# CARDIART Wireless 12-Lead Electrocardiograph Monitor

# User’s Manual

# (Draft)

TOP SECRET

Model no.: MCE12L001

20190320 Ver. 2.0

Be sure to read the original manual and follow the instructions before use.

# Content

Warning and Precaution ..... 2

Chapter 1 Outline ..... 4

Chapter 2 Composition ..... 5

Chapter 3 ECG electrode Hookup ..... 9

Chapter 4 Connecting setting ..... 12

Chapter 5 CaRDIaRT ECG APP Introduction ..... 13

Chapter 6 Environment and Maintenance ..... 17

Chapter 7 Product Specification ..... 20

Chapter 8 After-sales service and Warranty period ..... 22

Chapter 9 Symbol Description and Manufacturer Information ..... 23

Chapter 10 FCC Compliance Statement ..... 24

TOP SECRET

## Warning and Precaution

### Warning

1) It is not intended as a sole means of diagnosis.
2) Please remove the battery when not using for a long time, to avoid corrosion of the spring if the battery holder.
3) Do not use the product near any flammable gas (e.g., high concentrations oxygen, hydrogen or anesthetics), which can cause an explosion or fire.
4) To avoid electric shock, do not disassemble or modify the product of one' s own.
5) This product is a portable device, but the safety of the instrument is not able to be ensured in the transport process with a strong impact or fall.
6) Avoid the product from water, or the patient and the operator may involve in electric shock and other dangers.
7) To avoid infection, please follow the instruction below;
   ※ Regularly clean the parts that contact with patients.
   ※ Patients of open type infectious disease do not use the product for testing.
8) When placing the wires or cables, be aware to avoid the possibility of tripping people or winding the patient's neck.
9) To ensure using the equipment safely, follow the maintenance procedures contained in the original manual.
10) Improper battery disposal may result in explosion or contamination. Please recycle the battery in accordance with local regulations, do not throw the battery as common trash.
11) Do not use the product with Pacemaker.
12) Materials meet the biocompatibility requirements that comes in contact with the patient' s body.
13) The product is classified as CF type equipment; the product can be directly applied to the heart by using this product to be in contact with the patient to perform functions. Don not touch conductive parts and conductive parts of the system on the outside, including grounding wires.
14) Please use a defibrillation-proof wire to prevent burns which caused by the defibrillator discharge.

TOP SECRET

15) Limb lead and chest lead that do not recommend for use in newborns and child

**Precaution**

1) The conductor parts of the electrode of ECG signal record box and its connector (including the neutral electrode) should not contact with other conductor parts, including the earth.
2) The factory will yearly check whether the ECG signal record box and the cable are damaged.
3) Do not use the product with high frequency surgical equipment.
4) The product is classified as CF type equipment; it is an anti-defibrillation device
5) Do not use accessories that are not included in the product system. The use of non-original accessories may result in inaccurate patient data, damage to equipment, and invalid warranty.
6) Do not use accessories that are not included in the product system. The use of non-original accessories may result in inaccurate patient data, damage to equipment, and invalid warranty.
7) The electrodes is suggested to be placed by professional medical personnel.
8) To avoid the possible damage, do not contact the product with sharp or hard objects.
9) Do not expose the patient cable to strong ultraviolet radiation.
10) Do not stretch the patient cable for this may cause mechanical or electrical malfunction. Before storing the patient cable should be wrapped as a loose circle.
11) Avoid placing the patient cable where it may be caught, stretched, or stamped. Otherwise the results may be inaccurate and may require repair.
12) The surface of disposal electrodes should be checked if lint or dust is on the surface before use to avoid collecting poor patient data.
13) The product is protected against water and dust( IP33 classification, it' s protected against solid objects of 2.5mm diameter and greater and spraying water 60 degrees from vertical)

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# Chapter 1 Outline

## 1.1 Product Introduction

CaRDIaRT Wireless 12-Lead Electrocardiograph Monitor (Model no. MCE12L001) is a compact, lightweight, easy carry, and agile product. The data is transmitted through bluetooth, avoided the inconvenience of the traditional data transmission; also making transmission space and distance more flexible, convenient and smooth.The software can be installed on iOS devices, users can view data on iPad / iPhone / iTouch; this kind of working mode is more flexible than the traditional system composed of personal, laptop, the record box (with data lines), and the printer (with data transmission cable).

