



QT ECG RECORDER USER'S MANUAL



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Important Warnings

- Caution: Federal law restricts this device to sale by or on the order of a licensed medical practitioner.
- 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.
- Read this manual thoroughly before using the QT ECG system. 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 transmission of infection or disease, dispose of the Electrode Strip properly after each use. Contact your local authorities for the proper disposal method of potential bio-hazardous materials.
- Always use the latest version of the QT ECG App.
- If you have a history of sensitive skin or allergy, consult your doctor before using Electrode Strip.
- To avoid contact irritation, patients with large breasts should place a piece of gauze or a soft cloth between the underside of the left breast and the top edge of the Electrode Strip.



Introduction

This user's manual provides information about 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 5 major components:

The QT ECG Recorder

Compact device that records 12-lead, resting electrocardiograms and transmits the recorded data to a mobile device (smartphone, tablet, etc.) via Bluetooth. A Bluetooth-enabled mobile device (not included) is required in order to operate the QT ECG Recorder.

The Electrode Strip

Disposable, patented electrodes that are prepositioned on a self-adhesive strip.

The QT ECG App

Software that allows you to use your mobile device to operate the QT ECG recorder. You can send the recorded data to the cloud for a certified medical professional to review.

Analysis

The analysis module provides ECG measurement from the collected data.

Web Service

The web service provides an interface for communication.

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

Warning :

Use only manufacturer-approved accessories.

The QT ECG system is not intended for treatment or monitoring. It captures data that reflects 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 near real-time to enable review at a physician's office, hospital or other medical centers.

1.3 Intended Use

The QT ECG System is intended to condition an electrocardiographic signal so that it can be transmitted digitally via Bluetooth technology and cell-phone or communication device to a remote location.. The QT ECG System is designed to be used by a patient or another layperson or a healthcare worker to transmit a 12-lead ECG and rhythm strip in near real-time to enable review at a physician's office, hospital, or other medical centers.

1.4 Contraindications

Sensitive skin, allergy, or open wound.




1.5 Environment

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








1.6 Symbols




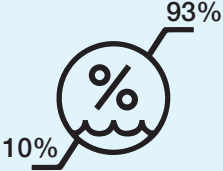
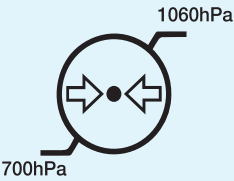
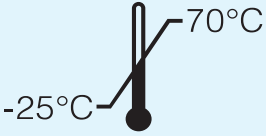

The following symbols are used in this manual and on the product and/or packaging:

The QT ECG Recorder	
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.
	"REFER TO MANUAL" : Follow operating instructions.
IP22	The degree of protection provided by the enclosure from particulate matter and water. First Number: 2 indicates protection against object sized >12.5mm (Fingers or similar objects) Second Number: 2 indicates 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.
 MR unsafe	"MR-unsafe": Do not expose the device to a magnetic resonance (MR) environment.



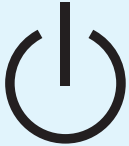
The QT ECG Recorder

Symbol/Marking	Description
  WEEE	The WEEE symbol, indicating separate collection for WEEE- Waste of Electrical and Electronic Equipment.
	Bluetooth wireless technology incorporated.
 Non-ionizing radiation	Non-ionizing radiation.
 CCAN18LP0670T1	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.
Model Number: QTERD100	The QT ECG Recorder model number.
FCC ID: 2AIBAQTERD100	FCC ID is a unique identifier assigned to a device registered with the United States Federal Communications Commission.
IC: 21780-QTERD100	IC ID is the product ID assigned by Industry Canada to identify wireless products in the Canadian market.

The QT ECG Recorder

Symbol/Marking	Description
	<p>“MANUFACTURER” : The name and the address of the manufacturer.</p>
 <p>(01) 0 4719872 58002 7 (21) 02011737100001</p>	<p>UDI data matrix barcode: it is intended to assign a unique identifier to medical devices within the United States.</p>
<p>Rx Only – USA</p>	<p>Caution: Federal law restricts this device to sale by or on the order of a licensed medical practitioner.</p>
	<p>Type CF is the most stringent classification, being required for those applications where the applied part is in direct conductive contact with the heart or other applications as considered necessary.</p>
	<p>Storage and transportation conditions: humidity range.</p>
	<p>Storage and transportation conditions: pressure range.</p>
	<p>Storage and transportation conditions: temperature range.</p>
	<p>“REFERENCE NUMBER” : The reference number of product, same as model number.</p>

The QT ECG Recorder

Symbol/Marking	Description
	"SERIAL NUMBER" : The manufacturer's serial number.
	Rated direct current input supply voltage and current.
	Power Button: Press and hold for 5 seconds to turn on/off the QT ECG Recorder.
PWR	The PWR LED indicates the power and charging status.
CON	The CON LED indicates the Bluetooth connection status of the QT ECG Recorder to the mobile computing device.
REC	The REC LED indicates the recording status of the QT ECG Recorder.



The QT ECG Electrode Strip

Symbol/Marking	Description
 Lot. No.	Lot No.: the manufacturer's lot number or batch code.
 Do Not Reuse	Do not reuse.
 Do not use if package is damaged	Do not use if package is damaged.
 Caution	General warning sign.
 Keep away from sunlight	Keep away from sunlight.
 Date Of Manufacture	Date of manufacture.

* The same symbols as recorder will not be explained.



Safety Information

Make sure you are familiar with the safety information in this section before using the QT ECG system. 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 Warnings

- 2.1.1. Inspection: Visually inspect the QT ECG system and all accessories to use. Do not use if any COMPONENTS ARE DAMAGED.
- 2.1.2. The QT ECG system is not defibrillator-proof. Remove the QT ECG system from the patient's body before using any high voltage device such as an AED (Automated External Defibrillator).
- 2.1.3. No modification of this equipment is allowed.
- 2.1.4. Never attempt to connect the QT ECG Recorder and its accessories to any other device. Only use manufacturer-approved accessories to connect with the QT ECG recorder.
- 2.1.5. Never use the conductive parts of the QT ECG Electrode Strip to contact any other conductive objects, including the earth.
- 2.1.6. Keep the device away from flammables, such as nitrous oxide and anesthetic mixtures with oxygen and air.
- 2.1.7. To prevent potential transmission of infection or disease, the one-time use QT ECG Electrode Strip must be properly disposed of after each use. The QT ECG Recorder may be cleaned before usage. refer to the section "Preventive Maintenance" to find information about cleaning methods.
- 2.1.8. The QT ECG system is not designed for use with high voltages or surgical equipment. To ensure the safety of the operator and the Patient, disconnect the device and all components prior to any medical procedure.
- 2.1.9. The QT ECG Electrode Strip may damage the skin if removed abruptly or carelessly.

