

LEPU MEDICAL

LeECG & NeoECG Series

Electrocardiograph

Operator's Manual

I Preface

Declaration

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Revision

P/N: SZ09.24300554-06

Release Date: July 2025

Revision: V1.6

General Notes

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

Special Notes

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



Warning

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



Caution

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



Note

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

II Manufacturer's Liability and Warranty

Manufacturer's Liability

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

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

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

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

Warranty

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

✦ Manufacturing Process and Raw Materials

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

✦ Software or Firmware

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

✦ Circuit Diagram

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

Note: Freight and other charges are excluded in the above warranty. This device contains no user serviceable parts. All repairs should be carried out by Carewell service personnel or its authorized distributors. Otherwise, Carewell will not be responsible for the safety, reliability and performance of the device.

Date of Manufacture and Service Life

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

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Chapter 1 Safety Guidance

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

1.1 Safety Warnings

1.1.1 Device Warnings



Warning

This device is not designed for direct cardiac application.



Warning

This device is not intended for treatment.



Warning

This device is not intended for home use.



Warning

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

Replacement of components by unauthorized personnel may lead to unacceptable risks.

 Warning

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

 Warning

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

 Warning

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

 Warning

This device cannot be used with diathermy related device.

 Warning

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

 Warning

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

 Warning

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

 Warning

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

 Warning

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

 Warning

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

 Warning

Do not use dissimilar metal electrodes.

 Warning

Indication of abnormal operation of the device: When the DC voltage at the input terminal is increased to $\pm 1V$, 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

To avoid risk of electric shock, do not touch the patient cable connector when acquiring an ECG.

 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

To avoid the risk of electric shock, when the device is used together with the recorder base, be sure that the recorder base must only be connected to a supply mains with protective earth.

1.1.2 Defibrillator and Pacemaker 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

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°C. 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°C to 40°C 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

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



Caution

When the device is connected to a separate power source other than SUPPLY MAINS, the separate power source is considered as part of medical equipment.



Caution

When the device is connected to the recorder base, they are considered as a medical system. While the separate recorder base is non-medical equipment.



Caution

Clinical interpretation of the ECG report may be affected by the filter settings.



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 DC adapter and remove the patient cable before cleaning and disinfection.



Caution

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



Caution

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



Caution

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



Caution

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 Symbols

Symbol	Description	Symbol	Description
	Type CF defibrillation-proof applied part		Power On/Off
	Polarity of d.c. power connector	TYPE-C	USB connector
	Direct current indicator		Battery indicator
	Alternating current indicator		Print ready indicator
	USB connector	100-240V~	Power connector of recorder base
	Network connector		Equipotentiality
	For indoor use only		Class II equipment
	Manufacturer		Country of manufacture (CN stands for Made in China)
	Serial number		Non-ionizing electromagnetic radiation
	Batch code		Unique device identifier
	Medical device		No alarm system

Symbol	Description	Symbol	Description
	MR unsafe		Importer
	General symbol for recovery/recyclable To indicate that the marked item or its material is part of a recovery or recycling process.		Caution Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	The symbol indicates that the device complies with the European Council Directive 93/42/EEC concerning medical devices.		Authorised representative in the European Community
	UK Responsible Person		Authorised representative in Switzerland
	Caution! Consult accompanying documents		Dispose of in accordance to your

Symbol	Description	Symbol	Description
			country's requirements
	General warning sign (Background: yellow; Symbol and outline: black)		Refer to Operator's Manual (Background: blue; Symbol: white)
IPX2	Protected against vertically falling water drops when the enclosure is tilted up to 15°		No stepping on surface
	This way up		Handle with care
	Keep away from rain		Stacking limit by number
	Temperature limit		Humidity limit
	Atmospheric pressure limit		Recovery / recyclable

 Note

Your device does not necessarily have all of the above symbols.

 Note

This manual is printed in Black and White.

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Chapter 2 Product Introduction

The NeoECG S120/LeECG OS12/NeoECG T120/NeoECG T180/LeECG OT12 electrocardiograph (hereinafter referred to as the “device”) is a portable ECG analysis device, with convenient and flexible product configuration.

There are two screen sizes: 7 inches (7") and 10.1 inches (10.1"). The 10.1" screen model device can be equipped with removable recorder base. This manual takes the 10.1" screen model as an example to introduce the device according to the maximum configuration, and therefore some contents may not be applicable to the device you purchased. If you have any question, please contact us.

2.1 Intended Use

The device is intended to be used in medical institutions to acquire resting ECG signals from adult and pediatric patients through body surface with ECG electrodes, and analyze the ECG data for clinical diagnosis and research.

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 Contraindication

No contraindication.

2.3 Structure and Composition

Standard Configuration:

The electrocardiograph (including multi-channel electrocardiograph software (V1) and Glasgow ECG analysis

program (V30)), power adapter, patient cable (model: ECG-FD10X4 or ECG-FD18X4 (IEC) and ECG-FD08X4 (AHA)) and ECG electrodes (chest electrode model: ECG-FQX41, limb electrode model: ECG-FJX42).

Optional Configuration:

CWECG-SLA ECG analysis program (V1), recorder base (for 10.1" screen model), chest electrode (ECG-EQD01), limb electrode (ECG-EJ01).

2.4 Model Difference

Model	9-lead and 12-lead Synchronous Acquisition	15-lead and 18-lead Synchronous Acquisition	Screen Size & Device Color	Remarks
NeoECG S120	●	N/A	7" white	N/A
LeECG OS12	●	N/A	7" black	
NeoECG T120*	●	N/A	10.1" white	Electrical and structural composition of 18-lead synchronous acquisition board is different from that only supports 12-lead.
NeoECG T180	●	●		
LeECG OT12	●	N/A	10.1" black	

Note

● indicates “default configuration”, and N/A indicates “not applicable”.

 Note

*: currently not included in the Declaration of Conformity for the electrocardiographs of our company.

2.5 Product View

2.5.1 7" Device

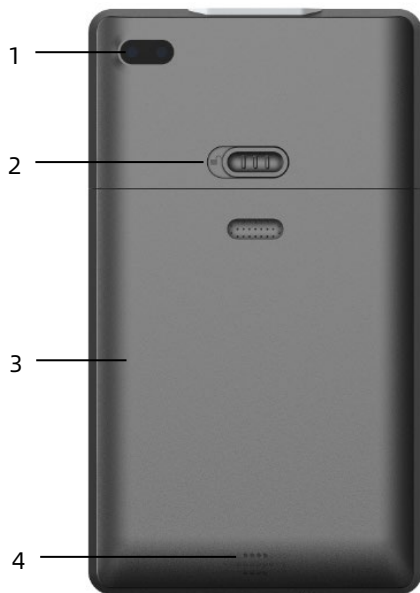
Front View



No.	Name	Description
1	Power On/Off	Press this key to turn on the device. Press and hold this key for about 5 seconds to turn off the device.

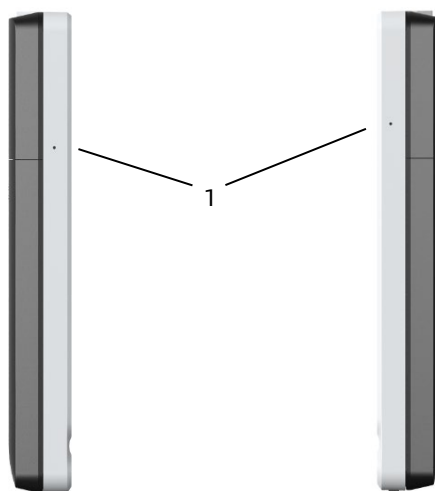
No.	Name	Description
		Press and hold this key for no less than 10 seconds to forcibly shut down the device if it could not be shut down normally.
2	Power-on indicator	Green: the device is on Off: the device is off
3	DC power indicator	Green: DC power connected Off: DC power disconnected
4	Battery indicator	Green: the battery is fully charged. Yellow: the battery is being charged. Off: the battery is not charged.

Rear View



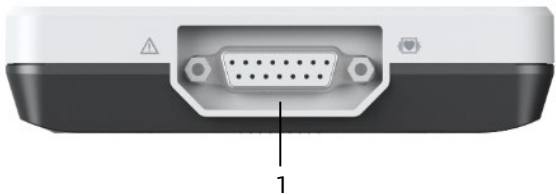
No.	Name	Description
1	Camera	Scan the code type supported to input patient information
2	Battery compartment cover lock	Lock/unlock battery compartment cover
3	Battery compartment	Built-in rechargeable lithium-ion battery
4	Speaker holes	Give notification tone, heartbeat tone, etc.

Left and Right View



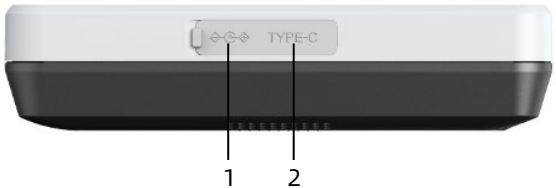
No.	Name	Description
1	Microphone	Reserved function

Top View



No.	Name	Description
1	Patient cable connector	Connect the patient cable for ECG acquisition

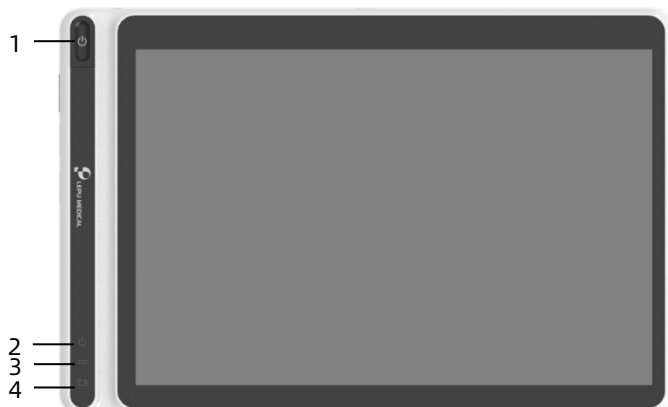
Bottom View



No.	Name	Description
1	DC power supply connector	Connect the DC power adapter to power the device and charge the built-in lithium battery.
2	USB connector	Used to connect a U disk for data transfer and system upgrades; and to connect an external printer.

