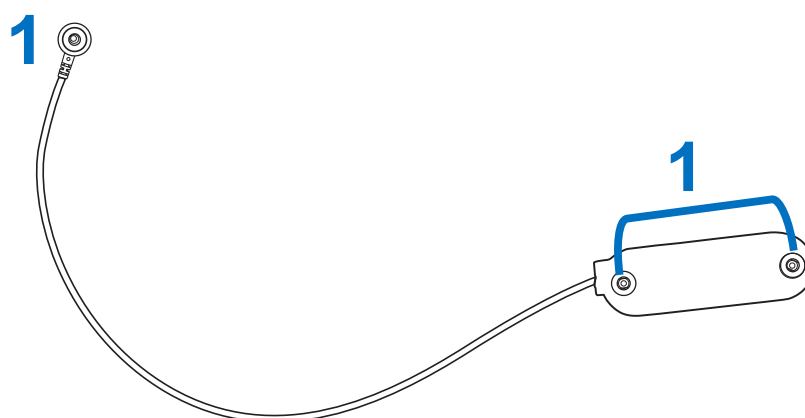
Back

1	Electrode Connectors

IMPORTANT: *If any wear or damage to the wire shielding is found on the patch during use, replace immediately.*

Product Requirements

In order to properly use the Smart Wearable ECG Monitoring Device the following items are required:

- The ECG Sensor
- For Wear with the Body Strap B1: (A) The Body Strap Patch and (B) The Body Strap B1
  For Wear with the Body Strap B2: The Body Strap B2
  For Direct Wear: (A) The Direct Wear Patch and (B) 3 ECG Electrodes*
  NOTE: _For more information on electrode specifications, see ECG Electrode Information._
- A Bluetooth-enabled Android Smartphone* (with Android version 5.0 or above and a display resolution of 1920x1080 or 2560x1440)
- The ECG Sensor App Q-COR*

* Items not included in the product package.

BEFORE YOU START

Before you start using the Smart Wearable ECG Monitoring Device you must:

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

Charging the Battery
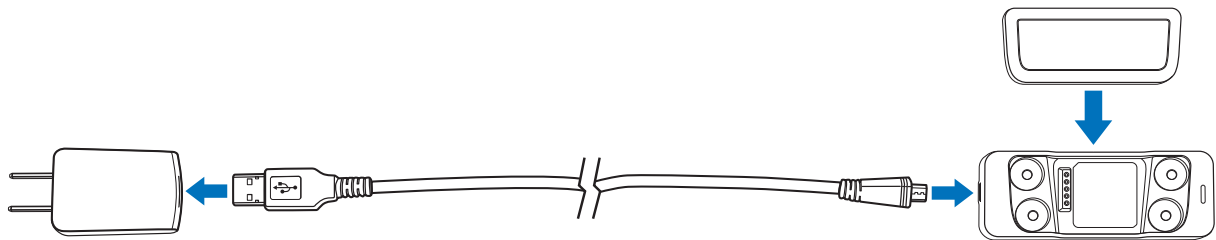
To charge the battery:

1. Plug the charger to a power source via the charging cable and adapter.
2. Place the sensor into the charger so that the charging contacts on both the sensor and charger make contact.
3. Charge the sensor until the charging indicator on the charger lights up solid green indicating that the battery is fully charged.

Installing the App

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

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

Enabling Bluetooth

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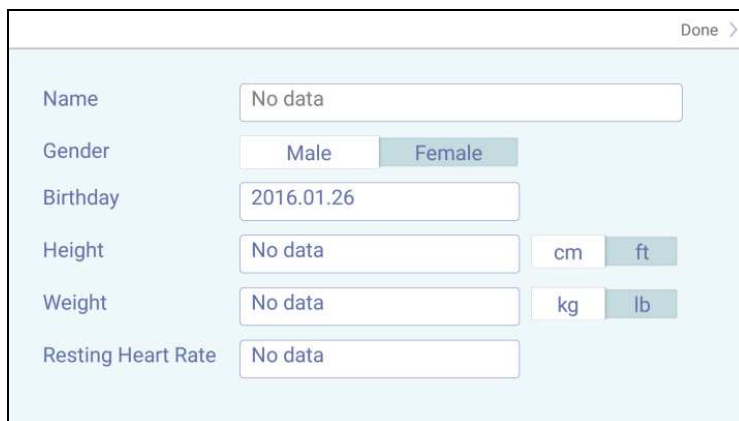
GETTING STARTED

