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SE-3&SE-300 Series

Electrocardiograph

Version 2.6

User Manual

CE 0123

EDAN

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 INSTRUMENTS, INC. (hereinafter called EDAN) can not be held liable.

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Product Information

Product Name: Electrocardiograph

Model: SE-3, SE-300A, SE-300B

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.

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 Safety Guidance

This chapter provides important safety information related to the use of the 3-Channel Electrocardiograph.

1.1 Intended Use/Indications for 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 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.

1.2 Warnings and Cautions

In order to use the electrocardiograph safely and effectively, and avoid possible dangers caused by improper operations, please read through the user manual and be sure to be familiar with all functions of the equipment and proper operation procedures before use.

Please pay more attention to the following warning and caution information.

1.2.1 Safety Warnings

WARNING

1. 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. Only qualified installation or service engineers can shift the mains supply shift switch (100V-115V~/220V-240V~) according to local mains supply specifications.
4. The results given by the equipment should be examined based on the overall clinical condition of the patient, and it can not substitute for regular checking.
5. This device is not intended for treatment or monitoring.
6. The EQUIPMENT is protected against malfunction caused by electrosurgery according to the clause 36.202.101 in the IEC60601-2-25.
7. Electrodes of dissimilar metals should not be used; it may cause a high polarization voltage.
8. **EXPLOSION HAZARD** - Do not use the electrocardiograph in the presence of flammable anesthetic mixture with oxygen or other flammable agents.
9. **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.
10. If the integrity of the external protective conductor is in doubt, the equipment should be operated by using the built-in rechargeable battery.
11. Do not use this equipment in the presence of high static electricity or high voltage equipment which may generate sparks.
12. This equipment is not designed for direct cardiac application.
13. 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.

WARNING

14. The use of patient cable and other accessories not supplied by the manufacturer may result in increased emissions or decreased immunity of the equipment.
15. Make sure that all electrodes are connected to the patient correctly before operation.
16. 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.
17. 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.
18. 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.
19. Do not touch the patient, bed, table or the equipment while using the ECG together with a defibrillator.
20. Do not touch accessible parts of electrical equipment and the patient simultaneously.
21. In order to avoid being burned, please keep the electrodes far away from the radio knife while using electrosurgical equipment.
22. Disposable electrodes must be used during defibrillation.
23. .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.
24. 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.
25. The summation of leakage current should never exceed leakage current limits while several other units are used at the same time; otherwise, electric shock may happen.

WARNING

26. 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.
27. If the wireless AP technology is used, in order to maintain compliance with the FCC RF exposure guidelines, the wireless AP 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 the wireless AP is used.
28. Fix attention on the examination to avoid missing important ECG waves.
29. The disposable electrodes can only be used for one time.
30. We recommend that the electrocardiograph should be working on AC power supply at least 8 hours per month to avoid DATE&TIME missing.
31. 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.
32. 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.
33. **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.
34. **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.

WARNING

35. 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.
36. 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.
37. The electrocardiograph shall not be serviced or maintained while in use with a patient.
38. 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.
39. The medical electrical equipment needs to be installed and put into service according to Appendix 2 EMC Information.
40. 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.
41. Portable and mobile RF communications equipment can affect medical electrical equipment, refer to the recommended separation distances provided in Appendix 2 EMC Information.
42. Assembly of the electrocardiograph and modifications during actual service life shall be evaluated based on the requirements of IEC60601-1.

1.2.2 Lithium Battery Care Warnings

WARNING

1. Improper operation may cause the lithium battery (hereinafter called battery) to be hot, ignited or exploded, and it may lead to the declination of the battery capacity. It is necessary to read the user manual carefully and pay more attention to warning messages.

WARNING

2. Only qualified service engineer 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. 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.
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 the battery, please contact your local Civic Office, or the shop where you purchased the product.
7. Remove the battery from the electrocardiograph when the electrocardiograph is not used for a long time.
8. If the battery is stored alone and not used for a long time, we recommend that the battery should be charged at least once every 6 months to prevent over-discharge.

1.2.3 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 ºC and 40 ºC during operation, and it should be kept between -20 ºC and 55 ºC during transportation and storage.
3. Do not use the equipment in a dusty environment with bad ventilation or in the presence of corrosive.

CAUTION

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. Before use, the equipment, the patient cable and electrodes etc. should be checked. Replacement should be taken if there is any evident defectiveness or aging symptom which may impair the safety or the performance.
6. Ruptured fuse must only be replaced with that of the same type and rating as the original.

1.2.4 Cleaning & Disinfection Cautions

CAUTION

1. Turn off the power before cleaning and disinfection. If the mains supply is used, the power cord should be dragged out of the outlet. Prevent the detergent from seeping into the equipment during cleaning.
2. Do not immerse the unit or the patient cable into liquid under any circumstances.
3. Do not clean the unit and accessories with abrasive fabric and avoid scratching the electrodes.
4. Any remainder of detergent should be removed from the unit and the patient cable after cleaning.
5. Do not use chloric disinfectant such as chloride, sodium hypochlorite etc.

1.3 List of Symbols

No.	Symbol	Description
1		Output
2		Input
3		DEFIBRILLATION-PROOF TYPE CF APPLIED PART
4		Attention, consult ACCOMPANYING DOCUMENTS
5		Operating instructions
6		Equipotential grounding
7		Alternating Current
8		"ON" (power)
9		"OFF" (power)
10		Battery check
11		Battery recharging indicator
12	 SE-3  SE-300 series	ON/OFF key

13		Print/Stop key
14		General symbol for recovery/recyclable
15	P/N	Part Number
16	SN	SERIAL NUMBER
17		Date of manufacture
18		MANUFACTURER
19	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
20	CE 0123	CE marking
21		Disposal method
22	Rx Only	Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician
23		Refer to User Manual (Background: Blue; Symbol: White)
24		Warning (Background: Yellow; Symbol&Outline: Black)

NOTE: The user manual is printed in black and white.

Chapter 2 Introduction

SE-300 series electrocardiograph has two models: SE-300A and SE-300B.

SE-3/SE-300 series 3-channel electrocardiograph gathers ECG signals of 12 leads simultaneously. It displays the operation menu, ECG parameters as well as electrocardiograms.

3-channel ECG waves can be viewed on the LCD screen and printed out by using a high-quality thermal recorder. The screen of SE-3 configuration A and SE-300A is black and white screen, and the screen of SE-3 configuration B and SE-300B is color screen.

The AUTO, MANU, OFF-AUTO, RHYT, OFF- RHYT and R-R modes can be chosen freely.

SE-3/SE-300 series can be powered by the mains supply or a built-in rechargeable lithium battery. Basic type and Net type are optional for each model, only the Net type electrocardiograph can support network transmission function. The DE12 ECG board is optional for all the models. With the DE12 ECG board, SE-3/SE-300 series can support full-scale pacemaker detection function.

With a high resolution thermal recorder, a 32-bit processor and a large-capacity memorizer, SE-3/SE-300 series has advanced performance and high reliability. The compact size makes it suitable for clinic, hospital and ambulance use.

Configuration: main unit, power cord, earth wire, patient cable, electrodes, thermal recorder paper, fuses and lithium battery

2.1 Top Panel

Figure 2-1 SE-3

Figure 2-2 SE-300 series

2.2 Control Panel and Keys

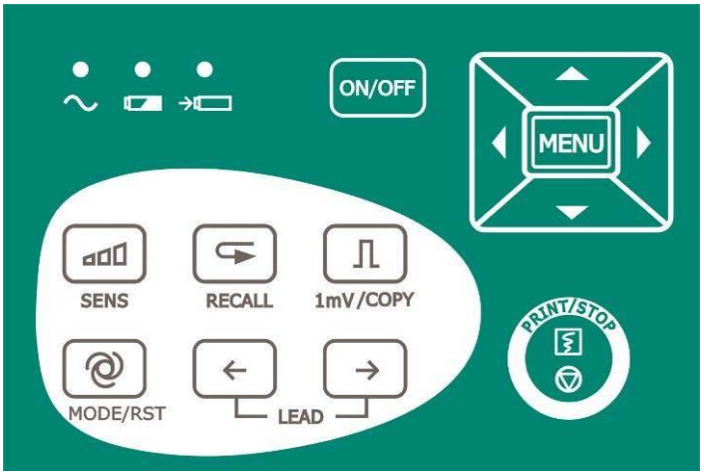


Figure 2-3 SE-3 Control Panel and Keys

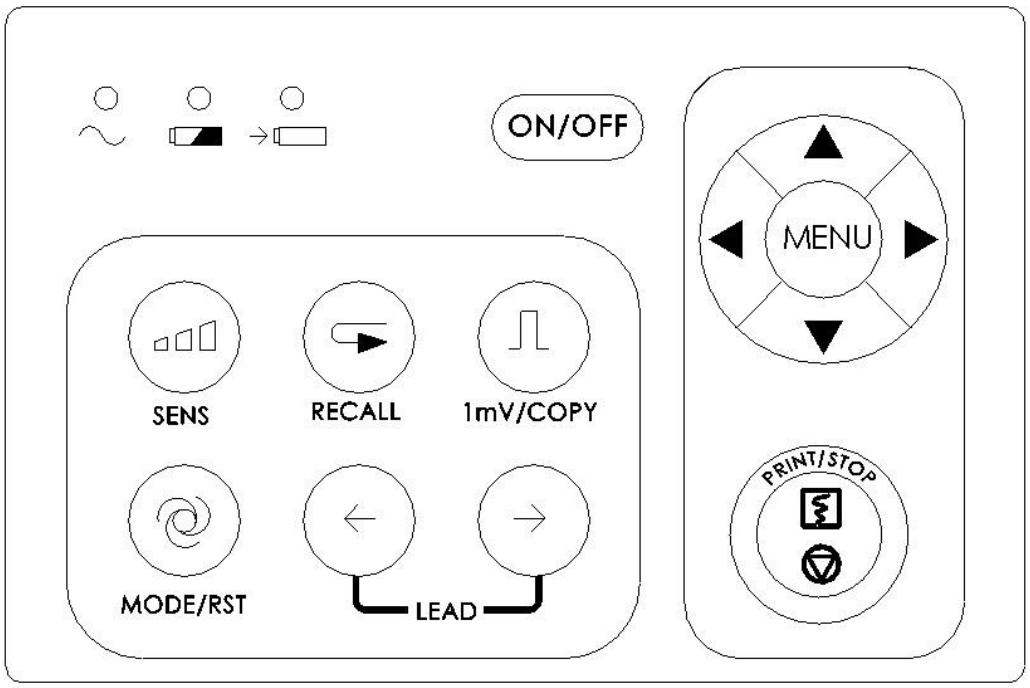


Figure 2-4 SE-300 series Control Panel and Keys

1) Indicator Lamp

~	Mains supply indicator lamp: when the device is powered by the mains supply, the lamp will be lit.
	Battery indicator lamp: when the device is powered by a built-in rechargeable lithium battery, the lamp will be lit.
	Battery recharging indicator lamp: when the battery is being recharged, this lamp will be lit.

2) Sensitivity Switch Key

(SE-3)


(SE-300 series)

The sensitivity switch order: ×10 mm/mV → ×20 mm/mV →10/5mm/mV → ×2.5 mm/mV → ×5 mm/mV.

3) Recall Key

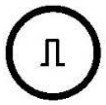
(SE-3)


(SE-300 series)

Press the **RECALL** key to open the File Manager screen. For details, see chapter 7,

"Managing ECG Records".

4) 1mV/COPY Key

(SE-3)


(SE-300 series)

In the **Manual** mode, press this key to print a 1mV calibration mark while printing ECG reports.

In the **AUTO** or **RHYT** mode, press this key to copy and print the recent report.

5) MODE/RST Key

(SE-3)


(SE-300 series)

Press this key to select a printing mode among **AUTO**, **MANU**, **OFF-AUTO, RHYT, OFF- RHYT** and **R-R**.

The switch order of lead groups in each mode is listed in Table 2-1.

In the **MANUAL** mode, press this key to reset the waveform quickly while printing ECG reports.

WARNING

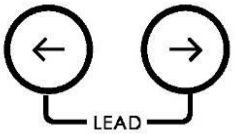
When using the device with a defibrillator, after the defibrillator discharges, you should press the **MODE/RST** key to reset the waveform quickly.

NOTE: The detailed information of the automatic mode can be set on the System Setup Screen.

Table 2–1 Switch Order of Lead Groups in Different Modes

Mode	Switch Order (from Left to Right)			
AUTO(Standard)	I/II/III	aVR/aVL/aVF	V1/V2/V3	V4/V5/V6
AUTO(Cabrera)	aVL/ I /-aVR	II /aVF/ III	V1/V2/V3	V4/V5/V6
MANUAL	In this mode, you need to press the Lead switch key to change the lead groups, the lead switch order can be that of AUTO (Standard) or AUTO (Cabrera), which is determined by settings of lead sequence and printing format on the System Setup Screen.			

6) LEAD Switch Key

(SE-3)


(SE-300 series)

In the **MANU** mode, press these two keys to switch the lead groups.

In System Setup→Record Info window, press these two keys to switch Setup 1 and Setup 2.

On the File Manager screen, press these two keys to go to the prev or next page of records.

7) PRINT/STOP Key

Press this key to begin or stop printing ECG reports.

8) ON/OFF Key

(SE-3)


(SE-300 series)

Press this key to turn on or off the device.

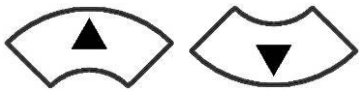
9) MENU Key

(SE-3)


(SE-300 series)

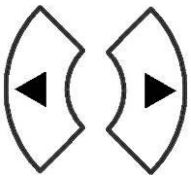
Press this key to open the System Setup Screen.

10) Up Arrow/Down Arrow Key


(SE-3)

(SE-300 series)

Press the Up or Down arrow to select an item on the Main Screen and the System Setup Screen.

11) Left Arrow/ Right Arrow Key


(SE-3)

(SE-300 series)

Press the Left or Right arrow to set the selected item.

2.3 Patient Cable Socket and Signal Interface

As shown in Figure 2-1 and Figure 2-5, on the right side of the main unit are the patient cable socket, the RS232 socket, the external input/output socket and the USB interface.

