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文件名称 : SE-601 Series Electrocardiograph Service Manual

文件编号 : 82-01.54.110350

版本 : 1.4

产品型号 : SE-601A;SE-601B;SE-601C

项目编码 : 2201C000

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EDAN

SE-601 Series

Electrocardiograph

Version 1.4

CE₀₁₂₃

About this Manual

P/N: 01.54.110350

MPN: 01.54.110350014

Release Date: January 2015

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Statement

This manual will help you understand the operation and maintenance of the product better. It is reminded that the product shall be used strictly complying with this manual. User's operation failing to comply with this manual may result in malfunction or accident for which EDAN INSTRUMENTS, INC. (hereinafter called EDAN) can not be held liable.

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EDAN holds the rights to modify, update, and ultimately explain this manual.

Product Information

Product Name: Electrocardiograph

Model: SE-601A, SE-601B, SE-601C

Responsibility of the Manufacturer

EDAN only considers itself responsible for any effect on safety, reliability and performance of the equipment if:

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by

persons authorized by EDAN, and

The electrical installation of the relevant room complies with national standards, and

The instrument is used in accordance with the instructions for use.

Upon request, EDAN may provide, with compensation, necessary circuit diagrams, and other information to help qualified technician to maintain and repair some parts, which EDAN may define as user serviceable.

Terms Used in this Manual

This guide is designed to give key concepts on safety precautions.

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 regarding a function or a procedure.

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Chapter 1 Warranty and Service

Standard Service

EDAN provides a one-year-warranty for the warranted products (accessories are included). The warranty period begins on the date the products are shipped to customers. If a customer promptly notifies EDAN of customer's warranty claim hereunder, EDAN will either repair, adjust or replace (with new or exchange replacement parts) EDAN's products. EDAN warrants that any service it provides to customers will be performed by trained individuals in a workmanlike manner.

Limitation of Warranty

Direct, indirect or final damage and delay caused by the following situations for which EDAN is not responsible may void the warranty:

- ✧ Groupware is dismantled, stretched or redebugged.
- ✧ Unauthorized modification or misuse.
- ✧ Damage caused by operating beyond the environmental specifications for the medical product.
- ✧ Change or remove original serial number label or Manufacturer symbol.
- ✧ Improper use.

Service Procedure

(1) Fill in the **Service Claim Form (SCF)**.

Fill in the SCF with detailed information including: **Model Name**, **Serial Number (SN)** and **Problem Phenomena**.

EDAN should not have any obligation to take over the case without this information. The form can be downloaded at: <http://www.edan.com.cn> or obtained from EDAN's Service Department.

(2) Send EDAN the SCF and Select a Solution.

Once the service department receives the fully filled SCF, EDAN's engineer will offer a solution in three working days. EDAN will follow out the case based on the two conditions below:

Within Warranty:

There are two options:

- i) After receiving the **Return Material Authorization (RMA)** form from EDAN service department, the customer sends EDAN the defective parts and informs about the shipment tracking number. Then we will dispatch new part(s) to your confirmed address with confirmed shipping invoice.
- ii) The customer signs the **Declaration Form** and sends it back by email or fax. This form is legally certificated to make sure the customer or end-user will return the defective parts to EDAN on time. We will, at this option, dispatch the replacement one(s) with confirmed shipping invoice.

NOTE:

- (1) Both Return Material Authorization Form and Declaration Form are offered by EDAN service department once the SCF is confirmed by service engineer.**
- (2) The customer is responsible for freight & insurance charges when the equipment is shipped to EDAN for service, including custom charges. EDAN is responsible for the freight, insurance & custom charges from EDAN to the customer.**

Out of Warranty:

After receiving the RMA form from the service department, the customer sends defective parts to EDAN. We will analyze the problems and discuss with the customer about either repairing or replacing the part(s). Once the maintenance fee is invoiced and paid, we will make sure to dispatch good part(s) to the confirmed address.

NOTE: The customer is responsible for any freight & insurance charge for the returned product.

- (3) Obtain the RMA Form.

Before the shipment of the materials, the customer must obtain an RMA form from our service department, in which the RMA number, description of returning parts and shipping instructions are included. The RMA number should be indicated on the outside of the shipping container.

NOTE: EDAN should not have any obligation to the end-user or customer who returns the goods without the notification by EDAN's service department. The sender takes full responsibility for the accounted fee.

(4) Send the Parts to EDAN.

Follow these recommended instructions:

- ✧ Please disassemble the parts with anti-static facility, do not touch the parts with naked hand.
- ✧ Please pack the parts safely before return.
- ✧ Please put the RMA number on the parcel.
- ✧ Please describe the returned parts as 'sample of *****' and put the total value on the invoice, and note on the invoice as 'sample, no commercial value'.
- ✧ Please confirm the invoice with Edan before shipment.
- ✧ Please send back the parts after Edan's confirmation.

Contact Information

If you have any question about maintenance, technical specifications or malfunctions of devices, do not hesitate to contact us.

EDAN Instruments, Inc.

TEL: +86-755-26898321, 26899221

FAX: +86-755-26882223, 26898330

E-mail: support@edan.com.cn

Chapter 2 Safety Guidance

This chapter provides important safety information related to the use of SE-601 series electrocardiograph.

2.1 Intended Use

The intended use of SE-601 series electrocardiograph is to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. However, the interpreted ECG with measurements and interpretive statements is offered to clinicians on an advisory basis only.

WARNING

1. This equipment is not designed for intracardiac use or direct cardiac application.
 2. This equipment is not intended for home use.
 3. This equipment is not intended for treatment or monitoring.
 4. This equipment is intended for use on adult and pediatric patients only.
 5. The results given by the equipment should be examined based on the overall clinical condition of the patient, and they can not substitute for regular checking.
-

2.2 Warnings and Cautions

In order to use the electrocardiograph safely and effectively, and avoid possible dangers caused by improper operation, 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.

2.2.1 Safety Warnings

WARNING

1. The electrocardiograph is intended to be used by qualified physicians or personnel professionally trained. They should be familiar with the contents of this user manual before operation.
 2. Only qualified service engineers can install this equipment, and only service engineers authorized by the manufacturer can open the shell.
 3. **EXPLOSION HAZARD** - Do not use the electrocardiograph in the presence of flammable anesthetic mixtures with oxygen or other flammable agents.
 4. **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.
 5. Make sure that the power is turned off and the power cord is disconnected from the AC socket before connecting or disconnecting equipment. Otherwise, electrical shock or other injuries may happen to the patient or operator.
 6. If the integrity of the external protective conductor is in doubt, the equipment should be powered by an internal li-ion rechargeable battery.
 7. Do not use this equipment in the presence of high static electricity or high voltage equipment which may generate sparks.
 8. Only the patient cable and other accessories supplied by the manufacturer can be used. Or else, the performance and electric shock protection can not be guaranteed. The electrocardiograph has been safety tested with the recommended accessories, peripherals, and leads, and no hazard is found when the electrocardiograph is operated with cardiac pacemakers or other stimulators.
 9. Make sure that all electrodes are connected to the patient correctly before operation.
 10. Ensure that the conductive parts of electrodes and associated connectors, including neutral electrodes, do not come in contact with earth or any other conducting objects.
 11. If reusable electrodes with electrode gel are used during defibrillation, the electrocardiograph recovery will take more than 10 seconds. The manufacturer recommends the use of disposable electrodes at all times.
-

WARNING

12. Electrodes of dissimilar metals should not be used; otherwise it may cause a high polarization voltage.
 13. The disposable electrodes can only be used for one time.
 14. Do not touch the patient, bed, table or the equipment while using the ECG together with a defibrillator.
 15. Do not touch accessible parts of non-medical electrical equipment and the patient simultaneously.
 16. The use of equipment that applies high frequency voltages to the patient (including electrosurgical equipment and some respiration transducers) is not supported and may produce undesired results. Disconnect the patient data cable from the electrocardiograph, or detach the leads from the patient prior to performing any procedure that uses high frequency surgical equipment.
 17. If WIFI technology is used, in order to maintain compliance with the FCC RF exposure guidelines, WIFI should be installed and operated with a minimum distance of 20cm between the radiator and the human body. There should be no shield in or around the room where WIFI is used.
 18. Fix attention on the examination to avoid missing important ECG waves.
 19. **SHOCK HAZARD** - Don't connect non-medical electrical equipment, which has been supplied as a part of the system, directly to the wall outlet when the non-medical equipment is intended to be supplied by a multiple portable socket-outlet with an isolation transformer.
 20. **SHOCK HAZARD** - Don't connect electrical equipment, which has not been supplied as a part of the system, to the multiple portable socket-outlet supplying the system.
 21. Do not connect any equipment or accessories that are not approved by the manufacturer or that are not IEC/EN 60601-1-1 approved to the electrocardiograph. The operation or use of non-approved equipment or accessories with the electrocardiograph is not tested or supported, and electrocardiograph operation and safety are not guaranteed.
 22. Any non-medical equipment (such as the external printer) is not allowed to be used within the patient vicinity (1.5m/6ft.).
-
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WARNING

23. Do not exceed the maximum permitted load when using the multiple portable socket-outlet(s) to supply the system.
24. Multiple portable socket-outlets shall not be placed on the floor.
25. Do not use the additional multiple portable socket-outlet or extension cord in the medical electrical system, unless it's specified as part of the system by manufacturer. And the multiple portable socket-outlets provided with the system shall only be used for supplying power to equipment which is intended to form part of the system.
26. Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the standard IEC/EN 60601-1-1. Therefore anybody, who connects additional equipment to the signal input 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/EN 60601-1-1. If in doubt, consult our technical service department or your local distributor.
27. Connecting any accessory (such as external printer) or other device (such as the computer) to this electrocardiograph makes a medical system. In that case, additional safety measures should be taken during installation of the system, and the system shall provide:
- a) Within the patient environment, a level of safety comparable to that provided by medical electrical equipment complying with IEC/EN 60601-1, and
 - b) Outside the patient environment, the level of safety appropriate for non-medical electrical equipment complying with other IEC or ISO safety standards.
28. All the accessories connected to system must be installed outside the patient vicinity, if they do not meet the requirement of IEC/EN 60601-1.
29. If multiple instruments are connected to a patient, the sum of the leakage currents may exceed the limits given in the IEC/EN 60601-1 and may pose a safety hazard. Consult your service personnel.
30. The potential equalization bar can be connected to that of other equipment when necessary. Make sure that all the equipment is connected to the potential equalization terminal.
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-

2.2.2 Li-ion Battery Care Warnings

WARNING

1. Improper operation may cause the internal li-ion battery (hereinafter called battery) to be hot, ignited or exploded, and it may lead to the decrease of the battery capacity. It is necessary to read the user manual carefully and pay more attention to warning messages.
 2. Only qualified service engineers authorized by the manufacturer can open the battery compartment and replace the battery, and batteries of the same model and specification as manufacturer configuration should be used.
 3. **DANGER OF EXPLOSION** -- Do not reverse the anode and the cathode when installing the battery.
 4. Do not heat or splash the battery or throw it into fire or water.
 5. Do not destroy the battery; Do not pierce battery with a sharp object such as a needle; Do not hit with a hammer, step on or throw or drop to cause strong shock; Do not disassemble or modify the battery.
 6. When leakage or foul smell is 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.
 7. Properly dispose of or recycle the depleted battery according to local regulations.
 8. Only when the device is off can the battery be installed or removed.
 9. Remove the battery from the electrocardiograph when the electrocardiograph isn't used for a long time.
 10. If the battery is stored alone and not used for a long time, we recommend that the battery be charged at least once every 6 months to prevent overdischarge.
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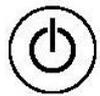
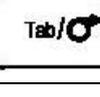
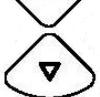
2.2.3 General Cautions

CAUTION

1. Avoid liquid splash and excessive temperature. The temperature must be kept between 5 °C and 40 °C during operation, and it should be kept between -20 °C and 55 °C during transportation and storage.
 2. Do not use the equipment in a dusty environment with bad ventilation or in the presence of corrosive.
 3. Make sure that there is no intense electromagnetic interference source around the equipment, such as radio transmitters or mobile phones etc. Attention: large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment etc. is likely to bring electromagnetic interference.
 4. Ruptured fuse must only be replaced with that of the same type and rating as the original.
 5. The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal. Batteries are hazardous waste. Do NOT dispose of them together with house-hold garbage. At the end of their lives hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or battery, please contact your local Civic Office, or the shop where you purchased the product.
 6. Federal (U.S.) law restricts this device to sale by or on the order of a physician.
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2.3 List of Symbols

	External output
	External input
	Equipment or part of CF type with defibrillator proof
	Caution
	Consult Instructions for Use
	Potential equalization
PATIENT	Patient Cable Socket
	USB socket
	Net port
	Mains supply
	Battery indicator
	Battery recharging indicator
	Delete key
	Enter key
	Fn key

	Esc key/Reset key
	Shift key
	Power On/Off key
	1mV/COPY key
	MODE key
	SLEEP/WAKE UP key
	PRINT/STOP key
	Tab key/Feed paper key
	UP/DOWN Arrow key
	LEFT/RIGHT Arrow key / Lead switch key
	Gender key
	Age Group key

	Recycle
P/N	Part Number
	Serial Number
	Date of Manufacture
	Manufacturer
	Authorized Representative in the European Community
	The symbol indicates that the device complies with the European Council Directive 93/42/EEC concerning medical devices.
Rx only (U.S.)	Federal (US) law restricts this device to sale by or on the order of a physician.
	With respect to electrical shock, fire and mechanical hazards only in accordance with UL 60601-1 and CAN/CSA C22.2 No. 601.1
	It indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life.

Chapter 3 Overview

The service manual is a reference for periodic preventive maintenance and corrective service procedures for SE-601 series electrocardiograph.

WARNING

When performing a service procedure, follow the instructions in this manual exactly. Failure to do so could damage the device, invalidate the product warranty, and lead to serious personal injury.

This guide provides troubleshooting information, disassembly procedures, and instructions for functional testing and performance verification. It is intended to be used by technically qualified service personnel only.

3.1 Technical Specifications

Safety Standards:

IEC 60601-1:2005, EN 60601-1:2006
EN 60601-1-2:2007, IEC 60601-1-2:2007
IEC/EN60601-2-25

Classifications:

Anti-electric-shock type:	Class I with internal power supply
Anti-electric-shock degree:	CF type with defibrillation-proof
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:	CISPR 11 Group 1, Class A

Environment Requirements:

	Transport and Storage	Working
Temperature:	-20°C (-4°F) ~ +55°C (+131°F)	+5°C (+41°F) ~ +40°C (+104°F)
Relative Humidity:	25%~93% Non-Condensing	25%~80% Non-Condensing
Atmospheric Pressure:	700hPa ~1060hPa	860hPa ~1060hPa

Power Supply Specifications:

1) Mains Supply:

Operating Voltage: 100V-240V~

Operating Frequency: 50Hz/60Hz

Input Power = 0.9A-0.4A

2) Internal li-ion rechargeable battery:

Rated voltage: 14.8V; Rated capacity: 2500mAh

3) Fuse Specification: T3.15AH250V, Ø5×20mm

3.2 Basic Theory of ECG Operation

The heart is a power organ of the blood circulation. Before the systole or the diastole, a cardiac impulse happens in the heart muscle, and a faint bioelectric signal is thus generated. The bioelectric signal is transmitted through the whole body, and the potential difference is generated on the different skin surfaces because of the different distances from the heart.

The cardiogram is a record of the amplification of the potential distribution on the body skin surface. The potential difference is sampled by the electrodes, and amplified and processed by the electrocardiograph. Then it is recorded on the paper. The cardiogram recorded by the electrocardiograph can help doctors to analyze and diagnose heart disease. The intended use of the electrocardiograph is to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiograph only records the heart's electrical activity, and does not produce any electricity of its own. The test does not hurt and has no known side effects. It does not require any preparations except possibly shaving chest hair to get a better recording. The recording itself takes only a few seconds.

It is more than one hundred years since the electrocardiograph was applied in clinical diagnosis. The electrocardiograph is an important measurement in clinical diagnosis of heart disease, and is equipped in almost every hospital and clinic.

3.3 Composition of ECG

The standard 12-lead electrocardiogram is a representation of the heart's electrical activity recorded from electrodes on the body surface. A normal ECG wave consists of a P wave, a QRS complex, an ST segment, a T wave and a U wave. In the following figure, the x-axis indicates time and the y-axis indicates voltage. When the printing speed is 25mm/s and the gain is 10mm/mV, one small grid on the x-axis represents 0.04 seconds, and one small grid on the y-axis represents 0.1mV.

This diagram illustrates ECG waves and intervals as well as standard time and voltage measures on the ECG paper.

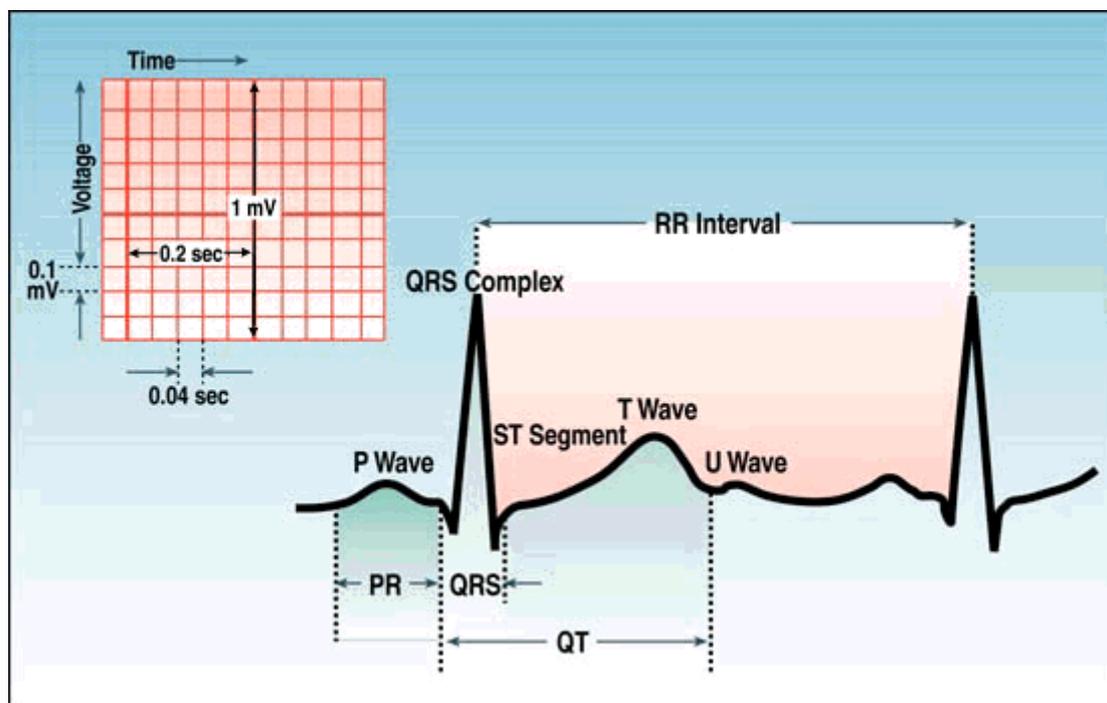


Figure 3-1 Composition of ECG

- P wave: the sequential activation (depolarization) of the right and left atria
- QRS complex: the right and left ventricular depolarization (normally the ventricles are activated simultaneously)
- ST-T wave: the ventricular repolarization
- U wave: the origin of this wave is not clear - but probably represents "after-depolarization" in the ventricles
- PR interval: the interval from the onset of the atrial depolarization (P wave) to the onset of the ventricular depolarization (QRS complex)
- QRS duration: the duration of the ventricular muscle depolarization
- QT interval: the duration of the ventricular depolarization and repolarization
- RR interval: the duration of the ventricular cardiac cycle (an indicator of the ventricular rate)
- PP interval: the duration of the atrial cycle (an indicator of the atrial rate)

3.4 Lead

The 12-lead ECG provides spatial information about the heart's electrical activity in three approximately orthogonal directions.

