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SE-301 Electrocardiograph Version 1.4

# Service Manual





**About this Manual** 

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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

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The user shall understand that nothing in this manual grants him, expressly or implicitly, any

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

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.

EDAN will make available on request circuit diagrams, component part lists, descriptions,

calibration instructions, or other information that will assist service personnel to repair those

parts of the equipment that are designated by EDAN as repairable by service personnel.

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### 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 dismounted, 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: <a href="http://www.edan.com.cn">http://www.edan.com.cn</a> 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 in advance. 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.

SE-301 Electrocardiograph Service Manual

Warranty and Service

**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

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### **Chapter 2 Safety Guidance**

This chapter provides important safety information related to the use of SE-301.

### 2.1 Indications for Use/Intended Use

The intended use of the 3-Channel Electrocardiograph is to acquire ECG signals from adult and pediatric patients (beginning at birth through 21 years of age) through body surface ECG electrodes. The electrocardiograph is intended to be used only in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the 3-Channel Electrocardiograph can help users to analyze and diagnose heart disease. However the ECG with measurements and interpretive statements is offered to clinicians on an advisory basis only.

#### **WARNING**

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

### 2.2 Warnings and Cautions

To use the system safely and effectively, firstly be familiar with the operation method of Windows and read the user manual in detail to be familiar with the proper operation method for the purpose of avoiding the possibility of system failure. The following warnings and cautions must be paid more attention to during the operation of the system.

### 2.2.1 Safety Warnings

- The electrocardiograph is provided for the use of 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. Otherwise, safety hazards may happen.
- 3. The EQUIPMENT is protected against malfunction caused by electrosurgery.
- 4. **EXPLOSION HAZARD** Do not use the electrocardiograph in the presence of flammable anesthetic mixture with oxygen or other flammable agents.
- 5. **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.
- 6. If the integrity of the external protective conductor is in doubt, the equipment should be operated by using the built-in 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.
- 9. The use of patient cable and other accessories not supplied by the manufacturer may result in increased emissions or decreased immunity of the equipment.
- 10. 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.
- 11. Make sure that all electrodes are connected to the patient correctly before operation.
- 12. Ensure that the conductive parts of electrodes and associated connectors, including neutral electrode, do not come into contact with earth or any other conducting objects.

- 13. To avoid a polarization or DC offset voltage, use non-polarizing electrodes(which will not form a DC offset voltage when subjected to a DC current) such as silver/silver-chloride types if there is a situation where there is a likelihood that a defibrillation procedure will be necessary.
- 14. There is no danger for patients with pacemakers. However, if a pacemaker is used, the results given by the equipment may be invalid, or lose the clinical significance.
  - 15. Disposable electrodes must be used during defibrillation.
- 16. Electrodes of dissimilar metals should not be used; it may cause a high polarization voltage.
- 17. The disposable electrodes can only be used for one time.
- 18. Do not touch the patient, bed, table or the equipment while using the ECG together with a defibrillator.
- 19. Do not touch accessible parts of electrical equipment and the patient simultaneously.
- 20. 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.
- 21. If WIFI technology is used, in order to maintain compliance with the FCC RF exposure guidelines, the wireless should be installed and operated with a minimum distance of 20cm between the radiator and the human body. Use the supplied antenna only. There should be no shield in or around the room where WIFI is used.
- 22. Fix attention on the examination to avoid missing important ECG waves.
- 23. 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.
- 24. **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.

- 25. Do not connect any equipment or accessories that are not approved by the manufacturer or that are not IEC/EN 60601-1 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.
- 26. Any non-medical equipment (such as the external printer) is not allowed to be used within the patient vicinity (1.5m/6ft.).
- 27. Multiple portable socket-outlets shall not be placed on the floor.
- 28. 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.
- 29. 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. 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. If in doubt, consult our technical service department or your local distributor.
- 30. 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.
- 31. 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.