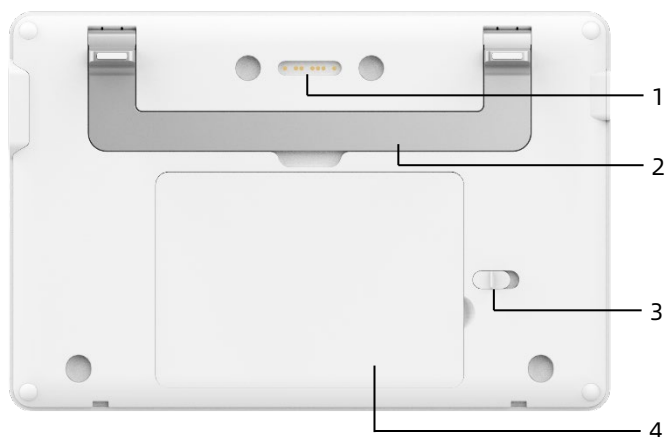
2.5.2 10.1" Device

Front View



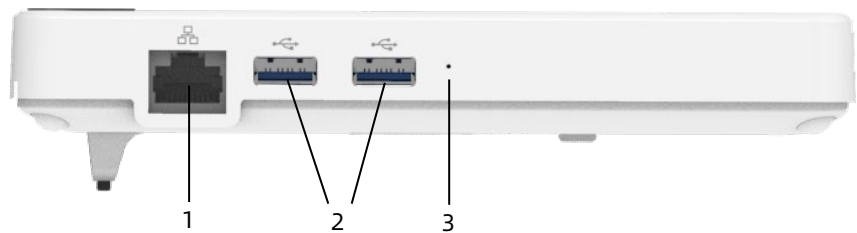
No.	Name	Description
1	Power On/Off	Press this key to turn on the device. Press and hold this key for about 5 seconds to turn off the device. Press and hold this key for no less than 10 seconds to forcibly shut down the device if it could not be shut down normally.
2	Power-on indicator	Green: the device is on Off: the device is off
3	DC power indicator	Green: DC power connected Off: DC power disconnected
4	Battery indicator	Green: the battery is fully charged. Yellow: the battery is being charged. Off: the battery is not charged.

Rear View



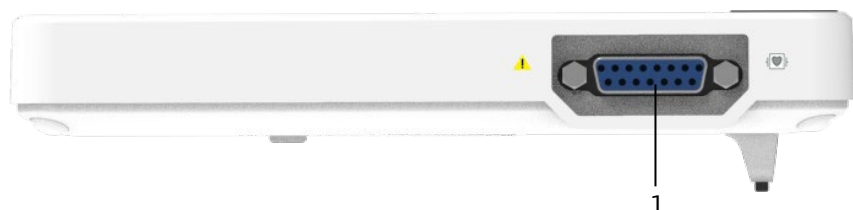
No.	Name	Description
1	Recorder base connector	Contact-type, matched with the device connector on the recorder base, connecting with the recorder base for data transmission and powering the device
2	Handle	Carry the device
3	Battery compartment cover lock	Lock/unlock battery compartment cover
4	Battery compartment	Built-in rechargeable lithium-ion battery

Left View



No.	Name	Description
1	Network connector	A standard RJ45 connector for LAN, connects the device to the network for data transmission
2	USB connector	Used to connect a U disk for data transfer and system upgrades; and to connect an external printer.
3	Microphone	Reserved function

Right View



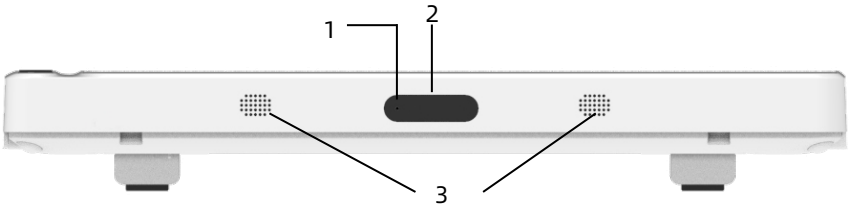
No.	Name	Description
1	Patient cable connector	Connect the patient cable for ECG acquisition

Top View



No.	Name	Description
1	DC power supply connector	Connect the DC power adapter to power the device and charge the built-in lithium battery

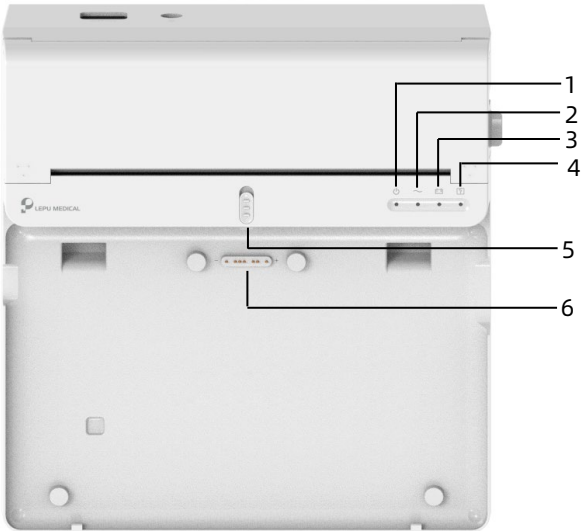
Bottom View



No.	Name	Description
1	Microphone	Reserved function
2	Camera	Scan the code type supported to input patient information
3	Speaker holes	Give notification tone, heartbeat tone, etc.

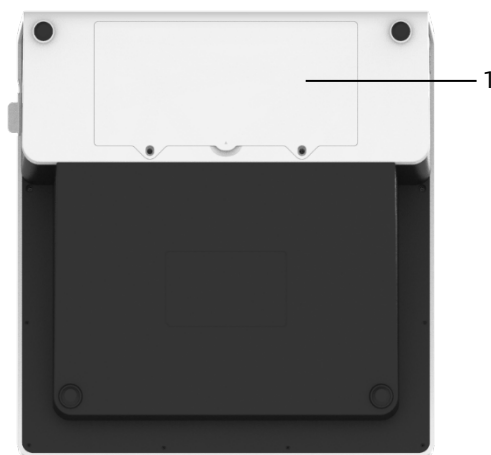
2.5.3 Recorder Base

Front View



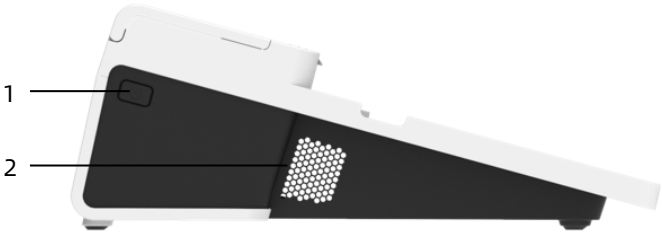
No.	Name	Description
1	Power-on indicator	Green: the recorder base is on Off: the recorder base is off
2	AC power indicator	Green: AC power connected Off: AC power disconnected
3	Battery indicator	Green: the battery is fully charged Yellow: the battery is being charged Off: The battery is not charged
4	Print ready indicator	Green: recorder ready (recording paper installed, paper compartment cover closed, and connected to the device) Off: the recorder is not ready
5	Device lock	Lock / unlock device
6	Device connector	Used to connect with the device, for data transmission, powering and charging the device

Rear View



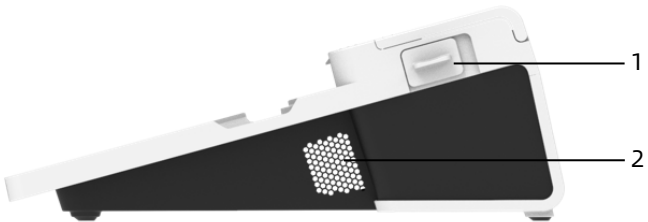
No.	Name	Description
1	Battery compartment	Built-in rechargeable lithium-ion battery

Left View



No.	Name	Description
1	Recorder switch	Turn on / off the recorder
2	Ventilation holes	Heat dissipation

Right View



No.	Name	Description
1	Paper compartment cover open button	Press this button to open the paper compartment cover

No.	Name	Description
2	Ventilation holes	Heat dissipation

Top View



No.	Name	Description
1	AC power input	Connect the AC power cable
2	Equipotential grounding terminal	Connect the grounding cable, for protective purposes and complying with the requirements of IEC 60601-1

Bottom View



2.6 Function Features

- Portable design, compact in size with low weight, easy for carry.
- Color touch screen, easy to operate.
- Can be powered by an external DC power supply or a built-in rechargeable lithium battery, or a recorder base.
- Support synchronous acquisition and display of 6/9/12/15/18-lead waveform, as well as heart rate detection.
- Provide ECG algorithm to automatically analyze the acquired ECG waveform, output measured values and diagnosis results.
- Support auto, manual and R-R mode.
- Provide 8 sampling modes: manual, pre-sampling, real-time sampling, periodic sampling, trigger sampling, R-R, 12-lead extend and pharma.
- Support 12-lead extension (applicable to models with only 12 leads): perform two consecutive 12-lead acquisitions to generate a 15-lead or 18-lead ECG report.
- Support automatic pacing detection and marking.
- Support ADS (Anti-drifting system) and EMG (electromyograph) interference.
- Accurately identify the electrode with poor contact and give instructions. The limb and chest leads are checked for signal quality.
- Both offline and online ECG acquisition are supported in the AI server login mode.
- Input patient information via full keyboard and barcode scanning.