## 1.2 Intended Use

It is mainly used for 12 leads on the front and horizontal planes. It records the electrical and physiological activities of the heart in twelve different directions. The depolarization waveform is observed from twelve different angles and transmitted to the software application via bluetooth. An electrocardiogram was generated, and changes in myocardial damage were observed with an electrocardiogram. This product cannot be used as the sole means for disease diagnosis.

TOP SECRET

## 1.3 Principle

The product collect the ECG signal through limb and chest limbs, initially amplifies the signal through preamplifier, and filter out the polarization voltage, baseline shift, and high frequency noise. Amplify the signal with the use of secondary amplification circuit, and convert the analog signal to digital signal with the A / D converter. Then transmit the signal to iOS mobile system through Bluetooth, at the same time, display on the screen for clinicians to diagnose and study.

## 1.4 **Features**

- Compact, lightweight and easy carry
- Bluetooth low energy
- Personalization report for storage and delivery
- Cloud ECG Transmission System
- Real-time data transmission, shortening ECG interpretation time

TOP SECRET

# Chapter 2 Composition

The product is composed of ECG acquisition recorder, ECG patient cable, limb leads/ chest leads and instruction manual.

## 2.1 Appearance

TOP SECRET

- Power indicator :

  Green light indicates power on;

  (1) Flashing green every 5 seconds indicates the battery power is 10%-19%, it is recommended to replace the battery;

  (2) Flashing green every 1 second, please replace the battery immediately (the battery power is 0%-9%)

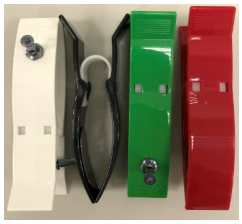
- Bluetooth repairing:

  When Bluetooth pairing or data transmission has been completed, green light on and flashing blue light.

ECG Acquisition Recorder (Back)

2 x AA 電池

Chest leads



Limb leads

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**Caution: If there' s any damage between the connection of the patient cable connector and ECG acquisition recorder, please replace with the specified lead wire.**

## 2.2 Content

| Item / No | Name | Amount |
|---|---|---|
| 1 | ECG acquisition recorder and | 1 |
| 2 | Ten-wire patient cable | 1 |
| 3 | User’s manual | 1 |
| 4 | Limb leads | 4 |
| 5 | Chest limbs | 6 |
| 6 | AA 電池 | 2 |
| 7 | Warranty card | 1 |
| 8 | Color box | 1 |
| **Optional** | | |
| 1) | ECG electrode with snap end | 10pcs/package |
| 2) | ECG electrode with clip end | 10pcs/package |
| 3) | Waterproof sleeve | 1 pcs |
| 4) | Wire organizer | 2 pcs |

TOP SECRET

## 2.3 Recommended suitable ECG electrode

| |
|---|
| 3M RED DOT MONITORING ELECTRODE<br>TFDA License number: MOHW-MD-No.006097 moh |
| "COVIDIEN" KENDALL ECG ELECTRODES<br>TFDA License number: MOHW-MD-No.012713 moh |

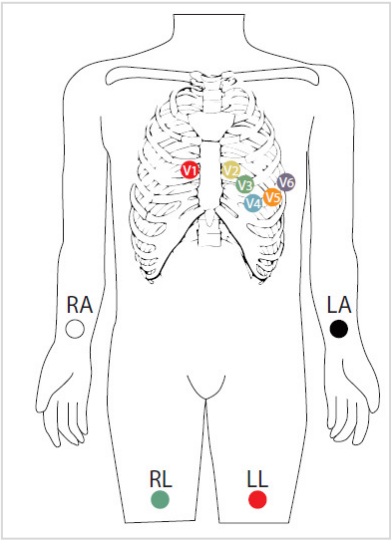
**The ECG electrode is a consumable and is purchased by the user**

⚠ **Caution**

1. **ECG electrode is a disposable of device and single-use. Please read its user’s manual carefully before using it.**
2. **Do not place disposable ECG electrode on any injured area of human skin.**
3. **If the ECG electrode is not used, it should be put in original package.**
4. **Disposable of ECG electrode according to local disposable and recycling laws.**

