EDAN INSTRUMENTS, INC.

CE 0123

SE-3 3-Channel Electrocardiograph

User Manual

Manual Ver: V1.7
Release Date: Aug. 2008
Part Number: MS1R-20055-V1.7

Copyright

Statement

Edan Instruments, Inc. (hereinafter called EDAN) makes no warranty of any kind with regard to this material, including, but not limited to the implied warranties of merchantability and fitness for a particular purpose. EDAN assumes no responsibility for any error that may appear in this document, or for incidental or consequential damage in connection with the furnishing, performance or use of this material.

No part of this document may be photocopied, reproduced or translated to another language without prior written consent of EDAN.

All information contained in this publication is believed to be correct. EDAN shall not be liable for errors contained herein nor for incidental or consequential damages in connection with the furnishing, performance, or use of this material. This publication may refer to information and protected by copyrights or patents and does not convey any license under the patent rights of this company, nor the rights of others. This company does not assume any liability arising out of any infringements of patents or other rights of third parties.

The information contained in this document is subject to change without notice.

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.

NOTE: This device is not intended for home use.

⚠**WARNING**⚠: This device is not intended for treatment.

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

Using This Label Guide

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.

Table of Contents

1 Safety Guidance

1.1 Safety Information

The design of SE-3 3-channel electrocardiograph complies with international standard IEC/EN 60601-1 Medical Electrical Equipment: General Requirements for Safety and IEC/EN 60601-2-25 Particular Requirements for the Safety of Electrocardiographs etc. The classification of this equipment is Class I, type CF, which means a higher degree of protection against electric shock and the patient connection is fully isolated and defibrillation protected.

This equipment is not explosion-proof. Do not use it in the presence of flammable anesthetics.

This equipment is designed for continuous operation and is 'ordinary' (i.e. not drip or splash-proof).

Classification:

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

1.2 Warnings and Cautions

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

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

1.2.1 Safety Warnings

⚠**WARNING**⚠:

1. The electrocardiograph is provided for the use of qualified physicians or personnel professionally trained. And 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 EDAN can open the shell.
3. Only qualified installation or service engineers can shift the mains shift switch (100V~115V/220V~240V) according to local mains supply.
4. The results given by the equipment should be examined with respect to the overall clinical condition of the patient. And it can not substitute for regular checking.

⚠**WARNING**⚠:

5. **EXPLOSION HAZARD**-Do not use the electrocardiograph in the presence of flammable anesthetic mixture with oxygen or other flammable agents.
6. **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.
7. If the integrity of external protective conductor in installation or arrangement is in doubt, the equipment should be operated from the built-in rechargeable battery.
8. Do not use this equipment in the presence of high static electricity or high voltage equipment which may generate sparks.
9. This equipment is not designed for direct cardiac application.

⚠**WARNING**⚠**:**

10. Only patient cable and other accessories supplied by EDAN can be used. Or else, the performance and electric shock protection can not be guaranteed.
11. Be sure that all electrodes have been connected to the patient correctly before operation.
12. Ensure that the conductive parts of electrodes and associated connectors, including neutral electrode, do not come in contact with earth or any other

conducting objects.

13. Electrodes with defibrillator protection should be used while defibrillating.
14. There is no danger for patients with pacemaker. However, if a pacemaker is used, the results given by the equipment may be invalid, or lose the clinical significance.
15. Do not touch the patient, bed, table and the equipment while using defibrillator or pacemaker simultaneously.
16. In order to avoid burning, please keep the electrode far away from the radio knife while using electrosurgical equipment simultaneously.
17. Always use electrode gel with reusable electrodes during defibrillation as ECG recovery will be greater than 10 seconds. EDAN recommends the use of disposable electrodes at all times.

⚠**WARNING**⚠:

18. Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the standard IEC/EN 60601-1-1. Therefore anybody, who connects additional equipment to the signal input connector or output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC/EN 60601-1-1. If in doubt, consult our technical service department or your local distributor.
19. The summation of leakage current should never exceed leakage current limits while several other units are used at the same time.
20. The potential equalization conductor can be connected to that of other equipment when necessary, to make sure that all these equipment are connected with the potential equalization bus bar of the electrical installation.

1.2.2 Battery Care Warnings

⚠**WARNING**⚠:

21. Improper operation may cause the battery to be hot, ignited or exploded, and it may lead to the declination of battery's capacity. It is necessary to read the user

manual carefully and pay more attention to warning messages.

22. Only qualified service engineer authorized by EDAN can open the battery compartment and replace the battery. And the battery of same model and specification provided by manufacturer should be used.
23. Danger of explosion -- Do not reverse the anode and cathode when connecting the battery.
24. Do not heat or splash the battery or throw it into fire or water.
25. When leakage or foul smell 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.
26. When the battery's useful life is over, contact the manufacturer or local distributor for disposal or dispose the battery according to local regulations.

1.2.3 General Cautions

CAUTION:

1. Avoid liquid splash and excessive temperature. The temperature must be kept between 5℃ and 40℃ while working. And it should be kept between -20℃ and 55℃ during transportation & storage.
2. Do not use the equipment in dusty environment with bad ventilation or in the presence of corrosive.
3. Be sure that there is no intense electromagnetic interference source around the equipment, such as radio transmitter or mobile phone etc. Attention: large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment etc. are likely to bring electromagnetic interference.

CAUTION:

4. Before use, the equipment, patient cable and electrodes etc. should be checked. Replacement should be taken if there is any evident defectiveness or aging symptom which may impair the safety or performance.
5. The following safety checks should be performed at least every 24 months by a qualified person who has adequate training, knowledge, and practical experience to

perform these tests.

a) Inspect the equipment and accessories for mechanical and functional damage.
b) Inspect the safety relevant labels for legibility.
c) Inspect the fuse to verify compliance with rated current and breaking characteristics.
d) Verify the device functions properly as described in the instructions for use.
e) Test the protection earth resistance according to IEC/EN 60601-1: Limit 0.2 ohm.
f) Test the earth leakage current according to IEC/EN 60601-1: Limit: NC 500 uA, SFC 1000uA.
g) Test the patient leakage current according to IEC/EN 60601-1: Limit: 10 uA (CF).
h) Test the patient leakage current under single fault condition with mains voltage on the applied part according to IEC/EN 60601-1: Limit: 50uA (CF).

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.

6. Ruptured fuse must only be replaced with the same type and rating as the original.
7. When the effective lifetime of the equipment and accessories is over, collect and classify them, and dispose them according to local regulations.
8. Federal (US) law restricts this device to sale by or on the order of a physician.

1.2.4 Cleaning & Disinfection Cautions

CAUTION:

9. Turn off the power before cleaning and disinfection. If mains supply used, the power cord should be drugged out of the outlet also. And prevent the detergent from seeping into the equipment.
10. Do not immerse the unit or patient cable into liquid under any circumstances.
11. Do not clean the unit and accessories with abrasive fabric and avoid scratching the electrodes.
12. Any remainder of detergent should be removed from the unit and patient cable after cleaning.
13. Do not use chloric disinfectant such as chloride and sodium hypochlorite etc.

2 Introduction

SE-3 is 3-channel electrocardiographs with 12 leads gathered simultaneously, visual display of operation menu, ECG parameters as well as electrocardiogram.

3-channel ECG can be viewed on the LCD (liquid crystal display) screen of SE-3 simultaneously. And it can be recorded by high-quality thermal recorder.

Auto, manual, rhythm, USB print and off mode can be chosen conveniently.

Either mains supply or built-in rechargeable Lithium battery can be used as power.

With a high resolution thermal printer, 32-bit processor and huge capacity memorizer, SE-3 has advanced performance and high reliability. And the compact size makes it suitable for clinic, hospital and ambulance use.

Configurations: Main unit and accessories (power cord, earth wire, patient cable, electrodes and thermal record paper)

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

⚠**WARNING**⚠: This equipment is intended for use in adult and pediatric patients only.

⚠**WARNING**⚠: This equipment is not designed for direct cardiac application.

⚠**WARNING**⚠: The results given by the equipment should be examined with respect to the overall clinical condition of the patient. And it can not substitute for regular checking.

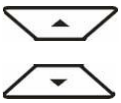
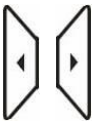
2.1 Function Features

- Low weight and compact size
- Touch key for easy operation
- High resolution thermal recorder, recording frequency response ≤150Hz

- 12-lead gathered and amplified simultaneously, 3-channel built-in recorder
- Auto mode, manual mode, rhythm mode, USB print mode and off mode optional
- Measurement function and interpretation function optional
- LOGIN/PRINT/GENERAL/SYSTEM menu for parameters setting (Only for the device with 320×240 dot single color LCD Screen)
- Built-in rechargeable Li battery with high capacity
- Hint information for lead off, lack of paper and low battery capacity etc.
- Automatic adjustment of baseline for optimal recording
- Standard input/output interface and RS232 communication interface for linking to special network and setting up ECG database

2.2 List of Symbols

	External output
	External input
	Equipment or part of CF type with defibrillator proof
	Attention – general warning (see accompanying document)
	Potential equalization
	Mains supply
	On (mains supply)

	Off (mains supply)
	Battery indicator
	Battery recharging indicator
	Sensitivity switch key
	Recall key
	1mV calibration key& Copy key
	Mode/RST switch key
	Lead switch key
	Print/Stop key
	ON/OFF key
	Menu key
	Up Arrow/Down Arrow key
	Left Arrow/ Right Arrow key

	Recycle
P/N	Part Number
SN	Serial Number
	Date of Manufacture
	Manufacturer
EC REP	Authorized Representative in the European Community
CE 0123	This item is compliant with Medical Device Directive 93/42/EEC of June 14, 1993, a directive of the European Economic Community.
	 It indicates that the equipment should be sent to the special agencies according to local regulation for separate collection after its useful life. ▬ It indicates that the equipment is put on the market after 13 August 2005.
Rx only	Federal (US) law restricts this device to sale by or on the order of a physician

3 General Information

3.1 Top Panel

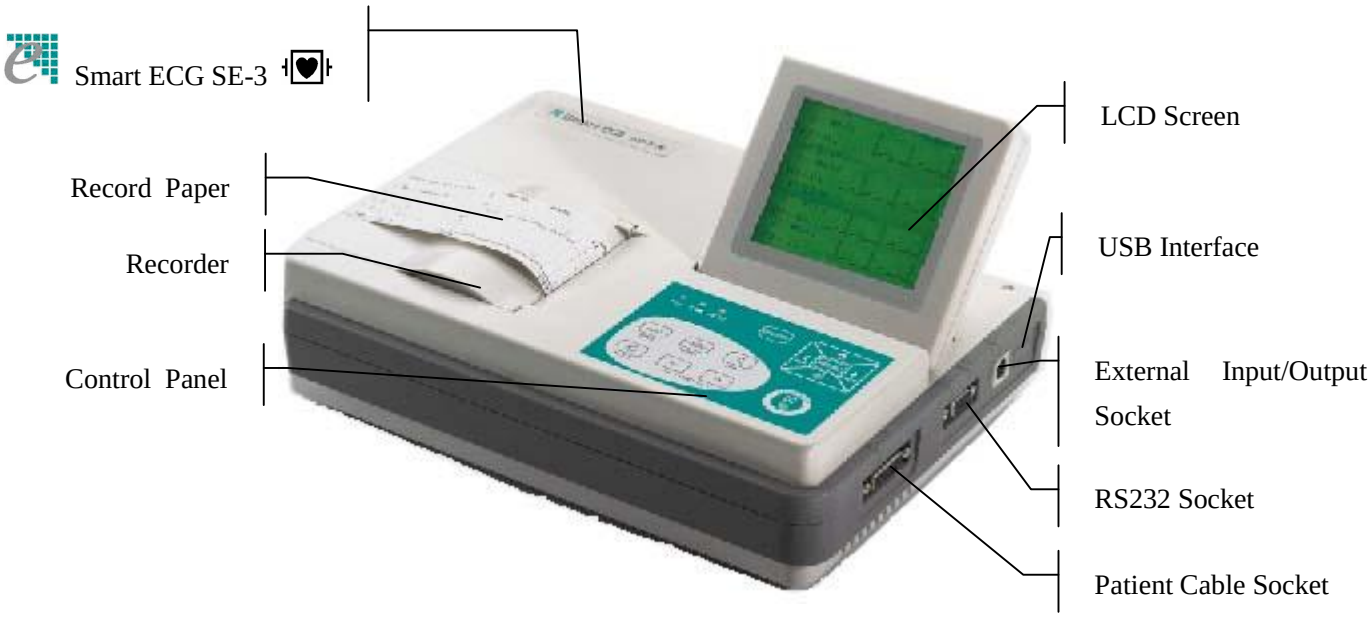


Figure 3-1 Main Unit (320×240 dot single color LCD Screen)

Product Information:

1) Trademark

2) Trade Name

Smart ECG

3) Model

SE-3 (3-channel electrocardiograph)

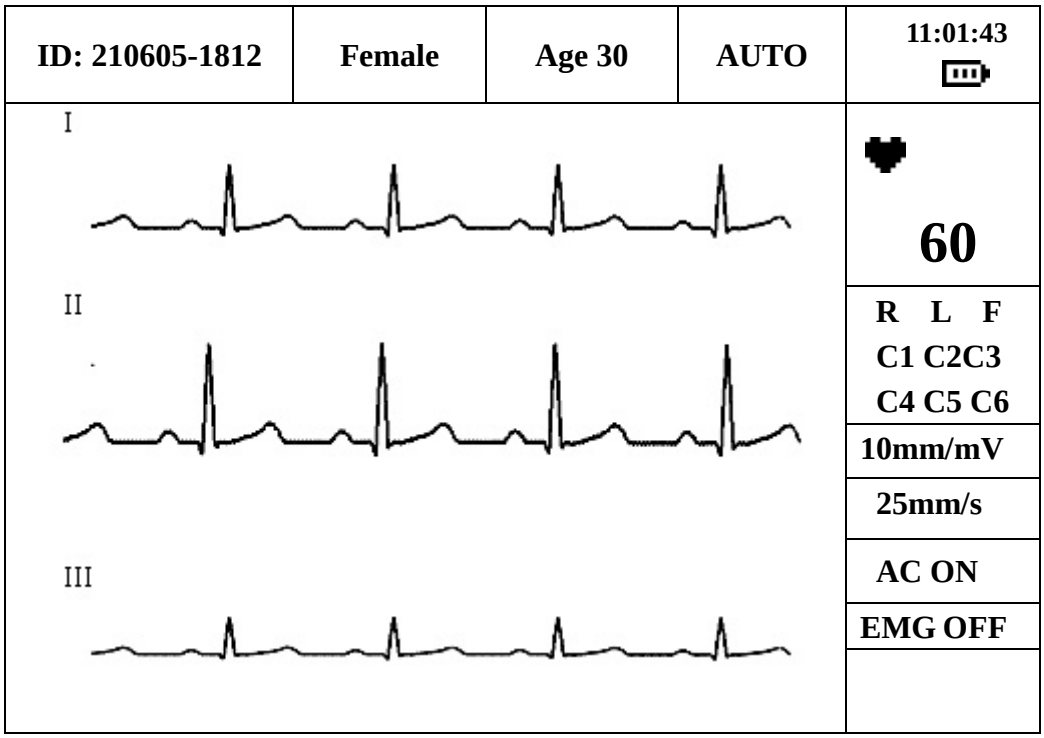
4) Classification Symbol

Equipment of CF type with defibrillator proof

3.1.1 LCD Screen

The LCD Screen has two specifications: 320×240 dot single color LCD Screen or 192×64 dot single color LCD Screen.

