User Manual for Electrocardiograph

Model: ECG-5512G

Date: 2024-09-19

File No.: MNU-ECG551202-01-Rev.C2

China Care Medical Equipment Co.,Ltd
Adress:Room B101, Zhongbang Business Building, PuXing Road No. 87, Tianhe, Guangzhou,
Chinaweb:www.chinacaremedical.com

Statement of the Manufacturer

Thank you for choosing our electrocardiograph (hereafter referred to as the device). This manual refers to the working principle, safety precautions, operation and use methods, maintenance and repairing, packaging, storage and transportation of the device. Please read this manual carefully before use and keep the manual together with the device for further reference.

This manual applies to the Resting ECG, with software version 2.33. Due to continuing product innovation, specifications in this manual are subject to change without notice. Please contact our sales or service team.

Responsibility of After-Sales Service

The company is only responsible for the performance and reliability of the device under the following conditions:
Assembly, commissioning, and repairing are performed by personnel approved by the company.
The relevant electrical device complies with national standards.
Using the device in accordance with the user manual.

User Manual Information:

Version	Revision Description	Issuing Date
C1	First release (in compliance with the latest standards)	2018/08/29
C2	Second release (in compliance with the latest standards)	2024/09/19

Content

Section 1 Safety Information

The design of the Electrocardiograph complies with IEC 60601-1 (Medical electrical equipment-Part 1: General requirements for basic safety and essential performance) and IEC 60601-2-25 (Medical Electrical Equipment Part 2: Particular Safety Requirements for Electrocardiographs). The classification concerning the protection against electrical shock of this device is CLASS I and the applied parts are TYPE CF APPLIED PARTS, which means a higher degree of protection against electric shock and the patient connection is fully insulated and defibrillation protected. The device is not water-proof. Please avoid water splashing when using. It is also not explosion-proof. Please do not use it in the presence of flammable anesthetics.

The device complies with IEC 60601-1-2 (Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance). When in the environment where the electromagnetism is beyond the limit of the standard, the device may not work properly. When the abnormal interference appears, please check and clear all the electromagnetism interference before the operation. Also, DO NOT use the device near a MRI equipment.

1.1 General safety warnings

* The user of the device must be qualified person with professional training and should be very familiar with the content of this manual.
* Before using the device, the user must check the device and accessories carefully to ensure that they can work properly and safely (Please refer to the packing list accompanying the device).
* Do not use the device in the presence of flammable anesthetic mixture with oxygen or other flammable agents, otherwise, there is a risk of explosion or fire.
* To avoid the risk of electric shock, this device must only be connected to a supply mains with protective earth. Please use the socket with protective earth and ensure the protective earth of the socket is in good situation.
* Before connecting or disconnecting the power cord to the device, please make sure the device is power off and the power cable is disconnected from the AC power socket. Or it may cause electric shock or other harm to the patient or the operator.
* If there is any doubts about the integrity of the protective earth cable, please disconnect the AC power and use the battery as power.
* Do not use the device in the environment with high-power, high-voltage or high-static electricity equipment, such as high-voltage cables, X-ray machines, ultrasound equipment and electrotherapy machines. Otherwise the safety and performance of the device may be affected.
* Do not open the enclosure of the device, otherwise there may be a danger of electric shock. Repairing or upgrading the device requires professional after-sales personnel.
* The device should be kept away from water and avoid storage or using in a place with poor ventilation, excessive atmospheric pressure, heat, moisture and dust, or with corrosive gas and chemicals.
* The device should be placed in a flat place, and should be handled gently to avoid excessive vibration or drop.
* The device is only allowed to connect with other equipment which comply with the standards of IEC 60601-1 or equivalent standards.
* Using this device with other ECG monitor to the same patient may cause mutual interference.
* The electrodes and connectors of the device can only be in contact with the patient and should not touch other conductor components, including the earth.
* When the device is working, the medical staff should not leave the working site and should pay attention to the patient. If necessary turn off the power or remove the electrodes to ensure the safety of patients. If any abnormality occurs during the usage, please shut down the device and check immediately.
* Chemicals released from a broken LCD may cause poison. Please carefully deal with the device which the LCD is broken.

* The electrocardiograph is an defibrillation-proof internal power supply Type CF device. The applied part of the device can not be directly applied to the human heart.
* If the electrocardiograph is used with defibrillator or other electric stimulation equipment, the users should use the anti-defibrillation patient cable and electrodes supplied by our company. If the defibrillation time is over 5 seconds or using with a high frequency electrosurgical equipment, the disposable electrodes must be used to prevent the metal electrodes burning the skin of patients. If the device is used with other electric stimulators, there should be a professional technical staff in present to instruct.
* While using the defibrillator, an instantaneous high voltage will be released from it. Do not touch the patient, otherwise it may cause serious injury or death.
* To prevent cross-infection, the following precautions should be taken: (1) Take regular cleaning of all parts in contact with the patient; (2) Avoid making ECG examination of patients with open infectious disease.
* The quality of the ECG signal acquisition can be affected by specific environmental conditions, the user's misuse, and certain conditions of the patient. For the relevant safety information, please refer to the corresponding section of this User Manual.
* The patient cable, limb electrodes and chest electrodes equipped with the device are consumables. The high-frequency use of them will lead to degradation, which may lower the anti-interference capacity of the device. The performance of the patient cable and the electrodes is required to be examined regularly. It is recommended to check at least once per month.
* The device is only an auxiliary means of diagnosis. It must be used in conjunction with the clinical indications and symptoms, as well as doctors' diagnosis.
* When the device is connected to any external equipment powered by the network power supply, it should ensure the connection comply with the safety requirements of medical electric system stipulated in IEC 60601-1 or equivalent standards.. If necessary, the external equipment should be powered by the isolation transformer. Any medical equipment connected to the device must comply with the safety requirements stipulated in IEC 60601-1or equivalent standards. Any non-medical equipment connected to the device must comply with relevant product safety standards. If in doubt, please consult the manufacturer or the local distributor.

1.2 Safety warnings for lithium battery

WARNING

* Improper usage may cause the battery become hot, catch fire, explode, destroy or the attenuate of the battery capacity. Please read this manual and precautions carefully before using the built-in rechargeable lithium battery (hereinafter named as 'battery').
* Only professionally trained service engineers are allowed to replace the battery. The replaced battery must be with the same specification offered by the manufacturer.
* It is forbidden to use metal to cut into the battery or violently hit the battery. Otherwise, the battery will be heated, smoked, deformed or burned, and will pose a danger.
* If the battery is not used for a long time, please charge and discharge the battery at least every six months.
* While installing or taking off the battery, the device must be powered off. Otherwise white screen or system crash will happen.
* If the device is not used for long time, please take out the battery and store it separately, to prevent battery leakage corroding the device.
* Do not disassemble the battery without the guidance of a professional technical personnel.
* Prevent the battery being splashed by water and do not throw the battery into water.
* Do not place the battery near an open flame, otherwise there is a danger of explosion.
* Do not directly connect the positive and negative terminals of the battery. Otherwise there is a danger of fire.
* The battery should be handled gently and must not fall on the ground or collide with other items.
* If the electrolyte of the battery leaks onto your skin or clothing, wash it off with water immediately. If the electrolyte gets into your eyes, do not rub your eyes, wash them immediately with clean water, and ask a professional doctor for advice.

* When the battery reaches the end of life (such as capacity reduced, not able to be charged, etc.), or if the battery leaks, emits an odor, and is deformed, please stop using the battery and dispose the used battery according to local regulations.

1.3 Warnings about usage

* To avoid being scalded, do not touch the print head immediately after printing, at which point the print head temperature may be high.
* To avoid malfunctions, please do not press the buttons and touch screen with sharp or hard objects. It only allows fingertips to press.
* If the device has any abnormality during the usage, it should be maintained by professional service engineer.
* Before turning the device on, make sure that the voltage and frequency of the power supply meet the requirements on the label of the device or the requirements specified in this manual.
* When the fuse needs to be replaced, it only allows to use the fuses supplied by the manufacturer.
* Only use the patient cable and other accessories supplied by the manufacturer, otherwise it may affect the performance and safety of the device.
* Using unspecified ECG recording paper may shorten the usage life of the printing parts of the device and it may result in unclear waveform.
* The communication cable (USB/RS232) connected to other equipment should have good electrical insulation and electromagnetic shielding, and the length should not exceed 3 meters. The communication cable configured by the manufacturer is suggested.
* Please do not maintain the device during usage.
* The device disconnects from the mains supply by means of a power plug. The device should be placed in a position where the user can easily disconnect from the mains supply.
* The inner and outer packaging materials of the device are in compliance with environmental protection requirements, and the packaging materials, the device and its accessories should be properly disposed of at the end of the life to meet the requirements of environmental protection regulations. After the end of its use life, the device and recyclable parts can be returned to the manufacturer for recycling or disposed of in accordance with local regulations.

