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ECG-1112M / ECG-1112 / ECG-1112L

Electrocardiograph

Operator's Manual

I Preface

Declaration

Shenzhen Carewell Electronics Co., Ltd. (hereinafter referred to as "Carewell") makes no warranties of any kind, including (but not limited to) implied warranties of merchantability and fitness for a particular purpose. Carewell assumes no responsibility for any errors that may appear in this document, or for incidental or consequential damage in connection with the furnishing, performance or use of this material.

Carewell will make continuous improvement in features and functions for future publication of new equipment without prior notice.

Copyright

Version

P/N: SZ09.24300603-02

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Version: V1.1

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 8 years. Please refer to the label on the back of the main unit for the date of manufacture.

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Table of Contents

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 Operator's 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

This device cannot be used with high frequency surgical equipment.

⚠ 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 of the CF-type application parts, 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. Replace the parts of evident defectiveness or aging which may impair the safety or performance before use the device.

⚠ 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-interference performance 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 display screen, otherwise it may damage the display screen.

⚠ Warning

The measurement and analysis results are for clinician's reference only, and cannot be directly used as the basis of clinical treatment.

1.1.2 Defibrillator / Pacemaker / ESU 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 from the patient in case of any possible burnt. When the electrode paddle 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 electrosurgical units (ESU) when using ESU.

⚠ 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 cannot be reused.

Caution

When installing the thermal recording paper, put the side with grids toward the thermal print head.

Caution

Use only thermal recording paper supplied by the manufacturer. Using other paper may shorten the service life of the thermal print head. And the deteriorated print head may lead to ECG recording of poor quality.

Caution

When used with other medical equipment, connect the equipotentiality of the device to the grounding terminal of the other equipment with the supplied grounding cable, to protect patients from any possible electric shock caused by the other equipment.

Caution

Connect one end of the grounding cable to the equipotentiality of the device and connect the other end to the ground to enhance reliability of grounding. Do not use water pipes or the like as the grounding cable, otherwise, the grounding cannot work and the patient has potential risk of electric shock.

Caution

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

Caution

The ADS filter cannot be set to greater than 0.05Hz and set the low-pass filter less than 150Hz during distortion testing, otherwise waveform distortion may result.

Caution

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

1.2.2 Cleaning & Disinfection Cautions

Caution

Turn off the device, disconnect the power cable 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

The print head gets hot when recording. Do not clean the print head immediately after recording.

Caution

The device shall be disinfected if it is touched by infected patient or suspected patient.

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	PATIENT	Patient cable connector
	External output		External input
LAN	Network port		USB connector
POWER	Alternating current power switch	~AC SOURCE	Alternating current power supply socket
	Equipotentiality terminal		Serial number
	Manufacturer		Date of manufacture
	Caution! Consult accompanying documents		Recovery and recycling
	General warning sign (Background: yellow; Symbol and line: black)		Refer to Operator's Manual (Background: blue; Symbol: white)

Symbol	Description	Symbol	Description
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
UK RP	UK responsible person	CH REP	Authorised representative in Switzerland

Note

Your device may not have all of the above symbols.

Note

This manual is printed in Black and White.

Chapter 2 Product Introduction

ECG-1112M / ECG-1112 / ECG-1112L electrocardiograph (hereinafter referred to as the “device”) is a digital 12-channel ECG test device.

2.1 Intended Use

The cardiogram and heart rate recorded by the ECG can help doctors to analyze and diagnose heart disease or arrhythmia in hospitals.

The device is to be used in medical institutions by qualified clinical professionals or under their guidance. The operators must have received adequate training and be fully competent in the use of the device.

2.2 Applicable Populations

The device is intended for use on adults and pediatrics.

2.3 Contraindication

No contraindication.

2.4 Structure and Composition

The device is mainly composed of main unit, power cable, patient cable, chest electrodes and limb electrodes.

2.5 Model Difference

Model	ECG-1112M	ECG-1112	ECG-1112L
Screen	7 inches, color LCD touch screen	7 inches, color LCD touch screen	7 inches, color LCD screen
User Interface	Colored	Colored	Black and white
Recording Paper	216mm, 210mm	216mm, 210mm	216mm, 210mm
Network Port	Wired network, Wi-Fi network	Wired network	N/A
Remarks	The three models of electrocardiographs have the same display screen, the same internal structure, and identical safety and effectiveness.		

☞ **Note**

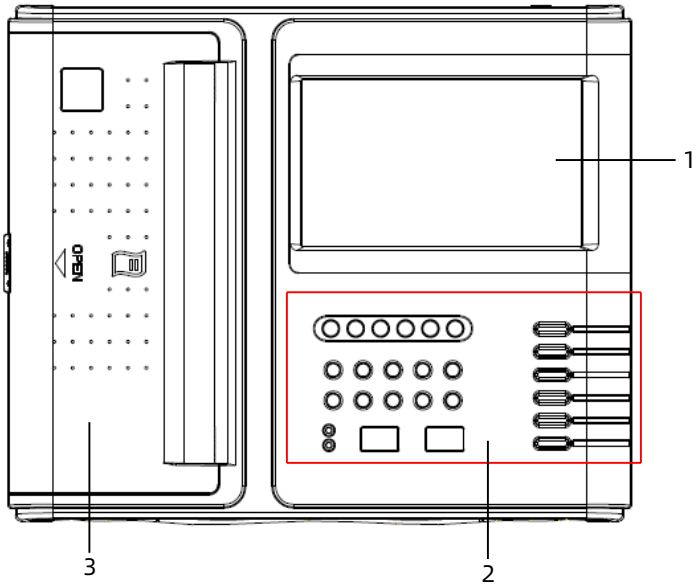
N/A indicates "not applicable".

☞ **Note**

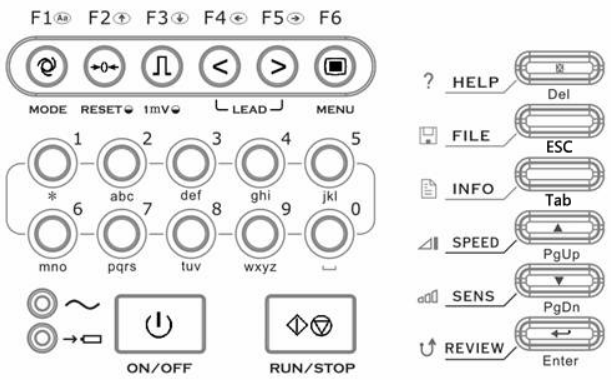
This manual takes the ECG-1112M electrocardiograph as an example to introduce the device, therefore some contents may not be applicable to the device you purchased. If you have any question, please contact us.

2.6 Product Views

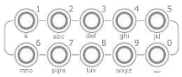
2.6.1 Front View

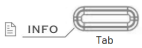


No.	Name	Description
1	LCD screen	Display ECG parameters and waveforms, patient information and system information, etc.
2	Control panel and keys	See description below
3	Thermal recorder	Print ECG report

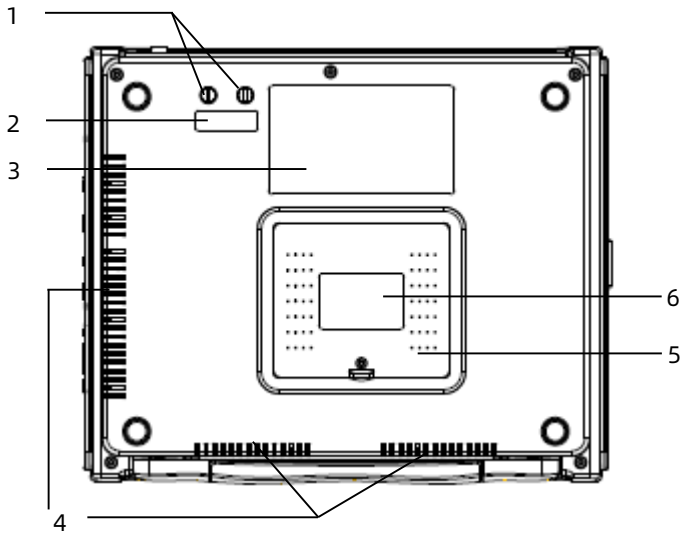


No.	Name	Description
~	AC power indicator	Green: AC power is connected. Off: AC power is disconnected.
→▭	Battery charging indicator	Green: The battery is being charged. Off: The battery is fully charged.
⏻ ON/OFF	Power On/Off key	Press this key to switch between power on and power off states. When using AC power, you need to turn on the AC power switch of the device first, and then press this key to turn on the device. In any screen (except during printing), it is possible to shut down the device, but it is recommended that the operator to shut down the device in the main screen.
◇▽ RUN/STOP	Start/Stop key	Start/Stop recording.