Once you have completed the steps described in *Before You Start*, you can begin using the Smart Wearable ECG Monitoring Device by following these steps:

1. Create a profile in the Q-COR app
2. Pair your smartphone to the ECG sensor via Bluetooth
3. Wear the Smart Wearable ECG Monitoring Device

Creating a Profile

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

- **Name**
- **Gender**
- **Birthday**
- **Height**
- **Weight**
- **Resting Heart Rate**
  IMPORTANT: Filling in your correct resting heart rate is vital to the operation of the Smart Wearable ECG Monitoring Device. To determine your resting heart rate measure your heart rate after at least 5 minutes of inactivity, you may also request a trained professional to measure your resting heart rate for a more accurate measure.

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

Pairing

After creating a profile, the Q-COR app will prompt you to pair the sensor to your smartphone. To pair the sensor to your smartphone:

Pairing with ECG accessory

Press and hold the hole on the device back
with the pairing tool until the green and orange light starts flashing,
and press OK button on the mobile screen.

Cancel   OK

1. Use the pin included in the package to push the Bluetooth pairing button on the sensor.
2. The status indicator on the sensor will alternately flash orange and green indicating that it is in pairing mode.
3. Once the sensor is in pairing mode tap **OK** on your smartphone.
4. Wait until you get a message on your smartphone indicating that the pairing was successful.

NOTE: After pushing the Bluetooth pairing button the sensor will stay in pairing mode for 1 minute. If pairing has not been completed during that time push the pairing button and follow the steps above again.
NOTE: Not all smartphones can pair with the ECG sensor directly through the Q-COR app as Bluetooth functionality may vary depending on smartphone model. In cases where pairing within the Q-COR app fails (as shown in the screenshot below), enter the Bluetooth menu in the Android Settings menu (Settings > Bluetooth > Pairing) and proceed to pair the two devices directly from there.

Wearing the ECG Sensor

Depending on the model you have purchased you may either wear the ECG sensor using the provided body strap, or wear the ECG sensor directly on your body.

IMPORTANT: When wearing the ECG sensor directly you must use separately purchased electrodes for the device to work properly. For more information on electrode specifications see ECG Electrode Information.
IMPORTANT: When wearing the ECG sensor either directly or with the body strap, ensure that the contacts on the electrodes or the strap are in direct contact with your skin and that the contact area on the skin is sufficiently clean and dry. You may wipe the skin clean with a wet towel or alcohol swab and allow it to dry to before wearing the ECG sensor.
IMPORTANT: If the skin at the contact point shows signs of rash/blisters/reddening or other discomfort, please contact a medical professional or physician.

Wearing the ECG Sensor with the Body Strap B1
To wear the ECG sensor using the body strap B1 follow the directions below:

1. Open up the front pocket of the body strap.
2. Attach the patch to the front of the body strap so that the left sensor side of the patch attaches to the connector on the strap next to the ring loop (see image below).
3. Attach the ECG sensor to the front of the patch so that all four patch connectors on the sensor are properly clicked into the four sensor connectors on the patch (see image below).

Sensor
Side

Ring
Loop
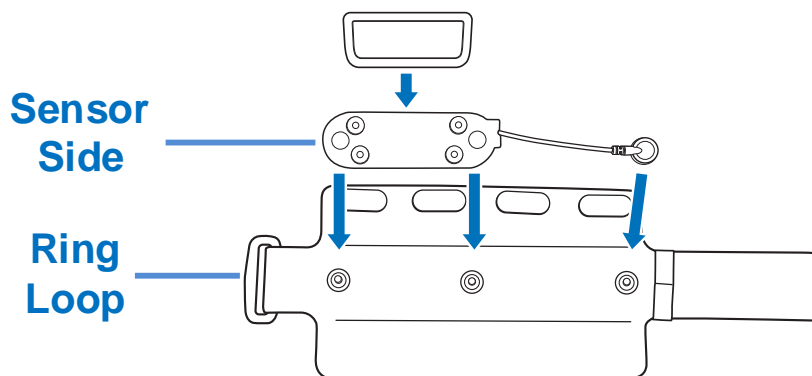
NOTE: Once connected, the status indicator on the sensor will light green then slowly flash indicating that the sensor is connected to the patch, but that the patch has not properly made contact with a body.