3.1.1.1 LCD Screen (320×240 dot single color)



Main Interface (320×240 dot single color LCD screen)

Normally, the contents displayed on the LCD screen include:

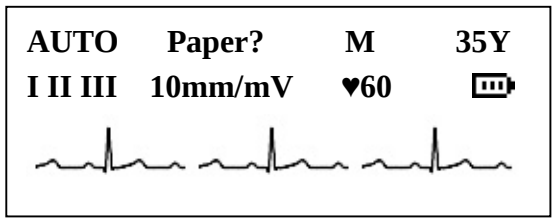
Top Row (describing from left to right)**:**

- Patient ID(created automatically according to current date and time)
- Sex (Male/Female) and Age
- Record mode(AUTO, MANUAL, RHYTHM, USBPRT or OFF)
- Current time and battery capacity(only when the built-in battery is used)

Right Row (describing from top to bottom)**:**

- Heart rate ♥ (Actual heart rate)
- Electrodes and electrode status (Black background shows the status of Lead OFF)
- Sensitivity (×2.5mm/mV, ×5mm/mV, ×10mm/mV, ×20mm/mV, AGC while in manual mode and auto sensitivity symbol while in auto mode)
- Record speed (5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s, 50mm/s)
- AC FILTER (AC ON, AC OFF)
- EMG FILTER (EMG OFF, EMG25Hz, EMG35Hz, EMG45Hz)
- Hint information (Paper?, Printing, Sampling, Bat Weak etc.)

3.1.1.2 LCD Screen (192×64 dot single color)



Main Interface (192×64 dot single color LCD screen)

Normally, the contents displayed on the LCD screen include: (descript from left to right)

First Row:

- Record mode(AUTO, MANUAL, RHYTHM, USBPRT or OFF)
- Hint information (Paper?, Printing, Sampling, Bat Weak etc.)
- Sex (Male/Female) and Age

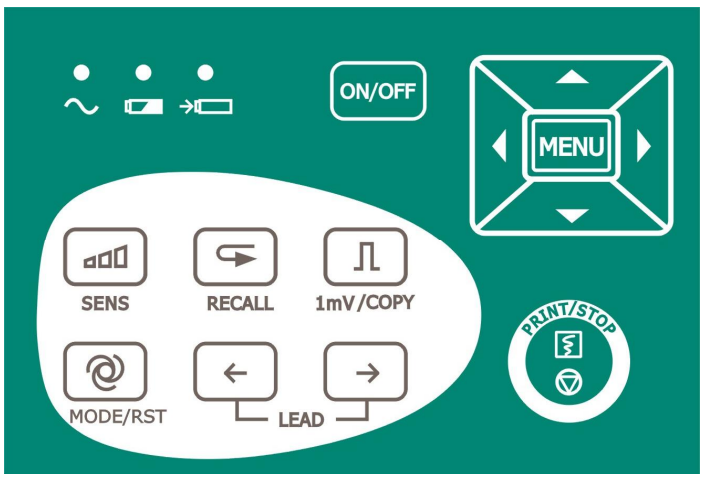
Second Row:

- Current lead (I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6)
- Sensitivity (×2.5mm/mV, ×5mm/mV, ×10mm/mV, ×20mm/mV, AGC while in manual mode and auto sensitivity symbol while in auto mode)
- Heart rate ♥ (Actual heart rate)
- Battery capacity(Only when the built-in battery is used)

Third Row:

- ECG wave

3.1.2 Control Panel and Keys



1) Indicator Lamp

~ Mains supply indicator lamp: when mains supply is used, the lamp will be light.

Battery indicator lamp: when the built-in rechargeable Lithium battery is used, the lamp will be light.

Battery recharging indicator lamp: when the battery is recharged, this lamp will be light.

2) SENS (Sensitivity Switch Key)

The sensitivity switching order: ×10 mm/mV→×20 mm/mV → AGC→×2.5 mm/mV→ ×5 mm/mV. And AGC means auto gain control.

3) Recall Key

Press this key to review the patient files saved in the recall window.

4) 1mV/COPY Key

Under MANUAL mode, this key can be pressed to record a 1mV calibration pulse at any time while recording.

Under AUTO mode, once the hint information “COPY” appears in the hint information field on the LCD screen, this key can be pressed to recall the electrocardiogram that recorded last time.

5) MODE/RST (Mode Switch Key)

This key can be pressed to select record mode between AUTO, MANUAL, RHYTHM, USBPRT and OFF. The switching order of lead groups is listed in Table 3-1.

Recording under Manual mode, this key can be pressed to reset the waveform quickly.

⚠**WARNING**⚠:

When using the device with defibrillator, after the defibrillator discharge, the MODE/RST key should be pressed to reset the waveform quickly.

Table 3-1 Lead Group Switching order of Different Mode

Mode	Switching Order (from left to right)			
AUTO(Standard)	I/Ⅱ/Ⅲ	aVR/aVL/aVF	V1/V2/V3	V4/V5/V6
AUTO(Cabrera)	aVL/ I /-aVR	II /aVF/ III	V1/V2/V3	V4/V5/V6
MANUAL	In this mode, need to press Lead Switch Key to change the lead , the lead switch order can be that of AUTO(Standard) or AUTO(Cabrera), which is determined by settings of lead sequence and record format in the MENU			

6) LEAD (Lead Switch Key)

Under MANUAL mode, press the key to switch the lead group.

For 192×64 dot single color LCD screen electrocardiograph, this key can be pressed to turn the pages in Recall window or Menu interface.

7) PRINT/STOP Key

Used to begin recording and stop recording.

8) ON/OFF Key

When the unit has been powered on, press this key to turn on it. Press again to turn off it.

9) MENU Key

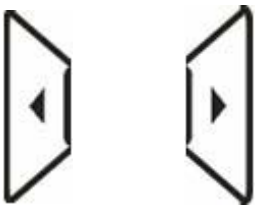
Press this key to enter menu settings.

10) Up Arrow/Down Arrow

Press the Up Arrow to select the items of main interface on the LCD screen counterclockwise while press the Down Arrow to select the items of main interface on the LCD screen clockwise. (hereinafter called **Up/Down**)

During MENU setting, the two keys can also be pressed to select the item of which the setting is to be changed.

11) Left Arrow/ Right Arrow

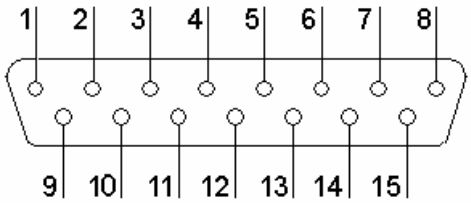


Press these keys to change the content of the selected item. During MENU setting, these keys can also be pressed to change the content of the selected item. (hereinafter called **Left/Right**)

3.2 Patient Cable Socket and Signal Interface

There are sockets including the patient cable socket, RS232 socket, external input/output socket and USB interface at the right side of the main unit as **Figure 3-1** shows.

1) Patient Cable Socket



 : Applied part of type CF with defibrillator proof

 : Attention – see accompanying document

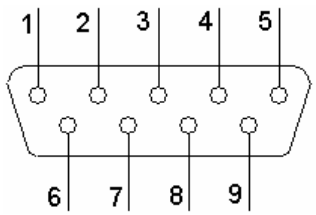
Definition of corresponding pins:

Pin	Signal	Pin	Signal	Pin	Signal
1	C2 (input)	**6**	SH	**11**	F (input)
2	C3 (input)	**7**	NC	**12**	NC
3	C4 (input)	**8**	NC	**13**	C1(input)
4	C5 (input)	**9**	R (input)	**14**	NC
5	C6 (input)	**10**	L (input)	**15**	N or RF (input)

2) RS232 Socket

⚠**WARNING**⚠:

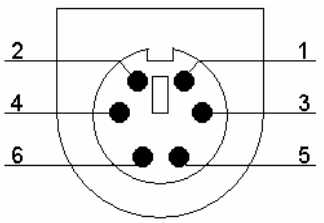
RS232 interface is 1500V AC isolated intensity and the maximum voltage applied should not exceed +15V DC.



Definition of corresponding pins:

Pin	Signal	Pin	Signal	Pin	Signal
1	NC	**4**	NC	**7**	NC
2	RxD (input)	**5**	GND	**8**	NC
3	TxD (output)	**6**	NC	**9**	NC

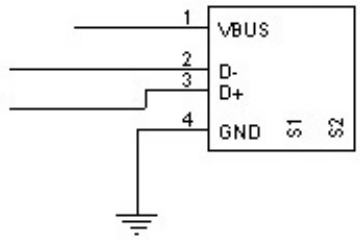
3) External Input/Output Socket



Definition of corresponding pins:

Pin	Signal	Pin	Signal
1	GND	**4**	GND
2	GND	**5**	ECG Signal (input)
3	GND	**6**	ECG Signal (output)

4) USB Interface



Definition of corresponding pins:

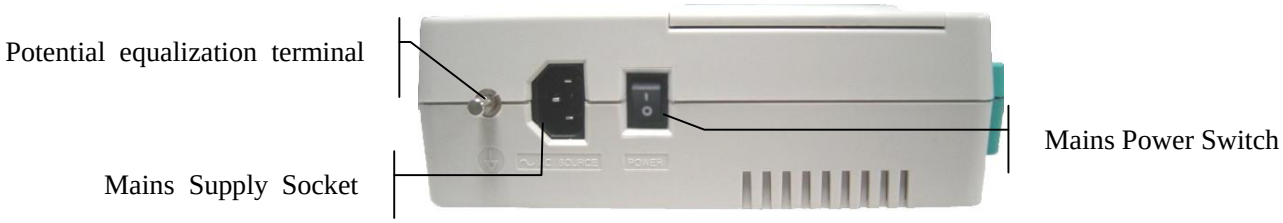
Pin	Signal	Pin	Signal
1	VBUS	**3**	D+
2	D-	**4**	GND

⚠**WARNING**⚠: Only the USB equipments recommended by EDAN can be connected to the USB interface.

⚠**WARNING**⚠:

- Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the standard IEC/EN 60601-1-1. Therefore anybody, who connects additional equipment to the signal input or output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC/EN 60601-1-1. If in doubt, consult our technical service department or your local distributor.
- The summation of leakage current should never exceed leakage current limits while several other units are used at the same time.

3.3 Mains Connection and Switch



1) Potential Equalization Terminal

Potential equalization conductor provides a connection between the unit and the potential equalization bus bar of the electrical installation.

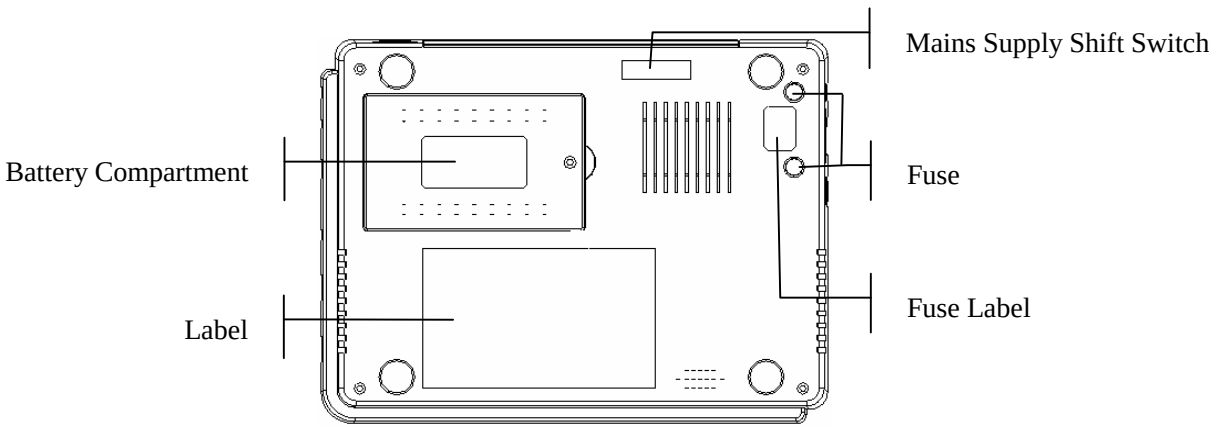
2) Mains Supply Socket

AC SOURCE: alternating current supply socket

3) Power Switch

: Switch on : Switch off

3.4 Bottom Panel



1) Battery Compartment

The battery label indicates the rated voltage and rated capacity of rechargeable Lithium battery pack. Rated voltage: 14.8V, Rated capacity: 2000mAh /2200mAh /2400mAh.

Attention – general warning (see accompanying document)

⚠**WARNING**⚠:

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

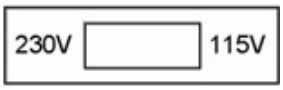
⚠**WARNING**⚠:

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

⚠**WARNING**⚠:

Only qualified service engineer authorized by EDAN can open the battery compartment and replace the battery. And the battery of same model and specification provided by manufacturer must be used.

2) Mains Supply Shift Switch

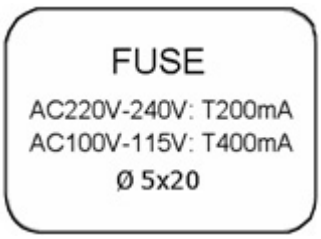


Mains supply with rated input voltage 230V (220V~240V) or 115V (100V~115V) can be chosen by the shift switch according to local mains supply specification.

⚠**WARNING**⚠: Only qualified installation or service engineers can shift the mains shift switch according to local mains supply.

3) Fuse

There are two same fuses installed on the bottom of the main unit. The specification is showed on the fuse label: AC220V-240V: T200mA; AC100V-115V: T400mA; Φ5×20.



⚠**WARNING**⚠: Ruptured fuse must only be replaced with the same type and rating as the original.