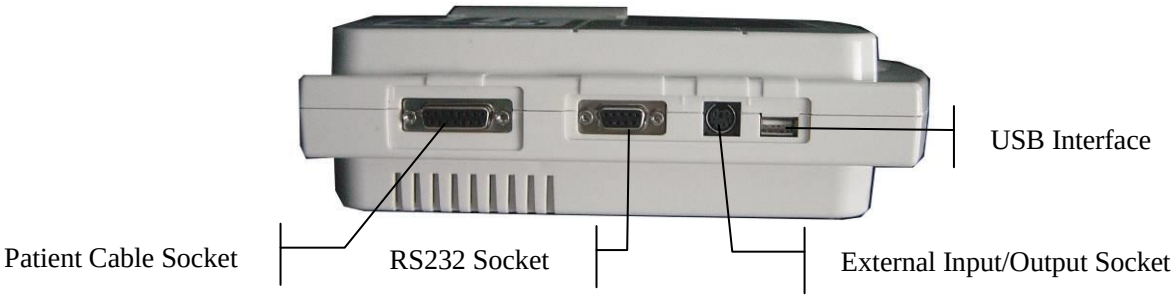


Figure 2-5 SE-300 series

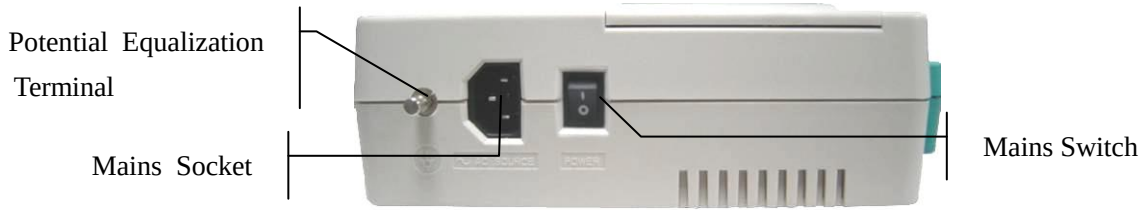
The net port (optional, only for Net type) is on the back of the main unit shown in the following figure. Only the electrocardiograph with net port can support network transmission function.

Figure 2-6 SE-3

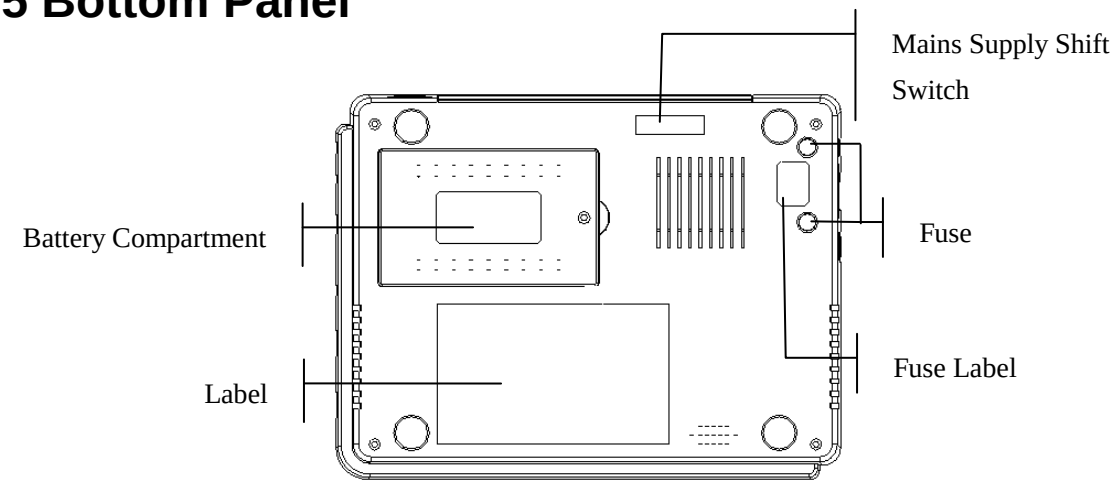
WARNING

1. Only the USB equipment recommended by the manufacturer can be connected to the USB interface.
2. The summation of leakage current should never exceed the leakage current limit while several other units are used at the same time.

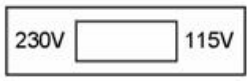
2.4 Mains Connection and Switch



2.5 Bottom Panel



1) Mains Supply Shift Switch



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

WARNING

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

2) Fuse

There are two fuses of the same specifications installed on the bottom of the main unit.

WARNING

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

2.6 Features

- Low weight and compact size
- High resolution thermal recorder, recording frequency response ≤150Hz
- ECG signals of 12 leads are gathered and amplified simultaneously, 3-channel waves are displayed and recorded simultaneously
- Offer AUTO, MANU, OFF-AUTO, RHYT, OFF- RHYT and R-R modes
- Measurement function and interpretation function are optional
- System Setup Screen for parameter settings
- Built-in rechargeable lithium battery with large capacity
- Hint information for lead off, lack of paper, low battery capacity etc.
- Automatic adjustment of baseline for optimal printing
- Standard input/output interface and RS232 communication interface
- ECG data can be transmitted to the PC software through the serial cable, net cable (optional, only for net type), or wireless AP (optional).

Chapter 3 About the Application Interface

The following sections provide an overview of the main functions in the SE-3/SE-300 series application. When switched on, the Main Screen pops up. Then you can press the **MENU** key to open the System Setup Screen. Or press the **RECALL** key to open the File Manager screen.

3.1 About the Main Screen

On the main screen, press the up and down arrows to move the cursor to the items that need to be modified, and press the left and right arrows to modify the value.

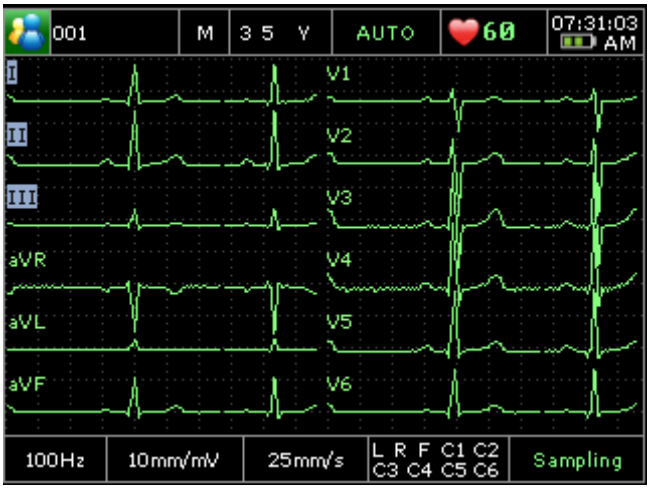


Figure 3-1 Main Screen

The Main Screen includes:

	Name	Explanation
A	Patient Symbol	Select the symbol and press the left or right arrow to open Patient Information window
B	ID	Patient ID
C	Gender	Patient Gender, press the left and right arrows to switch male and female
D	Age	Input Patient age or choose the age group
E	Work Mode	Include: AUTO, MANU, OFF-AUTO, RHYT, OFF-RHYT and R-R
F	HR	The actual HR value
G	Current Time	Show the current time

H	Battery Symbol	Identify the current capacity of the battery
I	Waveform zone	Show waveform
J	Hint Information	Including ***No Paper***, ***Paper Error***, ***Sampling***, ***Analyzing***, ***Recording***, ***Transmitting***, ***Memory Full***, ***U Disk***, ***USB Printer***, ***Lead Off***, ***Scanner, Reader***. For details, please refer to Chapter 10 "Hint Information".
K	Lead Name	Including ***DEMO***, ***Module Error***, ***Overload***, Lead Name (When the leads are off, the lead names will be highlighted. For details, please refer to Chapter 10 "Hint Information".
L	25mm/s	Speed
M	10mm/mV	Sensitivity
N	100Hz	Filter
NOTE: The speed, sensitivity or filter value modified in the main screen is only valid for the current exam.		

3.2 About the System Setup Screen

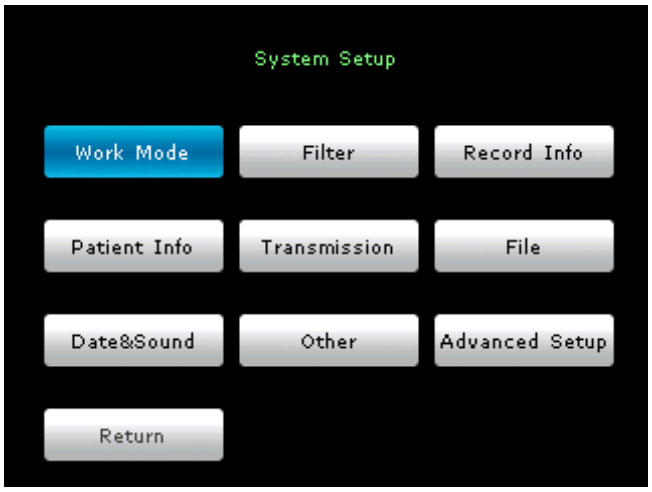


Figure 3-2 System Setup Screen

Press **MENU** on the main screen to display the **System Setup** screen.

On the **System Setup** screen, move the cursor on an item, and then press **MENU** to open the setup window of the item. And press Return or RECALL to exit the **System Setup** screen.

3.3 About the File Manager screen

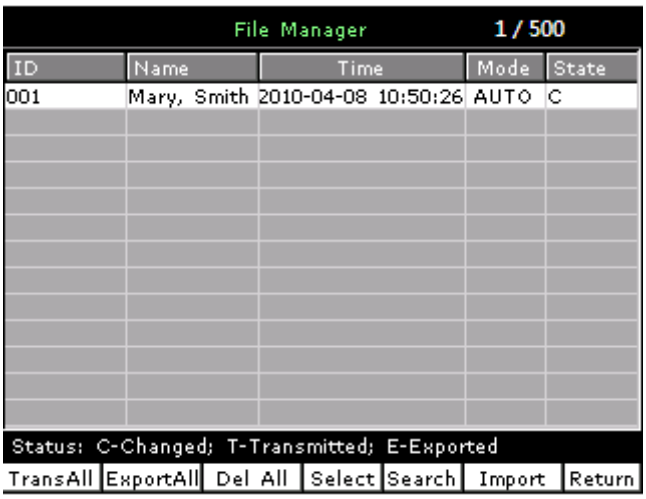


Figure 3-3 File Manager screen (a)

Press the Up or Down arrow to select the patient record, press Lead(→) or Lead (←) to switch the prev or next page.

Press the Left or Right arrow to move the cursor among **TransALL**, **ExportALL**, **Del All**, **Select**, **Search**, **Import** and **Return** buttons and then press the **MENU** key to conform the operation.

Press **RECALL** again to return to the main screen.

Press the Left or Right arrow to move the cursor to **Select** button and press **MENU** key to enter File Manager screen (b).

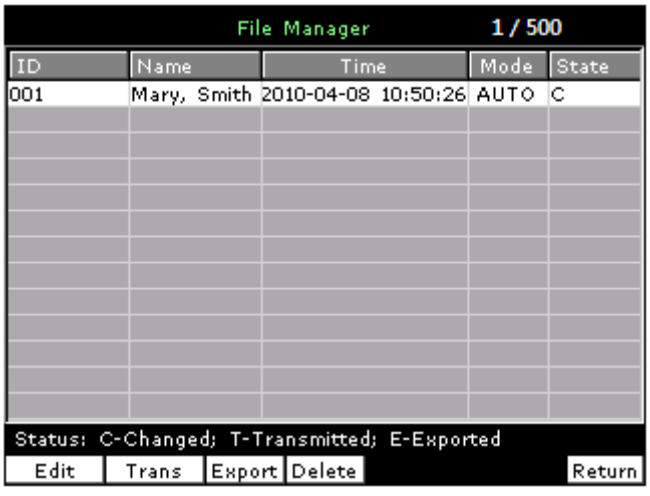


Figure 3-4 File Manager screen (b)

Press the Left or Right arrow to move the cursor among **Edit**, **Trans**, **Export**, **Delete** and **Return** buttons and then press the **MENU** key to conform the operation.

Press **RECALL** to return to the previous screen.

For details on managing patient records, please refer to chapter 7, “Managing ECG Records”.

Chapter 4 Operation Preparations

WARNING

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.

4.1 Power and Earthing

WARNING

If the integrity of the external protective conductor is in doubt, the equipment should be powered by the built-in rechargeable lithium battery.

Power Supply

The electrocardiograph can be powered either by the mains supply or a built-in rechargeable lithium battery.

- **Mains supply**

  The mains socket is on the left side of the unit. If the mains supply is used, connect the power cord to the socket first, and then connect the power cord to the hospital grade outlet.

Operating voltage:	100V-115V~ / 220V-240V~
Operating frequency:	50Hz / 60Hz
Input power:	35VA

  Make sure the mains supply meets the above requirements before power-on, and then press the mains switch. Then the mains supply indicator lamp (⏦) will be lit.

  If the built-in rechargeable battery is weak when the mains supply is used, it will be recharged automatically at the same time. Then both the mains supply indicator lamp (⏦) and the battery recharging indicator lamp (⇥▭) will be lit. The 3-channel electrocardiograph can not be recharged when it is printing reports, and the battery recharging indicator is black; when the 3-channel electrocardiograph is switched off, the battery recharging indicator lamp (⇥▭) is black if the battery is fully recharged.

♦ **Built-in rechargeable battery**

When the built-in rechargeable lithium battery is used, turn on the unit by pressing the **ON/OFF** key on the control panel directly. Then the battery indicator lamp ( ) will be lit and the battery symbol will be displayed on the LCD screen. Because of the consumption during the storage and transport course, the battery capacity may not be full. If the symbol and the Hint information *BAT WEAK* are displayed, which means the battery capacity is low, please recharge the battery first.

Please refer to the maintenance section for how to recharge the battery. When the battery is being recharged, SE-3/SE-300 series can be powered by the mains supply at the same time.

WARNING

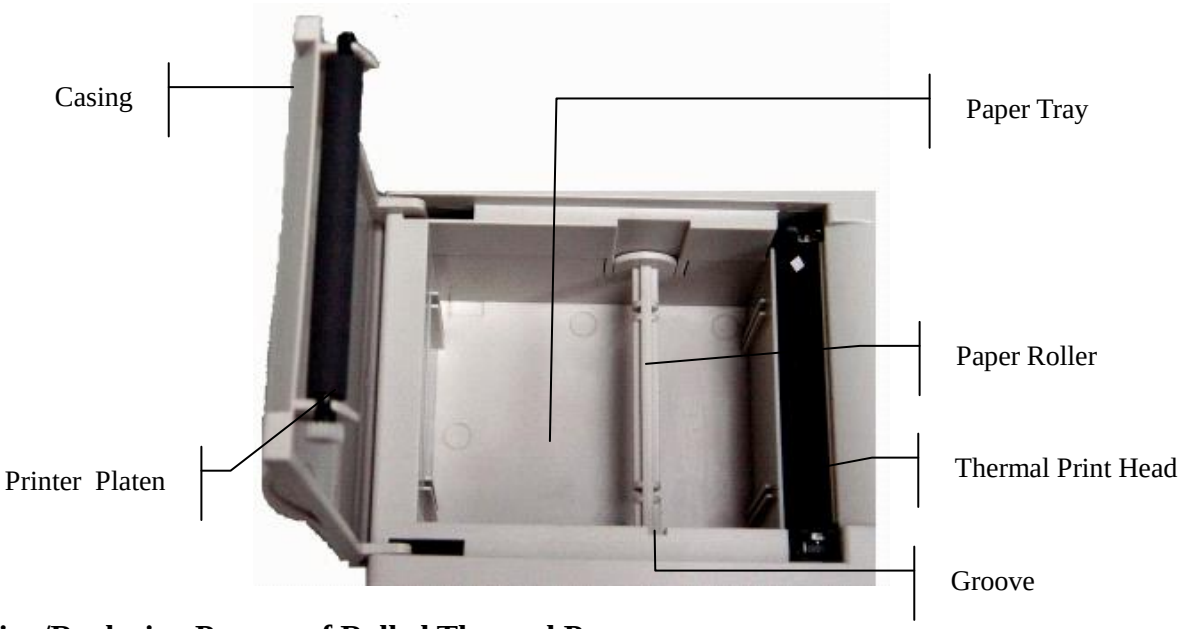
The potential equalization conductor of the unit should be connected to the potential equalization bus bar of the electrical installation when necessary.

