

COMEN

CE 0434

Three-Channel Electrocardiograph

CM300

User Manual

Shenzhen Comen Medical Instrument Co., Ltd.

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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.

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

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Chapter 1 Safety Guidance

1.1 Safety Information

The design of the 3-channel electrocardiograph complies with international standard IEC 60601-1 Medical 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) Disinfection/sterilization method: | Refer to the user manual for details |
| 5) Degree of safety of application in the presence of flammable gas: | Equipment not suitable for use in the presence of flammable gas |
| 6) Working Mode: | Continuous operation |
| 7) EMC: | Group I, Class A |

1.2 Warnings and Cautions

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.

1.2.1 Safety Warnings

 **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 operation.
- ◆ Only qualified service engineers can install this equipment. And only service engineers authorized by our company can open the shell.
- ◆ Only qualified installation or service engineers can shift the mains shift switch (100V~115V/220V~240V) according to local mains supply.
- ◆ The results given by the equipment should be examined with respect to the overall clinical condition of the patient. And it can not substitute for regular checking.

⚠WARNING⚠:

- ◆ **EXPLOSION HAZARD**-Do not use the electrocardiograph in the presence of flammable anesthetic mixture with oxygen or other flammable agents.
- ◆ **SHOCK HAZARD**-The power receptacle must be a hospital grade grounded outlet. Never try to adapt the three-prong plug to fit a two-slot outlet.
- ◆ 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.
- ◆ Do not use this equipment in the presence of high static electricity or high voltage equipment which may generate sparks.
- ◆ This equipment is not designed for internal use and direct cardiac application.

⚠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.
- ◆ Be sure that all electrodes have been connected to the patient correctly before operation.
- ◆ Be sure that the conductive parts of electrodes and associated connectors, including neutral electrode, should not contact with earth or any other conducting objects.
- ◆ Electrodes with defibrillator protection should be used while defibrillating.
- ◆ There is no danger for patients with pacemaker.
- ◆ Do not touch the patient, bed, table and the equipment while using defibrillator or pacemaker simultaneously.

- ◆ In order to avoid burning, please keep the electrode far away from the radio knife while using electrosurgical equipment simultaneously.

⚠WARNING⚠:

- ◆ Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the standard IEC 60601-1-1. Therefore anybody, who connects additional equipment to the signal input connector or output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC 60601-1-1. If in doubt, consult our technical service department or your local distributor.
- ◆ The summation of leakage current should never exceed leakage current limits while several other units are used at the same time.
- ◆ The potential equalization conductor can be connected to that of other equipment when necessary, to make sure that all these equipment are connected with the potential equalization bus bar of the electrical installation.

1.2.2 Battery Care Warnings

⚠WARNING⚠:

- ◆ Improper operation may cause the battery to be hot, ignited or exploded, and it may lead to the declination of battery's capacity. It is necessary to read the user manual carefully and pay more attention to warning messages.
- ◆ 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 should be used.
- ◆ Danger of explosion -- Do not reverse the anode and cathode when connecting the battery.
- ◆ Do not heat or splash the battery or throw it into fire or water.
- ◆ When leakage or foul smell found, stop using the battery immediately. If your skin or cloth comes into contact with the leakage liquid, cleanse it with clean water at once. If the leakage liquid splashes into your eyes, do not wipe them. Irrigate them with clean water first and go to see a doctor immediately.

- ◆ 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.

1.2.3 General Cautions

⚠CAUTION⚠:

- ◆ Avoid liquid splash and excessive temperature. The temperature must be kept between 5°C and 40°C while working. And it should be kept between -20°C and 55°C during transportation and storage.
- ◆ Do not use the equipment in dusty environment with bad ventilation or in the presence of corrosive.
- ◆ Be sure that there is no intense electromagnetic interference source around the equipment, such as radio transmitter or mobile phone etc. Attention: Large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment etc. are likely to bring electromagnetic interference.

⚠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.

1.2.4 Cleaning & Disinfection Cautions

⚠CAUTION⚠:

- ◆ Turn off the power before cleaning and disinfection. If mains supply used, the power cord should be plugged 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 cleaning.
- ◆ Do not use chloric disinfectant such as chloride and sodium hypochlorite etc.
- ◆ Do not use high temperature, autoclaving or radiation sterilization processes.

Chapter 2 Introduction

The machine is 3-channel electrocardiographs with 12 leads gathered simultaneously, visual display of operation menu, ECG parameters as well as electrocardiogram.

3-channel ECG can be previewed on the LCD (liquid crystal display) screen of the machine 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, the machine 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 thermal print paper)

2.1 Function Features

- ◆ Low weight and compact size
- ◆ Touch key for easy operation
- ◆ High resolution thermal printer, recoding frequency response $\leq 150\text{Hz}$
- ◆ 12-lead gathered and amplified simultaneously, 3-channel built-in printer.
- ◆ Automatic mode and manual mode optional
- ◆ LOGIN/PRINT/GENERAL/SYSTEM menu for parameters setting
- ◆ 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
- ◆ Standard input/output interface and RS232 communication interface for linking to special network and setting up ECG database