4 Operation Preparations

CAUTION:

Before use, the equipment, patient cable and electrodes should be checked. Replace it if there is any evident defectiveness or aging which may impair the safety or performance. And be sure that the equipment is in proper working condition.

4.1 Power and Earthing

WARNING:

If the integrity of external protective conductor in installation or arrangement is in doubt, the equipment should be operated from the built-in rechargeable battery.

Power Supply

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

♦ **Mains supply**

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

Rated input voltage: 100V~115V or 220V~240V

Rated frequency: 50Hz/60Hz

Rated input power: 35VA

Make sure the mains supply meets the above requirements before power on. And then press the mains power switch to power on the unit. Then the mains supply indicator lamp (∿) will be lit.

If the built-in rechargeable battery is weak when mains supply used, it will be recharged automatically at the same time. And both the mains supply indicator lamp (∿) and the battery recharging indicator lamp (→▭) will be lit.

♦ **Built-in rechargeable battery**

While using the built-in rechargeable lithium battery pack, turn on the unit by pressing **ON/OFF** key on control panel directly and the battery indicator lamp (▭) will be lit.

The battery symbol ▭ will be displayed on the LCD screen. Because of the

consumption during storage and transport, the capacity of battery may not be full. If the symbol and the hint information "BAT WEAK" are displayed, which means the battery capacity is weak, please recharge the battery first.

Please refer to the maintenance section for how to recharge the battery. During recharging the battery, SE-3 can be powered by mains supply at the same time.

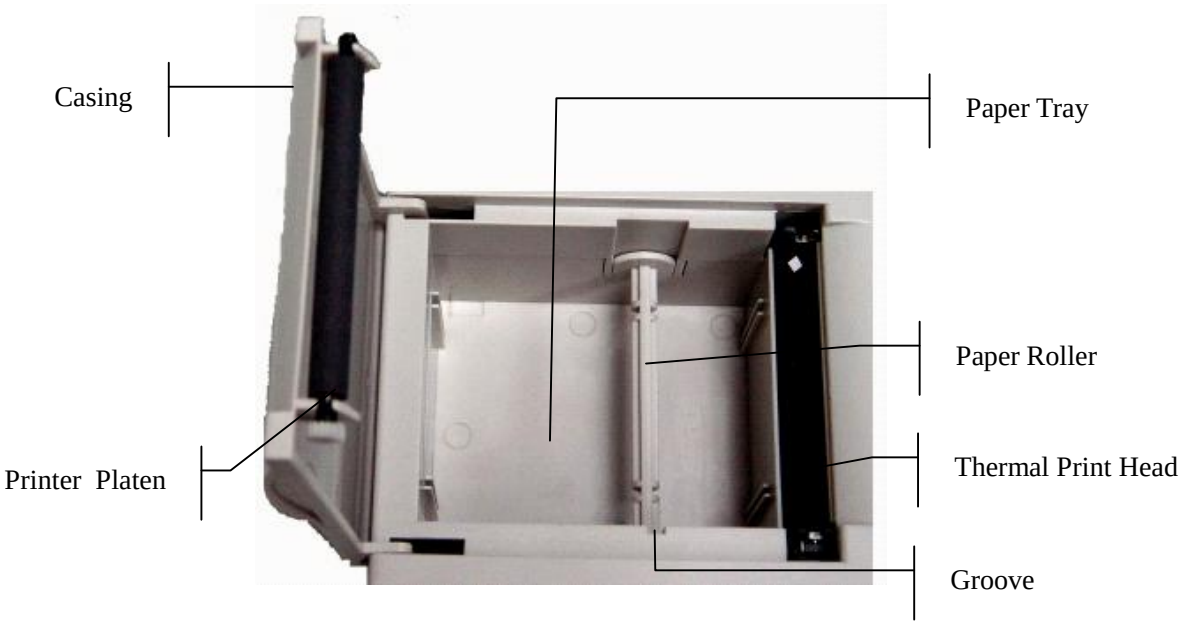
⚠**WARNING**⚠: Potential equalization conductor of the unit should be connected to the potential equalization bus bar of the electrical installation when necessary.

4.2 Loading/Replacing Record Paper

Two kinds of paper can be used as ECG record paper. One is Rolled thermal paper with 80mm width, and the other is folded thermal paper with 80mm width.

Note: When using folded thermal paper, the Paper Roller is unnecessary, and it can be taken out.

When there is no record paper loaded or it reaches the end of record paper, warning message "Paper?" will be given on the screen. Under this circumstance, record paper should be loaded or replaced immediately.



Loading/Replacing Process for Rolled thermal paper:

1) Place fingers under the flange of the recorder casing, pull upwards directly to release the casing;
2) Take out the paper roller, and remove remain paper from the left of roller if necessary;

3) Take off the wrapper of thermal paper roll, and then put through the roller from the left with the paper's grid side facing downward;
4) Place the paper and roller gently in the recorder with the roller pin on the roller's left side facing to the groove;
5) Pull about 2cm of paper out, and put down the recorder casing;
6) Secure the casing by pressing it firmly.

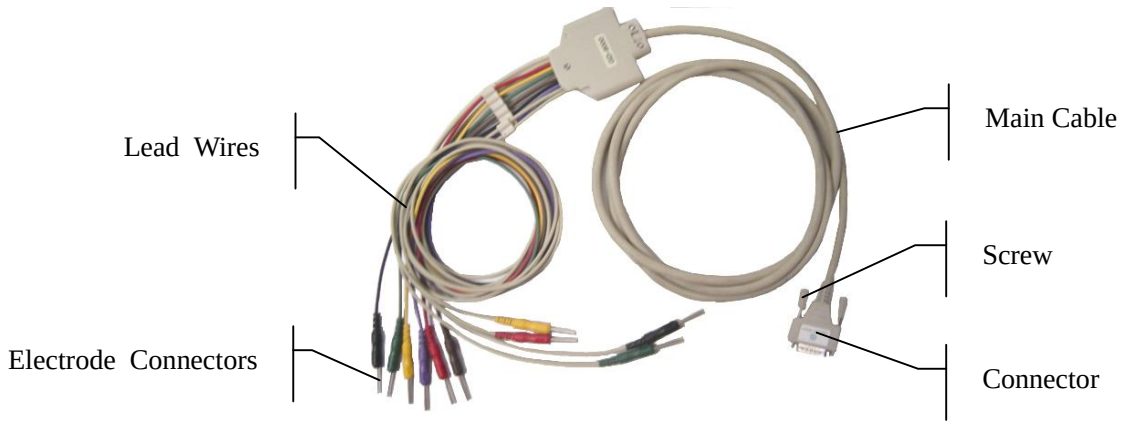
Loading/Replacing Process for Folded thermal paper:

1) Place fingers under the flange of the recorder casing, pull upwards directly to release the casing;
2) Remove residual paper in the Paper Tray if necessary;
3) Take off the wrapper of folded thermal paper, and then put it in the Paper Tray with the paper's grid side facing the thermal print head while put the free end of paper upright;
4) Pull about 2cm of paper out, and put down the recorder casing;
5) Secure the casing by pressing it firmly.

4.3 Patient Cable Connection

⚠**WARNING**⚠: The performance and electric shock protection can be guaranteed only if original EDAN patient cable and electrodes are used.

Patient cable includes two parts, main cable and lead wires with associated connectors, which can be distinguished from the color and identifier on the connectors.

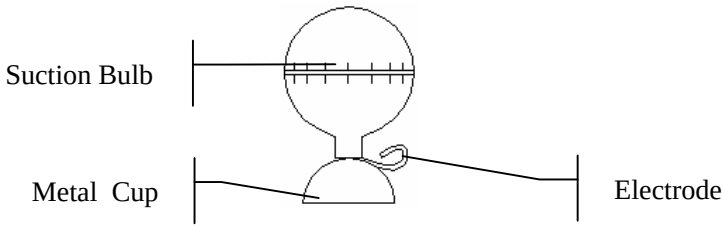


Connect Main Cable:

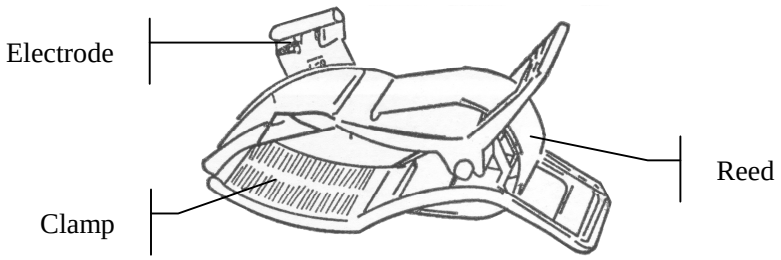
Plug the connector of main cable into the patient cable socket on the right side of the unit according to the direction of arrow on the plug, and then secure it with two screws.

4.4 Electrodes Connections

Chest Electrode:



Limb Electrode:



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

Table 4-1 Electrodes and their identifier and color code

	European		American	
Electrodes	**Identifier**	**Color code**	**Identifier**	**Color code**
Right arm	R	Red	RA	White
Left arm	L	Yellow	LA	Black
Right leg	N or RF	Black	RL	Green
Left leg	F	Green	LL	Red
Chest 1	C1	Red	V1	Red
Chest 2	C2	Yellow	V2	Yellow
Chest 3	C3	Green	V3	Green
Chest 4	C4	Brown	V4	Blue
Chest 5	C5	Black	V5	Orange
Chest 6	C6	Violet	V6	Violet

As the following figure shows, the chest electrodes' position on body surface is

C1: Fourth intercostals space at right border of sternum

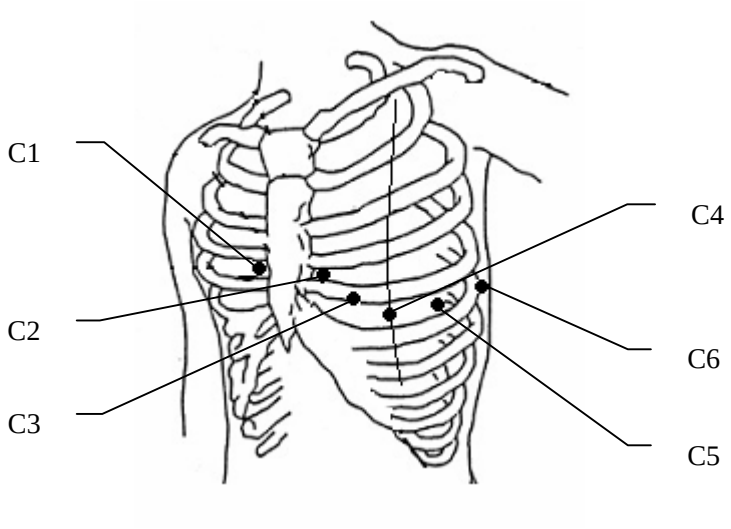
C2: Fourth intercostals space at left border of sternum

C3: Fifth rib between C2 and C4

C4: Fifth intercostals space on left midclavicular line

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

C6: Left midaxillary line at the horizontal level of C4



The contacting resistance between the patient and the electrode will affect the quality of ECG greatly. In order to get a high-quality ECG, the skin/electrode resistance must be minimized while connecting electrodes.

⚠**WARNING**⚠: Be sure that all electrodes have been connected to the patient correctly before operation.

⚠**WARNING**⚠: Be sure that the conductive parts of electrodes and associated connectors, including neutral electrode, should not contact with earth or any other conducting objects.

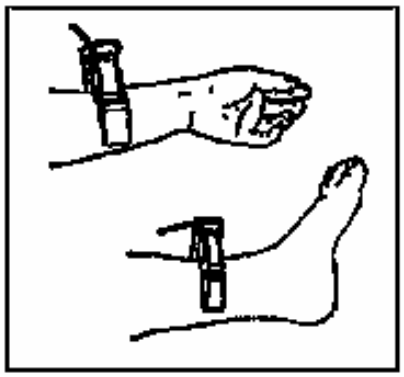
Chest electrodes connection:

1) Ensure the electrodes to be clean firstly;
2) Align all lead wires of patient cable to avoid twisting, and connect the associated electrode connectors with corresponding electrodes according to the color and identifier;
3) Clean electrode area on chest surface with alcohol;
4) Daub the round area of 25mm diameter on each electrode site with gel evenly;
5) Place a small mount of gel on the brim of chest electrode's metal cup;

6) Place the electrode on chest electrode site and squeeze the suction bulb. Unclench it and then the electrode is adsorbed on chest. Attach all chest electrodes in the same way.

Limb electrodes connection:

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



4.5 Inspection before Power On

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

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

2) **Power Supply**:

- If mains power used, please check whether the power cord has been connected to the unit well. And the grounded three-phase outlet should be used.
- Recharge the battery first when the battery capacity is weak before use.

3) **Patient Cable**:

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

4) **Electrodes**:

- Check whether all electrodes have been connected to lead wires of patient cable correctly according to the identifier and color.
- Ensure that the chest electrodes haven't contacted with each other.

5) **Recorder Paper**:

- Ensure that there is enough recorder paper loaded correctly.

6) **Patient**:

- The patient should not contact with conducting object such as earth, and metal part of bed etc.
- Ensure the patient is warm and relaxed, and breathe calmly.

⚠**WARNING**⚠: The electrocardiograph is provided for the use of qualified physicians or personnel professionally trained. And they should be familiar with the contents of this user manual before operation.

5 Operation Instructions

5.1 Switching On

- While using mains supply, press the power switch on the left side of the unit first, and the mains supply indicator lamp (∿) is lit. Then press **ON/OFF** key on the control panel to turn on the unit. Equipment information such as device name and version No. will be displayed on LCD screen after self-test. Then SE-3 is ready for examination and recording.
- While using built-in rechargeable lithium battery, press **ON/OFF** key on the control panel directly to turn on the unit, and then the battery indicator (▭) is lit. After self-test, SE-3 is ready for examination and recording.

5.2 AUTO Mode

Under AUTO mode, the lead groups are switched in order automatically while recording. When ECG signal of one lead group has been recorded, it will be switched to another lead group automatically and begin recording the ECG signal of that lead group. And there is a blank on the recording paper before recording the next ECG signal. Moreover, a 1mV calibration mark will be recorded at the beginning of recording. The lead group switching orders are listed in Table 3-1.

Operation Method:

1) Press **MODE/RST** key to choose AUTO mode, which will be displayed in the top right corner on LCD screen;
2) Press **MENU** key to enter the Menu window to set the record settings. Press it again to return after setup;
3) Press **PRINT/STOP** key to begin recording. It will stop automatically after recording a full 12-lead ECG.

Pressing PRINT/STOP again during the course of recording can stop recording. However, when begin recording later, ECG will be recorded from the first lead group again. And ID number will change automatically according to the current time. If the ID number needs to be unchanged, the user should adjust it before recording.

