Electrocardiograph

Operation Manual

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1. Notice for operation

1.1 Notice for use

Thank you for purchasing medical electrical product made by us.

This manual is provided necessary illumination for your first use of electrocardiograph, andry of this manual which is protected by The People's Republic of copyright law. All the information cannot be copied, amended or translated without permission. The content of this manual is subject to change without notice. Please read the manual carefully before using and get to know how to use the machine correctly.

1.2 Notice for safety

 **Danger**	**If ignore this symbol, it may cause die or severe injured, otherwise the device would be partly damaged or resulted in fire hazard.**
 **Warning**	**If ignore this symbol, it may cause human die or severe injured, otherwise the device would be partly or entirely damaged.**
 **Attention**	**If ignore this symbol, it may cause human injured or the device damaged.**
Notice	**Although it is not indication of warning, it provide the right method of use and operation in order to avoid error operation.**

Example of the symbol

	**Indicating the contents of danger, warning and attention, which are illustrated on the corresponding area.**

- **Warning and Attention**
- Precaution of using thermal paper
  - ✧ Don’t exposure thermal paper under the direct sunshine and high temperature.
  - ✧ Don’t put into the fluorescence light for a long time.
  - ✧ Don’t store thermal paper with PVC.
  - ✧ Don’t pile up thermal paper in long period to avoid waveform transfer.

1.3 Manufacturer's Declaration

As a specialized manufacturer of production and sa electronics, we takes every effort, is dedicating on the precise security and reliability for each device.

In order to ensure the reliable operation of the medical device, the user of ECG must take the responsibilities to guarantee the details as follows:

1. For the sake of guarantee the safety of the device, maintenance, repair and replacing the accessories should be operated by our company staff or the person who we have trained.
2. This unit only use or replace the accessories we recommend, which is the requirement for the safety of the device.
3. Insure to use the proper voltage and frequency according to the demand of the icons.
4. The device only can be used according to the user manual, and other purpose cannot be satisfied.
5. All the technical data (circuit diagram, list of components etc.) only are provided to the specialized staff that passed our technical training. For improving the technique, we will not notice in advance, and apologize to cause your inconvenience.
6. When an electrosurgical device (ESU) is used, the ECG electrode is placed in an intermediate position between the electrosurgical device ground plate and the electrosurgical blade to avoid burns. The cable of the electrosurgical device cannot be entangled with the ECG cable. The electrosurgical unit should be kept away from the ECG electrode as much as possible. The recommended distance is at least 15 cm (6 inch).
7. If using with a cardiac defibrillator or other electrical stimulation equipment, you must use the silver-silver chloride chest electrode provided by the company and the ECG lead wire provided by the company (see the specifications and model of the patient cable), if A disposable chest electrode must be used when the tremor time exceeds 5 seconds or when used with a high frequency surgical device to prevent the metal electrode from burning the patient's skin. It is best not to use it with other electrical stimulators. If you must use them at the same time, you must have a professional technician to be present.
8. When the electrocardiograph is used together with the high-frequency electrosurgical unit, the electrodes of the electrocardiograph should be kept away from the electrosurgical contact to prevent burns caused by high-frequency sparks and burning of the electrode wires. Plate electrodes can be used if necessary, with a large contact area and limiting the current density to an acceptable range.
9. This product should not be used where there is electromagnetic interference or where the power load is caused by electrosurgical equipment or diathermy.
10. This product is not directly applicable to the heart.
11. To protect the patient's safety, do not place the instrument where it may fall and reach the patient.
12. When the machine is in operation, the medical staff should not leave the operation site, should carefully observe the patient, turn off the power supply or remove the electrode if necessary, in order to ensure the safety of the patient. Electrodes can only contact patients, absolutely not other conductor components or medical personnel. In the event of an accident in the course of use, the machine must be shut down immediately.
13. Before using this device, please ensure that all requirements for EMC in this specification have been met.
14. As described in the IEC60601-1-2 table listed in the attachment, the user is responsible for ensuring that the device

and its nearby devices comply with the RF interference parameters indicated in the general security requirements.

15. In an electromagnetic environment that exceeds the standard limit or level, it will interfere with the instrument or degrade its performance. Therefore, if abnormal interference occurs in the process of use, it is important to confirm and eliminate the adverse effects of electromagnetic interference before continuing to use it.
16. Strong electromagnetic interference from nearby sources (such as radio, substation, CT scanning, microwave / high frequency therapeutic machines, as well as mobile phones, cellular phones, etc.). If there is interference from high-power equipment, please switch to somewhere else to place the equipment.
17. RF interference from other devices / systems will be transmitted to ECG machines through the power line: if such interference occurs, identify the cause of interference and remove possible sources of RF interference. If not, please switch to another AC power supply.
18. The effect of direct or indirect electrostatic discharge: before use, it is determined that all operators and patients are exposed to equipment and / or systems that do not have direct or indirect electrostatic energy. Tip: wetter rooms can effectively reduce this kind of interference.
19. The electromagnetic interference of a radio receiver, such as a television, radio, etc.: keep the instrument away from the radio receiver as much as possible.
20. This product should not be close to or superimposed with other equipment, if it must be close to or superimposed, it should observe and verify that it can function normally under the configuration it uses.
21. The use of accessories and cables outside the regulations may lead to an increase in the launch of this product or a reduction in immunity;
22. When the input signal amplitude is below the minimum amplitude specified in the technical specification, it may lead to inaccurate measurement.
23. We shall not be responsible for any interference caused by the use of unrecommended internal connection cables or unauthorized changes or modifications to the equipment.
24. It is forbidden to repair or maintain the instrument when connected to the patient.
25. Do not place the device in a location that is difficult for the operator to disconnect.

1.4 Icons for safety

ECG device strictly follows the standardIEC60601-1 that is the electromagnetism compatibility of medical equipment, corresponding to Type CF, Class Ⅱ.

Attention	**For sake of the patient's safety, please the electrodes connected with the body of patient and other unconnected electrodes don't touch electric conducting products, for example, your hands don't touch the ground.**

Attention	**Connected with other equipments increases leakage current may cause latent danger, please strictly operate according to the requirements. Connect with our company if necessary.**

Attention	**While using synchronously with cardiac pacemaker and other electric stimulator, these equipments occur baleful current, should adopting necessary measures to reduce the influence on the diagnosis which are resulted from these devices.**

Attention	**If non-isolating signal enters from external input, the end of this signal is not connected with protection ground, it will cause malfunction because of difference of is potential point.**
Attention	**Only the devices under IEC 60601-1 Type I can be connected with the input and output port of this device, please consult to the technical staff if necessary.**

✧ Explosion-proof requirements

Danger	**Don't use ECG device in the presence of inflammable gas and flammable gas such as anesthesia gas, oxygen, hydrogen, otherwise may be caused explosion and fire hazard.**

✧ Magnetic resonance interference

Danger	**Don't use ECG device during magnetic resonance imaging. Magnetic conduction can lead burning. ECG device can interfere magnetic resonance equipments meanwhile can be interfered by magnetic resonance equipments.**

✧ Defibrillation protection

Don't touch the device during defibrillation, which may cause electric short circuit for the patient and operator.

When the device is used synchronously with defibrillator, to avoid danger, please confirm the sort of lead cable, electrode fixing condition, and sort of electro cardio-electrodes, conductive gel used for defibrillator and the output energy of defibrillator. Besides, please confirm whether other devices are connected with ground.

1.5 Explanation of the symbols

	Remarks for special attention (see operating instructions for details)		Type CF equipment equipped with protector against defibrillation
	Output of the analog signal		Iso-potential point
	Input of the analog signal		Protective earth terminal

	POWER		1mV Scaling/ Function setting
	Forward and backward		Printing /Recording Mode
	Start/End record		

1.6 Precautions

- For the sake of improving the quality of product, specifications and design is subject to change without notice.
- AC power cable must be connected to medical three-cord electrical outlet. Using the power cable in the accessories to connect with medical three-cord electrical outlet can insure gounding reliably. Please use suitable sockets which can supply sufficient power to load for this device.
- Upgrading the procedure and maintenance should be operated by our technical staff, error operation may occur error. User doesn't do it without allowance.
- All the accessories must be used the appointed ones. If use other accessories, maybe cannot correspond to the device properly.
- Don't open the shell of the device.
- Must switch off the power while doing connection.
- Don't leak any liquid such as alcohol to the internal of the device and socket.
- Don't use any abstergent and dilution containing organic liquid, methyl benzene, gasoline etc., which is harmful to the BAL shell.
- Don't scrape shell with grinding ointment and chemical detergent.
- Don't touch input signal connector and output signal connector simultaneously, for example RS-232 and patient isn't allowed to touch at the same time.
- Don't apply vapor sterilization to the device and accessories. Don't sterilize with high-temperature or γ-Ray or apply electrical beam.
- While using sprayer of physic liquor to sterilize, please don't spray the liquid to the internal device and socket.
- Don't install the device near to the interfere source such as wireless transistor, hypercator, mobile phone or wireless telephone. Otherwise, the interference will impact on the device.
- After effective life time is over, please deal with the device according to the local law or return to the manufacturer for recycle in order to protect environment.
- **Pay attention to the following ECG measurement and interpretations:**

(1) AC/EMG Interference might cause mistakes in reading P Wave and Q Wave.

(2) Measuring error might occur due to blur endings of S wave and T Wave.

(3) Low voltage of QRS might cause the measurement result of HR not reliable.

(4) Low voltage of QRS might cause the ECG coordinate axes calculation or QRS not reliable.

(5) With frequent ventricular systole, at accidental situation, will be inspected out as heartbeat.

(6) <u>This device has self-interpretation function, which only analyze automatically the</u>

obtaining ECG trace, but don't reflect on all the conditions of patient. Maybe the analyzing result is different with the diagnosis by doctor, so the final conclusion must be made out by doctor to combine with patient clinic data and other analysis result.