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



Mains supply



Battery indicator

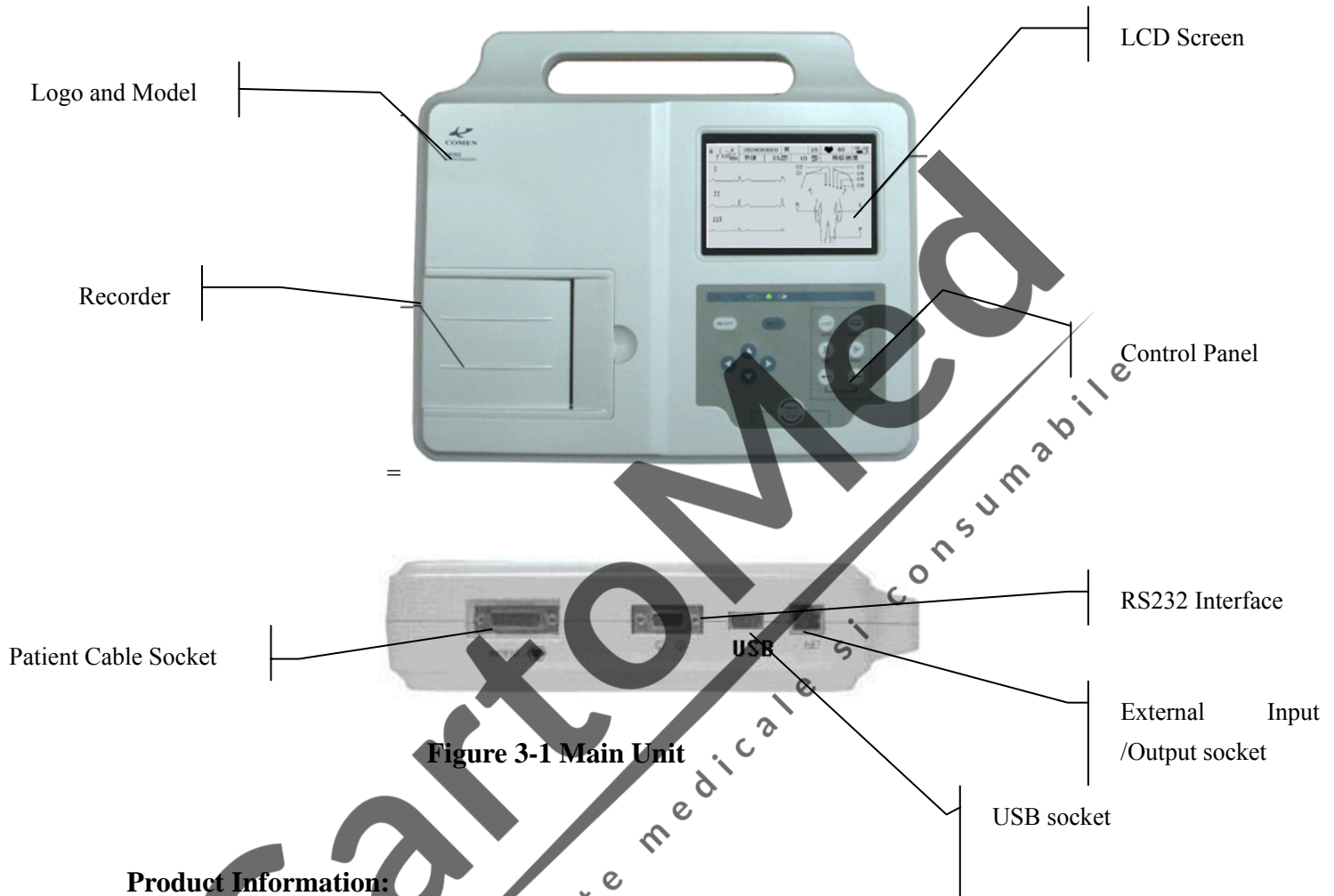


Battery recharging indicator

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Chapter 3 General Information

3.1 Top Panel



Product Information:

1) Logo



2) Model

CM300

3) Brand Name

Three-channel Electrocardiograph

4) Classification Symbol



Equipment of CF type with defibrillator proof

3.1.1 LCD Screen

The LCD Screen specification: 320×240 dot single color LCD Screen

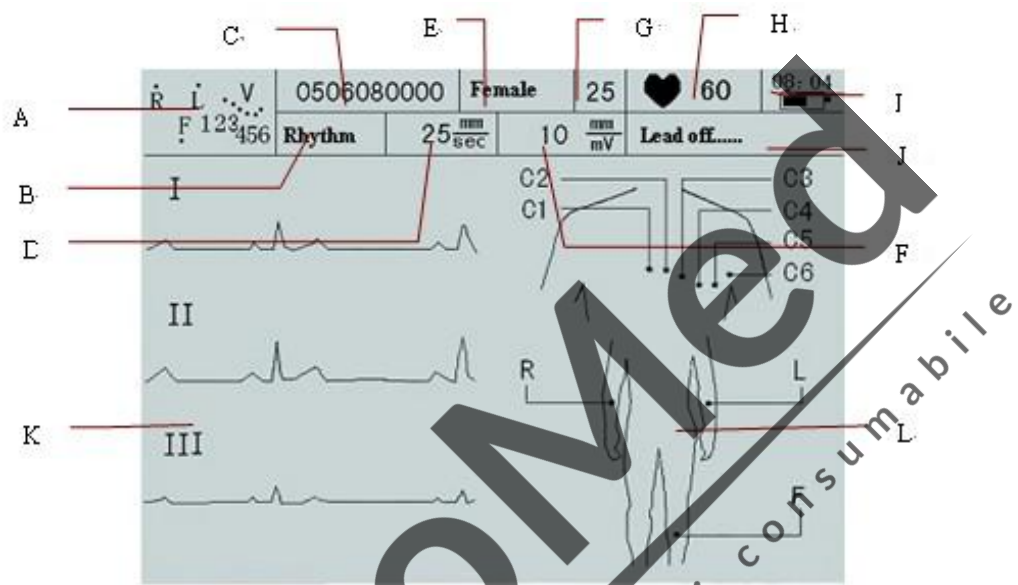
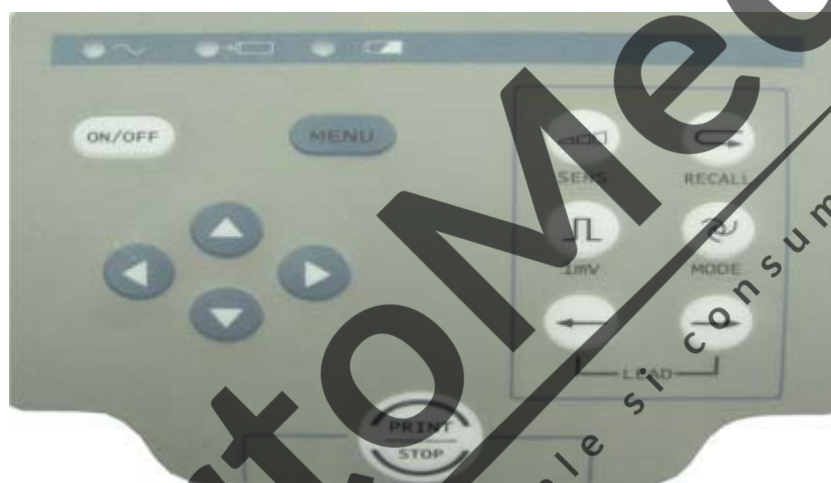


Figure 3-2 CM300 Main Interface

No.	Name	Explanation
A	Lead State Diagram	Show the falling off state of the lead, white color shows that the lead is connected and black point shows the falling off state of the lead.
B	Rhythm Lead	Rhythm Lead Modes: Auto/Manual/Rhythm
C	ID	Patient ID
D	Printing Speed	The selection of printing speed: 5mm/s、10mm/s、12.5mm/s、25mm/s、50mm/s
E	Sex	Sex: Male/Female
F	Gain	Gain: AGC、2.5mm/mV、5mm/mV、10mm/mV、20mm/mV、10/5mm/mV、20/10mm/mV
G	Age	Patient Age
H	Heart Rate	Display the current heart rate values

I	Time / Battery	Display and current time and battery capacity
J	Prompt Information	Display prompt information (“demonstration, lead off, printing, analyzing, sampling” and so on.)
K	Waveform Area	Current Waveform Display
L	Diagram Area	Lead State Diagram

3.1.2 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) SENS Sensitivity Switch Key



The sensitivity switching order:

$\times 10 \text{ mm/mV} \rightarrow \times 20 \text{ mm/mV} \rightarrow \text{AGC} \rightarrow \times 2.5 \text{ mm/mV} \rightarrow \times 5 \text{ mm/mV}$

3) Recall Key(Just for the device with 320×240 dot single color LCD Screen)



Press this key to review the patient records that saved in the record window.

4) 1mV Calibration Key



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

Under auto mode, this key can be pressed to review the electrocardiogram that recorded last time.

5) MODE Mode Switch Key



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

Note: The detailed automatic mode is set in MENU.

