

Service Manual of E30 Electrocardiograph

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Chapter I General Introduction

1.1 About the manual

(1) Users of the manual

The maintenance manual of E30 digital multi-channel electrocardiograph (ECG) is targeted to technicians and maintenance workers of biomedical instruments. The users shall have a good mastery of electronic technology (including simulation and digital electronics), and be familiar with microcomputer.

(2) Scope of usage

The maintenance manual serves as reference for professionals to conduct installation, maintenance and repairing of ECG.

(3) Main contents

The manual is composed of:

Chapter I General Introduction

Gives an account of the users, scope of usage, main contents, security information and service information of the maintenance manual.

Chapter II Introduction to ECG

Specifies the composition, appearance, interface and marks of the instrument.

Chapter III upgrade

Introduce the upgrade procedure of the ECG machine.

Chapter IV Disassembling

Includes disassembly procedure of ECG.

Chapter V Clean and Maintenance Includes working out maintenance plan and cleaning ;

Chapter VI Troublem Shooting Gives an account of the testing and troubles of the instrument and the ways of troubleshooting

1.2 Security information

1) Responsibilities of the manufacturer

Our company is responsible for the security, reliability and performance of the ECG under the following circumstances:

- (1) Professionals authorized by our company conduct installation and operation, upgrading of function, readjusting, modification and maintenance;
- (2) The correct rules are followed during the electric installation of connected rooms;
- (3) The instructions are followed to use the instrument correctly.

2) Cautions

- (1) This ECG complies with the security requirements of IEC60601-1.
- (2) Users of the ECG must be well-trained persons who can use the ECG correctly.
- (3) The socket of AC power of ECG can only be connected with the 3-phase wires provided by Company, instead of common wires.
- (4) Only the specified power of AC 100~240V, 50/60Hz or DC 11.1V, 2000mAH can be used for the ECG.
- (5) Only the parts and accessories produced or recommended by our company can be used to ensure the security of users.
- (6) Connect the adaptor with an appropriate grounding socket to avoid the instrument using the same socket with the equipment that switches between ON and OFF frequently, e.g. air-conditioner.
- (7) The ECG shall not be put in places tending to vibrate or shake.
- (8) Leave sufficient space around the ECG to ensure good ventilation.
- (9) Stable ambient temperature and humidity shall be guaranteed to avoid condensation during the operations of the ECG.

(10) Safe Operation Conditions

Methods of sterilization or disinfection recommended by the manufacturer	Sterilization: not applicable Disinfection: Refer to Clean and Maintenance Chapter
Electromagnetic interference	No mobile telephone nearby
Electrosurgical interference	No damage

damage	
Diathermy instruments influence	Displayed values and prints may be disturbed or erroneous during diathermy
Defibrillation shocks	The ECG specifications fulfill the requirements of IEC 60601-2-25

3) Classification

According to the State Food and Drug Administration of China, the ECG is classified as Type II equipment; according to the CE standard, the ECG is classified as Type IIa equipment. And according to IEC 60601-1, the ECG is classified as follows:

types of anti-shock	Type I equipment, with internal and external power source
degree of anti-shock	Type CF applied part, defibrillation protected
degree of protection against ingress liquid	ordinary equipment IPX0 (E30) (closed equipment without protection against liquid).
Degree of protection against explosion	equipment cannot be used when combustible anaesthesia gas mix with air, oxygen or nitrogen monoxide.
working system	continuous working
EMC	Group 1 class A

4) Terms

The terms in the manual (e.g. Caution, Take Care, Attention) point out the hazard, and inform users of the issues they should pay attention to during the operations according to different degrees of severity. Here “hazard” means potential cause that will produce damage to human beings.

Warning: means potential hazard or unsafe behavior that will cause death or serious damage;

Caution: means potential hazard or unsafe behavior that will cause damage to human beings or products;

Note: provides users with useful information and hints, and reminds

users of examination to ensure the ECG realizes its best performance.

1.3 Service information

1) Requirements

Please observe the following requirements:

- (1) Only consult the customer service center of our company for after-sales service of the instrument.
- (2) Damage of the instrument caused by unauthorized maintenance is not within the scope of guarantee for repair.
- (3) Conduct regular maintenance to the ECG according to the preset plan; otherwise, the instrument will have troubles, or even cause damage.
- (4) During the lifespan of the instrument, regular maintenance is one of the necessary measures to ensure the normal use of the ECG.

