

Digital ECG Machine User Manual



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Note: This device is not intended for home use.

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

Using this Label Guide

WARNING

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

CAUTION

A **CAUTION:** The 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 Safety Guidelines

1.1 Safety Instructions

The design of the digital ECG machine in line with general international security for medical electrical equipment standard IEC60601-1 and electrocardiogram machine general requirements for safety of IEC 60601-2-25, is class I, CF type equipment, satisfy the requirements of IEC 60601-1 for electric shock protection, and have the function of control chatter.

Digital ECG machine is continuous work type instrument, it is common equipment, pay attention to avoid being splashed water. The instrument is not explosion-proof, cannot be used in the place where contains flammable anesthetics.

Classification:

Prevent electric shock type:	I class, with internal power supply equipment
Prevent electric shock:	CF type equipment, with functions of control chatter
Into the liquid level:	General equipment, does not have waterproof in ability
A flammable gas safety degree:	Not suitable for use in the combustible gas environment
Working pattern:	Continuous work
Electromagnetic compatibility:	I set A class

Before using the instrument, must check the instrument, electrical cables and electrodes whether there is any damage that may affect patient safety, if it is found that obvious damage or aging phenomenon, should be replaced before using the unit. When the replacement parts must be used is the same as the original parts.

The instrument must be maintained by authorized qualified engineers. If you change and maintenance by authorized officers of the born without the company, the company will not responsible for the safety, reliability and performance of the instrument.

1.1.1 Environment

Digital ECG machine transportation storage and working environment requirements shown in the table below :

	Transportation and Storage	The Normal Work
Temperature:	- 10 °C ~ + 40 °C	+ 5 °C ~ + 40 °C
Relative Humidity:	80% or less	35% ~ 75%
Atmospheric Pressure:	700 hPa and 1060hPa	700hPa and 1060hPa

Electrocardiogram machine environment must be kept clean, away from the corrosive, high humidity, high heat and direct sunlight, in use should avoid vibration, banned the charged state of handling equipment.

1.1.2 The Power Supply

1) The ac power:

Rated voltage: a.c.100V~240V

Rated frequency:50Hz/60Hz $\pm$ 1Hz

Rated power: 120 VA

2) Built-in rechargeable lithium battery:

Rated voltage: 14.8V $\pm$ 10%

Nominal capacity: 2200 mAh

1.2 Using Attention

For the use of safe and effective instrument, to avoid possible damage, please read the instructions before use, familiar with the performance of the instrument, fully understand the right operation method and the matters needing attention.

 **Warning**  :

If the use of flammable anesthetics environment, there will be a danger of explosion.

 **Warning**  :

Don't use in the presence of high voltage equipment, or high electricity environment instrumentation, otherwise may be the result of the instantaneous discharge spark.

 **Warning**  :

Avoid shock hazard, instrument shell must be ground, and ensure the good grounding; Use a protected area of three phase socket, and make sure that the socket grounding protection in good condition.

 Warning :

The instrument shall be installed by qualified service engineers;
Only authorized maintenance engineer can open the instrument housing.

 Warning :

If you have questions about the integrity of the protective earthing conductor, please use the built-in battery, do not use ac power.

 Warning :

Connected the analog and digital interfaces of accessory equipment must be based on their respective IEC standards (for example, data processing equipment standard IEC 950, medical equipment standard IEC 60601-1) for verification. In addition, all configuration shall comply with IEC 60601-1-1 of valid version. Therefore, connection accessories to the signal input connectors or signal output connector personnel in the configuration of the medical system, make sure that the system conforms to the valid version of the requirements of IEC 60601-1-1. If in doubt, please consult us or your local agent.

 Warning :

In order to ensure patient safety, connect multiple devices at the same time, when patients caused by leakage summation must not exceed allowable values.

 Warning :

Or pacemakers and defibrillators use at the same time, do not contact with the patient, bed, table or instrument.

 Warning :

To avoid burns, at the same time when using electric surgical equipment shall ensure that the electrode from electric surgical knife.

 Warning :

Must use the company to provide patients with cable and other matching accessories, may damage the instrument use other types of attachment, impact performance and safety of the instrument.

 Warning :

Please make sure that all the electrode connections, and connect to the correct position of the patient's body. Avoid electrode (including the neutral electrode) and patients contact with any other conductive parts or earth.

 Warning :

The instrument operator must pass a qualified professional training, at the same time to ensure full understanding of the content of this manual before using.

The use of rechargeable lithium batteries :

 Warning :

Improper operation may cause the battery heat, fire, explosion, destroy or battery capacity attenuation. In the use of rechargeable lithium ion batteries (hereinafter referred to as the "battery") before, please read this manual carefully and use the matters needing attention.

 Warning :

Batteries are negative which can't connect opposite , otherwise may cause explosion.

 Warning :

Don't close the fire or temperature above 60 °C environment using battery, do not heat the battery or throw it into the fire. Pay

attention to avoid the battery was splashed water, don't put battery into the water.

 Warning :

Ban the battery with metal, hammering or break the battery or use other ways to damage the battery, otherwise it will cause the battery heat, smoke, deformation or burning, produce risk.

 Warning :

When find battery leakage or send out a bad smell, get away immediately. If electrolyte leakage to the skin or the clothes, clean with clear water immediately. If electrolyte leakage and into the eyes, don't rub eyes, wash with clean water immediately and go to see a doctor.

 Warning :

Only authorized installation or maintenance engineer who can open the battery lifted the lid, replace the battery. And our company must provide the same type of rechargeable lithium batteries.

 Warning :

Battery using period, finding that the battery is faulty, deformation, discoloration or distorted, should stop using the battery. And return to the company for processing or in accordance with local laws and regulations to deal with waste battery.

 Be Careful :

Pay attention to avoid the instrument by splashed water.

 Be Careful :

Avoid high temperature, the instrument should be used between 5 °C and 40 °C temperature range.

 Be Careful :

Avoid the too higher pressure, poor ventilation, dust, or contains salt, sulfur gas and chemical environment such as the use of the instrument.

 Be careful :

Ensure that the installation of the instrument using the environment without strong electromagnetic interference sources, such as wireless transmitter or mobile phone. Please note: electric surgical equipment, ultrasound machines, radiation machine and large electrical equipment such as magnetic resonance imaging may produce electromagnetic interference.

 Be careful :

Before using the instrument, must check the instrument, patient cable and electrodes whether there is any damage that may affect patient safety, if it is found that obvious damage or aging phenomenon, should be replaced before using the unit.

 Be careful :

The safety of the equipment should be periodically test, test cycle for at least two years, testing content mainly includes:

- a) Check the host and accessories if there is a mechanical and functional damage;
- b) Check whether the security identity is damaged;
- c) Check the fuse in line with the rated current and open circuit characteristic;
- d) According to the instructions to verify the function of the instrument;
- e) According to IEC 60601-1 for safety test as follows :

Impedance protection, limit: 0.2;

To floor drain current limit: NC 500 UA, SFC 1000 UA Patients with leakage current, limit: 10 UA (CF type equipment) When using

ac power source, the patients with single fault conditions leakage current, limit: 50 UA (CF type equipment)ESTS shall be made after the training, security testing knowledge experienced qualified personnel, and the test results are recorded.If any problems in the instrument in the test, must be maintained.

 **Be careful**  :

After the date for use, instruments and reusable components can be returned to the manufacturer to recycle or processing according to local regulations.

Cleaning, disinfection and maintenance:

 **Be careful**  :

Clean instruments must turn off the power before you use ac power supply,and must disconnect the ac power, cable and remove the power cord and patients.

 **Be Careful**  :

Don't immerse in a liquid of the patients with instruments and cables.

 **Be Careful**  :

Banning the use of wear materials for cleaning, avoid scratch electrode.

 **Be Careful**  :

Avoid any cleaning fluid residues after cleaning in the instrument and on the surface of the cable.

 **Be Careful**  :

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

 **Be careful**  :

Do not use chlorine disinfectants, such as bleaching powder, acid, etc.

2 Introduction

Electrocardiogram machine is to record the heart activity waveform (ECG) physiological function testing instrument, can provide various kinds of heart disease diagnosis and treatment of basic information, help to analysis and understanding of all kinds of arrhythmia, helps in the understanding of certain drugs and the effects on MYOCARDIAL, electrolyte imbalance and acid-base imbalances so electrocardiogram machine has an important position in the heart to check.

Digital ECG machine is a kind of twelve guide synchronization acquisition three and six printing digital ECG machine, has the ECG waveform display, with functions of automatic analysis options. Due to the hot array output system equipped with advanced, high-performance 32-bit processor and large internal memory capacity, performance and reliability of the electrocardiogram machine has been greatly improved, and special operation is simple, rich and practical function, the unit of electrocardiogram (ECG) is very suitable for all kinds of medical routine diagnostic use, especially suitable for medical use, this, ward and other occasions.

Standard configuration: electrocardiogram machine host;
Accessories: power cord, ground wire, lead wire, limb electrode, electrode, thermal printing paper.

2.1 Features

- 1) Chinese and English menu, 12-lead waveform display.
- 2) Real time record, 1 + rhythm, 3 1 the waveform, 6 waveform, 12 waveform, break up and automatic mode.
- 3) 12-lead synchronous acquisition.

