Twelve Channel
Digital Electrocardiograph

User Manual

Statements

Our company makes no warranty of any kind with regard to this material, including, but not limited to the implied warranties of merchantability and fitness for a particular purpose. Our company assumes no responsibility for any errors that may appear in this document, or for incidental or consequential damage in connection with the furnishing, performance or use of this material.

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**⚠

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

◈**CAUTION**◈

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

Contents

1 Safety Guidance

1.1 Safety Information

The design of 12-Channel electrocardiograph complies with international standard IEC 60601-1Medical Electrical Equipment: General Requirements for Safety and IEC 60601-2-25 Particular Requirements for the Safety of Electrocardiographs etc. The classification of this equipment is Class I, type CF, which means a higher degree of protection against electric shock and the patient connection is fully isolated and defibrillation protected.

This equipment is not explosion-proof. Do not use it in the presence of flammable anesthetics.

This equipment is designed for continuous operation and is „ordinary" (i.e. not drip or splash-proof).

Classification:

1) Anti-electric-shock type: Class I with internal power supply
2) Anti-electric-shock degree:CF
3) Degree of protection against harmful ingress of water:Ordinary equipment (Sealed equipment without liquid proof)
4) Degree of safety of application in the presence of flammable gas:Equipment not suitable for use in the presence of flammable gas
5) Working Mode:Continuous operation
6) EMC:Group I, Class A

In order to use the electrocardiograph safely and effectively, avoiding possible dangers caused by improper operations, please read through the user manual and be sure to be familiar with all functions of the equipment and proper operation procedures before use.

Please pay more attention to the following warning and caution information.
The electrocardiograph is provided for the use of qualified physicians or personnel professionally trained. And they should be familiar with the contents of this user manual before operation.

1.1.1 Environment

	Transport and storage	Normal operation
Humidity	-10℃~+40℃	+5℃~+40℃
Relative humidity	≤80%	35%~75%
Atmospheric pressure	700hPa~1060hPa	700hPa～1060hPa

The ECG surrounding environment must be kept clean,away from the corrosive,high humidity and direct sunlight,use should be avoided in vibration,prohibited under the conditions of charged handling equipment.

1.1.2 Power supply

1)AC supply:

Voltage rating： 220V±10%

Rated frequency： 50±1Hz

Rated power: 45 VA

2)Built-in rechargeable lithium-ion battery:

Voltage rating： 14.8V

Rated capacity: 2200mAh

3)Maxim Power Consumption:100VA

1.2 Caution

- Before use, the equipment, patient cable and electrodes etc. should be checked. Replacement should be taken if there is any evident defectiveness or aging symptom which may impair the safety or performance.
- The following safety checks should be performed at least every 24 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

  a) Inspect the equipment and accessories for mechanical and functional damage.

  b) Inspect the safety relevant labels for legibility.

  c) Inspect the fuse to verify compliance with rated current and breaking characteristics.

  d) Verify the device functions properly as described in the instructions for use.

  e) Test the protection earth resistance according IEC 601-1/1988: Limit 0.2 ohm.

  f) Test the earth leakage current according IEC 601-1/1988: Limit: NC 500 uA, SFC 1000uA.

  g) Test the patient leakage current according IEC 601-1/1988: Limit: 10 uA (CF).

  h) Test the patient leakage current under single fault condition with mains voltage on the applied part according IEC 601-1/1988: Limit: 50uA (CF).

  The data should be recorded in an equipment log. If the device is not functioning properly or fails any of the above tests, the device has to be repaired.

- Ruptured fused must only be replaced with the same type and rating as the original.
- The equipment and reusable accessories can be sent back to the manufacturer for recycling or proper disposal after their useful lives.
- Turn off the power before cleaning and disinfection. If mains supply used, the power cord should be drugged out of the outlet also. And prevent the detergent from seeping into the equipment.
- Do not immerse the unit or patient cable into liquid under any circumstances.
- Do not clean the unit and accessories with abrasive fabric and avoid scratching the electrodes.
- Any remainder of detergent should be removed from the unit and patient cable after clearing.
- Do not use chloric disinfectant such as chloride and sodium hypochlorite etc.
- Do not use high temperature, autoclaving or radiation sterilization processes.

2 Introduction

This ECG is 12 channel electrocardiographs with 12 leads gathered simultaneously, visual display of operation menu, ECG parameters as well as electrocardiogram. This product is not designed for internal use and direct cardiac application.

12 channel ECG can be viewed on the LCD (liquid crystal display) screen simultaneously. And it can be recorded by high-quality thermal printer.

Manual recording mode and automatic recording mode can be chosen conveniently.

Either mains supply or built-in rechargeable Lithium battery can be used as power.

With a high resolution thermal printer, 32-bit processor and huge capacity memorizer, 12 channel ECG has advanced performance and high reliability. And the compact size makes it suitable for clinic, hospital and ambulance use.

Configurations: Main unit and accessories (power cord, earth wire, patient cable, electrodes and thermosensitive record paper)

2.1 Function Features

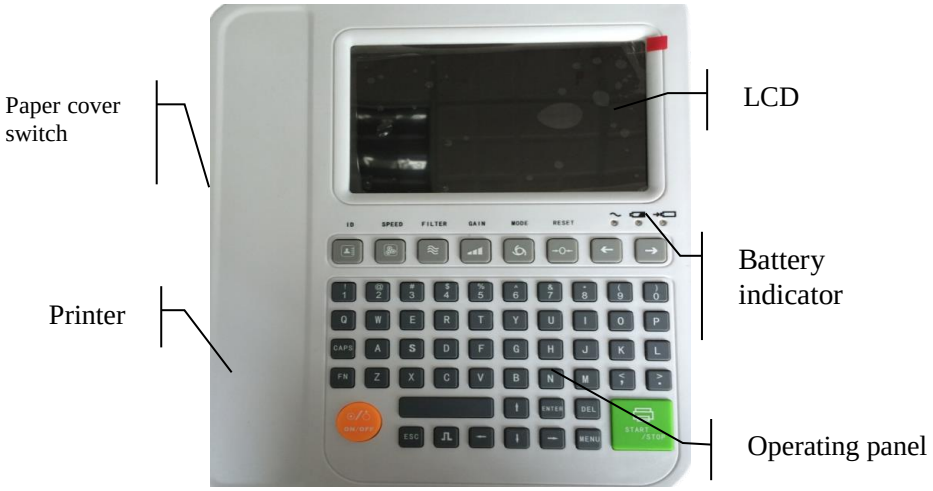
- ♦ 12-lead gathered and amplified simultaneously, built-in printer.
- ♦ Automatic mode and manual mode optional
- ♦ Real-Time recording 1,1+rhy,3,6,12 waveform
- ♦ 7 inch Color LCD screen with 800*480 dot
- ♦ Built-in rechargeable Li battery with high capacity
- ♦ Prompt information for lead off, lack of paper and low battery capacity etc.
- ♦ Automatic adjustment of baseline for optimal recording
- ♦ through the U disk to store data is OK
- ♦ Can store image files for computer to view and print directly
- ♦ Using digital isolation technology to the components to minimize the influence of temperature drift and time drift， ensure the instrument of high adaptability to the environment
- ♦ With functions of automated measurement and analysis of conventional electrocardiogram (more than 200 cases), reduce the financial burden on the doctor.
- ♦ With defibrillation protection and pacemaker and suppression circuit

2.2 List of Symbols

	External output
	External input
	Equipment or part of CF type with defibrillator proof
	Attention–general warning (see accompanying document)
	Potential equalization
	AC supply
	Battery indicator
	Battery recharging indicator
	Electronic information products pollution control symbol