No.	Name	Description
	Mode selection key	Under the main screen, press this key to enter the mode selection screen to select the recording mode and recording format. When editing name and hospital information, this key can be used for language switching.
	Filter setting keys	Under the main screen, press this key to enter the filter setting window to set the AC filter and baseline drift filter.
	1mV calibration key	Under manual mode, press this key to record a 1mV calibration pulse while recording.
	Lead switch key	Under manual mode, press F4/F5 to switch the lead group. In other modes, press F4/F5 to select the switch item. They're also direction keys leftward or rightward in other modes.
	Menu key	Press this key to enter the Menu screen, press it again to exit.
	Numeric/letter keys	Numbers can be entered when editing patient information.
	Help key	Press this key to read helpful information such as electrode

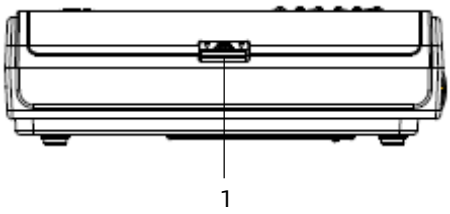
No.	Name	Description
		positioning, ECG basic knowledge, etc. In “Patient Information Input” screen, it can be used to delete input information.
	File key	Press this key to enter “FILE” interface. Press it again to return to main menu. In the main screen, press this key to enter the file management screen. Press it again to return to the main screen. When in other screens, press this key to exit the current screen.
	Info key	In the main screen, press this key to enter the patient information input screen. When in other screens, it has the same function like “Tab” of the PC keyboard.
	PgUp key	Press this key to move the cursor between different options.
	PgDn key	Press this key to move the cursor between different options.
	Enter key	Press this key to confirm

2.6.2 Rear View



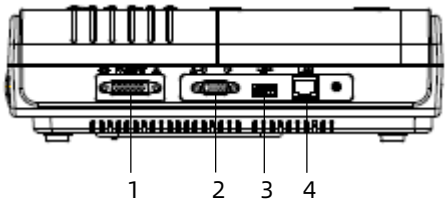
No.	Name	Description
1	Fuse	Two fuses of the same model are installed
2	Fuse label	Provide fuse information
3	Product information label	Provide product-related information, such as product model
4	Heat dissipation holes	Dissipate heat
5	Battery compartment	Built-in rechargeable lithium-ion battery
6	Battery label	Provide information such as the rated capacity of the battery

2.6.3 Left View



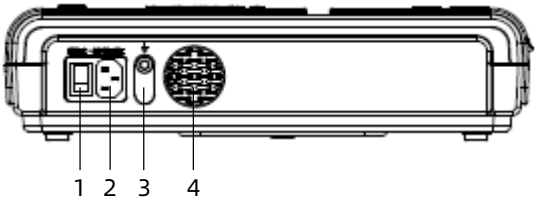
No.	Name	Description
1	Latch of the paper compartment cover	Open the paper compartment

2.6.4 Right View



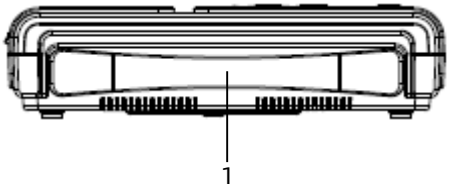
No.	Name	Description
1	Patient cable connector	Connect ECG lead wires for ECG data acquisition
2	RS232 serial port	Reserved function
3	USB port	Connect USB flash disk to transfer data and upgrade system; connect external printer, barcode reader, etc.
4	Network port	Standard RJ45 connector for LAN

2.6.5 Top View



No.	Name	Description
1	AC power switch	I : AC power connected O : AC power disconnected
2	AC power socket	Connect the AC power cable
3	Equipotentiality terminal	Connect the ground wire
4	Heat dissipation holes	For internal heat emission

2.6.6 Bottom View



No.	Name	Description
1	Hidden handle	For users to hold when carrying the device

2.7 Function Features

The device has the following features:

- 7-inch colourful touch screen, easy to operate.
- Multi-language support.
- Can be powered by AC power supply or a built-in rechargeable lithium battery.
- Support 12-lead automatic ECG acquisition, display and heart rate detection.
- Support 3 working modes: auto, manual, and R-R.
- Provide 4 sampling modes: pre-sampling, real-time sampling, periodic sampling and trigger sampling.
- Provide 7 printing modes: 3x4, 3x4+1R, 3x4+3R, 6x2, 6x2+1R, 12x1, 1x12.
- Support automatic pacing detection and marking.
- Support baseline anti-drifting and EMG (electromyograph) interference.
- Support entering patient information through the full keyboard or a barcode reader.
- Support freezing the ECG waveform on the current screen.
- Output files in multiple formats, such as DAT (Carewell ECG), XML, JPEG, PDF.
- Auto-saving function: save the ECG data when the report is printed.
- Store, preview, export, upload, print and search patient data.
- Print ECG reports through either the internal thermal recorder or external USB/network printer.
- Export patient data to USB flash disk via USB port.

- Support external barcode reader and printer via USB port.
- Support transmission of ECG data via LAN or WiFi.
- Provide the electronic help information.

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Chapter 3 Getting Started

3.1 Unpacking and Checking

Before unpacking, please check 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.

> ⚠ **Warning**
>
> **Use a three-pin socket with a protective ground, and ensure that the protective ground of the socket is intact.**

Caution

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

Caution

Make sure that the installation and use environment of this device is free of strong electromagnetic interference sources, such as wireless transmitters or mobile phones. Large electrical equipment such as electrosurgical equipment, ultrasound equipment, radiograph machine, and magnetic resonance imager may cause electromagnetic interference.

3.3 Preparing the Device

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

1. Using the Battery
2. Loading the Recording Paper
3. Connecting the Patient Cable and Electrodes
4. Connecting the AC Power Supply
5. Connecting the Grounding Cable
6. Inspections Before Power-On
7. Turning On/Off the Device
8. Setting Up the Device

3.3.1 Using the Battery

The device can be powered by a rechargeable lithium battery. When a battery is installed, the device will automatically run from battery power in case of power failure of the AC power supply.

✦ **Installing/Replacing the Battery**

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

1. Loosen the screws on the battery compartment cover with the accompanying screw driver, and remove the battery compartment cover.
2. Put the battery in place and correctly connect the battery plug to the socket.
3. Close the battery compartment cover and tighten the screws.

Replace the battery when the battery has been recharged over 300 times.

✦ **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.

The battery is charged whenever the device is connected to the AC power source 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 lower right corner of the main screen dynamically displays the charging state of the battery.

For charge time and run time of the battery, see *A.4 Power Supply Specifications*.

Caution

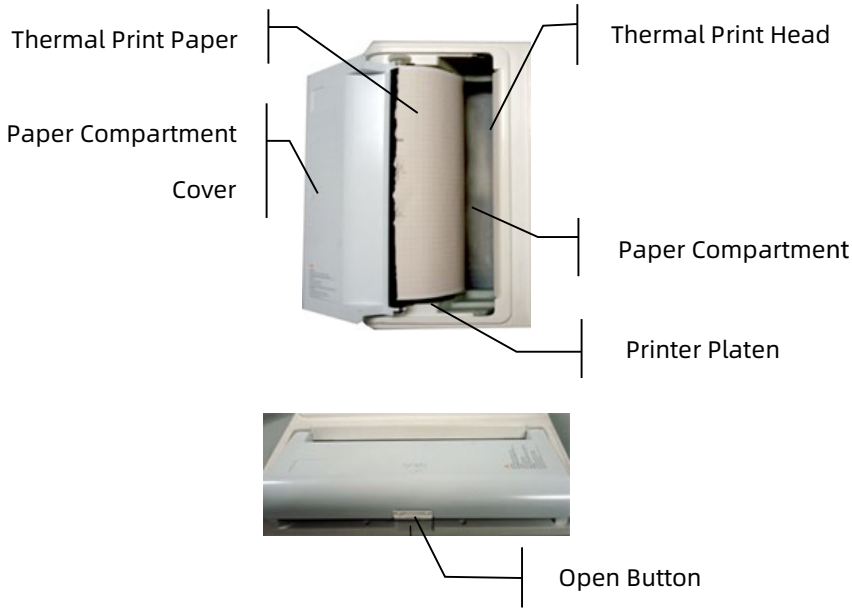
The battery is put into the battery compartment without connecting to the battery socket at factory. After receiving the device, if built-in rechargeable battery is to be used, connect the battery to the socket first.

Caution

Charge the battery for at least 5 hours before using it for the first time.

3.3.2 Loading the Recording Paper

The device uses 216mm/210mm width roll thermal sensitive paper as the recording paper. The prompt information area will display "No paper" when there is no paper or the paper is not properly installed.



To load the recording paper, follow the steps below:

1. Press and hold the Open Button, toggle it slightly downward to open the paper compartment cover.
2. Take out the paper roller, remove remaining paper if necessary. Insert the paper roller into the new paper roll, refer to the label at the bottom of the paper compartment

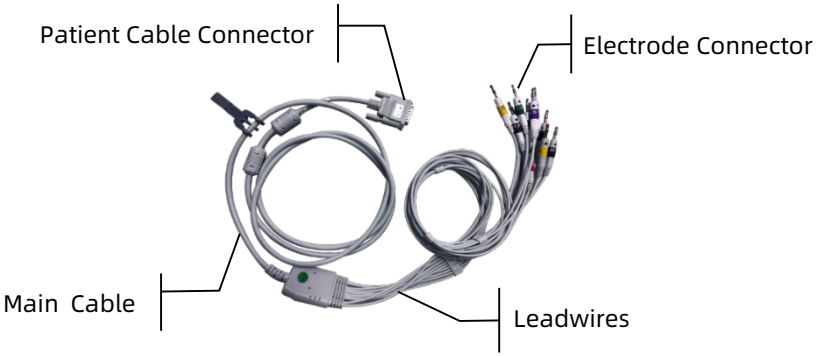
for the position of the paper roller. Be sure that the paper is installed with the paper's grid side facing upward.

