User Manual

EDAN

SE-1201

Electrocardiograph

Version 1.0

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About this Manual

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Statement

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

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Responsibility of the Manufacturer

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

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

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

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

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

Terms Used in this Manual

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

WARNING

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

CAUTION

A **CAUTION** label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

NOTE: A NOTE provides useful information regarding a function or a procedure.

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Chapter 1 Safety Guidance

This chapter provides important safety information related to the use of the 12-channel electrocardiograph.

1.1 Intended Use

The intended use of SE-1201 12-channel electrocardiograph (hereinafter called SE-1201) is to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. However, the interpreted ECG with measurements and interpretive statements is offered to clinicians on an advisory basis only.

WARNING

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

1.2 Warnings and Cautions

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

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

1.2.1 Safety Warnings

WARNING

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

WARNING

2. Only qualified service engineers can install this equipment, and only service engineers authorized by the manufacturer can open the shell.
3. **EXPLOSION HAZARD** - Do not use the electrocardiograph in the presence of flammable anesthetic mixtures with oxygen or other flammable agents.
4. **SHOCK HAZARD** - The power receptacle must be a hospital grade grounded outlet. Never try to adapt the three-prong plug to fit a two-slot outlet.
5. Make sure that the power is turned off and the power cord is disconnected from the AC socket before connecting or disconnecting equipment. Otherwise, electrical shock or other injuries may happen to the patient or operator.
6. If the integrity of the external protective conductor is in doubt, the equipment should be powered by an internal li-ion rechargeable battery.
7. Do not use this equipment in the presence of high static electricity or high voltage equipment which may generate sparks.
8. Only the patient cable and other accessories supplied by the manufacturer can be used. Or else, the performance and electric shock protection can not be guaranteed.
9. Make sure that all electrodes are connected to the patient correctly before operation.
10. Ensure that the conductive parts of electrodes and associated connectors, including neutral electrodes, do not come in contact with earth or any other conducting objects.
11. If reusable electrodes with electrode gel are used during defibrillation, the electrocardiograph recovery will take more than 10 seconds. The manufacturer recommends the use of disposable electrodes at all times.
12. Electrodes of dissimilar metals should not be used; otherwise it may cause a high polarization voltage.
13. The disposable electrodes can only be used for one time.
14. The electrocardiograph has been safety tested with the recommended accessories, peripherals, and leads, and no hazard is found when the electrocardiograph is operated with cardiac pacemakers or other stimulators.
15. Do not touch the patient, bed, table or the equipment while using the ECG together with a defibrillator.
16. Do not touch accessible parts of non-medical electrical equipment and the patient simultaneously.

WARNING

17. The use of equipment that applies high frequency voltages to the patient (including electrosurgical equipment and some respiration transducers) is not supported and may produce undesired results. Disconnect the patient data cable from the electrocardiograph, or detach the leads from the patient prior to performing any procedure that uses high frequency surgical equipment.
18. If the wireless AP technology is used, in order to maintain compliance with the FCC RF exposure guidelines, the wireless AP should be installed and operated with a minimum distance of 20cm between the radiator and the human body. There should be no shield in or around the room where the wireless AP is used.
19. Fix attention on the examination to avoid missing important ECG waves.
20. **SHOCK HAZARD** - Don't connect non-medical electrical equipment, which has been supplied as a part of the system, directly to the wall outlet when the non-medical equipment is intended to be supplied by a multiple portable socket-outlet with an isolation transformer.
21. **SHOCK HAZARD** - Don't connect electrical equipment, which has not been supplied as a part of the system, to the multiple portable socket-outlet supplying the system.
22. Do not connect any equipment or accessories that are not approved by the manufacturer or that are not IEC/EN 60601-1-1 approved to the electrocardiograph. The operation or use of non-approved equipment or accessories with the electrocardiograph is not tested or supported, and electrocardiograph operation and safety are not guaranteed.
23. Any non-medical equipment (such as the external printer) is not allowed to be used within the patient vicinity (1.5m/6ft.).
24. Do not exceed the maximum permitted load when using the multiple portable socket-outlet(s) to supply the system.
25. Multiple portable socket-outlets shall not be placed on the floor.
26. Do not use the additional multiple portable socket-outlet or extension cord in the medical electrical system, unless it's specified as part of the system by manufacturer. And the multiple portable socket-outlets provided with the system shall only be used for supplying power to equipment which is intended to form part of the system.
27. Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the standard IEC/EN 60601-1-1.

WARNING

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.

28. Parts and accessories used must meet the requirements of the applicable IEC/EN 601 series safety standards, and/or the system configuration must meet the requirement of the IEC/EN 60601-1-1 medical electrical systems standard.

29. Connecting any accessory (such as external printer) or other device (such as the computer) to this electrocardiograph makes a medical system. In that case, additional safety measures should be taken during installation of the system, and the system shall provide:

    a) Within the patient environment, a level of safety comparable to that provided by medical electrical equipment complying with IEC/EN 60601-1, and

    b) Outside the patient environment, the level of safety appropriate for non-medical electrical equipment complying with other IEC or ISO safety standards.

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

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

1.2.2 Li-ion Battery Care Warnings

WARNING

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

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

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

WARNING

4. Do not heat or splash the battery or throw it into fire or water.
5. Do not destroy the battery; Do not pierce battery with a sharp object such as a needle; Do not hit with a hammer, step on or throw or drop to cause strong shock; Do not disassemble or modify the battery.
6. When leakage or foul smell is found, stop using the battery immediately. If your skin or cloth comes into contact with the leakage liquid, cleanse it with clean water at once. If the leakage liquid splashes into your eyes, do not wipe them. Irrigate them with clean water first and go to see a doctor immediately.
7. Properly dispose of or recycle the depleted battery according to local regulations.
8. Only when the device is off can the battery be installed or removed.
9. Remove the battery from the electrocardiograph when the electrocardiograph isn't used for a long time.
10. If the battery is stored alone and not used for a long time, we recommend that the battery be charged at least once every 6 months to prevent overdischarge.

1.2.3 General Cautions

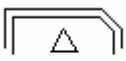
CAUTION

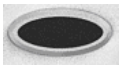
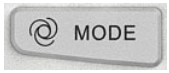
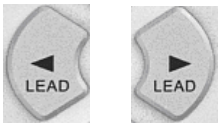
1. Avoid liquid splash and excessive temperature. The temperature must be kept between 5 ºC and 40 ºC during operation, and it should be kept between -20 ºC and 55 ºC during transportation and storage.
2. Do not use the equipment in a dusty environment with bad ventilation or in the presence of corrosive.
3. Make sure that there is no intense electromagnetic interference source around the equipment, such as radio transmitters or mobile phones etc. Attention: large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment etc. is likely to bring electromagnetic interference.
4. Ruptured fuse must only be replaced with that of the same type and rating as the original.

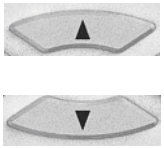
CAUTION

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

1.3 List of Symbols

	External output
	External input
	Equipment or part of CF type with defibrillator proof
	Caution
	Consult Instructions for Use
	Potential equalization
PATIENT	Patient Cable Socket
	SD Card port
	USB port
	Net port

	Mains supply
	Battery indicator
	Battery recharging indicator
 	Enter key
	Delete key
	Esc key
	RESET key
	Shift key
	Fn key
	Power On/Off key
	1mV/COPY key
	MODE key
	PRINT/STOP key
	Tab key
	FEED Paper key
	Lead switch key/LEFT/RIGHT Arrow key

	UP/DOWN Arrow key
	REVIEW key
	Gender key
	Age Group key
	Recycle
P/N	Part Number
SN	Serial Number
	Date of Manufacture
	Manufacturer
EC REP	Authorized Representative in the European Community
CE 0123	The symbol indicates that the device complies with the European Council Directive 93/42/EEC concerning medical devices.
Rx only (U.S.)	Federal (US) law restricts this device to sale by or on the order of a physician.
	It indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life.

Chapter 2 Introduction

SE-1201 gathers ECG signals of 12 leads simultaneously. It displays the operation menu, ECG parameters as well as electrocardiograms.

The 12-channel ECG waves can be viewed on the LCD screen and printed out by using a high-quality thermal recorder. The sampled ECG data can be saved, transmitted and exported.

The manual, auto, rhythm, R-R analysis or off mode can be chosen freely.

SE-1201 can be powered by the mains supply or the battery.

With a high resolution thermal recorder, a 32-bit processor and a large-capacity memorizer, SE-1201 has advanced performance and high reliability. The compact size makes it suitable for clinic and hospital uses.

SE-1201 adopts 800×480 multicolor LCD screen.

Configuration: main unit, power cord, patient cable, chest electrodes, limb electrodes, disposable electrodes, alligator clips, thermal recorder paper, fuses, battery.

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

2.1 Top Panel

Figure 2-1 SE-1201

	Symbol	Name	Explanation
A	~	Mains supply indicator	When the device is powered by the mains supply, this indicator is lit.
B		Battery indicator	When the device is powered by the battery, this indicator is lit.
C		Battery recharging indicator	When the device is powered on, the indicator flashes for a few seconds. When the battery is being recharged, this indicator is lit.

2.2 Keyboard and Keys

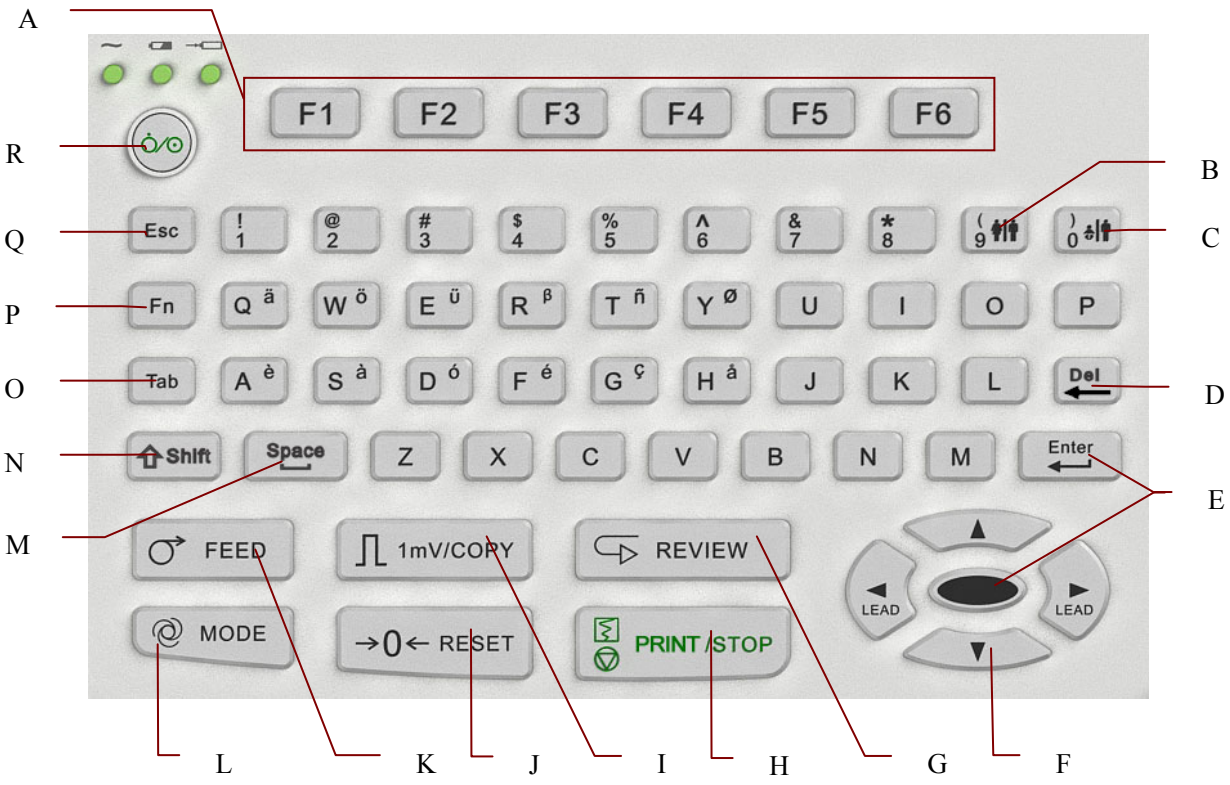


Figure 2-2 SE-1201 Keyboard

	Name	Explanation
A	Function Key	Press to select menu functions on the screen.
B	Gender Key	Press to select the gender for the patient when **Gender** is selected in the **Patient Information Setup** window.
C	Age Group Key	Press to select the age group on the main screen when you set **Age** to **Age Group** in the **Patient Information Setup** window.
D	Delete	Press to erase characters.
E	Enter	Press to confirm operation.
F	Arrow Keys	Moving the cursor (Up, Down, Left, Right). In the manual mode, press the Left or Right arrow to switch among the lead groups. Pressing **Shift** + Up/Down can turn pages on the **Order Manager** screen and the **File Manager** screen.
G	REVIEW	10s ECG data sampled before pressing the **REVIEW** key will be printed out in the AUTO mode. **NOTE:** The system will not respond to the **REVIEW** key unless 10s data has been collected on the main screen.
H	PRINT/STOP	Press to start or stop printing reports
I	1mV/COPY	In the manual mode, pressing the **1mV/COPY** key can insert a 1mV calibration mark in the printing course. In the auto or rhythm mode, pressing the **1mV/COPY** key can print the ECG report which was printed out last time.
J	RESET	Press to reset the baseline. **NOTE:** A large polarization voltage may cause baseline drift. On the main screen, pressing the **RESET** key can decrease the polarization voltage and draw the baseline to zero quickly.
K	FEED Paper	When the main screen, the freezing screen, the **File Manager** screen1/2 or the preview screen is displayed, if **Paper Marker** is set to **Yes**, you can press the **FEED** key to advance the recorder paper to the next black marker; if **Paper Marker** is set to **No,** you can press the **FEED** key to advance the paper for 2.5cm. Press the **FEED** key again to stop advancing the paper.

L	MODE	Press to select a working mode among the auto, manual, rhythm, R-R analysis and off modes. **NOTE:** Only if a working mode is selected in the **Work Mode Setup** window, can the working mode be selected by pressing the **MODE** key when the main screen is displayed.
M	Space	Press to add a space between typed characters or select/deselect a checkbox
N	Shift	Press Shift and a numeric key to input the special character in the top left corner of the key. If **Caps Lock** is set to **Off**, pressing Shift + **P** can type a capital **P**. If **Caps Lock** is set to **On**, pressing Shift + **P** can type a lowercase **p**.
O	Tab	Press to move the cursor. Pressing **Tab** can move the cursor forward, and pressing **Shift** + **Tab** can move the cursor backward.
P	Fn	Press **Fn** and a letter key to type special characters. Pressing **Fn** + **a** can type **è**.
Q	Esc	Press to cancel operation or return to the previous screen.
R	Power On/Off	Power-on/Power-off

2.3 Rear Panel

Figure 2-3 SE-1201 Rear Panel

	Name	Explanation
A	Potential Equalization Conductor	Potential equalization conductor provides a connection between the unit and the potential equalization bus bar of the electrical installation.
B	Mains Supply Socket	AC SOURCE: alternating current supply socket
C	Handle	Part for people to hold
D	Heat Emission Hole	Path for internal heat emission
E	Fuse	The specification is: T3.15AH 250V Ø5×20

2.4 Right Panel

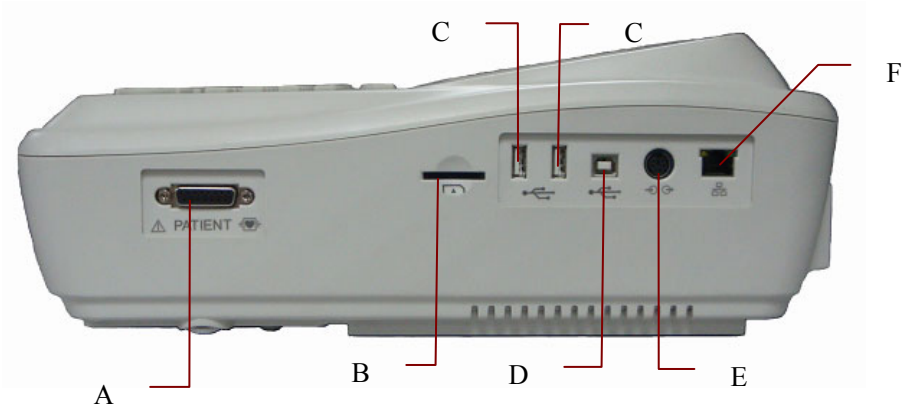
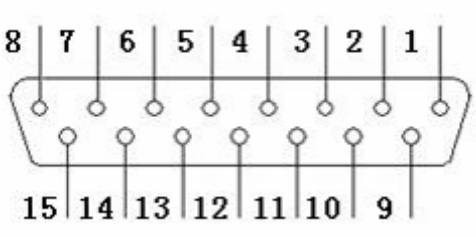


Figure 2-4 SE-1201 Right Panel

	Name	Explanation
A	Patient Cable Socket	Connecting to the patient cable
B	SD Card Socket	Connecting to SD card
C	USB Socket 1/2	Standard USB Host socket, connecting to a U disk, a bar code reader or a USB printer recommended by the manufacturer
D	USB Socket 3	Standard USB Device socket, connecting to a PC.
E	External Input / Output Socket	Connecting to the external signal device
F	Net port	Standard net port, connecting to a PC

1) Patient Cable Socket



: Applied part of type CF with defibrillator proof

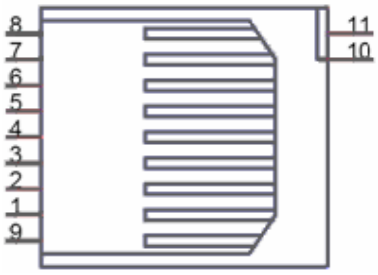
: Caution

Definitions of corresponding pins:

Pin	Signal	Pin	Signal	Pin	Signal
1	C2 (input)/ V2 (input)	**6**	SH	**11**	F (input)/ LL (input)
2	C3 (input)/ V3 (input)	**7**	NC	**12**	C1 (input) / V1 (input) or NC
3	C4 (input)/ V4 (input)	**8**	NC	**13**	C1(input) / V1 (input)
4	C5 (input)/ V5 (input)	**9**	R(input) / RA (input)	**14**	RF (N) (input)/ RL (input) or NC
5	C6 (input)/ V6 (input)	**10**	L (input)/ LA (input)	**15**	RF (N) (input)/ RL (input)

NOTE: The left side of "/" is European standard, and the right side is American standard.

