



GIMA

PROFESSIONAL MEDICAL PRODUCTS

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ECG CARDIOPOCKET CARDIOPOCKET ECG ECG CARDIOPOCKET ECG CARDIOPOCKET

Manuale d'uso - User manual Manuel de l'utilisateur - Guía de Uso



ATTENZIONE: Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.

ATTENTION: The operators must carefully read and completely understand the present manual before using the product.

AVIS: Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit.

ATENCIÓN: Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto.

REF 33257 / ECG80A



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PEOPLE'S REPUBLIC OF CHINA
Made in P.R.C.

CE 0123



EC REP

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Instructions to User

Dear Users, thank you very much for purchasing our product.

This Manual is written and compiled in accordance with the council directive 93/42/EEC for medical devices and harmonized standards.

The Manual is written for the current Electrocardiograph. In case of modifications and software upgrades, the information contained in this document is subject to change without notice.

The Manual describes, in accordance with the Electrocardiograph's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details.

Please read the Manual very carefully before using this equipment.

These instructions describe the operating procedures to be followed strictly,

Failure to follow these instructions can cause measuring abnormality, equipment damage and personal injury. The manufacturer is NOT

responsible for the safety, reliability and performance issues and any monitoring abnormality, personal injury and equipment damage due to user's negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.



WARNING:

- All the electrodes connected to the patients directly must be correct and tried.
- Make sure the battery voltage is normal when choosing the UPS.
- The AC power cable and the patient cable could not be enlaced.
- Please peruse the relative content about the clinical restrictions and caution.
- This device is not intended for treatment.

Contents

1	SAFETY	24
1.1	Instructions for safe operations	24
1.2	Warnings	24
1.3	Attentions	24
2	OVERVIEW	5
2.1	Features	6
2.2	Major applications and scope of application	6
2.3	Environment requirements	6
3	PRINCIPLE AND CAUTION	6
3.1	Principle of measurement	6
3.2	Caution	7
3.3	Clinical restrictions	7
4	TECHNICAL SPECIFICATIONS	7
5	ACCESSORIES	8
6	INSTALLATION	8
6.1	Sketch on each side and accessory	8
6.2	Electrode placement	9
6.3	Paper loading:	11
7	OPERATING GUIDE	11
8	THE NOTICE OF THE BATTERY OPERATING	14
9	REPAIRING AND MAINTENANCE	16
9.1	Maintenance	16
9.2	Cleaning	16
9.3	Sterilization	17
9.4	Disinfection	17
10	TROUBLESHOOTING	17
10.1	Automatic switch off	17
10.2	AC interference	17
10.3	EMG interference	18
10.4	Baseline drift	18
10.5	Troubleshooting	19
11	KEY OF SYMBOLS	20
12	FUNCTION SPECIFICATION	21

1 SAFETY

1.1 Instructions for safe operations

- Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect patient's safety and monitoring performance about cables and transducers. It is recommended that the device should be inspected once a week at least. When there is obvious damage, stop using the monitor.
- Necessary maintenance must be performed by qualified service engineers ONLY. Users are not permitted to maintain it by themselves.
- The Electrocardiograph cannot be used together with devices not specified in User's Manual.
- When the cardiac defibrillator be used with other electric stimulate devices, Please select the electrode provided by our company.
- The electrode and its connector of this ECG must keep from other conductor, for example, the earth.
- According the Standard IEC60601, this device is belonged to internal electrical power source, CF applied part. it is applied for cardiac examination. This device is safe and reliable.
- Please select the ECG cable which is provided by our company, if the defibrillation time is over 5 s, you should use one-off chest electrode, which can avoid the metal electrode burn patient's skin. Please don't use it with electric stimulator at the same time, if it is compulsory, a professional technician must guide on the scene.

1.2 Warnings

- Explosive hazard—DO NOT use the Electrocardiograph in environment with inflammable gas such as some ignitable anesthetic agents.
- When other device be joined with this ECG device, it must be accorded with Standard IEC60601, internal electrical power source. because creepage summation may injure the patient, the creepage current be inspected by the other device.
- The disposal of scrap instrument and its accessories (including battery) should follow the local laws and regulations.