➤ Right	↔	Left
➤ Superior	↔	Inferior
➤ Anterior	↔	Posterior

Each lead represents a particular orientation in space, as indicated below (RA = Right Arm, LA = Left Arm, LL = Left Leg):

- Bipolar limb leads (frontal plane):
 - Lead I: RA (-) to LA (+) (right left, or lateral)
 - Lead II: RA (-) to LL (+) (superior inferior)
 - Lead III: LA (-) to LL (+) (superior inferior)
- Augmented unipolar limb leads (frontal plane):
 - Lead aVR: RA (+) to [LA & LL] (-) (rightward)
 - Lead aVL: LA (+) to [RA & LL] (-) (leftward)
 - Lead aVF: LL (+) to [RA & LA] (-) (inferior)
- Unipolar (+) chest leads (horizontal plane):
 - Leads V1, V2, V3: (posterior anterior)
 - Leads V4, V5, V6: (right left, or lateral)

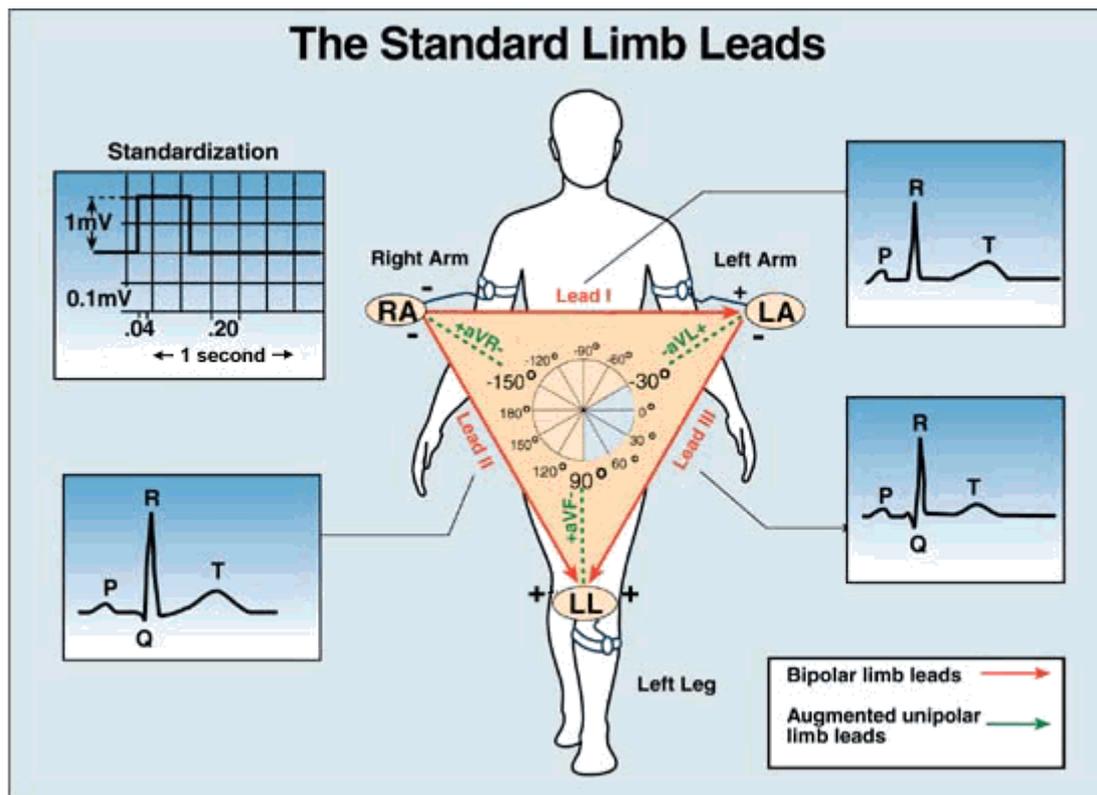


Figure 3-2 Standard Limb Leads

RA: Right arm

LA: Left arm

LL: Left leg

V1: Fourth intercostal space at the right border of the sternum

V2: Fourth intercostal space at the left border of the sternum

V3: Fifth rib between V2 and V4

V4: Fifth intercostal space on the left midclavicular line

V5: Left anterior axillary line at the horizontal level of V4

V6: Left midaxillary line at the horizontal level of V5

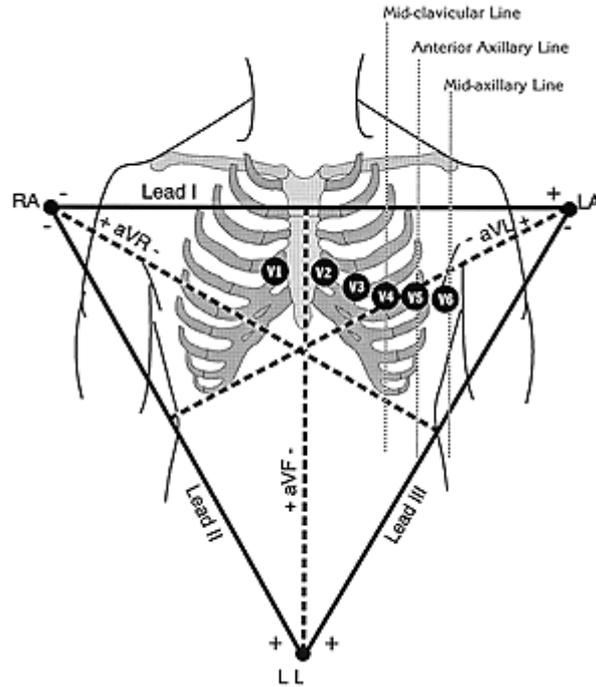


Figure 3-3 Standard Chest and Limb Leads

3.5 Description of Hardware Design Principle

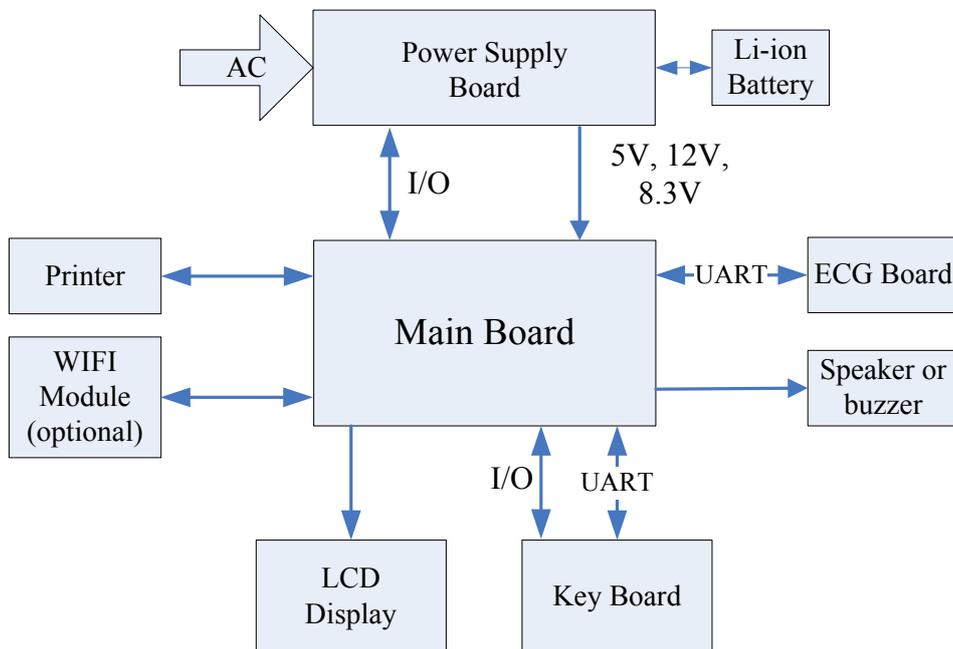


Figure 3-4 Block Diagram of the Electrocardiograph

SE-601 series electrocardiograph consists of the following functional blocks:

- 1) Key board
- 2) Main board
- 3) PS900G power supply board
- 4) ECG board
- 5) Thermal printer module
- 6) LCD display module
- 7) WIFI module (optional)
- 8) Speaker or buzzer

3.5.1 Main Board Description

The main board includes Core CPU, SDRAM, FLASH, buffer chip, Ethernet driver chip, power supply, printing interface, audio interface, TFT screen interface, USB interface, RS232-Serial port, analog input and output.

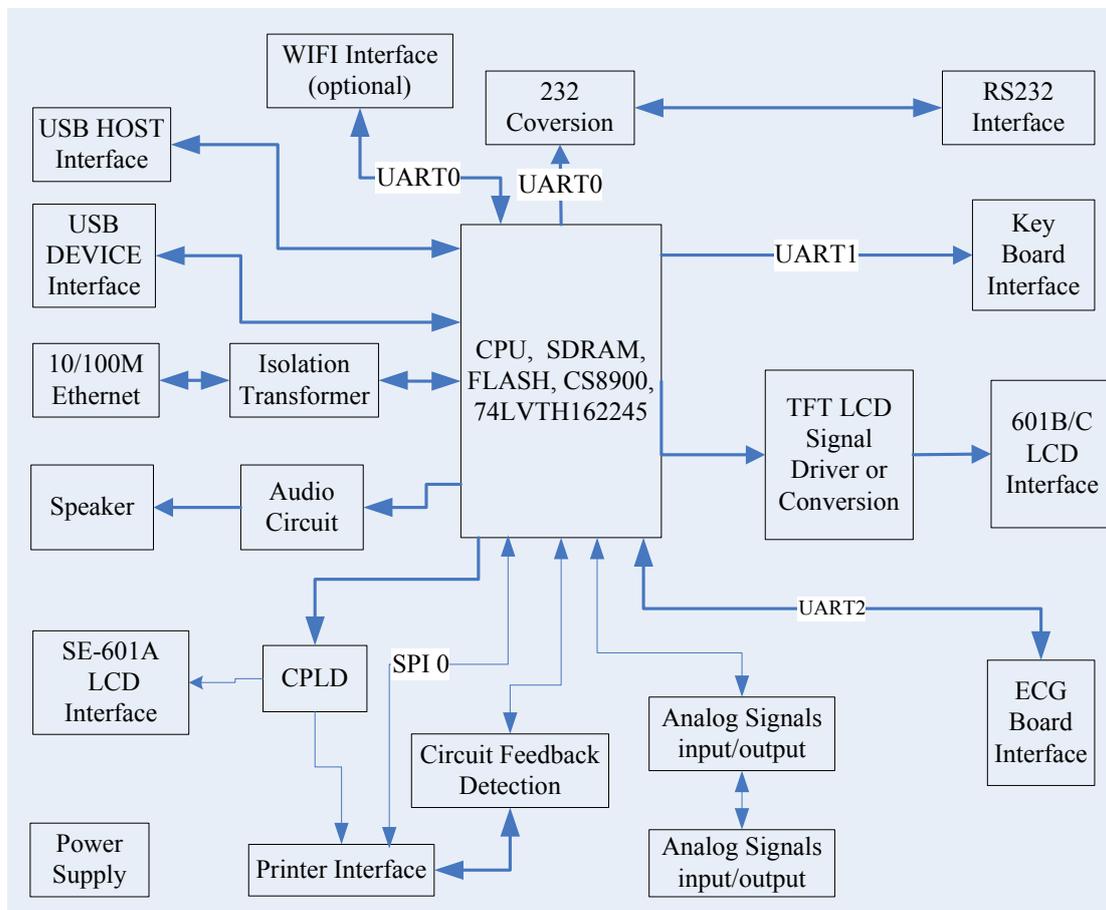


Figure 3-5 Main Board Diagram

3.5.2 ECG Board Description

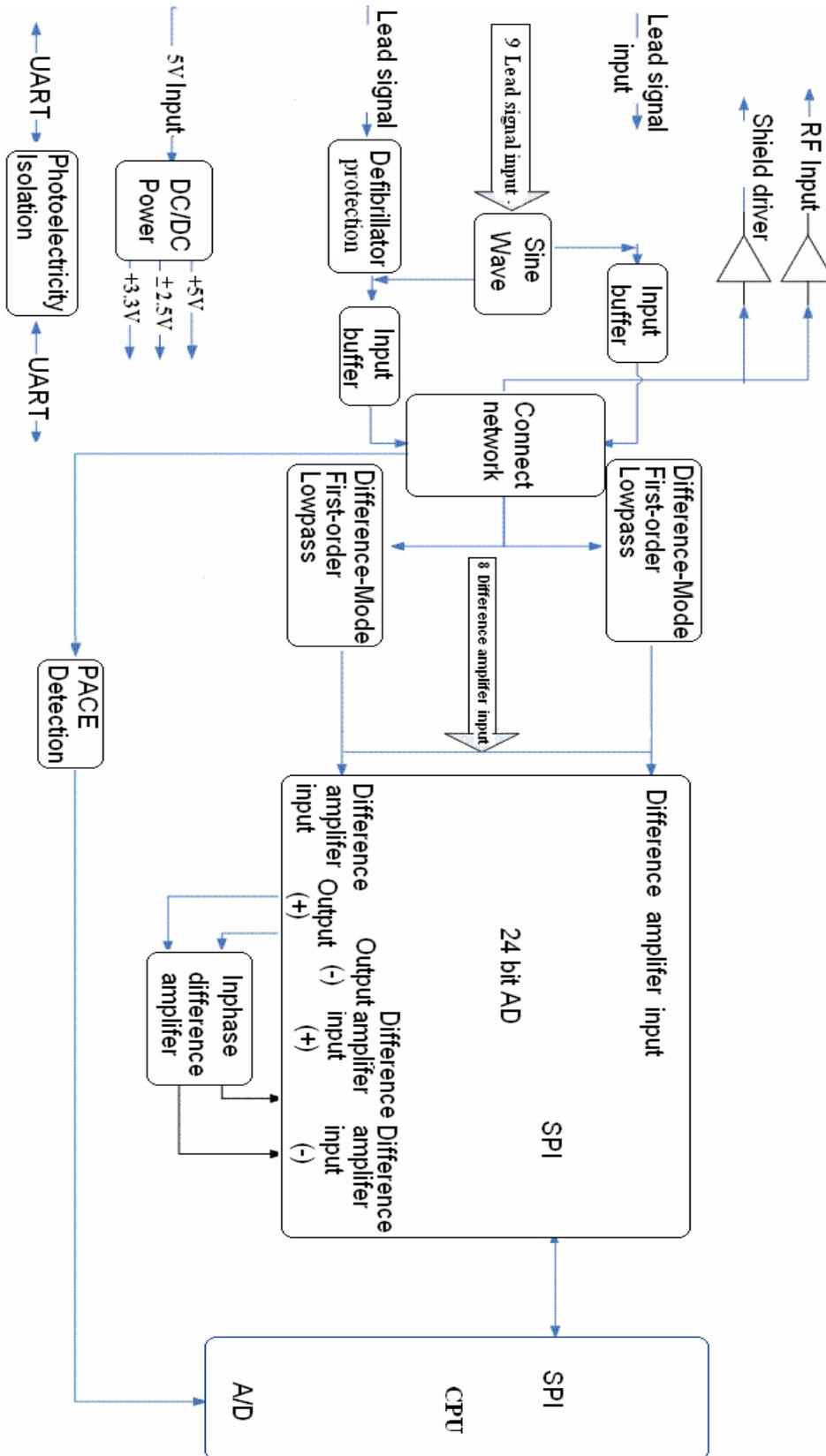


Figure 3-6 ECG Board Diagram

The electrocardiograph has 10 lead cables. The ECG signals pass through the defibrillator protection circuit, the buffering circuit, and enter the difference amplifier circuit. Then they continue to pass through the pacemaker pulse restraining, high-pass filter, low-pass filter, channel switch, second level amplification, and enter the A/D sampling port of ADC.

3.5.3 PS900G Power Supply Module Description

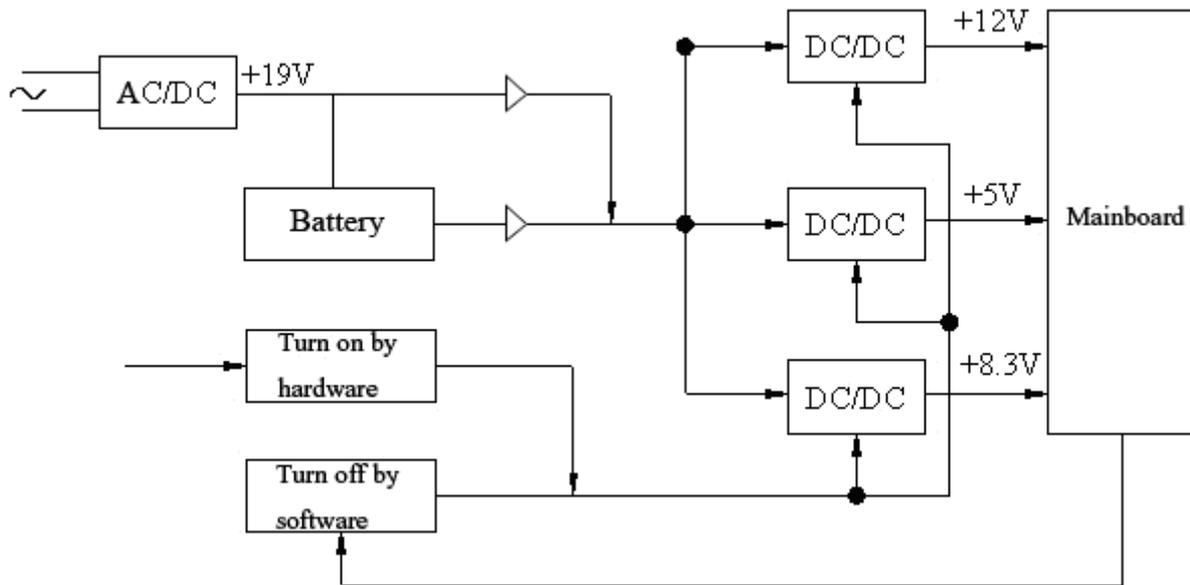


Figure 3-7 PS900G Power Supply Module Diagram

PS900G power supply module is shown in the above figure. This module provides +12V and +5V voltages for the main board, and also provides recharging circuit for the battery.

The hardware of the device can control the switch of DC/DC module to turn on the device. When the software of the device detects the signal of turnoff, it will save necessary data, and then control the system to turn off the device.

3.5.4 Key Board Description

The key board is shown in the figure below. When a key is pressed down, the interrupt logic of key matrix emits an interrupt signal. After CPU (ATmega161) detects the interrupt signal, it reads the key by row scan and column scan, and sends values to the main board through the serial port.

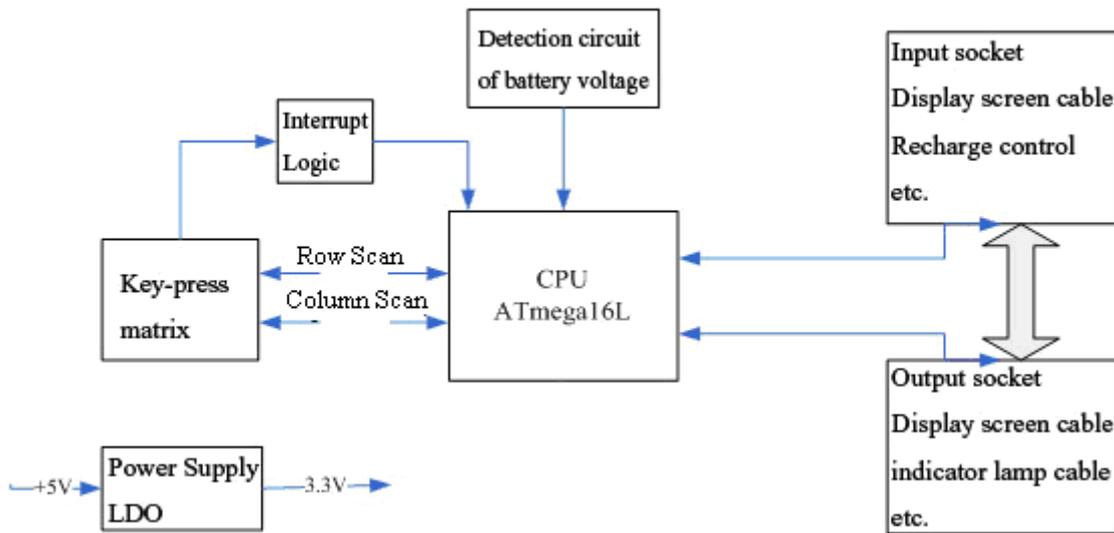


Figure 3-8 Key Board Diagram

3.5.5 WIFI Module Description (Optional)

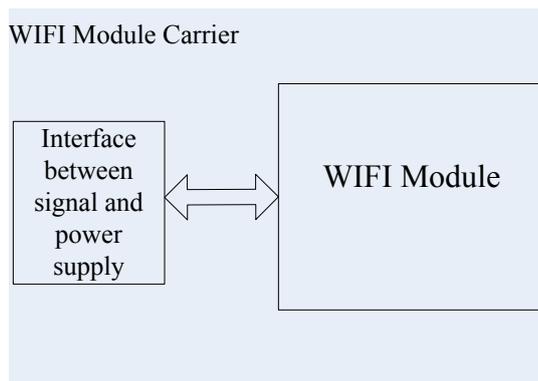


Figure 3-9 WIFI Module Diagram

The WIFI module is shown in the figure below. CPU interacts with WIFI module through the interface of the power supply to transmit and receive the wireless signal.

Chapter 4 Optional and Advanced Functions

When the **System Setup** screen is displayed, press **F1** on the keyboard to display the **Service Password** window. After you enter the correct password and press **Enter**, the **Advanced Setup** screen (Figure 4-1) appears.