- 32. 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.
- 33. The potential equalization conductor can be connected to that of other equipment when necessary, to make sure that all these devices are connected to the potential equalization bus bar of the electrical installation.
- 34. The electrocardiograph shall not be serviced or maintained while in use with a patient.
- 35. The appliance coupler or mains plug is used as isolation means from supply mains. Position the electrocardiograph in a location where the operator can easily access the disconnection device.
- 36. The medical electrical equipment needs to be installed and put into service according to Appendix 2 EMC Information.
- 37. The equipment should not be used adjacent to or stacked with other equipment, refer to the recommended separation distances provided in Appendix 2 EMC Information.
- 38. Portable and mobile RF communications equipment can affect medical electrical equipment, refer to the recommended separation distances provided in Appendix 2 EMC Information.
- 39. Assembly of the electrocardiograph and modifications during actual service life shall be evaluated based on the requirements of IEC60601-1.
- 40. The device is MR unsafe. It is not intended for use in an MRI environment.
- 41. Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the device comply with the relevant EMC requirements. X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.

### 2.2.2 Li-ion Battery Care Warnings

- 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.

#### 2.2.3 General Cautions

#### CAUTION

- 1. Federal (U.S.) law restricts this device to sale by or on the order of a physician.
- 2. 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.
- 3. Do not use the equipment in a dusty environment with bad ventilation or in the presence of corrosive.
- 4. Make sure that there is no intense electromagnetic interference source around the equipment, such as radio transmitters, mobile phones etc. Attention: large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment is likely to bring electromagnetic interference.
- 5. Ruptured fuse must only be replaced with that of the same type and rating as the original.
- 6. 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.
- 7. Before use, the equipment, the patient cable and electrodes should be checked. Replace them if there is any evident defectiveness or aging which may impair the safety or the performance. Make sure that the equipment is in proper working condition.

### 2.3 List of Symbols

No.	Symbol	Description
1	4	DEFIBRILLATION-PROOF TYPE CF APPLIED PART

2	$\triangle$	Caution
3	[]i	Operating instructions
4	$\Rightarrow$	Equipotential grounding
5	<b>ċ⁄⊚</b>	Power key
6	PRINT/STOP	Print/Stop key
7	PRESS	Casing Button
8	<b>E</b>	General symbol for recovery/recyclable
9	P/N	Part Number
10	SN	SERIAL NUMBER
11	~~ <u>~</u>	Date of manufacture
12	***	MANUFACTURER
13	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
14	<b>C</b> € <sub>0123</sub>	CE marking
15	Z	Disposal method
16	<u></u>	SD card slot
17	•	USB socket

18		Net port
19	19V <del></del>	Power adapter port
20	Rx Only	Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician
21		Refer to User Manual (Background: Blue; Symbol: White)
22		Warning (Background: Yellow; Symbol&Outline: Black)
23*	FCC ID: SMQSE301EDAN	Federal Communications Commission: FCC ID: SMQSE301EDAN
24*	(( <u>(</u> )))	Non- ionizing electromagnetic radiation
25	IMR	MR Unsafe–Keep away from magnetic resonance imaging (MRI) equipment
26	ETL CLASSIFIED  US  Intertek  4005997	Conforms to UL Std. 60601-1, IEC Std. 60601-2-25 Certified to CSA Std. C22.2 No 601.1,CSA Std. C22.2 No 60601-2-25
27	MD	Medical device
28	UDI	Unique Device Identifier

### NOTE:

- 1. 23\*, 24\*: Applicable to the Electrocardiograph configured with WIFI module.
- 2. The manual is printed in black and white.

### **Chapter 3 Overview**

The service manual is a reference for periodic preventive maintenance and corrective service procedures for the 3-channel 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

### 3.1.1 Safety Standards

IEC 60601-1:2015+A1:2012+A2:2020

EN 60601-1:2006/A1:2013

IEC 60601-1-2:2014+A1:2020

EN 60601-1-2:2015

IEC/EN 60601-2-25

#### 3.1.2 Classifications

Anti-electric-shock type:	Class I with internal power supply
Anti-electric-shock degree:	Type CF
Degree of protection against harmful ingress of water:	Ordinary equipment (Sealed equipment without liquid proof)
Disinfection/sterilization method:	Refer to the user manual for details
Degree of safety of application in the presence of flammable gas:	Equipment not suitable for use in the presence of flammable gas
Working mode:	Continuous operation
EMC:	CISPR 11 Group 1, Class A

