# Cardiart Wireless 12-Lead Electrocardiograph Monitor

# Owner's manual

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

2017.09.30 Ver. 1.0

Contents

## Warning and Precaution

### Warnings for product using

1) The product is not intended to diagnose.
2) Please remove the battery when not using for a long time, to avoid corrosion of the spring if the battery holder.
3) The product can be used continuously for at least 19 hours under normal use.
4) Do not use the product near any flammable gas (e.g., high concentrations oxygen, hydrogen or anesthetics), which can cause an explosion or fire.
5) To avoid electric shock, do not disassemble or modify the product of one's own.
6) Please contact the manufacturer before connecting the product to other equipment.
7) 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.
8) Avoid the product from water, or the patient and the operator may involve in electric shock and other dangers.
9) To avoid infection, please follow the instruction bellow
   - Regularly clean the parts that contact with patients.
   - Patients of open type infectious disease do not use the product for testing.
10) When placing the wires or cables, be aware to avoid the possibility of tripping people or winding the patient's neck.
11) To ensure using the equipment safely, follow the maintenance procedures contained inthe original manual.
12) 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
13) Do not use the product with Pacemaker.

### 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, but not directly used for the patient's heart.
5) There will be potential risks when using the product along with installation of cardiac rhythm or other electrical stimulator at the same time. Pay full attention to changes of the ECG to ensure safety and to ensure that the leakage current is within the allowable range.
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) Please use the original standard patient cable, otherwise it will reduce the minimum safety of the product.

8) The electrodes is suggested to be placed by professional medical personnel.

9) To avoid the possible damage, do not contact the product with sharp or hard objects.

10) Do not expose the patient cable to strong ultraviolet radiation.

11) 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.

12) Avoid placing the patient cable where it may be caught, stretched, or stamped. Otherwise the results may be inaccurate and may require repair.

13) Please use the original accessories. The use of non-designated accessories may result in degradation of equipment performance or unsafety.

14) Portable and mobile radio frequency (RF) communication equipment will affect the performance of the product.

15) Other medical devices (including but not limited to defibrillators, ultrasound instruments, pacemakers and other stimulators) can be used along with the product, but such equipment may interfere the signal.

## Chapter 1 Outline

1. Product introduction

   Wireless ECG monitor of IMEDIPLUS (hereinafter referred as the product; model: 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).

2. Intended use

   The product is mainly for checking abnormalities of the adults' heart through recording ECG by medical staff in hospital or clinic. The product cannot be used as the only basis for diagnosis.

3. Principle

   The product collect the ECG signal through lead wire, 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.

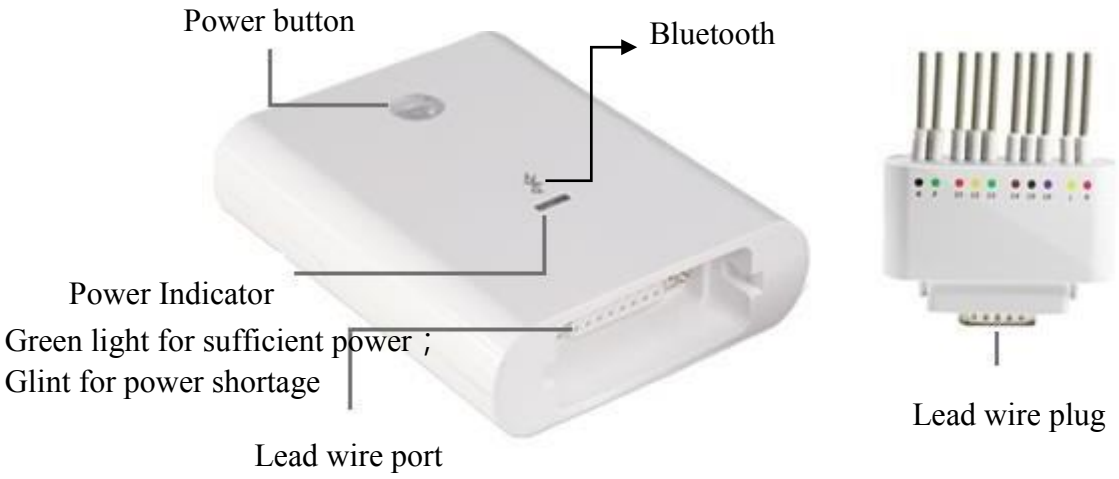
4. Features

   - Compact, lightweight, simple operation, and easy carry.
   - Breakthrough the limitation of traditional ECG (workstations).
   - Timely information transmission.
   - Low power-consuming Bluetooth.

## Chapter 2 Composition

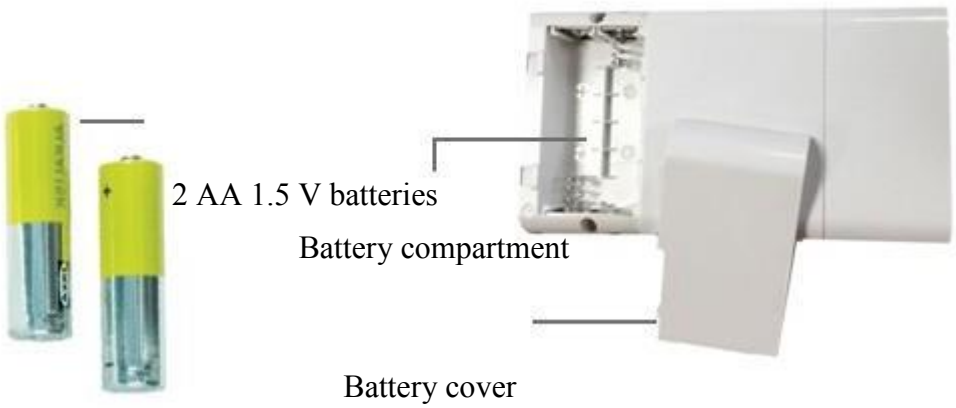
The product is composed of ECG record box, ECG lead wire, electrode patch/ suck ball and instruction manual.