4) Using digital isolation technology, the components to minimize the influence of temperature drift and time drift, ensure the equipment of high adaptability to the environment.

5) Adopting digital signal processing, through the ECG signal processor drift suppression, ac filter, motor electricity filtering and heart rate detection, such as processing, ensure the authenticity and reliability of the output signal.

6) Hot high resolution array printing, ECG graphics vivid, exquisite, print density is adjustable, print the waveform and the effect of the domestic leading characters.

7) Baseline stability testing, ensure each ECG waveform can hit neat and beautiful.

8)) High quality silica gel qwerty keyboard, long life feel is good.

9) Support Chinese input method.

10) Through the U disk, SD card can store data.(the model without SD card function)

11) Can store image files for computer to view and print directly.

12) Can connect the workstation to hospital digital management (optional).

13) Adopts precision hot spots formation of 12-lead Lillian electric wave and lead tag, filtering state, measuring parameters, gain, the feeding speed, on behalf of waveform, analysis report, such as information, EEG, waveform clear, accurate and available for clinical diagnosis and research.

14) With wide power design even in the case of the voltage instability can also print out the clear and accurate ECG waveform.

With AC/DC power supply mode, with rechargeable batteries are installed in the machine, battery charging circuit and perfect the management and protection system.

15) Design conforms to the IEC safety standard type CF, ECG amplifier full-floating, can be directly to the human body heart, special security.

16) With defibrillation protection and pacemaker and suppression circuit.

17) Built-in USB interface,.

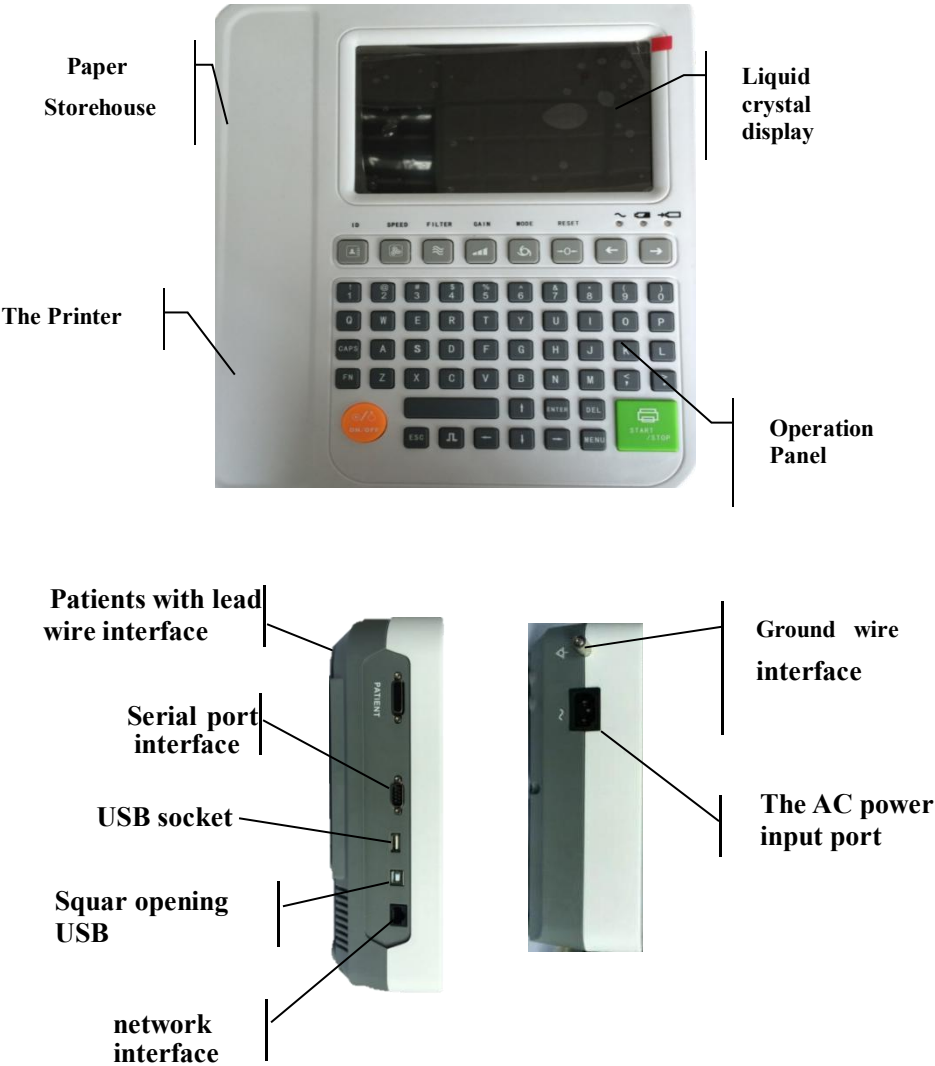
2.2 Symbols

	External output (if any)
	External input (if any)
	CF type device (parts), with functions of control chatter
	Attention!Refer to random file
	Equip torrential
	Alternating current (ac)
	Batteries work state
	Battery charging status
	Non-ionizing radiation
USB1	USB flash disk 2.0 socket

PATIENT	Patient Leads socket
USB2	USB communication socket
LAN	Network port
	Upwards
	Fragile, handle with care
	To avoid the rain
	Limit of stack layers
	Temperature limitation
	Manufacturing date
	Serial number
	Service life
	Waste equipment should be disposed according to environmental regulations

3 Instrument Appearance Description

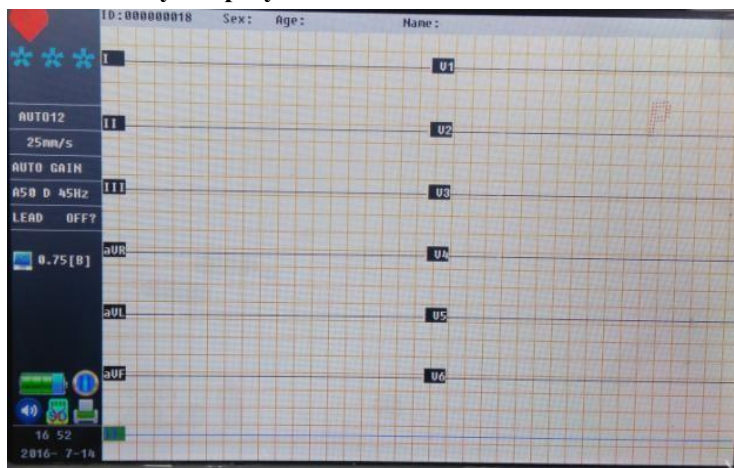
3.1 The Host Panel



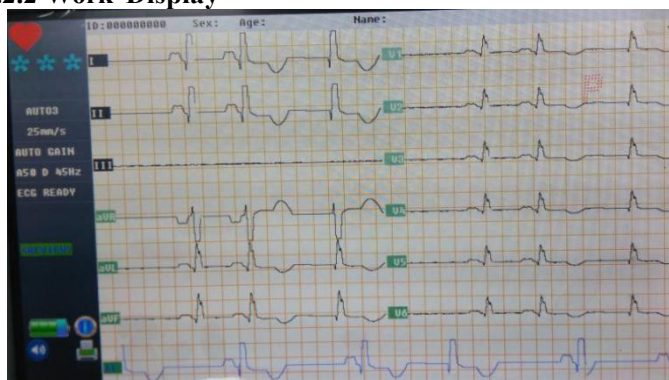
3.2 Liquid crystal display (LCD)

Three, six, twelve of electrocardiogram machine LCD 7 " color LCD liquid crystal display (LCD)

3.2.1 Standby Display



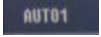
3.2.2 Work Display



Above from left to right in turn as follows:

- ◆ case ID, gender, age, name

The following order from top to bottom is:

- ◆  Heart rate (the actual heart rate value)
- ◆  Working mode (adjustable)
- ◆  The feeding speed (adjustable)
- ◆  Filter state (adjustable)
- ◆  Current working state machine
- ◆  Waveform display scale (adjustable)
- ◆  Built-in battery, the battery
- ◆  The ac power supply
- ◆  Printers standby,  printer status
- ◆  The key sound ,  Mute button
- ◆  Not insert SD card ,  Has been inserted into the SD card (the model without SD card function)
- ◆  Not installed printing paper,  Installed printing paper

3.3 The Control Panel and Buttons



1) Work Status Indicator

~ When using the ac power supply, communication status of the indicator.

 Battery indicator: when using built-in rechargeable lithium battery, the indicator lights.

→  The battery indicator light: when is the battery charging, the indicator light flashing reminder.

2) ON/OFF Switch ON/OFF Key

 Press the key in the boot and shutdown switch between two states. In through to alternating current (ac) or the built-in battery cases, sufficient light touch the buttons boot and shutdown can be realized.

3) FN function key



FN function keys is used, the input mode of the characters, pinyin Chinese input, input in English,

Numbers, or punctuation switching between the three kinds of input mode.

4) COPY/Calibration Key



- ◆ in manual or automatic mode, press the key, print 1 MV calibration waveform in the record.
- ◆ in automatic mode, press this key to copy the last print ECG data, and then press the print button to copy the ECG data can be printed out again, shut down after the data will be lost.
- ◆ in Chinese input mode, press the button, the type of the content of the spelling fill in the box.