# Chapter 3 ECG electrode Hookup

## 1. WILSON standard lead



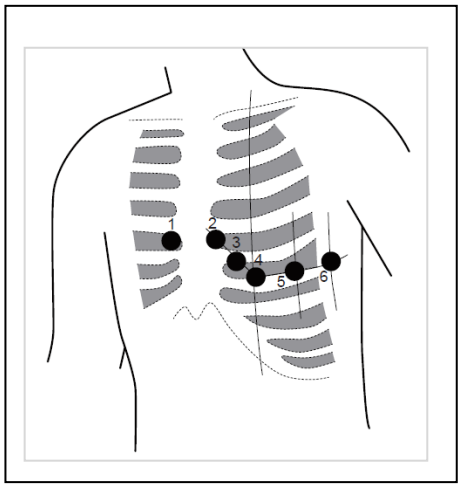

Hookup

TOP SECRET

| Electrode | AHA | Hookup |
|---|---|---|
| A | V1 red | The fourth intercostal space to the right of the sternum |
| B | V2 yellow | The fourth intercostal space to the left of the sternum |
| C | V3 green | Midway between electrode B and D |
| D | V4 blue | The fifth intercostal space in the mid-clavicular line |
| E | V5 orange | Horizontally even with D in the anterior axillary line |
| F | V6 purple | Horizontally even with D in the midaxillary line |
| G | LA black | Left arm (resting ECG) or left shoulder (exercise test) |
| J | RA white | Right arm (resting ECG) or right shoulder (exercise test) |
| H | LL red | Left foot (resting ECG) or left leg (exercise test) |
| I | RL green | Right foot (resting ECG) or right leg (exercise test) |

## 3.1 Electrode connection and position

★ Precordial lead: Coat the patient' s chest with conductive paste or wipe with alcohol cotton balls in correct position, then attach the lead and suck ball to the patient in the order as below:




Precordial lead position：

V1：The fourth intercostal space to the right of the sternum

V2：The fourth intercostal space to the left of the sternum

V3：Mid-point between V2 and V4

V4：The fifth intercostal space in the left clavicular midline

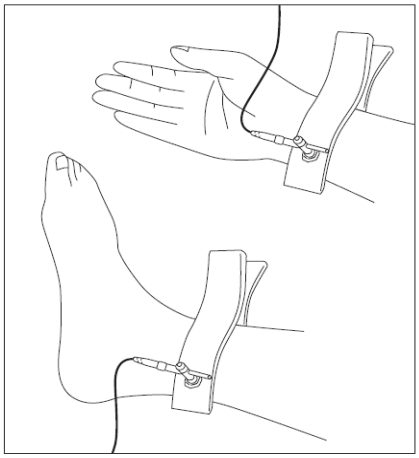
V5：The fifth intercostal space in the axillary line

V6：The fifth intercostal space in the axillary

TOP SECRET

★ Limb leads:

1) Clean the skin of the patient
2) Apply conductive paste or wipe with alcohol cotton balls
3) Attach the electrode clip, preferably on the inside of limbs
4) To prevent oxidation and poor connection, please clean the clips after use



Limb leads position：

RA：Right arm

LA：Left arm

RL：Right leg

LL：Left keg

## ⚠ Caution

1) It is recommended that electrodes be placed by medical trained personnel
2) To obtain correct ECG record, please previously clean the skin.
3) After using the device, proper clean limb leads of clip and chest leads of metal suction at the suction ball to prevent oxidation from poor contact.
4) After using the device, prevent ECG electrode with banana and snap end from being exposed in sunlight.
5) Before use, properly tighten the banana end of patient cable with limb leads or chest leads to avoid collecting poor patient data
6) If patient is with too much chest pair, remove it to prevent the disposal electrode from not being preferably attached.

★ Mounting ECG electrode with snap and clip into ECG lead wire

1. Align all lead wires of the patient cable to avoid twisting, and connect the ECG electrode with snap to the patient cable.

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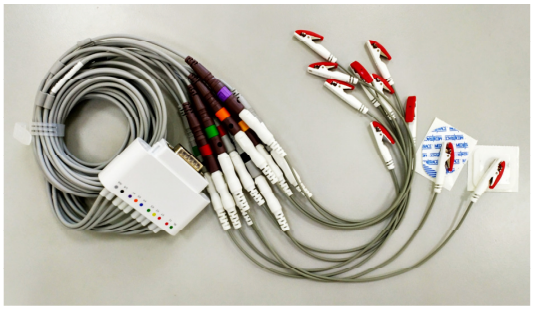
2. Attach the electrodes and lead wires

2.1 Attach the clips to the disposable electrode



2.2 Attach the snap to the disposable electrode

## Chapter 4 Connecting setting

★ Please use the latest version of **CaRDIaRT ECG App.** This APP. supports Android 4.4 and iOS 8.0 or later. Please confirm your mobile device operation system before use.