3. Pull about 2cm of the paper out, and close the paper compartment cover gently.

3.3.3 Connecting the Patient Cable and Electrodes

- ECG Accessories

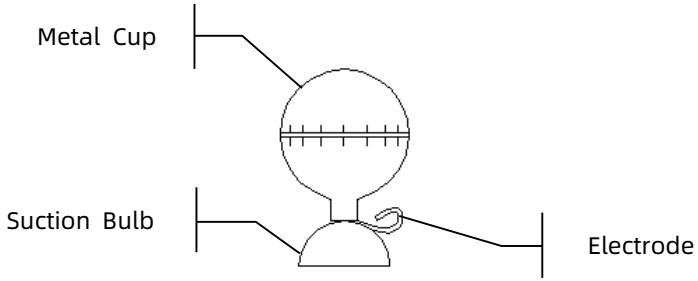
Patient Cable:



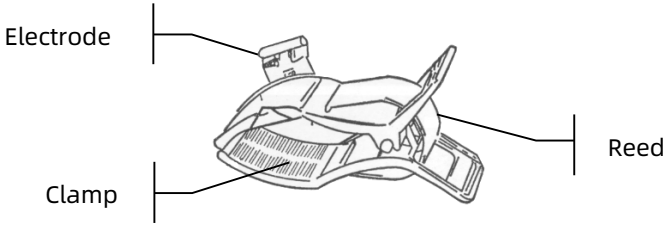
The patient cable consists of a patient cable connector, main cable, leadwires (4 limb lead wires and 6 chest lead wires) and electrode connectors:

- The patient cable connector is used to connect to the electrocardiograph.
- The leadwires are connected to the electrode connectors.
- The electrode connectors are used to connect chest electrodes and limb electrodes. Each electrode connector is labelled with corresponding color and letter. Electrodes have different codes and colors according to different standards.

Chest Electrode:



Limb Electrode (Clamp):



- Connecting the Patient Cable

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

- Connecting the Electrodes

Connect the electrode connectors with chest electrodes and limb electrodes respectively.

This device adopts Wilson lead system. According to different standards, electrode codes and colors are different.

The electrode identifiers and color codes of the internationally accepted IEC and AHA standards are shown in the table below.

IEC		AHA	
Identifier	**Color Code**	**Identifier**	**Color Code**
R	Red	RA	White
L	Yellow	LA	Black
N or RF	Black	RL	Green
F	Green	LL	Red
C1	White/Red	V1	Brown/Red
C2	White/Yellow	V2	Brown/Yellow
C3	White/Green	V3	Brown/Green
C4	White/Brown	V4	Brown/Blue
C5	White/Black	V5	Brown/Orange
C6	White/Violet	V6	Brown/Violet

3.3.4 Connecting the AC Power Supply

To connect the AC power to the device, follow the steps below:

1. Insert the three-wire plug of the power cable into an AC receptacle.
2. Insert the other end of the power cable into the AC power connector of the device.
3. Press the AC power switch (“I” means AC power is connected).
4. Check whether the AC power indicator is on to ensure that the AC power connection is normal.

3.3.5 Connecting the Grounding Cable

When using the device together with other devices, connect their equipotential grounding terminals together with

grounding cable to eliminate the potential differences between them.

3.3.6 Inspections Before Power-On

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

- Operating 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 that a battery is installed and fully charged if you want to run the device on battery power.

Check that power supply specification is met and the power cable is securely connected if the device is powered by AC power supply.

- 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 with each other.

- Recording paper:

Check that recording paper is correctly loaded.

- 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.

3.3.7 Turning On/Off the Device

- **Power On**

Press and hold the power switch for about 2 seconds, the device will display a startup screen, and then enters the main screen.

- **Power Off**

When AC power is used, after finishing ECG test, press and hold the power switch for about 3 seconds, the screen displays the prompt message “Power off?”. Select “Yes” and the device will be off after the screen turns black. And then pull off the power plug from the power connector.

When the built-in battery is used, after finishing ECG test, press and hold the power switch for about 3 seconds, the screen displays the prompt message “Power off?”. Select “Yes” and the device will be off after the screen turns black.

Caution

Press and hold the power button for no less than 6 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.

3.3.8 Setting Up the Device

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

1. Click the [Menu] button on the right side of the main screen to enter the main menu.
2. Select [System Setup].

3. Set the system date and time, and other items as required.

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

> ☞ **Note**
>
> **To operate this device, you can use the hard keys on the control panel or the touch screen, the second method of operation is described in this manual.**

3.4 Preparing the Patient

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

3.4.1 Preparing the Patient Skin

The patient's emotions and body conductivity can obviously affect the quality of 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.

3.4.2 Attaching Electrodes to the Patient

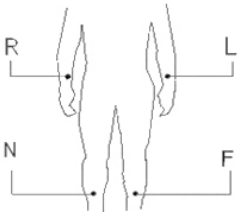
The quality of ECG waveform will be affected by the contact resistance between the patient and the electrode. In order to get a high-quality ECG, the skin-electrode resistance must be minimized when you attach electrodes to patients.

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

✦ **Electrode Placement**

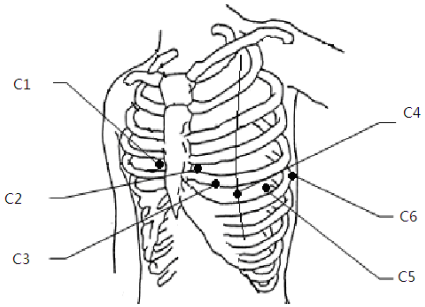
The electrode placement illustrations in this section adopt the IEC naming convention.

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 right border of sternum.

C2: on the fourth intercostal space at left 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 Limb 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.
5. Attach all limb electrodes in the same way.

✦ **Attaching Chest Electrodes**

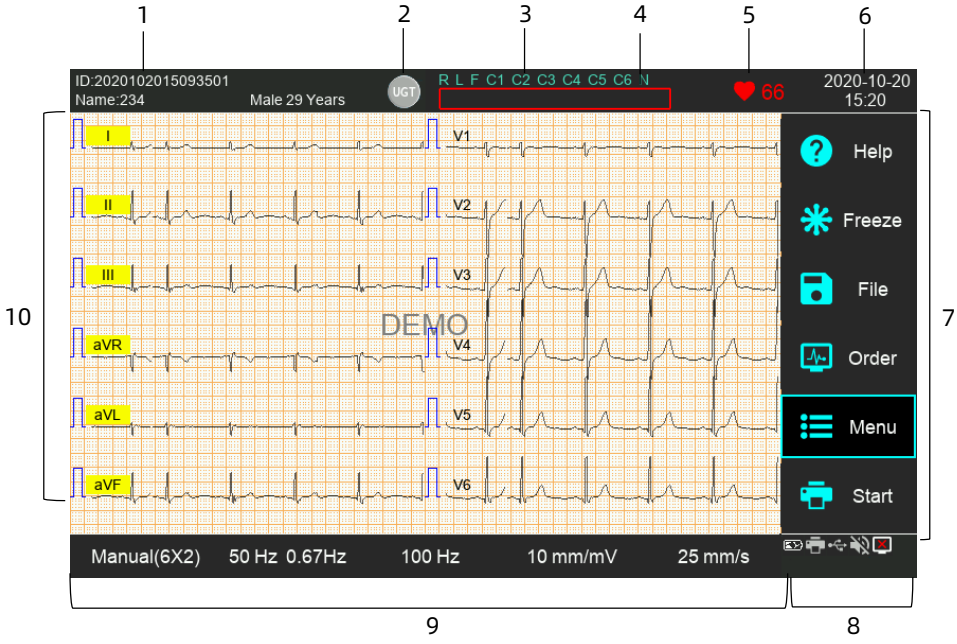
To attach the chest and back electrodes, follow the steps below:

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 / back.
3. Daub a thin layer of conductive paste on the brim of the metal cup of the 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.
5. Attach all chest electrodes in the same way.

Chapter 4 Screen Introduction

4.1 Main Screen

Press the power switch to enter the main screen, namely the normal ECG acquisition screen, as shown in the figure below:



No.	Name	Description
1	Patient information area	The patient information area displays the patient ID, name, gender, age, and age unit and other required information. Click the patient information area to enter the patient information input window to view and edit the detailed patient information, or create new patient information.

No.	Name	Description
2	Urgent button	The default state is not selected (gray). Click (the button turns yellow) to turn the current case into the urgent state. After the urgent case is saved, the urgent symbol (asterisk *) will be displayed in front of the patient ID in the file management screen. When uploading data, the urgent data displays the urgent symbol.
3	Lead indication area	Display the labels of the 12-lead electrodes. Click this area to view the electrode connection diagram and connection status in the pop-up window. The detached electrode will keep flashing.
4	Prompt information area	Display prompt information such as "Leads off: XX", "No paper".
5	Heart rate (HR) area	Display the heartbeat icon and real-time heart rate value. Heart rate measurement range: 30bpm~250bpm. When the heart rate exceeds the measurement range, this area displays "- -". When all the leads or the rhythm leads for calculating the heart rate fall off, this area displays "- -".
6	System time area	Display the system date and time. Click this area to pop up the system time setting window, in which you can quickly set the system date and time.

No.	Name	Description
7	System button area	Display the commonly used system buttons. For more information, see *4.2 System Buttons*.
8	Status icon area	Display the current network, built-in battery, external power supply, external USB device, printer, and sound status. ● Network ➢  : The Wi-Fi connection is successful and the wireless signal strength is displayed. ➢  : The remote diagnosis is turned on, and it is successfully connected to the AI analysis server through the network. ➢  : Successfully connected to third-party server. ➢  : The wired network is not connected, or no server is connected. ● Battery When the device runs on battery power, the battery icon is displayed: ➢  : Fully charged battery. ➢  : 75% power capacity. ➢  : 50% power capacity. ➢  : 25% power capacity. ➢  : The battery is depleted and the device is about to shut down.