Table 3-1 Lead Switching order of Different Mode

Mode	Switching Order (from left to right)			
AUTO(Standard3/3)	I/II/III	AVR/AVL/AVF	V1/V2/V3	V4/V5/V6
AUTO(Cabrera3/3)	AVL/ I/-AVR	II /AVF/ III	V1/V2/V3	V4/V5/V6
MANUAL	In this mode, need to press Lead Switch Key to change the lead , the lead switch order can be that of AUTO(Standard3/3) or AUTO(Cabrera3/3), which is determined by settings of lead sequence and print format in the MENU			

6) LEAD Switch Key



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

7) PRINT/STOP Key



Used to begin recording and stop recording.

8) ON/OFF Key



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

9) MENU Key

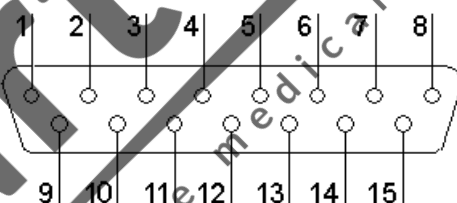


Press this key to enter menu settings.

3.2 Patient Cable Socket and Signal Interface

There are sockets including the patient cable socket, RS232 socket, external input/output socket and USB interface (reserved) at the right side of the main unit as **Figure 3-1** shows.

1) Patient Cable Socket



⚡: Applied part of type CF with defibrillator proof

⚠: Attention – see accompanying document

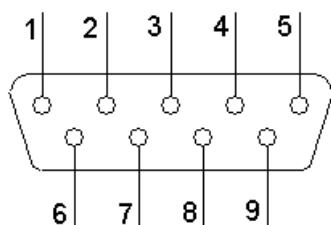
Definition of corresponding pins:

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

2) RS232 Socket

⚠️ WARNING ⚠️:

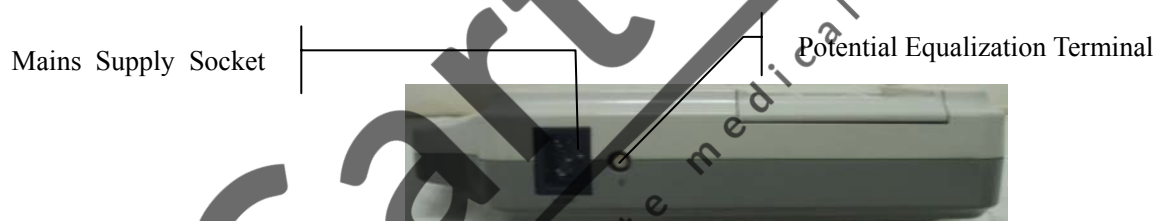
RS232 interface is 1500V AC isolated intensity and the maximum voltage applied should not exceed +15V DC.



Definition of corresponding pins:

Pin	Signal	Pin	Signal	Pin	Signal
1	NC	4	NC	7	NC
2	RxD (input)	5	GND	8	NC
3	TxD (output)	6	NC	9	NC

3.3 Mains Connection and Switch



1) Potential Equalization Terminal



Potential equalization conductor provides a connection between the unit and the potential equalization bus bar of the electrical installation.

2) Mains Supply Socket

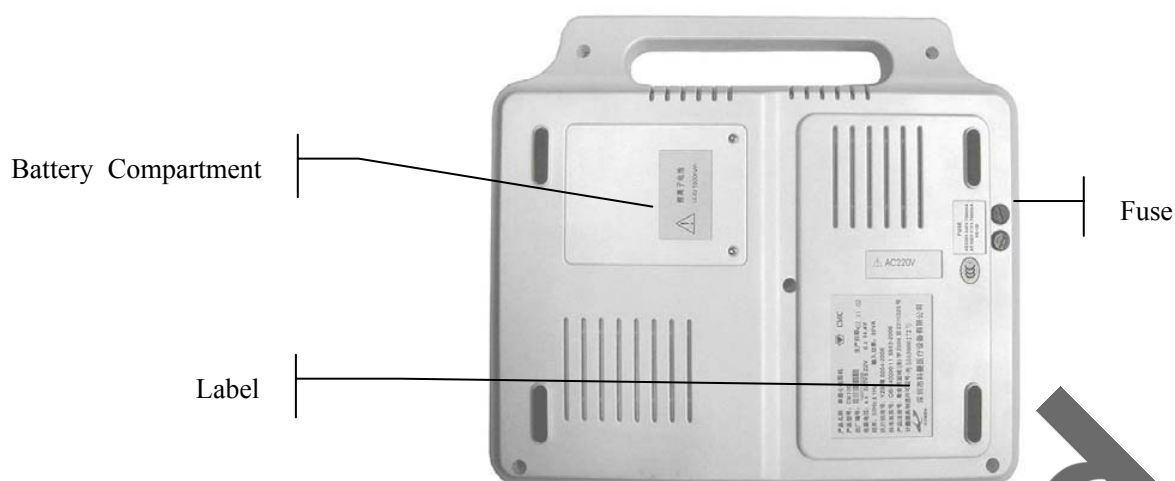
~ POWER: alternating current supply socket

3) Power Switch

| : Switch on

○ : Switch off

3.4 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: 2000mAh.

⚠ 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** ⚠:

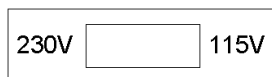
When leakage or foul smell found, stop using the battery immediately. If the leakage liquid gets to your skin or cloth, cleanse it with clean water at once. If the leakage liquid gets into your eyes, do not wipe them. Irrigate them with clean water first and go to see a doctor immediately.

⚠ **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.

2) Mains Supply Shift Switch



Mains supply with rated input voltage 230V (220V~240V) or 115V (100V~115V) can be chosen by the shift switch according to local mains supply specification.

⚠ WARNING ⚠: Only qualified installation or service engineer can shift the mains shift switch according to local mains supply.

3) Fuse

There are two same fuses installed on the bottom of the main unit. The specification is: (T200mA 250V Ø5×20)

⚠ WARNING ⚠: Ruptured fused must only be replaced with the same type and rating as the original.

Chapter 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: 100V~115V or 220V~240V

Rated frequency: 50Hz

Rated input power: 35VA

Make sure the mains supply meets the above requirements before power on. And then press the mains power switch to power on the unit.

If the built-in rechargeable battery is weak when mains supply used, it will be recharged automatically at the same time.

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. Because of the consumption during storage and transport, the capacity of battery may not be full. If the battery capacity is obviously weak, please recharge the battery first. the usage life of the battery is up to 300 times, please replace the battery with new one. Please refer to the maintenance section for how to recharge the battery. During recharging the battery, the machine can be powered by mains supply at the same time.

