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LEPU MEDICAL

LeECG & NeoECG Series

Pad Electrocardiograph

Operator's Manual

I Preface

Declaration

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Version

P/N: SZ09.24300554-01

Release date: May 2020

Revision: V1.0

General Notes

- *Italic* text is used to indicate prompt information or quote the referenced chapters or sections.
- [XX] is used to indicate the character string in the software.
- → is used to indicate operational procedures.
- All illustrations in this manual serve as examples only and may differ from what is actually seen.

Special Notes

The warnings, cautions and tips in this manual are used to remind readers of some specific information.

Warning

Indicates a potential hazard or unsafe practice, which, if not avoided, could result in death or serious injury.

Caution

Indicates a potential hazard or unsafe practice, which, if not avoided, could result in the loss or destruction of property.

Note

Provides important tips regarding the operation or function of the device.

II Manufacturer's Liability and Warranty

Manufacturer's Liability

Carewell is responsible for the safety, reliability and performance of the device, only if:

- Assembly operations, expansions, re-adjustments, improvements and repairs of this device are performed by personnel authorized by Carewell;
- The electrical installation of the relevant room complies with the applicable national and local requirements;
- The device is used in accordance with the instructions in this manual.

Carewell shall not be responsible for direct, indirect or ultimate damage or delay caused by:

- the device is disassembled, stretched and re-adjusted;
- maintenance or modification of the device is conducted by unauthorized personnel;
- subsequent damage caused by improper use or maintenance;
- replacement or removal of serial number label and manufacture label.
- mis-operation caused by the neglect to the instructions in this manual.

Warranty

The warranty period is subject to the terms in the sales contract.

The warranty covers all device failures caused by material, firmware or production process. Any faulty parts can be repaired and replaced free of charge during the warranty period.

Manufacturing Process and Raw Materials

Carewell warrants that there is no defect in raw material and manufacturing process. During warranty period, Carewell will repair or replace the defective part(s) free of charge if the defect has been confirmed as raw material or manufacturing process defect under normal operation and maintenance conditions.

Software or Firmware

Software or firmware installed in the products of Carewell will be repaired by replacing the software or devices upon receipt of reports proving that the software or firmware are defective, but Carewell cannot guarantee that the use of the software or devices will not be interrupted or error free.

Circuit Diagram

Upon request, Carewell may provide necessary circuit diagrams, component part lists, and other technical information to assist qualified service personnel in parts repair.

Note: Freight and other charges are excluded in the above warranty.

This device contains no user serviceable parts. All repairs should be carried out by Carewell service personnel or its authorized distributors. Otherwise, Carewell will not be responsible for the safety, reliability and performance of the device.

Date of Manufacture and Service Life

The service life of the device is 10 years. Please refer to the label on the back of the main unit for the date of manufacture.

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Chapter 1 Safety Guidance

This chapter provides important safety information related to the use of the device. In other chapters, it also contains relevant safety information for specific operations. In order to use the device safely and effectively, please read and strictly observe all of the safety information described in this manual before use.

1.1 Safety Warnings

1.1.1 Device Warnings

Warning

This device is not designed for direct cardiac application.

Warning

This device is not intended for treatment.

Warning

This device is not intended for home use.

Warning

This device is intended to be used by qualified physicians or personnel professionally trained. They should be familiar with the contents of this user manual before operation.

Warning

Only qualified service engineers can install this device.

Warning

Only service engineers authorized by the manufacturer can open the device housings.

Warning

Do not open the equipment housings while the power is connected.

Warning

EXPLOSION HAZARD - Do not use the device in the presence of flammable anesthetic mixture with oxygen or other flammable agents.

Warning

Do not use the device adjacent to or stacked with other device. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning

This device cannot be used with diathermy related device.

Warning

Do not use this device in the presence of high static electricity or high voltage device which may generate sparks.

Warning

Auxiliary equipment connected to the analog and digital interfaces must be certified according to IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the valid version of IEC 60601-1. If in doubt, consult our technical service department or your local distributor.

Warning

The summation of leakage current should never exceed leakage current limits while several other devices are used at the same time.

Warning

Only the patient cable and other accessories supplied by Carewell can be used. Otherwise, the performance, electric shock protection or defibrillator protection cannot be guaranteed.

Warning

Make sure that all electrodes are connected to the patient correctly before operation.

Warning

Make sure that the conductive parts of electrodes (including neutral electrodes) and lead wires, do not come in contact with earth or any other conducting objects.

Warning

Do not use dissimilar metal electrodes.

Warning

Indication of abnormal operation of the device: When the DC voltage at the input terminal is increased to ±1V, the device will display lead off.

Warning

Check the main unit , patient cable and electrodes etc. before operating the device. Replacement should be taken if there is any evident defectiveness or aging symptom which may impair the safety or performance.

Warning

Do not touch the patient and live parts simultaneously. Otherwise patient injury may result.

Warning

Do not carry out maintenance and repair of the device in use.

Warning

The frequency setting of AC filter should be consistent with the frequency of local mains supply, otherwise, the anti-jamming effect of the device will be seriously affected.

Warning

Before connecting the device to the power supply, check that the voltage and frequency ratings of the power supply are the same as those indicated on the device label or meet the requirements specified in this manual.

⚠ Warning

If the integrity of the external protective conductor is in doubt, the device should be powered by the built-in rechargeable battery.

⚠ Warning

Do not use sharp objects such as pens to touch the screen, otherwise it may damage the screen.

1.1.2 Defibrillator / Pacemaker / Radio Knife Warnings

⚠ Warning

When used with a defibrillator or pacemaker, all electrodes connected and not connected to the patient and the patient should not be grounded.

⚠ Warning

Before defibrillating, make sure the patient is completely isolated and avoid touching any metal part of the device in case of electric shock.

⚠ Warning

Before defibrillating, remove all electrodes, gel or cloth pieces from the patient in case of any possible burnt. When the electrode plate of defibrillator is in direct contact with these materials, the discharge capacity will cause severe electric burn of patients.

⚠ Warning

Before defibrillating, enable the ADS function and select 0.67Hz filter.

⚠ Warning

Use patient cable with defibrillator protection specified by the manufacturer while defibrillating. Otherwise there might be electric burnt of the patient or damage of the device. After defibrillation, under the standard sensitivity setting, the ECG waveform will return to 80% of the normal amplitude within 5 seconds.

⚠ Warning

During defibrillation, use disposable electrodes and ECG adapter wires specified by the manufacturer and use them in accordance with their instructions for use.

⚠ Warning

After defibrillation, the ADS filter is set at 0.67Hz, and the cardiogram is displayed and maintained within 10 seconds.

⚠ Warning

Use only the patient cable and electrodes supplied by the manufacturer while defibrillating.

⚠ Warning

In order to avoid being burnt, please keep the electrodes far away from the radio knife while using electrosurgical equipment simultaneously.

⚠ Warning

For patient with a pacemaker, since this device has a pacing signal suppression function, under normal circumstances, pacing pulses will not be included in the pulse rate detection and calculation. However, if the width of the pacing pulse exceeds 2ms, it is still possible to continue counting the pacing pulse. To reduce this possibility, the operator should closely observe the changes in the ECG waveform on the screen, and do not rely on the indications of the device itself, when the device is used for such patients.

1.1.3 Battery Warnings

⚠ Warning

Improper operation may cause the lithium battery (hereinafter called battery) to be hot, ignited or exploded, and it may lead to the decrease of the battery capacity. It is necessary to read this manual carefully and pay more attention to warning information.

Warning

Danger of explosion - Do not reverse the anode and the cathode when installing the battery.

Warning

Do not use the battery near a fire source or in the place where the temperature exceeds 60℃. Do not heat the battery or throw it into fire. Do not expose the battery to liquid.

Warning

Do not gouge the battery with metal, hammer or drop the battery or destroy the battery by other means, otherwise it will cause the battery over-heated, smoking, distorted or burning, even in danger.

Warning

When leakage or foul smell is found, stop using the battery immediately. If your skin or cloth comes into contact with the leakage liquid, cleanse it with clean water at once. If the leakage liquid splashes into your eyes, do not wipe them. Irrigate them with clean water first and go to see a doctor immediately.

Warning

Only qualified service engineers authorized by the manufacturer can open the battery compartment and replace the battery, and only batteries of the same model and specification provided by manufacturer should be used.

Warning

Stop using the battery when it reaches the end of its service life or any abnormal phenomenon is found from the battery, and dispose the battery according to local regulations.

Warning

Remove or install the battery only when the device is powered off.

Warning

Remove the battery from the device when the device is not used for a long time.

Warning

If the battery is stored alone and not used for a long time, we recommend that the battery should be charged at least once every 6 months to prevent over discharge.

1.2 Cautions

1.2.1 General Cautions

Caution

Avoid water splashing on the device.

Caution

Avoid high temperature, the device should be used in the temperature between 5℃ to 40℃ during operation.

Caution

Do not use the device in a dusty environment with bad ventilation or in the presence of corrosive materials.

Caution

Make sure that there is no intense electromagnetic interference source around the device, such as radio transmitters or mobile phones etc. Attention: large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment etc. is likely to bring electromagnetic interference.

Caution

Do not detach the electrodes from the patient during ECG analysis.

Caution

Disposable electrodes can not be reused.

Caution

The device and accessories are to be disposed of according to local regulations after their service lives.

Caution

The results given by the device should be examined based on the overall clinical condition of the patient, and they can not substitute for regular checking.

1.2.2 Cleaning & Disinfection Cautions

Caution

Turn off the device, disconnect the DC adapter and remove the patient cable before cleaning and disinfection.

Caution

Prevent the detergent from seeping into the device when cleaning. Do not immerse the main unit and accessories into liquid under any circumstances.

Caution

Do not clean the main unit and accessories with abrasive fabric and avoid scratching the electrodes.

Caution

Any remainder of detergent should be removed from the main unit and the patient cable after cleaning.

Caution

Do not use high temperature, high pressure steam and ionizing radiation for disinfection.

Caution

Carewell is not responsible for the effectiveness of the disinfectant or disinfection method used as a means of infection control. Please consult your hospital's infection control director or epidemiologist for advice.

1.3 Device Symbols

Symbol	Description	Symbol	Description
	Device or part of CF type with defibrillation proof		Power On/Off
	Polarity of d.c. power connector	TYPE-C	USB connector
	Direct current indicator		Battery indicator
	Manufacturer		Date of manufacture
CE 0123	The symbol indicates that the device complies with the European Council Directive 93/42/EEC concerning medical devices.	EC REP	Authorised representative in the European Community
SN	Serial number		Non-ionizing electromagnetic radiation
	Caution! Consult accompanying documents		Dispose of in accordance to your country's requirements
	General warning sign (Background: yellow; Symbol and line: black)		Refer to Operator's Manual (Background: blue; Symbol: white)

☞ **Note**

- **Your device does not necessarily have all of the above symbols.**
- **This manual is printed in Black and White.**

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Chapter 2 Product Introduction

This manual describes all features and options of the product basing on the maximum configuration. The product you purchased may not have all of them. If you have any question, please contact us.