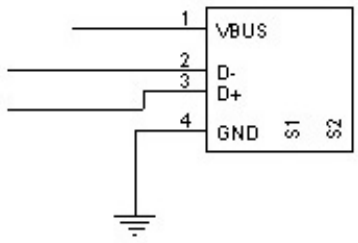
2) SD Socket



Definitions of corresponding pins:

Pin	Signal	Pin	Signal	Pin	Signal
1	CD DAT3	**5**	CLK	**9**	DAT2
2	CMD	**6**	Vss	**10**	CD
3	Vss	**7**	DAT0	**11**	WP
4	Vcc	**8**	DAT1		

3) USB Socket 1/USB Socket 2/USB Socket 3



CAUTION

Only the USB equipment recommended by the manufacturer can be connected to the USB socket 1/2.

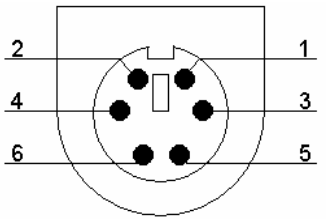
Definitions of corresponding pins:

Pin	Signal	Pin	Signal
1	+5V	**3**	D+
2	D-	**4**	GND

WARNING

1. Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the standard IEC/EN 60601-1-1. Therefore anybody, who connects additional equipment to the signal input or output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC/EN 60601-1-1. If in doubt, consult our technical service department or your local distributor.
2. If multiple instruments are connected to a patient, the sum of the leakage currents may exceed the limits given in the IEC/EN 60601-1 and may pose a safety hazard. Consult your service personnel.

4) External Input/Output Socket



Definitions of corresponding pins:

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

2.5 Bottom Panel

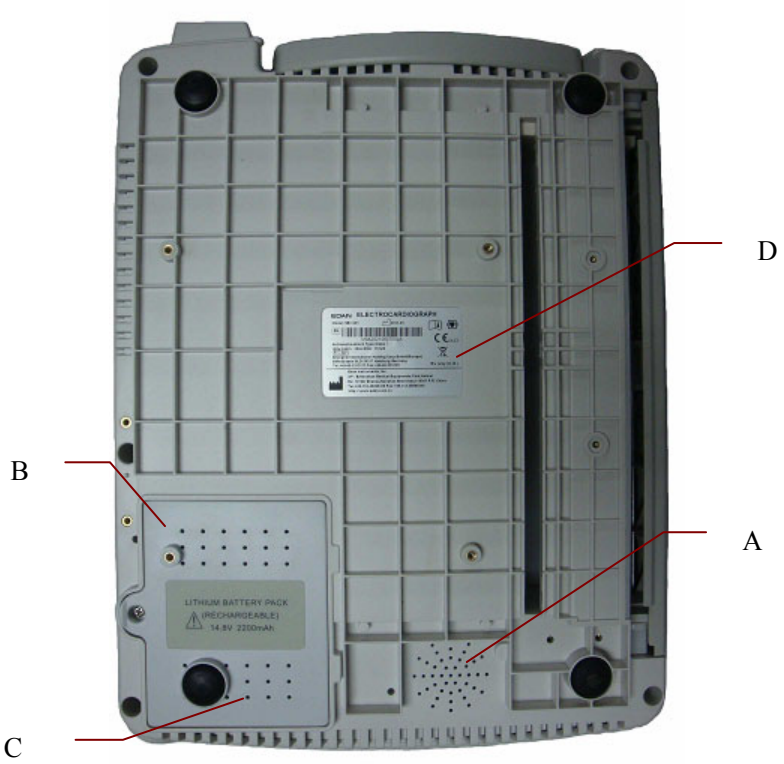


Figure 2-5 SE-1201 Bottom Panel

	Name	Explanation
A	Speaker Hole	Path for sound from speaker
B	Battery Compartment	Compartment for the battery
C	Heat Emission Hole	Path for internal heat emission
D	Label	Position for product information label

1) Battery Compartment

Rated Voltage: 14.8V

Rated Capacity: 2200mAh

WARNING

1. Improper operation may cause the battery to be hot, ignited or exploded, and it may lead to the decrease of the battery capacity. Therefore, it is necessary to read the user manual carefully and pay more attention to warning messages.
2. When leakage or foul smell is found, stop using the battery immediately. If your skin or cloth comes into contact with the leakage liquid, cleanse it with clean water at once. If the leakage liquid splashes into your eyes, do not wipe them. Irrigate them with clean water first and go to see a doctor immediately.
3. Only qualified service engineers authorized by the manufacturer can open the battery compartment and replace the battery, and batteries of the same model and specification must be used.
4. Only when the device is off can the battery be installed or removed.

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

2) Fuse

There are two fuses of the same specification installed on the bottom of the main unit. The specification is: T3.15AH 250V Ø5×20.

WARNING

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

2.6 Function Features

- Supporting AC and DC power supply modes, internal rechargeable li-ion battery with professional battery powered circuit, battery management and protection systems
- Supporting multi-language
- Full alphanumeric keyboard (touch screen is optional)
- ECG signals of 12 leads are gathered and amplified simultaneously, 12-channel waves are displayed and recorded simultaneously
- Correct detection for failure electrodes
- Convenient operation of recording by pressing the **PRINT/STOP** key with high efficiency

- High resolution thermal recorder, recording frequency response ≤150Hz
- Supporting external USB printer
- Supporting accurate digital filter to decrease the polarization voltage and other interferences
- Supporting folded paper recorded with high resolution waveforms, calibration mark, gain, speed and filter
- The auto, manual, rhythm, R-R analysis and off modes can be chosen freely
- Flexible printing formats
- Supporting ECG waves displaying with grid.
- Automatic baseline adjustment for optimal printing
- Convenient operation of system setup and file management
- Multiple file formats: DAT/SCP (optional) /FDA-XML (optional) /PDF
- Measurement function and interpretation function
- Supporting bar code reader
- ECG data can be transmitted to the PC software through the net cable, or wireless AP (optional).
- Real-time transmission to PC ECG
- Supporting order function

Chapter 3 Operation Preparations

WARNING

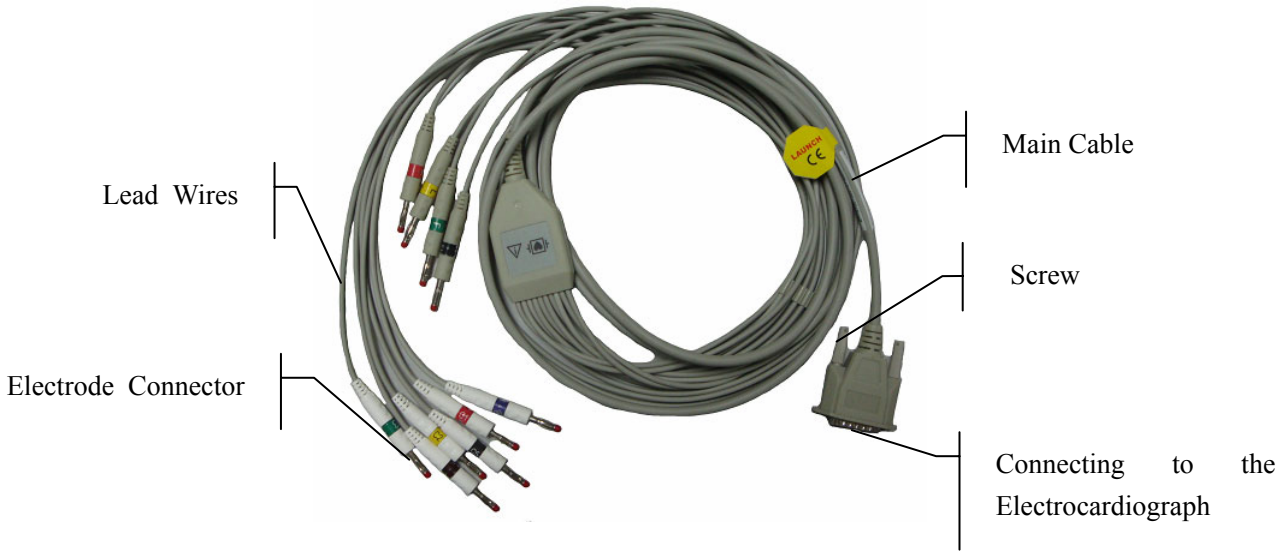
Before use, the equipment, patient cable and electrodes should be checked. Replace them if there is any evident defectiveness or aging which may impair the safety or the performance, and make sure that the equipment is in proper working condition.

3.1 Connecting the Patient Cable to the Electrocardiograph and Electrodes

WARNING

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

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



3.1.1 Connecting the Patient Cable to the Electrocardiograph

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

3.1.2 Connecting the Patient Cable to Electrodes

Align all lead wires of the patient cable to avoid twisting, and connect the lead wires to the reusable electrodes or the alligator clips. Firmly attach them.

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

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

	European		American	
Electrode Connectors	**Identifier**	**Color Code**	**Identifier**	**Color Code**
Right arm/Right deltoid	R	Red	RA	White
Left arm/Left deltoid	L	Yellow	LA	Black
Right leg/Upper leg as close to torso as possible	N or RF	Black	RL	Green
Left leg/Upper leg as close to torso as possible	F	Green	LL	Red
Chest 1	C1	White/Red	V1	Brown/Red
Chest 2	C2	White/Yellow	V2	Brown/Yellow
Chest 3	C3	White/Green	V3	Brown/Green
Chest 4	C4	White/Brown	V4	Brown/Blue
Chest 5	C5	White/Black	V5	Brown/Orange
Chest 6	C6	White/Violet	V6	Brown/Violet

3.2 Preparing the Patient

3.2.1 Instructing the Patient

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

3.2.2 Preparing the Skin

Thorough skin preparation is very important. The skin is a poor conductor of electricity and frequently creates artifacts that distort the ECG signals. By performing methodical skin preparation, you can greatly reduce the possibility of noise caused by muscle tremor and baseline drift, ensuring high-quality ECG waves. There is natural resistance on the skin surface due to dry, dead epidermal cells, oils and dirt.

To Prepare the Skin

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

3.3 Attaching Electrodes to the Patient

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

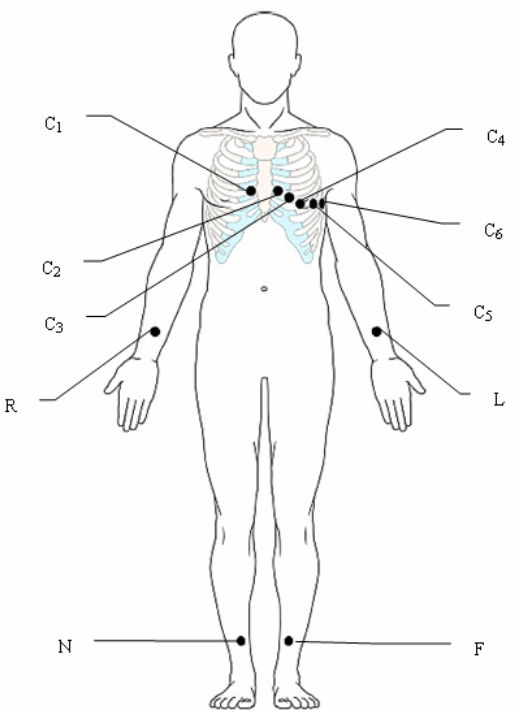
WARNING

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

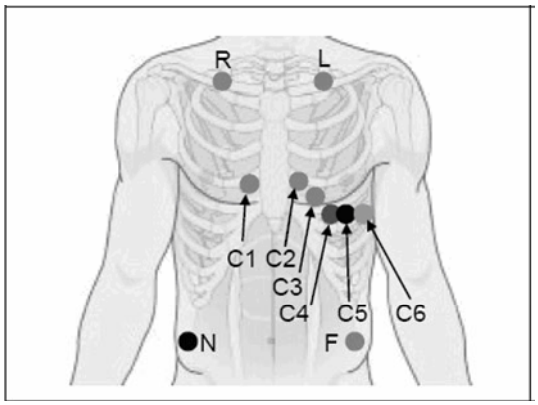
3.3.1 Electrode Placement

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

Standard 12-Lead Placement



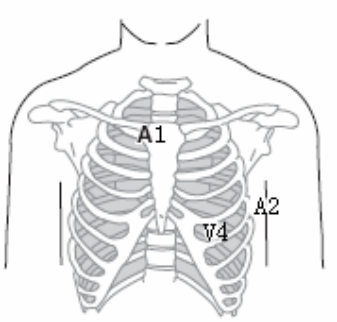
Only for the Reusable Electrodes



Only for the Disposable Electrodes

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

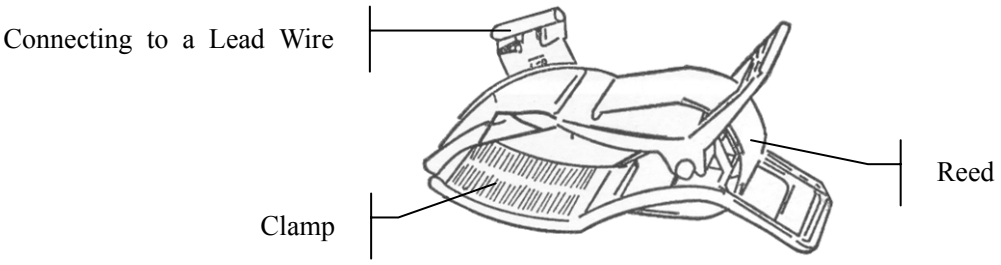
NEHB Placement



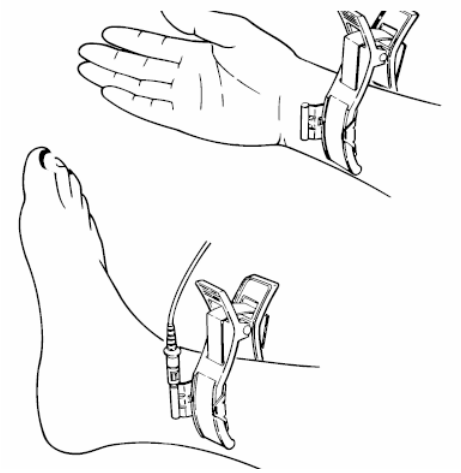
European Label	American Label	Electrode Placement
N_{st}	A1	Attachment point of the second rib to the right sternal edge
N_{ax}	A2	Fifth intercostal space on the left posterior axillary line
N_{ap}	V4	Left mid-clavicular line in the fifth intercostal space
R	RA	Right arm
L	LA	Left arm
N or RF	RL	Right leg
F	LL	Left leg

3.3.2 Attaching the Reusable Electrodes

3.3.2.1 Attaching the Limb Electrodes



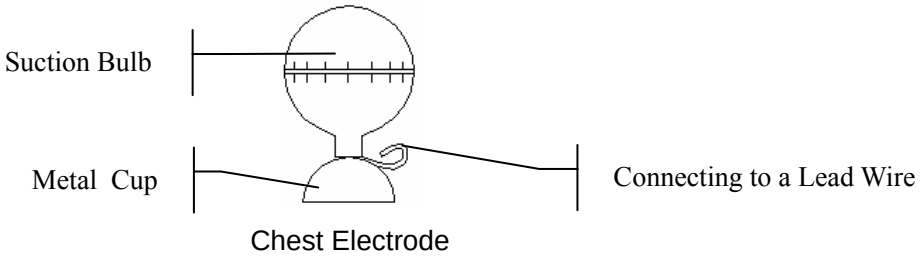
Limb Electrode



Limb Electrode Connection:

1) Ensure that the electrodes are clean;
2) Clean the electrode area which is a short distance above the ankle or the wrist with 75% alcohol;
3) Daub the electrode area on the limb with gel evenly;
4) Place a small amount of gel on the metal part of the limb electrode clamp;
5) Connect the electrode to the limb, and make sure that the metal part is placed on the electrode area above the ankle or the wrist;
6) Attach all limb electrodes in the same way.

3.3.2.2 Attaching the Chest Electrodes



Chest Electrode Connection:

1) Ensure that the electrodes are clean;
2) Clean the electrode area on the chest surface with 75% alcohol;
3) Daub the round area of 25mm in diameter on each electrode site with gel evenly;
4) Place a small amount of gel on the brim of the chest electrode's metal cup;
5) Place the electrode on the chest electrode site and squeeze the suction bulb. Unclench it and the electrode is adsorbed on the chest;
6) Attach all chest electrodes in the same way.

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

3.3.3 Attaching the Disposable Electrodes

CAUTION

The disposable electrodes can only be used for one time.

Disposable Electrode:

Alligator Clip:

Disposable electrodes must be used together with alligator clips.

Disposable Electrode Connection

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

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

3.4 Inspection Before Power-On

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

WARNING

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

1) **Environment**:

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

2) **Power Supply:**

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

3) **Patient Cable:**

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

4) **Electrodes**:

- ♦ Make sure that all electrodes are connected to lead wires of the patient cable correctly.
- ♦ Ensure that the chest electrodes do not contact with each other.