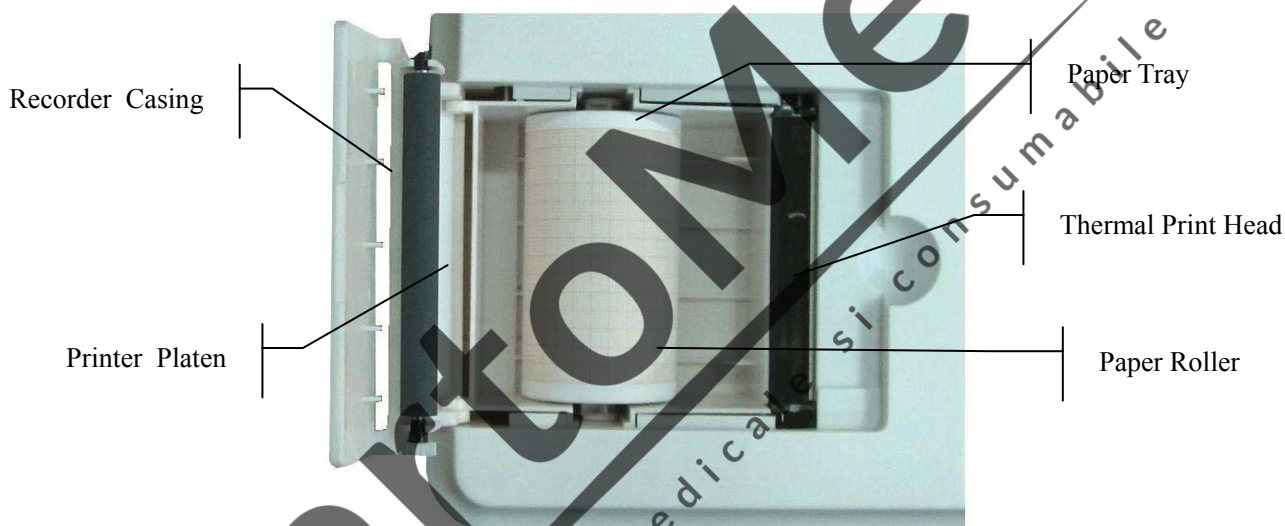
⚠WARNING⚠: Potential equalization conductor of the unit should be connected to the potential equalization bus bar of the electrical installation when necessary.

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 80mm width, and the other is folded thermosensitive paper with 80mm width.

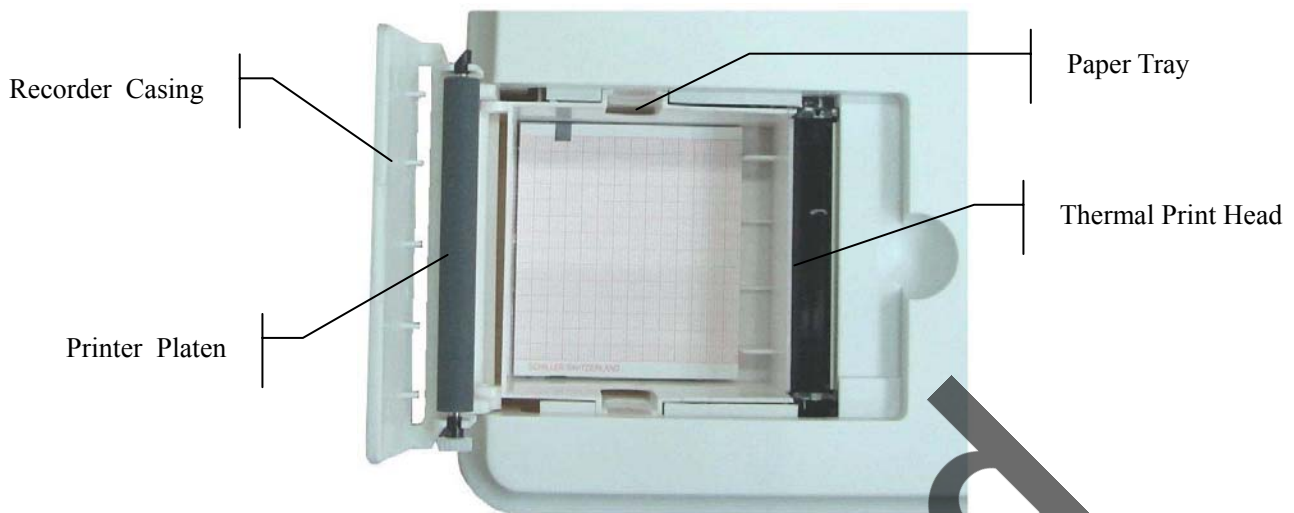
Note: When using folded thermosensitive paper, the Paper Roller is unnecessary, and it can be taken out.

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) Place fingers under the flange of the recorder casing, pull upwards directly to release the casing;
- 2) Take out the paper roller, and remove remain paper from the left of roller if necessary;
- 3) Take off the wrapper of thermosensitive paper roll, and then put through the roller from the left with the paper's grid side facing downward;
- 4) Place the paper and roller gently in the recorder with the roller pin on the roller's left side facing to the groove;
- 5) Pull about 2cm of paper out, and put down the recorder casing;
- 6) Secure the casing by pressing it firmly.



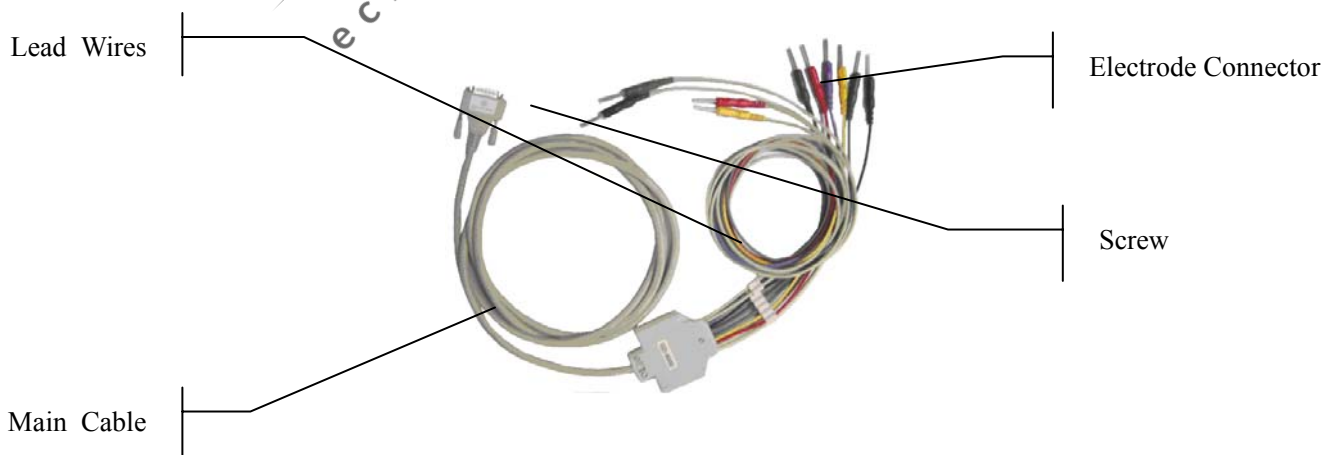
Loading/Replacing Process for Folded thermosensitive paper:

- 1) Place fingers under the flange of the recorder casing, pull upwards directly to release the casing;
- 2) Remove remain paper in the Paper Tray if necessary;
- 3) Take off the wrapper of folded thermosensitive paper, and then put it in the Paper Tray with the paper's grid side facing upward and the thermal print head;
- 4) Pull about 2cm of paper out, and put down the recorder casing;
- 5) Secure the casing by pressing it firmly.

4.3 Patient Cable Connection

⚠️WARNING⚠️: The performance and electric shock protection can be guaranteed only if original our company patient cable and electrodes are used.

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.

