

# QT ECG USER'S MANUAL

## IMPORTANT WARNINGS

- Federal law restricts sale of this device by or on the order of a physician.
- This device is not defibrillator-proof.
- MR Unsafe! Do not expose the device to a magnetic resonance (MR) environment.
- Do not try to charge the QT ECG Recorder while it is connected to the Electrode Strip.
- Do not place the Electrode Strip on yourself. Ask someone else to help you.
- Both you and the person helping you need to read this manual thoroughly before using the QT ECG. For your safety, follow the operating instructions and all safety measures, including warnings and cautions, listed in this manual to ensure safe and reliable performance of the system.
- The Electrode Strip is for one-time use only. Do not reuse. To prevent potential transmission of infection or disease, dispose the Electrode Strip properly after each use. Contact local authorities for proper disposal method of potentially bio-hazardous materials.
- Always use the latest version of the QT ECG App.

## 1. INTRODUCTION

This user manual provides information on the QT ECG system and instructions on how to use it.

### 1.1 System Description

The QT ECG system is a hand-held, cordless 12-lead electrocardiograph (ECG) system with Bluetooth connectivity. The QT ECG system consists of 3 major components:

- **The QT ECG Recorder** – Compact device that records 12-lead, resting electrocardiograms, then transmits the recorded data to a mobile device (smartphone, tablet, etc.) paired via Bluetooth. A Bluetooth-enabled mobile device (not included) is needed to operate the QT ECG Recorder, and to send the recorded rhythm strip to a cardiologist or licensed physician for review.
- **The QT Electrode Strip** – Disposable, patented electrodes that are prepositioned on a self-adhesive strip
- **The QT ECG App** – Software that lets you use your mobile device to operate the QT ECG recorder, then send the recorded data via email to a certified medical professional for review.

**Note: To use the QT ECG system, you will need to have a Bluetooth-enabled mobile device.**

**Warning: Use only manufacturer-approved accessories with the QT ECG.**

**Warning: The QT ECG is not intended for treatment or monitoring. It captures data that reflect the patient's physiological condition. The data must be reviewed and analyzed by a cardiologist or trained physician before a diagnosis is made.**

### 1.2 Indication for Use

The QT ECG System is intended to acquire, record and process an electrocardiographic signal so that it can be transmitted digitally via Bluetooth technology to a cell-phone or mobile device, then to a remote location. The QT ECG System is indicated for use on adult patients and pediatric patients age 18

– 22 years. It is designed to be used by a patient or other layperson in the home, or by healthcare workers in non-acute care clinical facilities (such as nursing homes, skilled nursing facilities), to record and transmit a 12-lead ECG and rhythm strip in real-time to enable review at a physician's office, hospital or other medical receiving centers.

### 1.3 Intended Use

The QT ECG System is intended for use on adult patients and pediatric patients age 18 – 22 years to acquire ECG signals so that it can be transmitted wirelessly via Bluetooth to a cell-phone or mobile device, then to a remote location. The QT ECG System is designed to be used by a patient to record ECG data and transmit to a physician's office, hospital or other medical receiving center for review

### 1.4 Contraindications


There are no known contraindications.





### 1.5 Environment




The QT ECG system is designed for home use and for use in non-clinical settings. No professional medical training is required to use this system.




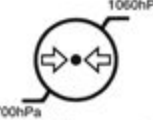


### 1.6 Symbols




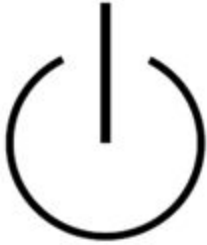
The following symbols are used in this manual and in the product:






<b>The QT ECG Recorder</b>	
Symbol/Marking	Description
 Federal Communications Commission	FCC Declaration of Conformity mark. Certification mark employed on electronic products manufactured or sold in the United States which certifies that the electromagnetic interference from the device is under limits approved by the Federal Communications Commission.

 <p>CCXXxxYYyyyZzW</p>	<p>NCC Declaration of Conformity mark. Certification mark employed on electronic products manufactured or sold in the Republic of China (Taiwan) which certifies that the electromagnetic interference from the device is under limits approved by the NCC.</p>
	<p>The WEEE symbol, indicating separate collection for WEEE- Waste of Electrical and Electronic Equipment, consists of the crossed-out wheeled bin.</p>
	<p>Bluetooth wireless technology incorporated</p>
	<p>Non-ionizing radiation</p>
<p>Model Number: QTERD100</p>	<p>The QT ECG Recorder reference number.</p>
<p>FCC ID: 2AIBAQTERD100 Contains FCC ID: SSSBC127-X</p>	<p>FCC ID is a unique identifier assigned to a device registered with the United States Federal Communications Commission.</p>
<p>IC: 21780-QTERD100 Contains IC: 11012A-BC127</p>	<p>IC ID is the product ID assigned by Industry Canada to identify wireless products in the Canadian market.</p>



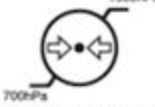



	<p>“REFER TO MANUAL”: Follow operating instructions</p>
 MR unsafe	<p>“MR-unsafe”: Do not expose the device to a magnetic resonance (MR) environment.</p>
<p><b>IP22</b></p>	<p>The degree of protection provided by the enclosure from particulate matter and water.</p> <p><b>2</b> represents that protection against object sized &gt;12.5mm (Fingers or similar objects)</p> <p><b>2</b> represents that the enclosure has a protection level of “water jet;”. Vertically dripping water shall have no harmful effect when the enclosure is tilted at an angle up to 15° from its normal position.</p>
 Manufacturer	<p>“MANUFACTURER”: The name and the address of the manufacturer.</p>

 <p>UDI: 0000012000017 01001-102-2-0000-00</p>	<p>UDI data matrix barcode is intended to assign a unique identifier to medical devices within the United States.</p>
<p><b>Rx Only – USA</b></p>	<p>Caution: Federal law restricts this device to sale by or on the order of a licensed medical practitioner.</p>
 <p>Type CF Applied Part</p>	<p>Type CF is the most stringent classification, being required for those applications where the <u>applied part</u> is in direct conductive contact with the heart or other applications as considered necessary.</p>
 <p>Storage &amp; Transportation Humidity Limit</p>	<p>Storage and transportation conditions: humidity range</p>
 <p>Storage &amp; Transportation Pressure Limit</p>	<p>Storage and transportation conditions: pressure range</p>
 <p>Storage Temperature Limit</p>	<p>Storage and transportation conditions: temperature range</p>
 <p>Reference No.</p>	<p>“CATALOGUE NUMBER”: The catalogue number of product.</p>

	<p>"BATCH CODE": The manufacturer's batch code.</p>
	<p>"SERIAL NUMBER": The manufacturer's serial number.</p>
<p>Packing Date</p>	<p>The packing date of QT ECG ECG Recorder.</p>
<p>Input 5V<sub>dc</sub>  1A</p>	<p>Rated direct current input supply voltage and current.</p>
	<p>Press and hold for 5 second to on/off the QT ECG Recorder.</p>
<p>PWR</p>	<p>The PWR LED indicates the power and charging status.</p>
<p>CON</p>	<p>The CON LED indicates the connecting status of the QT ECG ECG Recorder to the mobile computing device.</p>
<p>REC</p>	<p>The REC LED indicates the recording status of the recorder.</p>
<p><b>Electrode Strip</b></p>	

 <p>Do Not Reuse</p>	<p>Do not reuse</p>
 <p>Do not use if package is damaged</p>	<p>Do not use if package is damaged</p>
 <p>Caution</p>	<p>General warning sign</p>
 <p>Type CF Applied Part</p>	<p>Type CF is the most stringent classification, being required for those applications where the <u>applied part</u> is in direct conductive contact with the heart or other applications as considered necessary.</p>
 <p>Keep away from sunlight</p>	<p>Keep away from sunlight</p>



 <p>5°C 27°C Storage &amp; Transportation Temperature Limit</p>	<p>Storage and transportation Temperature Limit</p>
 <p>10% 93% Storage &amp; Transportation Humidity Limit</p>	<p>Storage and transportation conditions: humidity range</p>
 <p>700hPa 1060hPa Storage &amp; Transportation Pressure Limit</p>	<p>Storage and transportation conditions: pressure range</p>
 <p>Date Of Manufacture</p>	<p>Date of manufacture</p>
 <p>Reference No.</p>	<p>"CATALOGUE NUMBER": The catalogue number of product.</p>
 <p>Lot. No.</p>	<p>"BATCH CODE": The manufacturer's batch code.</p>

## 2. SAFETY INFORMATION

Make sure you are familiar with the safety information in this section before using

the QT ECG. Pay attention to all warnings and cautions to avoid personal injury and/or equipment damage.

WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in personal injury.
CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in damage to the equipment or other property.

## 2.1 Operating the Device

### 2.1.1 Warnings

- 2.1.1.1 Inspection: Visually inspect the QT ECG and all accessories prior to use. Do not use if any components are damaged.
- 2.1.1.2 Do not use high voltage device such as AED (Automated External Defibrillator) when using Electrode Strip. Please remove the QT ECG before using high voltage device on the individual. High voltage device will damage the Electrode Strip and the QT ECG Recorder if they are used at the same time.
- 2.1.1.3 No modification of this equipment is allowed.
- 2.1.1.4 Never attempt to connect the QT ECG Recorder and its accessories to any other device. Always follow the User Manual instructions for safe and reliable performance. Only connect the QT ECG Recorder with approved accessories to the device.
- 2.1.1.5 Never use the conductive parts of the Electrode Strip to contact any other conductive objects, including the earth.
- 2.1.1.6 Keep the device away from flammables, such as, nitrous oxide and anesthetic mixtures with oxygen and air.
- 2.1.1.7 To prevent potential transmission of infection or disease, the one-time use Electrode Strip must be properly disposed of after each use. The QT ECG Recorder may be cleaned before usage.

Please refer to the section “Preventive Maintenance” to find information about cleaning methods.

- 2.1.1.8 The QT ECG is not designed for use with high voltages or surgical equipment. To ensure the safety of the operator and the individual having the test, disconnect the device and all components prior to any procedure.
- 2.1.1.9 The Electrode Strip may damage the skin if removed too quickly or carelessly.
- 2.1.1.10 The Electrode Strip is for one-time use only. Do not reuse.
- 2.1.1.11 Do not place the Electrode Strip yourself. Ask someone else for help when applying the Electrode Strip.
- 2.1.1.12 Once the data has been collected, remove the Electrode Strip right away. Prolonged use of the Electrode Strip could cause allergic reaction or skin irritation. Contact your doctor if skin reaction persists.
- 2.1.1.13 To avoid strangulation and suffocation, use under adult supervision.
- 2.1.1.14 The summation of electrical current leakage when a QT ECG Recorder and a Electrode Strip are in use and interconnected is at most 50 uA.
- 2.1.1.15 Remove the device if it causes discomfort.
- 2.1.1.16 The use of applied part (Electrode Strip) is not intended for intracardiac use or direct cardiac application. It should not come in direct contact with the heart.
- 2.1.1.17 Use of the QT ECG adjacent to or stacked with other equipment should be avoided because it could result in improper operation or high current leakage. If such use is necessary, the QT ECG and

the other equipment should be observed to verify that they are operating normally.

2.1.1.18 Use of accessories or Electrode Strip other than those specified or provided by QT Medical of the QT ECG could result in increased electromagnetic emissions or decreased electromagnetic protection of the QT ECG and lead to improper functions.

2.1.1.19 Portable RF communication equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the QT ECG including Electrode Strip. Otherwise, degradation of the performance of the QT ECG could result.

#### 2.1.2 Cautions

2.1.2.1 Only use the device in environments described in the User Manual. Avoid presence of equipment with electromagnetic interference such as microwave ovens, radios, televisions, etc. The electromagnetic interference can degrade the performance of the device.

2.1.2.2 If the QT ECG is used in an environment with ESD (ElectroStatic Discharge), the ESD signal may interfere with ECG signals. Try to avoid this kind of environment.

2.1.2.3 Do not take apart the device or alter any component. For technical assistance please contact QT Medical.

2.1.2.4 For cybersecurity purposes, user should run regular virus checks on the mobile device.

2.1.2.5 Only use the QT ECG with compatible firmware as specified in the User Manual.

2.1.2.6 Follow the User Manual when connecting the device to its components. Assure all accessories and device are properly connected.