- Freeze the ECG waveform on the screen.
- Output files in multiple formats, such as Carewell ECG, PDF, BMP, DAT, JPG, HL7, DICOM, SCP.
- Auto-saving function: save the ECG data when the report is printed.
- Store, preview, review, edit, export, upload, print and search patient data.
- Support wireless transmission of ECG data via Wi-Fi and mobile networks.
- Print ECG reports through an external printer or an external thermal recorder.
- Export patient data to USB flash disk via USB connector.
- Send ECG reports via email.
- Support user login permission control, when using the AI Cloud Mode, input account & password to log into the device, and view the historical patient data of the department according to the login account.

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Chapter 3 Operation Preparations

3.1 Unpacking and Checking

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

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

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

Contact Carewell in case of any problems.



Warning

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

3.2 Selecting an Installation Location

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



Caution

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

3.3 Preparing the Device

If you purchased a thermal recorder base, the device preparation includes the following steps, and each step is described in detail in the following sections:

1. Using the Battery
2. Installing the Battery of Recorder Base
3. Loading the Recording Paper
4. Connecting the Device to the Base
5. Connecting AC Power to the Base
6. Connecting the Grounding Cable
7. Connecting the Patient Cable and Electrodes (Applied Part)
8. Inspections Before Power-On
9. Login and Account Management
10. Setting Up the Device

If you have not purchased a thermal recorder base, device preparation includes the following steps:

1. Using the Battery
2. Using the DC Power Source
3. Connecting the Patient Cable and Electrodes (Applied Part)
4. Inspections Before Power-On
5. Login and Account Management
6. Connecting the Printer
7. 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 DC power supply or the recorder base.

- Installing the Battery

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

1. Press and slide the battery compartment cover lock/unlock latch to the unlock position.
2. Push down to remove the battery compartment cover.
3. Place the battery in the battery compartment.
4. Reinstall the battery compartment cover and slide the latch to the lock position.

- Charging the Battery

Because of the power consumption during the storage and transportation, the battery capacity may not be full, so it is necessary to charge the battery before using it for the first time. The battery is charged whenever the device is connected to the recorder base or a DC 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 upper right corner of the main screen will dynamically display the charging state of the battery.

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

3.3.2 Installing the Battery of Recorder Base

The recorder base can be configured with a rechargeable lithium battery, which can be charged when it is installed in the base and the base is connected to the AC power supply.

To install the battery, follow the steps below:

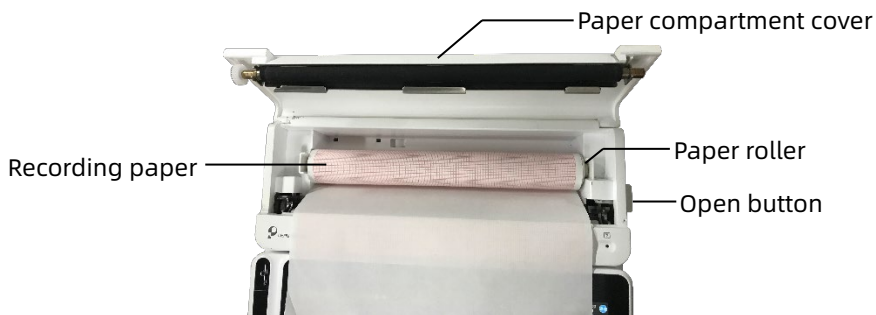
1. Gently turn the base over and use a screwdriver to remove the fixing screws on the battery compartment cover.

2. Plug the battery terminal into the battery connector on the base, and insert the battery into the battery compartment.
3. Close the battery compartment cover and tighten the fixing screws.

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

3.3.3 Loading the Recording Paper

The thermal recorder supports 210mm and 216mm width roll thermal sensitive paper. When the recording paper is not installed or the thermal recorder runs out of paper, the information prompt area of the device will display "Out of Paper" to remind the user to install the recording paper.



To install the recording paper, follow the steps below:

1. As shown in the figure above, push the open button on the right side of the base and press forward slightly to open the paper compartment cover.
2. Take out the paper roller, insert it into the new roll paper and put the paper with roller back into the paper compartment. Be sure to place the movable end of the paper roller close to the open button side, and make sure

that the paper is installed with the paper's grid side facing up.

3. Pull out the paper from the paper outlet of the recorder base and close the paper compartment cover.

3.3.4 Connecting the Device to the Base

Connect the device to the recorder base as shown in the figure below:



3.3.5 Connecting AC Power to the Base

To connect the AC power to the base, 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 input on the base.
3. Check whether the AC power indicator is on to ensure that the AC power supply is connected well.

3.3.6 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.

3.3.7 Using the DC Power Source

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

1. Insert the two-wire plug of the DC adapter into an AC receptacle.
2. Insert the connector of the DC adapter into the DC port of the device.
3. Check whether the DC power indicator is on to ensure that the DC power supply is connected well.

3.3.8 Connecting the Patient Cable and Electrodes (Applied Part)

- Connecting the Patient Cable

Connect the patient cable to the patient cable connector 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. The electrode identifiers and color codes of the internationally accepted European and American standards are shown in the table below.

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

European Standard		American Standard	
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
C3R	White/Pink	V3R	Brown/Yellow
C4R	White/Grey	V4R	Brown/Red
C5R	White/Green	V5R	Brown/Green
C7	White/Orange	V7	Brown/Black
C8	White/Blue	V8	Brown/Blue
C9	White/Yellow	V9	Brown/Yellow

3.3.9 Inspections Before Power-On

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

- 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 the batteries are installed in the device and the recorder base. Make sure that the batteries are fully charged.

Check that the power adapter is securely connected if the device is powered by DC power supply.

Check that the power cord is securely connected if the recorder is powered by AC power supply. Use only power socket that is properly grounded.

- **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.

- **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.

3.3.10 Login and Account Management

- **Power-On and Login**

Press the Power On/Off key to turn on the device, it will enter the startup screen, and then enter the main screen.

If you select the Diagnostic Mode as AI Cloud Mode in the System Setup menu, before the first use, you need to connect to the network, set the IP address and port number of the server,

and input an authorized account and password to log into the device after establishing a connection with the server.

- **Account Management**

Under the AI Cloud mode, in the main screen, click  → [Setup] → [System Setup] → [Account Management] to enter the account management screen, where you can view the current account and modify the password. Click [Logout] to exit the current account and return to the login screen.

3.3.11 Connecting the Printer

To use an external printer, select [Setup] → [Record Setup] to set the [Print Device]:

- When selecting the [Network Printer], you need to set the IP address and port number of the network printer, and use it after the connection is successful.
- When selecting the [USB Printer], plug the USB cable supplied with the printer into the USB port of the device. Make sure the USB printer is connected successfully.
- When selecting the [Thermal Printer], you need to connect the recorder base (for 10.1" screen model).
- When selecting [3-channel Thermal Printer], start the 3-channel thermal printer, and make sure it is connected successfully.

3.3.12 Setting Up the Device

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

1. Click the  button in the lower right corner of the main screen to open the menu screen.
2. Click the [Setup] button to enter the setting screen.

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

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

3.3.13 Turning off the Device

Follow the steps below to turn off the device:

1. Confirm that the patient's ECG examination has been completed.
2. Remove the electrodes from the patient.
3. Press and hold the power button for about 5 seconds, the screen displays the prompt message "Shutting down...", and then the device shuts down.
4. Or click the [Shutdown] button at the bottom of the [Setup] → [System Setup] screen to turn off the device.



Caution

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

3.4 Preparing the Patient

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.

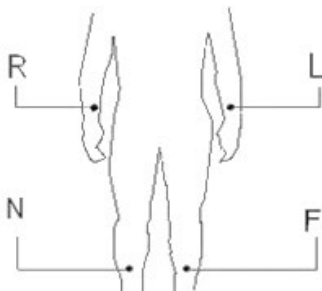
3.4.2 Attaching Electrodes to the Patient

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.

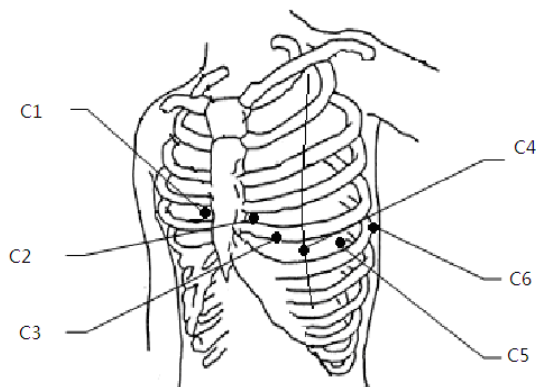
- Position of Electrodes
 - Standard 12-lead

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.

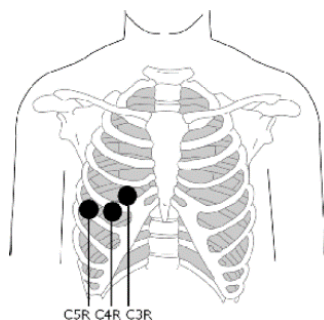
C3: midway between the C2 and C4 electrode positions.

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.