On the **Advanced Setup** screen, press **Tab/Shift + Tab**, or **F1/F2/F3/F4** to move the cursor to a certain sub-item, and then press **Enter** to open the screen related to the sub-item.

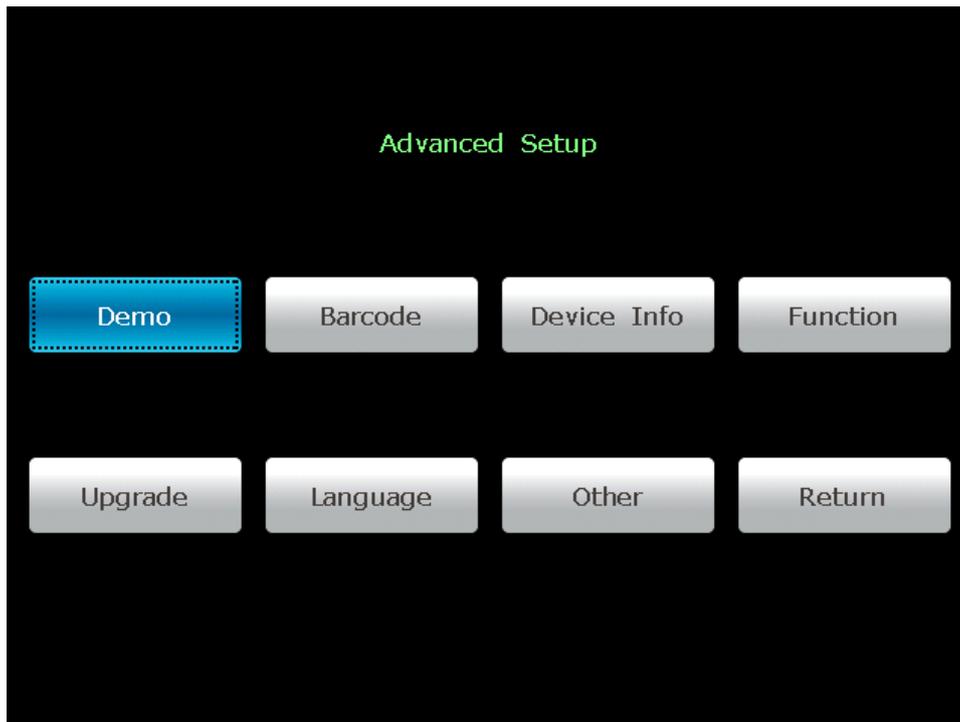


Figure 4-1 Advanced Setup Screen

4.1 Configuring a Bar Code Reader

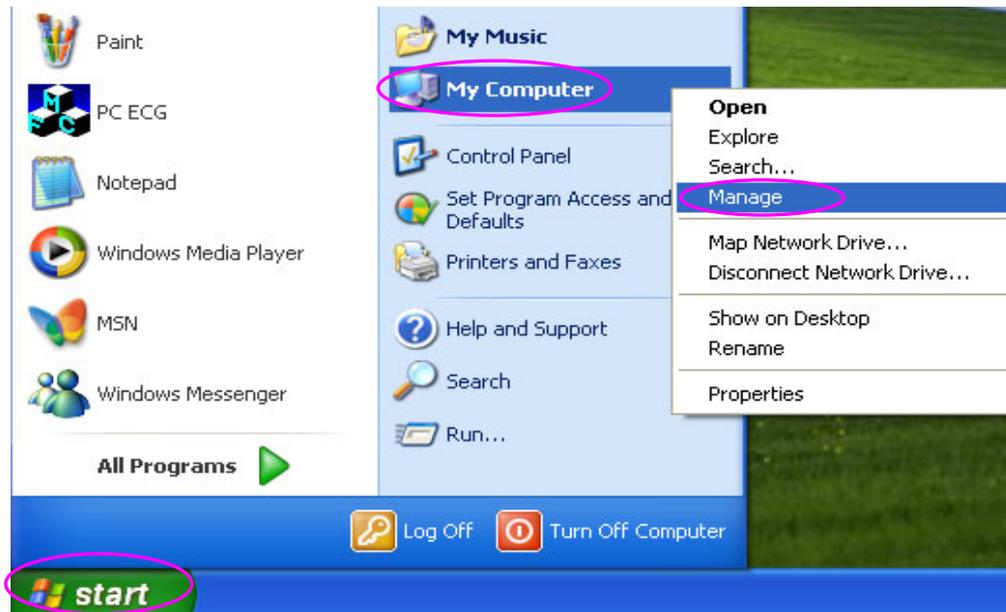
1. When the **Advanced Setup** screen is displayed, press **Tab/Shift + Tab**, or **F1/F2/F3/F4** to move the cursor to **Barcode**, and then press **Enter** to open the **Barcode Setup** window.

Barcode Setup			
Item	Start Address	End Address	
ID	1	---	12
First Name	0	---	0
Last Name	0	---	0
Gender	13	---	13
Year Of Birth	14	---	17
Month Of Birth	18	---	19
Day Of Birth	20	---	21
Male Code	1		
Female Code	2		
Vendor ID	04b4		
Product ID	0100		
OK		Cancel	

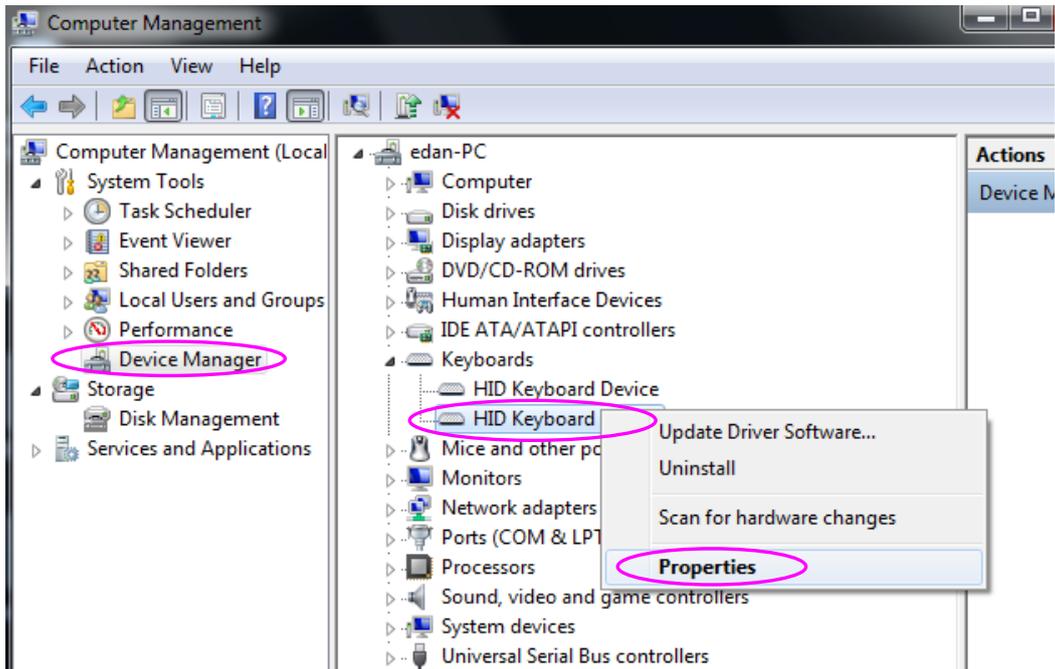
- Enter the start and end addresses, the male and female codes, the vendor ID and the product ID, and then press **Enter** to confirm.

View the vendor ID and product ID on the PC:

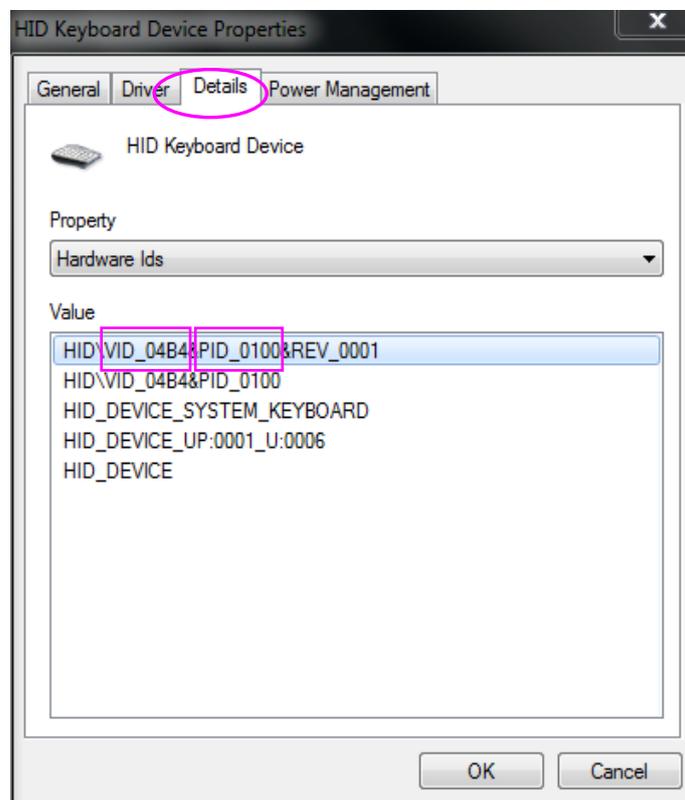
- Connect the bar code reader to the PC
- Click on **start**, right-click on **My Computer**, and then select **Manage** in the pop-up menu to open the **Computer Management** screen.



- 3) On the **Computer Management** screen, click on **Device Manager**. Right-click on **HID Keyboard Device**, and then select **Properties** in the pop-up menu.



- 4) Click on the **Details** tab in the **HID Keyboard Device Properties** window. View the vector ID (VID) and the product ID (PID). Take the following figure for example, the vector ID is 04B4, and the product ID is 0100.

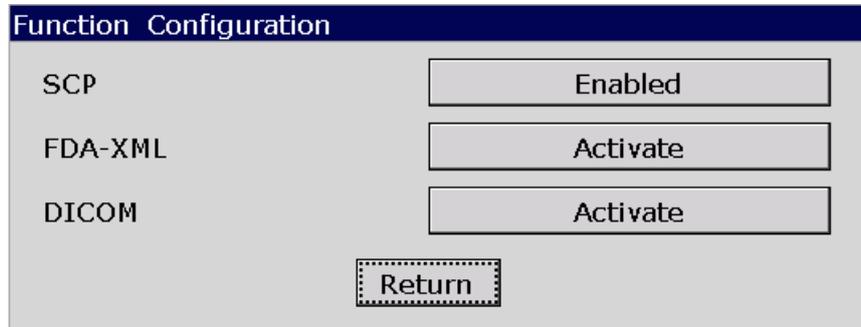


3. Press **Esc** to return to the main screen.

NOTE: Only bar code readers recommended by the manufacturer can be used.

4.2 Activating SCP/FDA-XML/DICOM Function

1. When the **Advanced Setup** screen is displayed, press **Tab/Shift + Tab**, or **F1/F2/F3/F4** to move the cursor to **Function**, and then press **Enter** to open the **Function** window.

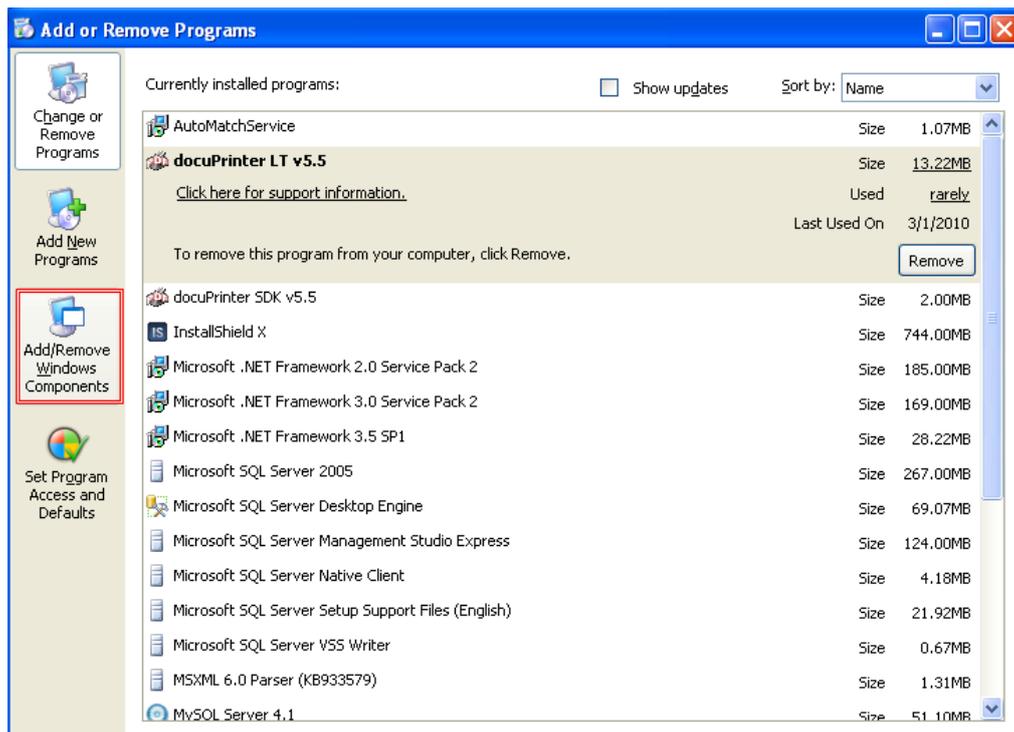


2. Press **Tab/Shift + Tab**, or **F1/F2/F3/F4** to move the cursor to the **Activate** button after the function is activated. Press **Enter** to open the **Activate Password** window. Enter the password and press **Enter** to activate the function.

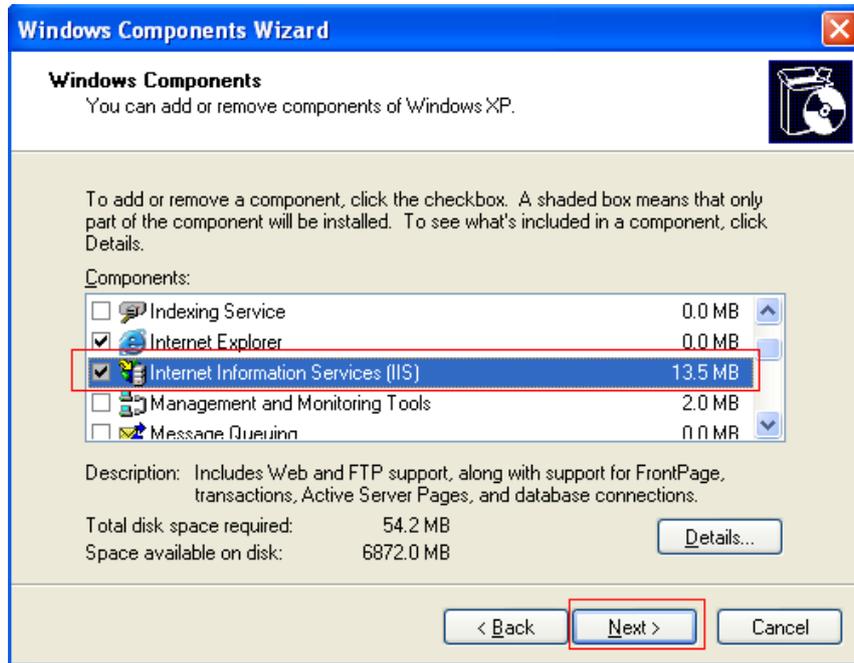
NOTE: Please contact local distributors to get the service password and the activating password.

4.3 Implementing FTP Protocol

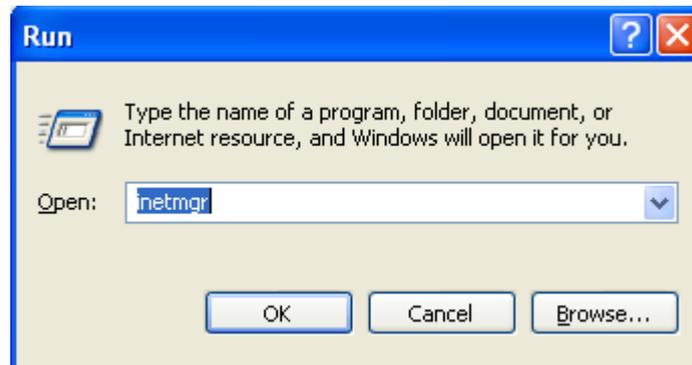
1. Configuring the PC
 - 1) Insert the original operating system CD, and click on **Start-> Control Panel-> Add or Remove Programs**.



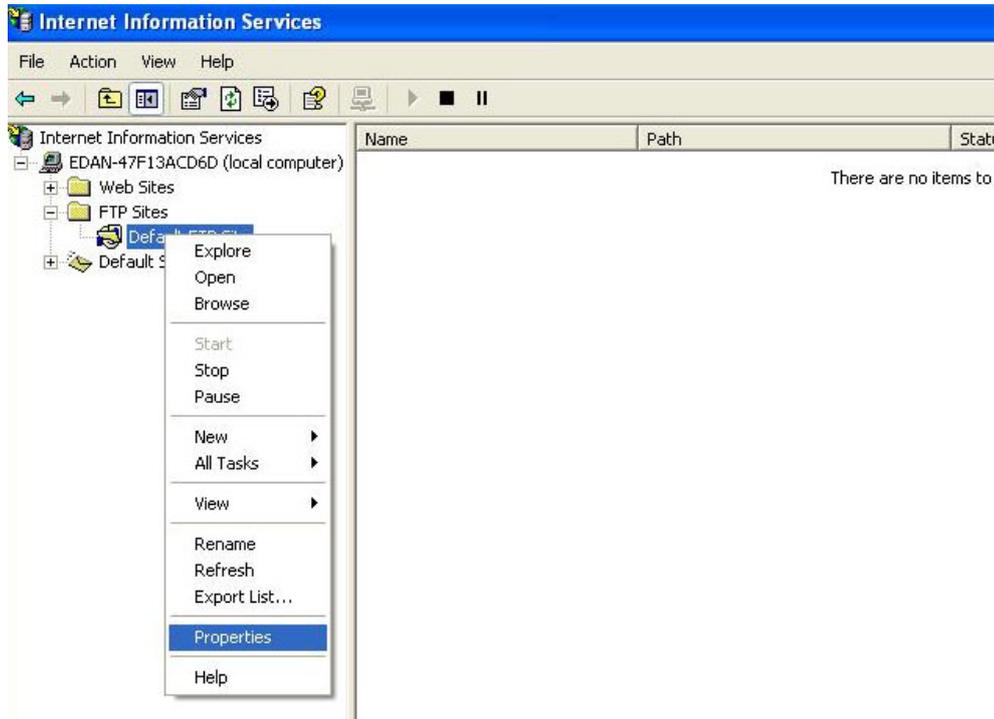
- 2) Click on **Add/Remove Windows Components** in the **Add or Remove Programs** window to open the **Windows Components Wizard** window.



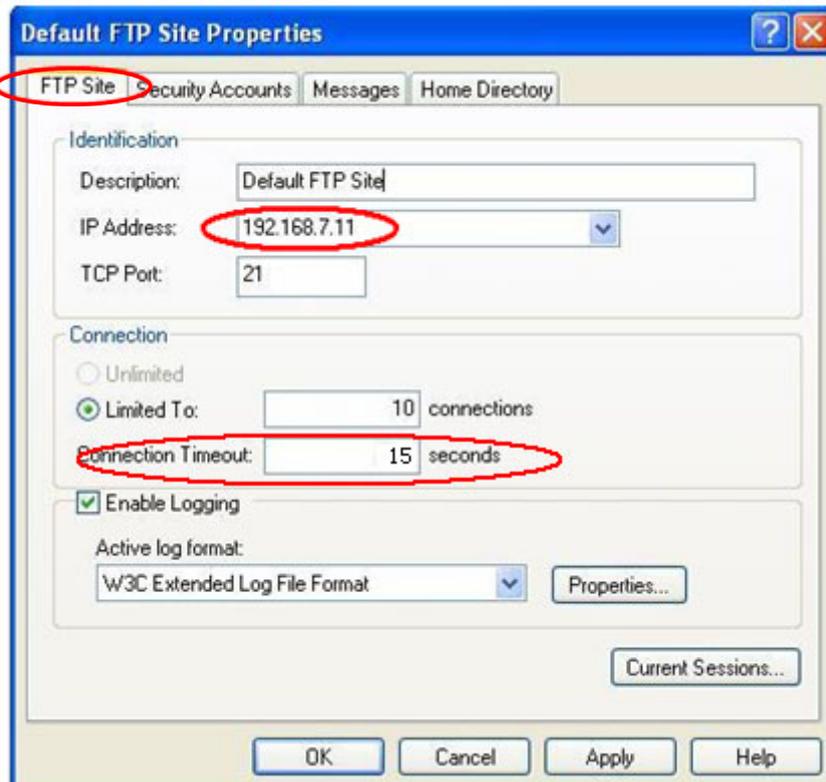
- 3) Select Internet Information Services (IIS) in the **Windows Components Wizard** window, and click on the **Next** button to install IIS components.
- 4) After installing IIS components, click on **Start->Run**, input **inetmgr** in the entry box, and then click on the **OK** button to confirm.



