SE-601 Series
Electrocardiograph
Version 2.3

User Manual

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.

Product Information

Product Name: Electrocardiograph

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

Responsibility of the Manufacturer

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

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by EDAN, and

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

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

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 SE-601 series electrocardiograph.

1.1 Intended Use/Indications for Use

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

SE-601 series is mainly used in ECG outpatient department, PE department, emergency department and inpatient department of hospitals or healthcare facilities.

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 operation, please read through the user manual and be sure to be familiar with all functions of the equipment and proper operation procedures before use.

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

1.2.1 Safety Warnings

WARNING

1. The electrocardiograph is intended to be used by qualified physicians or personnel professionally trained. They should be familiar with the contents of this user manual before operation.

2. Only qualified service engineers can install this equipment, and only service engineers authorized by the manufacturer can open the shell. Otherwise, safety hazards may happen.

3. **EXPLOSION HAZARD** - Do not use the electrocardiograph in the presence of flammable anesthetic mixtures with oxygen or other flammable agents.

4. **SHOCK HAZARD** - The power receptacle must be a hospital grade grounded outlet. Never try to adapt the three-prong plug to fit a two-slot outlet.

5. Make sure that the power is turned off and the power cord is disconnected from the AC socket before connecting or disconnecting equipment. Otherwise, electrical shock or other injuries may happen to the patient or operator.

6. If the integrity of the external protective conductor is in doubt, the equipment should be powered by an internal li-ion rechargeable battery.

7. Do not use this equipment in the presence of high static electricity or high voltage equipment which may generate sparks.

8. Only the patient cable and other accessories supplied by the manufacturer can be used. Or else, the performance and electric shock protection can not be guaranteed. The electrocardiograph has been safety tested with the recommended accessories, peripherals, and leads, and no hazard is found when the electrocardiograph is operated with cardiac pacemakers or other stimulators.

9. The use of patient cable and other accessories not supplied by the manufacturer may result in increased emissions or decreased immunity of the equipment.

10. Make sure that all electrodes are connected to the patient correctly before operation.

11. Ensure that the conductive parts of electrodes and associated connectors, including neutral electrodes, do not come in contact with earth or any other conducting objects.

WARNING

12. Disposable electrodes must be used during defibrillation.

13. Electrodes of dissimilar metals should not be used; otherwise it may cause a high polarization voltage.

14. The disposable electrodes can only be used for one time.

15. Do not touch the patient, bed, table or the equipment while using the ECG together with a defibrillator.

16. Do not touch accessible parts of electrical equipment and the patient simultaneously.

17. The use of equipment that applies high frequency voltages to the patient (including electrosurgical equipment and some respiration transducers) is not supported and may produce undesired results. Disconnect the patient data cable from the electrocardiograph, or detach the leads from the patient prior to performing any procedure that uses high frequency surgical equipment.

18. If WIFI technology is used, in order to maintain compliance with the FCC RF exposure guidelines, WIFI should be installed and operated with a minimum distance of 20cm between the radiator and the human body. There should be no shield in or around the room where WIFI is used.

19. Fix attention on the examination to avoid missing important ECG waves.

20. **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.

21. **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.

22. 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.

WARNING

23. Any non-medical equipment (such as the external printer) is not allowed to be used within the patient vicinity (1.5m/6ft.).

24. Do not exceed the maximum permitted load when using the multiple portable socket-outlet(s) to supply the system.

25. Multiple portable socket-outlets shall not be placed on the floor.

26. 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.

27. 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 configuration shall comply with the valid version of the standard IEC/EN 60601-1. Therefore anybody, who connects additional equipment to the signal input or output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC/EN 60601-1. If in doubt, consult our technical service department or your local distributor.

28. 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.

29. 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.

30. If multiple instruments are connected to a patient, the sum of the leakage currents may exceed the limits given in the IEC/EN 60601-1 and may pose a safety hazard. Consult your service personnel.

WARNING

31. The potential equalization bar can be connected to that of other equipment when necessary. Make sure that all the equipment is connected to the potential equalization terminal.

32. The electrocardiograph shall not be serviced or maintained while in use with a patient.

33. 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.

34. The medical electrical equipment needs to be installed and put into service according to Appendix 2 EMC Information.

35. 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.

36. Portable and mobile RF communications equipment can affect medical electrical equipment, refer to the recommended separation distances provided in Appendix 2 EMC Information.

37. Assembly of the electrocardiograph and modifications during actual service life shall be evaluated based on the requirements of IEC60601-1.

1.2.2 Li-ion Battery Care Warnings

WARNING

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

2. Only qualified service engineers authorized by the manufacturer can open the battery compartment and replace the battery, and batteries of the same model and specification as manufacturer configuration should be used.

3. **DANGER OF EXPLOSION** -- Do not reverse the anode and the cathode when installing the battery.

4. Do not heat or splash the battery or throw it into fire or water.

WARNING

5. Do not destroy the battery; Do not pierce battery with a sharp object such as a needle; Do not hit with a hammer, step on or throw or drop to cause strong shock; Do not disassemble or modify the battery.

6. When leakage or foul smell is found, stop using the battery immediately. If your skin or cloth comes into contact with the leakage liquid, cleanse it with clean water at once. If the leakage liquid splashes into your eyes, do not wipe them. Irrigate them with clean water first and go to see a doctor immediately.

7. Properly dispose of or recycle the depleted battery according to local regulations.

8. Only when the device is off can the battery be installed or removed.

9. Remove the battery from the electrocardiograph when the electrocardiograph isn't used for a long time.

10. If the battery is stored alone and not used for a long time, we recommend that the battery be charged at least once every 6 months to prevent overdischarge.

1.2.3 General Cautions

CAUTION
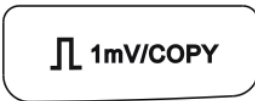
1. Avoid liquid splash and excessive temperature. The temperature must be kept between 5 ⁰C and 40 ⁰C during operation, and it should be kept between -20 ⁰C and 55 ⁰C during transportation and storage.

2. Do not use the equipment in a dusty environment with bad ventilation or in the presence of corrosive.

3. Make sure that there is no intense electromagnetic interference source around the equipment, such as radio transmitters or mobile phones etc. Attention: large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment etc. is likely to bring electromagnetic interference.

4. Ruptured fuse must only be replaced with that of the same type and rating as the original.
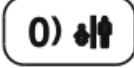
	CAUTION

5. The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal. Batteries are hazardous waste. Do NOT dispose of them together with house-hold garbage. At the end of their lives hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or battery, please contact your local Civic Office, or the shop where you purchased the product.

6. Federal (U.S.) law restricts this device to sale by or on the order of a physician.

1.3 List of Symbols

No.	Symbol	Description
1		External input/output
2		DEFIBRILLATION-PROOF TYPE CF APPLIED PART
3		Caution
4		Operating instructions
5		Equipotential grounding
6	PATIENT	Patient Cable Socket
7		USB socket

8		Net port
9		Alternating Current
10		Battery check
11		Battery recharging indicator
12	←Bksp	Delete key
13	Enter	Enter key
14	Esc	Esc key
15	Space ♂	Space key/Feed paper key
16	⇧Shift	Shift key
17	Fn	Fn key
18	☼/⊙	Power On/Off key
19	⊓ 1mV/COPY	1mV/COPY key
20	@ MODE	MODE key
21	→0← RESET	RESET key

22	🄴 PRINT/STOP	PRINT/STOP key
23	Tab	Tab paper key
24	9(♀♂	Gender key
25	0) ♂♀	Age Group key
26	♻	General symbol for recovery/recyclable
27	P/N	Part Number
28	SN	SERIAL NUMBER
29	⚒	Date of manufacture
30	🏭	MANUFACTURER
31	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
32	CE 0123	CE marking
33	Rx Only	Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.
34	🗑	Disposal method
35	📖	Refer to User Manual (Background: Blue; Symbol: White)

36		Warning (Background: Yellow; Symbol&Outline: Black)
37*		Non- ionizing electromagnetic radiation
38*	Contains FCC ID: YOPGS2011MIZ	Federal Communications Commission: Contains FCC ID: YOPGS2011MIZ
39		Conforms to AAMI Std. 60601-1, IEC Std. 60601-2-25 Certified to CSA Std. C22.2 No 60601-1,CSA Std. C22.2 No 60601-2-25

NOTE:

1. 37*/38*: Apply to devices with wireless functions.

2. The user manual is printed in black and white.

Chapter 2 Introduction

SE-601 series electrocardiograph has three models: SE-601A, SE-601B and SE-601C.

SE-601A adopts 3.5" single color LCD screen; SE-601B adopts 5.6"/5.7" multicolor TFT LCD screen; SE-601C adopts 5.6"/5.7" multicolor TFT LCD touch screen.

Configuration: main unit, power cord, patient cable, chest electrodes, limb electrodes, disposable electrodes, clip/snap/banana socket adaptors, thermal recorder paper, fuses and battery.

NOTE: The pictures and windows in this manual are for reference only.

2.1 Top Panel

Figure 2-2 Top panel (SE-601B/C)

2.2 Keyboard and Keys
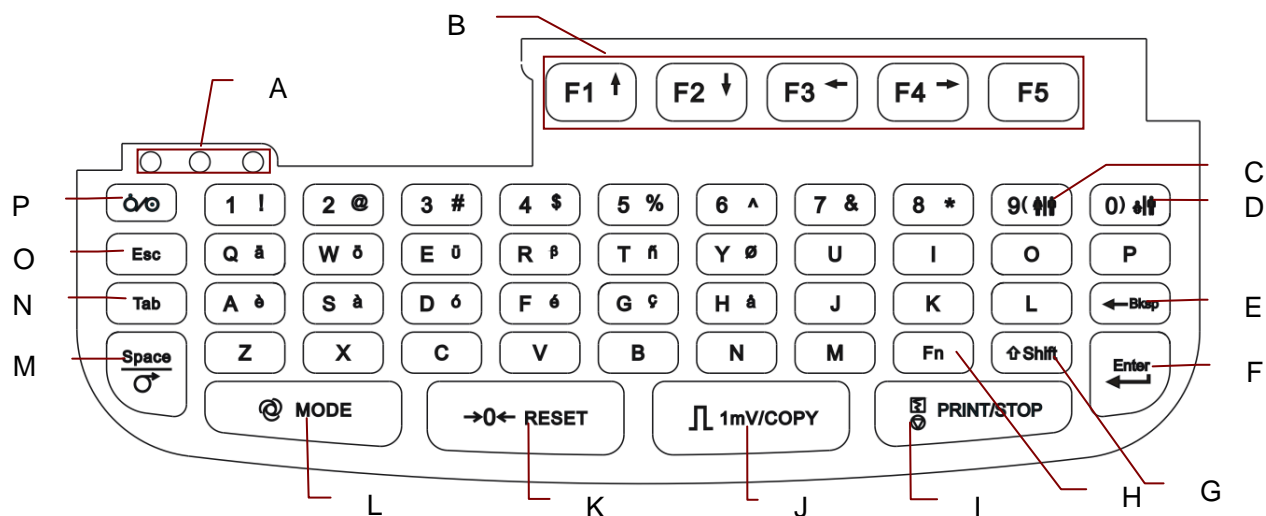
Figure 2-3 Keyboard

	Name	Explanation
A	Indicator	It indicates the working state.
B	Function Key	Press to select menu functions on the screen. Press **F1**, **F2**, **F3**, **F4** to move the cursor. Press **Shift + F1**/**F2** to turn pages on the **Order Manager** screen and the **File Manager** screen. Press **Shift + F3**/**F4** to slide the scroll bar on the **Order Manager** screen.
C	Gender Key	Press to quickly select the gender for the patient when **Gender** is selected in the **Patient Information Setup** window.
D	Age Group Key	Press to quickly select the age group on the main screen when you set **Age** to **Age Group** in the **Patient Information Setup** window.
E	Backspace Key	Press to delete characters.
F	Enter	Press to confirm operation.
G	Shift	Press **Shift + Tab** to move the cursor backward. Press **Shift** and a number key to input the special character in the top right corner of the key. If **Caps Lock** is set to **Off**, pressing **Shift + P** can type a capital **P**. If **Caps Lock** is set to **On**, pressing **Shift + P** can type a lowercase **p**.
H	Fn	Press **Fn** and a letter key to type special characters. Pressing **Fn + a** can type **è**.

