

Three & Six Channel Digital ECG Machine

User Manual



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Statements

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Responsibility of the Manufacturer

Our company only considers itself responsible for any effects on safety, reliability and performance of the equipment if:

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by personnel authorized by our company, and the electrical installation of the relevant room complies with safety standards, and the instrument is used in accordance with the instructions for use.

Note: This device is not intended for home use.

 **WARNING** : This device is not intended for treatment.

Using This Label Guide

 **WARNING** 

 **CAUTIONS**  A **CAUTION** label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

Note: A **NOTE** provides useful information about a function or procedure.

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1 Security Guide

1.1 Safety Instructions

The design of digital ECG comply with international safety standard IEC for medical electrical equipment 60601-1 and ECG machine safety requirements of IEC 60601-2-25, is a class of I and a type of CF equipment, meet the requirements of IEC 60601-1 for protection against electric shock, and has the function of preventing atrial fibrillation.

Digital ECG, a continuous working type instrument, is common equipment. Please pay attention to avoid water splashing; and this instrument is not explosion-proof, and it can not be used in places containing flammable anesthetics.

Classification:

Type of electric shock protection:	Class I, device with internal power supply
Degree of protection against electric shock:	CF type equipment, with the function of preventing and controlling fibrillation
Degree of waterproof:	It's a general equipment and it does not have the ability of waterproof immersion
Degree of safety of combustible gases:	It's not suitable for using in flammable gas environments
Working model:	Continuous operation
EMC:	Group I, class A

Before using the instrument, it is necessary to check the instruments, ECG cables and electrodes for possible damage to the patient's safety. If significant damage or aging is found, the component shall be replaced prior to use. When replacing parts, you must use the same components as before.

This instrument must be maintained by authorized qualified engineer. If you change and maintain without authorization by the personnel of our company, our company will be not responsible for the safety, reliability and performance of the instrument.

1.1.1 Environment

The requirements for the transport, storage, and normal working environment of the digital electrocardiograph are shown in the following table:

Transportation and storage		Normal work
Temperature:	-10°C~+40°C	+5°C~+40°C
Relative humidity:	≤80%	35%~75%

Strong atmospheric pressure:	700hPa ~1060hPa	700hPa ~1060hPa
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The surroundings of the ECG machine must be kept clean, away from corrosive, high humidity, high heat, and direct sunlight. You should avoid shock during use, and prohibit moving instruments in live electricity.

1.1.2 Power Supply

1) AC power supply:

Rated voltage: 220V±10%

Rated frequency: 50±1Hz

Rated power: 30VA

2) Built in rechargeable lithium battery:

Rated voltage: 14.8V

Rated capacity: 2200mAh

3) Maximum power consumption: 35VA

1.2 Use Warning

For the safe and effective use of instruments, avoiding possible injuries, please read the instructions before use, familiar with the performance of the instrument, fully understand the correct method of operation and precautions.

 Notice :

If it is used in a flammable anesthetic environment, there is a risk of explosion.

 Notice :

Do not use the instrument in an environment where there is a high voltage device or Gao Jing power, or it may spark because of an instantaneous discharge.

 Notice : Avoid the risk of electric shock

Instrument shell must be grounded and ensure good grounding, Please use a three-phase socket with a protective ground and make sure that the socket is protected in good condition.

 Notice :

The instrument shall be installed by a qualified maintenance engineer; only authorized

maintenance engineers can open the instrument shell.

 Notice :

If there is any doubt about the integrity of the protective ground wire, please use the built-in battery and do not use AC power.

 Notice :

Ancillary devices connected to analog and digital interfaces must be validated according to their respective IEC standards (such as data processing equipment standard IEC 950, and medical device standard IEC 60601-1). In addition, all configurations should conform to the valid version of IEC 60601-1-1. Therefore, when the connector connecting the accessory device to the signal input connector or the signal output, configuring the medical system, make sure that the system meets the requirements for the valid version of the IEC 60601-1-1. If you have any questions, please contact us or your local agent.

 Notice :

In order to ensure patient safety, the total leakage current can't exceed the allowable value when the patient is connected to a number of instruments at once.

 Notice :

Do not touch a patient, bed, table, or instrument while using a defibrillator and pacemaker at the same time.

 Notice :

In order to avoid burns, electrodes should be kept away from electrosurgical knives while using electrosurgical devices.

 Notice :

You must use the patient cable and other accessories provided by the company, the use of other types of accessories may damage the instrument, affecting the performance and safety of the instrument.

 Notice :

Make sure that all the electrodes are fully connected and connected to the correct position of the patient's body; please avoid electrodes (including neutral electrodes) to contact the patient with any other conductive component or earth.

 Notice :

The operator of the instrument must undergo professional training and ensure that the specifications are fully understood before use.

The use of rechargeable lithium batteries:

 Notice :

Improper operation may cause batteries to become hot, fire, explosion, damage, or decay of battery capacity. Before using rechargeable lithium battery (hereinafter referred to as "battery"), please read the manual and the precautions for use carefully.

 Notice :

The positive and negative poles of the battery cannot be connected, otherwise it may cause an explosion.

 Notice :

Do not use batteries near the fire source or at temperatures above 60 degrees. Do not heat the battery or put it in the fire. Avoid the battery is wet, and do not put the battery into the water.

 Notice :

Prohibit to use metal to cut the battery, hammer or beat the battery or use other methods to damage the battery, otherwise it will cause overheat, smoke, deformation, burning or danger.

 Notice :

Stay away immediately when you find a battery leak or an unpleasant odor. If the electrolyte leaks into the skin or clothing, please rinse it immediately. If the electrolyte is leaking into the eye, do not rub your eyes, rinse it immediately with clean water, and see a doctor.

 Notice :

Only authorized installation or maintenance engineers can remove the battery cover and replace the battery; and must use the same type of rechargeable lithium battery provided by our company.

 Notice :

When the battery reaches the service life, or when the battery is found to be smelly, deformed, discolored or distorted, the battery should be discontinued. And return it to the company for processing, or in accordance with local regulations on the disposal of waste batteries.

 Be careful :

Take care to avoid splashing the instrument with water.

 Be careful :

To avoid high temperature, the instrument should be used in the temperature range of 5 °C ~ 40 °C.

 Be careful :

Avoid the use of this instrument in situations such as excessive air pressure, poor ventilation, dust, or containing salts, sulfur, gas, chemicals, etc..

 Be careful :

To ensure that the using environment of the installation of the instrument without a strong source of electromagnetic interference, such as wireless transmitter or mobile phone, etc. Please note that electrical equipment such as electrosurgical devices, ultrasound instruments, radiating machines, and magnetic resonance imagers may cause electromagnetic interference.

 Be careful :

Before using the instrument, please check the instrument, the patient cable, and the electrode for damage that may affect the safety of the patient. If any significant damage or aging is found, please replace the part before use.

 Be careful :

The instrument should be subjected to periodic safety testing, the test cycle at least once two years, the detection of the main contents include:

- a) Check the host and accessories for mechanical and functional damage;
- b) Check that the safety mark is broken;
- c) Check whether the fuse meets the rated current and breaking characteristics;
- d) Verify the function of the instrument according to the instructions;
- e) Perform the following safety tests according to IEC 60601-1

Protection ground impedance, limit: 0.2 Ω ;

To ground leakage current, limit: NC 500uA, SFC 1000uA

Patient leakage current, limit: 10uA (CF type equipment)

When using AC power, the leakage current in a single fault condition, limit: 50uA (CF type equipment)

The test should be carried out by trained qualified personnel with experience in safety testing and to record the results of the tests. If the instrument has any problems in the above test, it must be repaired.

 Be careful :

Upon arrival of the service period, the instrument and the recyclable components may be returned to the manufacturer for recycling or processed in accordance with local regulations.

Cleaning, disinfection and maintenance:

 Be careful :

The power must be switched off before cleaning the instrument. If AC power supply is used, the AC power supply must be disconnected and the power cord and patient cable removed.

 Be careful :

Please be careful not to let the liquid seep into the instrument when cleaning. In any case, do not immerse the instrument and patient cable in the liquid.

 Be careful :

Do not use abrasive materials for cleaning to avoid scratching the electrodes.

 Be careful :

After cleaning, please avoid any cleaning liquid remaining on the instrument and patient cable surface.

 Be careful :

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

 Be careful :

Do not use chlorine disinfectants, such as bleach, sodium hypochlorite and so on.

2 Introduction

ECG is a physiological function test instrument that records the electrical activity waveform (ie, electrocardiogram) of the heart. It provides basic information about the diagnosis and treatment of various heart diseases. It helps to analyze and understand all kinds of arrhythmia and help to understand some drugs and electrolyte as well as the impact of acid-base imbalance on the myocardium, so ECG machine in the heart disease has an important position.

Digital electrocardiograph is a 12-channel synchronous collection of three and six print digital ECG machine, with ECG waveform display and automatic analysis options. Owing to the installation of advanced hot-lattice output system, high-performance 32-bit processor and high-capacity internal memory, the performance and reliability of the ECG machine has been greatly improved. In addition, the operation of the ECG machine is particularly simple, and it is rich in function and practical. Therefore, it very suitable in all types of medical units for the use of ECG routine diagnosis, especially for physical examination, emergency doors, wards and other occasions.

Standard configuration: ECG mainframe; accessories: power line, grounding wire, lead wire, limb electrode, chest electrode, thermal printing paper.