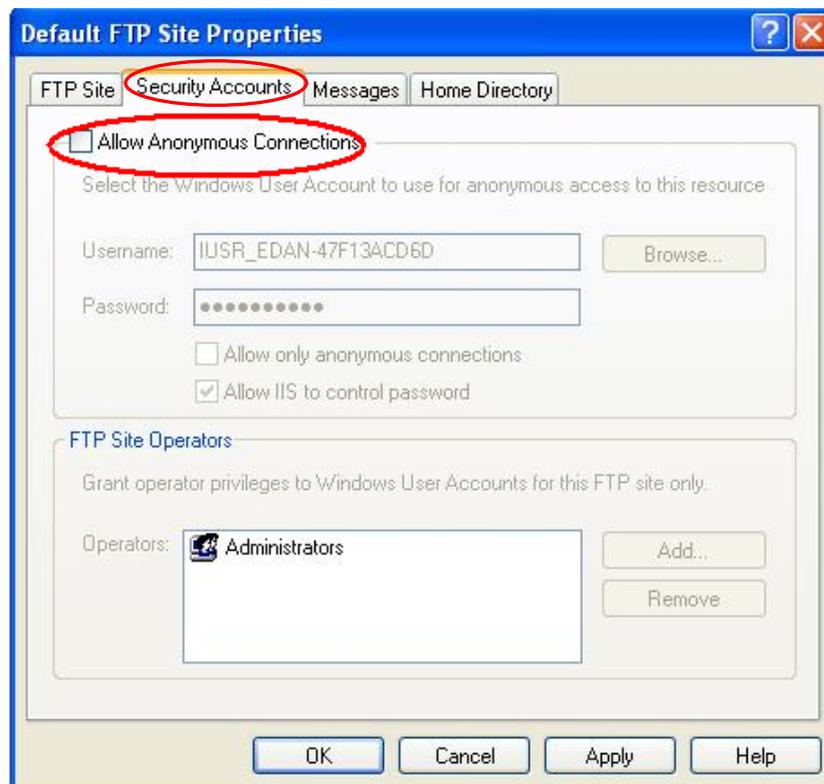
- 5) Right click on **Default FTP Site** in the pop-up **Internet Information Services** window, and then select **Properties**.



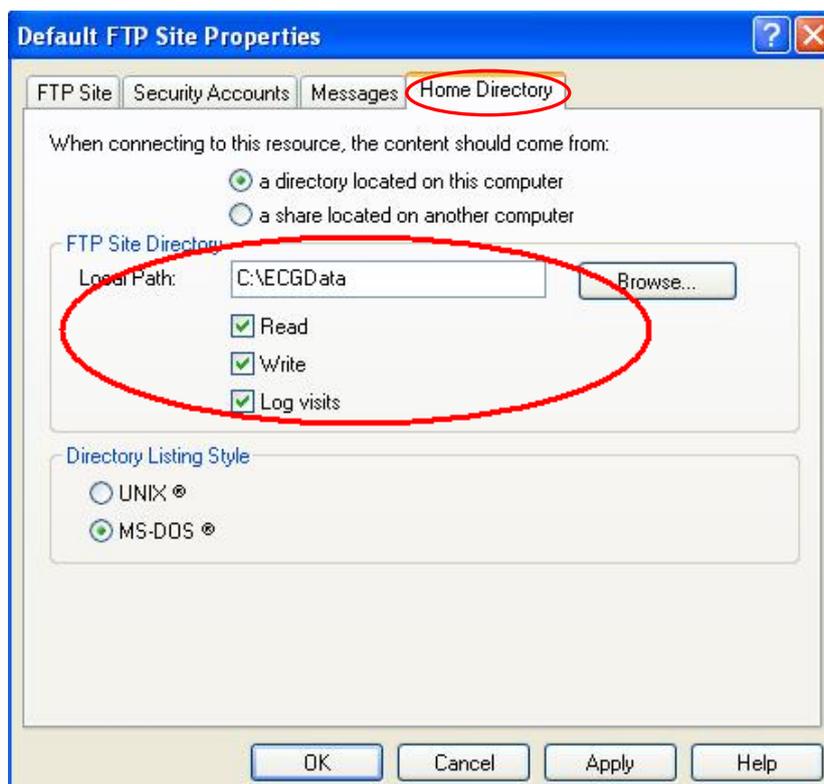
- 6) Select the **FTP Site** tab in the **Default FTP Site Properties** window, set **IP Address** to the address of the server, and set **Connection Timeout** to **15 seconds** (if other FTP is used, **Connection Timeout** also needs to be set to **15 seconds**). Please do not change the other items at random unless you have special needs.



- 7) Select the **Security Accounts** tab, and make sure **Allow Anonymous Connections** is deselected.



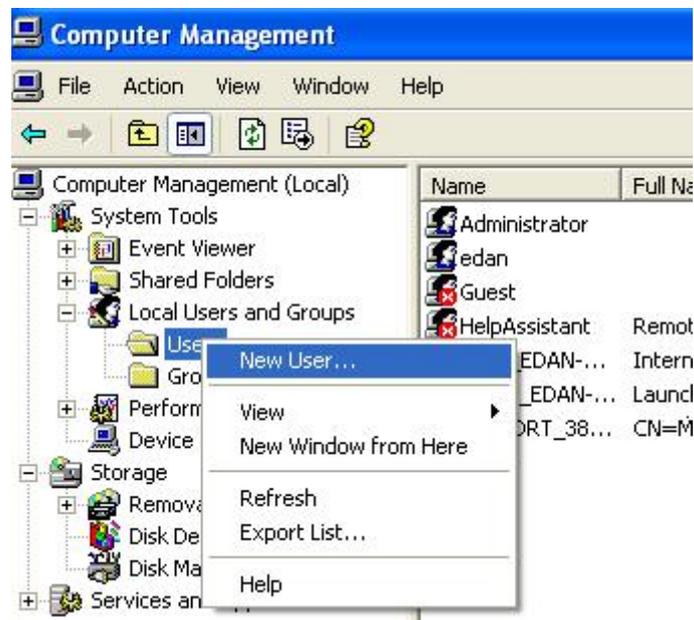
- 8) Select the **Home Directory** tab, select a valid path for **FTP Site Directory**, and then select the **Read**, **Write** and **Log visits** items. Please do not change the other items at random unless you have special needs.



- 9) Click on the **OK** button in the **Default FTP Site Properties** window to save the settings.
- 10) Right-click on **My Computer**, and select **Manage**.



- 11) Right-click on **User**, and select **New User...** in the **Computer Management** window.



- 12) Input the valid user name and the password, and then select **User cannot change password** and **Password never expires** in the **New User** window.

The screenshot shows the 'New User' dialog box with the following fields and options:

- User name: ENSData
- Full name: (empty)
- Description: (empty)
- Password: (masked with dots)
- Confirm password: (masked with dots)
- User must change password at next logon
- User cannot change password
- Password never expires
- Account is disabled
- Buttons: Create, Close

- 13) Click on the **Create** button in the **New User** window to save the settings.

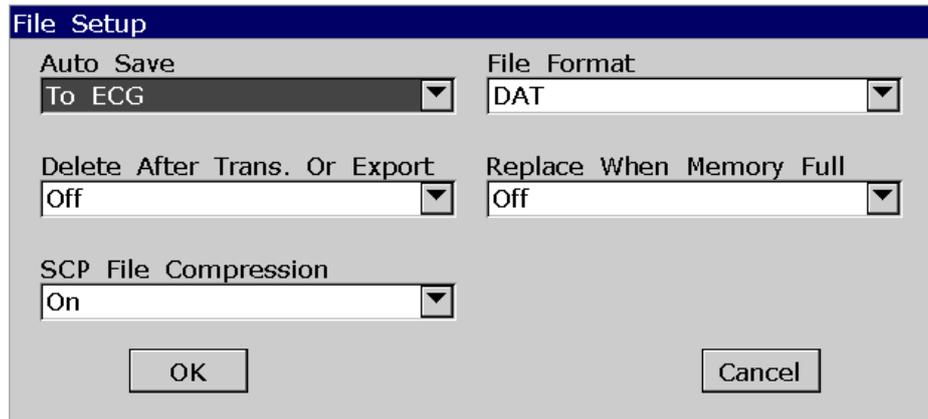
2. Configuring the electrocardiograph

- 1) Switch on the electrocardiograph.
- 2) Configure the **Transmission Setup** window

The screenshot shows the 'Transmission Setup' dialog box with the following fields and options:

- Device No.: 0
- Auto Transmission: Off
- Transmission Mode: Wired
- Server IP: 192 . 168 . 1 . 187
- Gateway: 192 . 168 . 1 . 1
- FTP User Name: (empty)
- FTP Password: (empty)
- FTP Path: (empty)
- Local IP: 192 . 168 . 1 . 134
- Subnet Mask: 255 . 255 . 255 . 0
- Buttons: OK, Cancel
- Footer: Press <Shift+F1> or <Shift+F2> to switch page.

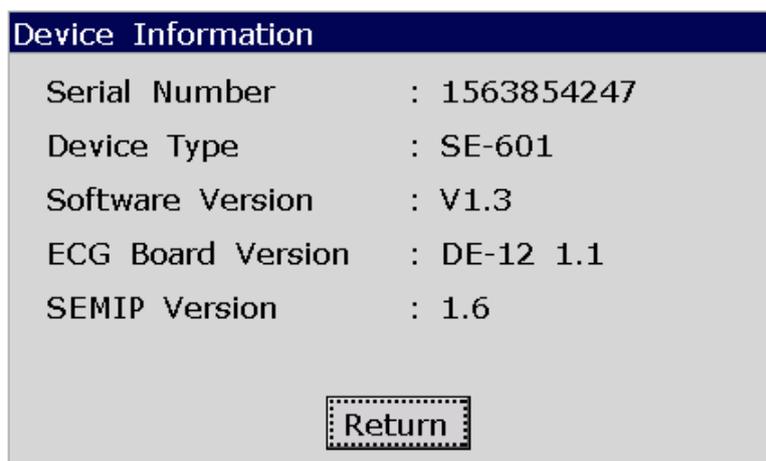
- a) Set **Auto Transmission** to **On**.
 - b) FTP Information: Set **FTP User Name** and **FTP Password** to the user name and the password you input in the **New User** window (refer to step 12 in configuring the PC). Set **FTP path** to the subdirectory of the path you input in the **Default FTP Site Properties - Home Directory** window (refer to step 8 in configuring the PC).
 - c) IP Addresses: Set **Server IP**, **Local IP**, **Gateway** and **Subnet Mask**
- 3) Select a file format from the **File format** text box in the **File Setup** window.



- 4) Press **Enter** to confirm.
3. Connect the electrocardiograph to the network of the PC with an Ethernet cable recommended by the manufacturer.
4. The electrocardiograph samples and analyzes the ECG data, and then transmits the ECG data automatically to the folder you input in the **Transmission Setup** window.

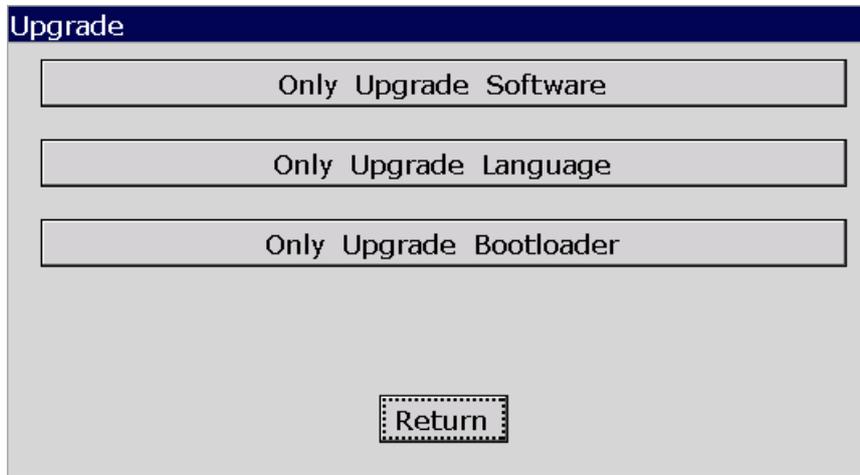
4.4 Viewing Device Information

When the **Advanced Setup** screen is displayed, press **Tab/Shift + Tab**, or **F1/F2/F3/F4** to move the cursor to **Device Info**, and then press **Enter** to open the **Device Information** window.



4.5 Updating by Using A U Disk

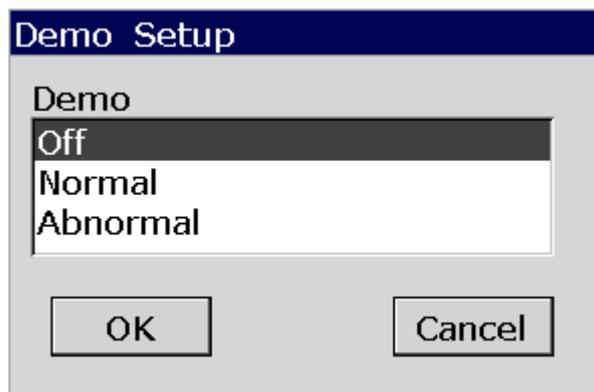
1. When the **Advanced Setup** screen is displayed, press **Tab/Shift + Tab**, or **F1/F2/F3/F4** to move the cursor to **Upgrade**, and then press **Enter** to open the **Upgrade** window.



2. Press **Tab** or **Shift + Tab** to move the cursor to an item, and then press **Enter** to open the **Activate Password** window. Enter the password and press **Enter** to activate the function.

4.6 Using DEMO Function

1. When the **Advanced Setup** screen is displayed, press **Tab/Shift + Tab**, or **F1/F2/F3/F4** to move the cursor to **Demo**, and then press **Enter** to open the **Demo Setup** window.



2. Press **Tab** or **Shift + Tab** to move the cursor to an item, and then press **Enter** to open the **Activate Password** window. Enter the password and press **Enter** to activate the function.

Chapter 5 Inspection and Troubleshooting

5.1 Function Tests

The following function tests should be performed at least every 12 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

Function tests do not require opening the device case.

WARNING

Only qualified service personnel should perform a full functional checkout procedure.

Whenever the electrocardiograph is serviced or problems are suspected, the manufacturer recommends a function test.

1. Equipment Requirement

Equipment	Model
ECG simulator	FLUKE MPS450
ECG detector	NMI EGC-1C

2. LCD Screen Tests

Observe whether some characters are missing, or there are bright spots and dark shadows on the LCD screen. Observe whether the waveforms, fonts and symbols displayed on the LCD screen are normal. In the **Display & Sound Setup** window, press the Up or Down arrow to adjust the **Brightness** progress bar, and the brightness of the LCD screen changes.

3. Lead Off Tests

In the **AUTO** mode, when the lead cables are pulled out from or inserted into the ECG simulator in sequence, the electrocardiograph will accurately identify the disconnection or the connection of the corresponding lead cable.

4. Key Tests

Press every key on the keyboard to test whether they work as described in the user manual.

5. System Setup Tests

- When the **System Setup** screen is displayed, press **Tab** or **Shift + Tab**, or the Up, Down, Left or Right arrow to move the cursor to **Maintenance**, and then press **Enter** to open the **System Maintenance** window. Press **Tab** or **Shift + Tab** to move the cursor to the **Load Factory Settings** button on the **System Maintenance** window, and then press **Enter** to load the factory settings from the ECG. Press **Enter** to confirm or press **Esc** to return to the **System Setup** screen. Press **Tab** or **Shift + Tab**, or the Up, Down, Left or Right arrow to move the cursor to **Date&Time**, and then press **Enter** to open the **Date&Time Setup** window. Set the current time, and then press **Enter** to confirm.
- Turn off the electrocardiograph, and turn it on five seconds later. When the electrocardiograph is ready for examination, observe whether the time displayed on the LCD screen is the current time, and open the sub-windows of the System Setup screen to see whether these items keep the default options. Then change some items and exit. Turn off the electrocardiograph. Five seconds later, turn on the electrocardiograph again. When the electrocardiograph is ready for examination, observe whether the items keep the changed options.

6. Heart Rate Display Tests

Set the heart rate output from the ECG simulator to different values, and the error of heart rate values displayed on the LCD screen of the electrocardiograph should be within ± 1 bpm.

7. Recording Tests

Set the following values:

- The heart rate output from the ECG simulator is 80bpm, the working mode of the electrocardiograph is auto, the speed is 25mm/s, the gain is 10mm/mV, the AC filter is off, the Lowpass filter is 150Hz and all the items in the **Auto Record Info** frame on the **Setup 2** sub-window of the **Record Info Setup** window are selected. Install the recorder paper and press the **PRINT/STOP** key to begin to print an ECG report. Examine whether the printed contents are integrated and consistent with the information displayed on the LCD screen.
- Make the ECG detector output sine waves with the amplitude of 2mV and the frequency of 10Hz. Press the **PRINT/STOP** key to begin to print ECG reports. Examine whether the printed contents are integrated and consistent with the information displayed on the LCD screen.
- The ECG report includes the date and time, ID, name, gender, age, gain, paper speed, filter, lead, 1mV calibration mark, ECG waveform, heart rate etc. The 1mV calibration mark and lead names are printed before ECG waves in the ECG reports. The printed characters and waveforms are clear.

- Open the recorder casing and remove the recorder paper, and then the hint information *No Paper* should be displayed. Install the recorder paper again and close the recorder casing, and then the hint information *No Paper* should disappear.

5.2 System Tests

The **System Test** screen is password protected and only technicians authorized by the manufacturer can open it. The password is 006363.

1. Opening the System Test Screen

When the **System Setup** screen is displayed, press **F2** on the keyboard to display the **Service Password** window (Figure 5-1). After you enter the correct password and press **Enter**, the **System Test** screen (Figure 5-2) appears.

On the **System Test** screen, press **Tab** or **Shift + Tab**, or the Up, Down, Left or Right arrow to move the cursor to a certain sub-item, and then press **Enter** to open the test screen related to the sub-item.



Figure 5-1 Service Password Window

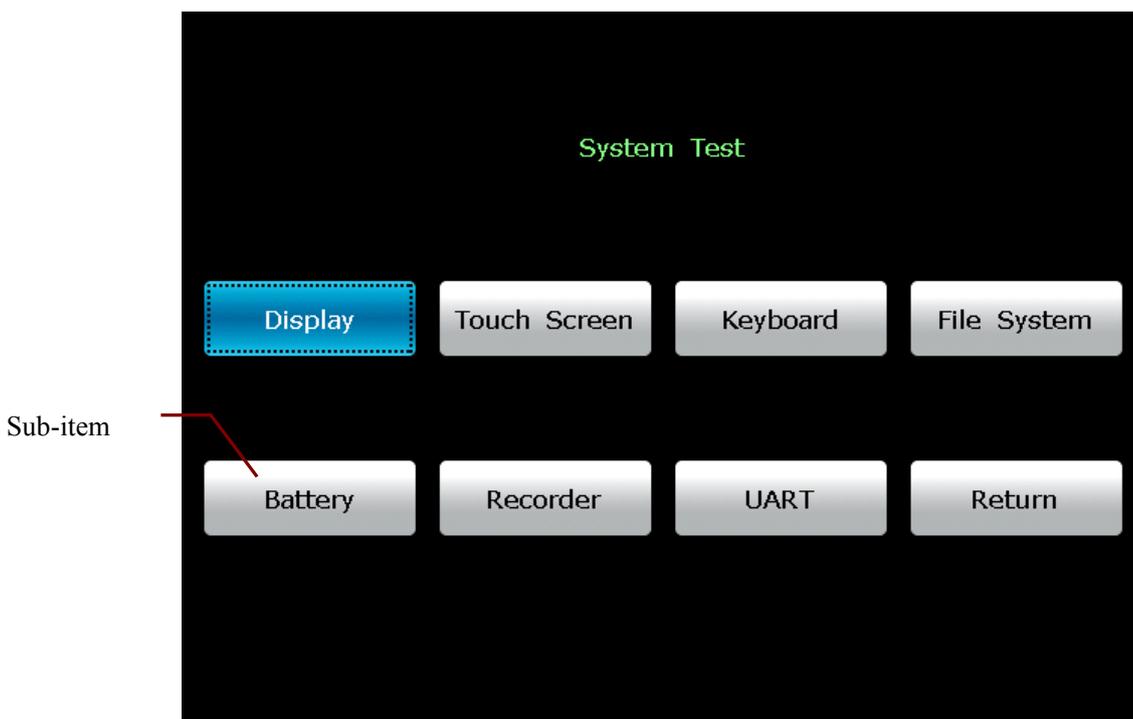


Figure 5-2 System Test Screen

2. Display Test

On the **System Test** screen, press **Tab/Shift + Tab**, or **F1/F2/F3/F4** to move the cursor to the **Display** item, and then press **Enter** to display the **Display** window (Figure 5-3). Press the Up or Down arrow to select **Pixel Verification Test** or **Gray Scale Test Patterns**.