- **Precautions for using electrode**
  - Whether clean the axunge on the skin of patient (where connect with electrodes) and wipe conductive gel on it.
  - When electrodes are sterilized and disinfected, please use cotton cloth to wipe and clean with medical alcohol or Glutamyl acetaldehyde disinfection.
  - If the electrodes are too dirty to clean, please use emery-paper to abrade gently, and repeat the above disinfecting method.
  - Whether the assembly of electrodes is loose. If it is too loose, please clamp closer.
  - Whether mix to use together different sorts of electrodes.
  - While the device is used synchronously with defibrillator, there will be super-voltage resulted from defibrillation which causes polarized voltage on the electrodes, so it can't measure in several seconds.
- **Precaution for cable lines**
  - Please use ECG cable line assembled with device.(or the accessories our factory provide)
  - Please use three-cord power line assembled with device, which can connect to the three-cord socket and realize grounding well.
  - When the device is used synchronously with defibrillator, please make sure to use the patient Cable. line which we assembled with defibrillating function.
  - Please check whether the connection of patient cable is loose or not.
  - Please notice whether patient cable is too closed to power cord during measuring. Please check whether the connection between each patient cable end and corresponding electrode is right or not.
  - Periodic inspect patient cable, and clean and disinfect it if it is necessary. Please use cotton with medical alcohol wipe gently, don't drag forcibly patient cable.
- **Precaution for rechargeable batteries**
  - The batteries built in the device are rechargeable batteries specialized for ECG-301.Please don't use for other equipments. Otherwise, maybe cause batteries to weep heat or rupture.
  - Don't throw the batteries into fire.
  - Don't weld directly the batteries to the device.
  - Don't disassemble and reconstruct battery. There is protecting circuit in the batteries to avoid danger. Maybe cause batteries weep or rupture after it is damaged.
  - Batteries contain the structure for discharging internal waste gas, which must be not obstructed, otherwise, will damage of batteries.
  - The liquid of batteries is harmful for your eyes. When it is splashed into your eyes, don't knead or wipe, please clean with water and see a doctor immediately.
  - Don't contact metal to the "+""-"polar of battery.
  - Don't flake or scrape the shell of batteries.
  - During charging, the process of charging isn't finish but exceeds rated charging time; please switch off AC power in time. Otherwise the batteries will heat severely until damage.
  - Internal liquid of batteries is rubbed to skin, which may cause burn, please clean with cleaner immediately.

- Don't use or put battery in homeothermic places. Otherwise may cause battery weep, decrease life time and function.
- Don't immerge battery into water, and moisten with medical liquid. Otherwise maybe cause battery heat or go moldy.
- If any abnormality is found during using battery, please stop using immediately.
- Don't store battery in the places out of touch by children.
- Don't impact strongly or throw battery.
- While battery is not used for a long period, please switch off the device, and pull out power cable from socket.
- Please paste isolated belt on the ends and connection cable of scrap battery, and hand in them to our service staff to deal with.
- The normal function of the product may be disturbed by strong Electro-Magnetic Interference. If so, simply reset the product to resume normal operation by following the instruction manual. In case the function could not resume, please use the product in other location.
- Rechargeable lithium-ion battery.

  Charging time (normal temperature 25±5° C shutdown charging):

  The battery is charged to 90% for no more than 2 hours and full for no more than 3 hours.

  Power supply time (normal temperature 25±5° C, when new battery is full):

  a. At least 50 automatic reports can be printed;

  b. At least 1 hour of continuous recording;

  c. At least 2 hours of unrecorded measurements can be taken.

2. Summary

Electrocardiograms are primarily used to record physiological electrical signals, caused by cardiac activity, to analyze rhythms and configurations for clinical diagnosis and research.

Intended use: Suitable for adult and child patients who need to have an electrocardiogram,Electrocardiogram and heart rate recorded by ECG can help doctors analyze and diagnose clinically. Its compact size makes it suitable for use in patients visiting homes.

Brief description of the principle

The electrocardiograph is a physiological function test instrument that records the waveform of cardiac electrical activity (ie, electrocardiogram). It provides basic information for various types of heart disease diagnosis and treatment, helps to analyze various types of heart diseases, understand certain drug and electrolyte disorders, and acid and alkali. The effect of imbalance on the myocardium plays an important role in routine examination of heart disease.

This series of electrocardiographs is a 12-lead synchronous digital electrocardiograph with LCD display and automatic analysis options. Thanks to the advanced high-performance processor and integrated thermal array printing system, the performance and reliability of the machine are greatly improved, and the operation is simple, the function is rich and practical, and it is suitable for routine diagnosis of electrocardiogram of various medical units. This machine has dual AC and DC, built-in rechargeable battery and safe charging circuit, with over-current and over-voltage protection, under-voltage shutdown and other functions.

NOTE:

- The patient who has a heart disease may have a normal electrocardiogram, so other tests are required for a full heart appraisal. This equipment cannot be connected to the heart directly

2.1 Features

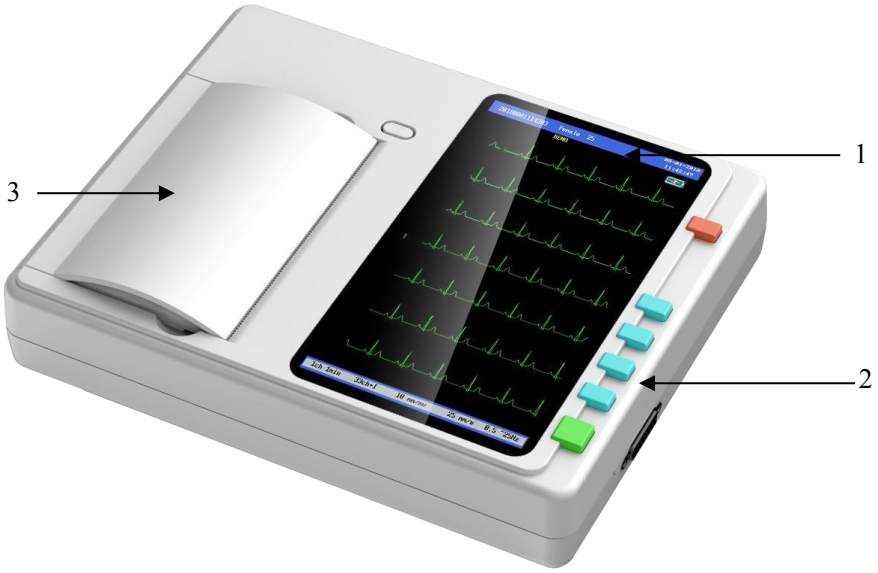
- ✧ Digital signal processor for effective inhibition of baseline drift, AC interference filter, EMG interference filter and the heart rate, to guarantee the authenticity and dependability.
- ✧ Auto-regulation of baseline drift can effectively inhibit baseline drift, optimizing the printing position to achieve high-quality ECG.
- ✧ Have regular automatically measuring and analyzing function for ECG parameters to lessen doctor's load.
- ✧ With a high –resolution thermal printer to print out ECG trace, describing the trace clear and accurate, annotation as well as related parameters for diagnostic reference.
- ✧ Roll recording paper for ECG is 80mm in width, simultaneous 12 lead acquisitions and 3 lead live record, high affectivity of ECG examination, good effect and economic utility.
- ✧ Function of rhythm lead for observing abnormal ECG trace & heart rate.
- ✧ Supported by AC/Rechargeable battery for continuous examination whenever necessary. For Battery operation, ECG is equipped with a battery charger and a system for battery capacity management and protection.
- ✧ Safety level for ECG corresponds to Type CF, Class Ⅱ according to the IEC60601-1 criterion. The amplifier is floating input circuit which can examine human cordis directly with safety and reliability.

2.2 safety classification

- ➢ Shock proof type :Class Ⅱ, internal power device
- ➢ Shock proof degree : CF device
- ➢ Anti-splash degree :common device
- ➢ Safety degree used in the presence of atmosphere(or oxygen, lachgas)mixed with flammable anesthesia gas: not suitable to be used in the presence of atmosphere(or oxygen, lachgas)mixed with flammable anesthesia gas