5) **Patient**:

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

3.5 Turning On/Off the Electrocardiograph

WARNING

1. If the integrity of the external protective conductor is in doubt, the equipment should be powered by the battery.
2. Potential equalization conductor of the unit should be connected to the potential equalization bus bar of the electrical installation when necessary.

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

To turn on the Electrocardiograph:

- When operating on AC power

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

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

- When operating on battery power

  Press  on the keyboard to turn on the unit, and then the battery indicator (▭) will be lit and the battery symbol will be displayed. The logo will be displayed on the LCD screen after self-test.

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

CAUTION

1. If the electrocardiograph is turned off because of low battery capacity or unexpected power failure, the settings or the current ECG report may not be saved.
2. The electrocardiograph cannot print an ECG report when the battery is weak.
3. The use of electrocardiograph accessories (such as barcode reader) will deplete battery power at a faster rate. The battery will require more frequent charging if these accessories are used with the electrocardiograph.

To turn off the Electrocardiograph:

- When operating on AC power

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

- When operating on battery power

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

NOTE:

1. When turning off the device, follow the above sequence strictly, or else there may be something wrong on the screen.
2. Do not hold down the  key when the device displays the hint information *System is shutting down…* on the screen.

3.6 Loading/Replacing Recorder Paper

Four kinds of folded thermal paper can be used. For details on selecting the paper style, please refer to Section 10.4.1 “Setup 1”.

NOTE:

1. When using the paper of 216mm in width, the two movable parts should be removed.

   For more detailed information about removing the two movable parts, please contact the manufacturer or the local distributor.
2. The exit edge can help you tear the recorder paper.

CAUTION

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

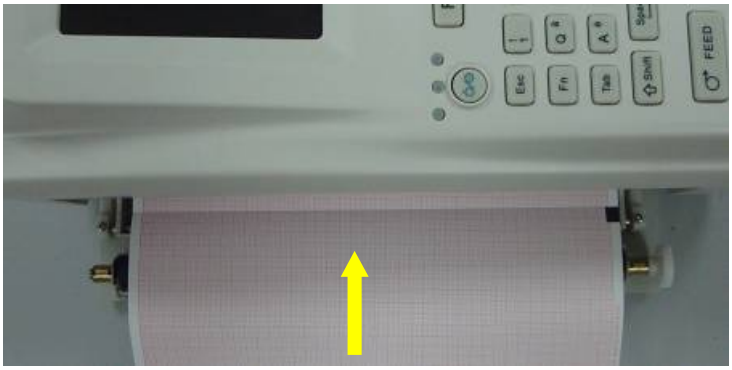
When the recorder paper runs out or is not loaded, the hint message *No Paper* will appear on the screen. Then you should load or replace the recorder paper immediately.

Loading/Replacing Paper:

1) Press the casing button downwards to open the recorder.

2) Remove the remainder paper from the paper tray if necessary.

3) Take off the wrapper of the new folded paper, and then put it in the paper tray.



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

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

5) Make settings of **Paper Marker** and **Paper Style** in the **Record Info Setup** window. For details, please refer to Section 10.4.1 “Setup1”.

6) Advance the recorder paper.

If **Paper Marker** is set to **Yes**, you can press **FEED** to advance the recorder paper to the next black marker; if **Paper Marker** is set to **No,** you can press **FEED** to advance the paper for 2.5cm. Pressing **FEED** again can stop advancing the paper.

Chapter 4 Basic Operation Guidance

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

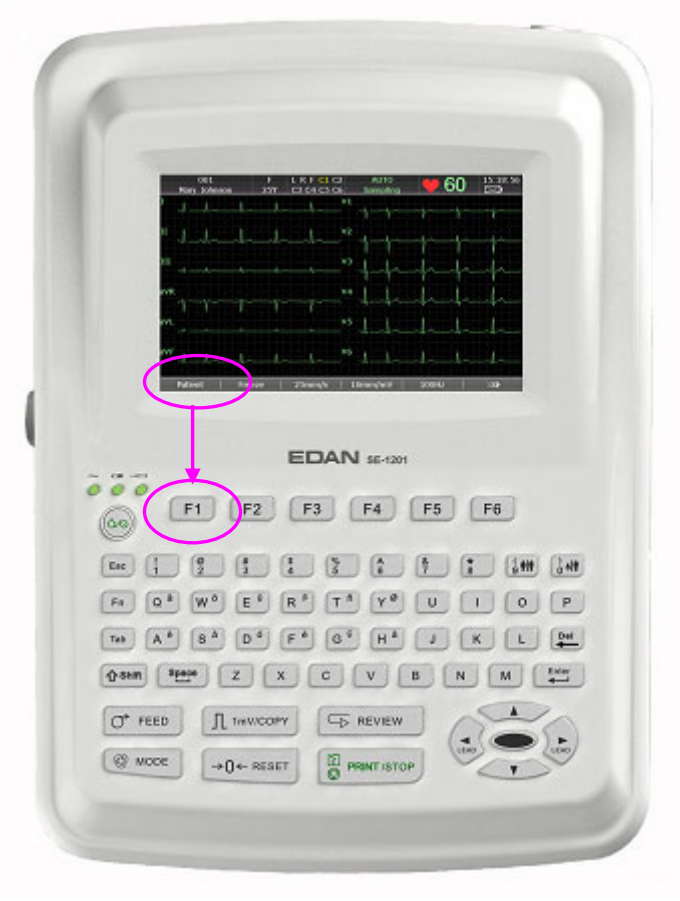
You can operate the electrocardiograph by using the touch screen (optional).

CAUTION

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

4.1 Navigation Tips

4.1.1 Selecting Menu Functions



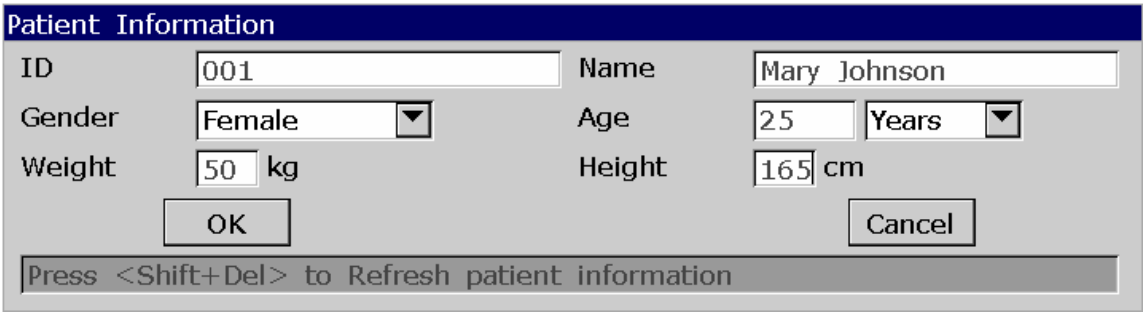
Press **F1**, **F2**, **F3**, **F4**, **F5** or **F6** to select the corresponding menu function.

- To select **Patient**, press the function key **F1** below **Patient** on the main screen1.
- To select **Setup**, press the function key **F1** below **Setup** on the main screen2.

For details about the main screen, please refer to Section 4.3.1 “About the Main Screen”.

4.1.2 Entering Data

Take the **Patient Information** window for example:



1. Press **F1** below **Patient** on the main screen1 to open the **Patient Information** window.
2. Press **Tab** or Shift + **Tab** to move the cursor to the **Name** textbox.
   - To input patient name, press the letter or numeric keys on the keyboard.
   - To input the special character in the top right corner of the key, press **Fn** and a letter key.

     For example, press **Fn** + **a** to input **è**.
   - To input the special character in the top left corner of the key, press **Shift** and a numeric key.

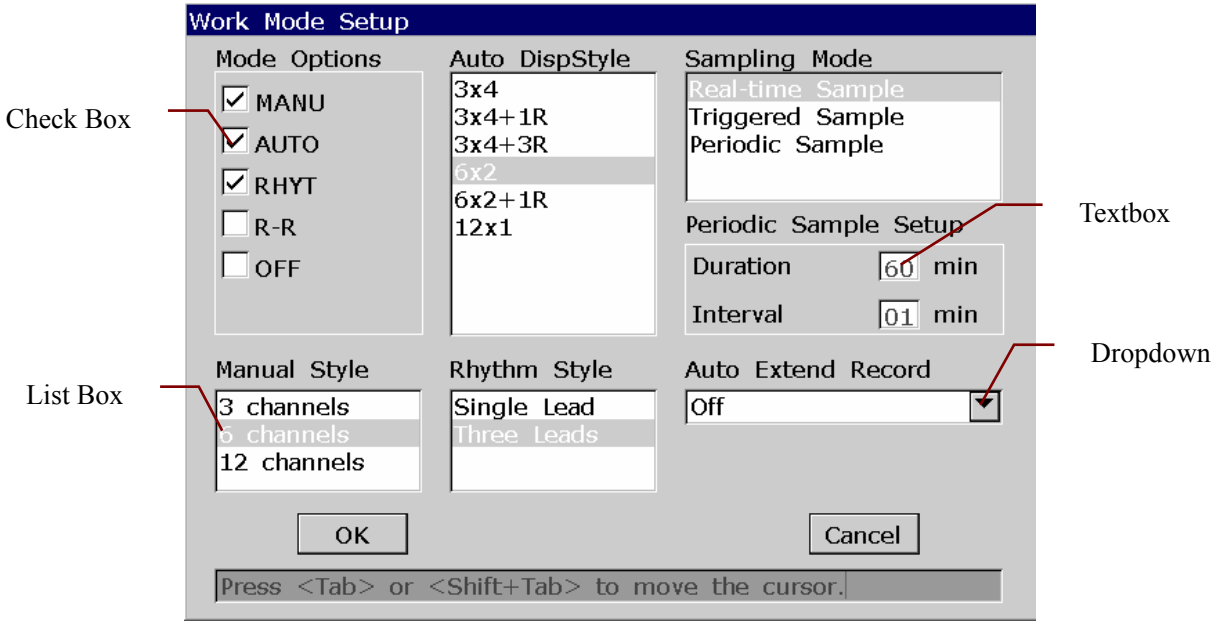
     For example, press Shift + **3** to input **#**.
   - When **Caps Lock** is set to **Off** in the **Other Setup** window, pressing **Shift** and a letter key can input a capital letter.

     For example, pressing **Shift** + **P** can type a capital **P**.
   - When **Caps Lock** is set to **On** in the **Other Setup** window, pressing **Shift** and a letter key can input a lowercase letter.

     For example, pressing **Shift** + **P** can type a lowercase **p**.
3. Press **Del** on the keyboard to erase the typed information.
4. Press **Enter** to confirm, or press **Tab** or Shift + **Tab** to move the cursor to the **OK** button, and then press **Enter** to confirm.
5. Press **Esc** to cancel the operation, or press **Tab** or Shift + **Tab** to move the cursor to the **Cancel** button, and then press **Enter** to cancel the operation.
6. Press **Shift**+**Del** to refresh all patient information except for the **Gender**, **Age Group**, **Exam.Room**, **Physician** and **Technician** information after you print an ECG report.

4.1.3 Selecting an Item

Take the **Work Mode Setup** window for example:



1. In the **Work Mode Setup** window, press **Tab** or Shift + **Tab** to move the cursor among different check boxes. Press **Space** to select a check box, and a check mark √ appears in the box.
2. In the **Work Mode Setup** window, press **Tab** or Shift + **Tab** to move the cursor to a list box or dropdown. Press the Up or Down arrow to highlight an option.
3. In the **Work Mode Setup** window, press **Tab** or Shift + **Tab** to move the cursor to a textbox. Enter data in the selected textbox.
4. Press **Enter** to confirm, or press **Tab** or Shift + **Tab** to move the cursor to the **OK** button, and then press **Enter** to confirm.
5. Press **Esc** to cancel the operation, or press **Tab** or Shift + **Tab** to move the cursor to the **Cancel** button, and then press **Enter** to cancel the operation.

4.2 Configuring the Electrocardiograph

For details on configuring the system settings and the order settings, please refer to Chapter 10 “System Setup” and Section 8.5 “Setting Orders”.

4.3 Screen Description

4.3.1 About the Main Screen

After the electrocardiograph is turned on, the main screen appears.