3 General Information

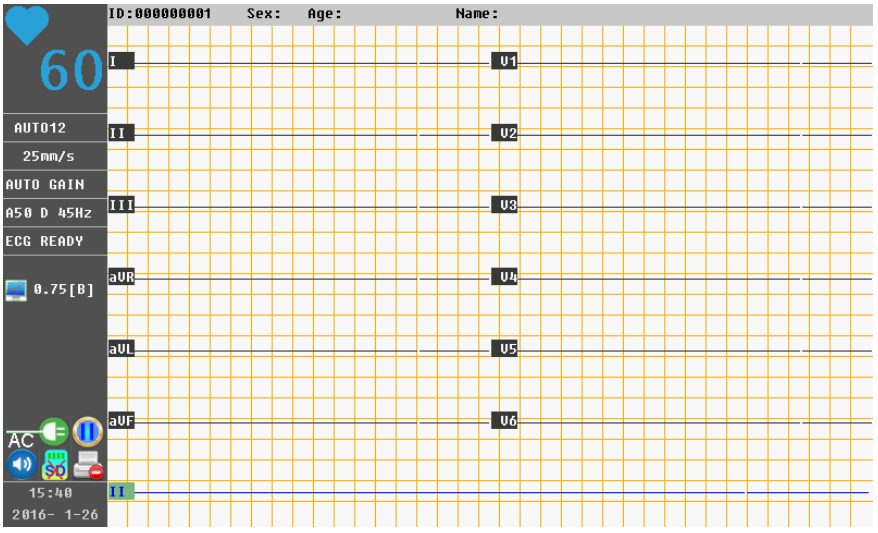
3.1 Top Panel



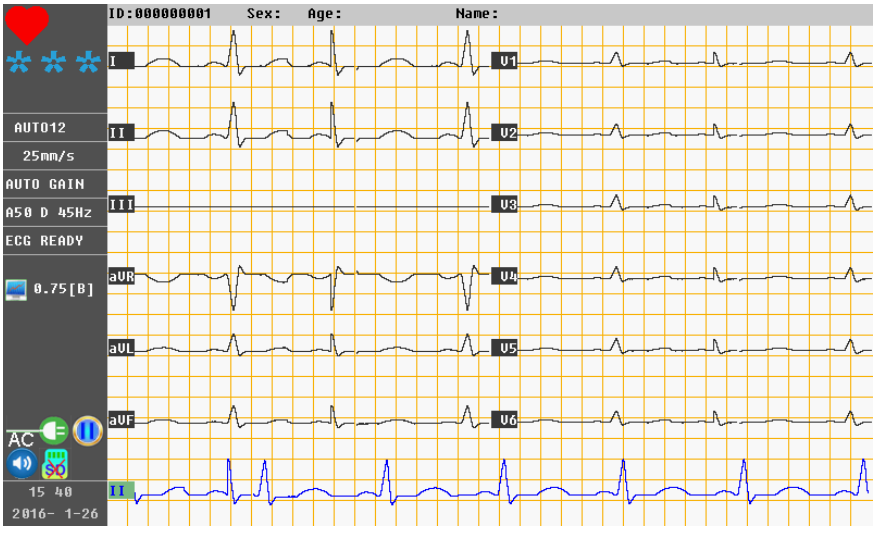
3.2 LCD Screen

The 7 inch Screen is 800*480 dot color LCD Screen .

3.2.1 Standby Display



3.2.2 Working Display



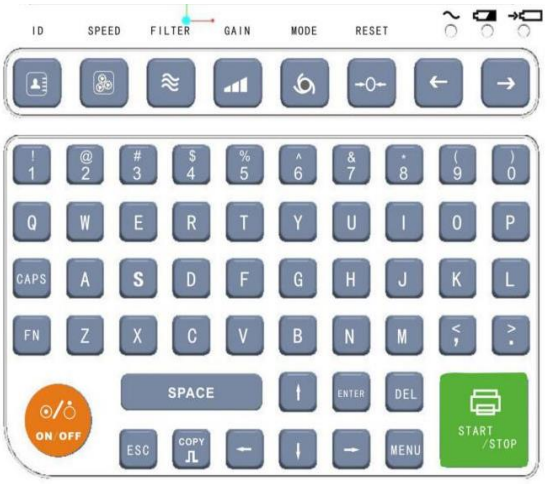
Above from left to right in turn as follows:The patient ID, gender, age, name

The left column from top to bottom in the order:

- 60 heart rate（The actual heart rate）
- AUTO12 working mode（adjustable）
- 25mm/s paper speed（adjustable）
- A50 D filter state（adjustable）
- ECG READY STARTING... the machine's current working state

- Waveform display scale (adjustable)
- Battery indication
- AC supply indication
- Printers standby mode，The printer is printing status
- Key Sound，tap to mute
- Not insert SD card，Has been inserted into the SD card(This model without SD card function)
- Not installed printing paper，Installed printing paper

3.3 Control Panel and Keys



1) Indicator Lamp

Mains supply indicator lamp: when mains supply is used, the lamp will be light.

Battery indicator lamp: when the built-in rechargeable Lithium battery is used, the lamp will be light.

Battery recharging indicator lamp: when the battery is recharged, this lamp will usually be light.

2) ON/OFF Key

When the unit has been powered on, press this key to turn on it. Press again to turn off it.

3）FN Key

In the input mode,Pinyin Chinese input,English input,Numbers or punctuation marks switch between the three kinds of input mode.

4) COPY Key

Under manual or auto mode, this key can be pressed to record a 1mV calibration pulse at any time while recording.

Under auto mode, once the prompt information "COPY" appears on the bottom right corner of LCD screen, this key can be pressed to review and print the electrocardiogram that recorded last time.

5) START/STOP Key

Used to begin recording and stop recording.

6) The patient information settings button

Used to set up the patient information，Can be set up including：ID number，name，age，gender，ID settings（Auto/Manual）

7) Speed Setting Key

Press the key can quickly adjust the printing speed，a total of 4 kinds of speed mode:
6.25mm/s,12.5mm/s,25mm/s,50mm/s

8) Filter Setting Key

There are four filter Setting mode：
[A]0.05-250Hz the filter function is closed
[B]A50 D AC filter is opened
[C]A50 D 85Hz AC filter is opened，High-pass filter is set to 85 Hz
[D]A50 D 45Hz AC filter is opened，High-pass filter is set to 45 Hz

9) Gain Switch Key

In manual mode to gain Settings，a total of 4 kinds of gain model:
2.5mm/mV,5mm/mV ,10mm/mV,20mm/mV

10) Mode Switch Key

This key can be pressed to select operation mode between Automatic mode, Manual mode and OFF. The switching order of lead groups in each mode is listed in Table 3-1.

Table 3-1 Lead Group Switching order of Different Mode

Mode	Switching Order (from left to right)
Auto 1	(1*12 mode)Print the single channel waveform,the order I/Ⅱ/Ⅲ/aVR/aVL/aVF/V1/V2/V3/V4/V5/V6
Auto 2	(1*12 +1 mode)Print 1+rhy waveforms,the order I/Ⅱ/Ⅲ/aVR/aVL/aVF/V1/V2/V3/V4/V5/V6
Auto 3	(3*4 mode)Print the three waveforms,I/Ⅱ/Ⅲ,aVR/aVL/aVF,V1/V2/V3,V4/V5/V6
Auto 6	(6*2 mode)Print the six waveforms,I/Ⅱ/Ⅲ/aVR/aVL/aVF,V1/V2/V3/V4/V5/V6
Auto 12	(12*1 mode)Print the twelve waveforms,I/Ⅱ/Ⅲ/aVR/aVL/aVF/V1/V2/V3/V4/V5/V6
Manual 1	(1*12 mode)Print the single channel waveform,need to manually switch the lead,the same order with Auto 1
Manual 2	(1*12 +1 mode)Print 1+rhy waveforms,need to manually switch the lead,the same order with Auto 2
Manual 3	(3*4 mode)Print the three waveforms,need to manually switch the lead,the same order with Auto 3
Manual 6	(6*2 mode)Print the six waveforms,need to manually switch the lead,the same order with Auto 6
Manual 12	(12*1 mode)Print the twelve waveforms,need to manually switch the lead,the same order with Auto 12

11) Recall Key

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

12) Lead Switch Key

Under manual mode, press the key to switch the lead.