2.1 Features

1. With Chinese and English menu, it can display 12 guided waveform.
2. Real-time record 1 channel, 1 + rhythm, 3 waveform, it includes manual and automatic mode.
3. 12 lead synchronous acquisition
4. Digital isolation technology is adopted to minimize the influence of temperature drift and time drift of the components, thus ensuring the high adaptability of the instrument to the environment.
5. Using digital signal processing, through the processor on the ECG signal drift suppression, AC filtering, electromyography and heart rate detection and other processing to ensure that the output signal authenticity and reliability.
6. High resolution hot spot array printing, ECG shape is realistic and exquisite, the printing density adjustable, the printing waveform and character effects are leading in china.
7. Baseline stability testing, to ensure that every time you can play neat and beautiful ECG waveform
8. High quality silicone keyboard, long life, good feel.
9. Support Chinese input method.
10. Data can be stored via the U disk and SD card.
11. It can store picture files for computer direct view and print.
12. It can connect workstations to facilitate the digital management of the hospital (accessories)
13. It support WIFI connection workstations (accessories)
14. With routine ECG parameters automatic measurement and automatic analysis function (more than 200 cases),it can reduce the burden of doctors. Both automatic and manual modes are available.
15. The precision hot matrix recorded 12 lead ECG wave and lead marker, filtering state, measurement parameters, gain, feeding speed, representing the waveform, analysis reports and other information, record the waveform clearly and accurately, it can be used for clinical diagnosis

and research.

16. With wide power supply, a clear and accurate ECG waveform can be printed even if the external voltage is unstable. The utility model has an AC and DC dual-purpose power supply mode, and a charging battery, and a battery charging circuit and a complete battery management and protection system are installed in the machine.

17. The design conforms to the IEC CF class security standard. The ECG amplifier is fully floating and can be used to detect the human heart directly. It is especially safe.

18. With defibrillation protection and pacing impulse suppression circuit.

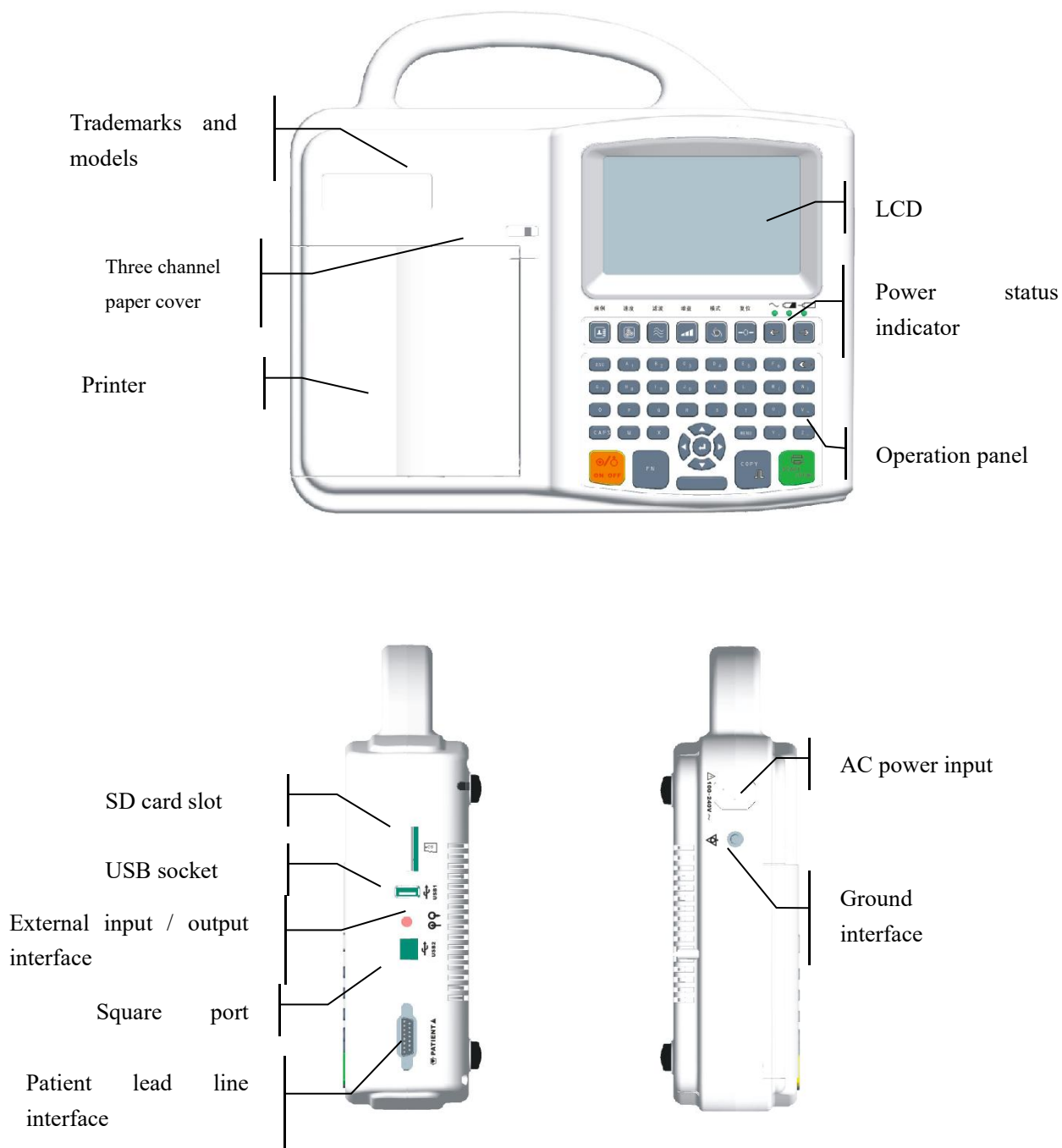
19. Built-in USB interface, WIFI (optional)

2.2 Symbol Description

	External output
	External input
	CF type equipment (parts), with the function of preventing and controlling fibrillation
	Note! Check the random file
	Equipotential
	Alternating current
	Battery working status
	Battery charge status

3 General Information

3.1 Host Panel



3.2 Product Name and Model

1) Trademark:

2) Product name:

Digital Three Channel Electrocardiograph
(Digital Six Channel Electrocardiograph)

3) Type:

Three Channel Electrocardiograph
(Six Channel Electrocardiograph)

4) Instrument type:

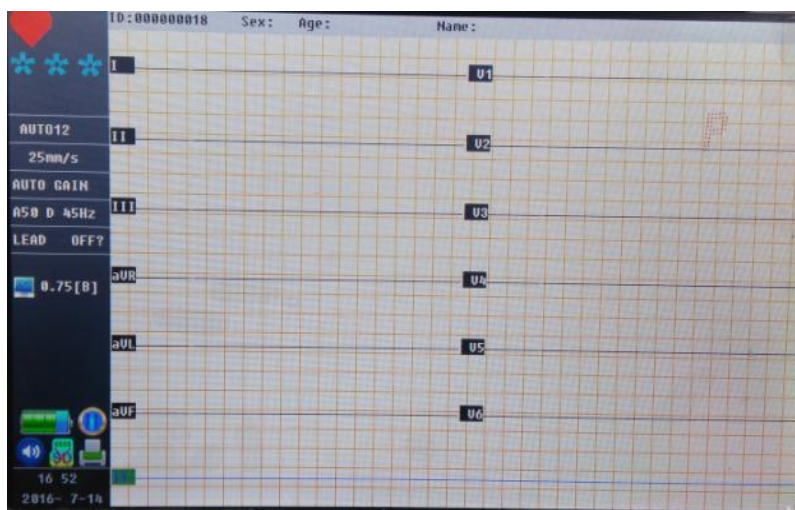


CF type equipment, with the function of preventing and controlling fibrillation

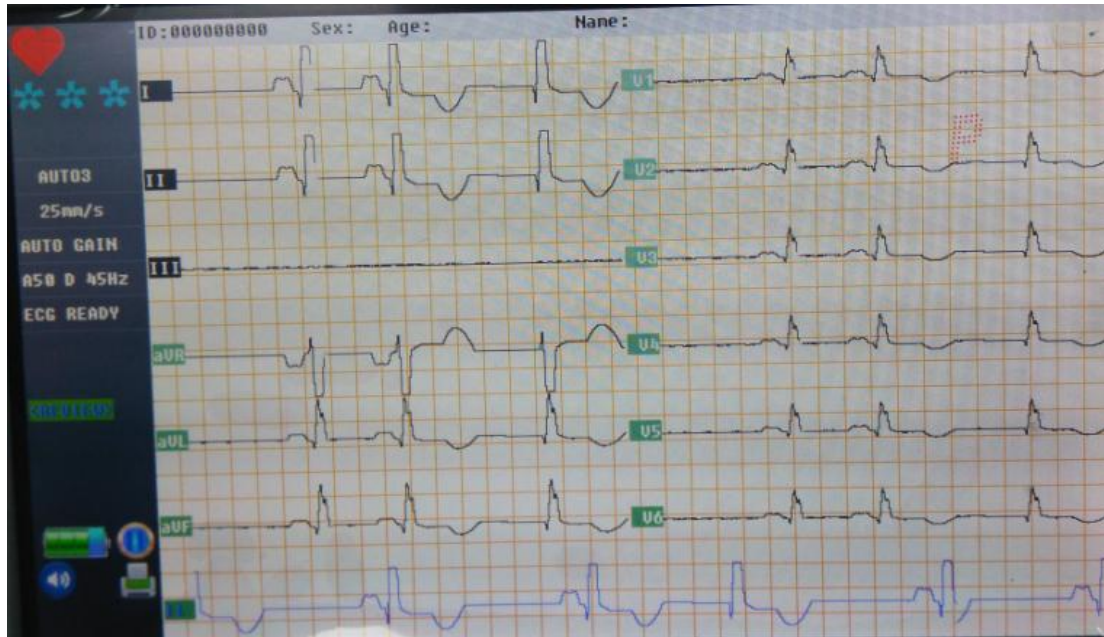
3.3 LCD Screen

Three channel and six channel ECG liquid crystal monitors, 5 Inch LCD display, color LCD