4. Fold over and adhere the Velcro tabs to close the front pocket of the body strap.
5. Wrap the body strap around your torso and tighten it so that it fits firmly around middle of your torso.
6. Adjust the positioning of the strap so that the pocket is slightly under your pectoral area and the midpoint between the first and second contact on the strap aligns with the middle of the rib cage (see image below).
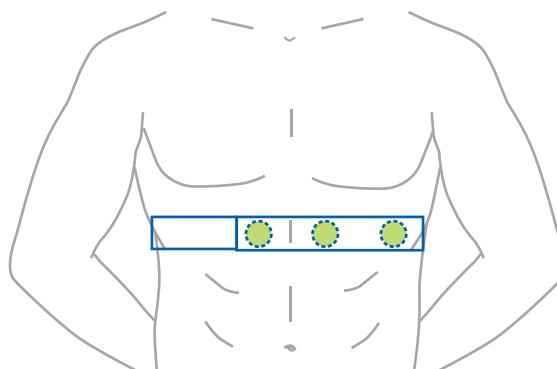
7. Once the ECG sensor is properly worn on your body the Q-COR app will start showing an ECG reading.

Wearing the ECG Sensor with the Body Strap B2

To wear the ECG sensor using the body strap B2 follow the directions below:

1. Attach the ECG sensor to the front of the body strap so that all four patch connectors on the sensor are properly clicked into the four sensor connectors on the body strap (see image below).

NOTE: Once connected, the status indicator on the sensor will light green then slowly flash indicating that the sensor is connected to the patch, but that the patch has not properly made contact with a body.

2. Wrap the body strap around your torso and then clip the strap clip to the front of the strap (see image below). Tighten the body strap so that it fits firmly around middle of your torso.

3. Adjust the positioning of the strap so that the pocket is slightly under your pectoral area and the second contact on the strap aligns with the middle of the rib cage (see image below).

4. Once the ECG sensor is properly worn on your body the Q-COR app will start showing an ECG reading.

Direct Wear

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

1. Attach an ECG electrode to each of the 3 connectors on the back of the patch (see image below).
   NOTE: For more information on electrode specifications, see ECG Electrode Information.
2. Attach the ECG sensor to the front of the patch so that all four patch connectors on the sensor are properly clicked into the four sensor connectors on the patch (see image below).
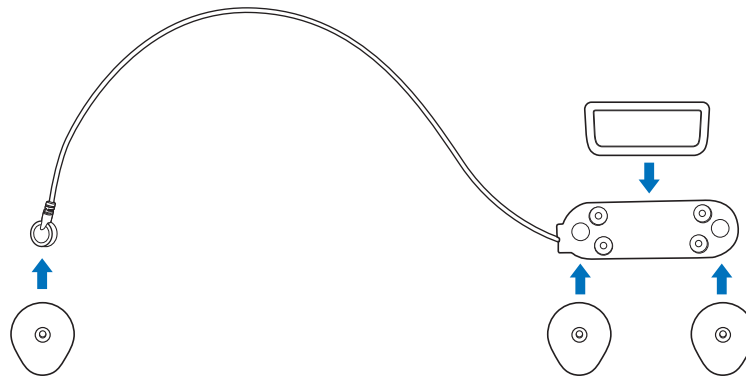
3. Unpeel the paper strips on the contact side of each of the ECG electrodes.
4. Adhere the 2 electrodes attached to the sensor side of the patch to under your left pectoral area (see image below).
   NOTE: The electrodes feature adhesive on the contact side to ensure that they adhere to your body, if an electrode does not properly adhere please replace the electrode with a new one.
5. Adhere the electrode attached to the cable side of the patch to the area slightly under your right collarbone (see image below).
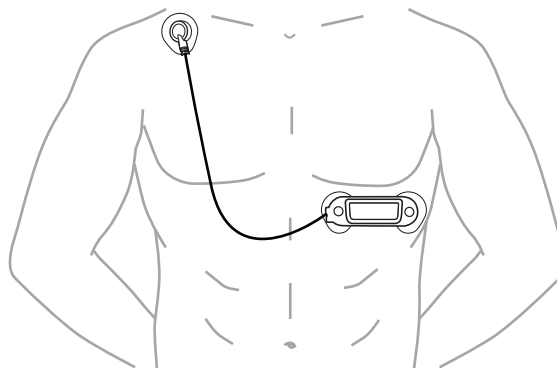
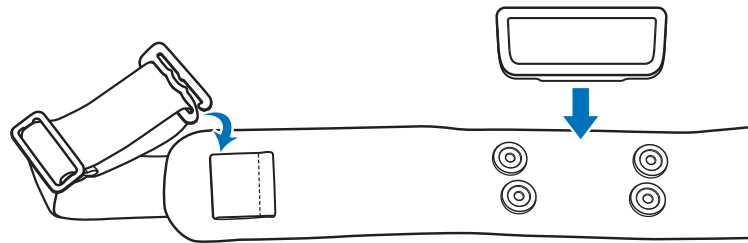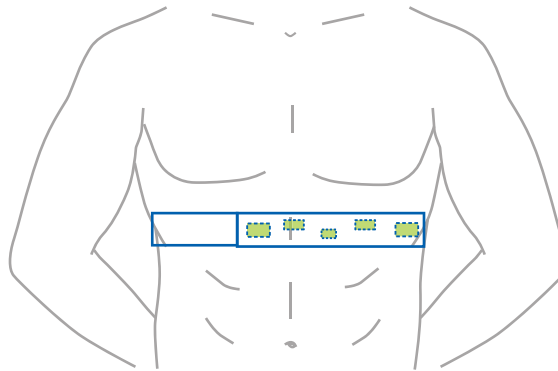6. Once the ECG sensor is properly worn on your body the Q-COR app will start showing an ECG.