13) E S C Key

Press this key,exit or cancel the current operation.

14) D E L Key

Delete the previous step input characters.

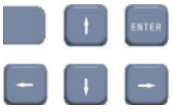
15) C P A S Key

In input letters, large/lowercase input switch

16) M E N U Key

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

17) N a v i g a t i o n / c o n f i r m Key



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

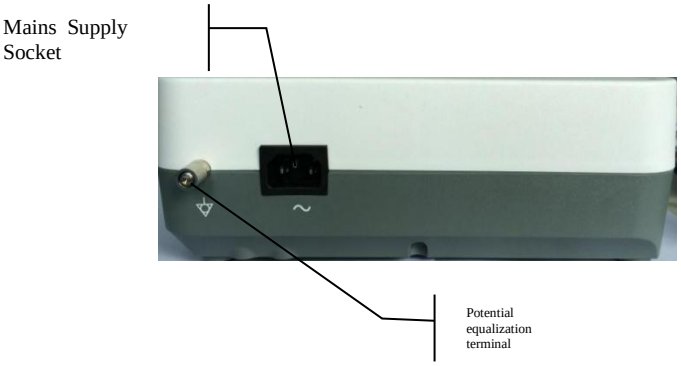
18) SPACE Key

In the condition of input, input a space character.

19) Small keyboard

- Achieve input Chinese, English, punctuation
- In the Settings menu or options，according to the menu or option [A] [B] [C] [D] the letter label, etc，press the ABCD letters key of the keypad，will quickly into the corresponding menu or option.
- In the main interface state press the letter key B，enter the display zoom setting，Can be adjusted to waveform shows that the proportion of.

3.4 Mains Connection and Switch



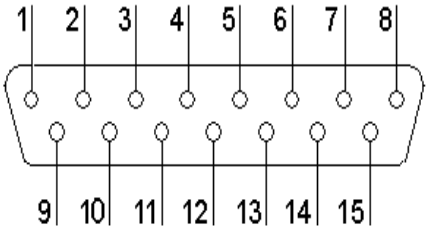
1) Potential Equalization Terminal

2) Mains Supply Socket

AC SOURCE: alternating current supply socket

Patient Cable Socket and Signal Interface

1) Patient Cable Socket



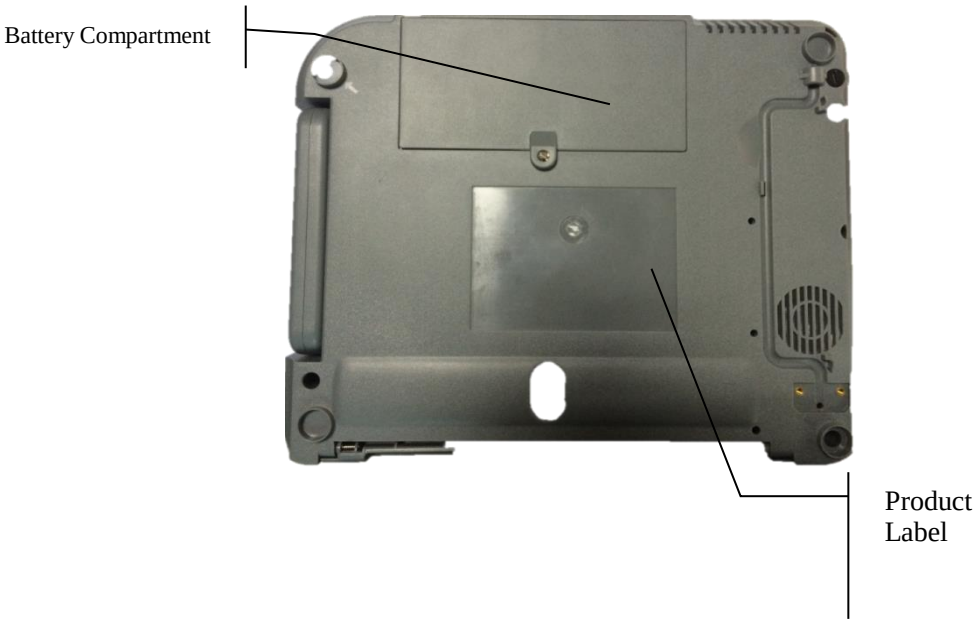
: Applied part of type CF with defibrillator proof

: Attention – see accompanying document

Definition of corresponding pins:

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

3.5 Bottom Panel



1) Battery Compartment

The battery label indicates the rated voltage and rated capacity of rechargeable Lithium battery pack. Rated voltage: 14.8V, Rated capacity: 2200mAh.

⚠ Attention – general warning (see accompanying document)

⚠WARNING⚠

Improper operation may cause the battery to be hot, ignited or exploded, and it may lead to the decrease of battery"s capacity. Therefore, it is necessary to read the user manual carefully and pay more attention to warning messages.

⚠WARNING⚠

Only qualified service engineer authorized by our company can open the battery compartment and replace the battery. And the battery of same model and specification provided by manufacturer must be used.

4 Operation Preparations

CAUTION:

Before use, the equipment, patient cable and electrodes should be checked. Replace it if there is any evident defectiveness or aging which may impair the safety or performance. And be sure that the equipment is in proper working condition.

4.1 Power and Earthing

WARNING:

If the integrity of external protective conductor in installation or arrangement is in doubt, the equipment should be operated from the built-in rechargeable battery.

1) Power Supply

The electrocardiograph can be powered either by mains supply or the built-in rechargeable lithium battery pack.

♦ **Mains supply**

The mains connection socket is on the left of the unit. If mains supply used, connect the power cord to the socket first, and then connect the plug of the cord to the hospital grade outlet.

Rated input voltage: 85V~265V

Rated frequency: 50Hz/60Hz

Rated input power: 4 5VA

Make sure the mains supply meets the above requirements before power on. And then press the mains power switch to power on the unit. Then the mains supply indicator lamp (∿) will be lit.

If the built-in rechargeable battery is weak when mains supply used, it will be recharged automatically at the same time. And both the mains supply indicator lamp (∿) and the battery recharging indicator lamp (⎓) will be lit.

2)Built-in rechargeable battery

While using the built-in rechargeable lithium battery pack, turn on the unit by pressing **ON/OFF** key on control panel directly and the battery indicator lamp (⎓) will be lit.

The battery symbol will be displayed on the LCD screen. Because of the consumption during storage and transport, the capacity of battery may not be full. If the symbol ⇨ and the prompt information “BAT WEAK” are displayed, which means the battery capacity is weak, please recharge the battery first.