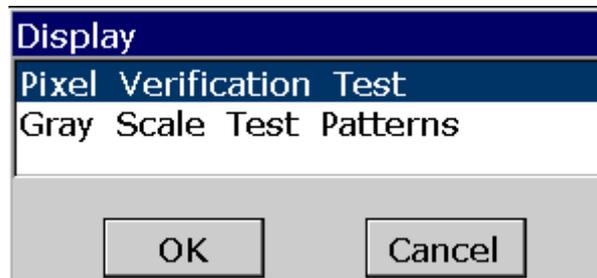


Figure 5-3 Display Window

Select **Pixel Verification Test** and press **Enter**, and then the **Pixel Verification Test** screen (Figure 5-4) appears.



Figure 5-4 Pixel Verification Test Screen

Press the Left or Right arrow to move the color bars across the screen, and you can inspect whether the LCD screen is intact and displays well.

Press **F1** to display a full screen, and then press **F1** to shift the color of the full screen among white, green, red and blue.

Press the **Esc** key to exit the **Pixel Verification Test** screen.

Select **Gray Scale Test Patterns** and press **Enter**, and then the **Gray Scale Test Patterns** interface1 (Figure 5-5) appears.

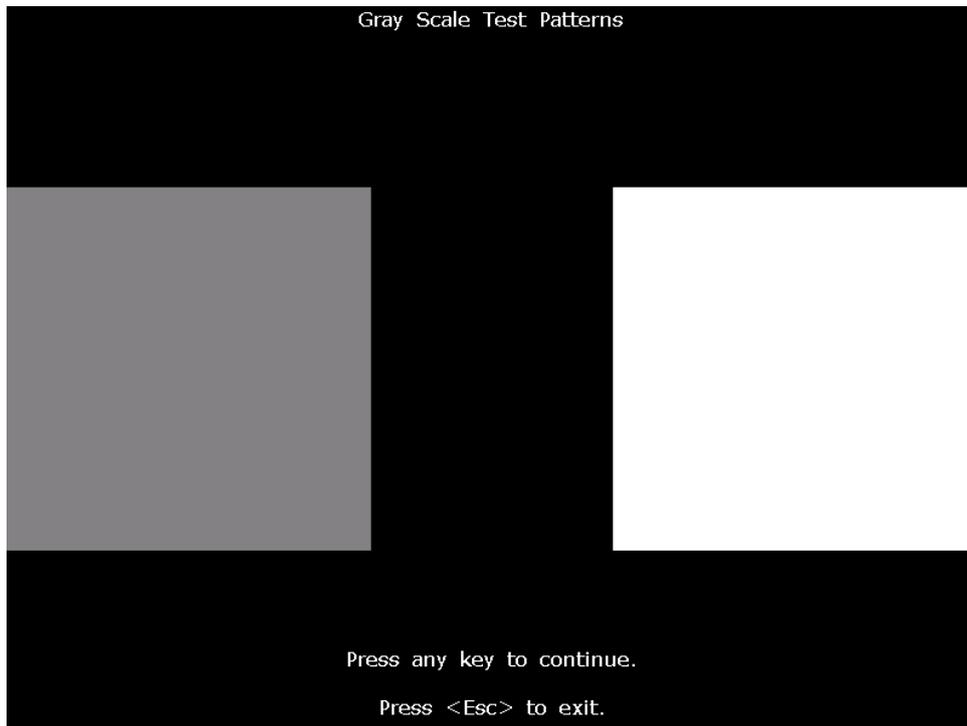


Figure 5-5 Gray Scale Test Patterns Interface1

Press any key to open the **Gray Scale Test Patterns** interface2 (Figure 5-6).

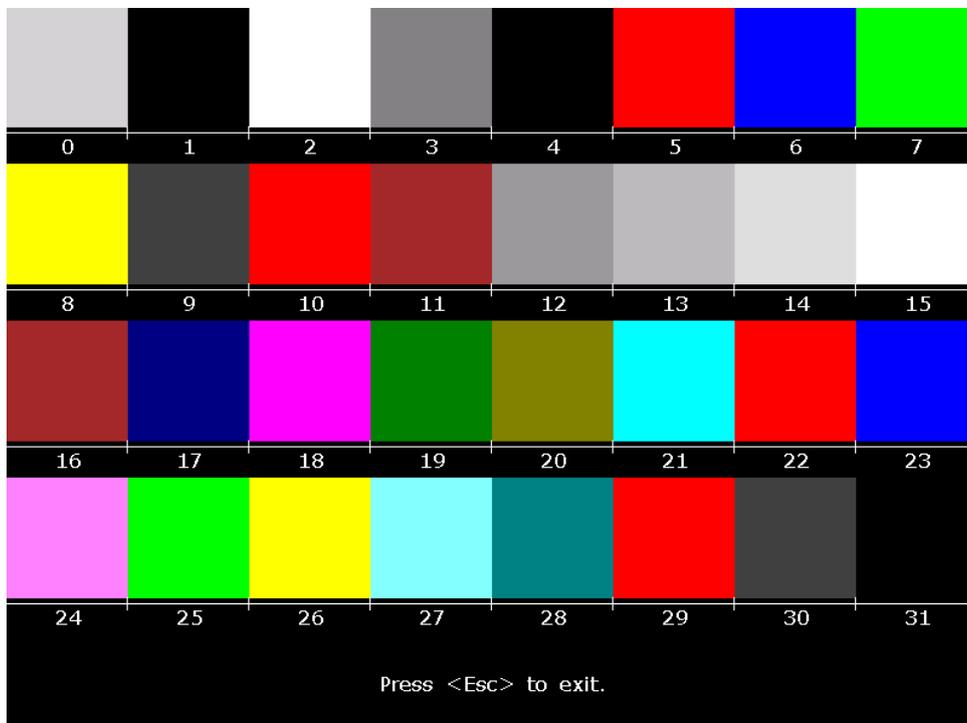


Figure 5-6 Gray Scale Test Patterns Interface2

Press **Esc** to exit the screen.

3. Touch Test (for the electrocardiograph configured with touch screen)

On the **System Test** screen, press **Tab/Shift + Tab**, or **F1/F2/F3/F4** to move the cursor to the **Touch Screen** item, and then press **Enter** to open **Touch Screen**.

On this screen, when you touch a key on the touch screen, this key will be displayed in the blank field on the top of the screen.

Press **Esc** to exit the screen.

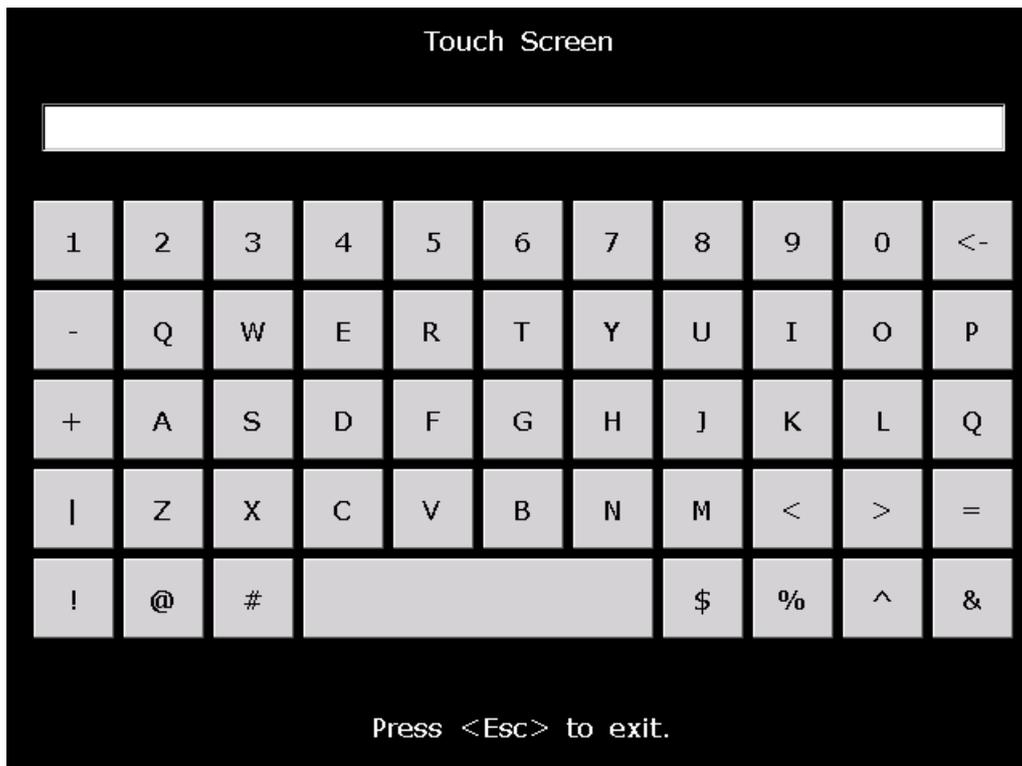


Figure 5-7 Touch Screen

4. Keyboard Test

On the **System Test** screen, press **Tab/Shift + Tab**, or **F1/F2/F3/F4** to move the cursor to the **Keyboard** item, and then press **Enter** to open the **Keyboard** screen.

When you press a key on the keyboard of the device, this key will be displayed in the corresponding position on the **Keyboard** screen.

Press **Esc** to exit the screen.

NOTE: When you press the  key, the device will be turned off.

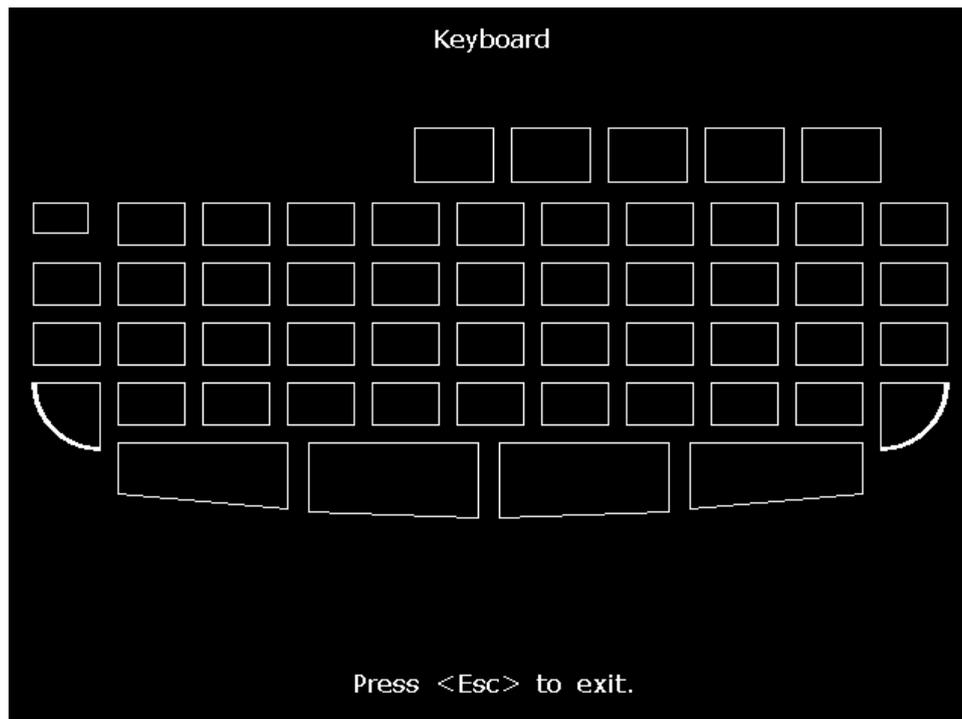


Figure 5-8 Keyboard Screen

5. File System Test

On the **System Test** screen, press **Tab/Shift + Tab**, or **F1/F2/F3/F4** to move the cursor to the **File System** item, and then press **Enter** to open the **File System** screen.

This screen displays the number of files, the total space, the used space and the use ratio.

Press **Esc** to exit the screen.

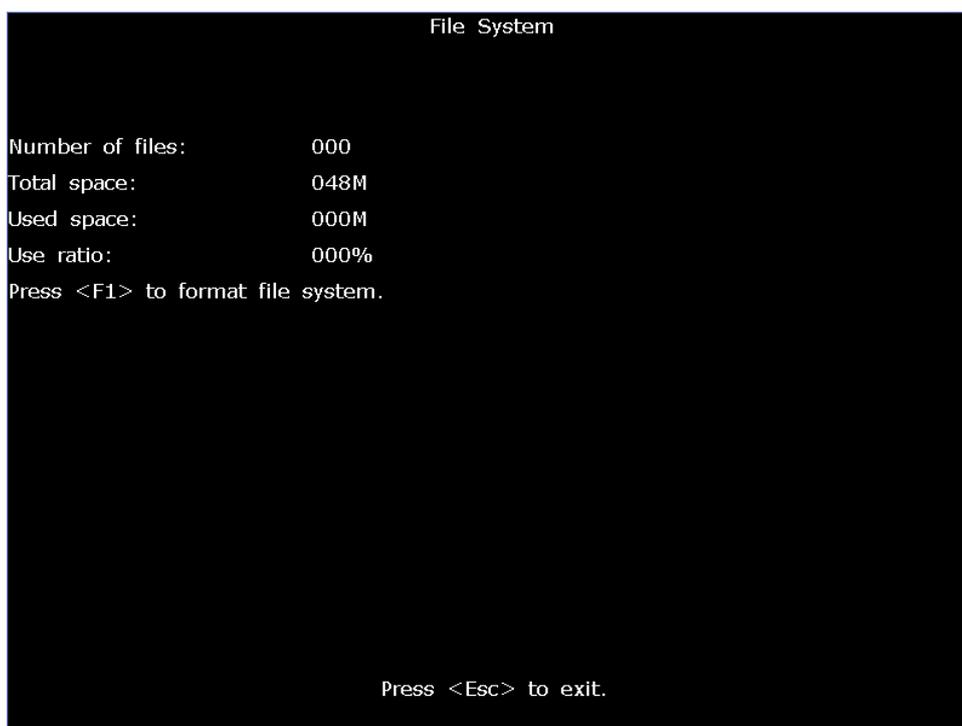


Figure 5-9 File System Screen

6. Battery Test

On the **System Test** screen, press **Tab/Shift + Tab**, or **F1/F2/F3/F4** to move the cursor to the **Battery** item, and then press **Enter** to display the **Battery** screen.

This screen displays the battery capacity, whether AC power is used and whether the battery is being charged.

Press **Esc** to exit the screen.

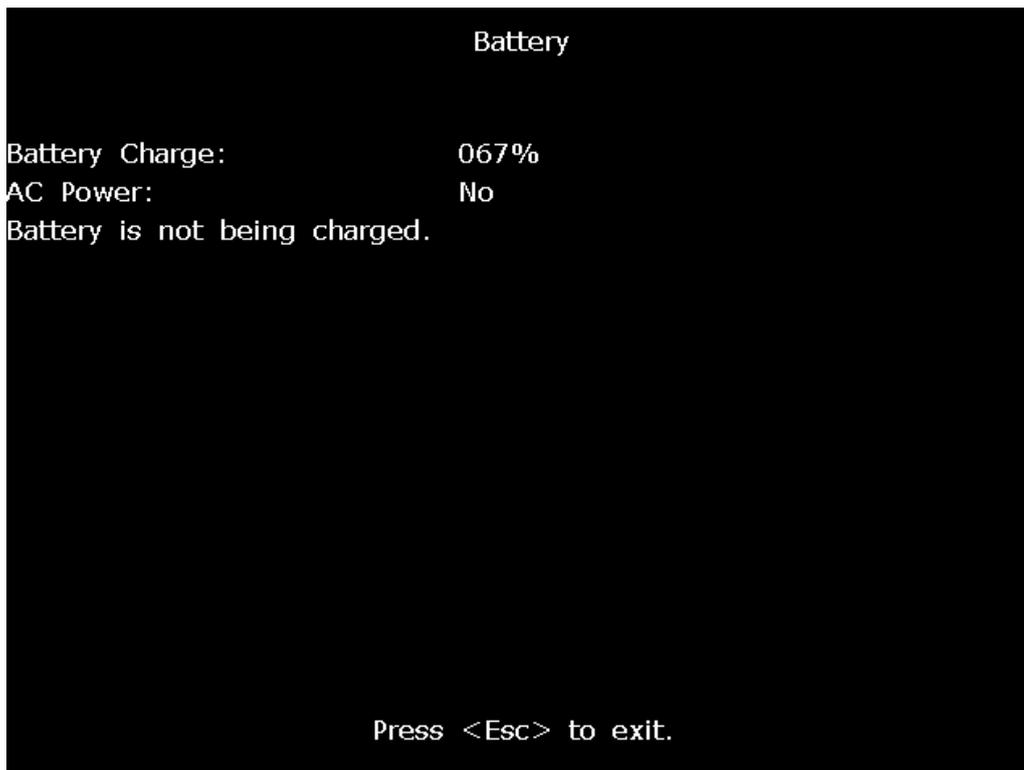


Figure 5-10 Battery Screen

7. Recorder Test

On the **System Test** screen, press **Tab/Shift + Tab**, or **F1/F2/F3/F4** to move the cursor to the **Recorder** item, and then press **Enter** to display the **Recorder** screen.

On this screen, press the **PRINT/STOP** key to begin to print the triangle waves in effective paper width. The status of the print head can be estimated from the triangle waves. Press **PRINT/STOP** again to stop printing.

Press **Esc** to exit the screen.

NOTE: During the printing course, you should not press the **Esc** key to exit.



Figure 5-11 Recorder Screen

8. UART Test

On the **System Test** screen, press **Tab/Shift + Tab**, or **F1/F2/F3/F4** to move the cursor to the **UART** item, and then press Enter to open the **UART** screen.

On this screen, pressing the **PRINT/STOP** key can make the system send and receive characters. If the character received is always the same as the character sent, which is displayed on the screen, it indicates that the system's UART works well.

Press **PRINT/STOP** again to stop testing. Press **Esc** to exit the screen.

NOTE: During the testing course, you should not press the **Esc** key to exit.



Figure 5-12 UART Screen

5.3 Module Tests

When a module is suspected of malfunction, the verification methods are described in this chapter.

5.3.1 Main Board Test

To verify the main board,

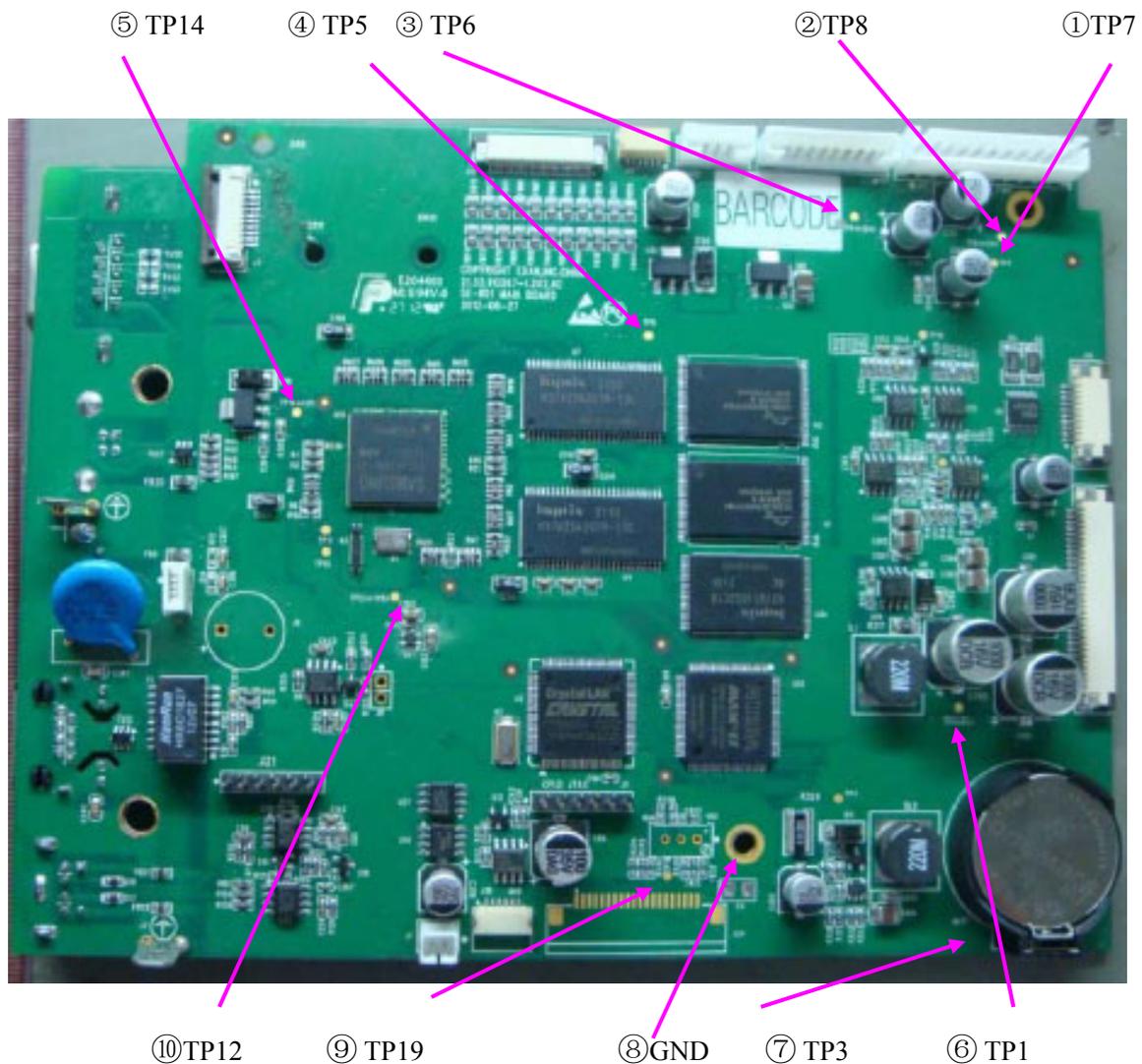
- 1) Open the main unit following the procedures described in Chapter 6, “Electrocardiograph Disassembly”.
- 2) Switch on the device.
- 3) Measure the voltage to earth of the test points listed below by using a multimeter.