Note: Whether under auto or manual mode, recording mode can not be changed during the course of recording. Stop recording before choose recording mode.

5.3 MANUAL Mode

Under MANUAL mode, users should switch the lead group manually. Users can determine which lead group needs to be recorded and set the record settings or other parameters according to different lead group.

Operation Method:

1) Press **MODE/RST** key to choose MANUAL mode, which can be discerned by the identifier in the top right corner of LCD screen;
2) Press **MENU** key to enter the Menu window to set the record settings. Press it again to return after setup;
3) Press **LEAD** left arrow or right arrow key to select leads to be recorded;
4) Press **PRINT/STOP** key to begin recording;
5) **1mV/COPY** key can be pressed to print out 1mV mark while ECG recording;
6) Press **PRINT/STOP** key to stop recording after finishing ECG record.

LEAD left and right arrow key can be pressed to switch the lead group during the course of recording. Pressing PRINT/STOP again during the course of recording can stop recording. However, when begin to record later, ID number will change automatically according to the current time. If the ID number needs to be unchanged, the user should adjust it before recording.

5.4 RHYTHM mode

Under Rhythm mode, the user can record 60s rhythm-lead ECG waveform.

1) Press **MENU** key to enter the Menu window to set the RHYTHM LEAD or other settings. Press it again to return after setup;
2) Press **MODE/RST** key to choose RHYTHM mode;
3) Press **PRINT/STOP** key and the hint information “Sampling” will be displayed in the hint information field, at the same time, response time will be counted. When the response time reaches 60s, it begins to record;
4) It will stop automatically after recording a full rhythm-lead ECG waveform.

Pressing PRINT/STOP again during the course of recording can stop recording.

5.5 USBPRT mode

Under USBPRT mode, ECG report can be printed out through USB printer.

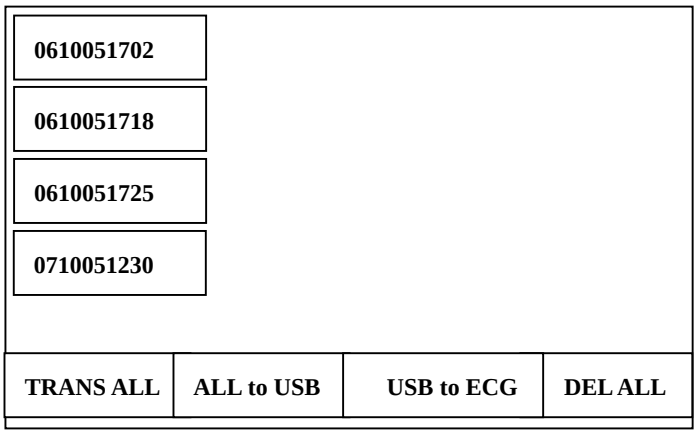
1) Connect SE-3 to the USB printer recommended by EDAN;
2) Press **MENU** key to enter Menu window to set corresponding options. Press it again to return after setup;
3) Press **MODE/RST** key to choose USBPRT mode;
4) Press **PRINT/STOP** key to begin recording. It will stop automatically after recording a full ECG report.

5.6 ECG Recall Operation

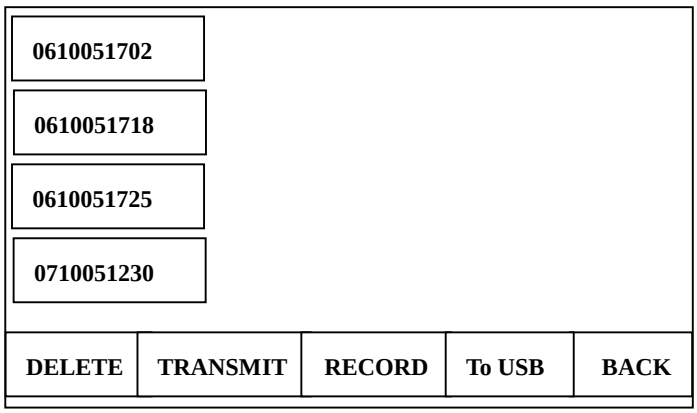
5.6.1 ECG Recall

Press **RECALL** key to enter the recall window where patient files are saved. The recall window allows files to be stored, deleted, printed and transmitted. When there is no space for more files to be stored in the recall window, the message “MemFull” is displayed.

Recall Window (a)



Recall Window (b)

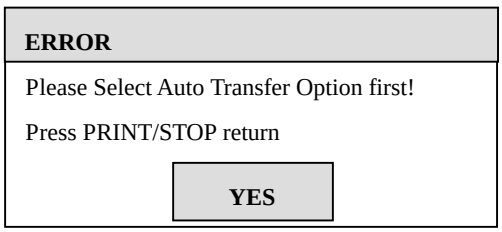


Operation for ECG RECALL:

1) Press **RECALL** key to enter the Recall Window (a) where patient files are saved;

2) If the user wants to transmit all the files, press **Up** or **Down** to choose **TRANS ALL**, and then press **PRINT/STOP** or **MENU** key to transmit all the files; If the "Auto Transfer" option is not selected before transmitting, WARNING (a) will pop up to remind the user to do it first.

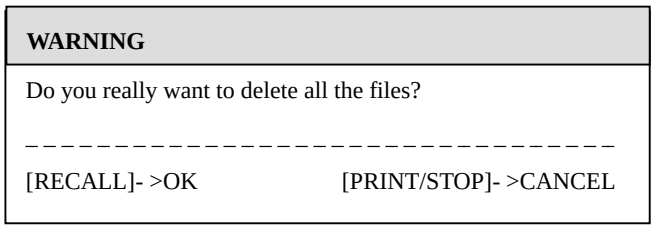
WARNING (a)



Note: Before transmitting patient files, please set the AUTO TRANSFER option in Menu window. Refer to **5.8.3.6 Transfer Settings** for detail.

3) If the user wants to delete all the files, press **Up** or **Down** to choose **DEL ALL**, and then press **PRINT/STOP** or **MENU** key to pop up the WARNING(b). Then press **RECALL** to delete all the files or **PRINT/STOP** to cancel deleting;

WARNING (b)



4) If the user wants to copy all the files from the electrocardiograph to the U disk, press **Up** or **Down** to choose **ALL to USB**, and then press **PRINT/STOP** or **MENU** key to begin to copy; after a while, all the files will be copied into the ECGDATA folder of the U disk automatically.

During the course of **ALL to USB**, if something wrong happens, the electrocardiograph will give the error information. And then the user should check whether the U disk is connected well, and correct it.

If the user wants to import files (The extended-name should be ".dat") from the ECGDATA folder of the U disk to the electrocardiograph, press **Up** or **Down** to choose **USB to ECG**, and then press **PRINT/STOP** or **MENU** key to begin to import;

Note: To import files in U disk to electrocardiograph, there should be some files in the folder named ECGDATA in the U disk. The folder name "ECGDATA" must be capital letters. And the user should not change the name of files in the ECGDATA folder.

During the course of **USB to ECG**, if something wrong happens, the electrocardiograph will give the error information. And then the user should do the following operations:

Firstly, check whether the U disk is connected well, and correct it.

If the error information is still displayed, the user should check whether some files exist in the ECGDATA folder of the U disk. If nothing is found, the user should build a folder named ECGDATA in the U disk and put some files (The extended-name is ".dat") into the ECGDATA folder.

If the error information is still displayed, then the user should check whether the total number of files in the ECGDATA folder of the U disk and in the recall window of the electrocardiograph has exceeded the limit (The limit of SE-3(192 × 64 dot single color LCD screen) is 120; The limit of SE-3(320 × 240 dot single color LCD screen) is 144). If the total number has exceeded the limit, the user should remove some files from the ECGDATA folder of the U disk and then continue to import.

If the error information is still displayed, then the user should check whether there are some files in the U disk having the same name with the files in the electrocardiograph. If it is true, the user should remove these files from the U disk, or delete these files in the electrocardiograph, and then continue to import. (Under this situation, this error information is "The same file found! Press PRINT/STOP return".)

After finishing importing files, the electrocardiograph will give a distinct indication.

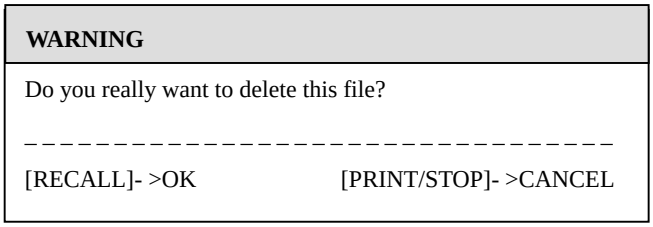
Note: The process of **TRANS ALL**, **ALL to USB** or **USB to ECG** needs long time to be finished, and the user should be patient to wait. During the course of copying, the U disk should not be pulled out.

Note: Only FAT format should be selected when formatting the U disk.

For one file, press **Up, Down, Left or Right** to choose one of the files in the recall window; Press **PRINT/STOP** or **MENU** key, and five operation buttons will come up on the bottom of recall window. They are **DELETE**, **TRANSMIT**, **RECORD**, **TO USB** and **BACK** (See Recall Window(b));

Press **Up** or **Down** to choose **DELETE** button, and then press **PRINT/STOP** or **MENU** key to pop up the WARNING(c). Then press **RECALL** to delete this file or **PRINT/STOP** to cancel deleting;

WARNING (c)



Press **Up** or **Down** to choose **TRANSMIT** button, and then press **PRINT/STOP** or **MENU** key to transmit the file; If the "Auto Transfer" option is not selected before transmitting, WARNING (a) will pop up to remind the user to do it first.

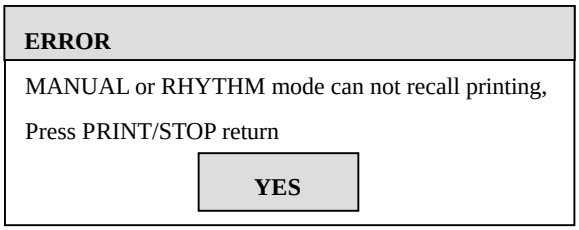
Press **Up** or **Down** to choose **RECORD** button, and then press **PRINT/STOP** or **MENU** key to begin recording; Pressing **PRINT/STOP** again during the course of recording can stop recording.

Note: If the user selects USBPRT mode to print, when PRINT/STOP key or MENU key is pressed, the electrocardiograph begins to analyze data, and after 8 seconds the USB printer begins to print.

Note: MANUAL or RHYTHM mode can not support recall printing.

If the user selects MANUAL or RHYTHM mode to record, WARNING (d) will pop up.

WARNING (d)



Press **Up** or **Down** to choose **To USB**, and then press **PRINT/STOP** or **MENU** key to begin to copy;

5) After finish recording, press **Up** or **Down** to choose **BACK** button, and then press **PRINT/STOP** or **MENU** key to return to the recall window(a);

6) Press **RECALL** key to return to the main interface.

Note: To save the ECG data to the recall window as patient files, please refer to **5.8.3.5 Save Option Settings**.

5.6.2 ECG Copy

Under auto mode, once the hint information "COPY" appears in the hint information field on the LCD screen, pressing **1mV/Copy** key can recall the electrocardiogram that was recorded last time.

Pressing PRINT/STOP during the course of recording can stop recording.

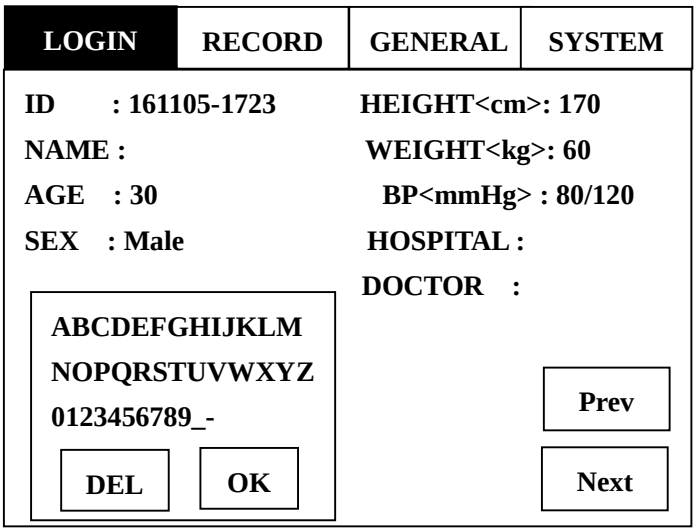
Note: After recording is finished, if RECORD FORMAT or SAMPLE MODE is changed, ECG Copy is not permitted.

5.7 Using the Menu System

5.7.1 Entering and Exiting the Menu

- **Menu (320×240 dot single color)**

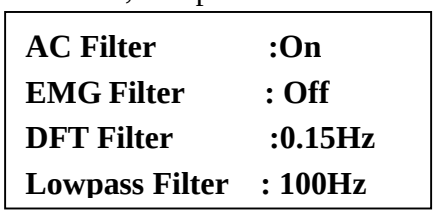
There are four Setup windows in the menu, LOGIN, RECORD, GENERAL and SYSTEM. Press the **MENU** key to enter the menu. And press the **MENU** key again to exit the menu.



320×240 dot single color LCD Screen

- **Menu (192×64 dot single color)**

Press the **MENU** key to enter the menu, and press the **MENU** key again to exit the menu.



192×64 dot single color LCD Screen

5.7.2 Moving in the Sub-menus

Press **Up** or **Down** to choose the setting items;

5.7.3 Parameter Modification

Press **Left** or **Right** to modify a parameter;

Note: When modifying Record Mode or Sensitivity on the main interface, to save the modifications, the user should enter the menu interface and exit. After that, the user will see the modifications in the main interface when he turns on the

electrocardiograph again.

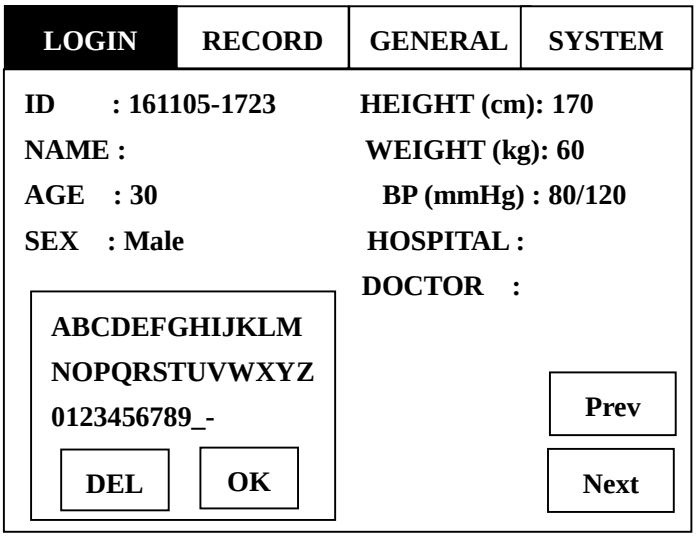
5.7.4 Switching between the Setup Windows (only for 320×240 dot single color LCD Screen)

Press **Up** or **Down** to choose **Prev** or **Next**, and then press **Left** or **Right** to switch to the previous or next setup window;

5.8 Settings (320×240 dot single color LCD screen)

5.8.1 LOGIN Settings

In the LOGIN Settings window, the user can input or edit patient information.