I	PRINT/STOP	Press to start or stop printing reports Pressing **Shift + PRINT/STOP** can quickly enable or disable the print out function in the auto or rhythm mode.
J	1mV/COPY	In the manual mode, pressing the **1mV/COPY** key can insert a 1mV calibration mark during the printing course. In the auto or rhythm mode, pressing the **1mV/COPY** key can print the ECG report which was printed out last time.
K	RESET	A large polarization voltage may cause baseline drift. On the main screen, pressing **RESET** can decrease the polarization voltage and draw the baseline to zero quickly.
L	MODE	Press to select a working mode among the auto, manual, rhythm and R-R analysis modes. **NOTE:** Only if more than one working mode is selected in the **Work Mode Setup** window, can the working mode be selected by pressing the **MODE** key when the main screen is displayed.
M	Space/Feed paper	Press to add a space between typed characters or select/deselect a checkbox. Press to feed paper: If **Paper Marker** is set to **Yes**, pressing **Tab** can advance the recorder paper to the next black marker; if **Paper Marker** is set to **No,** pressing **Tab** can advance the paper for 2.5cm. Pressing **Tab** again can stop advancing the paper.
N	Tab	Press to move the cursor: Pressing **Tab** can move the cursor forward, and pressing **Shift + Tab** can move the cursor backward. In the manual mode or on the previewing screen, press this key to switch the lead groups.
O	Esc	Press to cancel operation
P	Power On/Off	Power-on/Power-off

2.3 Rear Panel
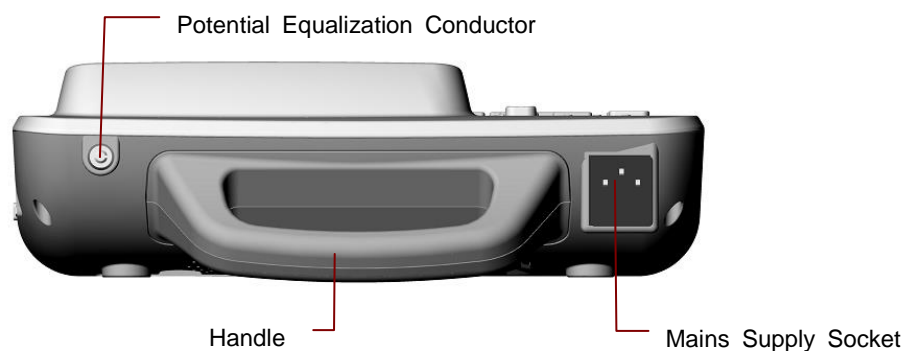
Figure 2-4 SE-601A/B/C Rear Panel

2.4 Right Panel
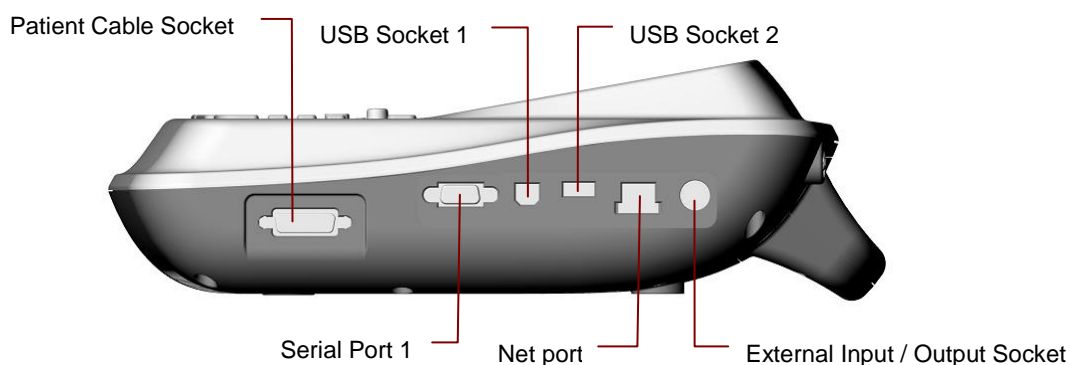
Figure 2-5 SE-601A/B/C Right Panel

	Name	Explanation
A	Patient Cable Socket	Connecting to the patient cable
B	Serial Port 1	Connecting to a PC
C	USB Socket 1	Standard USB socket, connecting to a PC
D	USB Socket 2	Standard USB socket, connecting to a U disk, a bar code reader or a USB printer recommended by the manufacturer
E	Net port	Standard net port, connecting to a PC

F	External Input / Output Socket	Connecting to the external signal device

WARNING

The isolated intensity of serial port 1 is 1500V AC and the maximum voltage applied should not exceed +15V DC.

CAUTION

Only the USB equipment recommended by the manufacturer can be connected to the USB interface.

2.5 Bottom Panel
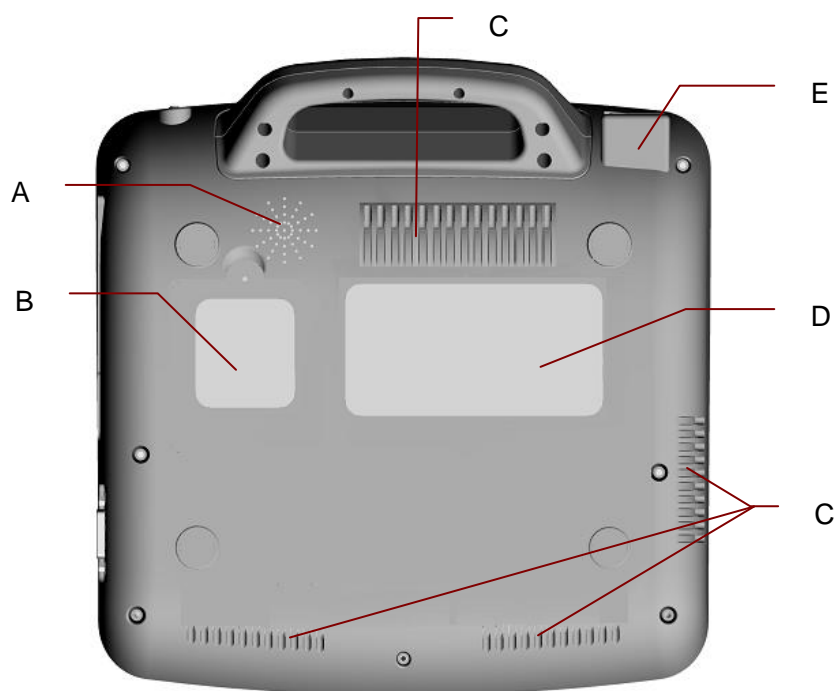
Figure 2-6 SE-601A/B/C Bottom Panel

	Name	Explanation
A	Speaker Hole	Path for sound from speaker (only configurable for SE-601B/C)
B	Battery Compartment	Compartment for battery
C	Heat Emission Hole	Path for internal heat emission

D	Label	Position for product information label
E	Fuse	The specification is: T3.15AH250V, φ5×20mm

WARNING

1. Improper operation may cause the battery to be hot, ignited or exploded, and it may lead to the decrease of the battery capacity. Therefore, it is necessary to read the user manual carefully and pay more attention to warning messages.

WARNING

2. 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.

3. Only qualified service engineers authorized by the manufacturer can open the battery compartment and replace the battery, and batteries of the same model and specification must be used.

4. Only when the device is off can the battery be installed or removed.

NOTE: If the battery has not been used for two months or more, you should recharge it before using it again.

2) Fuse

There are two fuses of the same specification 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

- ♦ Supporting AC and DC power supply modes, internal rechargeable li-ion battery with professional battery powered circuit, battery management and protection systems

- ♦ Supporting multi-language

- ♦ Full alphanumeric keyboard (SE-601C is also configured with touch screen.)

- ♦ ECG signals of 12 leads are gathered and amplified simultaneously, 12-channel waves are displayed and recorded simultaneously

- ♦ Correct detection for failure electrodes

- ♦ Convenient operation of recording by pressing the **PRINT/STOP** key with high efficiency

- ♦ High resolution thermal recorder, recording frequency response ≤150Hz

- ♦ Supporting external USB printer

- ♦ Supporting accurate digital filter to decrease the polarization voltage and other interferences

- ♦ Supporting rolled and folded paper recorded with high resolution waveforms, calibration mark, gain, speed and filter

- ♦ The auto, manual, rhythm and R-R analysis modes can be chosen freely

- ♦ Supporting order function (only configurable for SE-601B/C)

- ♦ Supporting bar code reader

- ♦ Supporting ECG waves displaying with grid

- ♦ Convenient operation of system setup and file management

- ♦ Multiple file formats: DAT, PDF and configurable formats (SCP/FDA-XML/DICOM)

- ♦ Supporting real-time sampling, pre-sampling, period sampling and arrhythmia triggering sampling

- ♦ Supporting high capacity data storage, transferring files by USB disk

- ♦ Measurement function and interpretation function

- ♦ LCD backlight and the device can be turned off automatically according to the set time

- ♦ ECG data can be transmitted to the Data Management Software through the serial cable, net cable or WIFI (configurable)

Chapter 3 Operation Preparations

WARNING
Before use, the equipment, 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, and make sure that the equipment is in proper working condition.

3.1 Connecting the Patient Cable to the Electrocardiograph and Electrodes

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

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

3.1.1 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.

3.1.2 Connecting the Patient Cable to Electrodes

Align all lead wires of the patient cable to avoid twisting, and connect the lead wires to the reusable electrodes or the clip/snap/banana socket adaptors. Firmly attach them.

The identifiers and color codes of electrode connectors used comply with IEC/EN requirements. In order to avoid incorrect connection, the identifiers and color codes are specified in Table 3-1. Moreover the equivalent codes according to American requirements are given in Table 3-1 too.

Table 3-1 Electrode Connectors and Their Identifiers and Color Codes

European		American	
Identifier	Color Code	Identifier	Color Code
R	Red	RA	White
L	Yellow	LA	Black
N or RF	Black	RL	Green
F	Green	LL	Red
C1	White/Red	V1	Brown/Red
C2	White/Yellow	V2	Brown/Yellow
C3	White/Green	V3	Brown/Green
C4	White/Brown	V4	Brown/Blue
C5	White/Black	V5	Brown/Orange
C6	White/Violet	V6	Brown/Violet

3.2 Preparing the Patient

3.2.1 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.

3.2.2 Cleaning the Skin

Thorough skin preparation is very important. The skin is a poor conductor of electricity and frequently creates artifacts that distort the ECG signals. By performing methodical skin preparation, you can greatly reduce the possibility of 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 Clean the Skin

Shave hair from electrode sites, if necessary. Excessive hair prevents a good connection.

Wash the area thoroughly with soap and water.

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.

3.3 Attaching Electrodes to the Patient

Two kinds of electrode can be used, one is the reusable electrode (including chest electrodes and limb electrodes), and the other is the disposable electrode.

WARNING

1. Make sure that all electrodes are connected to the patient correctly before operation.

2. Ensure that the conductive parts of electrodes and associated connectors, including neutral electrodes, do not come in contact with earth or any other conducting objects.

NOTE: The quality of ECG waveform will be affected by the contact resistance between the patient and the electrode. In order to get a high-quality ECG, the skin-electrode resistance must be minimized while connecting electrodes.

3.3.1 Electrode Placement

The electrodes' positions on the body surface are shown in the following table and figure.