1.4 List of the symbols

No.	Symbol	Description
1		Output
2		Input
3		Defibrillation-proof, Type CF applied part.
4		Caution
5		General Warning Symbol (background yellow; symbol black)
6		Refer to instruction manual/ booklet
7		Equipotentiality
8	PATIENT	Patient Cable Socket
9		USB
10	SD	SD Card slot
11		Network port

12		Power On/Off
13		DC Power
14		Charging Indicator
15		Charging Indicator
16		Recording Mode
17		Filter
18		INST
19		1mV Calibration
20		ECG File Management
21		Run/Stop
22		AC Power
23		Menu
24		Sensitivity
25		Patient
26		File
27		Help
28		Recovery/recyclable
29		Protective earth (ground)
30		Serial Number
31		Disposal in accordance with Directive 2012/19/EU (WEEE)
32		Complies with the European Medical Device Regulation 2017/745. Notified Body is 0123.
33		Non-ionizing electromagnetic radiation
34		Manufacturer
35		Date of Manufacture
36		Medical Device
37		Authorized representative in the European Community/European Union
38		Transportation and Storage Temperature Range
39		Humidity Limitation limitation
40		Atmospheric pressure limitation

Section 2 Product Description

2.1 Model configuration

Lead	Record format	Paper width	LCD	Touch Screen	Number of keys	Battery	Cases Storage	Bar Code Scan	USB
12	3ch+++, 6ch, 6ch+, 12ch	210mm	9inch	Yes	11	14.4V, 4400mAh	400	Yes	Yes

2.2 Software version

Main software release version	MAIN-V2.33
Acquisition software release version	AMP12-V2.11 (12 leads)

2.3 Structure

The device consists of a ECG main unit, an ECG patient cable, a grounded power cord, limb electrodes and chest electrodes.

2.4 Indication for use

Intended Use:

The intended use of this Electrocardiograph is to acquire ECG signals from adult and pediatric patients from body surface ECG electrodes and to record, display and store the ECG signals for review by user. The Electrocardiograph is intended to be used by trained healthcare professionals in medical institutions. The cardiogram recorded by the electrocardiograph can help users to diagnose heart disease, however it is offered to clinicians on an advisory basis only.

⚠ This device is not intended for home use.
⚠ This device is not intended for treatment or monitoring.
⚠ This device is only intended for use by trained professionals.

Intended User：

Doctors;
Professional trained healthcare professionals.

Intended patient:

Adult patient
Adolescent patient
Pediatric patient

Intended Use Environment

Medical institutions
About Power Supply and Environment Requirements of the device please refer to [Appendix A: Specification and Electrical Characteristics].

2.5 Software description

This device is equipped with an embedded system. It does not require other software environments and network conditions, and does not need to install anti-virus software and firewall.

WARNING
The update of the software (hardware) requires special software / hardware supplied by the manufacturer. The end user cannot update the software (hardware).

2.6 Communication description

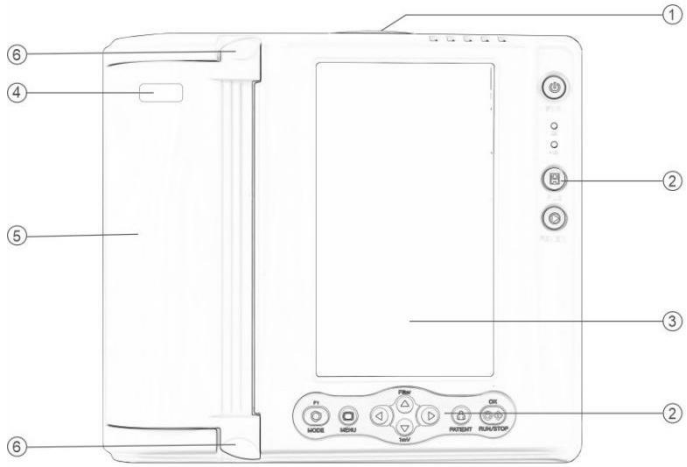
2.6.1 Interface description

Communication type	Transfer Protocol	Storage format
USB	USB2.0	U-disk (FAT32format)
UART	UART	115KBPS (3.3V level)

2.6.2 User access control
When special software is required to communicate with the device, the user is authenticated by the special software and the user type and authority are provided.

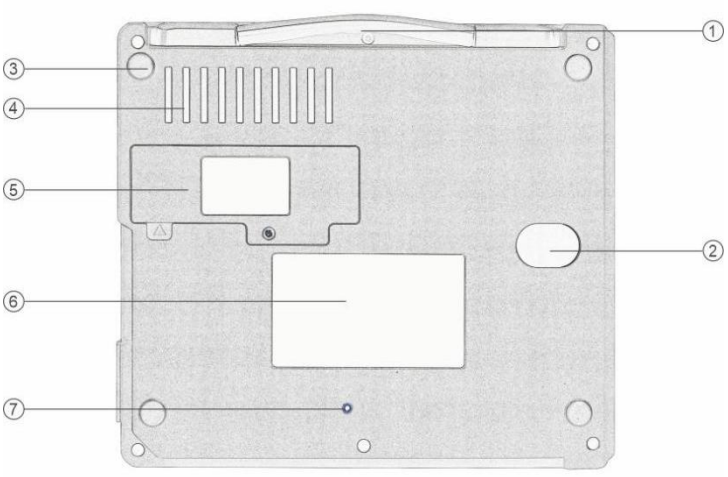
Section 3 Structure & Function

3.1 Front panel



No.	Explanation
①	Handle
②	Keyboard
③	LCD screen
④	Logo position
⑤	Paper compartment cover
⑥	Paper compartment cover switch

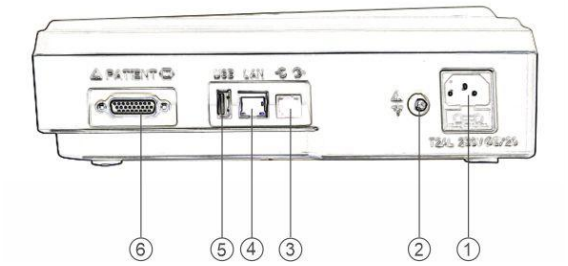
3.2 Bottom Panel



No.	Explanation
①	Handle
②	Regulating port for Z-fold paper
③	Non-Slip mat
④	Heat emission hole

⑤	Battery compartment
⑥	Label
⑦	Cart fixing screw hole

3.3 Lateral Panel



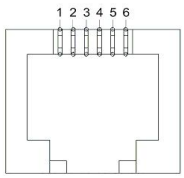
No.	Name	Explanation
①	Mains supply socket	AC power supply socket
②	Equipotential grounding post	Equipotential grounding post provides a connection between the device and the potential equalization bar of the electrical installation.
③	UART port	Connecting to bar-code scanner and factory debugging.
④	LAN	Not valid now.
⑤	USB/Host port	Connecting to USB flash drive to transfer data / Connecting to laser printer to print ECG report / Connecting to computer to PC ECG Management software.
⑥	Patient cable socket	Connecting to patient cable.

3.3.1 UART port (RJ11)

The UART port (RJ11) is used for

* Connecting to external bar-code scanner to scan the bar-code of patient information.
* Factory debugging mode: Debugging and update the ECG hardware and etc. (It needs special software)

PIN	Instruction	PIN	Instruction
1	GND	4	UART receive (3.3V)
2	NC	5	UART Send (3.3V)
3	NC	6	NC



3.3.2 LAN / RJ45 Port (Optional)

Not available.

3.3.3 USB Host Port

The USB Host Port (Optional) : Used for

* Transmit ECG file stored in the device to ECG Management Software stalled in personal computer. Please refer to the ECG Software Operation Manual for more information.
* Save ECG files stored in the device to an external USB disk (FAT File Format). The files can be imported into ECG Management Software. Please refer to the User Manual for more information.
* ECG files stored in the device can be printed on normal A4 paper through a USB printer (Now it only supports printer with HP PCL5 control language). For details about the supported USB printer models, please contact our service department.

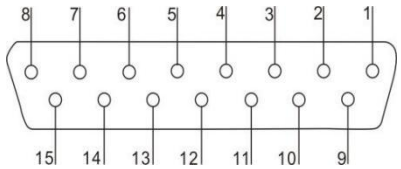
Caution: Signal output or input part only allow to connect with equipment with relevant certificates.