3. General Information

3.1 Name of components



1. LCD display screen
2. List button
3. Recorder

Fig. 1 top panel

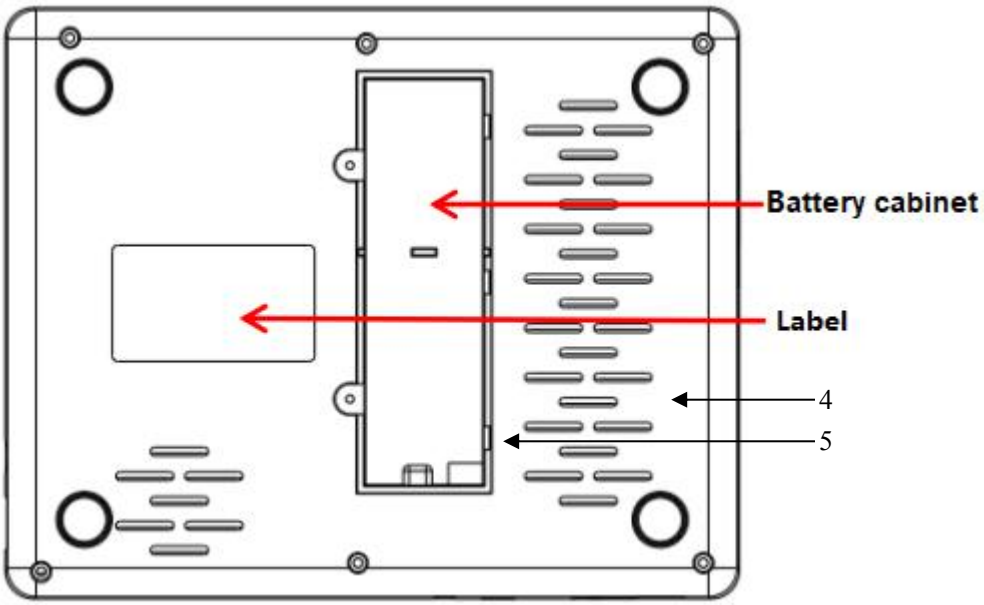


Fig. 2 bottom panel

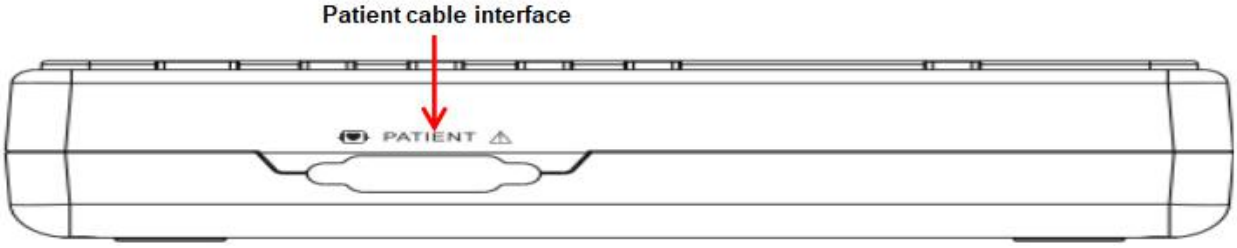


Fig. 3 right side panel of ECG

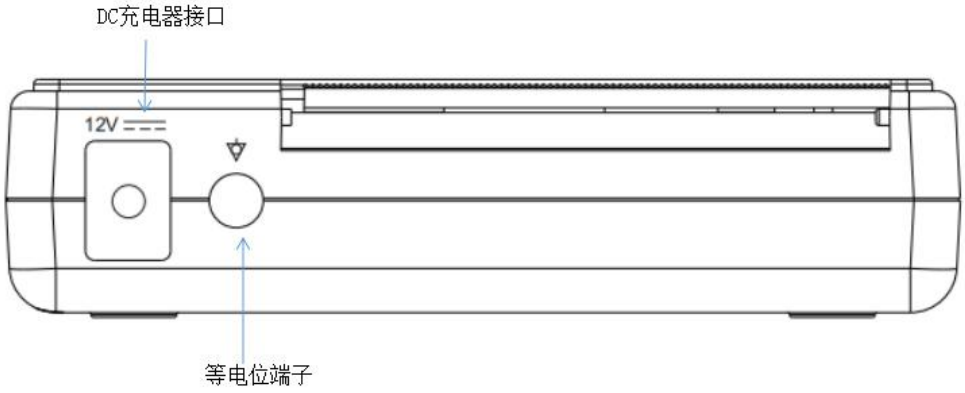


Fig. 4 left side panel of ECG

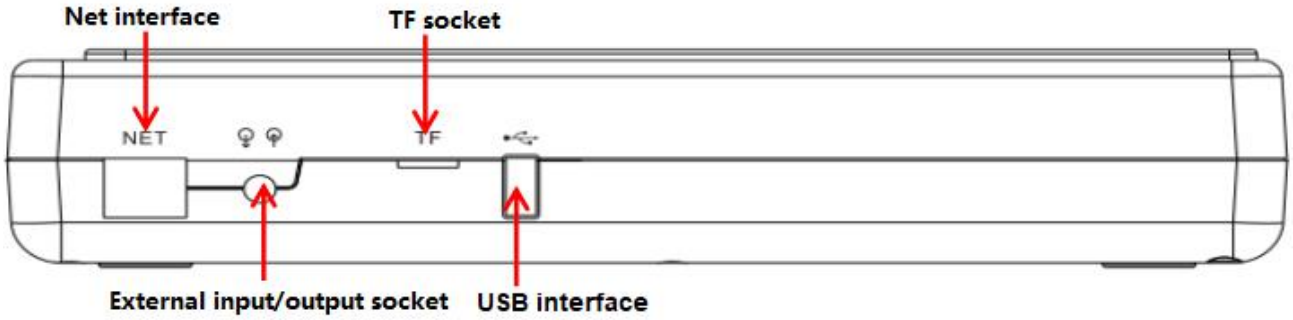


Fig. 5 Upper side panel of ECG

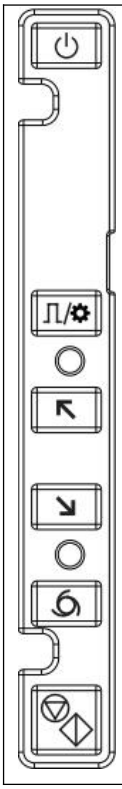
3.2 Content on LCD as follows

Display on LCD is as follows after power on:

No	Icon name	Description
	Patient ID	Display the ID of the currently inspected patient; ID is automatically generated by the system according to the printing time. The format of the ID number is the year, month, day, hour, minute, and second. For example, printing at 12:00:44 on January 11, 2019, the ID will be generated: 20190111120044.
②	Gender & Age	The gender of the patient being examined is entered by the operator Gender : Male, Female; The age of the patient being examined is entered by the operator.
③	Heart rate❤& Heart icon	Displays the actual heart rate; the heart rate icon flashes when the ECG detecting the heart rate
④	Battery capacity	Display battery capacity when the device is in internal battery powered mode This flag is not displayed when the device uses the network power mode.
⑤	System time	Display the current time. System time can be set by the operator

No	Icon name	Description
⑥	Operation mode	Displays the current analysis mode: a. In the automatic redirection mode, the automatic redirection time of each lead is displayed, for example, the retransmission time is 3 seconds, shows “automatic 3 s”; b. In manual redirection mode, shows "manual"; c. In 1 lead 1 minute mode, shows "1 lead 1 minute" d. In rhythm analysis mode, shows "rhythm analysis".
⑦	Sensitivity	Displays current sensitivity(2.5,5,10,20mm/mV): Example 1: The sensitivity of the system setting is 2.5mm/mV, shows 2.5mm/mV; Example 2: The sensitivity is automatically adjusted in the automatic commutation mode. When the signal is normal, the sensitivity is 10mm/mV, shows 10mm/mV; when the signal amplitude is too large, it will be automatically halved, the sensitivity is 5mm/mV, shows 5mm/mV.
⑧	Filters setting	AC Filter Freq：50Hz/60Hz EMG Filter：25Hz/35Hz/45Hz/75Hz/100Hz/150Hz High pass filter：0, 0.05, 0.5Hz
⑨	Function setup	Press this key to enter menu settings.
⑩	Current lead	Display the current lead (I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6) If the C1 lead falls off, the line mark of the off lead wire is displayed in the interface, which is displayed as “lead off V1”

3.3 Content on keyboard as follows



Button Symbol	Function
	ON/OFF Being used for power switch on and charging in standby condition.
	Mark/ Function Keys: Under MAN mode, press this key to record a 1mV calibration pulse at any time while recording. You can combine this key with the left and right direction keys to set automatic redirection mode and interval.
	Forward/backward switch key: Use to switch or exit settings between different functions on the button during function setting. It can be used to select different leads during manual redirection, 1 lead 1 minute or rhythm analysis.
	Recording mode: Transform from different recording mode: automatic, manual, 1 lead 1 minute or rhythm analysis.

		**Start/stop button:** Start or stop recording.

4. Operation preparation

WARNING:

Check the main unit and its accessories carefully before operating the ECG. Replacement should be taken if there is any evident defectiveness or aging symptom which may impair the safety or performance. Make sure that the equipment is in proper working condition.

4.1Connecting to power

WARNING:

To avoid any possible electric shock, please connect the ECG with AC power by a three-phase power cable. Don't open the ECG while it is powered on.

WARNING:

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

Insert one end of the 3-cord power cable into the device and the other end into the power socket in wall. Then bridge the grounding cable between the grounding terminal of the device and ground.

1) Mains Supply

The mains socket is on the left upper side of the ECG. Properly connect the ECG with mains supply.

Rated voltage: 100V-120V/220V-240V

Rated frequency: 50Hz/60Hz

Rated input power: 60A

Make sure the mains supply meets the above requirements before power on.

2) Built-in Rechargeable Battery

The built-in rechargeable battery pack is used, because of the consumption during storage and transport, the capacity of battery may not be full. In this case please recharge the battery first. Replace the battery when the battery has been recharged over 300 times.

NOTE:

The battery is put into the battery compartment without connecting to the battery socket at factory. After receiving the ECG, if built-in rechargeable battery is to be used, connect the battery to the socket first.

4.2 Paper loading

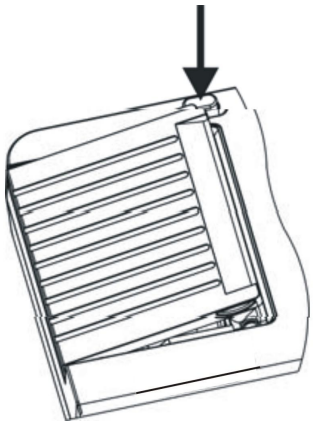


Fig. 1

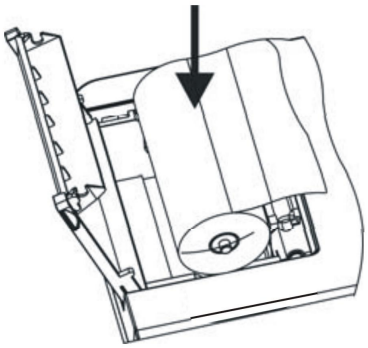


Fig. 2

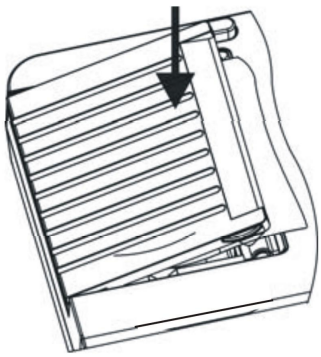


Fig.3

Step 1: Push the Open Button to open the paper compartment cover.

Step 2: Take out the paper rollers, remove remaining paper if necessary. Insert the rollers into the new roll paper and put the paper with rollers back into the paper compartment. Be sure that the paper is installed with the paper's grid side facing downward.

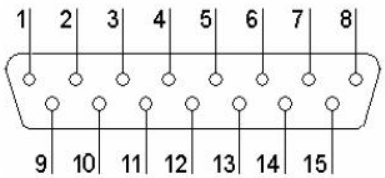
Step 3: Pull about 2cm of the paper out, and close the cover gently.