# 3.1.3 Environment Requirements

	Transport & Storage	Working
Temperature:	-20°C (-4°F) ~ +55°C (+131°F)	+5°C (+41°F) ~ +40°C (+104°F)
Polotivo Humidity	15% RH~95% RH	15% RH~95% RH
Relative Humidity:	Non-Condensing	Non-Condensing
Atmospheric Pressure:	70kPa ~106kPa	70kPa ~106kPa

## 3.1.4 Power Supply Specifications

	Operating voltage =100V-240V~	
Mains Supply:	Operating frequency = 50Hz / 60Hz	
	Power adapter output voltage: 19V, 2A	
	Rated voltage = 14.8V	
	Rated capacity = 2500mAh	
Built-in Lithium Battery Pack:	When the battery is fully charged, the 3-channel electrocardiograph can work normally about 8.5 hours. It can continuously record about 5 hours in Manual mode, and record at least 500 reports at most in the AUTO mode.	
	Necessary Charge time: ≤ 3.5 hours	
	Cycle life ≥ 300 times	

# 3.2 System Architecture and Connection

### 3.2.1 System Architecture

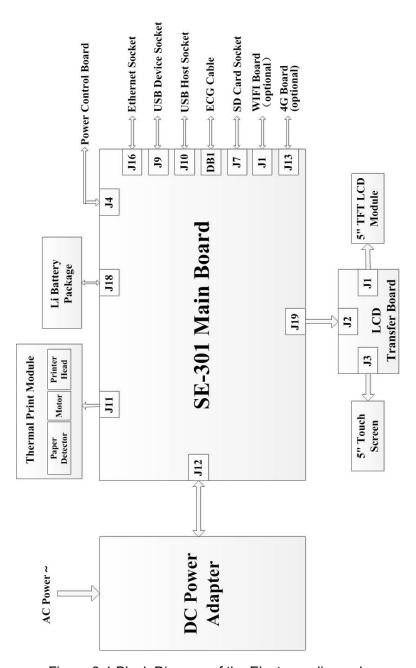


Figure 3-1 Block Diagram of the Electrocardiograph

## 3.2.2 Main Board

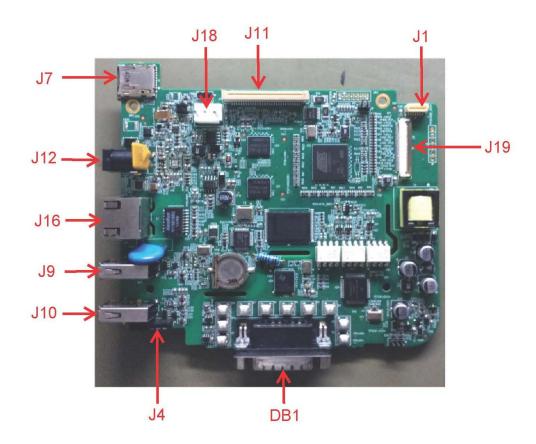


Figure 3-2 Main Board Interfaces

No.	Description
Α	J11: Socket for connecting to the printer head
В	J18: Socket for connecting to the lithium battery
С	J4: Socket for connecting to the Power Control Board
D	J16: Ethernet Socket
Е	J9: USB Device Socket
F	J10: USB Device Socket
G	DB1: Patient Cable Socket
Н	J7: Micro SD Card Slot
I	J19: Socket for connecting to J2 of the LCD Transfer board
J	J12: Power Adapter Socket

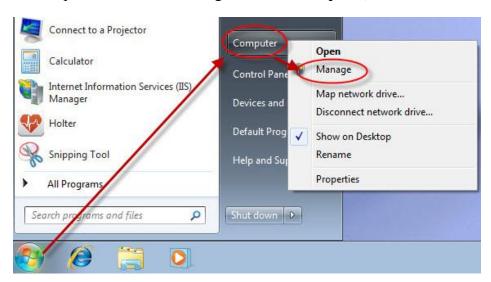
### **Chapter 4 Optional and Advanced Functions**