Caution:The USB cable should be well shielded and can not be longer over 3 meters. It's better to use the manufacturer's recommended USB cable.

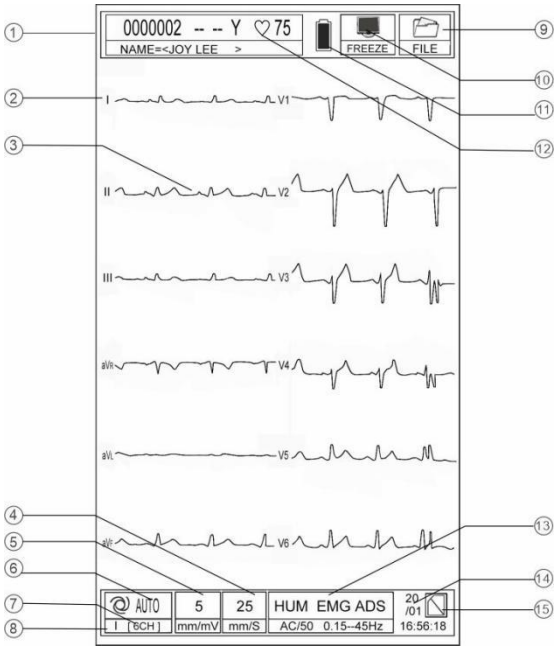
3.3.4 Patient cable socket (DB15)

Used for connecting patient cable:

PIN	NAME	PIN	NAME	PIN	NAME
1	C2	6	SHIELD	11	F
2	C3	7	NC	12	C1
3	C4	8	NC	13	NC
4	C5	9	R	14	RF(N)
5	C6	10	L	15	NC



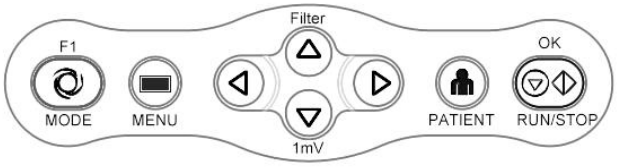
3.4 Screen display



No.	Explanation
①	Patient information: ID, Name, Gender and Age
②	Lead name I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
③	Lead waveform
④	Speed (paper feeding speed)
⑤	Sensitivity (gain sensitivity)
⑥	Working Mode
⑦	Sign of lead
⑧	Recording format
⑨	ECG file
⑩	Freeze

⑪	Battery level icon
⑫	Heart rate
⑬	Filter
⑭	Date and time
⑮	Prompt of no paper: Prompt when the machine cannot detect the printing paper.

3.5 Keypad panel and functions



Symbol	Explanation
≃	Power Indicator
⇥□	Battery Charging Indicator
PWR	Power on/off. Press it to turn on the device; Press it for 2 to 3 seconds, power-off.
File	ECG files. To enter the ECG files interface.
Review	To review the ECG.
MENU	Press it to confirm operation or to return to previous page (see prompt on screen) / To select working modes.
F1/MODE	Press it to confirm operation or to return to previous page (see prompt on screen) / To select working modes.
▲ / Filter	To move the cursor up to select item. / When inputting the patient age, height, weight, diastolic and systolic value, press the key Menu and ▲ at the same time, the value will decrease by 10. / To activate the filter (The filter icons will be shown on the screen).
▼ /1mV	To move the cursor down to select item. / When inputting the patient age, height, weight, diastolic and systolic value, press the key Menu and ▼ at the same time, the value will increase by 10. / 1mV calibration .
◀	To execute the operation command. / Switch the lead or lead group when recording ECG under Manual Mode. / Hold the key ◀ to prolong the current lead or lead group recording under Auto.Mode. / Move the cursor to the left in the interface of 'Patient'. / When inputting the patient I.D., age, height, weight, diastolic and systolic value, press the key Menu and ◀ at the same time the value will decrease by 1. / Switch the time of stored ECG for checking ECG of different time.
▶	To execute the operation command. / Switch the lead or lead group when recording ECG under Manual Mode. / Hold the key ▶ to prolong the current lead or lead group recording under Auto.Mode. / Move the cursor to the right in the interface of 'Patient'. / When inputting the patient I.D., age, height, weight, diastolic and systolic value, press the key Menu and ▶ at the same time, the value will increase by 1. / Switch the time of stored ECG for checking ECG of different time.
PATIENT	To input and edit patient information. Press it again to return.
RUN/ STOP	Start / stop sampling or recording ECG.

Section 4 Operation Preparation

4.1 Power supply and grounding

The device can be powered by mains supply and built-in rechargeable battery. Protective earth and potential equalization functions are offered. When the main supply interrupt, the built-in battery will power automatically.

Mains Supply: Please make sure the AC power strictly meet the requirements on the label of the device. Connect one head of the power cord to the mains supply socket of the device and plug the other head to the mains supply. The socket of mains supply must be grounded. Thus the device will ground automatically.

Please keep away from the mains supply when using the internal DC power, in order to reduce the AC interference. Please note the battery symbol on the screen. When the power capacity of the battery is not enough, please charge the battery in time.

Use terminal with protective earth and potential equalization: when using AC power, the cord must be connected to a 3-wire AC socket with protective earth to effectively reduce the patient leakage current and protect the patient. When this device is used with several other equipment, connect the grounding post on this device and the grounding cable offered with the device to the grounding cables of other equipment can ensure the potential equalization between several equipment.

4.2 Use battery to power

The device is equipped with big capacity rechargeable battery. AC power supply is preferred, however, when the AC power is not available, the device will automatically start battery power. The battery capacity symbol will be shown on the LCD. The device will be powered off with no operation for 5 minutes under the model of battery powering.

Note: The battery of this device should be charged for at least 6 hours before first use. When the battery voltage is too low, the device will automatically shut down to protect the battery and prevent excessive discharge.

4.3 Load the recording paper

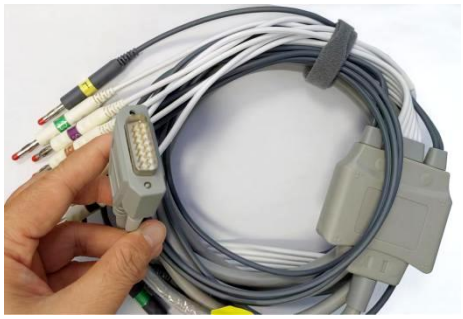
This device requires to use roll thermal paper. About the specification of recording paper please refer to Appendix 1. The way of loading the recording paper is as follows:

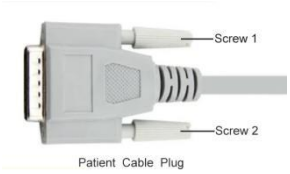
* Open the paper compartment cover and take out the paper shaft.
* Insert the paper roll to the paper shaft and pull out about 10cm and then load them into the paper compartment. Keep the printing paper grid downward (toward the print head)
* Close the paper compartment cover and make sure everything is in right position and situation.

Caution: If the device shows the icon of ‘Lack of paper‘, it means there is no paper in the paper compartment or the paper is not well loaded and therefore the device cannot print. It is suggested to re-load the paper according to the above method.

4.4 Connect patient cable to the device

The patient cable includes the main cable and lead wires which can be connected to electrodes.





Patient Cable

Loosen the screws on both sides of the main cable plug of the patient cable, align the plug to the patient cable socket of the device and insert, and then tighten the screws. Make sure the patient cable and the device are well connected.

4.5 Connect patient cable to electrodes

The identifiers and color codes of electrode connectors used comply with IEC/EN requirements. Correct connection of the electrodes is very important to record ECG.

In order to avoid incorrect connection, the identifiers and color codes are specified:

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

Caution:

* New/old electrodes or different type of electrodes cannot be used at the same time.
* The electrodes should be kept clean. If the surface is smudged, wash it off with alcohol or soapy water.

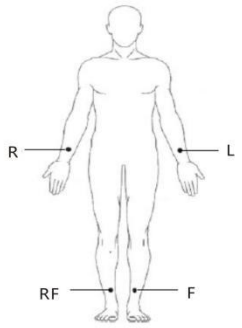
4.6 Electrode placement.

Place the electrodes on the correct positions of human body and ensure good connection and contact.

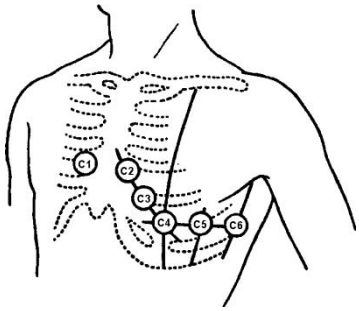
Caution:

* The human body, electrode and patient cable plug must not touch any conductors such as other metal surfaces.
* Clean the skin where the electrodes will be placed with 75% alcohol and apply a small amount of conductive gel on the cleaned skin.
* The electrodes must not touch each other.