### 2.1 Appearance




ECG Signal Record box

Front




Back

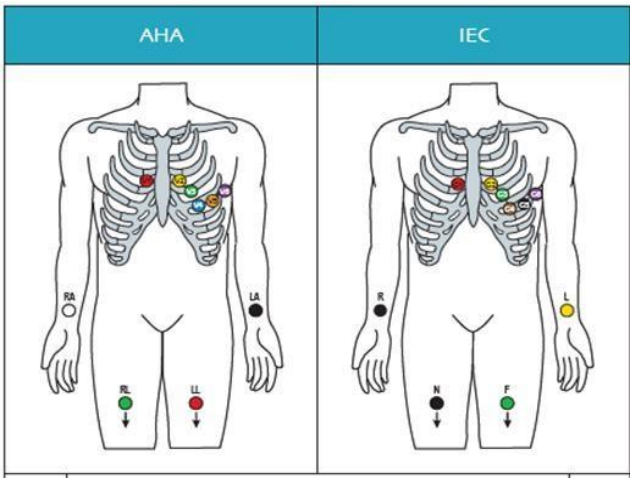
**Caution: If there's any damage between the connection of the lead wire and signal record box, please replace with the specified lead wire.**

## 2.2 Content

| No. Item | Name | Amount |
|---|---|---|
| **1** | ECG Signal record box | **1** |
| **2** | ECG lead cable | **1** |
| **3** | Instruction Manual | **1** |
| **4** | ECG Arm clamp | **4** |
| **5** | ECG Suck ball | **1 set** |

# Chapter 3 Electrode locations

## 3.1 WILSON standard lead

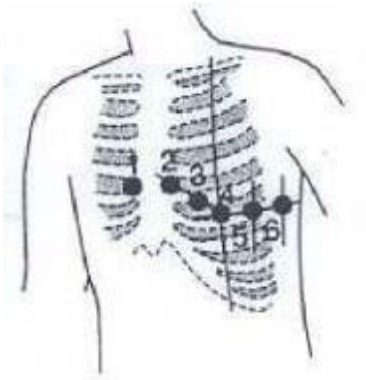



Electrode loctions

| Electrode | AHA | IEC | Hookup |
|---|---|---|---|
| A | V1 red | C1 red | The fourth intercostal space to the right of the sternum |
| B | V2 yellow | C2 yellow | The fourth intercostal space to the left of the sternum |
| C | V3 green | C3 green | Midway between electrode B and D |
| D | V4 blue | C4 brown | The fifth intercostal space in the mid-clavicular line |
| E | V5 orange | C5 black | Horizontally even with D in the anterior axillary line |
| F | V6 purple | C6 purple | Horizontally even with D in the midaxillary line |
| G | LA black | L yellow | Left arm (resting ECG) or left shoulder (exercise test) |
| J | RA white | R red | Right arm (resting ECG) or right shoulder (exercise test) |
| H | LL red | F green | Left foot (resting ECG) or left leg (exercise test) |
| I | RL green | N black | Right foot (resting ECG) or right leg (exercise test) |

### 3.2 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

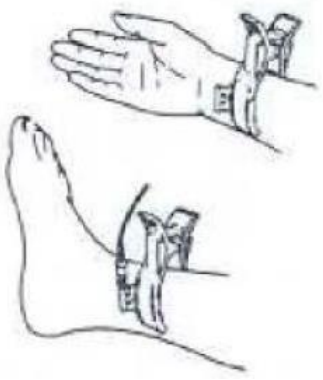
V4：The fifth intercostal space in the left clavicular midline

V5：The fifth intercostal space in the axillary line V6：The fifth intercostal space in the axillary midline

- Electrode clip:

Limb lead：

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 leas position：

RA：Right arm

LA：Left arm RL：Right leg LL：Left keg

Recommendation:

1) It is recommended that electrodes be placed by medical trained personnel.

2) To obtain correct ECG record, please previously clean the skin.

## Chapter 4 Installation

This chapter is divided into two parts. First, the components and the installation of hardware; second, the components and the installation of software.

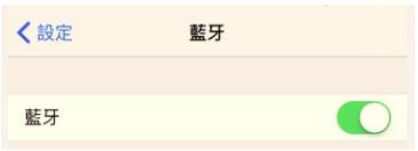
4.1 Hardware installation

The product is mobile device combines ECG record box (see 2.1 appearance) with iOS system, please follow the instructions before use.