Standard 12-Lead Placement
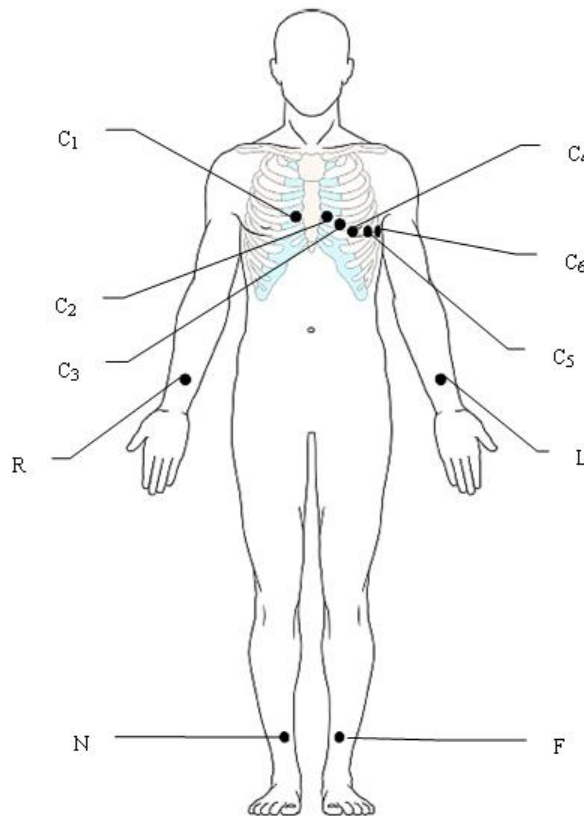
European Label	American Label	Electrode Placement
C1	V1	Fourth intercostal space at the right border of the sternum
C2	V2	Fourth intercostal space at the left border of the sternum
C3	V3	Fifth rib between C2 and C4
C4	V4	Fifth intercostal space on the left midclavicular line
C5	V5	Left anterior axillary line at the horizontal level of C4
C6	V6	Left midaxillary line at the horizontal level of C4
L	LA	Left arm
R	RA	Right arm
F	LL	Left leg
N	RL	Right leg

NEHB Placement (for SE-601B/C)
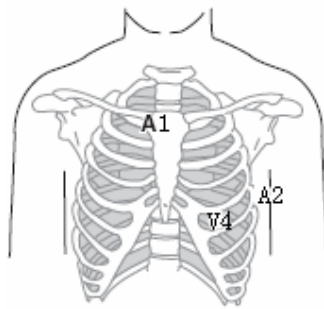
European Label	American Label	Electrode Placement
N_{st}	A1	Attachment point of the second rib to the right sternal edge
N_{ax}	A2	Fifth intercostal space on the left posterior axillary line
N_{ap}	V4	Left mid-clavicular line in the fifth intercostal space
R	RA	Right arm/Right deltoid
L	LA	Left arm/Left deltoid
N or RF	RL	Right leg/Upper leg as close to torso as possible
F	LL	Left leg/Upper leg as close to torso as possible

3.3.2 Attaching the Reusable Electrodes
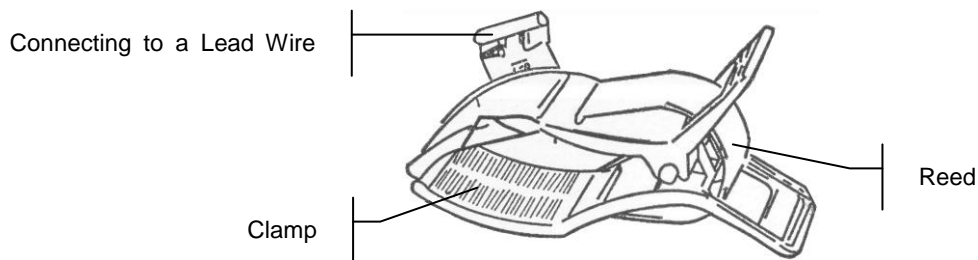
Limb Electrode
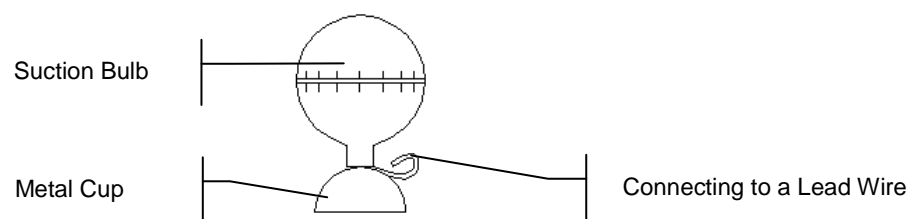
Chest Electrode

1) Ensure that the electrodes are clean;

2) Clean the electrode area which is a short distance above the ankle or the wrist with 75% alcohol;

3) Daub the electrode area on the limb with gel evenly;

4) Place a small amount of gel on the metal part of the limb electrode clamp or on the brim of the chest electrode's metal cup;

5) Attach the electrodes in place.

   When connecting the chest electrodes, place the electrode on the chest electrode site and squeeze the suction bulb. Unclench it and the electrode is adsorbed on the chest;

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

3.3.3 Attaching the Disposable Electrodes

CAUTION

The disposable electrodes can only be used for one time.

Disposable Electrode (clip style):   Clip/Snap/Banana Socket Adaptor

Disposable Electrode Connection (Clip Style)

1) Align all lead wires of the patient cable to avoid twisting, and connect the clip/snap/banana socket adaptors to the patient cable.

2) Clean the electrode areas on the body surface with 75% alcohol.

3) Attach the disposable electrodes to the electrode positions on the body surface.

4) Clip the disposable electrodes with the clip/snap/banana socket adaptors.

Snap/Banana Socket Adapters   Disposable Electrode (Snap Style)

Disposable Electrode Connection (Snap Style)

1) Align all lead wires of the patient cable to avoid twisting, and cnnect Snap/Banana Socket Adapters to connector of patient cable.

2) Clean the electrode areas on the body surface with 75% alcohol.

3) Attach the disposable electrodes to the electrode positions on the body surface.

4) Connect Snap/Banana Socket Adapters to the disposable electrodes.

3.4 Inspection Before Power-On

In order to avoid safety hazards and get good ECG records, the following inspection procedures are recommended before operation.

WARNING

The electrocardiograph is intended to be used by qualified physicians or personnel professionally trained, and they should be familiar with the contents of this user manual before operation.

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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. Turn off these devices when necessary.

   ♦ Keep the examination room warm to avoid muscle tremor 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-slot outlet should be used.

♦ When the battery capacity is low, recharge the battery before use.

3) **Patient Cable:**

♦ Make sure that the patient cable is connected to the unit firmly, and keep it far away from the power cord.

4) **Electrodes**:

♦ Make sure that all electrodes are connected to lead wires of the patient cable correctly.

♦ Ensure that the chest electrodes do not contact with each other.

5) **Patient**:

♦ The patient should not come into contact with conducting objects such as earth, metal parts etc.

♦ Ensure that the patient is warm and relaxed, and breathes calmly.

3.5 Turning On/Off the Electrocardiograph

WARNING

1. If the integrity of the external protective conductor is in doubt, the equipment should be powered by the battery.

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

The electrocardiograph can be powered by either the mains supply or the battery.

To turn on the Electrocardiograph:

♦ When operating on AC power

Make sure that the mains supply meets the requirements (refer to A1.4 Power Supply Specifications) before power-on, and then press 〔 ᐁ 〕 on the keyboard to turn on the unit. The mains supply indicator (∿) is lit, and the logo will be displayed on the LCD screen after self-test.

If the battery is weak when the mains supply is used, it will be recharged automatically at the same time. Both the mains supply indicator (∿) and the battery recharging indicator (⇥▭) will be lit.

♦ When operating on battery power

Press 〔 ᐁ 〕 on the keyboard to turn on the unit, and then the battery indicator (▭) will be lit and the battery symbol will be displayed. The logo will be displayed on the

LCD screen after self-test.

Because of the consumption during the storage and transport course, the battery capacity may not be full. If the symbol ▬ and the hint information *Battery Weak* are displayed, which means the battery capacity is low, please recharge the battery first.

CAUTION

1. If the electrocardiograph is turned off because of low battery capacity or unexpected power failure, the settings or the current ECG report may not be saved.

2. The electrocardiograph cannot print an ECG report when the battery is weak.

3. The use of electrocardiograph accessories (such as barcode reader) will deplete battery power at a faster rate. The battery will require more frequent charging if these accessories are used with the electrocardiograph.

To turn off the Electrocardiograph:

♦ When operating on AC power

Hold down the 🔘 key to display the hint *System is shutting down…* on the screen. Then the device will be off a few seconds later. Remove the plug from the outlet.

♦ When operating on battery power

Hold down the 🔘 key to display the hint *System is shutting down…* on the screen. Then the device will be off a few seconds later.

NOTE:

1. When turning off the device, follow the above sequence strictly, or else there may be something wrong on the screen.

2. Do not hold down the 🔘 key when the device displays the hint information *System is shutting down…* on the screen.

3.6 Loading/Replacing Recorder Paper

The recorder paper is the folded thermal paper.

NOTE:

1. The exit edge can help you tear the recorder paper.

2. If a sponge is placed in the paper tray, take it out before loading the recorder paper.

CAUTION

Make sure that the recorder paper, is installed in the center of the recorder, and the paper edge is parallel with the casing edge in the direction of advancing paper, in order to avoid paper deviation or damage to the paper edge.

When the recorder paper runs out or is not loaded, the hint message *No Paper* will appear on the screen. Then you should load or replace the recorder paper immediately.

Casing

Paper Tray
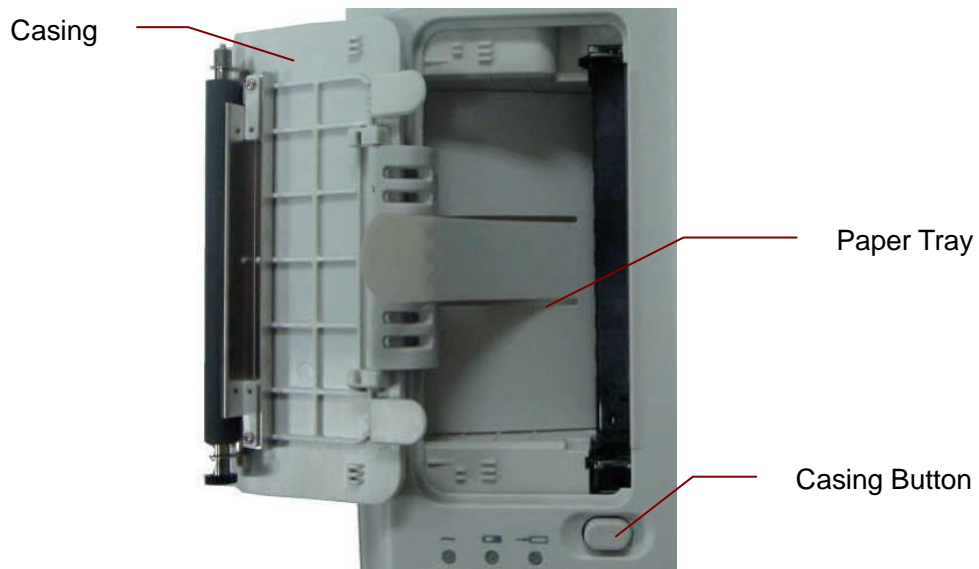
Casing Button

Loading/Replacing Process of Folded Paper:

Step 1)   Step 3)   Step 4)
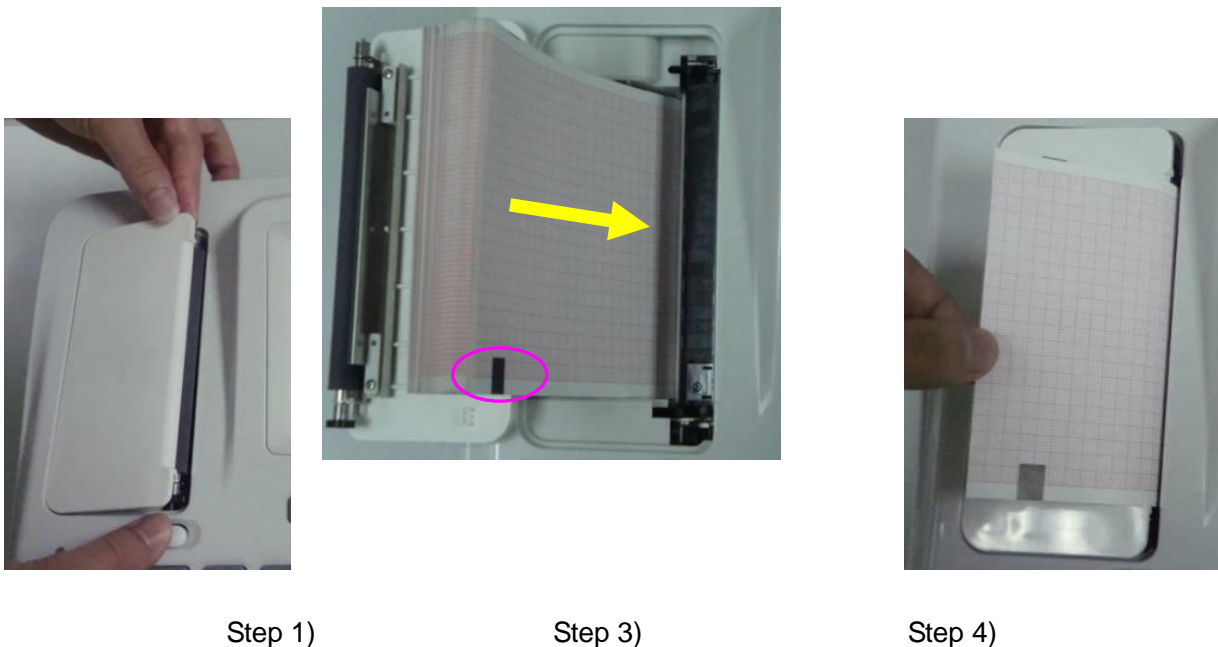
1) Press the casing button downwards with one hand and pull the casing upwards with the other hand to open the recorder.
2) Remove the remainder paper from the paper tray if necessary.
3) Take off the wrapper of the new folded paper, and then put it in the paper tray.