- 2.1.10.** The QT ECG Electrode Strip is for one-time use only. Do not reuse.
- 2.1.11.** Once the data has been collected, remove the QT ECG Electrode Strip right away. Prolonged use of the QT ECG Electrode Strip may cause allergic reaction or skin irritation. Contact your doctor if you have an allergic reaction or if skin irritation persists.
- 2.1.12.** To avoid strangulation and suffocation, use under adult supervision.
- 2.1.13.** The summation of electrical current leakage when a QT ECG Recorder and a QT ECG Electrode Strip are in use and interconnected is at most 50 uA.
- 2.1.14.** Remove the device if it causes any physical discomfort.
- 2.1.15.** The QT ECG Electrode Strip is not intended for intracardiac use or direct cardiac application. It should not come in direct contact with the heart.
- 2.1.16.** Use of the QT ECG system 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 system and the other equipment should be monitored to verify that they are operating normally.
- 2.1.17.** Use of accessories or the QT ECG Electrode Strip other than those specified or provided by QT Medical could result in increased electromagnetic emissions or decreased electromagnetic protection of the QT ECG system and lead to improper functions.
- 2.1.18.** Do not use Portable RF communication equipment (including peripherals such as antenna cables and external antennas) within 30 cm (12 inches) of any part of the QT ECG system including the QT ECG Electrode Strip. Radio Frequencies may degrade the performance of the QT ECG system.
- 2.1.19.** If you have any service or maintenance issue when in use, please contact QT Medical customer service support.

2.2 Cautions

- 2.2.1.** Only use the device in environments described in the User's Manual. Do not use the QT ECG system in close proximity of equipment with electromagnetic interference such as microwave ovens, radios, televisions, etc. The electromagnetic interference can degrade the performance of the device.
- 2.2.2.** If the QT ECG system is used in an environment with ESD (ElectroStatic Discharge), the ESD signal may interfere with ECG signals. Try to avoid this kind of environment. No modification of this equipment is allowed.
- 2.2.3.** Do not take apart the device or alter any component. For technical assistance please contact QT Medical.
- 2.2.4.** For cybersecurity purposes, users should run regular virus checks on the mobile device.

- 2.2.5.** Only use the QT ECG Recorder with compatible firmware as specified in the User's Manual.
- 2.2.6.** Follow the User's Manual when connecting the device to its components. Ensure all accessories and the device are properly connected.
- 2.2.7.** Cleaning the device incorrectly or exposure to harsh or abrasive cleanser and disinfectant can damage the device. Please follow the cleaning instructions carefully.
- 2.2.8.** Do not use non-recommended cleaning or disinfection solutions with the QT ECG Recorder and its accessories. Please follow the cleaning instructions carefully.
- 2.2.9.** Do not attempt to autoclave or sterilize the QT ECG Recorder and its accessories.
- 2.2.10.** Do not attempt to charge the QT ECG Recorder when it is connected to the QT ECG Electrode Strip.
- 2.2.11.** The QT ECG Electrode Strip should be applied only to intact, clean skin (i.e., not over open wounds, lesions, infected, or inflamed areas).
- 2.2.12.** Avoid using the QT ECG system 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 system.
- 2.2.13.** Do not open the QT ECG Electrode Strip package until time of use. If not stored properly, the QT ECG Electrode Strip might dry out, which can result in poor conductivity and poor data quality.
- 2.2.14.** Once the QT ECG 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 data quality. Keep it away from children and pets to avoid damage.
- 2.2.15.** Keep the device away from prolonged exposure to direct sunlight.
- 2.2.16.** Follow storage condition instructions as described in the User's Manual. Make sure the storage environment is appropriate.
- 2.2.17.** If necessary, contact local authorities to determine the proper method of disposal for potentially biohazardous parts and accessories.
- 2.2.18.** Charge the QT ECG Recorder fully (approximately 1.5 hours) before first use.
- 2.2.19.** Charge the QT ECG Recorder regularly, before the battery is depleted of power. Keeping the battery at a low charge for a prolonged period of time will damage the battery.
- 2.2.20.** The battery in the QT ECG Recorder may be charged approximately 300 times. If you have questions or concerns about the battery, please contact QT Medical customer support.

2.3 Note

- 2.3.1. Caution: Federal law restricts this device to sale by or on the order of a licensed medical practitioner.
- 2.3.2. The device does not require calibration.
- 2.3.3. Always use the latest version of the QT ECG App.
- 2.3.4. Before placing the QT ECG Electrode Strip on the patient's chest, locate the landmarks on the chest as described in the User's Manual or Quick Guide. A misplaced QT ECG Electrode Strip can lead to inaccurate results.
- 2.3.5. The diagnostic report renders ECG data in 1000-hz temporal resolution.
- 2.3.6. Patients should remain as still as possible when performing an ecg test. Excessive patient movement can lead to poor quality data.
- 2.3.7. For optimal data collection, the patient's skin should be free of oil and/or lotions before placing the QT ECG Electrode Strip on the chest.
- 2.3.8. When the battery level drops below 20%, charge the unit immediately. Depleting the charge will damage the battery.
- 2.3.9. The QT ECG Electrode Strip should only be used in consultation with QT Medical, Inc. or a healthcare provider familiar with its proper placement and use.
- 2.3.10. The QT ECG Electrode Strip should be replaced if the adhesive patches can no longer attach firmly to the skin.
- 2.3.11. Consult your healthcare provider for assistance with choosing the proper QT ECG Electrode Strip size and fit. The QT ECG Electrode Strip is designed to fit adult patients and pediatric patients 18 – 22 years of age.