5) START/STOP START/STOP button



Used to start or stop the print waveform

6) set key cases



Used to set the case information, can be installed include: ID number, name, age, gender, ID set (auto/manual)

7) speed setting key



Press the key can adjust the feeding speed fast, a total of 4 kinds of speed mode, respectively is 6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s

8) filter Settings button



Filter Settings have four modes, respectively is:

[A] 0.05 250 Hz filter function to shut down

[B] A50 D filter open communication

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

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

9) Gain Settings button



In manual mode, the gain setting, a total of 4 kinds of gain model, respectively is 2.5 mm/MV, 5 mm/MV, 10 mm/MV, 20 mm/MV

10) mode button



Is used to select guide transmittance switching mode, press the key lead mode to switch between manual and automatic, each mode guide transmittance conversion sequence are shown in table 3-1 below:

Single model	Lead a switching sequence (from left to right)
Automatic 1	(1 * 12) -channel waveform printing, order I Π/Ⅲ/AVR/AVL/AVF/V1 / V2 / V3 / V4 / V5 / V6
Automatic 2	(1*12+1) + single channel waveform of rhythm lead print
Automatic 3	(3*4) three waveform printing, I Π/Ⅲ, AVR/AVL/AVF, V1 /
Automatic 6	(6 * 2) six waveform printing, I/Π/Ⅲ/AVR/AVL/AVF, V1 / V2
Automatic 12	(12 *1) 12 waveform printing, I Π/Ⅲ/AVR/AVL/AVF/V1 /
Manual 1	(1*12) single-channel waveform printing, need to manually
Manual 2	(1*12 + 1) + single channel waveform of rhythm lead print, need to manually switch lead, the same as the automatic 1 order

Manual 3	(3 * 4) three waveform printing, need to manually switch lead,
Manual 6	(6 * 2) six waveform printing, need to manually switch lead, the same as the automatic 6 order
Manual 12	(12 * 1) 12 waveform printing, need to manually switch lead, the same as the automatic 12 order

11) waveform reset button



In acquisition mode, press the key waveform can be reset.

12) Lead the switch key



Press the key (- >) to the right or left (please) lead conversion.

13) ESC



ESC function keys, exit or cancel the current menu operation.

14) The Delete Key



Delete the previous step input characters.

15) key CAPS



In input letters, large/lowercase input switch.

16) The MENU Button



Enter the Settings menu, including parameter Settings, system Settings and data management

17) Navigation/confirm key



After entering the Settings menu, through the up, down, left and right direction key to move the cursor, confirm button to enter

sub menu or select Settings.

18) The Blank Space Key



In the condition of input, input a space character.

19) Small Keyboard



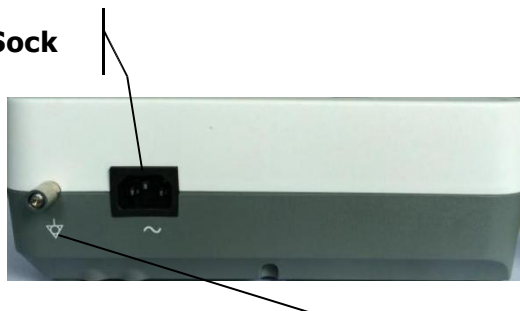
◆ can achieve input Chinese, English, punctuation

◆ in the Settings menu or option, according to the menu or option before [A] [B] [C] [D] label such as letters, press the small keyboard keys of the ABCD letters, can quickly into the corresponding menu or options.

◆ in the condition of main interface, press the B letter key, enter the display scale, set can be adjusted to the waveform shows the proportion of

3.4 Network and Switch Power Supply Connection

The AC Sock



Equipment Column

1) Equip Torrential Column



2) The AC Socket

AC SOURCE: the AC power cable socket

Cable socket, 3.6 patients and signal interface

⚠ warning ⚠ :

Connected to the analog and digital interfaces of accessory equipment must be based on their respective IEC standards (for example, data processing equipment standard IEC 950, medical equipment standard IEC60601-1) for verification. In addition, all configuration shall comply with IEC 60601-1-1 of valid version. Therefore, connection accessories to the signal input connectors or signal output connector personnel in the configuration of the medical system, make sure that the system conforms to the valid version of the requirements of IEC 60601-1-1. If in doubt, please consult us or your local agent.

⚠ warning ⚠ :

in order to ensure patient safety, when patients connect multiple devices at the same time, caused by leakage summation must not exceed allowable values

Patients with cable

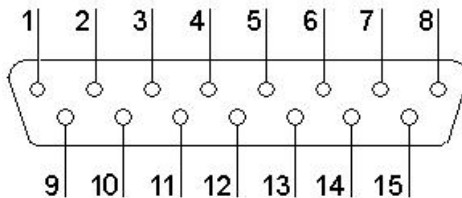
Output

USB

Network port



1) patients with cable socket



 : CF type application components, with functions of control chatter



: **Attention!Refer to random file**

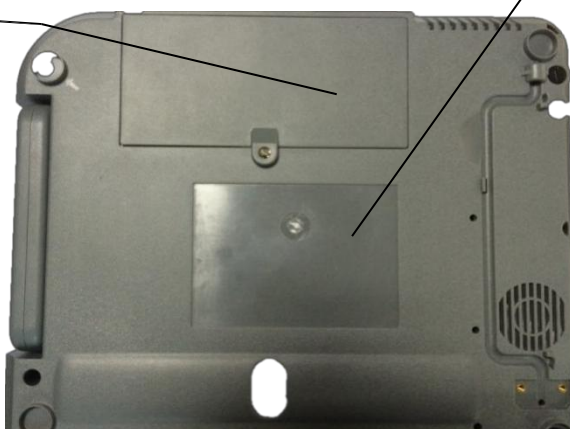
The Definitely of the Corresponding Pin:

connector	signal	connector	signal	connector	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

3.5 The Host Underside

Battery Pack

Back Label



1) A battery pack

**Rechargeable lithium-ion
battery pack**

attery pack label marked on the built-in rechargeable lithium
battery rated output voltage and rated power, as shown in the above.
Machine inscription

 **Attention!** **Warning messages (refer to random file)**

 warning  :

Improper operation may cause the battery heat, fire, explosion,
destroy or battery capacity attenuation. In the use of rechargeable
lithium ion batteries (hereinafter referred to as the "battery")
before, please read this manual carefully and use the matters
needing attention.

 **Warning**  :

Only authorized installation or maintenance engineer can open
the battery lifted the lid, replace the battery; And our company
must be used to provide the same type of rechargeable lithium
batteries.

2) Products using the interpretation of the symbols



CF type equipment, with functions of control chatter.



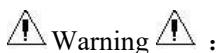
Be careful, see random data (handbook).

4 Operation to Prepare

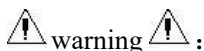


Must use the company to provide patients with cable and other matching accessories, may damage the instrument use other types of attachment, impact performance and safety of the instrument.

4.1 Connect the Power Supply and Grounding Line



To avoid electric shock risk - must be used with a protected area of three phase socket, and make sure that the socket grounding protection in good condition; And make sure the ground wire grounding is good; When the power supply connection do not open the shell of the instrument.



If you have questions about the integrity of the protective earthing conductor, please use the built-in battery, do not use ac power.

1) Use the AC Power

First determine the ac power is in accordance with the requirements:

Voltage range: a.c.100V~240 v

Rated frequency 50 Hz / 60 Hz $\pm$ 1Hz

Rated power: 120VA

Then insert the power cable joint apparatus on the left side of the alternating current (ac) interface end, insert the plug of the power cable three-phase ac power outlet.

2) Use the Built-in Battery

Digital ECG machine is referred to the user, has installed a built-in rechargeable lithium battery, can be used directly. But the power loss in the process of storage transport, lithium battery power in use for the first time may be less than, then need to for rechargeable batteries. Arrive when the battery service life (cycle life of 300 or higher), after a full charge after the use of the time significantly shortened, should replace the battery in time. The battery and replace the details please refer to the daily maintenance and maintenance section 7.4.1.

3) Connect Ground Wire

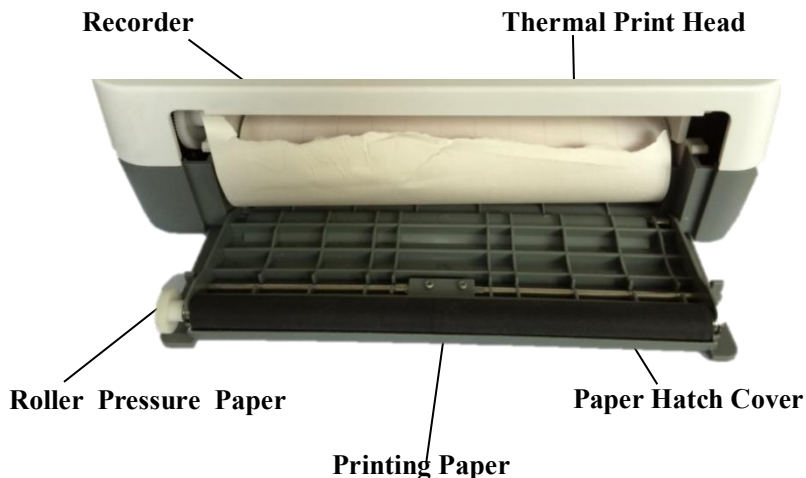
To end the grounding line clip on the left side of the instrument of equip torrential column, the other end connected to the hospital in public

4.2 Install the Recording Paper

The instrument used in recording paper has two kinds: scroll thermal printing paper, 215 mm wide and 215 mm wide folding thermal printing paper. When there is no installation record paper or paper used up, the LCD screen on the printer icon will flash, remind users to install or replace the paper.