NOTE: If the paper with black markers is used, make sure that the markers are on the bottom.

4) Pull the paper out with the grid side facing the thermal print head, and replace the casing on the recorder.

5) Press down the recorder casing firmly.

6) Advance the recorder paper.

When the main screen is displayed, if **Paper Marker** is set to **Beginning** or **End**, you

can press to advance the recorder paper to the next black marker; if **Paper**

Marker is set to **No,** you can press to advance the paper for 2.5cm. Press

 again to stop advancing the paper.

Chapter 4 Basic Operation Guidance

The following sections provide an overview of the main operations and functions.

If the touch screen is configured, you can operate the electrocardiograph by touching the screen.

CAUTION
Do not touch the LCD screen with sharp things such as pencils or pens; otherwise, it will be damaged.

4.1 Basic Operation

Operation	Keys
To select options on the bottom panel of the screen	Corresponding functional keys
To move the cursor	**Tab**; **Shift + Tab**; **F3**; **F4**
To erase the typed information	**Bksp**
To input special characters	**Shift** + numeric key
To switch between upper case and lower case	**Shift** +letter key
To select or deselect an item	**Space**
Switch between options	**F1/F2 (**SE-601B/C) **F3/F4 (**SE-601A)
To confirm and entering a screen	**Enter**
To cancel operation; return to the upper level	**ESC**
Refresh all patient information except for the **Gender**, **Age Group**, **Exam.Room**, **Physician** and **Technician** information after you print an ECG report	**Shift + Bksp**

4.2 About the Main Screen

After the electrocardiograph is turned on, the main screen appears.
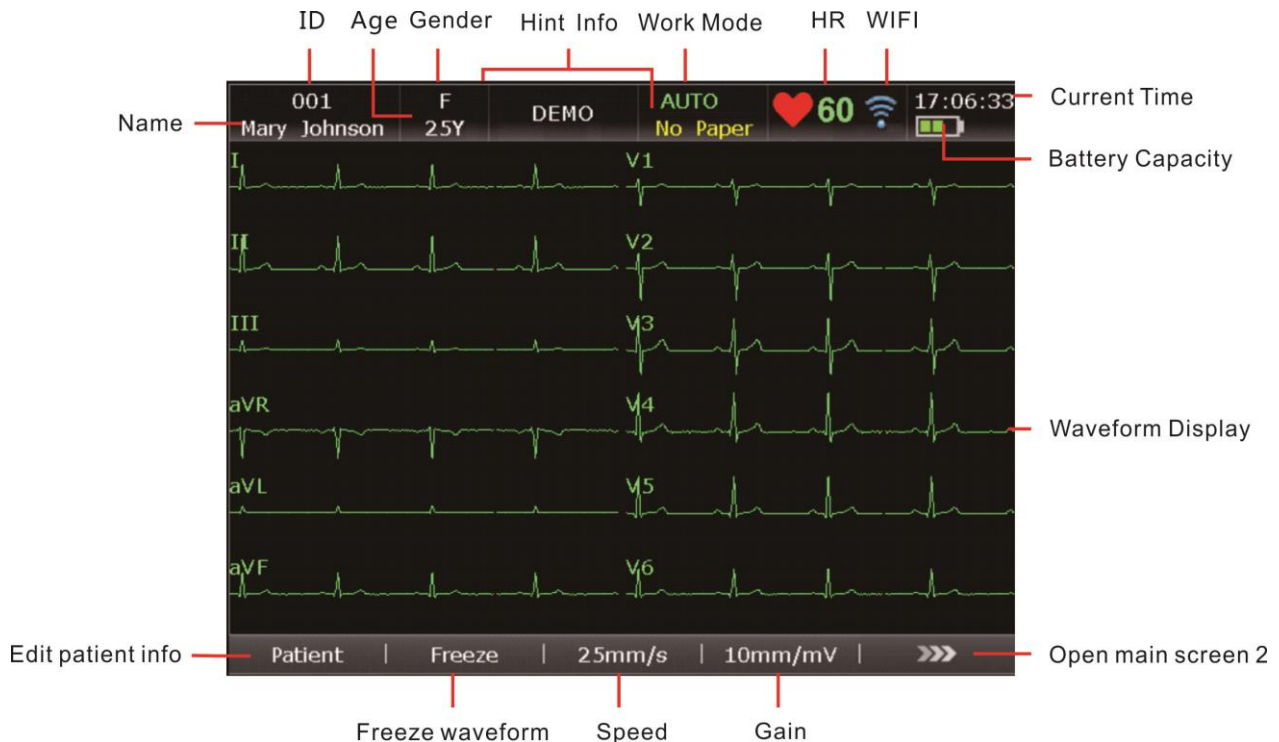
Figure 4-1 Main Screen1 (SE-601B/C)
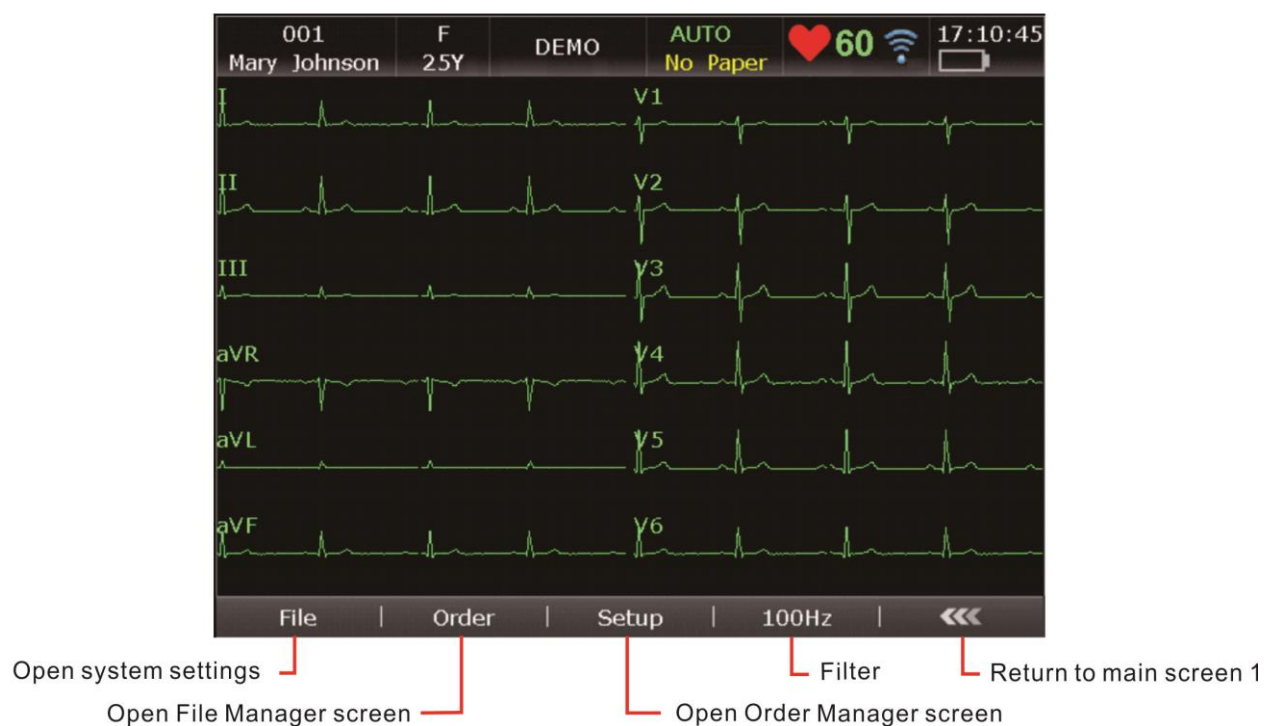
Figure 4-3 SE-601B/C Main Screen2

For the electrocardiograph configured with the touch screen, you can touch the displayed information to modify corresponding settings.

NOTE:

1. The modification of filter, gain, or speed on the main screen is only effective for the current patient.

2. When the leads are off, the lead names will be highlighted.

3. Work mode can be selected by pressing the **MODE** key when the main screen is displayed.

4.3 Work Mode Description

There are four work modes in SE-601 series electrocardiograph.

AUTO:	In the auto mode, the ECG data can be analyzed, saved, printed and transmitted. The lead groups are switched automatically according to the lead sequence during the printing course. After the ECG waves of one lead group are printed within a certain time, the system switches to print ECG waves of another lead group automatically. 1mV calibration marks will be printed at the beginning of an ECG report.
MANU:	In the manual mode, you can determine the lead group to be displayed and printed. Pressing **Tab** can switch among the lead groups.
RHYT:	In the rhythm mode, the ECG data can be saved and transmitted. You can print 60s rhythm-lead ECG waveform of one lead in the **Single Lead** style or 20s rhythm-lead ECG waveform of three leads in the **Three Leads** style.
R-R:	In the R-R analysis mode, you can select a lead to print its R-R histogram, R-R trend chart, 180s compressed ECG waveform and all the R-R interval values.

Chapter 5 Entering Patient Information

5.1 Entering Patient Information Manually

1. Configure the **Patient Information Setup** window. (Configurable)

2. Select **Patient** on the main screen1 to open the **Patient Information** window.

NOTE: The total number of supported characters may be fewer if special Latin characters are entered.

5.2 Entering Patient Information by Using a Reader (Configurable)

1. Configure the bar code

    For more detailed information about configuring the bar code, please contact the manufacturer or the local distributor.

2. Connect the bar code reader to USB socket 2 on the right panel of the electrocardiograph.

3. When the main screen is displayed, scan the patient's bar code with the bar code reader, and then the patient information will appear in the corresponding box.

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

5.3 Entering Patient Information by Acquiring Orders

NOTE: To use the order function, the ECG data management software (DMS) of the manufacturer must be installed in the PC.

Operation procedures are as follows:

1. Connect the electrocardiograph to the PC with Ethernet cable recommended by the manufacturer.

2. Log into the DMS.

3. Set **Server IP**, **Local IP**, **Gateway** and **Subnet Mask** in the **Transmission Setup** window.

4. Select **Order Acquired** function in **Setup-> Patient Info**.

5. Open the **Patient Information** window.

6. Enter the patient ID manually in the **ID** textbox or connect a bar code reader, press **Order**, and then the matched order will be loaded from the DMS and the order information will be displayed in the corresponding textboxes.

Chapter 6 Printing ECG Reports

```
┌─────────────────────────────┐
│      Select a work mode      │
└─────────────────────────────┘
              │
              ▼
┌─────────────────────────────┐        ┌─────────────────────────────┐
│ Configure printing and system│        │   Press PRINT/STOP to stop   │
│   parameters if necessary    │        │          sampling            │
└─────────────────────────────┘        └─────────────────────────────┘
              │                                        ▲
              ▼                    MANU               │
┌─────────────────────────────┐    mode    ┌─────────────────────────────┐
│  Press PRINT/STOP to start   │─ ─ ─ ─ ─ ─▶│   Manually switch lead group │
│          sampling            │            └─────────────────────────────┘
└─────────────────────────────┘
```
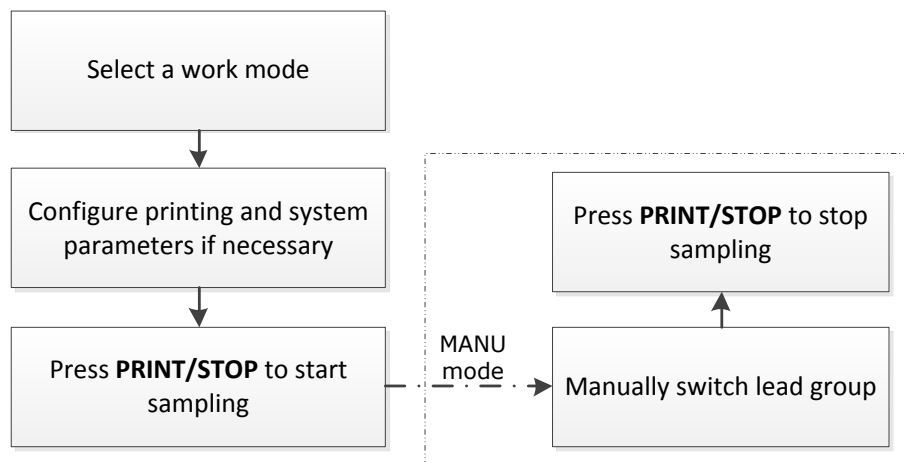
In the auto and rhythm modes, pressing the **1mV/COPY** key can print the ECG report which was printed out last time. Pressing the **PRINT/STOP** key can stop printing the ECG report.