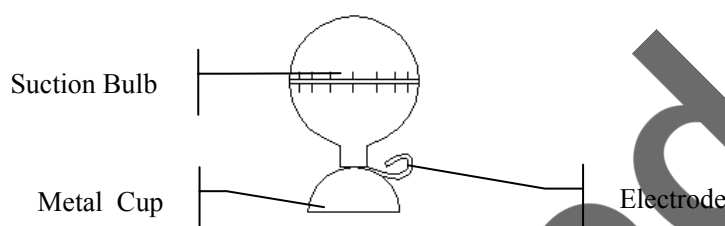


Connect Main Cable:

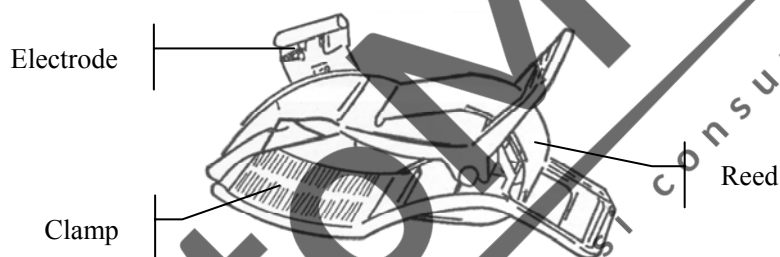
Plug the connector of main cable into the patient cable socket on the right side of the unit according to the direction of arrow on the plug, and then secure it with two screws.

4.4 Electrodes Connections

Chest Electrode:



Limb Electrode:



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

Electrodes	European		American	
	Identifier	Color code	Identifier	Color code
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/orange

Chest 5	C5	White/black	V5	Brown/orange
Chest 6	C6	White/violet	V6	Brown/violet

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

C1: Fourth intercostals space at right border of sternum

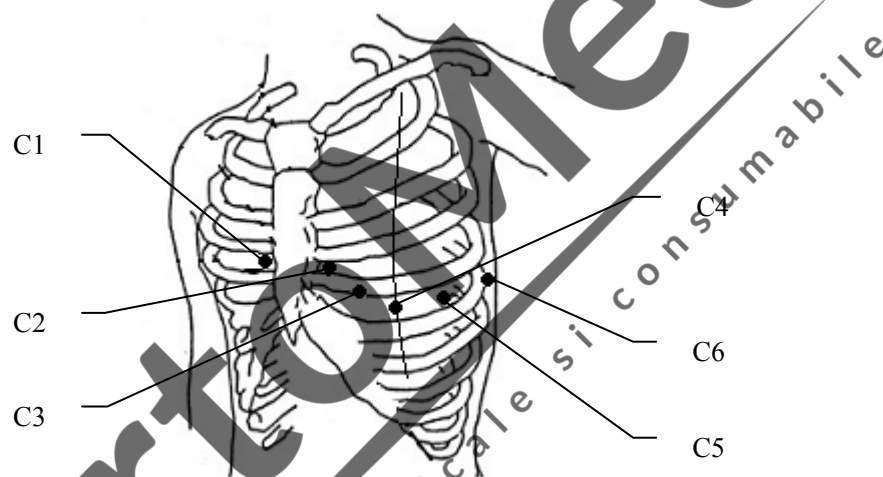
C2: Fourth intercostals space at left border of sternum

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.

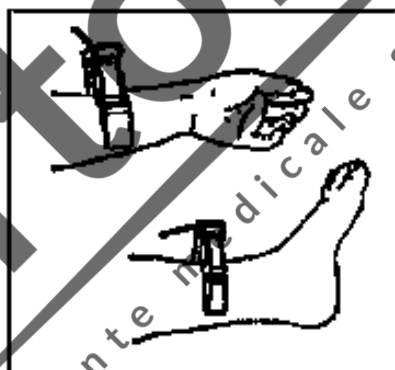
Chest electrodes connection:

- 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 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.

Chapter 5 Operation Instructions

5.1 Switching On

- ◆ While using mains supply, press the power switch on the 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. Equipment information such as manufacturer, device name, version No. and website address will be displayed on LCD screen after self-test. Then the machine 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 () is lit. After self-test, the machine is ready for examination and recording.

5.2 Automatic Mode

Automatic recording mode is provided by the machine. The lead switching orders under different modes are listed in Table 3-1.

Under automatic mode, leads will be switched in order automatically while recording ECG. That means when the ECG signal from one lead has been recorded for the set length such as 3 seconds, it will be switched to the next lead and begin recording another ECG signal. And there is a pause for several seconds before recording the next ECG. Moreover, a 1mV calibration pulse will be printed on the record automatically before ECG.

Operation Method:

- 1) Press **MODE** key to choose automatic mode, which will be displayed in the top right corner on LCD screen;
- 2) Press **PRINT/STOP** key to begin recording. It will stop automatically after printing out a full 12-lead ECG.

Pressing PRINT/STOP again during the course of recording can stop printing. However, when begin record later, ECG will be recorded in order from the first lead again. And ID number will change automatically according to the current time. If the ID number needs not to be changed, the user should adjust it before recording.

Note: Recording mode can not be changed during the course of printing. Stop recording before choose recording mode.

5.3 Manual Mode

Under MANUAL mode, users can determine which lead need to be recorded and set the record settings or other parameters according to different leads.

Operation Method:

- 1) Press **MODE** key to choose MANUAL mode, which can be discerned by the identifier in the top right corner of LCD screen;
- 2) Press **LEAD** left arrow or right arrow key to select the 3 leads to be recorded;
- 3) Press **MENU** key to set the record settings or other settings. Press it again return after setup;
- 4) Press **PRINT/STOP** key to begin recording;

5) **1mV** calibration key can be pressed to print out 1mV pulse wave in the record while ECG recording;

6) Press **PRINT/STOP** key to stop printing after finishing ECG record.

LEAD left and right arrow key can be pressed to switch the lead during the course of recording.

5.4 ECG Recall

Once the recall prompt message “COPY” appears on the bottom right corner of LCD screen, it means the ECG data is ready to be recalled.

Operation for ECG RECALL:

- 1) Press **RECALL** key to enter the record window where patient records saved;
- 2) Press **ID** up or down key to choose one of the records in the record window;
- 3) Press **M/F** key or **AGE** key, and four operation buttons will come up on the bottom of record window. They are **DELETE**、**TRANSMIT**、**PRINT** and **BACK**;
- 4) Press **ID** up or down key to choose **PRINT** button, and then press **PRINT/STOP** key or **M/F** key or **AGE** key to begin recording;
- 5) After finish recording, press **ID** up or down key to choose **BACK** button, and then press **PRINT/STOP** key or **M/F** key or **AGE** key to return to the record window without operation buttons;
- 6) Press **RECALL** key to return to the main interface.

Pressing **PRINT/STOP** again during the course of recording can stop printing.

The user can also press **ID** up or down key to choose the other operation buttons to carry out the relative functions. And the operation method is the same as the above.

Note: To save the ECG data to the record window as patient records, please refer to **5.6.3.4 Save Option Settings**.

5.5 Using the menu system

5.5.1 Entering and exiting the menu

Press the **MENU** key to enter one of the setup windows. And press the **MENU** key again to exit the menu.

There are four Setup windows in the menu, REGISTER, GENERAL, PRINT, and SYSTEM.