2.1 Intended Use

NeoECG S120/LeECG OS12 pad electrocardiographs (hereinafter referred to as "the device") are intended to acquire resting ECG signals from adult and pediatric patients through body surface ECG electrodes, and analyze the ECG data for clinical diagnosis and research.

2.2 Contraindication

No contraindication.

2.3 Indications for Use

The device is intended to be used in medical institutions. It should be used by clinical professionals or persons who have received adequate training in its use.

2.4 Structure and Composition

The pad electrocardiograph consists of a main unit (including multi-channel electrocardiograph software (V1) and ECG analysis program (V30)), power adapter, patient cable (model: ECG-FD10X4 (CE) and ECG-FD08X4 (US)) and ECG electrodes (chest electrode model: ECG-FQX41 and ECG-EQD01 (optional), limb electrode model: ECG-FJX42 and ECG-EJ01 (optional)).

2.5 Product View

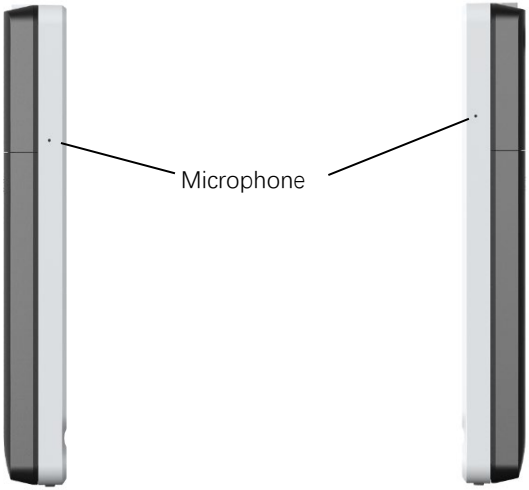
2.5.1 Front View

No.	Icon	Name	Description
1	⏻	Power On/Off	Press this key to turn on the device. Press and hold this key for about 5 seconds to turn off the device. Press and hold this key for no less than 10 seconds to forcibly shut down the device if it could not be shut down normally.
2	⏻	Power-on indicator	Green: the device is on Off: the device is off

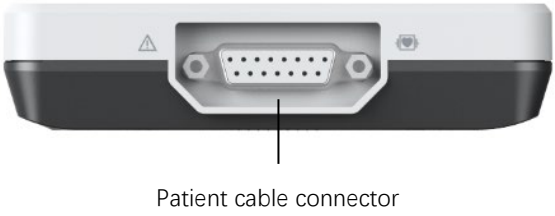
No.	Icon	Name	Description
3		DC power indicator	Green: DC power connected Off: DC power disconnected
4		Battery indicator	Green: the battery is fully charged. Yellow: the battery is being charged. Off: the battery is not charged.

2.5.2 Rear View

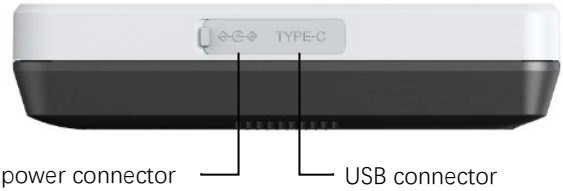
2.5.3 Left / Right View



2.5.4 Top View



2.5.5 Bottom View



2.6 Function Features

- Portable design, compact in size with low weight, easy for carry.
- Color touch screen, easy to operate.
- Can be powered by an external DC power supply or a built-in rechargeable lithium battery.
- Support synchronous acquisition and display of 9/12-lead waveform, as well as heart rate detection.
- Provide ECG algorithm to automatically analyze the acquired ECG waveform, output measured values and diagnosis results.
- Support auto, RR analysis, HRV, medicine test, ECG event mode.
- Provide 4 sampling modes: pre-sampling, real-time sampling, periodic sampling and trigger sampling.
- Support automatic pacing detection and marking.
- Support ADS (Anti-drifting system) and EMG interference.
- Accurately identify the electrode with poor contact and give instructions. The limb and chest leads are checked for signal quality.
- Support both offline and online ECG acquisition modes.
- Input patient information via full keyboard and barcode scanning.
- Freeze the ECG waveform on the screen.
- Output files in multiple formats, such as Carewell ECG, PDF, BMP, HL7, DICOM, SCP.
- Auto-saving function: save the ECG data when the report is printed.
- Store, preview, review, edit, export, upload, print and search patient data.

- Support wireless transmission of ECG data via WiFi and mobile networks.
- Print ECG reports by external laser printer.
- Export patient data to USB flash disk via USB connector.
- Support the user login permission control, use password or account & password authentication to use the device.
- Support online and offline login to the device, and view the historical patient data of the department according to the login account.
- In case of emergency, support rapid ECG examination without logging in.

2.7 Operating Modes

2.7.1 Routine Use

When the device is turned on, it automatically enters the routine use mode, which is most frequently used clinical mode. In this mode, you can perform ECG measurement, record waveforms, measured values and analysis results, set up the system, print ECG reports and export ECG data.

2.7.2 Emergency Use

In case of emergency, click the [Emergency] button to enter the emergency use mode. This mode only displays the acquisition interface. You can collect, display, obtain and print measured values (no diagnosis results).

Click the [Exit] button in the upper right corner of the screen to exit the emergency mode and return to the login interface.

2.7.3 Standby Mode

When there is no user operation and all leads off within the set time, the device automatically enters the standby mode if the device is inactive for a predefined time limit.

To set the time to automatically enter the standby mode, follow the steps below:

1. Click [ ] button in the lower right corner of the main interface to open the menu interface.
2. Click the [Setup] button to enter the setting interface.
3. Click [System Setup] → [Other Setup] → [Auto Standby].
4. Set the time to automatically enter standby mode.

In the standby mode, the display screen is black, and the device enters the power saving state.

To exit the standby mode, short press the Power On/Off key or click the touchscreen.

2.7.4 Demo Mode

In this mode, the device can demonstrate its main functions when a patient or patient simulator is not connected.

To enter the demo mode, follow the steps below:

1. Click [ ] button in the lower right corner of the main interface to open the menu interface.
2. Click the [Setup] button to enter the setting interface.
3. Click [System Setup] → [Demo].
4. Select [Normal ECG] or [Abnormal ECG].

When the demo mode is enabled, both the waveform area of the acquisition interface and the parameter information area at the bottom of the printed report display the word "Demo" .

To exit the demo mode, click the [Exit] button in the upper right corner of the screen.

Warning

The Demo mode is mainly used to show the performance of the device and to train users. In clinical use, do not set the device to Demo mode when connecting patients, to avoid mistaking the Demo waveform for patient's waveform, which may result in delayed diagnosis and treatment.

Chapter 3 Operation Preparations

3.1 Unpacking and Checking

Before unpacking, examine the packaging carefully for signs of damage. If any damage is found, please contact the carrier immediately.

If the packaging is intact, perform unpacking inspection according to the following steps:

1. Open the package and take out the device and accessories carefully.
2. Check all materials according to the packing list.
3. Check the device for any mechanical damage.
4. Check the accessories for scratches or defects.

Contact Carewell in case of any problems.

Warning

Keep the packaging materials out of the reach of children. When disposing of the packaging materials, be sure to comply with your local waste control regulations or the hospital's waste disposal system.

3.2 Selecting an Installation Location

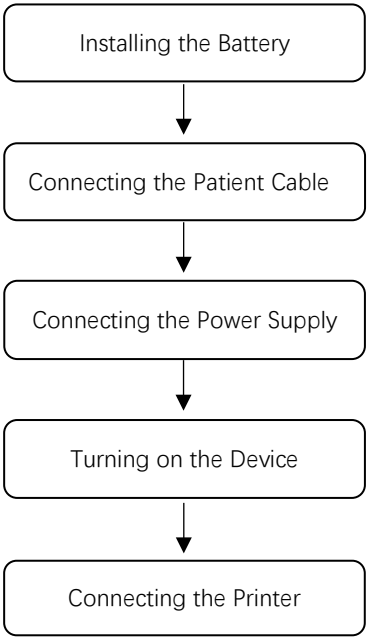
Select a place where the infrastructure and mains supply is well set up. Place the device in a flat operating table. The operating environment of the device must meet the requirements specified in this manual.

Caution

Do not locate the device in a place where the power plug is difficult to plug in and out.

3.3 Preparing the Device

When using the device for the first time, the preparation steps are as follows:



3.3.1 Using the Battery

The device can be powered by a rechargeable lithium battery. If the device is equipped with a battery, the device will automatically switch to battery power when the DC power supply is interrupted.

- Installing the Battery

To install or replace the battery, follow the steps below:

1. Press and slide the battery compartment cover lock/unlock latch to the unlock position.
2. Push down to remove the battery compartment cover.

3. Place the battery in the battery compartment.

4. Reinstall the battery compartment cover and slide the latch to the lock position.

- Charging the Battery

Because of the power consumption during the storage and transportation, the battery capacity may not be full, so it is necessary to charge the battery before using it for the first time.

When the device is connected to the DC power supply, the battery is charged regardless of whether or not the device is currently turned on.

When the battery is being charged, the battery indicator illuminates in yellow. When the device is on, the battery power icon in the upper right corner of the main interface will dynamically display the charging state of the battery.

For charge time and run time of the battery, see *A.3 Physical and Hardware Specifications*.

3.3.2 Connecting the Patient Cable

Connect the patient cable to the patient cable connector on the top side of the device, and then tighten the knobs on both sides of the patient cable plug to secure it.

3.3.3 Connecting the DC Power Supply

To connect the DC power supply, follow the steps below:

1. Insert the connector of the DC adapter into the DC port on the bottom side of the device.

2. Insert the two-wire plug of the DC adapter into an AC receptacle.

3. Check whether the DC power indicator is on to ensure that the DC power supply is connected well.

3.3.4 Inspections Before Power-On

To ensure the safe and effective operation of the device, perform the following inspections before power-on and operation.

- Environment:

Make sure that there is no electromagnetic interference source around the equipment, such as electrosurgical device, ultrasonic diagnostic device, radioactive device, etc. Switch off these devices when necessary.

- Power Supply:

Check whether the battery is installed in the device. When the battery capacity is low, recharge the battery before use. When the DC power supply is used, check whether the DC power adapter is connected to the device well.

- Patient Cable:

Make sure that the patient cable is connected to the device firmly.

- Electrodes:

Make sure that all electrodes are connected to lead wires of the patient cable correctly. Ensure that the electrodes, especially the chest electrodes do not contact.

- Patient:

The patient’ s hands and feet should not come into contact with conducting objects such as the metal part of the bed.

Ensure that the patient is warm and relaxed, and breathes calmly.

3.3.5 Power-On and Login

Press the Power On/Off key to turn on the device, it will enter the startup screen, and then enter the login interface. The login method depends on the diagnostic mode configured by the device.

- Auto diagnosis mode

You need to input the correct password (initial password: 135790) to enter the main interface of the device.