## 4.1 Configuring a Barcode Reader

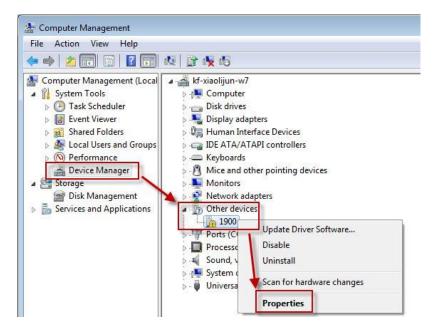
1. On the **System Setup** screen, Click **Advanced Setup**, enter the correct service password, and then click **Barcode**. Configure each sub-item based on the actual situation.

**NOTE:** Please contact the manufacturer or local distributor to get the service password.

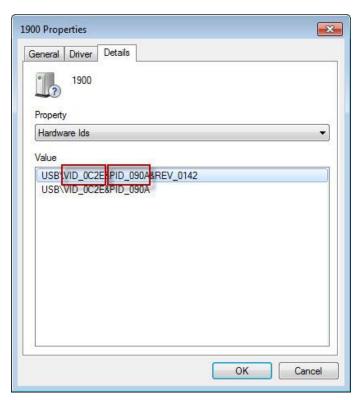
- 2. If the barcode reader cannot be used, you have to manually configure the port by performing the following operations:
  - 1) Connect the USB barcode reader to the computer.
  - 2) On the computer, click Start and right-click on Computer, and then choose Manage.



 On the Computer Management screen, click Device Manager, and right-click on the barcode reader in Other Devices and select Properties.



4) Open the **Details** tab and note down the vector ID (VID) and the product ID (PID). Take the following figure for example, the vector ID is 0C2E, and the product ID is 090A.

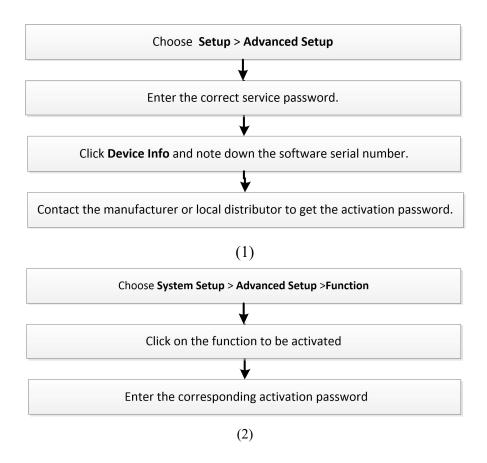


5) On the electrocardiograph, open the barcode setup window, and set the **Vendor ID** to the VID, and **Product ID** to PID.

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

Replaceable Part	Part Number
Barcode Scanner (One-Dimension)	01.23.068023
Barcode Scanner (Two-Dimension)	21.18.052311

# 4.2 Activating SCP/FDA-XML/DICOM Function



# 4.3 Implementing FTP Protocol

Please contact the manufacturer or local distributor for details.

## 4.4 Upgrading the Software

Item	Part Number
Software	02.05.250994
SE-301 Logo	02.05.250995
SE-301 Logo (EDAN2)	02.05.250997

- 1. Put the software files under the root directory of a U disk or Micro SD card, and then connect the U disk or Micro SD card to the electrocardiograph.
- 2. Open Setup > Advanced Setup > Upgrade.
- 3. Select **Upgrade All**, and all the items in the U disk or Micro SD card will be upgraded automatically.
  - To upgrade only one item, select the corresponding option.
- 4. Restart the electrocardiograph after the upgrade.

#### NOTE:

- Please insert the external memory recommended by the manufacturer. The external memory should be formatted before use. Please set the format to FAT or FAT32 when formatting the external memory.
- 2. The storage of the external memory should be within 16G.
- 3. Do not remove the external memory when upgrading.

### **Chapter 5 Inspection and Troubleshooting**

### 5.1 Appearance Inspection

Perform the following inspection procedures before operation.