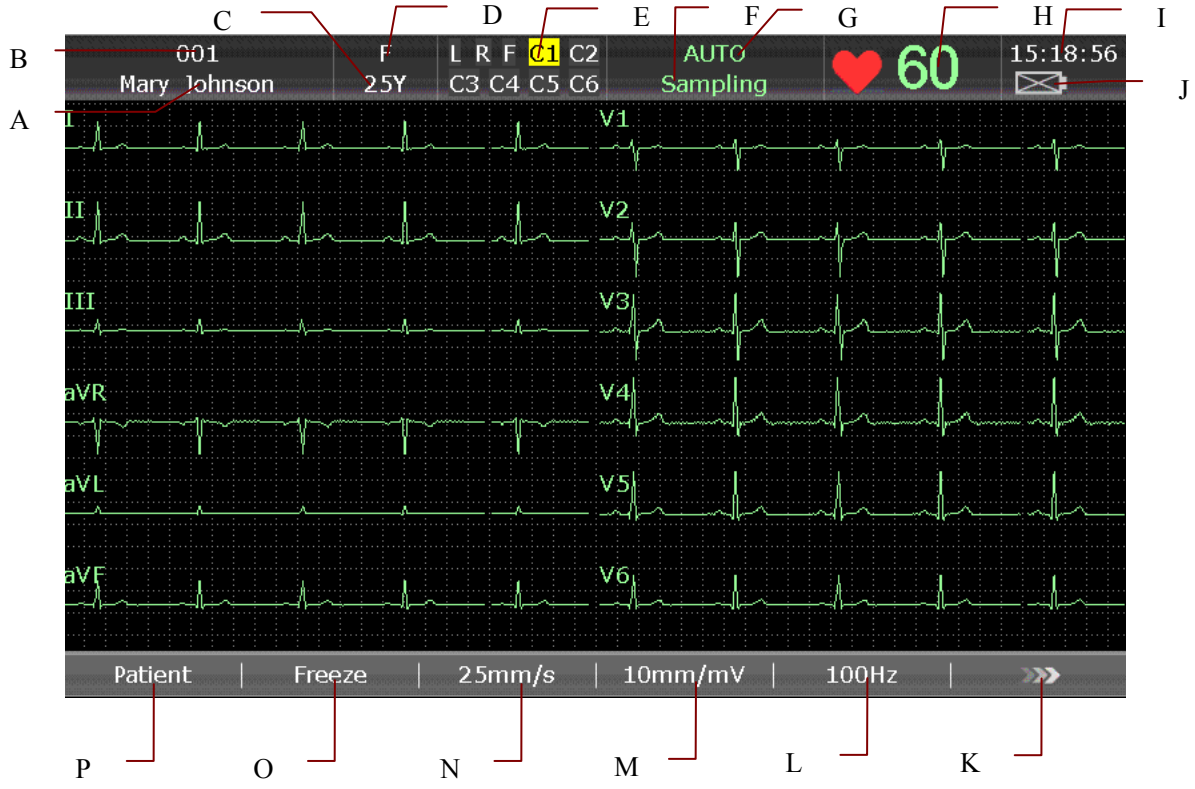


Figure 4-1 SE-1201 Main Screen1

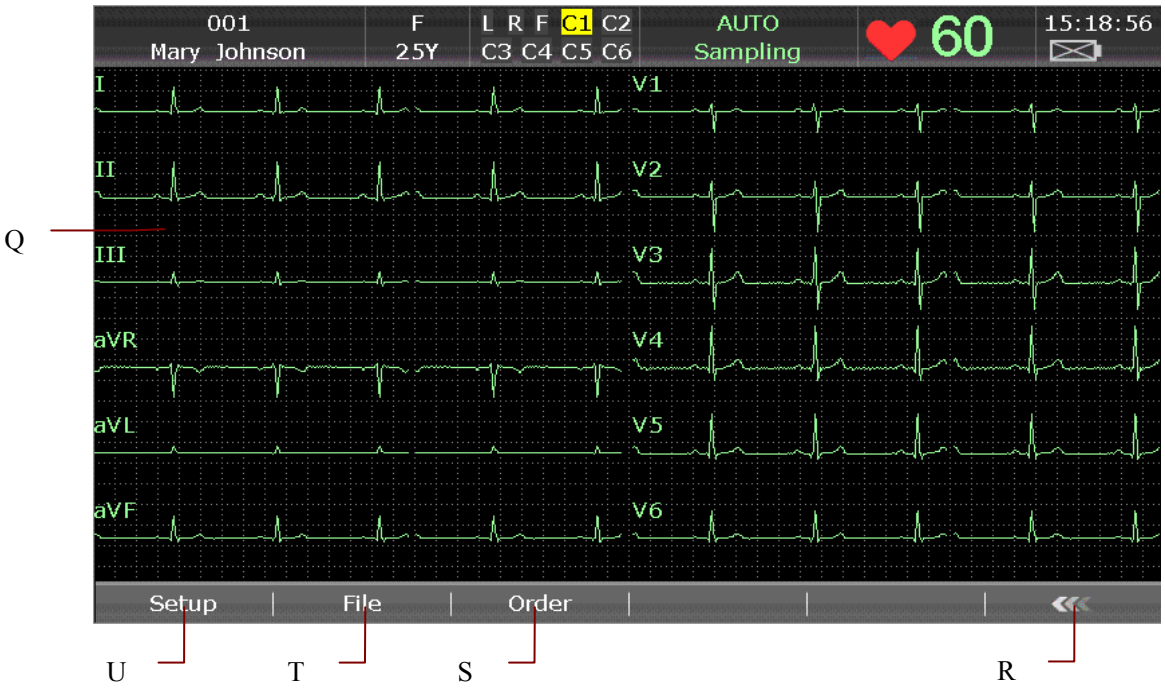


Figure 4-2 SE-1201 Main Screen2

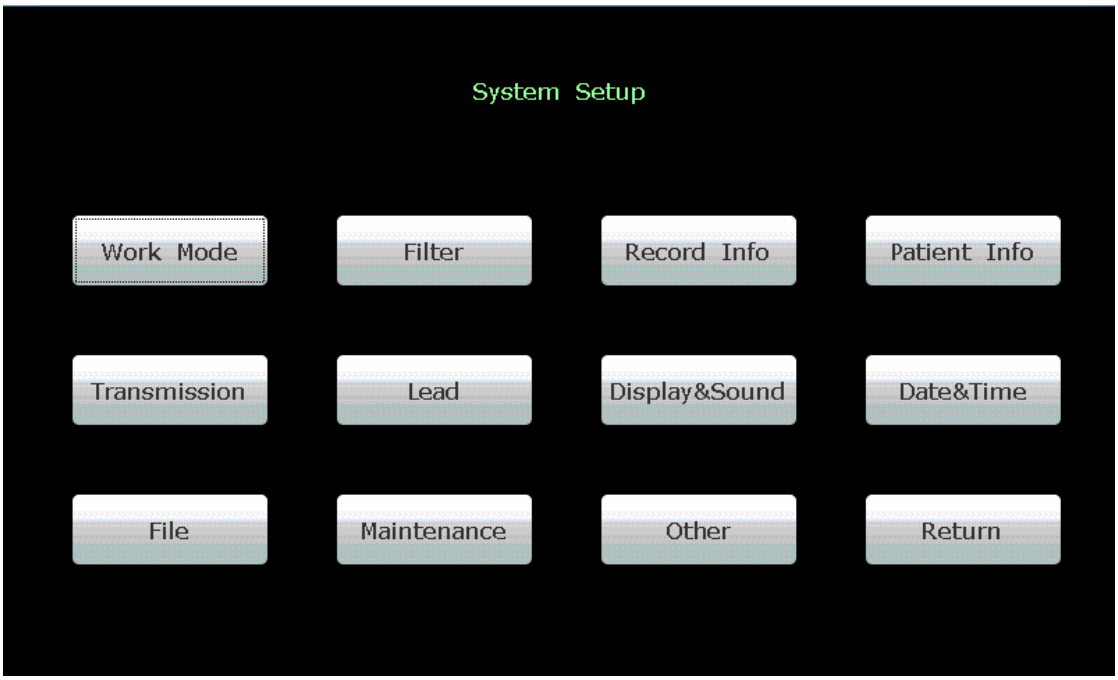
	Name	Explanation
A	Name	Patient Name: within 60 ASCII characters or the equivalent number of other characters that can be supported by equivalent memory used by 60 ASCII characters
B	ID	When **ID Mode** is set to **Manual**, the patient ID is within 30 ASCII characters. When **ID Mode** is set to **Auto**, the patient ID is 0~1999, 999, 999. When **ID Mode** is set to **Time**, the patient ID can be automatically generated according to the time when you press the **PRINT/STOP** key to print an ECG report. Entering the patient ID manually is not supported.
C	Age	Patient Age The patient age value and the age unit can be set in the **Patient Information** window.
D	Gender	Patient Gender (Male/Female/Cleared)
E	Hint Information 1	Including *DEMO*, *Module Error*, *Overload*, Lead Name (When the leads are off, the lead names will be shown in black on a yellow background.) For details, please refer to Chapter 11 "Hint Information".
F	Hint Information 2	Including *No Paper*, *Paper Error*, *Battery Weak*, *Sampling*, *Analyzing*, *Recording*, *Testing*, *Learning*, *Transmitting*, *Transmit Fail*, *Detecting*, *Memory Full*, *U Disk*, *SD Card*, *USB Printer*, *Lead Off*, *USB Scanner.* For details, please refer to Chapter 11 "Hint Information".
G	Work Mode	Manual, Auto, Rhythm, R-R Analysis or Off
H	Heart Rate	Actual Heart Rate
I	Current Time	Current examination time. Refer to Section 10.9, "Date & Time Setup".
J	Battery Symbol	Identify the current capacity of the battery
K		Press to open the main screen2.
L	Filter	EMG Filter: 25Hz, 35Hz or 45Hz Lowpass Filter: 75Hz, 100Hz or 150Hz **NOTE:** This setup modified on the main screen is only effective for the current patient.

M	Gain	Gain: 2.5 mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV, 40 mm/mV10/5 mm/mV or AGC **NOTE:** This setup modified on the main screen is only effective for the current patient.
N	Speed	In the manual mode, you can set **Speed** to **5mm/s**, **6.25mm/s**, **10mm/s**, **12.5mm/s**, **25mm/s** or **50mm/s**. In the auto and rhythm modes, only **25mm/s** and **50mm/s** are available. In the R-R analysis mode, only **25mm/s** is available. **NOTE:** This setup modified on the main screen is only effective for the current patient.
O	Freeze	Freezing ECG waves. For details, please refer to Section 6.3, "Freezing ECG Waves".
P	Patient	Press the function key **F1** below **Patient** to open the **Patient Information** window. For details, please refer to Chapter 5, "Entering Patient Information".
Q	ECG waveform	Display ECG waveform
R		Press to return to the main screen1.
S	Order	Press to open the **Order Manager** screen. For details, please refer to Chapter 8 "Managing Orders".
T	File	Press to open the **File Manager** screen. For details, please refer to Chapter 9 "Managing Files".
U	Setup	Press to open the **System Setup** screen. For details, please refer to Chapter 10 "System Setup".

4.3.2 About the System Setup Screen

Select **Setup** on the main screen2 to display the **System Setup** screen.

NOTE: If you set the system password in the **System Maintenance** window, you need enter the password before opening the **System Setup** screen. For details, refer to Section 10.11, “System Maintenance Setup”.



On the **System Setup** screen, move the cursor on an item, and then press **Enter** to open the setup window of the item.

4.3.3 About the Order Manager Screen

Select **Order** on the main screen2 to open the **Order Manager** screen.

You can press **Load** to load orders and select a loaded order to start an order examination.

Or, you can press **Esc** to return to main screen1.

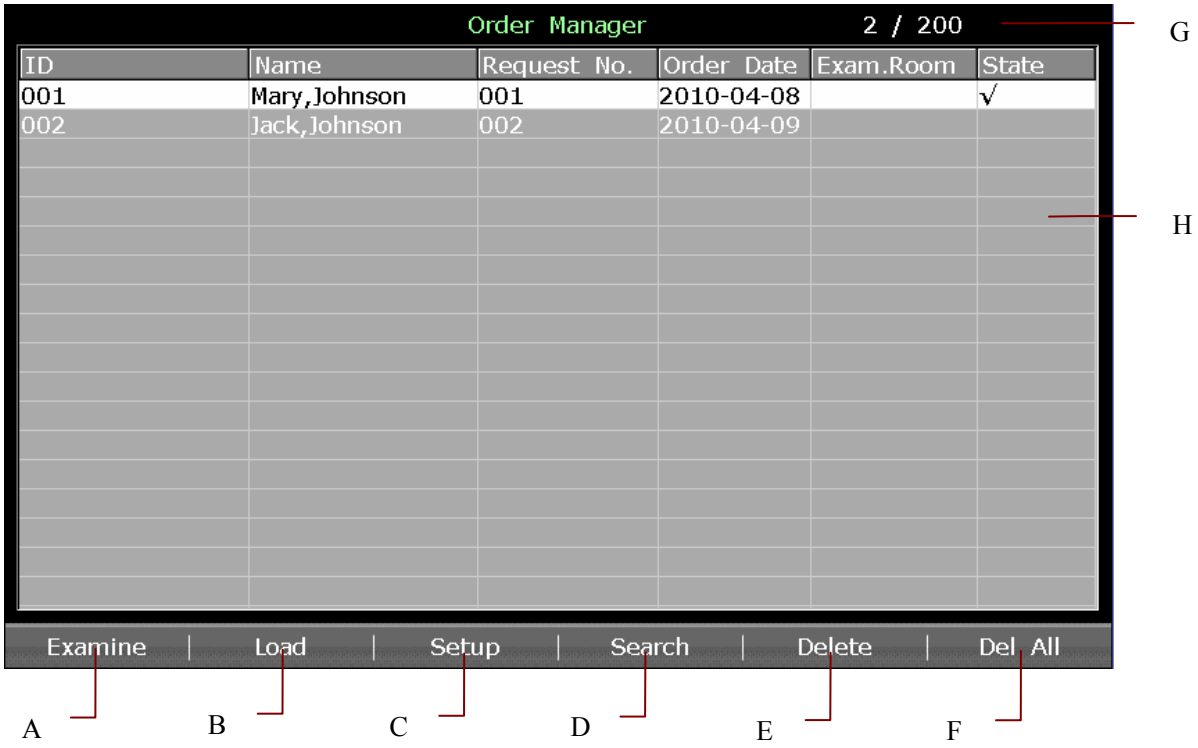


Figure 4-3 Order Manager Screen

	Name	Explanation
A	Examine	Press to return to main screen1 for starting examination of the selected order.
B	Load	Press to load orders to the electrocardiograph.
C	Setup	Press to make the related settings.
D	Search	Press to search for orders on the **Order Manager** screen.
E	Delete	Press to delete the selected order from the electrocardiograph.
F	Del All	Press to delete all the orders from the electrocardiograph.
G	Order Count	For example, 2/200

		200 is the total number of orders that can be stored in the electrocardiograph. 2 is the current number of orders stored in the electrocardiograph.
H	Order List	Orders will be loaded and displayed in the order list. The order information includes ID, Name, Request No., Order Date, Exam.Room and State. State includes two options: √ mark and no mark. An order without examination will not be marked on the **Order Manager** screen. An order with examination will be marked by √ on the **Order Manager** screen.

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

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

4.3.4 About the File Manager Screen

Switch to the File Manager Screen 1/2

- To open the **File Manager** screen1, select **File** on the main screen2.
- To open the **File Manager** screen2, select a file on the **File Manager** screen1, and then press **Select**.
- To return to the **File Manager** screen1 from the **File Manager** screen2, press **Esc**.
- To return to the main screen from the **File Manager** screen1, press **Esc**.

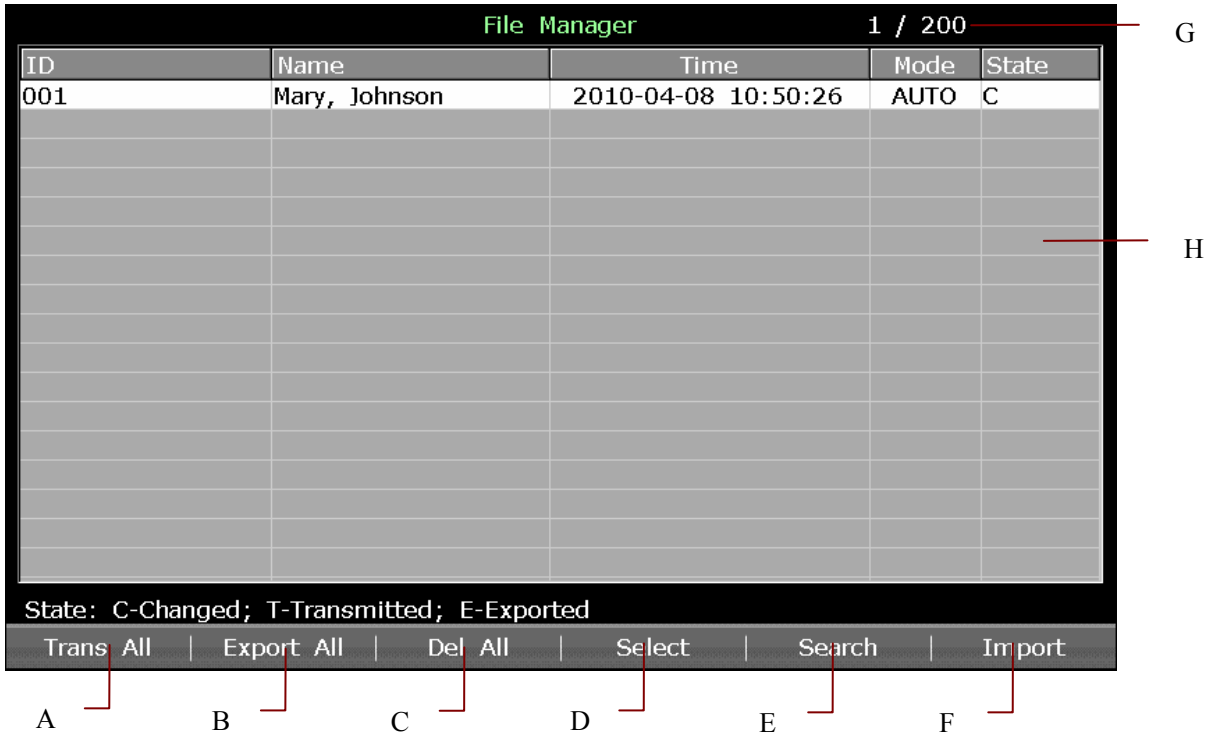


Figure 4-4 File Manager Screen1

Figure 4-5 File Manager Screen2

	Name	Explanation
A	Trans All	Press to transmit all the files to the PC.
B	Export All	Press to export all the files from the electrocardiograph to the U disk or SD card.
C	Del All	Press to delete all the files from the electrocardiograph.
D	Select	Press to highlight a file on the **File Manager** screen1, and then press **Select** to select the file and display the **File Manager** screen2.
E	Search	Press to open the **SearchInfo Setup** window.
F	Import	Press to import files from the U disk or SD card to the electrocardiograph.
G	File Count	For example, 1/200 200 is the total number of files that can be stored in the electrocardiograph. 1 is the current number of files stored in the electrocardiograph.
I	Edit	Press to open the **Patient Information** window. Then you can edit the patient information.
J	Record	Press to print the selected file.
K	Trans	Press to transmit the selected file to the PC.
L	Export	Press to export the selected file from the electrocardiograph to the U disk or SD card.
M	Delete	Press to delete the selected file from the electrocardiograph.
N	Preview	Press to open the file preview screen.

4.4 Work Mode Description

There are five work modes in SE-1201.

AUTO: In the auto mode, the ECG data can analyzed, saved, printed and transmitted. The lead groups are switched automatically according to the lead sequence during the printing course. After the ECG waves of one lead group are printed within a certain time, the system switches to print ECG waves of another lead group automatically. 1mV calibration marks will be printed at the beginning of an ECG report.

MANU: In the manual mode, you can determine the lead group to be displayed and printed. Pressing the Left or Right arrow can switch among the lead groups.

RHYT: In the rhythm mode, the ECG data can be saved and transmitted. You can print 60s rhythm-lead ECG waveform of one lead in the **Single Lead** style or 20s rhythm-lead ECG waveform of three leads in the **Three Leads** style.

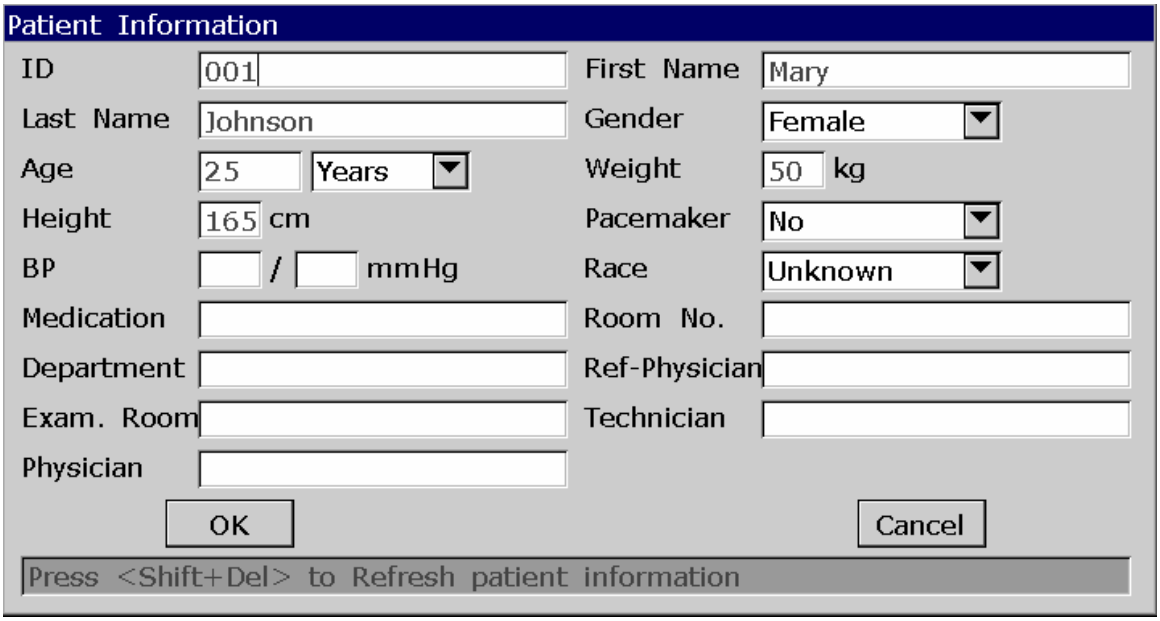
R-R: In the R-R analysis mode, you can select a lead to print its R-R histogram, R-R trend chart, 180s compressed ECG waveform and all the R-R interval values.

OFF: In the off mode, the ECG data can be analyzed, saved and transmitted, but can not be printed, which is the only difference between AUTO and OFF mode.

For details on printing ECG reports in the Auto, Manual, Rhythm or R-R analysis mode, please refer to Section 6.1 “Printing an ECG Report”.

Chapter 5 Entering Patient Information

5.1 Entering Patient Information Manually



Operation procedures are as follows:

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

   1) Select the desired items.