- AI cloud mode

Before the first use, you need to connect to the network, set the IP address and port number of the server, and input an authorized account and password to log into the device after establishing a connection with the server.

> ☞ **Note**
>
> **In an emergency situation, click the [Emergency] button to quickly perform ECG examination without logging in.**

3.3.6 Connecting the Printer

To connect a USB printer, plug the USB connector end of the USB cable supplied with the printer into the USB port on the bottom side of your device.

To connect to a network printer, set the network printer's IP address and port number, and use it after the connection is successful. For more information, see *6.5 Printing Reports* for details.

3.3.7 Setting Up the Device

Set up the device before using it for the first time. The operation steps are as follows:

1. Click the [ ] button in the lower right corner of the main interface to open the menu interface.
2. Click the [Setup] button to enter the setting interface.
3. Set the system date and time, screen brightness and other items as required.

For more information about device settings, see Chapter 8 System Settings for details.

3.3.8 Turning off the device

Follow the steps below to turn off the device:

1. Confirm that the patient's ECG examination has been completed.
2. Remove the electrodes from the patient.
3. Press and hold the power button for about 5 seconds, the screen displays the prompt message "Shutting down...", and then the device shuts down.

Caution

Press and hold the power button for no less than 10 seconds to forcibly shut down the device if it could not be shut down normally. However, this operation may cause data loss or corruption, please proceed with caution.

3.4 Preparing the Patient

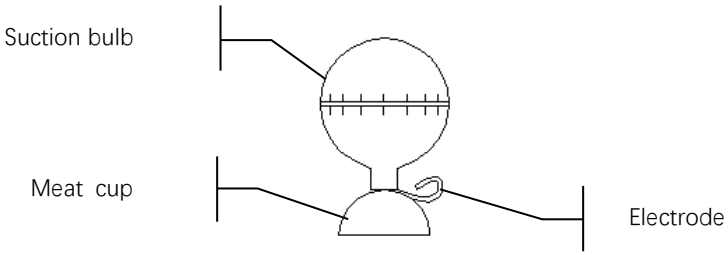
3.4.1 ECG Accessories

- Patient cable

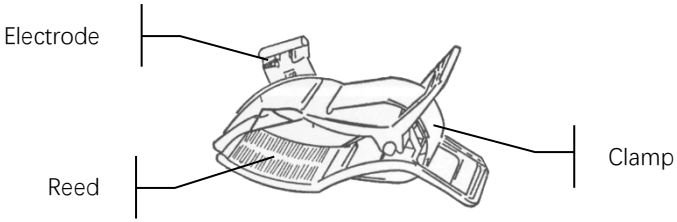
The patient cable is composed of a patient cable connector, a main cable, lead wires and electrode connectors.

- Patient cable connector: connected to the electrocardiograph.
- Lead wires: consists of 6 chest leads and 4 limb leads, can be connected to electrode connectors.
- Electrode connectors: can be distinguished from the colors and identifiers on them, can be connected to chest electrodes and limb electrodes. According to different standards, electrode codes and colors are different.

- Chest electrode



- Limb electrode



3.4.2 Connecting the Electrodes

Connect the electrode connectors with chest electrodes and limb electrodes respectively. The electrode identifiers and color codes of the internationally accepted European and American standards are shown in the table below.

This device adopts Wilson lead system.

	European Standard		American Standard	
Lead	**Identifier**	**Color Code**	**Identifier**	**Color Code**
Right arm	R	Red	RA	White
Left arm	L	Yellow	LA	Black
Right leg (neutral)	N or RF	Black	RL	Green
Left leg	F	Green	LL	Red

	European Standard		American Standard	
Lead	**Identifier**	**Color Code**	**Identifier**	**Color Code**
Chest 1	C1	White/Red	V1	Brown/Red
Chest 2	C2	White/Yellow	V2	Brown/Yellow
Chest 3	C3	White/Green	V3	Brown/Green
Chest 4	C4	White/Brown	V4	Brown/Blue
Chest 5	C5	White/Black	V5	Brown/Orange
Chest 6	C6	White/Violet	V6	Brown/Violet

3.4.3 Preparing the Patient

Correct operation is very important to get the best quality ECG.

To properly preparing the patient, follow the steps below:

1. Ask the patient to lie down comfortably and be relaxed.
2. Remove the clothing from the patient where the electrode was placed.
3. Clean the skin where the electrodes are placed with alcohol. Shave hair from electrode sites, if necessary. Excessive hair prevents a good connection.

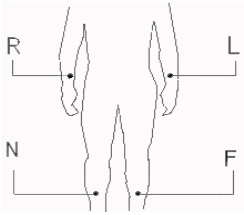
3.4.4 Attaching Electrodes to the Patient

The quality of ECG waveform will be affected by the contact resistance between the patient and the electrode. In order to get a high-quality ECG, the skin-electrode resistance must be minimized when you attach electrodes to patients.

Before placing the electrode, make sure that the electrode is clean. Reusable electrodes should be cleaned immediately after each use.

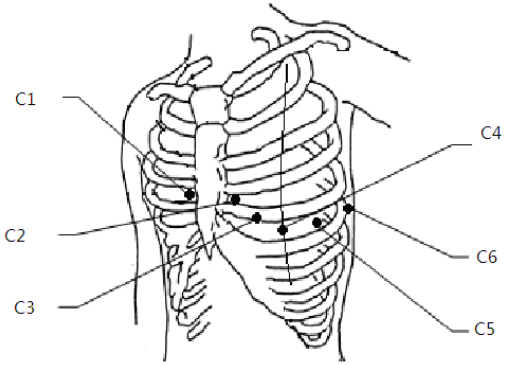
- Position of Electrodes

Limb electrodes should be placed on the upper part of the forearm wrist joint and the ankle joint inside the calf (avoiding the bones), and the electrodes should be placed in close contact with the skin.



R: right arm, L: left arm, N: right leg, F: left leg

The chest electrodes can be placed at the following positions:



C1: on the fourth intercostal space at left border of sternum.

C2: on the fourth intercostal space at right border of sternum.

C3: midway between the C2 and C4 electrode positions.

C4: on the fifth intercostal space at the left midclavicular line.

C5: on the left anterior axillary line, horizontal with the C4 electrode position.

C6: on the left midaxillary line, horizontal with the C4 electrode position.

- Attaching Lime Electrodes

To attach lime electrodes, follow the steps below:

1. Check the electrodes and ensure that they are clean.
2. When the patient's skin is ready, daub a thin layer of conductive paste evenly to the electrode area on the limb.
3. Daub a thin layer of conductive paste on the metal part of the limb electrode clamp.
4. Connect the electrode to the limb, and make sure that the metal part is placed on the electrode area above the ankle or the wrist. Attach all limb electrodes in the same way.

- Attaching Chest Electrodes

To attach chest electrodes, follow the steps below:

1. Check the electrodes and ensure that they are clean.
2. When the patient's skin is ready, daub a thin layer of conductive paste evenly to the electrode area on the chest.
3. Daub a thin layer of conductive paste on the brim of the metal cup of the chest electrode.
4. Place the electrode on the chest electrode site and squeeze the suction bulb, and then release it until the electrode is firmly attached to the corresponding part. Attach all chest electrodes in the same way.

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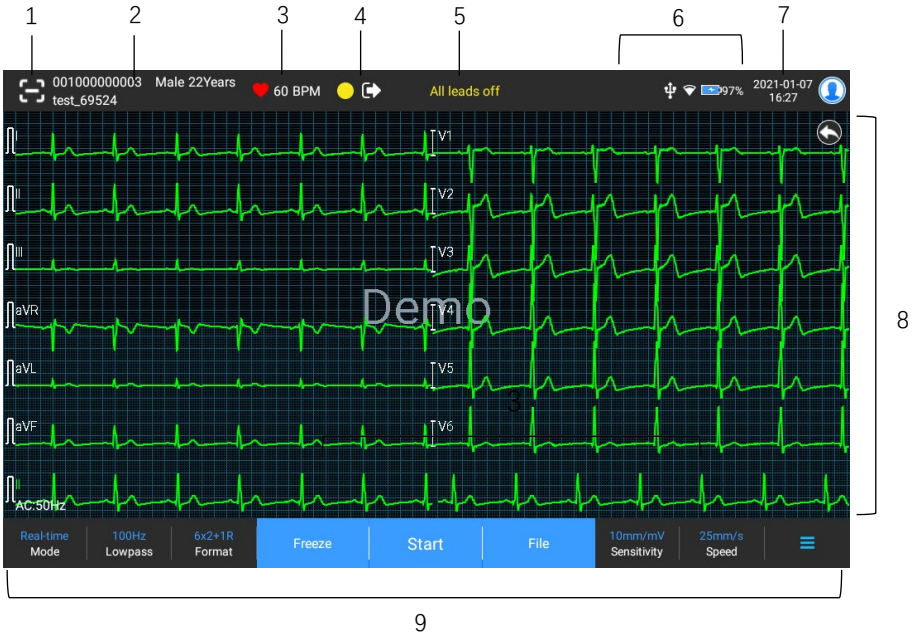
Chapter 4 Interface Introduction

4.1 Main Interface

After logging into the device, the normal ECG acquisition interface is displayed, as shown in the figure below:



1 Barcode scaning button

Click the [ ] button to enter the patient ID by scanning the patient's barcode with the built-in camera.

2 Patient information area

- The patient information area displays the patient ID, name, gender, age and other required information.
- Click the patient information area to enter the **Patient Info** interface

to view and edit the detailed patient information.

- This area will be left blank if information not inputted.

3 Heart rate (HR) area

- Display the heartbeat symbol and real-time HR value and unit. The refreshing speed of the dynamic icon is the same as the heart beating speed.
- When the HR exceeds the detectable HR range, the HR value area is displayed as "-".
- 0 means cardiac arrest, displayed as 0.
- When all leads / rhythm leads fall off, the HR will be displayed as "-" by default.

4 Lead indication area

- Display the lead signal quality detection indicator:
  - **Green**: lead connection is normal, waveform quality is good and free from interferences.
  - **Orange**: lead connection is normal, but waveform is interfered.
  - **Yellow**: the lead is off.
- Click the [ ] icon to view the electrode connection diagram and connection status in the popup window. The name and position of the electrode that fell off are displayed in yellow, and that of the one not fell off are displayed in green.

5 Prompt information area

Display prompt information such as "All leads off", "HR overrange".

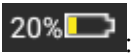
6 Status display area

Display the current network, internal battery, external power, external USB device, external printer connection status of the device.

- Wireless networks
  - : indicates that a WiFi wireless network is connected. The solid part indicates network signal strength. Not displayed when not connected.
  - : indicates that the mobile network is connected and displays the name of the operator to which it belongs. The solid part indicates network signal strength. Not displayed when not connected.
- Battery

  If a battery is installed, the percentage of remaining battery power and the battery icon will be displayed; otherwise, it will not be displayed.
  -

: indicates that the battery is being charged.
  -

: indicates that the device is powered by a battery.
  - 

: indicates that the device is powered by a battery and the battery power is low.
  -

: indicates that the battery is almost depleted and needs to be charged immediately. Otherwise, the device will automatically shut down soon.
  - : indicates that no battery is installed or battery charging fault.