The electrodes' positions on the body surface are shown in the following tables and figures.



Limb electrodes position diagram



Chest electrodes position diagram

IEC	AHA	Electrode Placement
R	RA	Right arm
L	LA	Left arm
F	LL	Left leg
N or RF	RL	Right leg
C1	V1	The fourth intercostal space at the right border of the sternum
C2	V2	The fourth intercostal space at the left border of the sternum
C3	V3	The fifth rib between C2 and C4
C4	V4	The fifth intercostal space on the left midclavicular line
C5	V5	Left anterior axillary line at the horizontal level of C4
C6	V6	Left midaxillary line at the horizontal level of C4

Caution: Do not mix the conductive gel of two electrodes together. Do not make one chest electrodes contact another to prevent short circuit.

Caution: If there is no conductive gel, 5% normal saline can be used for short-time ECG examination.

Please use accessories, replaceable parts and materials supplied by our company. Using other parts or materials may cause safety problems. Electrodes and other conductive part of connector (including neutral electrodes) must not contact other conductor, especially not contact the earth.

Note: If accessories, replaceable part and other materials are required to be replaced, please contact the manufacturer.

Section 5 Operation Instructions and Setting

5.1 Check the device before start

In order to ensure the safe operation of the device and to get high quality ECG waveform, please make the following inspection before start the device:

5.1.1 Check the grounding
Make sure the cord is properly connected the earth.

5.1.2 Check the working environment
The working environment should be clean and dry. The temperature is suitable and there should be no electromagnetic interference such as MRI, X-ray machine or ultra-short wave device nearby. The beds used for ECG should not be too narrow.

5.1.3 Check the power supply
The AC power supply should meet the power supply requirements of the device, and the cord must not be entangled with other patient cables. If the device is powered by built-in battery, make sure the battery remaining power is enough.

5.1.4 Check the patient cable
Keep the patient cable away from other AC cable. The lead wires must be smooth and not tangled or knotted with each other.

5.1.5 Check the electrodes:
The patient cable lead wire should be properly connected to the corresponding electrodes. The electrodes should be place on the correct position of human body. The collection and contact should be good.

5.1.6 Check the patient
* If the patient is too nervous, the operator should explain that the ECG examination is simple and non-invasive to make him relaxed.
* The patient should be relaxed and should not move and speak during the examination.
* The body of the patient cannot touch the metal part of the bed, otherwise AC interference may occur.
* The skin position where the electrodes are placed should be clean.

5.1.7 Check the recording paper
Check if the recording paper is enough and well loaded.

5.2 The working modes of the device

The working modes of the device include MAN (Manual Mode) / AUTO (Auto Mode) / R-R (Rhythm Mode) / STOR (Store Mode).

The default startup mode is Auto Mode with default sensitivity. The drift/AC filtering and thermal printing are also turned on by default.

5.2.1 Manual Mode
Under Manual Mode, the user needs to switch the ECG lead or lead group manually. The operation steps are as follows:
* Press the key F1 to select the MAN Mode.
* Set the recording format of Manual Mode in the menu Basic settings.
* According to the actual situation, make necessary adjustments to the sensitivity and filter before recording.
* Press the key Patient, the interface of Patient will come out. Input the patient information.
* When the ECG waveform on the screen is stable, press the key RUN/STOP to start recording the ECG.
* During the printing, users can press the key ◀ or ▶ manually to switch the lead or lead group.

* Press the key RUN/STOP again to stop printing.

Note: When the printing is [TEST], it is used to print the test triangle waveform (print head test).

5.2.2 Automatic Mode

The automatic mode has two modes: Review recording and automatic Real-Time recording. When the Automatic Mode is set to Review in the menu Basic settings, it is the Review recording format, and the others are automatic real-time recording formats.

(1) Review Recording Mode.

Press the key F1 to select Auto mode, then set the mode as Review in the item ' Auto Mode' in the menu Basic settings.

When the automatic mode is set as Review, uses can observe the waveform on the screen. After the waveform is stable, press the key RUN/STOP. The electrocardiogram of 10-12 seconds will be recorded. The ECG report will be printed automatically (If the ECG waveform stabilization time is insufficient, it will automatically prompt [==Please wait ==], then automatically start printing).

(2) Automatic Real-Time Recording Mode.

When the automatic mode is Automatic Real-Time recording, the operation steps are as follows:

* Press the key F1 to select Auto Mode.
* Set the recording format of Auto Mode in the menu Basic Settings.
* After the waveform and heart rate are stable, press the key RUN/STOP to start printing the ECG.
* Under Auto Mode, during the printing process, the sensitivity and baseline position are automatically adjusted according to the waveform amplitude.
* The lead is automatically switched in the automatic mode. You can also press the ◀ or ▶ to extend the recording time of the current lead until it is released.
* When the last lead is printed, the printing stops automatically. The user can also stop printing by pressing the key RUN/STOP at any time.

Note: After the automatic mode printing stops automatically, if in the Advance settings it is set to automatically prompt to save the ECG, the prompt 'Press F1 to confirm saving' will appear on the screen. Press the key F1 to save the ECG (press other keys to give up the saving).

5.2.3 Rhythm Mode

Under the Rhythm Mode, the device will sampling one minute ECG leads signal and print the ECG report of rhythm lead. The operation steps are as follows:

* Press the key F1 to select the Rhythm mode.
* Select the rhythm lead in the menu Basic settings.
* Press the key RUN/STOP to start sampling the ECG signals. When the sampling time exceeds 60 seconds, the sampling stops automatically.

Note: When the ECG sampling is completed, the device automatically starts printing the ECG report. If in the Advance settings in the menu it is set to automatically prompt to save the ECG, the prompt 'Press F1 to confirm saving' will appear on the screen. Press the key F1 to save the ECG (press other keys to give up the saving).

5.2.4 Store Mode

Under the Store Mode, the device will record the ECG but will not print the ECG report. It only saves ECG file in internal memory card. The operation steps are as follows:

* Press the key F1 to select the STOR mode.
* Press the key RUN/STOP to start the ECG sampling (maximum 90 seconds). During the period, users can press the key F1 to stop sampling.
* When the sampling time is less than 12 seconds, the storage operation will be abandoned.
* After the sampling is finished, the ECG file will be saved automatically.

Note:

Under the Automatic Mode, after pressing the key RUN/STOP to complete the recording and the recording

already stops automatically, the patient ID is automatically incremented. If the user stops the operation by pressing the key RUN/STOP, the patient ID is not automatically incremented.
Under the manual mode, the patient ID is not automatically incremented.

5.3 Set the Menu

5.3.1 Menu items

The system menu is divided into four main menus: Clock, Basic, Advance and Tools. Press the key Menu to switch the main menu items; Press the key ▲ or ▼ to select the menu items. Press the key ◀ or ▶ to modify the selected items. Press the key F1 to return.

5.3.2 Set the menu of Clock

[Clock]	Basic	Advance	Tools
1. Local Date		YYYY-MM-DD	
2. Local Time		HH:MI:SE	
3. Date Format		Y-M-D	
4. Color Theme		Theme1 / 2 / 3 / 4	
5. LCD Backlight		Level 1 / 2 / 3 / 4 / 5	
6. Auto Pow-off Time		5min., 10min.	
[MENU]: Item	[F2/F3]: Select	[F4/F5]: Exec.	[F1]: Return

No.	Item	Description
1	Local Date	Set current date (Year-Month-Date). It will be recorded on the recording paper.
2	Local Time	Set current time (Hour-Minute-Second). It will be recorded on the recording paper.
3	Date Format	Set the date format as Year-Month-Date or Date-Month-Year.
4	Color Theme	4 color theme can be set: Theme 1 / 2 / 3 / 4.
5	LCD Backlight	5 brightness level can be set: Brightness 1 / 2 / 3 / 4 / 5.
6	Auto Pow-off Time	Set the automatic power-off time when no operation as 5min, 10min .....50min.