      Select the desired items in the **Patient Information Setup** window, and then press **Enter** to confirm. For details, please refer to Section 10.5 “Patient Information Setup”.

   2) Select a mode from the **ID** list box.

      For details, please refer to Section 10.5 “Patient Information Setup”.

   3) Press **Enter** to confirm.

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

3. Enter data in a desired textbox.

4. Press **Enter** to confirm or press **Esc** to return to the main screen.

First Name	Within 30 ASCII characters
Last Name	Within 30 ASCII characters
Age	Age Unit: **Years**, **Months**, **Weeks** or **Days**
Gender	Patient Gender (Male/Female/Empty)
Pacemaker	If you select **Pacemaker** in the **Patient Information Setup** window, **Pacemaker** appears in the **Patient Information** window. If **Pacemaker** is set to **Yes**, the pacemaker signals are easy to be detected. If **Pacemaker** is set to **No**, the pacemaker signals are not easy to be detected.
BP	Patient Systolic Blood Pressure/Diastolic Blood Pressure
Race	Patient Race (unknown/ Oriental/ Caucasian/ Black/ Indian/ Mongolian/ Hispanic/ Asian/ Pacific/ Chinese/ Malay/ other)

NOTE:

1) In the auto, rhythm or off mode, when **ID** is set to **Manual** and **ID Hint** is set to **On**, if you do not input the patient ID before pressing the **PRINT/STOP** key, a hint will pop up to remind you to input the patient ID.
2) The total number of supported characters may be fewer if either special Latin characters or Chinese characters are entered.
3) If you select **D.O.B** in the **Patient Information Setup** window, the **D.O.B** textbox appears and the **Age** textbox becomes unavailable in the **Patient Information** window, you can enter the birthday of the patient, and the system will calculate the patient age automatically.
4) If you select **Age Group** in the **Patient Information Setup** window, the **Age Group** textbox appears in the **Patient Information** window.

5.2 Entering Patient Information by Using a Bar Code Reader (Optional)

Operation procedures are as follows:

1. Configure the bar code

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

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

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

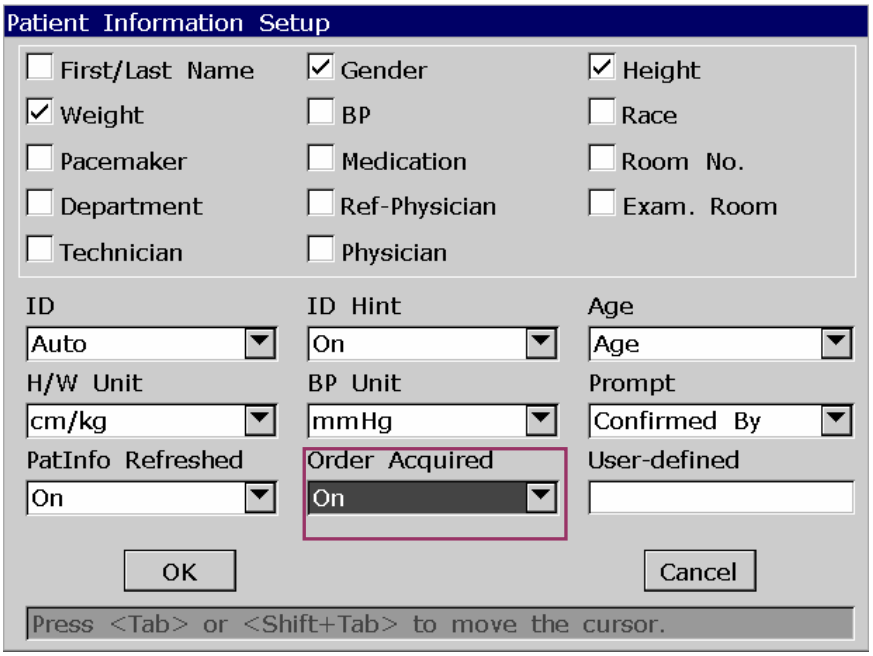
NOTE: Only bar code readers, complying with the standards Bar Code 128 and Bar Code 93 and recommended by the manufacturer, can be used.

5.3 Entering Patient Information by Acquiring Orders

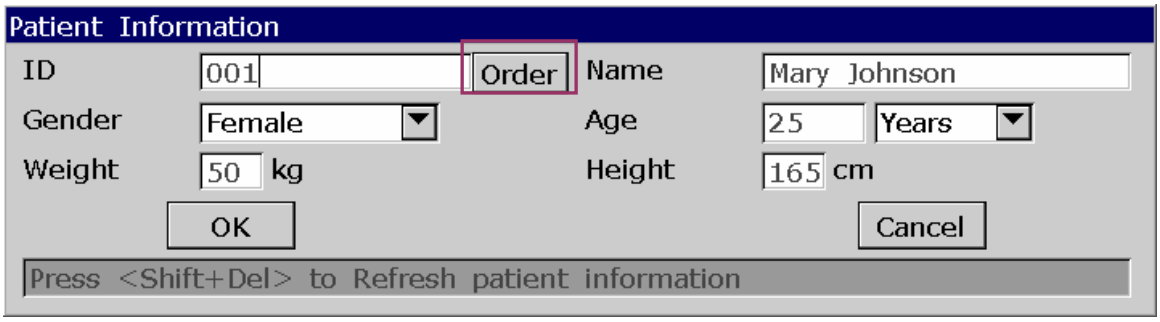
NOTE: To use the order function, the Smart ECG Viewer software of the manufacturer must be installed in the PC.

Operation procedures are as follows:

1. Connect the electrocardiograph to the PC with Ethernet cable recommended by the manufacturer.
2. Log into the Smart ECG Viewer software.
3. Set **Remote IP**, **Local IP**, **Gateway** and **Subnet Mask** in the **Transmission Setup** window. For details, please refer to Section 7.1.1 "Transmitting ECG Data in DAT Format through Ethernet Cable".
4. Select **Order Acquired** function.
   1) Select **Setup> Patient Info** to open the **Patient Information Setup** window.
   2) Select **On** from the **Order Acquired** list box, and then press **Enter** to confirm.



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



6. Enter the patient ID manually in the **ID** textbox and press **Order**, then the matched order will be loaded from Smart ECG Viewer software and the order information will be displayed in the corresponding textboxes.

   Or, you can acquire orders by using a bar code reader.

   1. Select **On** from the **Order Acquired** list box in the **Patient Information Setup** window.
   2. Connect the bar code reader to USB socket 2 on the right panel of the electrocardiograph.
   3. Select **Patient** to open the **Patient Information** window, and then move the cursor to the **ID** textbox.
   4. Scan the patient's bar code with the bar code reader, and then the related order will be loaded from Smart ECG Viewer software and the order information will be displayed in the corresponding textboxes.

Chapter 6 Printing ECG Reports

NOTE:

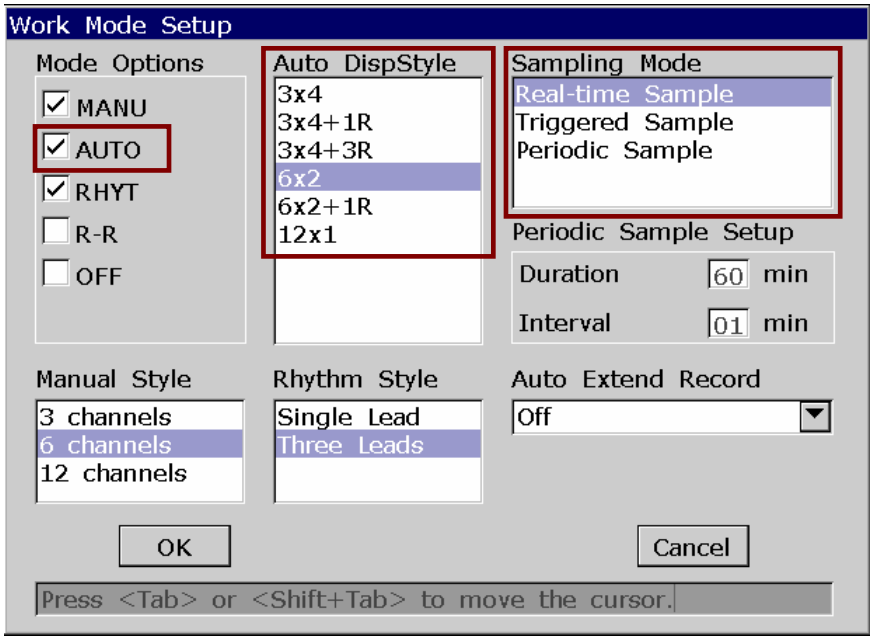
1. The working mode can not be changed during the printing course. Stop printing reports before changing the working mode.
2. Within three seconds after returning to the main screen, if you press the **PRINT/STOP** key to print an ECG report in the auto quick mode or the manual mode, the recorder will not respond.
3. In the auto, rhythm or R-R mode, if **Paper Maker** is set to **Yes** in the **Setup1** window, pressing the **PRINT/STOP** key can stop printing an ECG report and start detecting the black marker, pressing the **PRINT/STOP** key again can stop advancing the paper. If **Paper Maker** is set to **No** in the **Setup1** window, pressing the **PRINT/STOP** key can stop printing an ECG report and advancing the paper immediately.

6.1 Printing an ECG Report

6.1.1 Auto Mode

Operation Method:

1. To set **Mode Options**, **Auto DispStyle**, **Sampling Mode**, **Record Style**, **Rhythm Lead1/2/3**, or **Lead Sequence** (Optional)
   1) Select **AUTO** from the **Mode Option** list in the **Work Mode Setup** window.
   2) Select a style from the **Auto DispStyle** list in the **Work Mode Setup** window.
   3) Select a mode from the **Sampling Mode** list in the **Work Mode Setup** window
   4) Select a style from the **Record Style** list in the **Record Info Setup** window.
   5) Select a lead from the **Rhythm Lead1/2/3** list in the **Lead Setup** window.
   6) Select a sequence from the **Lead Sequence** list in the **Lead Setup** window.
   7) Press **Enter** to confirm.

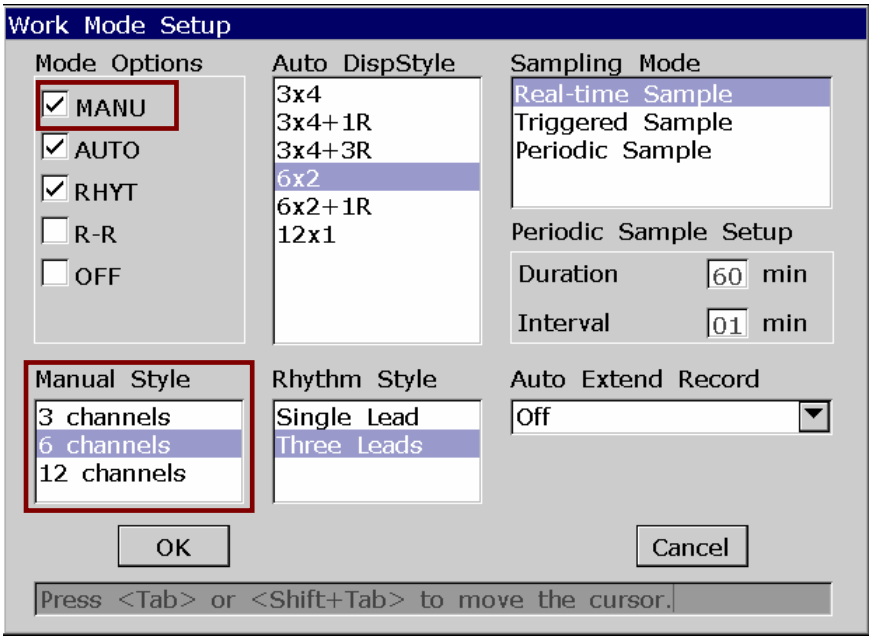


2. When the main screen is displayed, press the **MODE** key to select the auto mode. Press **F3** to select a paper speed. Press **F4** to switch the gain. Press **F5** to set the EMG filter or the Lowpass filter.
3. Press the **PRINT/STOP** key to print an ECG report. It will stop automatically after printing a complete ECG report of 12 leads. Or press the **PRINT/STOP** key again to stop printing the report.

6.1.2 Manual Mode

Operation Method:

1. To set **Mode Options**, **Manual Style** or **Lead Sequence** (Optional)
   1) Select **MANU** from the **Mode Option** list in the **Work Mode Setup** window.
   2) Select a style from the **Manual Style** list in the **Work Mode Setup** window.
   3) Select a sequence from the **Lead Sequence** list in the **Lead Setup** window.
   4) Press **Enter** to confirm.

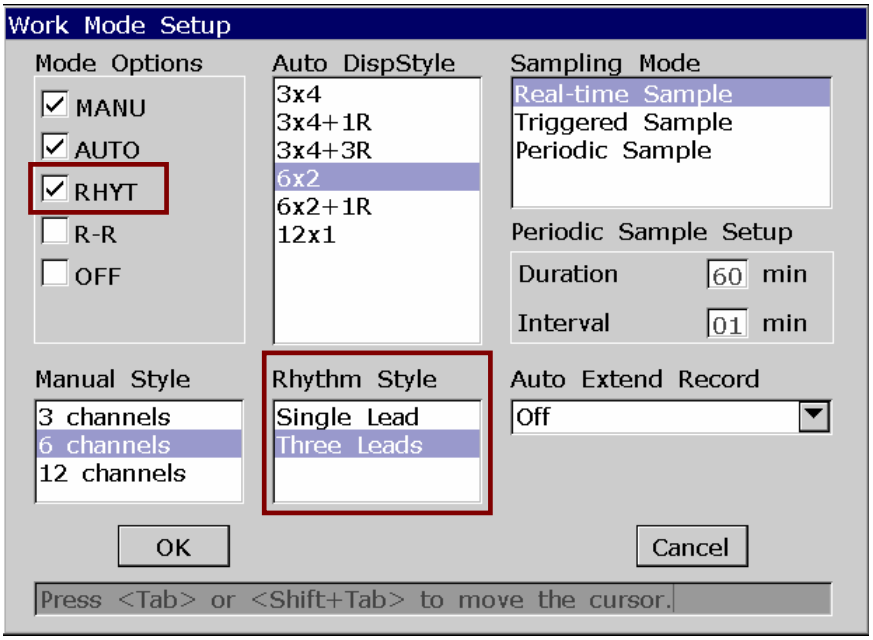


2. When the main screen is displayed, press the **MODE** key to select the manual mode. Press **F3** to select a paper speed. Press **F4** to switch the gain. Press **F5** to set the EMG filter or the Lowpass filter.
3. Press the Left or Right arrow to select the lead group to be displayed and printed.
4. Press the **PRINT/STOP** key to print an ECG report. Or press the **PRINT/STOP** key to stop printing the ECG report.

6.1.3 Rhythm Mode

Operation Method:

1. To set **Mode Options**, **Rhythm Style**, **Rhythm Lead1/2/3** or **Lead Sequence** (Optional)
   1) Select **RHYT** from the **Mode Option** list in the **Work Mode Setup** window.
   2) Select a style from the **Rhythm Style** list in the **Work Mode Setup** window.
   3) Select a lead from the **Rhythm Lead1/2/3** list in the **Lead Setup** window.
   4) Select a sequence from the **Lead Sequence** list in the **Lead Setup** window.
   5) Press **Enter** to confirm.

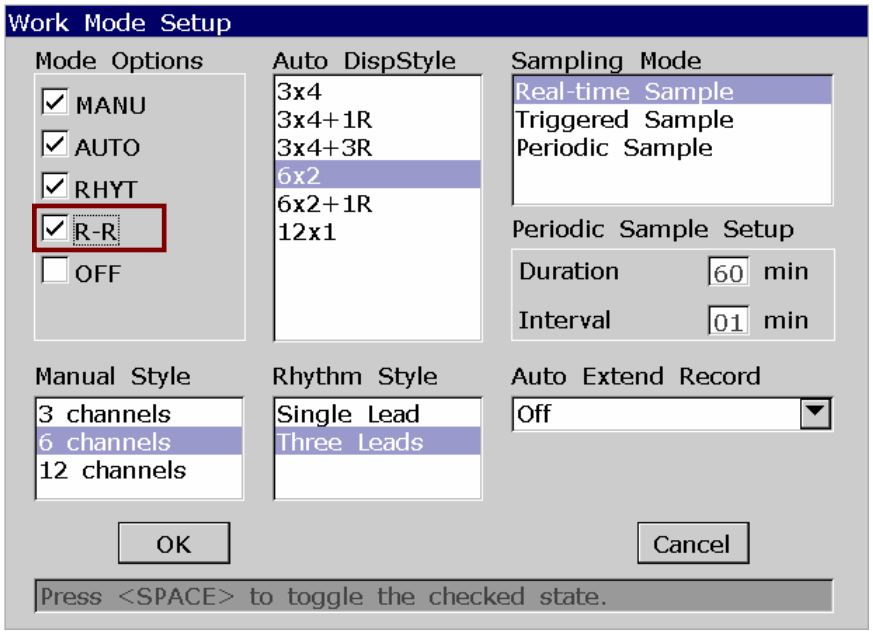


2. When the main screen is displayed, press the **MODE** key to select the rhythm mode. Press **F3** to select a paper speed. Press **F4** to switch the gain. Press **F5** to set the EMG filter or the Lowpass filter.
3. Press the **PRINT/STOP** key to begin sampling, the sampling time will be displayed on the main screen. When the sampling time reaches 60s in the **Single Lead** style or 20s in the **Three Leads** style, it begins to print an ECG report.
4. It will stop automatically after printing a complete report of rhythm-lead ECG waveforms. Or press the **PRINT/STOP** key again to stop printing the ECG report.