2.1.2.7 Cleaning the device incorrectly or exposure to cleanser and

disinfectant can damage the device. Please follow the cleaning instructions carefully.

- 2.1.2.8 Do not use non-recommended cleaning or disinfection solutions with the QT ECG Recorder and its accessories. Please follow the cleaning instructions carefully.
- 2.1.2.9 Do not attempt to autoclave or sterilize the QT ECG Recorder and its accessories.
- 2.1.2.10 Do not attempt to charge the QT ECG Recorder when it is connected to the Electrode Strip.
- 2.1.2.11 The Electrode Strip should be applied only to intact, clean skin (e.g., not over open wounds, lesions, infected, or inflamed areas).
- 2.1.2.12 Avoid using the QT ECG when it is in the presence of equipment with known electromagnetic interference, such as MRI, CT, and ultrasound machines. Such equipment may affect the quality of signals recorded by the QT ECG. A list of advice to avoid or minimize the interference is noted in the Appendix.
- 2.1.2.13 Do not open the Electrode Strip package until time of use. If not stored properly, the Electrode Strip might dry out, which can result in poor conductivity and poor quality data.
- 2.1.2.14 Once the Electrode Strip package is opened, use it as soon as possible. Keep it away from lint and dust, which may result in poor conductivity and poor quality data. Keep it away from children and pets to avoid damage.
- 2.1.2.15 Keep the device away from exposure to direct sunlight.
- 2.1.2.16 Follow storage condition instructions as described in the User Manual. Make sure the storage environment is appropriate.
- 2.1.2.17 If necessary, contact local authorities to determine the proper method of disposal for potentially biohazardous parts and accessories.

## 2.2 Note

- 2.2.1 Federal law restricts sale of this device by or on the order of a physician.
- 2.2.2 The device does not require calibration.
- 2.2.3 The QT ECG is not intended for treatment or monitoring. It captures data that reflect the patient's physiological condition. The data can be shared with the patient after it has been reviewed and analyzed by a cardiologist or trained physician.
- 2.2.4 Always use the latest version of the QT ECG App
- 2.2.5 Before placing the Electrode Strip on the patient's chest, locate the landmarks on the chest as described in the User Manual or quick guide. A misplaced Electrode Strip can lead to inaccurate results.
- 2.2.6 When necessary, properly dispose of the Electrode Strip after use in compliance with local regulations.
- 2.2.7 The ECG data displayed on the mobile device is 500 Hz. A computer or server based diagnostic report, can display up to 1000 Hz should the physician need higher resolution data.
- 2.2.8 Patients should remain as still as possible when collecting ECG data. Excessive patient movement can lead to poor quality data.
- 2.2.9 For optimal data collection, the patient's skin should be free of oil and/or lotions before placing the Electrode Strip on the chest.
- 2.2.10 Please charge the device fully before the first use.
- 2.2.11 The Electrode Strip should only be used in consultation with QT Medical, Inc. or a health care provider familiar with its proper placement and use.
- 2.2.12 The Electrode Strip should be replaced if the adhesive patches can no longer attach firmly to the skin.
- 2.2.13 Please consult your healthcare provider for assistance with choosing the proper Electrode Strip size and fit. The Electrode Strip is designed to fit adult, pediatric and newborn patients.



### 3. PRIOR TO OPERATION

#### 3.1 Know your Unit

Your package contains the following items:

- A. QT ECG Recorder
- B. Quick Guide
- C. Wall Charger

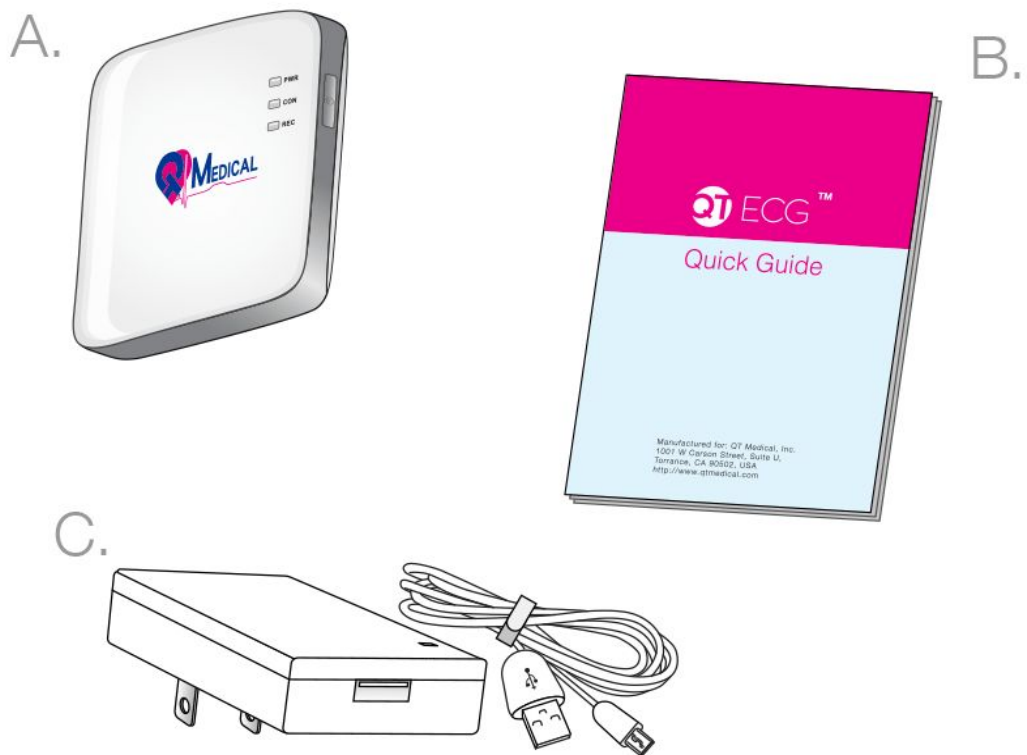
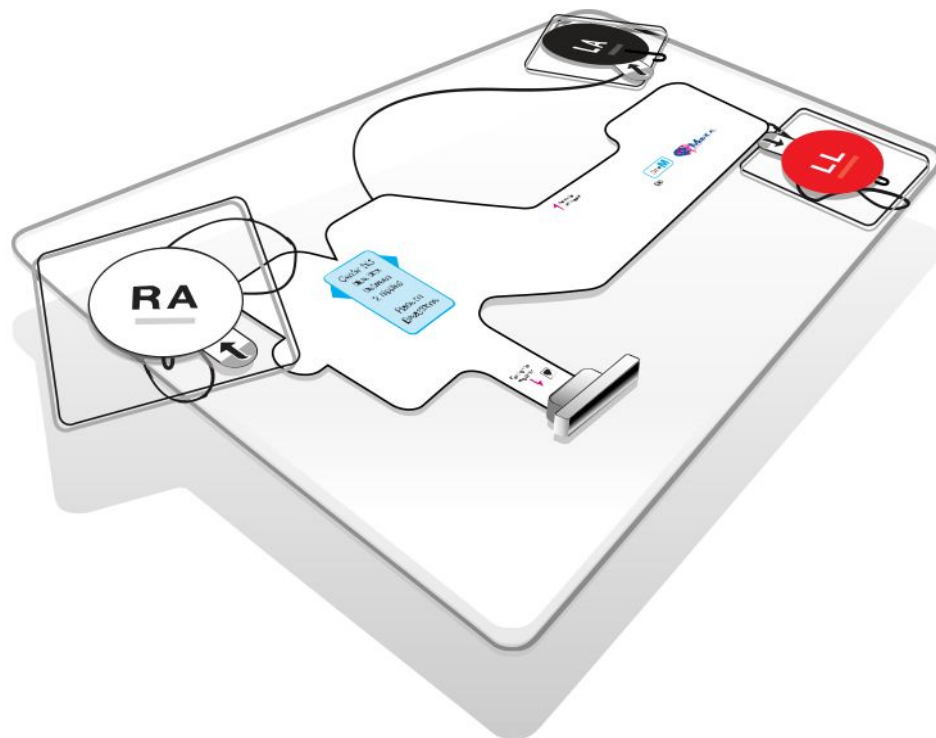


Fig. 3.1a



The Electrode Strip is packaged and sold separately

Fig. 3.1b



### 3.1.1 QT ECG Recorder (Main Device)

The three-view diagram of the QT ECG Recorder is shown in Fig 3.1.1a To turn on/off the QT ECG Recorder, press and hold the power button for 5 seconds. The Power (PWR) LED indicator will turn solid green when the power is on. The QT ECG Recorder has two ports; one is used to connect with the Electrode Strip, and the other is used for charging with a Micro USB wall charger (Fig 3.1.1b & Fig 3.1.1c). Do not attempt to charge and plug-in the Electrode Strip at the same time. Do not use any charger other than the one provided in the original case. Do not attempt to connect the QT ECG Recorder with any other cable, connector or power cord because such practice can damage the QT ECG Recorder.

There are three LED indicators; PWR, CON and REC which indicate the device status.

Power Button

Micro USB port of the Recorder

Recorder Receptacle

LED Indicators

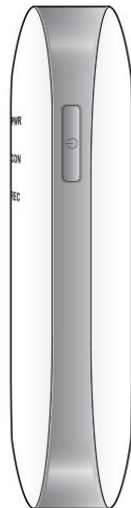


Fig. 3.1.1a

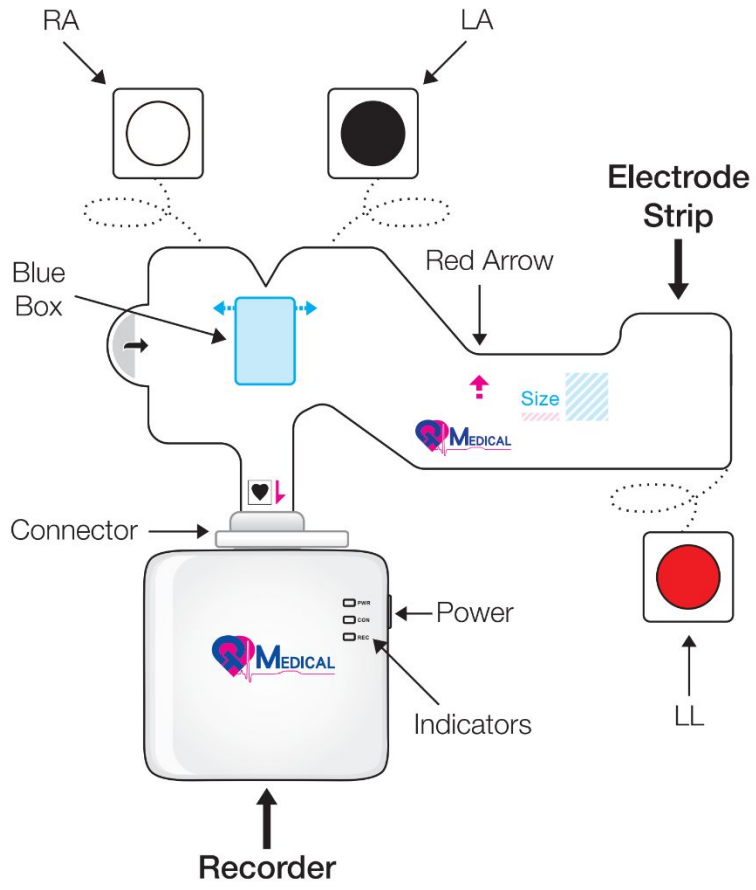


Fig. 3.1.1b

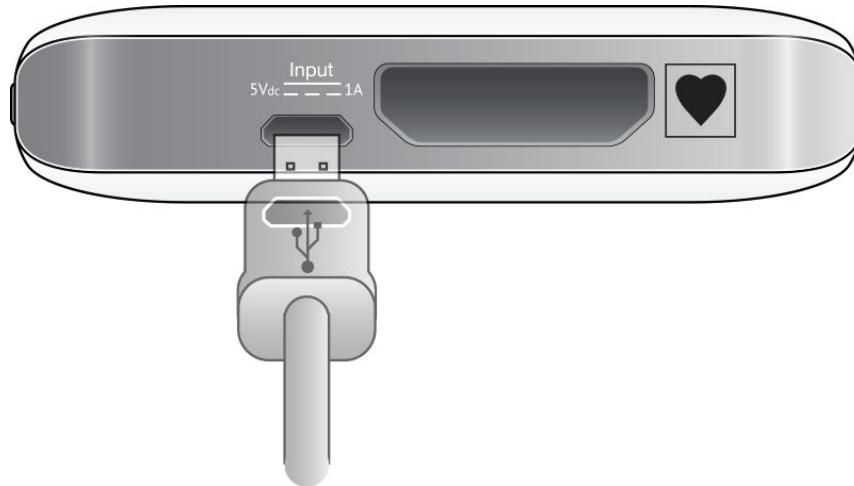


Fig 3.1.1c

- A. Power Button:** To turn on/off the QT ECG Recorder, press and hold the power button for 5 seconds. The Power (PWR) LED indicator will turn solid green when the power is on.
- B. Micro USB Port:** Used for charging the QT ECG Recorder with the wall charger
- C. Recorder Receptacle:** Used to connect with the Electrode Strip
- D. LED Indicators**