Prior to Operation

3.1 Know your Unit

Your package contains the following items:

- A. QT ECG Recorder
- B. Quick Guide
- C. Wall Charger & Micro-USB Cable
- D. Sizing Guide

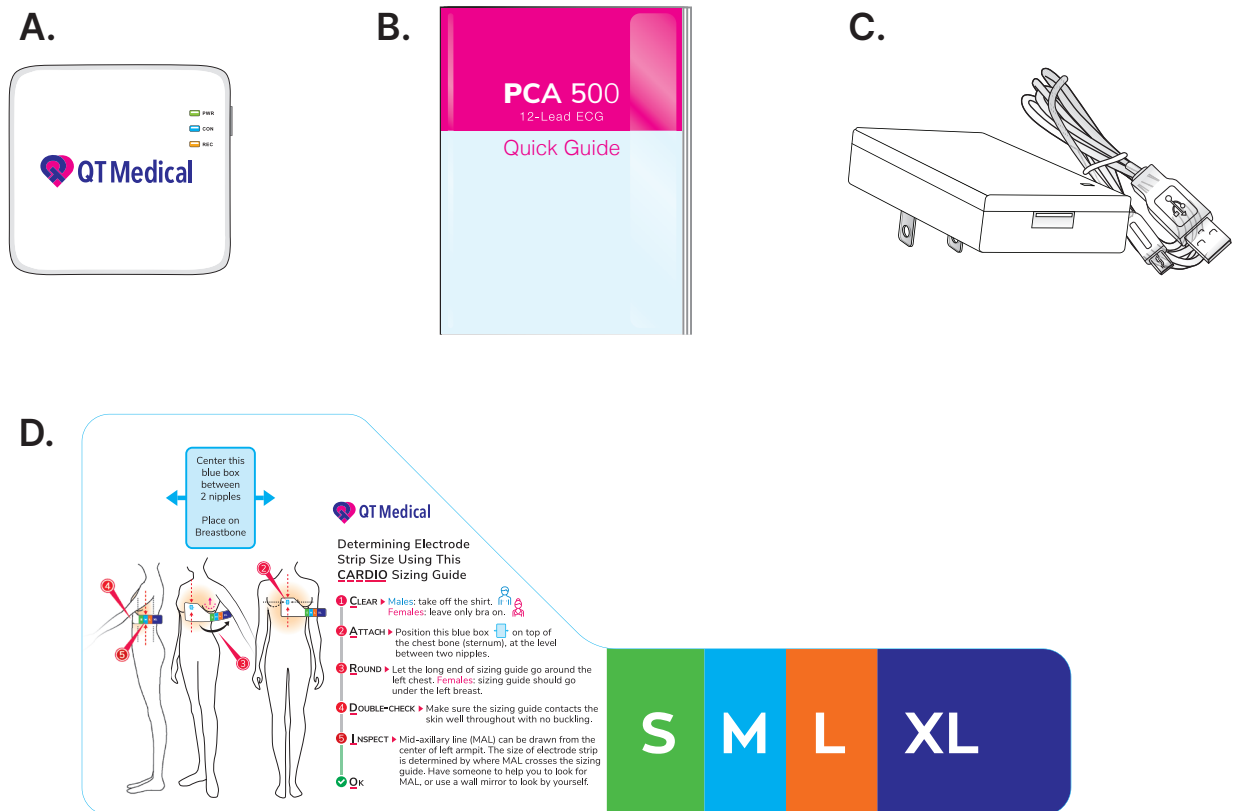
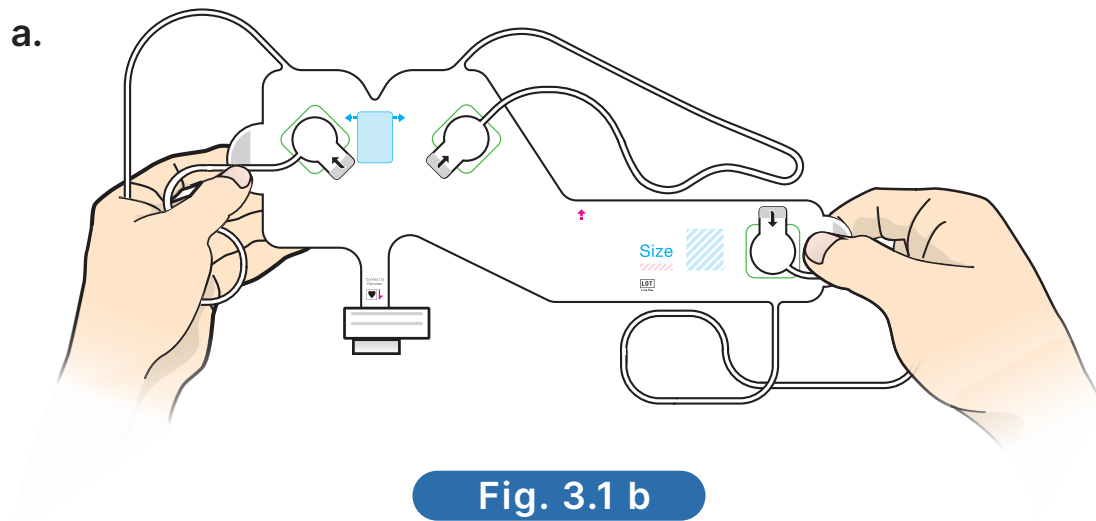


Fig. 3.1 a



The QT ECG Recorder can be used with the following:

a. **Electrode Strip** (packaged and sold separately)



3.1.1. QT ECG Recorder (Main Device)

The three-view diagram of the QT ECG Recorder is shown in **Fig 3.1.1a**.

Warning :

- Do not attempt to charge the Recorder and plug-in the Electrode Strip at the same time.
- Do not use any charger other than the one provided in the original case.
- To avoid risk of product damage, do not attempt to connect the QT ECG Recorder with any other cable, connector or power cord.