3.3.1 Standby Display Interface



3.3.2 Work Display Interface

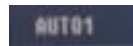
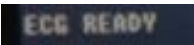


The contents of the LCD display include: (as shown above)

Top is from left to right:

- ◆ Case ID, gender, age, name

The left column is from top to bottom:

- ◆  Heart rate (actual heart rate value)
- ◆  Working mode (adjustable)
- ◆  Speed of moving paper (adjustable)
- ◆  Filter status (adjustable)
- ◆  The current working state of the machine
- ◆  Waveform display scale (adjustable)
- ◆  Built in battery power status, current battery power
- ◆  AC power supply status
- ◆  Printer standby status,  Printer status
- ◆  Button sound,  Mute key

- ◆  SD card not inserted,  Inserted SD card
- ◆  No print paper is installed,  Printed paper has been installed

3.4 Control Panel and Key Instructions



1) Work Status Indicator

- ~ AC indicator: when the AC power supply is used, the indicator light is on.
-  Battery indicator: when the battery is powered by a built-in rechargeable lithium battery, the indicator light is on.
-  Battery charging indicator: when the battery is being charged, the indicator blinks.

2) ON/OFF Power On / Off Key



Press this button to switch between two states of power on and off. When the alternating current or the built-in battery is enough, the touch button can be switched on and off.

3) FN Function Key



The function key of FN is to switch between three input modes of Pinyin Chinese input, English input, numeral or punctuation mark in the mode of input characters.

4) COPY/ Calibration Key



- ◆ In manual or automatic mode, press this key to print the 1mV calibration waveform when recording.
- ◆ In the automatic mode, press the key to copy the last printed ECG data, and press the print key to copy the ECG data again. After the shutdown, the data will be lost.
- ◆ In the Chinese input mode, press this key to type the spelling in the box

5) START/STOP Start /Stop Key



Used to start or stop printing waveforms

6) Case Setup Key



For setting case information, settings include: ID number, name, age, gender, ID setting (automatic / manual)

7) Speed Setting Key



Press the key to adjust the speed of moving paper quickly. There are 4 speed modes, 6.25mm/s, 12.5mm/s, 25mm/s and 50mm/s

8) Filter Setting Key



There are 4 modes of filter setting, respectively:

[A]0.05-250Hz filter function off

[B]A50 D AC filter open

[C]A50 D 85Hz AC filter open, high pass filter set to 85Hz

[D]A50 D 45Hz AC filter open, high pass filter set to 45Hz

9) Gain Setting Key



In manual mode, there are 4 gain modes, 2.5mm/mV, 5mm/mV, 10mm/mV and 20mm/mV, respectively

10) Mode Setting Key



Used to select the lead group switching mode, press the key lead mode to switch between manual and automatic, and each mode lead group conversion order is shown as shown in the table below:

Five Leads

Mode	Lead handoff sequence (from left to right)
Auto1	(1*7 mode) single channel waveform print output, the order of I/II/III/aVR/aVL/aVF/V
Auto2	(1*7 +1 mode) single channel waveform + rhythm lead print output, same as automatic 1 order.
Auto3	(3*2+1 mode) three wave print output, I/II/III/aVR/aVL/aVF/,V

Manual 1	(1*7 mode) single channel wave printing output, manual switching lead, and automatic 1 in the same order.
Manual 2	(1*7 +1 mode) single channel waveform + rhythm lead print output, manual switching lead, and automatic 1 in the same order.
Manual 3	(3*2+1 mode) three wave printing output, manual switching lead, and automatic 3 in the same order.

11) Waveform Reset Key



In the acquisition state, press the key to reset the waveform.

12) Lead Swift Key



Press the key turn right ($\rightarrow$) or turn left ($\leftarrow$) to swift the leads

13) ESC key



ESC function key, to exit or cancel the current menu operation.

14) Delete Key



Delete the characters entered in the previous step

15) CAPS Key



In the state of entering the letter, the capital / small letter input switch

16) Menu Key



Enter the setup menu, including parameter settings, system settings, data management

17) Navigation / Confirmation Key



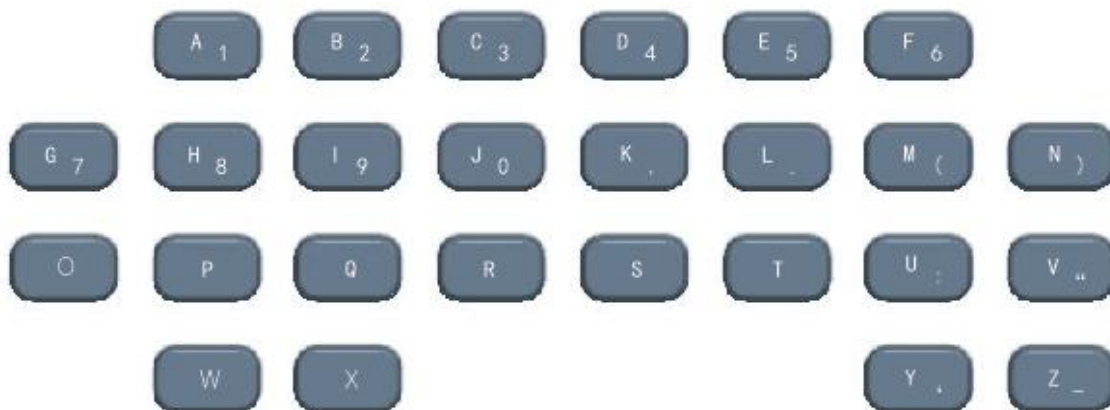
After entering the setup menu, move the cursor through the up, down, left and right arrow keys, press confirmation key to enter the submenu or select the setting option.

18) Space Key



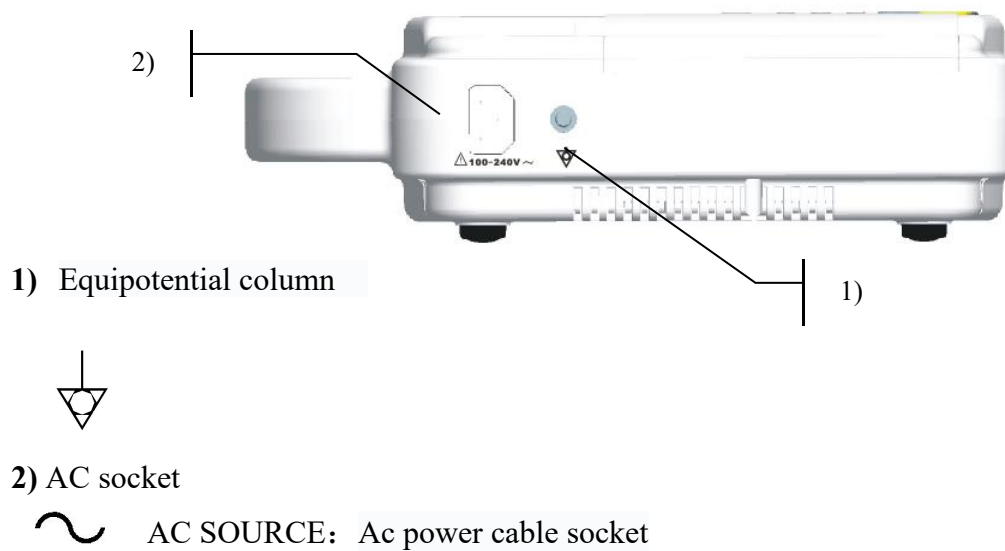
In the input state, enter the space character

19) Small Keyboard



- ◆ Chinese, English, punctuation input can be implemented
- ◆ In the setup menu or option, press the ABCD letter key in the keypad according to the [A] [B] [C] [D] letters of the menu or the option to quickly enter the corresponding menu or option.
- ◆ In the main interface mode, press the B letter key to enter the display zoom setting to adjust the ratio of the waveform display

3.5 Main Connection and Switch



3.6 Patient Cable Socket and Signal Interface

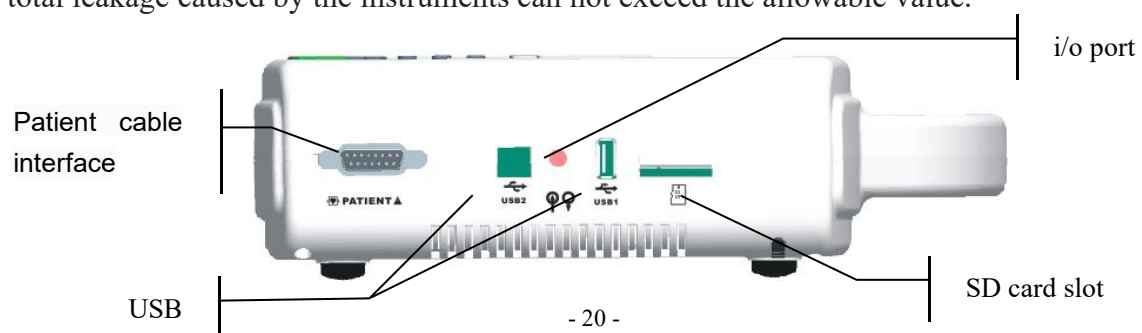
⚠Warning⚠:

Accessory equipment connected to analog and digital interfaces must be verified according to their respective IEC standards (e.g. data processing equipment standard IEC 950, medical device standard IEC 60601-1). Moreover, all configurations should be in accordance with the valid version of IEC 60601-1-1. Therefore, the person who connects the accessories equipment to the signal input connector or the signal output connector must ensure that the system complies with the requirements of the valid version of IEC 60601-1-1 when configuring the medical system

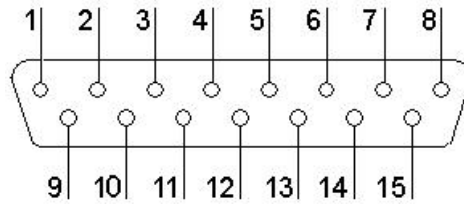
If you have any questions, please contact us or your local agent.