- The recording paper applied to the device is 80mm three channel roll thermal paper.
- Cover the paper cabinet, and leave the beginning of paper.
- Make the square side downward.

4.3 Connection of patient cable

Connection of patient cable is involved whether record ECG is accurate or not. Please ensure to connect the patient cable well. New and old electrodes or reusable and disposable electrodes can't be used synchronously. Different type of electrodes can't be used together, which will have great influence on ECG record. Electrodes or cable plug can't touch other surface or conductor, such as metal bed. Renovate all the electrodes together.

1) Patient Cable Socket



Definition of corresponding pins:

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

Patient Cable Definition of Pins

2) Placement of limb electrodes

a) Ensure the electrodes are clean;

b) Align lead wires of patient cable to avoid twisting, and connect the electrode connectors to corresponding electrodes according to the color and identifier;

c) Clean electrode area on a short distance above the ankle or wrist with alcohol;

d) Daub the electrode area on limb with gel evenly;

e) Place a small amount of gel on the metal part of limb electrode clamp;

f) 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.

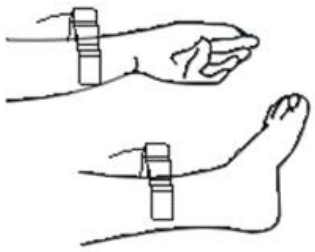
R(RA) for right arm

L(LA) for left arm

RF(RL) for right leg

F(LL) for left leg

It shows as the right picture:



3) Placement of chest electrodes

a) Ensure the electrodes are clean;

b) Align all lead wires of patient cable to avoid twisting, and connect the associated electrodeconnectors with corresponding electrodes according to the color and identifier;

c) Clean electrode area on chest surface with alcohol;

d) Daub the round area of 25mm diameter on each electrode site with gel evenly;

e) Place a small amount of gel on the brim of chest electrode's metal cup;

f) 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.

The chest electrode should be placed on body surface as shown below.

V1: Fourth inter-costal space at right border of sternum.

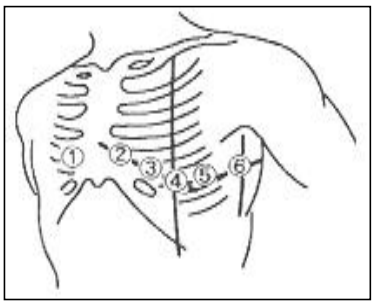
V2: Fourth inter-costal space at left border of sternum.

V3: Midway between V2 and V4.

V4: Fifth inter-costal space at left mid-clavicles line.

V5: Left anterior axillary line at the horizontal lever of V4.

V6: Left mid-axillary line at the horizontal lever of V4.



Attention

Tangling of electrodes or overlap from one place to another of ECG cream is not allowed to avoid short circuit. If there is no ECG scream, inspecting ECG can be used 75% alcohol to clean each electrodes, and connect the electrodes to related position immediately to ensure that the attached skin is wet. Don't use normal saline instead of ECG scream to avoid rusting electrodes.

Attention

Patient cable plug should be screwed down to insert to the socket!

4) Electrode connection definitions and color code

	European		**American**		
Electrodes	**Identifier**	**Color code**	**Identifier**	**Color code**	**Socket Number**
Right arm	R	Red	RA	White	9
Left arm	L	Yellow	LA	Black	10
Right leg	RF	Black	RL	Green	14
Left leg	F	Green	LL	Red	11
Chest 1	C1	White/red	V1	Brown/red	12
Chest 2	C2	White/yellow	V2	Brown/yellow	1
Chest 3	C3	White/green	V3	Brown/green	2
Chest 4	C4	White/brown	V4	Brown/Blue	3
Chest 5	C5	White/black	V5	Brown/orange	4
Chest 6	C6	White/violet	V6	Brown/ violet	5

5) ECG lead sequence:

two options for lead mode: standard lead, European lead.

The lead mode is defined as follows:

No.	1	2	3	4	5	6	7	8	9	10	11	12
Standard leads	I	II	III	aVR	aVF	aVF	V1	V2	V3	V4	V5	V6
European lead CABRERA	aVL	I	-aVR	II	aVF	III	V1	V2	V3	V4	V5	V6

4.4 Inspection before Startup

In order to avoid safety hazards and get good ECG record, the following inspection procedures are recommended before turning on the ECG and beginning 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 ECG and it is properly grounded.
   - ◆ Recharge the battery first before use when the battery capacity is low.
3) Grounding:
   - ◆ Check the grounding cable is properly connected.
4) Patient Cable:
   - ◆ Check whether the patient cable has been connected to the ECG firmly, and keep it far away from the power cord.
5) Electrodes:
   - ◆ Check whether all electrodes have been connected with lead wires of patient cable correctly according to the identifier and color.
   - ◆ Be sure that all electrodes have been connected to the patient correctly.
   - ◆ Ensure that the chest electrodes haven't contacted with each other.
6) Recorder Paper:
   - ◆ Ensure that there is enough recording paper loaded.
   - ◆ Make sure the case of the recorder has been secured.
7) 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.
8) AC Filter Frequency
   - ◆ Check the setup of AC Filter Frequency and make sure is identical with the local regulations, or it will influence the anti-jamming effect.

⚠WARNING⚠:

The ECG is provided for the use of qualified physicians or personnel professionally trained. The operator is supposed to be familiar with the contents of this Operation Manual before use.

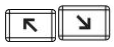
5. Operation Instructions

NOTE:

- Whether boot or shutdown should hold down the ON / OFF key a few seconds. Hold the boot until the display shows information on manufacturers, equipment model and version, shut down until the screen display closed.

5.1 Operation mode

5.1.1 Manual Mode

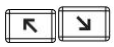
- Press  key to choose “Manual Mode”, which will be displayed in the lower left corner of the LCD screen.
- Set the recording format of the “Manual Mode” in the menu.
- Press the “Manual Mode” to select the sensitivity (wave gain), filter according to the requirement before recording.
- Press  arrow key to select the leads to be recorded.
- Press  **RUN/STOP** to start recording; manually switch the leads while recording.
- Press  during recording to stop recording at any time.

  Patient ID will be changed automatically if the recording is interrupted. If the ID number needs to be unchanged, the operator should adjust patient ID before continuing recording.

5.1.2 Auto Mode (Auto 3s Mode)

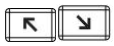
- Press  key to choose “Auto 3s Mode”, which will be displayed in the lower left corner of the LCD screen.
- Set the recording format of the “Auto 3s Mode” in the menu.
- Press the “Auto 3s Mode” to select the sensitivity (wave gain), filter according to the requirement before recording.
- After the waveform and heart rate are stabilized, press  to print a complete ECG waveform.
- During printing, the operator can press  key to stop recording any time.

5.1.3 One channel one minute mode (1ch 1min Mode)

- Press  key to choose “1ch 1min Mode”, which will be displayed in the lower left corner of the LCD screen.
- Set the recording format of the “1ch 1min Mode” mode in the menu.
- Touch the “1ch 1min Mode” to select the sensitivity (wave gain), filter according to the requirement before recording.
- Press  arrow key to select the leads to be recorded.
- Press  to start collecting ECG data for 48 seconds then print it out.
- Automatic stop after printing. During printing, the operator can press  key to stop recording any time.

5.1.4 Rhythm Mode

- Press  key to choose “Rhythm Mode”, which will be displayed in the lower left corner of the LCD screen.
- Set the recording format of the “Rhythm Mode” mode in the menu.
- Press the “Rhythm Mode” to select the sensitivity (wave gain), filter according to the requirement before recording.

- Press  arrow key to select the leads to be recorded.
- Press  to start collecting ECG data for 240 seconds then print it out.
- Automatic stop after printing. During printing, the operator can press  key to stop recording any time.

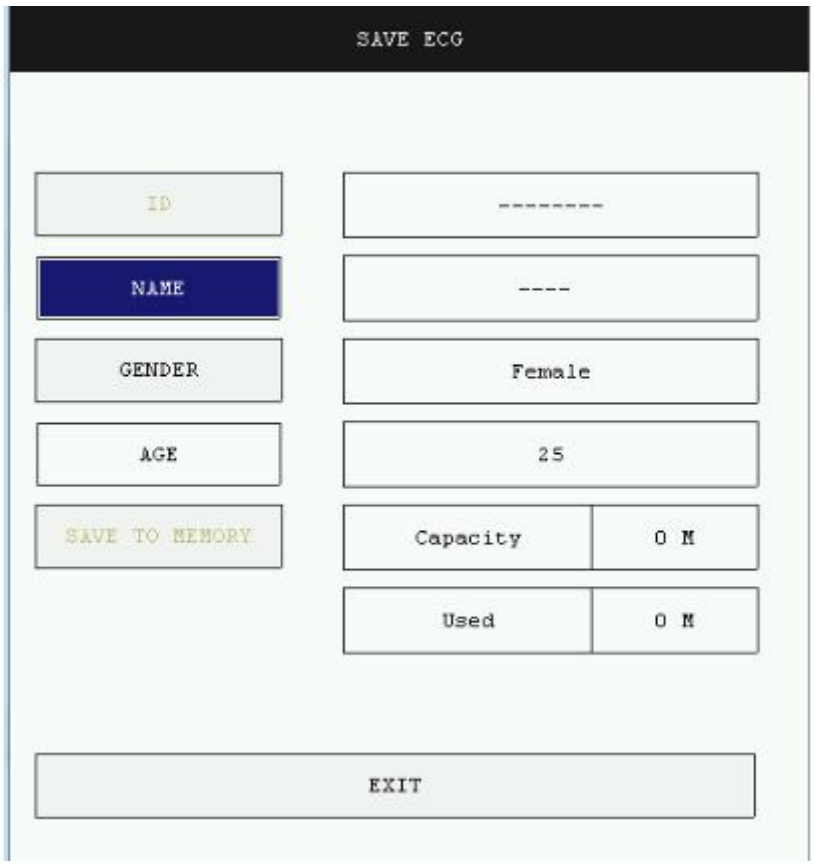
5.2 Operation Menu

5.2.1 Function Setup

Press  or touch “Function Setup” in the lower right corner of the LCD screen go to main menu. Touch the corresponding position of the screen then go to the submenu.