- Power supply

  : indicates that a DC power supply is connected. Not displayed when not connected.

- USB device

  : indicates that a USB device is connected. Not displayed when not connected.

- Printer

  : indicates that an external printer is connected. Not displayed when not connected.

7 System time area

Displays the system date and time. The time format can be set to 12h or 24h.

8 Waveform area

- Displays the ECG waveform.
- The waveform layout is the same as the waveform display format set in different working modes.

9 System button area

Displays the commonly used system buttons. For more information, see *4.2 System Buttons*.

4.2 System Buttons

At the bottom of the main interface, there are the following buttons: working mode, low-pass filter, display format, waveform freezing, start / stop button, file, sensitivity, speed and menu.

- Quick keys

Support quick setting of working mode, low-pass filter, display format, sensitivity and speed.

The specific options of working mode are consistent with the settings in [Setup] → [ECG Setup] → [Sampling Mode]. Under different working modes, the buttons and setting items configured in this mode are displayed. For detailed settings, see *8.1 ECG Setup*.

- Waveform freezing

After clicking the [Freeze] button, the ECG waveforms stop refreshing and scrolling. The frozen waveform is the 130-second waveform before pressing the freeze button. If the data is less than 130 seconds, the waveform of the actual duration from the beginning of waveform refresh to the time when the button is clicked is displayed.

You can switch the speed, sensitivity and lead format of the frozen waveform, as well as store and print ECG reports.

You can manually add or modify diagnosis results.

You can quickly select the diagnosis results you want by entering keywords, because the device has loaded the diagnosis result template.

For the diagnosis that is not in the diagnosis result template, you can add the diagnosis result, and then select it from the custom menu.

- File

Click the [File] button to enter the patient archive management interface, where you can add and modify patient information, view, query, export and print ECG report. For more information, see *Chapter 7 File Management*.

- Menu Expand / Hide button

Click the [ ] button in the lower right corner of the main interface to open the system menu. After the menu is expanded, click the [ ] button again to hide the menu.

In the expansion interface, you can quickly perform the following operations:

- Copy

  Click the [Copy] button to directly print the most recently stored report.

- Settings

  Click the [Setup] button to set the device comprehensively. For more information, see *Chapter 8 System Settings*.

- STAT

  Click this button, the word "STAT" appears on the interface. You can click the [STAT] button before and during the acquisition process, and click the [Cancel STAT] button to cancel the STAT ECG. After taking an urgent/STAT ECG, the stored report in the file list is marked as STAT.

- Start / Stop button

Click the [Start] button to start the acquisition and printing operation immediately.

During acquisition, the button displays "stop and sampling time (current sampling time / set sampling time)".

During acquisition and printing, click the [Stop] button to stop the acquisition or printing operation immediately.

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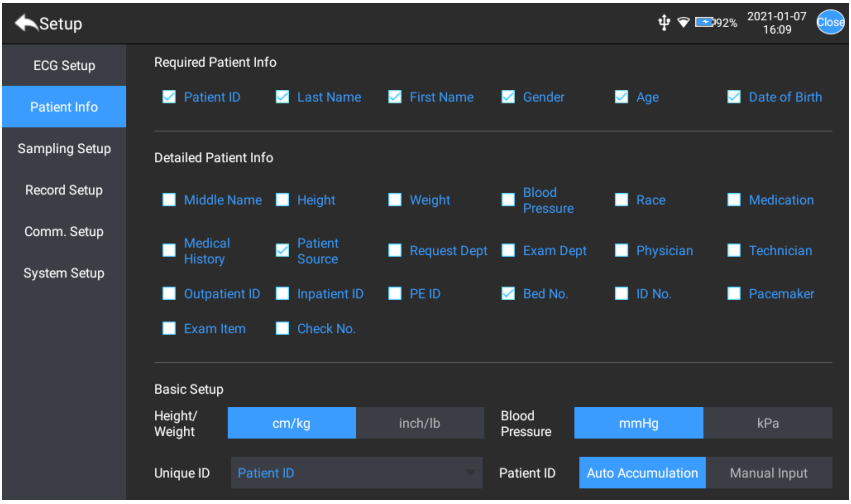
Chapter 5 Entering Patient Information

5.1 Setting Patient Information

Certain patient information directly affects ECG analysis, correct and complete patient information is helpful to the accuracy of analysis and treatment of the patient. Patient information is classified as required information and detailed information. The required information must be entered. In the [Patient Info] interface, an asterisk (*) is placed behind the required information. The detailed information helps you to know more about the patient.



To set patient information, follow the steps below:

1. In the main interface, click [☰] → [Setup] to enter the setting interface.
2. Click [Patient Info] to enter the patient information setting interface.
3. Select the required information items, ID mode, etc.
4. For specific setting information, see *8.2 Patient Info Setup*.

5.2 Entering Patient Information

Use any of the following methods to enter patient information before taking an ECG examination.

- Enter patient information manually
- Read patient ID with the device’ s camera
- Read patient ID with a barcode reader
- Select a patient from the Order List

Entering Patient Information Manually

To manually enter the patient information, follow the steps below:

1. Click the patient information area in the main interface to open the patient information interface. Or click [File] → [Patient Info] to enter the patient information interface.
2. Enter patient information in the patient information interface.
3. Click the [OK] button to save the patient information.
4. Click the [Reset] button to clear and re-enter the patient information.
5. Click the [Cancel] button to exit without saving the patient information.

> ☞ **Note**
>
> **You can save patient information only when all the required patient information is entered.**

Reading Patient ID with the Device’s Camera

To read the patient ID with the built-in camera of the device, follow the steps below:

1. Click the [ ] button to start scanning.
2. Use the device's camera to scan the linear barcode or QR code, and enter the decoded content into the patient ID text box.
3. Enter other patient information manually.
4. Click the [OK] button to save the patient information.

Reading Patient ID with a Barcode Reader

To read the patient ID with the barcode reader, follow the steps below:

1. Connect the barcode reader to the USB connector of the device.
2. Press down the button on the reader handle, and target the reader to the barcode. Then the [Patient Info] menu pops up with the patient ID entered.

Selecting a Patient from the Order List

To select a patient from the order list, follow the steps below:

1. In the main interface, click [File] → [Order List] to enter the order list interface.
2. Select a patient and edit the patient information as necessary.

The patient information in the order list is automatically downloaded from the AI server. You can also create patient information manually. The newly added information is synchronized to the AI server. The patient information of the day is displayed by default.

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Chapter 6 Acquisition, Analysis and Printing

6.1 Selecting the Working Mode

The device supports automatic measurement (pre-sampling, real-time sampling, periodic sampling, trigger sampling), RR analysis, HRV analysis, pharmaceutical test, ECG event recording.

To select the working mode, follow the steps below:

1. In the main interface, click [ ] → [Setup] to enter the setting interface.
2. Click [ECG Setup] → [Sampling Mode] to configure the sampling mode as needed.
3. Return to the main interface after setting.
4. Click the [Mode] button at the bottom of the main interface to quickly select the desired working mode.

Caution

The working mode can not be changed during the printing course. Stop printing the report before changing the working mode.

6.2 Selecting the Lead Mode

The device supports two lead modes: 9-lead and standard 12-lead.

To select the lead mode, follow the steps below:

1. In the main interface, click [ ] → [Setup] to enter the setting interface.
2. Click [ECG Setup] → [Lead Mode] to set the required lead mode.
3. Return to the main interface after setting.

6.3 Setting ECG Waveform and Report

Set the ECG waveform and report before starting an ECG measurement. Operation procedures:

1. Click the quick keys at the bottom of the main interface to set the speed, sensitivity, display format and filter frequency respectively.
2. Click [Setup] → [ECG Setup] and [Record Setup] to check other waveform setting items and report setting items, and make relevant settings as needed.

For more information, see *Chapter 8 System Settings*.

6.4 Acquisition and Analysis

6.4.1 Auto Diagnosis Mode

After the ECG waveform is stable, click the [Start/Stop] button, the device starts recording the ECG waveform. After the ECG data is acquired for the set time period, the device automatically starts analysis, and selects whether to print ECG report according to the settings.

In the Auto measurement mode, ECG analysis provides:

- Measurement parameters, including:

  Heart rate (bpm), P duration (ms), PR interval (ms), QRS duration (ms), QT/QTc interval (ms), P/QRS/T axis (°), RV5/SV1 amplitude (mV), RV5+SV1 amplitude (mV), RV6/SV2 amplitude (mV)

- Algorithm analysis results
- Minnesota code
- Average template

  Gives the average template waveform of each lead.

- Measurement matrix

  Gives 14 measurements of each lead, including:

  P amplitude (mV), Q amplitude (mV), R amplitude (mV), S amplitude (mV), T amplitude (mV), ST1 amplitude (mV), STJ amplitude (mV), ST20 amplitude (mV), ST40 amplitude (mV), ST60 amplitude (mV), ST80 amplitude (mV), Q duration (ms), R duration (ms), S duration (ms)

In the R-R mode, ECG analysis provides:

- Measurement parameters, including:

  Sampling Time (s), Total QRS, Heart Rate (bpm), Average RR Interval (ms), Max RR Interval (ms), Min RR Interval (ms),Max/Min (Ratio of Maximum RR Interval to Minimum RR Interval)

  Time-domain analysis index:

  SDNN (Standard Deviation of Normal to Normal Intervals) (ms)

  RMSSD (The Root Mean Square Successive Difference) (ms)

  Frequency-domain analysis indexes:

  Total Power (ms*ms), VLF (extremely low frequency, ms*ms), LF (low frequency, ms*ms), LFnorm (nu), HF (high frequency ms*ms), HFnorm (nu), LF/HF

- RR Histogram
- RR Diff Histogram
- Frequency Chart

In the HRV mode, ECG analysis provides:

- Measurement parameters, including:
  - Heart rate statistical parameters:

    Sampling Time (s), Total QRS, Heart Rate (bpm), Average RR Interval (ms), Max RR Interval (ms), Min RR Interval (ms), Max/Min

  - HRV parameters:

    Time-domain analysis index:

    SDNN (ms), RMSSD (ms), NN50, PNN50 (%)

    Frequency-domain analysis index:

    Total Power (ms*ms), VLF (extremely low frequency, ms*ms), LF (low frequency, ms*ms), LFnorm (nu), HF (high frequency ms*ms), HFnorm (nu), LF/HF
- RR Histogram
- RR Diff Histogram
- Frequency Chart

In Pharma test mode, ECG analysis provides:

- Heart rate trend chart

  The results of measurement and analysis are recorded in ECG report by default.

6.4.2 AI Cloud Mode

After the ECG waveform is stable, click the [Start/Stop] button, the device starts recording the ECG waveform. If you have enabled [Auto Upload] from the [ECG Setup] interface, ECG data is automatically uploaded to the connected server for analysis at the completion of ECG acquisition. After the server returns the diagnosis report, the status of the relevant patient record in the file management menu will change to "Diagnosed", you can view the diagnosis result and print the report.