- Check if there are any obvious defects on the electrocardiograph and patient cable.
- Check if there are any obvious defects on the external cables, power plug and power cable.
- Ensure that all the exposed screws are firmly fixed.
- Check if there are any crackles, rifts or distortions on the outer-casing of the device.

If any failure is detected, use the ECG Device only after maintenance has been carried out by the service personnel of the manufacturer or the distributor.

#### 5.2 Power-On Test

Connect the ECG Device with the mains supply through the power adapter, check if the mains supply indicator is lit in green.

Switch on the ECG Device and carry out the following inspections:

- Check whether the battery recharging indicator is lit in green when the device starts up.
- If the built-in battery is used, check whether the battery indicator is green, and the battery status on the LCD screen is full or recharging.

Detach the ECG Device from the mains supply, and start up the device with built-in battery.

- Check whether the battery indicator is lit in blue.
- Check whether the hint "BAT WEAK" is displayed on the screen.

If any failure is detected, refer to section 5.7 "Trouble-shooting" for details.

### 5.3 Checking Battery Charging Condition

1. Insert the batteries into the battery compartment and connect the electrocardiograph to the AC mains; check and see if the power indicator is in green or orange.

- 2. Switch on the electrocardiograph and wait until the main screen appears, and then check whether the battery status symbol at the top right corner on the screen is full in green or in recharging status.
- 3. If both the power indicator and the battery status symbol are in green, disconnect the electrocardiograph from the AC mains and let the electrocardiograph remain powered on for approximately half an hour; meanwhile, check whether the battery remaining power indicated by the battery status symbol changes.
- 4. Connect the electrocardiograph to the AC mains again and check whether the colors of both the power indicator and the battery status symbol change.

If any failure is detected, refer to section 5.7 "Trouble-shooting" for details.

**NOTE**: Please read through the li-ion battery care warnings carefully before battery check.

### 5.4 Checking Networking Function

- 1. Network the electrocardiograph to the ECG DMS of EDAN via wired or wireless way.
- 2. Switch on the electrocardiograph.
- 3. Check the networking symbol on the main screen and see if it indicates the electrocardiograph is networked.

If any failure is detected, refer to section 5.7 "Trouble-shooting" for details.

### 5.5 Checking Output Interface

- Connect a U disk or Micro SD card to the electrocardiograph and switch on the electrocardiograph; check whether the USB ports function properly.
- Connect cable to the VGA output; check whether the interfaces function properly.

If any failure is detected, refer to section 5.7 "Trouble-shooting" for details.

### 5.6 System Tests

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

#### 1. Opening the System Test Screen

Click System Test and input the correct password in the **Service Password** window displayed, the **System Test** screen appears.

On the **System Test** screen, click on a certain sub-item to open the corresponding test screen and click **Esc** to exit.

#### 2. Display Test

Click Display and select Pixel Verification Test or Gray Scale Test Patterns.

Select Pixel Verification Test and the Pixel Verification Test screen appears.

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

> Select Gray Scale Test Patterns and the Gray Scale Test Patterns interface appears.

#### 3. Touch Test

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.

If the touch screen is not sensitive, calibrate it as follows:

- 1. Hold down the PRINT/STOP key while switching on the electrocardiograph, the system will enter the touch screen calibration screen.
- 2. Operate as indicated on the screen.

#### 4. Battery Test

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

#### 5. Recorder Test

On this screen, select **Start** to begin to print the triangle waves in effective paper width. The status of the print head can be estimated from the triangle waves. Select **Stop** to stop printing.

**NOTE**: During the printing course, you should not select Return to exit.

#### 6. File System Test

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

Click Format file system to remove all the files in the Electrocardiograph.

### 5.7 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

1. Test whether the volta plug is 19V.	
Start-up fails when using the mains supply  1 Power adapter failure 2 Power control board failure 3 Connection cable failure 4 LCD transfer board failure 5 Main board failure 5 Main board failure  3 Test whether the voltage the Power Control 18V~20V.  If not, reconnect the retest.  If yes, go to step 2.  If not, replace the Power Control 18V~20V.  If not, reconnect the retest.  If yes, replace the Power Control 18V~20V.  If not, reconnect the retest.  If yes, replace the Power Control 18V~20V.  If not, reconnect the retest.  If yes, test whether the voltage the Power Control 18V~20V.  If not, reconnect the retest.  If yes, test whether the voltage the Power Control 18V~20V.	ower adapter.  ge of TP2 and TP3 of Board is within  e power adapter and  Power Control Board ce. If the start-up still  ge of TP18 is 5V.  ower control board.