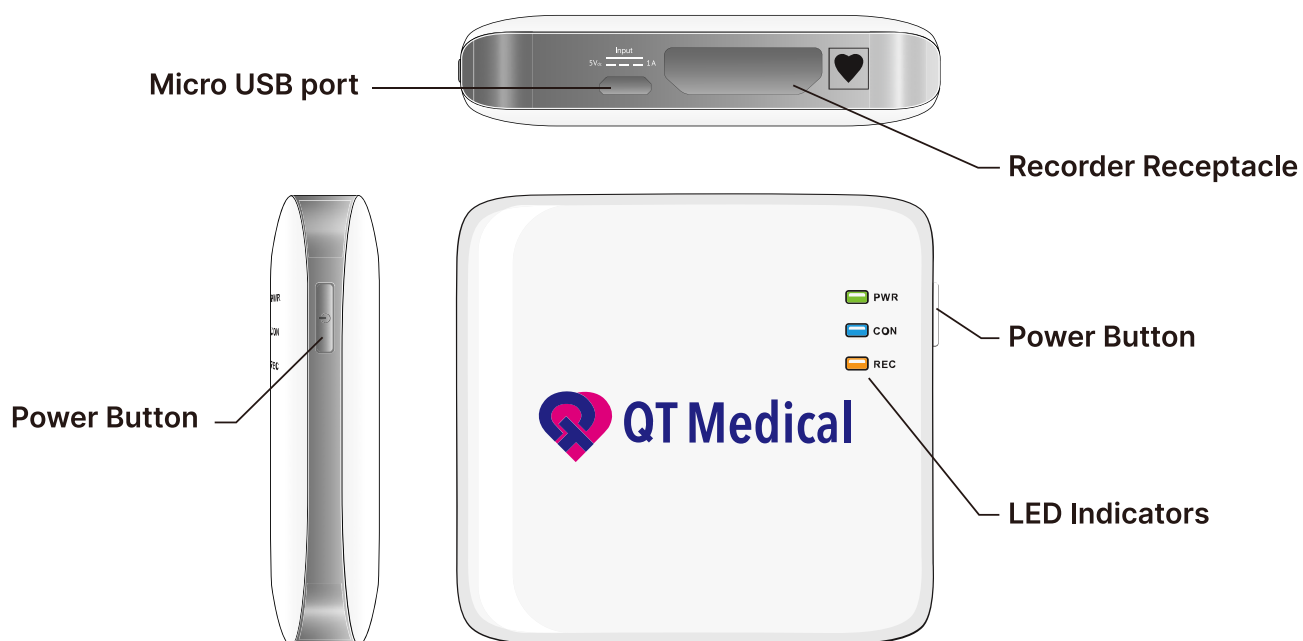


Fig. 3.1.1a

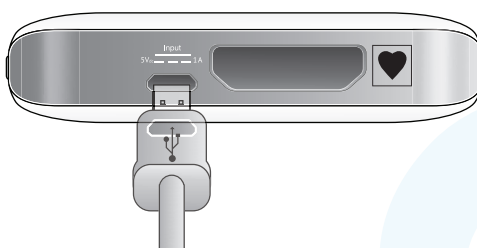


Fig. 3.1.1b

- 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 (included) (Fig. 3.1.1b)
- C. Recorder Receptacle :** Used to connect with the QT ECG Electrode Strip Connector (Fig. 3.1.2b)
- D. LED Indicators :** There are three LED indicators: PWR, CON, and REC, which indicate the device status.

Table 3.1.1a Operation of the LED Indicators

LED Indicators	PWR LED	CON LED	REC LED
ON	Green: Powered on or the battery is fully charged Soft white: battery charging	Blue: Connected	N/A
OFF	Power off	N/A	N/A
Blink	Soft White: Low Battery	Blue: Bluetooth is not connected, ready to connect	Amber: Recording
Blink Fast	Red: System Error	N/A	N/A



Table 3.1.1b Specification of the QT ECG Recorder

Feature	Specification
Brand Name	QT ECG
Model Name	PCA 500
Model Number	QTERD100
Dimension	72×68.02×18.60 mm (2.83 × 2.68 x 0.735 in)
Weight	67 g
Enclosure Material	Polycarbonate
Wireless Technology	Bluetooth 4.0 dual mode Operation frequency range: 2.402 GHz ↔ 2.480 GHz (BLE); 2,402 MHz to 2,480 MHz (BT)
LED	PWR: Power/Status LED (RGB)
	CON: Connection LED (Blue)
	REC: Recording LED (Amber)
External Port	Micro USB port (charging port)
	Recorder Receptacle (to connect with the QT ECG Electrode Strip)
Physical Button	Power On/Off switch
Battery	Rechargeable lithium-ion polymer battery, 3.7 V, 700 mAh
Battery Charge Time	1.5 hours

Feature	Specification
Battery Operating Time	17 hours of continuous use 24 hours of normal use (use: standby = 1:5) with new battery
Battery Charging Procedure	Connect the QT ECG Recorder to wall charger through the Micro USB port on the recorder
Battery Replacement	Not user-replaceable
Charging Indicator	Soft white
Low Battery Indicator	Blinking green
Shelf-Life	6 months Note: It is recommended to charge the device every 30 days.
Service Life	5 years Note: Battery \geq 300 cycle
Signal Sampling Rate	1000 Hz
Channel Skew	0
Acquisition Mode	Simultaneous sampling on all channels
A/D Resolution	24-bit
Quantization Error	0.047 μ V/LSB
Frequency Response	0.05 to 150 Hz

Feature	Specification
Triangle Response	6% maximum reduction 20 ms vs 200 ms triangle wave
Filters	Default off.
Input Impedance	6.875 MΩ
DC-offset Voltage	+/- 399 mV
Multichannel Crosstalk	≤15 uV
CMRR	99 dB
Noise Level	≤10 uV
Overload Tolerance	Up to 1 V
Wireless Distance	10 m
Bluetooth Transmission Rate	3 Mbps
Standard Leads Acquired	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Sensitivity	5, 10, 20 mm/mV auto (I~aVF: 10 mm/mV, V1~V6: 5 mm/mV)
Calibration	Automatic
Data Storage	In mobile device
Lead-off Detection	Yes

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



3.1.2. QT ECG Electrode Strip

All 10 electrodes are integrated into the self-adhesive QT ECG Electrode Strip. It is attached to the body and plugs into the QT ECG Recorder as shown in **Figure 3.1.2a**.