Table 3.1.1a Specification of the QT ECG Recorder

LED Indicators	PWR(RGB)	CON(BLUE)	REC(Amber)
<b>ON</b>	<b>Green: Power on or Charging complete</b> <b>Soft white: charging</b>	<b>BLE connected</b>	<b>No information</b>
<b>OFF</b>	<b>Power off</b>	<b>No information</b>	<b>No information</b>
<b>Blink</b>	<b>Green: Low Battery &lt; 10%</b>	<b>BLE disconnected/Advertising</b>	<b>Record ongoing</b>
<b>Fast Blink</b>	<b>Red: System error</b>	<b>No information</b>	<b>No information</b>

Table 3.1.1b Specification of the QT ECG Recorder

Feature	Specification

<b>Brand Name</b>	<b>QT ECG</b>
<b>Model Number</b>	<b>QTERD100</b>
<b>Dimension</b>	<b>72.00x68.02x18.60 mm (2.83 x 2.68 x 0.735 in)</b>
<b>Weight</b>	<b>85 g</b>
<b>Enclosure Material</b>	<b>Polycarbonate</b>
<b>Wireless Technology</b>	<b>Bluetooth 4.0 dual mode Operation frequency range: 2.402 GHz &lt;-&gt; 2.480 GHz (BLE); 2,402MHz to 2,480 MHz (BT)</b>
<b>LED</b>	<b>PWR: Power/Status LED (RGB)</b>
	<b>CON: Connection LED (Blue)</b>
	<b>REC: Recording LED (Amber)</b>
<b>External Port</b>	<b>Micro USB port of the recorder (charging port)</b>
	<b>Recorder Receptacle (connect with the Electrode Strip)</b>
<b>Physical Button</b>	<b>Power On/Off switch</b>
<b>Battery</b>	<b>Rechargeable lithium-ion polymer battery, 3.7 V, 700 mAh</b>

<b>Battery Charge Time</b>	<b>1.5 hours</b>
<b>Battery Operating Time</b>	<b>17 hours of continuous use 24 hours of normal use (use: standby = 1:5) with new battery</b>
<b>Battery Charging Procedure</b>	<b>Connect the QT ECG Recorder to wall charger through the Micro USB port of the recorder</b>
<b>Battery Replacement</b>	<b>Irreplaceable</b>
<b>Charging Indicator</b>	<b>Solid white</b>
<b>Low Battery Indicator</b>	<b>Blinking green</b>
<b>Service Life</b>	<b>Battery: <math>\geq 300</math> cycle The QT ECG Recorder: 5 years</b>
<b>Signal Sampling Rate</b>	<b>1000 Hz</b>
<b>Channel Skew</b>	<b>0</b>
<b>Acquisition Mode</b>	<b>Simultaneous sampling approach for each channel</b>
<b>A/D Resolution</b>	<b>24-bit</b>
<b>Quantization Error</b>	<b>0.047 <math>\mu</math>V/LSB</b>
<b>Frequency Response</b>	<b>0.05 to 150 Hz</b>



<b>Triangle Response</b>	<b>6% maximum reduction 20 ms vs 200 ms triangle wave</b>
<b>Filters</b>	<b>Default off.</b>
<b>Input Impedance</b>	<b>6.875 M<math>\Omega</math></b>
<b>DC-offset Voltage</b>	<b>+/- 399 mV</b>
<b>Multichannel Crosstalk</b>	<b><math>\leq</math>15 <math>\mu</math>V</b>
<b>CMRR</b>	<b>97 dB</b>
<b>Noise Level</b>	<b><math>\leq</math>10 <math>\mu</math>V</b>
<b>Overload Tolerance</b>	<b>Up to 1 V</b>
<b>Wireless Distance</b>	<b>20-30 m</b>
<b>Bluetooth Transmission Rate</b>	<b>3 Mbps</b>
<b>Standard Leads Acquired</b>	<b>I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6</b>
<b>Sensitivity</b>	<b>5, 10, 20 mm/mV auto (I~aVF: 10 mm/mV, V1~V6: 5 mm/mV)</b>
<b>Calibration</b>	<b>Automatic</b>
<b>Data Storage</b>	<b>In mobile device</b>
<b>Lead-off Detection</b>	<b>Yes</b>

<b>Pacemaker Detection</b>	<b>Yes</b>
<b>Operating Temperature</b>	<b>5~40°C; 41~104°F</b>
<b>Operating Relative Humidity</b>	<b>15% – 93%, Non-condensing</b>
<b>Operating Atmospheric Pressure</b>	<b>700 hPa – 1060 hPa</b>
<b>Storage and Transport Temperature</b>	<b>-25~70°C; -13~158°F</b>
<b>Storage and Transport Relative Humidity</b>	<b>10% – 93%, Non-condensing</b>
<b>Storage and Transport Atmospheric Pressure</b>	<b>700 hPa – 1060 hPa</b>
<b>Charge Temperature</b>	<b>0~55°C; 32~131°F</b>

### 3.1.2 QT ECG Electrode Strip

The Electrode Strip is a self-adhesive, one-piece integrated electrode system. It attaches to the body and plugs into the QT ECG Recorder as shown in figure 3.1.2a.

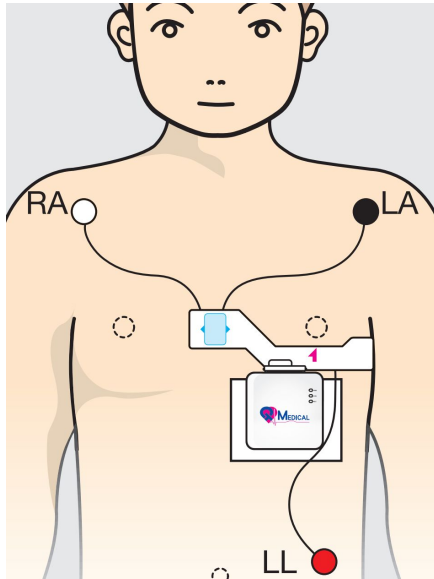


Fig. 3.1.2a

The Electrode Strip comes in 4 different sizes, depending on body size and shape. Find the right size by using the sizing chart (Table 3.1.2a).

Table 3.1.2a

Size	Shoulder width (cm)
S	28-36
M	36-40
L	40-46
XL	>46

**Warning: The Electrode Strip is not defibrillator-proof. Do not use high**

**voltage device such as AED while the Electrode Strip is still attached to the body.**

**Caution: The Electrode Strip shelf life is one year. Do not use if past expiration date.**

### 3.1.3 Wall Charger

This medical grade AC-to-DC power adapter provides external isolation from AC mains. Use the wall charger provided to charge your QT ECG Recorder. Use only 100-240v wall socket-outlet.

**Warning: Do not use any external power supply such as portable battery charger or PC to charge the QT ECG Recorder**

**Caution: Use only wall charger provide by QT Medical. If your wall charger is lost, contact [support@QTMedical.com](mailto:support@QTMedical.com) for replacement.**

### 3.1.4 QT ECG App

The QT ECG App is an integral part of the QT ECG system. It works with most Apple and Android-based mobile devices. ~~See Table# on page # for a list of compatible devices. To see how this app works, watch our video tutorial (URL).~~

**Warning: Always use the latest version of the QT ECG App.**

**Warning: Run virus scan regularly on your mobile device.**

## 3.2 System Setup

A one-time setup is required before you can begin using the QT ECG system. Have your

Bluetooth-enabled mobile device and the QT ECG Recorder ready, then follow the steps below:

### **1. New User Registration**

Email the serial number of your QT ECG Recorder to [service@QTMedical.com](mailto:service@QTMedical.com). Your username and password will be emailed to you after your unit is registered

### **2. Download the Mobile App**

Download the QT ECG App from the Apple App store or Google Play

### **3.-Log-in**

Open the QT ECG App on your mobile device and login using the username and password provided in step 1 above.

### **4. Bluetooth Pairing**

- I. While the App is open on your mobile device and you are logged into your account, turn on your QT ECG Recorder by pressing down on the power button for 5 seconds until the PWR indicator light turns solid green.
- II. Tap the “Connect” button shown in the QT ECG App on your mobile device, which will begin scanning for the QT ECG Recorder.
- III. When the CON indicator light turns solid blue, the units are paired.

### **5. Enter Patient Profile**

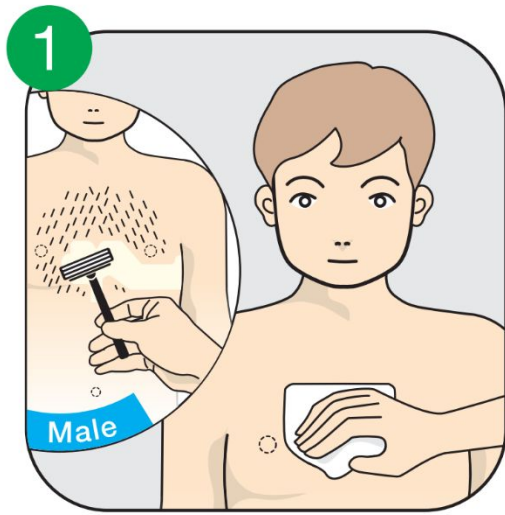
## **3.3 Equipment Preparation**

Charge the QT ECG Recorder fully before the first use.

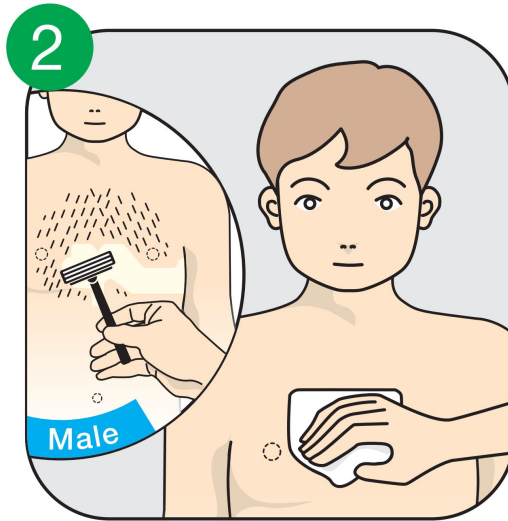
**Warning: Visually inspect the QT ECG and all accessories before use. Do not use if any component appears damaged. For support contact [service@QTmedical.com](mailto:service@QTmedical.com)**

## **3.4 Patient Preparation**

- Make sure the skin on the chest is clean and dry, free of lotion or oil. For males with lots of hair on the chest, shave the chest along the area indicated



- The patient should rest (sit still or lie down) for at least 5 minutes before taking an ECG recording.



### 3.5 Selecting Electrode Strip Size

The Electrode Strips come in 4 different sizes. Use the sizing chart below to find the size that is right for you.