IMPORTANT: When directly wearing the ECG sensor, ensure that all 3 electrodes are firmly adhered to your body and that neither parts of the patch are left dangling, as seen in the image below, which may lead to damage or short-circuit if contact is made with another power

supply.
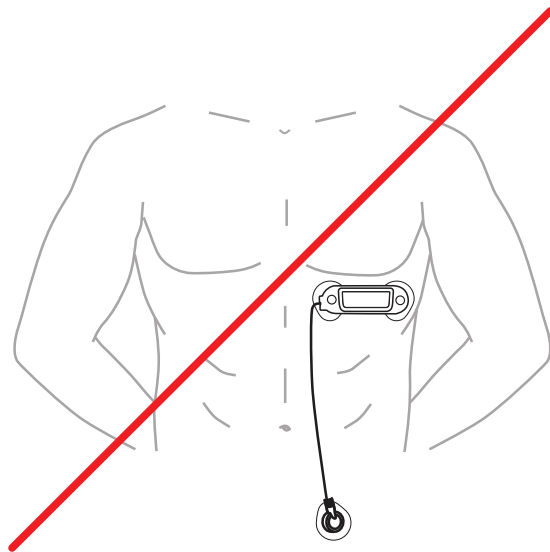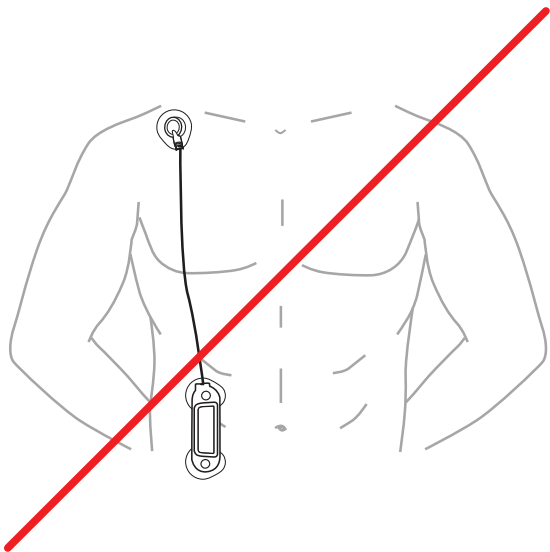
THE Q-COR APP