Item	Test point	Reference result
①	TP7	+8.3V±0.42V
②	TP8	+5V±0.25V
③	TP6	+12V±0.60V
④	TP5	+3.3V±0.16V

⑤	TP14	+2.0V±0.10V
⑥	TP1	+7.75V±0.75V
⑦	TP3	+28V±1.40V, see NOTE1
⑧	GND	GND
⑨	TP19	-6.95 ~ -6.85V, see NOTE2
⑩	TP12	+1.8V±0.09V

NOTE1: Only test TP3 on SE-601C with the AUO 5.7" V0 display.

NOTE2: Only test TP19 on SE-601A. If display problem occurs and the voltage exceeds the range, you can adjust potentiometer VR2 to make TP19 meet the requirements by using the debugging pen.



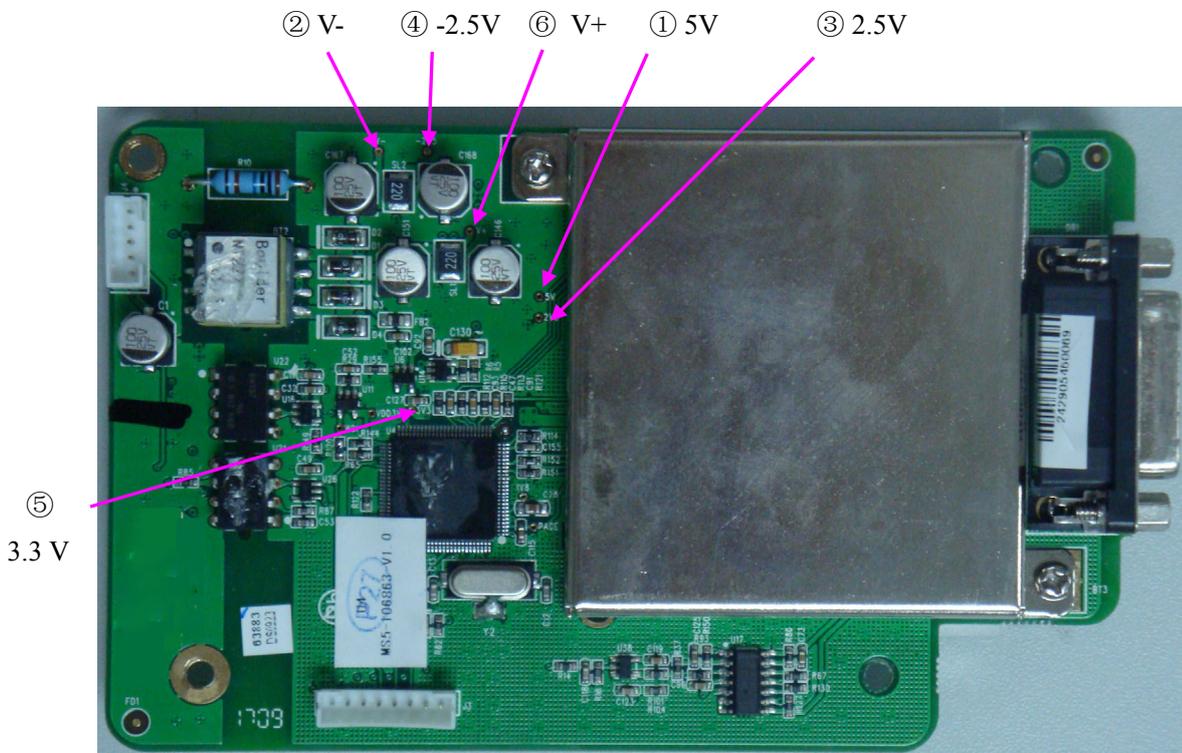
- 4) Compare the measurement results with the reference results in the list. If any one of the results exceeds the reference range, the main board deflection is confirmed. Replacement of the main board is recommended.

5.3.2 ECG Board Test

To verify the ECG board,

- 1) Make sure that the malfunction of ECG measurement is not caused by other defects, such as defective connection, inoperative electrodes or main board, etc.
- 2) Open the main unit following the procedures described in Chapter 6, “Electrocardiograph Disassembly”.
- 3) Switch on the device.
- 4) Measure the voltage to earth of the test points listed below by using a multimeter.

Item	Test Point	Reference Result
①	5V	5.0V±0.15V
②	V-	≤-5.9V
③	2.5V	2.5V±0.085V
④	-2.5V	-2.5V±0.05V
⑤	3.3V	3.3V±0.1V
⑥	V+	≤5.9V



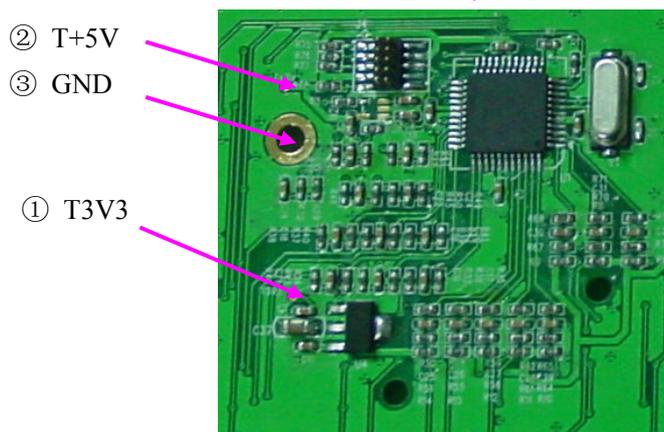
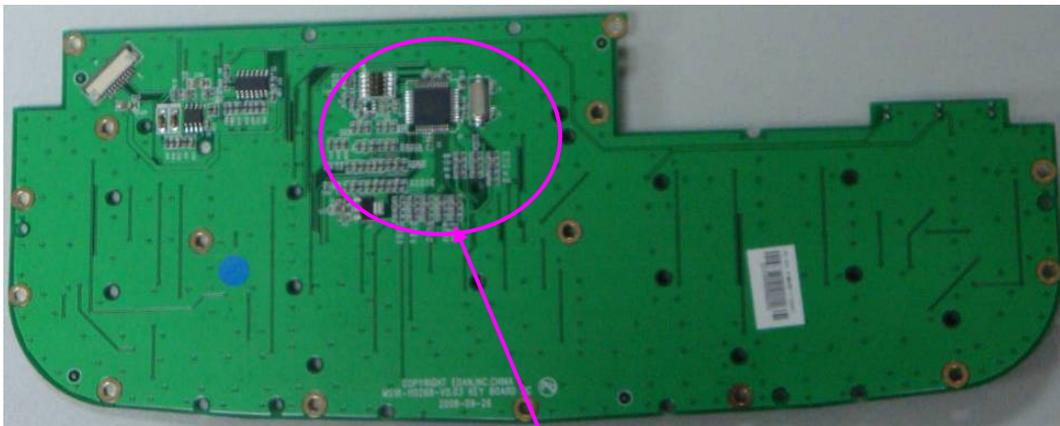
- 5) Compare the measurement results with the reference results in the list. If any one of the results exceeds the reference range, the ECG board deflection is confirmed. Replacement of the ECG board is recommended.

5.3.3 Key Board Test

To verify the key board,

- 1) Open the main unit following the procedures described in Chapter 6, “Electrocardiograph Disassembly”.
- 2) Switch on the device.
- 3) Measure the voltage to earth of the test points listed below by using a multimeter.

Item	Test point	Reference result
①	T3V3	$3.3\pm 0.1V$
②	T+5V	$5\pm 0.5V$
③		GND



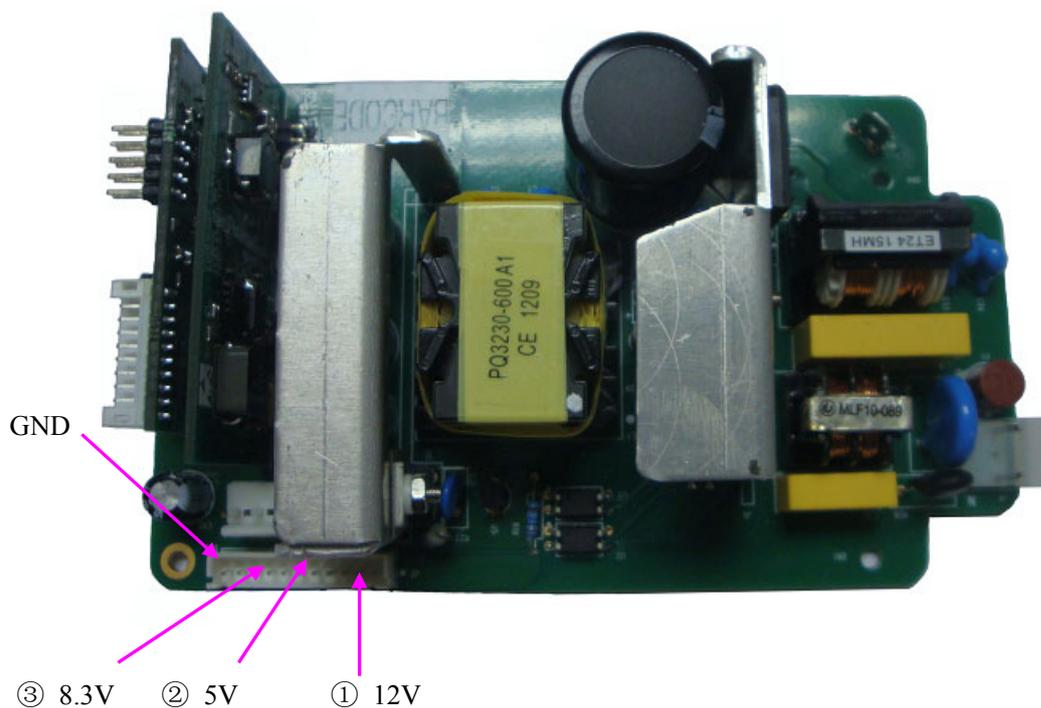
- 4) Compare the measurement results with the reference results in the list. If any one of the results exceeds the reference range, the key board deflection is confirmed. Replacement of the key board is recommended.

5.3.4 Power Supply Board Test

To verify the power supply board,

- 1) Open the main unit following the procedures described in Chapter 6, “Electrocardiograph Disassembly”.
- 2) Switch on the device.
- 3) Measure the voltage to earth of the test points listed below by using a multimeter.

Item	Test Point	Reference Result
①	12V	+12V±0.6V
②	5V	+5V±0.25V
③	8.3V	8.3V±0.3V
④		GND



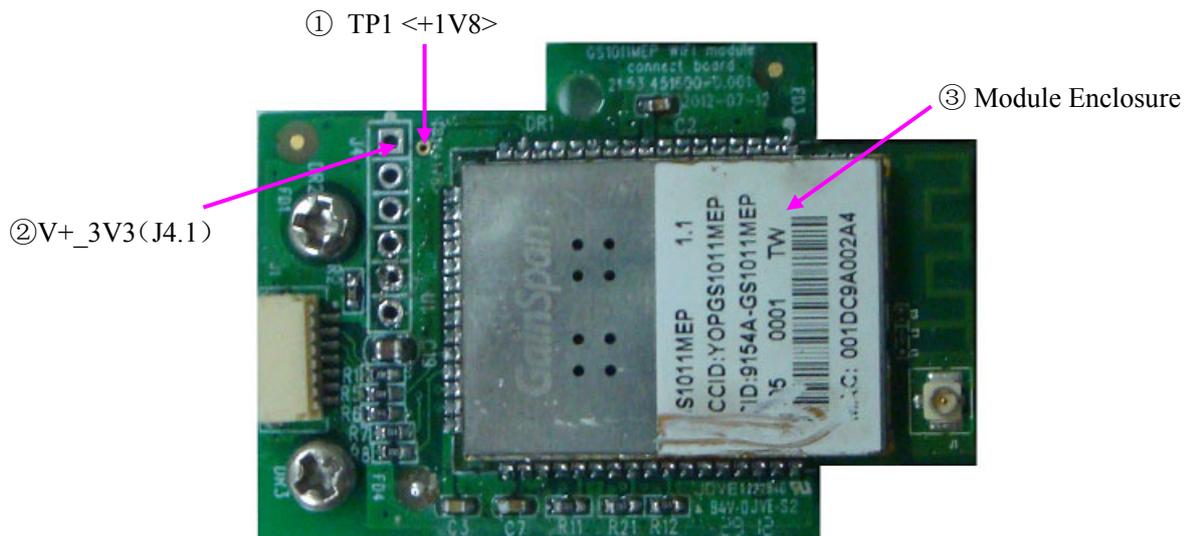
- 4) Compare the measurement results with the reference results in the list. If any one of the results exceeds the reference range, the power supply board deflection is confirmed. Replacement of the power supply board is recommended.

5.3.5 WIFI Module Test (Optional)

To verify the WIFI module,

- 1) Open the main unit following the procedures described in Chapter 6, “Electrocardiograph Disassembly”.
- 2) Switch on the device.
- 3) Measure the voltage to earth of the test points listed below by using a multimeter.

Item	Test Point	Reference Result
①	TP1 <+1V8>	+1.8V±0.1V
②	V+_3V3 (J4.1)	+3.3V±0.17V
③	Module Enclosure	GND



- 5) Compare the measurement results with the reference results in the list. If any one of the results exceeds the reference range, WIFI carrier plate deflection is confirmed. Replacement of WIFI carrier plate is recommended.

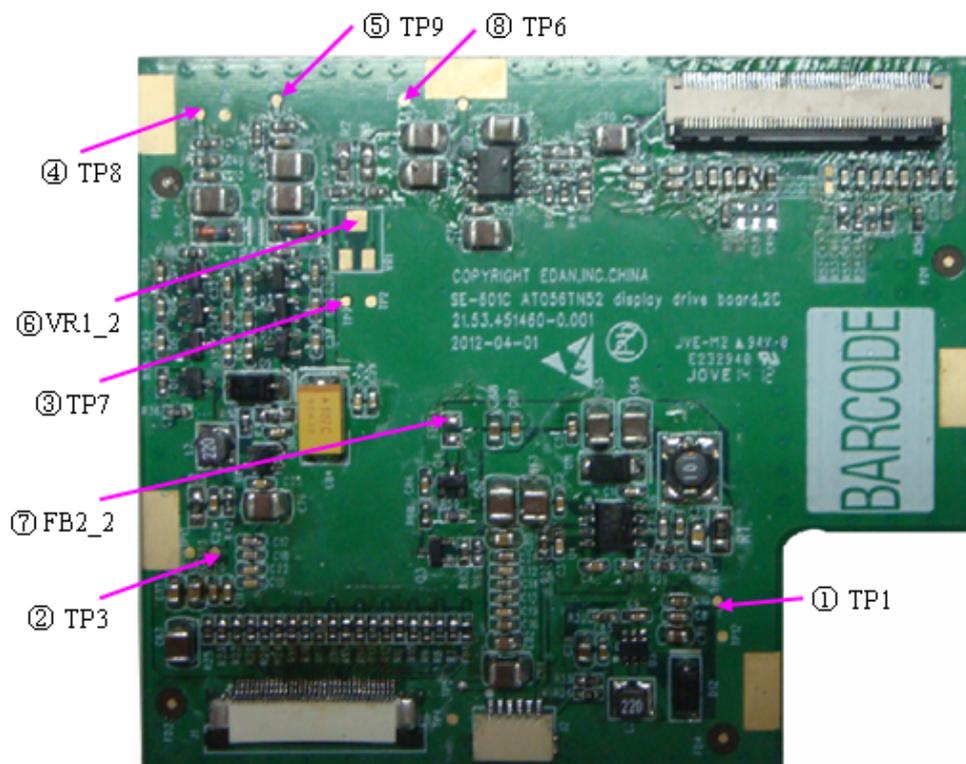
5.3.6 Display Drive Board Test

NOTE: Only test the display drive board on SE-601B/C.

To verify the display drive board,

- 1) Open the main unit following the procedures described in Chapter 6, “Electrocardiograph Disassembly”.
- 2) Switch on the device.
- 3) Measure the voltage to earth of the test points listed below by using a multimeter.

Item	Test Point	Reference Result
①	TP1	8.40~10.50V
②	TP3	3.14~3.46V
③	TP7	4.75~5.25V
④	TP8	-10.50 ~ -9.50V
⑤	TP9	14.30~15.70V
⑥	VR1_2	1.80~2.20V
⑦	FB2_2	5.00~5.56V



- 6) Compare the measurement results with the reference results in the list. If any one of the results exceeds the reference range, the deflection of the display drive board is confirmed. Replacement of the display drive board is recommended.

5.4 Troubleshooting

WARNING

Replace parts, components, or accessories only with parts supplied or approved by the manufacturer. The use of any other parts can lead to inferior device performance and will void the product warranty.

This troubleshooting guide introduces the suitable actions for correcting the problems, replacing the accessories or calling the service personnel. It can also help you describe the fault symptoms more exactly when calling for service, which greatly makes the service fast and efficient.

1. System Troubles

Conditions	Possible Causes	Actions
When the mains supply is used, you can not turn on the electrocardiograph.	<ul style="list-style-type: none"> ① Fuse failure ② Power board failure ③ Main board failure ④ Silicone keyboard failure 	<ul style="list-style-type: none"> ① Replace the fuse ② Replace the power board ③ Replace the main board ④ Replace the silicone keyboard
When the battery is used, you can not turn on the electrocardiograph.	<ul style="list-style-type: none"> ① Battery failure ② Main board failure ③ Silicone keyboard failure 	<ul style="list-style-type: none"> ① Replace the battery ② Replace the main board. ③ Replace the silicone keyboard
After power-on, the ECG stays on the logo screen and doesn't open the main screen.	<ul style="list-style-type: none"> ① There is a key pressed down, without springing up ② The software fails to function 	<ul style="list-style-type: none"> ① Find that key, and make it spring up ② Restart the electrocardiograph

The electrocardiograph fails to function.	<ul style="list-style-type: none"> ① Strong interference of electric networks ② Main board failure ③ The plug-in unit on the main board or the power supply failure 	<ul style="list-style-type: none"> ① Inspect the power supply and grounded system ② Replace the main board ③ Replace or repair the plug-in unit
Fuse is burned when you turn on the electrocardiograph.	The power supply or other components short-circuit.	Open the electrocardiograph for further examination
Fuse is burned when the device connects to a certain component.	This component short-circuits.	Replace this component.