2) Identification of the instrument

Each of the ECGs produced by our company is attached with a unique production serial number for identification and after-sales service.

3) Consultation by phone

You have made the correct choice for buying ECG with high standards of quality and reliability. Whenever you need help, feel free to dial the after-sales service hotline of Company. Before dialing, please confirm:

- ① You have read the User's Manual, and are sure that the operation is correct.
- ② You have read the installation instructions and answers to difficult problems in the manual, and still cannot solve your problem.
- ③ Before dialing, be sure to get the following information ready:
 - Serial number of the ECG(the label is at the back of the ECG)
 - Type of the ECG (the label is at the back of the ECG)
 - Program version of the ECG
 - Troubles of the ECG

1.4 Signs in this manual



Warning: Indicates a potential hazard or unsafe practice that, if not avoided, will result in death or serious injury.



Caution: Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.



Note: Provides application tips or other useful information to ensure that you get the most from your product.

Chapter II Introduction to ECG

2.1 Usage

ECG is applicable to medical units for patients' ECG collection, analysis of the ECGs collected, and providing of accurate measurement values and reference diagnosis information. It can conduct data saving, review, display and recording of the ECGs analyzed.

Electrocardiograph must be used under guidance of professionals, and is not suitable for family use.



Warning: The cardiograph is intended for use only by clinical professionals or under their guidance. It must only be used by persons who have received adequate training in its use. Anyone unauthorized or untrained must not perform any operations on it.

2.2 Contraindications

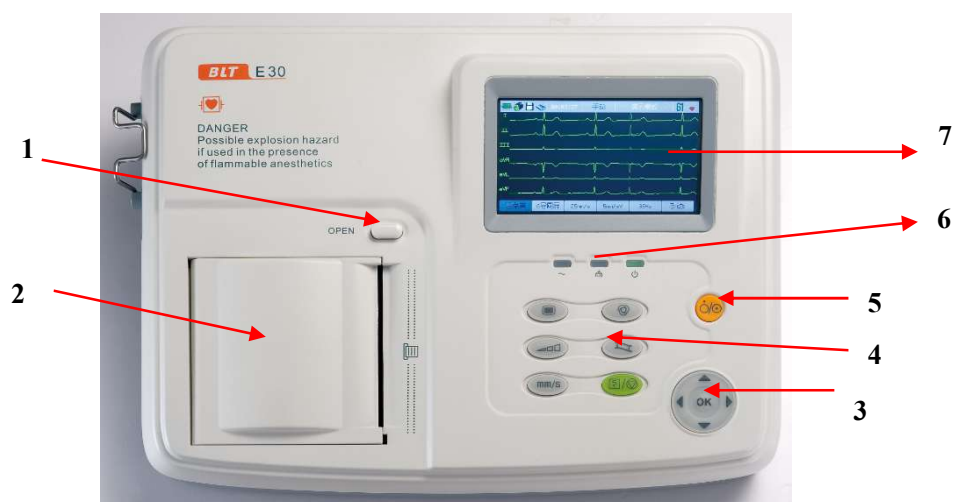
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2.3 Manufacture Config

ECG mainly consists of mainframe, ECG cables and electrodes.




2.4 Main Unit

(1) View

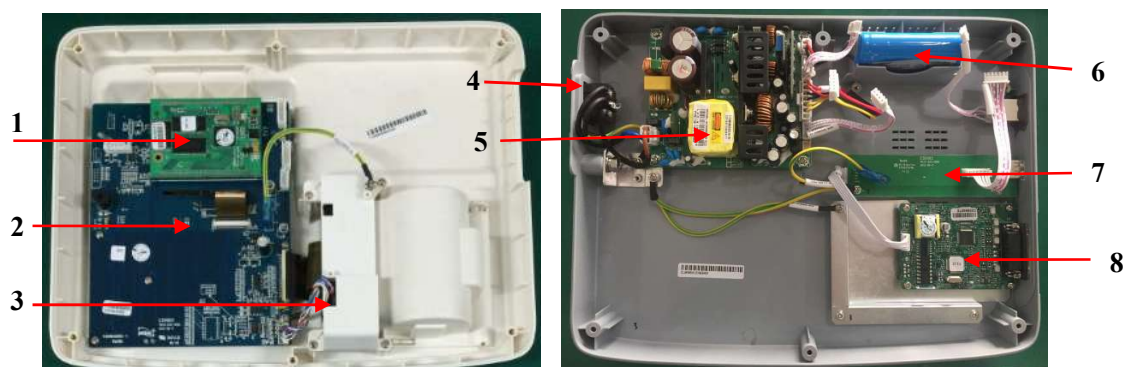


No.	Item	No.	Item
1	Paper bin open button	2	Recorder
3	Direction and confirm button	4	Function button area
5	On/off button	6	Indicator lamp
7	LCD		