		<ul> <li>If not, change the power control board.</li> <li>If yes, replace the LCD transfer board and restart the device. If the start-up still fails, go to step 4.</li> <li>4. Test whether the voltage of TP1 on the LCD transfer board is about 26V.</li> <li>If yes, replace the LCD transfer board.</li> </ul>
		➤ If not, replace the LCD screen.
Start-up fails when using the battery as the power supply.	<ol> <li>Battery failure</li> <li>Battery control board failure</li> <li>Main board failure</li> <li>LCD transfer board failure</li> <li>LCD screen failure</li> </ol>	After loading the battery, test whether the voltage of J18-PIN3 higher than 16V.  If not, replace the battery.  If yes, refer to the step 3 and step 4 above.
	Strong interference of the mains supply	Inspect the power supply and grounded system
Occasional break-down	The connecting parts on the power board, main board, or touch screen driver board fails.	Change or repair the connecting parts
	Main board failure	Change the main board
	Software failure	Restart the device

### 2. Display Troubles

Possible Causes	Actions
LCD screen failure.	Replace the LCD screen
<ol> <li>Software failure</li> <li>LCD screen failure</li> </ol>	<ol> <li>Restart the device.</li> <li>Replace the LCD screen</li> </ol>
	LCD screen failure.  ① Software failure

### 3. Transmission Troubles

Problem Description	Possible Causes	Actions
Fail to transmit ECG data through the net port  Fail to copy data from the electrocardiograph to the U disk or Micro SD card	<ol> <li>Setup error</li> <li>Connection cable failure</li> <li>Net Port failure</li> <li>U disk failure</li> <li>Micro SD card failure</li> </ol>	<ol> <li>Examine whether the transmission settings are correct.</li> <li>Replace the connection cable</li> <li>Replace the net port</li> <li>Replace the U disk</li> <li>Replace the SD card</li> </ol>
Fail to connect or transmit ECG data through WiFi	<ol> <li>WiFi module failure</li> <li>WiFi related cable is disconnected or damaged</li> <li>Software installed on PC is abnormal</li> <li>Main board failure</li> </ol>	<ol> <li>Replace WiFi module</li> <li>Check whether WiFi related cable is well connected, restart the electrocardiograph. Or, replace the WiFi related cable.</li> <li>Restart the software</li> <li>Replace the main board</li> </ol>

### 4. Operation Troubles

Problem Description	Possible Causes	Actions
Key failure	The key is damaged	Repair the key board
No key beep or key beep is raucous	Speaker failure	Replace the speaker
The electrocardiograph	① The recorder paper runs	Install the recorder paper
can not print reports.	out	② Reset the paper marker
	② The paper marker setting is	settings and load the correct
	incorrect	recording paper
	③ Print module failure	③ Replace the print module
	④ Main board failure	④ Replace the main board
The printed report is	① The rubber roller of the	① Clean the rubber roller
illegible	recorder casing has stain.	② Replace the print module
Some characters or	② Print module failure	③ Clean the thermal print head
waveforms printed are	③ Dirty thermal print head	④ Replace the recorder frame
missing.	④ The recorder frame is not	
	good.	
Fail to detect paper	① There is a stain on the	① Clean the stain on the detecting
	detecting position of the	position of the printing bracket
	printing bracket.	② Reset the paper marker
	② The paper marker setting is	settings and load the correct
	incorrect	recording paper
	③ Print head failure	③ Replace the print module