NOTE:

1. The working mode can not be changed during the printing course. Stop printing reports before changing the working mode.

2. Within three seconds after returning to the main screen, if you press the **PRINT/STOP** key to print an ECG report in the auto quick mode or the manual mode, the recorder will not respond.

3. If **Print Out** is set to **Off** in the **Record Info Setup1** window, the ECG report can be saved and transmitted, but cannot be printed out by pressing the **PRINT/STOP** key in the auto and rhythm modes.

4. In the R-R analysis mode, you can not set the speed. The constant speed is 25mm/s and the printing speed is 5mm/s, because in the R-R analysis mode, the ECG wave length is compressed to one fifth of the original wave length.

5. Within 10 seconds after returning to the main screen, pressing **F2** can not display the freezing screen.

Chapter 7 Transmitting ECG Data

ECG data in DAT/PDF/SCP/FDA-XML/DICOM format can be transmitted to the PC. To transmit ECG data in DAT format, the DMS of the manufacturer must be installed in the PC. To transmit ECG data in PDF/SCP/FDA-XML/DICOM format, the FTP receiving software must be installed in the PC.

NOTE: SE-601A can only transmit ECG data in DAT format.

CAUTION

It is forbidden to connect or disconnect a U disk or a USB printer during the transmission course.

WARNING

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1) this device may not cause harmful interference, and

2) this device must accept any interference received, including interference that may cause undesired operation.

NOTE:

1. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
   - Reorient or relocate the receiving antenna.
   - Increase the separation between the equipment and receiver.
   - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
   - Consult the dealer or an experienced radio/TV technician for help.
2. Any changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

7.1 Transmitting ECG Data in DAT Format Through Serial Cable

1. If the PC has RS232 socket, connect the PC RS232 socket to the electrocardiograph RS232 socket with an RS232 cable.

2. Set **Auto Transmission** to **On** and **Transmission Mode** to **UART** in the **Transmission Setup** window.

3. Log into the DMS.

4. In the auto or rhythm mode, ECG data will be transmitted through the serial cable automatically after an ECG report is printed out.

7.2 Transmitting ECG Data Through Network

7.2.1 Transmitting ECG Data in DAT Format

1. Log into the DMS.

2. Connect the electrocardiograph to the PC with an Ethernet cable recommended by the manufacturer.

3. Configure the **Transmission Setup** window.

   NOTE: For more information on configuring network settings, see your Network Administrator.

For Ethernet Transmission:

1) Press **Shift + F1** in the **Transmission Setup** window to open the **Basic Setup** window.

2) Set **Auto Transmission** to **On** and **Transmission Mode** to **Wired**.

3) Set the **Server IP** item to the IP of the PC, and FTP username and password to **EDANDAT**.

   For details, please refer to Section 10.5.1 "Basic Setup".

4) Press **Enter** to confirm, and then press **Esc** to return to the main screen.

For Wireless Network Transmission:

1) Press **Shift + F1** in the **Transmission Setup** window to open the **Basic Setup** window.

2) Set **Auto Transmission** to **On** and **Transmission Mode** to **Wireless**.

3) Set the **Server IP** item to the IP of the PC.

   For details, please refer to Section 10.5.1 "Basic Setup".

4) Press **Shift + F2** in the **Transmission Setup** window to open the **WIFI Setup** window.

   For details, please refer to Section 10.5.2 "WIFI Setup".

5) Connect the wireless network.

4. Set **File Format** to **DAT** in the **File Setup** window.

5. In the auto or rhythm mode, ECG data will be transmitted through the network automatically after an ECG report is printed out.

7.2.2 Transmitting ECG Data in SCP/FDA-XML/PDF/DICOM Format

NOTE: SCP/FDA-XML/DICOM function can be activated on the **Advanced Setup** screen. For details, please contact the manufacturer or the local distributor.

1. Log into the FTP receiving software.

2. Connect the electrocardiograph to the PC with an Ethernet cable recommended by the manufacturer.

3. Configure the **Transmission Setup** window.

1) Press **Shift + F1** in the **Transmission Setup** window to open the **Basic Setup** window.

2) Set **Auto Transmission** to **On** and **Transmission Mode** to **Wired** or **Wireless**.

3) Set the **Server IP** item to the IP of the PC.

For details, please refer to Section 10.5.1 "Basic Setup".

4) Set the **FTP User Name**, **FTP Password** and **FTP Path** items.

a) The user name and the password you input in the **FTP User Name** and **FTP Password** items must be available for FTP server.

b) The path you input in the **FTP Path** item must be the subdirectory of the path you input in the FTP receiving software.

NOTE: For more information about FTP server, see your Network Administrator.

4. Set **File Format** to SCP/FDA-XML/PDF/DICOM in the **File Setup** window.

5. In the auto or rhythm mode, ECG data will be transmitted through the network automatically after an ECG report is printed out.

Chapter 8 Managing Orders
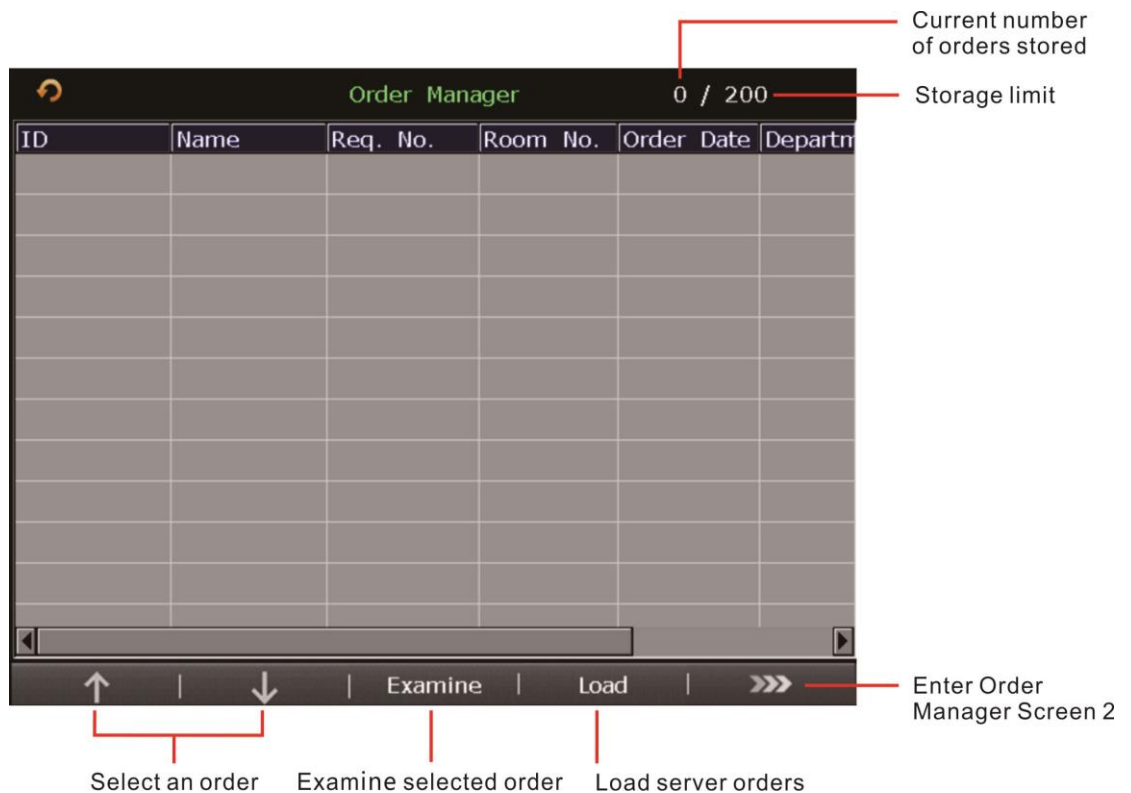
Figure 8-1 Order Manager Screen1 (SE-601B/C)

Figure 8-2 Order Manager Screen2 (SE-601B/C)

NOTE:

1. The order function is only configurable for SE-601B/C.

2. To use the order function, the ECG data management software (DMS) of EDAN must be installed in the PC.8.1 Loading Orders

Once the electrocardiograph is turned on, you can open the **Order Manager** screen by pressing **Patient** if orders without examination exist on the **Order Manager** screen.

After you press **Examine** on the **Order Manager** screen to return to main screen1, you cannot open the **Order Manager** screen by pressing **Patient** until you complete an order examination next time.

To load order information:

1. On the electrocardiograph, configure the **Order Setup** screen.
2. Connect the electrocardiograph to the PC installed with the DMS by using an Ethernet cable recommended by the manufacturer.
3. Set **Server IP**, **Local IP**, **Gateway** and **Subnet Mask** in the **Transmission Setup** window. For details, please refer to Section 10.5 "Transmission Setup".
4. Select **Load** on the **Order Manager** screen to load orders from the DMS.

   If **Auto Refresh** is enabled in Order Setup, the system will automatically refresh the order information every time you enter the **Order Manager** screen.

   NOTE: If orders are modified on the DMS, the corresponding orders existing on the **Order Manager** screen will be refreshed after you load orders from the software.