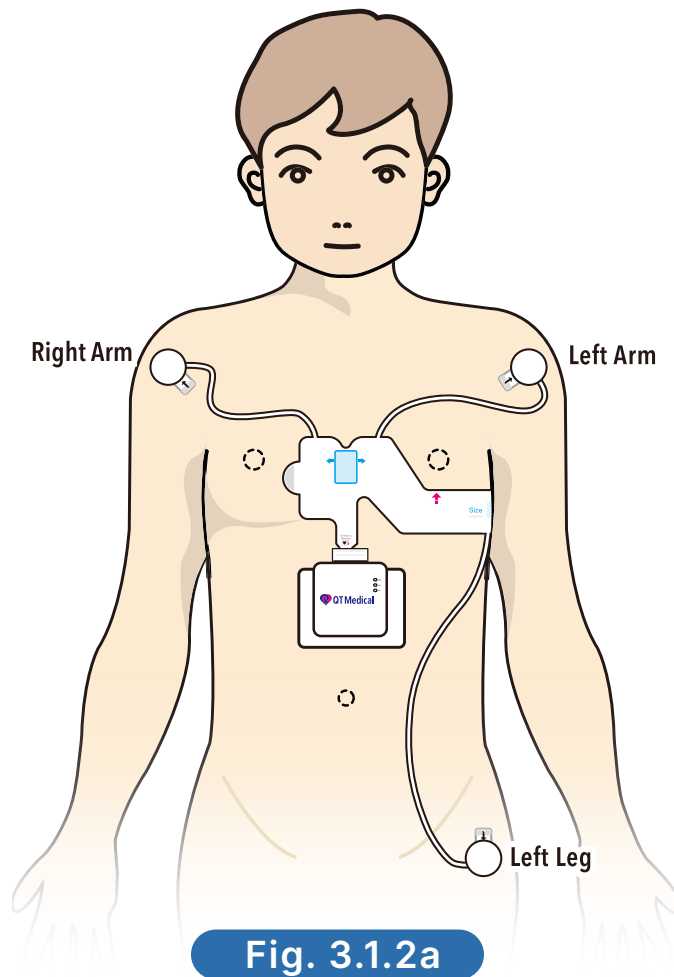


Fig. 3.1.2a

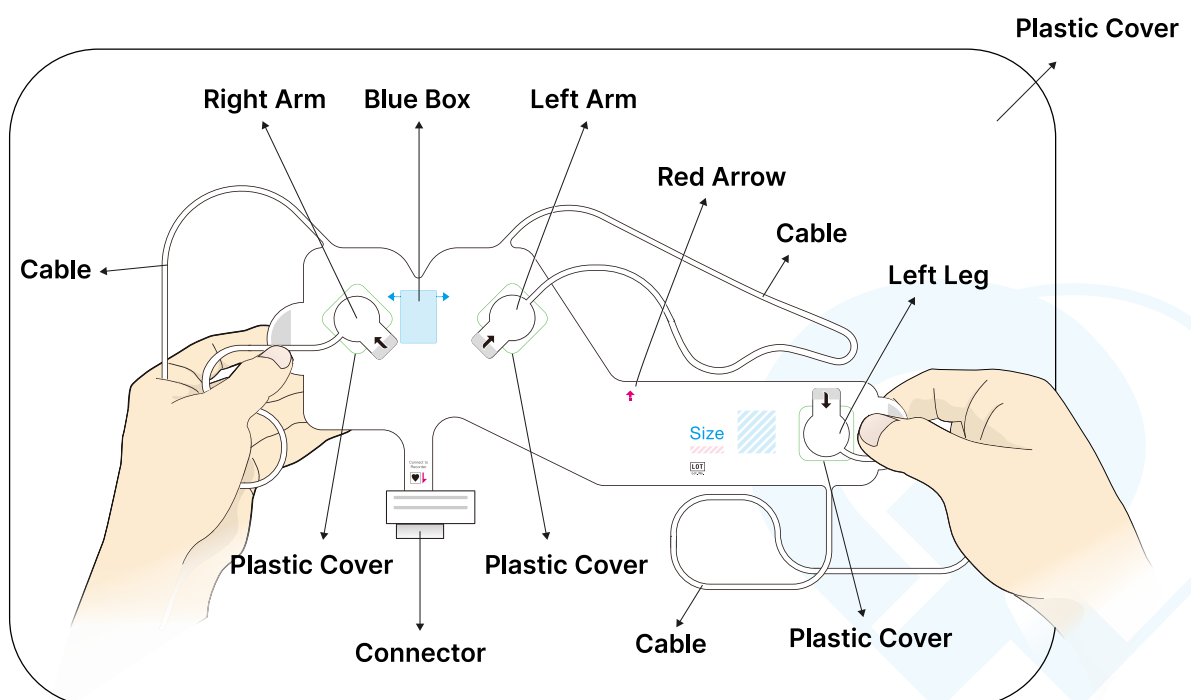


Fig. 3.1.2b

The Electrode Strip comes in 4 different sizes, depending on body size and shape.

Warning :

- Patient’s cardiologist or ECG technician should help the patient find the right size of the QT ECG Electrode Strip.
- The Electrode Strip is not defibrillator-proof. Do not use high-voltage devices such as AED while the Electrode Strip is still attached to the body.

Caution :

- The Electrode Strip has a shelf life of two years (1.5 year for aviation use). Do not use it past the expiration date.