4.2 Loading/Replacing Recorder Paper

There are two kinds of recorder paper. One is the rolled thermal paper with the width of 80mm, and the other is the folded thermal paper with the width of 80mm.

NOTE: When the folded thermal paper is used, the paper roller is unnecessary and must be taken out.

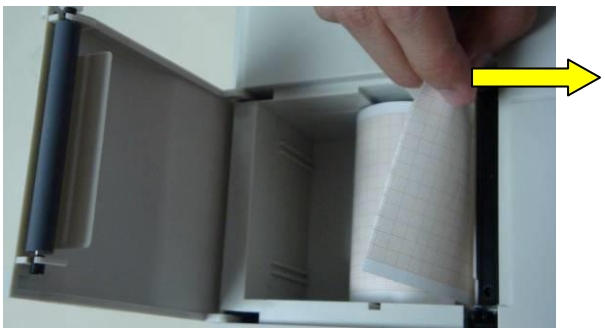
When the recorder paper runs out or is not loaded, warning message *Paper?* will appear on the screen. Then you should load or replace the recorder paper immediately.



Loading/Replacing Process of Rolled Thermal Paper:

1) Place fingers under the two flanges of the recorder casing, pull them upwards directly to release the casing.

2) Take out the paper roller, and remove remainder paper from the roller if necessary.
3) Take off the wrapper of the new thermal paper roll, and then put the paper roll through the roller.
4) Place the paper and the roller gently in the recorder with the roller pin clicking into the groove.
5) Pull about 2 cm of paper out with the grid side of the paper facing the thermal print head, and shut the recorder casing.

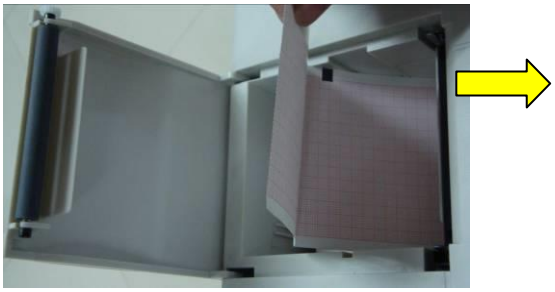


6) Press down the recorder casing firmly.

Loading/Replacing Process of Folded Thermal Paper:

1) Place fingers under the two flanges of the recorder casing, pull them upwards directly to release the casing.

2) Remove remainder paper in the paper tray if necessary.
3) Take off the wrapper of the new folded thermal paper, and then put it in the paper tray.
4) Pull about 2 cm of paper out with the grid side of the paper facing the thermal print head, and shut the recorder casing.



5) Press down the recorder casing firmly.

4.3 Preparing the Patient

4.3.1 Instructing the Patient

Before attaching the electrodes, greet the patient and explain the procedure. Explaining the procedure decreases the patient's anxiety. Reassure the patient that the procedure is painless. Privacy is important for relaxation. When possible, prepare the patient in a quiet room or area where others can't see the patient. Make sure that the patient is comfortable. The more relaxed the patient is, the less the ECG will be affected by noise.

4.3.2 Preparing the Skin

Thorough skin preparation is very important. The skin is a poor conductor of electricity and frequently creates artifact that distorts the ECG signal. By performing methodical skin preparation, you can greatly reduce the possibility of the noise caused by muscle tremor and

baseline drift, ensuring high-quality ECG waves. There is natural resistance on the skin surface due to dry, dead epidermal cells, oils and dirt.

To prepare the skin

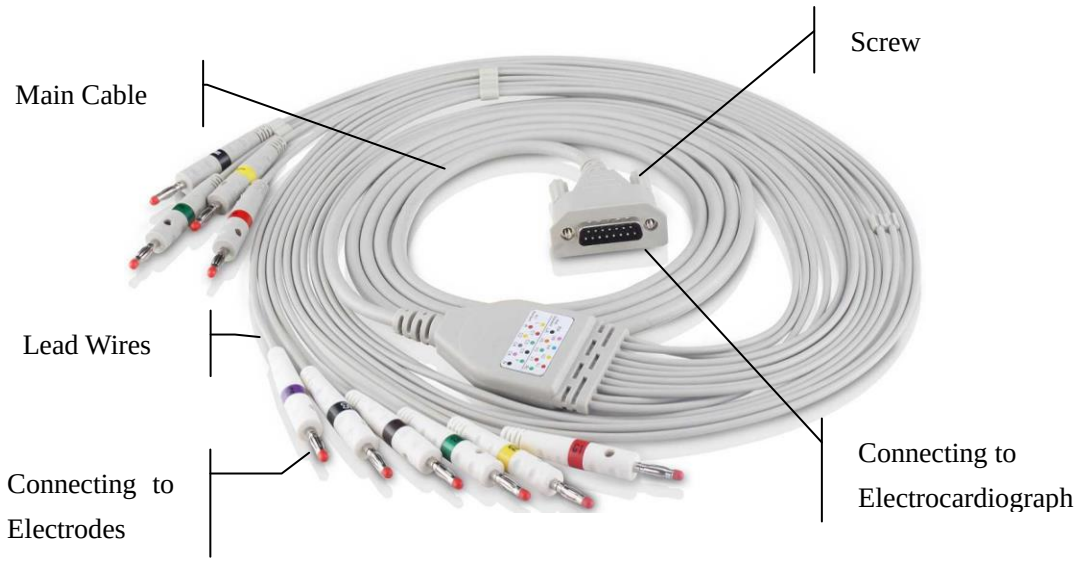
1. Shave hair from electrode sites, if necessary. Excessive hair prevents a good connection.
2. Wash the area thoroughly with soap and water.
3. Dry the skin with a gauze pad to increase capillary blood flow to the tissues and to remove the dead, dry skin cells and oils.

4.4 Connecting the Patient Cable to the Electrocardiograph and Electrodes

WARNING

The performance and electric shock protection can be guaranteed only if original patient cable and electrodes of the manufacturer are used.

The patient cable includes main cable and lead wires which can be connected to electrodes according to the colors and identifiers.



1. Connecting the Patient Cable to the Electrocardiograph

Connect the patient cable to the patient cable socket on the right side of the main unit, and then secure them with two screws.

2. Connecting the Patient Cable to Electrodes

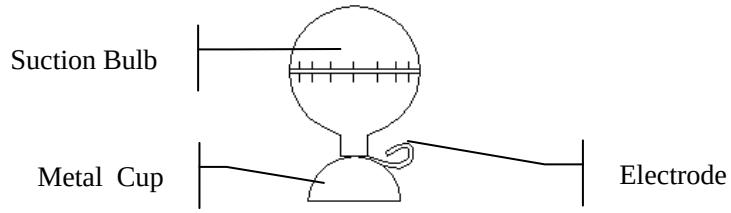
Align all lead wires of the patient cable to avoid twisting, and connect the lead wires to the corresponding electrodes according to the colors and identifiers. Firmly attach them.

4.5 Attaching Electrodes to the Patient

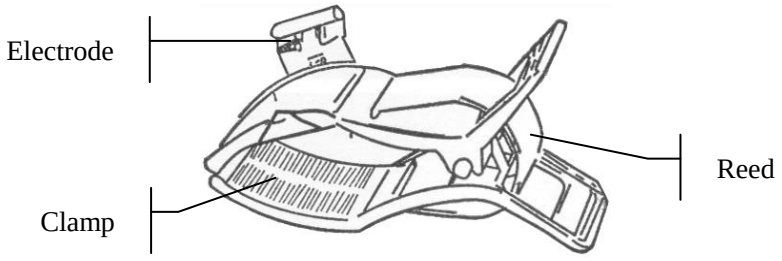
There are two types of electrode for you to choose, one is the reusable electrodes, and the other is the disposable electrodes. The uses of the two types of electrode are as shown below:

4.5.1 Reusable Electrodes

Reusable Electrodes is divided into Limb electrode and Chest Electrode, as the following figure shows:



Chest Electrode



Limb Electrode

The identifiers and color codes of electrodes used comply with IEC/EN requirements. In order to avoid incorrect connections, the electrode identifiers and color codes are specified in Table 4-1. Moreover the equivalent codes according to American requirements are given in Table 4-1 too.

Table 4–1 Electrodes and Their identifiers and color codes

	European		American	
Electrodes	**Identifier**	**Color code**	**Identifier**	**Color code**
Right arm	R	Red	RA	White
Left arm	L	Yellow	LA	Black
Right leg	N or RF	Black	RL	Green
Left leg	F	Green	LL	Red
Chest 1	C1	White/red	V1	Brown/red
Chest 2	C2	White/yellow	V2	Brown/yellow
Chest 3	C3	White/green	V3	Brown/green
Chest 4	C4	White/brown	V4	Brown/blue
Chest 5	C5	White/black	V5	Brown/orange
Chest 6	C6	White/violet	V6	Brown/violet

As the following figure shows, the positions of chest electrodes on the body surface are

C1: Fourth intercostal space at the right border of the sternum

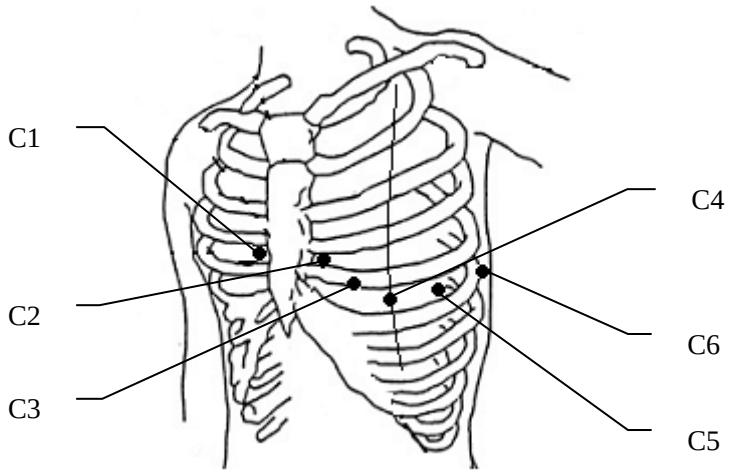
C2: Fourth intercostal space at the left border of the sternum

C3: Fifth rib between C2 and C4

C4: Fifth intercostal space on the left midclavicular line

C5: Left anterior axillary line at the horizontal level of C4

C6: Left midaxillary line at the horizontal level of C4



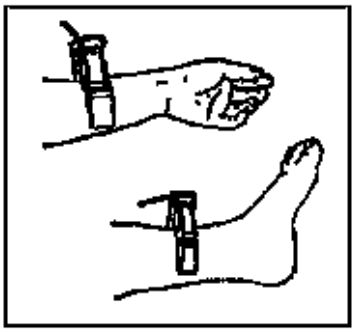
Chest Electrode Connection:

1) Ensure that the electrodes are clean;
2) Align all lead wires of the patient cable to avoid twisting, and connect the lead wires to the corresponding electrodes according to the colors and identifiers;
3) Clean the electrode area on the chest surface with 75% alcohol;
4) Daub the round area of 25mm in diameter on each electrode site with gel evenly;
5) Place a small amount of gel on the brim of chest electrode's metal cup;
6) Place the electrode on the chest electrode site and squeeze the suction bulb. Unclench it and the electrode is adsorbed on the chest;
7) Attach all chest electrodes in the same way.

NOTE: Long-time measurement with a strong negative pressure on the suction bulb may cause reddening of the skin. When using the electrode on small children or patients with delicate skin, squeeze the suction ball lightly.

Limb Electrode Connection:

2) Ensure that the electrodes are clean;
3) Align all lead wires of the patient cable to avoid twisting, and connect the lead wires to the corresponding electrodes according to the colors and identifiers;
4) Clean the electrode area which is a short distance above the ankle or the wrist with alcohol;
5) Daub the electrode area on the limb with gel evenly;
6) Place a small amount of gel on the metal part of the limb electrode clamp;
7) Connect the electrode to the limb, and make sure that the metal part is placed on the electrode area above the ankle or the wrist;
8) Attach all limb electrodes in the same way.



4.5.2 Disposable Electrodes

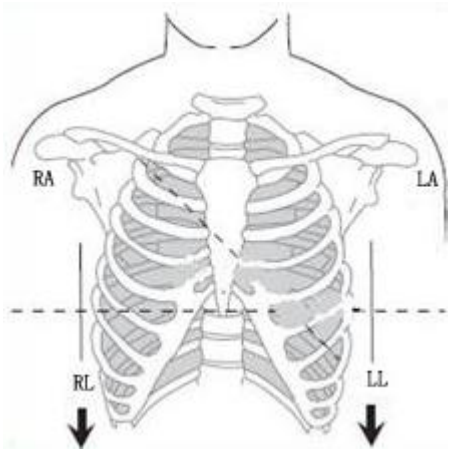
Disposable Electrode

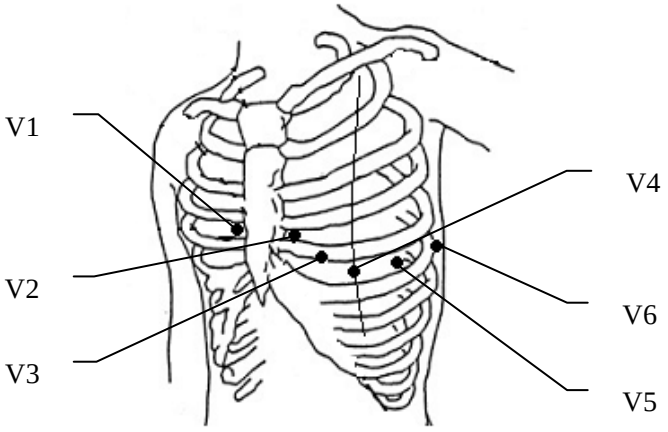
Alligator Clip

Disposable electrode must be used together with the alligator clip.

The electrodes' positions on body surface are as the following table and figures:

American label	European label	Electrode placement
RA	R	Right deltoid
LA	L	Left deltoid
RL	N or RF	Above right ankle (Alternate placement, upper leg as close to torso as possible)
LL	F	Above left ankle (Alternate placement, upper leg as close to torso as possible)
V1	C1	Fourth intercostals space at right border of sternum
V2	C2	Fourth intercostals space at left border of sternum
V3	C3	Fifth rib between V2 and V4
V4	C4	Fifth intercostals space on left midclavicular line
V5	C5	Left anterior axillary line at the horizontal level of V4
V6	C6	Left midaxillary line at the horizontal level of V4





Disposable Electrode connection

1) Align all lead wires of the patient cable to avoid twisting, and connect the alligator clips to the lead wires.
2) Clean the electrode areas on the body surface with 75% alcohol.
3) Attach the disposable electrodes to the electrode positions on body surface.
4) Clip the disposable electrodes with the alligator clips.