1.3 Attentions

- Keep the Electrocardiograph away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- If the Electrocardiograph gets wet, please stop operating it.
- When it is carried from cold environment to warm and humid environment, please do not use it immediately.
- Do not operate keys on front panel with sharp materials.
- Do not have the product immersed in liquid.
- When cleaning the device with water, the temperature should be lower than 60°.
- The design of the instrument is considered sufficiently with the safety requirement, but the observation of the patient and the instrument can not be ignored.
- The instrument has normal useful life for five years since the first electrified use.
- The instrument dose not have low-voltage alarm function, it only shows the battery energy, please change the battery when the battery energy is used out.

2 OVERVIEW

Through the broading market investigation, our company assembles a lot of talents in the following majors: the appearance design of the product, structure design, transmission structure design, and circuit design, they produced ECG successfully after their deep research and reduplicate tests. This equipment adopts the thermal recording mode (the key point of thermal recording technique is the core component---thermal recording probe. The thermal recording probe is the high-tech component with advanced component integrated technology, integrating a large amount of heating elements (8points/millimetre) and its controlled circuit based on the ceramic basal body. It doesn't have the false difference which caused by non-linearity, damping, and incongruence of pen warmth of the traditional hot pen ECG. In the frequency response which is the important index of affecting the descriptive authenticity, the product can reach 0.05-150Hz frequency response which is the world level, aslo the equipment has advanced digital baseline drifting filter, Alternating Current filter, and Myo- electricity disturbance filter. The sampling rate of lead signal is 800Hz, the closure frequency of low pass filter machine with guards against mixes folds is (-3dB) 220Hz. The sampling rate is higher than the standard of not lower than 500Hz which made by American AHA Association and European CSE Association.

2.1 Features

- Operation of the product is simple and convenient.
- The product is small in volume, light in weight (total weight is about 800g including batteries) and convenient in carrying.
- The instrument can be used under AC&DC, with the lithium rechargeable battery inside, and it will record eighty ECG waveform persistently under the best DC conditions.
- Voltage indication will be displayed when power on.
- Classification: internal electrical power source, CF applied part.
- EMC complies with the requirements of IEC60601-1-2:2001 (refer to the appendix 2).

2.2 Major applications and scope of application

This product is single channel,12 leads electrocardiograph ,can be widely applied in ECG check-up under different circumstances such as in hospital consultation, doctor's diagnosis, physical check-up,social medical organizations etc. it can implement real time continuous records of clear and exact single-channel ECG waveform using thermo sensitive printer at the same time. waveforms also can be frozen at any time. It has manual and automatic modes to be chosen and Chinese/English operation interface,it is easy to be used.

2.3 Environment requirements

- a. Ambient temperature: $+5^{\circ}\text{C}\sim+35^{\circ}\text{C}$;
Transportation and Storage Temperature: $-40^{\circ}\text{C}\sim55^{\circ}\text{C}$.
- b. Relative humidity: $<95\%$ (without condensation);
Transportation and Storage humidity: $\leq 95\%$.
- c. Power:
POWER ADAPTOR: Input AC: 100-240V, 50/60Hz;
Output DC: 12V;
DC: 7.4V rechargeable battery;
The instrument could normally work for more than 4 hours under DC supply.
- d. Barometric: 860hPa~1060hPa.

3 PRINCIPLE AND CAUTION

3.1 Principle of measurement

The equipment is constituted by power source system, signal gathering and processing, and controlling system etc. The power source system converts the Alternating Current or battery volt to the stable Direct Current which the equipment needs, meantime, it completes the charge of battery and the conversion of alternating current and direct current. The signal gathering and processing part is responsible for the clustering of input signal, digital filter

and gaining controlling, etc. The controlling system coordinates the operation of print controlling equipment, liquid crystal screen and keyboard driver, it is responsible for the profile print driver, controlling information demonstration, keyboard management and some other control.