No.	Name	Description
		When the device runs on AC power supply, the battery charging icon is displayed: ➢  : The battery is almost depleted and it is being charged. ➢  : 25% power capacity has been charged. ➢  : 50% power capacity has been charged. ➢  : 75% power capacity has been charged. ➢  : Fully charged. ● Power supply  : AC power is connected. Not displayed when not connected. ● USB device  : USB device is connected. Not displayed when not connected. ● Printer ➢  : Thermo-sensitive printer or external printer is connected. ➢  : No printer is connected. ● Sound status ➢  : The mute mode is turned off. ➢  : The mute mode is turned on.
9	Quick key area	Support quick setting of the record mode and record format, filter, gain, and paper feed speed.

No.	Name	Description
10	Waveform area	Display 12 ECG waveforms in auto and manual working mode. Display a single channel or 3-channel waveform(s) in R-R mode.

4.2 System Buttons

Button	Description
Help	Click this button to enter the ECG help screen, which contains help instructions such as electrode placement, basic knowledge of ECG, common failure and troubleshooting methods.
Freeze	After clicking this button, the ECG waveforms on the screen stop refreshing and scrolling. For details, see *6.7 Freezing Waveforms*.
File	Click this button to enter the file management screen, where you can add and modify patient information; perform operations such as viewing, querying, exporting, and printing ECG data. For details, see *Chapter 7 File Management*.
Order	Click this button to enter the order list screen. After connecting to the AI analysis server, the patient order information will be automatically downloaded from the server. You can also create a new patient order on this device.
Menu	Click this button to enter the main menu screen, and set the electrocardiograph. Click each submenu item to enter the corresponding setting screen. For details, see *Chapter 8 System Setup*.

Button	Description
Start/Stop	After clicking the [Start] button, the acquisition and printing operations will be started immediately if the required patient information is complete. During the acquisition and printing process, click the [Stop] button to immediately stop the acquisition or printing operation.

Chapter 5 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. Set the items displayed in the patient information input window according to your needs. Patient ID, gender, age and age unit are required by default (marked with an asterisk *) and displayed permanently.

To set patient information, follow the steps below:

1. Press [Menu] → [Patient Info] to enter the patient information setting screen.
2. Select the required information item and set it to [Enable].
3. Press the [Save] button to confirm the settings.

For specific setting information, please refer to *8.4 Patient Info Setup*.

To select the ID generation method, follow the steps below:

1. Press the patient information area on the main screen to open the Patient Information Input screen.
2. Press the [>] area on the right side of the patient ID input box to pop up the patient ID setting window.
3. Select the ID generation method as needed: Auto Generated, Manual Input.
4. Press the [X] button in the upper right corner to automatically save the settings and exit the current window.

5.2 Entering Patient Information

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

- Enter patient information manually
- Read patient ID with a barcode reader
- Read patient's ID info with an ID card reader
- Select a patient from the order list

✦ **Entering Patient Information Manually**

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

1. Press the patient information area on the main screen to open the Patient Information Input screen.
2. Enter or change patient information as needed.
3. Press the [Save] button to save the patient information and exit the current screen.

☞ **Note**

You can save patient information only when all the required patient information is entered.

✦ **Reading Patient ID with a Barcode Reader**

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

1. Connect the barcode reader (Please use the model recommended by our company) 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 Information Input screen pops up with the patient ID entered.
3. Enter other required information manually.

4. Press the [Save] button to save the patient information and exit the current screen.

⚠ Warning

After scanning, please check the scanning result to ensure that the correct patient information is entered.

✦ **Selecting a Patient from the Order List**

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

1. Set up and connect to a wired network or Wi-Fi.
2. Connect to the ECG analysis software server.
3. Press [Order] on the main screen to enter the order list screen.
4. Press the [Refresh] button to obtain updated data from the server.
5. Select the patient from the patient list.
6. Press the [Acquire] button to go to the waveform acquisition screen.

5.3 Editing Patient Information

Operation procedures:

1. Enter the Patient Information Input screen in either of the following ways:
   - Press the patient information area on the main screen.
   - Press [Order] → [Add].
   - Press the patient information area on the preview screen.
2. Enter or change patient information as needed.
3. Press the [Save] button to save the patient information.

After the edited patient information is saved, the corresponding patient information in the order list and file list will be updated.

Chapter 6 Acquisition, Analysis and Printing

6.1 Selecting the Working Mode

The device supports auto (real-time sampling, pre-sampling, periodic sampling, trigger sampling), manual and R-R working modes.

To select the working mode, follow the steps below:

1. Press the first quick key at the bottom of the main screen to enter the ECG record mode setting window.
2. Select the required record mode and record format.
3. After setting, close this window and return to the main screen.

Caution

The working mode cannot be changed during the recording course. Stop recording before changing the working mode.

6.2 Setting ECG Waveform

Set the ECG waveform before starting an ECG test.

Operation procedures:

1. Press the second quick key at the bottom of the main screen to enter the filter setting window, set whether to turn on the AC filter and adjust the baseline drift filter frequency.
2. Press the third quick key at the bottom of the main screen to enter the filter setting window, adjust the low-pass filter frequency.
3. Press the fourth quick key at the bottom of the main screen to enter the gain setting window, adjust the gain of the waveform.

4. Press the fifth quick key at the bottom of the main screen to enter the paper feed speed setting window, adjust the speed of waveform recording.

You can also enter the [ECG Setup] and [Print Setup] menus to make other settings for the ECG waveform.

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

6.3 Setting ECG Report

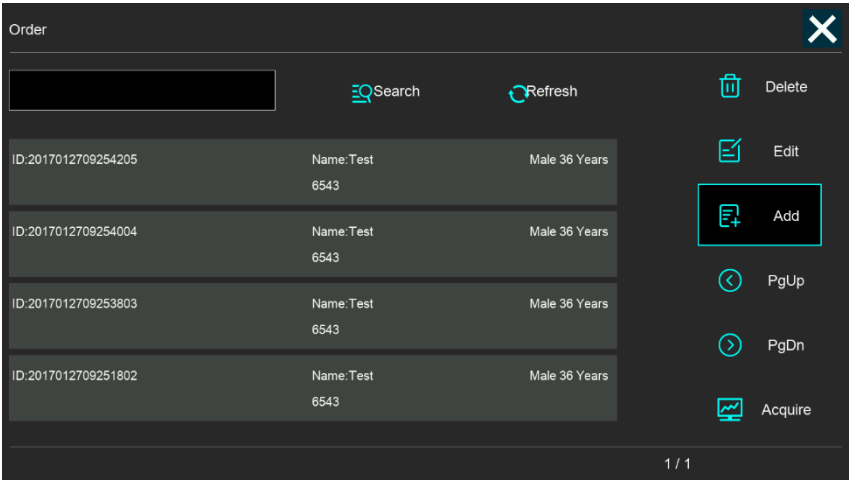
You can enter the [Print Setup] menu to set the content and format of the ECG report.

For more information, see *8.2 Print Setup*.

6.4 Examination Order

When the device is successfully connected to the AI-ECG server, the order list from the ECG analysis software can be obtained on the device to perform ECG test for the patients.

Press the [Order] button on the main screen of the device to enter the order screen. Each order displays the patient ID, name, gender, age, ID number, bed number, and test items. The specific display items are determined by the setting of the order source. The order list screen is as shown in the figure below:



Button	Description
Acquire	Select an order, and then press the [Acquire] button to automatically go to the acquisition screen, press the [Start] button to acquire ECG data for this patient. After the acquisition is completed and saved, the order will no longer be displayed in the order list. If the acquisition is interrupted unexpectedly, the order is still in the list for acquisition. After the acquisition is completed, you can enter the [File] screen to view the acquired ECG data of the patient.
Add	Click this button to enter the Patient Information Input screen. After successfully adding a patient, it returns to the order list screen and adds a patient order record to the list. When the remote diagnosis is enabled, the newly added patient data on this device can be synchronized to the AI analysis server.

Button	Description
Edit	Select a patient, press this button to enter the Patient Information Input screen, input or change the patient information as needed. ☞ **Note** **The patient information downloaded from the AI analysis server can't be edited.**
Delete	Click this button to delete the selected patient record. ☞ **Note** **The patient information downloaded from the AI analysis server can't be deleted.**
Refresh	Press this button to manually update the order list. The newly added patients on this device are ranked before the patients downloaded from the server. The most recently added patient on this device is sorted in the front; the latest order record obtained from the server is sorted at the last.
Search	Support searching by patient ID, name, ID No. and other elements. After entering the search criteria, press this button to search for all eligible cases. If the input content is empty, all content is searched by default.
PgUp/PgDn	Press the [PgUp] and [PgDn] buttons to turn pages and view the order records.

6.5 Acquisition and Analysis

6.5.1 Real-time Sampling

According to the current parameter settings, when the [Start] button is pressed in this mode, the device automatically records the ECG waveform of the set acquisition time and then automatically analyzes the latest 10s waveform. After the analysis is over, the patient information, measurement parameter information and analysis results are output according to the system settings.

The device automatically stops recording when the ECG report has been printed. You can also press [Stop] during the printing process to terminate the recording.