Please refer to the maintenance section for how to recharge the battery. During recharging

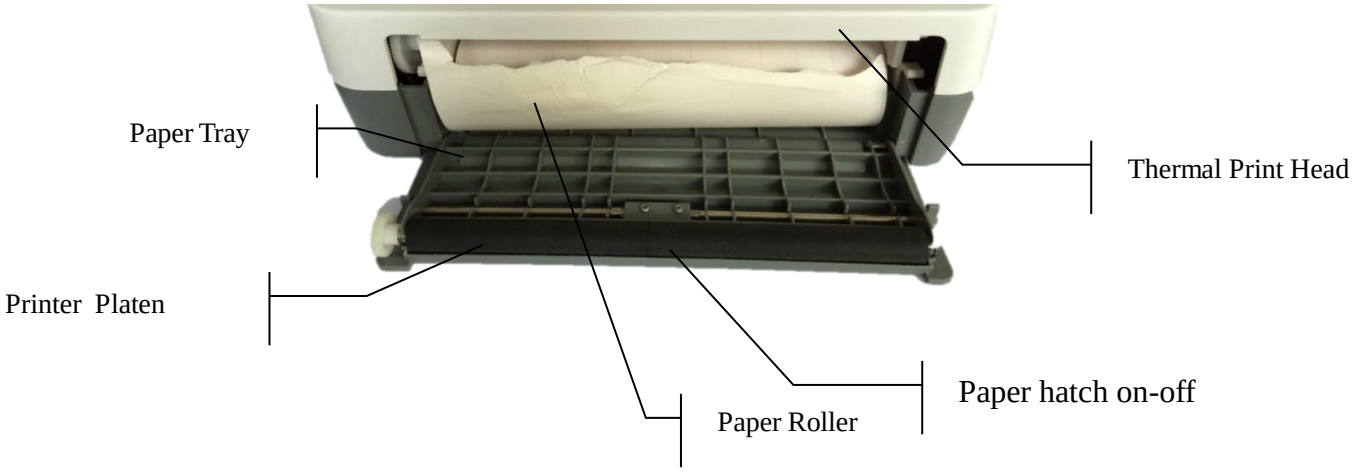
the battery, 12 channel ECG can be powered by mains supply at the same time.

⚠**WARNING**⚠: Potential equalization conductor of the unit should be connected to the potential equalization bus bar of the electrical installation when necessary.

4.2 Loading/Replacing Record Paper

There are two kinds of paper can be used as ECG record paper. One is Rolled thermosensitive paper with 215mm width, and the other is folded thermosensitive paper with 215mm width.

When there is no record paper loaded or it reaches the end of record paper, warning message "Paper?" will be given on the screen. Under this circumstance, record paper should be loaded or replaced immediately.



Loading/Replacing Process for Rolled thermosensitive paper:

1) Pull outward paper cover switch, open the recorder;

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

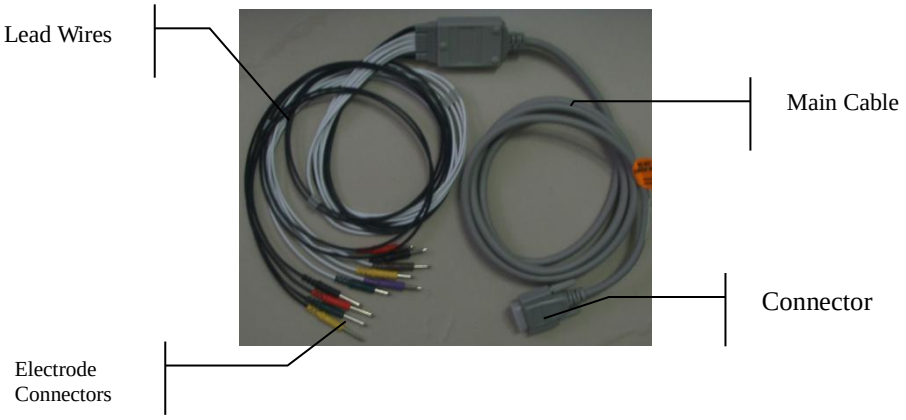
3)Unveils new record pincer-like device on paper tape,Slot in the new paper roll gently ,Installing a recording paper sheet of grid oriented;

4) Paper scroll on both ends of the flat, gently into the slot;

5) Pull about 2cm of paper out, and put down the recorder casing;

4.3 Patient Cable Connection

Patient cable includes two parts, main cable and lead wires with associated connectors, which can be distinguished from the color and identifier on the connectors.



Connect Main Cable:

Plug the connector of main cable into the patient cable socket on the right side of the unit according to the direction of arrow on the plug, and then secure it with two screws.

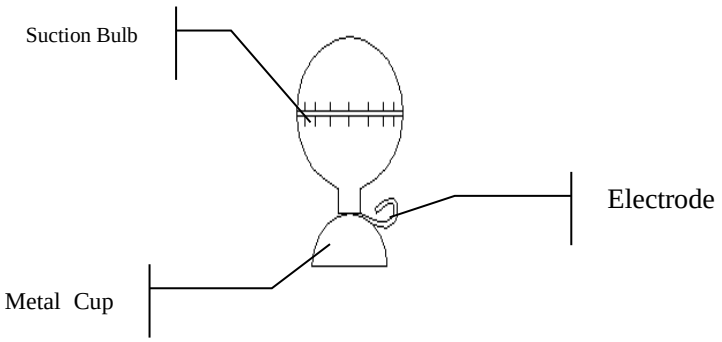
4.4 Electrodes Connections

The identifier and color code of electrodes used complies with IEC requirements. In order to avoid incorrect connections, the electrode identifier and color code is specified in Table 4-1. Moreover the equivalent code according to American requirements is given in Table 4-1 too.

Table 4-1 Electrodes and their identifier and color code

	European		American	
Electrodes	**Identifier**	**Color**	**Identifier**	**Color**
Right arm	R	Red	RA	White
Left arm	L	Yellow	LA	Black
Right leg	RF	Black	RL	Green
Left leg	F	Green	LL	Red
Chest 1	C1	White/red	V1	Brown/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/violet	V6	Brown/violet

Chest Electrode:



As the following figure shows, the chest electrodes position on body surface is

C1: Fourth intercostals space at right border of sternum

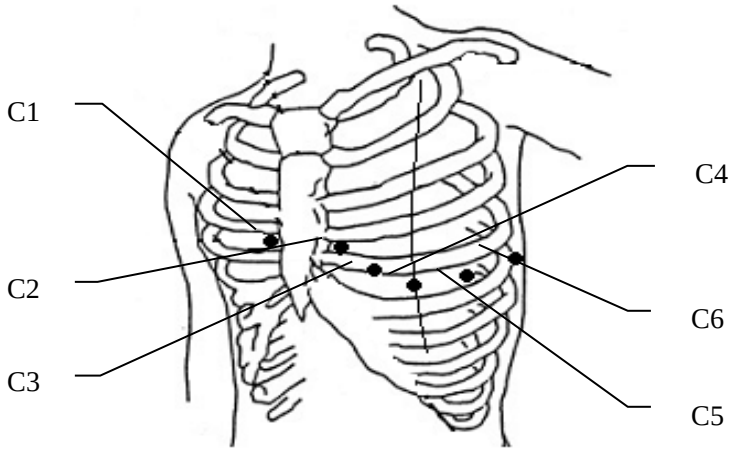
C2: Fourth intercostals space at left border of sternum

C3: Fifth rib between C2 and C4

C4: Fifth intercostals space on left midclavicular line

C5: Left anterior axillary line at the horizontal level of C4

C6: Left midaxillary line at the horizontal level of C4



The contacting resistance between the patient and the electrode will affect the quality of ECG greatly. In order to get a high-quality ECG, the skin/electrode resistance must be minimized while connecting electrodes.

⚠**WARNING**⚠: Be sure that all electrodes have been connected to the patient correctly before operation.

⚠**WARNING**⚠: Be sure that the conductive parts of electrodes and associated connectors, including neutral electrode, should not contact with earth or any other conducting objects.