5.3.3 Set the menu of Basic

Clock	[Basic]	Advance	Tools
1. Sensitivity (mm/mV)		Auto	
2. Speed(mm/s)		25	
3. Man. Mode		6ch+	
4. Auto. Mode		12ch	
5. Rhythm Lead		II, V1, V5	
6. Auto Rec. Length		Normal	
7. Lead Mode		CABERA	
8. AC Filter Freq.		50Hz	
9. EMG Filter Freq.		25Hz	
10. Report Print Format		All Param	
11. Store Mode Timer		12ch/18S	
12. STOR/Storage Mode		SAVE-ECG	
[MENU]: Item	[F2/F3]: Select	[F4/F5]: Exec.	[F1]: Return

No.	Item	Description
1	Sensitivity (mm/mV)	Set the sensitivity as 2.5 / 5 / 10 / 20 / 40mm/mV, and Auto (Default).
2	Paper Speed (mm/s)	Set the paper speed as 6.25 / 12.5 / 25 / 50mm/s.
3	Man.Mode	Set the record format as 3ch+++, 6ch, 6ch+ or 12ch. 3ch+++ means the waveform of three leads plus the waveform of three rhythm leads. 6ch means the waveform of six leads, and so on so forth.
4	Auto. Mode	Set the record format as 3ch+++, 6ch, 6ch+, 12ch or Review. 3ch+++ means the waveform of three leads plus the waveform of three rhythm leads. 6ch means the waveform of six leads, and so on so forth. **Explication:** The manual and automatic mode rhythm leads (also known as long leads) are convenient for doctors to observe and contrast ECG rhythm changes during lead switching.
5	Rhythm leads	To select the rhythm lead. It is used to specify the rhythm leads (any one of the 12 leads). If the the rhythm lead is set as +++, it is used to specify the first rhythm lead, and the second and third rhythm leads are fixed to V1 and V5.
6	Auto Rec. Length	Set the recording time in automatic mode. There are 4 options: short, normal, longer, and long+ (see the description in the table 5.3.3.1).
7	Lead Mode	Two options for lead mode: Standard lead (WILSON) and European lead (CABERA). The lead mode is defined in Table 5.3.3.2.
8	AC Filter Freq.	Two options for AC filter frequency: AC50Hz or AC60Hz. **Note:** The AC filter frequency must comply with the AC grid frequency, otherwise AC interference may not be effectively suppressed.
9	EMG Filter Freq.	Two options for myoelectric filtering frequency: EMG25Hz or EMG45Hz. The default EMG filtering frequency is 45Hz. When the myoelectric interference is serious and cannot be eliminated, EMG25Hz can be used. At this time, the amplitude of the QRS wave of the ECG is attenuated.
10	Report Print Format	There are three options for Report Print Format: Print all parameters, print parameters and print without parameters.
11	Store Mode Timer	To set the recording time under Storage Mode.
12	STOR/Storage Mode	To set to save the ECG report or not after printing under Auto and R-R modes.

Table 5.3.3.1

Auto Recording Length of Different Record Format

Format	Short	Normal	Long	Long+
3ch (or plus rhythm lead)	10 Sec.	15 Sec.	20 Sec.	25 Sec.
6ch (or plus rhythm lead)	7.5 Sec.	10.5 Sec.	14.5 Sec.	18 Sec.
12ch (or plus rhythm lead)	3.5 Sec.	5.5 Sec.	7.5 Sec.	9 Sec.

Table 5.3.3.2

Lead Mode Definition

No.	1	2	3	4	5	6	7	8	9	10	11	12
WILSON	I	II	III	aVR	aVL	aVF	V1	V2	V3	V4	V5	V6
CABERA	aVL	I	-aVR	II	aVF	III	V1	V2	V3	V4	V5	V6

2.5.3 Set the menu of Advance

Clock	Basic	[Advance]	Tools
1. Pen Heater		[X]	
2. QRS Beeper		[X]	
3. Keypad Beeper		[√]	
4. Lead-off Beeper		[X]	
5. Enable Ext. Input		[√]	
6. ADS Filter		[√]	
7. Stylus Printing		[√]	
8. ECG Simulator		[X]	
9. Local Language		[√]	
10. View of 12 Lead ECG		[√]	
11. Prompt to Save ECG		[X]	
12. Grid(mm) Printing		[X]	
13. 210mm Thermal Paper		[X]	
14. Auto Z-fold Paper		[X]	
15. ECG Aux.Analysis		[X]	
16. Prompt Repeated Patient ID		[X]	
[MENU]: Item	[F2/F3]: Select	[F4/F5]: Exec.	[F1]: Return

No.	Item	Description
1	Pen Heater	To deepen the print tracks. When the device is after long time use or the thermal paper is lower quality, users can set it on. It is not suggest to use this function when the device is in good state. Good quality thermal paper is necessary to ensure the normal performance and using life of the device. The default setting is off.
2	QRS Beeper	When a QRS heartbeat is detected, internal beep sounds to remind. The default setting is off.
3	Keypad Beeper	When there is operation of pressing the key or touch the soft key, an internal beep sounds to remind.The default setting is on.
4	Lead-off Beeper	When the lead is detected to fall off, the corresponding lead waveform will become straight line and an internal beep sounds to remind (in situation of all 12 leads are off or any two limb electrodes are disconnected or the limb electrode on the right leg is disconnected). When any chest electrode is disconnected, the corresponding lead waveform will become straight line but no beep to remind. The default setting is on.
5	Enable Ext. Input	Display / print analog signal of the external input in the TEST status of the manual mode. The default setting is on.
6	ADS Filter	Automatically suppresses ECG baseline drift & optimizes print position. The default setting is on.
7	Stylus Printing	Locally bold print ECG waveform, simulate hot pen printing effect.The default setting is on.
8	ECG Simulator	A simulated electrocardiogram is generated in the device for testing or demonstration. The default setting is off.
9	Local Language	Select [English] or [Local Language]. The default one is decided by the version of the operation software.
10	View of 12 Leads ECG	Select to display format of all 12 leads ECG waveform on screen. The default setting is on.
11	Prompt to Save ECG	Under automatic mode, it prompts to save the ECG after printing (press F1 to confirm). The default setting is off.

12	Grid (mm) Printing	Print a millimeter grid when printing to use plain thermal paper without a grid. The default setting is off.
13	210mm Thermal Paper	To adjust the recording width to adapt for the 210mm thermal paper. The default setting is off.
14	Auto Z-fold Paper	This item is only used for folding paper. The paper is automatically detected to the next page after the recording is completed. The default setting is off.
15	ECG Aux. Analysis	When this function is on, the ECG analysis interface will come out automatically after printing the waveform and before the ECG parameters and interpretation is printed. The default setting is off.
16	Prompt Repeated Patient ID	This item to remind the user to pay attention when the patient ID is repeated before each recording / sampling. The default setting is off.

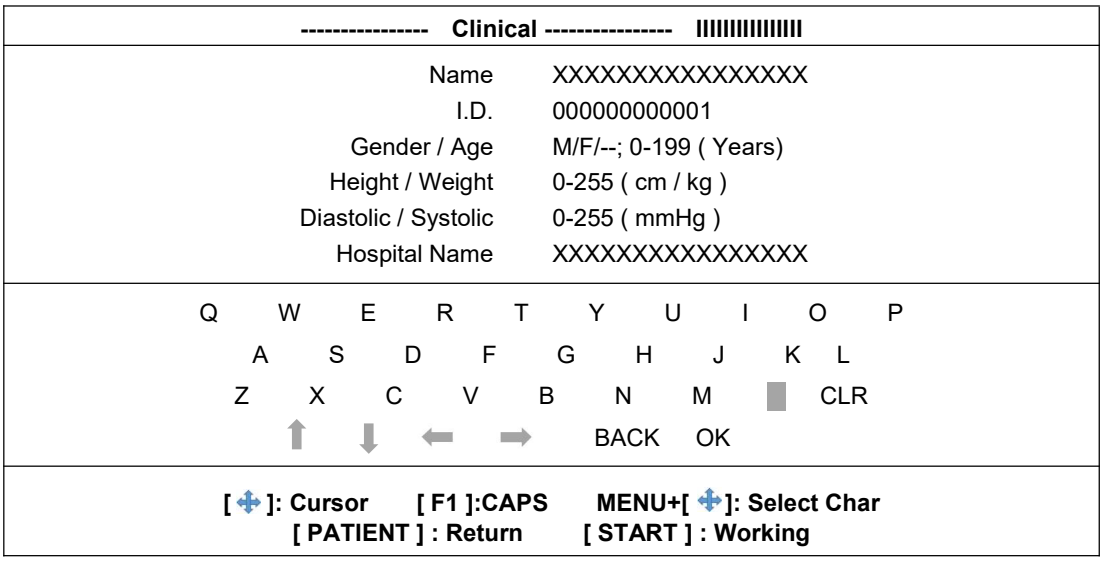
5.3.4 Set the menu of Tools

Clock	Basic	Advance	[Tools]
1. Load Default--AC50Hz		◄►	
2. Load Default--AC60Hz		◄►	
3. ECG File(s)		◄►	
4. Last Record Review		◄►	
5. UART/Real-time ECG		◄►	
6. Touch screen calibration		◄►	
[MENU]: Item	[F2/F3]: Select	[F4/F5]: Exec.	[F1]: Return