If the report preview function is enabled, the device automatically enters the report preview screen after ECG data is acquired and analyzed. At this moment, you can press the [Print] button on the screen to print the current report.

6.5.2 Pre-sampling

In this mode, press the [Start] button, and the ECG data acquired 10s before the button is pressed will be recorded and output.

6.5.3 Periodic Sampling

In this mode, press the [Start] button to start recording according to the periodic printing length and periodic printing interval set in the [Print Setup] screen. At this moment, the upper right corner of the screen displays the countdown of the total time of periodic sampling. Start sampling, analysis, and printing according to the periodic printing interval until the

cycle duration is reached, and perform the last sampling, analysis and printing.

6.5.4 Trigger Sampling

In this mode, if the device acquires arrhythmia data during the data acquisition process, it automatically triggers a recording, print out the waveform of the arrhythmia, and then perform automatic analysis and automatically print out patient information, measurement parameters information and analysis results.

After printing, the system prompts: "Continue to monitor arrhythmia?", select "Yes" to continue monitoring, or select "No" to exit this acquisition.

6.5.5 Manual Mode

In this mode, the device can continuously print the ECG waveform of the selected lead in real time when you press the [Start] button, and it will stop when you press the [Stop] button.

The manual mode can only print the waveform report through the thermal recorder, and does not provide measurement and analysis results. The acquired waveform can't be stored in the device, nor can it be sent to an external device through the network.

> ☞ **Note**
>
> **In manual mode, during recording, press the lead switching combination key on the device panel to select the lead to be recorded.**

6.5.6 R-R Mode

In this mode, the ECG waveform of 60s or 180s is acquired, and the ECG of the set rhythm lead is recorded. After starting the R-

R recording, the screen displays the timing of the rhythm waveform acquisition. After the timing is over, the automatic analysis starts. After the analysis is over, the report can be previewed, saved and printed.

6.6 Remote Diagnosis

To enable the remote diagnosis function, follow the steps below:

1. Press [Menu] → [Network Setup] to enter the network setting screen.
2. Enter the obtained [Technician No.] (user account).
3. Enable the [Remote Diagnosis].
4. Select the applicable network type and connect to the network.
5. Set the [Server] IP address and port number.
6. Press the [Network Testing] button to test the network connection. Ensure that the connection with the AI analysis server is successful.

In auto mode, press the [Start] button, the device will automatically record the ECG waveform of the set acquisition time, and then automatically upload the ECG data to the AI analysis server for analysis. After the server returns the diagnosis report, the status of the relevant case in the file management screen changes to “Diagnosed”, and you can view the diagnosis result and print the report.

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 acquire enough data for at least 10 seconds before freezing.

Operation procedures:

1. In the main screen, press the [Freeze] button to enter the waveform freezing screen.
2. Press the [10 mm/mV] and [25 mm/s] quick keys at the bottom of the screen to adjust the gain and speed.
3. Press the [Step] button to open the step setup window and adjust the step. Step options: 1s, 2.5s, 5s, 10s; the default setting is 5s.
4. Press the [Prev] and [Next] buttons to turn pages and preview the waveform according to the set step.
5. Press the [Print] button to print the currently frozen waveform. You can select to print the corresponding page.
6. Press the [Report] button to analyze the current waveform, then automatically enter the report preview screen, and turn pages to view, print, and save the report.
7. Press the patient information area in the upper left corner of the screen to open the Patient Information Input screen and edit patient information.

6.8 Printing Reports

The device is equipped with a thermal recorder, and it can also be connected to an external printer to print ECG reports.

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

- 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.

- 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.

Before printing a report, check that the paper is properly loaded.

- For the paper loading method of the thermal recorder, refer to *3.3.2 Loading the Recording Paper*.
- To load the paper for the external printer, refer to the printer's accompanying instructions for use.

> ☞ **Note**
>
> **In manual mode, you can only use the thermal recorder to print reports.**

> ☞ **Note**
>
> **When the remote diagnosis mode is enabled, only the paper-saving print mode is supported.**

> ☞ **Note**
>
> **When [USB Printer] or [Network Printer] is selected for [Print Device], only paper-saving print mode is supported.**

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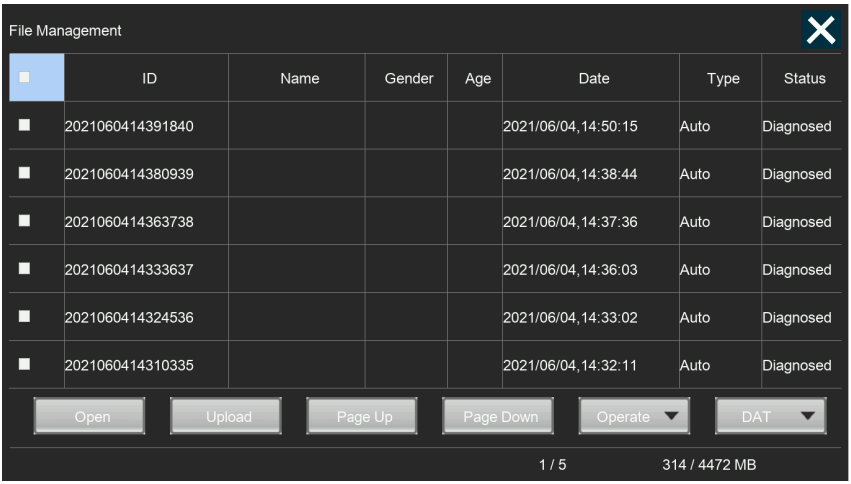
Chapter 7 File Management

On the main screen, press the [File] button on the right side to enter the patient file management screen, as shown in the figure below.



In this screen, all files are listed in chronological order, and the latest files are displayed on the top. The maximum storage capacity of this device is 6000 ECG data in 10s auto mode. When the storage is full, it directly overwrites the earliest saved data. The lower right corner of the screen displays the capacity information (occupied capacity / total capacity).

The type of the patient file is the corresponding record mode during data acquisition.

The data may be in one of the following statuses.

- Not uploaded: The data has not been uploaded to the server, or the upload failed.
- Undiagnosed: Data that needs to be diagnosed remotely and uploaded successfully.

- Diagnosed: After remote diagnosis, the diagnosis result sent back to the device.

You can view, query, edit, upload, export, print, and delete the stored historical records.

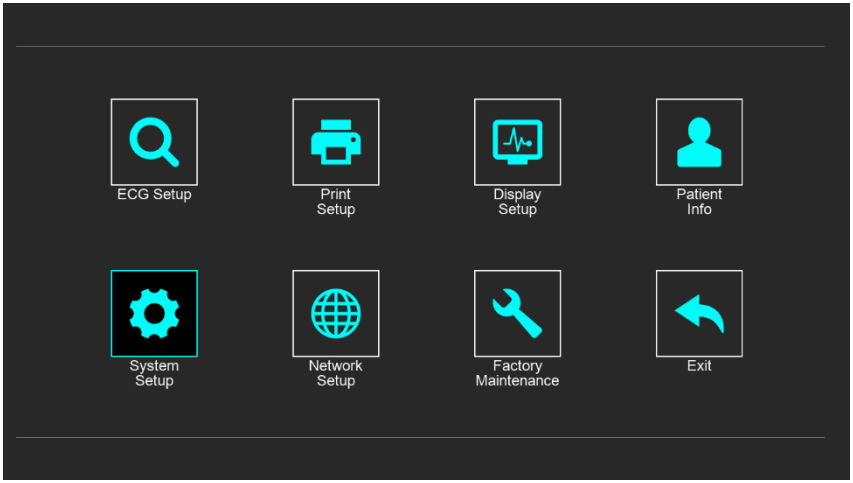
Button	Description
Open	Select a data record, press this button to enter the preview screen and perform the following operations: ● Press the patient information area in the upper left corner of the screen to open the Patient Information Input screen, where you can modify the current patient information. ☞ **Note** **The patient information downloaded from the AI analysis server can't be modified.** ● Press the [10 mm/mV] and [25 mm/s] quick keys at the bottom of the screen to adjust the gain and speed. ● Press the [Prev] and [Next] buttons to view the selected data record. ● Press the [Save] button to save the modified data. If the patient ID has not changed, the original data will be automatically replaced. ● Press the [Print] button to print the selected data record. ● Press the [Exit] button to exit the preview screen.
Upload	Select one or several data records, and press this button to upload the selected data record(s) to the designated server.

Button	Description
PgUp / PgDn	Press [PgUp] and [PgDn] buttons to turn pages to view patient files.
Select All / Unselect	Press [Operate] → [Select All] or [Unselect] to select or unselect all files ☞ **Note** **Press the box on the left of the ID on the screen to select all files on the current page.**
Refresh	Press [Operate] → [Refresh] to refresh the data list.
Export	Select one or several data records, and press [Operate] → [Export] to export the selected data record(s) to the USB flash disk.
Delete	Select one or several data records, press [Operate] → [Delete], and then press [Yes] to confirm the deletion of the selected data.
Search	Press [Operate] → [Search] to open the search dialog box. It supports searching based on patient ID, name, age, time and other elements. After entering the search criteria, press the [Search] button to search for all eligible cases.
Re-sample	Select a data record, press [Operate] → [Resample] to enter the acquisition screen, and press [Start] button to re-acquire ECG for the selected patient. ☞ **Note** **Cannot perform re-sample for diagnosed records.**

Button	Description
DAT	Press to select the export format of the file. DAT (default), XML, JPEG and PDF formats are available.