The Installation of ECG Recording Paper

Use of the instrument recording paper: 215 mm wide scrolls thermal printing paper folding thermal printing paper or 215 mm wide. When there is no installation record paper or paper used up, the LCD screen will show "lack of paper," to remind users to install or replace the paper.



Install a Scroll Therm Sensitive Paper:

1) with the hand to pull the paper cover switch, open the recorder cover;

2) from the paper slot typed out gently, if you have the rest of the paper roll, directly from the paper slot typed gently remove;

3) unveils new record pincer-like device on the paper tape, gently slot in the new paper from the paper roll, installing a recording paper note on the grid for recording paper;

4) will be on flat paper slot on both ends of the scroll, gently into the paper slot;

5) to pull recording paper about 2 cm, close the recording paper cover.

4.3 Patients with Connection Cable



Patients with cable is divided into two parts: the main line and electrocardiogram machine connections lead wire of the patient.

Lead wire including six chest I ERT the lead wire and four limbs, the user can through the label on the color of lead wire and connectors to differentiate between the chest and limb lead.

Cable connection patients: insert the plug of cable patients electrocardiogram machine on the right side of the cable socket (Patient), tighten the plug on both sides of the knob.

4.4 Install the electrodes

 **Warning**  :

Please make sure that all the ECG electrode connection, and connect to the correct position of the patient's body. To avoid cable electrode (including neutral electrode) and the patients contact with any other conductive parts or earth.

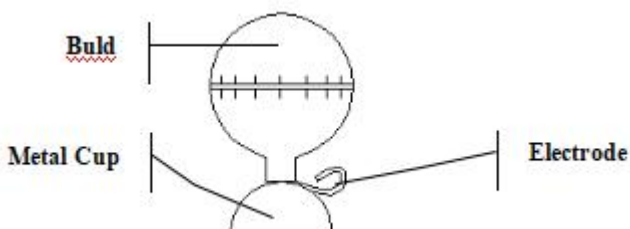
The contact resistance between patients with electrodes on the quality of the electrocardiogram (ECG) has a great influence, therefore in the connection when installing electrodes, try to reduce the contact resistance, in order to get good electrocardiogram (ECG).

Electrode of the logo and color coding (European standard) as shown in table 4-1. Electrode according to different standards, the coding and color is different, in table 4-1 at the same time the corresponding American standard logo and color coding.

Table 4-1 Electrode Logo and Color Coding

lead	European standard		American standard	
	logo	color	logo	color
Right arm	R	red	RA	white
Left arm	L	Huang	LA	black
Right foot	RF	black	RL	green
Left foot	F	green	LL	red
Chest 1	C1	White/red	V1	Brown and red
Chest 2	C2	White/yellow	V2	Brown/yellow
Chest 3	C3	White/green	V3	Brown/green
Chest 4	C4	White/brown	V4	Brown/blue
Chest 5	C5	White/black	V5	Brown/orange
Chest 6	C6	White/purple	V6	Brown/purple

Chest Electrode:



Chest electrode placement site for six commonly, the clearance between the frame as the location, C1 ~ C6:

C1: external right edge of the fourth floor clearance

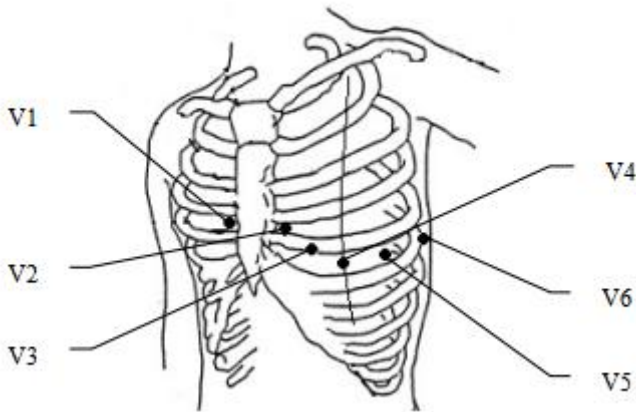
C2: external left margin in the fourth rib gap

C3: at the point of the C2 and C4

C4: external left margin between fifth rib and left collarbone
mid-line intersect

C5: parallel to the left and C4 level before a maxillary line

C6: the left and C4 level of maxillary line

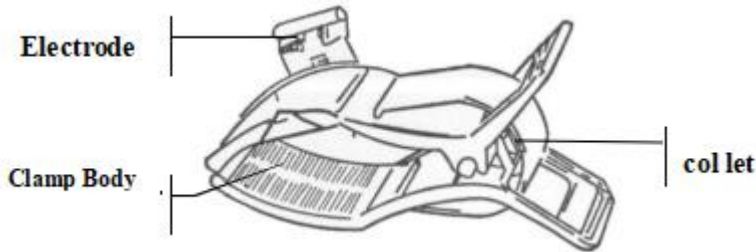


Connect the chest electrode:

- 1) check whether the electrode is clean;
- 2) straighten out lead wire, avoid distortion, electrodes connector connected to the electrode firmly;
- 3) use alcohol wipe it discharge with the skin;
- 4) put the electrode in the chest every parts, evenly daub is about 25 mm diameter range of conductive paste;
- 5) in the breast electrode bulb edge evenly coated with a thin layer of conductive paste;
- 6) electrodes placed on the skin squeeze the rubber ball, the company the rubber ball, electrode in chest accordingly absorption.

Note: don't put too much conductive paste, coating should be separated from each other, otherwise it will cause short circuit between the electrodes, cause the ECG signal recorded error.

Limb Electrode (clamp type) :



Limb electrode placed above the front arm joints and inside of the leg ankle above, can make the electrodes in contact with the skin tight parts. Connect body electrode:

- 1) Check whether the electrodes is clean;
- 2) to straighten out the lead wire, avoid distortion, and connect the electrode connector and electrode firmly;
- 3) place electrode parts of the surface of the skin clean with alcohol;
- 4) conducting paste evenly on the surface of the skin;
- 5) in the body electrode surface coated with a thin layer of conductive paste;
- 6) good put electrodes on the surface of the skin.

4.5 Before Starting the Inspection

Please read carefully before using the digital ECG machine operation instruction, familiar with the performance of the instrument and must master the operation method and the matters needing attention; It is recommended that you check before starting the following matters:

1) The Environment :

Check whether there is any other electrical equipment in the surrounding environment, such as electric surgical equipment, ultrasonic instrument, radiation machine etc, these devices may produce interference, if necessary, turn off the power of this equipment;

Keep warm indoor requirements (not less than 18 °C), in order to avoid motor electricity interference caused by cold.

2) Power Supply:

When using the ac power, please check the power cable connected to the instrument is strong, three-phase power sockets should be used with protected land socket;

3) Ground:

Ground wire is connected correctly;

4) Lead:

Check whether the lead plug connection is firm, avoid lead wire close to the ac power cord; Check whether the lead wire is connected to the corresponding electrode right;

5) Electrode:

Check whether the electrodes is strong; Electrode, especially the chest electrode if they touch each other;

6) Recording Paper:

Determine the recording paper is enough, installed correctly;

7) inspection:

check whether by inspectors of the hands and feet touching the metal parts of the bed, examination room environment is comfortable, be obliged not to be too nervous, asked inspectors relax the body, to stay calm

5 Operation Method

5.1 Boot

When using the ac power, on the left side first plug in the power cord, connect the ac power, at this time Alternating current indicator () ON, and then press "ON/OFF" button  After boot,

instrument display manufacturers logo trademark, enter the working state;

When using the ac power, the machine power supply status display for ac power supply  , And the ac power indicator light () Light up, battery indicator () And the battery charge indicator () Put out

When using the built-in battery, the machine power supply status display for the batteries  , And battery indicator () on the ac power indicator light () and the battery indicator light () go out

Instructions : This instrument only in the shutdown state can be carried out on the built-in battery charging, the method is: instrument is turned off, connect the ac power, the battery charge indicator () show that is charging, when the indicator light from flashing to normally on, indicates that the battery has been filled.

5.2 Automatic Mode

Automatic mode can be divided into 1 (1 * 12), 2 (1 * 12 + 1) automatically, automatic 3 (3 * 4), 6 (6 * 2) automatically, automatic 12 (12 * 1) five kind of print mode, in the process of ECG records, guide transmitter will automatically switch, in order that when a group lead in setting the time period of ECG signals The record has been completed, will automatically switch to the next guide transmitter, and start to record the transmitter of ECG signal.If you have any requirements can also be manually switch lead for printing.After printing, automatic save cases.

Specific Operation Method:

1)Through the "mode" button  the working mode to automatic mode, each time you press the "mode" button,work mode that jump again

2)According to the "speed" button  setting up the appropriate record speed, each time you press the "speed" button, record speed will jump again

3)Press "cases"  have been losing information, including ID number, name, age, gender

4) press the "START/STOP" key, the screen display working state "acquisition of....."Printer START, after a few seconds, after the stay of 12 lead all print, according to analysis report, press the "START/STOP" button again to report print out.