5.2.2 Save ECG

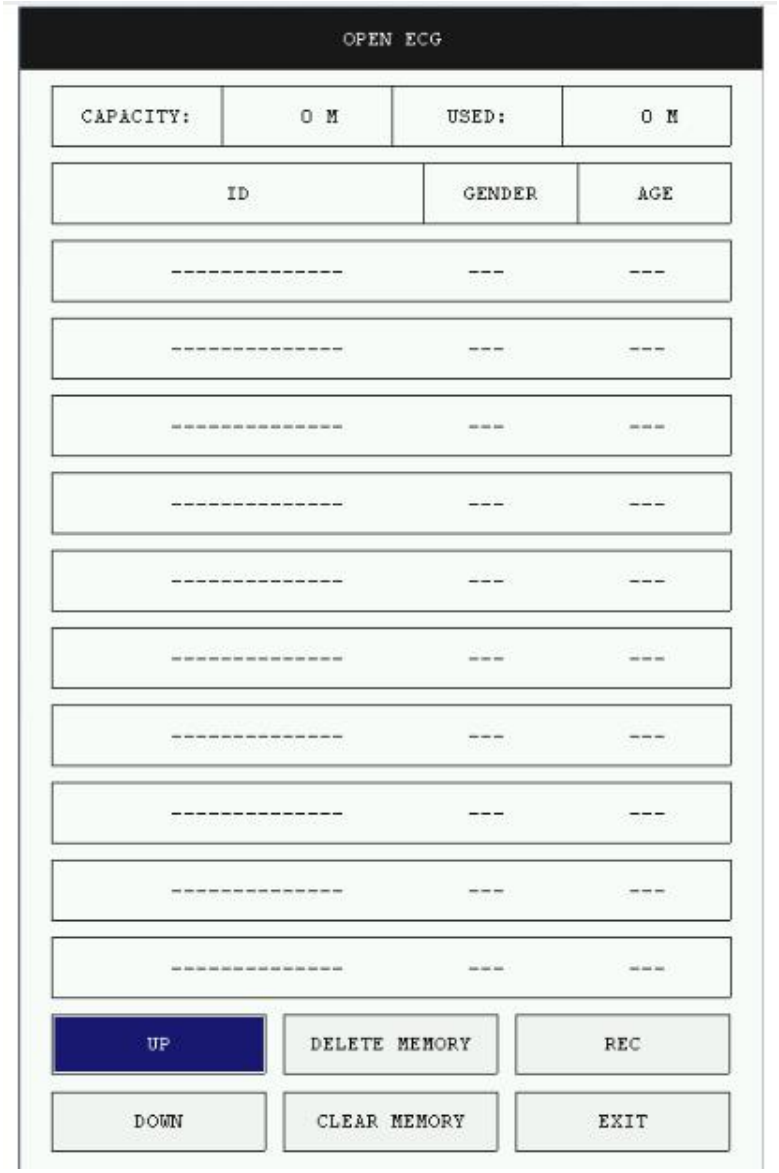
Extended storage can be supported. Select “SAVE ECG” from the Function setup. Only the ECG which has been printed out the report normally can be saved. The saved cases can be played back or print it out.



Enter the corresponding patient information to save the ECG report.

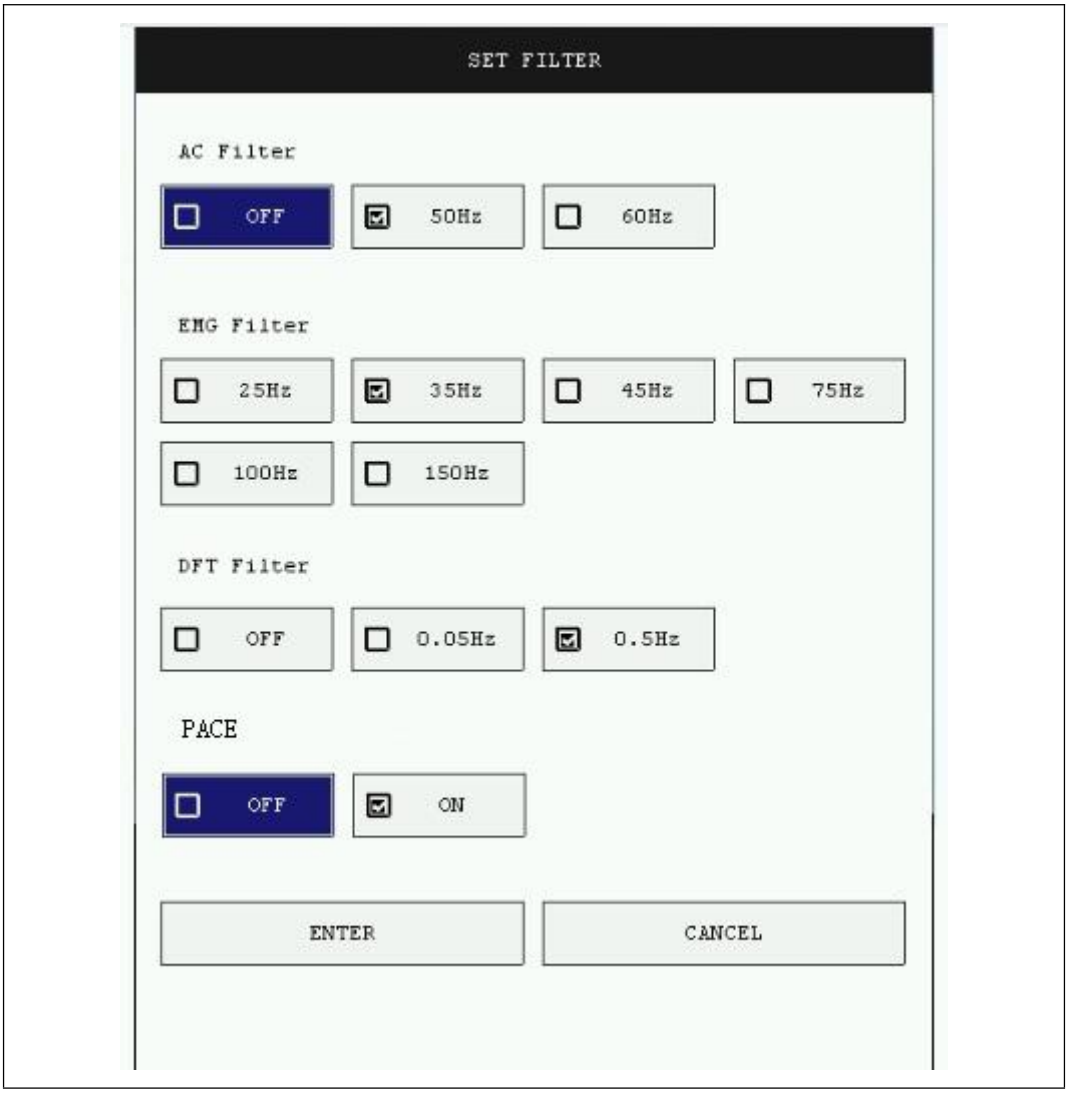
5.2.3 Open ECG

Press “ Open ECG”, all saved ECG reports can be viewed, printed, and deleted.



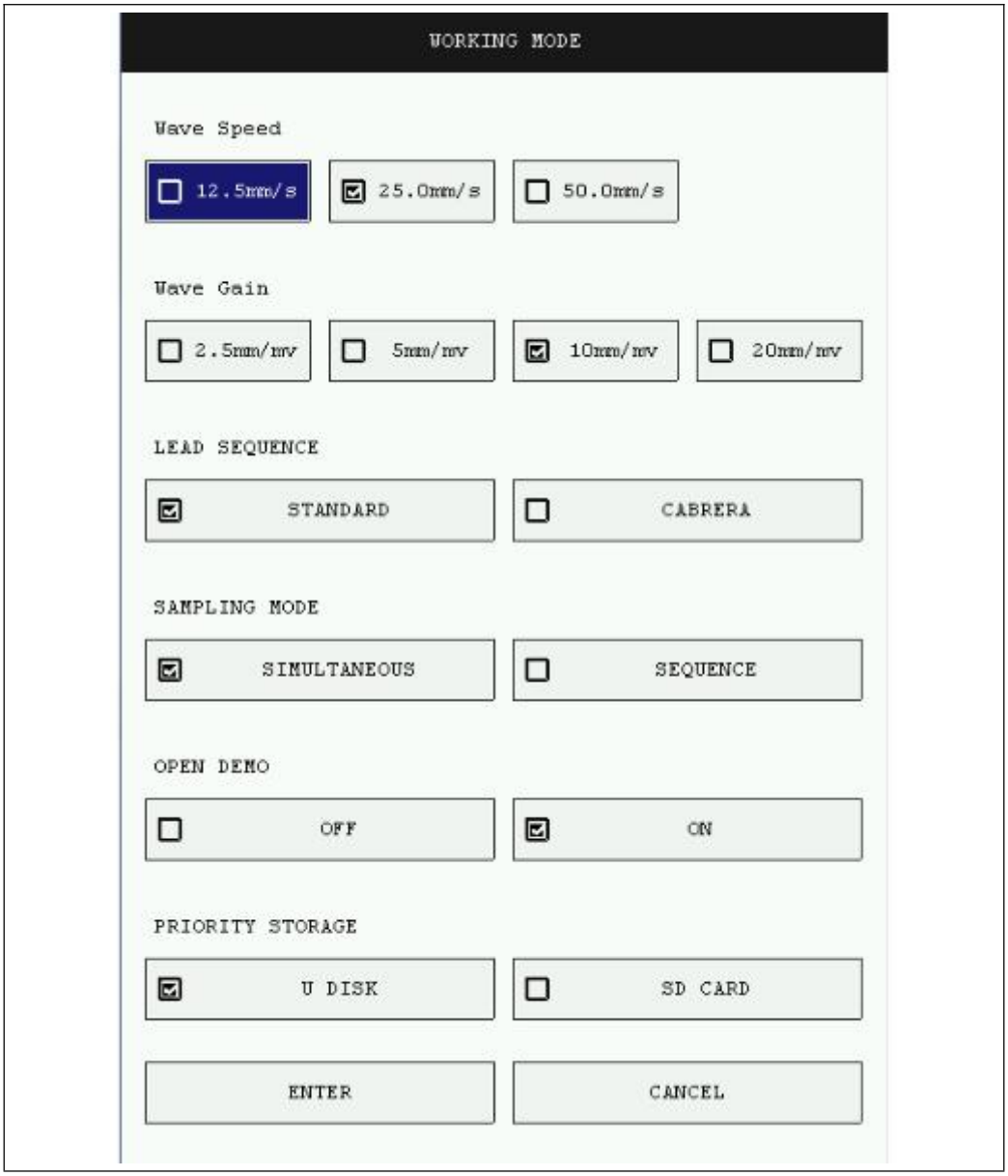
5.2.4 Set filter

Press “Set filter”, AC Filter, EMG Filter and DFT Filter can be setup.