Chapter 8 System Setup

In the main screen, press the [Menu] button to enter the setting screen, as shown below:



The settings made in the main menu will be saved as the default user settings, and will still be effective the next time you turn on the device. The menu items, options and their descriptions are detailed in the following subsections.

Note

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

8.1 ECG Setup

Menu Item	Option	Description
Lead Sequence	Standard, Cabrera	Select ECG lead sequence for displaying and printing. [**Standard**]: the sequence is I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6. [**Cabrera**]: the sequence is aVL, I, -aVR, II, aVF, III, V1, V2, V3, V4, V5, V6.
Lowpass Filter	25 Hz, 35 Hz, 45 Hz, 75 Hz, 100 Hz, 150 Hz, 300 Hz, Off	Set the frequency of the lowpass filter.
ADS Filter	0.01 Hz, 0.05 Hz, 0.32 Hz, 0.67 Hz	Set the frequency of the ADS (Anti-drifting system) filter.
AC Filter	Disable, Enable	Select whether to enable the AC filter. If selected, the AC filter is enabled to filter electrical interference from AC line voltage.
Rhythm Mode	Single Lead, Three Leads	Select how many rhythm leads are recorded during R-R mode.
Rhythm Time	60 s, 180 s	Set the acquisition time of R-R mode.
Rhythm Lead 1	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6	Set the first rhythm lead to be recorded during auto and R-R mode.

Menu Item	Option	Description
Rhythm Lead 2	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6	Set the second rhythm lead to be recorded during auto and rhythm measurement mode.
Rhythm Lead 3	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6	Set the third rhythm lead to be recorded during auto and rhythm measurement mode.
Record Mode	Real-time, Pre Sample, Periodic Sample, Trigger Sample, Manual, R-R	Select the recording mode.
Record Format	3x4, 3x4+1R, 3x4+3R, 6x2, 6x2+1R, 12x1, 1x12	Select the display format of the ECG waveforms in each mode. [**3x4**]: displays 12-lead ECG waveforms in 3 lines and 4 columns. [**3x4+1R**]: displays 12-lead ECG waveforms in 3 lines and 4 columns, and one rhythm lead waveform at the bottom of the screen. [**3x4+3R**]: displays 12-lead ECG waveforms in 3 lines and 4 columns, and three rhythm lead waveform at the bottom of the screen.

Menu Item	Option	Description
		[**6x2**]: displays 12-lead ECG waveforms in 6 lines and 2 columns. [**6x2+1R**]: displays 12-lead ECG waveforms in 6 lines and 2 columns, and one rhythm lead waveform at the bottom of the screen. [**12x1**]: displays 12-lead ECG waveforms in 12 lines on the same screen. [**1x12**]: displays 12-lead ECG waveforms in 1 line on the same screen. ☞ **Note** **The record format options in the paper-saving printing mode are: 3x4, 3x4+1R, 6x2, 6x2+1R.** ☞ **Note** **One or three rhythm lead waveform(s) are recorded during R-R mode.**
Acquisition Time	10 s, 20 s, 30 s, 60 s	Set the total acquisition time in real-time sampling mode.
HR Lower Limit	30-300 bpm	Set the lower limit of the heart rate. The default setting is 30 bpm.

Menu Item	Option	Description
HR Upper Limit	30-300 bpm	Set the upper limit of the heart rate. The default setting is 300bpm.
Auto Save	Disable, Enable	Set whether the ECG report is automatically saved on the internal storage after measurement finishes. When set to [Enable], the device will automatically save the ECG report except for manual mode. ☞ **Note** **When the memory space of the device is full, the earliest report is automatically deleted when a new report is saved.**

8.2 Print Setup

Menu Item	Option	Description
Speed	5 mm/s, 6.25 mm/s, 10 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s	Select the speed of waveform recording. When the [**Print Mode**] is set to [**Save Paper**], the speed is 25 mm/s.
Gain Setup	1.25 mm/mV, 2.5 mm/mV, 5 mm/mV,	Set the amplitude of 1mV signal. The greater the gain is, the greater the waveform amplitude.

Menu Item	Option	Description
	10 mm/mV, 20 mm/mV, 40 mm/mV, 10/5 mm/mV, 20/10 mm/mV, Auto	[**10/5 mm/mV**]: displays the limb lead waveforms at an amplitude of 10 mm/mV; displays chest lead waveforms at an amplitude of 5 mm/mV. [**20/10 mm/mV**]: displays the limb lead waveforms at an amplitude of 20 mm/mV, displays chest lead waveforms at an amplitude of 10 mm/mV. [**Auto**]: automatically selects the appropriate gain according to the amplitude of the ECG waveforms.
Print Mode	Quick Mode, Save Paper	[**Quick Mode**]: if selected, press the [Start] button in the main screen during the auto measurement mode, the ECG waveform will be printed out immediately. Then according to the configuration, the patient information, measurement information and analysis results are recorded on other printing papers. [**Save Paper**]: if selected, press the [Start] button, the ECG report will be printed after sampling and analysis are completed. Patient information, measurement information, analysis results and

Menu Item	Option	Description
		ECG waveforms will be recorded on the same printing paper.
Report Preview	Disable, Enable	When using auto diagnosis, set whether to enter the report preview screen after data analysis is completed in real-time sampling, pre-sampling, and trigger sampling mode.
Measurement Matrix	Disable, Enable	Set whether the measurement matrix information is included on the ECG report generated by auto measurement. When set to [Enable], 12 measurement values for each lead are provided, including: P amplitude (mV), Q amplitude (mV), R amplitude (mV), S amplitude (mV), T amplitude (mV), ST20 amplitude (mV), ST40 amplitude (mV), ST60 amplitude (mV), ST80 amplitude (mV), Q duration (ms), R duration (ms), S duration (ms).
Average Template	Disable, Enable	Set whether the average template is included on the ECG report generated by auto measurement. When set to [Enable], Average Template displays the average template waveform for each lead in 3x4 format.

Menu Item	Option	Description
Analysis Result	Disable, Enable	Set whether the analysis result is included on the ECG report generated by auto measurement.
Measurement Parameters	Disable, Enable	Set whether the measurement parameters are included on the ECG report generated by auto measurement. Measurement parameters include: Heart rate (bpm), P duration (ms), PR interval (ms), QRS duration (ms), QT/QTc duration (ms), P/QRS/T axis (°), RV5/SV1 amplitude (mV), RV5+SV1 amplitude (mV), RV6/SV2 amplitude (mV).
Time Scale	Disable, Enable	Set whether to print the start time scale under the waveform of the report.
Minnesota Code	Disable, Enable	Set whether to display and print the Minnesota code corresponding to the diagnosis conclusion under the measurement parameters of the report.
Printout Grid	Disable, Enable	Select whether a grid is printed on the waveform area of the ECG report produced by the external printer.

Menu Item	Option	Description
Print Sequence	Sequential, Synchronous	Set the printing sequence of each column of waveforms when outputting reports. [**Sequence**]: the lead group is recorded one by one in a certain sequence. [**Synchronous**]: all leads are recorded synchronously.
Periodic Duration	/	Set the duration of periodic printing. The default setting is 60 min.
Periodic Interval	/	Set the periodic printing interval, that is, select how often to print and analyze the ECG waveform. The default setting is 1 min. ☞ **Note** **The input value of the periodic interval must not be greater than the set value of the periodic duration, or else the setting will not be effective.**
Print Device	Disable, Thermal Printer, USB Printer, Network Printer	Select which printing device is used to output the reports. When set to [Disable], the report won't be printed.

Menu Item	Option	Description
External Printer	Disable, USB Printer, Network Printer	When the printing device is turned off or the built-in thermal printer is selected, "Disable" is displayed. When an external USB printer is selected as the printing device, "USB Printer" is displayed. Click the text box to pop up a system prompt: "Ensure that the USB printer is connected and turned on.". When an external network printer is selected as the printing device, "Network Printer" is displayed. Click the text box to pop up the network printer setting window, and set the IP address and port.

8.3 Display Setup

Menu Item	Option	Description
Display Style	Classic White, Classic Black	Set the background color display style of the waveform area on the screen.
Background Grid	Disable, Enable	Set whether to display the background grid in the waveform area of the screen.
Lead Standard	IEC Standard, AHA Standard	Set the lead naming standards. According to the settings here, the lead indication area displays

Menu Item	Option	Description
		the corresponding standard electrode name.

8.4 Patient Info Setup

Menu Item	Option	Description
Age	Disable, Enable	Choose whether to record the patient's age as patient information on the ECG report.
Date of Birth	Disable, Enable	Choose whether to record the patient's date of birth as patient information on the ECG report.
Height	Disable, Enable	Choose whether to record the patient's height as patient information on the ECG report.
Weight	Disable, Enable	Choose whether to record the patient's weight as patient information on the ECG report.
BP	Disable, Enable	Choose whether to record the patient's blood pressure data as patient information on the ECG report.
Technician	Disable, Enable	Choose whether to record the technician who conducts the ECG measurement as patient information on the ECG report.
Physician	Disable, Enable	Choose whether to record the physician who supervises the ECG as patient information on the ECG report.