1. Install **CaRDIaRT ECG App**

※ iOS Operating System

Use the 〝App Store〞 to search and download **CaRDIaRT ECG App.**

TOP SECRET

※ Android Operating System

Use the 〝Play Store〞 to search and download **CaRDIaRT ECG App.**

2 . ECG Acquisition Recorder

※ Power on: Green light indicates power on; flashing light indicates the batteries are getting low and should be replaced.

※ Power off: Shut down automatically after 5 minutes when connection is without any operation between the acquisition recorder and the iOS mobile device

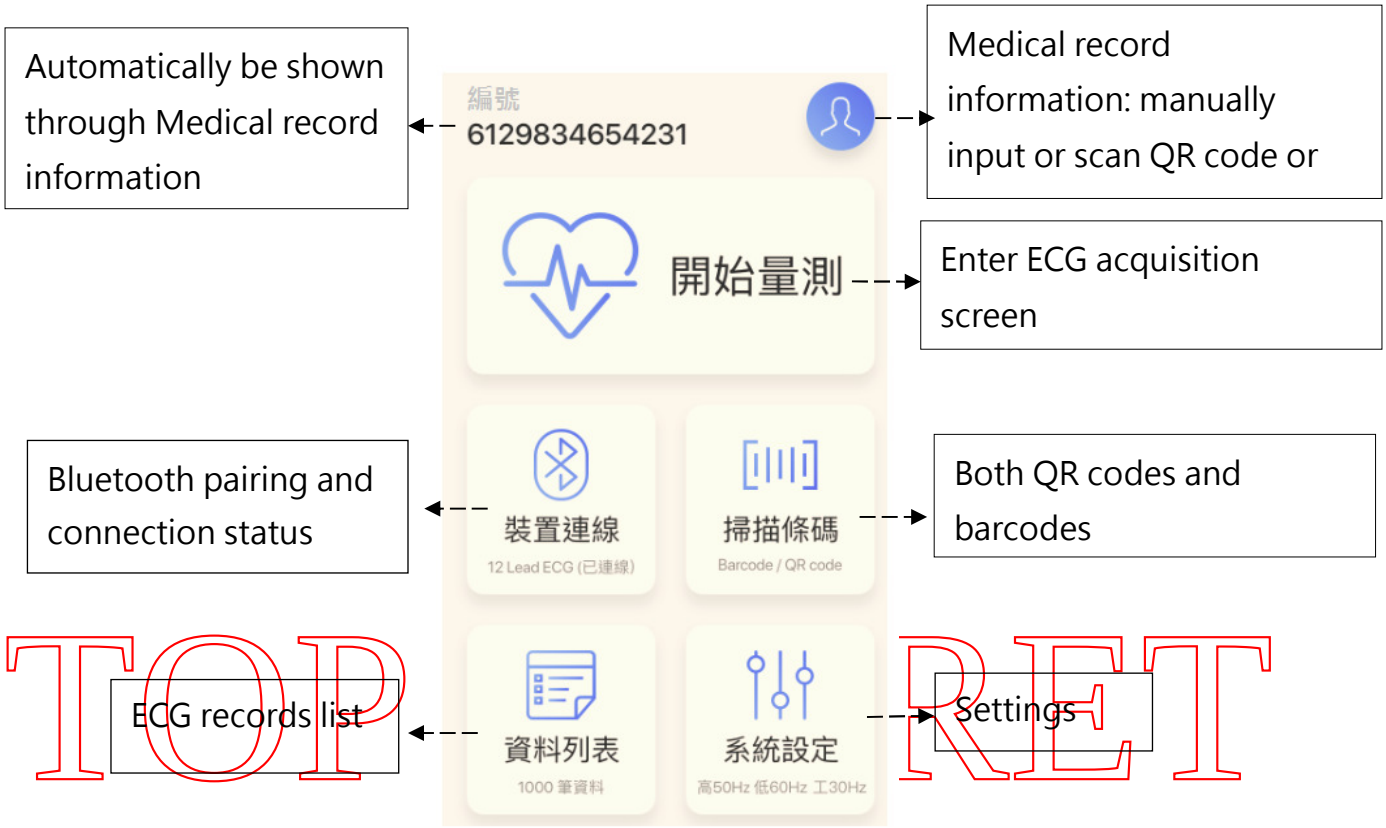
3. To connect vis bluetooth, first turn on your mobile device Bluetooth.