The quality of ECG waveform will be affected by the contacting resistance between the patient and the electrode. In order to get a high-quality ECG, the skin-electrode resistance must be minimized when you attach electrodes to patients.

CAUTION

The disposable electrodes can only be used for one time.

WARNING

1. Make sure that all electrodes are connected to the patient correctly before operation.
2. Make sure that the conductive parts of electrodes and associated connectors, including neutral electrode, do not come in contact with earth or any other conducting objects.

4.6 Inspection Before Power On

In order to avoid safety hazards and get good ECG records, the following inspection procedure is recommended before power-on and operation.

1) **Environment**:

- ♦ Make sure that there is no electromagnetic interference source around the equipment, especially large medical electrical equipment such as electrosurgical equipment, radiological equipment, magnetic resonance imaging equipment etc. Switch off these devices when necessary.
- ♦ Keep the examination room warm to avoid muscle action voltages in ECG signals caused by cold.

2) **Power Supply**:

- ♦ If the mains supply is used, please check whether the power cord is connected to the unit well. The grounded three-phase outlet should be used.
- ♦ When the battery capacity is low, recharge the battery before use.

3) **Patient Cable**:

- ♦ Check whether the patient cable is connected to the unit firmly, and keep it far away from the power cord.

4) **Electrodes**:

- ♦ Check whether all electrodes are connected to lead wires of the patient cable correctly.
- ♦ Ensure that the chest electrodes do not contact.

5) **Recorder Paper**:

- ♦ Ensure that there is enough recorder paper loaded correctly.

6) **Patient**:

- ♦ The patient should not come into contact with conducting objects such as earth, metal parts etc.
- ♦ Ensure the patient is warm and relaxed, and breathe calmly.

WARNING

The electrocardiograph is provided for the use of qualified physicians or personnel professionally trained, and they should be familiar with the contents of this user manual before operation.

Chapter 5 Switching On the Electrocardiograph

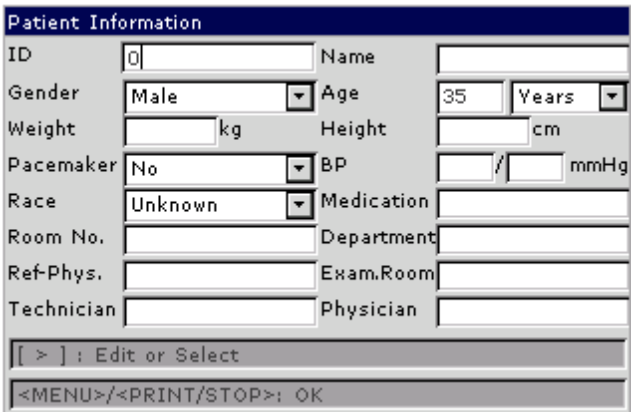
- When the mains supply is used, connect the power cord, press the mains switch on the left side of the unit, and then the mains supply indicator lamp (∿) is lit. Then press the **ON/OFF** key on the control panel to turn on the unit. Then SE-3/SE-300 series is ready for use.
- When a built-in rechargeable lithium battery is used, press the **ON/OFF** key on the control panel directly to turn on the unit, and then the battery indicator (▭) is lit. The equipment information such as the device name, the version number will be displayed on the LCD screen after self-test. Then SE-3/SE-300 series is ready for use.

Chapter 6 Sampling and Printing ECG

6.1 Entering Patient Information

After switched on, the electrocardiograph enters the main screen.

1. Configure the **Patient Information Setup** window. (Optional)
   1) Press **MENU** to enter System Setup Screen.
   2) Choose Patient Inof tab and press **MENU** to enter the sub-window.
   3) Configure according to actual use. See more information in "Patient Info Setup".
   4) After configuration, press **MENU or PRINT/STOP to save and quit the current window.**
   5) **Press Return or RECALL to return to the main screen.**
2. Move the cursor to the patient symbol. Press the Left or Right arrow to enter the patient information window on the Main Screen.
   1) Press the Up or Down arrow to select the ID textbox, and press the Left or Right arrow to pop up the editing window.
   2) Press the Left or Right arrow to choose letter or number, and press MENU to confirm the operation.
   3) If the content need to be modified, press **RECALL** to delete.
   4) After editing, press **MENU** or **PRINT/STOP** to confirm the operation and return to the main screen.



NOTE: The patient information cannot be set or changed during the printing course.

Gender	Patient Gender (Male/Female/Empty)
Age	Age Unit: **Years**, **Months**, **Weeks** or **Days**

BP	Patient Systolic Blood Pressure/Diastolic Blood Pressure
Pacemaker (optional, with DE12 ECG board)	Select **Yes** to detect very small pacemaker pulses. However, when **Pacemaker** is set to **Yes**, the system is very sensitive, and should not be close to equipment emitting high frequency radiation. High frequency radiation can interfere with pacemaker pulse detection and normal ECG acquisition. **NOTE: Pacemaker** is recommended to be set to **No** unless it is known that the majority of the electrocardiograph usage will be on patients with pacemakers.
Race	Patient Race (unknown/ Oriental/ Caucasian/ Black/ Indian/ Mongolian/ Hispanic/ Asian/ Pacific/ Chinese/ Malay/ other)

6.2 Printing ECG Reports

There are four modes to print ECG reports.

In the **AUTO** mode, the lead groups are switched in order automatically during the printing course. There is a blank area on the recorder paper before printing the ECG signals of the next lead group. Moreover, a 1mV calibration mark will be printed at the beginning of ECG reports. The switch orders of lead groups are listed in Table 2-1.

In the **MANUAL** mode, you should switch the lead group manually. You can determine the lead group to be printed and set the printing settings or other parameters for different lead groups.

In the **RHYTHM** mode, you can print 60s rhythm-lead ECG waveforms.

In the **USBPRT** mode, ECG reports can be printed out through a USB printer.

NOTE: The printing mode cannot be changed during the printing course. Stop printing reports before changing the printing mode.

6.2.1 AUTO Mode

In the **AUTO** mode, the lead groups are switched in order automatically during the printing course. There is a blank area on the recorder paper before printing the ECG signals of the next lead group. Moreover, a 1mV calibration mark will be printed at the beginning of ECG reports. The switch orders of lead groups are listed in Table 2-1.

1) Press the **MODE/RST** key to select the **AUTO** mode, which will be displayed in the upper right corner of the LCD screen.

2) Press the **SENS** key to set the sensitivity.
3) Set the suitable speed value and filter value.
4) Or press the **MENU** key to open the System Setup Screen to set the detailed settings. Press the **Return** to return to the Main Screen.
5) Press the **PRINT/STOP** key to begin printing ECG reports. It will stop automatically after printing a complete ECG report of 12 leads.

Press **PRINT/STOP** during the printing course to stop printing ECG reports. Then when you begin printing ECG reports again, the system will print ECG reports from the first lead group.

6.2.2 MANU Mode

In the MANU mode, you need to switch lead groups by pressing the Lead switch key.

1) Press the **MODE/RST** key to select the **AUTO** mode, which will be displayed in the upper right corner of the LCD screen.
2) Press the **SENS** key to set the sensitivity.
3) Set the suitable speed value and filter value.
4) Or press the **MENU** key to open the System Setup Screen to set the detailed settings. Press the **Return** to return to the Main Screen.
5) Press the Lead switch key to select the lead group to be printed.
6) Press the **PRINT/STOP** key to begin printing reports.
7) Press the Lead switch key to switch the lead group while printing ECG reports and the system will automatically print 1mV calibration mark. Press the **1mV/COPY** key to print out 1mV mark in the ECG report.
8) Press the **PRINT/STOP** key to stop printing ECG reports.

6.2.3 RHYT mode

In the RHYT mode, you can choose single lead type or three-lead type.

1) Press the **MODE/RST** key to select the **RHYTHM** mode; which will be displayed in the bottom right corner of the LCD screen.
2) Press the **SENS** key to set the sensitivity.
3) Set the suitable speed value and filter value.
4) Press the **PRINT/STOP** key, the hint information *Sampling* will be displayed on the Main Screen, and the sampling time will be counted. When the preset sampling time reaches, it begins to print ECG reports.

5) It will stop automatically after printing a complete report of rhythm-lead ECG waveforms. Or press the **PRINT/STOP** key again to stop printing ECG reports.

6.2.4 R-R mode

In the R-R mode, you can print ECG waveforms of 180s.

1) Press the **MODE/RST** key to select the **R-R** mode; which will be displayed in the bottom right corner of the LCD screen.
2) Press the **SENS** key to set the sensitivity.
3) Set the suitable speed value and filter value.
4) Press the **PRINT/STOP** key to begin printing reports. Or press the **PRINT/STOP** key again to stop printing ECG reports.

6.3 Sample ECG Reports

6.3.1 ECG Reports in the AUTO Mode

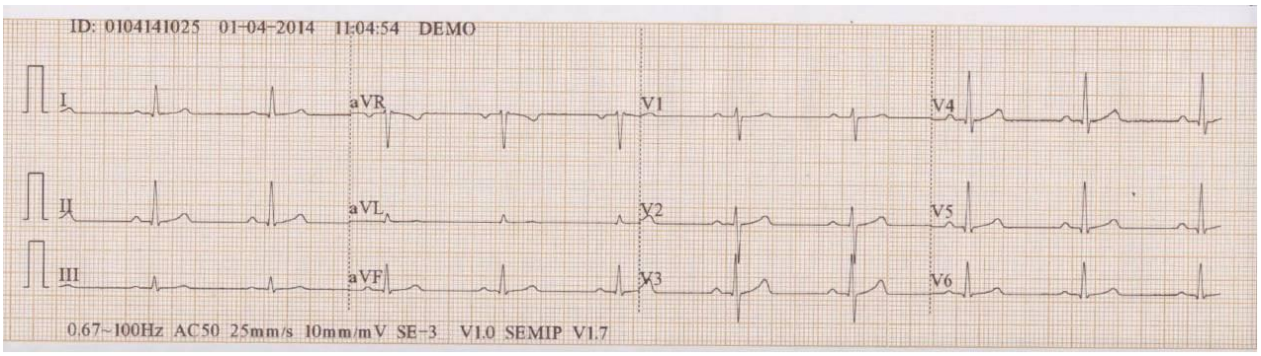


Figure 6-1 ECG Reports in the AUTO Mode (a)

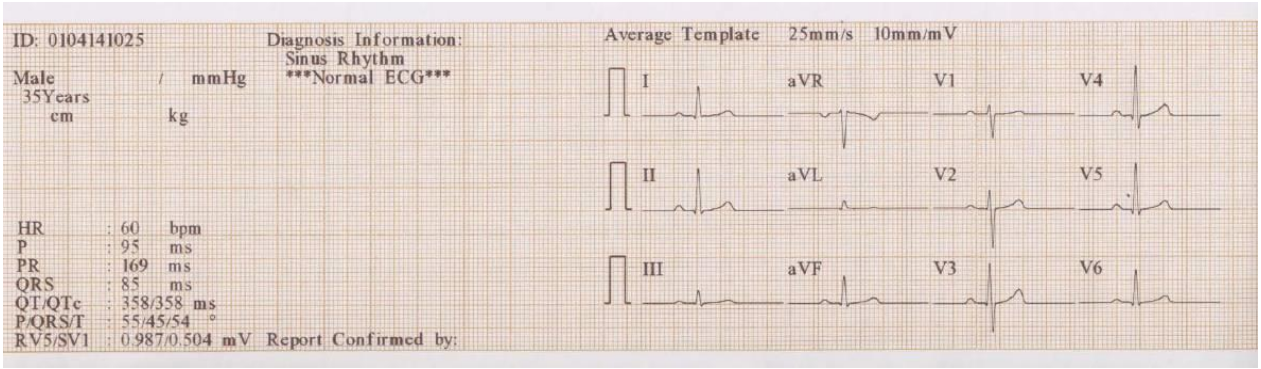


Figure 6-2 ECG Reports in the AUTO Mode (b)

Figure 6-1 and Figure 6-2 show an ECG report in the auto mode. **Template** is selected, and **Record Style** is set to **3×4**.

The ECG report includes:

3×4 ECG waves

ID, Current Date and time

Patient Information: ID, Name, Age, Gender, Height, Weight, BP, Race, Department, Exam Room, Medication

Measure Information:

HR	Heart Rate
P	P wave duration: the average P-wave duration from several selected dominant beats;
PR	P-R interval: the average P-R interval from several selected dominant beats;
QRS	QRS complex duration: the average QRS complex duration from several selected dominant beats;
QT/QTc	Q-T interval: the average Q-T interval from several selected dominant beats / Normalized QT interval;
P/QRS/T	Dominant direction of the average integrated ECG vectors;
RV5/SV1	The maximum of the amplitude of R or R' wave of one selected dominant beat from lead V5 / The maximum absolute value of the amplitude of S or S' wave of one selected dominant beat from lead V1;
RV5+SV1 (optional)	Sum of RV5 and SV1;
RV6/SV2 (optional)	The maximum of the amplitude of R or R' wave of one selected dominant beat from lead V6 / The maximum absolute value of the amplitude of S or S' wave of one selected dominant beat from lead V2;

Average Template: Average template shows the average value of 10s sampled ECG signals of every lead.

The broken lines on the template are position markers. They respectively mark the start and end points of the P and QRS waves, and the end point of the T wave.

Diagnosis Information: Diagnosis information shows the auto diagnosis result.