⚠Warning⚠:

To ensure patient safety, when the patient connect to several instruments at the same time , the total leakage caused by the instruments can not exceed the allowable value.



1) Patient cable interface



☠ :

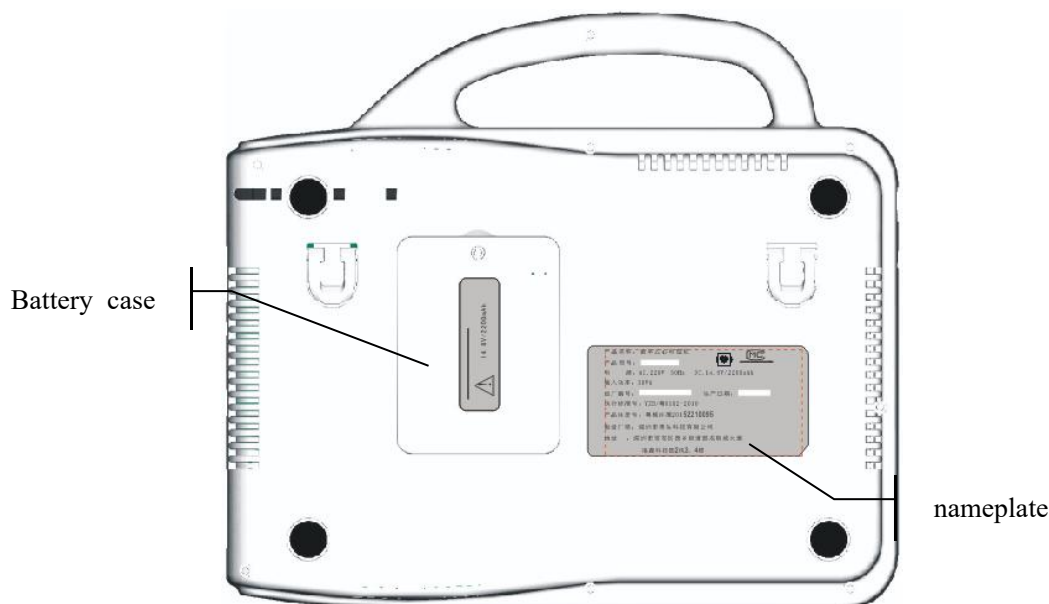
CF type of application components, with anti-defibrillation function

⚠: look out ! Check the file attached

Corresponding pin definition:

Pin	Signal	Pin	Signal	Pin	Signal
1	C2 (input)	6	SH (input)	11	F (input)
2	C3 (input)	7	NC	12	C1
3	C4 (input)	8	NC	13	NC
4	C5 (input)	9	R (input)	14	RF (input)
5	C6 (input)	10	L (input)	15	NC

3.7 Main Unit Bottom



1) battery case

Rechargeable lithium battery pack
14.8V 2200mAh

The label on the battery compartment indicates the rated output voltage and rated power of the built-in rechargeable lithium battery pack, as shown above

 Warning! warning message (Check the file attached)

 **Warning** :

Improper operation may cause the battery to become hot, fire, explode, destroy, or battery capacity attenuating. Before using a rechargeable lithium ion battery (hereinafter referred to as "battery"), please read this manual carefully and use precautions.

 **Warning** :

Only authorized installation or maintenance engineers can remove the battery cover and replace the battery; and must use the same type of rechargeable lithium battery provided by our company.

2) The product symbolic explanation



CF equipment, with anti-defibrillation function.



Beware, refer to information attached (this manual).

4 Ready for Operation

Warning :

You must use the patient cable and other accessories provided by our company, the use of other types of accessories may damage the instrument, affecting the performance and safety of the instrument.

4.1 Power and Earthing

 **Warning**  : Avoid the risk of electric shock - you must use a three-phase socket with a protective ground and ensure that the protective earth of the socket is well grounded; and make sure that the earth wire is well grounded; do not open the shell of the instrument when the power is connected

 **Warning**  : If you have questions about the integrity of the protective earth conductor, use the built-in battery and do not use AC power.

1) Use AC power

First determine whether the AC power supply meets the requirements:

Voltage Range: 85V-265VAC

Rated Frequency: 50Hz/60Hz

Rated Power: 30VA

Then plug the power cable connector into the AC electrical connector on the left side of the instrument and plug the pin of the power cable into the three-phase AC outlet.

2) Use the Built-In Battery

Digital ECG machine in the delivery of users has been installed built-in rechargeable lithium battery, can be used directly. However, due to power consumption during storage and transportation process, lithium battery power may be insufficient in the initial use, then need to charge the battery firstly. When the battery reaches the service life (cycle life ≥ 300 times), the use of time is significantly shorter after fully charged, the battery should be replaced. Refer to Section 7.4.1 Daily Maintenance and Maintenance for details on battery charging

and replacement.

3) Connect ground wire

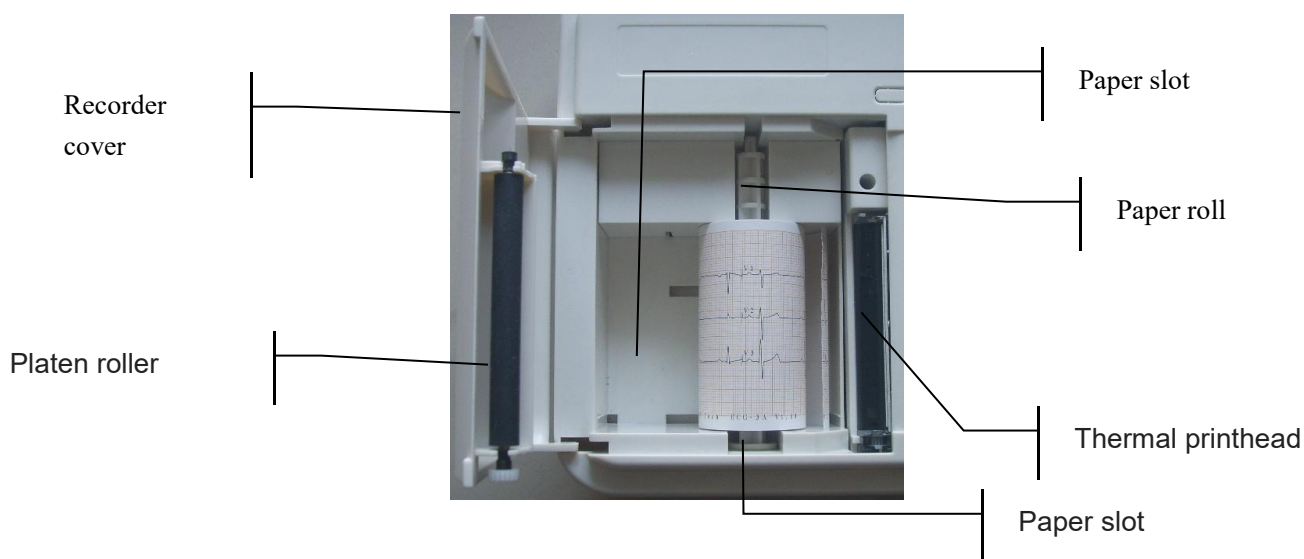
Connect one end of the ground wire to the equipotential column on the left side of the instrument and the other end to the public place of the hospital

4.2 Loading/Replacing Recording Paper

4.2.1 three channel ECG Recording Paper Installation

The instrument uses two kinds of recording paper: 80mm wide roll thermal printing paper and 80mm wide folding thermal printing paper. When the recording paper is used up, the printer icon on the LCD will blink to remind the user to install or replace the recording paper

Note: When using folding thermal paper, the paper roll should be removed



Install Roll Thermal printing paper:

- 1) Hold the flanges on both sides of the recorder cover by hand and open the recorder cover upwards slightly
- 2) Gently remove the reel from the paper slot. If there is recording roll paper remaining, remove the roll paper from the left side of the paper roll
- 3) Remove the sealing tape on the new recording paper, install the new recording paper along the left side of the reel, please be noted that the recording paper grid facing down
- 4) Align the locating pin on the left side of the reel with the groove on the left side of the

bin and gently put into the bin;