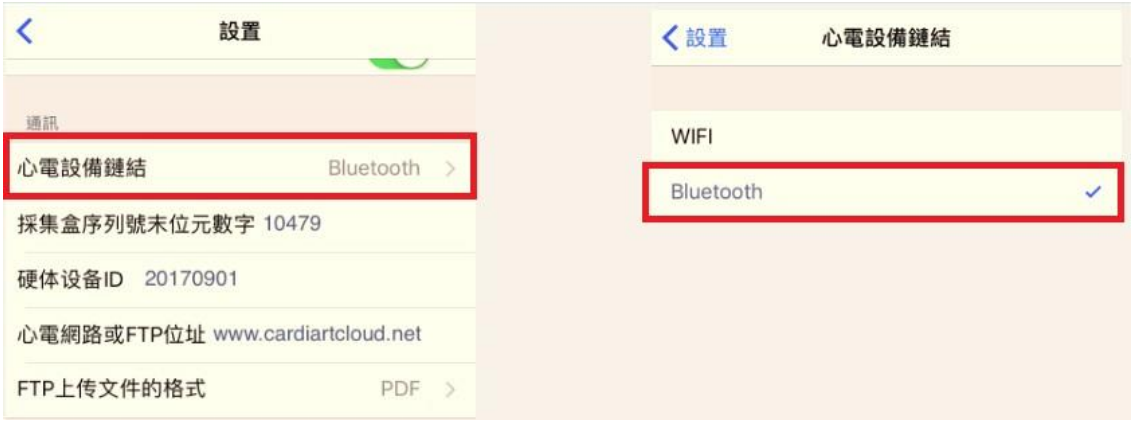
4.2 Download vhECG from Apple App Sore

Step 1: Turn on the ECG record box; press the power  , the indicator would light (green light for sufficient power while glint for power shortage).

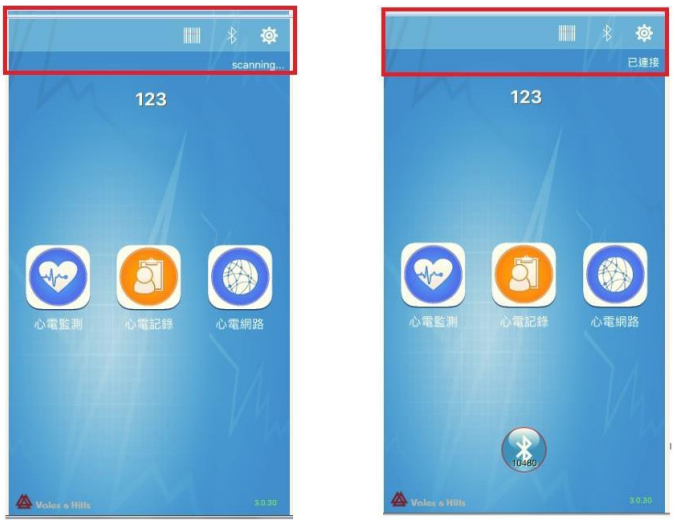
Step 2: Turn on the mobile device; click 〝Settings〞, select and turn on 〝Bluetooth〞.


Step 3: Open the Cardiart  , enter the home page, enter the settings  , then click "ECG device link" and select Bluetooth. As below:




Step 4: Back to the home page and click  to scan the device. When successfully connected, you will press  to start working.




Device connection diagram

**Notice:**

The last five digits of the factory number of the ECG record box will be displayed at the bottom of the mobile device and you will need to select the same device number to connect.

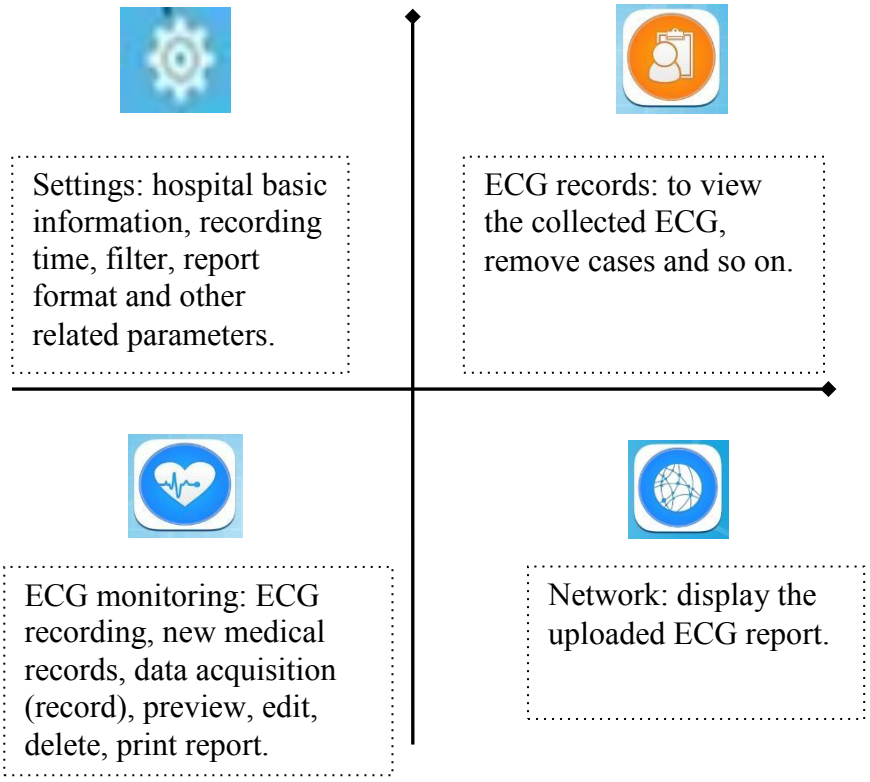
## Chapter 5 Software Operation

ECG software (Cardiart ECG) is an easy-to-use application that offers professional electrocardiographic tools and an excellent user experience. Most of the operation is the same as iOS system. If you are familiar with the Apple app and have the basic knowledge of ECG, there won't be any problem of operation. This chapter portrays the basic operation of the software, please read carefully.

When the connection between mobile device and the record box is completed, click the Cardiart icon  to run the software and enter the home page (as below):


Home page

- Software is mainly composed of settings, ECG monitoring, records, and network




## 5.1 Settings

You can customize your vhECG with your own prefernece. Click the icon  to enter the settings which consists of four parts:

### 1）General

- Hospital Name – Input your hospital or organization name.
- Physician Name - Used for diagnosis signatures.