6.1.4 R-R Analysis Mode

Operation Method:

1. To set **Mode Options** or **Rhythm Lead1**
   1) Select **R-R** from the **Mode Option** list in the **Work Mode Setup** window.
   2) Select a lead from the **Rhythm Lead1** list in the **Lead Setup** window.
   3) Press **Enter** to confirm.



2. When the main screen is displayed, press the **MODE** key to select the R-R analysis mode. Press **F4** to switch the gain. Press **F5** to set the EMG filter or the Lowpass filter.
3. Press the **PRINT/STOP** key to begin sampling, the sampling time will be displayed on the main screen. When the sampling time reaches 180s, it begins to analyze and print an ECG report.
4. It will stop automatically after a complete R-R analysis report is printed, or press the **PRINT/STOP** key to stop printing the ECG report.

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

6.1.5 Review Printing

In the auto or off mode, after you press the **Review** key， 10s ECG data sampled before you press the key will be printed out.

NOTE: The system will not respond to the **REVIEW** key unless 10s data has been sampled on the main screen.

6.2 Copy Printing

In the auto and rhythm modes, pressing the **1mV/COPY** key can print the ECG report which was printed out last time. Pressing the **PRINT/STOP** key can stop printing the ECG report.

6.3 Freezing ECG Waves

You can freeze the ECG waves displayed on the main screen.

Operation Method:

1) Press **F3** to set the paper speed, press **F4** to set the gain, and press **F5** to set the filter on the main screen1.
2) Select **Freeze** to display the freezing screen.

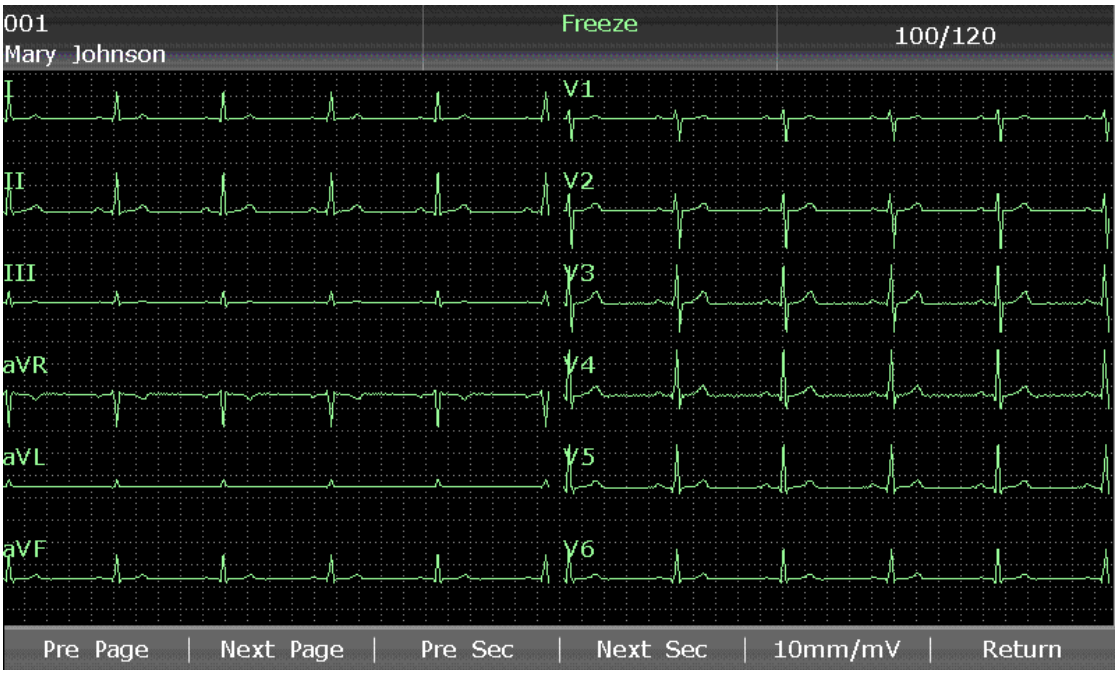


Figure 6-1 Freezing Screen

NOTE: Within ten seconds after returning to the main screen, pressing **F2** can not display the freezing screen.

3) Select **Pre Page** or select **Next Page** to turn pages.
4) Select **Pre Sec** or select **Next Sec** to view the ECG waves of the previous or next second.
5) Select **10mm/mV** to set the gain of the ECG waves.
6) Select **Return** to return to the main screen1.

6.4 Printing a Stored ECG Report

6.4.1 Printing on the File Manager Screen1/2

On the File Manager screen 1:

1. Select **File** on the main screen to open the **File Manager** screen1.
2. Select a file on the **File Manager** screen1, and then press **PRINT/STOP** to print the file.
3. Or, press **PRINT/STOP** again to stop printing the file.

On the File Manager Screen2:

1. Select **File** on the main screen2 to open the **File Manager** screen1.
2. Select a file on the **File Manager** screen1, and then press **Select** to select the file and open the **File Manager** screen2.
3. Press **PRINT/STOP** or **Record** on the **File Manager** screen2 to print the selected file.
4. Or, press **PRINT/STOP** again to stop printing the file.

6.4.2 Printing on the Preview Screen

Operation Method:

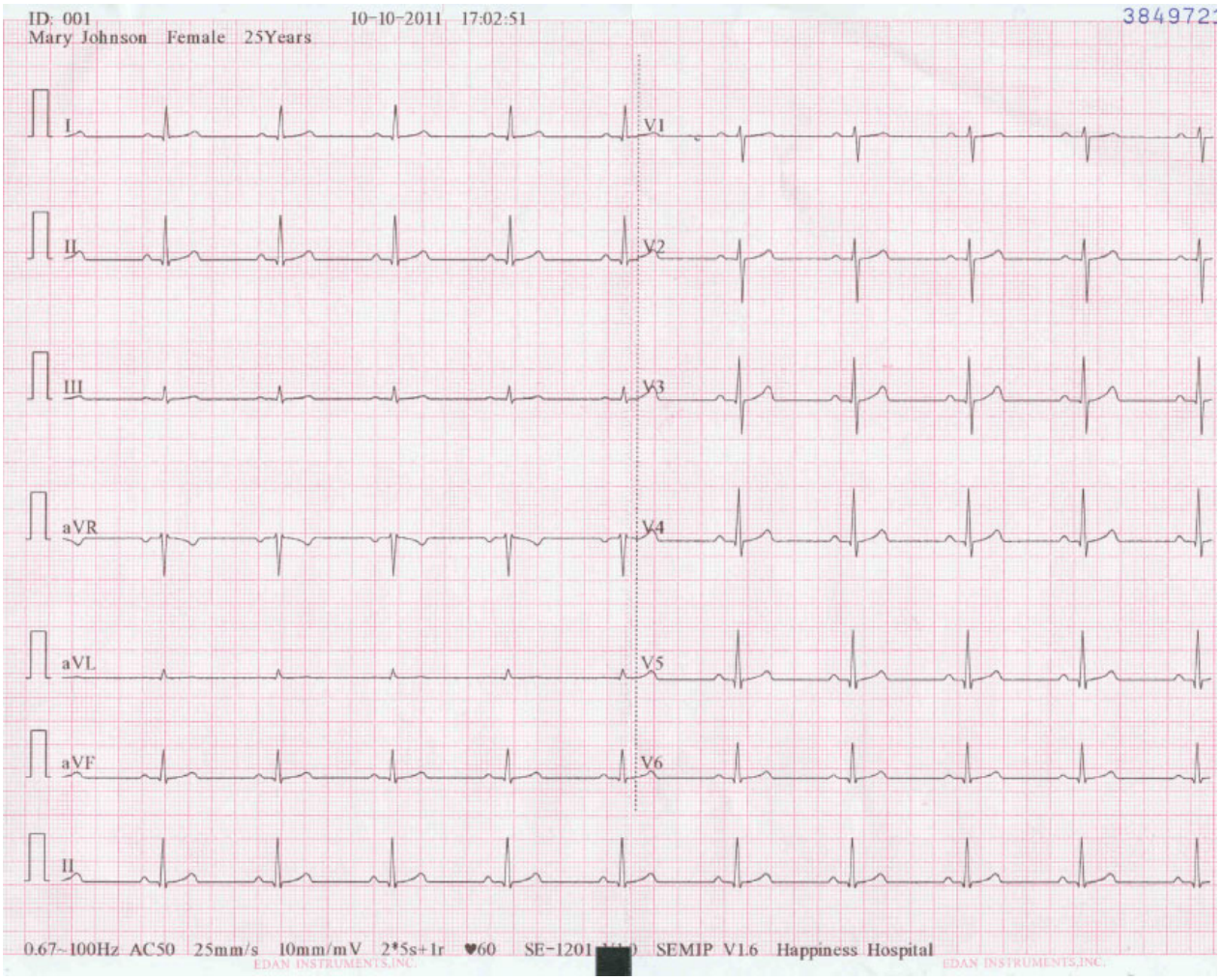
1. Select **File** on the main screen to open the **File Manager** screen1.
2. Select a file on the **File Manager** screen1, and then press **Select** to select the file and display the **File Manager** screen2.
3. Select **Preview** on the **File Manager** screen2 to open the preview screen.
4. Press **PRINT/STOP** or select **Record** on the preview screen to print the selected file.
5. Or, press **PRINT/STOP** again to stop printing the file.

NOTE: Rhythm data can not be previewed.

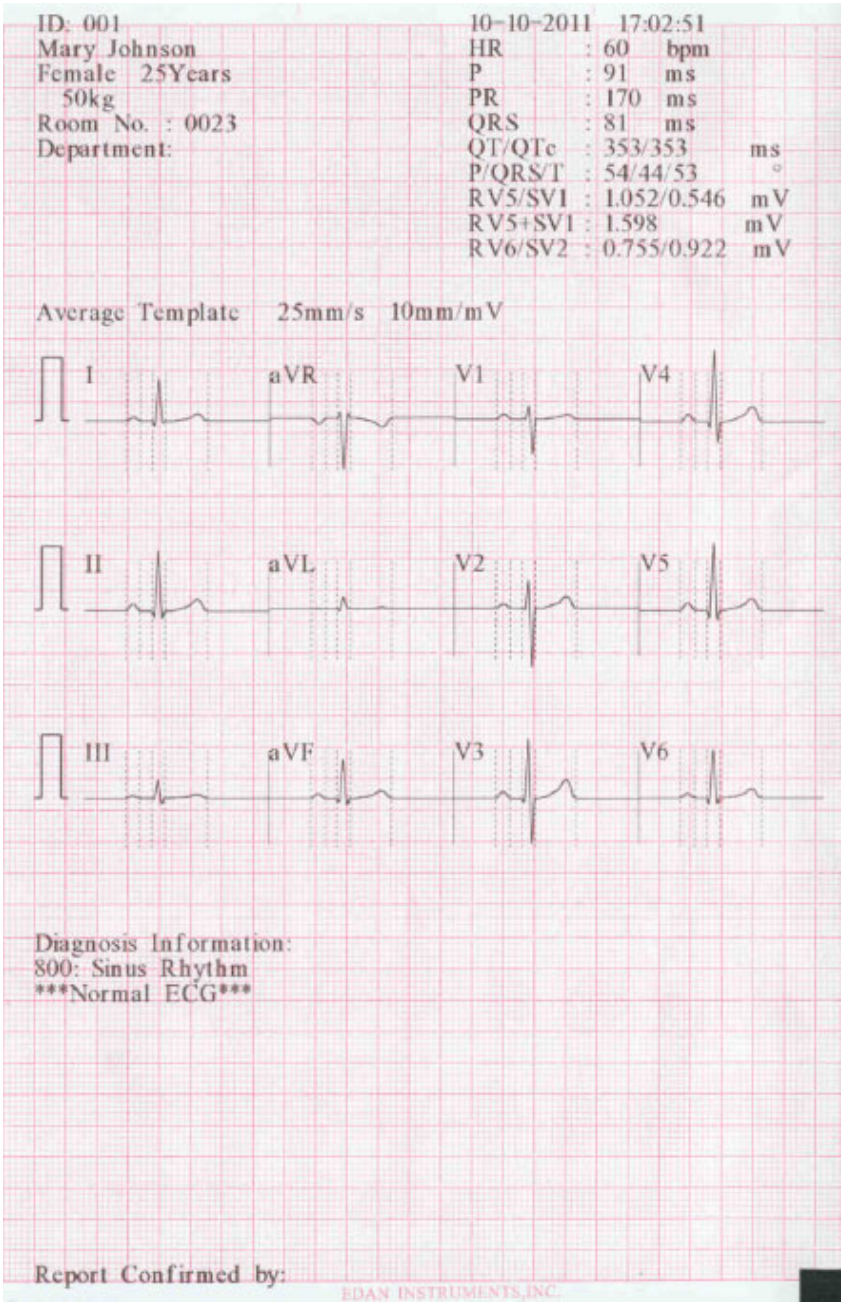
6.5 Sample ECG Reports

6.5.1 ECG Reports in the Auto Mode

Quick Mode



(a)



(b)

The above figure (a) and (b) show an ECG report in the auto mode. **Template** is selected, and **Record Style** is set to **6×2+1r**.

The ECG report includes:

Patient Information, Measure Information, Diagnosis Information,

Report Confirmed by, Current Date and Current Time,

6×2+1r ECG waves, 0.67~100Hz (0.67Hz DFT Filter, 100Hz Lowpass Filter),

AC50 (50Hz AC Filter), 25mm/s (Paper Speed), 10mm/mV (Gain),

♥80 (Heart Rate),

2*5s+1r (12 leads are printed in 2 groups of 6 with the ECG wave of one lead on the bottom, and every group is printed for about 5s),

V1.0 (Software Version), SEMIP V1.6 (Algorithm Version),

SE-1201 (Electrocardiograph Model), Institution Name.

Measure Information includes:

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

Diagnosis Information:

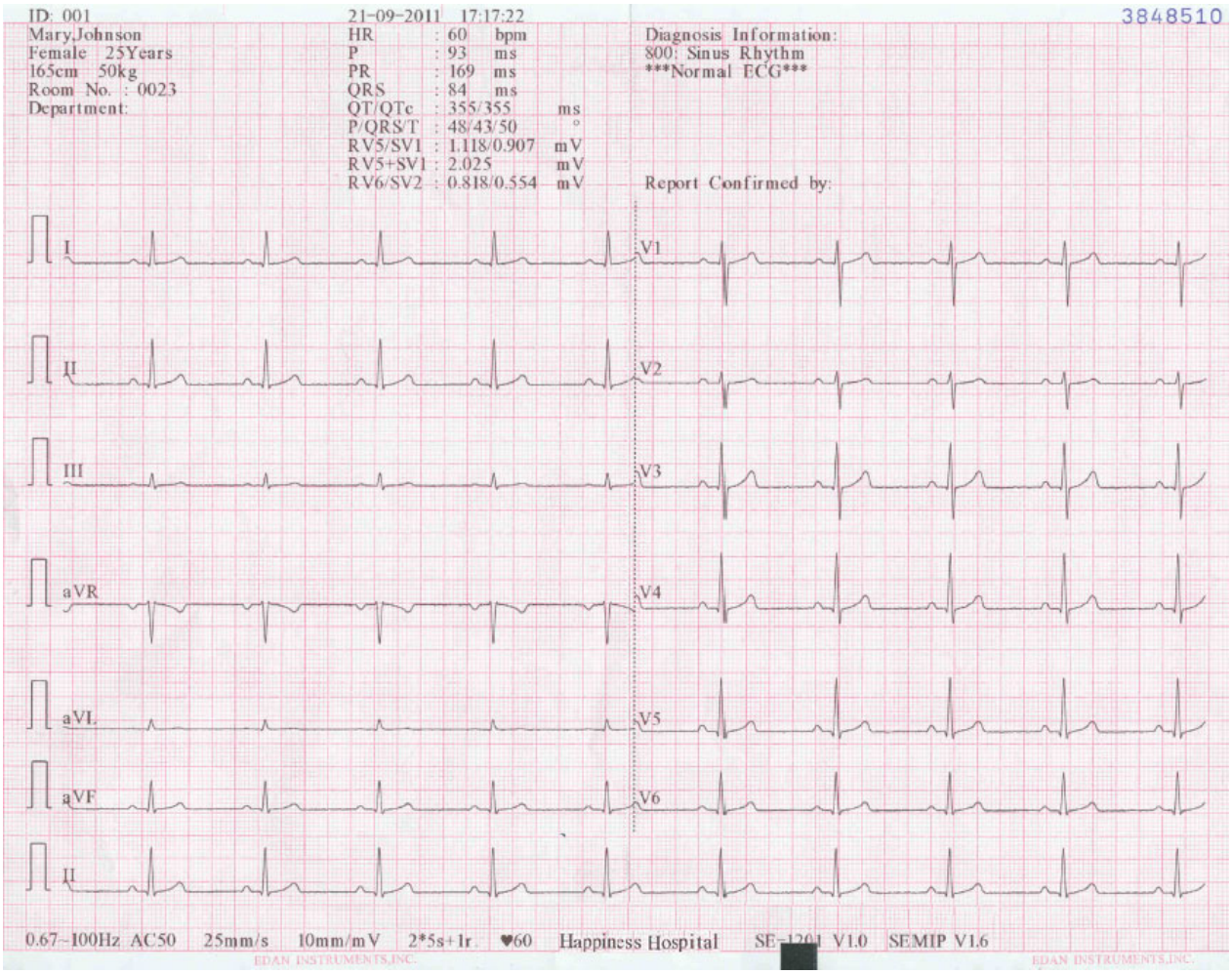
Diagnosis information shows the auto diagnosis result.