- 5) Pull the recording paper out about 2cm and close the recording paper cover

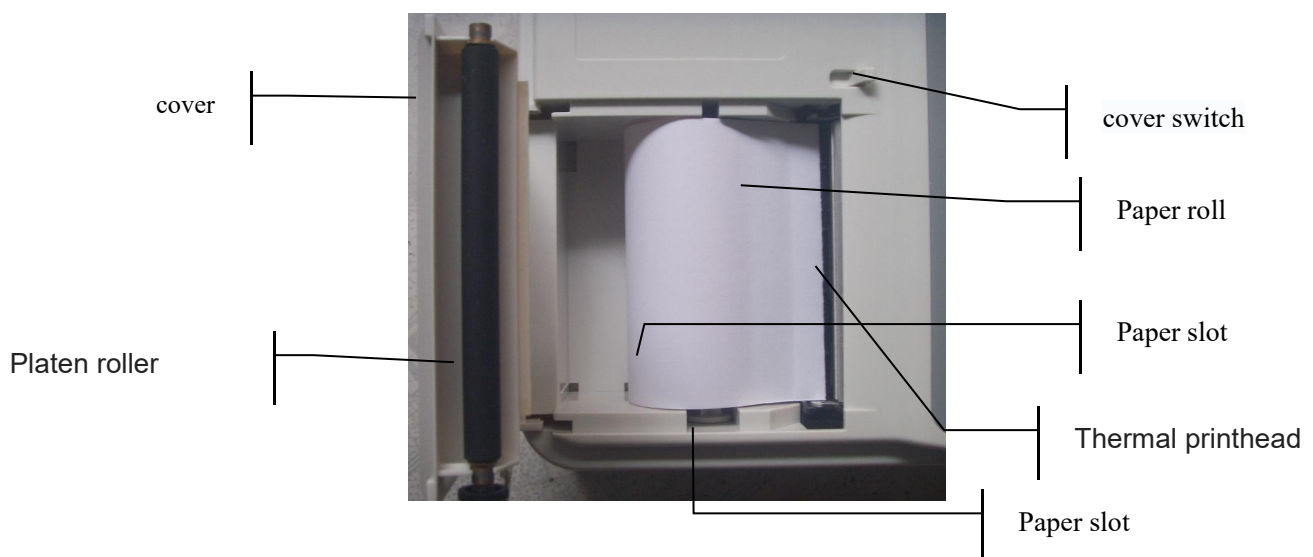
Install folding thermal printing paper:

- 1) Hold the flanges on both sides of the recorder cover by hand and open the recorder cover upwards slightly
- 2) Uncover the packaging of the new folded recording paper and place it in the bin. Be
Note that when the free end of the recording paper is erected, the recording paper grid face should be facing the thermal print head;
- 3) Pull the recording paper out about 2cm and close the recording paper cover.

4.2.2 Six channel ECG Recording Paper Installation

The recording paper used in the instrument: 112mm wide roll thermal printing paper. When no recording paper or recording paper is used up, the LCD will show "out of paper" to remind the user to install or replace the recording paper.

Note: When using folding thermal paper, the paper roll should be removed

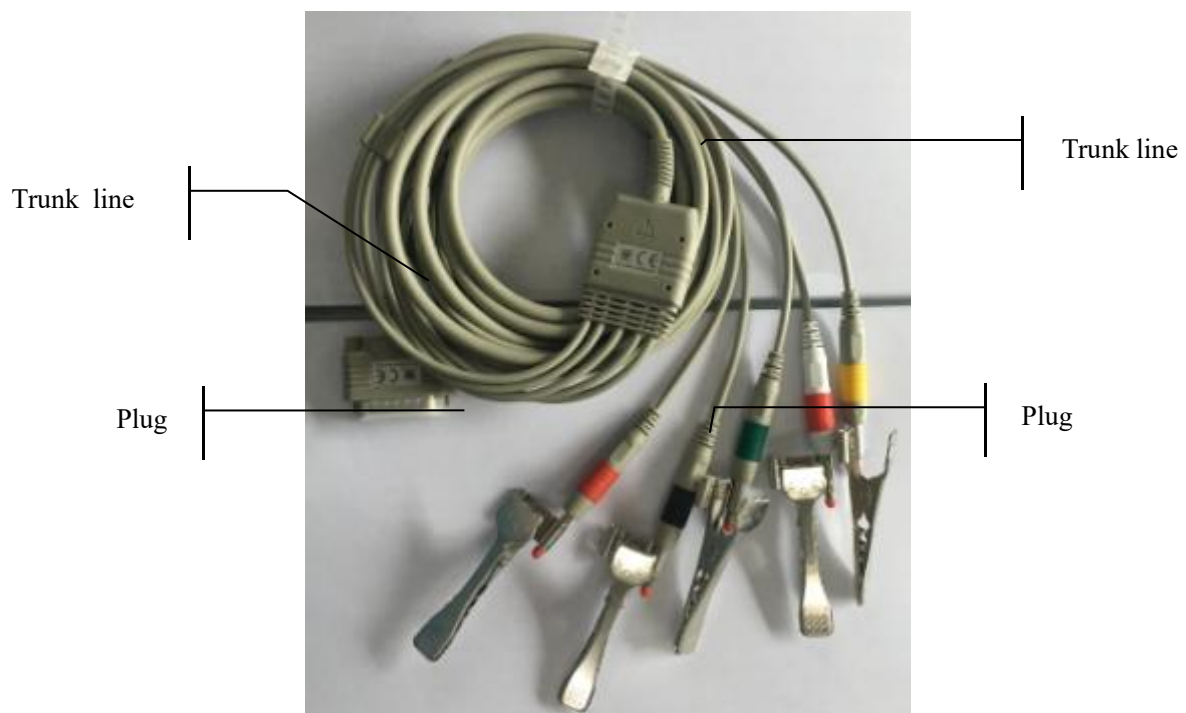


Install roll thermal printing paper:

- 1) Press the paper cover switch down, to open the recorder cover

- 2) Remove the reel from the paper slot gently and remove the roll paper from the left side of the paper roll if there is remaining recording paper
- 3) Unscrew the sealing tape on the new recording paper, insert the new recording paper roll along the left side of the reel. Please be noted that the grid of the recording paper is facing down when installing the recording paper;
- 4) Align the locating pin on the left side of the reel with the groove on the left side of the bin and gently put into the bin;
- 5) Pull the recording paper out about 2cm and close the recording paper cover

4.3 Connecting Patient Cable



The patient cable is divided into two parts: the trunk line connecting the ECG machine and the lead wire connecting the patient. The lead wire consists of six chest leads wire and four limbs leads wire, and the user can distinguish the lead and limb leads by the color of the lead wire and the identification on the connector.

Connect patient cable:

Insert the patient cable plug into the cable socket on the right side of the ECG and tighten the knobs on both sides of the plug.

4.4 Electrode Connections

⚠ Warning ⚠: Make sure that all ECG electrodes are connected and connected to the correct location of the patient's body; avoid electrode (including neutral electrodes) and patient cables in contact with any other conductive parts or earth.

The contact resistance between the patient and the electrode has a great effect on the quality of the ECG waveform, so when connecting the electrode, try to reduce the contact resistance as low as possible to get reliable ECG.

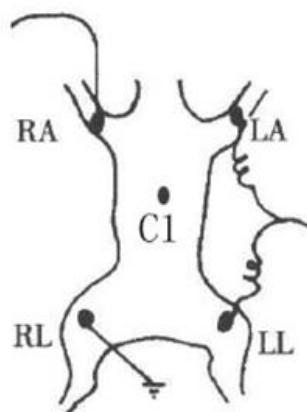
Electrode identification and color coding (European standard) are shown in Table 4-1. Electrode according to different standards, its coding and color are different, Table 4-1 also lists the corresponding US standard identification and color coding.

Table 4-1 Electrode identification and color coding

European standard			
lead	Logo	color	note
Right arm	R	Red	RA
Left arm	L	Yellow	LA
Righ foot	RF	Black	RL
Left foot	F	Green	LL
Chest	C1	White/Red	C1

Chest electrode:

There is generally 1 Chest electrode placement, with the ribs gap as a basis for positioning



Connect the electrode

Check whether the electrode is clean;

- 1) Straighten the lead line, to avoid distortion, connect the electrode connector and the electrode firmly
- 2) Wipe the skin with alcohol
- 3) Apply the conductive paste in the range of about 25 mm diameter evenly in the area where the electrodes are placed in the chest;

Note: do not wipe too much conductive paste, the coating should be separated from each other, otherwise it will cause short-circuit between the electrodes, causing ECG signal recording error

4.5 Inspection Before Power On

Please read the user manual carefully before using the digital ECG machine, familiar with the performance of the instrument and the operation method and precautions that must be grasped.

We recommend that you check the following before starting the machine:

1) Environment:

Check for the presence of other electrical equipment in the surrounding environment, such as electrosurgical equipment, ultrasound equipment, radiating machines, etc., which may cause interference and, if necessary, turn off the power of these devices;

Keep the Indoor requirements warm (not less than 18 °C), in order to avoid the EMG interference caused by cold

2) Power supply:

When using AC power, check that the power cable is firmly connected to the instrument. The power outlet should use a three-phase socket with a protective ground;

3) Grounding:

Whether the ground wire is properly connected;

4) lead:

Check that the lead plug is connected firmly and avoid the lead wire close to the AC power cord; check that the lead wire is properly connected to the corresponding electrode;

5) Electrode:

Check whether the electrode is installed firmly; whether the electrode, especially the chest electrode, is in contact with each other;

6) Recording paper:

Make sure the recording paper is adequate and installed correctly;

7) Objective: Check whether the hands and feet of the objective touch the metal part of the bed, check whether the room environment is comfortable, check the objective is too nervous, asked the objective to relax the body, keep calm

5 Operation

5.1 Switch On

When using AC power, plug the power cord on the left side, turn on the AC power, then



the AC indicator (⌚) is lit, press “ON/OFF” key to start up, After the instrument shows the manufacturer logo, enter the working state;

When using AC power, the machine power supply status is shown as AC power , And the AC indicator (⌚) is lit, The battery indicator (🔋) and the battery charge indicator (➡🔋) are off.