	Register	Ge.	Pr.	Sy.
NAME	:			
SEX	: Male			
AGE	: 35			
HEIGHT (cm)	: 0			
WEIGHT(kg)	: 0			
SYS(mmHg)	: 0			
DIA(mmHg)	: 0			
HOSPITAL	:			
DOCTOR	:			

320×240 dot single color LCD Screen

5.5.2 Moving in the sub-menus

Press **UP** arrow key or **DOWN** arrow key to choose the setting items;

5.5.3 Parameter modification

Press **LEFT** arrow or **RIGHT** arrow key to modify a parameter;

5.6 Settings

5.6.1 Register Settings

Press Menu key to select “Setting” Menu, select the “Register”, as shown in the following figure:

	Register	Ge.	Pr.	Sy.
NAME	:			
SEX	: Male			
AGE	: 35			
HEIGHT (cm)	: 0			
WEIGHT(kg)	: 0			
SYS(mmHg)	: 0			
DIA(mmHg)	: 0			
HOSPITAL	:			
DOCTOR	:			

Register Interface

Select the Sub-item of the Register Setting Window

Press the arrow keys group to select the five options settings of “Register, Lead Options, Filter Options, Print Options and System Options”. Press the arrow keys group to set a submenu.

(1) Input the Characters

Input the patient information on the “Register” setting interface:

The diagram illustrates the 'Character Input Interface'. At the top, there is a label '姓名:' (Name) followed by a long horizontal text entry field. Below this field is a numeric keypad with four rows of buttons. The first row contains digits 1 through 0, followed by '-' and '='. The second row contains letters q through l. The third row contains letters a through /, followed by a space key. The fourth row contains letters z through ., followed by a space key. To the left of the keypad is a 'SPC' button, and to the right is a 'DEL' button. Below the keypad is a long horizontal text entry field.

Character Input Interface

Inputting Method:

Press MENU key to Patient Information Setting item

Press the up and down arrow key to move the cursor to “Name” menu, then press the left and right key of the combination keys to the editing window.

Press the corresponding arrow group keys, then press START/STOP key to confirm the selection. To delete the input information, press the RECALL key.

In the editing window, press MODE to switch big or small letters.

Press MENU key to back to the upper menu

Edit the hospital, doctor, parameters or other items in the setting window of the “Register” setting menu, the parameters setting and characters input are same as described above.

For age, height, weight, blood pressure setting, press the figure keyboards to set up.

Note: In the recording process, the patient information can not be modified.

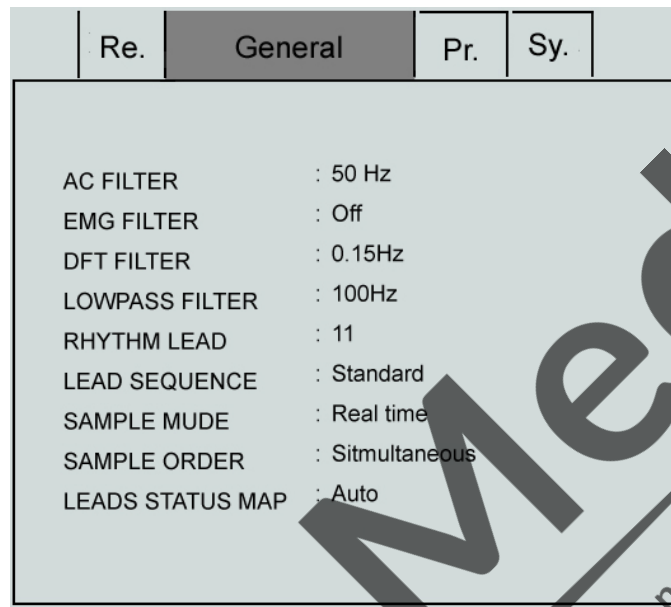
- (1) NAME: Patient’s Name (Letters: not more than 20 characters; English: not more than 10 letters)
- (2) SEX: Sex of the Patient (Male/Female)
- (3) AGE: Patient’s Age (Range: 0~99)
- (4) HEIGHT (cm): Patient’s Height (Range: 0~999)
- (5) WEIGHT (kg): Patient’s Body Weight (Rand: 0~999)
- (6) SYS (mmHg): Patient’s Systolic Pressure
- (7) DIA (mmHg): Patient’s Diastolic Pressure

(8) HOSPITAL: Hospital Name (Letters: not more than 20 characters; English: not more than 10 letters)

(9) DOCTOR : Doctor's Name (Letters: not more than 20 characters; : not more than 10 letters)

5.6.2 General Settings

Press the “MENU” key to enter the “Setting” menu, select the “General” as shown in the following figure:



General Interface

Filter setting menu includes 4 filter settings: AC filter, EMG filter, drift filter and lowpass filter.

- (1) AC FILTER: 50HZ, 60HZ and off

AC filter is used to resist the interference of the AC power supply to avoid the reducing or distortion of the ECG signal.

- (2) EMG FILTER: 25HZ, 35HZ, 45HZ and off

EMG filter is used to resist the interference on the ECG signal caused by strong muscle vibration. The cutoff frequencies the user can select are 25Hz, 35Hz, and 45Hz or turn off.

- (3) DFT FILTER: 0.05Hz, 0.15Hz, 0.25Hz and 0.50Hz

Drift filter is used to resist the drift of the baseline and ensure the ECG signal is on the baseline in the recording process. The set option values are the lower limits of the frequency range which include four options such as 0.05Hz, 0.15Hz, 0.25Hz and 0.5Hz.

- (4) LOWPASS FILTER: 70HZ, 100Hz and 150Hz

Lowpass filter is used to limit the bandwidth of the input signal and reduce the signal with the frequency higher than the set cutoff frequency. The cutoff frequencies the user can select are 70Hz, 100Hz or 150Hz.

- (5) RHYTHM LEAD : “I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6”.

- (6) LEAD SEQUENCE: Standard and Cabrera

Lead Order: as shown in the following table

Lead Order	Lead Group 1	Lead Group 2	Lead Group 3	Lead Group 4
Standard	I, II, III	aVR, aVL, aVF	V1, V2, V3	V4, V5, V6
Cabrera	aVL, I, -aVR	II, aVF, III	V1, V2, V3	V4, V5, V6

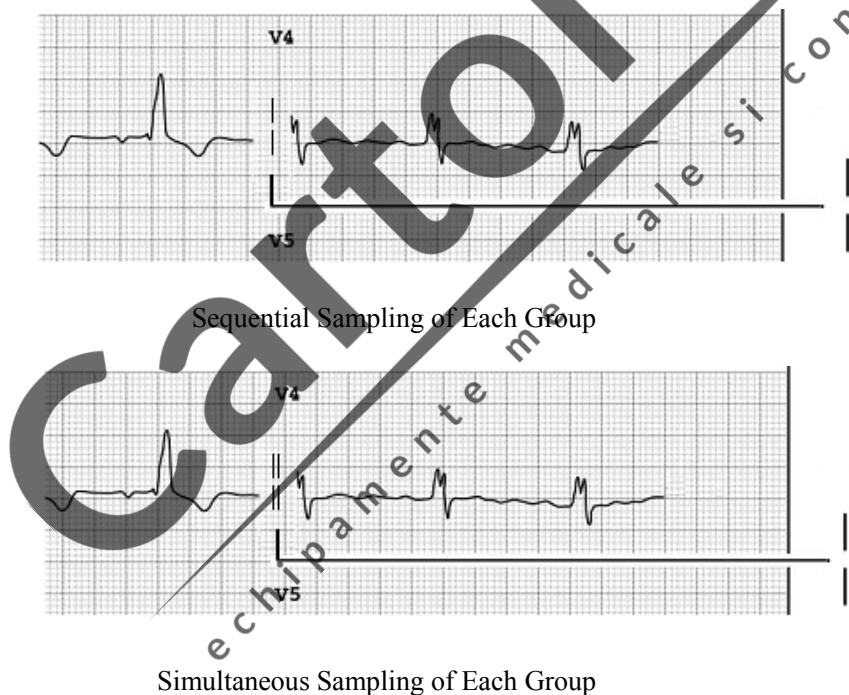
(7) SAMPLE MODE: Real time and Pre-sampling