Report Confirmed by Confirmed by the physician

Bottom Information: 0.67~100Hz (0.67Hz DFT Filter, 100Hz Lowpass Filter),

AC50 (50Hz AC Filter)

25mm/s (Paper Speed)

10mm/mV (Gain)

♥60 (Heart Rate)

Electrocardiograph Model

V1.0 (Software Version)

SEMIP V1.7 (Algorithm Version)

Institution Name

6.3.2 PDF Report

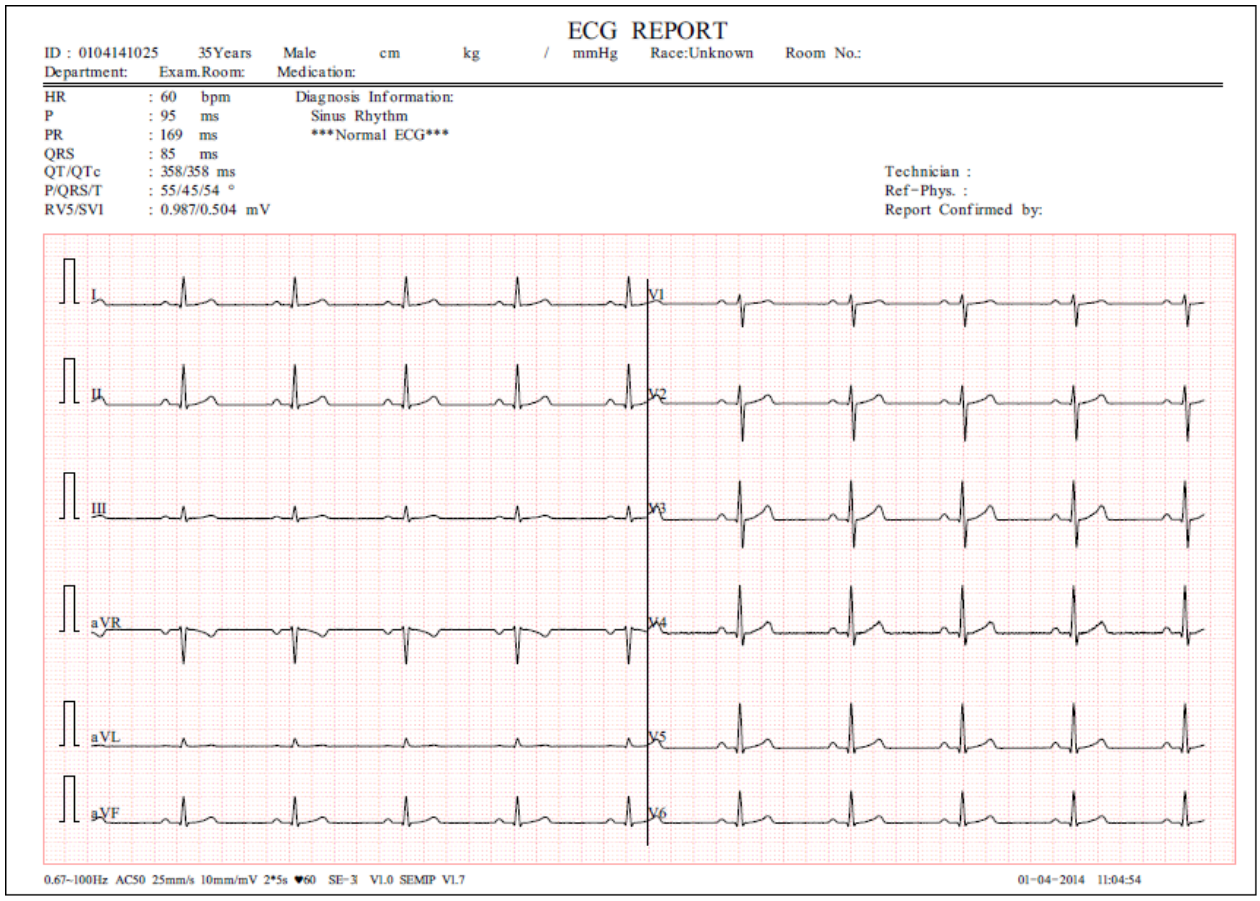


Figure 6-3 PDF Report

Chapter 7 Managing ECG Records

If you want to save the ECG records, you should set the **Auto Save** to **To ECG** or **To USB**. The default value is **To ECG**. Then the ECG records will be saved in the File Manager or in the U disk automatically.

Press the **RECALL** key to open the File Manager where patient records are displayed. The File Manager allows records to be stored, deleted, printed and transmitted. When there is no space for more records to be stored in the File Manager, the message *MemFull* will be displayed.

7.1 Transmitting ECG Records to the PC

NOTE: To transmit ECG records to the PC, Smart ECG Viewer software of the manufacturer must be installed in the PC. You should log into the Smart ECG Viewer software before the transmission.

7.1.1 Transmitting ECG Records through the Serial Port

Connect the RS232 socket of the PC to the RS232 socket of the electrocardiograph with a RS232 cable. If the PC has no RS232 socket, connect the USB socket of the PC to the RS232 socket of the electrocardiograph by using the RS232-USB assembly.

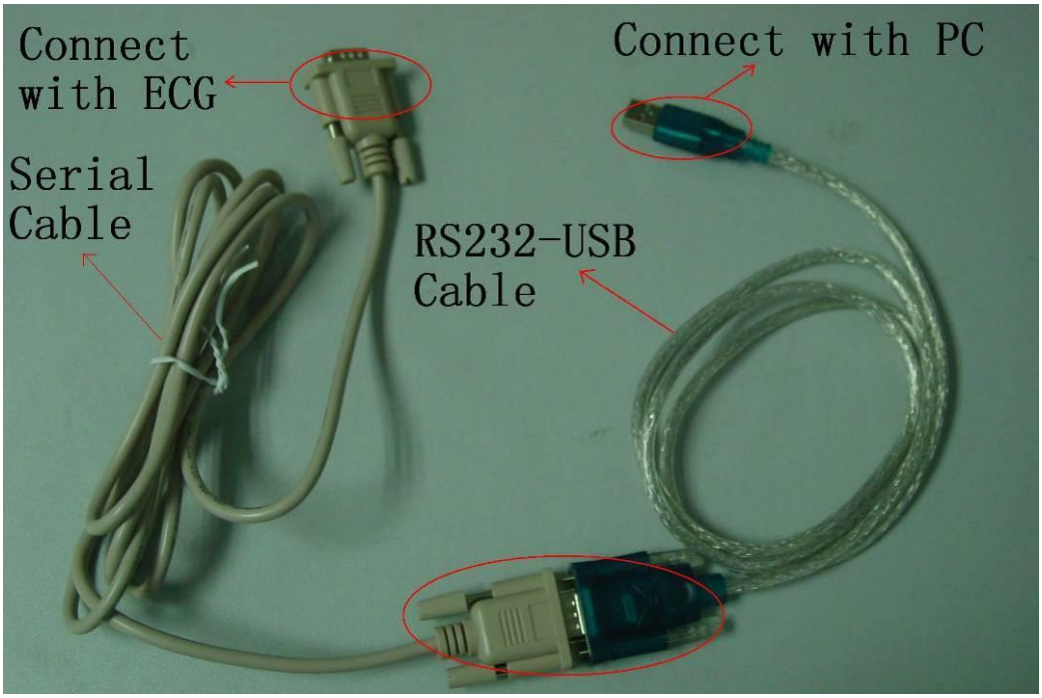


Figure 7-1 RS232-USB Assembly

- **Auto Transmission:**

1 Press the **MENU** key to open the System Setup Screen.

2 Select the **Transmission** button, and then press the **MENU** key to enter the sub-window.

3 Set **Auto Transmission** to **On** and set **Transmission mode** to **UART**. Then press the **MENU** key again to return to the Main Screen.

4 In the **AUTO, RHYT, OFF-AUTO** or **OFF-RHTY** mode, ECG data can be transmitted through the UART port automatically after an ECG report is printed out.

- **Manual Transmission:**

1 Press the **MENU** key to open the System Setup Screen.

2 Select the **Transmission** button, and then press the **MENU** key to enter the sub-window.

3 Set **Auto Transmission** to **Off** and set **Transmission mode** to **UART**. Then press the **MENU** key again to return to the Main Screen.

4 Press the **RECALL** key to open the File Manager screen (a).

1) Select the **TransAll** button, and then press the **MENU** key to confirm the operation.

NOTE: Please make sure the settings of **Auto Transmission** and **Transmission** Mode in Transmission is correct.

2) If you want to transmit only one record, choose the patient record in the table, press the **MENU** key to enter the File Manager screen (b). Select the **Trans** button and then press the **MENU** key to confirm the operation.

NOTE: The transmission process is long, and please be patient to wait.

3) Press the **RECALL** key to return to the Main Screen.

7.1.2 Transmitting ECG Records through the Net Port (Optional, Only for Net Type)

Connect the PC to the electrocardiograph with an Ethernet cable recommended by the manufacturer. If the wireless AP transmission is used, connect the PC to one wireless AP, and connect the electrocardiograph to the other wireless AP.

NOTE:

1) Only the wireless AP recommended by the manufacturer can be used.

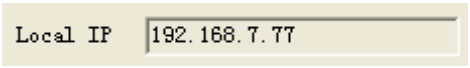
2) For details on configuring the wireless AP, please refer to the user manual delivered with the wireless AP.

3) There should be no shield in or around the room where the wireless AP is used, or else the wireless transmission may fail.

- **Auto Transmission:**

1. Press the **MENU** key to open the System Setup Screen.
2. Select the **Transmission** button, and then press the **MENU** key to enter the sub-window.
3. Set **Auto Transmission** to **On** and set **Transmission mode** to **Ethernet.**
4. Set the **Server IP** to the IP of Smart ECG Viewer.
5. Set the first three numbers of the **Local IP** to the first three numbers of the IP of Smart ECG Viewer. The last number of the **Local IP** item can be set at random, but it can't be the same as the last number of the IP of Smart ECG Viewer.

   For example, check the IP on the **System Setting** interface of the Smart ECG Viewer software.



   Set the **Server IP** to the IP of Smart ECG Viewer. Set the first three numbers of the **Local IP** to the first three numbers of the IP of Smart ECG Viewer. The last number of the **Local IP** can be set at random, but it can't be the same as the last number of the local IP of Smart ECG Viewer.

6. In the **AUTO, RHYT, OFF-AUTO** or **OFF-RHYT** mode, ECG data can be transmitted through the net automatically after an ECG report is printed out.

- **Manual Transmission:**

1. Press the **MENU** key to open the System Setup Screen.
2. Select the **Transmission** button, and then press the **MENU** key to enter the sub-window.
3. Set **Auto Transmission** to **Off** and set **Transmission mode** to **Ethernet.**
4. For IP address setting, refer to step 4 and 5 for auto transmission.
5. Other steps for transmission operation, refer to step 4 for manual transmission in section 7.1.1 "Transmitting ECG Record through the Serial Port".

NOTE: The transmission process is long, and please be patient to wait.

7.2 Copying ECG Records between the ECG Machine and U Disk

1. Connect the U disk to the electrocardiograph.
2. Press the **RECALL** key to open the File Manager screen (a).
3. Select the **TransAll** button, and then press the **MENU** key to confirm the operation. And then the **ECGDATA** folder of all the records will be transmitted to the U disk automatically.

   During the transmission, if something wrong happens, the electrocardiograph will give the error information. Then you should check whether the U disk is connected to the electrocardiograph well.
4. If you want to import records from the **ECGDATA** folder of the U disk to the electrocardiograph, select the **Import** button, and then press the **MENU** key. The extended-name of imported records should be ".dat".

NOTE: To import records from the U disk to the electrocardiograph, there should be some records in the folder named ECGDATA in the U disk. The folder name ECGDATA must be capital letters. You should not change the name of records in the **ECGDATA** folder.

During the transmission from the U disk to the electrocardiograph, if something wrong happens, the electrocardiograph will give the error information. Then you should do the following operations:

1) Firstly, check whether the U disk is connected well.
2) If the error information is still displayed, you should check whether there is the **ECGDATA** folder including some records with the extended-name of ".dat" in the U disk. If not, you should create an ECGDATA folder in the U disk and add records to be imported to the U disk.
3) If the error information is still displayed, you should check whether the total number of records in the **ECGDATA** folder of the U disk and the File Manager of the electrocardiograph exceeds the limit. The limit of the electrocardiograph is 500. If the total number exceeds the limit, you should remove some records from the **ECGDATA** folder of the U disk, and then continue to import the remainder records to the electrocardiograph.
4) If the error information *The same record found! Press PRINT/STOP return* is displayed, you should check whether there are cognominal records in the U disk and the

electrocardiograph. If it is true, you should remove these records from the U disk, or delete these records in the electrocardiograph, and then continue to import records to the electrocardiograph.

After records are imported, the electrocardiograph will give a hint.

5. If you want to export only one record, choose the patient record in the table, press the **MENU** key to enter the File Manager screen (b). Select the **Export** button and then press the **MENU** key to confirm the operation.
6. Press the **RECALL** key to return to the Main Screen.

NOTE:

1. The transmission process is long, and please be patient to wait.
2. During the transmission, the U disk should not be pulled out.
3. Only the U disk with FAT format can be used.

7.3 Deleting Patient Records

1. Press the **RECALL** key to open the File Manager screen (a).
2. If you want to delete all the records, select the **DEL ALL** button, and then press the **MENU** key.
3. If you want to delete a record, choose the patient record in the table, and then select **Delete** button.
4. Press the **RECALL** key to return to the Main Screen.

7.4 Printing a Patient Record in the File Manager screen

1. Press the **RECALL** key to open the File Manager screen (a).
2. If you want to print the patient record, choose the patient record in the table, and then press **PRINT/STOP** key.

NOTE: If you use USB printer to print the patient record, when the PRINT/STOP key is pressed, the electrocardiograph begins to analyze data. Then the USB printer begins to print the ECG record after 8 seconds.

3. Press the **RECALL** key to return to the Main Screen.

7.5 ECG Copy

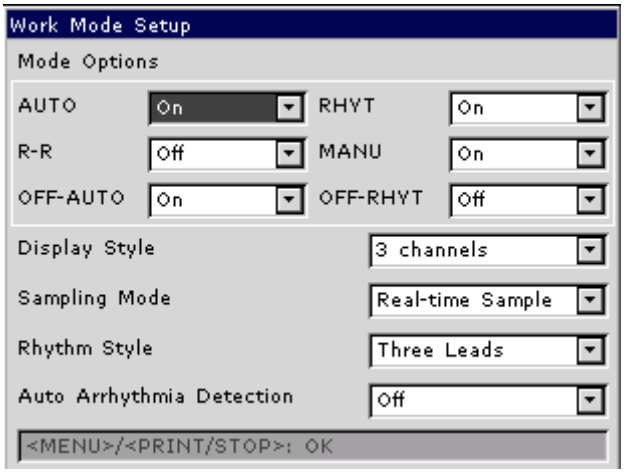
In the **AUTO** mode, after an ECG report is printed out, pressing the **1mV/Copy** key can print the ECG report which was printed out last time. Pressing the **PRINT/STOP** key can stop printing the ECG report.

NOTE: After an ECG report is printed out in the AUTO mode, if you change the printing mode or the printing format, the ECG report can not be printed again by pressing the **1mV/Copy** key.

Chapter 8 Settings

Press the Up or Down or Left or Right arrow to select the function button, and then press the MENU or PRINT/STOP to enter sub-window.

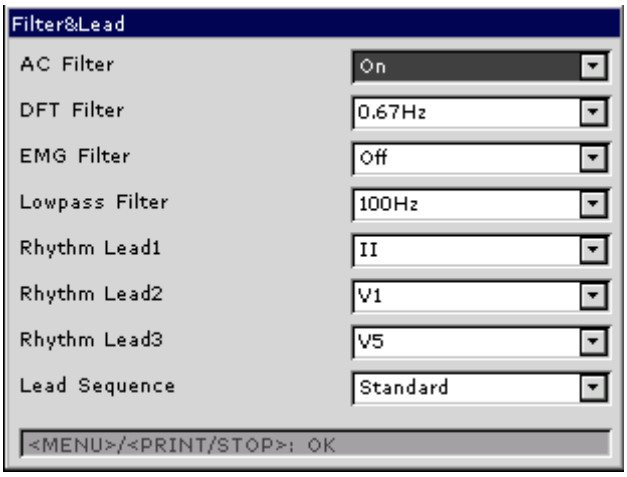
8.1 Work Mode



Item	Description
Mode Options	Including: **AUTO**, **RHYT**, **R-R MANU**, **OFF-AUTO** and **OFF-RHYT**. Each item can be set to On. When set to On, it will be available on the main screen, and you can press **MODE/RST** to switch to the mode. In the **MANU** mode, you can press the lead switch button to switch the lead group. In the **OFF-AUTO** or **OFF-RHYT** mode, the electrocardiograph samples ECG signal as well as save the patient record but doesn't print ECG report.
Display Style	Choose from: **3 channels**, **6 channels** and **12 channels**, the default value is **12 channels**
Sampling Mode (Only available in the auto mode)	Choose from: **Pre-Sample** and **Real-time**, the default value is **Real-time** Select **Pre-Sample**, 10s ECG data sampled before pressing the **PRINT/STOP** key will be printed out. **NOTE:** When **Sampling Mode** is set to **Pre-Sample**, if you press the **PRINT/STOP** key before the electrocardiograph samples for 10s, the recorder will not respond.