➤ V3R+V4R+V5R Right-sided Chest Leads

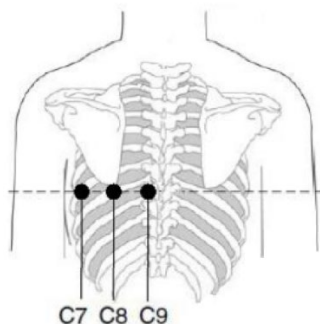


C3R: on the right side of chest, opposite to the C3 electrode position.

C4R: on the right side of chest, opposite to the C4 electrode position.

C5R: on the right side of chest, opposite to the C5 electrode position.

➤ V7+V8+V9 Posterior Chest Leads

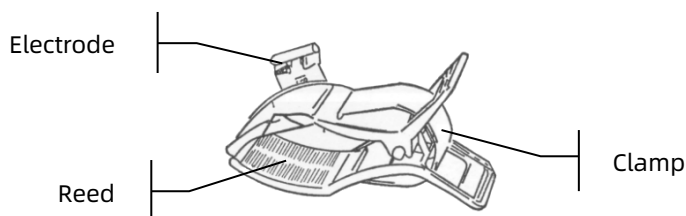


C7: on the left posterior axillary line, at the same level as C4~C6

C8: on the left scapular line, at the same level as C4~C7

C9: on the left paraspinal border, at the same level as C4~C8

- Attaching Limb Electrodes

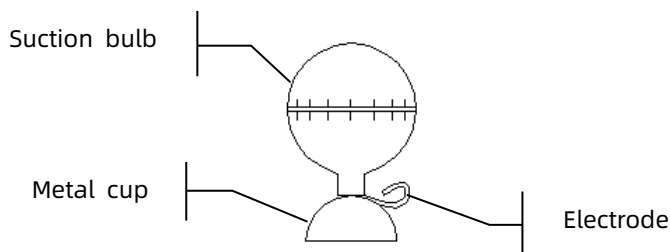


To attach limb electrodes, follow the steps below:

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 and Back Electrodes



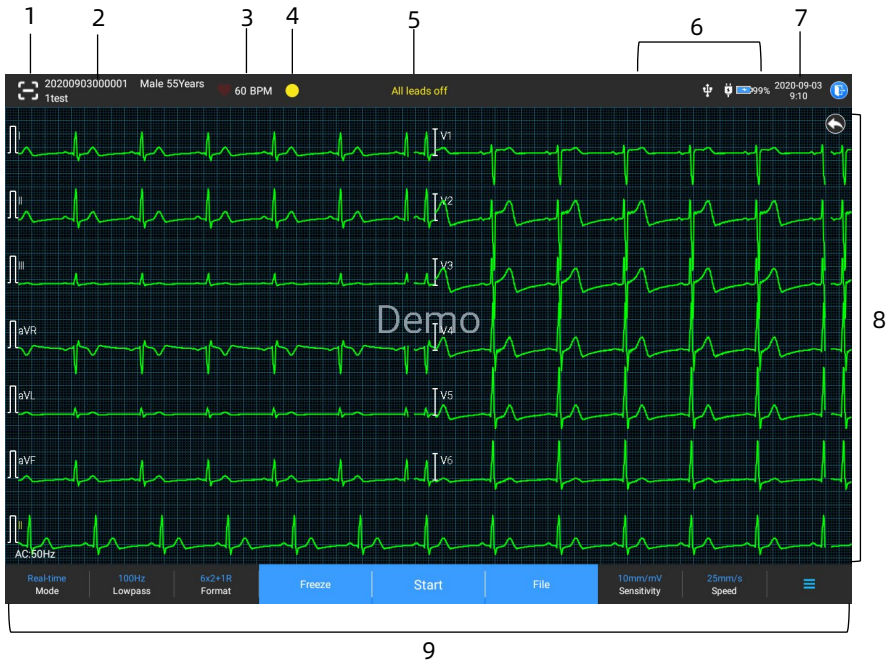
To attach the chest and back electrodes, follow the steps below:

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

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



1 Barcode scanning button

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

2 Patient information area

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

3 Heart rate (HR) area

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

4 Lead indication area

Click the  icon to view the electrode connection diagram and connection status in the popup window. The name and position of the electrode that fell off are displayed in yellow, and that of the one not fell off are displayed in green.

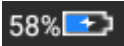
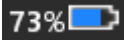
5 Prompt information area

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

6 Status display area

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

- Wired network (for 10.1" device)
 - : indicates that the device is connected to a wired network successfully. Not displayed when not connected.
- Wireless networks
 - : indicates that a Wi-Fi wireless network is connected. The solid part indicates network signal strength. Not displayed when not connected.

- : indicates that the mobile network is connected and displays the name of the operator to which it belongs. The solid part indicates network signal strength. Not displayed when not connected.
- Battery
 - If a battery is installed, the percentage of remaining battery power and the battery icon will be displayed; otherwise, it will not be displayed.
 - : indicates that the battery is being charged.
 - : indicates that the device is powered by a battery.
 - : indicates that the device is powered by a battery and the battery power is low.
 - : indicates that the battery is almost depleted and needs to be charged immediately. Otherwise, the device will automatically shut down soon.
 - : indicates that no battery is installed or battery charging fault.
- Power supply
 - : indicates that a DC power supply is connected. Not displayed when not connected.
- USB device
 - : indicates that a USB device, such as USB printer, keyboard, etc., is connected. Not displayed when not connected.
 - : indicates that a USB flash disk is connected. Not displayed when not connected.

7 System time area

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

8 Waveform area

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

9 System button area

Displays the commonly used system buttons.

For more information, see *4.2 System Buttons*.

4.2 System Buttons

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

- Quick keys

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

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

- Waveform freezing

After clicking the [Freeze] button, the ECG waveforms stop refreshing and scrolling.

For more information, see *6.7 Freezing Waveforms*.

- File

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

- Menu Expand / Hide button

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

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

- Copy

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

- Setup

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

- STAT

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

- Cal

During a manual measurement, click this button to place a 1mV calibration square wave on each waveform on the acquisition screen and ECG report.

- Lead Switch

During a manual measurement, click this button to switch the leads to be recorded.

- Start / Stop button

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

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

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

Chapter 5 Entering Patient Information

5.1 Setting Patient Information

Patient information is classified as required information and detailed information. The required information must be entered. In the [Patient Info] screen, an asterisk (*) is placed behind the required information. The detailed information helps you to know more about the patient.

Setup

ECG Setup

Patient Info

Sampling Setup

Record Setup

Comm. Setup

System Setup

Required Patient Info

☐ Patient ID ☐ Last Name ☐ First Name ☐ Gender ☐ Age ☐ Date of Birth

☐ ID No.

Detailed Patient Info

☐ Middle Name ☐ Height ☐ Weight ☐ Blood Pressure ☐ Race ☐ Medication

☐ Medical History ☐ Request Dept ☐ Exam Dept ☐ Physician ☐ Technician ☐ Outpatient ID

☐ Inpatient ID ☐ PE ID ☐ Bed No. ☐ Exam ID ☐ MRN ☐ Accession No.

☐ Exam Item ☐ Advanced Item ☐ Email

User Defined

Basic Setup

Height/Weight Blood Pressure

Unique ID

To set patient information, follow the steps below:

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

5.2 Entering Patient Information

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

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

✦ **Entering Patient Information Manually**

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

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

Note

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

✦ **Reading Patient ID with the Device's Camera**

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

1. Click the [] button to start scanning.

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

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

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

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



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

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

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Chapter 6 Acquisition, Analysis and Printing

6.1 Selecting the Working Mode

To select the working mode, follow the steps below:

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



Caution

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

6.2 Selecting the Lead Mode

The device supports 6 lead modes: 6-lead, 9-lead, 12-lead, 15-lead (Standard + right chest), 15-lead (Standard + posterior), 15-lead (Pediatric) and 18-lead.

To select the lead mode, follow the steps below:

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

6.3 Setting ECG Waveform and Report

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

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

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

6.4 Acquisition and Analysis

6.4.1 Auto Diagnosis

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

If the [Preview] option in the [ECG Setup] screen is disabled, the device automatically prints the ECG report after ECG data is acquired and analyzed.

If the [Preview] option in the [ECG Setup] screen is enabled, the preview of waveforms displays after ECG data is acquired and analyzed. You can do the following operations in the preview screen:

- Select [I] in the lead selection area in the lower left corner of the thumbnail area to switch the lead whose waveform needs to be observed.
- Use the measurement tool in the upper right corner of the screen to measure the interval and amplitude of the waveforms.

- Switch the lead format, sensitivity and speed of the waveforms.
- Select [Re-analyze] to re-analyze the ECG data and overwrite the original analysis results.
- Select [Save] to save the report.
- Select [Print] to enter the print preview screen to print or export the report:
 - Select [Print] to print the report.
 - Select [Export] → [PDF] to export the report to a USB flash disk.
 - Select [Export] → [Email] to send the report to the specified email address.
- Select [Diagnosis] to modify the diagnosis results, or confirm the auto analysis result.
- Select the return icon  in the upper left corner of the screen to return to the main screen.

Note

In the Manual mode, the device continuously prints the waveforms of selected leads in real time. The manual measurement provides only printed report without measurement and analysis results. You cannot save the report or send it to the external device.