3.2 Caution

- 3.2.1** Observe the status of the patients and the instrument momentarily.
- 3.2.2** Use the patient cable only to connect the patient and instrument.
- 3.2.3** Do not move the instrument and patient when the instrument working.
- 3.2.4** Turn off the instrument after using it.
- 3.2.5** Shut off the power supply, remove the patient cable gently without overexertion.
- 3.2.6** Put away the instrument and its accessories for reuse.

3.3 Clinical restrictions

1. If used with heart defibrillator or other stimulating equipment, the silver and silver chloride chest electrode and heart electric conductance line of our company can be chosen. If the defibrillating time surpassed 5, there needs to use disposable chest electrode to resist burning the patients' skin by metal electrode. Please don't use with other electronic stimulating equipment, if it has to, it needs conduction of professors.
2. If other machine used connecting with device, the machines have to fit in with the standard of IEC60601, because the sum total of leakage is able to hurt patients, so the monitor of leakage current is responsible by the inserting side.

4 TECHNICAL SPECIFICATIONS

1. Display Format: LCD Display;
Battery Voltage Indication: three segments display.
2. Power Requirements:
POWER ADAPTOR: Input AC: 100-240V, 50/60Hz;
Output DC: 12V;
DC: 7.4V Lithium rechargeable battery.
3. Input Power: $\leq 55VA$.
4. Sensitivity Setting: 5, 10, 20 (mm/mV), conversion deviation $\leq 5\%$.
5. Fuse Standard: AC 250V/2A.
6. Paper Speed: 25mm/s, 50mm/s $\pm 5\%$.

5 ACCESSORIES

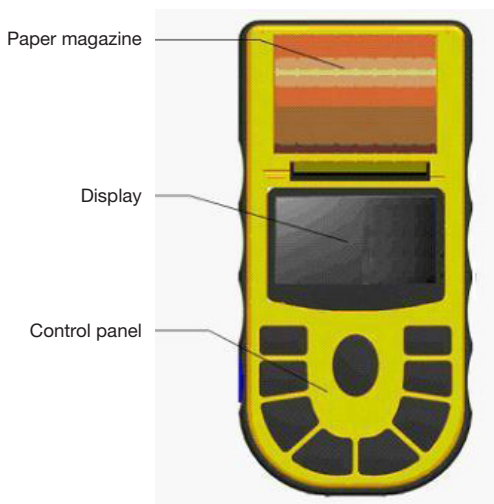
Attention: Followed is the models of accessories provided by the factory. It may damage this equipment if using the accessories with different models.

- Power adapter
(Input AC: 100-240V, 50/60Hz Output DC: 12V)
Attention: User can choose the power cord according the request of local power net and also the safe standard.
Power supply adapter should be accorded with relevant regulation according to IEC60601-1.
- One lithium rechargeable battery DC
(7.4V lithium rechargeable battery; The battery can keep on working for more than four hours when it is fully charged.)
- ECG leads: (BIP0075/BIT0107) ×1
Attention: The equipment must be connected with the lead cable with anti-defibrillate function or lead cable manufactured by us to insure normal operation and safety.
- Suction Bulb: (BGN0001) ×6.
- Clamp: (BIN0015) ×4.