Note: The patient information can not be set or changed during the course of recording.

ID : Patient ID No. HEIGHT (cm): Patient Height (Range: 0~255)

NAME : Patient Name (Within 11 character) WEIGHT (kg): Patient Weight (Range: 0~255)

AGE : Patient Age (Range: 0~99)

BP (mmHg): Patient Systaltic Pressure/Diastole Pressure

SEX : Patient Gender (Male/Female) HOSPITAL: Hospital Name

DOCTOR: Doctor Name

Method to enter Name:

1) Press **Up** or **Down** to choose the Name item, and a textbox will come up after the Name item;
2) Press **Left** or **Right** and the textbox will display reversed. That means the letters and

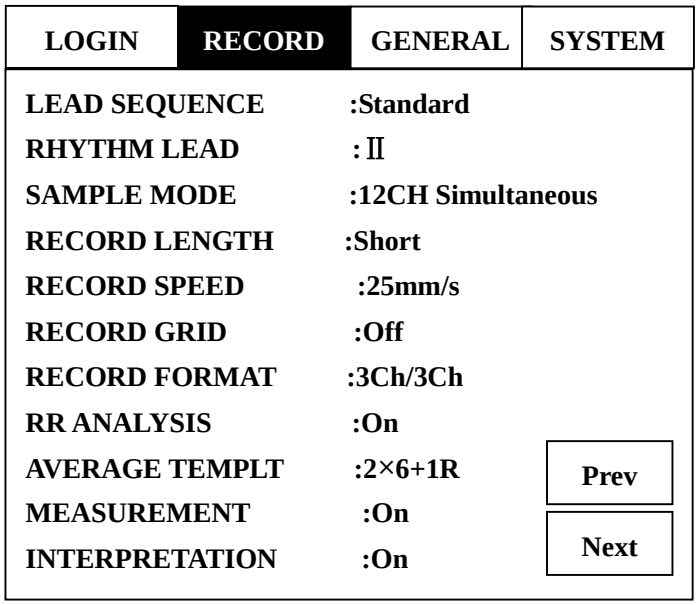
numbers in the pane can be selected to enter the textbox by pressing **Up**, **Down, Left** or **Right**. After selecting a letter or number, **MENU** key should be pressed to confirm.

3) If something wrong is entered, to delete wrong letter, firstly press **Up**, **Down, Left** or **Right** to choose the **DEL** item, and then press **MENU** key to delete the wrong letter.

4) After the name is finished, press **Up**, **Down, Left** or **Right** to choose **OK** item, and press **MENU** key to confirm.

The user can enter HOSPITAL name and DOCTOR name with the same method above.

5.8.2 RECORD Settings



5.8.2.1 Lead Settings

LEAD SEQUENCE: Standard/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

RHYTHM LEAD:

The rhythm lead can be one of 12 standard leads: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, and V6.

5.8.2.2 Sample Mode Settings

1CH Sequential:

Lead is sampled one by one in a certain sequence.

3CH Sequential:

Lead group is sampled one by one in a certain sequence.

12CH Simultaneous:

All leads are sampled simultaneously.

5.8.2.3 Recording Settings

RECORD LENGTH

Short form means that each lead group will be recorded about 2.5 seconds.

Medium form means that each lead group will be recorded about 5 seconds.

Long form means that each lead group will be recorded about 7.5 seconds.

Longest form means that each lead group will be recorded about 10 seconds.

RECORD SPEED

Under MANUAL/RHYTHM mode, **RECORD SPEED** can be set as 5, 6.25, 10, 12.5, 25 or 50mm/s.

Under AUTO/OFF/USBPRT mode, **RECORD SPEED** can be set as 25 or 50mm/s.

RECORD GRID

When **RECORD GRID** is **On**, the dashed grids which are 5 mm by 5 mm will be recorded on the paper.

When **RECORD GRID** is **Off**, dashed grids will not be recorded on the paper.

RECORD FORMAT

When **RECORD FORMAT** is **3Ch/3Ch**, all leads will be recorded in 4 groups of 3.

When **RECORD FORMAT** is **3Ch/2Ch**, lead I, II, III, aVR, aVL and aVF will be recorded in 2 groups of 3, and lead V1, V2, V3, V4, V5 and V6 will be recorded in 3 groups of 2.

When **RECORD FORMAT** is **1Ch+1R**, all leads will be recorded one by one in a sequence, with one rhythm lead at the bottom of recoding paper.

When **RECORD FORMAT** is **1Ch**, all leads will be recorded one by one in a sequence.

When **RECORD FORMAT** is **3Ch+1R**, all leads will be recorded in 4 groups of 3, with one rhythm lead at the bottom of recoding paper.

RR ANALYSIS

When **RR ANALYSIS** is **On**, RR Analysis results, including RR Interval measurement information, RR Histogram and RR Trend Chart, will be recorded after rhythm wave is recorded in RHYTHM mode.

When **RR ANALYSIS** is **Off**, there will be no RR Analysis results after rhythm wave is recorded in RHYTHM mode.

AVERAGE TEMPLT

When AVERAGE TEMPLT is **2×6+1R/4×3**, AVERAGE TEMPLT will be recorded with the format of **2×6+1R** or **4×3**.

The format of **2×6+1R** means that leads are averaged over the entire 10 second recording and recorded in 2 groups of 6, with the one rhythm lead at the bottom of page.

The format of **4×3** means that leads are averaged over the entire 10 second recording and recorded in 4 groups of 3.

When AVERAGE TEMPLT is **Off**, there will be no average template when recording.

5.8.2.4 Measurement and Interpretation

In MEASUREMENT function, those common parameters, such as Heart Rate, P-R interval, QRS complex duration, Q-T interval, P/QRS/T axis, RV5/SV1 amplitude etc. can be automatically measured.

The INTERPRETATION function provides automatic diagnosis for hundreds of abnormal cases, such as Arrhythmia, AV Block, Ventricular Conduction Block, Myocardial Infarction, Ventricular Hypertrophy and Atrial Enlargement, ST-T Abnormality and Electrical Axes Deviation.

MEASUREMENT

When MEASUREMENT is **On**, the measure information will be recorded when recording in AUTO mode.

When MEASUREMENT is **Off**, there will be no measure information when recording.

INTERPRETATION (Optional)

When INTERPRETATION is **On**, interpretation information will be recorded when recording.

When INTERPRETATION is **Off**, there will be no interpretation information when recording.

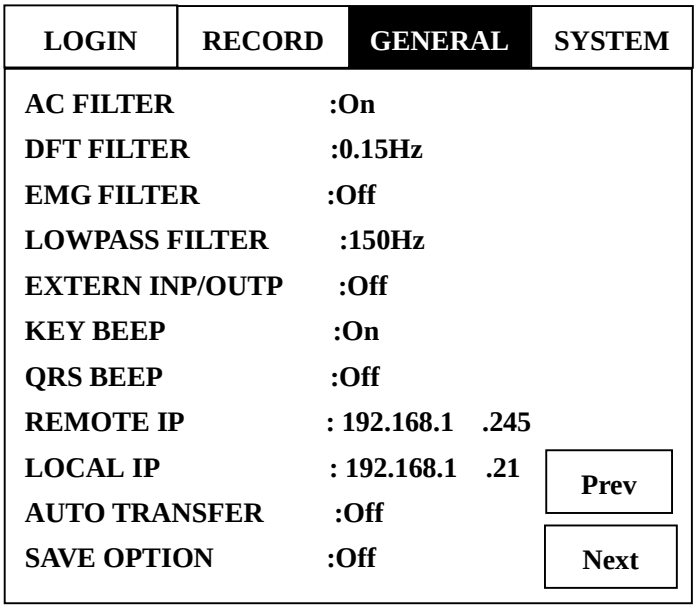
Note: To get the content of MEASUREMENT and INTERPRETATION, please refer to **Chapter 5.9 ECG Record**.

5.8.2.5 Parameter Options

In the Options column, the value double underlined is default settings.

No.	Items	Options
1	LEAD SEQUENCE	Standard, Cabrera
2	RHYTHM LEAD	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
3	SAMPLE MODE	1CH Sequential, 3CH Sequential, 12CH Simultaneous
4	RECORD LENGTH	Short, Medium, Long, Longest
5	RECORD SPEED	25mm/s, 50mm/s, 5mm/s, 6.25mm/s, 10 mm/s, 12.5mm/s
6	RECORD GRID	Off ,On
7	RECORD FORMAT	3Ch/3Ch, 3Ch/2Ch, 1Ch+1R, 1Ch, 3Ch+1R
8	RR ANALYSIS	Off ,On
9	AVERAGE TEMPLATE	2×6+1R, Off, 4×3
10	MEASUREMENT	Off ,On
11	INTERPRETATION(Optional)	Off ,On

5.8.3 GENERAL Settings



5.8.3.1 Filter Settings

Four filters can be set in the **GENERAL Settings** window. They are: AC FILTER、DFT FILTER、EMG FILTER and LOWPASS FILTER.

AC FILTER

AC FILTER suppresses AC interference without attenuating or distorting the ECG. Select **On** to turn on the function and select **Off** to turn off.

DFT FILTER

DFT FILTER greatly reduces the baseline fluctuations without affecting the ECG signal. The purpose of this filter is to keep the ECG signals on the baseline of the printout. The setting value is the low limit of the frequency range, including **0.05Hz**, **0.15Hz**, **0.25H**z, **0.5Hz**, and is normally set to **0.15**Hz.

EMG FILTER

EMG FILTER suppresses disturbances caused by strong muscle tremor. The cutoff frequency is user-defined at **25Hz, 35Hz** or **45Hz**. Select **Off** to turn off the function.

LOWPASS FILTER

LOWPASS FILTER restricts the bandwidth of input signal. The cutoff frequency is user defined at **150Hz**, **100Hz** or **75Hz**. All the input signals whose frequency is higher than the setting cutoff frequency will be attenuated.

5.8.3.2 External Input/Output Settings

External input/output signal interface is equipped in SE-3, through which SE-3 can receive ECG signal from external equipment, or output ECG signal to other external equipment. Set this item as **On** to turn on the function and **Off** to turn off.

5.8.3.3 Key Beep & QRS Beep Settings

KEY BEEP Setting

When KEY BEEP is **On**, a short beep sound will be made when press the control key.

When KEY BEEP is **Off**, there is no sound while pressing the key.

QRS BEEP Setting

During the course of ECG recording, if QRS BEEP is **On**, the unit will make a short beep sound when an R wave has been detected. So in normal recording, continuous and regular sound of beep will be heard.

5.8.3.4 IP Settings

REMOTE IP

IP address of the remote computer which receives ECG data from electrocardiograph through net

LOCAL IP

IP address of electrocardiograph

5.8.3.5 Save Option Settings

When SAVE OPTION is **On**, the ECG data will be saved into the recall window automatically while it is being recorded in AUTO recording mode.

When SAVE OPTION is **Off**, the ECG data will not be saved into the recall window while it is being recorded in AUTO recording mode.

Note: When there is no space for more files to be stored in the recall window, the message ”MemFull” is displayed.

5.8.3.6 Transfer Settings

Note: To transfer ECG data to PC machine, Smart ECG-Viewer software of EDAN must be installed in PC machine. Receive ECG Data window in the software should be opened up, transfer type should be selected, and other settings should be finished.

AUTO TRANSFER

When **AUTO TRANSFER** is **OFF**, the patient files can not be transferred;

When **AUTO TRANSFER** is **UART AUTO**, firstly connect the serial port of PC machine and the RS232 socket of 3-channel electrocardiograph with serial cable recommended by the manufacturer. Then open the Receive ECG Data window of Smart ECG-Viewer software in PC, select the transfer type "Serial Trans", set the right PortNum and press **Connect** button. Under AUTO mode or OFF mode, ECG data can be transferred through UART port automatically after ECG recording is finished.

When **AUTO TRANSFER** is **Net AUTO**, firstly connect the net interface of PC machine and the net interface of 3-channel electrocardiograph with Ethernet cable recommended by the manufacturer. Secondly open the Receive ECG Data window of Smart ECG-Viewer software in PC, select the transfer type "Net Trans" and press **Connect** button. Then set the REMOTE IP and LOCAL IP in Menu window in 3-channel electrocardiograph. Under AUTO mode or OFF mode, ECG data can be transferred through net automatically after ECG recording is finished.

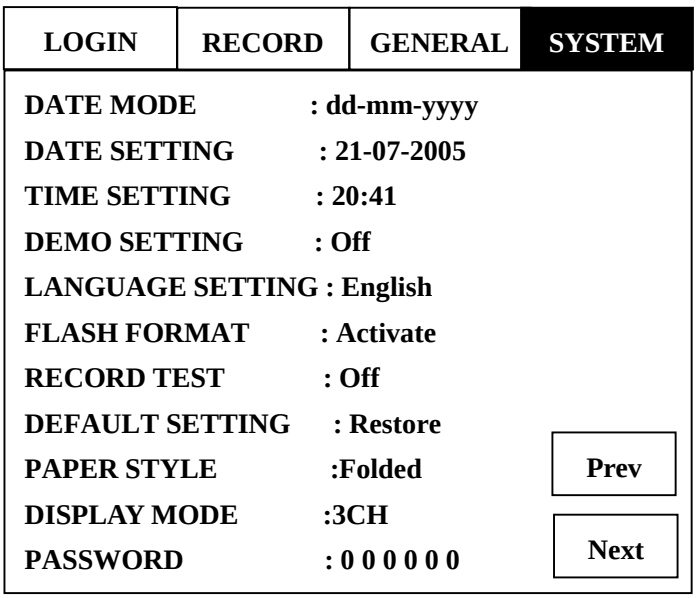
Note: During the course of transferring or saving data, if the power supply is suddenly cut off, File System error may arise in the electrocardiograph. After the error is displayed, the user should format the File System.

5.8.3.7 Parameter Options

In the Options column, the value double underlined is default settings.