Main Screen

Once you have successfully paired and worn the ECG sensor, the Q-COR app's main screen will be displayed on your mobile device. The main screen displays a real-time ECG which you can present to a medical professional for evaluation. The following items can comprise the main screen:

No	Item	Description
1	Menu Button	Tap to access the app menu. For more information see *NOTE: When using the Q-COR app the default Back button on your Android smartphone will be disabled, in order to exit the Q-COR app you must use the Quit button in the Q-COR app's menu, for more information see Quit.* *NOTE: The Q-COR will trigger your smartphone to vibrate when the battery on the sensor is low.* Menu.
2	Profile Settings	Displays the profile settings that were entered during the profile creation process. For more information on changing profile settings, see *Profile*.
3	Real-Time ECG	Displays your real-time ECG in 5 second intervals.
4	Battery Status	Displays the current charge level for the battery.
5	Connection Status	Displays the connection status for the ECG sensor. If the ECG sensor is disconnected while in use, see *Pairing* for instructions on pairing your device.

NOTE: When using the Q-COR app the default Back button on your Android smartphone will be disabled, in order to exit the Q-COR app you must use the Quit button in the Q-COR app's menu, for more

information see Quit.
<u>NOTE</u>: *The Q-COR will trigger your smartphone to vibrate when the battery on the sensor is low.*

Menu

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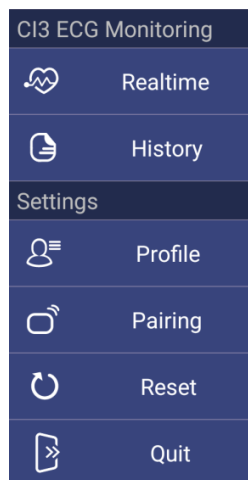
History

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

No	Item	Description

1	Date Button	Tap to view an ECG from a different date, for more information, see *Date.*
2	Menu Button	Tap to access the app menu.
3	ECG History	Displays your ECG history. Swipe left or right to move to forward or backward on your ECG history.
4	Display Options Button	Tap to rescale the view of the ECG history, for more information, see *Date* When you tap the date button in the History screen a calendar view will appear. The calendar view allows you to view your ECG on days when an ECG was recorded (indicated by a circled date) by tapping on the respective date. *NOTE: The Q-COR app will store ECG data for up to 7 days.* <table><tr><td>‹ History</td><td colspan="5">2016.02</td><td>Done ›</td></tr><tr><td>Sun</td><td>Mon</td><td>Tue</td><td>Wed</td><td>Thu</td><td>Fri</td><td>Sat</td></tr><tr><td></td><td>01</td><td>02</td><td>03</td><td>04</td><td>05</td><td>06</td></tr><tr><td></td><td>07</td><td>08</td><td>09</td><td>10</td><td>11</td><td>12</td><td>13</td></tr><tr><td></td><td>14</td><td>15</td><td>16</td><td>17</td><td>18</td><td>19</td><td>20</td></tr><tr><td></td><td>21</td><td>22</td><td>23</td><td>24</td><td>25</td><td>26</td><td>27</td></tr></table> *Display Options*
5	Timeline Scroll Bar	Allows you to quickly scroll to a different point in time of your ECG history. The numbers on the scroll bar represent the hour of the day shown, and each point on the scroll bar represents 10 minutes.

Date

When you tap the date button in the History screen a calendar view will appear. The calendar view allows you to view your ECG on days when an ECG was recorded (indicated by a circled date) by tapping on the respective date.

NOTE: The Q-COR app will store ECG data for up to 7 days.