If the auto upload function is not enabled or the upload fails, ECG data will be automatically stored in the device, and they can be manually uploaded to the server in the file management menu.

6.5 Printing Reports

You can print ECG reports through an external printer.

To use an external printer, select [Setup] → [Record Setup], and set [Print Device] to [Network Printer] or [USB Printer].

- When selecting [Network Printer], you need to set the IP address and port number of the network printer, which can be used after successful connection.
- When selecting [USB Printer], you need to properly connect the USB printer to the device’ s USB port. Make sure the USB printer is connected successfully and powered on.

Before printing a report, check to make sure that there is enough paper in the printer.

To load paper for the external printer, refer to the printer’ s accompanying instructions for use.

☞ **Note**

If the “Preview” option in the “ECG Setup” interface is disabled, the device automatically prints the ECG report after the ECG data is acquired and analyzed.

☞ **Note**

If the "Printout" option in the "Record Setup" interface is disabled, click the [Start/Stop] button to save but can not print the ECG report.

6.6 Copying Reports

The device can print another copy of the latest ECG report.

Operation procedure: In the main interface, click [ ] → [Copy] button:

- When the archived data is not empty, the most recently stored report will be printed directly.
- When there is no report, a “No data!” message appears. Acquire ECG data first.

6.7 Freezing Waveforms

You can freeze the currently displayed waveforms on the screen for a careful observation or printing. If the ECG data is less than 10 seconds before freezing, it is necessary to wait for the device to collect enough data for 10 seconds before freezing.

Operation procedures:

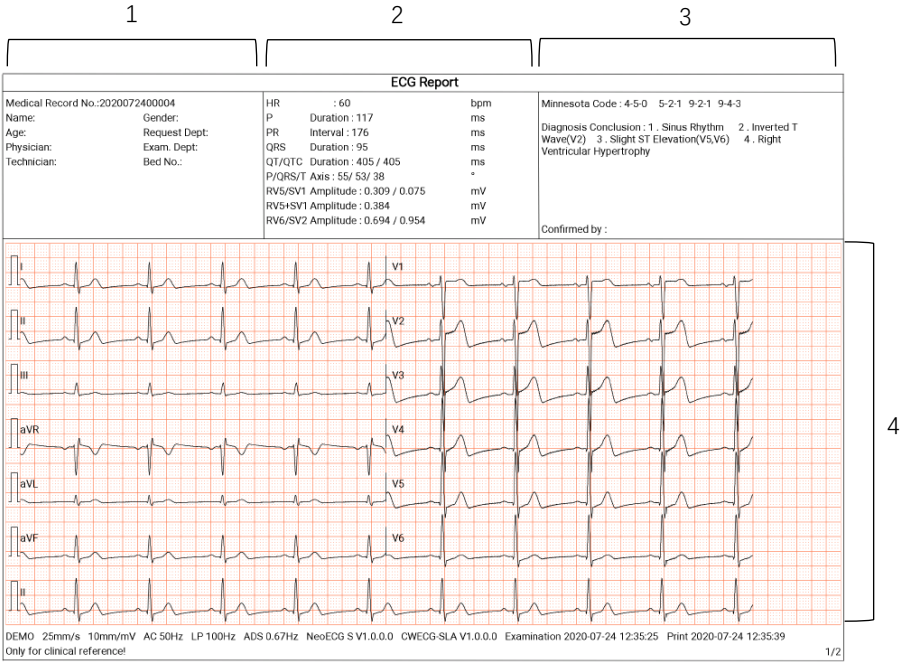
1. In the main interface, click [Freeze] button to enter the waveform freezing interface.
2. Click the [Print] button to print the report.

6.8 Report Examples

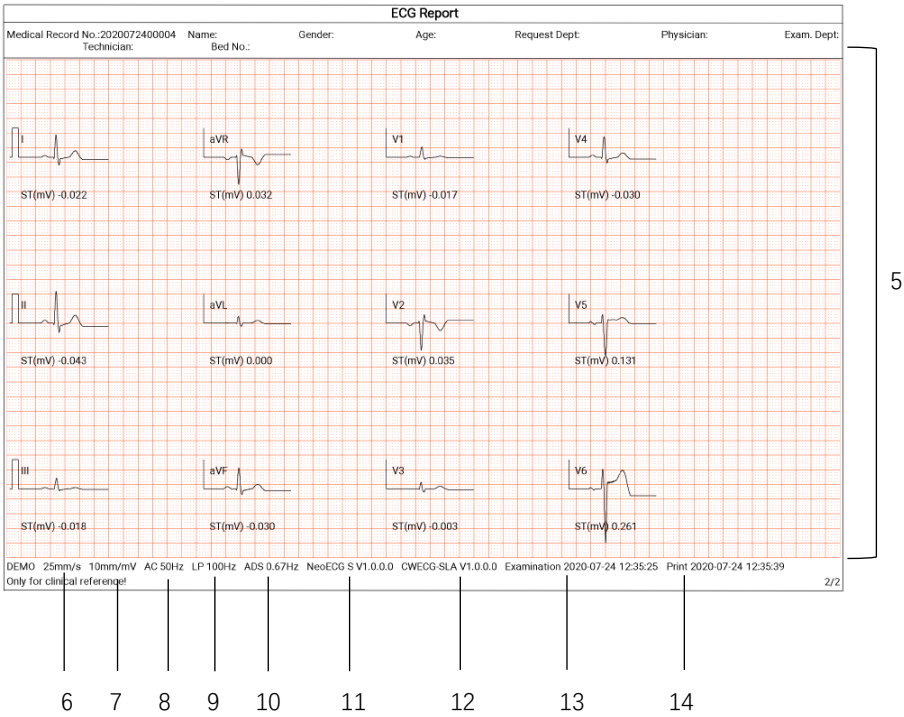
The layout and contents of the reports are configurable, refer to *6.3 Setting ECG Waveform and Report* for details.

6.8.1 Auto mode

Take a 6x2+1R real-time sampling ECG report under the standard 12-lead auto working mode as an example to illustrate the elements in the report. A report usually contain waveform area, patient information area, measurement parameter area, diagnosis conclusion area and average template area (if required).



12-lead 6x2+1R Report (Page 1)

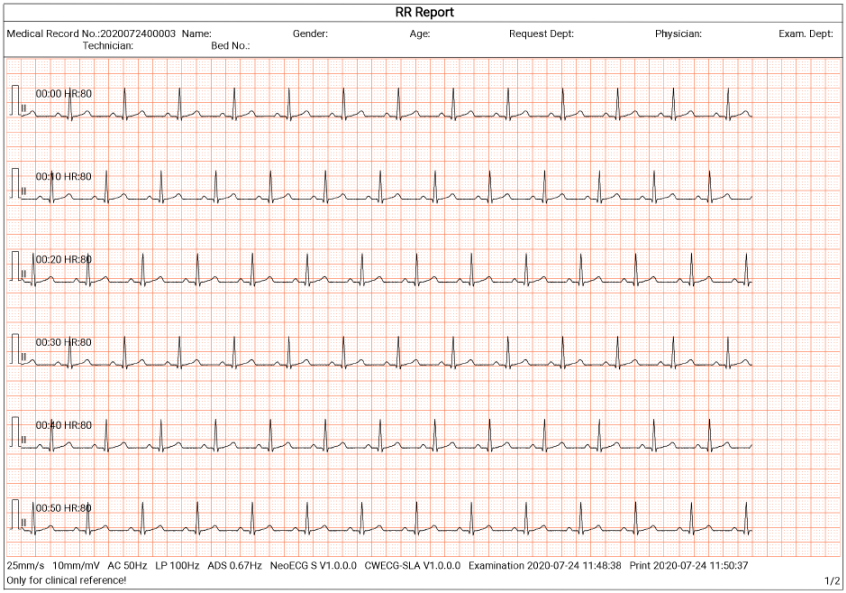


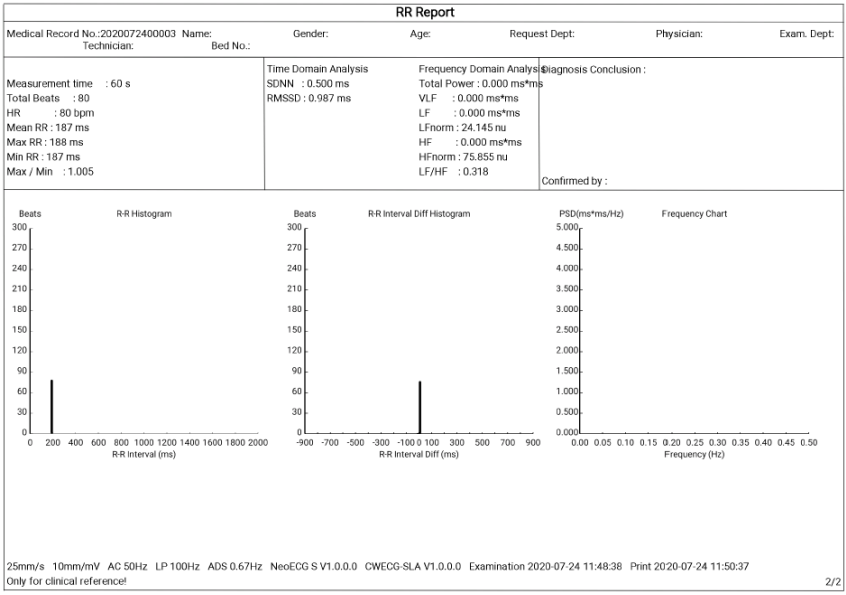
12-lead 6x2+1R Report (Page 2)

1. Patient information area
2. Measurement parameters and auto measurement result area
3. Diagnosis conclusion area
4. Waveform area
5. Average template area
6. Speed
7. Sensitivity
8. AC filter
9. Lowpass filter
10. ADS filter
11. System software version
12. Algorithm version
13. Examination date and time
14. Print date and time