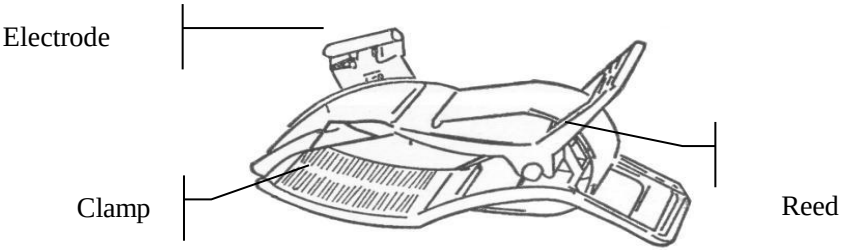
Chest electrodes connection:

1) Ensure the electrodes to be clean firstly;
2) Align all lead wires of patient cable to avoid twisting, and connect the associated

electrode connectors with corresponding electrodes according to the color and identifier;

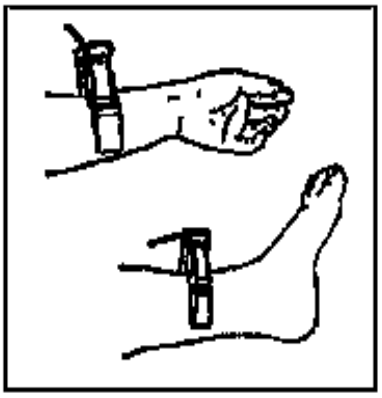
3) Clean electrode area on chest surface with alcohol;
4) Daub the round area of 25mm diameter on each electrode site with gel evenly;
5) Place a small mount of gel on the brim of chest electrode"s metal cup;
6) Place the electrode on chest electrode site and squeeze the suction bulb. Unclench it and then the electrode is adsorbed on chest. Attach all chest electrodes in the same way.

Limb Electrode:



Limb electrodes connection:

1) Ensure the electrodes to be clean firstly;
2) Align lead wires of patient cable to avoid twisting, and connect the electrode connectors to corresponding electrodes according to the color and identifier;
3) Clean electrode area on a short distance above the ankle or wrist with alcohol;
4) Daub the electrode area on limb with gel evenly;
5) Place a small amount of gel on the metal part of limb electrode clamp;
6) Connect the electrode to limb, and be sure that the metal part be placed on the electrode area above the ankle or wrist. Attach all limb electrodes in the same way.



4.5 Inspection before Power On

⚠**WARNING**⚠: The electrocardiograph is provided for the use of qualified physicians or personnel professionally trained. And they should be familiar with the contents of this user manual before using.

In order to avoid safety hazards and get good ECG record, the following inspection procedure is recommended before power on and operation.

1) **Environment**:
   - ♦ Check and make sure that there is no electromagnetic interference source around the equipment, especially large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment etc. Switch off these devices when necessary.
   - ♦ Keep the examination room warm to avoid muscle action voltages in ECG signal caused by cold.

2) **Power Supply**:
   - ♦ If mains power used, please check whether the power cord has been connected to the unit well. And the grounded three-phase outlet should be used.
   - ♦ Recharge the battery first when the battery capacity is weak before use.

3) **Patient Cable**:
   - ♦ Check whether the patient cable has been connected to the unit firmly, and keep it far away from the power cord.

4) **Electrodes**:
   - ♦ Check whether all electrodes have been connected to lead wires of patient cable correctly according to the identifier and color.
   - ♦ Ensure that the chest electrodes haven″t contacted with each other.

5) **Recorder Paper**:
   - ♦ Ensure that there is enough recorder paper loaded correctly.

6) **Patient**:
   - ♦ The patient should not contact with conducting object such as earth, and metal part of bed etc.
   - ♦ Ensure the patient is warm and relaxed, and breathe calmly.

⚠**WARNING**⚠: The electrocardiograph is provided for the use of qualified physicians or personnel professionally trained. And they should be familiar with the contents of this user manual before using.

5 Operation Instructions

5.1 Switching On

- While using mains supply, connct power cord to left side of the unit first, and the mains supply indicator lamp is lit. Then press **ON/OFF** key on the control panel to turn on the unit. Then ECG is ready for examination and recording.
- While using built-in rechargeable lithium battery, press **ON/OFF** key on the control panel directly to turn on the unit, and then the battery indicator lit. After self-test, the ECG is ready for examination and recording.

5.2 Automatic Mode

Automatic recording mode is provided by 12 channel ECG. The lead group switching orders under different modes are listed in Table 3-1.

Under automatic mode, 12 leads are divided into 5 groups. The lead groups will be switched in order automatically while recording ECG, and if this lead group signal recording has been finished, it will be switched to the next lead group automatically and begin recording the following lead group signal. And there is a blank on the recording paper before recording the next ECG. Moreover, a 1mV calibration mark will be recorded at the beginning of recording.

Operation Method:

1) Press key to set the working mode to automatic mode ;

2) Press key to set the print speed;

3) Press key to set the patient's information;

4) Pressing **START/STOP** key,screen shows working status "acquisition of.....",after a few seconds printer began to work,after the 12 lead all print,according to the analysis,press the "START/STOP" button again to report print out.

5) In the process of recording,if necessary can press the "START/STOP" button to STOP recording,but when it began to record again,Will start guide transmitte order to trace, the patient information remains the same;

6)In the process of recording,press the "COPY" button to manually add calibration logo on the record paper;

7) In the process of recording,press the "" button to manually switch leads guide for printing, until all 12 leads to be printed.

5.3 Manual Mode

Under **MANUAL** mode, 12 leads are divided into 5 groups,The lead group switching orders under different modes are listed in Table 3-1.

Users can determine which lead group needs to be recorded and set the record settings or other parameters according to different lead group.

Operation Method:

1) Press  key to set the working mode to automatic mode ;

2) Press  key to set the print speed;

3) Pressing **START/STOP** key,screen shows working status "acquisition of.....",after a few seconds printer began to work,after the 12 lead all print,according to the analysis,press the "START/STOP" button again to report print out.

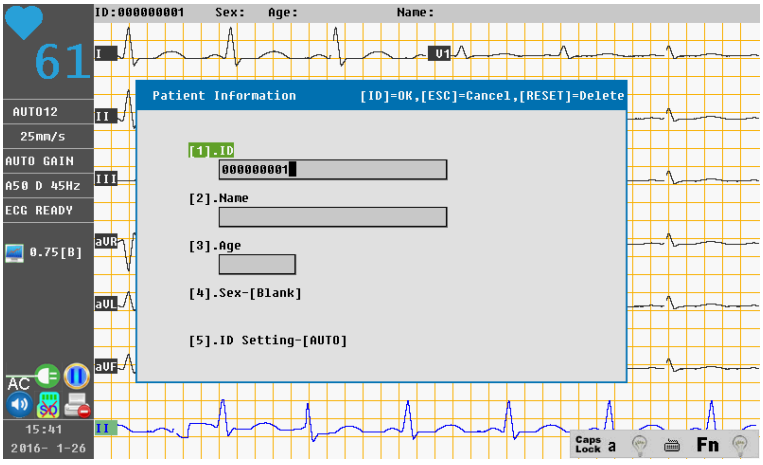
4) In the process of recording,press the "  " button to manually switch leads guide for printing, until all 12 leads to be printed.

5) In the process of recording,if necessary can press the "START/STOP" button to STOP recording,but when records began again, will continue to lead from stops records began.