Chapter 9 Managing Files
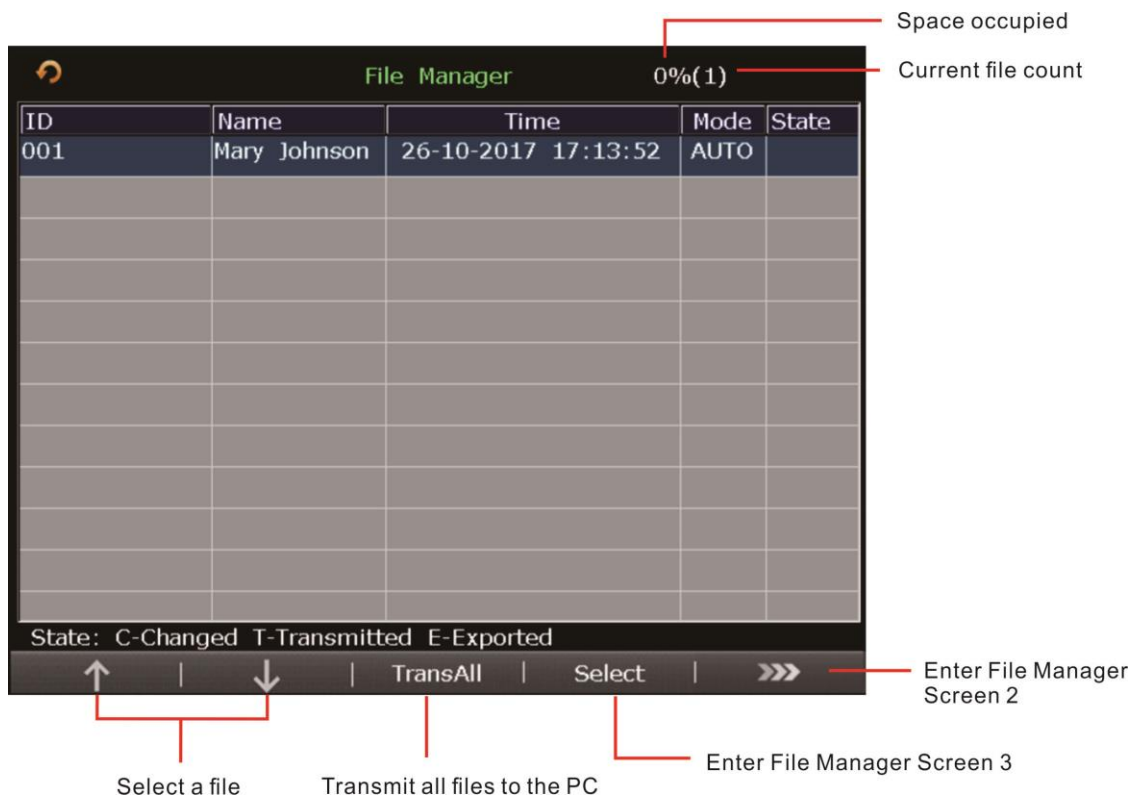
Figure 9-1 File Manager Screen1
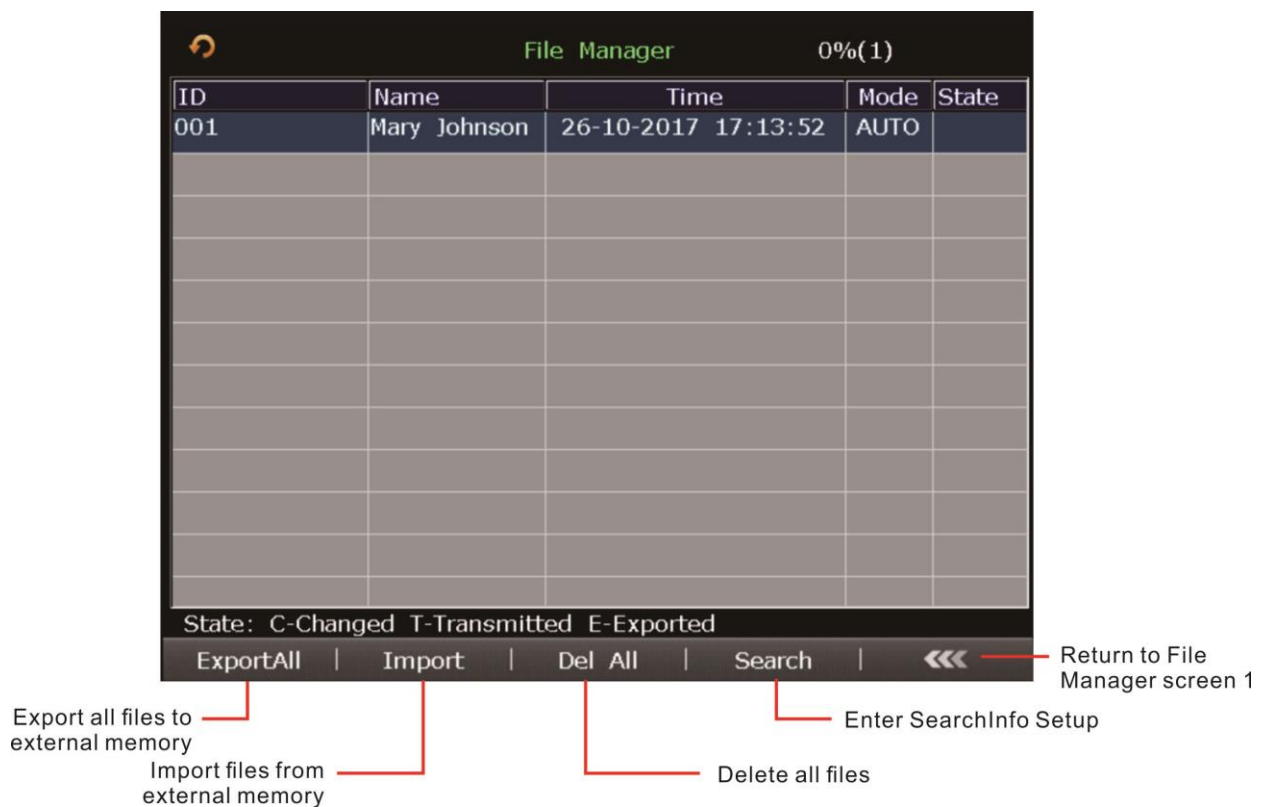
Figure 9-2 File Manager Screen2
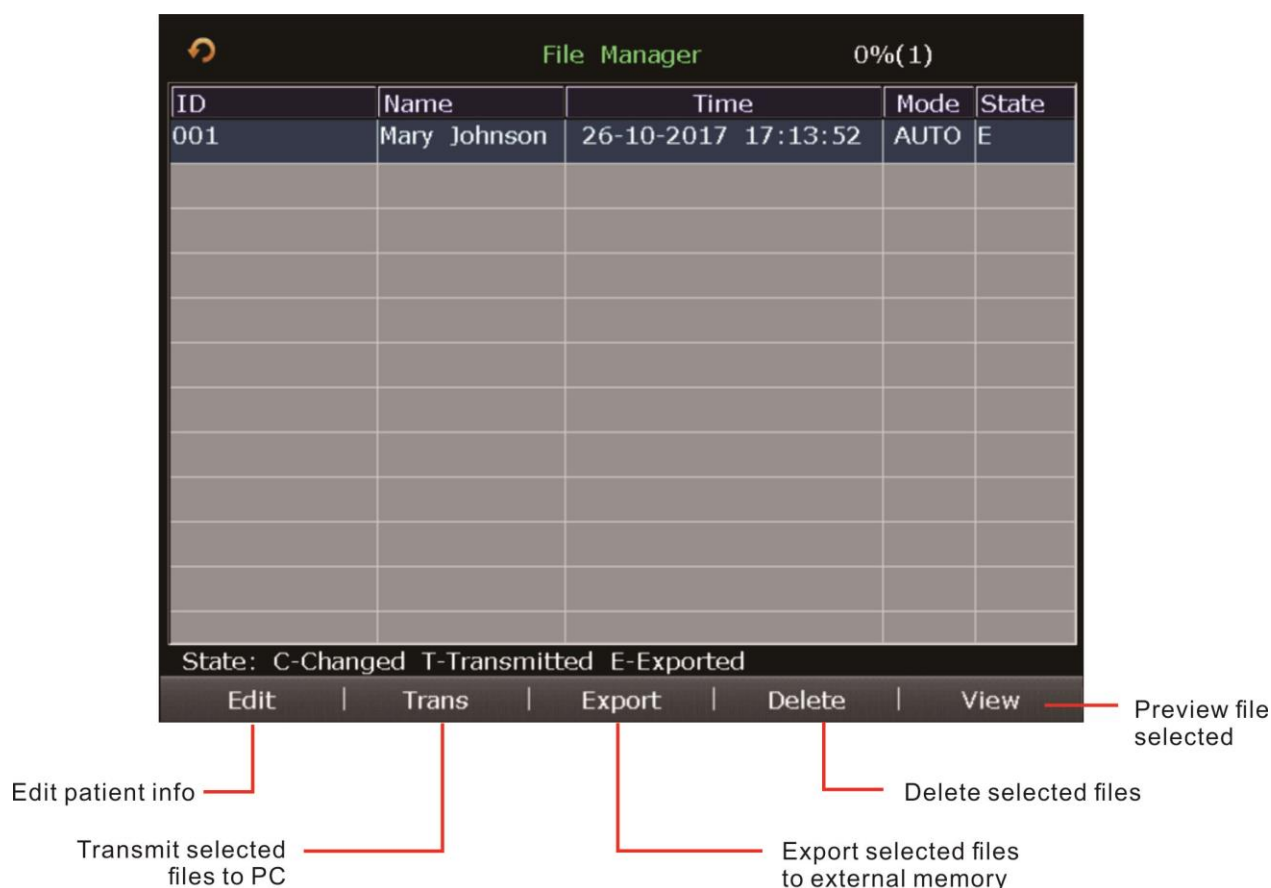
Figure 9-3 File Manager Screen3

Export file path: *ECGDATA\ECG-x\Export\ Export Date and Time*

Import file path: *ECGDATA\Import*

CAUTION

1. Do not cut off the mains supply directly when no battery is installed in the device, or else, the stored data may be lost.

2. When files are being printed, transmitted, deleted or exported, you can not turn off the electrocardiograph.

3. It is forbidden to connect or disconnect a U disk or a USB printer during the transmission course.

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\Export\Export Date and Time*** can be set in the **Device No.** textbox in the **Transmission Setup** window.

3. If you select **Delete After Trans. Or Export** in the **File Setup** window, the files will be deleted from the **File Manager** screen after they are exported.

4. Only the ECG files in DAT format produced by the electrocardiograph of the manufacturer can be imported.

5. Rhythm data cannot be previewed.

6. On the previewing screen, you can press Tab to switch the lead groups.

Chapter 10 System Setup

Select **Setup** on the main screen1 to display the **System Setup** screen.

10.1 Work Mode Setup

Items	Default	Default (Only in the U.S.)
Mode Options	Auto, Manual, Rhythm	Auto, Manual, Rhythm, R-R
Display Style	6×2	3×4+1R
Sampling Mode	Real-time Sample	Real-time Sample
Rhythm Style	Three Leads	Three Leads
Duration (Periodic Sample)	60 min	60 min
Interval (Periodic Sample)	1 min	1 min
Preview	Off	Off
Auto Arrhythmia Detection	Off	Off

10.2 Filter Setup

Items	Default	Default (Only in the U.S.)
AC filter	On	On
EMG filter	Off	Off
DFT filter	0.67Hz	0.67Hz
Lowpass filter	100Hz	100Hz

SE-601A: CMRR $\geq$ 121dB (when AC filter is ON)

SE-601B/C: CMRR $\geq$ 140dB (when AC filter is ON)

NOTE:

1. AC frequency can be set to **50Hz** or **60Hz** on the **Advanced Setup** screen according to local mains supply specifications.
2. Only when **EMG Filter** is set to **Off**, can the setting of **Lowpass Filter** be effective.
3. To pass the distortion test, the electrocardiograph has to be configured with the highest bandwidth in filter settings. Otherwise, ECG signal may be distorted.

10.3 Record Info Setup

10.3.1 Setup 1

Items	Default	Default (Only in the U.S.)
Auto Record Style	6×2	3×4+1R
Manual Style	6 channels	6 channels
Rhythm Record Mode	Save Paper	Save Paper
Record Sequence	Sequential	Sequential
Record Length	Medium (5s)	Medium (5s)
Gain	10mm/mV	10mm/mV
AGC	Off	Off
Print Out	On	On
Paper Marker	Beginning	Beginning
Speed	25mm/s	25mm/s
Sample Time	10s	10s

Item	Description
Record Device	Choose from: **Thermal**, **HP2010/1050/2000, HPM401/2015/2035, HP1106/1020P, HP1106/1020P, HP4729/3638, HPM202D/1525/M403d, HP3638/4729.** **NOTE:** 1. During the USB printing course, pressing the **PRINT/STOP** key again can not stop printing ECG reports.

2. USB printing is ineffective in the auto periodic sampling mode, auto 11~60s sampling mode, manual mode and R-R analysis mode.

3. Make sure that paper is installed in the USB printer before printing. Error may occur if no paper is loaded in the USB Printer.

4. You should connect the corresponding USB printer to the electrocardiograph.

5. **Print Out** configuration is effective only under the AUTO or RHYT mode.

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.

10.3.2 Setup 2

Items	Default	Default (Only in the U.S.)
Measure / Analysis	On	On
Template / Position Marker / Time Scale / Minnesota Code / Device No.	Off	Off
Baseline Adjustment	Horizontal	Horizontal
RR Interval List	Off	Off
Grid of Thermal Report	Off	Off
Grid of USB Report	On	On
Prompt	Confirmed By	Confirmed By

10.4 Patient Information Setup

Items	Default	Default (Only in the U.S.)
Gender / Pacemaker	On	On
First\Last Name / BP / Race / Height / Weight / Medication / Room No. / Department / Physician / Technician / Ref-Physician / Exam. Room	Off	Off
ID Mode	Auto	Manual
ID Hint	On	On
Age Mode	Age	D.O.B
H/W Unit	cm/kg	inch/lb.
BP Unit	mmHg	mmHg
PatInfo Refreshed	On	On
Order Acquired	Off	Off
User-defined	Cleared	Cleared

Item	Description
Patient Options	Select the item displayed in the **Patient Information** window.

NOTE:

1. **Pacemaker** appears in the **Patient Information** window after it is selected in the **Patient Information Setup** window. Set **Pacemaker** to **Yes** in the **Patient Information** window, and the **Pacemaker** information will be displayed on the report printed out.

2. **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.

10.5 Transmission Setup

Items	Default	Default (Only in the U.S.)
Auto Transmission	Off	Off
Transmission Mode	Wired	Wired
FTP User Name / FTP Password/ FTP Path	Cleared	EDANDAT
Enable WIFI	Disabled	Disabled
Auto Get IP	Off	Off

10.5.1 Basic Setup

NOTE: To transmit ECG data, the DMS of the manufacturer or the FTP receiving software must be installed in the PC.