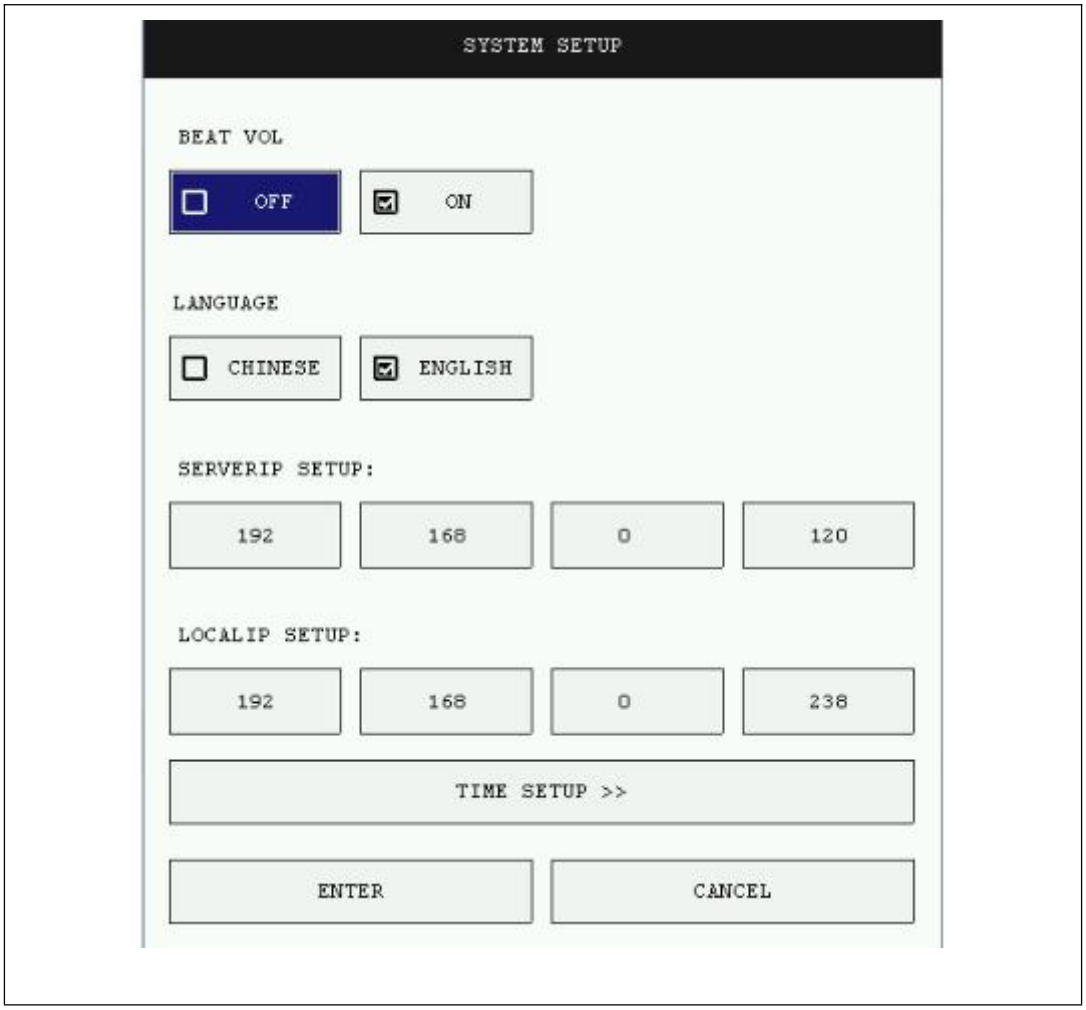
5.2.5 Working Mode

Press “Working Mode”, wave speed, wave gain, load sequence, sampling mode, open demo and priority storage can be setup.



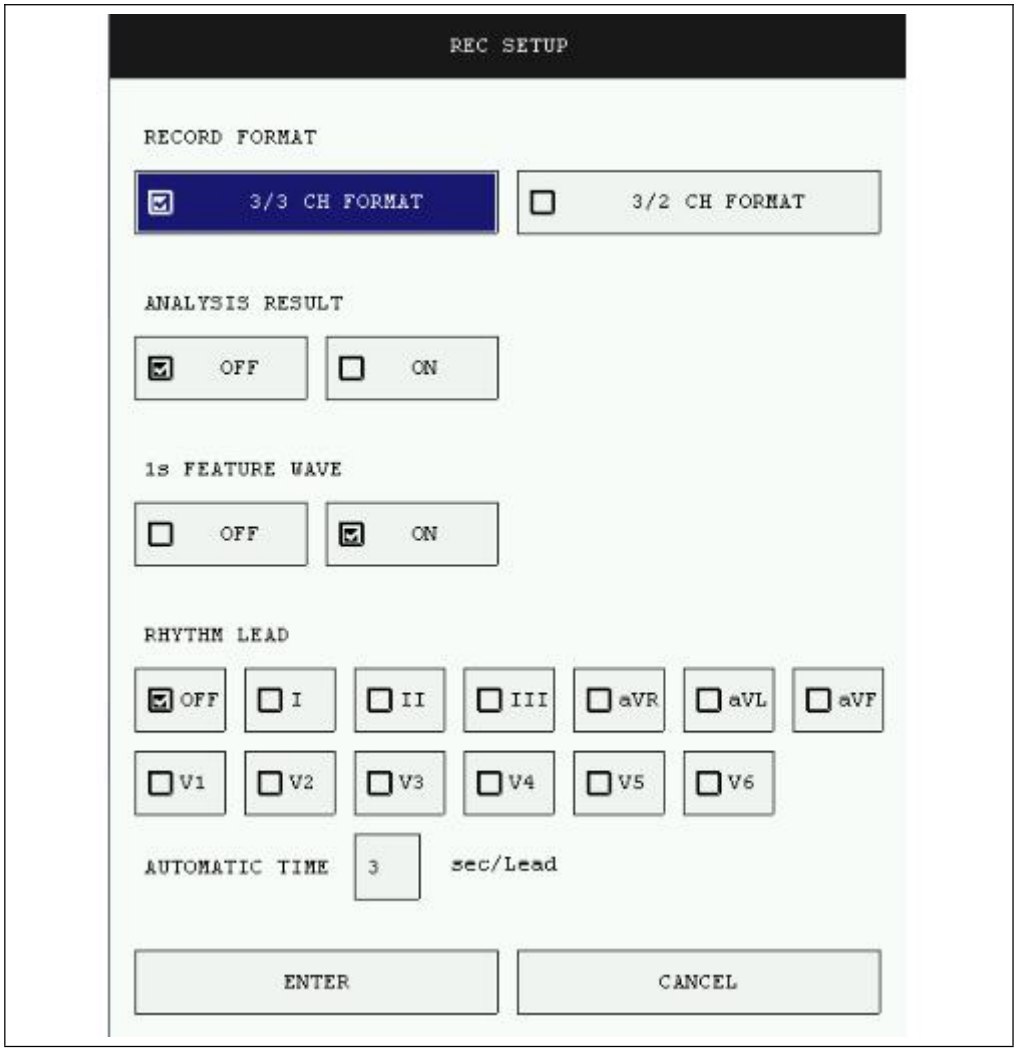
5.2.6 System setup

Press “System setup”, beat vol, language, server IP and local IP can be setup.



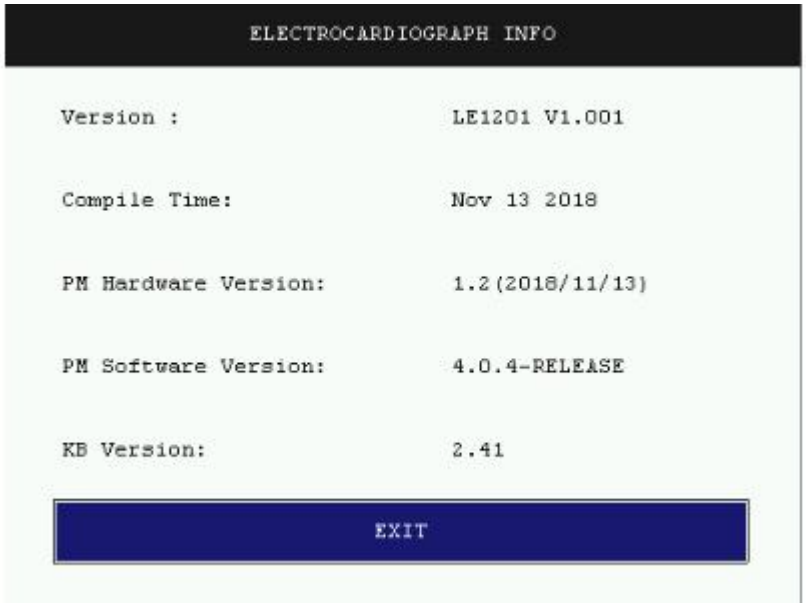
5.2.7 Printer setup

Press “Printer setup”, auto REC format, analysis result, avg wave, rhythm lead can be setup.