Indicating lamp

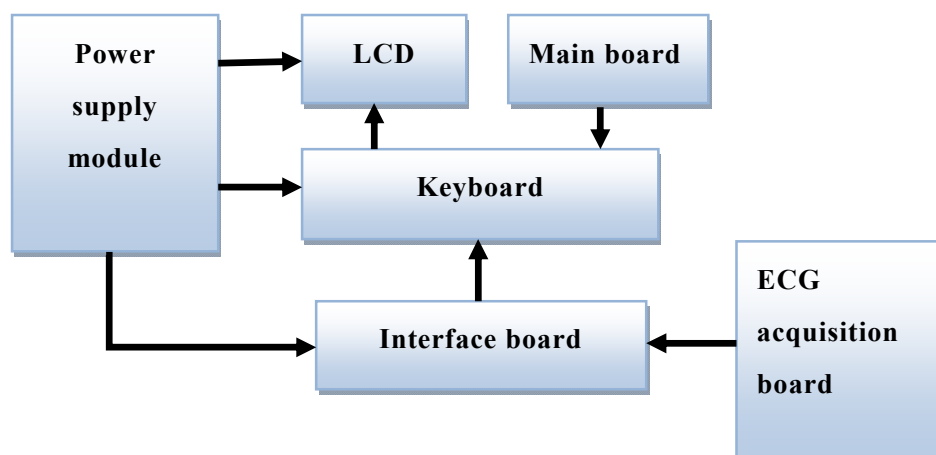
NO.	Name	Note
1	 AC power indicating lamp	Green light turns on if with AC power.
2	 Battery status indicating lamp	Orange light turns on if battery is in process of recharging .The light will be off after recharging finished.
3	 Equipment operation indicating lamp	Green light turns on when equipment is running.

2.5 Inner structure of the ECG machine



No.	Item	No.	Item
1	Main board	2	Keyboard
3	Stepping motor	4	AC power interface
5	Power supply module	6	Battery
7	Interface board	8	ECG acquisition board

2.6 Schematic diagram



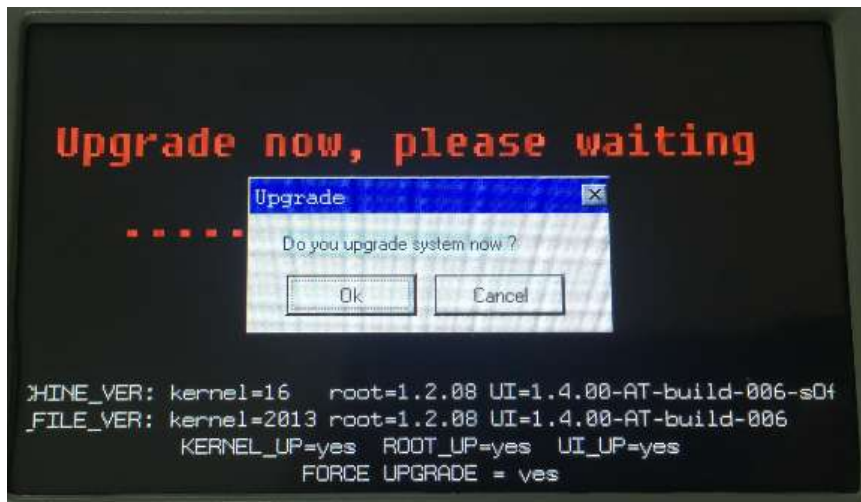
2.7 Accessories



Chapter III Upgrade

Tool : USB disk

- 1) Copy the upgrade file into the USB disk;
- 2) Plug the USB disk to the USB interface;
- 3) Switch on the machine;
- 4) Press enter key and select “OK” when appears the pop-up window “Do you upgrade system now?”;



- 5) Unplug the USB disk and press enter key to reboot;