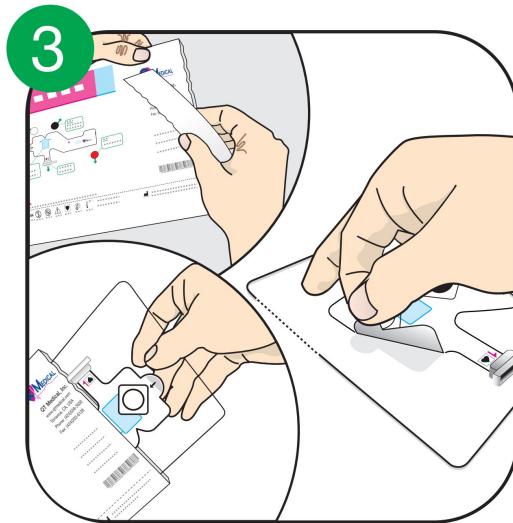
## 4. OPERATING PROCEDURES

### 4.1 Attaching the Electrode Strip

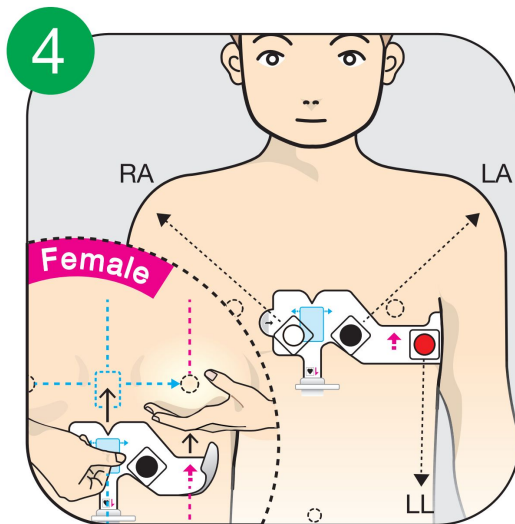
**Warning:** Do not attach the Electrode Strip onto yourself. Ask a trusted adult to help you.

**Caution:** Do not tug at the cables attaching the electrodes (RA, LA, LL) to the Electrode Strip. Keep the cables and the 3 external electrodes clear of the adhesive side of the Electrode Strip.

1. Tear open the QT ECG Electrode Strip (Strip) package. Remove the plastic cover to expose the sticky side of the Strip.



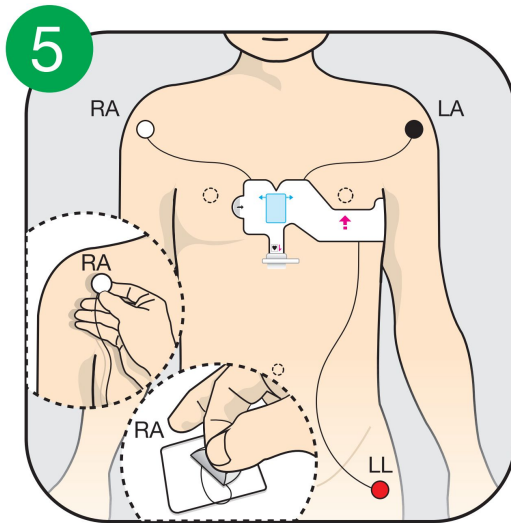
2. With the sticky side facing patient, place the strip on the patient's chest. First, position the Blue Box at the center of the chest, between the nipples. Then, wrap the strip from the center of the chest around the left side of the chest. The Red Arrow should be pointing to the left nipple. For females, the Strip should go under the left breast.



**If placement of the Electrode Strip needs adjustment, the Electrode Strip**

**can be lifted off for repositioning**

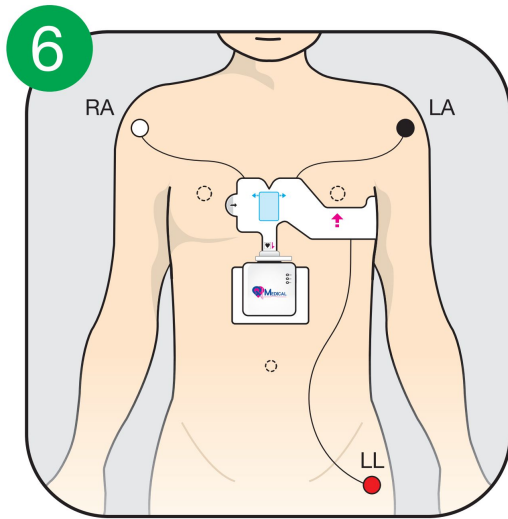
3. Remove the adhesive backing of the other 3 electrodes (RA, LA, LL), one at a time.
  - The Black electrode (LA) goes on the upper left arm of the patient
  - The White electrode (RA) goes on the upper right arm of the patient
  - The Red electrode LL goes on the left hip joint
4. Press firmly on the Electrode Strip and all electrodes to ensure the attachments are secure



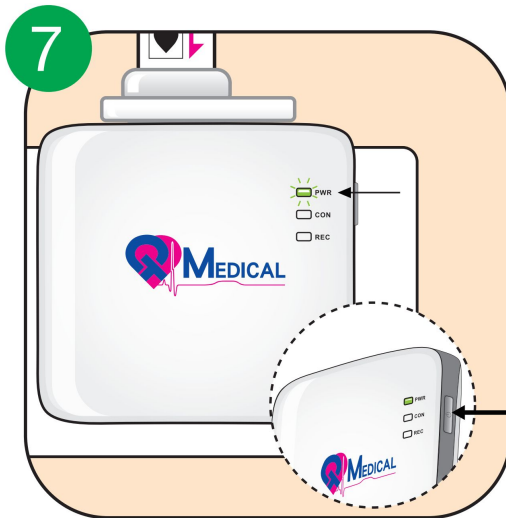
#### 4.2 Connecting the QT ECG Recorder

1. Connect the Recorder to the Strip by inserting QT ECG into the connector on the Electrode Strip. Insert the strip firmly until it is fully attached.





2. Do not directly place QT ECG on the body, use a gauze pad to separate the device with the skin.
3. Press and hold the Power button for 5 seconds to turn on the QT ECG Recorder.



4. The Recorder is recording when Power (PWR) is Green, Connection (CON) is Blue, and Recording (REC) is blinking Amber.



### 4.3 Taking an ECG Recording

For the QT ECG App software operation, please see the following

- Tap the QT ECG App icon to activation of the app



- **Log in:** Input username and password, then press the login button.

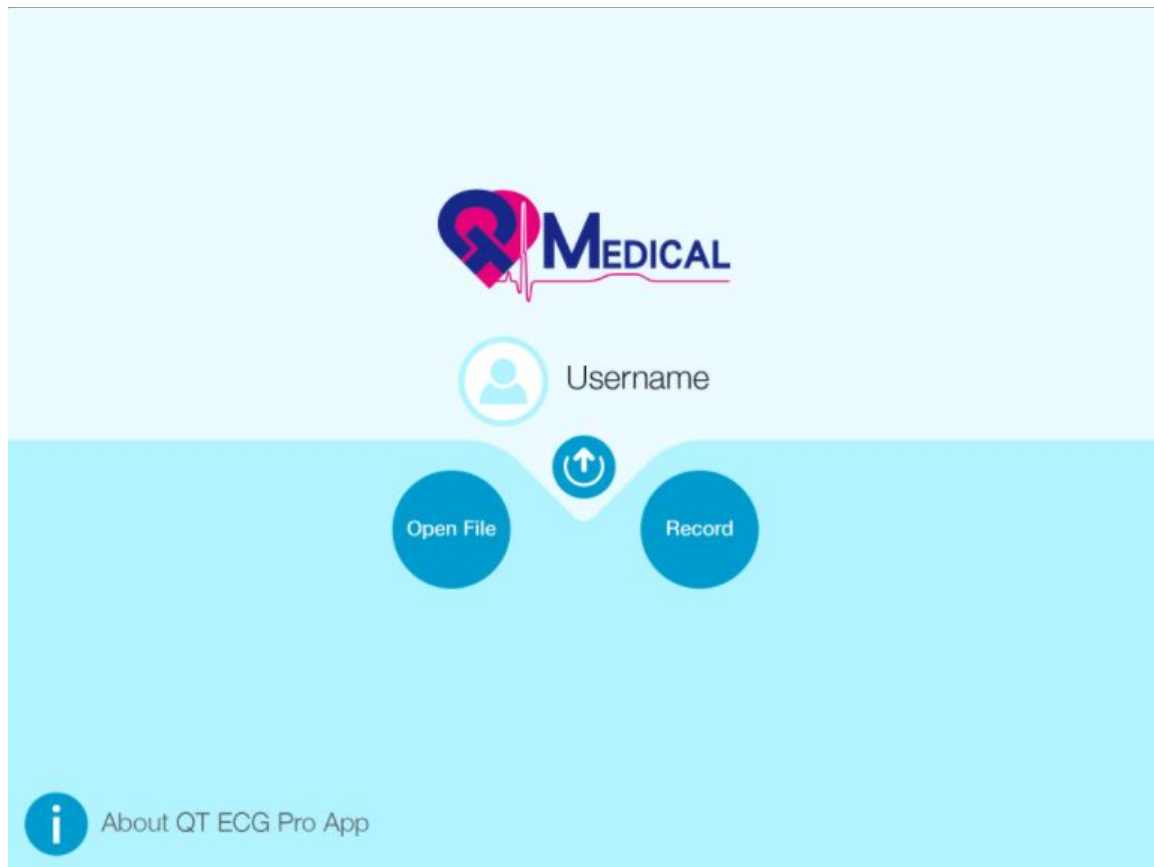


Username

Password

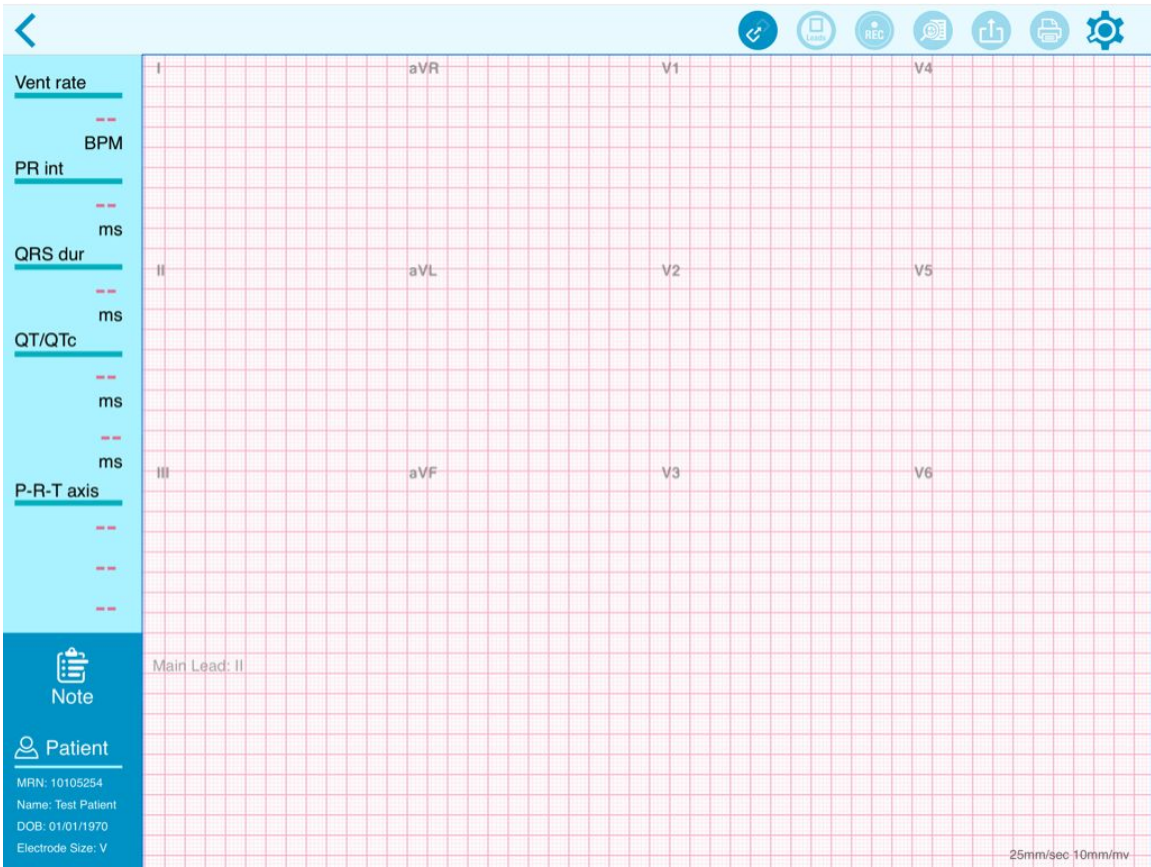


 About QT ECG Pro App




- **Input patient's profile:** Click the "Patient", to input the patient's medical record number (MRN, if applicable), Name, DOB, Electrode Strip size.