### 2）ECG Signal capture

- Use demo data - ON / OFF: Data DEMO in monitoring
- Fallback record mode - ON / OFF, Recording mode.
- High-pass Filter Frequency- Cutoff frequency of high-pass filter: 0.05-0.5Hz, default: 70Hz.
- Low-pass Filter Frequency - Cutoff frequency of low-pass filter: 30-250Hz, default: 70Hz.
- Notch Filter Frequency: Eliminate power-line interference.

- Anti-Baseline Drift - ON / OFF：Keep the baseline stable.
- ENG filter - ON / OFF：Remove the EMG from the ECG signal

3）Communication

- ECG Device Connectivity – Bluetooth

4）Report

Custom the printing form:

- Title – title on the printed report
- Report format – PDF or JPG
- Lead layout - 12×1\2×6\3*4+1
- Paper orientation – A4 or B5, vertical or horizontal

***Notice:***

- Anti-Baseline Drift: This function can effectively remove the baseline drift due to respiration or body movement without affecting the ECG frequency response, such as ST segment.
- Muscle noise can be removed by setting LPF with low cutoff frequency but it will severely affect ECG high frequency component such as QRS complex. vhECG EMG filter can effectively remove muscle noise with little affection to ECG signal.

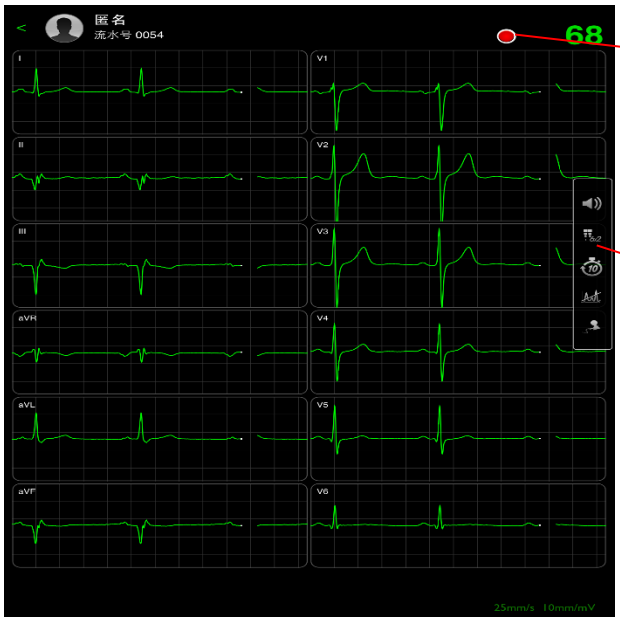
## 5.2 Monitoring and Recording

This section shows the way to record ECGs.

Step 1: click “ECG monitoring”  to enter the recording page.

**Notice:** Make sure the ECG record box has successfully connected to mobile device, if not, please refer to chapter 4 for reconnection.

If successfully connected, enter the "recording" stage (as below)

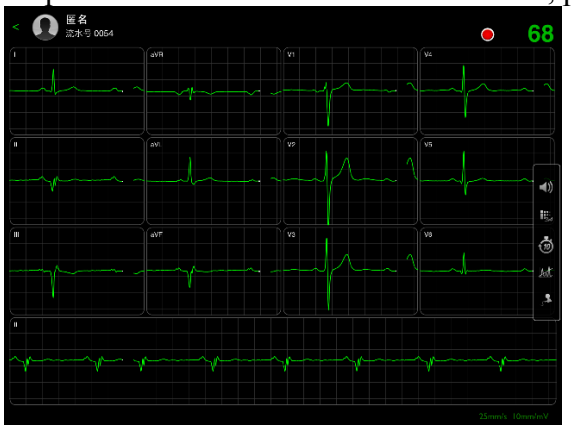



Start recording (roll down with two fingers)

Lead display switching：12*1、6*2、3*4。

"Pre -recording stage" interface

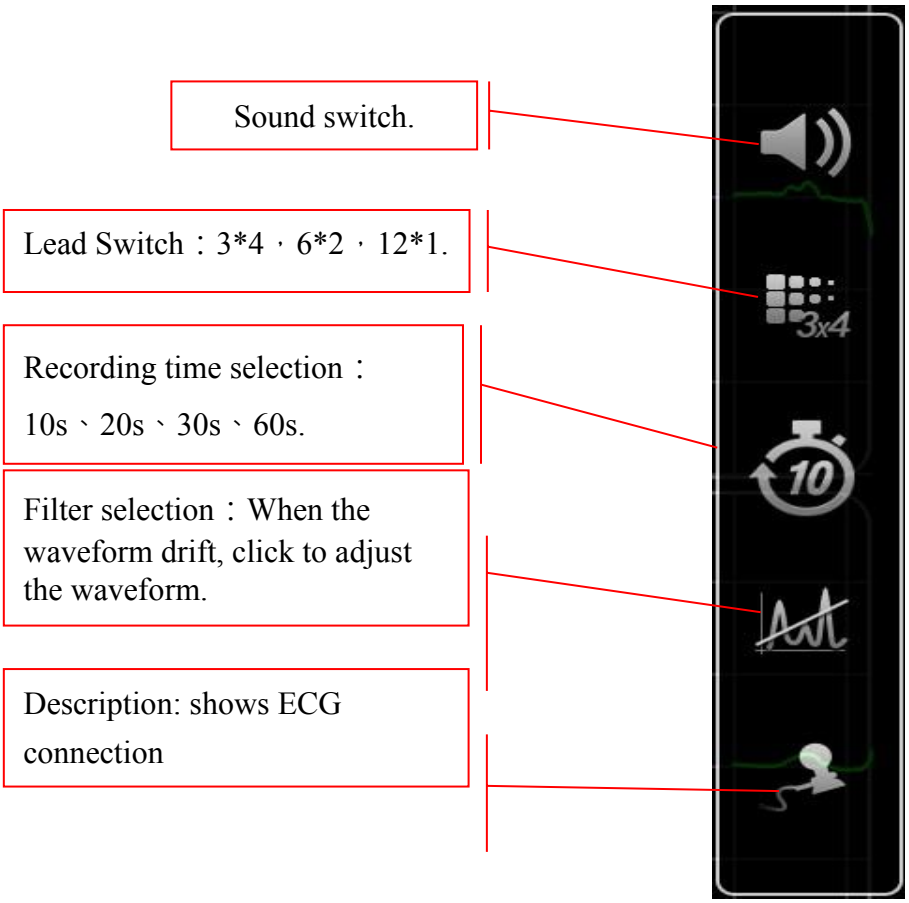
Step 2: When the ECG waveform is stable, press "Start" button  to record.