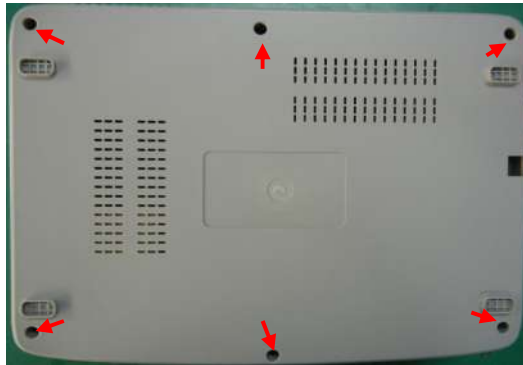
- 6) Upgrade complete;

Chapter IV Disassembling

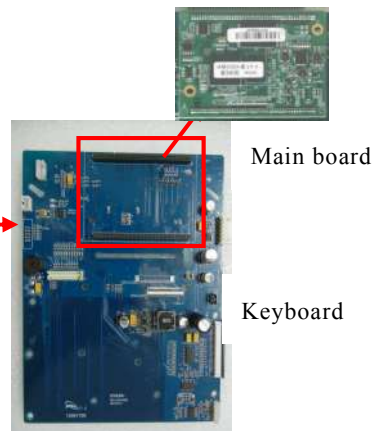
Tool: cross screwdriver

Disassembly procedure:

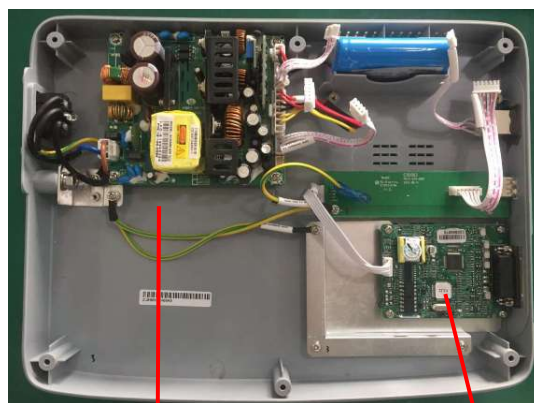
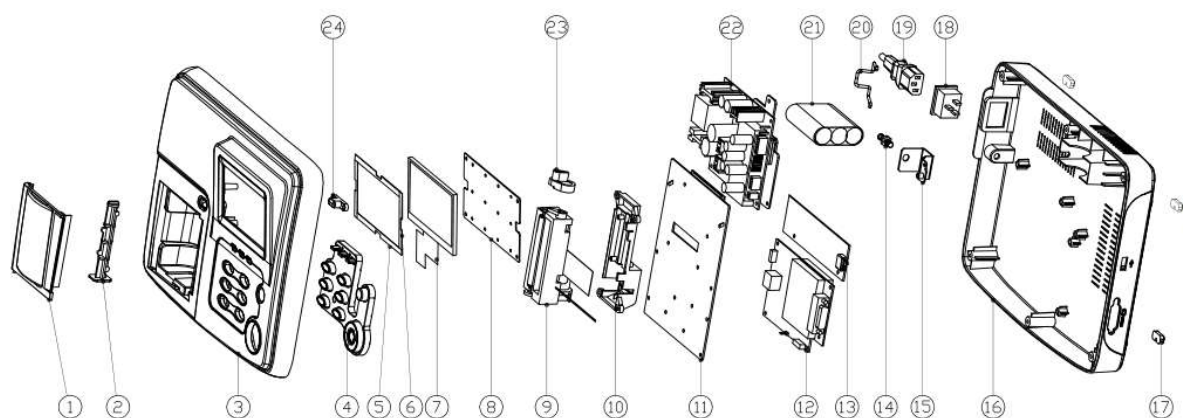
1. Remove the screws and open the machine;



2. Unplug the LCD flat cable and remove the screws and take out the keyboard & main board;



3. Unplug the cables and remove the screws and take out the power supply module, interface board and ECG acquisition board

**Power supply module****ECG acquisition board****Exploded view:**

No.	Item	No.	Item	No.	Item
1	Recorder cover	2	Printing roller	3	Front case
4	Silica gel keypad	5	Sponge A	6	Sponge B
7	LCD	8	LCD fixing plate	9	Recorder
10	Recorder bracket	11	Keyboard	12	ECG acquisition board
13	Interface board	14	Earth terminal	15	Earth plate
16	Rear care	17	Pad	18	AC socket
19	Power code	20	Power code mousing-hook	21	Battery
22	Power supply module	23	Paper bin open button	24	Printer button

Chapter V Clean and Maintenance

4.1 Summarize

Keep your equipment and accessories free of dust and dirt. To avoid damage to the equipment, follow these rules:

1. Always dilute according the manufacturer's instructions or use lowest possible concentration.
2. Do not immerse part of the equipment in the liquid.
3. Do not pour liquid onto the equipment or accessories.
4. Do not allow liquid to enter the case.
5. Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).