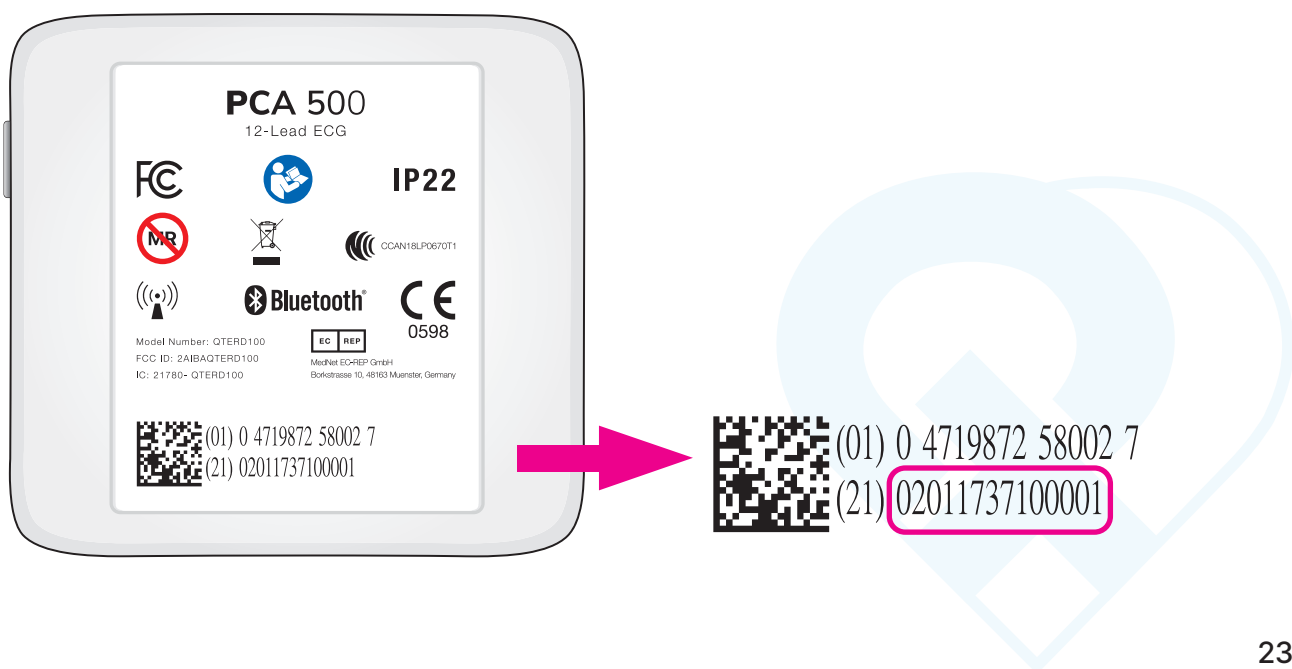
3.1.3. Wall Charger

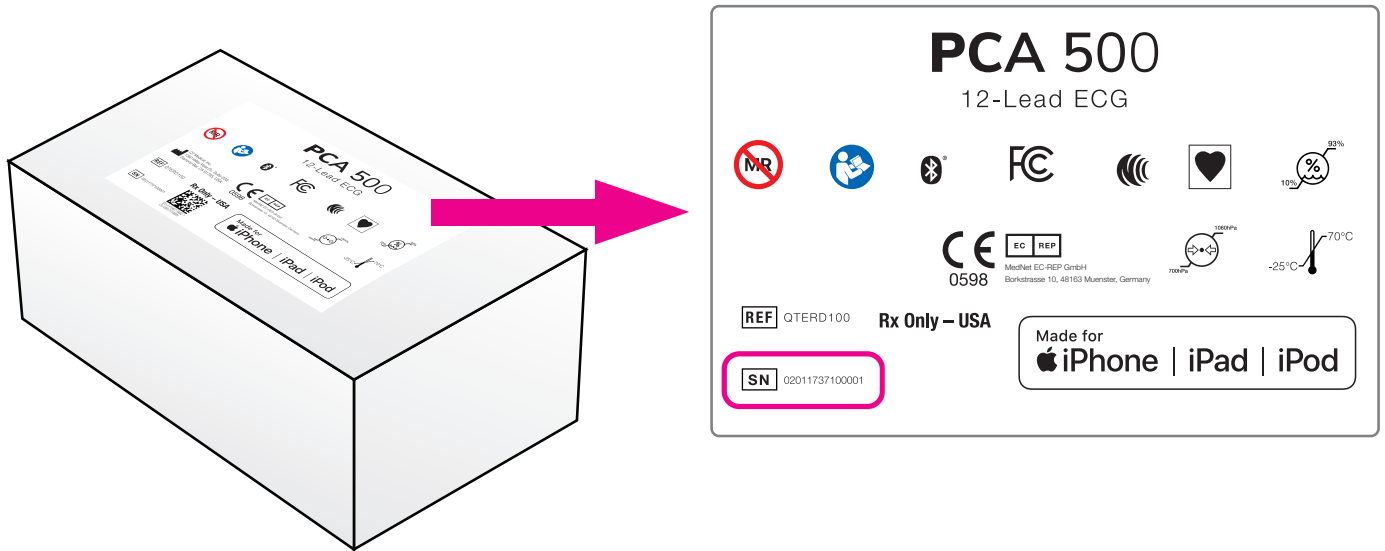
This medical-grade AC-to-DC power adapter provides external isolation from AC mains. Use the provided wall charger to charge your QT ECG Recorder. Only use 100-240 V wall-socket outlets.

Warning :

- Do not use any external power supply such as a portable battery charger or PC to charge the QT ECG Recorder.

You can get the serial number from the back of the recorder or the case of the recorder.





3.1.4. Equipment Preparation

1. Charge the QT ECG Recorder fully before the first use.

Warning :

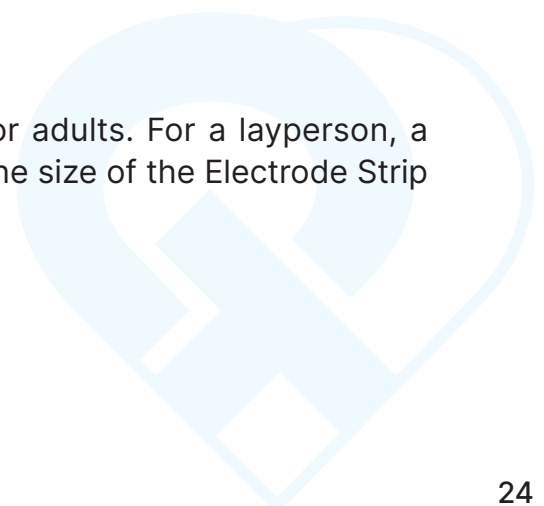
Visually inspect the QT ECG Recorder and all accessories before use.
Do not use if any component appears damaged.

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



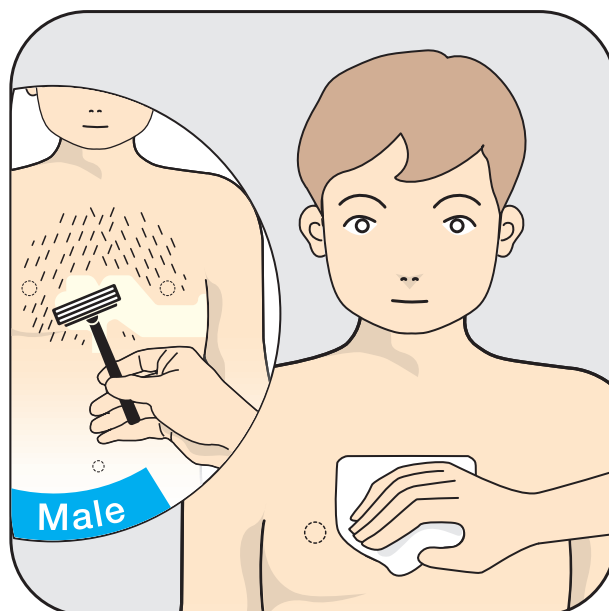
3. Selecting Electrode Strip Size.

The Electrode Strips come in 4 different sizes for adults. For a layperson, a cardiologist or ECG technician should determine the size of the Electrode Strip for you.



3.2 Patient Preparation

- Make sure the skin on the chest is clean, dry, and free from lotion or oil. For males with dense hair on the chest, shave the chest along the area indicated in the following illustration.
- For females, to keep the bra on or not depends on whether the electrode strip can be applied correctly and comfortably with or without the bra. This can be a personal decision.