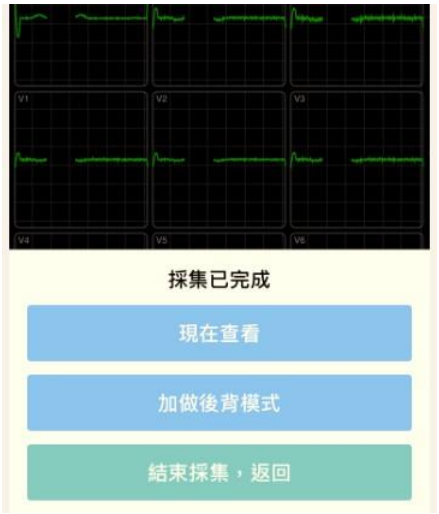

"Formal recording" interface

Notice: Double-click will refresh the interface to restart recording.

**Icon description：**



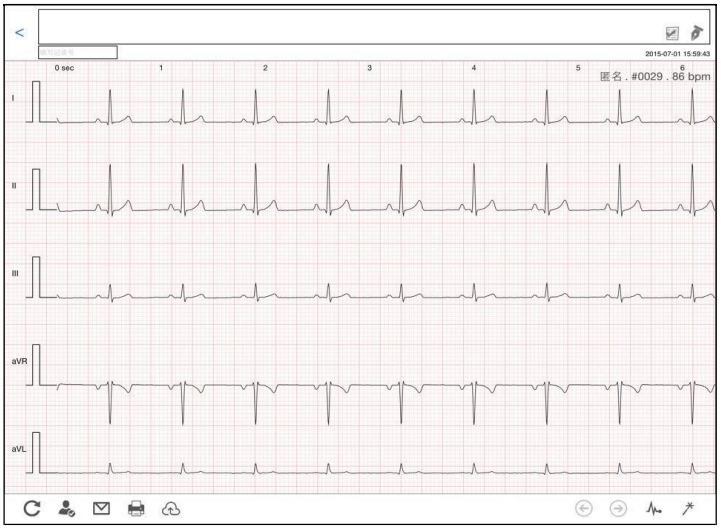

Step 3: After recording, the user can choose the operation according to the actual needs: view now, uploading, add the back mode, end recording.




"End recording" interface

### （1） View Now

ECG report browsing interface, drag to view the complete ECG report.




ECG report browsing

### （2）Background mode

Add background continues to ECG

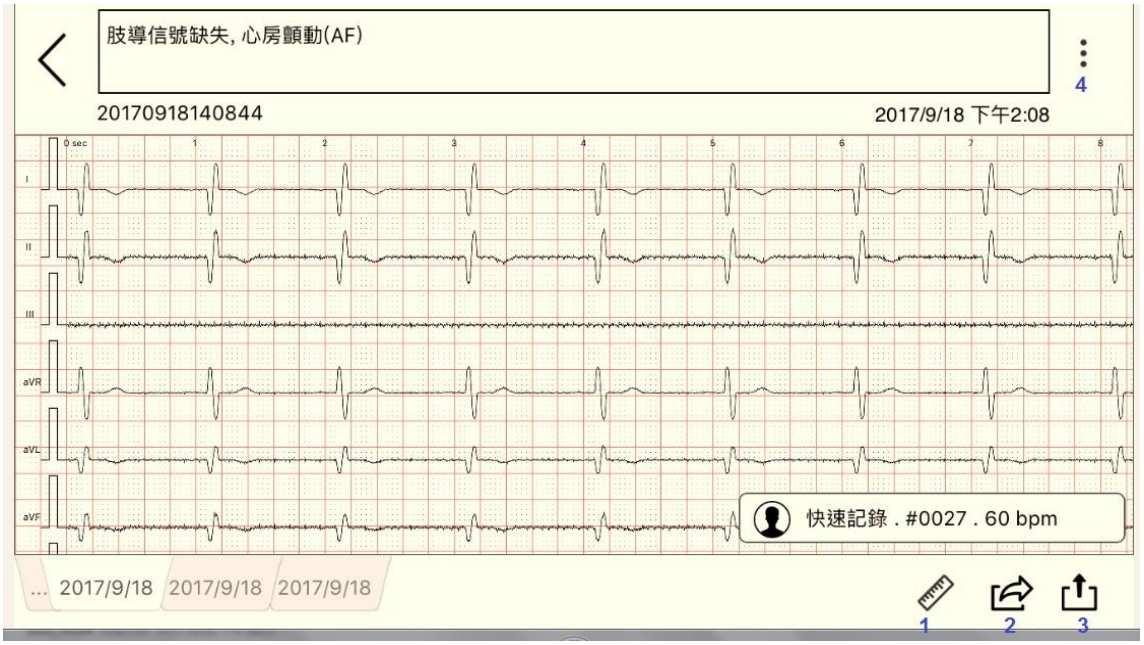
### （3）End recording

Return to home page.