Rhythm Style	Choose from: **Single Lead** or **Three Leads**, the default value is **Three Leads**
Auto Arrhythmia Detection	Choose from: **On** or **Off**, the default is **Off** Select **On**, if arrhythmia is detected in the auto mode, a hint will pop up to ask you whether to print an extra rhythm report after the 12-lead ECG report.

8.2 Filter & Lead



Item	Description
AC Filter	Choose from: **On** or **Off**, the default value is **On** AC filter is used to suppress interference of AC power supply. **NOTE:** AC frequency can be set to **50Hz** or **60Hz** on the **Advanced Setup** screen according to local mains supply specifications.
DFT Filter	Choose from: **0.05Hz**, **0.15Hz**, **0.25Hz**, **0.32Hz**, **0.5Hz** or **0.67Hz**, the default value is **0.67Hz** DFT Filter greatly reduces the baseline fluctuations without affecting the ECG signals. The purpose of this filter is to keep the ECG signals on the baseline of the printout. The set value is the low limit of the frequency range.
EMG Filter	The cutoff frequency can be set to **25Hz**, **35Hz**, **45Hz** or **Off**, the default value is **Off** EMG Filter suppresses disturbance caused by strong muscle tremor.

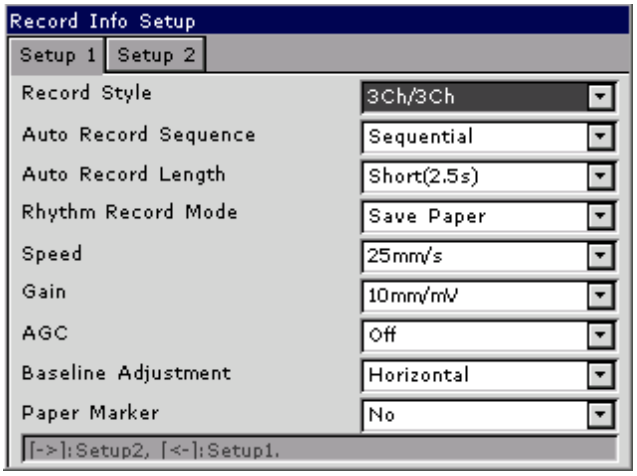
Lowpass Filter	The cutoff frequency can be set to **75Hz**, **100Hz** or **150Hz**, the default value is **100Hz** Lowpass Filter restricts the bandwidth of input signals. All the input signals whose frequency is higher than the set cutoff frequency will be attenuated. **NOTE:** Only when **EMG Filter** is set to **Off**, can the setting of **Lowpass Filter** be effective.
Rhythm Lead1/2/3	Choose from: **I**, **II**, **III**, **aVR**, **aVL**, **aVF**, **V1**, **V2**, **V3**, **V4**, **V5**, or **V6**, the default value is of Rhythm Lead 1 is **II**, the default value is of Rhythm Lead 2 is **V1,** the default value is of Rhythm Lead 3 is **V5** In the auto mode: When **Record Style** is set to **3×4+1R** or **6×2+1R**, the rhythm lead selected in the **Rhythm Lead1** list box will be printed in the ECG reports; In the rhythm mode: When **Rhythm Style** is set to **Single Lead**, 60s wave of the rhythm lead selected in the **Rhythm Lead1** list box will be printed in the ECG reports; When **Rhythm Style** is set to **Three Leads**, 20s waves of three rhythm leads selected respectively in the **Rhythm Lead1/2/3** list box will be printed in the ECG reports. In the R-R analysis mode: The R-R analysis report of the rhythm lead selected in the **Rhythm Lead1** list box will be printed. NOTE: Rhythm Lead 1/2/3 must be different from each other.
Lead Sequence	Choose from: **Standard** or **Cabrera**, the default value is **On**

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

NOTE: To pass the distortion test, the electrocardiograph has to be configured with the highest bandwidth in filter settings. Otherwise, ECG signal may be distorted.

8.3 Record Info Setup

8.3.1 Setup 1

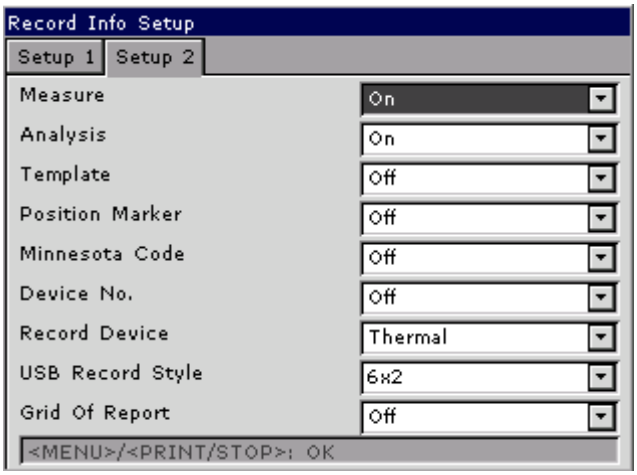


Item	Description
Record Style	Choose from: **3Ch/3Ch**, **3Ch/2Ch**, **1Ch+1R**, **1Ch** or **3Ch+1R**, the default value is **3Ch/3Ch** Select a style to print the ECG waves of 12 leads in the auto mode. When **Record Style** is set to **3Ch/3Ch**, ECG waves of all leads will be printed in 4 groups of 3. When **Record Style** is set to **3Ch/2Ch**, ECG waves of lead I, II, III, aVR, aVL and aVF will be printed in 2 groups of 3, and ECG waves of lead V1, V2, V3, V4, V5 and V6 will be printed in 3 groups of 2. When **Record Style** is set to **1Ch+1R**, ECG waves of all leads will be printed one by one in a sequence, with ECG waves of one rhythm lead on the bottom of the ECG reports. When **Record Style** is set to **1Ch**, ECG waves of all leads will be printed one by one in a sequence. When **Record Style** is set to **3Ch+1R**, ECG waves of all leads will be printed in 4 groups of 3, with one rhythm lead on the bottom of the ECG reports. **NOTE: Record Style** is corresponding with **Work Mode**.
Auto Record Sequence	Choose from: **Sequential** or **Synchronous**, the default value is **Sequential** Select **Sequential**, the lead group is printed one by one in a certain

	sequence. The start time of a lead group is just the end time of the previous lead group. Select **Synchronous**, the lead group is printed one by one in a certain sequence. All leads are printed with the same start time.
Auto Record Length	Choose from: **Short (2.5s)**, **Medium (5s)** and **Long (10s)**, the default value is **Short (2.5s)** When **Auto Record Length** is set to **Short (2.5s),** ECG waves of each lead group will be printed for about 2.5 seconds. When **RECORD LENGTH** is set to **Medium (5s),** ECG waves of each lead group will be printed for about 5 seconds. When **RECORD LENGTH** is set to **Long (10s)** ECG waves of each lead group will be printed for about 10 seconds. **NOTE:** 1. **Auto Record Length** is corresponding with **Record Device, Sampling Mode** and **Record Sequence.** 2. The device acquires ECG signals from patients undergoing short-term resting test. The time range can be 2.5s, 5s or 10s.
Manual REC Style	Choose from **3 channels**, **6 channels** and **12 channels**, the default value is **12 channels** Select a style to print the ECG waves in the manual mode.
Rhythm Record Mode	Choose from: **Save Paper** or **Quickly**, the default value is **Save Paper** Select **Save Paper**, 10s after pressing the **PRINT/STOP** key on the main screen, an ECG report is printed in the RHYT mode. Select **Quickly**, pressing the **PRINT/STOP** key on the main screen to begin printing an ECG report immediately in the RHYT mode.
Speed	Choose from: **5mm/s**, **6.25mm/s**, **10mm/s**, **12.5mm/s**, **25mm/s** or **50mm/s**, the default value is **25mm/s** In the manual mode, select **5mm/s**, **6.25mm/s**, **10mm/s**, **12.5mm/s**, **25mm/s** or **50mm/s**. Only **25mm/s** and **50mm/s** are available in the Auto, OFF-Auto, RHTY, and OFF-RHTY modes. Only **25mm/s** is available in the R-R analysis mode.
Gain	You can set the indicated height of 1mV ECG on the paper. Choose from: **2.5mm/mV, 5mm/mV, 10mm/mV**, **20mm/mV** or

	10/5mm/mV, the default value is **10mm/mV** **10/5mm/mV** means that the gain of limb leads is set to **10mm/mV**, while the gain of chest leads is set to **5mm/mV**.
AGC	**AGC** means auto gain control. Choose from: **On** or **Off**, the default value is **Off** Select **On**, the gain can be automatically adjusted according to actual signals.
Baseline Adjustment	Choose from: **Horizontal**, **Auto** or **Off**, the default value is **Horizontal** Select **Horizontal**, the baselines of the lead groups are adjusted simultaneously, and the baselines of the leads in the same row are on the same line. Select **Auto**, the baselines of the lead groups are adjusted respectively. Select **Off**, the baselines of the lead groups are adjusted equally in the ECG reports.
Paper Marker	**Paper Marker** is used to identify the start point of each page of the recorder paper. Choose from: **Yes** or **No**, the default value is **No** Select **Yes** if the paper with black markers on the bottom is used, and the device can identify the start point of each page of the recorder paper while printing ECG reports.

8.3.2 Setup 2



Item	Description
Measure	Choose from: **On** or **Off**, the default value is **On** When it is set to **On**, the Measure information will be printed in the ECG report.
Analysis	Choose from: **On** or **Off**, the default value is **On** When it is set to **On**, the Analysis information will be printed in the ECG report.
Template	Choose from: **2×6+1R, 3×4** or **Off**, the default value is **Off** When it is set to **Off**, the template will not be printed in the ECG report
Position Marker	Choose from: **On** or **Off**, the default value is **Off** When it is set to **Off**, the template printed in the ECG report will not have position marker.
Minnesota Code	Choose from: **On** or **Off**, the default value is **On** When it is set to **On**, the Minnesota Code will be printed in the ECG report.
Device No.	Choose from: **On** or **Off**, the default value is **On** When it is set to **On**, the Device No. will be printed in the ECG report.
Record Device	Choose from: **Thermal**, **HP 2010/1050/2000**, **HP 2015/2035/1525, or HP 1020, or HP 1505**, the default value is **On** You should connect the corresponding USB printer **HP 2010/1050/2000** and **HP 2015/2035** to the electrocardiograph. **WARNING** If the printer used is not the type listed above, additional safety measures (such as applying an isolation transformer to supply the medical system) should be taken when the safety of the medical system has not been evaluated. If in doubt, consult our technical service department or your local distributor. **CAUTION** It is forbidden to connect or disconnect a U disk or a USB printer during the transmission course.

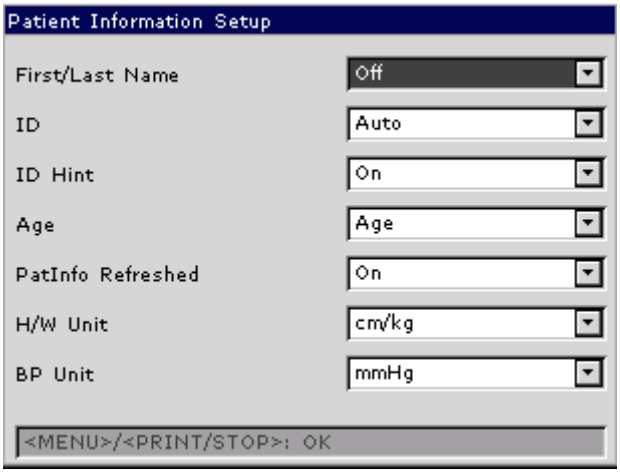
Options	Corresponding USB Printers
HP 2010/1050/2000	HP Deskjet 2010
	HP Deskjet 1050
	HP Deskjet 2000
HP2015/2035/1525	HP Laserjet P2015
	HP Laserjet P2035
	HP Laserjet P1525
HP 1020	HP Laserjet 1020
HP 1505	HP Laserjet 1505

NOTE:

1. During the USB printing course, pressing the **PRINT/STOP** key again cannot stop printing ECG reports.
2. For details of the ECG report printed by the USB printer, please refer to section 6.3.2 "PDF Report".
3. USB printing is ineffective in the auto mode, OFF-AUTO, RHYT mode and OFF- RHYT mode.
4. Make sure that paper is installed in the USB printer before printing. Error may occur if no paper is loaded in the USB Printer.
5. Make sure the type of USB printer connected is matched with the type you choose in the Record Device. Error may occur if the USB printer type is not matched.

USB Record Style	Choose from: **3×4**, **3×4+1R, 3×4+3R, 6×2, 6×2+1R** or **12×1**, the default value is **6×2** It defines the style of USB report.
Grid of Report	Choose from: **On** or **Off**, the default value is **Off** When it is set to **On**, the grid will be printed while printing ECG reports with the thermal recorder or USB printer.

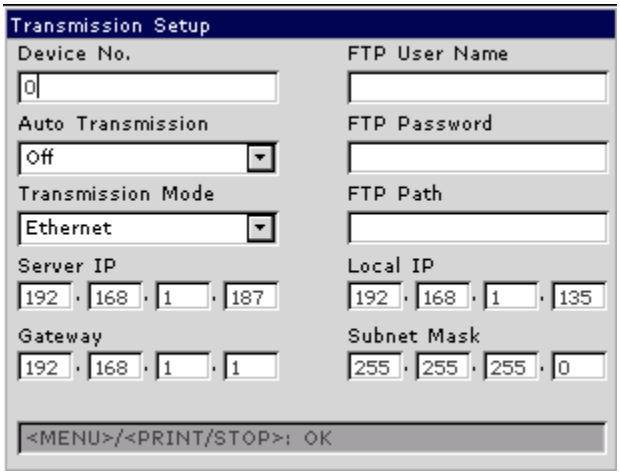
8.4 Patient Information Setup



Item	Description
First/Last Name	Choose from: **On** or **Off**, the default value is **Off** When it is set to **On**, patient name will be divided into first name and last name.
ID	Choose from: **Auto, Time** or **Manual**, the default value is **Auto** Select **Manual**, the patient ID which is within 30 ASCII characters needs to be input manually. Select **Auto**, ID accumulates from 0. The patient ID is 0~1999, 999, 999. Select **Time**, when you press the **PRINT/STOP** key to print an ECG report, the patient ID can be automatically generated according to the time. Entering the patient ID manually is not supported.
ID Hint	Choose from: **On** or **Off**, the default value is **Off** In the auto, rhythm mode, when **ID** is set to **Manual** and **ID Hint** is set to **On**, if you do not input the patient ID before pressing the **PRINT/STOP** key, a hint will pop up to remind you to input the patient ID.
Age	Choose from: **Age**, **D.O.B** or **Age Group**, the default value is **Age** Select **Age**, you can enter the patient age manually in the **Patient Information** window. Select **D.O.B**, the **D.O.B** textbox appears and the **Age** textbox becomes unavailable in the **Patient Information** window, you can enter the birthday of the patient, and the system will calculate the patient age automatically.