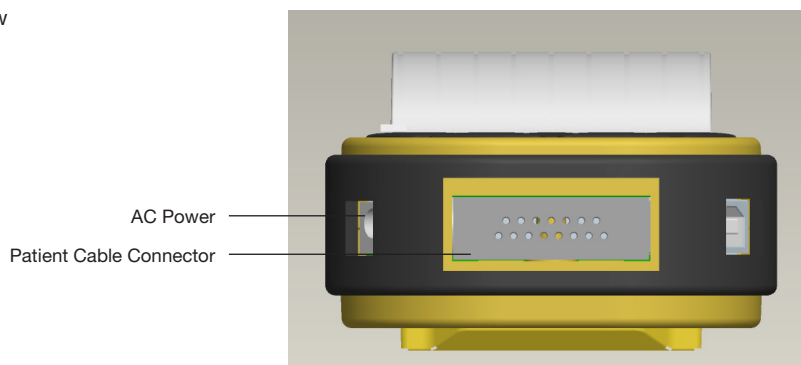
6 INSTALLATION

6.1 Sketch on each side and accessory Sketch on each side and accessory

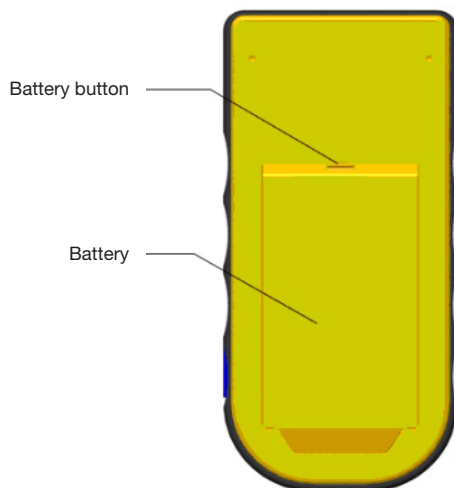
Front view



Bottom View



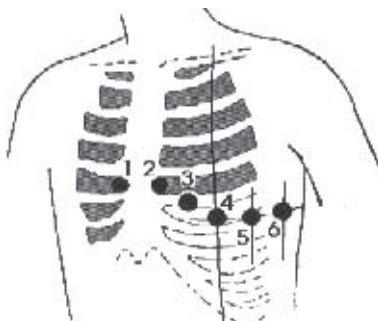
Back View



6.2 Electrode placement

Advice: Set the chest electrode first, then the limb electrode.

6.2.1 Elettrodo del petto:



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-clavicular line.

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

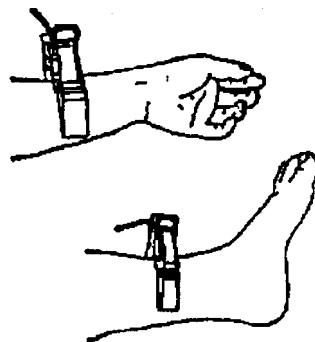
V6: Left mid-axillary line at the horizontal lever of V4.

Clean the positions around to which chest electrodes are to be attached with alcohol, lay the ECG medical gel on dia.25cm area around the position and the edge of chest electrode cap, press the suction bulb, firmly attach the electrodes to the positions between V1 and V6.

Attention: The ECG medical gel coating should be separated, and the touching chest electrode may result in short circuit.

6.2.2 Limb electrode

Place the electrode on the hand and leg, clean the positions around to which limb electrodes are to be attached with alcohol, then lay some ECG medical gel on the cleaned skin.

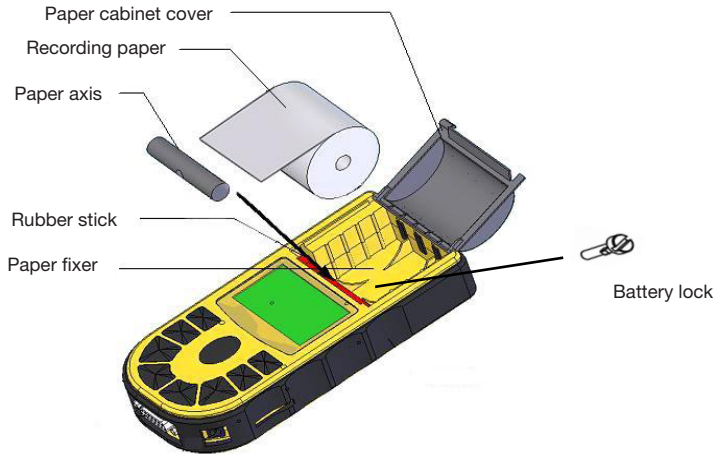


Attention: Tighten the knob after inserting the mainframe patient cable pin in the patient cable socket.