‹ History			2016.02			Done ›
Sun	Mon	Tue	Wed	Thu	Fri	Sat
	01	02	03	04	05	06
07	08	09	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
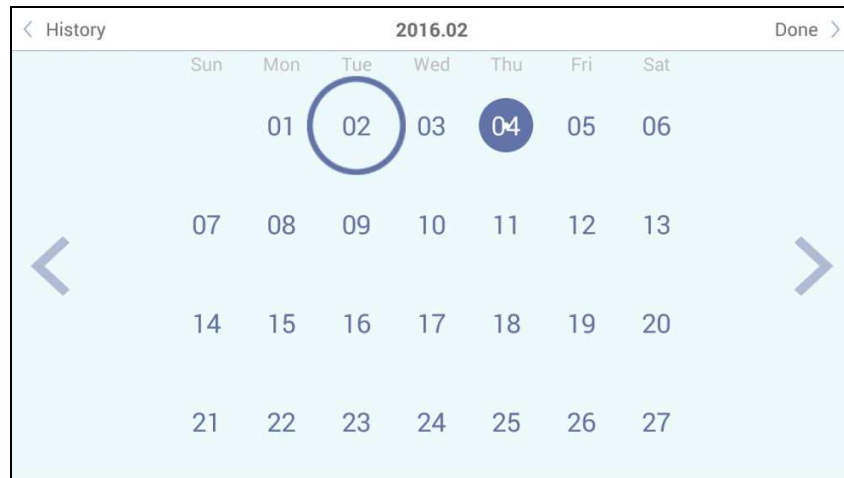
Display Options

The ECG displayed on the Q-COR app is displayed on a grid where the horizontal axis measures time (in seconds), and the vertical axis measures the electrical activity (in millivolts). Each unit on the grid is 1mm in size. By changing the display options for the ECG history you will be able to rescale the ECG on the grid for either a more detailed or a more general view. The following display options are available for the ECG history:
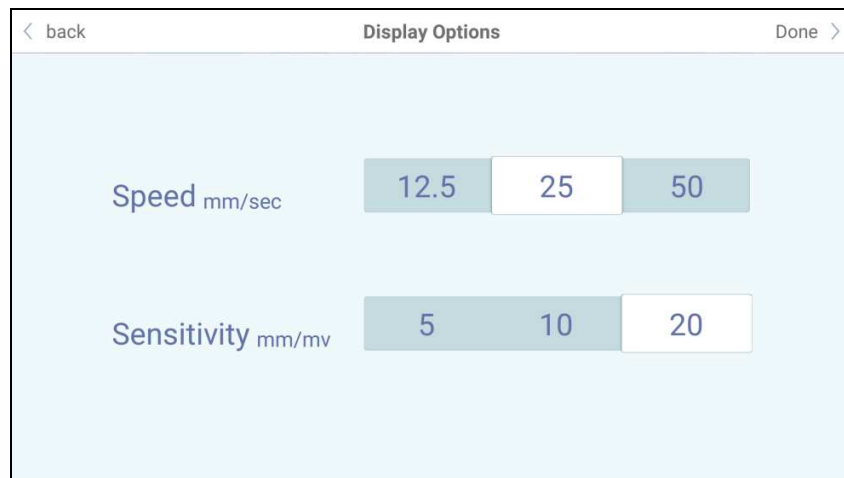
- **Speed**: Using a lower speed option will shrink the ECG along the horizontal axis of the grid, while using a higher speed option will expand the ECG along the horizontal axis of the grid.
- **Sensitivity**: Using a lower sensitivity option will shrink the ECG along the vertical axis of the grid, while using a higher sensitivity option will expand the ECG along the vertical axis of the grid.

Profile

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

Pairing

Tap **Pairing** in the Q-COR app menu to pair/re-pair the ECG sensor to an Android smartphone. Follow the same instructions in

Pairing to pair the ECG sensor to a smartphone.

Reset

Tap **Reset** in the Q-COR app to reset the app so that all previous profile settings and ECG history are deleted. Pairing information will still be stored on the device after resetting.

Quit

Tap **Quit** in the Q-COR app to exit the app and return to the Android interface.

ADDITIONAL INFORMATION

LED Indicators

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

Status Indicator (Sensor)

Indicator Color	Status
Flashing Orange	Battery Low
Alternate Green and Orange (1 min. intervals)	Pairing in Progress
Green for 5 seconds followed by 3 flashes	Connected to Sensor Connectors

Charging Indicator (Charger)

Indicator Color	Status
Solid Orange	Charging In Progress
Solid Green	Fully Charged

Cleaning

Below is a table that describes the cleaning methods for various items included with the Smart Wearable ECG Monitoring Device:

Item	Cleaning Method
CI3 Sensor	Wipe with a dry cloth
CI3 Charger	Wipe with a dry cloth
Patch	Carefully wipe with a dry cloth
Body Strap B1/B2	Place within a wash bag for use in a washing machine; DO NOT USE BLEACH; DO NOT DRY IN A CLOTHES DRYER