6)In the process of recording,press the "COPY" button to manually add calibration logo on the record paper;

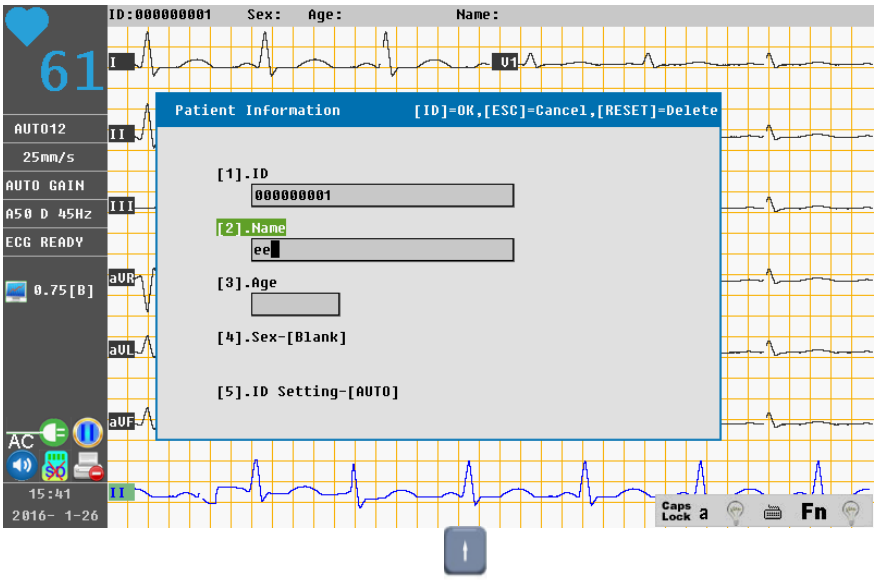
5.4 Text input method

5.4.1 The input of Numbers and punctuation marks



In order to input a numeric value,Using the left arrow and right arrow keys to move the cursor, using the up arrow and down arrow keys to change values; In order to input a character, First press the keyboard's FN key, the bottom in the right hand corner of the screen Fn small bulb icon into a state of light,at the same time, the keyboard has been switch to digital input mode with punctuation,press the keyboard keys have Numbers or punctuation,and then input the corresponding Numbers or punctuation marks;If you want to modify the input in the process of input content,you can use "DEL"  button will delete content;

5.4.2 English input

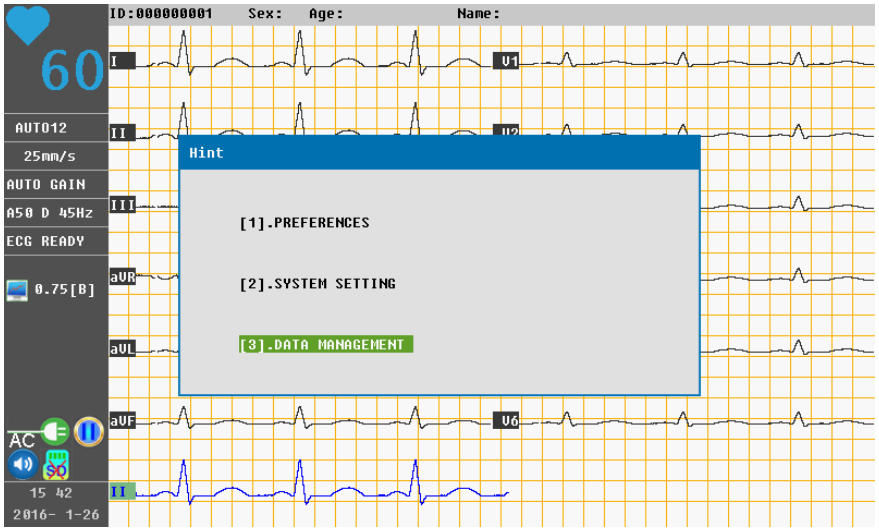


As shown in the above,through the button in the upper and lower direction key move the cursor in the input box,press the "FN" button many times,the spelling in the dialog box input state input mode is set to English[EN],Caps Lock and FN keys of small light bulb icon to put out state,at this time,keyboard input to English lowercase letter input mode,press the keyboard contains letters buttons, can input lowercase English letters;If need to switch the capital letters,press CAPS key,and then, the keyboard input to uppercase input mode; If you want to modify the input in the process of input content,you can use "DEL" DEL button will delete content;

5.5 Using setup windows

5.5.1 Menu page

In standby mode， Press the "MENU" MENU key of the keyboard,enter the MENU Settings interface，As shown in the figure below:



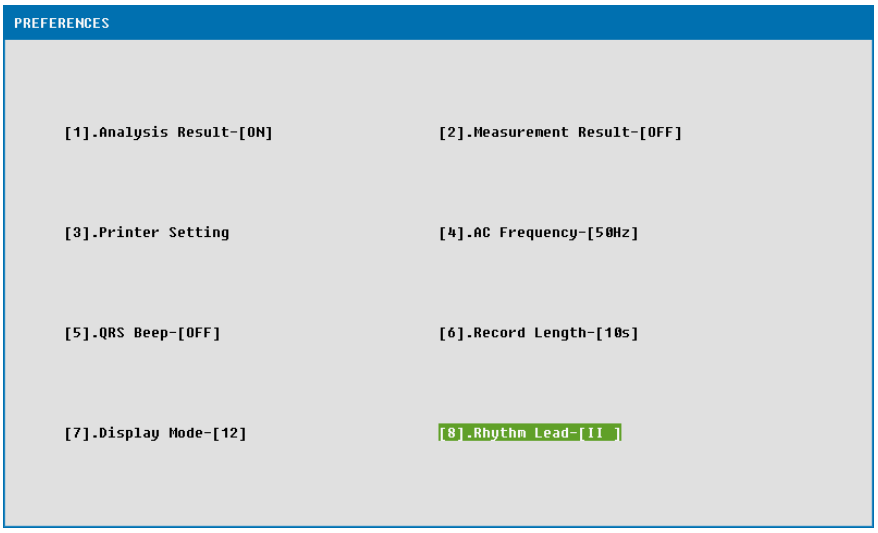
Setting up the project include:[1]preferences [2]system setting[3]data management,use the key

to move the cursor to setting up the project,press the "ENTER" button to enter setting up the 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 the "ESC" key or "MENU" button to quit setup;

5.5.2 Preferences

After entering the menu,choose [1] preferences,or press the keypad 1 key,into "preferences" interface, as shown in the figure below:



Each option introduction:

[1]Analysis Result

OFF:in auto mode,print report does not contain disease analysis results;

ON:in auto mode,print report contains disease analysis results;

[2]Measurement Result

OFF:in auto mode,after the ecg waveform printing, print directly analysis report;

ON:in auto mode,after the ecg waveform printing,need to manually print analysis report;

[3]Printer Setting

Baseline With:Adjust the width of print baseline,the bigger the numerical baseline width;

Print Mode:Can be set up synchronization or realtime printing;

Gray Level:According to the actual circumstance of printing paper,adjust the waveform and clarity of the characters,the bigger value to print more clear;

Paper Type:Set the printing paper type;

Printer Test:Test the print function is normal or not;

[4]AC Frequency

50Hz:The working frequency of 50 Hz area select this option;

60Hz:The working frequency of 60 Hz area select this option;

[5]QRS Beep

OFF:In the process of detection, no heart rate notifysound;

ON:In the process of detection,with heart rate notifysound;

[6]Record Length

In auto mode,each group lead recording time can be set up for 3 ~ 12 seconds;

[7]Display Mode

3:The Screen displays 3 channel waveform signal,press the lead's switch button,will switch display;

6:The Screen displays 6 channel waveform signal,press the lead's switch button,will switch display;

12:Synchronous display 12 waveform signal;