Item	Description
IP Addresses	Set **Server IP, Local IP, Gateway, Subnet Mask** For the cross-network transmission, a) Set the first two sections of the **Local IP** item to the first two sections of the IP of the PC. b) Set the third section of the **Local IP** item to the network segment of the electrocardiograph which depends on the configuration of Router. c) The last section of the **Local IP** item can be set at random. For the same network transmission, a) Set the first three sections of the **Local IP** item to the first three sections of the IP of the PC. b) The last section of the **Local IP** item can be set at random, but it can't be the same as the last section of the IP of the PC. **NOTE:** If WIFI is enabled and **Auto Get IP** is selected in the **WIFI Setup** window, IP addresses can be acquired automatically.

10.5.2 WIFI Setup (Configurable)*

NOTE:

1. *Not available in Canada.
2. The WIFI transmission function is only available for the machine configured with the WIFI module.

Item	Description
Auto Get IP	Select this item, addresses of **Local IP**, **Gateway** and **Subnet Mask** will be acquired automatically after the wireless network is connected successfully. **NOTE:** 1. Only if WIFI is disabled, can **Auto Get IP** option be available. 2. To use **Auto Get IP**, DHCP function needs to be enabled on the routing end.
View MAC Address	View the MAC address of the WIFI module.

10.6 Lead Setup

Items	Default	Default (Only in the U.S.)
Lead Sequence	Standard	Standard
Nehb	Off	Off
Rhythm Lead 1	II	II
Rhythm Lead 2	V1	V1
Rhythm Lead 3	V5	V5

Item	Description
Lead Sequence	Choose from: **Standard** or **Cabrera**

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

Nehb   Choose from: **On** or **Off**.

                Lead Sequence: I, II, III, ND, NA, NI

                NOTE: If you set **Nehb** to **On**, the working mode is fixed to be manual.

10.7 Display&Sound Setup

Items	Default	Default (Only in the U.S.)
Brightness	10	10
Key Volume	Medium	Medium
Hint Volume	Medium	Medium
QRS Volume	Off	Off
Notify Volume	Medium	Medium
Display Colors	Option 1	Option 1
Antialiasing	Off	Off
Grid	On	On

Item	Description
Antialiasing	Reserved for future use.

10.8 Date&Time Setup

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

Items	Default	Default (Only in the U.S.)
Date Mode	DD-MM-YYYY	DD-MM-YYYY
Time Mode	24 Hours	24 Hours
Power Off/ LCD Off	Cleared	Cleared

10.9 File Setup

Items	Default	Default (Only in the U.S.)
Auto Save	To ECG	To ECG
File Format	DAT	PDF
Delete After Trans. Or Export	Off	Off
Replace When Memory Full	Off	Off

Item	Description
Auto Save	Choose from: **Off, To ECG** or **To External Memory** 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 External Memory**, 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.

10.10 System Maintenance Setup

Items	Default	Default (Only in the U.S.)
System Password	Cleared	Cleared

Item	Description
System Password	If you set the system password in the **System Maintenance** window, you need enter the password before opening the **System Setup** screen.

10.11 Other Setup

Items	- 50 - Default	Default (Only in the U.S.)
External Input	Off	Off
External Output	Off	Off
Caps Lock	Off	Off
Institution	Cleared	Cleared
Language	English	English

Item	Description
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** 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.

Chapter 11 Error Messages

Error Messages and the corresponding causes provided by the electrocardiograph are listed in Table 11-1.

Table 11-1 Error Messages and Causes for Resting ECG

Error Messages	Causes
Lead off	Electrodes fall off the patient or the patient cable falls off the unit, or a high polarization voltage occurs.
Battery Weak	The battery is weak.
No Paper	Recorder paper runs out or is not loaded.
Testing	The ECG data is being sampled periodically.
Paper Error	When **Paper Marker** is set to **Yes**, the electrocardiograph advances the recorder paper to the next black marker. If it advances the paper for 300mm and can not find the next black marker, the hint *Paper Error* is displayed.
Sampling/Analyzing/Recording	ECG signals are being sampled / analyzed / recorded.
Learning	The self-study process of arrhythmia arithmetic in the **Trigger Sample** mode
Detecting	The examining process of arrhythmia data in the **Trigger Sample** mode
Transmitting	ECG data is being transmitted from the electrocardiograph to the PC through the net or serial cable in the auto or rhythm mode.
Loading Order…	Orders are being loaded to the electrocardiograph.
Memory Full	The amount of files on the File Manager screen reaches 800.
Module Error	There is something wrong with the signal sample module.
DEMO	The system is in the demonstration mode.
Overload	The direct current offset voltage on an electrode is too high.
U Disk / USB Printer / USB Scanner	A U disk, a USB printer or a bar code reader is connected to the USB interface.

Chapter 12 FAQ

1. Operating Problems

Q1: I was trying to select a file from the file list on the **File Manager** screen, but the file was in the middle of the long list. Is there any way to make the selection faster?

A1: Actually, the system provides a method for fast moving: pressing **Shift** + **F1** or **F2** can move the cursor up or down in the file list very fast.

Q2: I was just about to input the age when I suddenly realized that I had entered the **Name** textbox unintentionally, can I just go back without pressing **Tab** for a whole circle?

A2: As a matter of fact, the system does take such unintentionalities into consideration by providing **Shift** + **Tab** as the way back, as the Microsoft Windows operating system does.

Q3: I want to save the ECG data without printing, could it be possible?

A3: Yes, you can set **Print Out** to **Off** in the **Record Info Setup1** window. Or, in the auto or rhythm mode, you can directly press **Shift** + **PRINT/STOP** to enable or disable the print out function. The ECG data will be collected and saved without printing. In the same way, if the transmission settings are configured, the ECG data could be transmitted to the PC without printing.

Q4: I want to input the patients' phone number in the **Patient Information** window, but there is no such item. Can I add it manually?

A4: Yes, there is a user-defined item for entering patient information. It works in this way: first input the name of the item in the **User-defined** textbox in the **Patient Information Setup** window, e.g. Tel. Then return to the main screen1, and open the **Patient Information** window, the **Tel** item will be displayed in this window. Now it's possible to input the phone number of the patient in the **Tel** textbox.

Q5: *Memory Full* is displayed on the main screen; Or, the hint *Memory full! Replace the earliest file?* pops up every time when I save an ECG report to the electrocardiograph. What am I supposed to do?

A5: *Memory Full* is used to remind you that the amount of stored file reaches the upper limit.

The display of the pop-up hint *Memory full! Replace the earliest file?* is related to the settings of the **File Setup** window.

Select **Off** from the **Replace When Memory Full** list box, when the amount of stored files

reaches the upper limit and you save an ECG report to the electrocardiograph, the hint *Memory full! Replace the earliest file?* pops up.

Select **On** from the **Replace When Memory Full** list box, when the amount of stored files reaches the upper limit and you save an ECG report to the electrocardiograph, the hint *Memory full! Replace the earliest file?* does not pop up.

You can deal with the hint as follows:

1) You can just delete several stored files from the electrocardiograph to ensure the amount of stored file not to reach the upper limit.

2) When *Memory Full* is displayed on the main screen, you can set **Auto Save** to **To External Memory** to save the added ECG reports. However, the amount of stored files in the electrocardiograph still reaches the upper limit.

2. Printing Problems

Q1: I was encountered with paper-jam, what was I supposed to do?

A1: 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 recorder 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 it happened several times, it might have something to do with your configuration. If **Paper Maker** is set to **Beginning** or **End** and you frequently press **PRINT/STOP** to stop the printing in the auto or rhythm mode, the rolling back recorder will cause the paper-jam. In this case, you should set **Paper Maker** to **No** in the **Recorder Setup** window.

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

Q2: The hint *Paper Error* is displayed on the screen, what should I do?

A2: It might be the result of unsuccessful detection of the black markers, first open the recorder casing so as to clear the error information, and then check whether the black marker is on the bottom 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.

Q3: The hint *No Paper* is displayed on the screen, what should I do?

A3: Check whether the paper runs out, or the black marker is just facing the black marker detection window on the thermal printing head, as the following figure shows.

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

Q4: I want to print the hospital name in the report, but I can't find the place to enter it, where is it?

A4: Please open the **Other Setup** window, and move the cursor to the **Institution** textbox, and then input the hospital name. The content you input in this textbox will be printed in the report. For details, please refer to Section 10.12, "Other Setup".

Q5: I pressed the **PRINT/STOP** key, but the ECG didn't start printing, what's wrong with it?

A5: The system will not respond to the **PRINT/STOP** key during the first 3s after you return to the main screen. Therefore, you have to wait for a few seconds, and then you are able to start the printing by pressing the **PRINT/STOP** key.

If you wait for a few seconds, but you still unable to start the printing by pressing the **PRINT/STOP** key, please check whether there is any error information displayed on the screen.

If the hint *No Paper* or *Paper Error* is displayed on the screen, please deal with it according to the above-mentioned measures.

If the hint *Transmitting…* is displayed 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 is transmitted.

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

Q6: I set the filter, speed and gain on the main screen1, but these settings were changed after printing.

A6: The filter, speed and gain which are set on the main screen1 will not be saved, and they are changed when you exit the main screen1 or after printing. If you want to save these settings, please set them in the **Record Info Setup** window and the **Filter Setup** window.

3. Transmitting Problems

Q1: The ECG doesn't respond to any keys after a long time of transmission. It transmits nothing for there is no new data appearing on the screen 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 connect the net cable well. If it doesn't work, please restart the ECG.

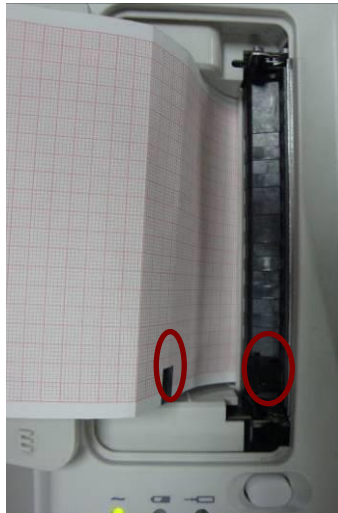If the problem still exists, please contact the manufacturer or the local distributor for further disposal.

4. Main Unit Problems

Q1: After power-on, the ECG stays on the logo screen and doesn't open the main screen. I have restarted the machine several times, but there is no better change.

A1: The reason for this problem might be: there is a key pressed down, without springing up. Find that key, and make it spring up, the problem should be solved.

Q2: I was doing the examination when the machine suddenly gave out a sound and displayed the hint ***Lead Off***. What should I do?

A2: The corresponding electrodes are not connected well. Please find out which lead is off by checking the Lead Name area on the main screen (please refer to Section 4.3.1, "About the Main Screen"). The lead whose name is highlighted is off. Please check whether the corresponding electrode of the lead is 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 takes effect, please contact the manufacturer or the local distributor for further disposal.

Chapter 13 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.

13.1 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

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

2. The equipment is chemically resistant to most cleaning agents, disinfectants and non-caustic detergents used in hospital, but cleaning agents or disinfectants that are not listed in this manual are not recommended. For example, didecyl dimethyl ammonium bromide, which contains quaternary ammonium salt, may corrode the equipment and accessories.

13.2 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.

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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.

13.3 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' 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.

2. Do not use chloric disinfectant such as chloride, sodium hypochlorite etc.

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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.

13.4 Care and Maintenance

CAUTION

Operate the cardiograph, charge the battery, and store the battery at a temperature of 40℃ (104⁰F) or lower. Exposure to higher temperature may reduce battery life, damage the battery, and degrade overall cardiograph performance.

13.4.1 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.

◻◻◻▸: Full capacity;

◻◻▪▸: 2/3 capacity;

◻▪▪▸: 1/3 capacity;

▪▪▪▸: Low capacity

2) Recharge

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

flashing, and the battery recharging indicator (➔▭) is black.

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

Recharging process:

| Precharge | → | Recharge at constant current | → | Recharge at constant voltage | → | Recharge complete |
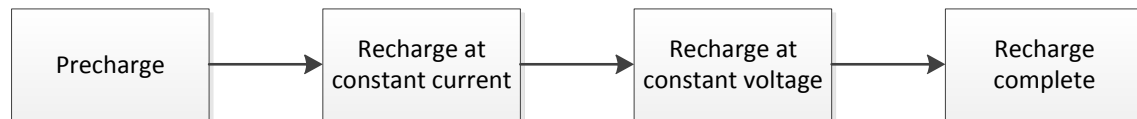
NOTE: The battery will automatically stop charging if you print an ECG report.