In the auto measurement mode, ECG analysis provides:

- Measurement parameters, including:
Heart rate (bpm), P duration (ms), PR interval (ms), QRS duration (ms), QT/QTc interval (ms), P/QRS/T axis (°), RV5/SV1 amplitude (mV), RV5+SV1 amplitude (mV), RV6/SV2 amplitude (mV)
- Algorithm analysis results
- Minnesota code

- Average template
Gives the average template waveform of each lead.
- Measurement matrix
Gives 14 measurements of each lead, including:
P amplitude (mV), Q amplitude (mV), R amplitude (mV), S amplitude (mV), T amplitude (mV), ST1 amplitude (mV), STJ amplitude (mV), ST20 amplitude (mV), ST40 amplitude (mV), ST60 amplitude (mV), ST80 amplitude (mV), Q duration (ms), R duration (ms), S duration (ms)

In the R-R mode, ECG analysis provides:

- Measurement parameters, including:
Sampling Time (s), Total QRS, Heart Rate (bpm), Average RR Interval (ms), Max RR Interval (ms), Min RR Interval (ms), Max/Min (Ratio of Maximum RR Interval to Minimum RR Interval)
Time-domain analysis index: SDNN (Standard Deviation of Normal to Normal Intervals) (ms)
RMSSD (The Root Mean Square Successive Difference) (ms)
Frequency-domain analysis index: Total Power (ms*ms), VLF (extremely low frequency, ms*ms), LF (low frequency, ms*ms), LFnorm (nu), HF (high frequency ms*ms), HFnorm (nu), LF/HF
- RR Histogram
- RR Interval Diff Histogram
- Frequency Chart

6.4.2 AI Diagnosis

In the AI Server login mode, after the ECG waveform is stable, click the [Start] button, the device starts recording the ECG waveform. If you have enabled [Auto Upload] from the [ECG

Setup] screen, ECG data is automatically uploaded to the connected AI server for analysis at the completion of ECG acquisition. After the server returns the diagnosis report, the status of the relevant patient record in the file management menu will change to "Diagnosed", you can view the diagnosis result and print the report.

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

6.5 Printing Reports

You can print ECG reports through an external printer. Refer to 3.3.11 *Connecting the Printer* for methods for connecting the printer to your device. Before printing a report, check that the paper is properly loaded. To load the paper for the external printer, refer to the printer's accompanying instructions for use. The 10.1" device can also be configured with a recorder base to output the ECG reports. Before printing a report, refer to 3.3.3 *Loading the Recording Paper* for loading paper for the recorder base.

Note

If the [Printout] option in the [Record Setup] screen is disabled, click the [Start] button to save but cannot print the ECG report.

6.6 Copying Reports

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

In the main screen, click  → [Copy] button:

- When the archived data is not empty, the most recently stored report will be printed directly.

- When there is no report, a “No data!” message appears. Acquire ECG data first.

6.7 Freezing Waveforms

You can freeze the currently displayed waveforms on the screen for a careful observation or printing. If the ECG data is less than 10 seconds before freezing, it is necessary to wait for the device to collect enough data for 10 seconds before freezing. The device can freeze waveforms for up to 300 seconds. If the data is less than 300 seconds, the waveform of the actual duration from the beginning of waveform refresh to the time when the button is clicked is displayed.

In the main screen, click [Freeze] button to enter the waveform freezing screen:

- You can switch the speed, sensitivity and lead format of the frozen waveform, as well as store and print ECG reports.
- You can manually add or modify diagnosis results.
- You can quickly select the diagnosis results you want by entering keywords, because the device has loaded the diagnosis result template.
- For the diagnosis that is not in the diagnosis result template, you can add the diagnosis result, and then select it from the custom menu.

6.8 Report Examples

6.8.1 Auto Mode

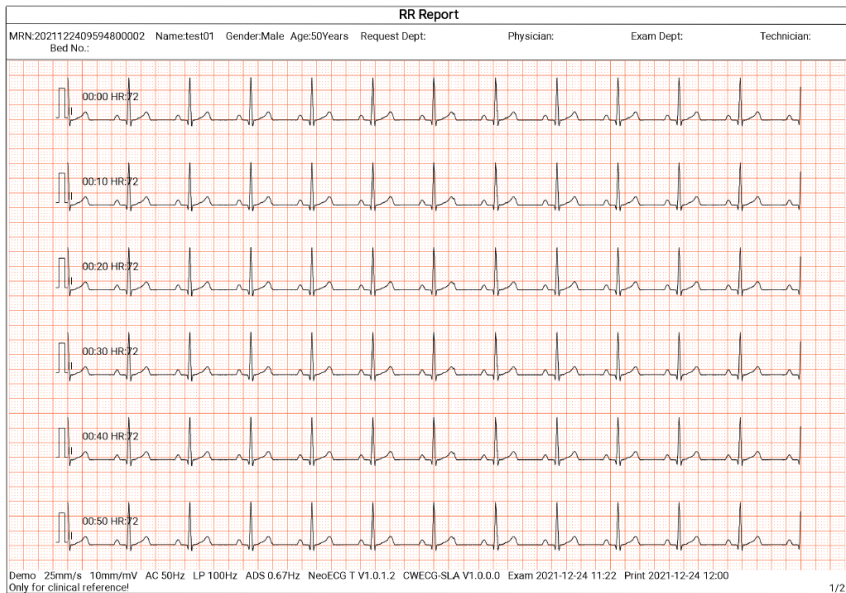
Take a 6x2+1R real-time sampling ECG report under the 12-lead auto measurement mode as an example to illustrate the elements in the report.

1		2		3	
ECG Report					
Patient ID: 2021122409594800002 Name: test01 Gender: Male Age: 50 Years Request Dept: Physician: Exam Dept: Technician: Bed No.:		HR : 72 P Duration: 92 PR Interval: 164 QRS Duration: 96 QT/QTc Duration: 356 / 377 P/QRS/T Axis: 58/ 55/ 57 RV5/SV1 Amplitude: 0.877 / 0.410 RV5+SV1 Amplitude: 1.287 RV6/SV2 Amplitude: 0.000 / 0.000		bpm ms ms ms * mV mV mV Diagnosis Result: 1. [R]Sinus rhythm 2. [S]Normal ECG Report confirmed by: <i>Li</i>	
Demo 25mm/s 10mm/mV AC 50Hz LP 100Hz ADS 0.67Hz NeoECG T V1.0.1.2 Glasgow V30.4.0 Exam 2021-12-24 13:14 Print 2021-12-24 13:16 Only for clinical reference!					

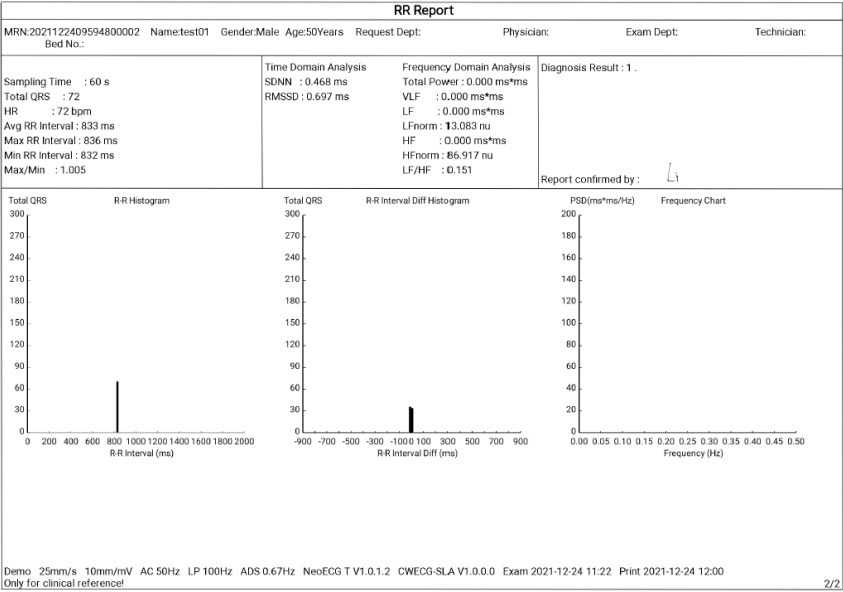
- 1 Patient information area
- 2 Measurement parameters area
- 3 Diagnosis result area
- 4 Waveform area
- 5 Speed
- 6 Sensitivity
- 7 AC filter
- 8 Lowpass filter

- 9 ADS filter
- 10 System software version
- 11 Algorithm software version
- 12 Examination date and time
- 13 Print data and time
- 14 Page information

6.8.2 RR Analysis



Page 1 - 1 min rhythm waveform of lead II

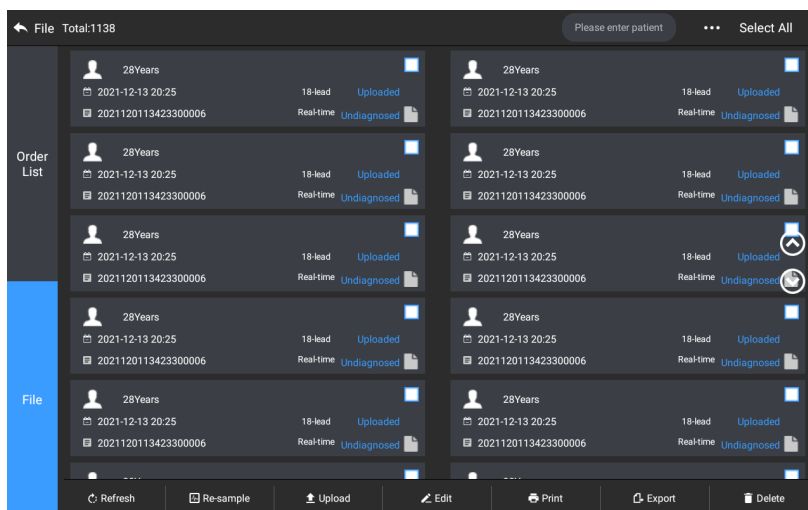


Page 2 - RR measurement and analysis result

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Chapter 7 File Management

In the waveform acquisition screen, click the [File] button 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. You can re-acquire, re-analyze, upload, preview, edit, export, print, query and delete the stored historical records. The device can store 10000 routine ECG reports.