	Select **Age Group**, the **Age Group** textbox appears in the **Patient Information** window.
PatInfo Refreshed	Choose from: **On** or **Off**, the default value is **On** Select **On**, the patient information will be refreshed after the ECG report is printed out and all the leads are off.
H/W Unit	Choose from: **cm/kg** or **inch/lb**, the default value is **cm/kg**
BP Unit	Choose from: **mmHg** or **kPa**, the default value is **mmHg**

8.5 Transmission Setup



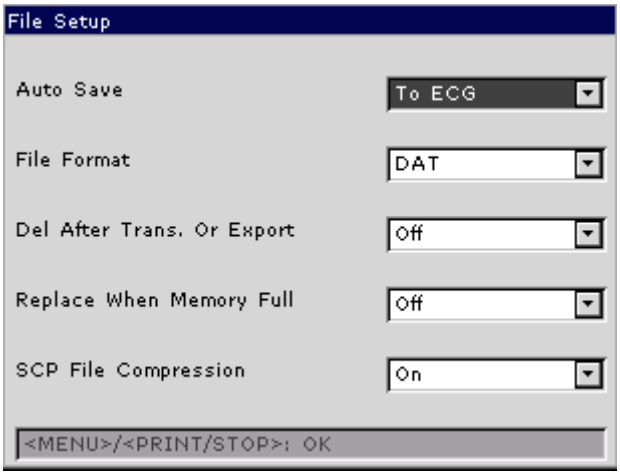
NOTE:

1. To transmit ECG data to the PC in DAT format, the Smart ECG Viewer software produced by the manufacturer must be installed in the PC. You should log into the Smart ECG Viewer software before transmission.
2. To transmit ECG data to the PC in DICOM/SCP/FDA-XML/PDF format, the FTP receiving software must be installed in the PC. You should log into the FTP receiving software before transmission.

Item	Description
Device No.	Enter Device No., it should be within 7 ASCII characters.
Auto Transmission	Choose from: **On** or **Off**, the default value is **Off** Select **On**, ECG data will be transmitted automatically after an ECG report is printed out in the auto or rhythm mode; in the off mode, 10s ECG data sampled before pressing the **PRINT/STOP** key can be saved and transmitted, but cannot be printed.

Transmission Mode	Choose from: **Ethernet** or **UART**, the default value is **Ethernet** Select **Ethernet**, ECG data will be transmitted to the PC through the net port. Select **UART**, ECG data will be transmitted to the PC through the serial port.
FTP Information	Enter data in the **FTP Path**, **FTP User Name** textboxes.
IP Addresses	Set **Server IP, Local IP,** Set **Gateway,** Set **Subnet Mask** For details, please refer to Section 7.1.1 "Transmitting ECG Data in DAT Format". **NOTE:** If WIFI is enabled and **Auto Get IP** is selected in the **WIFI Setup** window, IP addresses can be acquired automatically.

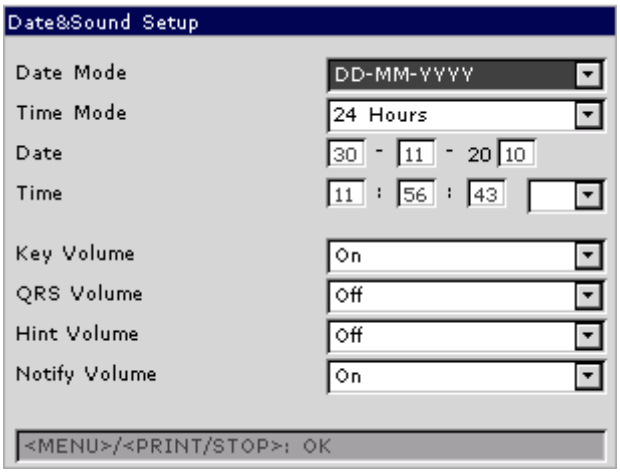
8.6 File Setup



Item	Description
Auto Save	Choose from: **Off, To ECG** or **To U Disk**, the default value is **To ECG** Select **Off**, ECG data will not be saved. Select **To ECG**, ECG data in the auto or rhythm mode will be saved in the ECG automatically. Select **To U Disk**, ECG data in the auto or rhythm mode will be automatically saved to the directory of ***ECGDATA\ECG-X\Store\Examination Date*** of the U disk after an ECG report is printed out.

	NOTE: 1. Please insert the U disk recommended by the manufacturer. Please set the format to **FAT** or **FAT32** when formatting the U disk. 2. X in the directory of ***ECGDATA\ECG-X\Store\Examination Date*** can be set in the **Device No.** textbox in the **Transmission Setup** window.
File Format	Choose from: **DAT, PDF, SCP, FDA-XML** and **DICOM**, the default value is **DAT** To select **SCP/FDA-XML/DICOM**, you should first activate the SCP/FDA-XML/DICOM function on the **Advanced Setup** screen. For details, please contact the manufacturer or the local distributor.
Del. After Trans. Or Export	Choose from: **On** or **Off**, the default value is **Off** Select **On**, the files will be automatically deleted from the **File Manager** screen after they are transmitted to the PC or exported to the U disk.
Replace When Memory Full	Choose from: **On** or **Off**, the default value is **On** Select **On**, if the stored files reaches 200, the files will replace the earliest one automatically.
SCP File Compression	Choose from: **On** or **Off**, the default value is **Off** Select **On**, the SCP file will be compressed.

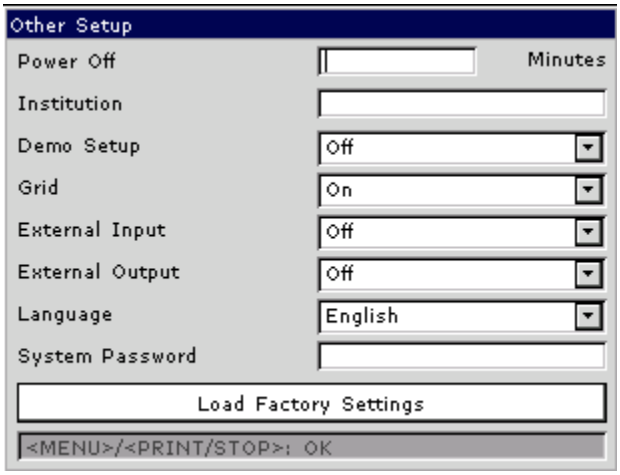
8.7 Date&Sound Setup



NOTE: Please set DATE&TIME correctly when it's the first time you use the electrocardiograph.

Item	Description
Date Mode	Choose from: **DD-MM-YYYY**, **MM-DD-YYYY** or **YYYY-MM-DD**, the default value is **DD-MM-YYYY**
Time Mode	Choose from: **24 Hours** or **12 Hours**, the default value is **24 Hours**
Date&Time	Enter the current date and time displayed on the main screen and in the ECG reports.
Key Volume	Choose from: **On** or **Off**, the default value is **Off** Select **On,** the electrocardiograph gives a short sound when you press keys on the keyboard. Select **Off**, there is no sound.
QRS Volume	Choose from: **On** or **Off**, the default value is **On** Select **On**, the electrocardiograph gives a sound when an R wave is detected. Select **Off**, there is no sound when an R wave is detected
Hint Volume	Choose from: **On** or **Off**, the default value is **On** Select **On**, the electrocardiograph gives a sound when a hint such as ***Lead Off***, ***Overload***, ***Battery Weak*** etc. is displayed. Select **Off**, there is no hint sound.
Notify Volume	Choose from: **On** or **Off**, the default value is **On** Select **On**, the electrocardiograph gives a sound after ECG report is printed. Select **Off**, there is no sound after ECG report is printed.

8.8 Other Setup



Item	Description
Power Off	Input the power-off time manually. If you enter **0 Minutes** or nothing, this function will not be effective. **NOTE:** 1. Power-off time is counted from the time when you last press the keys on the keyboard. 2. Only when the device is powered by the battery, can the set automatic power-off time be effective.
Institution	Input the institution name manually within 40 ASCII characters. **NOTE:** The total number of supported characters may be fewer if special Latin characters are entered.
Demo Setup	Choose from: **Normal**, **abnormal** or **Off**, the default value is **Off** When it is set to **Normal**, the main screen will display demo of normal ECG signal. When it is set to **abnormal**, the main screen will display demo of abnormal ECG signal.
Grid	Choose from: **On** or **Off**, the default value is **Off** Select **On**, the waveforms on the main screen will be displayed with a background grid.

External Input	The external input socket is equipped in the electrocardiograph, through which the electrocardiograph can receive signals from the external equipment. Choose from: **On** or **Off**, the default value is **Off** Select **On**, the electrocardiograph will display the signals which it receives from external input port.
External Output	The external output socket is equipped in the electrocardiograph, through which the electrocardiograph can send rhythm lead signals to the external equipment. Choose from: **Off, Standard** or **Triggered**, the default value is **Off** Select **Standard**, the electrocardiograph sends ECG signals of rhythm lead 1. Select **Triggered**, the electrocardiograph sends pulses with the height of 5V and the width of 45ms, based on the data of rhythm lead 1.
Language	Select the language displayed on the main screen and in the ECG reports.
System Password	Type a password that allows you to access the **System Setup** window.
Load Factory Settings	Press to restore the factory settings.

Chapter 9 Switching Off the Electrocardiograph

When the built-in battery is used, press the **ON/OFF** key directly to turn off the unit.

When the mains supply is used, press the **ON/OFF** key, and then press the mains switch on the left side of the unit. Pull out the plug from the outlet.

NOTE: When switching off the device, please follow the above sequence strictly, or else there will be something wrong on the screen.

Chapter 10 Hint Information

Hint information provided by SE-3/SE-300 series and the corresponding causes are listed in Table 10-1.

Table 10–1 Hint Information and Causes

Hint Information	Causes
Lead off	Electrodes fall off the patient or the patient cable falls off the unit.
Paper?	Recorder paper runs out or is not loaded.
PaperErr	The system doesn't detect any black signs while the paper style is set as "Folded" on the System Setup Screen.
BAT WEAK	The built-in battery is weak.
Demo	The system is in the demonstration mode.
Sampling/Analyzing/ Recording	ECG signals are being sampled / analyzed / recorded.
Transmitting	ECG data is being transmitted from the electrocardiograph to the PC through the net or serial cable in the auto or rhythm mode.
Transmitting fails!	Transmitting ECG data fails.
MemoryFull	There is no space for saving more records.
U Disk / USB Printer / USB Scanner / Reader / keyboard	A U disk, a USB printer or a bar code reader / security reader / ID card reader is connected to the USB interface.

Chapter 11 Troubleshooting

1) Operating Problems

Q1: I want to save the ECG data without any printing, could it be possible?

A1: Yes, set the current mode to OFF-AUTO or OFF-RHYT. In the same way, if the transmission settings have been configured, the ECG data could be transmitted to the PC without printing.

2) Printing Problems

Q1: There was double impression in printing when I printed ECG reports by using an ink-jet printer. What's wrong with it?

A1: It may be the result of the coexisting black and color ink cartridges. Taking out the color ink cartridge may solve the problem.

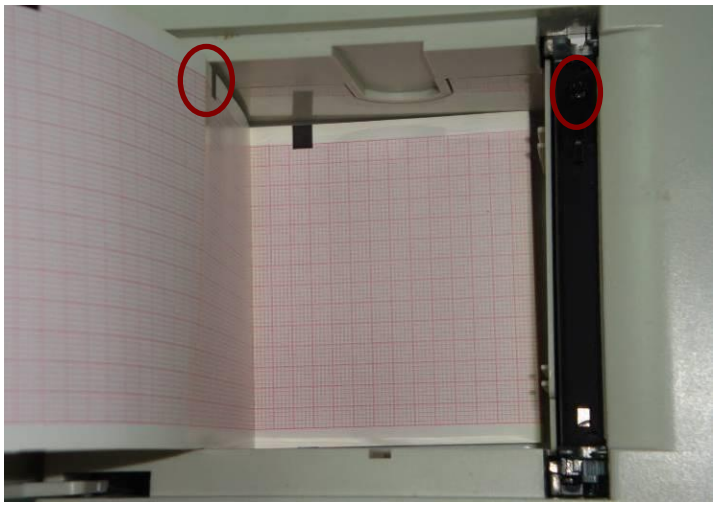
Q2: I was encountered with paper-jam, what was I supposed to do?
A2: If it happened for the first time, it might be the result of an inappropriate placement of the paper. In this case, please open the paper casing, pull the paper out of the paper tray, tear the pages with rumples, and then put the paper in the paper tray again, adjust the position of the paper carefully and close the casing.

If the above-mentioned situation is not applicable, there might be some problem with the printing module. Please contact the manufacturer or the local distributor for further disposal.

Q3: The hint PaperErr is displayed on the screen, what should I do?
A3: Check if the paper maker setting is right or might be the result of unsuccessful detection of the black markers, first open the paper casing so as to clear the error information, and then check whether the black marker is on the top of the paper. Reload the paper in the paper tray. If it doesn't work, change the paper.

If the problem still exists, please contact the manufacturer or the local distributor for further disposal.

Q4: The hint Paper? is displayed on the screen, what should I do?
A4: Check whether the paper runs out, or the black marker is just facing the black maker detection window on the thermal printing head, as the following figure shows.



Reload the paper in the paper tray, close the paper casing firmly. If the problem still exists, please contact the manufacturer or the local distributor for further disposal.

Q5: I pressed the **PRINT/STOP** key, but the ECG didn't start printing, what's wrong with it?
A5: Please check whether there is any error information displayed on the screen.

If the hint *Paper?* or *PaperErr* is shown on the screen, please deal with it according to the above-mentioned measures.

If the hint *Transfer* is shown on the screen, which means that the ECG is transmitting the data to the PC, please wait a few seconds. You can start the printing after the data has been transmitted.

If the problem still exists, please contact the manufacturer or the local distributor for further disposal.

3) Transmitting Problems

Q1: The ECG doesn't respond to any keys after a long time of transmitting. It transmits nothing for there is no new data appearing on the interface of the PC software. What should I do?

A1: Some error may occur during the transmission course, for example, the connection between the ECG and the net cable may loosen. In this case, please restart the ECG. If it doesn't work, please restart the PC.

If the problem still exists, please contact the manufacturer or the local distributor for further disposal.

4) Main Unit Problems

Q1: I was doing the examination when the machine suddenly gave out a sound and displayed the hint *Lead Off*. What should I do?

A1: The leads are not connected well. Please check whether the electrodes are connected to the patient skin well, and then make sure that the patient cable socket is connected to the patient cable firmly.

If none of the above-mentioned measures take effect, please contact the manufacturer or the local distributor for further disposal.