## 5.3 ECG records

### 5.3.1 View the record

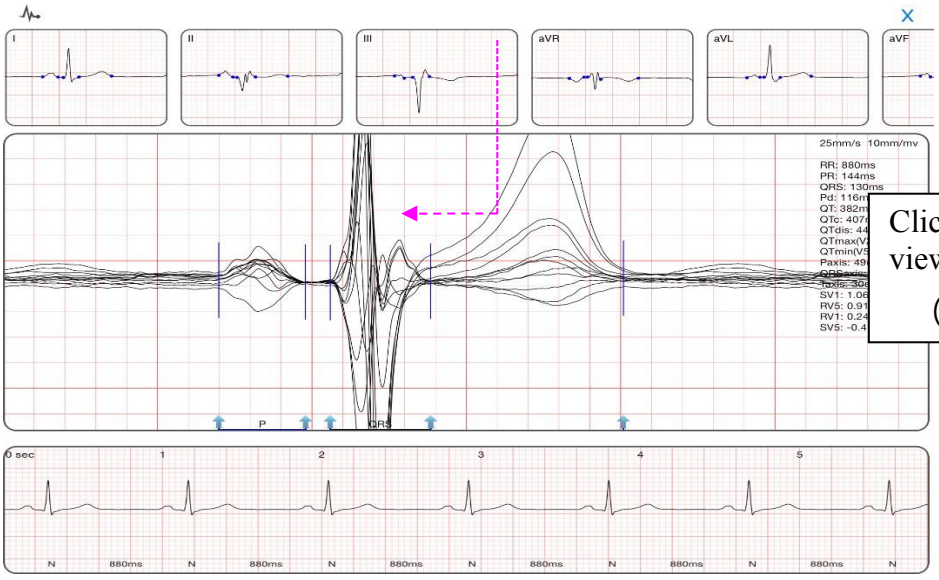
(1) Click  to view all recorded ECG.




(2) Icon Description

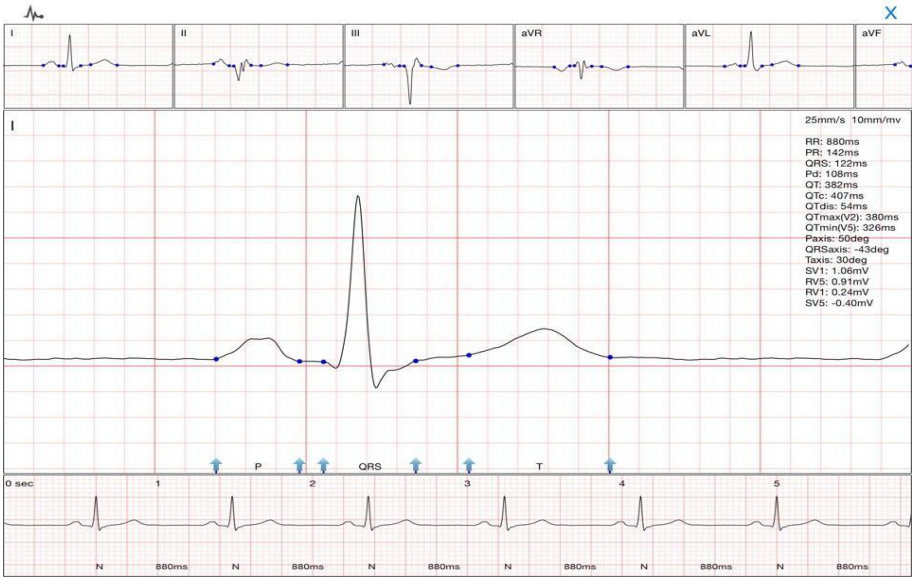
- Click  to display the icon as the below

| | |
|---|---|
|  | Compare with the previous data |
|  | ● Press  for QRS wave adjustment window, drag left and right to view QRS lead wave. |




"QRS" window

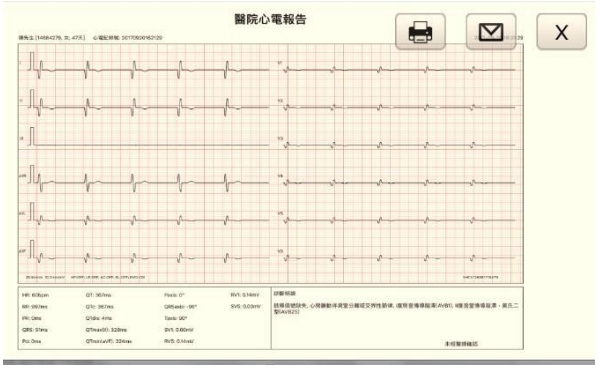
In "QRS" window, the bottom of the report shows single lead waveform. Click on a lead to view the waveform (as below).