2. Display Troubles

Conditions	Possible Causes	Actions
Some characters displayed on the LCD screen are missing.	<ul style="list-style-type: none"> ① LCD screen failure ② The LCD related cable is disconnected ③ The LCD related cable is damaged ④ Display drive board failure 	<ul style="list-style-type: none"> ① Replace the LCD screen ② Check whether the LCD related cable is well connected ③ Replace the LCD related cable ④ Replace the display drive board
The LCD screen is dark.	<ul style="list-style-type: none"> ① The brightness of the LCD screen is not adjusted well. ② LCD screen failure ③ Display drive board failure 	<ul style="list-style-type: none"> ① Adjust the brightness of the LCD screen in the Display Setup window. ② Replace the LCD screen ③ Replace the display drive board

3. Transmission Troubles

Conditions	Possible Causes	Actions
<p>Fail to transmit ECG data through the net port</p> <p>Fail to copy data from the electrocardiograph to the U disk</p>	<p>① Setup error</p> <p>② Connection cable failure</p> <p>③ Port failure</p> <p>④ U disk failure</p>	<p>① Examine whether the transmission settings are correct. (The first three sections of Local IP and Remote IP must be set the same as the first three sections of the IP of the PC.)</p> <p>② Replace the connection cable</p> <p>③ Replace the port</p> <p>④ Replace the U disk</p>
<p>Fail to connect or transmit ECG data through WIFI</p>	<p>① WIFI module failure</p> <p>② WIFI related cable is disconnected or damaged</p> <p>③ Software installed on PC is abnormal</p> <p>④ SE-601C main board failure</p>	<p>① Replace WIFI carrier plate</p> <p>② Check whether WIFI related cable is well connected, restart the electrocardiograph. Or, replace the WIFI related cable.</p> <p>③ Replace the software</p> <p>④ Replace SE-601 main board</p>

4. Operation Troubles

Conditions	Possible Causes	Actions
<p>Key failure</p>	<p>① The key board is damaged.</p> <p>② Main board failure</p> <p>③ The key board related cable is disconnected</p> <p>④ The key board related cable is damaged</p>	<p>① Replace the key board</p> <p>② Replace the main board</p> <p>③ Check whether the key board related cable is well connected</p> <p>④ Replace the key board related cable</p>

No Key Beep or Key Beep is raucous(only for Model A)	Buzzer failure	Change buzzer
No Key Sound or Key Sound is raucous (only for Model B/C)	Speaker failure	Change Speaker
The electrocardiograph can not print reports.	<ul style="list-style-type: none"> ① The recorder paper runs out. ② Print head failure ③ Main board failure ④ Recorder related cable failure ⑤ Dirty black marker detector ⑥ The black marker detector is covered by the black marker of the recorder paper 	<ul style="list-style-type: none"> ① Install the recorder paper ② Replace the print head ③ Replace the main board ④ Replace or repair the recorder related cable ⑤ Clean the black marker detector ⑥ Pull a little of paper out
The printed report is illegible	<ul style="list-style-type: none"> ① The rubber roller of the recorder casing has stains. ② The elasticity of the spring of the recorder frame is not good. 	<ul style="list-style-type: none"> ① Clean the rubber roller ② Replace the spring
Some characters or waveforms printed are missing.	<ul style="list-style-type: none"> ① The rubber roller of the recorder casing has stain. ② Print head failure 	<ul style="list-style-type: none"> ① Clean the rubber roller ② Replace the print head
Fail to detect paper	<ul style="list-style-type: none"> ① There is a stain on the detecting position of the print head. ② Print head failure ③ Main board failure 	<ul style="list-style-type: none"> ① Clean the stain on the detecting position of the print head. ② Replace the print head. ③ Replace the main board.

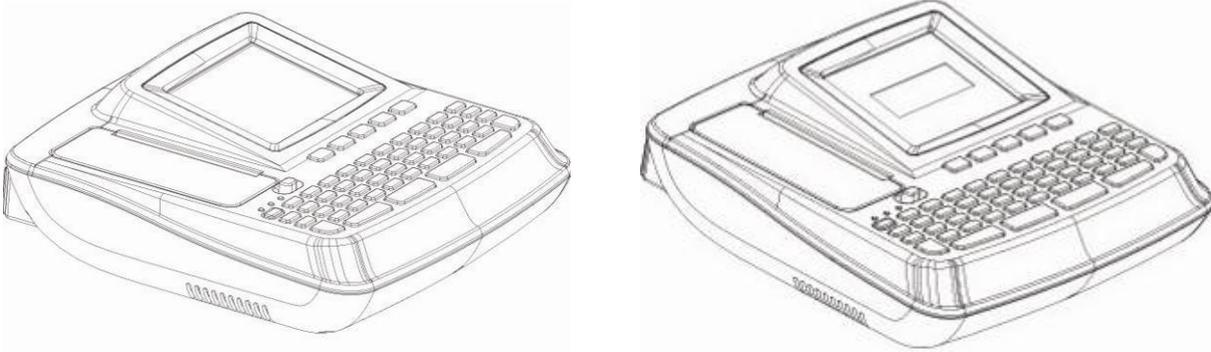
5. Parameter Troubles

Conditions	Possible Causes	Actions
No ECG waveform	<ul style="list-style-type: none"> ① Defective connection between the patient and the electrodes ② Defective connection between the patient cable and the unit ③ ECG board failure 	<ul style="list-style-type: none"> ① Attach the electrodes to the patient again or clean the electrode area on body surface with alcohol ② Connect the patient cable to the unit ③ Replace the ECG board
ECG waveform is abnormal or disturbed	<ul style="list-style-type: none"> ① Defective connection between the patient and the electrodes ② Patient cable failure ③ ECG board failure 	<ul style="list-style-type: none"> ① Attach the electrodes to the patient again or clean the electrode area on body surface with alcohol ② Replace the patient cable ③ Replace the ECG board
Heart rate is not accurate	Waveform measuring failure	Adjust connections
ECG waveform has burrs	<ul style="list-style-type: none"> ① Defective connection between the patient and the electrodes ② ECG board failure ③ Electrical interference from another device (microwave oven, cellular phone, wireless device, etc.) ④ An improperly-grounded electrical device near the electrocardiograph 	<ul style="list-style-type: none"> ① Attach the electrodes to the patient again or clean the electrode area on body surface with alcohol ② Replace the ECG board ③ Look for devices that could be causing electrical interference, and then unplug the devices. Or run the electrocardiograph on the battery power. ④ Lay the lead wires alongside the limbs and away from any electrical devices. Turn on the AC filter on the Filter Setup window

Chapter 6 Electrocardiograph Disassembly

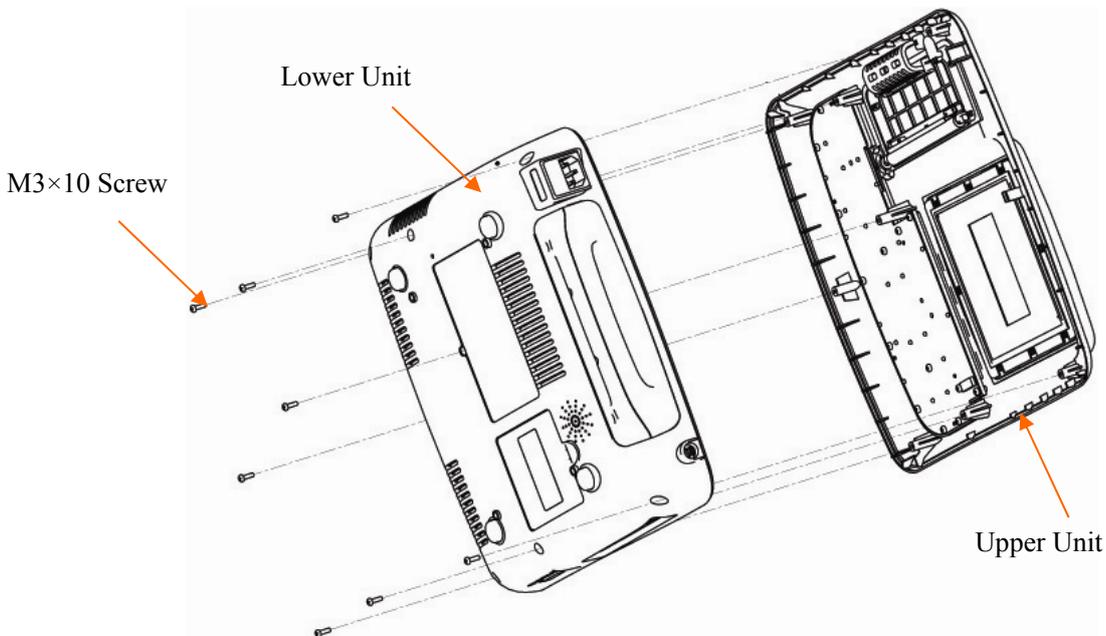
6.1 Disassembly Procedures

1. Main Unit



2. Disassembly Procedures of the Main Unit

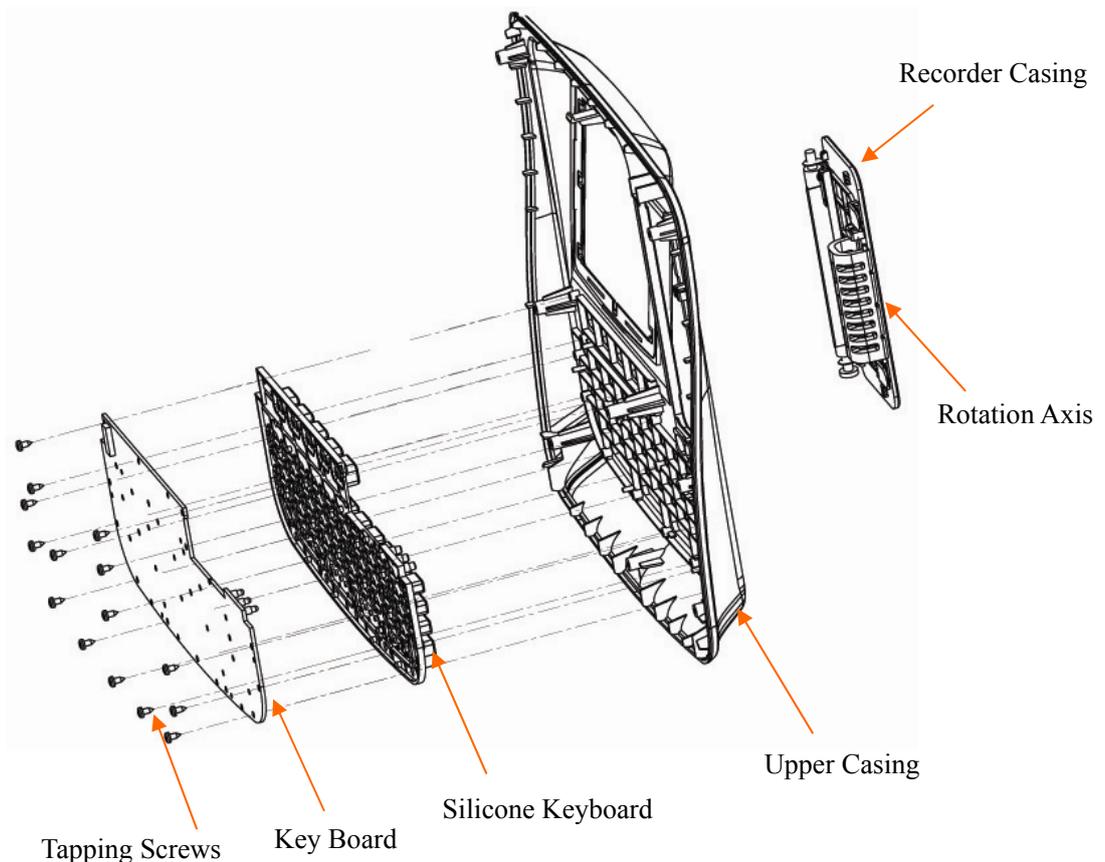
Remove the eight M3×10 screws on the lower unit to open the device. But the upper unit and the lower unit can not be separated because there are signal cables between them. Therefore when disassembling the device, you should be careful to avoid destroying the signal cables. Remove these signal cables that can be dismantled directly and move them out of the shield box in the lower unit to uncover the hidden signal cables. Then dismantle these hidden signal cables to separate the upper and lower units as the following figure shows.



1) Disassembly Procedures of the Upper Unit

The upper unit consists of the keyboard assembly, recorder casing and upper casing. The disassembly sequence is: keyboard assembly > recorder casing -> upper casing.

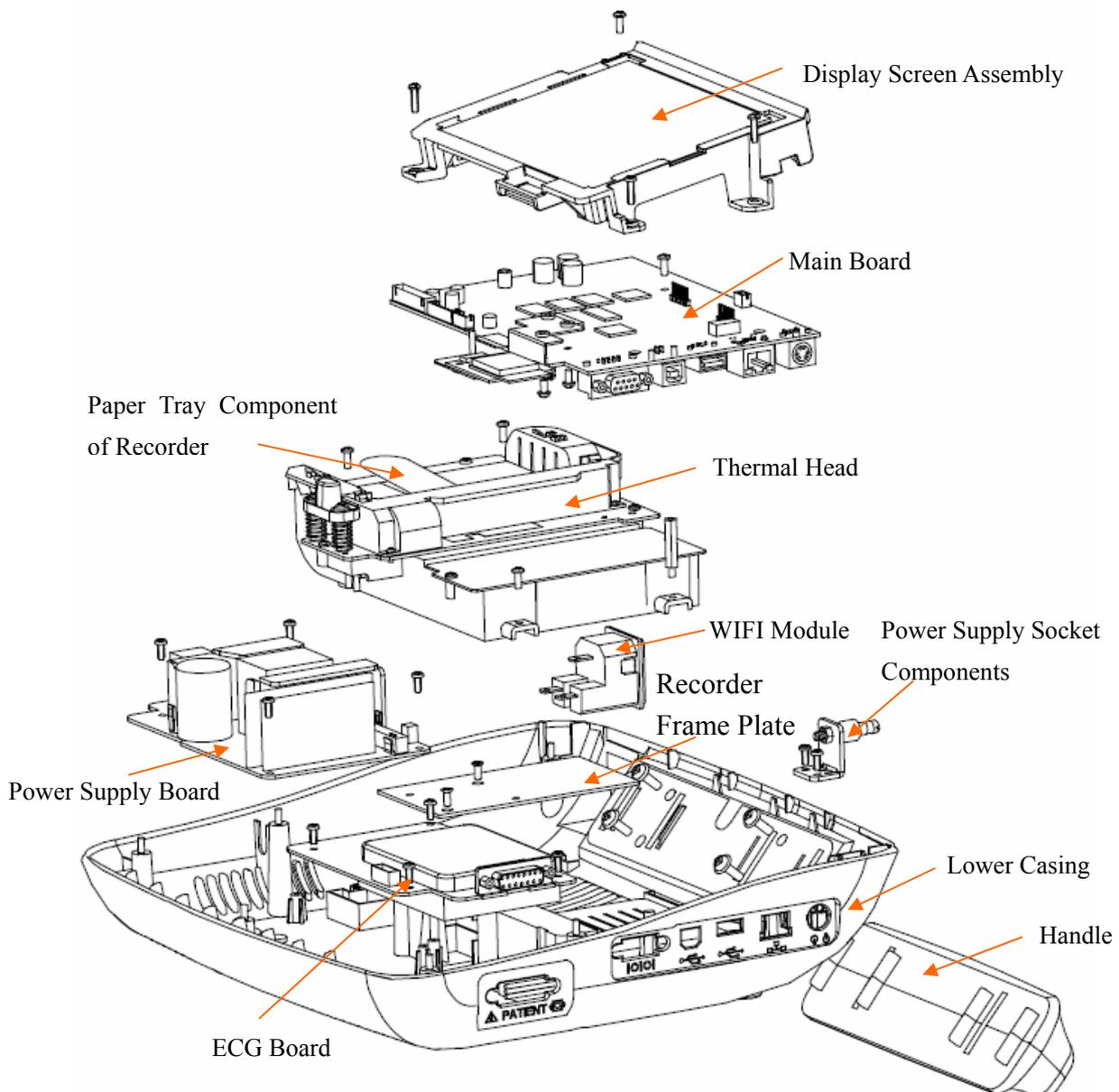
Remove the fifteen tapping screws, and then the key board and the silicone keyboard can be dismantled from the upper unit, pull out the rotation axis between the recorder casing and the upper casing, and then the recorder casing can be dismantled from the upper unit, as the following figure shows.



2) Disassembly Procedures of the Lower Unit

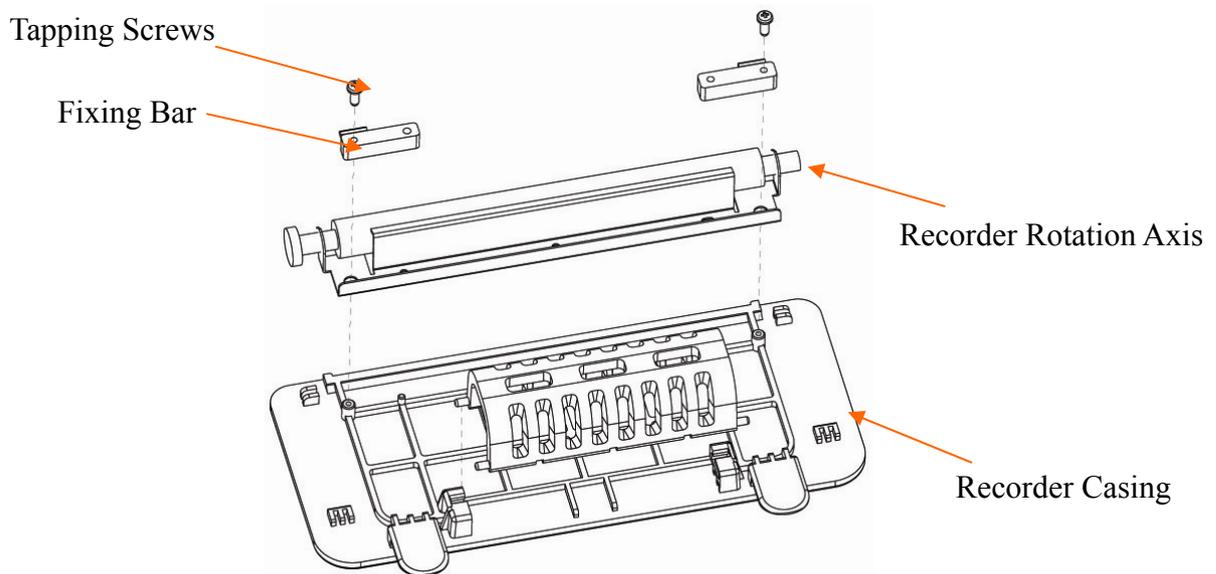
First remove all the relevant cables that can be moved out directly, and dismantle the lower unit in the following sequence, as the following figure shows.

Display Screen Assembly → WIFI Module → Main Board → Paper Tray Component of Recorder → Power Supply Board → ECG Board → Recorder Frame Plate → Handle → Power Supply Socket Components



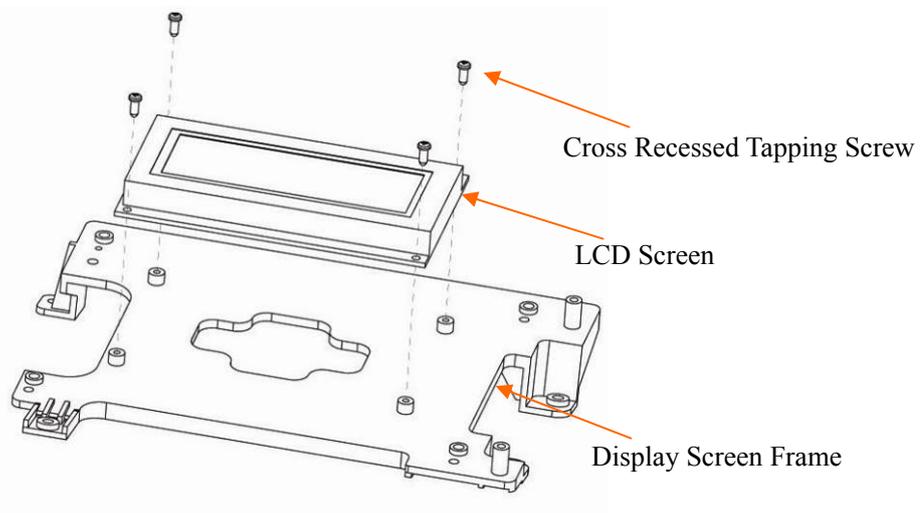
3) Disassembly Procedures of the Recorder Casing

Remove the two tapping screws and the two groups of fixing bars, and then the recorder rotation axis can be dismantled from the recorder casing, as the following figure shows.