Button	Description
Refresh	Click to refresh the data list.
Re-sample	Click to re-acquire ECG for the selected patient.
Re-analyze	Click a record under the "Undiagnosed" status, then select [Re-analyze] at the bottom of the screen, and select "OK" in the pop-up window to modify the diagnosis conclusion and measurement parameter values.

Button	Description
Upload	Click to upload the currently selected ECG data to the required server.
Edit	Click to perform the following operations on the selected patient data: ● View and measure the waveform data, change waveform display format, sensitivity and speed. ● Edit the patient information (the unique ID cannot be modified). After the current patient information is edited, the corresponding patient information in the patient information list will be updated. ● Edit the diagnosis. ● Re-analysis. ● Save analysis results. ● Print the ECG report of the patient.
Print	Click to print one or more selected patient reports.
Export	Click to export the currently selected report to USB flash disk. Click [Export] → [Email] to send the selected report(s) to the specified email address.
Delete	Click to delete one or more selected patient data.
...	Enter keywords into the search box to search out all eligible patient files. Click the icon ... behind the search box, the search condition setting screen will pop up, you can set relevant search conditions for precise search.
Select All / Unselect All	Click to select all / deselect all patient data.

Chapter 8 System Settings

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

Note

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

8.1 ECG Setup

Menu Items	Description
Sampling Mode	Manual, <u>Real-time</u> , Pre-sampling, Periodic, Trigger, R-R, 12-Lead Extend, Pharma  Note The Glasgow algorithm does not support trigger sampling.
Lead Setup	
Lead Mode	6-lead, 9-lead, <u>12-lead</u> , 15-lead (Standard + right), 15-lead (Standard + posterior), 15-lead (Pediatric), 18-lead
Layout	For 6-lead: 6×1, 3×2 For 9-lead: 9×1, 3×3, <u>3×3+1R</u> , 3×3+3R, 6+3 For 12-lead: 12×1, 6×2, <u>6×2+1R</u> , 3×4, 3×4+1R, 3×4+3R For 15-lead: 15×1, 6+9, 6+6+3, <u>6+6+3+1R</u> , 3×5, 3×5+1R, 3×5+3R For 18-lead: 12×1+6×1, <u>6×3+1R</u> , 6×2+6×1, 6×2+6×1+2R, 3×6

Menu Items	Description
Lead Standard	<u>IEC</u> , AHA
Lead Sequence	<u>Standard</u> , Cabrera
Rhythm Setup	
Rhythm Type	<u>Single Lead</u> , Three Leads
Rhythm Lead 1	I, <u>II</u> , III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6, V3R, V4R, V5R, V7, V8, V9
Rhythm Lead 2	I, II, III, aVR, aVL, aVF, <u>V1</u> , V2, V3, V4, V5, V6, V3R, V4R, V5R, V7, V8, V9
Rhythm Lead 3	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, <u>V5</u> , V6, V3R, V4R, V5R, V7, V8, V9
Filter Setup	
ADS Filter	0.01Hz, 0.05Hz, 0.32Hz, <u>0.67Hz</u>
EMG Filter	25Hz, 35Hz, 45Hz, <u>Off</u>
Lowpass Filter	75Hz, <u>100Hz</u> , 150Hz, 300Hz, Off
AC Filter	<u>On</u> , Off
Display Setup	
Speed	5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, <u>25mm/s</u> , 50mm/s
Sensitivity	Auto, 2.5mm/mV, 5mm/mV, <u>10mm/mV</u> , 20mm/mV, 10/5mm/mV, 20/10mm/mV, 40mm/mV
Arrhythmia Threshold	

Menu Items	Description
Brady	Manually enter a maximum of 3-digit integer number in the text box. The default value is 60. The unit is bpm.
Tachy	Manually enter a maximum of 3-digit integer number in the text box. The default value is 100. The unit is bpm.  Note The tachycardia value should not be less than the bradycardia value. If the entered value of tachycardia is less than that of bradycardia, a prompt "The tachycardia value cannot be less than the bradycardia value" will pop up.
Other Setup	
Auto Upload	On, <u>Off</u>
Auto Save	<u>On</u> , Off
Preview	On, <u>Off</u>

8.2 Patient Info Setup

Menu Items	Description
Patient Info Configuration	
Required Patient Info	Patient ID, Last Name, First Name, Gender, Age, Date of Birth, ID No.
Detailed Patient Info	Middle Name, Height, Weight, Blood Pressure, Race, Medication, Medical History, Request Dept, Exam Dept, Physician, Technician, Outpatient ID, Inpatient ID, PE (physical examination) ID, Bed No.,

Menu Items	Description
	Exam ID, MRN, Accession No., Exam Item, Advanced Item, Email
Basic Setup	
Height/Weight Unit	<u>cm/kg</u> , inch/lb
Blood Pressure Unit	<u>mmHg</u> , kPa
Unique ID	<u>Patient ID</u> , Inpatient ID, Outpatient ID, MRN, PE ID, Accession No., Exam ID
Patient ID	Auto Accumulation, <u>Manual Input</u>

8.3 Sampling Setup

Menu Items	Description
Sampling Time Setup	
Real-time Sampling	<u>10 Sec</u> , 20 Sec, 30 Sec, 60 Sec
Periodic Sampling	Manually enter an integer number in minutes into the text box The input range is 1-60 Min, and the default value is 60 Min
Periodic Interval	Manually enter an integer number in minutes into the text box The input range is 1-60 Min, and the default value is 1 Min

Menu Items	Description
	 Note The periodic interval cannot be greater than the total time of periodic sampling.
RR	60 Sec, <u>180 Sec</u> , 300 Sec
Manual	5 Min, 10 Min, <u>Unlimited</u>
Pharma	Immediately after injection, 1 Min, 2 Min, 3 Min, 5 Min, 7 Min, 10 Min, 15 Min, 20 Min, 30 Min

8.4 Record Setup

Menu Items	Description
Print Setup	
Print Sequence	Synchronous, <u>Sequential</u>
Print Mode	<u>Save Paper</u> , Quick Mode  Note Save paper mode and quick mode are only suitable for printing ECG report in auto mode.
Print Device	Thermal Printer, Network Printer, USB Printer, 3-channel Thermal Printer Click the icon on the right to view supported printer models.
Print Preview	On, <u>Off</u> When set to Off, the device does not enter the print preview screen after completing ECG data acquisition and analysis.

Menu Items	Description
Printout	<u>On</u> , Off When set to Off, the device does not send a report to the printer.
Network Printer	
Network IP	When "Network Printer" is selected for "Print Device", set the network IP and port.
Port	
Test	Click this button to test whether the network printer is connected successfully.
Printout Grid	<u>On</u> , Off
Report Setup	
Measurement Parameters	Select whether Measurement Parameters are included in the ECG report generated by auto measurement. Checked by default.
Average Template	Select whether Average Template is included in the ECG report generated by auto measurement. Unchecked by default.
Diagnosis Result	Select whether Diagnosis Result is included in the ECG report generated by auto measurement. Checked by default.
Minnesota Code	Select whether Minnesota Code is included in the ECG report generated by auto measurement. Unchecked by default.
Print Time	Select whether Print Time is included in the report. Unchecked by default.

Menu Items	Description
Measurement Matrix	Select whether Measurement Matrix is included in the ECG report generated by auto measurement. Unchecked by default.  Note The 3-channel thermal printer does not support printing measurement matrix.
Time Scale	Select whether to print the start time and timescale lines for each column of waveforms below the waveforms in the report. Unchecked by default.

8.5 Communication Setup

8.5.1 Wired Network

Connect the network cable to the RJ45 network port on the left side of the 10.1" device.

In the setting screen, click [Comm. Setup] → [Ethernet] to enter the Ethernet setting screen.

You can choose to automatically obtain IP address for network connection, or set IP address, gateway and subnet mask according to the actual situation. After successful connection, ECG data can be transmitted through wired network.

8.5.2 Mobile Network

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



Caution

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

8.5.3 WLAN Setup

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

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

8.5.4 Server Setup

When the diagnostic mode is AI Cloud Mode, you can upload local data to the configured AI server.

When the diagnostic mode is Auto Diagnosis, you can upload local data to the configured FTP or DICOM server.

You can set the AI server, FTP, or DICOM server as needed in the communication setup screen.



Note

In local Auto Diagnosis mode, when uploading data to the server, the device and the server need to be connected to the same local area network.

8.5.5 Mailbox Setup

Menu Items	Description
Sender	Enter the report sender's email address.
Authorized Password	Enter the authorized password of the SMTP service of the sender's email address.