◆ In the process of recording, if there is need to press the "START/STOP" key  stop recording, but began to record again, will begin to guide transmitter order or EEG case information remains the same.

◆ In the process of recording, press the "COPY/calibration" button  Can be identified manually add calibration record in the chart

◆ Lead in the process of recording, press the "switch" key   switch can be manually guide for printing, until the end of 12 lead all print.

5.3 Manual Mode

Manual mode can be divided into manual 1 (1×12), 2 ($1 \times 12 + 1$) manual, manual 3 (3×4), 6 (6×2) manual, manual 12 (12×1) five kind of print mode, in the process of ECG records, guide transmitter need to manually switch, if you don't switch will always record the transmitter of ECG signal. Manual mode, the cases cannot be saved.

Specific operation method:

1) Through the "mode" button  will work mode to manual mode, each time you press the "mode" button, the working mode that jump again

2) According to the "speed" button  setting up the appropriate record speed, each time you press the "speed" button, record speed will jump again

3) Press the "START/STOP" button , the screen display working state "acquisition of....." And a few seconds later the printer began to work

4) Lead to press the "switch" key   switch manual guide for printing, until the end of 12 lead all print.

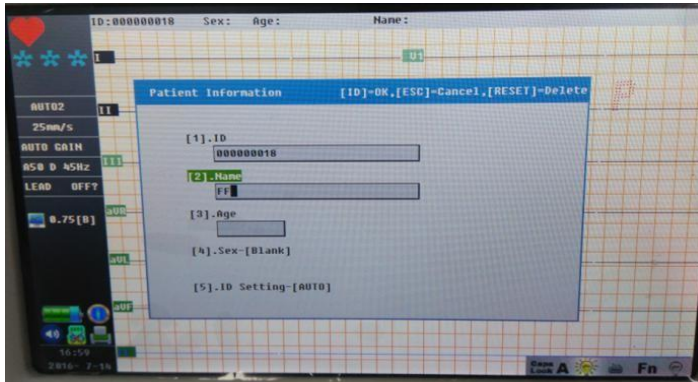
◆ In the process of recording, if there is need to press the "START/STOP" key.  stop recording, but began to record again, will continue to start from stops of the lead records.

◆ In the process of recording, press the "COPY/calibration"

button  Can be identified manually add calibration record in the chart

5.4 Text Input Window Operation Method

5.4.1 The Input of Numbers and Punctuation marks

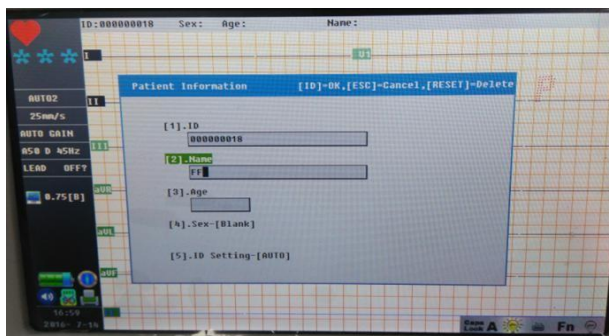


As shown in the above, through the "navigation/validation"

button   The upper and lower direction key move the cursor to the input box, press the "FN" function key  The bottom right hand corner of the screen, FN small bulb icon into a state of light  , At this point, the keyboard has been switch to

Numbers and punctuation input mode, press the keyboard keys have Numbers or punctuation marks in, can input the corresponding Numbers or punctuation marks.If you want to modify the input in the process of input content, you can use the "delete" button  Delete the content.

5.4.2 The Chinese input



As shown in the above, through the "navigation/validation"



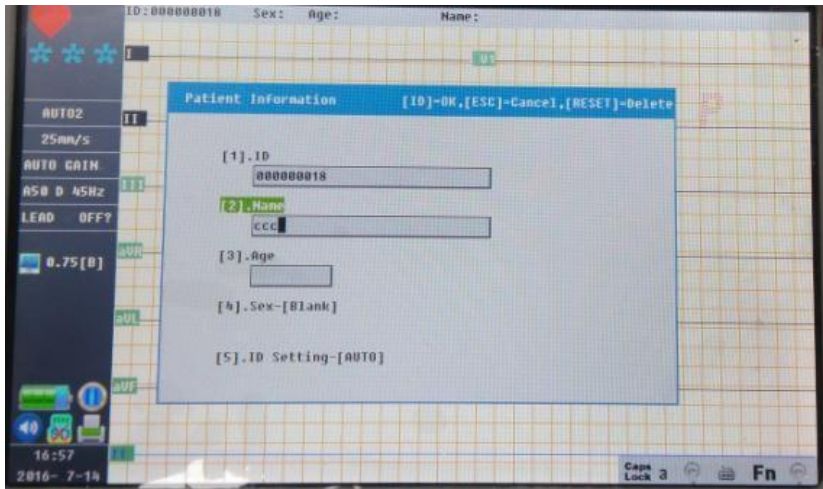
button  The upper and lower direction key move the cursor to the input box, repeatedly press the "FN" function key  Sets the spelling in the dialog box input status to pinyin  input mode, *pinyin*, caps Lock and FN function state of small bulb icon to go out, at this point, the keyboard input into Chinese pinyin input mode, according to the spelling of Chinese characters pinyin spelling rules, when spelling out several characters, Chinese characters, use

the left and right direction key   Move the cursor to select



text, press the upper and lower direction  Page, press the "confirm" button  Selected the Chinese characters, each can only spell a Chinese characters, words spelling, according to "COPY/calibration" button  The text will enter the input box, the Chinese character input. If you want to modify the input in the process of input content, you can use the "delete" button  Delete the content.

5.4.3 English character Input



As shown in the above, through the "navigation/validation" button  The upper and lower direction key move the cursor to

the input box, repeatedly press the "FN" function key , The spelling in the dialog box input

state input mode is set to English , Caps Lock and FN

functions of small light bulb icon to put out state, at this point, the keyboard input into English lowercase input mode, press the keyboard contains buttons, can input lowercase letters, such as the need to switch the capital letters, press the "caps" button



Small caps Lock status indicator light bulb into light state



At this point, the keyboard input to uppercase input mode. If you want to modify the input in the process of input

content, you can use the "delete" button  Delete the content.

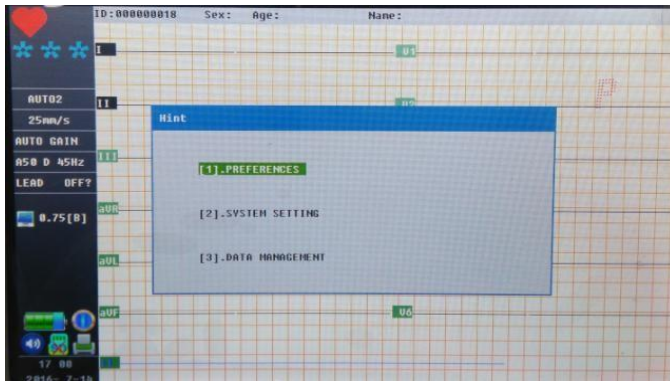
5.5 The MENU MENU Settings

5.5.1 The MENU MENU page

In standby mode, press "MENU" button in the keyboard



Enter the MENU Settings MENU interface, as shown in the figure below,



Set the project include:

- [1]. The parameter Settings
- [2]. System Settings
- [3]. The data management,



use the "navigation" keys    Move the cursor to setup



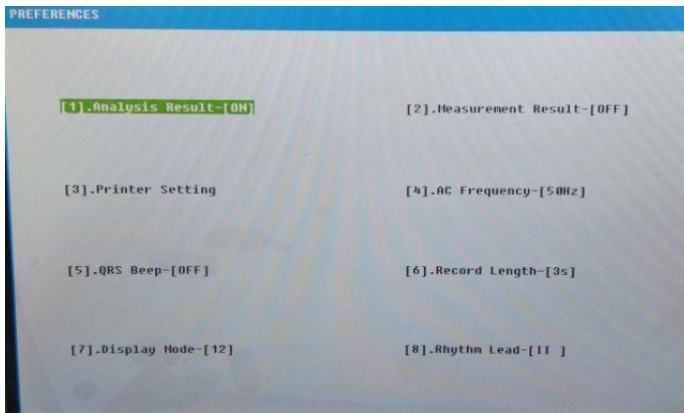
program, press the "confirm" key  Enter setup project, also can use the 1, 2, 3, in the small keyboard keys into the corresponding setting project quickly.

Set up a complete or cancel the relevant Settings, press

"ESC" key  Or "MENU" button  To exit the setup.