Menu Item	Option	Description
Request Dept	Disable, Enable	Choose whether to record the request department as patient information on the ECG report.
Bed No.	Disable, Enable	Choose whether to record the patient's bed number as patient information on the ECG report.
Inpatient ID	Disable, Enable	Choose whether to record the patient's Inpatient ID number as patient information on the ECG report.
Outpatient ID	Disable, Enable	Choose whether to record the patient's Outpatient ID number as patient information on the ECG report.
PE ID	Disable, Enable	Choose whether to record the patient's physical examination ID number as patient information on the ECG report.
Pacemaker	Disable, Enable	Choose whether to record the patient's paced status as patient information on the ECG report. When set to [Enable], you need to set the pacemaker on the patient information input screen. Option: Yes, No.
ID No.	Disable, Enable	Choose whether to record the patient's ID number as patient information on the ECG report.

Menu Item	Option	Description
User Defined	Disable, Enable	Enter other information that needs to be recorded on the ECG report as patient information. [User Defined] is displayed by default. You can change it to other names as needed. You can enter up to 40 English characters and 20 Chinese characters.

8.5 System Setup

☞ **Note**

If the [System Password] function is enabled, the user name and password are required to enter the system setting menu. For details, please refer to the description of [System Password] and [Password Setup] in the following table.

Menu Item	Option	Description
System Language	English, 中文, Português, Français, Español, Italiano, Русский, Deutsch, Türkçe, Polski, Română, Magyar, Ελληνικά	Set the system display language.
Date & Time	**Date Format:** YYYY-MM-DD, DD-MM-YYYY, MM-DD-YYYY **Time Format:**	Set the system date and time. ☞ **Note** **Press the system time area in the upper right corner of the screen to pop up the system time setup dialog box, and**

Menu Item	Option	Description
	12 h, 24 h Time Zone: UTC+, UTC- (0-12)	**quickly set the system date and time.** **Note** **In remote diagnosis mode, after connecting to the AI server, the time of the electrocardiograph is synchronized with that of the server.**
Auto Power-Off	Off, 30min, 1h, 2h, 3h	Set the waiting time before the device turns off automatically. In non-demo mode, if the user does not perform any operation within the set automatic shutdown time when all leads fall off, the device will automatically shut down. When set to [Off], the device will not turn off automatically.
Auto Standby	Off, 5min, 10min, 30min, 1h, 2h	Set the time for the device to automatically enter the standby state. In non-demo mode, if the user does not perform any operation within the set standby time when all leads fall off, the device enters the standby state and the screen turns off.

Menu Item	Option	Description
		When set to [Off], the device will not automatically enter the standby state.
Silent Mode	Disable, Enable	When set to [Enable], all beeps are turned off by default. The mute icon is displayed in the status icon area on the acquisition screen. When set to [Disable], the sound icon is displayed in the status icon area of the acquisition screen.
QRS Tone	Disable, Enable	Choose whether the system will give a sound prompt when the QRS wave is detected.
Key Tone	Disable, Enable	Choose whether to turn on the touch tone.
Print End Tone	Disable, Enable	Choose whether the system will give a sound prompt when printing is complete.
Low Battery Tone	Disable, Enable	Choose whether the system will give a sound prompt when it detects that the battery power is lower than 10%.
Lead Off Tone	Disable, Enable	Choose whether the system will give a sound prompt when the lead falls off.

Menu Item	Option	Description
No Paper Tone	Disable, Enable	Choose whether the system will give a sound prompt when the printer is out of paper.
Upload End Tone	Disable, Enable	Choose whether the system will give a sound prompt when the data upload is complete.
Barcode Setup	Click to Enter	Click to enter and set the barcode.
Demo Mode	Normal ECG, Arrhythmia ECG, Disable	Select the ECG waveform type in the demo mode.
Touchscreen Calibration	Click to Enter	Click to enter to perform touch screen calibration.
Factory Default	Click to Enter	Restore the current settings to the default settings. Factory reset will not change the current language settings.
AC Frequency	50 Hz, 60 Hz	Set the frequency of the AC filter.
Memory Space	6000	Display the storage capacity of the device.
System Password	Disable, Enable	Choose whether to set a system password. When set to [Enable], you need to enter the user name

Menu Item	Option	Description
		and password to enter the system setup menu. The default user name of the system is “admin” and the password is “888888”.
Password Setup	Click to Enter	After the system password function is enabled, this menu item is activated. Click to enter and modify the user name and password.
Institution	/	Enter the name of the medical institution. You can enter up to 40 English characters or 20 Chinese characters.
About the Machine	Click to Enter	Click to enter and view system information, including application software version, algorithm software version and device ID.

8.6 Network Setup

Menu Item	Option	Description
Technician No.	/	Enter the technician number registered on the remote AI-ECG system management website. ☞ **Note** **When uploading data to the AI analysis server, the technician number will also be uploaded at the same time.**
Auto Upload	Disable, Enable	The device supports uploading ECG data via wired network or WiFi network. Choose whether to enable the automatic upload function. When set to [Enable], the acquired data will be automatically uploaded to the specified server. ☞ **Note** **When [Remote Diagnosis] or [Acquisition Box Mode] is enabled, this function is not available. Alternatively, when [Auto Upload] is enabled, [Remote Diagnosis] and [Acquisition Box Mode] are disabled.**
Remote Diagnosis	Disable, Enable	Choose whether to enable the remote diagnosis function. When set to [Enable], the acquired data will be automatically

Menu Item	Option	Description
		uploaded to the AI analysis server for remote AI diagnosis.
Auto Print After Remote Dianosis	Disable, Enable	Set whether to automatically print the report after receiving the diagnosis report when the remote diagnosis function is enabled.
Acquisition Box Mode	Disable, Enable	Set whether to enable the acquisition box mode. When set to [Enable], the acquired data will be transmitted to the specified server in real time. ☞ **Note** **When the acquisition box mode is enabled, [Auto Upload], [Remote Diagnosis], [Auto Print After Remote Dianosis] is disabled.**
Server Setup	/	Set the server. Click to enter the server IP address and port number.
Network Setup	LAN, WiFi, Disable	Select the type of network used. When set to [Disable], network settings can't be made.
LAN DHCP	Disable, Enable	Choose whether to obtain an IP automatically. When set to [Enable], the IP address is automatically obtained when connecting.

Menu Item	Option	Description
LAN	/	Set up a wired network. Users can transmit ECG data through the wired network. When [LAN] is selected in [Network Setup] and [LAN DHCP] is disabled, you can set the wired network. Click to enter the IP address, subnet mask and default gateway.
Network Testing	Click to Test	Click to test the network. When the [Network Setup] is set to [Disable], you cannot perform network testing.
WiFi	Click to Enter	Click to enter the WiFi setup screen.

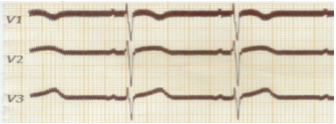
8.7 Factory Maintenance

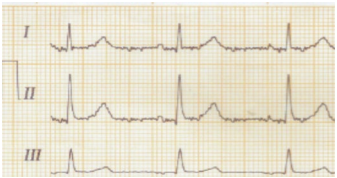
Enter the manufacturer's account and password to enter the manufacturer maintenance screen. It is convenient for maintenance personnel to maintain the device.

Chapter 9 Prompt Messages and Troubleshooting

No.	Messages or Troubles	Solutions
1	*Low battery!*	Charge the battery immediately.
2	*No paper*	Load the paper properly.
3	*Lead off: XX* XX represents the label of the lead that fell off.	1. Open the lead connection diagram, check the corresponding electrodes and lead wires. Re-apply the electrodes or reconnect the lead wires if necessary. 2. Check that the patient cable is properly connected to the device.
4	*Export failed!*	Try the export again.
5	*Upload failed!*	Try uploading again.
6	*Storage will be full!*	Delete unnecessary historical files, or change the storage device/location.
7	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

No.	Messages or Troubles	Solutions
		stable if all leads are in good contact before ECG measurement.
8	The printed ECG waveform has a breakpoint in the vertical direction	Generally, it is caused by dirt on the surface of the print head, so the print head needs to be cleaned. If it persists after cleaning, it may be related to the damage of some heating units of the thermal print head. Please contact customer service department of Carewell or designated service outlet for replacement.
9	The printed ECG waveform is out of the grid area of the printing paper.	It is caused by the great fluctuation of the ECG signal. Set the sensitivity to "Auto". The device will automatically adjust the sensitivity according to the amplitude of the ECG signal.
10	AC interference Symptom: There is an overlap of 50Hz sine wave with certain amplitude and regularity on the ECG traces, and obvious jitter appears on the ECG baseline.	Check the following aspects of the device for solving problems: ● The device is properly grounded. ● The electrodes and leadwires are correctly connected.

No.	Messages or Troubles	Solutions
		● 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.**
11	EMG interference Symptom: The ECG has irregular fluctuation while	Check the following aspects of the device for solving problems:

No.	Messages or Troubles	Solutions
	the baseline demonstrates no change.  	● 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? **If the interference cannot be cleared after the above measures, use an EMG filter, and the recorded waveform is slightly attenuated.**
12	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.

No.	Messages or Troubles	Solutions
		● Mixed use of old and new electrodes. **If the interference cannot be cleared after the above measures, use an ADS filter.**

Caution

When performing distortion tests, set the filter to the maximum bandwidth, otherwise it may cause waveform distortion.

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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 Main Unit

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 main unit, 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.

10.2.3 Cleaning the Thermal Print Head

Dirty print head deteriorates the printing quality. Clean the print head at least once a month or as needed.