※ iOS Operating System: Click 〝Settings 〞 to Bluetooth switch on

※ Android Operating System: Click 〝Settings 〞 to Bluetooth switch on

# Chapter 5 CaRDIaRT ECG APP Introduction

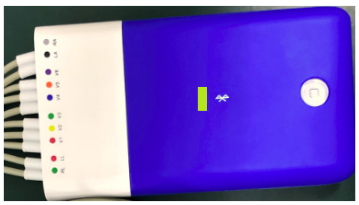
## 1. Main screen



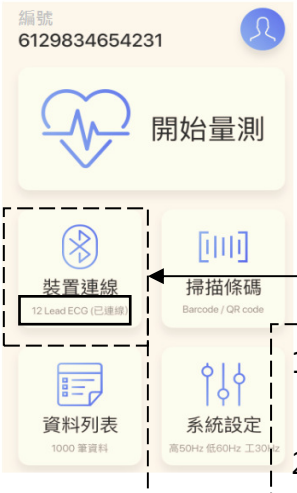

2. Operation Step:

STEP 1 Settings

STEP2 Make sure your Bluetooth is turned on in your mobile device. If the pairing was successful, the pairing number will show up on the main screen.



Turn on power button and continuous green light.



1. Bluetooth pairing number will be shown on the meter label.
2. The Bluetooth pairing number must be the same as the label on the back of the

Bluetooth connection status

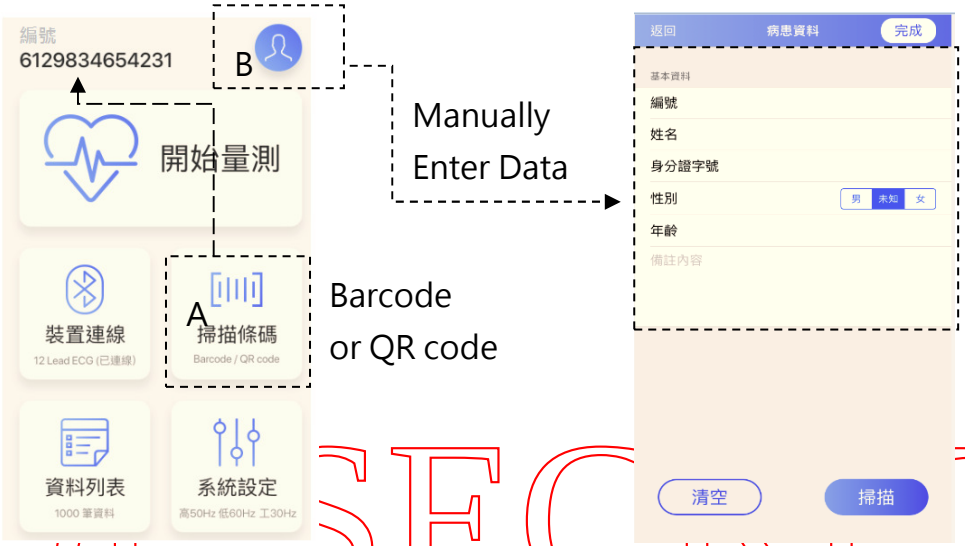
Note: If it is not pairing: Try completely closing and reopening the ECG acquisition recorder and APP

STEP 3 Establish the subject information

(1) Click 〝A〞 by scanning the barcode, then click B enter Medical Record Information to fill in the information

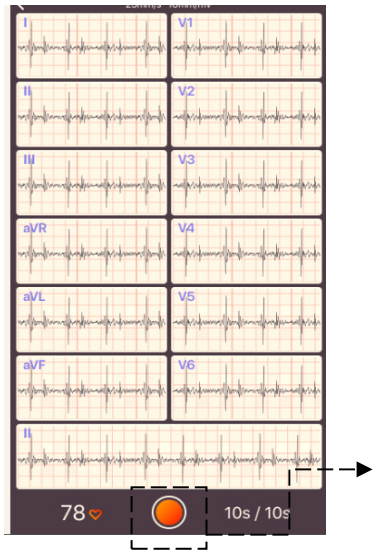
(2) Click

measure ECG signal directly(Automatically create a series of numbers), then click B enter Medical Record Information to fill in the information.