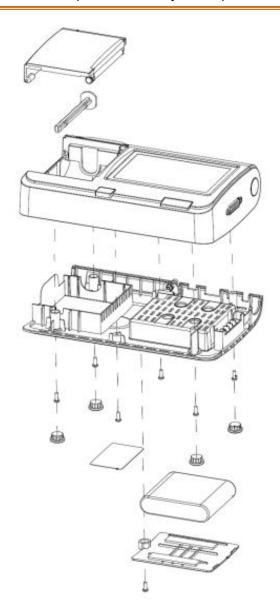
### 5. Parameter Troubles

Problem Description	Possible Causes	Actions
No ECG waveform	Defective connection between the patient and the electrodes     Defective connection between the patient cable and the unit     Main board failure	Attach the electrodes to the patient again or clean the electrode area on body surface with alcohol     Connect the patient cable to the unit     Replace the Main board
ECG waveform is abnormal or disturbed	<ol> <li>Defective connection between the patient and the electrodes</li> <li>Patient cable failure</li> <li>Main board failure</li> </ol>	Attach the electrodes to the patient again or clean the electrode area on body surface with alcohol     Replace the patient cable     Replace the Main board
Heart rate is not accurate	Waveform measuring failure	Adjust connections
ECG waveform has burrs	Defective connection between the patient and the electrodes      Main board failure      Electrical interference from another device (microwave oven, cellular phone, wireless device, etc.)      An improperly-grounded electrical device near the electrocardiograph	<ol> <li>Attach the electrodes to the patient again or clean the electrode area on body surface with alcohol</li> <li>Replace the Main board</li> <li>Look for devices that could be causing electrical interference, and then unplug the devices. Or run the electrocardiograph on the battery power.</li> <li>Lay the lead wires alongside the limbs and away from any electrical devices. Turn on the AC filter on the Filter Setup window.</li> </ol>

## **Chapter 6 Electrocardiograph Disassembly**

#### **WARNING**

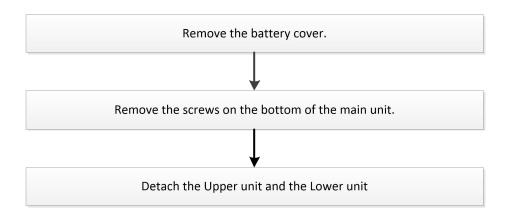
- 1. Only qualified service personnel shall open the shell.
- 2. Switch off the electrocardiograph and unplug the mains supply (remove the battery if configured) before disassemble the device.
- 3. After any repair of the device, perform safety tests prior to use..



## 6.1 Tools Required

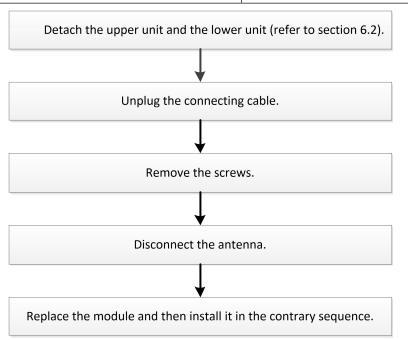
M3 Philips Screwdriver, Antistatic wrist straps or gloves

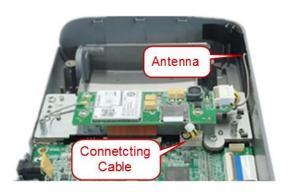
# 6.2 Disassembling the Main Unit



# 6.3 Replacing the Mobile Network Module

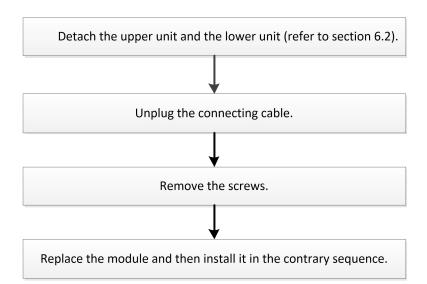
Replaceable Part	Part Number
SE-301 Mobile Network Module	02.02.452013

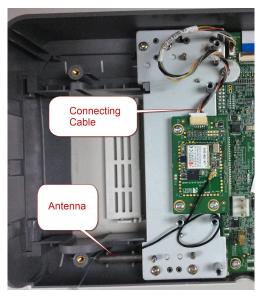




# 6.4 Replacing the WiFi Module

Replaceable Part	Part Number
SE-301 WIFI Interface Board	02.02.452015





# 6.5 Replace the Thermal Recorder

Replaceable Part	Part Number
Thermal Recorder Groupware	02.04.242233
Thermal Print Head	01.17.107042