CAUTION

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

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3)   Replacement

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

WARNING

1. Only qualified service engineers authorized by the manufacturer can open the battery compartment and replace the battery, and the battery of the same model and specification provided by the manufacturer must be used.

2. Danger of explosion -- Do not reverse the anode and the cathode when installing the battery.

3. When the battery's useful life is over, contact the manufacturer or the local distributor for disposal or dispose of the battery according to local regulations.

4. Remove the battery from the electrocardiograph when the electrocardiograph isn't used for a long time.

5. If the battery is stored alone and not used for a long time, we recommend that the battery be charged at least once every 6 months to prevent over-discharge.

CAUTION

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

13.4.2 Recorder Paper

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

Storage Requirements:

♦ Recorder paper should be stored in a dry, dark and cool area, avoiding excessive temperature, humidity and sunshine.

♦ Do not put the recorder paper under fluorescence for a long time.

♦ Make sure that there is no polyvinyl chloride or other chemicals in the storage environment, which will lead to color change of the paper.

♦ Do not overlap the recorder paper for a long time, or else the ECG reports may trans-print each other.

13.4.3 Visual inspection

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

♦ Check the case and display screen for cracks or other damage.

♦ Regularly inspect all plugs, cords, cables, and connectors for fraying or other damage.

♦ Verify that all cords and connectors are securely seated.

♦ Inspect keys and controls for proper operation.

13.4.4 Maintenance of the Main Unit and the Patient Cable

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

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

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

b) Inspect the safety related labels for legibility.

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

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

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

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

♦ Put the dustproof coat on the main unit after use and prevent shaking it violently when moving it to another place.

♦ Prevent any liquid from seeping into the equipment; otherwise the safety and the performance of the electrocardiograph can not be guaranteed.

2) **Patient Cable**

♦ Integrity of the patient cable, including the main cable and lead wires, should be checked regularly. Make sure that it is conductible.

♦ Do not drag or twist the patient cable with excessive stress while using it. Hold the connector plug instead of the cable when connecting or disconnecting the patient cable.

♦ Align the patient cable to avoid twisting, knotting or crooking in a closed angle while using it.

♦ Store the lead wires in a big wheel to prevent any people from stumbling.

♦ Once damage or aging of the patient cable is found, replace it with a new one immediately.

3) Reusable Electrodes

♦ Electrodes must be cleansed after use and make sure there is no remainder gel on them.

♦ Keep suction bulbs of chest electrodes away from sunshine and excessive temperature.

♦ After long-term use, the surfaces of electrodes will be oxidized because of erosion and other causes. By this time, electrodes should be replaced to achieve high-quality ECG records.

CAUTION

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

Chapter 14 Accessories

14.1 Standard Accessories

Table 14-1 Standard Accessories List

Accessory	Part Number
Power cord (European)	01.13.036638
Power cord (England)	01.13.036641
Power cord (American)	01.13.037122
Patient Cable (European)	01.57.471500
Patient Cable (American)	01.57.471499
Chest electrodes	01.57.040163
Limb electrodes	01.57.040162
Thermal recording paper	01.57.107560
Fuse	21.21.064172
Rechargeable Lithium Battery	21.21.064149

14.2 Optional Accessories

Table 14-2 Optional Accessories List

Accessory	Part Number
Patient Cable (European)	01.57.107402 (Banana Style)
	01.57.471016 (Banana Style)
	01.57.107581 (Snap Style)
	01.57.107583 (Grabber Style)
Patient Cable (American)	01.57.110375 (Banana Style)
	01.57.471017 (Banana Style)
	01.57.107582 (Snap Style)

	01.57.107584 (Grabber Style)
Pediatric Chest Electrodes	01.57.040168
Pediatric Limb Electrodes	01.57.040169
Grounding Wire	01.13.114214
Adult Disposable Adhesive Electrodes	01.57.471858
Disposable Adult ECG Electrodes	01.57.471862
Pediatric Disposable Adhesive Electrodes	01.57.471859
Disposable Resting Electrodes	01.57.471863
Snap/Banana Socket Adapters	01.57.471864
Clip/Snap/Banana Socket Adapter	01.57.040172
U disk	01.18.052275
SE-601 Backpack	01.56.465627
LS4208 Bar Code Reader (One-Dimension)	01.23.068023
1900GSR-2 Bar Code Reader (Two-Dimension)	21.18.052311
MT-201 Trolley	83.61.111847
	83.61.360760
CA-100 Lead wire bracket	02.04.111902
	02.04.242639

SE-601 series electrocardiograph and accessories are available by contacting the manufacturer or your local distributor.

NOTE:

1   The chest electrodes, 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 15 Warranty & Service

15.1 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.

15.2 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 60601-1-2:2014 EN 60601-1-2:2015 IEC/EN 60601-2-25
Anti-electric-shock type:		Class I with internal power supply
Anti-electric-shock degree:		CF type with defibrillation-proof
Degree of protection against harmful ingress of water:		Ordinary equipment (Sealed equipment without liquid proof)
Disinfection/sterilization method:		Refer to Chapter 13 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:	-20ºC (-4ºF) ~ +55ºC (+131ºF)	+5ºC (+41ºF) ~ +40ºC (+104ºF)
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	310mm×322mm×101mm (12.2in×12.7in×3.98in)	
Weight	Approx. 3.0 kg (excluding recorder paper and battery)	
Display	SE-601A:	3.5" single color LCD screen;
	SE-601B:	5.6" multicolor TFT LCD screen;
	SE-601C:	5.6"multicolor TFT LCD touch screen.

A1.4 Power Supply Specifications

Mains Supply:	Operating Voltage = 100V-240V~
	Rated Voltage: 14.8 V
	Operating Frequency = 50Hz/60Hz
	Input Power = 0.9A-0.4A
Internal Li-ion Battery Pack:	Rated capacity = 2500mAh
	When the battery is fully charged, the electrocardiograph can work normally at a temperature of 23ºC (±3ºC) for at least 5 hours; and it can continually print at least 1.5 hours in the **MANU** mode or print at least 300 ECG reports of 3×4+1R in the **AUTO** mode.
	100% Charge time: 5 hours 90% charge time: 4.5 hours
Fuse:	T3.15AH250V, φ5×20mm

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: 110mm×140mm, 150 pages
Effective Width:	104mm
Paper Speed:	5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s, 50mm/s (±3%)
HR Recognition	
HR Range:	30 bpm ~300 bpm
Accuracy:	±1 bpm
ECG Unit	
Leads:	12 standard leads
Acquisition Mode:	Simultaneously 12 leads
A/D:	24 bits
Resolution:	2.52uV/LSB
Time Constant:	≥3.2s
Frequency Response:	SE-601A:	0.05Hz ~ 150Hz
	SE-601B/C:	0.01Hz～300Hz
Gain:	2.5, 5, 10, 20, 40, 10/5, AGC (mm/mV), ±5%
Input Impedance:	SE-601A:	≥50MΩ (10Hz)
	SE-601B/C:	≥100MΩ (10Hz)
Input Circuit Current:	≤0.01μA
Input Voltage Range	≤±5 mVpp
Calibration Voltage:	1mV±2%
DC Offset Voltage:	±600mV

Minimum Amplitude:		20 μVp-p	
Noise:		≤12.5μVp-p	
Multichannel crosstalk		≤0.5mm	
Filter	AC Filter:	On /Off	
	DFT Filter:	SE-601A:	0.05Hz/0.15Hz/0.25Hz/0.32Hz/0.5Hz/0.67Hz
		SE-601B/C:	0.01Hz/0.05Hz/0.15Hz/0.25Hz/0.32Hz/0.5Hz/0.67Hz
	EMG Filter:	25Hz/35Hz/45Hz/OFF	
	LOWPASS Filter:	SE-601A:	150Hz/100Hz/75Hz
		SE-601B/C:	300Hz/270Hz/150Hz/100Hz/75Hz
CMRR		SE-601A:	≥115dB (AC OFF)
		SE-601B/C:	≥123dB (AC OFF)
Sampling Frequency		SE-601A:	1,000/sec/channel
		SE-601B/C:	16, 000/sec/channel
Pacemaker Detection			
Amplitude		SE-601A:	±2 mV to ±700 mV
		SE-601B/C:	±750uV to ±700 mV
Width		SE-601A:	0.1ms to 2.0 ms
		SE-601B/C:	50μs to 2.0 ms
Sampling Frequency		SE-601A:	10,000/sec/channel
		SE-601B/C:	16,000/sec/channel
External Input/Output (Configurable)			
Input		≥100kΩ; Sensitivity 10mm/V±5%; Single ended	
Output		≤100Ω; Sensitivity 1V/mV±5%; Single ended	
WIFI (Configurable)			

Transmitting Frequency	2400-2497MHz
Frequency Band	2400-2497MHz
Wireless protocol	IEEE 802.11b/g/n
Modulation Type	DSSS, CCK, OFDM
Transmitting Power	6~17dBm
Effective Radiated Power	6~17dBm

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

Appendix 2 EMC Information

Electromagnetic Emissions

Guidance and manufacture's declaration – electromagnetic emission		
SE-601 series electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of SE-601 series electrocardiograph should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	SE-601 series 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	SE-601 series 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 buildings used for domestic purposes.
Harmonic emissions IEC/EN 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC/EN 61000-3-3	Complies	

Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity			
SE-601 series electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of SE-601 series electrocardiograph should assure that it is used in such an environment.			
Immunity test	**IEC/EN 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC/EN 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC/EN 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 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.
Power frequency (50Hz/60Hz) magnetic field IEC/EN 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	0 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Mains power quality should be that of a typical commercial or hospital environment. If the user of SE-601 series

	0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles) Single phase: at 0° 0 % U_T; 250/300 cycle	0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles) Single phase: at 0° 0 % U_T; 250/300 cycle	electrocardiograph requires continued operation during power mains interruptions, it is recommended that SE-601 series electrocardiograph be powered from an uninterruptible power supply or a battery.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity			
SE-601 series electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of SE-601 series electrocardiograph should assure that it is used in such an environment.			
Immunity test	**IEC/EN 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC/EN 61000-4-6	3 V$_{rms}$ 150 kHz to 80 MHz 6Vrms[c)] in ISM bands between 0.15 MHz and 80 MHz	3V$_{rms}$ 150 kHz to 80 MHz 6Vrms[c)] in ISM bands between 0.15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of SE-601 series electrocardiograph, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF	3 V/m	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz

IEC/EN 61000-4-3	80 MHz to 2.7 GHz	80 MHz to 2.7 GHz	$d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz $d = 6\sqrt{P}/\mathrm{E}$ at RF wireless communications equipment bands (Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the PADECG, including cables specified by the manufacturer). 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: $((\cdot))$
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.			

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 environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which SE-601 series electrocardiograph is used exceeds the applicable RF compliance level above, SE-601 series electrocardiograph should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating SE-601 series electrocardiograph.

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

c   The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test Frequency (MHz)	Brand [a)] (MHz)	Service [a)]	Modulation [b)]	Maximum Power(W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380-390	TETRA 400	Pulse modulation[b)] 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [C)] ±5 kHz deviation 1kHz sine	2	0.3	28
710 745 780	704-787	LTE Brand 13, 17	Pulse modulation[b)] 217 Hz	0.2	0.3	9
810	800-960	GSM	Pulse	2	0.3	28

870		800/900,TETRA 800, iDEN 820, CDMA 850, LTE Band 5	modulation^{b)} 18 Hz			
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation^{b)} 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN,802.11 b/g/n, RFID 2450, LTE Brand 7	Pulse modulation^{b)} 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation^{b)} 217 Hz	0.2	0.3	9
5500						
5785						
Note: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM maybe reduce to 1m. The 1 m test distance is permitted by IEC 61000-4-3.						
a) For some services, only the uplink frequencies are included.						
b) The carrier shall be modulated using a 50% duty cycle square wave signal.						
c) As an alternative FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.						

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM

Recommended separation distances between		
portable and mobile RF communications equipment and SE-601 series electrocardiograph		
SE-601 series electrocardiograph is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of SE-601 series electrocardiograph can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and SE-601 series 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 2.7 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

Abbreviation	Statement
LCD	Liquid Crystal Display
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
NC	Normal Condition
SFC	Single Fault Condition

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