TOP SECRET

STEP4 ECG signal acquisition



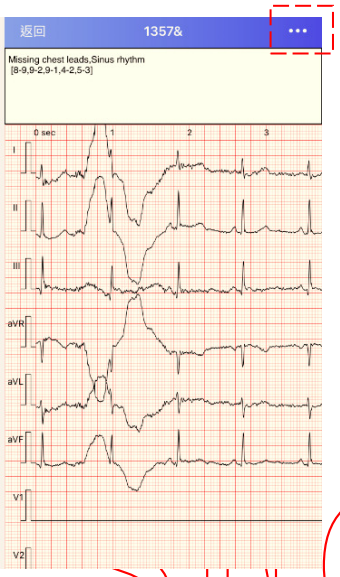

Click the Red button to start ECG signal acquisition.
Default time is 10 seconds

STEP 5　ECG Recorder upload

(1) Click ••• select upload format (PDF, JPG, XML).

(2) Select the email, line, wechat or other message software to send ECG record.

(3) If the ECG record is an invalid record, you can delete the record directly via click 〝delete〞.

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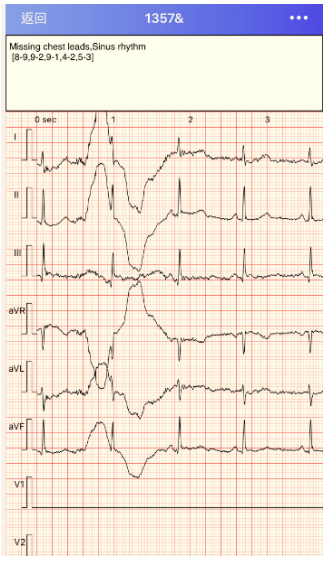
Note: please make sure your wireless or mobile internet is working before using App.

STEP 6 Review or ECG record

Click the record that you want to view



# Chapter 6 Environment and Maintenance

## 6.1 Environment

Avoid sunlight and keep dry; avoid wet and dust to remain the cooling channel smooth; keep away from strong magnetic field.

※ Operating temperature：5~40℃

(At -20~ 50°C; humidity 15-95%, it can run normally for more than 20 minutes)

※ Relative Humidity: 25%-95%（Non-condensation）

※ Atmospheric pressure: 700hPa ~ 1060hPa

## 6.2 Transportation and Storage

※ Environmental temperature ：-20℃~55℃

※ (If stored in -20 or 55 ° C environment, it is recommended to sit at room temperature for more than 30 minutes, let the product return to the operable temperature, in Start using this product)

※ Relative Humidity：≤93%

TOP SECRET

## 6.3 Cleansing

**Clean after each use to prevent the infection**

**ECG Acquisition recorder**

※ Wipe the surface with soft, damp cloth, soaked with neutral detergent after each use.

※ Do not use strong detergent to avoid damaging the plastic surface.

**Patient cable wires**

※ Disconnect the patient cable before cleaning or disinfecting.

※ Wipe the surface with soft, damp cloth, soaked with neutral detergent after each use.

※ Do not immerse patient cable wires in liquid.

**Limb leads and Chest leads**

※ Please contact the original manufacturer, if any damage is noted.

※ Clean the electrode area on the Limb leads and Chest leads with 75% alcohol after each use.

**6.4** Maintenance

Make sure whether the ECG Patient cable are damaged before using; if damaged, stop using and contact the manufacturers in time.

**Warning :**

※ Please remove the battery whenever the ECG acquisition recorder will not be used for a long time to avoid corroding the spring in the battery seat.

※ Pay attention to battery orientation.

※ If the battery leaks and accidentally touches your eyes or skin, rinse immediately with clean water and seek medical attention immediately.

※ Mixing old and new batteries or mixing types will reduce performance and may even damage your device or cause battery leakage or rupture.

TOP SECRET

**6.5 Troubleshooting**

The following table describes different possible action to try to resolve this:

| **Common problem** | **Solution** |
|---|---|
| Unable to start the ECG acquisition recorder | Please insert a battery with sufficient power. |
| Unable to record | Check the connection between the mobile device and the ECG acquisition recorder |
| | Restart the ECG acquisition recorder |
| Collected wave form appears straight or noise | 1. Check the connection between lead wire and record box.<br>2. Make sure there' s no strong magnetic field (e.g. MRI) in the room. |
| Collected wave form appears abnormal or reverse | Please confirm that the leads are connected correctly |

If the information in this section cannot resolve your issue, please contact

manufacturer.