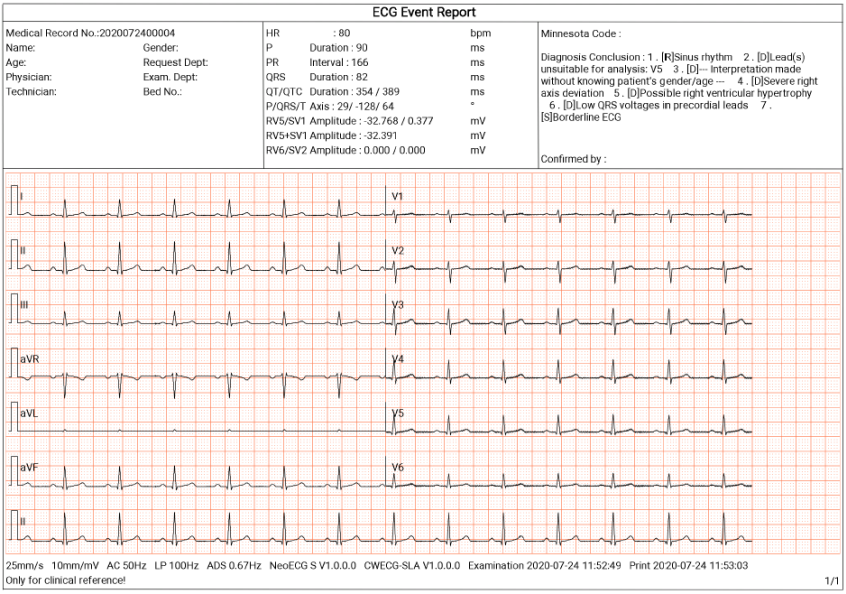
6.8.2 RR analysis

1ch, 1min

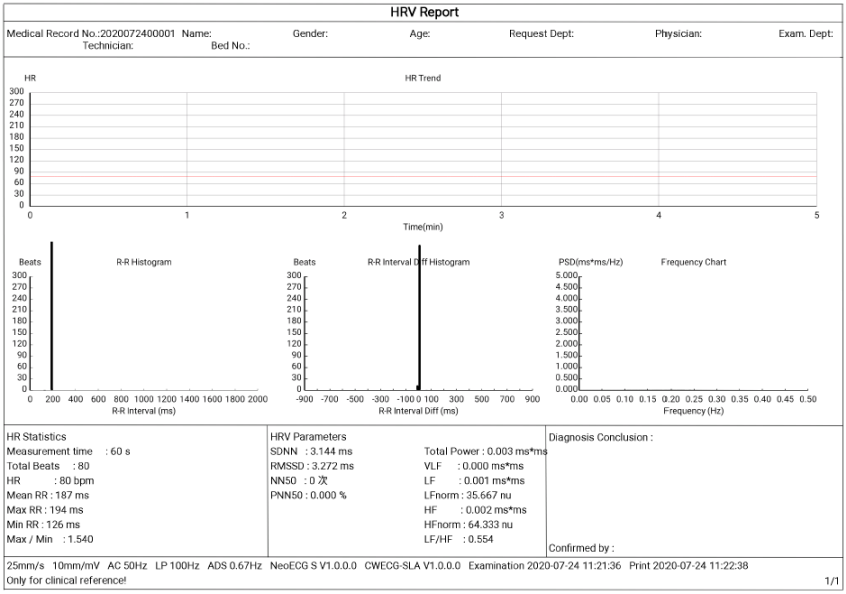




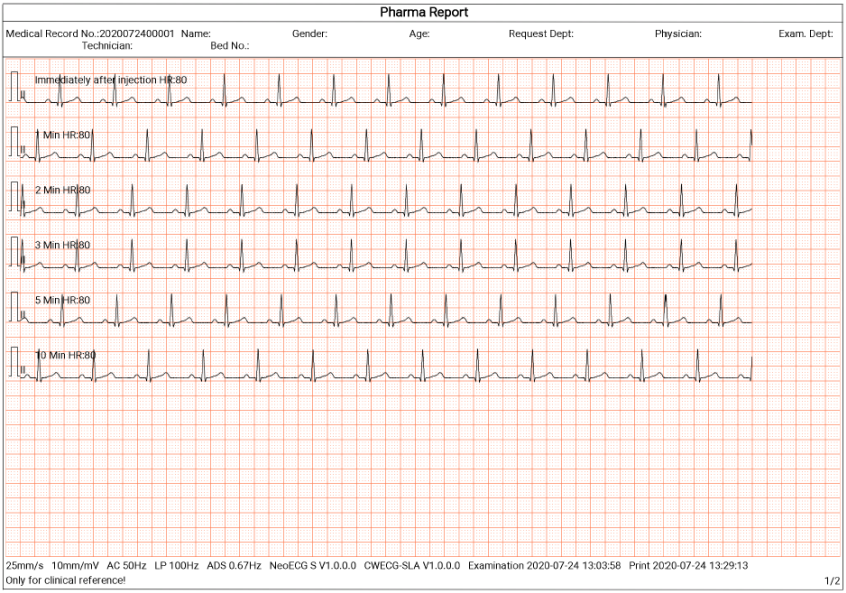
6.8.3 ECG event

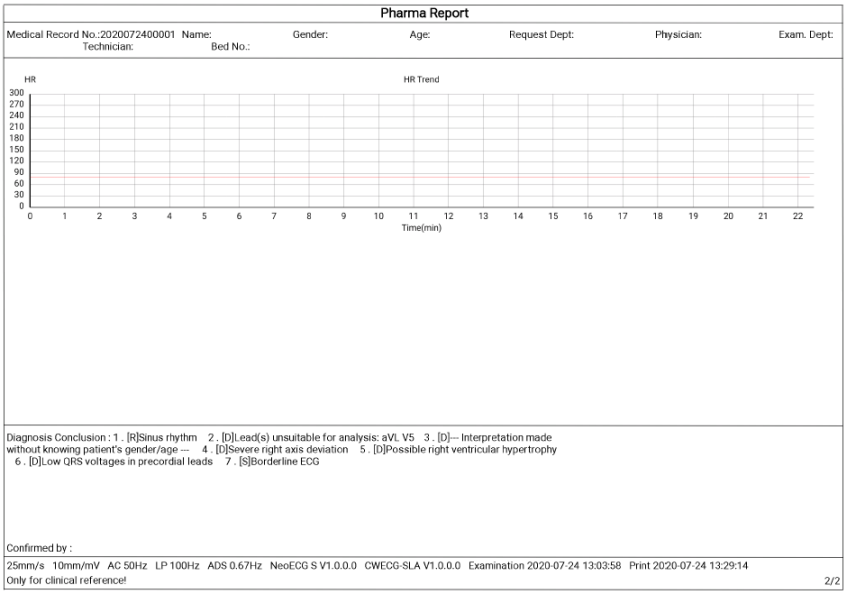


6.8.4 HRV analysis



6.8.5 Pharmaceutical test



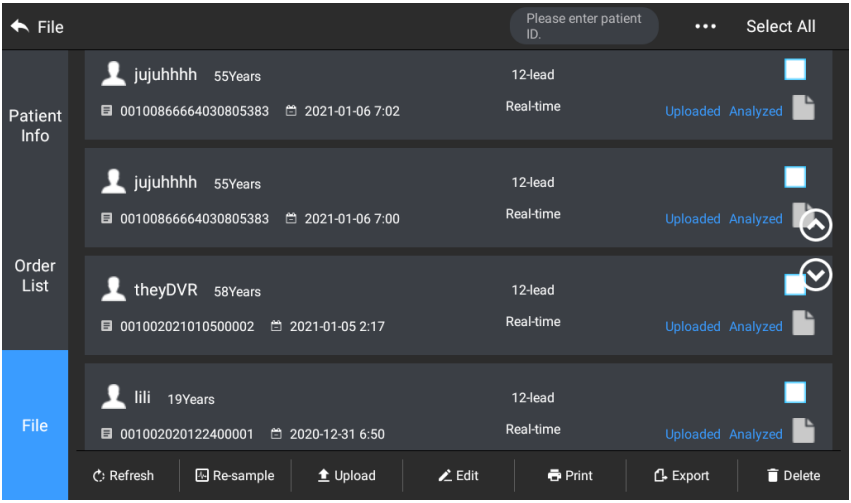


Chapter 7 File Management

In the waveform acquisition interface, click the [File] button to enter the patient file management interface, as shown in the figure below.

In this interface, all files are listed in chronological order, and the latest files are displayed on the top. You can re-acquire, upload, preview, edit, export, print, query and delete the stored historical records.

The device can store 10000 routine ECG reports.



Button	Description
Refresh	Click to refresh the data list.
Re-sample	Click to re-acquire ECG for the selected patient.
Upload	Under the AI cloud mode, click to upload the currently selected ECG data to the AI server.
Edit	Click to perform the following operations on the selected patient data:

Button	Description
	● View waveform data, change waveform display format, sensitivity and speed. ● Edit the patient information (the unique ID cannot be modified). After the current patient information is edited, the corresponding patient information in the patient information list will be updated. ● Edit the diagnosis. ● Re-analysis. ● Save analysis results. ● Print the ECG report of the patient.
Print	Click to print one or more selected patient reports.
Export	Click to export the currently selected report. The system supports exporting reports to USB flash disk in any format of Carewell ECG, PDF, BMP, HL7, DICOM and SCP.
Delete	Click to delete one or more selected patient data.
Search	Enter keywords into the search box to search out all eligible patient files. Click the icon ••• behind the search box, the search condition setting interface will pop up, you can set relevant search conditions for precise search.

Chapter 8 System Settings

In the main interface, click [ ] → [Setup] to enter the setting interface.

Note

The underlined options in the following table are the system default settings.

8.1 ECG Setup

Menu Items	Description
Sampling Mode	Real-time, Trigger, Periodic, Pre-sampling, R-R, Pharma, ECG Event, HRV
Lead Setup	
Lead Mode	9-lead, 12-lead
Layout	For 9-lead: 9×1, 3×3, 3×3+1R, 3×3+3R, 6+3 For 12-lead: 12×1, 6×2, 6×2+1R, 3×4, 3×4+1R, 3×4+3R
Lead Standard	IEC, AHA
Lead Sequence	Standard, Cabrera
Rhythm Setup	
Rhythm Type	Single Lead, Three Leads
Rhythm Lead 1	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Rhythm Lead 2	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Rhythm Lead 3	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Filter Setup	
ADS Filter	0.01Hz, 0.05Hz, 0.32Hz, 0.67Hz

Menu Items	Description
EMG Filter	Off, 25Hz, 35Hz, 45Hz
Lowpass Filter	75Hz, 100Hz, 150Hz, 300Hz, Off
AC Filter	On, Off
Display Setup	
Speed	5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s, 50mm/s
Sensitivity	Auto, 2.5mm/mV, 5mm/mV, 10mm/mV, 20mm/mV, 10/5mm/mV, 20/10mm/mV, 40mm/mV
Arrhythmia Threshold	
Brady	Manually enter a maximum of 3-digit integer number in the text box. The default value is 60. The unit is bpm.
Tachy	Manually enter a maximum of 3-digit integer number in the text box. The default value is 100. The unit is bpm. ☞ **Tip** **The tachycardia value should not be less than the bradycardia value. If the entered value of tachycardia is less than that of bradycardia, a prompt "Tachycardia value should not be less than bradycardia value." will pop up.**
Other Setup	
Auto Upload	Options: On, Off Set whether the ECG report is automatically sent out through the network after measurement finished. You can enable Auto Upload only when the Preview function is disabled.
Auto Save	Options: On, Off Set whether the ECG report is automatically saved on the internal storage after measurement finished.

Menu Items	Description
	If Auto Save is disabled, you can manually save a report when a preview of the report is generated.
Preview	Options: On, Off Set whether to enter the preview interface after measurement finished.