When using the built-in battery, the machine power status is shown as battery powered , And the battery indicator (🔋) lights up, the AC power indicator (⌚) and the battery charge indicator (➡🔋) are off

Note: The instrument can only charge the built-in battery in the power off state. The method is: When the instrument is turned off, connect the AC power source. At this time, the battery charging indicator(➡🔋) flashes, which indicate that it is charging. When the indicator change to be lit from flashing, indicating that the battery is fully charged.

5.2 Auto Mode

Three channel automatic mode include automatic 1 (1 * 7), automatic 2 (1 * 7 + 1), automatic 3 (3 * 2+1) three printing modes .

During ECG recording, the lead group is automatically switched sequentially, that is, when a group of lead ECG signals are recorded within the set time, they are automatically switched to the next lead group and the recording The ECG signal of the lead group. If necessary, you can also manually switch the lead and print, after printing, it will save the case automatically

operation:

- 1) through the "mode" button  to adjust the work mode to automatic mode, press the "mode" button every time, the work mode alters

- 2) Press the "Speed" key  to set the appropriate recording speed. Every time you press the "Speed" button, the recording speed will be changed once

- 3) Press "Case" key  to input the information of the subject, including ID number, name, age, gender

- 4) Press "START / STOP" key , the screen display the working status "in acquisition ...". After a few seconds, the printer will start working. After all the printing is finished, the analysis report will be displayed, press "START / STOP" key again to print out the report

- ◆ During recording, you can press the "START / STOP" key to stop recording if necessary, but it will record in the order of the lead group again after restart recording, and the case information will remain unchanged.

- ◆ During the recording process, press the "COPY / Scaling" key  to manually add the calibration mark on the recording paper

- ◆ During the recording process, press the "Lead switch" key   to manually switch the lead to print, until all 12 leads printing finished

5.3 Manual Mode

Three channel manual mode include manual 1 ($1 * 7$), manual 2 ($1 * 7 + 1$), manual 3 ($3 * 2 + 1$) three print modes, in the ECG recording process, the leads group have to be switched manually, the device will record the ECG signals of the lead Group without switch. In manual mode, the

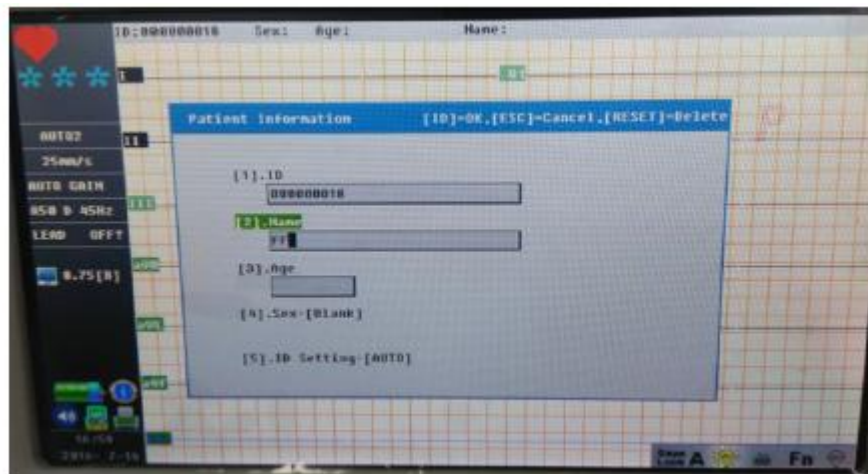
case can't be saved.

Operation

- 1) Press the "mode" key  to adjust the work mode to manual mode, every time press the "mode" button, the work mode changes once
- 2) Press the "Speed" key  to set the appropriate recording speed. Every time you press the "Speed" button, the recording speed changes once
- 3) Press "START / STOP" key , the screen displays the working status "in acquisition ...", the printer starts working after a few seconds
- 4) Press the "LEADS SWITCH" key   to manually switch the lead to print, until the 12 leads printing finished
 - ◆ During recording, you can press the "START / STOP" key to stop recording if necessary, after restart recording, device will continue to record from the lead of the stop point
 - ◆ During the recording process, press the "COPY / Scaling" key  to manually add the calibration mark on the recording paper

5.4 Windows Text Input

5.4.1 Numbers and Symbols Inputs



As shown above, through the up and down arrow keys of "navigation / confirmation" button



to move the cursor to the input box, press the "FN" key , the "Fn" "small bulb icon

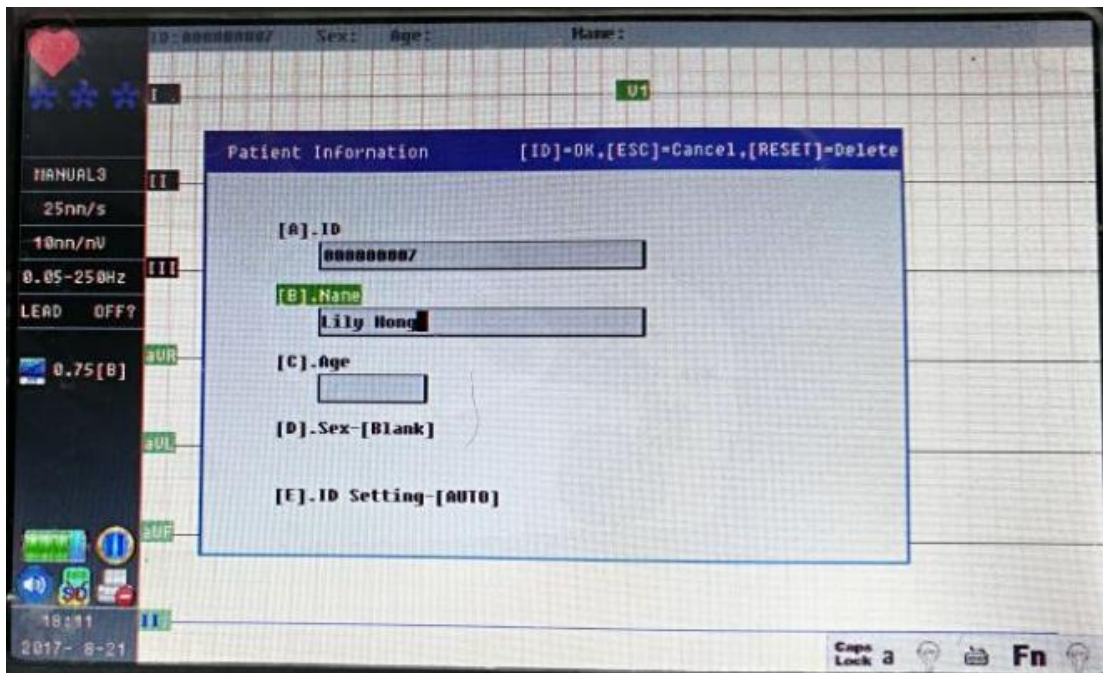


on the lower right corner of the display screen becomes lit, at this time, the keyboard input has been switched to numbers and punctuation input mode, press any keys with the number or punctuation, you can input the corresponding number or punctuation. If you want to modify the



entered content during the input process, use the "Delete" button to delete the contents.

5.4.2 Patient Information Input

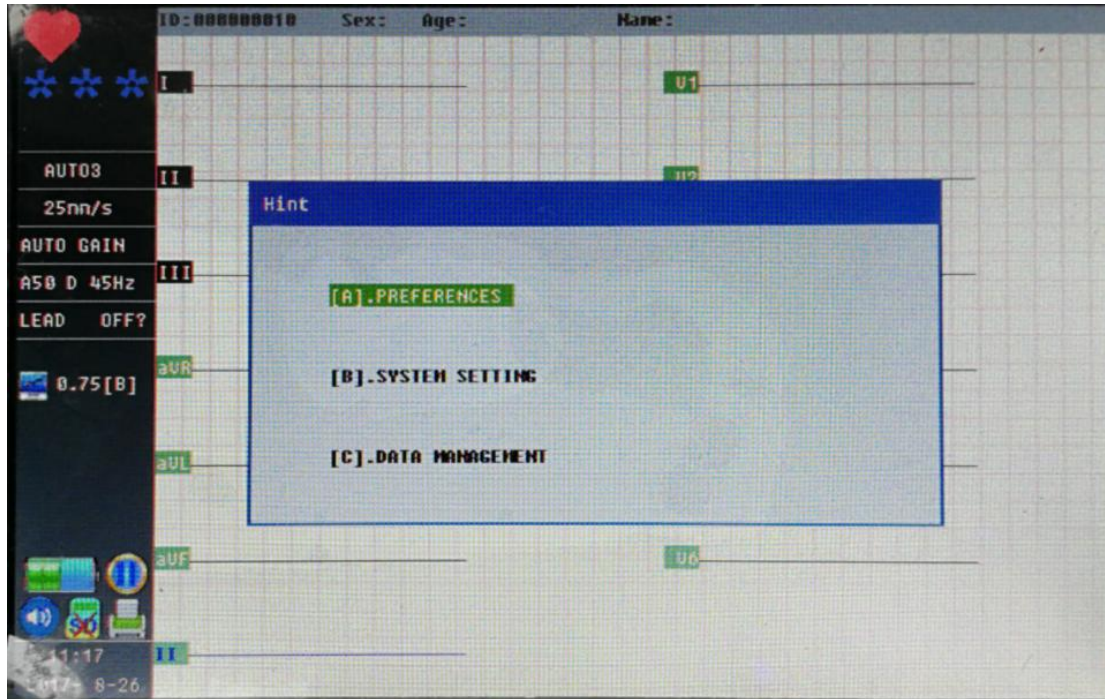


As shown in above picture, Press  bottom to choose what you need to input, press , the bulb will be light on  in the lower right corner of the screen, then you can input numbers. If need to change the numbers, press  to delete. If need to input letters, press  to transfer the mode to letters, FN bulb will be turn off. Use CAPS to change caps look.