To clean the thermal print head, follow the steps below:

1. Turn off the device.
2. Open the recorder door and take out the recording paper.
3. Wipe the print head gently with a clean soft cloth dampened in a small amount of alcohol. For stubborn stain, soak it with a small amount of alcohol first and wipe it off with a clean soft cloth.
4. Reload the recording paper and close the recorder door after the print head is completely air dried.

10.3 Disinfection

Disinfection of the main unit 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 Care and 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 and 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 cannot 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 Reusable Electrodes

Follow the below guidelines to maintain the reusable 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.

10.4.4 Recording Paper

Follow the below guidelines to store the thermal recording paper:

- Recording paper should be stored in dry, dark and cool area, avoiding excessive temperature, humidity and sunshine.
- Do not put the paper under fluorescence for a long time.
- Be sure that there is no polyvinyl chloride or other chemicals in the storage environment, which will lead to color change of the paper.
- Do not stack up the recording paper for a long time, or else the ECG record may trans-print each other.

Chapter 11 Accessories

When using the device, the manufacturer recommends the following accessories:

Name	Model/Specification	Quantity
Power cable	10A/250V	1 pcs
Patient cable	ECG-FD10X4 (IEC) or ECG-FD08X4 (AHA)	1 set
Adult chest electrode	ECG-FQX41	6 pcs
Pediatric chest electrode (optional)	ECG-EQD01	6 pcs
Adult limb electrode	ECG-FJX42	4 pcs
Pediatric limb electrode (optional)	ECG-EJ01	4 pcs
Adult disposable adhesive electrodes (optional)	915W50	50 pcs
ECG adapter (optional)	Banana plug (4.0) female	10 pcs
Thermal sensitive paper	Ø 216mm or Ø 210mm	1 roll
Paper roller	Plastic ABS pearl white	1 pcs
Ground lead	/	1 pcs
Small flat-head screwdriver	/	1 pcs
Touch pen	Black resistive type with rope	1 pcs

Name	Model/Specification	Quantity
Rechargeable lithium battery	4400mAh, 14.4V	1 pack

For the replacement cycle and replacement method of the accessories, 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+A2:2020	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 basic safety and essential performance of electrocardiographs
	IEC 60601-1-2: 2014+A1:2020	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 I with internal power supply
	Anti-electric-shock degree:	Type CF with defibrillation protection

	Degree of protection against harmful ingress of water:	IPX0, non-waterproof
	Installation and use:	Portable, not permanent installation device
	Working mode:	Continuous operation
	EMC:	Group I, Class A
	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

	Transport	Storage	Operation
Temperature	-20℃~+55℃	-10℃~+40℃	+5℃~+40℃
Relative Humidity	25%~95%	25%~85%	25%~85%
Atmospheric Pressure	700hPa~ 1060hPa	700hPa~ 1060hPa	700hPa~ 1060hPa

A.3 Physical and Hardware Specifications

Main unit	Dimensions	338mm × 280mm × 85mm (Width × Depth × Height)
	Net Weight	About 3.7kg
	Display	7.0 inches, color LCD touch screen; resolution: 800×480 pixels
Recorder	Recording method	Thermal sensitive dot matrix record
	Print resolution	Vertical resolution: 8 dots/mm Horizontal resolution: 40 dots/mm (with paper speed 25mm/s)
	Recording paper	Rolled thermal sensitive paper
	Paper width	Rolled paper: 210/216mm
	Effective width	Rolled paper: 200/206mm
	Paper speed	Auto/Manual mode: 5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s, 50mm/s R-R mode/Save Paper print mode: 25mm/s Accuracy: ±3%

A.4 Power Supply Specifications

Mains supply	Rated voltage: 100-240V~
	Rated frequency: 50Hz/60Hz
	Rated power: 240VA
Built-in rechargeable lithium-ion battery	Rated voltage: 14.4V
	Rated capacity: 4400mAh
	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 4 hours (not including printing).
	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
Fuse	F-Slow T2A 250V Ø5×20

A.5 ECG Specifications

HR measurement	Method	Peak-peak detection
	Measurement range	30 bpm-300 bpm
	Accuracy	±1 bpm
Main unit	Leads	12 standard leads

	Sampling rate	Max. 32,000 points / sec per channel
	Acquisition mode	Simultaneous 12-lead ECG acquisition
	A/D conversion	24 bits
	Common mode rejection ratio (CMRR)	≥140 dB (AC filter on, common mode point voltage 450Vp-p) ≥120 dB (AC filter off)
	Time constant	≥5 s
	Frequency response	0.01 Hz - 350 Hz $^{+0.4\ dB}_{-3.0\ dB}$, 10Hz
	Sensitivity	Auto, 2.5mm/mV, 5mm/mV, 10mm/mV, 20mm/mV, 40mm/mV Accuracy: ±5%
	Paper speed	5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s and 50mm/s Accuracy: ±3% (0.2s - 2.0s)
	Filter	AC filter: 50Hz, 60Hz, Off
		ADS filter: 0.01Hz, 0.05Hz, 0.32Hz, 0.67Hz
		Lowpass filter: 25Hz, 35Hz, 45Hz, 75Hz, 100Hz, 150Hz, 300Hz, Off
	Input impedance	≥100 MΩ (10Hz)

	Minimum detectable signal	20μVp-p
	Calibration voltage	1mV±2%
	Depolarization voltage	±900 mV, ±5%
	Recovery time after defibrillation discharge	<10 s
	Input circuit current	≤10 nA
	Input voltage range	±5mVp-p
	Skew between channels	No skew
	Amplitude quantisation	0.95 μV/LSB
	Pacing detection	Amplitude: ±2 mV ~ ±700 mV Pulse Width: 0.1 ms - 2.0 ms There should be a pacing mark of not less than 2mm

Appendix B EMC and Radio Regulatory Compliance

B.1 EMC Compliance

Basic performance: The device can acquire and print ECG data.

⚠ Warning

Don't use near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

⚠ Warning

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

⚠ Warning

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ Warning

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 in (30 cm) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ 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 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.	Cable Name	Cable Length	Shield (Yes/No)
1	Patient cable	3.5m	Yes
2	Power cable	1.8m	No

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

Table 1

Guidance and manufacturer's declaration – electromagnetic emission		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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 establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 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 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/output lines	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode line-line	± 0.5 kV, ± 1 kV differential mode line-line	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT (100 % dip in UT) for 0.5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270°, and 315° 0 % UT (100 % dip in UT) for 1 cycle at 0° 70 % UT (30 % dip in UT) for 25/30 cycles at 0° 0 % UT (100 % dip in UT) for 250/300 cycle at 0°	0 % UT (100 % dip in UT) for 0.5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270°, and 315° 0 % UT (100 % dip in UT) for 1 cycle at 0° 70 % UT (30 % dip in UT) for 25/30 cycles at 0° 0 % UT (100 % dip in UT) for 250/300 cycle at 0°	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 uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m, 50/60Hz	30 A/m, 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a. c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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 6 Vrms 150 kHz to 80 MHz in ISM bands	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz in ISM bands	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 $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80MHz to 800MHz $d = 2,3\sqrt{P}$ 800MHz to 2.7GHz 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
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	

			survey[a], should be less than the compliance level in each frequency range [b] 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 are 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 re-orienting or relocating the device.

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

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the Device			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device 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**		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	80MHz to 800MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$	800MHz to 2.7GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.37	0.12	0.23
1	1.17	0.35	0.7
10	3.7	1.11	2.22
100	11.7	3.5	7.0
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 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Table 5

Recommended separation distances between RF wireless communications equipment					
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between RF wireless communications equipment and the device as recommended below, according to the maximum output power of the communications equipment.					
Frequency/ MHz	**Maximum Power /W**	**Distance**	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
385	1.8	0.3	27	27	RF wireless 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: $E = \frac{6}{d}\sqrt{P}$ Where P is the maximum output
450	2	0.3	28	28	
710	0.2	0.3	9	9	
745					
780					
810	2	0.3	28	28	
870					
930					
1720	2	0.3	28	28	
1845					
1970					
2450	2	0.3	28	28	

5240 5500 5785	0.2	0.3	9	9	power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.					

⚠ Warning

This device should not be used in the vicinity or on the top of other electronic equipment such as cell phone, transceiver or radio

control products. If you have to do so, the device should be observed to verify normal operation.

⚠ Warning

The use of accessories and power cord other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.

B.2 Radio Regulatory Compliance

The basic RF parameters are shown in the table below:

2.4GHz Specification	
WLAN standard	IEEE 802.11b/g/n wireless transmission standard protocol
Frequency range	2.400 - 2.4835GHz (2.4GHz ISM Band)
Number of channels	2.4GHz: Ch1 - Ch13
Modulation	802.11b: DQPSK, DBPSK, CCK 802.11g/n: OFDM / 64-QAM, 16-QAM, QPSK, BPSK
5GHz Specification	
WLAN standard	IEEE 802.11a/n/ac & Wi-Fi compliant
Frequency range	5.15 – 5.35GHz, 5.47 – 5.725GHz, 5.725 – 5.85GHz (5GHz UNII Band)
Number of channels	5.18 – 5.35GHz: Ch36 – Ch64 5.5 – 5.72GHz: Ch100 – Ch144 5.745 – 5.825GHz: Ch149 – Ch165
Modulation	802.11a: OFDM/64-QAM, 16-QAM,·QPSK,·BPSK 802.11n: OFDM/64-QAM, 16-QAM, QPSK, BPSK 802.11ac: OFDM/256-QAM, OFDM/64-QAM, 16-QAM, QPSK, BPSK

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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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