8.2 Patient Info Setup

Menu Items	Description
Patient Info Configuration	
Required Patient Info	The configured unique ID (the default is patient ID), Last Name, First Name, Gender, Age, Date of Birth The unique ID is checked by default and cannot be unchecked.
Detailed Patient Info	Middle Name, Weitht, Height, Blood Pressure, Race, Medication, Medical History, Patient Source, Outpatient ID, Inpatient ID, PE (physical examination) ID, Bed No., ID No., Request Dept, Exam Dept, Physician, Technician, Exam Item, Exam No. and Pacemaker
Basic Setup	
Height / Weight	cm/kg, inch/lb
Blood Pressure	mmHg, kPa
Unique ID	Patient ID, Inpatient ID, Outpatient ID, Accession No.
Patient ID	Auto Accumulation, Manual Input

8.3 Sampling Setup

Menu Items	Description
Sampling Time Setup	
Real-time Sampling	10 Sec, 20 Sec, 30 Sec, 60 Sec
Periodic Sampling	Manually enter an integer number in minutes into the text box The input range is 1-60 Min, and the default value is 60 Min
Periodic Interval	Manually enter an integer number in minutes into the text box The input range is 1-60 Min, and the default value is 1 Min ☞ **Note** **The periodic interval cannot be greater than the total time of periodic sampling.**
HRV	5 Min, 10 Min, 15 Min, 20 Min, 25 Min, 30 Min
RR	1 Min, 3 Min
Pharma	Immediately after injection, 1 Min, 2 Min, 3 Min, 5 Min, 7 Min 10 Min, 15 Min, 20 Min, 30 Min

8.4 Record Setup

Menu Items	Description
Print Setup	
Print Sequence	Synchronous, Sequential
Print Mode	Save Paper, Quick Mode ☞ **Note** **Save paper mode and quick mode are only suitable for printing ECG report in auto mode.**
Print Device	Network Printer, USB Printer
Print Preview	On, Off
Printout	On, Off
Network Printer	
Network IP	When "Network Printer" is selected for "Print Device", set the network IP and port.
Port	
Test	Click this button to test whether the network printer is connected successfully.
Printout Grid	On, Off
Report Setup	
Measurement Parameters	Select whether Measurement Parameters are included in the ECG report generated by auto measurement. Checked by default.
Average Template	Select whether Average Template is included in the ECG report generated by auto measurement. Unchecked by default.

Menu Items	Description
Diagnosis Conclusion	Select whether Diagnosis Conclusion is included in the ECG report generated by auto measurement. Checked by default.
Minnesota Code	Select whether Minnesota Code is included in the ECG report generated by auto measurement. Unchecked by default.
Print Time	Select whether Print Time is included in the report. Unchecked by default.
Measurement Matrix	Select whether Measurement Matrix is included in the ECG report generated by auto measurement. Unchecked by default.
Time Scale	Select whether Time Scale is included in the ECG report generated by auto measurement. Unchecked by default.

8.5 Communication Setup

8.5.1 Mobile Network

The device can be equipped with mobile network module. Insert the mobile network card and enable the [Mobile Network] function to transmit ECG data through mobile network.

Caution

To ensure the normal network connection, please make sure that the account of the mobile network card has not been in arrears.

8.5.2 WLAN Setup

Enter the WLAN setting interface and turn on/off the WLAN switch to enable or disable the WLAN.

After WLAN is enabled, the device starts to search for available wireless networks in the area. Select the one you would like to connect. If the wireless network is secured, there will pop up a window requiring password. Enter the correct password, then click [Connect]. In a short while, a wireless connection is set up.

8.5.3 Server Setup

Menu Items	Description
AI Server	Options: Platform, CardIot Set the AI server that needs to connect.
IP Address	Enter the IP address of the AI server. Then click the [Test] button to test the network connection.
Local IP	Enter your local IP.

8.6 System Setup

8.6.1 Display & Sound

Menu Items	Description
Brightness	Drag the slider to adjust the brightness of the screen
Volume	Drag the slider to adjust the volume of the device.
Touch Tone	On, Off
QRS Beep	On, Off
Low Battery Beep	On, Off
Lead-off Beep	On, Off
Print End Beep	On, Off

8.6.2 Date & Time

Menu Items	Description
Date Format	Options: yyyy-mm-dd, mm-dd-yyyy, dd-mm-yyyy
Time Format	Options: 12h, 24h
Current Date	Set the current date
Current Time	Set the current time

☞ **Note**

In AI cloud mode, after connecting to the network, the time of the device is synchronized with that of the server.

8.6.3 Other Setup

Menu Items	Description
Language	Set the system language. Options: Simplified Chinese, English
Demo	Options: Off, Normal ECG, Abnormal ECG
Diagnostic Mode	Options: Auto Diagnosis, AI Cloud Mode
Glasgow Algorithm	Options: On, Off Get authorization first to enable Glasgow algorithm analysis function. When enabled, the Glasgow algorithm is automatically used for ECG analysis at the completion of ECG acquisition in the auto measurement mode.
Institution Name	Enter the name of the medical institution.
Auto Standby	Set the time for the device to automatically enter standby mode. Options: Off, 5 Min, 10 Min, 20 Min, 30 Min, 60 Min When you select [Off], the device will not automatically enter the standby mode.
Technician No.	Enter the number of the examining technician.
Restore Default Settings	Click to confirm whether to restore the default settings. This operation will restore all settings to their default values (record data will not be deleted).

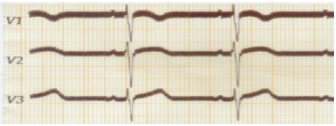
8.7 System Maintenance

In the setting interface, click [System Setup] → [System Maintenance] to enter the system maintenance interface.

Menu Items	Description
AC Frequency	Set the frequency of AC filter. Options: 50Hz, 60Hz
SCP	It can only be used after authorization, and "Authorized" will be displayed after authorization.
HL7	It can only be used after authorization, and "Authorized" will be displayed after authorization.
DICOM	It can only be used after authorization, and "Authorized" will be displayed after authorization.
Glasgow Algorithm	It can only be used after authorization, and "Authorized" will be displayed after authorization.
QR Code Setting	Set the start address and end address of each field, as well as the gender code, according to actual needs.
Factory Maintenance	Enter the password to access the factory maintenance interface.

Chapter 9 Prompt Messages and Troubleshooting

No.	Messages or Troubles	Solutions
1	*XX lead off (All leads off)*	1. Open the lead connection map to check the placement of electrodes. Re-apply the electrodes or reconnect the lead wires if necessary. 2. Check that the patient cable is properly connected to the device.
2	*Low battery!*	Charge the battery immediately.
3	*Battery depleted. Power off soon.*	Connect the DC power supply to power the device and charge the battery immediately.
4	*Export failed*	Close the prompt window. Export data again.
5	*Insufficient memory space*	Delete unwanted historical files or change the storage device / location.
6	Some Lead without Waveform Printout	If you acquire the ECG data immediately after the leadwires are applied to the patient, the ECG traces may not display because the ADS is not stable yet. Normally it is necessary to wait for the waveform of each lead to be stable if all leads are in good contact before ECG measurement.
7	AC Interference Symptom: There is an overlap of 50Hz sine wave with certain amplitude and regularity on the ECG traces, and obvious	Check the following aspects of the device for solving problems: ● The device is properly grounded.

No.	Messages or Troubles	Solutions
	jitter appears on the ECG baseline. 	● The electrodes and leadwires are correctly connected. ● Enough conductive paste is applied to the electrodes and the patient's skin. ● Patient bed is properly grounded. ● Patient not come into contact with conducting objects such as metal parts of the patient bed. ● Nobody is touching the patient. ● There is no powerful electrical equipment operating nearby, such as X-ray machines or ultrasonic instruments. ● The patient is not wearing glass or diamond ornaments. ● AC filter frequency is properly set. **If the interference cannot be cleared after the above measures, use an AC filter, and the recorded waveform is slightly attenuated.**
8	EMG Interference Symptom: The ECG has irregular fluctuation while the baseline demonstrates no change. 	Check the following aspects of the device for solving problems: ● The room is uncomfortable? ● The patient is nervous or feels cold? ● The bed is too narrow? ● The patient is talking? ● The limb electrode clamps are attached too tightly?

No.	Messages or Troubles	Solutions
		If the interference cannot be cleared after the above measures, use an EMG filter, and the recorded waveform is slightly attenuated.
9	The printed ECG waveform is out of the grid area of the printing paper.	It is caused by the great fluctuation of the waveform. Set the sensitivity to "Auto". The device will automatically adjust the sensitivity according to the amplitude of the ECG signal.
10	Baseline drift. Symptom: The printed ECG baseline irregularly moves up and down.	Check the following aspects of the device for solving problems: ● The electrodes are firmly attached? ● The lead wires are properly connected to the electrodes? ● The electrodes and the patient's skin are clean? ● Whether enough conductive paste is applied to the electrodes and the patient's skin. ● During the recording, the patient moves or breathes. ● Mixed use of old and new electrodes. **If the interference cannot be cleared after the above measures, use an ADS filter.**

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Chapter 10 Cleaning, Disinfection and Maintenance

Sterilization is not recommended for this device and its accessories, but they should be kept clean. If the device has become contaminated, clean it before disinfection.

10.1 Recommended Cleaning Agents

Supported cleaning agents: water, neutral soap solution, ethanol solution (volume ratio: 70% to 80%).

Supported cleaning tools: cotton ball, soft gauze, soft brush, soft cloth.

10.2 Cleaning

10.2.1 Cleaning the Device

Clean the exterior surface of the device monthly or more frequently if needed. Before cleaning the device, consult your hospital’ s regulations for cleaning the device.

To clean the device, follow the steps below:

1. Turn off the device and disconnect it from the power cable and accessories.
2. Clean the surface of the device with a clean soft cloth moistened with one of the recommended cleaning agents.
3. Wipe off all the cleaning agent residue with a clean dry cloth. Dry your device in a ventilated, cool place.

10.2.2 Cleaning Patient Cable and Electrodes

Before cleaning the patient cable and electrodes, remove the patient cable from the device.

For the cleaning of the patient cable and electrodes, refer to their instructions for use delivered with the accessories.

10.3 Disinfection

Disinfection of main unit of the device is not necessary. To avoid permanent damage to the device, disinfection can be performed only when it has been considered as necessary according to your hospital’s regulations. Before disinfection, clean the device first.

For the disinfection of the patient cable and electrodes, refer to their instructions for use delivered with the accessories.

10.4 Routine Maintenance

To ensure the performance and safety of the device and its accessories, routine care and maintenance should be carried out.

10.4.1 Main unit

Follow the below guidelines to maintain the main unit:

- Avoid excessive temperature, sunshine, humidity or dirt. Prevent shaking it violently when moving it to another place.
- Prevent any liquid from penetrating into the device, otherwise the safety and performance of the device can not be guaranteed.
- Regularly check the device performance by the medical device service department.