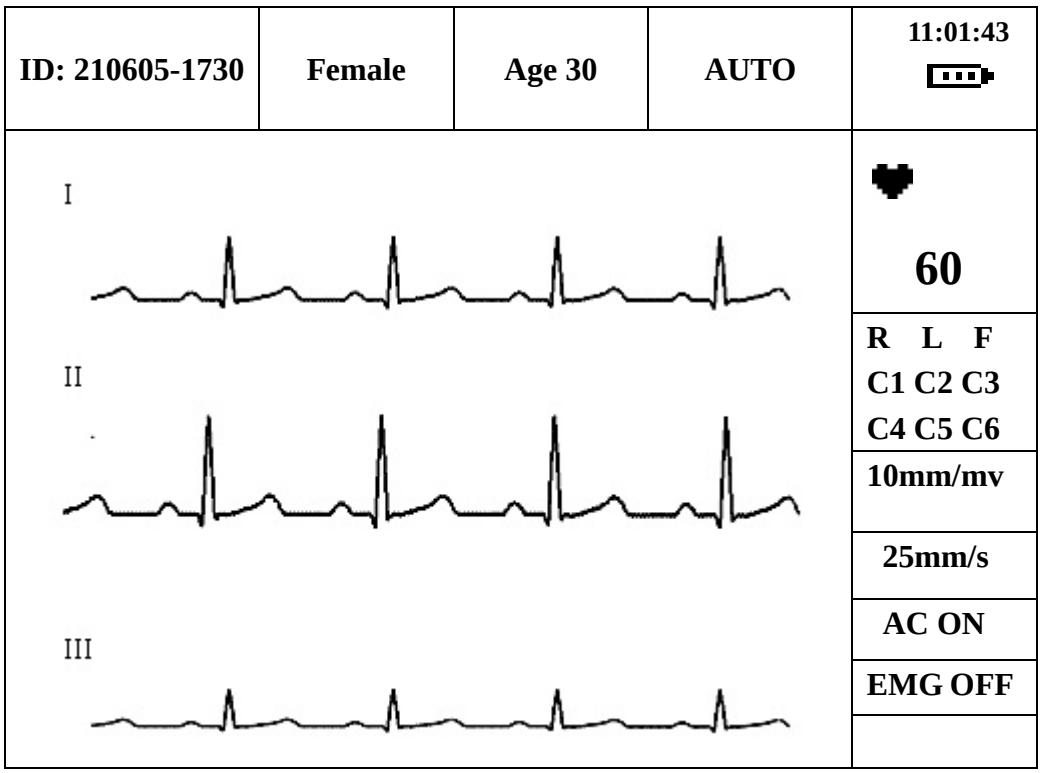
No.	Items	Options
1	AC FILTER	On, Off
2	DFT FILTER	0.05Hz, 0.15Hz, 0.25Hz, 0.5Hz
3	EMG FILTER	OFF, 45Hz, 35Hz, 25Hz
4	LOWPASS FILTER	150Hz, 100Hz, 75Hz
5	EXTERN INPUT/OUTPUT	On, Off
6	KEY BEEP	On, Off
7	QRS BEEP	On, Off
8	AUTO TRANSFER	Off, UART AUTO, Net AUTO
9	SAVE OPTION	On, Off

5.8.4 SYSTEM Settings

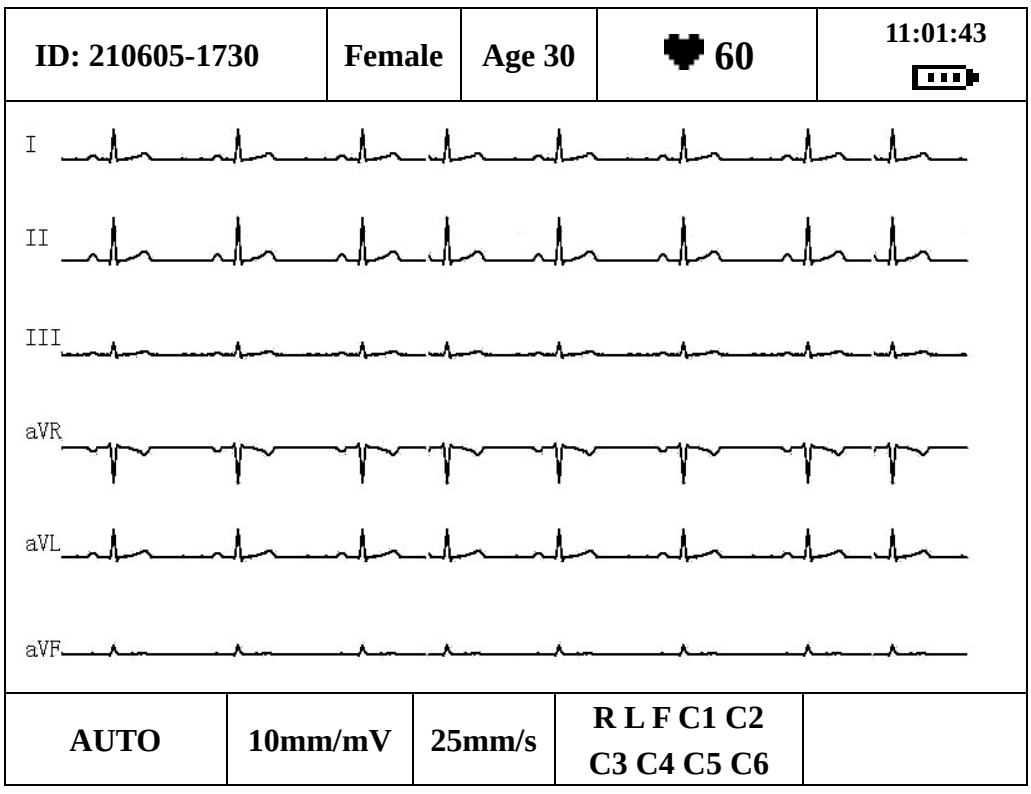


5.8.4.1 Display Mode Settings

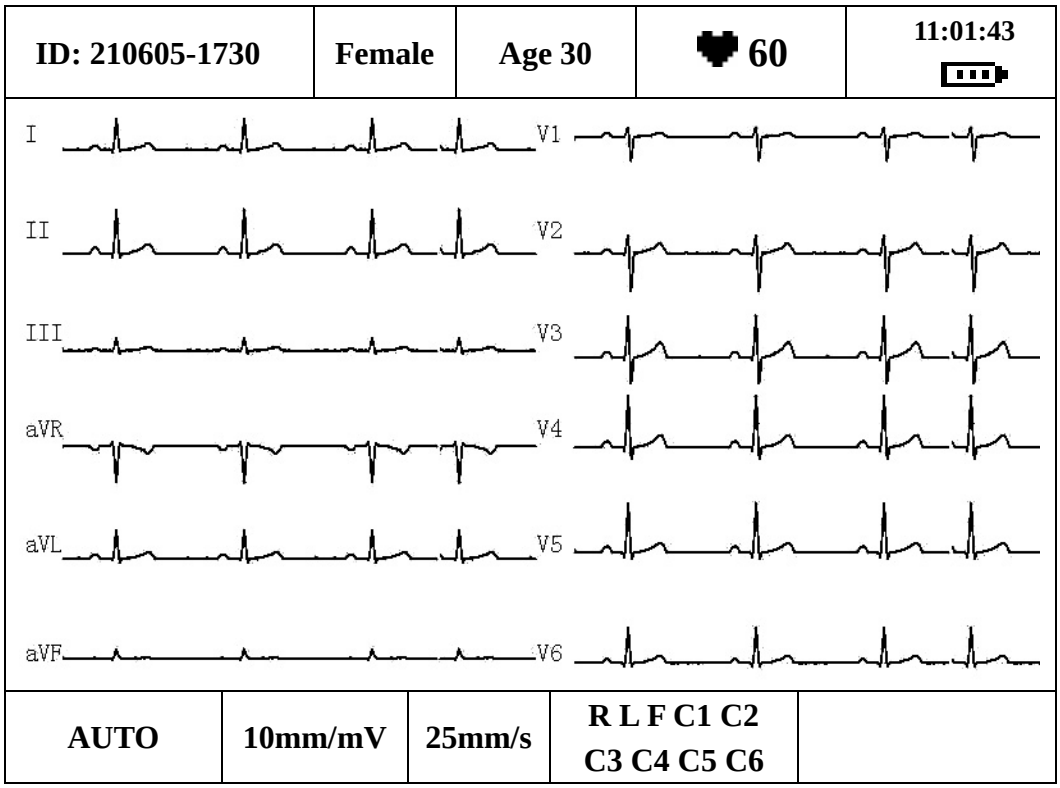
Three display modes can be selected: 3CH, 6CH and 12CH. And the display interface shows as follows.



3CH Display Mode



6CH Display Mode



12CH Display Mode

DATE MODE: Date mode can be set as dd-mm-yyyy, mm-dd-yyyy or yyyy-mm-dd. After set, the current date format will change according to the DATE MODE you selected.

DATE&TIME SETTING: Set current Date and time. It will be recorded on the record paper.

DEMO SETTING: Select **On** to enter the Demo mode.

LANGUAGE SETTING: The user can set the system language.

FLASH FORMAT: Select **Activate** to pop up the WARNING "Do you really want to format the file system?" And then press RECALL key to format the file system; press PRINT/STOP key to cancel operation.

RECORD TEST: Press **Left** or **Right** to start record test when the record paper has been loaded. Then the triangle wave in effective paper width will be recorded. The status of print head can be estimated from this triangle wave. Press **Left** or **Right** again to stop record test.

DEFAULT SETTING: Select **Restore** to resume default setting value.

Note: In the Parameter Options Column, some parameters' options have no underline, which means these parameters have no default settings. And when the user restores default settings, these parameters will not change.

PAPER STYLE: Record paper style. Rolled thermal paper and folded thermal paper can be selected as record Paper.

Note: If the user sets the PAPER STYLE as Folded paper, when recording in Auto mode or RHYTHM mode, recording will not stop until a black sign is met.

PASSWORD: Password for entering the advanced control interface

5.8.4.2 Parameter Options

In the Options column, the value double underlined is default settings.

No.	Items	Options
1	DATE MODE	dd-mm-yyyy, mm-dd-yyyy, yyyy-mm-dd
2	RECORD TEST	Testing, Off
3	DEFAULT SETTING	Restore
4	PAPER STYLE	Folded, Rolled
5	DISPLAY MODE	3CH, 6CH, 12CH

5.8.5 Settings (192×64 dot single color)

Note: The common menu items of the two kinds of device have common functions. Please refer to the function explanation of 320×240 dot single color LCD screen.

AC Filter :On
EMG Filter : Off
DFT Filter :0.15Hz
Lowpass Filter : 100Hz

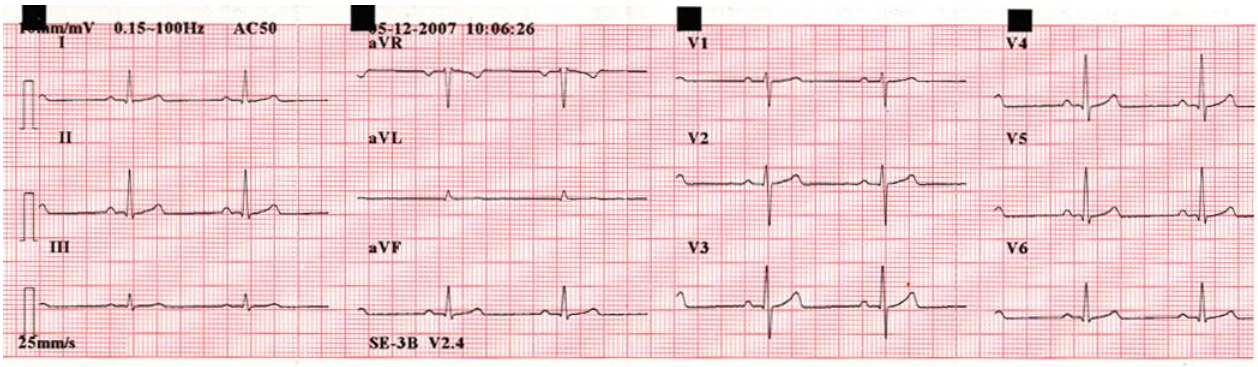
192×64 dot single color LCD Screen

Press **Up** or **Down** to switch to the next setting interface and view the setting items. The setting items in the menu of 192×64 dot single color LCD screen are as follows:

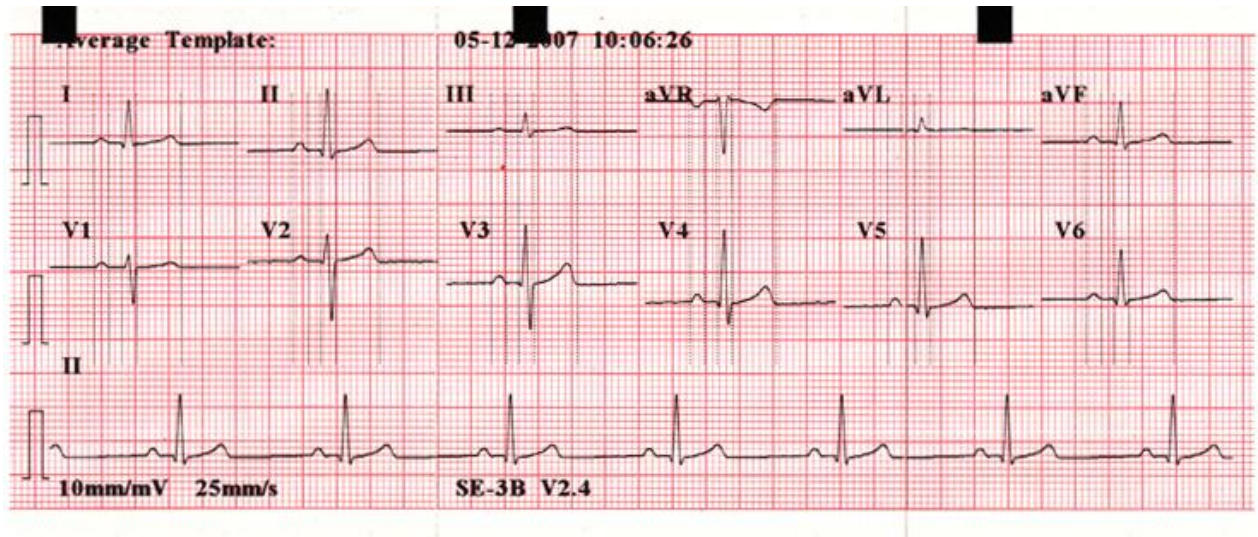
No.	Items	Explanation
1	AC Filter	Refer to **Chapter 5.8.3.1**
2	EMG Filter	
3	DFT Filter	
4	Lowpass Filter	
5	Record Format	Refer to **Chapter 5.8.2.3**
6	Record Grid	
7	Record Speed	