圖示



< QT Screen

 Patient Profile

MRN: 10105254

Name: Test Patient

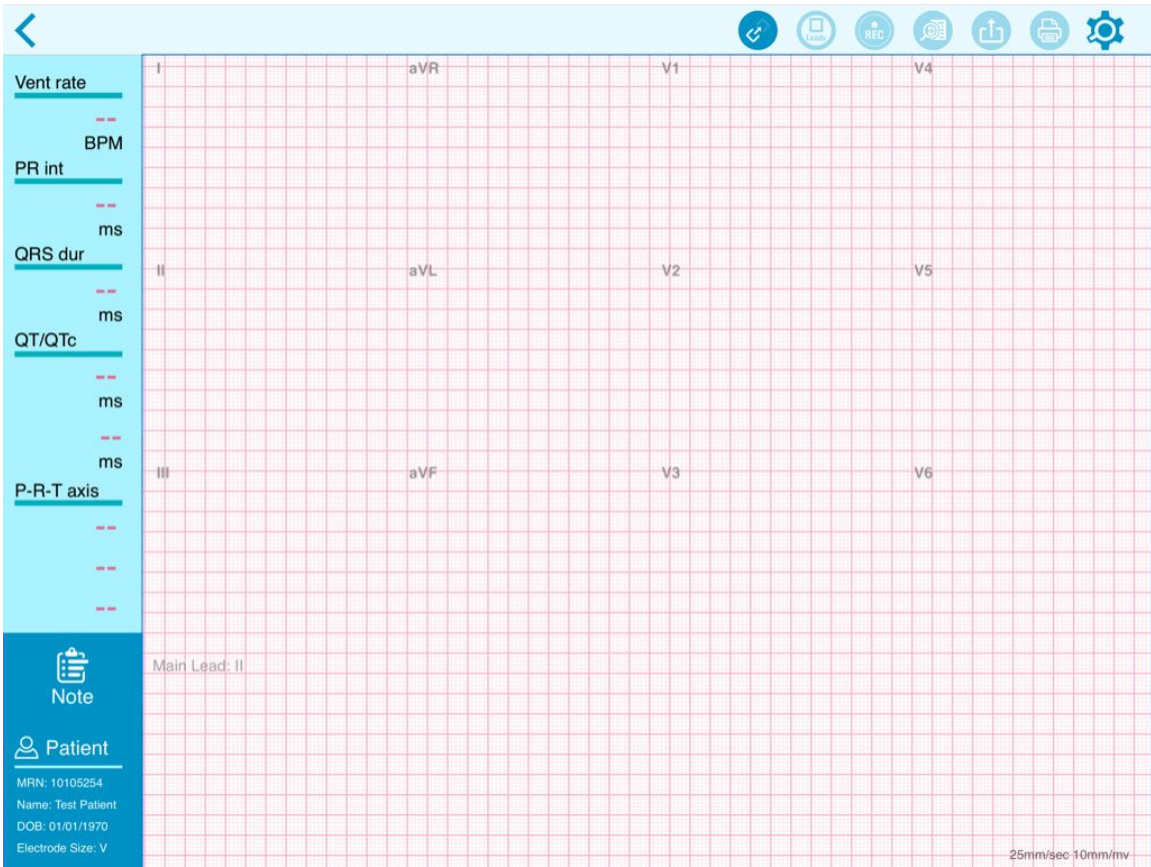
Gender: Male

DOB : 01/01/1970

Electrode size : Size 5

MD : Doctor Alpha

- **Input patient's symptoms:** Click the "Note" button to input patient's symptoms.

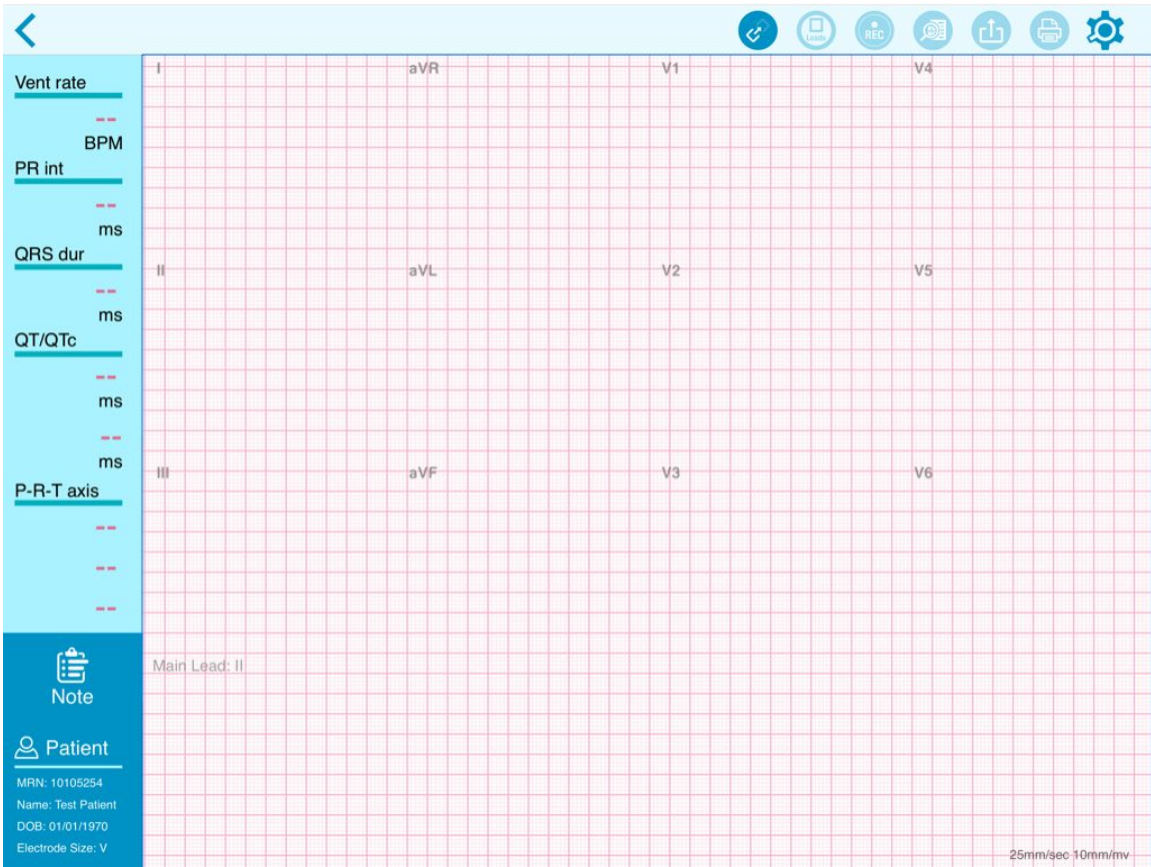


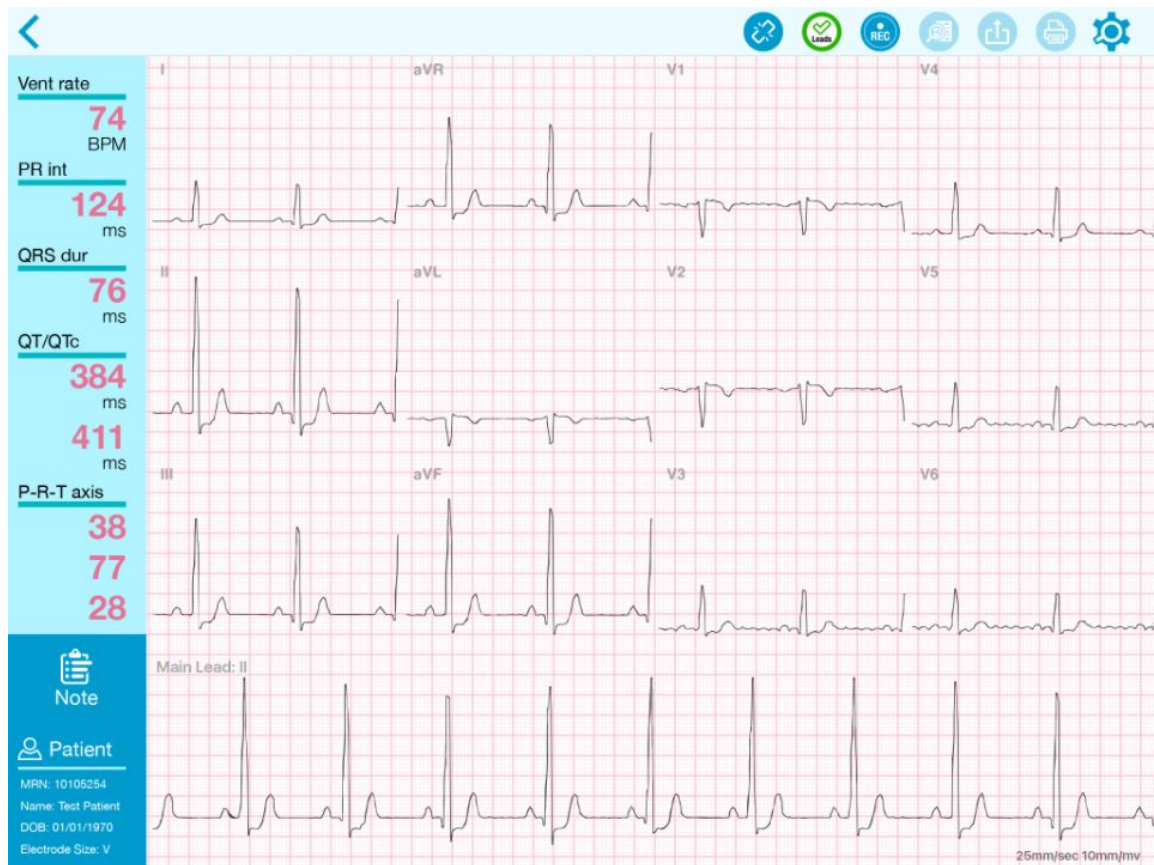


- **Scan and connect QT ECG Recorder:** Tap on the “Connect” button, device will scan for the recorder. If found, the device will automatically connect and start receiving signals from the QT ECG Recorder