5.2.8 Version

Press “Version” can check the ECG info.



5.2.9 Load default

Press “Load default” can restore the factory settings.

6. Daily maintenance

6.1 Battery charging, capacity indicator and replacement

ECG device is built in rechargeable battery to realize AC/DC operation. The illustration on charging, indicating capacity and replacement are as follows:

- Charging battery

  ECG device is designed with a charger and protector for the rechargeable battery. It is required to charge & discharge the battery at least every 3 months, and device is in spare condition. Charging indicator will blink while charging, and keep in light when charging is completed.

- Capacity indicator

  Whenever the machine is powered by DC battery, there will be a prompt, in the middle of first line on the LCD screen, to indicate battery capacity as follows.

 Sufficient battery capacity

 Insufficient battery capacity, charging is required.

 Battery capacity is running out, immediate charging is demanded.

- Battery replacement

  Battery replacement shall be carried out by a service engineer as follows.

  a. Power switches off and disconnects power cable.

  b. According to the bottom figure of device, open the cover of battery cabinet.

  c. Pull out the plug of battery and remove the damaged battery.

  d. Replace the battery with a new one and plug in the battery socket to connect well.

  e. Reassemble the instrument.

Notice:

- Don’t connect directly anode and cathode of the battery with lead otherwise may cause fire hazard.
- Don’t put battery near to open fire, otherwise may cause explosion hazard.
- Don’t disassemble battery without allowance.
- Please take and put battery gently, don’t fall it to the ground or strike on other items.

6.2 Recording paper

For the sake of recording quality of ECG trace, please use the recommended or provided thermal paper. If purchase other thermal paper, maybe shorten the life time of thermal lattice printing head, cause recording trace to blur, or bad paper running.

Please do notice!

a. Avoid use of grayish and blackish paper or with wax; otherwise may cause printer head damaged.

b. High temperature, high humidity and direct sunshine will cause paper color to change. Please keep the paper in a dry and cool place;

c. Do not expose the paper in fluorescent light for a long time, otherwise will have influence on recording quality.

d. Do not store the paper with PVC to avoid color change;

e. Do not pile up the recorded paper for a long time to avoid waveform transfer.

f. Please pay highly attention to the specification of recording paper. The thermal lattice printing head or the silicon-rubber axis will damage by the wrong paper.

6.3 Maintenance Following Operation

After using ECG device, please notice:

A. While pulling out the leads and power cable, please grasp the plug to pull out, don't grasp the cable.

B. Clean the machine as well as accessories and cover the instrument with a shade.

C. Place the device in a dry and shading environment. Vibration in the process of transportation should be avoided.

D. Don't immerse the device into cleaner while cleaning the device, please cut off power supply while cleaning the shell of device. Please use neutral solvent to clean which doesn't contain alcohol or bactericide.

6.4 Patient cable maintenance

- Check the patient cable continuity with a multi-meter. The resistance should be less than 10 ohms.

  Following table is the continuity of the patient cable.

Electrode	R	L	F	RF	C1	C2	C3	C4	C5	C6
Patient Lead	9	10	11	14	12	1	2	3	4	5

  Please periodic inspecting patient cable to keep it well, any piece of the cable is damaged will occur corresponding or all lead to appear false wave. Patient cable can be cleaned with water or soap, or disinfected by 75% alcohol. (Don't immerse patient cable into the liquid).

- Curve or tie patient cable will shorten its life time, please make it in line and then connect with electrodes.
- All the electrodes should be kept well, after being used for a long time, the surface of electrodes will be oxidized to effect on recording the trace, and please renew electrodes.

6.5 Silicon rubber axis maintenance

Silicon rubber axis should be kept smooth and clean, otherwise will have an influence on the effect of ECG record. Please use clean and soft cotton with few alcohols to clean the smear on the silicon rubber axis along portrait, and rotate to the direction of conveying the recording paper until make it clean.

6.6 Thermal Printer Maintenance

Residue and dirt on the thermal printer could affect the clarity of printing out ECG trace.

To clean the thermal printer, you are required to open the paper magazine and clean the printer with cotton dipped with alcohol. It is not permitted to operate on the printer with a sharp object. Otherwise, permanent damage could be resulted. After the alcohol is volatilized completely, close the cabinet. Thermal printer maintenance should be done at least once a month.

7. Troubleshooting and solution

7.1 Some lead without waveform

- When the cables are connected well with the patient, the device usually needs several seconds to get ready.Press RESET and start recording after 2~3 seconds to solve the problem.
- Patient cabel is at fault.checking the patient cable according to 5.4,if patient cable breaks down,please connect with our after-sale department or appointed maitenance center.
- Excluded the above cause,the device still exist problem,normally it is resulted from the problem of signal channel, please connect with our after-sale department or appointed maitenance center.

7.2 Vertical broken track of printed waveform

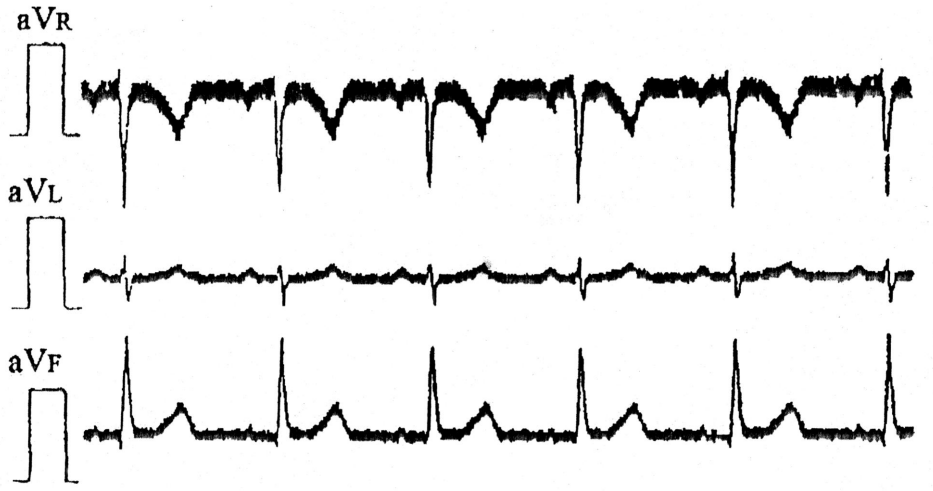
Whenever a printer fault occurs, which manifests itself as not continuous trace on the recording paper; you are required to clean the thermal printer with soft cotton with alcohol. If this action does not work, certain thermal emitting component is probable damaged, and you are required to contact the manufacturer or the local agent for help.

7.3 Control Panel Failure

Control panel failure is probably caused by bad continuity between the panel and the Keyboard Control Module due to transportation or vibration. If a reconnection of the control panel to the Keyboard Control Module does not work, you are required to contact a service engineer.

7.4 AC Interference

In the process of recording ECG trace,there are some interference and apparent wobble of baseline as follows:



Please check the following:

1. Make sure that the unit is properly grounded according to instructions.
2. Check for good electrode attachment and patient cable connection.
3. Check the cleaning of electrode and patient body surface.
4. Make sure that the exam bed is properly grounded.
5. The patient shall not be in touch with the metal parts of the exam bed.
6. The patient shall not be in touch with anybody else.

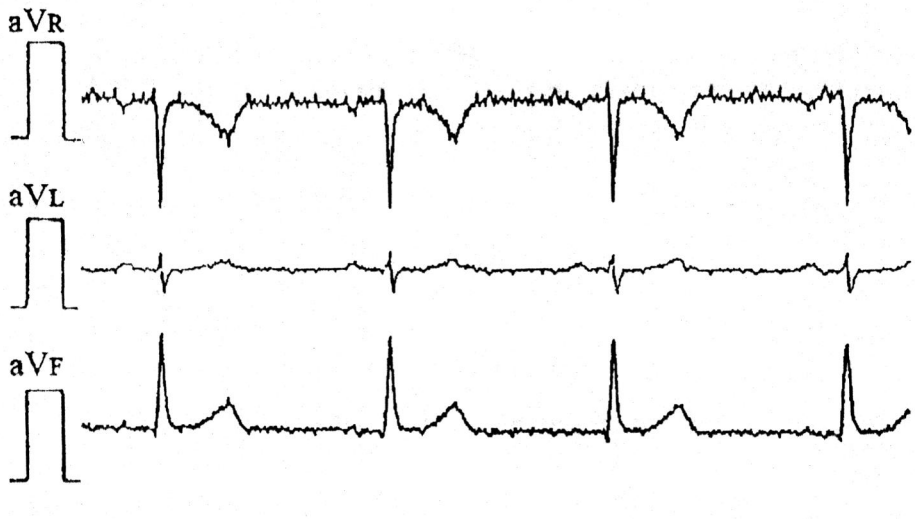
7. There shall be no large power electric equipment working nearby.

8. The patient shall put off such things as ring and the like.

Please use AC filter if still exists above-mentioned interference.

7.5 EMG interference

EMG interference may cause irregular wobble of waveform.