No.	Item	Description
1	Load Default-AC50Hz	Restore the default factory settings (the AC power frequency defaults to 50Hz).
2	Load Default-AC60Hz	Restore the default factory settings (the AC power frequency defaults to 60Hz).
3	ECG Files	ECG files stored. Refer to [5.7 File Management and Playback] for details.
4	Last Record Review	The last recorded ECG waveform is played back on the screen. Press the key Menu to enter the interface of operation to save, save to U disk, copy to USB printer or thermal printer. This function should be performed immediately after recording, otherwise other operations (such as ECG playback) may clear the last recorded data. Note: This function can only play back the last 12 seconds of the last recorded ECG data.
5	UART/Real-time ECG	This function is to activate the UART interface to transfer real-time ECG.
6	Touch screen calibration	To calibrate the touch screen. Activate this function, the four icons of (1) (2) (3) (4) will display on the screen. Click on the four points in order, then the icon [OK] appears. Click on [OK] to complete the touch screen correction.

5.4 Input patient information

Before examination the ECG, users can input patient information. Press the key PATIENT, the interface of patient information will come out (Press the key PATIENT again to get back). The key ▲ or ▼ is for selecting different items. The key ◄ or ► is for moving the cursor to the left or to the right or for executing the operation command. The key F1 is for selecting between upper case, lower case, numbers, punctuation and symbols.
The patient bar-code number is displayed on the right side of the title bar. If the device is equipped with a bar-code scanner, the patient number can be quickly entered by scanning the bar-code. The patient bar-code number can be up to 16 ASCII characters.



The device is equipped with touch screen. Users can select items or input letters or digit, or execute other operation commands by clicking on the touch screen.

Item	Description
Name	Up to 16 characters. Press the key ▲/Filter to switch between upper / lower case. Click on the letter keys or the indication keys on the touch screen to input or edit patient name.
I.D.	Up to12 digits. Press the key ◀ or ▶ to move the cursor. Click on the digit on the touch screen to input digit. Or press the key Menu and ◀ or ▶ at the same time to decrease the numerical value or increase the numerical value. All set to 0 means no number. The record number is automatically incremented each time.
Gender	Click on the soft key F or M on the touch screen to input patient gender. Or press the key Menu and ◀ or ▶ at the same time to select different gender between Male, Female and None.
Age	The value is 0-199 years. Click on the digit on the touch screen to input patient age. Or press the key Menu and ▲ or ▼ at the same time, the digit will decrease or increase by 10 (from 0, 10, 20, 30 ...); Press the key Menu and ◀ or ▶at the same time, the digit will decrease or increase by 1 (from 0, 1, 2, 3 ...).
Height / Weight	The value is 0-255cm and 0-255kgs. The operation is same as inputting patient age.
Diastolic / Systolic	The value is 0-255Kpa. The operation is same as inputting patient age.
Hospital Name	Up to 16 characters. The operation is same as inputting patient name.

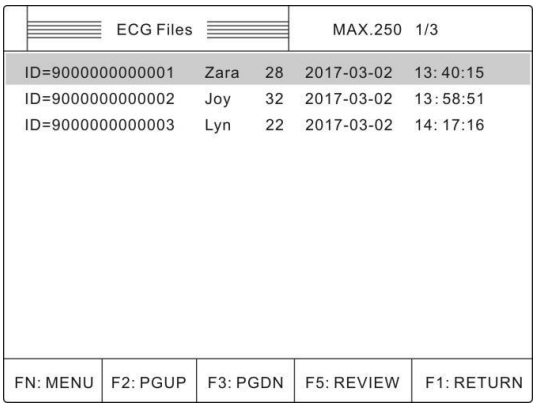
5.5 Record ECG

Press the key RUN/STOP to start recording the ECG waveform. Press the key RUN/STOP again to stop recording. In the working mode of ‘Storage’, press the key RUN/STOP to start sampling the ECG (not recorded), and then prompt whether to save the ECG will show up (Press F1 to confirm the save).

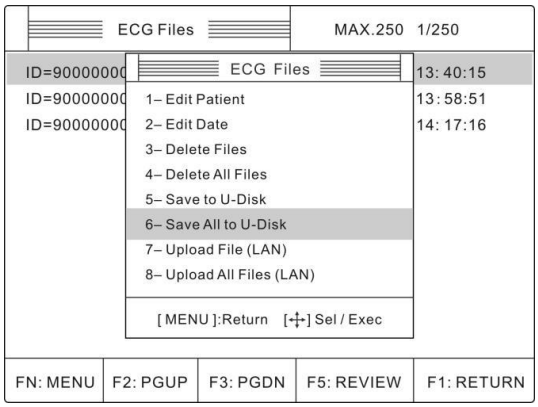
5.6 File management and playback

5.6.1 File Management

The device can store 400 patient cases in internal memory card. (If necessary, users can choose add an internal SD card to extend the storage). Click on the icon ‘File’ on the screen to enter the ECG file interface. Or Press the key Menu to the menu ‘Tools ’. Click on the item ‘ECG Files’ or press the key ▲ or ▼ to select the item ‘ECG File(s)’ . Press the key ◀ or ▶ to enter the ‘ECG Files’ interface (See Picture 1 below). Press the key ▲ or ▼ to move the cursor to select an ECG case. Press the key Menu to enter the interface of ‘ECG Files’ management (See Picture 2 below).



Picture 1



Picture 2

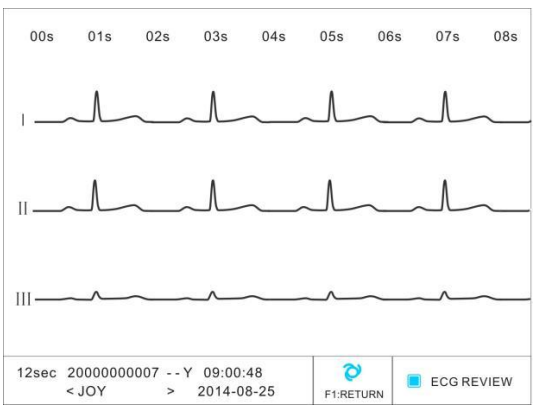
Press the key ▲ or ▼ to move the cursor to select different operation items. Press the key ◀ or ▶ to execute the operation. Press the key F1 or Menu to get back to inferior interface.

Note: The functions of Item 7-Upload File (LAN) and Item 8-Upload All Files (LAN) is for future software upgrade. For all current ECG models, the functions do not be valid now.

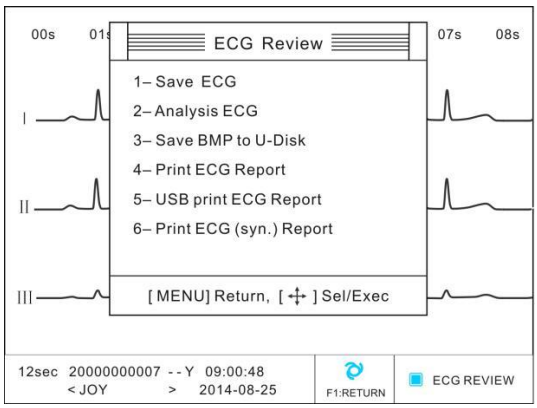
No.	Item	Description
1	Edit Patient	To modify the patient information of the selected patient case. The detailed operation is the same as [5.4 Input Patient information] .
2	Edit Date	To modify the date/time of the ECG record.
3	Delete File	To delete the selected ECG file.
4	Delete All Files	To delete all ECG files stored.
5	Save File to U-Disk	To transmit the selected ECG file to U-Disk.
6	Save All Files to U-Disk	To transmit all the ECG files to U-Disk.
7	Upload File (LAN)	Not valid now.
8	Upload All Files (LAN)	Not valid now.

5.6.2 Playback ECG

Click on the ECG case list to to select an ECG case or press the key ▲ or ▼ to move the cursor to select an ECG case. Press the key ◀ or ▶ to playback the stored ECG. Press the key ◀ or ▶ to check the ECG of different time. Press key Menu to enter the interface of ‘ECG Review ’. (Press the key F1 to get back to interior interface).