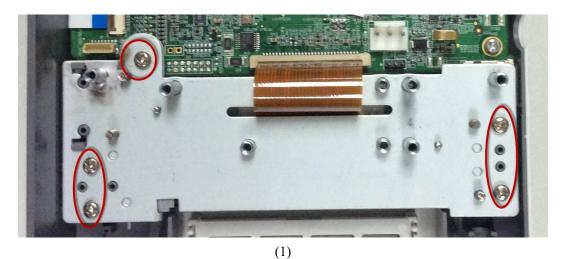
Detach the upper unit and the lower unit (refer to section 6.2).

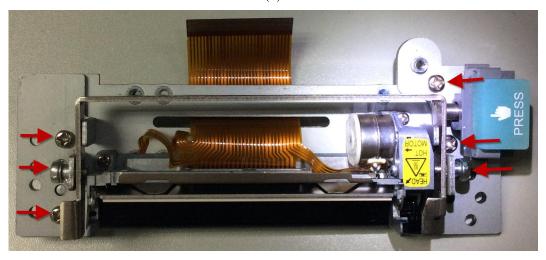
Remove the WIFI module (if configured)

Unplug the WIFI connecting cable and remove the screws on the thermal recorder groupware

Detach the thermal recorder groupware and remove the screws left.

Replace the thermal recorder groupware and then install it in the contrary sequence.

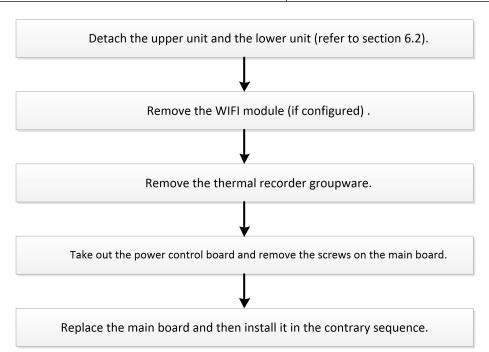




(2)

# 6.6 Replacing the Main Board

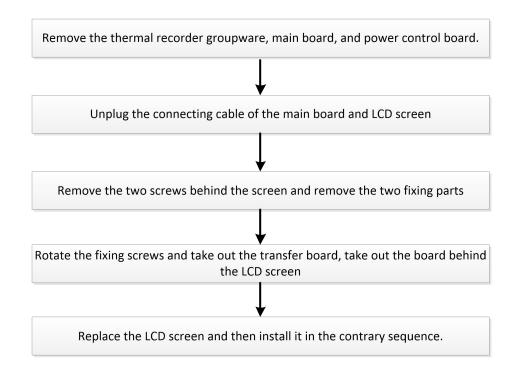
Replaceable Part	Part Number
SE-301 Main Control Board	02.03.452021





# 6.7 Replacing the LCD Screen

Replaceable Part	Part Number
LCD Screen	01.16.045111
Touch Screen	01.16.045240



# **Chapter 7 Renewable Parts**

### **WARNING**

Only the patient cable and other accessories supplied by the manufacturer can be used. Or else, the performance and electric shock protection cannot be guaranteed.

Renewable Part	Part number
SE-301 Main Control Board	02.03.452021
Recorder Casing Kits	02.04.242232
Thermal Recorder Groupware	02.04.242233
Print Head	01.17.107042
LCD Screen	01.16.045111
Touch Screen	01.16.045240
SE-301 LCD Interface Board	02.02.452017
SE-301 Power Interface Board	02.02.452019
SE-301 WIFI Interface Board	02.02.452015
SE-301 Mobile Network Module	02.02.452013
Rechargeable Lithium Battery	21.21.064149
Power Adapter	21.21.064244
Barcode Reader (One-Dimension)	01.23.068023
Barcode Reader (Two-Dimension)	21.18.052311

**NOTE**: The part name may vary depending on context, but the part number is constant.

P/N: 01.54.457006

MPN: 01.54.457006014







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