圖示

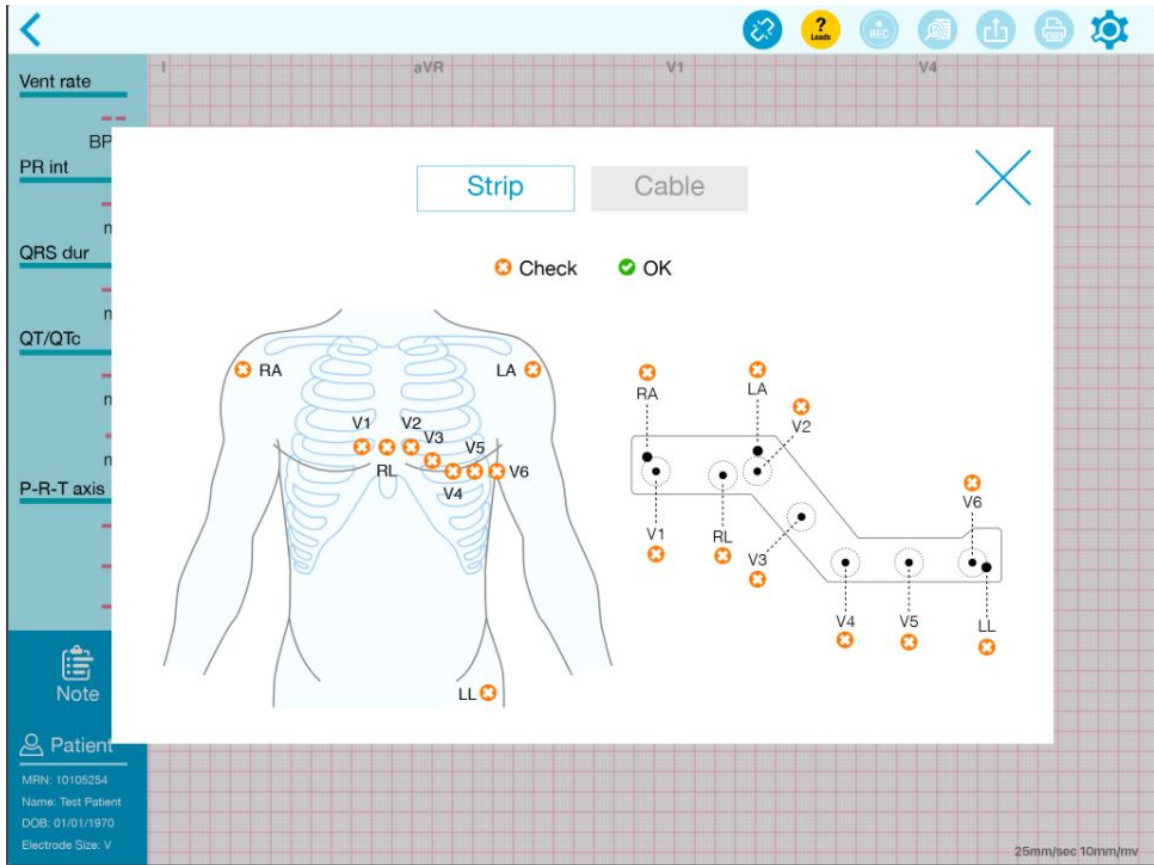






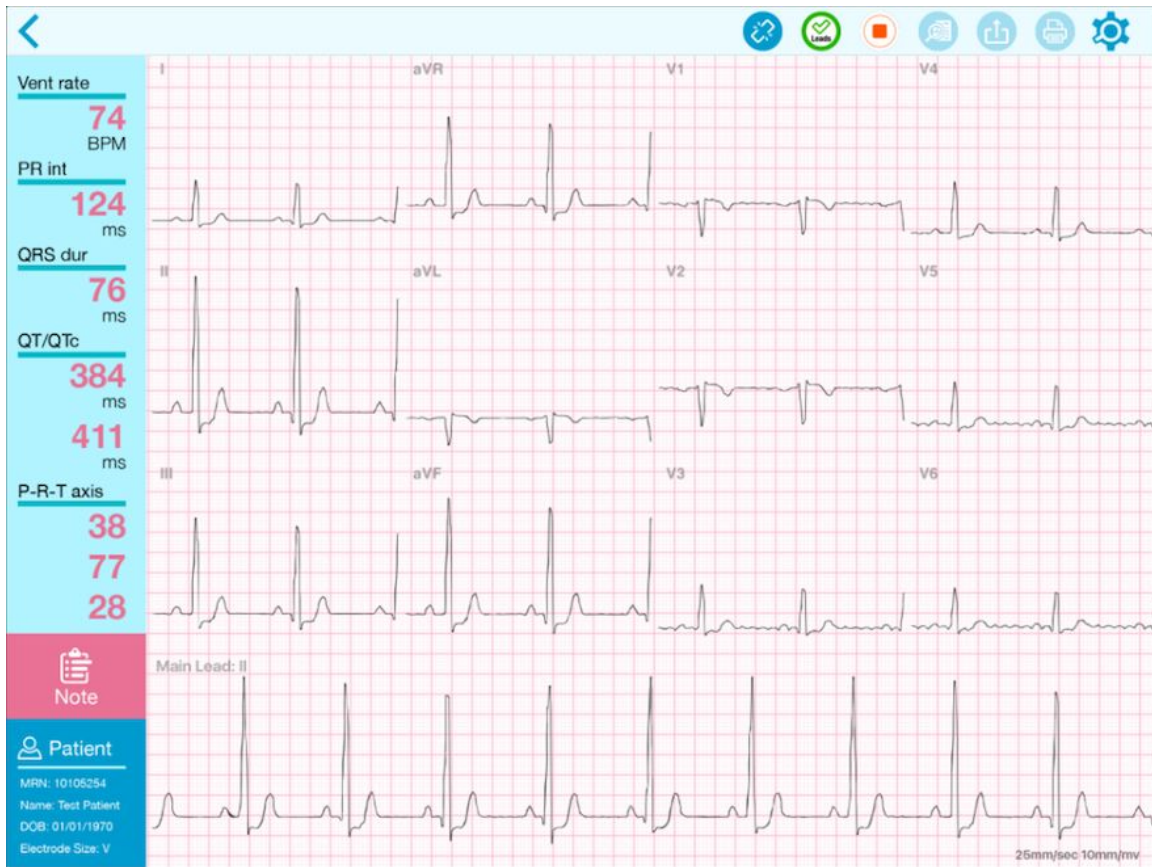
- **Check lead-off:** The screen displays the status of all leads on the user's chest. Check the "Lead" button, make sure all the leads are in green color. If "Lead off" alert is shown (amber), please trouble- shoot the electrode attachment. Refer to the User Manual if needed.

圖示



- **Record ECG Data:** An ECG tracing will be displayed on the screen. Tap on the “Record” button. The ECG will be recorded.

圖示



- **Upload ECG file:** When record ECG complete, app will upload ECG file automatically.
  - **ECG file list:** If upload ECG file complete, you can tap "Open File" button to get the file list.