### 6.6 Environmental protection

Disposing of the battery and equipment shall be done within the area approved by local recycling regulations, to avoid environmental pollution.

TOP SECRET

## Chapter 7 Product Specification

| | |
|---|---|
| 1. Model | MCE12L001 |
| 2. Dimension | 9.5 x 7.5 x 24.0( cm; L x W x H) |
| 3. Weight (g) | 414 (includes battery) |
| 4. ECG acquisition recorder color | Water blue、Dark blue、green、orange |
| 5. Power supply | ※ Battery: 2* AA battery<br>※ Power indicator:<br>Green light indicates power on; Flashing light indicates the batteries are getting low and should be replaced.<br>Show down automatically after 5 minutes when connection is without operation between the acquisition recorder and the iOS/ Android mobile device. |
| 6. Input Dynamic range | ± 5mVpp |
| 7. Input impedance | ≥ 50MΩ |
| 8. CMRR | ≥90dB |
| 9. Overall System error | < ±5% |
| 10. Noise | <30 uV |
| 11. Channel crosstalk | < -34dB |
| 12. Frequency Response | 0.05Hz~150 Hz (-3dB) |
| 13. Filter | ■ AC Notch Filter：50/60Hz<br>■ Low-pass filter：30/40/45/70/75/100/150/200 Hz<br>■ High-pass filter：0.05/0.08/0.1/0.15/0.25/0.5 Hz<br>■ EMG Filter：ON/OFF |
| 14. Instrument Type | 12-lead electrocardiograph |
| 15. Input Channels | Simultaneous acquisition of all 12 leads |
| 16. Gain settings and accuracy | ■ Gain settings：5mm/mv、10mm/mv、20mm/mv<br>■ Gain accuracy：±5% |

TOP SECRET

| | |
|---|---|
| 17. Time base selection<br>Time base accuracy | ■ Time base selection：12.5mm/s、25mm/s、50mm/s<br>■ Time base accuracy：±5% |
| 18. Channel display | ■ 2X6 |
| 19. Device Classification | Class II, Type CF defibrillation-proof applied parts |
| 20. Data transmission | ■ Bluetooth Low Energy (BLE)<br>■ Support long distance transmission for 10m |
| 21. Sampling rate | 500sps/channel |

TOP SECRET

## Chapter 8 After-sales service and Warranty period

The main components of this product (ECG acquisition recorder, patient cable) have one year warranty period. If any defects are found in the material or manufacturing during the warranty period, Please return the device to IMEDIPLUS INC. for free repair, except for man-caused or accidential damage

Please feel free to contact IMEDIPLUS INC. Customer Service, If you have any question for more information.

Manufacturer: IMEDIPLUS INC.
Manufacturer Address: 2F, 12, Sheng Yi Rd. Sec. 2, Chupei City, Hsinchu County 30261, Taiwan (R.O.C)
Customer mail address：service@imediplus.com
TEL：03-658-7700
Fax：03-658-9535
Website: http://www.imediplus.com

TOP SECRET

# Chapter 9 Symbol Description and Manufacturer Information

| | | | |
|---|---|---|---|
| Manufacturer name & address | Manufacturing date (year/ month/ day) | LOT<br>Lot number | SN<br>Serial number |
| Expiration (limited to year/ month/ day) | Only for single use | Do not use if package is damaged | Indicates the need for the user to consult the instructions for use |
| Notice, please check the warning / precautions | Anti-Automated External Defibrillator CF type | Bluetooth | Avoid high temperature and sunlight |
| Upper / lower temperature limitation | Electromagnetic wave warning | IP33<br>Protected from tools and wires greater than 2.5 millimeters and protected from water spray less than 60 degrees from vertical. | Indicates the range of humidity to which the medical device can be safely exposed |
| Indicates the range of atmospheric pressure to which the medical device can be safely exposed | | | |

TOP SECRET

# Chapter 10 FCC Compliance Statement

15.21

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

15.105(b)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-Reorient or relocate the receiving antenna.

-Increase the separation between the equipment and receiver.

-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-Consult the dealer or an experienced radio/TV technician for help.

TOP SECRET

**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 of the device.

**FCC RF Radiation Exposure Statement:**

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

2) This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 cm between the radiator and your body.