8	Record Length	
9	Average Template	
10	Measurement	Refer to **Chapter 5.8.2.4**
11	Interpretation	
12	RR Analysis	Refer to **Chapter 5.8.2.3**
13	Lead Sequence	Refer to **Chapter 5.8.2.1**
14	Sample Mode	Refer to **Chapter 5.8.2.2**
15	Rhythm Lead	Refer to **Chapter 5.8.2.1**
16	Paper Style	Refer to **Chapter 5.8.4**
17	Save Option	Refer to **Chapter 5.8.3.5**
18	Auto Transfer	Refer to **Chapter 5.8.3.6**
19	Local IP	Refer to **Chapter 5.8.3.4**
20	Remote IP	
21	Key Beep	Refer to **Chapter 5.8.3.3**
22	QRS Beep	
23	Extern Inp/Outp	Refer to **Chapter 5.8.3.2**
24	Record Test	Refer to **Chapter 5.8.4**
25	Demo Setting	
26	Language Setting	
27	Flash Format	
28	Default Setting	
29	Data Mode	
30	Date Setting	
31	Time Setting	
32	ID	Refer to **Chapter 5.8.1**
33	Password	Password for entering the advanced control interface

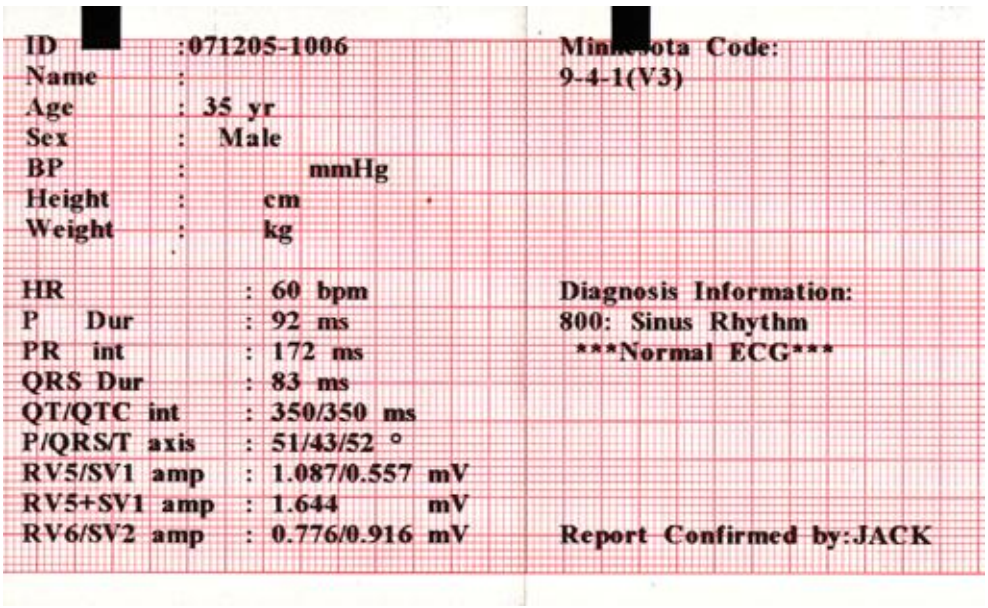
5.9 AUTO mode record



(a)



(b)



(c)

Figure (a) shows the following content:

10mm/mV----Sensitivity 0.15~100Hz----Filter information

AC50----50Hz AC Filter 05-12-2007 10:06:26----Date and time

⎍----1mV calibration mark

I, II, III, V1, V2, V3, V4, V5, V6, aVR, aVL, aVF----Lead name

ECG wave of 12 leads in the format of 3Ch/3Ch

25mm/s----Paper speed

SE-3B V2.4----Model of the equipment and version number

Figure (b) shows the AVERAGE TEMPLET when set the item as 2×6+1R in the Menu window.

Figure (c) shows the MEASUREMENT and INTERPRETATION when set the two items as ON in the Menu window. And the items of the MEASUREMENT include:

ID, Name, Age, Sex, BP, Height, Weight, HR (Heart Rate)

P Dur----P wave duration: mean of duration of P-wave from several of 12 selected dominant beats;

PR int----P-R interval: mean of P-R interval from several of 12 selected dominant beats;

QRS Dur----QRS complex duration: mean of duration of QRS complexes from several of 12 selected dominant beats;

QT/QTC int----Q-T interval: mean of Q-T interval from several of 12 selected dominant beats/Normalized QT interval;

P/QRS/T axis----dominant direction of the average integrated ECG vectors;

RV5/SV1 amP----The maximum of amplitude of R or R' wave of one selected dominant beat from lead V5/ The maximum of amplitude of S or S' wave of one selected dominant beat from lead V1;

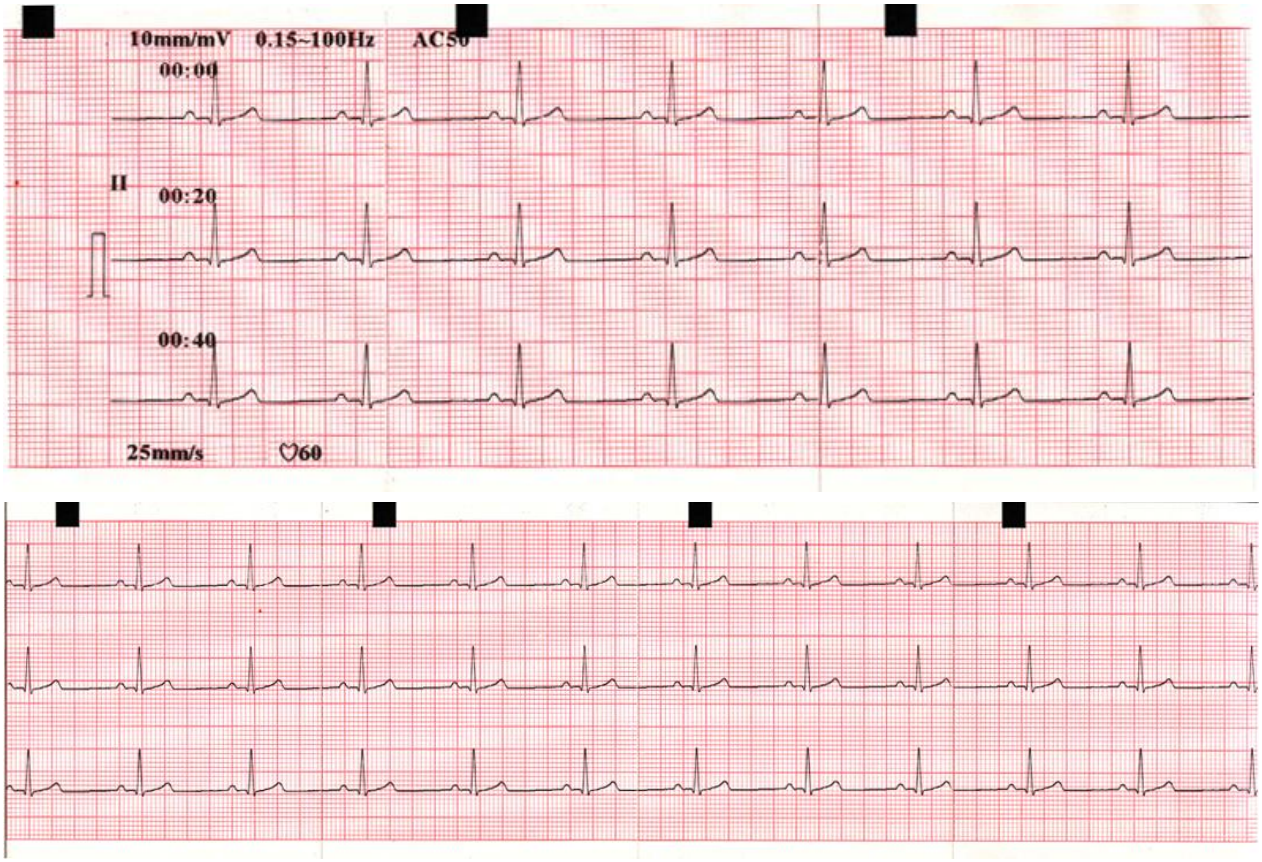
RV5+SV1 amP---- Sum of RV5 and SV1;

RV6/SV2 amP---- The maximum of amplitude of R or R' wave of one selected dominant beat from lead V6/ The maximum of amplitude of S or S' wave of one selected dominant beat from lead V2;

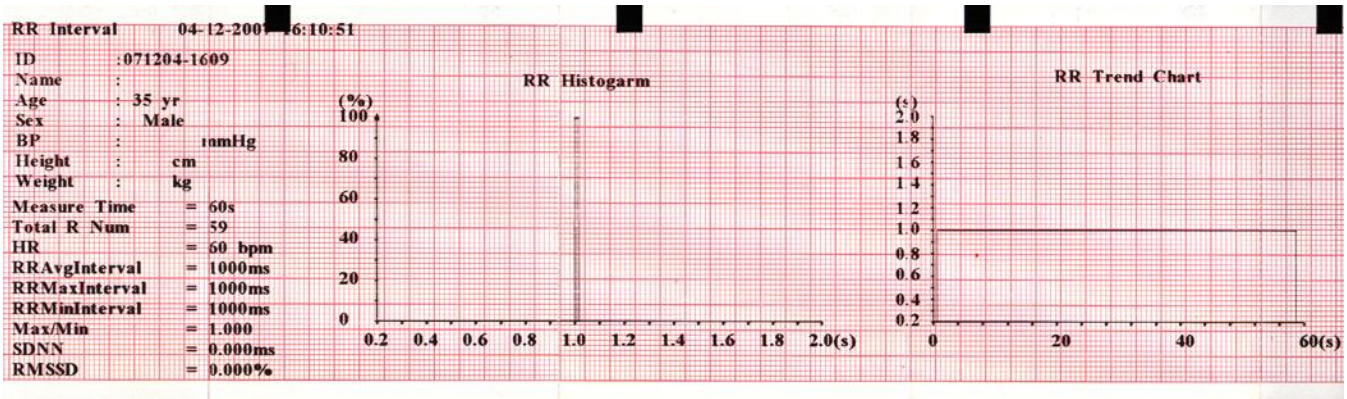
The items of the INTERPRETATION include: Minnesota Code, Diagnosis Information and Report Confirmed by.

Note: Recording under AUTO mode or MANUAL mode, if the Sensitivity is set as 20mm/mV, only one calibration mark will be displayed on the paper.

5.10 RHYTHM mode record



(a)



(b)

Figure (a) shows the following content:

10mm/mV (Sensitivity)

0.15~100Hz (Filter information)

AC50 (50Hz AC Filter)

⎍ (1mV calibration mark)

II (Lead name）

60 seconds rhythm waveform of lead II

00:00, 00:20, 00:40 (Timer）

25mm/s (Paper speed）

♡60 (Heart rate）

Figure (b) shows RR Analysis Results, including RR Interval measurement information, RR Histogram and RR Trend Chart.

RR Interval measurement information includes the following content:

Current Date & Current Time

Patient Information (ID, Name, Age, Sex, BP, Height, Weight)

Measure Time

Total R Num (Total R-wave number)

HR (Heart Rate)

RR Avg Interval (Average RR interval)

RR Max Interval (Maximum RR interval)

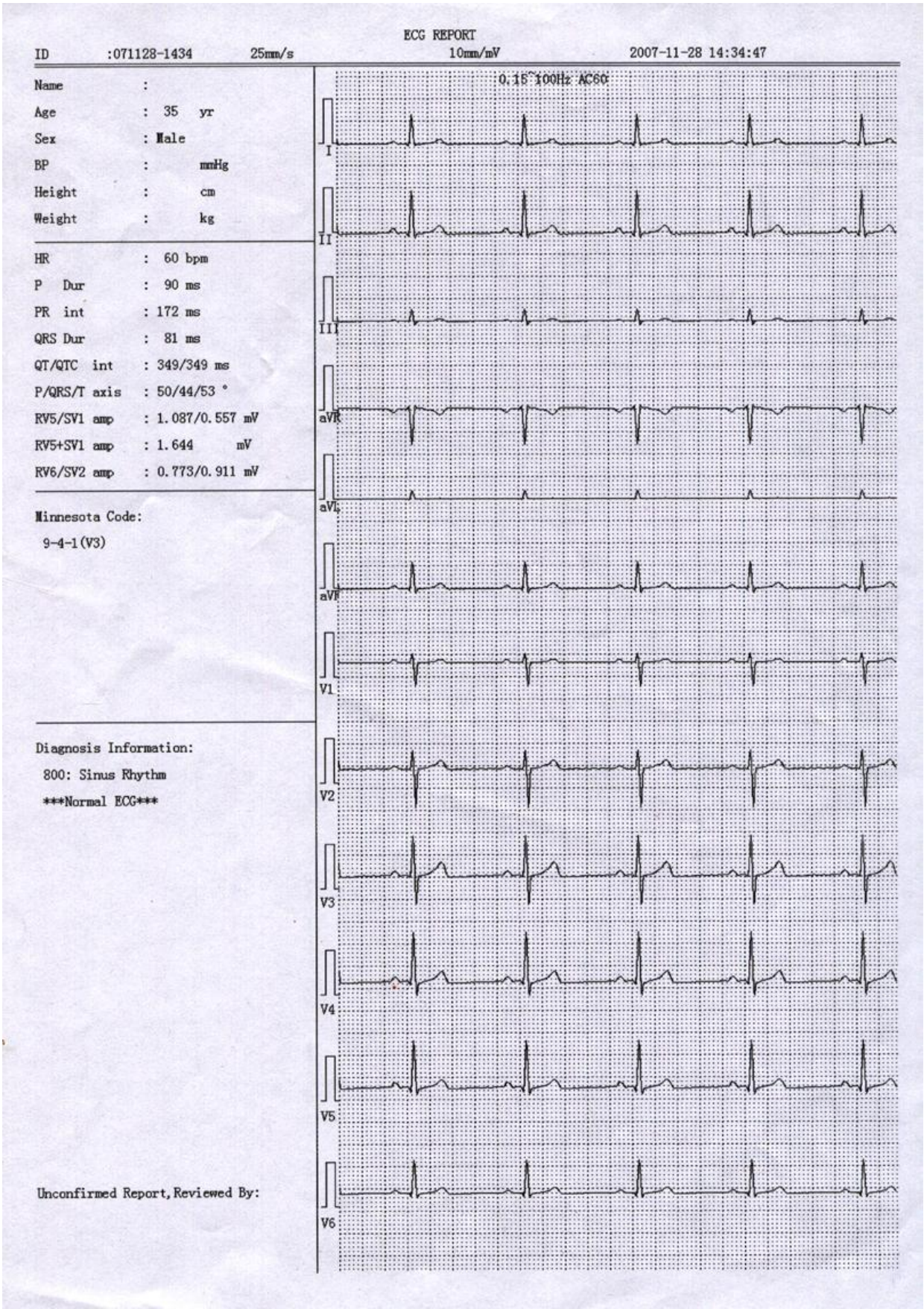
RR Min Interval (Minimum RR interval)

Max/Min (Ratio of Maximum RR interval to Minimum RR interval)

SDNN (Standard Deviation of Normal to Normal Intervals)

RMSSD (The Root Mean Square Successive Difference)

5.11 USBPRT mode record



As figure above shows, the USBPRT mode record includes:

ID, Record speed, Sensitivity, Date and time;

Name, Age, Sex, BP, Height, Weight;

Heart Rate, P duration, PR interval, QRS duration, QT/QTC interval, P/QRS/T axis, RV5/SV1 amplitude, RV5+SV1 amplitude, RV6/SV2 amplitude;

Minnesota code;

Diagnosis information;

Unconfirmed Report, Review By;

ECG waveform of 12 leads;

5.12 Switch Off

When built-in battery pack used, press **ON/OFF** key directly to turn off the unit after finishing ECG record.