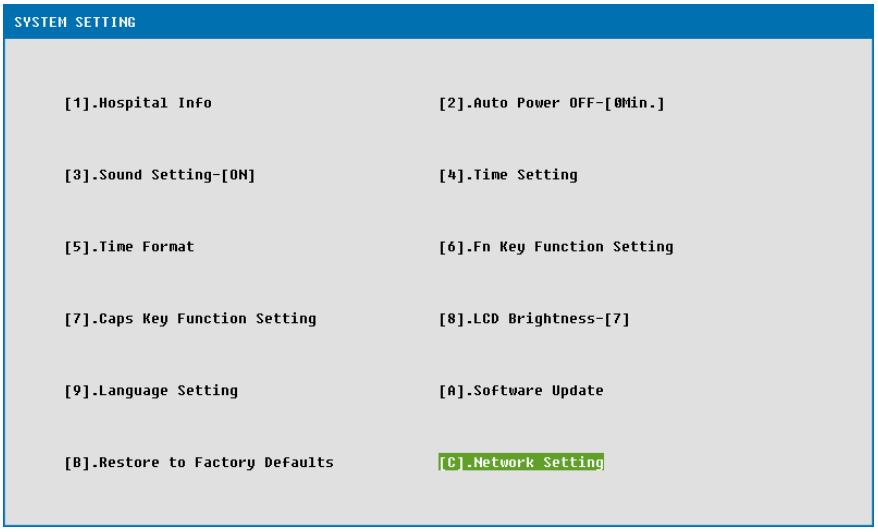
[8]Rhythm Lead

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 Setting

After entering the menu,choose [2]System Setting,or press the keypad 2 key 

,into "System Setting" interface, as shown in the figure below:



Each option introduction:

[1]Hospital Info

Set up hospital or user information;

[2]Auto Power OFF

Set up machine standby time,standby time can be set up 10 to 60 minutes,after startup without any operation in the set time,the machine will automatic shutdown,when set 0 minute,automatic shutdown function is closed,the machine will continue to work;

[3]Sound Setting

OFF:No noise while keystrokes;

ON: Keystrokes with noise;

[4]Time Setting

According to the local time zone set the local time;

[5]Time Format

According to the custom time;

[6]Fn Key Funtion Setting

Normally open:After opening Fn function can enter multiple consecutive Numbers or punctuation marks;

Exactly-once:After opening Fn function,enter a number or a punctuation,Fn function will shut down;

[7]Caps Key Function Setting

Normally open:Open Fn function can enter multiple continuously after the capital letters;

Exactly-once:Open Fn function,after input a capital letter,Caps function will shut down;

[8]LCD Brightness

Display brightness can be adjusted according to the demand, the greater the number, the greater the brightness;

[9]Language Setting

Chinese:Sets the system to Chinese interface;

English:Sets the system to English interface;

[A]Software Update

Through the U disk on the system upgrade;

[B]Restore to Factory Defaults

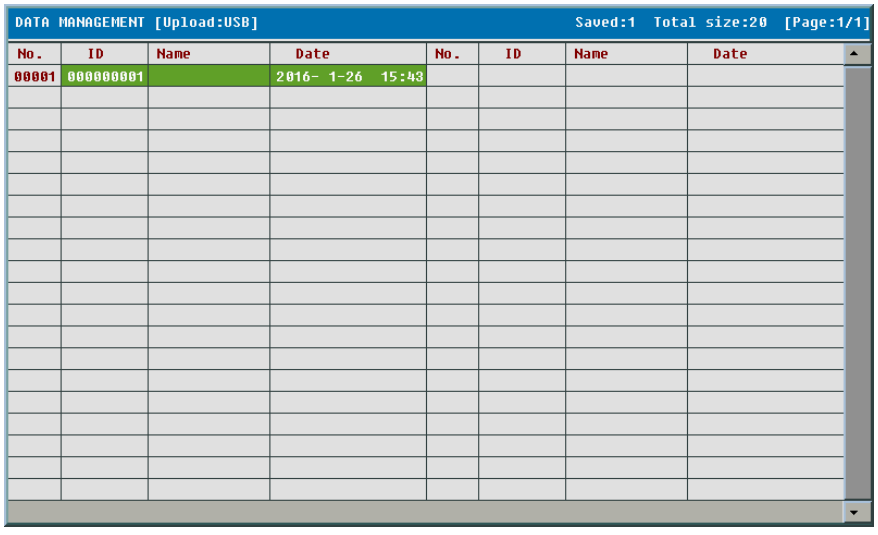
Use this option, the key parameters, the system can be set back to the original shape system;

[C]Network Setting:Optional

5.5.4 Data Management

After entering the menu,choose [3]data management,or press the keypad 3 key 

,into "data management" interface, as shown in the figure below:



In the “Data Management” interface,through the  button in the upper and lower direction key move the cursor to the saved cases,press the "ENTER 

" button ,Open operation options, each option introduction as follows:

[1]Open:Perform this operation,will open the selected cases,repeat cases ecg waveform and parameters;

[2]Data search:When the case is large,use this search function,can quickly open the case after input the case ID number;

[3]Upload:Cases will be stored in the specified location,such as U disk;

[4]Format:Perform this operation will delete all the machine's store cases;

[5]Select all:Select all cases/Uncheck all cases;

[6]Save to FLASH DRIVE:In the usb drive to establish a folder named "ECG", and copies the selected cases to the folder;

[7]Save to SD CARD:This machine has no function of SD card;

[8]Edit:To edit the selected cases,such as ID number, name, age, etc;

[9]Delete:Delete the selected cases;

[A]Data Upload
USB:The transmission of data to the computer via USB or U disk;
WIFI:To transmit the data to computer by WIFI;

[B]Save format:Cases of storage format
[*.EAS]:Case is EAS file;
[*.BMP]:Case is BMP format picture;

5.6 Switch Off

When built-in battery pack used, press **ON/OFF** key directly to turn off the unit after finishing ECG record.

When mains supply is used, press **ON/OFF** key first after finishing ECG record and then pull off the plug from the outlet last.

6 Prompt Information

Prompt information will be displayed on the bottom right corner of LCD screen when there is something wrong. Prompt information provided by ECG and corresponding cause is listed in Table 6-1.

Table 6-1 Prompt Information and Causes

Prompt Information	**Causes**
CABLE OFF	Electrodes fall off from the patient or the patient cable falls off from the unit.
Battery Volt too low	The built-in battery is weak.
Paper Out	Record paper has not been loaded or it has been run out.
Smpling/Printing	ECG signal is being sampled /printed.
Storaging, please later	Cases are preserved in the fuselage to save memory or cases to external storage
Error,Storage[0]	Not connected to external storage
transferring	transferring the data to the computer or external storage
upgrading	the system is upgrading
Promotion, please restart	System upgrade, need to restart the machine

7 Clean, Care and Maintenance

7.1 Clean

CAUTION:

Turn off the power before cleaning and disinfection. Mains supply must be switch off if it has been in use.

1) Clean the Main Unit and Patient Cable

The surface of the main unit and patient cable can be wiped with a clean soft cloth damped in soapy water or non-caustic neutral detergent. After that, remove detergent remainder with a clean dry cloth.

2) Clean the Electrodes

Remove the remainder gel from the electrodes with a clean soft cloth first. Take the suction bulb and mental cup of chest electrodes apart, and take the clamp and the metal part of the limb electrodes apart. Clean them in warm water and be sure there is no remainder gel. Dry the

electrodes with a clean dry cloth or air dry naturally.

3) Clean the Print Head

Dirty and soiled thermal print head will deteriorate the record definition. So it should be cleaned at least once a month regularly.

Open the recorder casing 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 shut the casing of the recorder.

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.