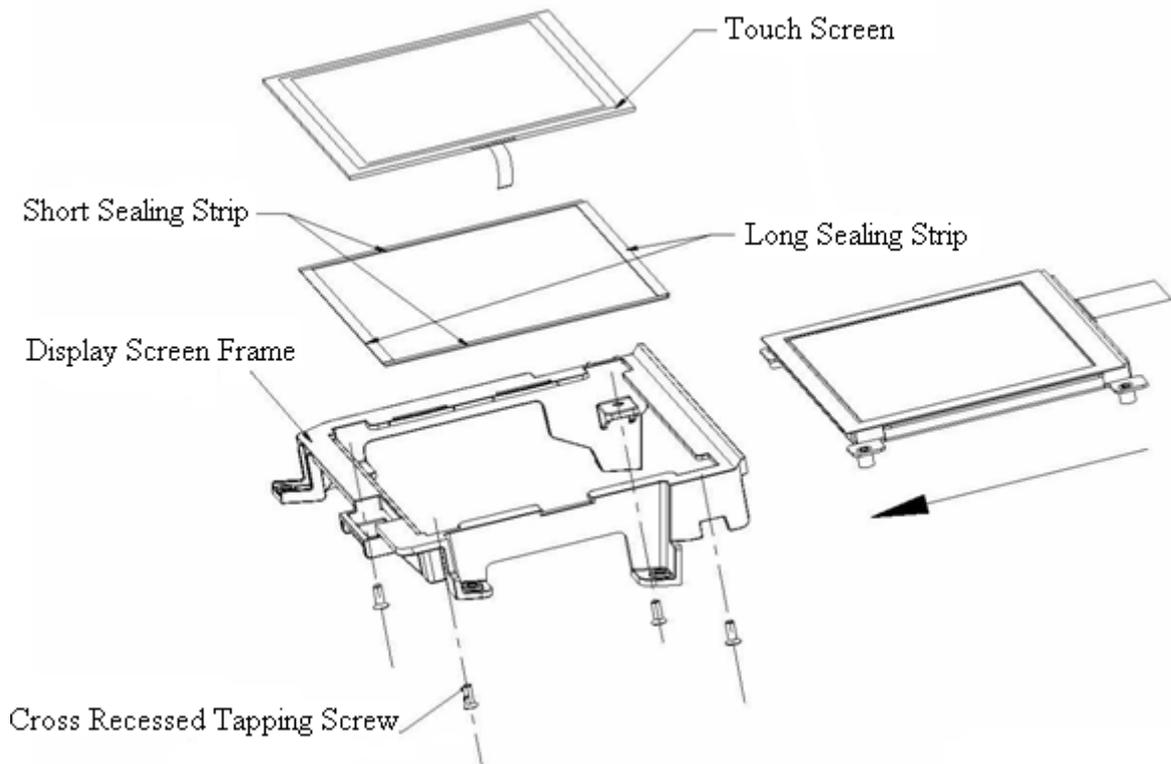
4) Disassembly Procedures of the Display Screen for SE-601A

Remove the four cross recessed tapping screws to separate the LCD Screen and Display Screen Frame, as shown in the following figure.



5) Disassembly Procedures of the Display Screen for SE-601B/C

Remove the four cross recessed tapping screws to separate the LCD screen and the display screen frame, as the following figure shows.



3. Disassembly Procedures of the fuse

To replace the blown fuse,

- 1) Unplug the electrocardiograph from AC power. Pull out the AC power cord from the AC power connector on the rear of the electrocardiograph.
- 2) Locate the AC fuse, which is directly below the AC power connector, as the picture shows:



Fuse Socket

3) Pull out the fuse socket from the fuse socket slot.



4) Remove the old fuse. Insert the new fuse using the same specification (T3.15AH250V, Ø5×20mm) supplied by the manufacturer.

5) Push the fuse all the way into the fuse socket slot.

WARNING

Ruptured fuses must only be replaced with those of the same type and rating as the original.

6.2 Internal Boards and Interfaces

1. ECG Board -- Receiving and Processing ECG Signals



① J4-- connected to main board J15.

Pin	Description
2	GND
3, 4	Data transmitting
5	Vcc +5V

2. PS900G Power Supply Board -- Providing Power Supply



① J5 -- connected to the power supply

② J1 -- connected to the li-ion battery

Pin	Description
1	Battery supply
2	Battery detecting
3	GND

③ J3 -- connected to J17 power output of the main board

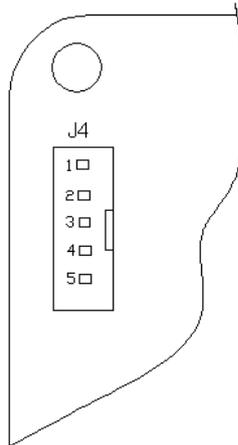
Pin	Description
1, 2	+12V
3, 4, 7, 10, 11	GND
5, 6	+5V
8, 9	+8.3V

④ J1 (power control board) -- connected to main board J13

Pin	Description
1, 7, 9	GND
10	Turn on/off
5	Recharging Lock
3	Turnoff detecting

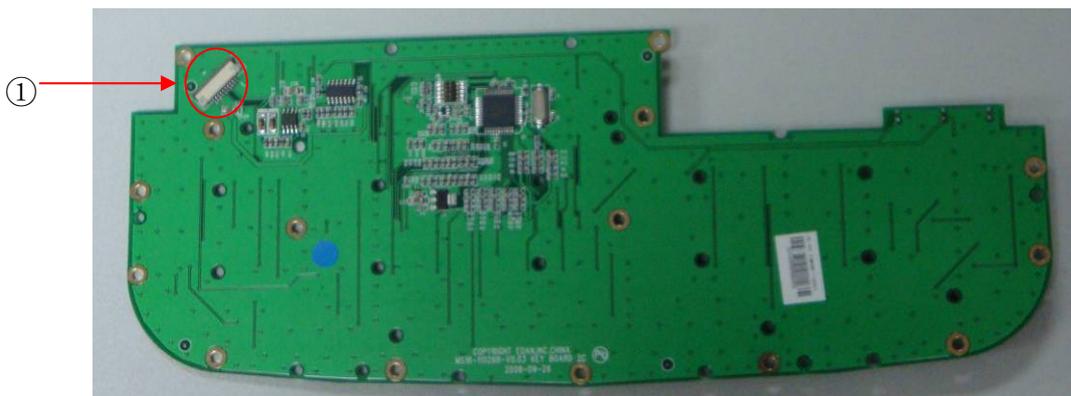
6	Mains supply
8	Battery measure
2	Turnoff by software
4	Battery detecting

⑤ J4-- connected to main board J3



Pin	Description
2	GND
5	DVcc+5V
3, 4	Data transmitting

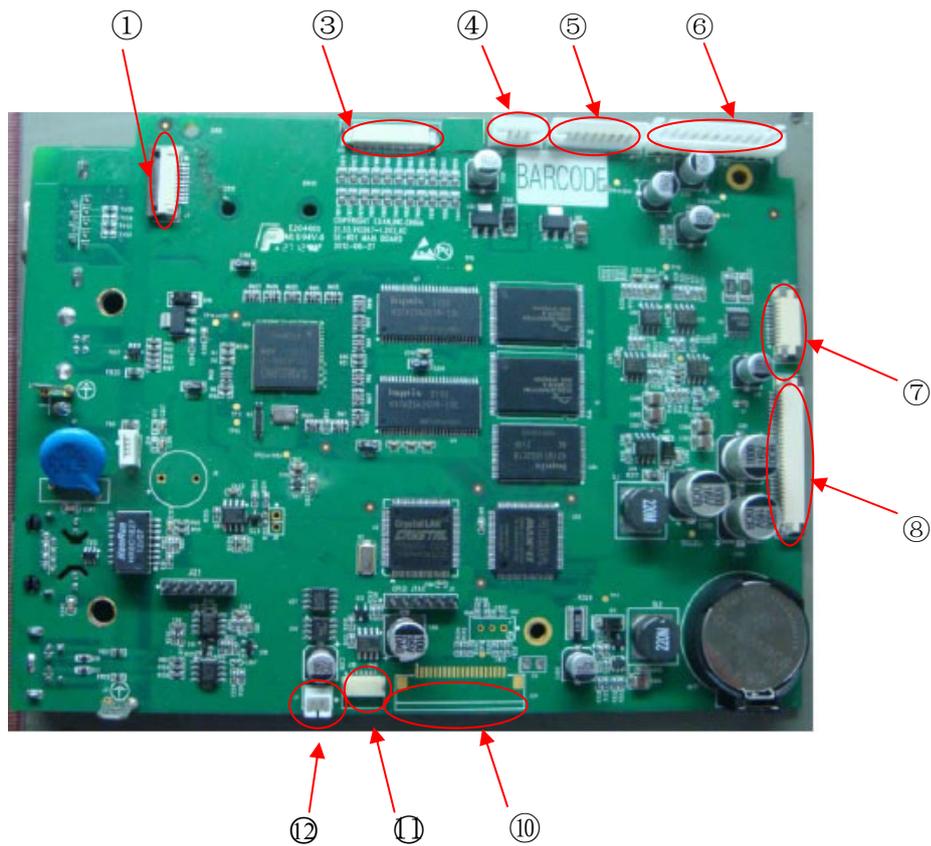
3. Key Board -- Input Interface

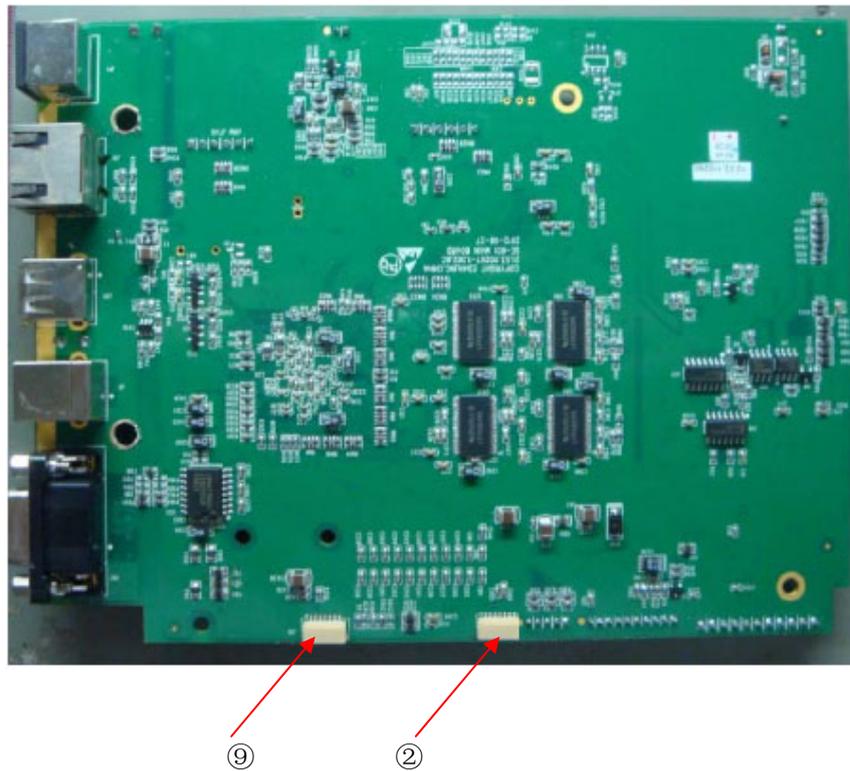


① J6 -- connected to main board J7

Pin	Description
1	Vcc+ 5V
2, 3,10	GND
4, 5	Data transmitting
6	Turn on/off
7	Mains supply
8	Provide power supply for the battery indicator circuit
9	Provide power supply for the recharging indicator circuit

4. Main board





① J7 -- connected to key board J6

Pin	Description
1	Vcc+ 5V
2, 3, 10	GND
4, 5	Data transmitting
6	Turn on/off
7	Mains supply
8	Provide power supply for the battery indicator circuit
9	Provide power supply for the recharging indicator circuit

② J14 -- connected to SE-601B/C backlight screen

Pin	Description
1, 2	+12V
3, 4	GND
5	Brightness adjustment signal for LCD backlight
6	Control signal for LCD backlight

③ J12 -- connected to SE-601B/C screen

Pin	Description
1, 5, 12, 19, 26, 33	GND
28, 29	Vdd+3V
others	Signal port of LCD

④ J15 -- connected to ECG board J4

Pin	Description
2	GND
3, 4	Data transmitting
5	Vcc+5V

⑤ J13 -- connected to power control board J1

Pin	Description
1, 7, 9	GND
10	Turn on/off
5	Recharging lock
3	Turnoff detecting
6	Mains supply
8	Battery measure
2	Turnoff by software
4	Battery detecting

⑥ J17 -- connected to power supply board J3

Pin	Description
1, 2	+12V
3, 4, 7, 10, 11	GND
5, 6	+5V
8, 9	8.1V

⑦ J16 -- connected to the step motor

Pin	Description
1,9,10	GND
2	Vcc+5V
3	Input port for paper detecting signal
4, 5, 6,7,8	Signal port of step motor

⑧ J11 -- connected to the thermal print head

Pin	Description
2, 11, 12, 13, 14, 15, 16, 17, 18, 20,	GND
1,24	Vdd+3V
3,4,5,28,29,30	VHH+8.3V
others	Signal port of thermal print head

⑨ J19 -- connected to SE-601B Background brightness

Pin	Description
1	Vcc+5V
2	GND

⑩ J18 -- connected to SE-601C Background brightness

Pin	Description
1,2,3	Vcc+28V
4,5,6	GND

⑪ J24 -- connected to SE-601A Screen

Pin	Description
1,20	GND
2	Vcc+5V
19	Background brightness control
others	Signal port of LCD

⑫ J1 -- connected to speaker

Pin	Description
1	Signal port of Audio
2	GND(MCU control)

Chapter 7 Cleaning, Care and Maintenance

CAUTION

1. Turn off the power before cleaning and disinfection. The mains supply must be switched off if it is used.
2. Prevent the detergent from seeping into the equipment.

7.1 Cleaning

CAUTION

Any remainder of detergent should be removed from the unit and the patient cable after cleaning.

7.1.1 Cleaning the Main Unit and the Patient Cable

Wipe the surfaces of the main unit and the patient cable with a clean soft cloth damped in diluent ammonia (not exceed 3%), 75% ethanol, 70% isopropanol or soapy water (not exceed 60°C).

7.1.2 Cleaning the Reusable Electrodes

Wipe the surfaces of the suction bulb and the electrodes with a clean soft cloth damped in mild water (not exceed 35°C), 75% ethanol or 70% isopropanol.

CAUTION

Do not clean the unit and accessories with abrasive fabric and avoid scratching the electrodes.

7.1.3 Cleaning 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% ethanol or 70% isopropanol. For stubborn stain, soak it with a little alcohol first and wipe it off with a clean soft cloth. After air dried, load the recording 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 the patient cable into liquid under any circumstances.

7.2 Disinfection

Disinfection of the main unit is not necessary need in daily maintenance, it is only necessary in operating room.

NOTE: Clean and disinfect the chest and limb electrodes after each use.

Wipe the surface of the main unit, the suction bulb and the electrodes with a clean soft cloth damped in glutaraldehyde (not exceed 3.6%), 75% ethanol or 70% isopropanol.

CAUTION

1. Do not use high-temperature, high-pressure vapour or ionizing radiation as disinfection methods.
 2. Do not use chloric disinfectant such as chloride, sodium hypochlorite etc.
 3. Always clean and disinfect reusable electrodes after patient use.
-
-

7.3 Care and Maintenance

CAUTION

Operate the cardiograph, charge the battery, and store the battery at a temperature of 40°C (104°F) or lower. Exposure to higher temperature may reduce battery life, damage the battery, and degrade overall cardiograph performance.

7.3.1 Recharge and Replacement of Battery

1) Capacity Identification

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

: Full capacity;

: 2/3 capacity;

: 1/3 capacity;

: Low capacity

2) Recharge

SE-601 series electrocardiograph is equipped with the recharge control circuit together with the battery. When the unit is connected to the mains supply, the battery will be recharged automatically. Then the battery recharging indicator (→□) and the mains supply indicator (∞) will be lit at the same time. During the recharging course, the symbol □ flashes in the top right corner of the LCD screen. After the battery is fully recharged, the symbol stops flashing, and the battery recharging indicator (→□) is black.

Because of the capacity consumption during the storage and transport course, the battery capacity is not full when it is used for the first time. Battery recharge should be considered before the first use.

NOTE: The battery will automatically stop charging if you print an ECG report.

CAUTION

Repeated undercharging of the battery will damage the battery and reduce battery life.

3) Replacement

When the useful life of the battery is over, or foul smell and leakage are found, please contact the manufacturer or the local distributor for replacement.

WARNING

1. Only qualified service engineers authorized by the manufacturer can open the battery compartment and replace the battery, and the battery of the same model and specification provided by the manufacturer must be used.
 2. Danger of explosion -- Do not reverse the anode and the cathode when installing the battery.
 3. When the battery's useful life is over, contact the manufacturer or the local distributor for disposal or dispose of the battery according to local regulations.
 4. Remove the battery from the electrocardiograph when the electrocardiograph isn't used for a long time.
 5. If the battery is stored alone and not used for a long time, we recommend that the battery be charged at least once every 6 months to prevent overdischarge.
-
-

CAUTION

If the battery has been fully charged and requires recharging after printing only a few ECGs, consider replacement.

7.3.2 Recorder Paper

NOTE: Recorder paper provided by the manufacturer should be used. Other paper may shorten the life of the thermal print head. The deteriorated print head may lead to illegible ECG reports and block the advance of the paper.

Storage Requirements:

- ◆ Recorder paper should be stored in a dry, dark and cool area, avoiding excessive temperature, humidity and sunshine.
- ◆ Do not put the recorder paper under fluorescence for a long time.
- ◆ Make 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 recorder paper for a long time, or else the ECG reports may trans-print each other.

7.3.3 Visual inspection

Perform a visual inspection of all equipment and peripheral devices daily. If you notice any items that need repair, contact a qualified service engineer to make the repairs.

- ◆ Check the case and display screen for cracks or other damage.
- ◆ Regularly inspect all plugs, cords, cables, and connectors for fraying or other damage.
- ◆ Verify that all cords and connectors are securely seated.
- ◆ Inspect keys and controls for proper operation.

7.3.4 Maintenance of the Main Unit and the Patient Cable

CAUTION

Besides the maintenance requirements recommended in this manual, comply with local regulations on maintenance and measurement.

The following safety checks should be performed at least every 12 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 related labels for legibility.

- c) Inspect the fuse to verify compliance with the rated current and circuit-breaking characteristics.
- d) Verify that the device functions properly as described in the instructions for use.
- e) Test the protection earth resistance according to IEC/EN 60601-1: Limit: 0.1 ohm.
- f) Test the earth leakage current according to IEC/EN 60601-1: Limit: NC 500 μ A, SFC 1000 μ A.
- g) Test the enclosure leakage current according to IEC/EN 60601-1: Limit: NC 100 μ A, SFC 500 μ A.
- h) Test the patient leakage current according to IEC/EN 60601-1: Limit: NC a.c. 10 μ A, d.c. 10 μ A; SFC a.c. 50 μ A, d.c. 50 μ A.
- i) Test the patient auxiliary current according to IEC/EN 60601-1: Limit: NC a.c. 10 μ A, d.c. 10 μ A; SFC a.c. 50 μ A, d.c. 50 μ A.
- j) Test the patient leakage current under single fault condition with mains voltage on the applied part according to IEC/EN 60601-1: Limit: 50 μ A (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 this equipment to implement a satisfactory maintenance schedule may cause undue equipment failures and possible health hazards.

1) Main Unit

- ◆ Avoid excessive temperature, sunshine, humidity and dirt.
- ◆ Put the dustproof coat on the main unit after use and prevent shaking it violently when moving it to another place.
- ◆ Prevent any liquid from seeping into the equipment; otherwise the safety and the performance of the electrocardiograph can not be guaranteed.

2) Patient Cable

- ◆ Integrity of the patient cable, including the main cable and lead wires, should be checked regularly. Make sure that it is conductible.
- ◆ Do not drag or twist the patient cable with excessive stress while using it. Hold the connector plug instead of the cable when connecting or disconnecting the patient cable.

- ◆ Align the patient cable to avoid twisting, knotting or crooking in a closed angle while using it.
- ◆ Store the lead wires in a big wheel to prevent any people from stumbling.
- ◆ Once damage or aging of the patient cable is found, replace it with a new one immediately.

3) Reusable Electrodes

- ◆ Electrodes must be cleansed after use and make sure there is no remainder gel on them.
- ◆ Keep suction bulbs of chest electrodes away from sunshine and excessive temperature.
- ◆ After long-term use, the surfaces of electrodes will be oxidized because of erosion and other causes. By this time, electrodes should be replaced to achieve high-quality ECG records.

CAUTION

The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal.

Chapter 8 Renewable Parts

The following list is intended as a guide for ordering parts for SE-601 series electrocardiograph.

Part Number	Description
01.16.045078	3.5 inch STN LCD
01.16.045044-11	5.7 inch STN LCD
01.60.110325-11	Silicone keyboard
02.03.110287	Key board
01.17.078176	Thermal printer module
02.01.210040-11	PS900G power supply assembly
02.01.106864	DE12 ECG board
12.03.110278-12	SE-601A main board
12.03.110279-12	SE-601B main board
12.03.110280-12	SE-601C main board

P/N: 01.54.110350

MPN: 01.54.110350014

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