When the sampling mode is set as real-time sampling, the user press the “START/STOP” key or “START/STOP” key, then ECG data of 10 seconds after pressing of the key will be recorded and output.

When the sampling mode is set as pre-sampling, once the leads connect with the patient the ECG data will be collected and it is not necessary to wait for the user to press the START/STOP key to collect the ECG data. After the user press the START/STOP key, ECG data of 10 seconds after pressing of the key will be recorded and output.

(8) SAMPLE ORDER : Simultaneous and Sequential

In the sequential sampling of each group, “|” shows in the place of printing lead waveform; and in the Simultaneous sampling of each group, “||” shows in the place of the printing lead waveform. As shown in the following figure:



(9) LEADS STATUS MAP: Auto, on and off

Note: LEADS STATUS MAP is a reference to the conductivity of ECG leads. WHITE color to well connected, BLACK color to the failure connect.

5.6.3Print Settings

Press the MENU key to enter the “Setting” menu, select the “Print” as shown in the following figure:

Re.	Ge.	Print	Sy.
RECORD LENGTH		: 3s	
RECORD SPEED		: 25mm/s	
CHANNEL FORMAT		: 3x4+1R	
REPORT TEXT		: Detailed	
AVERAGE TEMPLATE		: Off	
SAVE OPTION		: Print & Save	
PAPER STYLE		: Folded	
PRINTER TEST		: Off	

Figure 5-6 Print Interface

(1) RECORD LENGTH : 3S,6S,10S.

(2) RECORD SPEED: the paper driving speed of the recorder, there are five options for the user to set such as 5mm/sec, 10mm/sec, 12.5mm/sec, 25mm/sec and 50mm/sec.

Note: For the rhythm mode and automatic mode, the print only supports the paper driving speed of 25mm/s and 50mm/s.

(3) CHANNEL FORMAT: 3×4, 3×4+1R, 12×1., 1x12+1R

When it is set as 3×4, 12 leads are recorded in 3 channels and 4 sequences, record 2.5 seconds for each sequence.

When it is set as 3×4+1R, 12 leads are recorded in 3 channels and 4 sequences, record 2.5 seconds for each sequence and add 1 channel of rhythm lead waveform.

When it is set as 12×1, 12 leads are recorded in 12 channels and 1 sequences, record 2.5 seconds for each sequence.

When it is set as 12×1+1R, 12 leads are recorded in 12 channels and 1 sequences, record 2.5 seconds for each sequence and add 1 channel of rhythm lead waveform.

(4) REPORT TEXT: Off, basic, detailed.

When it is set as “Off”, there is only information set in the “Register”;

When it set as “Basic”, the print information include: information set in the “Register”, interval, electrical axis, amplitude, etc;

When it is set as “Detailed”, the print information include: information set in the “Register”, interval, electrical axis, amplitude, Minnesota code, diagnosis information, etc.

(5) Average Template: 4×3, 6×2+1R, Off.

When it is set as 3×4, 12 leads of average template waveforms are recorded in 3 channels and 4 sequences .

When it is set as 6×2+1R, 12 leads of average template waveforms are recorded in 6 channels and 2 sequences and add 1 average template waveform of the rhythm lead.

When it is set as “Off”, there is no average template output.

(6) SAVE OPTIONS: Save only, Print&Save, off

When the storage option is set as “Save only”, the ECG data recorded under the automatic working mode will be stored in the document management “File” interface automatically.

When the storage option is set as “Print&Save”, the ECG data recorded under the automatic working mode will be printed out, and stored in the document management “File” interface automatically in the same time.

When the storage option is set as “off”, the ECG data recorded under the automatic working mode will not be stored in the document management “File” interface.

(8) PAPER TYPES: rolled, folded.

There are two kinds of record paper supported by the twelve-channel electrocardiograph: rolled thermosensitive record paper and folded thermosensitive record paper. When no record paper is loaded or the record paper is used up, “Lack of Paper” will display on the LCD screen to remind the user of loading or replacing the record paper.

Note: If incorrect paper type is selected, the equipment may not print normally.

Types and Specifications of the Paper: specification of the rolled paper: 80mm×20m; specification of the folded paper: 80mm×20m

(9) PRINTER TEST: Off, testing. In the print head test the triangle wave is printed normally.

⚠ WARNING ⚠: When the printer is abnormal, it must be maintained by the qualified engineer. The modification and maintenance should be conducted by the personnel authorized by the Our Company; otherwise Our Company will not be responsible for the safety, reliability and performance of the instrument.

5.6.4 SYSTEM Settings

Press the MENU key to enter the “Setting” menu, select the “System Options” as shown in the following figure:

Re.	Ge.	Pr.	System
LANGUAGE : English DEMO MODE : Off KEY BEEP : Off QRS BEEP : Off EXTERN IN/OUT : Off DEFAULT CONFIG : Restore IP ADDR : 192.168.1.1 2005-6-15 6:05 CMECG V2.00			

System Interface

- (1) LANGUAGE: The user can set the language set on the display screen in the electrocardiograph and the language used in the ECG records. English and English are provided to select.
- (2) DEMO MODE: On, Off.

⚠WARNING⚠:

Waveform demonstration is the simulated demonstrate waveform set by the manufacturer to show the equipment performance and help the user to conduct training. In the practical clinical application, demonstration waveform is forbidden to use, because it is easier to mislead the medical personnel to consider it as the monitored patient waveform and parameters and which may affect the patient care and delay the diagnosis and treatment of the disease.

- (3) KEY BEEP: On, off.

Key tone is the brief “Di” sound send out by the equipment when the user presses the keys on the keyboard. When it is set as “off”, there will be no sound when pressing the key.

- (4) QRS BEEP: On, off.

Heartbeat sound volume is the brief “Di” sound send out by the equipment when the R wave is detected in the main interface waveform display and recording process. When the heartbeat sound volume is set as “Off”, there will be no sound.

- (5) EXTERN IN/OUT: on, off
- (6) Default Setting: The user can select whether to recover the default value.