⇒ In order to guarantee the normal operating life-span of the device, safety tests in a 6~12 month cycle should be taken. The main contents of test are shown as below:

1. Validating the functions of the electrocardiograph according to the user's manual.
2. Checking whether the electrocardiograph or the accessories is damaged.
3. Processing relevant safety tests according to IEC60601-1.



Warning: Be sure to shut down the system and disconnect all power cables from the outlets before cleaning the equipment.



Caution: If you spill liquid onto the equipment or accessories, contact manufacturer or your service personnel.

4.2 Cleaning of the Electrocardiograph

⇒ Common detergent and non-corrosive disinfectant used in hospital can be applied to clean electrocardiograph, however you must be aware that many kinds of detergents must be diluted prior to utilization, and please use it

according to the instruction of detergent manufacturer.

- ⇒ Avoid the use of alcohols, amino or acetonyl detergent.
- ⇒ The enclosure and screen of electrocardiograph shall be free of dust, and they can be wiped with lint-free soft cloth or sponge soaked in detergent. While cleaning,
Be careful and do not spill liquid onto the instrument and keep any liquid out of it. When wiping the side panel of electrocardiograph, you must be especially careful to keep water out of all kinds of cable and outlet on the panel.
- ⇒ Do not use abrasive material including wire brush or metal brightener during cleaning because this material will damage the panel and electrocardiograph screen.
- ⇒ Do not submerge the electrocardiograph in liquid.
- ⇒ While cable or plug of attachment accidentally gets wet, please rinse it with distilled water or deionized water and dry it in the environment of temperature 40℃ to 80℃ for at least one hour.



Caution:

- **Avoid high temperature.**
 - **Avoid sunshine, dust or bump, and avoid shaken acutely while moving.**
-

4.3 Cleaning and Sterilization of Accessories

1. ECG cable

- a) Please clean cable before disinfection.
- b) Clean the surface of cable by use of soft cloth dipped with appropriate quantity of clean water or neutral soap water;
- c) Dip soft cloth with appropriate quantity of disinfectant, and wipe the cable;
- d) Clean the residual disinfectant on cable by use of soft cloth dipped with clean water;
- e) Air dries the cable at a shady and cool place.



Caution:

- **It is necessary to regularly check the cable and lead wire of the**

patient to ensure their completeness and good conduction;

- **Damaged or aging cable or wire shall be replaced timely;**
 - **In the course of use, tidy up the lead wire as much as possible, and do not pull it forcibly.**
-

2. Chest electrode and limb electrode

- a) Please clean chest electrode and limb electrode before disinfection.
 - b) Wipe off the conductive paste on surface of electrode with soft cloth;
 - c) Take apart the electrode plate and clamp of limb electrode as well as rubber ball and metal cup of chest electrode;
 - d) Put electrode into clean warm water (not higher than 35℃) and clean it to ensure no residue of conductive paste;
 - e) Air dries the electrode at a shady and cool place.
-



Caution:

- **Electrode shall be timely cleaned after use;**
 - **Rubber ball of chest electrode shall be prevented from direct sunlight; otherwise, aging will be caused;**
 - **Electrode with eroded surface shall be timely replaced with new electrode.**
-

Caution:

- ☞ Do not disinfect cable and lead wire with high voltage, radial or steam.
 - ☞ Do not dip cable or lead wire directly in liquid.
 - ☞ To prevent long-term damage to cable, it is suggested that the product be disinfected only when your hospital regulation deems it as necessary.
 - ☞ Do not clean or reuse disposable electrode.
-



Warning: Do not use EtO, phenyl, amido or iodo for disinfection of the machine.



Caution: Disinfection possibly causes damage to Electrocardiograph to some extent. It is suggested that disinfection be conducted only when your hospital maintenance plan deems

it as necessary. The equipment shall be cleaned before disinfection.



Note: Electric schematic diagram and list of components are provided to the qualified maintenance station or personnel certified by the manufacturer only.