Picture 1



Picture 2

No.	Item	Description
1	Save ECG	Save the ECG data frozen or recorded in last time to the internal flash memory (or SD card). The data will not be lost after the data is stored. The patient information, date / time and ECG parameters will be saved as well.
2	Analysis ECG	To check the auto interpretation result on the screen.
3	Save BMP to U-Disk	Save the ECG report (BMP format) to the USB flash drive (external) through the USB/HOST interface of the unit.
4	Print ECG Report	Copy the ECG report to the built-in thermal printer to print out.
5	USB print ECG Report	Copy the ECG report to the USB printer (external) through the USB/HOST interface of this unit to print out.
6	Print ECG (syn.) Report:	Copy the synchronized ECG report to the built-in thermal printer.

⚠ Precautions for using USB flash drive and USB printer:

* The external USB flash drive must be formatted (FAT16/FAT32 format). There is no U disk formatting function on this unit.
* If the prompt [Read and Write Failure (Timeout)] is prompted, it may be because the U disk file system error / too many files and directories / old-fashioned slow U disk. It is recommended to reformat or replace the U disk (recommended to use the manufacturer's recommended U disk).
* Please confirm that the U disk is read and written after the U disk is read and written. If the U disk is unplugged during reading and writing, it may cause data loss due to a U disk file system error. Therefore, please note: back up the user data on the USB flash drive before using the USB flash drive.
* This function is an optional function of the device, not a standard configuration. Please consult your dealer for device configuration.

Note: System test, frequency and impulse response test methods: System test methods using Method A and Method D. Due to their sampling characteristics and the asynchronous nature of the sampling rate and signal rate, the digital system produces an appreciable modulation effect from one cycle to the next, especially for pediatric electrocardiograms.

Section 6 Cleaning, Disinfection and Maintenance

6.1 About the recording paper

To ensure the quality of printing results, please make sure to use the recording paper provided together with the device or with the same specifications. Otherwise, it may cause problems such as shortening the service life of the printing head, blurred waveform, and poor paper feed. At the same time, the following points should be noted.:

* Do not use surface-waxed, gray-black recording paper, otherwise the wax will stick to the printing head and the head will not work properly.
* Store the recording paper in a dry, cool place. Exposing to high temperatures, humidity, and sunlight can fade the recording paper.
* Do not leave the recording paper under fluorescent light for a long time, otherwise it will affect the recording effect.
* Do not store the recording paper with polyvinyl chloride, as this may cause discoloration of the recording paper.
* The specifications of the recording paper should be given special attention. Failure to meet specifications may damage the thermal print head or silicone rubber shaft.
* When the recording paper is overlapped for a long time, the recorded waveforms may be transferred to each other

6.2 Maintenance after using

After using the device, please pay attention to the following items:

* Press the key POWER to turn off the device, then unplug the plug from the AC power outlet.
* Carefully disconnect the patient cable and power cord, and do not pull the wires with force.
* Carefully disconnect the electrodes and collect them aside.
* Clean the device surface with a dust cover. Neutral detergent should be used for cleaning and the device should not be immersed in detergent.
* Place the device in a cool, dry environment and avoid severe vibration when moving.
* Bending or knotting will shorten the service life of the patient cable. While using it, please straighten the patient cable as much as possible.
* After long-term use, the electrode shall be replaced if its surface is affected by corrosion, oxidative discoloration, etc.

6.3 Cleaning and maintenance for patient cable

Regularly check the integrity of the patient cable and use a multi-meter to check the continuity of each lead (Its resistance should be less than 50Ω). Any damage will result in no picture for the corresponding lead or all leads.

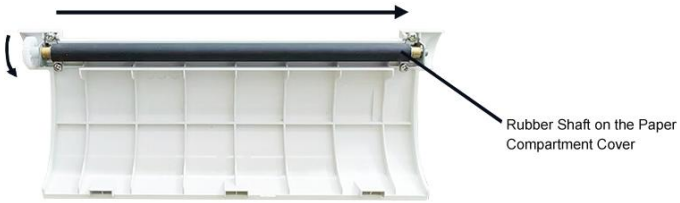
The patient cable can be cleaned with water and soap and disinfected with 75% alcohol (the patient cable must not be immersed in the liquid). A small angle of bending / knotting / stretching will shorten the service life of the lead wire. When using it, please straighten the lead wire and connect it to the electrode.

6.4 Cleaning and maintenance for electrodes

The electrodes must be well preserved. The electrodes can be sterilized with 75% alcohol. After prolonged use, the electrode shall be replaced if it is affected by corrosion, surface oxidative discoloration, etc.

6.5 Cleaning the rubber shaft

The rubber shaft should be cleaned regularly to keep it smooth and free of smudging, otherwise it will affect the ECG recording effect. The cleaning method is as follows: clean the soft cotton swab with alcohol, then use the soft cotton swab to wipe the rubber shaft in the longitudinal direction, and wipe it while turning the rubber shaft in the direction of the paper discharge until it is wiped clean.



6.6 Cleaning the printing head

Smudges and dirt on the surface of the thermal print head can affect the clarity of the printed waveform. The print head should be cleaned regularly. The specific method is: open the paper compartment cover and gently wipe the surface of the print head with a clean soft cloth dampened with alcohol. If there is residue, first infiltrate with a little alcohol, then wipe it with a soft cloth. Do not scratch the surface of the print head with a sharp object, as this may cause damage. The paper compartment cover can only be closed after the alcohol has completely evaporated. The print head is recommended to be cleaned once a month.

⚠ Do not clean the print head immediately after printing. At this time, the print head has a high temperature and be careful of burns.

6.7 Replace the fuse

When the AC power is supplied, if the power indicator is off and the battery capacity symbol is displayed after the power is turned on, the AC fuse may be damaged. Replace it as follows:

* Remove the AC power cord.
* Press the fuse cover with a screwdriver. The fuse cover will pops out;
* Remove the burnt fuse and replace the fuse of the specified specification;
* Push and fasten the fuse cover and make sure the fuse cover is locked.

⚠ If the fuse is blown again after replacing the fuse, there may be other malfunctions in the device. Please turn off the power, and contact the after-sales service department or the designated service agent.

6.8 Maintenance for battery

The device is equipped with a rechargeable battery. For the voltage, capacity, and charging time of the battery, please see Appendix 1 Product Model and Product Specifications. When AC power is supplied, the battery is charged when the device is in standby. During the charging process, the charging indicator on the control panel is always on, and when the battery is full, the indicator changes from blinking to off.

⚠ When using the battery for the first time, it must be charged for more than 6 hours. If the battery was not used for a long time, it should be charged and discharged at least once every six months.
The fully charged battery can guarantee the continuous operation of the device for 8 hours. The screen

displays the battery capacity symbol during battery operation. If the symbol flashes empty, it indicates that the battery capacity is seriously insufficient, and the device will automatically turn off the power to protect the battery. Battery replacement must be carried out by a qualified person according to the prescribed procedures. When the battery is defective, there will be insufficient battery capacity or power failure, and it should be replaced at this time.

The method of taking out battery:

		
Unscrew the screws and open the cover of the battery box	Pull and disconnect the cable of the battery.	Take out of the battery. If the user can not take out the battery manually, a proper tool can be used. But please operate carefully and do not damage the battery and cable

The process of installing the new battery is just the opposite. Users need to put the battery back to the battery box, connect the cable, make the cable in proper position, then close the battery box cover.

⚠ Do not disassemble the battery without the guidance of a professional.

⚠ Do not place the battery near an open flame as there is a danger of explosion.

⚠ Do not directly connect the positive and negative terminals of the battery. Otherwise there is a danger of fire.

⚠ The battery should be handled gently and must not fall on the ground or collide with other item.

Section 7 Common Faults and Troubleshooting

7.1 No waveform displaying

During the printing process, the reasons why individual lead waveform are not displayed are as follows:

* Do not start recording immediately after connecting the patient cable. Since the baseline drift and amplitude detection requires a stabilization time of about 2 seconds, the individual leads are not shown.
* If the patient cable is not in good contact or the internal wire breakage is faulty, the individual lead will not be displayed. Check the patient cable as described in “6.3 Lead Wire Maintenance”. If you are sure that the patient cable is faulty, please contact our after-sales service department or designated service point.

After eliminating the above two reasons, if the unit still has a fault, it is usually caused by the fault of the signal channel amplification unit. At this time, you must contact our after-sales service department or the designated service agent.

7.2 Print head failure

The main problem of the print head failure is that the printed ECG waveform or character has a break-point in the vertical direction. Generally, it is because the surface of the thermal print head is contaminated with dust or smudges. It must be cleaned to eliminate the malfunction(Refer to 6.6 Cleaning the print head) . After cleaning, if there is still this phenomenon, it indicates that the heating unit of the print part of the device may be damaged. Please contact our after-sales service department or designated service agent.