5.5 Menu Setting

5.5.1 Menu Setting Page

In Standby mode, press  to enter the setting page, as picture:



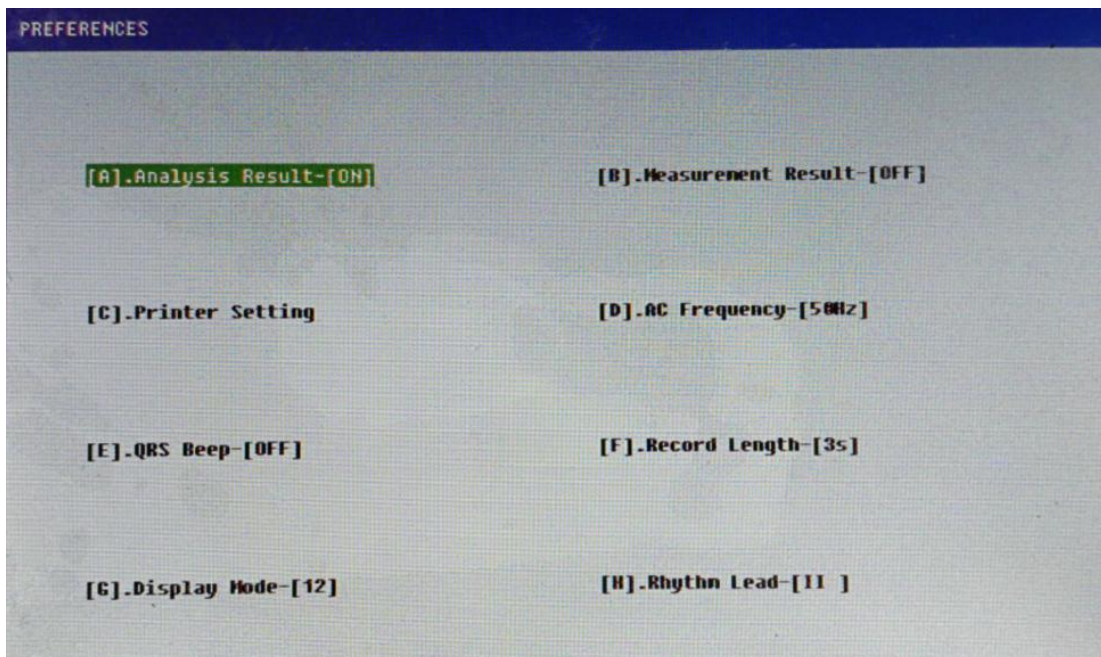
It have three parts: [A].PREFERENCES [B].SYSTEM SETTING [C].DATA MANAGEMENT.

Use  to choose, press  to enter setting part. Also you can use A, B, C button in the keyboard to enter faster.

After setting finish, press  or  to exit.

5.5.2 Reference Setting Page

After enter the menu page, choose [A]. PREFERENCES or press  in the keyboard to enter “Reference” page, picture as below:



Set options:

[A]. Analysis Result

- [A]. OFF: In Auto mode, disease analysis will not include in the printing report
- [B]. ON: In Auto mode, disease analysis will include in the printing report

[B]. Measurement Result

- [A]. OFF: In Auto mode, analysis result will be print directly after the ECG wave printed
- [B]. ON: In Auto mode, analysis result need to print manually after the ECG wave printed

[C]. Printer Setting

- [A]. Baseline width: Adjust the printing baseline width, the bigger the value, the wider the baseline
- [B]. Print model: Set the printing process in real-time or synchronization
- [C]. Gray level: Adjust clarity, the bigger the value, much clearer.
- [D]. Page type: Setting the paper type
- [E]. Printer test: To test the printer function is normal

[D]. AC Frequency

- [A].50Hz: Select this option for AC power 50Hz area
- [A].50Hz: Select this option for AC power 50Hz area
-

[E]. QRS Beep

- [A]. OFF: Without QRS warning tone during the test
- [B]. ON: With QRS warning tone during the test

[F]. Record Length

- In Auto Mode, set lead recording time to 3~12 seconds.

[G]. Display Mode

- A]. 3: Display 3 signal waves in the screen, press   to switch the lead
- [B]. 6: Display 3 signal waves in the screen, press   to switch the lead
- [B]. 12: Synchronous display 12 signal waves

[H]. Rhythm Lead

- Set any of the I/II/III/aVR/aVL/aVF/V lead as rhythm lead signal

5.5.3 System Setting Page

After enter the menu page, choose [B]. SYSTEM SETTING or press  in the keyboard to enter “System setting” page, picture as below:



Set the options:

[A]. Hospital Info: Set hospital or institution name information

[B]. Auto Power off: Set standby time, within the standby time, it will be shutdown automatically if there are no operation after boot. Standby time can set between 10~60mins, when set 0, then auto shutdown will be turn off, the body will keep working all the time.

[C]. Sound Setting

- [A]. OFF: No operating sound
- [B]. ON: With operating sound

[D]. Time setting: Setting local time

[E]. Time format: User define time display type

[F]. Fn Function Setting:

- [A]. Always ON: After you turn on the Fn function, you can enter multiple digits or punctuation marks consecutively
- [B]. Once: After opening the Fn function, enter a number or punctuation mark, the Fn function automatically closes

[G]. Caps Key Function Setting

- [A]. Always ON: After you turn on the Caps function, you can enter uppercase letter consecutively
- [B]. Once: After opening the Caps function, enter a uppercase, the Fn function automatically closes

[H]. LCD Brightness: Adjust the brightness of screen, the bigger the value, more bright

[I]. Language Setting

- [A]. Chinese: Setting the system in Chinese interface
- [B]. English: Setting the system in English interface
- [C]. Türk: Setting the system in English interface Turkish

[J]. Software Update: Use a U-disk to update the system.

Create a folder named ASUPD  ASUPD in the root of U-disk, place the * .AS format system

pack  ASUPD.AS
AS 文件
4,096 KB into the ASUPD folder. Plug the U-disk to the machine, turn on the machine, enter [Software Update], press “START/STOP” to start, after get reminder of updated done, press the power button to reboot and complete the system upgrade.

[K]. Restore to Factory Defaults: Use this function, critical parameters and system settings can be restored to the initial system

[L]. Network Setting(Options)

5.5.4 Data Management Page

After enter the menu page, choose [C]. Data Management or press  in the keyboard to enter “Data Management” page, picture as below:

[J]. Upload from

- [A].USB: To transmit data to computer or U-disk through USB
- [B]. WIFI: To transmit data to computer via WIFI

[K]. Storage format: Set the cases storage format

- [A]. [*].EAS]: Cases stored in EAS format
- [B]. [*].BMP]: Cases stored in BMP format

5.7 Switch off

When using the built-in battery, press “ON/OFF” key directly to power off the machine.

When using AC power supply, press “ON/OFF” key, then pull out the power plug.

6. Prompt Information

While using this ECG machine, it may have the indication information like as “Lead off”, “Paper out”, “Low battery”, please find details as following table 6-1.

6-1 Indication information and cause

Indication information	cause
Lead off, for example showing “C1-off”	C1 electrode falls off the patient
Paper Out. The printer icon is flashing	Paper is using out or not yet install the paper
Low battery. The battery Icon is flashing or machine automatic shutdown	Battery is weak
Starting	Data acquisition is in progress, or it is printing
Saving	Storing the data in built-in memory or to extra memory
Error!! Stored [0]	Not yet connect to extra memory
Transferring	Transferring the data to PC or extra memory
Upgrading, do not power off	System is upgrading
Upgrading successfully, please restart	Upgrading is finished, restart the machine

7. Cleaning, Disinfection, Sterilization and Maintenance

7.1 Cleaning

CAUTION :

Turn off the machine before cleaning. AC power supply must be switched off if it has been in use.

1) Clean the main unit and patient cable

Apply a soft & clean lint-free cloth with mild soapy water, or soak in a non-corrosive diluted wash solution, wipe the main unit and patient cable's surfaces, clean with a clean & dry soft cloth.

2) Clean the Electrodes

After using the electrode, use a clean soft cloth to wipe the conductive paste, take apart the rubber ball of the chest electrode and the metal cup, also take apart the electrode of limb electrode and its clamp, cleaning them in the warm water (below 35 °C), make sure there is no residual conductive paste, naturally dry or cleaning with clean & dry soft cloth.

3) Clean the Printer head

The smear and dirt on the surface of the thermal recording head will affect the clarity of the recording, so the user should clean the printer head surface regularly (at least once a month).

Open the recorder cover and remove the paper. Wipe the print head gently with a clean soft cloth damped in 75% alcohol. For stubborn stain, soak it with a little alcohol first and wipe it off with a clean soft cloth. After air dried, load the record paper and close the paper cover.

CAUTION :

Prevent the detergent from seeping into the main unit while cleaning. Do not immerse the unit or patient cable into liquid under any circumstances.

CAUTION :

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

CAUTION :

Avoid any cleaning fluid remaining on the machine and patient cable surface after cleaning.

7.2 Disinfection

To avoid permanent damage to the equipment, disinfection can be performed only when it has been considered as necessary according to your hospital's regulations.

Before disinfection, we suggest to clean the units first.

CAUTION :

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

CAUTION :

Do not use chlorine disinfectants, such as bleach, sodium hypochlorite and so on.

7.3 Sterilization

To avoid long-term damage to the product, we recommend that sterilization should be performed only if it is necessary according to your hospital's regulations. We also suggest to clean the product first before sterilization.