When mains supply used, press **ON/OFF** key first after finishing ECG record and then switch off the mains supply by pressing the switch on the left side of the unit. Pull off the plug from the outlet last.

Note: When switching off the device, please operate it according to the sequence above strictly, or else there will be something wrong on the screen.

6 Hint Information

Hint information will be displayed in the bottom right corner of LCD screen when there is something wrong. Hint information provided by SE-3 and corresponding cause is listed in Table 6-1.

Table 6-1 Hint Information and Causes

Hint Information	Causes
Lead off	Electrodes fall off from the patient or the patient cable falls off from the unit.
BAT WEAK	The built-in battery is weak.
Paper?	Record paper has not been loaded or it has been run out.
PaperErr	Feed paper error.
Sampling/Printing	ECG signal is being sampled / Printed.
Modu Err	There is something wrong with the signal sample module.
Demo	The system is in demonstration mode.
Copy	The ECG data recorded last time is ready to be reviewed.
Process	The ECG data is being processed.
Transfer	The patient file in recall window is being transferred through UART port or Ethernet.
MemFull	There is no space for more files to be saved.
Overload	The direct current voltage on an electrode is too high.
Uprinter	An USB printer is connected to the USB interface.
USBExist	An U disk is connected to the USB interface.

7 Technical Specifications

Safety Standards	1) EN 60601-1: 1990(A1 + A2), 2) IEC/EN 60601-1-2: 2001, 3) IEC/EN 60601-2-25, 4) ANSI/AAMI EC-11.		
Classification	Anti-electric-shock type:	Class I with internal power supply	
	Anti-electric-shock degree:	Type CF	
	Degree of protection against harmful ingress of water:	Ordinary equipment (Sealed equipment without liquid proof)	
	Disinfection/sterilization method:	Refer to the user manual for details	
	Degree of safety of application in the presence of flammable gas:	Equipment not suitable for use in the presence of flammable gas	
	Working mode:	Continuous operation	
	EMC:	Group I, type A	
Dimensions	288mm×210mm×70mm		
Weight	About 2.5kg		
Display	320×240 dot single color LCD Screen 192×64 dot single color LCD Screen		
Environment		Transport/Storage	Working
	Temperature:	-20℃~+55℃	+5℃~+40℃
	Relative Humidity:	25%~93% Non-Condensing	25%~80% Non-Condensing
	Atmospheric Pressure:	700hPa ~1060hPa	860hPa ~1060hPa
Power Supply	Mains Supply:	Rated input voltage =100V~115V/220V~240V	
		Rated frequency = 50/60Hz	
		Rated input power = 35VA	
	Built-in Lithium Battery Pack:	Rated voltage = 14.8V	
		Rated capacity = 2000mAh /2200mAh /2400mAh	

		When the capacity of battery is full, SE-3 can work continuously at least 249 minutes.
		Charge mode: Constant current/voltage
		Charge current (standard) = $0.2C_5A$ (320mA)
		Charge voltage (standard) = (17±0.1V)
		Cycle life ≥ 300 times
	Power Consumption:	35VA (max)
	Fuse:	T400mA250V Ø5×20/T200mA 250V Ø5×20
Recording	Recorder:	Thermal dot-matrix printer
	Record Paper:	Folded thermal paper, 80mm width Rolled thermal paper, 80mm width
	Effective Width:	72mm
	Paper Speed:	5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s, 50mm/s（±3%）
	Accuracy of data:	±5% (x-axis), ±5%(y-axis)
HR Recognition	Technique:	Peak-peak detection
	HR Range:	30 BPM ~300 BPM
	Accuracy:	±1BPM
ECG Unit	Leads:	12 standard leads
	Acquisition Mode:	simultaneously 12 leads
	A/D Resolution:	12 bits
	Time Constant:	≥3.2s
	Frequency Response:	0.05Hz ~ 150Hz
	Sensitivity:	2.5, 5, 10, 20 (mm/mV)
	Input Impedance:	50MΩ(10Hz)
	Input Circuit Current:	≤50nA
	Input Voltage Range:	<±5 mVpp
	Calibration Voltage:	1mV±3%

	DC Offset Voltage:	±500mV
	Noise:	<12.5㎷ Vp-p
	Multichannel crosstalk:	≤0.5mm
	Filter:	AC Filter: On/Off
		DFT Filter: 0.05/0.15/0.25/0.5
		EMG Filter: 25Hz/35Hz/45Hz/OFF
		LOWPASS Filter:150Hz/100Hz/75Hz
	CMRR:	≥110dB
	Sampling Frequency:	1000Hz
Patient Leakage Current:		<10㎂ A (220V~240V)
Patient Auxiliary Current:		<0.1㎂ A (DC)
Dielectric Strength:		4000V rms
External Input/Output (Optional)	Input:	≥100kΩ; Sensitivity 10mm/V±5%; Single ended
	Output:	≤100Ω; Sensitivity 1V/mV±5%; Single ended

8 Clean, Care and Maintenance

8.1 Clean

CAUTION:

Turn off the power before cleaning and disinfection. Mains supply must be switch off if it has been in use.

8.1.1 Clean the Main Unit and Patient Cable

The surface of the main unit and patient cable can be wiped with a clean soft cloth damped in soapy water or non-caustic neutral detergent. After that, remove detergent remainder with a clean dry cloth.

8.1.2 Clean the Electrodes

Remove the remainder gel from the electrodes with a clean soft cloth first. Take the suction bulb and mental cup of chest electrodes apart, and take the clamp and the metal part of the limb electrodes apart. Clean them in warm water and be sure there is no remainder gel. Dry the electrodes with a clean dry cloth or air dry naturally.

8.1.3 Clean the Print Head

Dirty and soiled thermal print head will deteriorate the record definition. So it should be cleaned at least once a month regularly.

Open the recorder casing and remove the paper. Wipe the print head gently with a clean soft cloth damped in 75% alcohol. For stubborn stain, soak it with a little alcohol first and wipe it off with a clean soft cloth. After air dried, load the record paper and shut the casing of the recorder.

CAUTION:

Prevent the detergent from seeping into the main unit while cleaning. Do not immerse the unit or patient cable into liquid under any circumstances.

CAUTION:

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

8.2 Disinfection

To avoid permanent damage to the equipment, disinfection can be performed only when it has been considered as necessary according to your hospital's regulations.

Before disinfection clean the equipment first. Then wipe the surface of the unit and patient cable with hospital standard disinfectant.

CAUTION:

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

8.3 Care and Maintenance

8.3.1 Recharge and Replacement of Battery

1) Capacity Identification

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

: Full capacity

: Capacity is limited, and recharge should be taken into account

: Battery is weak; and warning message "BAT WEAK" will be displayed on LCD screen. The battery should be recharged immediately

2) Recharge

SE-3 is equipped with recharge control circuit together with built-in rechargeable lithium battery. When connect with the mains supply, the battery will be recharged automatically. And then the battery recharge indicator lamp (→) and the mains supply indicator lamp (~) will be lit at the same time. During the course of recharging, the symbol " " will flash in the top right corner of LCD screen. When the capacity of battery is full, the symbol " " will stop flashing, and the battery recharge indicator lamp (→) will usually be black. But if SE-3 is power off, the lamp will still lit just because the equipment will not monitor the recharge status; so you need to power on the device to verify the status.

Because of the capacity consumption during storage and transport, the capacity of battery is not full while using at the first time. Battery recharge should be considered before first

usage.

Note: If the battery has not been used for two or three months above, recharge should be done before use the battery again.

3) Replacement

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

⚠**WARNING**⚠:

- Only qualified service engineer authorized by EDAN can open the battery compartment and replace the battery. And the battery of same model and specification provided by manufacturer must be used.
- Danger of explosion -- Do not reverse the anode and cathode when connecting the battery.
- When the battery's useful life is over, contact with the manufacturer or local distributor for disposal or dispose the battery according to local regulations.

8.3.2 Record Paper

Note: Record paper provided by manufacturer should be used. Other paper may shorten thermal print head's life. And the deteriorated print head may lead to illegible ECG record and block the advance of paper etc.

Storage requirements:

- Record paper should be stored in dry, dark and cool area, avoiding excessive temperature, humidity and sunshine.
- Do not put the paper under fluorescence for long time.
- Be sure that there is no polyvinyl chloride or other chemicals in the storage environment, which will lead to color change of the paper.
- Do not overlap the recorded paper long time, or else the ECG record may trans-print each other.

8.3.3 Maintenance of Main Unit, Patient Cable & Electrodes

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

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

b) Inspect the safety relevant labels for legibility.

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

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

e) Test the protection earth resistance according to IEC/EN 60601-1: Limit 0.2ohm.

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

g) Test the patient leakage current according to IEC/EN 60601-1: Limit: 10uA (CF).

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

The leakage current should never exceed the limit. The data should be recorded in an equipment log. If the device is not functioning properly or fails any of the above tests, the device has to be repaired.

⚠**WARNING**⚠: Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

1) Main Unit

- Avoid excessive temperature, sunshine, humidity and dirt.
- Put on the dustproof coat after use and prevent from shaking violently when moving it to another place.
- Prevent any liquid from seeping into the equipment, for it will affect the safety and performance of electrocardiograph.

2) Patient Cable

- Integrity of patient cable, including main cable and lead wires, should be checked regularly. And be sure that it is conductible.
- Do not drag or twist the patient cable with excessive stress while using. Hold the connector plugs instead of the cable when connect or disconnect the patient cable.
- Align the patient cable to avoid twisting, knotting or crooking in closed angle while using.
- Store the lead wires in bigger wheel to prevent any people from stumbling.
- Once damage or aging of the cable patient has been found, replace it with a new one immediately.

3) Electrodes

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

CAUTION:

The equipment should be sent to the special agencies according to local regulation for separate collection after its useful life.

9 Accessories

⚠**WARNING**⚠: Only patient cable and other accessories supplied by EDAN can be used. Or else, the performance and electric shock protection can not be guaranteed.

Table 9-1 Accessories List

No.	Accessory	Manufacturer / Part Number
1	Power cord	EDAN / M13-36014
2	Patient cable	Tsingtao KOHDEN / MS1-18503
3	Chest electrodes	Tsingtao KOHDEN / MS1-18504
4	Limb electrodes	Tsingtao KOHDEN / MS1-18505
5	Paper roller	EDAN / MS1-19927
6	Thermal paper	EDAN / MS1-19917
7	Earth wire	EDAN / MS2-01952
8	Input/output signal cable	EDAN / MS1-19907
9	Cable for electrodes with defibrillator protection	EDAN / MS1-20035
10	Electrode	MSB1010
11	Carrying case	EDAN

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

Manufacturer:

EDAN INSTRUMENTS, INC.

Address: 3/F - B, Nanshan Medical Equipments Park, Nanhai Rd 1019#, shekou, Nanshan Shenzhen, 518067 P.R. China

Zip code: 518067

Tel: +86-755-26882220

Fax: +86-755-26882223

10 Warranty & Service Policy

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 period begins on the date the products are shipped to distributors.

The warranty is void in cases of:

a) damage caused by handling 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.

Service Policy

All repairs on products must be performed or approved by EDAN. Unauthorized repairs will void the warranty. In addition, whether or not covered under warranty, any product repair shall be exclusively be performed by EDAN certified service personnel.

If the product fails to function properly - or if you need assistance, service, or spare parts - contact EDAN's service center. A representative will assist you troubleshooting the problem and will make every effort to solve it over the phone or Email, avoiding potential unnecessary returns.

In case a return can not be avoided, the representative will record all necessary information and will provide a Return Material Authorization (RMA) form that includes the appropriate return address and instructions. An RMA form must be obtained prior to any return.

Freight policy:

Under warranty: the service claimer is responsible for freight & insurance charges when a return

is shipped to EDAN for service including custom charges. EDAN is responsible for freight, insurance & custom charges from EDAN to service claimer.

Out of warranty: the service claimer is responsible for any freight, insurance & custom charges for product.

Contact information:

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

Telephone: +86-755-2689-9221, 2689-9914

Fax: +86-755-2689-8330

Email: support@edan.com.cn

11 EMC Information - Guidance and Manufacture's Declaration

11.1 Electromagnetic Emissions - for all EQUIPMENT and SYSTEMS

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

11.2 Electromagnetic Immunity - for all EQUIPMENT and SYSTEMS

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

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

11.3 Electromagnetic Immunity - for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture's declaration – electromagnetic immunity			
The *Electrocardiograph* is intended for use in the electromagnetic environment specified below. The customer or the user of *Electrocardiograph* should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the *Electrocardiograph*, including cables, than the

			recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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 the *Electrocardiograph* is used exceeds the applicable RF compliance level above, the *Electrocardiograph* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *Electrocardiograph*.

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

11.4 Recommended Separation Distances

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
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.

EDAN INSTRUMENTS, INC.

3/F - B, Nanshan Medical Equipments Park, Nanhai Rd 1019#, shekou, Nanshan

Shenzhen, 518067 P.R. China

TEL:86-755-26882220 FAX: ＋86-755-26882223

EC REPRESENTATIVE

Shanghai International Holding Corp. GmbH (Europe)

Eiffestrasse 80, D-20537 Hamburg Germany

TEL: +49-40-2513175 FAX: +49-40-255726

E-mail: antonjin@yahoo.com.cn