4.4 Cleaning and Maintenance of Recorder

To prevent stain on surface of thermosensitive printing head due to excessive long period of use of printer and clarity of recording is adversely affected, the users shall regularly (at least once every month) clean the surface of recording head:

- ⇒ Open the box cover of recorder;
- ⇒ Take out the remaining chart paper;
- ⇒ Gently wipe the surface of recording head by use of clean soft cloth dipped with small quantity of diluted alcohol;
- ⇒ Air dry the recorder at a cool and ventilated place;
- ⇒ Place the chart paper properly, and close the box cover of recorder.

Chapter VI Trouble shooting

E30 Digital Electrocardiograph main parts include: power supply module, main board, keyboard, interface board, ECG acquisition board, recorder and LCD. so, the normal malfunctions(problems) come from those parts. Below are detail normal malfunctions and how to solve them.

1. Power supply module

E30 Digital Electrocardiograph uses a high stability switching power supply which fewly causes problem.

Malfunctions:

- 1、Machine can't start , power indication lamp does not work;
- 2、When AC supply is cut off and using battery supply, ECG machine alarms low power voltage and then shut down automatically, and the battery can not be recharged;
- 3, The machine can start and work, but cannot be shut down.

Solutions:

- 1、Check whether the power cable is well connected to the power socket of ECG, if there is no problem with the connection, change another fine power cable to confirm whether the power cable is fine. If the power cable is fine, open the ECG machine and use a multimeter to check whether the outputs of power supply is right. If they are not right, the switching power supply board is out of order, needs to be changed.
- 2、Open the ECG machine, then check the output of the battery, if the voltage between its positive and negative pole is lower then +10V(normally 12V), then it is out of order, replace it with a new one.
3. The switching power supply board is out of order, needs to be changed.

2. Main board

Main board is the main control board of the machine, software and LCD driver are stored in it, so its malfunction can be easily judged.

Malfunctions:

1、 Stay in the initial LOGO screen and can not get in to working screen after switching on.

2、 LCD screen becomes abnormal or white

3、 System halted sometimes

Solutions:

1、 upgrade the software, if the working screen still can not be entered, then the main board is out of order, change it;

2、 If the LCD is ok, then main board needs to be changed;

3、 If power supply is ok, then main board needs to be changed

3. Keyboard

Malfunctions: Keys are not working, or system time cannot be saved;

Solutions: replace the keyboard

4. Interface board

USB interface on the interface board, so if the system cannot read the USB disk, maybe the problem comes from the interface board.

5. ECG acquisition board

ECG acquisition board is for ECG signal acquisition and processing.

Malfunctions:

1. ECG acquisition board cannot communicate with the system, no ECG scan line on the screen;

2. ECG signal interference

Solutions:

- 1) Clean the skin where paste the Chest Suction Electrode;
- 2) check the connection of Chest Suction Electrode and Limb Clip Electrode;
- 3) replace the ECG cable;
- 4) If the ECG cable is normal, then the ECG acquisition board is out of order, need to be changed.

6. Recorder

Malfunctions: vague printing, cannot printout

Solutions: check the printing paper in a correct direction, if the installation of the printing paper is correct, then maybe the recorder is out of order, need to be replaced.

7. LCD

Malfunctions: Blank display, whitish display or dull display;

Solutions: open the machine, check whether the LCG flat cable connect is good or not, if the cable is well connected, then maybe the LCD is out of order, need to be changed.

Common troubleshooting

Breakdown	Solutions
Cannot printout the waveform of datas	Pull out about 2cm chart paper from the paper outlet of recorder, keep the thermosensitive side (printed with grids) downward
Printing is not clear	clean the printing head
Cannot switch off	Check the setting(LCD off delay or power off delay)
No waveform display	Check the connection of the Limb Clip Electrode , Chest Suction Electrode and patient cable

ECG waveform interference	<ol style="list-style-type: none">1. Check if the filter is correct, select different filter in different situation;2. Check if the Limb Clip Electrode and Chest Suction Electrode are placed firmly and the position is correct. Before placing the electrode, the skin of the patient should be cleaned and the grease or sweat on skin should be wiped off with alcohol. If necessary, shave off the hair at the place where the electrode is to be placed, abrade the stratum corneum of skin of the patient, and clean with alcohol.3. Check if the power socket protection is properly grounded. For big disturbance, equal-potential ground wires should be connected.
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Product name: Digital Electrocardiograph

Product type: E30

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