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 clean the equipment first. Then wipe the surface of the unit and patient cable with hospital standard disinfectant.

CAUTION:

Do not use chloric disinfectant such as chloride and sodium hypochlorite etc.

7.3 Sterilization

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

The equipment should be cleaned before sterilization.

CAUTION:

Sterilization, if required, can not be done with high temperature, autoclaving or radiation.

Note: Our company 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 Care and Maintenance

7.4.1 Recharge and Replacement of Battery

1) Capacity Identification

Current capacity of the rechargeable battery can be identified according to the battery symbol in the top right corner on LCD screen.

: Full capacity

: Capacity is limited, and recharge should be taken into account

: Battery is weak; and warning message "BAT WEAK" will be displayed on LCD screen. The battery should be recharged immediately

2) Recharge

12 channel ECG is equipped with recharge control circuit together with built-in rechargeable lithium battery. When connect with the mains supply, the battery will be recharged automatically. And then the battery recharge indicator lamp ( ) and the mains supply indicator lamp ( ) will be lit at the same time. During the course of recharging, the symbol " " will flash in the top right corner of LCD screen. When the capacity of battery is full, the symbol "" will stop flashing, and the battery recharge indicator lamp ( ) will usually be black. But if 12 channel ECG is power off, the lamp will still lit just because the equipment will not monitor the recharge status; so you need to power on the device to verify the status. Because of the capacity consumption during storage and transport, the capacity of battery is not full while using at the first time. Battery recharge should be considered before first usage.

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.

⚠**WARNING**⚠:

- Only qualified service engineer authorized by our company can open the battery compartment and replace the battery. And the battery of same model and specification provided by manufacturer must be used.
- Danger of explosion -- Do not reverse the anode and cathode when connecting the battery.
- When the battery's useful life is over, contact with the manufacturer or local distributor for disposal or dispose the battery according to local regulations.

7.4.2 Record Paper

Note: Record paper provided by manufacturer should be used. Other paper may shorten thermal print head's life. And the deteriorated print head may lead to illegible ECG record and block the advance of paper etc.

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

The following safety checks should be performed at least every 24 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

a) Inspect the equipment and accessories for mechanical and functional damage.
b) Inspect the safety relevant labels for legibility.
c) Inspect the fuse to verify compliance with rated current and breaking characteristics.
d) Verify the device functions properly as described in the instructions for use.
e) Test the protection earth resistance according IEC 601-1/1988: Limit 0.2ohm.
f) Test the earth leakage current according IEC 601-1/1988: Limit: NC 500uA, SFC 1000uA.
g) Test the patient leakage current according IEC 601-1/1988: Limit: 10uA (CF).
h) Test the patient leakage current under single fault condition with mains voltage on the applied part according IEC 601-1/1988: Limit: 50uA (CF).

The leakage current should never exceed the limit. The data should be recorded in an equipment log. If the device is not functioning properly or fails any of the above tests, the device has to be repaired.

⚠**WARNING**⚠: Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

1) Main Unit

- Avoid excessive temperature, sunshine, humidity and dirt.
- Put on the dustproof coat after use and prevent from shaking violently when moving it to another place.
- Prevent any liquid from seeping into the equipment, for it will affect the safety and performance of electrocardiograph.

2) Patient Cable

- Integrity of patient cable, including main cable and lead wires, should be checked regularly. And be sure that it is conductible.

- Do not drag or twist the patient cable with excessive stress while using. Hold the connector plugs instead of the cable when connect or disconnect the patient cable.
- Align the patient cable to avoid twisting, knotting or crooking in closed angle while using.
- Store the lead wires in bigger wheel to prevent any people from stumbling.
- Once damage or aging of the cable patient has been found, replace it with a new one immediately.

3) Electrodes

- Electrodes must be cleansed after use and be sure there is no remainder gel on them.

- Keep the suction bulb of chest electrode from sunshine and excessive temperature.
- 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 high-quality ECG

⚠CAUTION⚠:

The equipment and reusable accessories can be sent back to the manufacturer for recycling or proper disposal after their useful lives.

8 Service Warranty

Material and Manufacture

The warranty period for the main unit and the accessories is 12 months from the date of shipment.

Our company warrant that there's no defect in material and manufacture. During the warranty period, our company will repair or replace the defective part free if the defect has been confirmed as material or manufacture defect.

Software or Firmware

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

Note: All services must be done by the engineers authorized by our company.

Limit of Warranty

The charges of freight and others are excluded under warranty.

The warranty is void in the case of

- 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;

9 Accessories

⚠**WARNING**⚠ : Only patient cable and other accessories supplied by our company can be used. Or else, the performance and electric shock protection can not be guaranteed.

No	Accessory	Qty
1	Main unit	1 pc
2	Power cord	1 pc
3	Patient cable	1 pc
4	Chest electrodes	6pcs
5	Limb electrodes	4pcs
6	Paper roller	1 pc
7	Gel	1 pc
8	User Manual	1 pc

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

10 Technical Specifications

Safety Standards	MDD93/42/EEC, IEC60601-1,GB9706.1 IEC60601-2-25,GB10793 EN 60601-1-4, EN 60601-2-51, EN ISO14971, ANSI/AAMI EC-11, YY1139
Dimensions	310mm×220mm×89mm
Weight	About 2kg
Display	800×480 dot 7 inch color LCD Screen

Environment		Transport and Storage	Working
	Temperature:	-10℃~40℃	5℃~40℃
	Relative Humidity:	≤80%	30%~75%
	Atmospheric Pressure:	700hPa ~1060hPa	700hPa ~1060hPa
Power Supply	Mains Supply:	Rated input voltage =220V	
		Rated frequency = 50/60Hz	
		Rated input power = 45VA	
	Built-in Lithium Battery	Rated voltage = 14.8V	
		Rated capacity = 2200mAh	
		Charge mode: Constant current/voltage	
		Charge current (standard) = 0.2C_5A (440mA)	
		Charge voltage (standard) = (16.8±0.1V)	
		Continuous charge current =2200mA (max)	
		Continuous discharge current=2200mA (max)	
		Cycle life ≥ 300 times	
	Power Consumption	100VA (max)	
	Fuse	F1.5A,220V	
Recording	Recorder	Thermal dot-matrix printer	
	Record Paper	Rolled thermosensitive paper, 215mm width	
	Effective Width:	214mm	
	Paper Speed:	6.25mm/s,12.5mm/s,25mm/s, 50mm/s（±3%）	
	Accuracy of data:	±5% (x-axis), ±5%(y-axis)	
HR	Technique:	Peak-peak detection	
	Heart rate range	30BPM~300BPM	
	Accuracy	±1 BPM	

ECG Unit	Leads:	12 standard leads
	Acquisition Mode:	simultaneously 12 leads
	A/D Resolution:	14 bits/1000Hz
	Time Constant:	≥3.2s

	Frequency Response:		0.05Hz ~ 250Hz
	Sensitivity:		2.5, 5, 10, 20 (mm/mV),*10mm/mV（AUTO)
	Input Impedance:		≥50MΩ
	Input Circuit Current:		≤0.1μA
	Calibration Voltage:		1mV±2%
	Noise:		<15 μ Vp-p
	Multichannel crosstalk		≤0.5mm
	Filter		AC Filter
			EMG Filter: 25Hz/35Hz/OFF
	CMRR		>100dB
Patient Leakage Current:			＜10μA
Patient Auxiliary Current:			<0.1 μ A (DC)
Dielectric Strength:			4000V rms
External Input/Output (Optional)		Input	≥100kΩ; Sensitivity 10mm/0.5V±5%; Single ended
		Output	≤100 Ω; Sensitivity 0.5V/mV±5%; Single ended