ECG Electrode Information
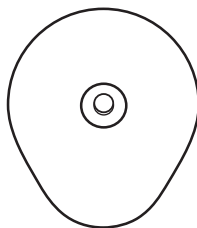
When using the direct wear patch for the Smart Wearable ECG Monitoring Device you must use separately purchased electrodes for the ECG sensor to work properly. Suggested electrodes include Kendall Ag/AgCl electrodes or any electrodes that feature the following specifications:

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

Specifications

Sensor Specifications

ECG Sensor	Continuous ECG data acquisition and calculation
	Measuring Lead: Lead 1 (Lead 2 with direct wear patch) Frequency Response: Monitor 0.1 to 40 Hz (-3db) Heart rate measurement range: 30 – 240 bpm *HR is calculated based on R-R interval of ECG **If HR calculated falls out of 30-240bpm range, Q-COR app will display "--". Heart rate accuracy: ± 3 bpm or ±3% whichever is greater Differential Input Impedance: > 10MΩ Common Mode Rejection Ratio: > 70 dB Sampling rate: 256Hz
Activity Detection	Activity Status detection by G-sensor G-sensor (3 axis): ±8g G-sensor sampling rate: 52Hz G-sensor accuracy: ±0.0156g
Energy Expenditure	Calculated from HR and activity data
Lead-off Detection	Detect when the sensor gets loosened from patch or belts
Network	Bluetooth 4.0 Dual mode (BT3.0+BLE) Transmit distance: 10 meters (open space)
USB	USB2.0
Battery	3.7V/140mAh
Battery Life	9 – 10 hours
Working Temperature / Humidity	$5 – 45^0C$, 10% – 95% non-condensing
Storage Temperature / Humidity	$-20 – 60^0C$, 10% – 95% non-condensing
Atmospheric Pressure Range	800 hPa to 1013 hPA
Altitude	2000m
Enclosure Rating	IP22
Weight	20g
Dimension	69.89mm (L) x 29.6mm(W) x 10.7mm(H)

Charger Specifications

Charging indicator	Green LED: Fully charge Orange LED: Charging in process
Input	5V/0.5A
Working Temperature	0 – 40°C
Storage Temperature	-20 – 60°C
Weight	25g
Dimension	90mm (L) x 34.4mm(W) x 13.66mm(H)

Trouble shooting

1. Cannot pair CI3 sensor with Q-COR app: refer to the notes listed in the Pairing chapter.

2. LED on cradle does not light up when Smart Wearable ECG Monitoring Device is placed in: check the AC adaptor input or try to put Smart Wearable ECG Monitoring Device in again.

Customer Support

For additional technical information, contact Quanta Customer Support Department:
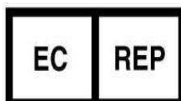
Quanta Computer Inc.(QCI)
Address:
No. 188, Wenhua 2nd Rd., Guishan Dist., Taoyuan City 333, Taiwan
TEL: +886-3-327-2345
FAX: +886-3-318-4207
Email: MedicalSales@quantatw.com

EU Representative

EC	REP

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

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.

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:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Manufacture Date

The year of manufacture label and format of the wireless home health management system's body sensor, charger and ECG electrodes are shown below:

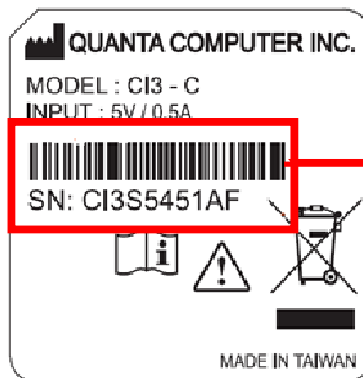## Smart Wearable ECG Monitoring Device (CI3)

Charger (CI3-C)

SN: CI3S5451AF

In the serial number on the product label, the 5th character starting from the left represents the sensor and charger's year of manufacture, while the 6th and 7th character represents the week of manufacture. In the example shown the "5" represents a manufacture year of 2015 and the "45" represents the 45th week of 2015.

Supplier's Declaration

The Quanta Smart Wearable 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.