5.5.2 Parameter Settings page

After entering the MENU MENU, choose "[1]. The parameter Settings" option, or press the keypad 1 key , into the "parameter setting" interface, as shown in the figure below



Set the options:

[1]. The analysis of the output

- [1]. Shut: automatic mode and print report does not contain disease analysis results
- [2]. Open: automatic mode and print report contains condition analysis results

[2]. The measurement display

- [1]. Shut: automatic mode, the ECG waveform after the print print directly analysis report
- [2]. Open: automatic mode, the ECG waveform print need to manually after the print analysis report

[3]. The print Settings

- [1]. The baseline width: adjust the width of print baseline, the greater the numerical baseline width is larger
- [2]. Print mode: can be set up for synchronous real-time print or print
- [3]. Print gray scale: typed according to actual situation, adjust the clarity of waveform and characters, the greater the numerical print more clear
- [4]. The paper type: typed set type
- [5]. Print test: test the print function is normal

[4]. The frequency of communication

- [1]. 50 Hz: ac power frequency 50 Hz area select this option
- [2]. 60 Hz: ac power frequency is 60 Hz area select this option

[5].Heart sound

- [1].Close: in the process of testing, no heart rate prompt
- [2].Open: in the process of testing, heart rate prompt

[6].Record length

- automatic mode, each team lead recording time, can be set up for 3 ~ 12 seconds

[7]The display mode

- [1].3: the screen 3 signal, press the switch of "lead" key, the display can switch
- [2]. 6: screen display 6 signal, press the switch of "lead" key, the display can switch
- [3].12: synchronous display screen 12 signal

[8].Lead rhythm

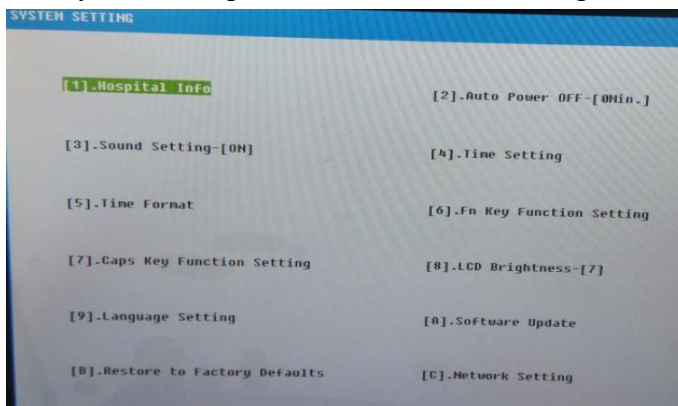
- can be set up I II/III/AVR/AVL/AVF/V1 / V2 / V3 / V4 / V5 / V6 lead any lead as rhythm signal

5.5.3 System Settings page

After entering the MENU MENU, choose "[2]. The



system Settings" option, or press the small keyboard 2 keys into the "system Settings" interface, as shown in the figure below



Set the options:

[1].Hospital information: can set up a hospital or use the information such as name

[2].Automatic shutdown, standby time can be set up machine, the boot after a set period of time without any operation, the machine automatic shutdown, standby time can be set up 10 to 60 minutes, is set to 0 minutes, close the automatic shutdown function, the machine worked.

[3].Sound Settings

- [1].Keys: operation without voice
- [2].Open: keystrokes is a voice

[4].Time setting: according to the local time zone set the local time

[5].Time type: custom time display type

[6].FN feature set

- [1]. always open: after open the FN function, can enter multiple consecutive Numbers or punctuation marks
 - [2]. only once: after open FN function, input a numeric or punctuation, FN functions automatically shut down
- [7]. Caps feature set
- [1].always open: open Caps, can enter multiple consecutive capitals
 - [2].only once: open the Caps, the input to write a great mother, Caps function automatically close

[8].The LCD brightness: display brightness can be adjusted according to the demand, the greater the value, the greater the brightness

[9].Language Settings

- [1].English: sets the system to Chinese interface
- [2].English : The system interface is set to English

[A]. Software upgrade: can U disk on the system upgrade The method is: set up folder named ASUPD in U packing



list



Will *. AS the format of package system
 Into ASUPD folder, USB interface insert U disk machine, opening machine, enter the software upgrade option, according to the prompt, press the "START/STOP" button to upgrade system, prompt "are upgrading, please do not power!!!!", wait a moment, **Data management page** prompt "upgrade successful, please restart", press the power button, after the reboot to complete the system upgrade.Upgrade process of the machine can't power outages, otherwise will damage the machine!

B] to restore Settings: use this option, the key parameters, the system can be set back to the original shape system.

[C]. Network Settings: (optional)

5.5.4 Data management page

After entering the MENU MENU, choose "[C]. Data management" option, or press the small keyboard  keys "Data management" into the interface, as shown in the figure below

DATA MANAGEMENT [Upload:USB]				Saved:20 Total size:20 [Page			
No.	ID	Name	Date	No.	ID	Name	Date
00001	000000000		2016-7-13 08:27				
00002	000000001		2016-7-13 08:28				
00003	000000000		2016-7-13 19:46				
00004	000000001		2016-7-13 19:48				
00005	000000002		2016-7-13 19:50				
00006	000000003		2016-7-13 19:51				
00007	000000004		2016-7-14 08:05				
00008	000000005		2016-7-14 08:36				
00009	000000006		2016-7-14 08:46				
00010	000000007		2016-7-14 08:47				
00011	000000008		2016-7-14 08:47				
00012	000000009		2016-7-14 08:48				
00013	000000010		2016-7-14 08:48				
00014	000000011		2016-7-14 08:49				
00015	000000012		2016-7-14 08:49				
00016	000000013		2016-7-14 08:51				
00017	000000014		2016-7-14 08:51				
00018	000000015		2016-7-14 09:46				
00019	000000016		2016-7-14 09:47				
00020	000000017		2016-7-14 09:48				

In the "data management" interface, through the  "navigation/validation" button  The upper and lower direction key move the cursor to the saved cases, press the "confirm" button  , open operation options, each operating option function is as follows:

- [1]. Open: do this, will open the selected cases, cases of ECG waveform, parameter
- [2]. Data retrieval: when are too many cases, use the search function, can quickly open the case after the case ID number
- [3]. Upload: the transmission of cases to the specified storage location, such as U disk
- [4]. Format: perform this operation will delete the machine to store all the cases

[5]. The selection/reverse choice: select/deselect all the cases of all the cases

The save to U disk: USB flash drive to establish a named after "ECG" folder, and copies the selected cases to the folder

[7]. The save to SD card: established in SD card named after "ECG" folder, the folder and copies the selected cases to (the model without SD card function)

[8]. Edit: for information to edit the selected cases, such as ID number, name, age and other information

[9]. Delete: delete the selected cases

[A]. Upload form

- [1].USB: USB way to transmit data to the computer or USB drive

[B].The storage format of save format: set the cases

- [1].[*].EAS] : Case file storage for EAS
- [2].[*].BMP] : Case is stored as a BMP format picture

5.6 To turn it off

When using the built-in battery, check finished, press the "ON/OFF" to turn it OFF.

When using the ac power, after the inspection, according to the "ON/OFF", and then pull out the power plug.

6 Prompt information

Digital ECG machine in use tool tips including lead off, lack of paper, low battery, as shown in table 6

Table 6-1 Hint Information and Cause

Prompt information	The reason of causing
Lead off, such as show "c1 - off"	C1 electrode fall off from the patients
Lack of paper, printer icon flash	No installation record paper or paper finished
Low battery, the battery icon in the lightning logo or automatic shutdown	The battery is low
Acquisition of...	Ongoing data acquisition/are printed
Are stored, please later...	Cases are preserved in the fuselage memory or cases can save to external storage
Error!!!!Existing [0]	Don't answer the external storage
Is passed	Is to transfer the data to a computer or external storage
Is upgrading, please do not power!	Power system upgrade (at this point cannot be otherwise just damage the machine!
Promotion, please restart	System upgrade, need to restart

7 Equipment Cleaning, Disinfection, Sterilization, and Maintenance

7.1 Clean

 Be careful .

Clean instruments must turn off the power before, if you use ac power supply must disconnect the ac power, remove the ac power cable and the patient cable.

1) The Host and Patient Cable Cleaning:

Soft clean without flannelette with a mild soap and water, or in the absence of corrosive after dilution of soaked in the liquid detergent, wipe the surface of ECG machine and patient cable, with clean, dry and soft cloth to clean.

2) The Cleanness of Electrode:

After using the electrode, the conductive paste wipe with clean soft cloth, the rubber ball chest electrode and metal cup apart, limb electrode electrode slice and clamp apart, in the warm water (below 35°C) of clean cleaning, ensure that no residue of conductive paste; Natural airing or with clean, dry and soft cloth to clean.

3) The print Head Cleaning:

Thermos sensitive stains and dirt on the surface of the head will affect the records of clarity, so users should regularly (at least once a month) clean the surface of the recording head:

Cover, open the recorder paper recorded paper out record paper roll, with dip of 75% alcohol in a small amount of clean soft cloth gently wipe the surface of the recording head, impregnation to stubborn stains can be used with a little alcohol, then wipe with a clean soft cloth; After natural drying, put into the recording paper, close the paper cover.

 Be careful  :

When cleaning liquid infiltration electrocardiogram machine internal; In any case will not immersed in liquid instruments and accessories.

 Be careful  :

Banning the use of wear materials for cleaning, avoid scratch electrode.

 Be careful  :

Avoid any cleaning fluid residues after cleaning in the instrument and on the surface of the cable.

7.2 Disinfection

In order to avoid do long-term damage to the product, we suggest that the only discipline in your hospital think it is necessary to disinfection products; We also recommend to clean to disinfection products first.