Note: We will not bear the responsibility for the effectiveness of infectious diseases control measure by using the disinfectant or sterilization process. It would be better to consult epidemic experts for advices.

7.4 Maintenance

7.4.1 Battery Capacity, Charging and Replacement



Improper operation may cause the battery to become hot, fire, explode, destroy, or attenuate battery capacity. Before using a rechargeable lithium ion battery (hereinafter referred to as "battery"), please read this manual and the precautions carefully.

1) Capacity Indication

The battery symbol is located at the top right of the screen, it shows the capacity of the built-in rechargeable lithium battery.



: Full capacity



: Capacity is limited, should charge the battery



: Capacity is weak, battery should be recharged immediately or the machine will be automatic power off

2) Recharge

This ECG machine has built-in rechargeable lithium battery and charge control circuit. The initial use of the battery, please charge the battery first, because the capacity may not sufficient during the storage and transportation.

The machine is only charged in the shutdown state, so in the shutdown state, the user only need to connect the AC power, when the battery charge indicator (→□) is flashing, indicate that the battery is charging. When the battery is full, the battery charge indicator (→□) stops flashing, and keep lighting.

3) Replacement

When the useful life of battery is over, or foul smell and leakage has been found, please contact with manufacturer or local distributor for replacement of battery.



Only qualified service engineer authorized by us can open the battery compartment and replace it. Make sure to use the same model of battery that we supplied.



Danger of explosion – Do not reverse the positive and negative of battery when connecting.



CAUTION

Disused batteries should be returned to us or processed in accordance with local regulations.

7.4.2 Recording and Recording Paper

Note: Please use the recording paper that we provide, other brand of paper may shorten the life of thermal recording head, and occur blur waveform, stuck paper or other problem.

Storage requirements:

- ◆ Record paper should be stored in dry, dark and cool area, avoiding excessive temperature, humidity and sunshine.
- ◆ Do not put the paper under fluorescence for 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 overlap the recorded paper long time, or else the ECG record may trans-print each other.

7.4.3 Maintenance of Main Unit, Patient Cable & Electrodes



CAUTION

The instrument should be subjected to periodic safety testing, the test cycle at least once a year, the detection of the content includes following:

- A) Check the main unit and accessories for mechanical and functional damage;
- B) Check whether the safety sign is damaged;
- C) Check whether the fuse meets the rated current and breaking characteristics;
- D) Verify the function of the instrument according to the instructions;
- E) Perform the following safety tests according to IEC 60601-1:

Protection ground impedance, limit: 0.2;

Ground leakage current, limit: NC 500uA, SFC 1000uA

Patient leakage current, limit: 10uA (CF type equipment)

When using AC power, the leakage current in a single fault condition, the limit: 50uA (CF type equipment)

The test should be carried out by trained qualified personnel with experience in safety testing and record the results of the tests. If the instrument has any problem in the above tests, it must be repaired.

1) Main Unit

- ◆ Avoid excessive temperature, sunshine, humidity and dirt. Cover the dust cover after using and prevent from shaking violently.
- ◆ Prevent any liquid from seeping into the equipment, for it will affect its safety and performance
- ◆ The performance of the ECG should be checked regularly by medical equipment maintenance department.

2) Patient Cable

- ◆ The integrity of the patient's cable and lead wires must be checked regularly and make sure they are in good condition.
- ◆ Align the patient cable to avoid twisting, knotting or crooking in closed angle while using

- ◆ Do not drag or twist the patient cable with excessive stress while using. Hold the plug instead of the cable when connect or disconnect the patient cable.
- ◆ Cables and leads should be put in a larger plate, or hanged well, to avoid the twisting or acute angle folding.
- ◆ Once damage or aging of the cable patient has been found, replace it with a new one immediately.

3) Electrodes

- ◆ Electrodes must be cleaned after using to prevent the conductive paste from remaining.
- ◆ Keep the suction bulb of chest electrode from sunshine or overheating.
- ◆ After long-term use, the surface of electrodes will be oxidized because of erosion and other causes. By this time, electrodes should be replaced to achieve good ECG recording.

8. Service and Warranty

Manufacturing process and raw materials

We guarantee to manufacture this instrument under using raw materials and processes that meet the requirement, we will repair or replace the defective part if such defect has been confirmed to cause by material or manufacture process.

Software or firmware

For the software or firmware installed, we will replace the software or firmware free if the problem has been confirmed during 12 months from the date of shipment. But we can not guarantee it will not interrupt the use of the product.

Limit of Warranty

The charges of freight and others are excluded under warranty.

The warranty is void in the case of following:

- ◆ Assembly, extensions, readjustments of any parts
- ◆ Modification and repair by unauthorized persons
- ◆ Subsequent damage caused by improper use or maintenance
- ◆ Replacement or remove of Serial number label and manufacturer label
- ◆ Improper operation

9. Accessories

Following accessories are recommended by us when using this machine.



Please must use the ECG cables and other accessories that we supplied, other types of accessories may damage the instrument, affecting the performance and safety of the instrument.

No.	Name	QTY
1	Main unit	1 pc

2	Power cable	1 pc
3	ECG/Patient cable	1 pc
4	electrodes, 5pcs/pack	1 pack
6	Roller	1 pc
7	Recording paper	1 roll
8	User manual	1 pc

Note: Accessories are available by contacting the manufacturer or your local distributor.

Appendix 1 – Technical Specifications

Safety Standard	MDD93/42/EEC	Medical equipment instruction
	IEC60601-1 GB9706.1-1995	Medical electrical equipment - Part 1: General requirements for safety
	IEC 60601-2-25 GB10793-2000	Medical electrical equipment - Part 2: Particular requirements for safety of electrocardiographs
	EN 60601-1-4	Medical electrical equipment - Part 1-4: General requirements for safety. Supplementary standard: Programmatic electrical medical systems
	EN 60601-2-51	Medical electrical equipment - Part 2-51: Particular requirements for safety - Basic performance, recording and analysis of single and multi -channel electrocardiographs
	EN ISO14971	Medical equipment, Application of Risk Management for Medical Devices
	ANSI/AAMI EC-11	Diagnostic electrocardiogram recording device
	YY1139-2000	single and multi -channel electrocardiographs

Classification	Anti-shock type	I class, internal power supply equipment
	Anti-shock degree	CF type, with anti-defibrillation function equipment
	Anti-liquid level	ordinary equipment, do not have the ability to water immersion
	Safety of combustible gases	Not suitable for use in flammable gases
	Working mode	continuous work
	Electromagnetic compatibility	Group I Class A

Dimensions	310mm×270mm×73mm
Weight	About 2kg
Display	5 inch color LCD screen, Resolution: 800 x 480

Environment		Transport and storage	Operation
	Temperature	-10°C~40°C	5°C~40°C
	Relative humidity	≤80%	30%~75%
	Atmospheric pressure	700hPa ~1060hPa	700hPa ~1060hPa
Power supply	AC power supply	Rated Voltage: 220V	
		Rated frequency: 50Hz / 60Hz	
		Rated power: 30VA	
	DC power supply (Built-in rechargeable Li-ion battery)	Rated capacity: 2200mAh	
		Rated voltage: 14.8V	
		Discharge termination voltage $\geq 12.8V$	
		Charging mode: constant current / constant voltage	
		Charge current (standard): 0.2C5A (440mA)	
		Charging voltage (standard): $(16.8 \pm 0.1V)$	
		Continuous maximum charge current: 2200mA	
		Continuous maximum discharge current: 2200mA	
		Cycle life ≥ 300 times	
	Power consumption	35VA (Maximum)	
	Fuse specifications		

Recording	Recording method	Thermal dot matrix printing
	Paper specification	Thermal printer paper, roll type
	Recording paper	80mm (3 channel), 112mm (6 channel)
	Effective record width	70mm (3 channel), 110mm (6 channel)
	Paper speed	6.25mm/s, 12.5mm/s, 25mm/s, 50mm/s ($\pm 3\%$)
	Record accuracy	$\pm 5\%$ (X axis), $\pm 5\%$ (Y axis)

Heart rate calculation	Calculation way	Peak detection
	Heart rate range	30BPM~300BPM
	Calculation accuracy	± 1 BPM

ECG host	Input Circuit	Floating, protection circuit against defibrillator effect
	Lead	Standard 12 leads
	Acquisition	Simultaneous 12 leads
	A/D converter	14bit/1000Hz
	Polarization Voltage Tolerance	$\geq \pm 500\text{mV}$
	Time constant	$\geq 3.2\text{s}$
	Frequency response	0.05Hz ~ 250Hz
	Sensitivity	10mm/mV (AUTO, 2.5mm/mV, 5mm/mV, 10mm/mV, 20mm/mV)
	Input Impedance	$\geq 50\text{M}\Omega$
	Input Circuit Current	$\leq 0.1\mu\text{A}$
	Sensitivity Threshold	$\leq 20\mu\text{V}$
	Calibrating Voltage	1mV $\pm 2\%$
	Noise Level	$< 15\mu\text{V}_{\text{p-p}}$
	Inter-channel interference	$\leq 0.5\text{mm}$
	Patient Current Leakage	$< 10\mu\text{A}$
	Patient assisted leakage current	$< 0.1\mu\text{A}$ (DC)
	Dielectric strength	4000V RMS
	Filter	AC filter EMG filter
	CMRR	$\geq 100\text{dB}$ (with AC filter)

External input and output (Optional)	Single-ended input	$\geq 100\text{k}\Omega$; sensitivity 10mm / 0.5V $\pm 5\%$
	Single-ended output	$\leq 100\text{k}\Omega$; sensitivity 0.5V / mV $\pm 5\%$
Signal interface	USB interface	