6.2.3 Electrode connection definitions and color code:

Electrode Location	Electrode Code	Line Color	Electrode Color	Socket Number
Right arm	R	Black	Red	9
Left arm	L	Black	Yellow	10
Left leg	F	Black	Green	11
Right leg	RF	Black	Black	14
Chest 1	V1/C1	White	Red	12
Chest 2	V2/C2	White	Yellow	1
Chest 3	V3/C3	White	Green	2
Chest 4	V4/C4	White	Brown	3
Chest 5	V5/C5	White	Black	4
Chest 6	V6/C6	White	Purple	5

6.3 Paper loading:

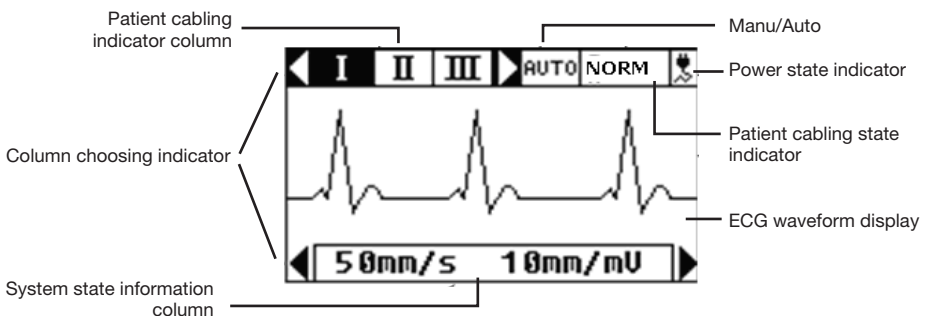


1. The instrument uses 50mm single track wrap-round recording paper.
2. Open the paper cabinet cover, take out the paper axis, and put it into the recording paper according to the illustration, and place the side with gridding adown, then clip them in the relevant position in paper fixer.
3. Close the paper cabinet cover, and protrudes 2cm in the top of the recording paper.







7 OPERATING GUIDE

7.1 The instrument starts self checking after its turning on. In the self checking process.







7.2 The instrument will show the following state after self checking (under DEMO mode):



1. Patient cabling indicator column:

Press the button   to choose the patient cabling indicator column, the guide arrow in the column just turning (for example:  ) , then press the button   to choose the corresponding patient cable, the instrument switches to the corresponding patient cable inspection. The relevant patient cable No. just turn when choosing the patient cable. Press I II III aVR aVL aVF VI V2 V3 V4 V5 V6 to change the order.

2. System state information column:

Press the button   to choose the patient cabling indicator column, the guide arrow in the column just turning (for example:  ) , then press the button   to switch the relevant information, this column is read-only. The state and other indicator information are all read-only. Mode Conversion: shows the mode conversion of the systemic lead, it divides into Auto lead conversion (AUTO) and Manual lead conversion (MANU).

Leading condition indication: it will show “NORM” when the leads collecting signals normally, and “OVER” when the leads fall off or the collected signals too big and results in system saturation.

3. Leads state indication:

When the leads state is “NORM”, you can print the ECG.




When the leads state is “OVER”, you can't print the ECG, please check whether electrodes are placed well.

When the leads state is “SAT”, printed ECG is disordered, please check whether electrodes are placed well.


When the leads state is “DROP”, leads shown on the screen have been off. Please reconnect them.

4. Printing:

Under this conditions, press  to startup the printer's printing-system information setting and the ECG waveform; press  again to close down the printer.

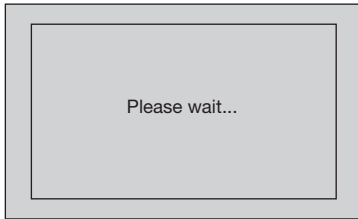
Attention: When there is no paper in the paper cabinet, the instrument will indicate you to install the paper when you press the  or the  button as followings. Press  button to return after installing paper.

5. Calibrating:

Press  button to print a 1 mV standard voltage mark in order to observe the current sensitivity directly.

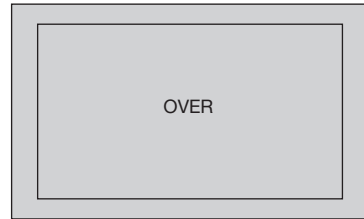
The LCD will display the following picture when in calibrating process:

In calibrating process



English Interface



Ending the Calibrating



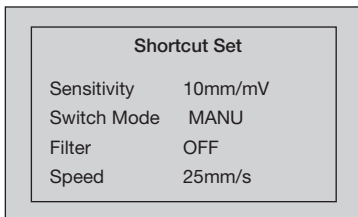
English Interface

Attention: The calibrating process is operated automatically without pressing any button, and it will return after ending the calibrating.