 Be careful  :

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

 Be careful  :

Do not use chlorine disinfectants, such as bleaching powder, acid, etc.

7.3 The Sterilization

In order to avoid do long-term damage to the product, we suggest that the only in your hospital sterilization procedures think it is necessary to product; We also recommend to clean to sterilization products first.

Attention:Used by the company for the disinfectant or sterilizing method as a means of infection control effectiveness is not liable.Consult your, head of the hospital infection control and epidemiologists.

7.4 Daily maintenance and maintenance

7.4.1 The capacity of the battery, charging and replacement

 **Warning**  :

Improper operation may cause the battery heat, fire, explosion, destroy or battery capacity attenuation.In the use of rechargeable lithium ion batteries (hereinafter referred to as the "battery") before, please read this manual carefully and use the matters needing attention.

1) Battery Capacity Display:

Located in the battery symbol at the top right of the LCD display shows a built-in rechargeable lithium battery capacity:



: Power is enough



: Low power, should consider to charge batteries



: Low power, charging immediately, otherwise the system will automatically shut down

2) Battery:

first time, because the power loss in the process of storage and transportation, power generally is not enough, can consider before use, for the battery to charge in advance.

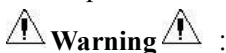
This machine only in shutdown state, therefore, in the shutdown state, the user only needs to connect the ac power, the battery indicator on the control panel at this time () Flashing lights, which indicates that the battery is charging.After the battery, the battery indicator light () Stop flashing, normally on.

3) Replace the Battery:

When the built-in rechargeable lithium battery to use period, or discover when the battery is faulty, discharge, should be timely contact with the local maintenance engineer or manufacturers, replace a new battery.



Only authorized installation or maintenance engineer can open the battery lifted the lid, replace the battery; And our company must be used to provide the same type of rechargeable lithium batteries.



Batteries are negative can't meet the, otherwise may Cause explosion.



Waste battery should be returned to the company, and would be treated or according to local regulations for processing.

7.4.2 Recorder and Record Paper

Pay attention to : Please use the vendor record paper paper, otherwise may shorten the life of thermos sensitive head, a record waveform fuzzy, such problems as poor paper.

The preservation of the paper should be paid attention to the following requirements:

- ◆ recording paper should be stored in a dry place, avoid high temperature, humidity and direct sunlight;
- ◆ Place under fluorescent lights to avoid long time;
- ◆ recording paper storage environment cannot have PVC plastic, otherwise it will lead to recording paper color;

◆ Overlapping “ don't long time pressure has recorded waveform recording paper, otherwise the record waveform may transfer to each other.

7.4.3 The maintenance of the host, lead and electrode

◆ Be careful ◆ :

The safety of the equipment should be periodically test, test cycle for at least two years, testing content mainly includes:

A) check whether the host and accessories mechanical and functional damage;

B) check whether the security identity is damaged;

C) check the fuse is in line with the rated current and open circuit characteristic;

D) according to the instructions to verify the function of the instrument

E) according to IEC 60601-1 for safety test as follows: To floor drain current limit: NC 500 UA, SFC 1000 UA Patients with leakage current, limit: 10 UA (CF type equipment) When using ac power source, the patients with single fault conditions leakage current, limit: 50 UA (CF type equipment)

Tests shall be made after the training, security testing knowledge experienced qualified personnel, and the test results are recorded. If any problems in the instrument in the test, must be maintained.

The Host :

◆ electrocardiogram (ECG) host should avoid high temperature, insulation, be affected with damp be affected with damp, dust, or impact, need not when cover dust cover; Mobile should avoid violent vibration;

- ◆ prevent liquid infiltration instrument internal, affect the performance of the instrument and security;

- ◆ Should ask medical instrument maintenance department regularly test the performance of the electrocardiogram machine.

Lead :

- ◆ Have to check the integrity of cable and lead wire, and determine its conduction in good condition;

- ◆ Will lead wire straighten out as soon as possible when using, avoid the knot and small Angle bending;

- ◆ Patients with cable conductor or shield is easy to damage, especially near the opposite sides of the plug, push pull or twist of avoid by all means when using, should use the hand hold the plug part;

- ◆ Cable and guide the collection should be in large diameter disc, or suspension, avoid reverse or acute Angle to fold;

If you find I ERT the cable and damaged or aging, lead a new cable and should be replaced.

Electrode:

- ◆ After the electrodes in use, must be clean, avoid conductive paste residue;

- ◆ Chest electrode of the rubber ball should avoid sun direct sun or overheating;

Electrode after using for a long time, due to reasons such as corrosion, electrode surface will be oxidized and change color, then a new electrode should be replaced in order to obtain good ECG records.

8 The warranty

Manufacturing process and materials

Company to ensure compliance with requirements of raw materials and manufacture process of this instrument, in the condition of normal use and maintenance, if received proof belongs to the manufacturing process and material failure report, will be taken to repair or replace the hardware method to repair.

Software or firmware

To install the software or firmware on your company's hardware products, if you receive proof belongs to the software or firmware fault report, will take to replace the method of software or firmware medium to repair, but the company does not guarantee the use of the hardware, software or firmware products not be interrupted or there are no errors.

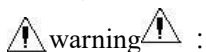
Description: company's obligation under this warranty does not include the freight and other fees.

Company to the following situation and delay the damage of direct, indirect, or eventually irresponsible:

- * components be tear open outfit, stretching, to debug
- *the company authorized personnel or changes to the instrument maintenance
- * within the prescribed conditions of use damage caused by abnormal use
- *the original serial number label or logo to replace or remove use improper operation

9 Attachment and ordering information

In the use of the electrocardiogram machine manufacturers recommend using the following attachment in the packing list:



Must use the company provided by ECG cable and other matching accessories, may damage the instrument use other types of attachment, impact performance and safety of the instrument.

NO.	Product Name	Qty
1	Main unit	1 pc
2	AC power cord	1 pc
3	ECG Cable	1 pc
4	Chest electrode	6 pcs
5	Limb electrode	4 pcs
6	User Manual(English)	1 pc
7	Thermal printing paper	1 roll

Attachment to replace please contact factory after-sales department. Matters needing attention

1 out of the box, pay attention to press the tip on the packing box;

2 when unpacking the case count accessories and random file according to the packing list, check again after start inspection instruments;

3 boot check if found packing content does not conform to the requirements or instrument can't work normally, please immediately contact the company's sales or after-sales service;

4 please use the company to provide matching accessories, otherwise it may affect the machine performance and safety, if use other companies provide attachments, should consult the company's after-sales service;

5 in order to allow us to provide service for you in time, please fill out the warranty card (copy) and send it back to the company;

6 boxes should be properly kept, in case the instrument verification or the use of instrument maintenance on a regular basis.

Appendix A technical specification

Safety standards	MDD93/42/EEC	Medical device directive
	IEC60601-1 GB9706.1	Medical electrical equipment part 1: general requirements for safety
	IEC60601-2-25 GB10793	Medical electrical equipment part 2: electrocardiogram machine safety special requirements
	EN 60601-1-4	The safety of medical electrical equipment part 1-4: general requirements supplement standard: programmed electrical medical system
	EN 60601-2-51	The safety of medical electrical equipment - 51 part2: particular requirements ChanDaohe multiply channel electrocardiogram machine basic performance, recording and analysis
	EN ISO14971	The application of risk management for medical equipment of medical equipment
	ANSI/AAMI EC-11	Diagnosis with electrocardiogram recording device
	YY1139-2013	Change multiply channel electrocardiogram

Overall dimensions		320mm×255mm×89mm	
The weight of the		About 3.15 kg	
According to		7 " LCD color LCD, 800×480 resolution	
The environment		Transportation and storage	work
	Temperature	-10°C~40°C	5°C~40°C
	relative humidity	≤80%	30%~75%
	atmospheric pressure	700hPa ~1060hPa	700hPa ~1060hPa

The power supply	The ac power	Rated voltage : a.c.100V~240V
		rated frequency : 50Hz/60Hz
		rated power : 120VA
	Dc power supply (built-in rechargeable lithium battery)	rated capacity : 2200mAh
		rated voltage : 14.8V

Heart rate calculation	Calculation method	Peak detection
	Heart rate range	30bPM~300bPM
	Calculation accuracy	± 1 bPM
The external input and output (optional)	Single-ended input	$\geq 100k\Omega$, Sensitivity 10 mm / 0.5V $\pm 5\%$
	Single-ended output	$\leq 100k\Omega$, Sensitivity 0.5 V / m V/ $\pm 5\%$
The signal interface	The USB interface	

recorder	record	Thermal matrix printed
	recording paper specifications	Scroll thermos sensitive paper
	Recording paper width	215mm
	Effective width of records	214mm
	The feeding speed	6.25mm/s、12.5mm/s、 25mm/s、50mm/s ($\pm 3\%$)

	filter	Ac filter
		Motor electricity interference filter
	common mode rejection ratio (CMRR)	>60dB (plus communication interference filter)