Chapter 12 Cleaning, Care and Maintenance

Use only the EDAN-approved substances and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by using unapproved substances or methods.

Edan Instruments has validated the cleaning and disinfection instructions provided in this User Manual. It is the responsibility of the healthcare professional to ensure that the instructions are followed so as to ensure adequate cleaning and disinfection.

12.1 General Points

Keep your electrocardiograph and accessories free of dust and dirt. To prevent the device from damage, please follow the instructions:

- Use only the recommended cleaning agents and disinfectants listed in this manual. Others may cause damage (not covered by warranty), reduce product lifetime or cause safety hazards.
- Always dilute according to the manufacturer's instructions.
- Unless otherwise specified, do not immerse any part of the equipment or any accessories in liquid.
- Do not pour liquid onto the equipment.
- Do not allow liquid to enter the case.
- Never use abrasive material (such as steel wool or silver polish).
- Inspect the electrocardiograph and reusable accessories after they are cleaned and disinfected.

CAUTION

If you spill liquid on the equipment or accessories, or they are accidentally immersed in liquid, contact your service personnel or EDAN service engineer.

12.2 Cleaning

If the equipment or accessory has been in contact with the patient, then cleaning and disinfection is required after each use.

The validated cleaning agents for cleaning the electrocardiograph and reusable accessories are:

- Mild near neutral detergent
- Ethanol (75%)
- Isopropanol (70%)

Cleaning agents should be applied or removed using a clean, soft, non-abrasive cloth or paper towel.

WARNING

Turn off the power before cleaning. The mains supply must be switched off if it is used.

1. Switch off the main unit and disconnect it from the power cord.
2. Wipe the exterior surface of the electrocardiograph, patient cable, and reusable electrodes (suction bulbs of chest electrodes and the clamps of limb electrodes) using a soft cloth dampened with the cleaning solution until no visible contaminants remain.
3. Wipe off the cleaning solution with a fresh cloth or towel dampened with tap water after cleaning until no visible cleaning agent remains.
4. Dry the electrocardiograph, patient cable, and reusable electrodes in a ventilated and cool place.

CAUTION

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

12.3 Disinfection

To avoid permanent damage to the equipment, it is recommended that disinfection is performed only when it is considered as necessary according to your hospital's regulations.

Clean the equipment and reusable accessories before they are disinfected. The validated disinfectants for disinfecting the electrocardiograph and reusable accessories are:

- Ethanol (75%)
- Isopropanol (70%)

If Ethanol or Isopropanol is used for both cleaning and disinfecting, then a new cloth is required to be used for the disinfection step.

CAUTION

1. Do not use high-temperature, high-pressure vapour or ionizing radiation as disinfection methods.

CAUTION

2. Do not use chloric disinfectant such as chloride, sodium hypochlorite etc.
3. Clean and disinfect reusable electrodes after each use.

WARNING

Turn off the power before disinfection. The mains supply must be switched off if it is used.

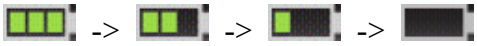
1. Switch off the main unit and disconnect it from the power cord.
2. Wipe the exterior surface of the electrocardiograph, patient cable, and reusable electrodes (suction bulbs of chest electrodes and the clamps of limb electrodes) using a soft cloth dampened with the disinfectant solution.
3. Wipe off the disinfectant solution with a dry cloth after disinfection if necessary.
4. Dry the electrocardiograph, patient cable, and reusable electrodes for at least 30 minutes in a ventilated and cool place.

12.4 Care and Maintenance

12.4.1 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.

 -> -> ->

Capacity is from full to empty.

2) Recharge

SE-3/SE-300 series is equipped with the recharge control circuit together with the built-in rechargeable lithium battery. When the unit is connected to the mains supply, the battery will be recharged automatically. Then the battery recharging indicator lamp (⇥▭) and the mains supply indicator lamp (∿) will be lit at the same time. During the recharging course, the symbol  flashes in the top right corner of the LCD screen. When the battery capacity is full, the symbol  stops flashing, and the battery recharging indicator lamp (⇥▭) is black. When the 3-channel electrocardiograph is switched off, the battery recharging indicator lamp (⇥▭) is black if the battery is fully recharged.

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: If the battery has not been used for more than two months, it should be recharged before use.

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.

12.4.2 Recorder Paper

NOTE: Recorder paper provided by the manufacturer should be used. Other paper may shorten the life of the thermal print head. And the deteriorated print head may lead to illegible ECG reports and block the advance of 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 recorded paper for a long time, or else the ECG reports may trans-print each other.

12.4.3 Maintenance of the Main Unit, the Patient Cable and Electrodes

The following safety checks should be performed at least every 24 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

a) Inspect the equipment and accessories for mechanical and functional damage.

b) Inspect the safety related labels for legibility.

c) Inspect the fuse to verify compliance with rated current and breaking characteristics.

d) Verify the device functions properly as described in the instructions for use.

e) Test the protection earth resistance according to IEC/EN 60601-1: Limit: 0.1ohm.

f) Test the earth leakage current according to IEC/EN 60601-1: Limit: NC 500 μA, SFC 1000μA.

g) Test the enclosure leakage current according to IEC/EN 60601-1: Limit: NC 100μA, SFC 500μA.

h) Test the patient leakage current according to IEC/EN 60601-1: Limit: NC a.c. 10μA, d.c. 10μA; SFC a.c. 50μA, d.c. 50μA.

i) Test the patient auxiliary current according to IEC/EN 60601-1: Limit: NC a.c. 10μA, d.c. 10μA; SFC a.c. 50μA, d.c. 50μA.

j) Test the patient leakage current under single fault condition with mains voltage on the applied part according to IEC/EN 60601-1: Limit: 50μA (CF).

k) Test the essential performance according to IEC/EN 60601-2-25, or methods recommended by the hospital or local distributor.

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 or 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 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) 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 13 Accessories

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.

13.1 Standard Accessories

Table 13-1 Standard Accessories List

Accessory	Part Number
Power cord (European)	01.13.036638
Power cord(American)	01.13.037122
Patient Cable (European)	01.57.107402
	01.57.471500
	01.57.471613
	01.57.471876
Patient Cable (American)	01.57.110375
	01.57.471499
	01.57.471614
	01.57.471877
Adult Chest electrodes	01.57.040163
Adult Limb electrodes	01.57.040162
Thermal Recorder Paper (Roll, 80mm×20m)	01.57.78076
Paper roller	01.51.19993
Fuse	21.21.064183
Rechargeable Li-ion Battery	21.21.064149

13.2 Optional Accessories

Table 13-2 Optional Accessories List

Accessory	Part Number
Patient Cable (European)	01.57.107581 (Snap Style)
	01.57.107583 (Grabber Style)
Patient Cable (American)	01.57.107582 (Snap Style)
	01.57.107584 (Grabber Style)
Pediatric Chest Electrodes	01.57.040168
Pediatric Limb Electrodes	01.57.040169
Snap/Banana Socket Adapters	01.13.107449
Clip/Snap/Banana Socket Adapter	01.57.040172
Alligator Clip/Banana Socket Adapters	01.57.040173
Adult Disposable Adhesive Electrodes	01.57.471056
Pediatric Disposable Adhesive Electrodes	01.57.471057
Disposable Resting electrodes	01.57.471031
Thermal Recorder Paper (Folded, 80mm ×70mm ×200P)	01.57.78079
Grounding Wire	01.13.112114
U Disk	01.18.052275
ECG Bag	01.56.465628
MT-201 Trolley	83.61.360759
CA-100 Lead wire bracket	02.04.111902

SE-3/SE-300 series and accessories are available by contacting the manufacturer or your local distributor.

NOTE:

1. The adult chest electrodes, adult limb electrodes, pediatric chest electrodes and pediatric limb electrodes are not available in the U.S.
2. The part name may vary depending on context, but the part number is constant.

Chapter 14 Warranty and Service

14.1 Warranty

EDAN warrants that EDAN's products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within warranty period.

The warranty is void in cases of:

a) damage caused by mishandling during shipping.

b) subsequent damage caused by improper use or maintenance.

c) damage caused by alteration or repair by anyone not authorized by EDAN.

d) damage caused by accidents.

e) replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, EDAN will, at its discretion, repair or replace the defective part(s) free of charge. EDAN will not provide a substitute product for use when the defective product is being repaired.

14.2 Contact information

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor.

Alternatively, you can send an email to EDAN service department at: support@edan.com.cn.

Appendix 1 Technical Specifications

A1.1 Safety Specifications

Comply with:		IEC 60601-1:2005/A1:2012 EN 60601-1:2006/A1:2013 IEC 60601-1-2:2007 EN 60601-1-2:2007/AC:2010 IEC/EN 60601-2-25
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
Patient Leakage Current:	NC	<10μA (AC) / <10μA (DC)
	SFC	<50μA (AC) / <50μA (DC)
Patient Auxiliary Current:	NC	<10μA (AC) / <10μA (DC)
	SFC	<50μA (AC) / <50μA (DC)

A1.2 Environment Specifications

	Transport & Storage	Working
Temperature:	-20℃ (-4℉) ~ +55℃ (+131℉)	+5℃ (+41℉) ~ +40℃ (+104℉)
Relative Humidity:	25%RH~93%RH Non-Condensing	25%RH~80%RH Non-Condensing
Atmospheric Pressure:	70 kPa ~106 kPa	86 kPa ~106 kPa

A1.3 Physical Specifications

Dimensions	SE-3: 290mm×220mm×85mm, ±2mm SE-300 series: 300mm ×260mm×85mm, ±2mm
Weight	Approx. 2.0 kg (4.4 lbs) (Excluding recorder paper and battery)
Display	3.5", 320×240 LCD Screen (black and white screen is for configuration A, color screen is for configuration B)

A1.4 Power Supply Specifications

Mains Supply:	Operating voltage =100V-115V~ / 220V-240V~
	Operating frequency = 50Hz / 60Hz
	input power = 35VA
Built-in Lithium Battery Pack:	Rated voltage = 14.8V
	Rated capacity = 2500mAh
	When the battery is fully charged, the 3-channel electrocardiograph can work normally about 6.5 hours. It can continuously record about 3 hours in Manual mode, and record 330 reports at most in the AUTO mode.
	Necessary Charge time: 5 hours
	Cycle life ≥ 300 times
Fuse:	T400mAH250V, Ø5×20mm

A1.5 Performance Specifications

Recording	
Recorder:	Thermal dot-matrix recorder
Printing Density	8 dots per mm / 200 dots per inch (amplitude axes) 40 dots per mm / 1000 dots per inch (time axes, @ 25 mm/s)
Recorder Paper:	Folded thermal paper, 80mm×70mm×200pages Rolled thermal paper, 80mm×20m
Effective Width:	72mm
Paper Speed:	5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s, 50mm/s (±3%)
Accuracy of data:	±5% (x-axis), ±5%(y-axis)
HR Recognition	
Technique:	Peak-Peak Detection
HR Range:	30 bpm ~ 300 bpm
Accuracy:	±1 bpm
ECG Unit	
Leads:	Standard 12 leads
Acquisition Mode:	simultaneously 12 leads
A/D:	12bits/24bits(optional, with DE12 ECG board)
Resolution:	2.52uV/LSB
Time Constant:	≥3.2s
Frequency Response:	0.05Hz ~ 150Hz (-3dB)
Sensitivity:	2.5mm/mV, 5mm/mV, 10mm/mV, 20mm/mV, 10/5mm/mV, AGC
Input Impedance:	≥50MΩ(10Hz)
Input Circuit Current:	≤0.05μA / ≤0.01μA (optional, with DE12 ECG board)
Input Voltage Range	≤±5 mVpp
Calibration Voltage:	1mV±3%

DC Offset Voltage:	±500mV / ±600mV(optional, with DE12 ECG board)
Minimum Amplitude:	20 μVp-p
Noise:	≤12.5μVp-p
Multi-channel Crosstalk	≤0.5mm
Filter	AC Filter: On / Off
	DFT Filter: 0.05Hz / 0.15Hz / 0.25Hz / 0.32Hz / 0.5Hz / 0.67Hz
	EMG Filter: 25Hz / 35Hz / 45Hz / OFF
	LOWPASS Filter:150Hz / 100Hz / 75Hz
CMRR	≥110dB / ≥115dB (optional, with DE12 ECG board)
Sampling Frequency	1000Hz
Pacemaker Detection (Optional, with DE12 ECG board)	
Amplitude	±2mV ~ ±700mV
Width	0.1ms ~ 2.0ms
Sampling Frequency	10,000/sec/channel
External Input/Output	
Input	≥100kΩ; Sensitivity 10mm/V±5%; Single ended
Output	≤100Ω; Sensitivity 1V/mV±5%; Single ended

NOTE:

1 Operation of the equipment below the minimum amplitude may cause inaccurate results.

2 The DE12 ECG board is not available in the U.S.

Appendix 2 EMC Information

Guidance and manufacture's declaration - electromagnetic emissions- for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission		
The Electrocardiograph is intended for use in the electromagnetic environment specified below. The user of the Electrocardiograph should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Electrocardiograph uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class A	The Electrocardiograph is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacture's declaration - electromagnetic immunity - for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The Electrocardiograph is intended for use in the electromagnetic environment specified below. The user of Electrocardiograph should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	It is recommended the use of antistatic materials. If floor are covered with synthetic material, the relative humidity should be at least 50%.
Electrical fast transient/burst	±2 kV for power supply lines	±2 kV for power supply lines	It is recommended the use of filters on power input

IEC 61000-4-4			lines and enough separation between signal lines and power lines.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to ground	±1 kV line to line ±2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration - electromagnetic immunity - for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

<table>
<tr><th colspan="4">Guidance and manufacture's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The Electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of Electrocardiograph should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted RF
IEC/
61000-4-6</td><td>3 V_{rms}
150 kHz to 80 MHz</td><td>3 V_{rms}</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the electrocardiograph, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = 1.2\sqrt{P}$

$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Radiated RF
IEC
61000-4-3</td><td>3 V/m
80 MHz to 2.5 GHz</td><td>3 V/m</td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic</td></tr>
</table>

environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Electrocardiograph is used exceeds the applicable RF compliance level above, the Electrocardiograph should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Electrocardiograph.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM - for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and electrocardiograph

The electrocardiograph is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the electrocardiograph can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the electrocardiograph as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	**0.12**	**0.12**	**0.23**
0.1	**0.38**	**0.38**	**0.73**
1	**1.2**	**1.2**	**2.3**
10	**3.8**	**3.8**	**7.3**
100	**12**	**12**	**23**

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix 3 Abbreviation

Abbr	English
BP	Blood Pressure
ECG	Electrocardiogram/Electrocardiograph
HR	Heart Rate
aVF	Left Foot Augmented Lead
aVL	Left Arm Augmented Lead
aVR	Right Arm Augmented Lead
LA	Left Arm
LL	Left Leg
RA	Right Arm
RL	Right Leg
ID	Identification
AC	Alternating Current
USB	Universal Serial Bus
AGC	Auto Gain Control
Wireless AP	Wireless Access Point
NC	Normal Condition
SFC	Single Fault Condition

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