Menu Items	Description
Receiver	Enter the report recipient's email address.
Send Format	<u>PDF</u> , BMP

8.6 System Setup

8.6.1 Display & Sound

Menu Items	Description
Brightness	Drag the slider to adjust the brightness of the display screen
Volume	Drag the slider to adjust the volume of the device.
Touch Tone	<u>On</u> , Off
QRS Beep	On, <u>Off</u>
Low Battery Beep	<u>On</u> , Off
Lead Off Beep	<u>On</u> , Off
Print End Beep	<u>On</u> , Off
Upload Success Beep	On, <u>Off</u>
AI Analysis Completed Beep	On, <u>Off</u>
Diagnosis Completed Beep	<u>On</u> , Off

8.6.2 Date & Time

Menu Items	Description
Automatic Synchronization	On, <u>Off</u> After being turned on, when connected to the network, the time of the device is synchronized with the server time.
Date Format	Options: <u>yyyy-mm-dd</u> , mm-dd-yyyy, dd-mm-yyyy
Time Format	Options: 12h, <u>24h</u>
Current Date	Set the current date
Current Time	Set the current time

8.6.3 Other Setup

Menu Items	Description
Language	Select the UI language. Options: 简体中文, 繁體中文, <u>English</u> , Español, Português, Français, Русский язык, Italiano, Deutsch, Polski, Ελληνικά
Demo	In this mode, the device can demonstrate its main functions when a patient or patient simulator is not connected. Options: <u>Off</u> , Normal ECG, Abnormal ECG  Warning The Demo mode is mainly used to show the performance of the device and to train users. In clinical use, do not set the device to Demo mode when connecting patients, to avoid mistaking the

	Demo waveform for patient's waveform, which may result in delayed diagnosis and treatment.
Diagnostic Mode	Auto Diagnosis, AI Cloud Mode
Glasgow Algorithm	Options: On, <u>Off</u> Select whether to use the Glasgow algorithm for ECG analysis. The device incorporates the Glasgow algorithm, developed by the University of Glasgow, to provide an interpretation of the resting 12-lead ECG.
Auto Standby	Set the time for the device to automatically enter standby mode. Options: <u>Off</u> , 5 Min, 10 Min, 20 Min, 30 Min, 60 Min When you select [Off], the device will not automatically enter the standby mode. If there is no user operation and all leads off within the set time, the device automatically enters the standby mode.
Institution Name	Enter the name of the medical institution.
Technician No.	Enter the number of the examining technician.
PDF Name Prefix	Enter the required PDF name prefix.
Restore Default Settings	Click to confirm whether to restore the default settings. This operation will restore all settings to their default values (record data will not be deleted).

8.7 System Maintenance

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

Menu Items	Description
AC Frequency	Set the frequency of AC filter. Options: <u>50Hz</u> , 60Hz
QTc Formula	Select the QTc formula. Options: <u>Hodeges</u> , Bazett, Fredericia, Framingham
SCP	It can only be used after authorization, and "Authorized" will be displayed after authorization.
HL7	It can only be used after authorization, and "Authorized" will be displayed after authorization.
DICOM	It can only be used after authorization, and "Authorized" will be displayed after authorization.
QR Code Setting	Set the start address and end address of each field, as well as the gender code. You can add other field according to your actual need by clicking +.

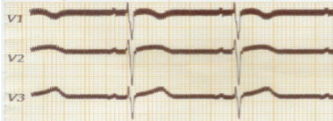
8.8 Factory Maintenance

In the setting screen, click [System Setup] → [System Maintenance] → [Factory Maintenance], and input password to enter the factory maintenance screen, where you can perform the following operations:

- Export log
- Factory upgrade
- Set filename
- Restore factory settings

Chapter 9 Prompt Messages and Troubleshooting

No.	Messages or Troubles	Solutions
1	<i>Recorder out of paper</i>	Load the paper properly.
2	<i>Recorder door not closed</i>	Close the recorder door.
3	<i>XX lead off (All leads off)</i>	1. 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. 3. If you have done all of the above steps, but still no waveforms, check that whether the device is inoperable due to an overload or saturation of any part of the amplifier.
4	<i>Low battery!</i>	Charge the battery immediately.
5	<i>Battery depleted. Power off soon.</i>	Connect the DC power supply or use the recorder base to power the device, or charge the battery immediately.
6	<i>Export failed</i>	Check the USB device and export data again.
7	<i>Insufficient memory space</i>	Delete unwanted historical files or change the storage device / location.

No.	Messages or Troubles	Solutions
8	Some Lead without Waveform Printout	If you acquire the ECG data immediately after the leadwires are applied to the patient, the ECG traces may not display because the ADS is not stable yet. Normally it is necessary to wait for the waveform of each lead to be stable if all leads are in good contact before ECG measurement.
9	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. ● 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.

No.	Messages or Troubles	Solutions
		● 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.
10	EMG Interference Symptom: The ECG has irregular fluctuation while the baseline demonstrates no change. 	Check the following aspects of the device for solving problems: ● The room is uncomfortable? ● The patient is nervous or feels cold? ● The bed is too narrow? ● The patient is talking? ● The limb electrode clamps are attached too tightly? If the interference cannot be cleared after the above measures, use an EMG filter, and the recorded waveform is slightly attenuated.

No.	Messages or Troubles	Solutions
11	The printed ECG waveform is out of the grid area of the printing paper.	It is caused by the great fluctuation of the waveform. Set the sensitivity to "Auto". The device will automatically adjust the sensitivity according to the amplitude of the ECG signal.
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. ● Mixed use of old and new electrodes. If the interference cannot be cleared after the above measures, use an ADS filter.

Chapter 10 Cleaning, Disinfection and Maintenance

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

10.1 Recommended Cleaning Agents

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

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

10.2 Cleaning

10.2.1 Cleaning the Device

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

To clean the device, follow the steps below:

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

10.2.2 Cleaning Patient Cable and Electrodes

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

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

10.2.3 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 recorder base.
2. Open the paper compartment cover and take out the recording paper.
3. Wipe the print head gently with a clean soft cloth dampened in 75% 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 paper compartment cover after the print head is completely air dried.

10.3 Disinfection

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

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

10.4 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 Device and Recorder Base

Follow the below guidelines to maintain the device and recorder base:

- 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.

10.5 Regular Maintenance

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

10.6 Viewing System Information

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

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

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Chapter 11 Accessories

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

Accessory	Model/Type	Quantity
Power cable (recorder base)	10A/250V	1
DC power adapter	PH30-12	1
Patient cable (12-lead)	ECG-FD10X4 (IEC) ECG-FD08X4 (AHA)	1
Patient cable (18-lead)	ECG-FD18X4 (IEC/AHA)	1
Chest electrodes	ECG-FQX41	6 pcs
Pediatric chest electrodes (optional)	ECG-EQD01	6 pcs
Limb electrodes	ECG-FJX42	4 pcs
Pediatric limb electrodes (optional)	ECG-EJ01	4 pcs
Adult disposable adhesive electrodes (optional)	915W50	50 pcs
ECG adapter (optional)	Banana connector (4.0) female	10 pcs
Recording paper	Ø 210mm or Ø 216mm	1
Paper roller	Plastic ABS pearl white	1
Rechargeable lithium battery (device)	1054090 / 7.4V / 5000mAh	1

Accessory	Model/Type	Quantity
Rechargeable lithium battery (recorder base)	KMD-18650-14.4-4400B	1

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



Warning

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



Warning

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



Warning

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

Appendix A Technical Specifications

A.1 Safety Specifications

Standards	MDD 93/42/EEC	Medical Device Directive
	IEC 60601-1: 2005+A1:2012+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:	Device: Class II with internal power supply Device equipped with recorder base: Class I with internal power supply

	Anti electric-shock degree:	Defibrillation proof Type CF applied part
	Degree of protection against harmful ingress of water:	7" device: IPX2 10.1" device: IPX0
	Installation and use:	Portable, not permanent installation device
	Working mode:	Continuous operation
	EMC:	Group I, Class B
	Degree of safety of application in the presence of flammable gas:	Equipment not suitable for use in the presence of flammable gas

A.2 Environment Specifications

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

A.3 Physical and Hardware Specifications

Main unit	Dimensions	7" device: 197mm × 112mm × 26mm (Width × Depth × Height)
		10.1" device: 273mm × 182mm × 40mm

		(Width × Depth × Height)
	Weight	7" device: 0.8kg, including the main unit and battery, excluding accessories
		10.1" device: 1.2kg, including the main unit and battery, excluding accessories
	Display	7" device: 7 inches, color LCD touch screen Resolution: 1024 × 600 pixels
		10.1" device: 10.1 inches, color LCD touch screen Resolution: 1280 × 800 pixels
	Input voltage and current	12V  2.5A
Power supply	AC power	Rated voltage: 100-240V~
		Rated frequency: 50/60Hz
	Built-in rechargeable lithium-ion battery	Rated voltage: 7.4V
		Rated capacity: 5000mAh
		Run time: When using only the internal battery, under normal circumstances, when the battery is fully charged, the device can work normally for more than 10 hours (acquiring ECG every 5 minutes); and if putting the device into standby mode, the battery can last for at least 60 hours.
		Charge time:

		Charge the battery for at least 5 hours before using it for the first time. For a depleted battery with the device power off: ≤4h to 90% capacity ≤5h to 100% capacity
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Recorder base		
Physical Specifications	Dimensions	295mm × 288mm × 111.2mm (Width × Depth × Height)
	Weight	About 2.5kg (including battery)
Power supply	AC power	Rated voltage: 100-240V~
		Rated frequency: 50/60Hz
	Built-in rechargeable lithium-ion battery	Rated voltage: 14.4V
		Rated capacity: 4400mAh
		Run time: When powered by a new fully-charged battery, the device can work normally for nearly 12 hours (print every 5 minutes); and when the device is in the standby mode, the battery can last for up to 72 hours.
		Charge Time: Charge the battery for at least 5 hours before using it for the first time. For a depleted battery: less than 4 hours to 90% when the device is off; less than 5 hours to 100% when the device is off.