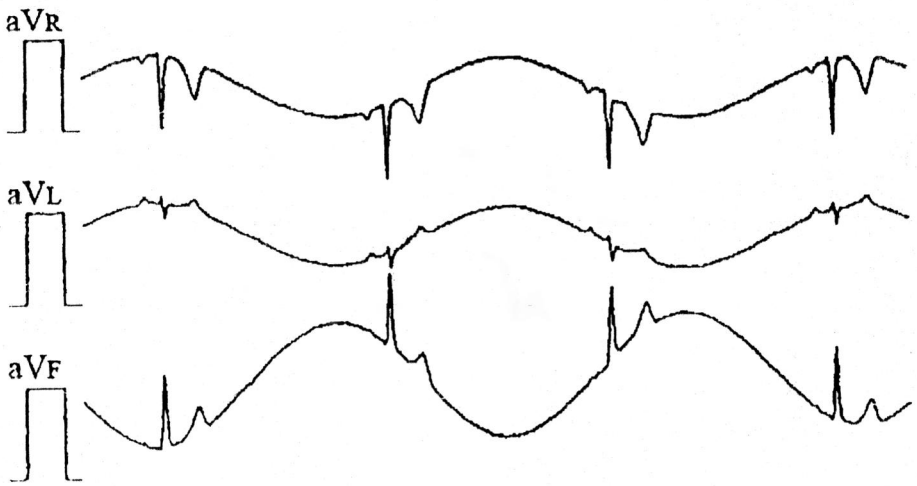
Please check the following:

- Make sure that the exam room is comfortable for examination.
- Soothe the patient from irritation or excitement.
- Make sure the exam bed shall be in suitable size.
- Never have talks with the patient during ECG trace is recorded.

Please apply EMG filter if still exists above-mentioned interference. The waveform will be weakened a little more, which will decline obviously on R wave.

7.6 Baseline drift

There is irregular movement on the baseline of wave, shown as below:



Check the following:

- Verify the electrode attachment and lead wire performance.
- Check the connection between patient cable and electrodes.
- Check the cleaning of electrode and patient body surface.
- Is there enough ECG cream on skin and electrodes?
- Keep the patient from motion or hyperventilation.
- Old electrodes and new ones mixed up

If still exists, Please contact with our service department or appointed maitenance center.

8.Common faults and troubleshooting

8.1 individual leads cannot print waveforms

In the printing process, the reasons why individual leads are unable to draw are as follows:

Do not start recording immediately after connecting the lead line. Due to the stable time of about 2 seconds for baseline drift detection, individual leads cannot be drawn. At this time, you can press the reset key, can quickly stabilize each lead waveform, or re-record it once.

If the lead line is not in contact or the internal line is broken, it will also produce the phenomenon that individual leads can not draw out the diagram. The lead line can be checked as described in 6.3 lead maintenance. If the lead line does fail, please contact our after-sales service department or designated maintenance point.

After eliminating the above two reasons, if there is still a fault in this machine, it is generally caused by the fault of the signal channel amplification unit. At this time, we must contact our after-sales service department or designated maintenance point.

8.2 print head failure

The principal fault of the print head is that the printed ECG waveform or the character breaks the breakpoint in the vertical direction. It is generally due to dust or stains on the surface of the thermal print head, which must be cleaned to correct the problem. After cleaning, there is still such a phenomenon that the part of the heating unit of the print head may be damaged, and it shall be in contact with the after-sales service department of the company or the designated maintenance point.

8.3 AC interference.

Ac interference showed that the recorded ECG was regularly superimposed with a certain amplitude of 50Hz/60Hz sine wave interference waveform, and the base line was obviously jitter. The possible causes of AC interference are as follows: please check and eliminate in turn:

There is no reliable grounding in the ECG machine.

The electrode or lead line is incorrectly connected.

There was no conductive ointment at the corresponding part of the electrode and the skin of the patient's body surface.

The patient touches the metal part of the wall or bed, or others.

There are X-ray machines, ultrasonic instruments and other high-power electrical equipment in the vicinity of the turbine.

The setting of AC filter frequency is inconsistent with the frequency of local AC power supply.

●The patient is wearing jewelry.

The above-mentioned measures can still not clear the AC interference. Use an AC filter, at which time the recording waveform will be slightly attenuated.

8.4 EMG interference

EMG interference showed irregular jitter at the printed electrocardiogram (ECG) base line. EMG interference may be caused by the following factors, please check and eliminate in turn:

The temperature in the room is too low and the patient feels uncomfortable.

The bed is narrow and the patient is nervous or nervous.

Talk to the patient during the recording.

The limb electrode or chest electrode is clamped too tightly.

The above measures still can not eliminate interference, please use EMG filter. However, the ECG waveform recorded at this time will be attenuated, and the attenuation of R wave is more obvious.

8.5 baseline drift

The electrocardiogram (ECG) base line was not stable and showed irregular up and down movement. The possible causes of this phenomenon are described below. Please check, exclude, or correct it in turn:

The installation of skin electrodes is unstable.

During the recording process, the patient's body moves or breathes.

The skin of the patient's surface is not clean or is not coated with foot conductive ointment.

The old electrode is mixed with the new electrode.

If the above-mentioned measures are still unable to clear the base line drift, use the base line drift filter (ADS).

9. Specifications

Main technical specification

Items	specification
Lead	standard 12 leads
lead acquisition	synchronously 12 leads
Input Impedance	≥50MΩ
Input circuit current	≤0.0.05μA
Record mode	Automatic: 3×4;3×2+2×3 Rhythm: Any lead selectable.
Filter	EMG Filter: 25 Hz / 35 Hz / 45Hz/75 Hz / 100 Hz / 150Hz DFT Filter: 0.05 Hz/ 0.5 Hz AC Filter: 50 Hz / 60Hz
CMRR	>100dB
Patient current leakage	＜10μA
Input Circuit Current	＜0.05μA
Frequency Response	0.05Hz~150Hz (-3dB)
Sensitivity	2.5mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV
Anti-baseline Drift	Automatic
Time constant	≥3.2s
Noise level	＜15μV_{p-p}
Paper speed	12.5 mm/s, 25 mm/s, 50 mm/s
Recording mode	Thermal printing system
Paper specification	80mmx20m paper roll
AD sampling rate	1000 samples/s
LCD display	7” graphic LCD
Safety classification	IEC60601-1 class Ⅱ, type CF
Power supply	AC: 100~240V, 50/60Hz, 30VA~100VA
	DC: 7.4V/4400mAh, built-in lithium battery

Environment requirement

Storage

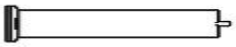
Temperature -10℃～+40℃ Humidity 30％～80％ Pressure 700hPa~1060hPa

Operation

Temperature +5℃~+40℃ Humidity 25％～95％ Pressure 860hPa~1060hPa

10. Accessory List

In order to obtain a good ECG trace, you are required to use the accompanying accessories of this unit. Following is the demonstration of the standard accessories for the unit.

序号	Item	Quantity	pattern
1	Patient Cable	1	
2	Limb Electrode	4pcs/set	
3	Chest Electrode	6pcs/set	
4	Grounding Cable	1	
5	Thermal Recording Paper	1	
6	Paper Shaft	1	
7	Three plugged power cable	1	

Responsibility of Manufacturer

2. **The device is strictly operated according to user manual.**

Electromagnetic Capability

GUIDANCE AND DECLARATION – ELECTROMAGNETIC EMISSION		
The ECG is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
RF emissions CISPR 11	Group 1	The ECG uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The ECG is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

GUIDANCE AND DECLARATION – ELECTROMAGNETIC IMMUNITY			
The ECG is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
IMMUNITY TEST	IEC60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ±1 kV for input/output lines	± 2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	± 1 kV differential mode ±2 kV common mode	
Power frequency (50Hz/60Hz)	3A/m	3A/m	Power frequency magnetic fields should be at

magnetic field IEC61000-4-8			levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in UT) for 0.5 cycle 40% U_T (60% dip in UT) for 5 cycles 70% U_T(30% dip in UT) for 25 cycles <5% U_T(>95% dip in UT) for 5 sec	<5% U_T (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% U_T(30% dip in UT) for 25 cycles <5% U_T(>95% dip in UT) for 5 sec	Mains power quality should be that of atypical commercial or hospital environment. If the user of the ECG requires continued operation during power mains interruptions,it is recommended that the ECG be powered from an uninterruptible power supply or a battery.

<table>
<tr><th colspan="4">GUIDANCE AND DECLARATION – ELECTROMAGNETIC IMMUNITY</th></tr>
<tr><td colspan="4">The ECG is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.</td></tr>
<tr><th>IMMUNITY TEST</th><th>IEC60601 TEST LEVEL</th><th>COMPLIANCE LEVEL</th><th>ELECTROMAGNETIC ENVIRONMENT – GUIDANCE</th></tr>
<tr><td rowspan="2">Conducted RF
IEC61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz
outside ISM bands</td><td>3Vrms
(V1)</td><td rowspan="3">Portable and mobile RF communications equipment should be used no closer to any part of the ECG, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = \left[\frac{3.5}{V1}\right]\sqrt{P}$
$d = \left[\frac{12}{V2}\right]\sqrt{P}$
$d = \left[\frac{12}{E1}\right]\sqrt{P}$ 80 MHz～800 MHz
$d = \left[\frac{23}{E1}\right]\sqrt{P}$ 800 MHz～2.5 GHz
Interference may occur in the vicinity of equipment marked with the following symbol:  </td></tr>
<tr><td>10 Vrms
150 kHz to 80 MHz in
ISM bands</td><td>10Vrms
(V2)</td></tr>
<tr><td>Radiated RF
IEC61000-4-3</td><td>10V/m
(80MHz～2.5GHz)</td><td>30V/m
(E1)</td></tr>
<tr><td colspan="4">NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ECG is used exceeds the applicable RF compliance level above, the ECG should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ECG
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/</td></tr>
</table>

Recommended separation distances between portable and mobile RF communications equipment and the ECG.

The ECG is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ECG as recommended below, according to the maximum output power of the communications equipment.

Separation distance (m) / Power(W) / Frequency(Hz)		0.01	0.1	1	10	100
150KHz～80MHz	Outside ISM bands $d = \left[\frac{3.5}{V1}\right]\sqrt{P}$	0.04	0.11	0.35	1.11	3.5
	ISM bands $d = \left[\frac{12}{V2}\right]\sqrt{P}$	0.04	0.11	0.35	1.11	3.5
80MHz～800MHz	$d = \left[\frac{12}{E1}\right]\sqrt{P}$	0.04	0.11	0.35	1.11	3.5
800MHz～2.5GHz	$d = \left[\frac{23}{E1}\right]\sqrt{P}$	0.07	0.22	0.7	2.21	7.00

For transmitters rated at a maximum output power not listed above, the recommended separation distances in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 2: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.