QRS window of Single Lead

In the operating area, slide with two fingers to call out ruler to measure the waveform (Figure: blue dotted lines and numbers); adjust the locating point of QRS wave by dragging the blue arrow 

- Click  to display the icon as the below

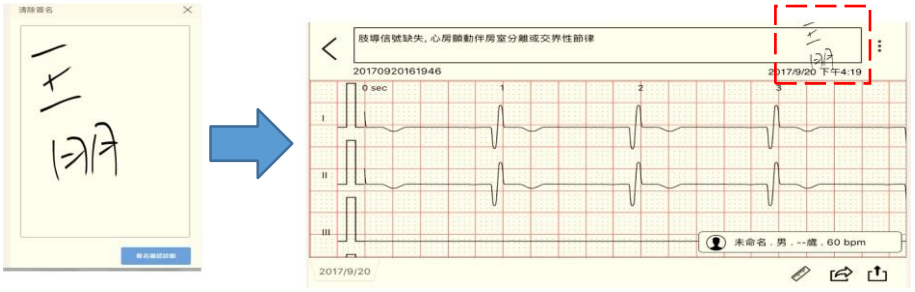
| | |
|---|---|
|  | ● Sending email: send the current record through email.<br>● If you have not set up sender's mailbox, a prompt would bump out (as below). Click “Yes” to exit the software, return to desktop and set up the mailbox. |
|  | Print preview for current ECG report.<br>  |

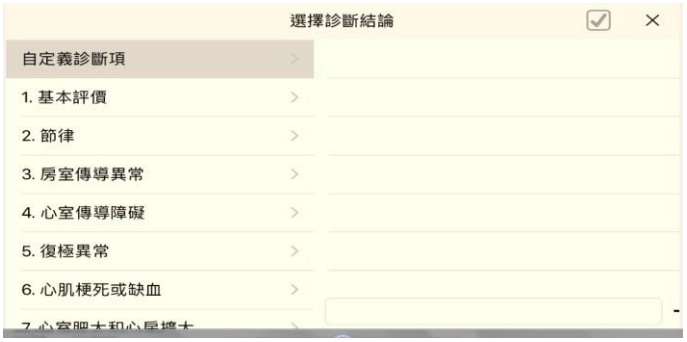
(3)  : uploading

- Please link http://www.cardiartcloud.net to register your data before uploading
- The recorded ECG could be uploaded to Cloud or computer.

(4) Click 

Signature for confirming diagnosis (physicians’ signature)



| | |
|---|---|
|  | Select the diagnostic result<br>  |
|  | Delete the diagnostic result |
|  | Refresh the diagnostic results, the diagnosis and signature will all be covered. |

5.4 VIEW/ Add/ Delete the patient data

1) Create a patient profile: Click  and enter a patient profile interface to review the record.