Recorder	Recorder type	Thermal recorder
	Recording paper	Rolled thermo-sensitive paper, paper width: 210mm, 216mm
	Paper speed	5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s, 50mm/s Accuracy: $\pm 3\%$
	Number of waveform channels	Maximum 18
	Resolution	Vertical resolution: 8 dots/mm Horizontal resolution: 40 dots/mm (with paper speed 25mm/s)

A.4 ECG Specifications

HR Measurement	Method	Peak-peak detection
	Measurement range	30bpm~300bpm
	Accuracy	± 1 bpm
Main unit	Leads	6-lead, 9-lead, 12-lead, 15-lead and 18-lead synchronous acquisition and analysis
	A / D conversion	24 bits
	Sampling rate	32000 points / sec
	Skew between channels	No skew

	Amplitude quantisation	0.95 μ V/LSB
	Duration of contact for all applied parts and accessible parts	10s < t < 1min
	Common mode rejection ratio (CMRR)	≥ 140 dB (AC filter on) ≥ 120 dB (AC filter off)
	Time constant	≥ 5 s
	Frequency response	0.01 Hz~350 Hz $\pm \frac{0}{3}$: $\frac{4}{0}$ dB, 10Hz
	Sensitivity	Auto, 2.5mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV, 40 mm/mV Accuracy: $\pm 5\%$
	Filter	AC filter: 50Hz, 60Hz, Off
		EMG filter: 25Hz, 35Hz, 45Hz, Off
		ADS filter: 0.01Hz, 0.05Hz, 0.32Hz, 0.67Hz
		Lowpass filter: 75Hz, 100Hz, 150Hz, 300Hz, Off
	Paper speed	5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s and 50mm/s Accuracy: $\pm 3\%$
	Input impedance	$\geq 100\text{M}\Omega$ (10Hz)

	Input circuit current	$\leq 10\text{nA}$
	Calibration voltage	$1\text{mV} \pm 2\%$
	Depolarization voltage	$\pm 900\text{mV}, \pm 5\%$
	Noise	$\leq 12.5\mu\text{V}$
	Recovery time after defibrillation discharge	$< 10\text{s}$
	Pacing pulse display	Pacing pulse with amplitude of $\pm 2\text{mV} \sim \pm 700\text{mV}$, duration of $0.1\text{ms} \sim 2.0\text{ms}$, rise time of less than $100\mu\text{s}$, and frequency of 100/min can be displayed on the ECG recording.
	Minimum detectable signal	$20\mu\text{Vp-p}$

Appendix B EMC and Radio Regulatory Compliance

B.1 EMC Compliance

Basic performance: The device can acquire ECG data normally.



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 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device 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 (20 μ Vp-p) specified in the technical specifications, the measurement result may be inaccurate.

 Caution

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

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

No.	Name	Length	Shield (Yes/No)
1	Patient cable	Approximately 3.2m	Yes
2	DC power adapter cable	1.2m	No
3	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 Emissions	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Clause 5

Table 2

Guidance and Manufacturer's Declaration - Electromagnetic Immunity		
Immunity Test	IEC 60601 Test Level	Compliance Level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines
Surge IEC61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
NOTE: UT is the a.c. mains voltage prior to application of the test level.		

Table 3

Guidance and Manufacturer's Declaration - Electromagnetic Immunity		
Immunity Test	IEC 60601 Test Level	Compliance Level
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m

Table 4

Guidance and Manufacturer's Declaration - IMMUNITY to proximity fields from RF wireless communications equipment					
Immunity Test	IEC60601 Test Level				Compliance Level
	Test Frequency	Modulation	Maximum Power	Immunity Level	
Radiated RF IEC 61000-4-3	385 MHz	**Pulse Modulation : 18Hz	1.8W	27 V/m	27 V/m
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation : 217Hz	0.2 W	9 V/m	9 V/m

810 MHz 870 MHz 930 MHz	**Pulse Modulation : 18Hz	2 W	28 V/m	28 V/m
1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation : 217Hz	2 W	28 V/m	28 V/m
2450 MHz	**Pulse Modulation : 217Hz	2 W	28 V/m	28 V/m
5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation : 217Hz	0.2 W	9 V/m	9 V/m
Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.				

B.2 Radio Regulatory Compliance

Hereby, Shenzhen Carewell Electronics Co., Ltd. declares that the radio equipment type [designation of type of radio equipment] is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: www.carewell.com.cn/en

This device can be operated in all member states of the EU.

According to Article 10 (10) of Directive 2014/53/EU, the packaging shows that this radio equipment will be subject to some restrictions when placed on the market in Belgium (BE), Bulgaria (BG), the Czech Republic (CZ), Denmark (DK), Germany (DE), Estonia (EE), Ireland (IE), Greece (EL), Spain (ES), France

(FR), Croatia (HR), Italy (IT), Cyprus (CY), Latvia (LV), Lithuania (LT), Luxembourg (LU), Hungary (HU), Malta (MT), Netherlands (NL), Austria (AT), Poland (PL), Portugal (PT), Romania (RO), Slovenia (SI), Slovakia (SK), Finland (FI), Sweden (SE), the United Kingdom (UK), Turkey (TR), Norway (NO), Switzerland (CH), Iceland (IS), and Liechtenstein (LI).

Specification For EU:

Band(for EU)	Maximum output Power (dBm)
LTE B1	24.5
LTE B3	24.5
LTE B7	24
LTE B8	24.5
LTE B40	23.5
2.4G WIFI	16.17
5G WIFI	14.73



Warning

This device was tested for typical body-support operations. To comply with EU RF exposure requirements, a minimum separation distance of 0.5 cm must be maintained between the user's body and the device, including the antenna. Third-party belt-clips, holsters, and similar accessories used by this device should not contain any metallic components. Body-support accessories that do not meet these requirements may not comply with RF exposure requirements and should be avoided. Use only the supplied or an approved antenna.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a

residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.



Warning

This device was tested for typical body-Support operations. To comply with FCC RF exposure requirements, a minimum separation distance of 1.0 cm must be maintained between the user's body and the device, including the antenna. Third-party belt-clips, holsters, and similar accessories used by this device should not contain any metallic components. Body-support accessories that do not meet these requirements may not comply with RF exposure requirements and should be avoided. Use only the supplied or an approved antenna.



Warning

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any

interference received, including interference that may cause undesired operation.



Warning

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.



Warning

The WLAN function for this device is restricted to indoor use only when operating in the 5150 to 5350 MHz frequency range.

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 100 μ s, 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 ± 1 mm.
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.

Appendix D Cybersecurity Measures

D.1 Personal Information Security

Protecting personal health information is a major component of security strategy. To protect the personal information and ensure the proper device performance, the user should take necessary precautions in accordance with local laws and regulations and institution's policies. The manufacturer recommends health care organizations or medical institutions to implement a comprehensive and multifaceted strategy to protect the information and systems from internal and external security threats.

To ensure the patients' safety and protect their personal health information, the user should implement security practices or measures that include:

- Physical safeguards - physical safety measures to ensure that unauthorized personnel do not have access to the software.
- Operational safeguards - safety measures during operation.
- Administrative safeguards - safety measures in management.
- Technical safeguards - safety measures in technical field.

D.2 Network Security

1. Under the AI Cloud Mode, the access/operation of the device is restricted to authorized personnel only. Assign only staff with a specific role the right to use the device.

2. Ensure that all device components maintaining personal information (other than removable media) are physically secure (i.e. cannot remove without tools).
3. Ensure that the device is connected only to the device authorized/approved by the manufacturer. Users should operate all systems deployed and supported by the manufacturer within specifications authorized by the manufacturer, including the software, software configuration, security configuration, etc.
4. Protect all the passwords to prevent unauthorized changes. Only the manufacturer's service personnel are allowed to modify the factory maintenance settings and factory upgrade.
5. Anti-virus measures such as virus scanning should be carried out on the USB device before using it for software upgrade or other purpose.
6. When connecting the system to a shared network, data security issues of the network topology and configuration must be considered. Since the patient sensitive data are not encrypted and might be transmitted from the system to the network, the medical institution should be responsible for the network security. Firewalls and/or other security devices should be in place between the medical system and any externally accessible systems. It's recommended to use Windows defender firewall or any other firewall that can defend against Dos and DDos attacks, and keep it up to date.
7. DoS and DDos protection of the router or switch must be turned on for defending against attacks.

8. When the device is returned for maintenance, disposed of, or removed from the medical institution for other reasons, it is necessary to ensure that all patient data are removed from the device.
9. When deploying the network, it is recommended to isolate the network and the intranet system of the hospital by using VLAN so as to ensure the network security. Only trusted devices are allowed to join the VLAN network.
10. Make sure networking function is used in a secure network environment.
11. Please protect the privacy for the information and the data displayed on the screen, and for the information and the data stored in the system and external storage devices.
12. When building the networking environment: 1) If a wireless router is used, please turn on the MAC address filtering function of the wireless router and add the MAC address of the device to the rule list. The wireless router only allows devices in the rule list to access the wireless network. 2) It is suggested to build a VLAN, assign the LAN ports where the approved switch port, device and AI ECG server are into the same VLAN, and isolate it from other VLANs.
13. The device and the third-party server must be used on the same LAN. A specific IP address is required for the connection.
14. Authentication is required on the connected end. For example, password authentication is required for the WiFi connection to connect to the required and available WLAN.
15. The encryption of WiFi is configured by the router and supports WAP, WAP2 or WAP3 encryption protocols.

16. Using TCP/IP transmission protocol, if the transmission is unsuccessful, there will be a message indicating whether it needs to be retransmitted.
17. The device displays the network connection status.
18. To avoid malicious tampering and theft of data transmitted by the network, the device will authenticate the accessed AI ECG server and encrypt the transmitted data to ensure the security.

 Note

Log files generated by the software do not contain protected medical data.



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