ECG host

Input circuit	Float to input, have fight defibrillator effect protection circuit
lead	Standard 12 lead, automatically change
Acquisition mode	12 synchronization
A/D conversion	When AC/DC conversion, the ELECTRO cardiogram machine should have corresponding power indication, and the action of each switch should be normal
Polarization resistance voltage	Add $\pm 500\text{mV}$ DC polarization voltage, the sensitivity change should be $\pm 5\%$
Time constant	$\geq 3.2\text{s}$
frequency response	Based on 10Hz, it should be 1Hz ~ 150Hz(+0.4dB,-3.0dB)
sensitivity	*10mm/MV (AUTO) , 2.5mm/MV , 5mm/MV , 10mm/MV , 20mm/MV
the input impedance	$\geq 50\text{M}\Omega$
Input loop current	$\leq 0.1\mu\text{A}$
sensitive threshold	$\leq 20\mu\text{V}$
calibration voltage	1mV $\pm 5\%$
noise level	$< 15\mu\text{V p-p}$
the interference	$\leq 0.5\text{mm}$
Leakage current patients	$< 10\mu\text{A}$

Appendix B product name and content of the poisonous and harmful substances or elements

Shenming Biro poisonous and harmful substances or elements

Part name	Poisonous and harmful substances or elements					
	Lead (Pb)	Mercury (Hg)	cadmium (Cd)	hexavalent chromium (Cr(VI))	polybrominated biphenyls (PBBS)	polybrominated diphenyl ether (PBDE)
shell	○	○	○	○	○	○
operation panel	○	○	○	○	○	○
PCBA	○	○	○	○	○	○
labeling	○	○	○	○	○	○
display	○	○	○	○	○	○
packaging materials	○	○	○	○	○	○
fittings	○	○	○	○	○	○
power cord	○	○	○	○	○	○
battery	○	○	○	○	○	○

Note:

"○": it means the toxic and harmful substances in the parts of homogeneous material content are all in SJ/T11363-2006 The standard of set limit to request the following.

× : Said the toxic and harmful substances in the parts of at least one homogeneous material is beyond the SJ/T 11363-2006 in the limited requirements stipulated in the standard

At the end of the products and batteries, and normal use, to scrap, please abide by the laws of the local government and the regulations.

Appendix C - EMC

This equipment can produce, use and radiate radio frequency energy. This device can cause other medical equipment or medical device, and electromagnetic interference between the radio communication. According to the statement in YY0505-2012, this product belongs to the emission limits for the first group, A level medical equipment, to provide corresponding protection measures to avoid interference. But not completely guarantee in electromagnetic interference phenomenon does not occur under the condition of a specific installation.

When the equipment is found that the interference phenomenon caused by (need to switch device for confirmation), the operator (or authorized maintenance personnel) according to the following measures to eliminate interference:

- adjustment or to re position the affected device;
- increase the equipment and the distance of the affected equipment;
- use another power supply power to the device;
- consulting maintenance engineer, for more advice.



Pay attention to :

Before using this device, please make sure that the hand contains all about EMC requirements and satisfaction.



Pay attention to :

This section will include YY0505-2012 form described in the content, the user shall have the responsibility to ensure that the equipment and its nearby equipment conforms to the indicated in the general safety requirements of radio frequency interference parameters.

 Pay attention to :

Don't use in the vicinity of the equipment intended to launch the RF signal devices (mobile phones, radio transceiver or radio control products), which may cause more than the value stipulated in the operation. When near the device, please close this type equipment. Operators shall have the responsibility to the patient or other personnel in the accessories to fully comply with the above requirement.

 Pay attention to :

Internal connection cable due to the use of a proposal or unauthorized changes or modifications to this equipment caused by any interference, the manufacturer will not take any responsibility.

Table 1

Guide and the manufacturer's statement - electromagnetic emission		
Systems and equipment is expected in the following provisions of electromagnetic environment, buyers or users shall ensure that its use in the electromagnetic environment		
Emission testing	compliance	electromagnetic environment - guidelines
Rf launch GB 4824	1 set	system or equipment only for its internal function and use of radio frequency energy. As a result, its radio emission is very low, and there is little possibility of nearby electronic equipment to produce interference.
Radio frequency GB 4824	Class A	system or equipment is suitable for the household and household residential low-voltage supply network of public and not direct connection of all the facilities.
harmonic emission GB 17625.1	not applicable	
The voltage fluctuation/radiation GB 17625.2	not applicable	

Table 2

Guide and the manufacturer's statement-electromagnetic immunity			
Systems and equipment is expected in the following provisions of electromagnetic			
environment, buyers or users shall ensure that its use in the electromagnetic			
Immunity test	IEC60601 The test level	In line with the level	Electromagnetic environment - guidelines
electrostatic discharge GB/T 17626.2	Plus or minus 6KV contact discharge Plus or minus 8KV air discharge	Plus or minus 6KV contact discharge Plus or minus 8 KV air discharge	The ground should be wood, concrete or ceramic tile.If the ground covered by synthetic materials, at least 30% relative humidity.
electrical pulse GB/T 17626.4	Plus or minus 2KV for the power cord Plus or minus 1KV for input/output line	Plus or minus 2 KV power supply cord	Network power supply should be used in the quality of a typical commercial or hospital environment.
Surge GB/T 17626.5	Plus or minus 1KV line to line Plus or minus 2KV line to ground	Plus or minus 1 KV line to line Plus or minus 2 KV line to ground	Network power supply should be used in the quality of a typical commercial or hospital environment.

The power input line voltage sag and short supply interruption and the voltage change GB/T 17626.11	< UT by 5% for 0.5 cycles (on the UT, >95% of the sag) UT by 40% for 5 cycles (on the UT, 60% of the sag) UT, 70% for 25 cycles (on the UT, 30% of the sag) < UT by 5% for 5 s (on the UT, >95% of the sag)	<5% UT drop >95% (UT) 0.5 cycles 40% UT fell 60% (UT) 5 cycles 70% UT fell 30% (UT) 25 cycles < 5% UT drop >95% (UT) for 5 seconds	Network power supply should be used in the quality of a typical commercial or hospital environment. If [equipment or system] users need to run continuously during power outage, the recommended [equipment or system] adopts uninterruptible power supply or batteries.
Power frequency magnetic field (50/60Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic field should have in a typical commercial or hospital environment level of power frequency magnetic field characteristics of the typical place
Note: UT refers to the communication network voltage before the test voltage applied			

Table 3

Guide and the manufacturer's statement -electromagnetic immunity			
[Systems and equipment]Expected in the following provisions of electromagnetic environment, buyers or users shall ensure that its use in the electromagnetic environment			
Immunity test	IEC60601 The test level	In line with the level	Electromagnetic environment - guidelines
The radio frequency transmission GB/T 17626.6	3 VMS 150k ~ 80MHz	3 VMS	Portable and mobile radio frequency communication equipment should not be larger than the distance recommended any part closer to the mobile devices, including the cables.The distance should be calculated by the transmitter frequency and the corresponding formula. The recommended separation distance $D = 1.2\sqrt{P}$ $D = 1.2\sqrt{P}$ 80 MHZ to 800 MHZ $d = 2.3\sqrt{P}$ 800 MHZ ~ 2.5 GHz Type in the : P---According to the transmitter manufacturers transmitter maximum rated power output and the unit of watts (W);

Radio frequency radiation	3 V/m	3 V/m	D - the recommended distance, the unit is meter (m). Fixed field strength of the Rf transmitter based on electromagnetic survey to determine a,b in each frequency range should be less than in line with the level. Near the mark symbol of the following equipment possible interference. 
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Note 1: in the 80 MHZ to 800 MHZ frequency point, USES the high frequency formula.

Note 2: these guidelines may not be suitable for all situation, electromagnetic propagation by buildings, objects, and the influence of the absorption and reflection.

Stationary transmitter, such as wireless cellular/cordless phones and ground mobile radio base station, amateur radio, am and FM radio and television broadcasting, etc., the field intensity in theory can predict. For the evaluation of fixed Rf transmitter electromagnetic environment, electromagnetic site survey should be taken into account. If the measured field strength of the mobile devices are higher than the above applicable radio frequency (Rf) in line with the level, the mobile devices should be observed to verify their works. If the observed abnormal performance, the supplementary measures may be required, such as to adjust the direction of the mobile device or location.

B in all 150 KHZ ~ 80 MHZ frequency range, the field strength should be lower than 3v/m.



Table 4

Portable and mobile radio communications equipment and [ECG] equipment or system, between the recommended separation distance			
[Equipment or system] Expected in radio frequency radiation harassment controlled electromagnetic environment. Communications equipment based on maximum rated power output, the buyers or users but equipment or system with the following recommended portable and mobile radio communication equipment (transmitter) and the minimum distance between/equipment or system to prevent electromagnetic interference			
The maximum rated power output of the transmitter W	According to the frequency of the transmitter to calculate isolation distance (m)		
	150 kHz to 80MHz $d=1.2\sqrt{P}$	80 MHz to 800MHz $d=1.2\sqrt{P}$	800 MHz to 2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.37
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For not listed above rated maximum output power transmitter, recommended isolation distance d, in meters (m), a formula to determine the available transmitter frequency corresponding column, P here is provided by the transmitter manufacturers transmitter, maximum output power rating in watts (W) as the unit.			
Note 1: in 80 MHz and 800 MHz, formula is used at a high frequency range.			
Note 2: these guidelines may not be suitable for all situation, the electromagnetic propagation by buildings, objects and the effect of absorption and reflection of the body.			