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

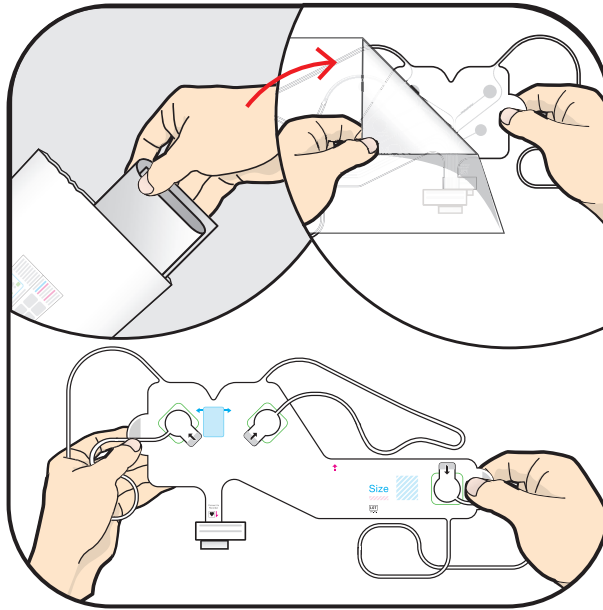


Operating Procedures

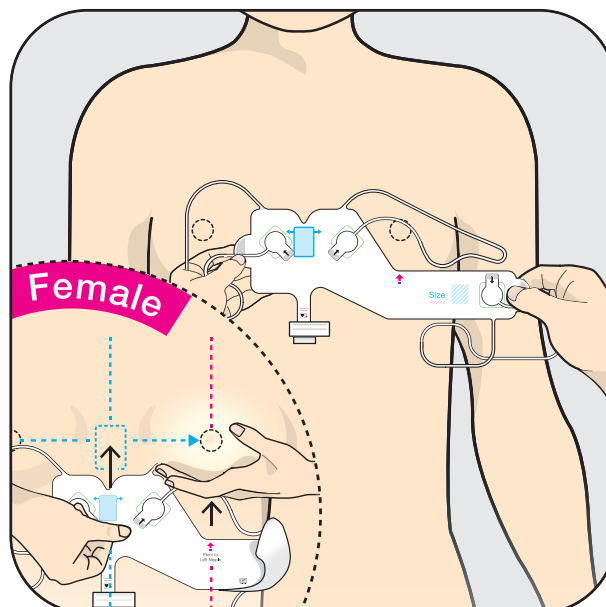
4.1 Attaching the Electrode Strip

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

4.1.1. Open the QT ECG Electrode Strip package. Remove the release liner using the Attaching the Electrode Strip.



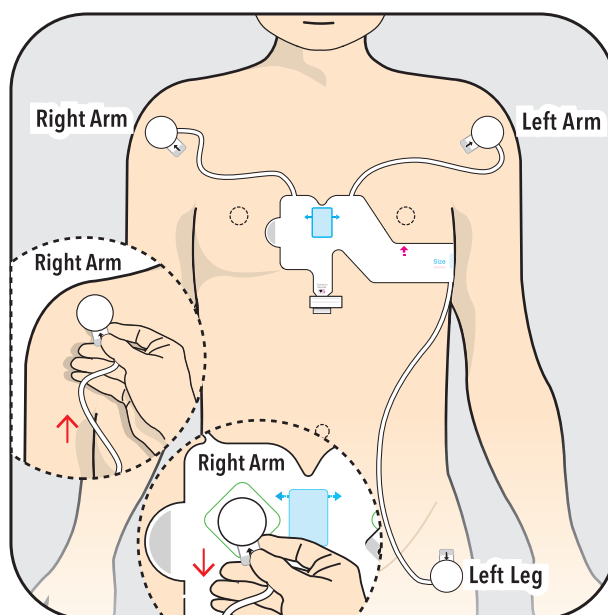
4.1.2. With the adhesive side facing the patient, place the strip on the patient's chest. First, position the blue box at the center of the chest, between the nipples. Then, wrap the strip from the center of the chest around the left side of the chest. The Red Arrow should be pointing to the left nipple. For females, the Strip should go under the left breast. For patients with large breasts, it may be easier to apply the electrode strip by lying supine (face up) with the left breast up.



If placement of the Electrode Strip needs adjustment, the Electrode Strip can be taken off and reapplied for repositioning.

4.1.3. Pull the lead marked "Left Arm" and stick to left arm, the lead marked "Left Leg" to left leg, and the lead marked "Right Arm" to right arm.

- Press firmly on the Electrode Strip and all electrodes to ensure the attachments are secure.

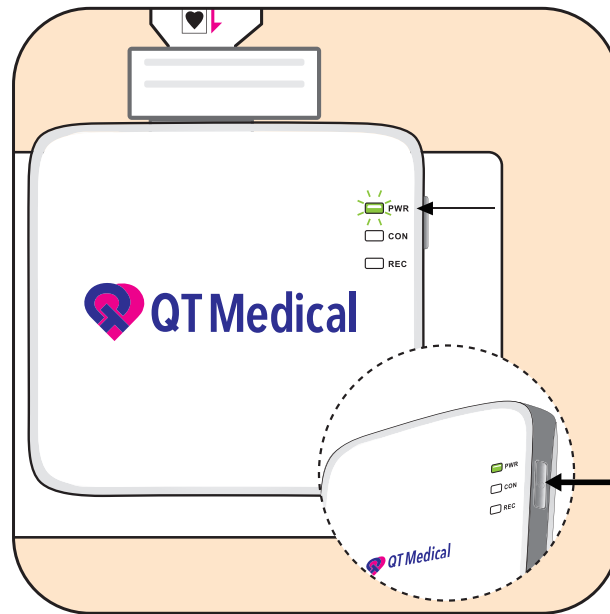


4.2 Connecting the QT ECG Recorder

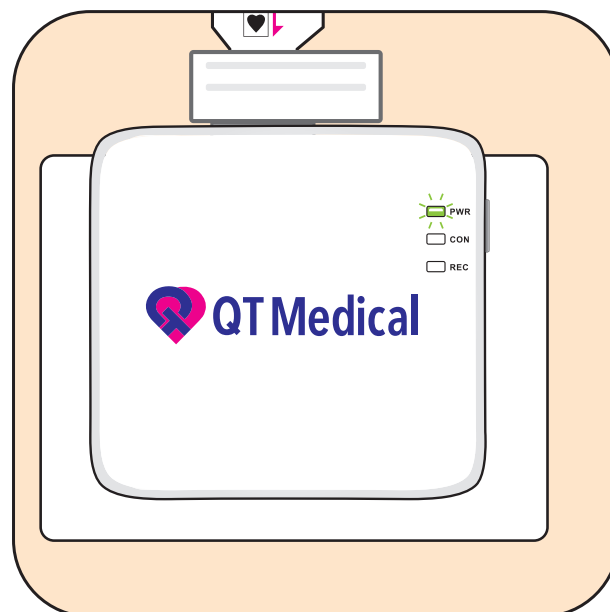
Connect the QT ECG Recorder to the Strip or Patient Cable by inserting the connector on the Electrode Strip or Patient Cable into the Recorder Receptacle on the QT ECG Recorder. Insert the connector firmly until it is fully attached (see **Fig. 3.1.2a**).



- Do not place the QT ECG Recorder directly on the body; place a piece of gauze under the Recorder to separate the device from skin.
- Press and hold the Power button for 5 seconds to turn on the QT ECG Recorder.