6. Waveform-freezing:

Press  to freeze the current ECG waveform displayed on the LCD in order to preview. Press the  again to renew the operation.

7.3 Shortcut setup menu:



Interfaccia Inglese

1. Short menu:

Press  to enter this interface. Press   to choose the relevant items and the item just turning, then press   button to set the information, and then press  to return.

2. Contents explanation:

Sensitivity: 5mm/mV, 10mm/mV, 20mm/mV, these three types of sensitivities.

Switch Mode: MANU, AUTO, shows the two operation mode: Manual and Automatic.

In the Auto mode, the instrument records the twelve patient cables automatically, three seconds ECG signal each patient cable.

Filter: OFF, 50Hz, 60Hz, 50Hz+, 60Hz+, totally five types of filter, among them, 50Hz+ and 60Hz+ denote the opening of 35Hz EMG filter.

Attention: Switching on the EMG interference filter will fall the range of the recorded R-wave.

Speed: 25mm/s, 50mm/s, totally two types of paper skipping speed mode.

System Manual:

Menu	
Backlight	99s
Contrast	10
Language	English
Demo	ON
About	Ver.

English Interface

3. Short menu:

Press  to enter this interface. Press   to choose the relevant items and the item just turning, then press   button to set the information, and then press  to return.

4. Contents explanation:



Backlight: 0-99 seconds, the time of turning on the backlight, and the backlight normally off when it sets 0 second.

Contrast: 00-20, set the corresponding number according to different types of instrument.

Language: English, Chinese, etc.








Demo: ON, OFF, choose ON in demo when it dose not need to be actual checked.


8 THE NOTICE OF THE BATTERY OPERATING

1. This device includes hermetical chargeable lithium battery, which needn't maintenance. This battery is with perfect automatic charge and discharge circuit. When you connect power supply adapter with alternating current, the charge will be start automatically. When this device is on, an icon  is displayed on top right corner of LCD screen.  means the battery is on charge. The whole charge process needs four hours when it is exhausted.
2. When the battery is full, the device can be operated for four hours, when the battery be used as power supply, An icon of battery will be displayed in the LCD screen of front panel, this icon indicates power of battery. When the battery is power off, the device will turn off automatically; this

setting is for avoiding permanent damage on battery caused by excessive discharge.

3. Please charge the battery after power off. When this device be deposit for long time, the battery should be charge once every six months, this operation will prolong the use –pan of battery.
4. The icon of seven different state of power supply as following:

	AC power is on (no battery)
	The battery is only power supply and its power is full.
	The battery is only power supply and its power is not full
	
	
	The battery is only power supply and its power is exhausted.
	The battery is charging

5. If the battery is full, but the power of battery is exhausted within 10 minutes. Please change new battery. If the battery can't be charged, please change new battery.
6. When the icon  display on screen. Please charge the battery immediately, or the device will turn off.

Warning

- Please don't connect the anode and cathode with lead of battery directly, it will cause danger.
- Please don't put the battery on fire. It may cause explosion.
- Please don't disassemble the battery privately.
- The battery should be taken gently, please don't strike it with other article.

9 REPAIRING AND MAINTENANCE

Attention:

Before cleaning the device, make sure that the equipment is switched off and disconnected from the power line.
If there is any sign that the ECG cable may be damaged or deteriorated, replace it with a new one instead of continuing its application on the patient.

9.1 Maintenance

- Do not open the shell of the instrument avoiding the possible electric shock. Any reparation and update of the instrument must be operated by professional being trained and authorized. Only repair with the accessories produced by our company.
 - The instrument guarantees for one year, and do not arbitrary disassembly.
 - Remove the electric plug when there is power cut, the instrument must be kept cool and dry when it is unused for long time; electrify the instrument every three months.
 - Inspect and maintain of Lead, electrode.
1. The state of leads can be checked by multimeter, please check the leads according to following list. If the resistance between electrode and relevant insert needle is less than 100ohm, the lead is up to grade. Please check the leads periodically, because damage of any lead will cause wrong waveform, the lead can be cleaned by water and soap, be disinfected with 75% alcohol (please don't dip the lead in the liquid).