Username



Open File

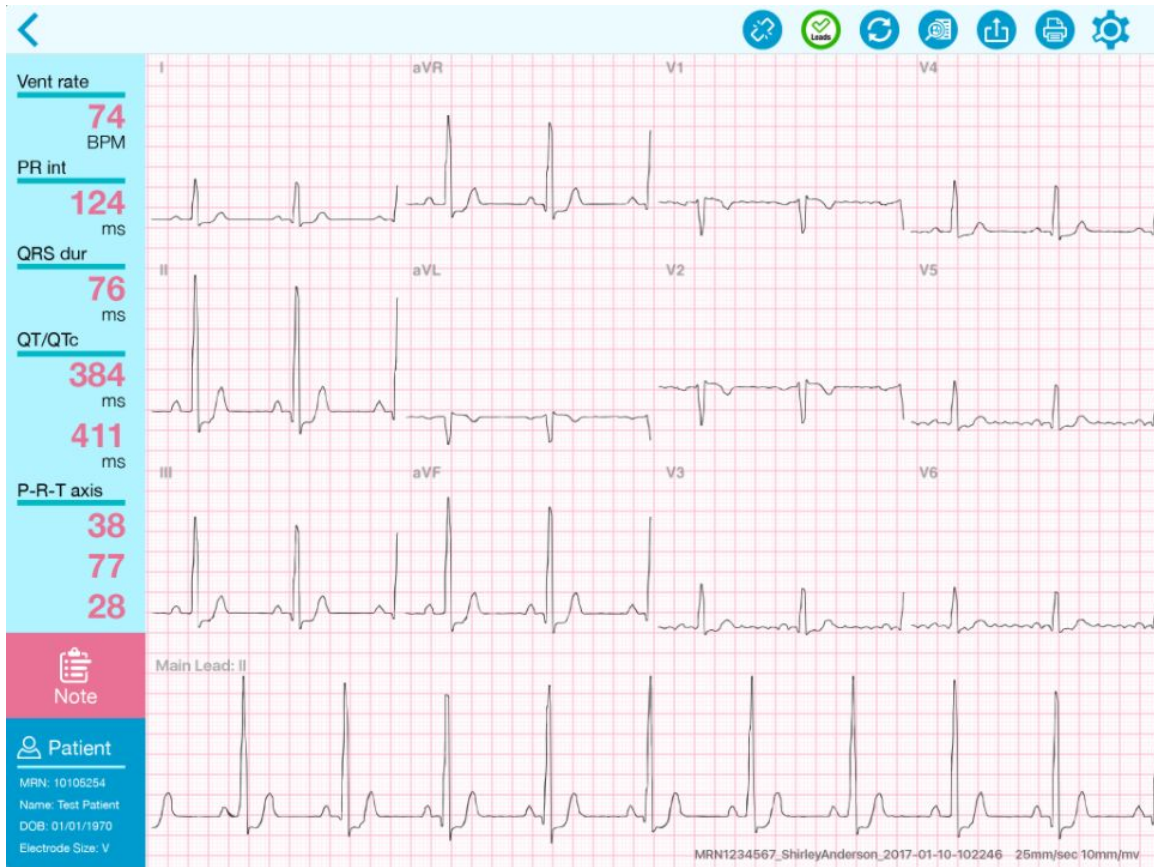
Record

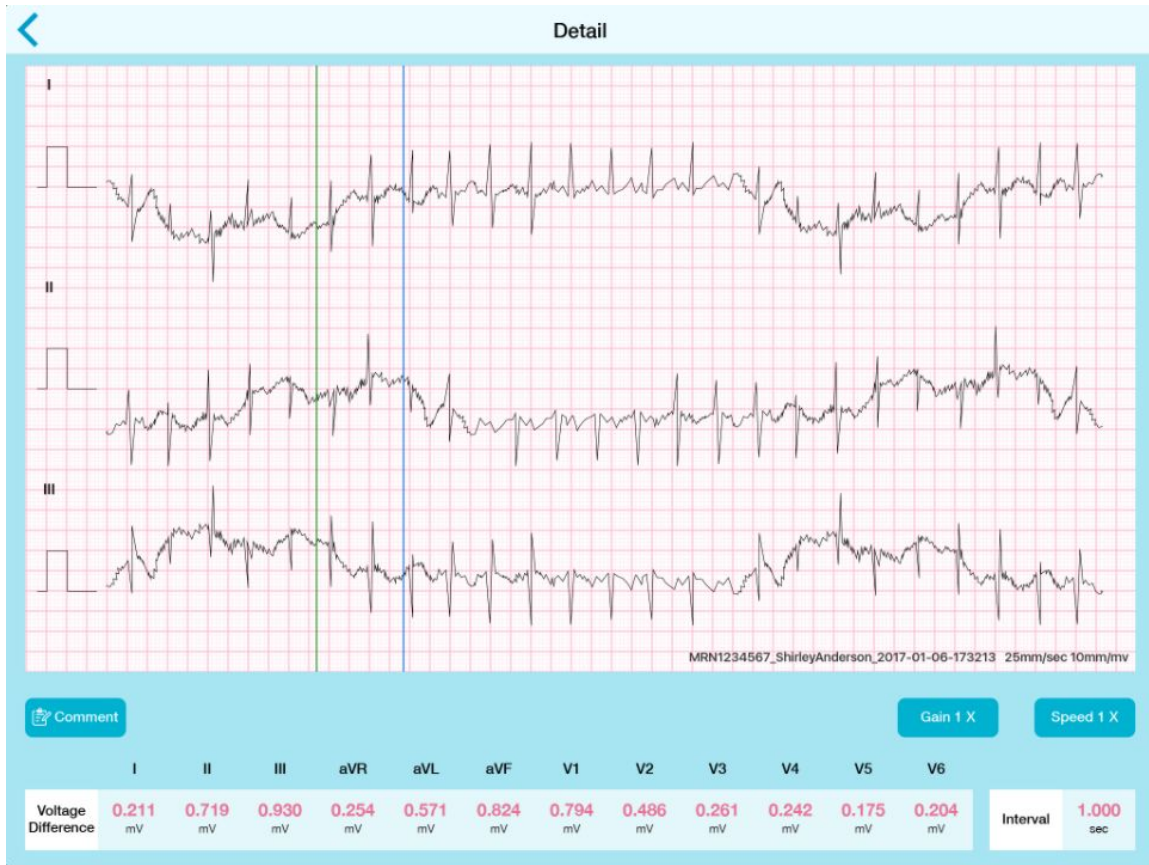


About QT ECG Pro App



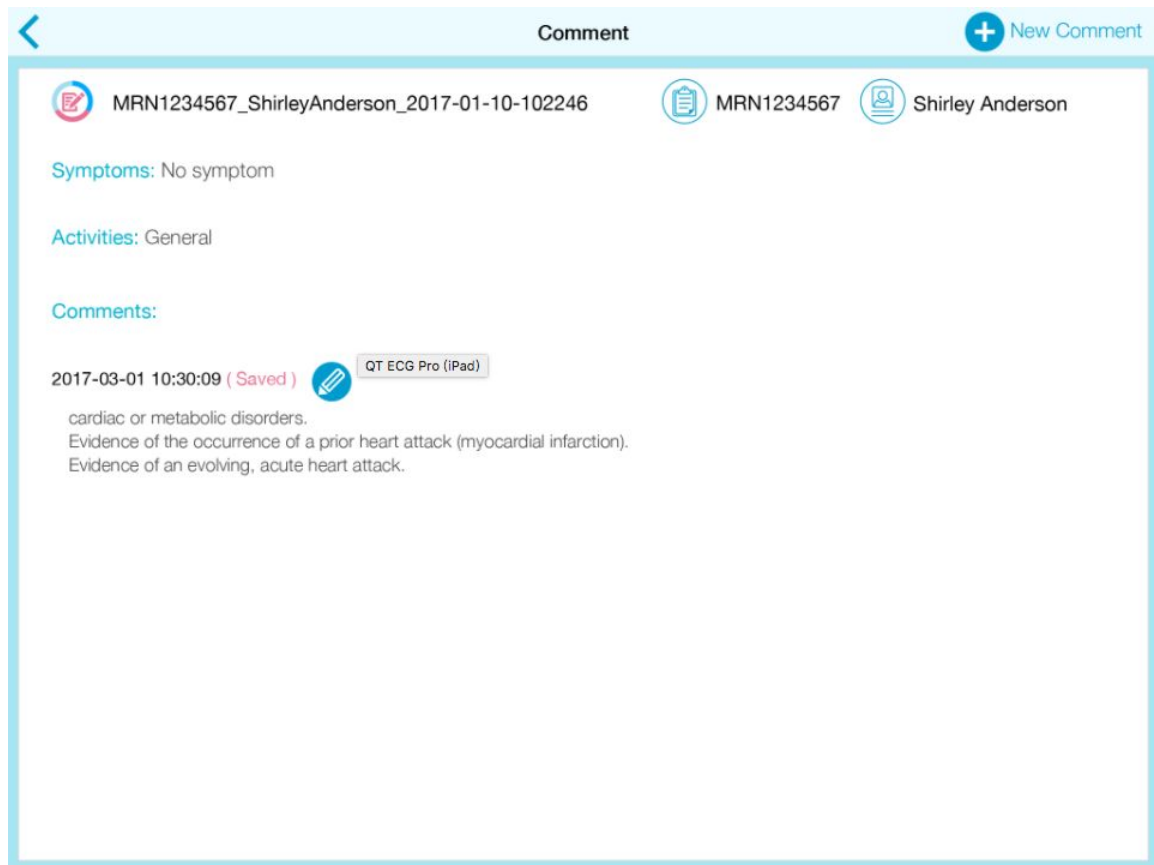
- **Detail view:** Click the "Detail" button, you can get more than 12 ECG details. And can use the caliper to measure the value of each point.





- **Add comment:** Click the “New Comment” button, you can add new comment.
























- **Serial comparison:** Choose any two ECG files of the same person, and click the "Serial comparison" button to conduct ECG comparison.

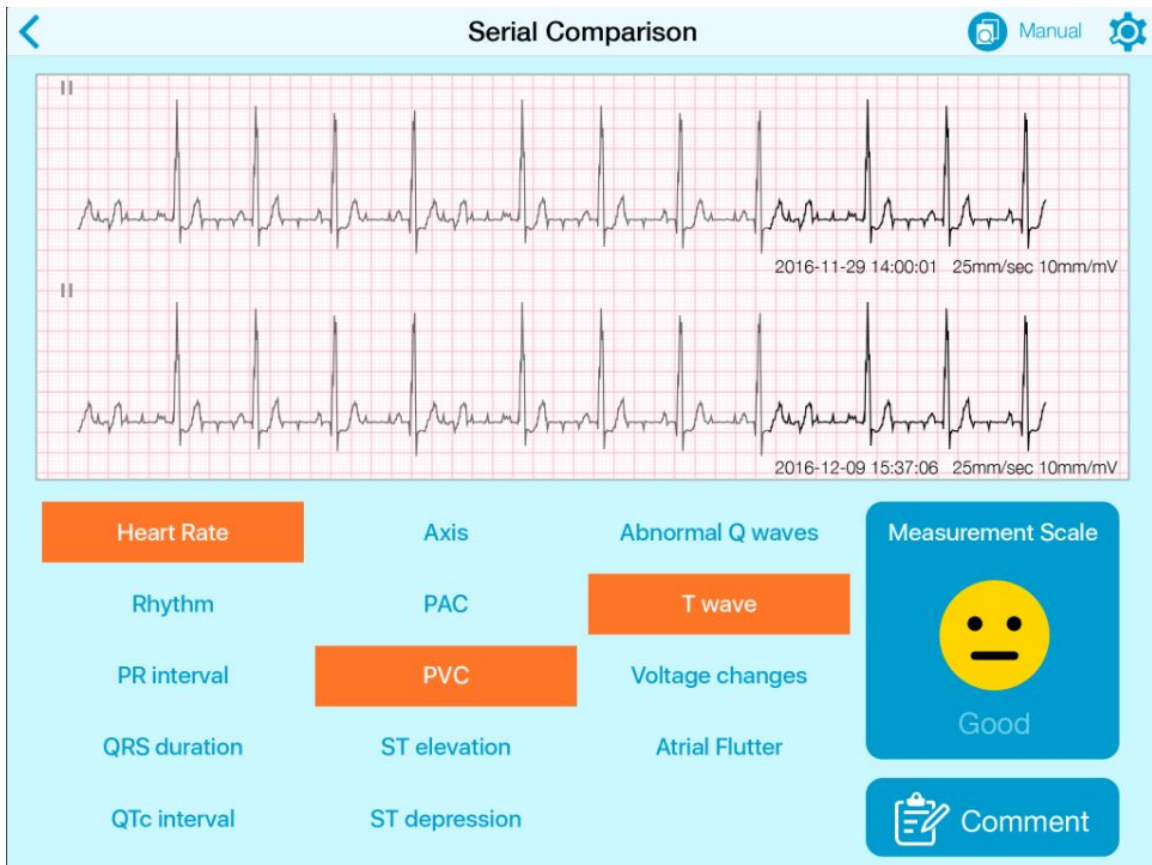
**File List** Shirley Anderson

Search Recent

  MRN1234567  Shirley Anderson		MRN1234567_ShirleyAnderson_2017-01-10-102246	
		MRN1234567_ShirleyAnderson_2017-01-09-131932	
		MRN1234567_ShirleyAnderson_2016-12-30-094401	
		MRN1234567_ShirleyAnderson_2016-12-18-175810	
		MRN1234567_ShirleyAnderson_2016-11-29-151205	

  MRN2316754  Richard Bailey			
  MRN7451236  Dennis Carter			
  MRN5162743  Jean Diaz			



#### 4.4 Detaching the Device

After finish record ECG, disconnect the bluetooth and turn off QT ECG recorder.

### 5. TROUBLESHOOTING

#### 5.1 QT ECG Recorder

- Problem: PWR LED indicator does not light up during charging
  - Solution: PWR LED indicator will turn off after it is fully charged, If the PWR LED does not light up with charging, this may indicate that battery is fully charged.
- Problem: Unable to turn on the QT ECG Recorder
  - Solution: Press and hold the power button for 30 seconds. If

Power LED indicator still does not light up, please try again after charging the device for 1 hour.

- Solution: If above solution does not work, please contact our customer service.
- Problem: Unable to turn off the QT ECG Recorder
  - Solution: Make sure the micro-USB cable is not connected
  - Solution: Press and hold power button for 30 seconds. If still unable to turn off the QT ECG Recorder, please contact our customer service.
- Problem: Unable to connect the QT ECG Recorder to the mobile device via Bluetooth
  - Solution: If Bluetooth is not connected when it is on, please turn off the recorder then turn on the recorder again.

## 5.2 QT Electrode Strip

- Problem: Package opened or damaged before use
  - Solution: Do not use the Electrode Strip, contact our customer service for replacement.
- Problem: 7 chest lead electrodes or 3 limb lead electrodes are damaged or missing
  - Solution: Do not use the Electrode Strip and contact our customer service.
- Problem: Size of Electrode Strip enclosed does not match with package labels
  - Solution: Do not use the Electrode Strip and contact our customer service.

### 5.3 QT ECG App

- Problem: Crashed during use
  - Solution: Reboot and restart, if problem persists, please contact our customer service.
- Problem: Cannot boot up application or the app quits unexpectedly
  - Solution: Please contact our customer service.
- Problem: Application is not performing smoothly
  - Solution: Too many apps may be open and running at the same time. Please reboot the mobile device and try again.
- Problem: All ECG tracings disappear on the display. The screen display looks like the following:
  - Solution: The problem may be caused by system overload or saturation. Please carefully remove the Electrode Strip from the patient's chest and disconnect the QT ECG ECG Recorder. Please restart the entire process. If the problem persists, please contact our customer service.
- Problem: Lead-off warning. The screen display is as follows:
  - Solution: Check the corresponding chest electrode. Make sure the electrode is attached properly to the skin and making a good contact.
- Problem: Low battery warning. The screen displays the following:
  - Solution: Disconnect the Recorder from the Electrode Strip, and remove electrode from the user. Charge the QT ECG Recorder using the wall charger with the micro-USB cable. Do not record and charge at the same time.

### 5.4 Others

- Problem: Cannot record ECG signals
  - Solution: Review the user manual to ensure all steps and

instructions are properly followed.

- Solution: If the instructions are properly followed but the app problem persists, please shut down the application, reboot, and try again.
- Solution: If instructions are followed but the problem persists, press the power button to shut down and reboot the QT ECG Recorder and try again.
- Solution: If all steps are followed, but the recorder still cannot record ECG, please contact our customer service.
- Problem: Cannot find the recorder while connection
  - Solution: Check the recorder is on.

## 6. PREVENTIVE AND MAINTENANCE

The following sections describe how to clean and/or disinfect the QT ECG system, including recommended cleaning and disinfecting solutions and methods. It also covers the routine preventive maintenance for the QT ECG Recorder.

### 6.1 QT ECG Recorder

To clean the QT ECG Recorder, dampen a soft cloth with lukewarm soapy water or natural cleaner and gently wipe down the recorder. The QT ECG Recorder should never be immersed in water under any circumstances. Take care not to scratch the device with abrasive cleaners or excessively wipes on the label. The QT ECG Recorder should be gently cleansed before every use. To disinfect the QT ECG Recorder, dampen a soft cloth with isopropyl alcohol. Regularly inspect the QT ECG Recorder for damage such as warping or cracking. If there is any damage, please do not use it and contact the customer service.

### 6.2 QT Electrode Strip

The Electrode Strip is for one-time use only. There is no need to clean.

### 6.3 Wall Charger

The cleaning procedure for the wall charger is the same as the QT ECG Recorder. Please disconnect the wall charger from power sources before beginning any cleaning procedure.

## 7. TROUBLESHOOTING

### 7.1 QT ECG Recorder

- Problem: PWR LED indicator does not light up during charging
  - Solution: PWR LED indicator will turn off after it is fully charged, If the PWR LED does not light up with charging, this may indicate that battery is fully charged.
- Problem: Unable to turn on the QT ECG Recorder
  - Solution: Press and hold the power button for 30 seconds. If Power LED indicator still does not light up, please try again after charging the device for 1 hour.
  - Solution: If above solution does not work, please contact our customer service.
- Problem: Unable to turn off the QT ECG Recorder
  - Solution: Make sure the micro-USB cable is not connected
  - Solution: Press and hold power button for 30 seconds. If still unable to turn off the QT ECG Recorder, please contact our customer service.
- Problem: Unable to connect the QT ECG Recorder to the mobile device via Bluetooth
  - Solution: If Bluetooth is not connected when it is on, the blue CON LED indicator will blink. When properly connected, CON LED indicator will be a solid light. If CON LED indicator is off or blinking when turned on, please contact our customer service.

### 7.2 QT Electrode Strip

- Problem: Package opened or damaged before use
  - Solution: Do not use the Electrode Strip, contact our customer service for replacement.
- Problem: 7 chest lead electrodes or 3 limb lead electrodes are damaged or missing
  - Solution: Do not use the Electrode Strip and contact our customer service.
- Problem: Size of Electrode Strip enclosed does not match with package labels

- o Solution: Do not use the Electrode Strip and contact our customer service.

### 7.3 QT ECG App

- Problem: Crashed during use
  - o Solution: Reboot and restart, if problem persists, please contact our customer service.
- Problem: Cannot boot up application or the app quits unexpectedly
  - o Solution: Please contact our customer service.
- Problem: Application is not performing smoothly
  - o Solution: Too many apps may be open and running at the same time. Please reboot the mobile device and try again.