Average Template:

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

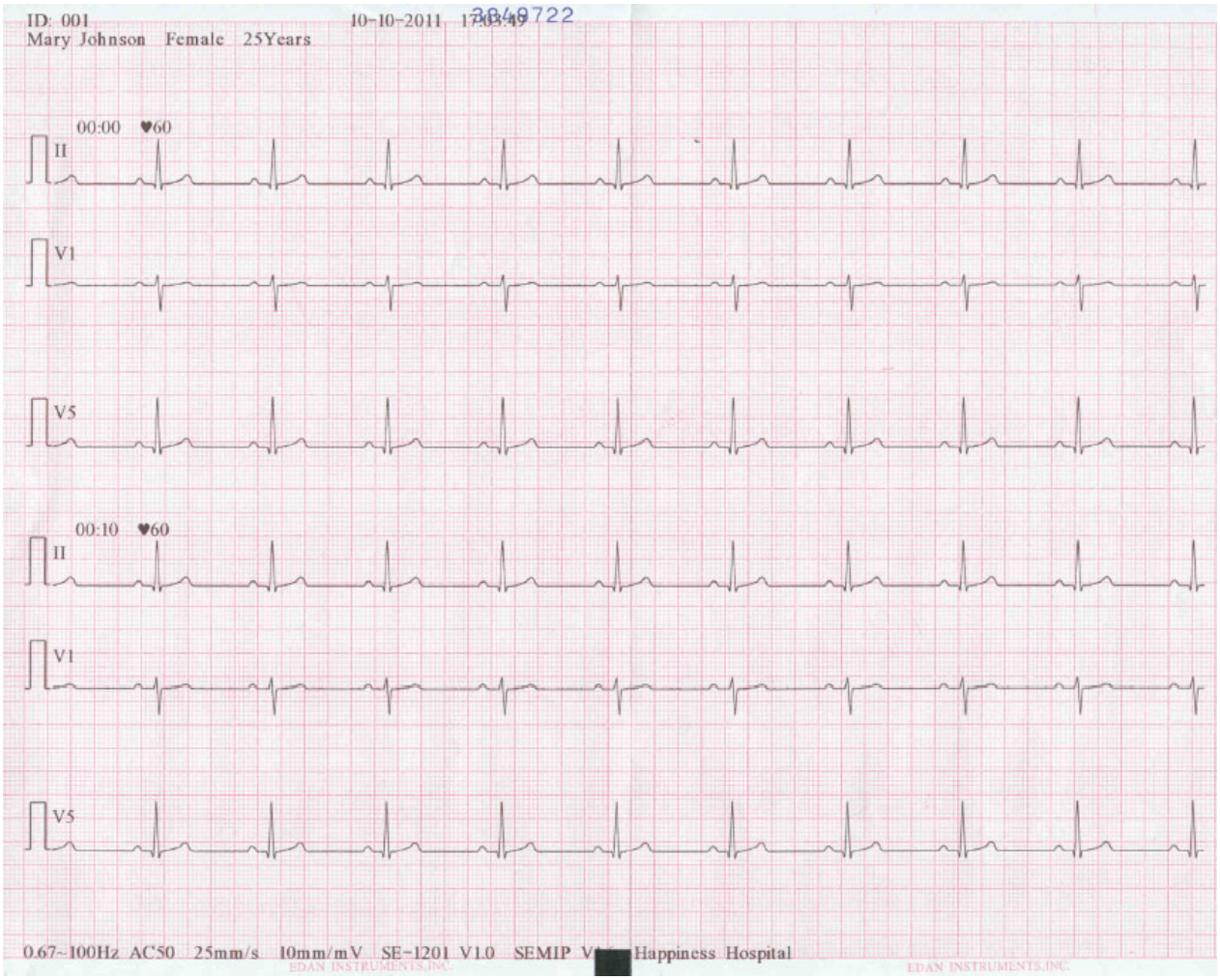
The broken lines on the template are position markers. They respectively mark the start and end points of the P and QRS waves, and the end point of the T wave.

Save Paper Mode



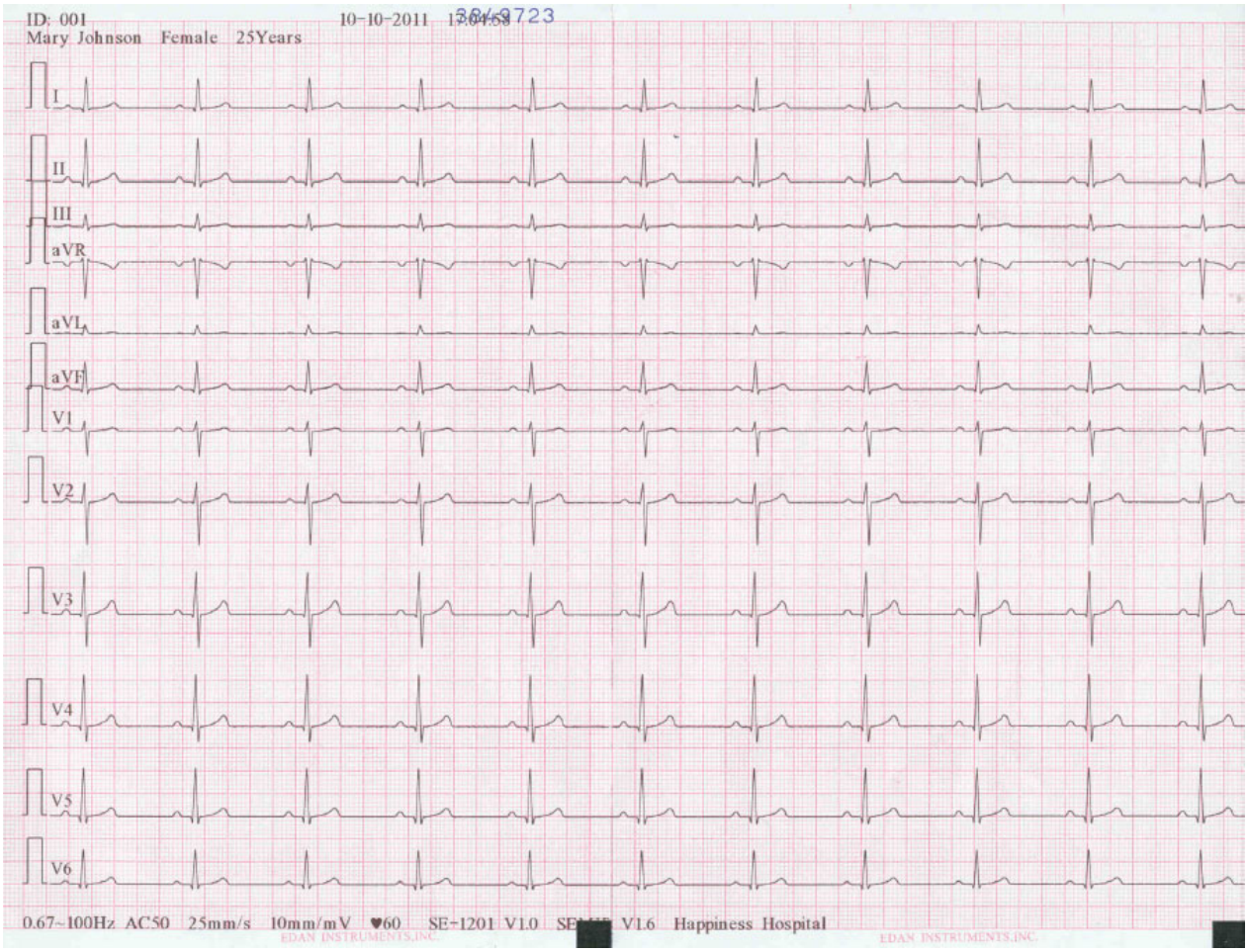
The above figure shows an ECG report in the auto mode. The style is 6×2+1R.

6.5.2 ECG Reports in the Rhythm Mode



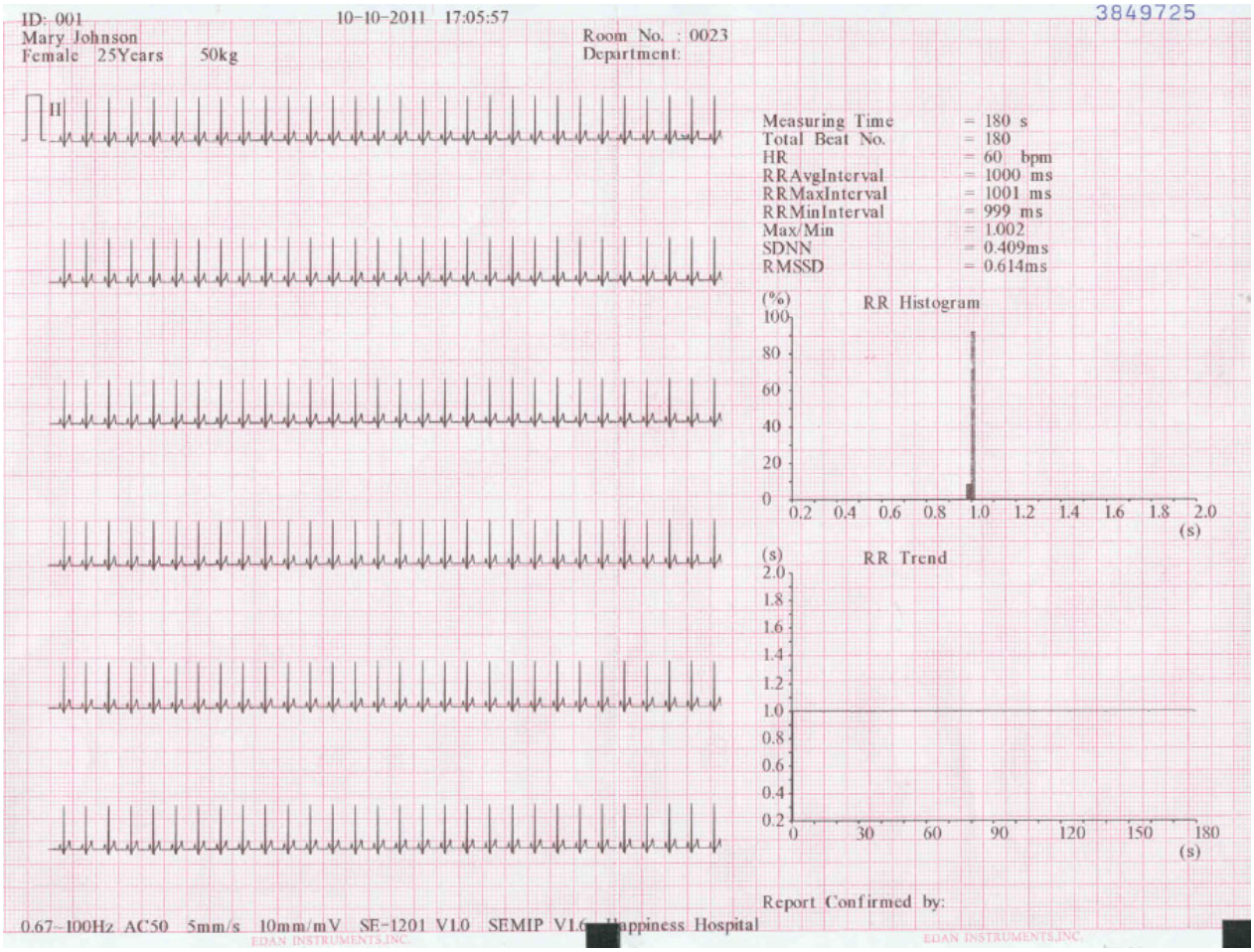
The above figure shows an ECG report in the rhythm mode, and **Rhythm Style** is set to **Three Leads**.

6.5.3 ECG Reports in the Manual Mode

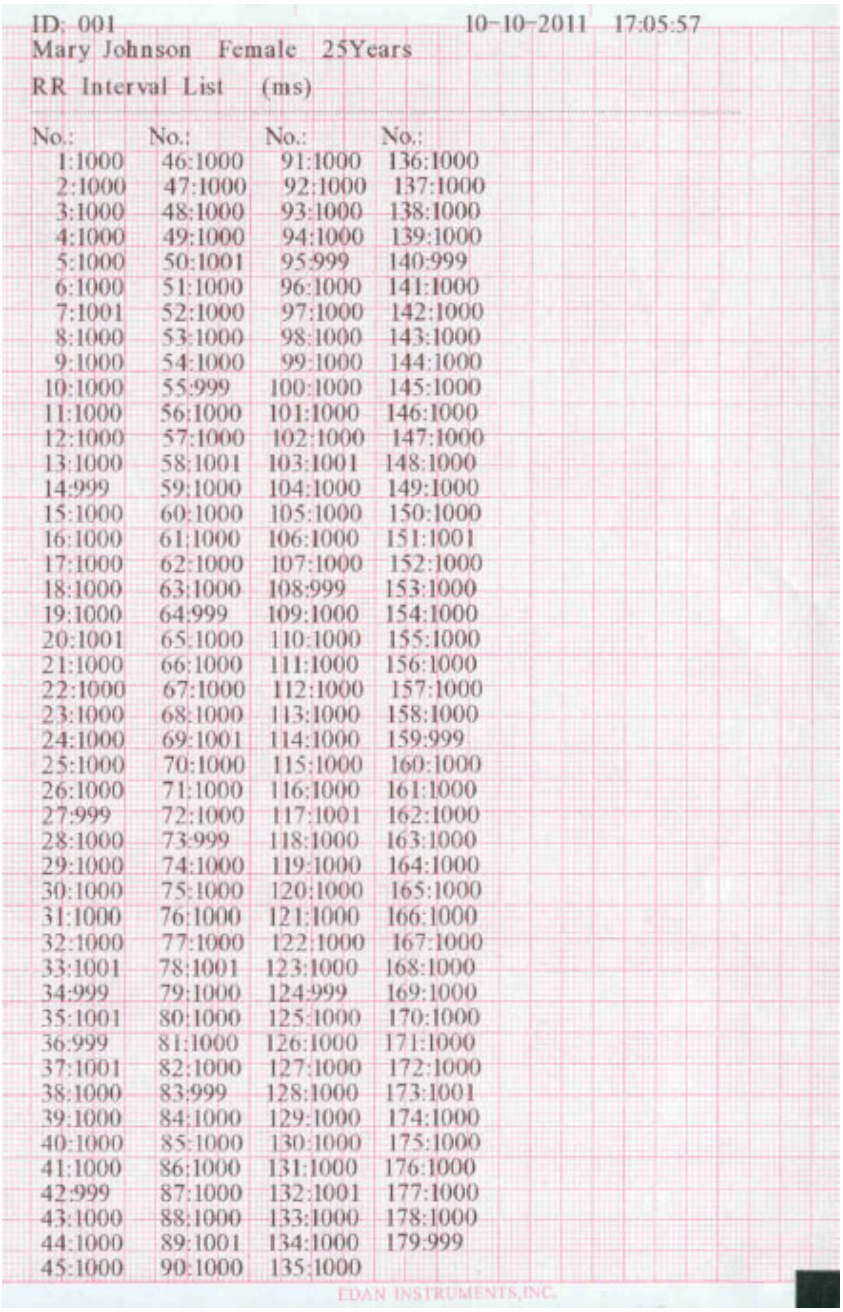


The above figure shows an ECG report in the manual mode, and **Manual Style** is set to **12 channels**.

6.5.4 ECG Reports in the R-R Analysis Mode



(a)



ID: 001 10-10-2011 17:05:57
Mary Johnson Female 25Years
RR Interval List (ms)

No.:	No.:	No.:	No.:
1:1000	46:1000	91:1000	136:1000
2:1000	47:1000	92:1000	137:1000
3:1000	48:1000	93:1000	138:1000
4:1000	49:1000	94:1000	139:1000
5:1000	50:1001	95:999	140:999
6:1000	51:1000	96:1000	141:1000
7:1001	52:1000	97:1000	142:1000
8:1000	53:1000	98:1000	143:1000
9:1000	54:1000	99:1000	144:1000
10:1000	55:999	100:1000	145:1000
11:1000	56:1000	101:1000	146:1000
12:1000	57:1000	102:1000	147:1000
13:1000	58:1001	103:1001	148:1000
14:999	59:1000	104:1000	149:1000
15:1000	60:1000	105:1000	150:1000
16:1000	61:1000	106:1000	151:1001
17:1000	62:1000	107:1000	152:1000
18:1000	63:1000	108:999	153:1000
19:1000	64:999	109:1000	154:1000
20:1001	65:1000	110:1000	155:1000
21:1000	66:1000	111:1000	156:1000
22:1000	67:1000	112:1000	157:1000
23:1000	68:1000	113:1000	158:1000
24:1000	69:1001	114:1000	159:999
25:1000	70:1000	115:1000	160:1000
26:1000	71:1000	116:1000	161:1000
27:999	72:1000	117:1001	162:1000
28:1000	73:999	118:1000	163:1000
29:1000	74:1000	119:1000	164:1000
30:1000	75:1000	120:1000	165:1000
31:1000	76:1000	121:1000	166:1000
32:1000	77:1000	122:1000	167:1000
33:1001	78:1001	123:1000	168:1000
34:999	79:1000	124:999	169:1000
35:1001	80:1000	125:1000	170:1000
36:999	81:1000	126:1000	171:1000
37:1001	82:1000	127:1000	172:1000
38:1000	83:999	128:1000	173:1001
39:1000	84:1000	129:1000	174:1000
40:1000	85:1000	130:1000	175:1000
41:1000	86:1000	131:1000	176:1000
42:999	87:1000	132:1001	177:1000
43:1000	88:1000	133:1000	178:1000
44:1000	89:1001	134:1000	179:999
45:1000	90:1000	135:1000	

EDAN INSTRUMENTS,INC.

(b)

The above figure (a) and (b) show an ECG report in the R-R analysis mode.