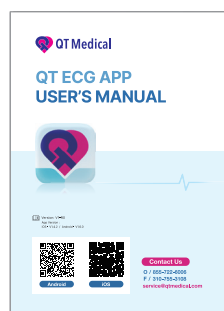


- The Recorder is recording when Power (PWR) is Green, Connection (CON) is Blue, and Recording (REC) is blinking Amber.
- In a low humidity environment, electrodes may dry up, preventing adhesion to the skin. If the electrodes have been stored in a dry environment, and a "lead-off" alert is shown in the app during use, please use a moist cloth to dampen the hydrogel circle(s) of unattached electrode(s) indicated in the app alert, then reattach the electrode.



4.3 Recording the ECG

Refer to "QT ECG APP User's Manual".



Preventive Maintenance

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

5.1 QT ECG Recorder

To clean the QT ECG Recorder, dampen a soft cloth with lukewarm soapy water or natural cleanser and gently wipe down the recorder. The QT ECG Recorder should not be immersed in water under any circumstances. Take care not to scratch the device with abrasive cleansers or excessive wiping on the label. The QT ECG Recorder should be gently cleaned before every use. To disinfect the QT ECG Recorder, dampen a soft cloth with isopropyl alcohol and gently wipe the Recorder. Regularly inspect the QT ECG Recorder for damage such as warping or cracking. If there is any damage, do not use the QT ECG Recorder and contact QT Medical customer service.

5.2 QT ECG Electrode Strip

The Electrode Strip is clean and ready to use straight out of the package. There is no need to clean it. Electrode Strips are for one-time use only and should be discarded after use.

5.3 Wall Charger

The cleaning procedure for the wall charger is the same as that for the QT ECG Recorder. Disconnect the wall charger from the power outlet before any cleaning procedure.

Troubleshooting

6.1 QT ECG Recorder

Problem : PWR LED indicator does not light up during charging

Solution : PWR LED indicator will turn off after the battery is fully charged. If the PWR LED does not light up while charging, this may indicate that the battery is fully charged.

Problem : Unable to turn on the QT ECG Recorder

Solution : Press and hold the power button for 30 seconds. If the Power LED indicator still does not light up, try again after charging the device for 1 hour.

If above mentioned solution does not work, please contact QT Medical 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 QT Medical customer service.

Problem : Unable to connect the QT ECG Recorder to the mobile device (iPad, Android tablet, etc) via Bluetooth

Solution : If Bluetooth is not connected when the QT ECG Recorder is on, the blue CON LED indicator will blink. When Bluetooth is properly connected, the CON LED indicator will be a solid light. If the CON LED indicator is off when the Recorder is turned on, please contact QT Medical customer service.



6.2 QT ECG Electrode Strip

Problem : Package or contents arrive opened or damaged out of the box

Solution : Do not use the Electrode Strip. Contact QT Medical customer service.

Problem : One or more of the 10 electrodes (7 chest leads and 3 limb leads) are damaged or missing out of the box

Solution : Do not use the Electrode Strip. Contact QT Medical customer service.

Problem : Size of Electrode Strip does not match with that labeled on its enclosing package

Solution : Do not use the Electrode Strip. Contact QT Medical customer service.



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

Appendix C. 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:

QT ECG system 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.		
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:

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.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment –guidance
Electrostatic discharge (ESD)	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
IEC 61000-4-2			
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 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) 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 UT is the a.c. mains voltage prior to application of the test level.

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.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			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>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>Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a, should be less than the compliance level in each frequency range ^b.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1. At 80 MHz and 800 MHz, 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.

^a 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.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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 D. 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 FCC Part 15C

Appendix E. WIRELESS TECHNOLOGY

This appendix covers the following topics:

- A summary of wireless functions and specific wireless technology incorporated into the device including equipment or system specifications.
- A summary of the operating characteristics of the wireless technology, effective RF radiated power output and operating range, modulation, specification of each RF frequency or frequency band of transmission, and bandwidth of receiving section.
- A brief description of the wireless QoS needed for safe and effective operation.
- Functions and performance of the wireless data transmissions including data rate, and data integrity.
- A brief description of the recommended wireless security measures such as the WPA2 wireless encryption for IEEE 802.11 technology.

Bluetooth LE Specification	
Bluetooth Standards	Bluetooth 4.0 Core Specification
Compliance	FCC Part 15 Class B (47 CFR 15.247)
Operation frequency range	2.402 GHz - 2.480 GHz
Modulation	GFSK
Channel width	2 MHz
Output power	+0 dBm
Sensitivity	-94 dBm
Antenna	Chip Antenna
Data Transmission Range	< 10 meters
Data Rate	8 KB / sec
Spurious emissions	< 30 dBuV/m (@ 3m; 30 MHz - 1 GHz) < 40 dBuV/m (@ 3m; 1 GHz ~ 25 GHz)

Bluetooth Specification	
Bluetooth Standards	Dual Mode: Bluetooth and Bluetooth Low Energy(BLE), use Bluetooth only
Compliance	FCC Part 15 Class C (47 CFR 15.212)
Operation frequency range	2.402 GHz - 2.480 GHz
Modulation	8 DPSK, PI/4 DQPSK, GFSK
Channel width	1 MHz
Output power	BR/EDR Class 2 < 4 dBm, BLE < 10 dBm
Sensitivity	0.1% BER at -88 dBm
Antenna	Chip Antenna
Data Transmission Range	10 meters
Data Rate	3 Mbps (typical 1.6 Mbps)
Encryption	Yes
QoS	Best effort
Data integrity check	Done by Bluetooth link layer. Moreover, the QT ECG Recorder uses sequence numbers to make sure no data are lost during bulk ECG data transfer.



Characteristic	Bluetooth BR/EDR		Bluetooth Low Energy	
	Prior to 4.1	4.1 onwards	Prior to 4.2	4.2 onwards
RF Physical Channels	79 channels with 1 MHz channel spacing		40 channels with 2 MHz channel spacing	
Discovery / Connect	Inquiry / Paging		Advertising	
Number of Piconet Slaves	7 (active) / 255 (total)		Unlimited	
Device Address Privacy	None		Private device addressing available	
Max Data Rate	1-3 Mbps		1 Mbps via GFSK modulation	
Pairing Algorithm	Prior to 2.1: E21/E22/SAFER+ 2.1-4.0: P-192 Elliptic Curve ⁹ , HMAC-SHA-256	P-256 Elliptic Curve, HMAC-SHA-256	AES-128	P-256 Elliptic Curve, AES-CMAC
Device Authentication Algorithm	E1 / SAFER	HMAC-SHA-256	AES-CCM ¹⁰	
Encryption Algorithm	E0 / SAFER+	AES-CCM	AES-CCM	
Typical Range	30m		50m	
Max Output Power	100 mW (20dBm)		10 mW (10dBm) ¹¹	