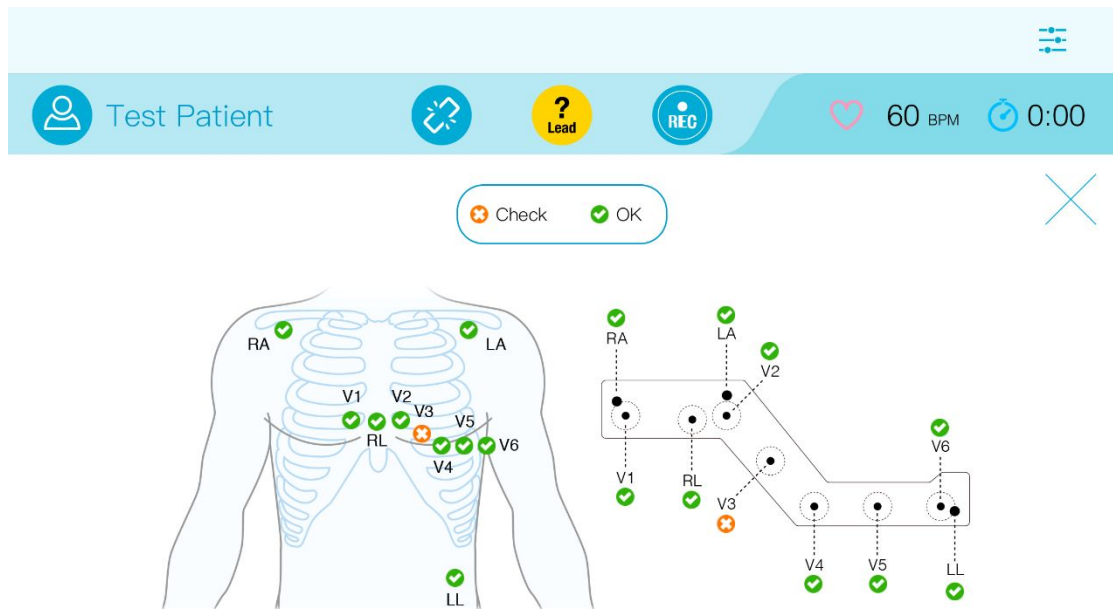


- Problem: All ECG tracings disappear on the display. The screen display looks like the following:



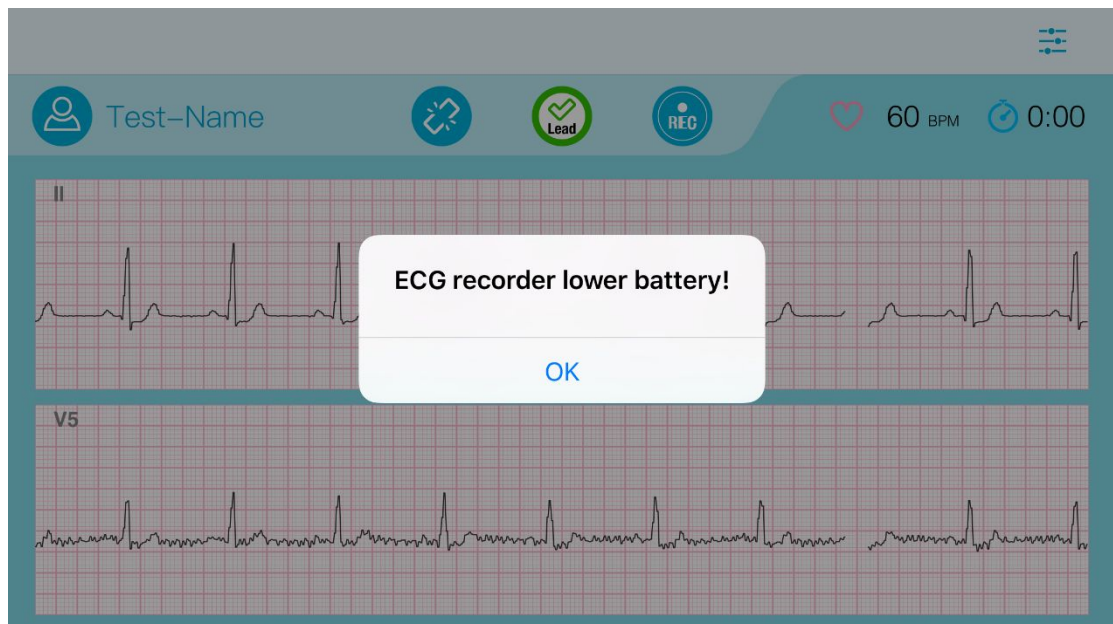
- o Solution: The problem may be caused by system overload or saturation. Please carefully remove the Electrode Strip from the patient's chest and disconnect the QT ECG ECG Recorder. Please restart the entire process. If the problem persists, please contact our customer service.

- Problem: Lead-off warning. The screen display is as follows:



- o Solution: Check the corresponding chest electrode. Make sure the electrode is attached properly to the skin and making a good contact.

- Problem: Low battery warning. The screen displays the following:



- o Solution: Disconnect the Recorder from the Electrode Strip, and remove electrode from the user. Charge the QT ECG Recorder using the wall charger with the micro-USB cable. Do not record and charge at the same time.

#### 7.4 Other

- Problem: Cannot record ECG signals
  - o Solution: Review the user manual to ensure all steps and instructions are properly followed.
  - o Solution: If the instructions are properly followed but the app problem persists, please shut down the application, reboot, and try again.
  - o Solution: If instructions are followed but the problem persists, press the power button to shut down and reboot the QT ECG Recorder and try again.
  - o Solution: If all steps are followed, but the recorder still cannot record ECG, please contact our customer service.

## 8. CUSTOMER SERVICE SUPPORT

For customer service support, please contact:

QT Medical, Inc.

1001 W Carson Street, Suite U, Torrance, CA90502, U.S.A.

TEL (424) 558-3500

FAX (310) 755-3108

service@qtmedical.com

Manufactured for: QT Medical, Inc.

1001 W Carson Street, Suite U, Torrance, CA90502, U.S.A.

<http://www.qtmedical.com>

## 9. WARRANTY

The Company warrants the QT ECG against defects in materials and workmanship under ordinary clinical use for one year from the delivery date. During this warranty period, if a defect arises in the QT ECG, the Company will at its option, to the extent permitted by law, either (i) repair the QT ECG ECG Screen using either new or refurbished parts, (ii) replace QT ECG with a new or refurbished device that is equivalent to the device to be replaced, or (iii) if (i) or (ii) are not reasonably possible, refund you all or part of the purchase price of QT ECG, as deemed appropriate by the Company. This limited warranty applies, to the extent permitted by law, to any repair, replacement part or replacement device for the remainder of the original warranty period or for ninety days, whichever period is longer. All replaced parts and devices for which a refund is given shall become the Company's property. This limited warranty applies only to hardware components of the QT ECG that are not subject to accident, misuse, neglect, fire or other external causes, alterations, or repair. Should a warranty repair be required, please contact customer service at [service@qtmedical.com](mailto:service@qtmedical.com). In general, the Company will send you packaging that you can use to return the device to the appropriate customer service location. Third party tablets or computer devices are not covered under the Company's warranty. Warranty claims for tablets or other mobile computing devices should be directed to the original manufacturer of those devices.

## APPENDIX

- A. FCC Statement
- B. IC Statement
- C. Advice for Electromagnetic interference

## **APPENDIX A**

### **FCC Statement**

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

- (1) This device may not cause harmful interference, and
- (2) This device must accept any interference received, including interference that may cause undesired operation.

NOTE: 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.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

**APPENDIX B**  
**IC Statement**



## **APPENDIX B**

### **IC Statement**

This device complies with Industry Canada license-exempt RSS standard(s). 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.

Le present appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisee aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioelectrique subi, meme si le brouillage est susceptible d'en compromettre le fonctionnement.

## APPENDIX C

### Taiwan regulatory information(NCC)

## 低功率電波輻射性電機管理辦法

第十二條 經型式認證合格之低功率射頻電機，非經許可，公司、商號或使用者均不得擅自變更頻率、加大功率或變更原設計之特性及功能。

第十四條 低功率射頻電機之使用不得影響飛航安全及干擾合法通信；經發現有干擾現象時，應立即停用，並改善至無干擾時方得繼續使用。

前項合法通信，指依電信法規定作業之無線電通信。低功率射頻電機須忍受合法通信或工業、科學及醫療用電波輻射性電機設備之干擾。

## APPENDIX D

### Advice for Electromagnetic interference

The following is information on potential electromagnetic interference and advice on how to avoid or minimize such interference.

#### Guidance for Electromagnetic Emissions:


<p>QT ECG is intended for use in the electromagnetic environment specified below. The customer or the user of QT ECG should assure that it is used in such an environment.</p>		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 2	QT ECG must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	QT ECG 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	Complies	

#### Guidance for Electromagnetic Immunity:

<p>QT ECG is intended for use in the electromagnetic environment specified below. The customer or the user of QT ECG should assure that it is used in such an environment.</p>			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment –guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact	±6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
	±8 kV air	±8 kV air	

Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines  ±1 kV for input/output lines	±2 kV for power supply lines  ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s)  ±2 kV line(s) to earth	±1 kV line(s) to line(s)  ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % <i>UT</i> (>95 % dip in <i>UT</i> ) for 0.5 cycle  40 % <i>UT</i> (60 % dip in <i>UT</i> ) for 5 cycles  70 % <i>UT</i> (30 % dip in <i>UT</i> ) for 25 cycles  <5 % <i>UT</i> (>95 % dip in <i>UT</i> ) for 5 sec	<5 % <i>UT</i> (>95 % dip in <i>UT</i> ) for 0.5 cycle  40 % <i>UT</i> (60 % dip in <i>UT</i> ) for 5 cycles  70 % <i>UT</i> (30 % dip in <i>UT</i> ) for 25 cycles  <5 % <i>UT</i> (>95 % dip in <i>UT</i> ) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of QT ECG requires continued operation during power mains interruptions, it is recommended that QT ECG be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE <i>UT</i> is the a.c. mains voltage prior to application of the test level.			

<p>QT ECG is intended for use in the electromagnetic environment specified below. The customer or the user of QT ECG should assure that it is used in such an environment.</p>			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			<p>Portable and mobile RF communications equipment should be used no closer to any part of QT ECG, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p>

<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2,5 GHz</p>	<p>3 Vrms</p> <p>3 V/m</p>	<p><b>Recommended separation distance</b></p> <p><math>d = 1.2 \sqrt{P}</math></p> <p><math>d = 1.2 \sqrt{P}</math> 80 MHz to 800 MHz</p> <p><math>d = 2.3 \sqrt{P}</math> 800 MHz to 2,5 GHz</p> <p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p><sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which QT ECG is used exceeds the applicable RF compliance level above, QT ECG should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating QT ECG.</p> <p><sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

## Recommended Separation Distances between Mobile RF

## Communications Equipment and QT ECG:

QT ECG is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of QT ECG can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters). According to the maximum output power of the communications equipment, recommended environment for QT ECG is described below,

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 2.5 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.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## Appendix E. Compliance for Emissions and Immunity Standard

Standard	Edition
Biocompatibility	ISO 10993-10:2002/Amd 1:2006, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization; ISO 10993-5:1999, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.

Electrical Safety	IEC 60601-1:2005+AMD1:2012 CSV/COR1:2012,  IEC 60601-1-11:2015,  EN 60601-1:2006+A1:2013+A12:2014+US DEVIATION,  IEC 60601-2-25:2011
Electromagnetic Compatibility (EMC Safety)	IEC 60601-1-2:2014
Electrode	ANSI/AAMI EC12:2000/(R)2010,
Battery	IEC 62133:2012
Wall-Charger	EN60601-1-2:2014_GROUP 1 Class B FCC PART 15 & PART 18 CLASS B UL ES60601-1:2005 CSA C22.2 NO.60601-1:2008 EN60601-1:2006 IEC 60601-1:2005 EN60601-1-11 BSMI CNS 14336-1
Electrocardiograph Performance	IEC 60601-2-25:2011
RF	Meet FCC, IC, CE, NCC CE R&TTE EN 301489-1V1.9.2 CE R&TTE EN 301489-17v2.1.1 CE R&TTE EN 300328 V2.1.1 FCC Part 15B