The system default values are shown in the following table:

The system default values are shown in the following table:

No.	Setting	System Default Value
1	Channel Mode	3×4+1R
2	Lead Mode	Standard
3	Sampling Mode	Real-time Sampling
4	Lead State Diagram	Close
5	Sampling Order	Synchronous Sampling of Each Group
6	Rhythm Lead	I
7	AC Filter	50HZ
8	EMG Filter	Close
9	Drift Filter	0.15Hz
10	Lowpass Filter	100Hz
11	Printing Speed	25mm/s
12	Patient Information	Detailed
13	Storage Option	Print and Store

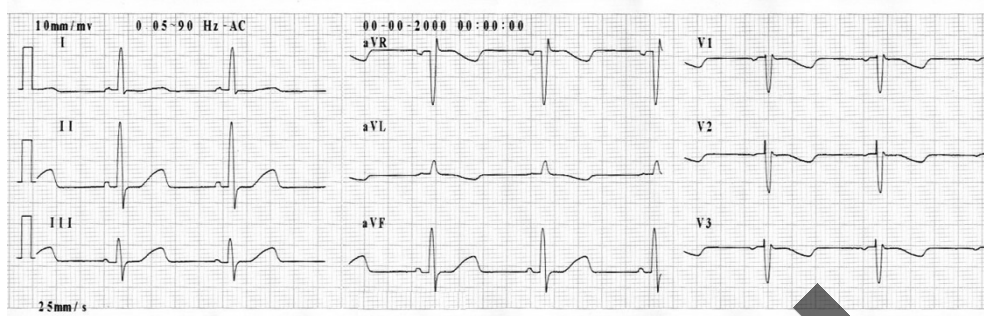
14	Paper Type	Rolled Paper
15	Print Head Testing	Close
16	Average Template	Off
17	Language Setting	English
18	Demonstration Mode	Close
19	Key Tone	Close
20	Keyboard Back Light	Off
21	Heartbeat Sound	Close

(7) Date and Time Settings

The user can set the current date and time which will appear on the thermosensitive record paper in the recording process.

Ver 2.0 (Version Information of the Equipment)

5.7 ECG Record



As the above figure shows, the ECG record includes: sensitivity, filter settings, date and time, 1mV calibration pulse, lead name, ECG, paper speed, heart rate, model of the equipment and version number.

The user can recall the ECG waveform to observe. If the ECG data before the recall is less than 10s, the user need to wait until the electrocardiograph has gathered data for 10s to freeze the operation.

Specific Operation Methods:

Press the “Recall” key on the keyboard and start to recall the ECG, as shown in the following figure;

0712060030	0712060020	0712060010	
0712060029	0712060019	0712060008	
0712060028	0712060018	0712060007	
0712060027	0712060017	0712060006	
0712060026	0712060016	0712060005	
0712060025	0712060015	0712060004	
0712060024	0712060014	0712060003	
0712060023	0712060013	0712060002	
0712060022	0712060012	0712060001	
0712060021	0712060011	0712060000	
Print	Delete	Del All	USB Copy

ECG Recall Interface

- 1) Press Arrow Combination key to choose the record in the memory
- 2) Press “LEAD” key to select “Print, Delete, Delete All, USB Copy”
- 3) Press “MENU” key to confirm “Print, Delete, Delete All, USB Copy” according to the prompt information
- 4) Press “Recall” key to back to the main interface
- 5) USB COPY is option function. Transfer data from ECG to USB disk, then to computer. ECG report can print out from computer directly. PC software has special software to read ECG waveform.

5.8 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 used, press **ON/OFF** key first after finishing ECG record and then switch off the mains supply by pressing the switch on the left side of the unit. Pull off the plug from the outlet last.

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Chapter 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 the machine and corresponding cause is listed in Table 6-1.

Table 6-1 Prompt Information and Causes

Prompt Information	Causes
LEAD OFF	Electrodes fall off from the patient or the patient cable falls off from the unit.
BAT WEAK	The built-in battery is weak.
Smpling/Printing	ECG signal is being sampled/printed.
Copy	The ECG data is ready to be recalled.
Process	The ECG data is being processed.
Transfer	The patient record in record window is being transferred through UART port or TCP/IP.
MemFull	The number of patient records in record window is 60.

Chapter 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.

7.1.1 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.

7.1.2 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.

7.1.3 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

The machine 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 the machine 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: 40uA (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.

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Chapter 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 warrants 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;

Appendix I Accessories and Ordering Information

⚠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.

Table 9-1 Accessories List

No.	Accessory	Quantity
1	Power cord	1 pc
2	Patient Cable	1 unit
3	Chest electrodes	6 pcs
4	Limb electrodes	4 pcs
5	Paper roller	1 pc
6	Thermosensitive paper	1 roll
7	Earth wire	1 unit

The machine and accessories are available by contacting the manufacturer or your local distributor.

Appendix II Technical Specifications

Safety Standards	MDD93/42/EEC, IEC60601-1, EN 60601-1-4, IEC60601-2-25, EN 60601-2-51, EN ISO14971, EN 55011, ANSI/AAMI EC-11	
Classification	Anti-electric-shock type:	Class I with internal power supply
	Anti-electric-shock degree:	Type CF
	Degree of protection against harmful ingress of water:	Ordinary equipment (Sealed equipment without liquid proof)
	Disinfection/sterilization method:	Refer to the user manual for details
	Degree of safety of application in the presence of flammable gas:	Equipment not suitable for use in the presence of flammable gas
	Working mode:	Continuous operation
	EMC:	Group I, type A
Dimensions	277mm×317mm×65mm	
Gross Weight	2.2kg	
Display	320×240 dot single color LCD Screen	
Word Environment	Temperature:	5℃~40℃
	Relative Humidity:	25%~90%(No condensation)
	Atmospheric Pressure:	70kPa ~106kPa
Transport:	Must avoid severe shock ,vibration, rain and snow during transport	
Storage	Packed monitors must be stored in well ventilated rooms with -10℃ ~+40℃ temperature, relative humidity no more than 80%(No condensation), and without corrosive gases	
Power Supply	Mains Supply:	Rated input voltage =220V ± 22V
		Rated frequency = 50HZ ± 1Hz
		Rated input power = 35VA
	Power Consumption:	35VA (max)
	Fuse:	T315mAL 250V、T500mAL 110V $\phi 5 \times 20$
Recording	Recorder:	Thermal dot-matrix printer

	Record Paper:	Folded thermosensitive paper Rolled thermosensitive paper
	Width of the Record Paper	80mm
	Effective Record Width	72mm
	Paper Speed:	5 mm/s, 10mm/s, 12.5 mm/s, 25mm/s, 50mm/s ($\pm 2\%$)
ECG Unit	Leads:	12 standard leads
	Acquisition Mode:	simultaneously 12 leads
	A/D Resolution:	12 bits
	Time Constant:	$\geq 5s$
	Frequency Response:	0.05Hz ~ 150Hz
	Sensitivity:	2.5, 5, 10, 20 (mm/mV), AGC, the error is $\pm 2\%$.
	Input Impedance:	$\geq 50M\Omega$
	Input Circuit Current:	$\leq 50nA$
	Calibration Voltage:	1mV $\pm 1\%$
	Noise:	$< 15 \mu V_{p-p}$
	Multichannel crosstalk	$\leq 0.5mm$
	Filter	AC Filter
		DFT Filter
		EMG Filter
		LOWPASS Filte
	CMRR	$> 100dB$
Communication Interface	RS232	



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