Lead symbol	R	L	F	RF	C1	C2	C3	C4	C5	C6
Insert needle's position	9	10	11	14	12	1	2	3	4	5

2. Curve and knot of the lead will shorten the leads' lifespan, so please tidy the leads orderly before use, then connect it with ECG machine.
3. The electrode must be reserved in proper way, after long period use, its surface will be oxidated, which may affect test result, so please change the electrode.

9.2 Cleaning

Use fine-hair cloth moistened in mild soap liquid or cleaning agent containing 70% ethanol to clean the equipment.

9.3 Sterilization

To avoid extended damage to the equipment, sterilization is only recommended when stipulated as necessary in the Hospital Maintenance Schedule. Sterilization facilities should be cleaned first.

Recommended sterilization material:

- Ethylate: 70% alcohol, 70% isopropanol;
- Acetaldehyde.

9.4 Disinfection

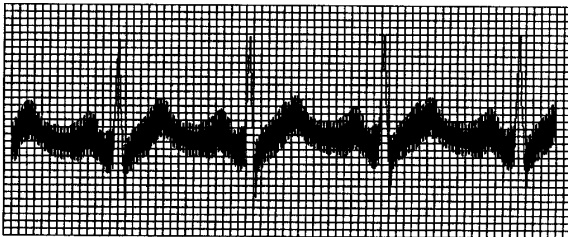
To avoid extended damage to the equipment, disinfection is only recommended when stipulated as necessary in the Hospital Maintenance Schedule. Disinfection facilities should be cleaned first.

10 Troubleshooting

10.1 Automatic switch off

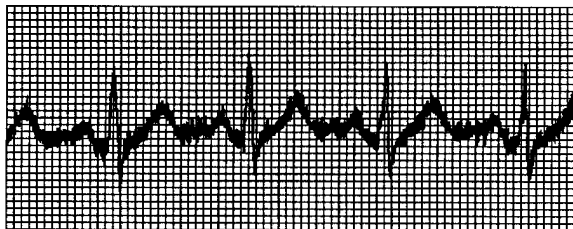
1. Check battery capacity. The instrument has the function of protecting the electrocircuit when the battery is over discharged.
2. Check the AC power voltage. The instrument has the function of protecting the electrocircuit when its overvoltage.
3. Check AC interference, check the knob on the plug of the patient cable. The instrument has the function of protecting the electrocircuit when over loading.

10.2 AC interference



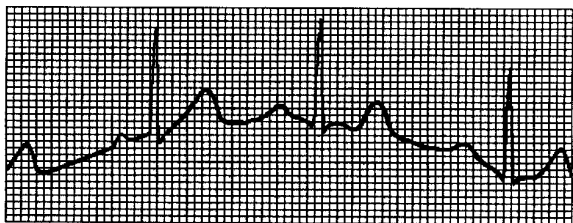
1. Make sure that the unit is properly grounded.
2. Verify the electrode attachment and patient cable wire performance.
3. Daub enough ECG medical gel on the electrodes and patients' body.
4. Make sure that the metal-bed is properly grounded.
5. Keep the patient from contact with the wall or other metal parts of the sickbed.
6. Keep the patient from physical contact with other patients.
7. Check for electrical devices in the surrounding area, X-ray machine, ultrasound equipment.

10.3 EMG interference



1. A comfortable patient room.
2. Soothe the patient from irritation or excitement.

10.4 Baseline drift
























1. Make sure the steady installation of the electrodes.
 2. Verify the electrode attachment and patient cable wire performance.
 3. Check the cleaning of electrode and patient skin. Daub enough ECG medical gel on the electrodes and patients.
 4. Keep the patient from motion or hyperventilation.
 5. Check the connection between patient cable and electrodes.
- Please use filter if still having above-mentioned interference.