10.4.2 Patient cable

Follow the below guidelines to maintain the patient cable:

- Regularly check the integrity of the patient cable. Make sure that it is conductible.
- Do not drag or twist the patient cable with excessive stress while using it.
- Hold the connector plug instead of the cable when connecting or disconnecting the patient cable.
- When cables and leadwires are not to be used, coil it with a larger diameter or hang it up to avoid twisting or folding at acute angles.
- Once damage or aging of the patient cable is found, replace it with a new one immediately.
- For the replacement cycle of the patient cable, refer to its instructions for use.

10.4.3 Electrodes

Follow the below guidelines to maintain the electrodes:

- Clean the electrodes after each use and make sure there is no remainder gel on them.
- Keep the rubber bulbs of chest electrodes away from direct sunshine and excessive temperature.
- After long-term use, the surfaces of electrodes will be oxidized because of erosion and other causes. At this time, electrodes should be replaced to achieve high-quality ECG records.
- For the replacement cycle of the electrodes, refer to their instructions for use.

10.5 Regular Maintenance

The device shall be calibrated and measured at least once a year according to local regulations.

10.6 Viewing System Information

When performing maintenance for the device, you may need to check the system information.

In the main interface, click [ ] → [Setup] → [System Setup] → [My Device] to view the software version, algorithm version, unique device identifier (UDI) of the device, and perform system upgrades.

Chapter 11 Accessories

The recommended standard and optional accessories are listed in the table below:

Accessory	Model/Type	Quantity
DC power adapter	PH30-12	1
Patient cable	ECG-FD10X4 (CE) ECG-FD08X4 (US)	1 set
Chest electrodes	ECG-FQX41	6 pcs
Pediatric chest electrodes (optional)	ECG-EQD01	6 pcs
Limb electrodes	ECG-FJX42	4 pcs
Pediatric limb electrodes (optional)	ECG-EJ01	4 pcs
Adult disposable adhesive electrodes (optional)	915W50	50 pcs
ECG adapter (optional)	Banana connector (4.0) female	10 pcs
Rechargeable lithium battery	1054090 / 7.4V / 5000mAh	1

For the replacement cycle and replacement method of the patient cable and electrodes, refer to the instructions for use provided with the accessory.

Warning

Use accessories specified in this chapter. Using other accessories may cause damage to the device or not meet the claimed specifications in this manual. Or else, the performance and electric shock protection or defibrillation protection cannot be guaranteed.

⚠ Warning

Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.

⚠ Warning

Reuse of disposable accessories may cause a risk of contamination and reduce the performance of the device.

Appendix A Technical Specifications

A.1 Safety Specifications

Standards	MDD 93/42/EEC	Medical Device Directive
	IEC 60601-1: 2005+A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	IEC 60601-2-25: 2011	Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs
	IEC 60601-1-2: 2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
Classifications	Anti electric-shock type:	Class II with internal power supply
	Anti electric-shock degree:	Type CF with defibrillation protection
	Degree of protection against harmful ingress of water:	IPX2
	Installation and use:	Portable, not permanent installation device
	Working mode:	Continuous operation
	EMC:	Group Ⅰ, Class B
	Degree of safety of application in the presence of flammable gas:	Equipment not suitable for use in the presence of flammable gas

A.2 Environment Specifications

Environment	Temperature	Relative Humidity (non-condensing)	Atmospheric Pressure
Operating	0℃ ~ 40℃	15% ~ 85%	700hPa ~ 1060hPa
Transport & Storage	-20℃ ~ +55℃	15% ~ 95%	700hPa ~ 1060hPa

A.3 Physical and Hardware Specifications

Main unit	Dimensions	197mm×112.4mm×26.1mm (Length×Width×Height)
	Weight	0.8kg, including the main unit and battery, excluding accessories
	Display	7 inches, color LCD touch screen Resolution: 1024 × 600 pixels
Power supply	AC Power	Rated voltage: 100-240V~
		Rated frequency: 50/60Hz
	Built-in rechargeable lithium-ion battery	Rated voltage: 7.4V
		Rated capacity: 5000mAh
		Run time: When using only the internal battery, under normal circumstances, when the battery is fully charged, the device can work normally for more than 12 hours (acquiring ECG every 5 minutes); and if putting the device into standby mode, the battery can last for at least 72 hours.
		Charge time: Charge the battery for at least 5 hours before using it for the first time. For a depleted battery with the device power off: ≤4h to 90% capacity ≤5h to 100% capacity

A.4 ECG Specifications

HR Measurement	Method	Peak-peak detection
	Measurement range	30bpm~300bpm
	Accuracy	±1bpm
Main unit	Leads	9-lead and 12 lead synchronous acquisition
	A / D conversion	24 bits
	Sampling rate	32000 points / sec
	Common mode rejection ratio (CMRR)	⩾140dB (AC filter on) ⩾120dB (AC filter off)
	Time constant	⩾5s
	Frequency response	0.01Hz ~ 350Hz $^{+0.4dB}_{-3.0dB}$, 10Hz
	Sensitivity	Auto, 2.5mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV, 40 mm/mV Accuracy: ±5%
	Filter	AC filter: 50Hz, 60Hz, Off
		EMG filter: 25Hz, 35Hz, 45Hz, Off
		ADS filter: 0.01Hz, 0.05Hz, 0.32Hz, 0.67Hz
		Lowpass filter: 75Hz, 100Hz, 150Hz, 300Hz, Off
	Paper speed	5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s and 50mm/s Accuracy: ±3%

	Input impedance	⩾100MΩ (10Hz)
	Input circuit current	⩽10nA
	Calibration voltage	1mV±2%
	Depolarization voltage	±900mV, ±5%
	Noise	⩽12.5μV
	Amplitude quantization	0.95μV/LSB
	Recovery time after defibrillation discharge	<10s
	Pacing pulse display	Pacing pulse with amplitude of ±2mV~±700mV, duration of 0.1ms~2.0ms, rise time of less than 100μs, and frequency of 100/min can be displayed on the ECG recording.
	Minimum detectable signal	20μVp-p
Analysis algorithm	Glasgow Resting ECG Analysis Program	

Appendix B EMC and Radio Regulatory Compliance

B.1 EMC Compliance

Basic performance: The device can acquire ECG data normally.

Warning

Using accessories other than those specified for the device may result in increased emissions or decreased immunity of the device.

Warning

The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify that it can run normally in the configuration in which it is used.

Warning

The device may still be interfered even if other devices meet the emission requirements of the corresponding national standards.

Caution

Users shall install and use the device according to the EMC information provided in the this manual.

Caution

Mobile or portable RF communication equipment may affect the performance of the device. Avoid strong electromagnetic interference when in use, such as near mobile phones, microwave ovens, etc.

Caution

When the input signal amplitude is lower than the minimum amplitude (20μVp-p) specified in the technical specifications, the measurement result may be inaccurate.

Caution

The customer or the user of the device should assure that the device is used under the electromagnetic environment specified below, otherwise the device may not work normally.

The following cables must be used to meet electromagnetic emission and anti-interference requirements:

No.	Name	Length	Shield (Yes/No)
1	Patient cable	Approximately 3.2m	Yes

The guidelines and manufacturer’ s declaration are detailed in the following tables:

Table 201

Guidance and manufacturer's declaration – electromagnetic emission		
The device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group I	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The device is suitable for use in all establishments, other than domestic and those

Harmonic emissions IEC 61000-3-2	Class A	directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 202

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 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%.
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 differential mode	±1 kV differential mode	Mains power quality should be that of a typical commercial or

	±2 kV common mode	±2 kV common mode	hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 sec	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (30% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterrupted power supply or a battery.
Power frequency (50/60Hz) 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: U_T is the a.c. mains voltage prior to application of the test level.			

Table 204

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 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 metres (m). 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).
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

			Interference may occur in the vicinity of equipment marked with the following symbol:

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 the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

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

Table 206

Recommended separation distances between portable and mobile RF communications equipment and the electrocardiograph			
The electrocardiograph is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the electrocardiograph as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output of transmitter/W	Separation distance according to frequency of transmitter/m		
	150kHz to 80MHz $d=[\frac{3,5}{V_1}]\sqrt{P}$	80MHz to 800MHz $d=[\frac{3,5}{E_1}]\sqrt{P}$	800MHz to 2.5GHz $d=[\frac{7}{E_1}]\sqrt{P}$
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 metres (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 80MHz and 800MHz, 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.**			

B.2 Radio Regulatory Compliance

RF parameters are shown in the table below:

WiFi compliance standard	IEEE 802.11 ac/b/g/n (2.4G & 5G)
3G system / frequency band	TD-SWCMDA: B34, B39
	WCDMA: B1
4G system	FDD: FDD B1 / B3 / B5 / B7
	TDD: TDD B38 / B39 / B40 / B41

Appendix C Sensitivity Test and ECG Waveform Distortion Test

C.1 Sensitivity Test

Testing device: Calibration Device for Electric Cardiac Monitor

Testing method:

1. Connect the tested electrocardiograph with the calibrator through patient cable, and set the sensitivity of electrocardiograph at 10mm/mV. The calibrator outputs a sine wave signal with a peak value of 1mV and a frequency of 10Hz to the tested electrocardiograph.
2. Adjust the sensitivity of the electrocardiograph, and adjust the peak-peak value of the calibrator according to the set sensitivity, input a sine wave signal with the frequency of 10Hz to make the peak value of the waveform display theoretically be 10mm, and confirm the peak-peak value displayed by lead I of the electrocardiograph.
3. According to the methods in steps 1 and 2 above, change the leads of the electrocardiograph in turn, and connect the output signal of the calibrator to the corresponding lead of the electrocardiograph to complete the test of all channels. Select the test results with the largest relative deviation from the test results of each test point as the verification result of this item.

Acceptance criteria: The measured calibration voltage is within 5%.

Test cycle: Test the sensitivity once a year according to the above method.

C.2 ECG Waveform Distortion Test

The function of the electrocardiograph will not be affected by pacemaker, which can be verified by the following methods:

1. Superimpose the pulse wave with peak value of 200mV, rise time of less than 100μs, pulse width of 1ms, repetition rate of 100 times / min and sine wave signal with peak valley value of 1mV and frequency of 40Hz, input them to the electrocardiograph, and the time taken for the recorded sine wave signal to return to 70% of the initial value (which should be 10mm when the peak valley value is 1mV and the sensitivity is 10mm/mV) should not be more than 50ms. In the above test, the maximum baseline drift accumulated in 10s is less than 10mm. In the case of pulse and without pulse, the amplitude difference of sine wave signal recording (record after the waveform is stable) is no more than ±1mm.
2. To carry out distortion test, the filter of the electrocardiograph must be turned on.

The electrocardiograph can pass the following tests:

1. Output triangular pulse, 120bpm, 2mV, pulse width 100ms to LA (L). Measure lead I and record the amplitude as B.
2. Set the pacing pulse to 200mV, pacing interval 1ms, pacing rate 120bpm.
3. When measuring lead I, the difference between the amplitude recorded by triangle wave signal and the amplitude B without pulse shall not exceed 20%. And on the ECG record, the position of pacemaker pulse can be clearly identified.

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P/N: SZ09.24300554-01 Revision: V1.0