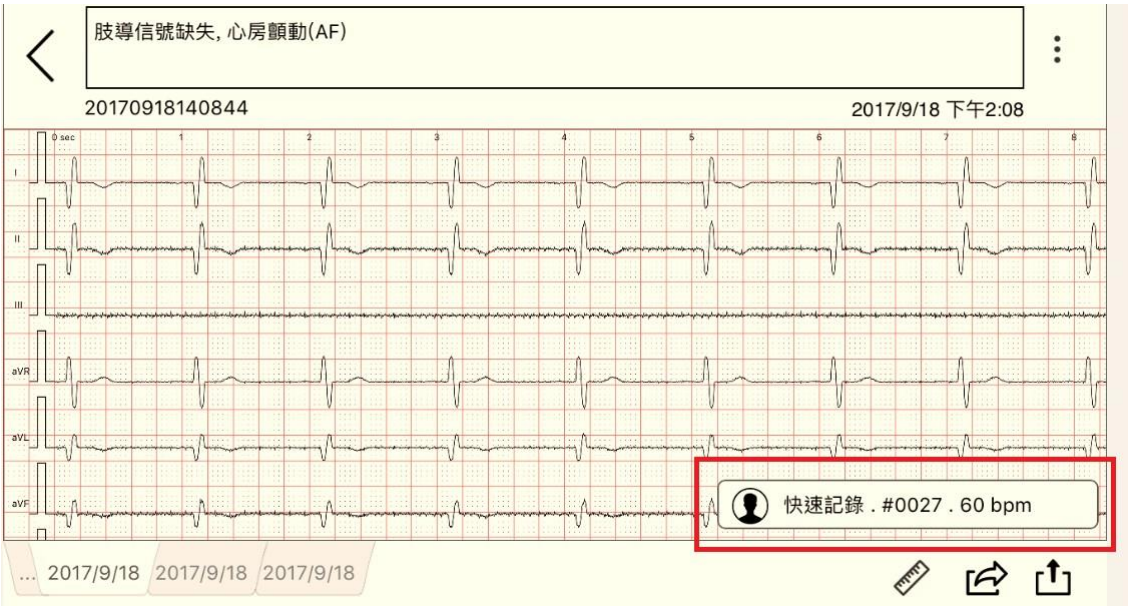


2) Create a patient report

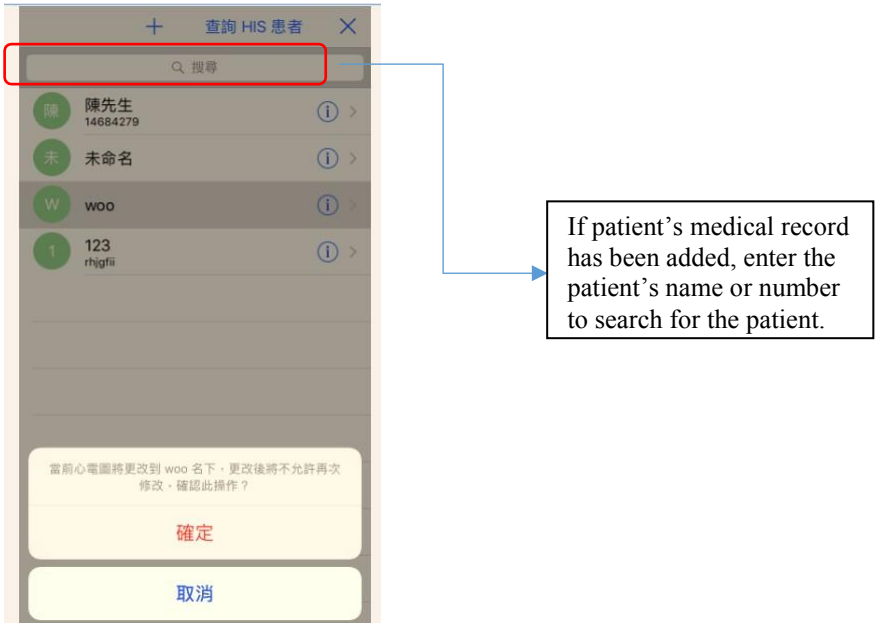
2.1 Enter 〝ECG record〞

2.2 Click a 〝patient report〞

2.3 Click 〝quickly record〞




5.5 Select a patient profile to creative a profile for patient report




5.6 View a patient report

Enter ECG record to review a patient report

# 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℃
- Humidity: 25%-95%（no condensation）
- Atmospheric pressure: 700hPa ~ 1060hPa

## 6.2 Transportation and Storage

- Temperature: -20℃~55℃
- Humidity: ≤93%

## 6.3 Cleansing

**ECG record box**

- Wipe the surface with soft, damp cloth, soaked with neutral detergent.
- Do not use strong detergent to avoid damaging the plastic surface.

**ECG Cable**

- Disconnect the lead before cleaning or disinfecting.
- Wipe the surface with soft, damp cloth, soaked with neutral detergent.
- Do not immerse lead wires in liquid.

## 6.4 Maintenance

- Make sure whether the record box and lead wires are damaged before using; if damaged, stop using and contact the manufacturers in time.
- The ECG record box shall be verified every two years only by the original factory or recognized professionals.

**Warning:**

- Please remove the battery whenever the ECG will not be used for a long time to avoid corroding the spring in the battery seat.
- Forbidden to use while charging.

6.5 Troubleshooting

| **Common problem** | **Solution** |
|---|---|
| Unable to start the record box | Please insert a battery with sufficient power. |
| Unable to record | Check the connection between the mobile device and the record box. |
| | Restart the record box. |
| 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. |

Above are the common fault for mobile ECG, if the fault repeatedly occurs or there's any other problems, please contact the original factory.

6.6 Description of electromagnetic interference

This section is the special tips for electromagnetic compatibility. The wireless ECG monitor of IMEDIPLUS should be installed and used according to this section. The basic function of this product is to record common ECG for doctors to diagnose; the error of sensitivity is ± 5%.

**Precaution:**

★ Portable and mobile RF communication devices may influence the use of mobile ECG; it is recommended to keep away from or turn off portable and mobile RF communication devices while using ECG.

★ The lead wire must be provided by IMEDIPLUS. Among this, the length of the cable: lead wire: 1.7m with shelter.

★ To ensure the product can be used normally, the electromagnetic emission is not increased, and the immunity is not reduced, please use the cable and related accessories provided by IMEDIPLUS; the other accessories may result in increasing the electromagnetic emission and reducing immunity.

★ This product should not be used near or stacked with other equipment with the same or similar frequency of operation. If it is unavoidable, make sure the product works properly in its configuration.

★ Using the product along with accessories other than the provided ones may result in increasing equipment or system emissions or reducing immunity.

★ Bluetooth module parameters: emission frequency: 2400MHz-2483.5MHz; Modulation type: GFSK; Effective radiated power: -30dBM ~ -40dBM

★ WARNING: The equipment or system may still be interfered, even if other equipment complies with appropriate national standard emission requirements

FCC Warning

FCC Intentional Radiator Certification
Cardiart Wireless 12-Lead Electrocardiograph Monitor (Model no.: MCE12L001)
FCC ID: 2AM7N-MCE12L001

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 undesirable operation.

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.

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.

6.7 Environmental protection

Disposing of the battery and equipment shall be done within the area approved by municipal unit, to avoid environmental pollution. The service life of the device is 5 years.

## Chapter 7 Products Specification

| | |
|---|---|
| Model | MCE12L001 |
| Intended Use | The product is mainly for checking abnormalities of the adults' heart through recording ECG by medical staff in hospital or clinic. |
| Lead | 12 lead |
| Input circuit | Built-in anti-defibrillation protection |
| Recording mode | Synchronous 12-lead recording |
| Dynamic measurement range | ± 5mVpp |
| The time constant | ≥ 3.2s |
| Frequency response | 0.05Hz~150Hz(-3dB) |
| Calibration voltage | 1mV± 3% |
| Sensitivity | Divided into three gear: 5mm / mv, 10mm / mv, 20mm / mv, the error range: ± 5%. |
| Input resistance | ≥ 50MΩ |
| Noise voltage level | No more than 30μ A |
| Anti-baseline drift | automatic / manual |
| Patient leakage | ≦ 10μA |
| Common-mode rejection ratio | ≥90dB |
| Data transmission | wireless |
| Bluetooth transmission distance | 10m |
| Power supply | Two AA 1.5 V Alkaline battery |
| Sampling rate | 500sps/channel |
| Safety classification： | Class II, CF type |

## Chapter 8 Symbol Description and Manufacturer Information

| | | | |
|---|---|---|---|
|  **Manufacturer name & address** |  **Manufacturing date (year/ month/ day)** |   **Lot number** |   **Serial number** |
|  **Expiration (limited to year/ month/ day)** |  **Only for single use** |  **Do not use if package is damaged** |  **Do not use if package is damaged** |
|  **Notice, please check the warning / precautions** |  **Anti-Automated External Defibrillator CF type** |  **Blue tooth** |  **Avoid high temperature and sunlight** |
|  **Upper / lower temperature limitation** |  **Electromagnetic wave warning** | | |

Manufacturer / Drug maker: IMEDIPLUS INC.
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