10.5 Troubleshooting

Trouble	Possible Reason	Solution
Big interference; Random waveform.	<ol style="list-style-type: none"> 1. V1. It is firm whether the grounding connections. 2. The joint of two sides of conductance line is not stable. 3. AC interference. 4. The patient from irritation or excitement. 	<ol style="list-style-type: none"> 1. Checking ECG leaders, grounding, and Power source. 2. Please make sure the patient is calm.
The baseline possess the burr.	<ol style="list-style-type: none"> 1. AC interference is big. 2. The patient excitement, EMG interference is big. 	<ol style="list-style-type: none"> 1. Improvement environment. 2. If iron and steel bed, Need change. 3. The power source line and joint line of the ECG machine is non- parallel or too near.
The waveform is not Regular; Big undulation, Right line.	<ol style="list-style-type: none"> 1. Electrode electric conductivity is not good. 2. The batteries are drained. 3. The electrode is loose contact against skin. 4. The joint line and leader's plug part is not connection enough. 5. The connection between patient cable and electrodes is not well. 	<ol style="list-style-type: none"> 1. The alcohol of use is asked for well. 2. Use ethyl alcohol to wash electrode wafer and the skin under the electrode. 3. The battery has run out, please charge the lithium battery. 4. The electrode reed tightly clip.
Baseline drift.	<ol style="list-style-type: none"> 1. The batteries are drained. 2. Patient moves. 	<ol style="list-style-type: none"> 1. Be charged to the battery. 2. Keep patients quietly.
The waveform is not understand.	<ol style="list-style-type: none"> 1. There is the filthy matter in the print head face. 2. Paper problem. 	<ol style="list-style-type: none"> 1. The situation of the power off Wash print head by alcohol,it may be print after the alcohol has volatilized. 2. Replace thermal paper which assigned.

11 KEY OF SYMBOLS

Symbol	Description
	Defibrillation-proof type CF applied part
	Warning – See User Manual
	Direction Key: Up
	Direction Key: Down
	Direction Key: Left
	Direction Key: Right
	Keep away from sunlight
	Keep in a cool, dry place
	Please read instructions carefully
	Function key: power supply/acknowledgment/shortcut menu
	Function Key: Pause/On
	Function Key: System Menu
	Function Key: Print
	Function Key: Calibrate
	AC power is on (no battery or full of battery)
	The battery solely powered and the battery is full of electricity
	The battery solely powered and the battery is not full of electricity
	
	
	The battery solely powered and the electric power is going to be used up
	On charging

12 FUNCTION SPECIFICATION

Function	Specification
Cardiograph	LCD
System information	LCD
Battery Requirement	
POWER ADAPTOR: Input AC: 100-240V, 50/60Hz Output DC:12V DC 7.4V lithium rechargeable battery	
Battery Useful Life	
The battery can keep on working for more than one hour when it is fully charged	
Dimensions and Weight	
Dimensions	19(L)×9(W)×4(H)cm
Weight	About 500g (with the batteries)



Disposal: *The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment. For further information on recycling points contact the local authorities, the local recycling center or the shop where the product was purchased. If the equipment is not disposed of correctly, fines or penalties may be applied in accordance with the national legislation and regulations.*

GIMA WARRANTY CONDITIONS

Congratulations for purchasing a GIMA product. This product meets high qualitative standards both as regards the material and the production. The warranty is valid for 12 months from the date of supply of GIMA. During the period of validity of the warranty, GIMA will repair and/or replace free of charge all the defected parts due to production reasons.

Labor costs and personnel traveling expenses and packaging not included.

All components subject to wear are not included in the warranty. The repair or replacement performed during the warranty period shall not extend the warranty.

The warranty is void in the following cases: repairs performed by unauthorized personnel or with non-original spare parts, defects caused by negligence or incorrect use.

GIMA cannot be held responsible for malfunctioning on electronic devices or software due to outside agents such as: voltage changes, electro-magnetic fields, radio interferences, etc. The warranty is void if the above regulations are not observed and if the serial code (if available) has been removed, cancelled or changed. The defected products must be returned only to the dealer the product was purchased from. Products sent to GIMA will be rejected.