7.3 AC interference

The AC interference is manifested by the fact that the recorded electrocardiogram is regularly superimposed with a certain amplitude of 50 Hz/60 Hz sinusoidal interference waveform, and the baseline exhibits significant shake. The possible causes of AC interference are as follows. Please check the exclusion in order:

* The is not reliably grounded.
* There is no conductive gel on the electrode and the corresponding part of the patient's body surface.
* The patient touches the metal part of the wall or bed, or touches someone else.
* There are X-ray machines, ultrasonic instruments and other high-power electrical equipment in the vicinity.
* The setting of [AC Filter Frequency] is inconsistent with the frequency of the local AC power supply.
* The patient wears jewelry.

If the above measures still cannot clear the AC interference, please use the AC filter, and the recorded waveform will be slightly attenuated.

7.4 Myoelectric interference

Myoelectric interference is manifested by an irregular spike in the printed ECG baseline. The possible causes of myoelectric interference are as follows. Please check the exclusion in order:

* The room temperature is too low and the patient feels uncomfortable.
* The bed is small and the patient is mentally or physically nervous .
* The patient is talking with others during the recording process.
* The limb electrode or the chest electrode is too tightly clamped.

If the above measures still do not remove the interference, please use the myoelectric filter. At this time, the recorded ECG waveform will be attenuated, and the attenuation of the R wave is more obvious.

7.5 Baseline drift

The ECG baseline is unstable and exhibits irregular up and down fluctuations. The possible causes of this phenomenon are as follows. Please check, exclude, or correct them in order:

* The electrode is not installed securely.
* During the recording process, the patient's body moves or breathes.
* The patient's skin is not clean or has no conductive gel.
* The old electrode is mixed with the new electrode.

If the above measures still can not clear the baseline drift, please use the baseline drift filter (ADS).

Section 8 Product Warranty

The company guarantees the use of raw materials and processes that meet the requirements to manufacture the device. In the normal use and maintenance state, if it proves to be a manufacturing process and raw material failure, the company will offer the service of repairing or replacing the hardware.

For the software or firmware installed in the hardware of the machine, if it proves to be a software or firmware failure , the software or firmware media will be replaced . Although fully tested, the company cannot guarantee the use of hardware, software or firmware won't be interrupted or error free.

Note: The company's obligations under this warranty do not include freight and other charges. The company is not responsible for any direct, indirect or eventual damage or delay caused by:

* The components are disassembled, stretched, and re-commissioned;
* Not authorized by the company to repair or modify the device;
* Damage caused by abnormal use beyond the specified conditions of use;
* This product serial number label nameplate or manufacturing mark is replaced or removed;
* The user is not using it properly.

Section 9 Information about Accessories

No.	Description	Quantity	Comment
1	Patient cable	1 pc.	
2	Limb electrode (4pcs/set)	1 set	
3	Chest electrodes (6pcs / set)	1 set	
4	Grounding cable	1 pc.	
5	Paper axis	1 pc.	
6	Thermal paper	1 pc.	
7	Fuse	2 pcs.	
8	Power cord	1 pc.	Different type, please specify before order.

If there is any questions or comments during usage, please contact your local dealer or our customer service department.

Section 10 Appendix

Appendix 1 Technical Characteristics

Main Unit	Lead	Standard 12 leads
	lead acquisition	12 leads synchronously acquisition
	Work mode	MAN, AUTO, R-R, STOR
	Filter	AC Filter : 50Hz / 60Hz / Off EMG Filter : 25Hz / 45Hz / Off
	CMRR	≥120dB (with AC Filter)
	Input circuit	Floating; Protection against defibrillator effect
	Input Impedance	≥50MΩ
	Electrode DC current	≤0.1μA
	Input dynamic range	±5mVp-p DC bias voltage ≥±620mV
	Patient current leakage	＜10μA
	Calibrating voltage	1mV±5％
	Lag	<0.5mm
	Sensitivity	2.5,5, 10, 20, 40, mm/mV (±3%)
	Paper speed	6.25, 12.5, 25, 50mm/s（±3％）
	System error	< ±5% or < ±40μV
	Impulse and frequency response	Method A and Method D system test method
	Inter-channel Interference	<2%
	System Noise	＜30μ Vp-p
	HR range	30 - 300 BPM (±1 BPM)
Pacing pulse display capability	Amplitude	2mV - 250mV
	Width	0.1ms - 2.0ms
	Sampling rate	4000Hz / channel
Recorder	Recording way	Thermal dot matrix recording
	Recording format	3ch+++, 6ch, 6ch+, 12ch
	Paper Specification	210mmx30m, Roll paper
Others	LCD display	800x480 graphic 9 inch color touch LCD
	Patient cases storage	400 patient cases (Internal SD card is optional)
	Communication interface	USB , UART
	AC Power	100V-240V (±10%), 50/60Hz (±1Hz), power 60VA
	DC Power	Rated voltage / capacity: 14.4V / 4400mAh (Li-ion battery) Rated charging current: 1300mA (constant voltage constant current) Rated charging cycle number: not less than 500 times (Li-ion battery)
	Fuse specification	TZAH/250W, ф5x20
	Measurement and weight	310mm x 278mm x 76mm, 3.0kgs

Appendix 2 Product Type

Type of anti electric shock	Type I, internal power supply equipment
Degree of anti electric shock	CF type application part, with anti-defibrillation function
Degree of anti Immersion in liquid	Ordinary equipment, does not have anti waterproof immersion ability
Degree of safety of being in presence with flammable gases	It is not suitable for use in environments with flammable gases
Working mode	Continuously work
Electromagnetic compatibility	CISPR 11 Group 1 Class A

Appendix 3 Environmental Requirements

Transportation and storage environment	Working environment
Ambient temperature: -20 ° C ~ +55 ° C Relative humidity: 25% to 93% Atmospheric pressure: 700hPa~1060hPa	Ambient temperature: +5°C～+40°C Relative humidity: 25% to 80% (no condensation) Atmospheric pressure: 700hPa ~ 1060hPa

Appendix 4 Product Configuration

Lead	Record format	Paper width	LCD	Touch Screen	Number of keys	Battery	Cases Storage	Bar Code Scan	USB
12	3ch+++, 6ch, 6ch+, 12ch	210mm	9inch	Yes	11	14.4V, 4400mAh	400	Yes	Yes

Appendix 5 Product EMC Performance

⚠

* Digital electrocardiograph meets the requirements of IEC60601-1-2 standard electromagnetic compatibility;
* Users should install and use the device according to the electromagnetic compatibility information provided in the files attached with device provided by manufacturer;
* Portable and mobile RF communication equipment may affect the performance of digital electrocardiographs, avoiding strong electromagnetic interference when used, such as near mobile phones, microwave ovens, etc.
* The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

⚠

* Digital electrocardiographs should not be used close to or stacked with other equipment. If they must be used close to or stacked, they should be observed to operate properly in the configuration in which they are used.
* In addition to cables sold by manufacturers of digital electrocardiographs as spare parts for internal components, the use of extra-standard accessories and cables may result in increased emissions or reduced immunity of the digital electrocardiograph
* Don’t 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.
* 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.
* 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.
* 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 equipment, including cables specified by the manufacturer.

Otherwise, degradation of the performance of this equipment could result.

* Digital electrocardiograph operation below the minimum amplitude or minimum may result in inaccurate consequences.

Cable Information :

Name	Length (m)	Shield for not	Remark
Power Cable	1.8	No	/
Patient Cable	2.6	Yes	With Magnetic ring
Grounding Cable	1.5	No	/

Manufacturer's Statement 1

Guidance and Manufacturer’s Declaration - Electromagnetic Emissions	
Emissions test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class [A]
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Comply

Manufacturer's Statement 2

Guidance and Manufacturer’s Declaration - Electromagnetic Immunity		
Immunity Test	**IEC 60601-1-2 Test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV for power supply lines ±1 kV signal input/output(Not Applicable) 100 kHz repetition frequency
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode
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 cycle	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 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Radiated RF IEC61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE U_T is the a.c. mains voltage prior to application of the test level.		

Manufacturer's Statement 3

Guidance and Manufacturer's Declaration - Electromagnetic Immunity							
	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Modulation (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380-390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27
	450	430-470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
	710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0.3	9
	745						
	780						
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
	870						
	930						
	1720	1 700-1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
	1845						
	1970						
	2450	2 400-2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
	5240	5 100-5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0.3	9
	5500						
	5785						