Emission Testing	Compliant Standard	Electromagnetic Environment Guidelines
The recommended electromagnetic environment for this instrument is shown in the table below. The customer or user should ensure that this instrument is used in the described environment.		
RF Emissions CISPR 11	Group 1	Radio-frequency is only used by the internal functions of this instrument. The emission energy is also very low and does not interfere with nearby electronic instruments.
RF Emissions CISPR 11	Class B	This instrument is suitable for home use (including residential or other mixed residential/public low-voltage power grids)
Harmonic Emissions	IEC 61000-3-2	
Voltage Fluctuations/ Flicker Emissions	IEC 61000-3-3	

Testing	IEC 60601-1-2 testing	Compliant Standard	Electromagnetic Environment Guidelines
The recommended electromagnetic environment for this instrument is shown in the table below. The customer or user should ensure that it is used in the described environment.			
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	The floor should be timber, concrete or ceramic tile. If the floor is covered in a synthetic material then it should have a relative humidity of at least 30%.
Power Frequency (50/60Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency and magnetic field in representative commercial or hospital environments.

Supplier's declaration and guidelines — Electromagnetic Immunity

Testing	IEC 60601-1-2 testing	Compliant Standard	Electromagnetic Environment Guidelines
The recommended electromagnetic environment for this instrument is shown in the table below. The customer or user should ensure that it is used in the described environment.			

No part of the Quanta Smart Wearable ECG Monitoring Device should be placed near portable and mobile radio-frequency communications equipment. The recommended safety distance can be calculated using the radio frequency and the following formula.			
Radio-frequency IEC 61000-4-6 Radio-frequency IEC 61000-4-3	3 V/m 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	[3] V [3] V/m	Recommended safety distance $d=1.17\sqrt{P}$ $d=1.17\sqrt{P}$ 80 MHz to 800MHz $d=2.33\sqrt{P}$ 800MHz to 2.5 GHz P is the maximum output of the transmitter (Unit: Watt) d is the recommended safety distance (Unit: Meter) The field intensity of the fixed RF transmitter (after an EM site survey) should be lower than the recommended values for the above frequency ranges. Interference may be produced near instruments that have the following symbol:

The field intensity of fixed RF transmitters (e.g. radio, mobile phone, ham radio, FM and AM radio broadcasts and TV stations) cannot be predicted from the frequency alone. To evaluate the EM field intensity of the environment, an EM site survey may be necessary. If the measured field intensity for a region exceeds the above recommended range, the device should be observed or checked to make sure it operates normally. If abnormal operation is observed, further action such as adjusting the direction or re-positioning of the equipment should be taken.

Attention:
For frequencies between 80 MHz and 800 MHz, use the higher frequency range.

Attention:
These guidelines may not be applicable to all situations. Electromagnetic waves can be absorbed or reflected by buildings, objects and people.

Recommended safety distance

The following table lists the recommended safety distance between the device and mobile RF communications equipment.

The recommended EM environment for the Quanta Smart Wearable ECG Monitoring Device is where RF interference is controlled. The user should maintain the recommended safety distance with the devices and portable/mobile RF communications equipment listed in the following table (corresponding to the maximum output of the RF transmitter).			
	Recommended Safety Distance (corresponding to RF transmitter output)		
Maximum output of RF transmitter (Watt)	150 kHz to 80 MHz d=1.17 $\sqrt{P}$	80 MHz to 800 MHz d=1.17 $\sqrt{P}$	800 MHz to 2.5 GHz d=2.33 $\sqrt{P}$

0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

If the maximum output of the transmitter is not shown in the above table, use the formula to derive the recommended safety distance d (Meter) with P (Watt) being the maximum output of the transmitter.

Attention:

For frequencies between 80 MHz and 800 MHz, use the higher frequency range.

Attention:

These guidelines may not be applicable to all situations. Electromagnetic waves can be absorbed or reflected by buildings, objects and people.

Regulatory Marks

The Quanta Smart Wearable ECG Monitoring Device conforms to the following regulatory requirements. Administrative Regulations on Low Power Radio Waves Radiated Devices (930322)

Article 12

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

Article 14

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

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

CE 0120	CE Mark: Indicates that the body sensor has been certified and conforms to EC Directive 93/42/EEC on medical devices.
♥	Type CF applied part
(WEEE symbol)	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
📖ℹ	Indicates the need for the user to consult the instructions for use.