Figure (a) shows:

Current Date & Current Time

Patient Information (Name, ID, Gender, Age, Height, Weight)

Measuring Time

Total Beat Number

Gain, Speed, Filter

 (1mV calibration mark)

II (Lead name)

180s compressed ECG wave of Lead II

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 (Root Mean Square Successive Difference)

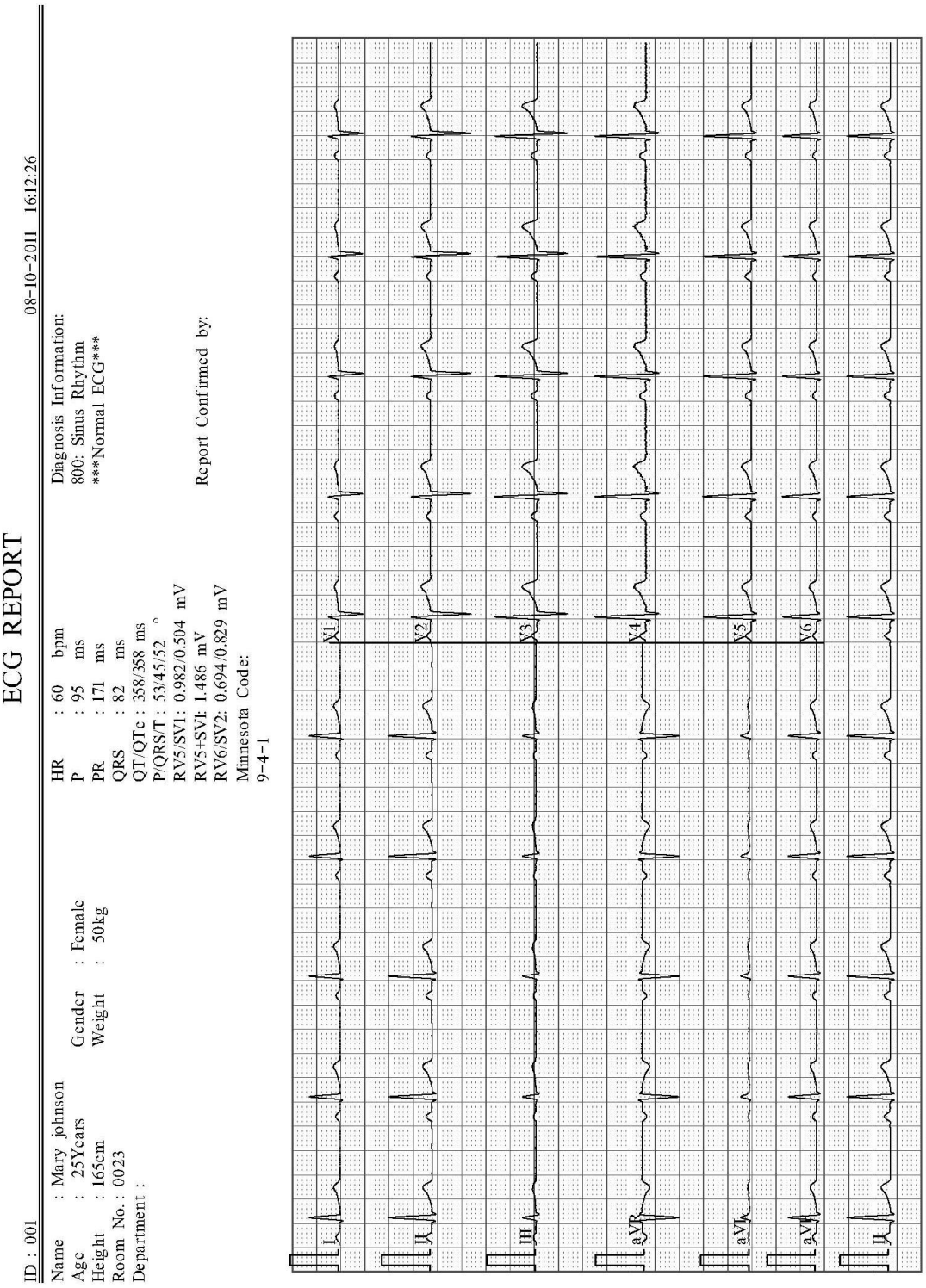
RR Histogram

RR Trend

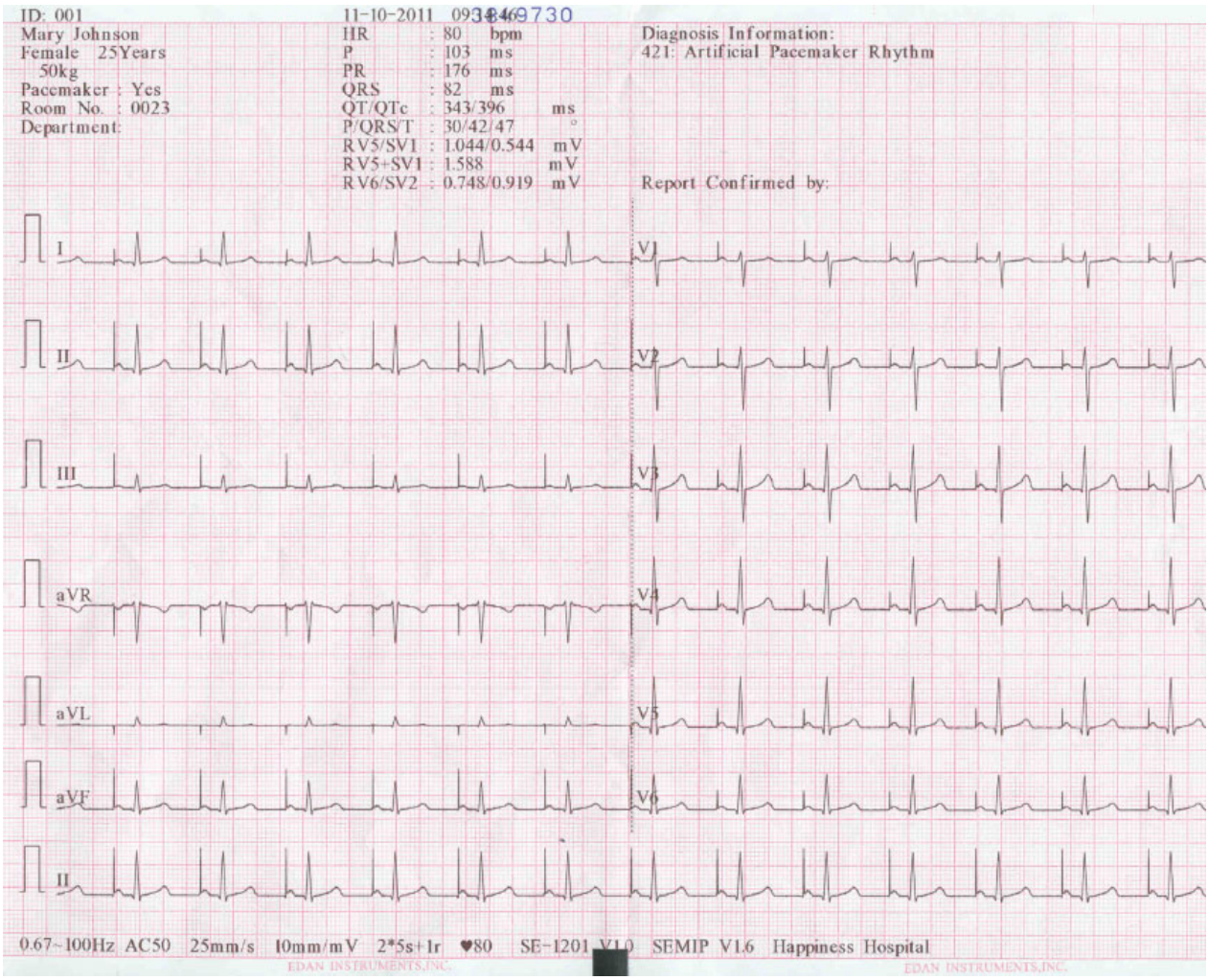
Figure (b) shows:

All the RR interval values within the measuring time

6.5.5 ECG Reports Printed by the USB Printer

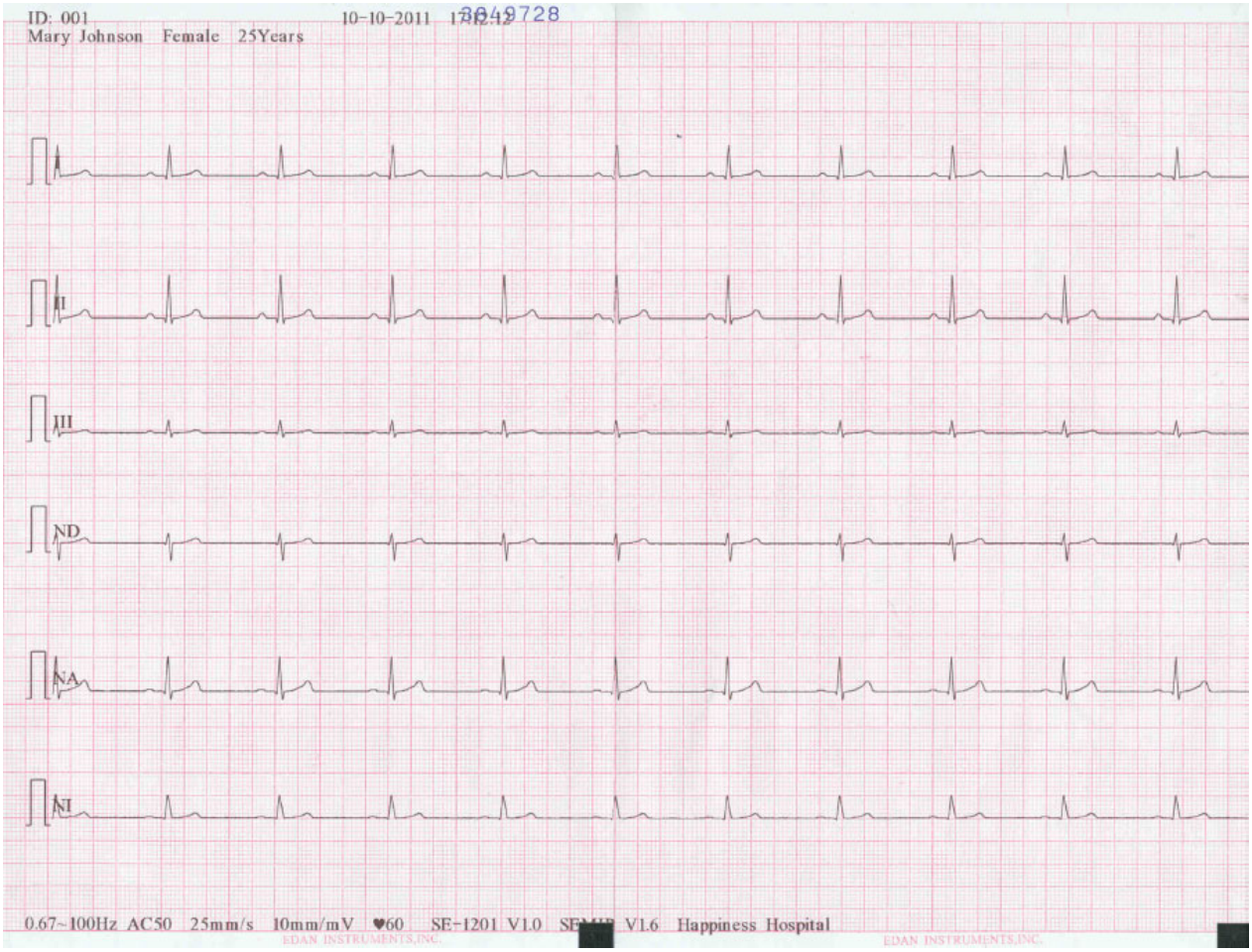


6.5.6 ECG Report of Patient with Pacemaker



The above figure shows the ECG report of a patient with a pacemaker.

6.5.7 ECG Report of Nehb Lead



The above figure shows the ECG report of Nehb lead.

Chapter 7 Transmitting ECG Data

7.1 Transmitting ECG Data to the PC

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

CAUTION

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

7.1.1 Transmitting ECG Data in DAT Format through Ethernet Cable

1. Log into the Smart ECG Viewer software.
2. Connect the electrocardiograph to the network of the PC with an Ethernet cable recommended by the manufacturer.

   NOTE:

   1) If the wireless AP transmission is used, please refer to the user manual delivered with the wireless AP.
   2) There should be no shield in or around the room where the wireless AP is used, or else the wireless transmission may fail.
3. Configure the **Transmission Setup** window.

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

   1) Set **Auto Transmission** to **On**.
   2) Set the **Server IP** item to the IP of the PC.
   3) Set the **Local IP** item.

      For the cross-network transmission,

      a) Set the first two sections of the **Local IP** item to the first two sections of the IP of the PC.

      b) Set the third section of the **Local IP** item to the network segment of the electrocardiograph which depends on the configuration of Router.

c) The last section of the **Local IP** item can be set at random.

For the same network transmission,

a) Set the first three sections of the **Local IP** item to the first three sections of the IP of the PC.

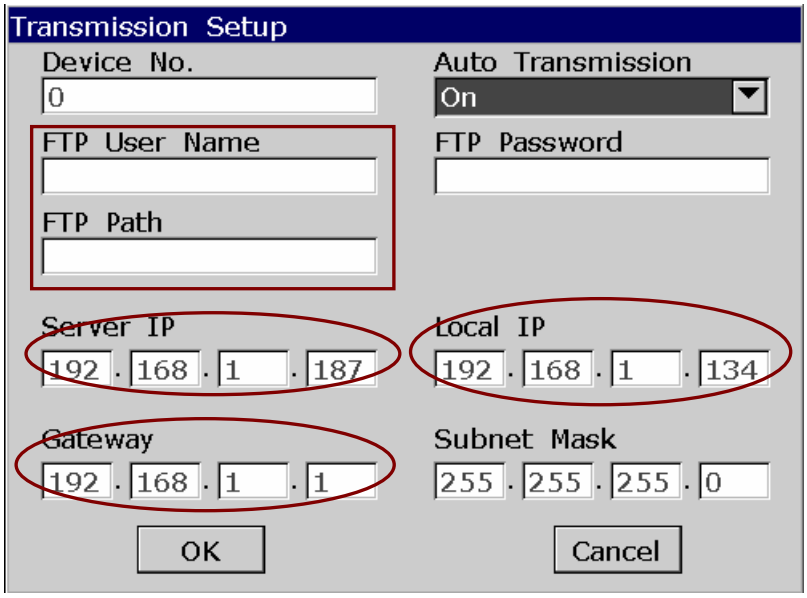
b) The last section of the **Local IP** item can be set at random, but it can't be the same as the last section of the IP of the PC.

4) Set the **Gateway** item.

Set the first three sections of the **Gateway** item to the first three sections of the IP of the electrocardiograph. The last section of the **Gateway** item must be set to **1**.

5) Set the **Subnet Mask** item to **255.255.255.0**.

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



4. Set **Auto Transmission** to **On** in the **Transmission Setup** window.
5. In the auto or rhythm mode, ECG data will be transmitted through the net cable automatically after an ECG report is printed out. In the off mode, the sampled ECG data can be saved and will be transmitted through the net cable automatically after the **PRINT/STOP** key is pressed, but it can not be printed.

7.1.2 Transmitting ECG Data in SCP/FDA-XML/PDF Format through Ethernet Cable

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

1. Log into the FTP receiving software.
2. Connect the electrocardiograph to the network of the PC with an Ethernet cable recommended by the manufacturer.

   NOTE:

   1) If the wireless AP transmission is used, please refer to the user manual delivered with the wireless AP.
   2) There should be no shield in or around the room where the wireless AP is used, or else the wireless transmission may fail.

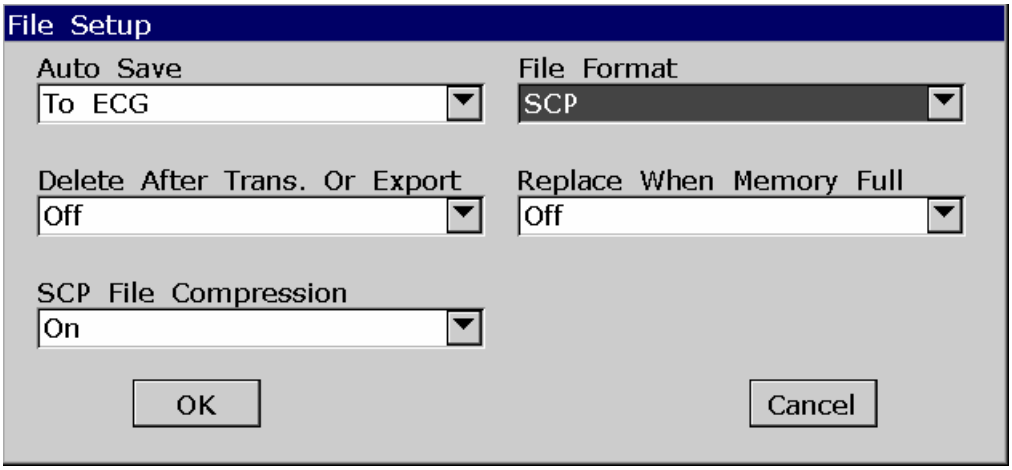
3. Configure the **Transmission Setup** window.
   1) Set **Auto Transmission** to **On**.
   2) Set IP addresses

      For details, please refer to Section 7.1.1 “Transmitting ECG Data in DAT Format through Ethernet Cable”.

   3) Set the **FTP User Name**, **FTP Password** and **FTP Path** items.
      a) The user name and the password you input in the **FTP User Name** and **FTP Password** items must be available for FTP server.
      b) The path you input in the **FTP Path** item must be the subdirectory of the path you input in the FTP receiving software.

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

3. Set file format to SCP/FDA-XML/PDF
   1) Select **Setup> File** to open the **File Setup** window.
   2) Select a desired format from the **File Format** list box.

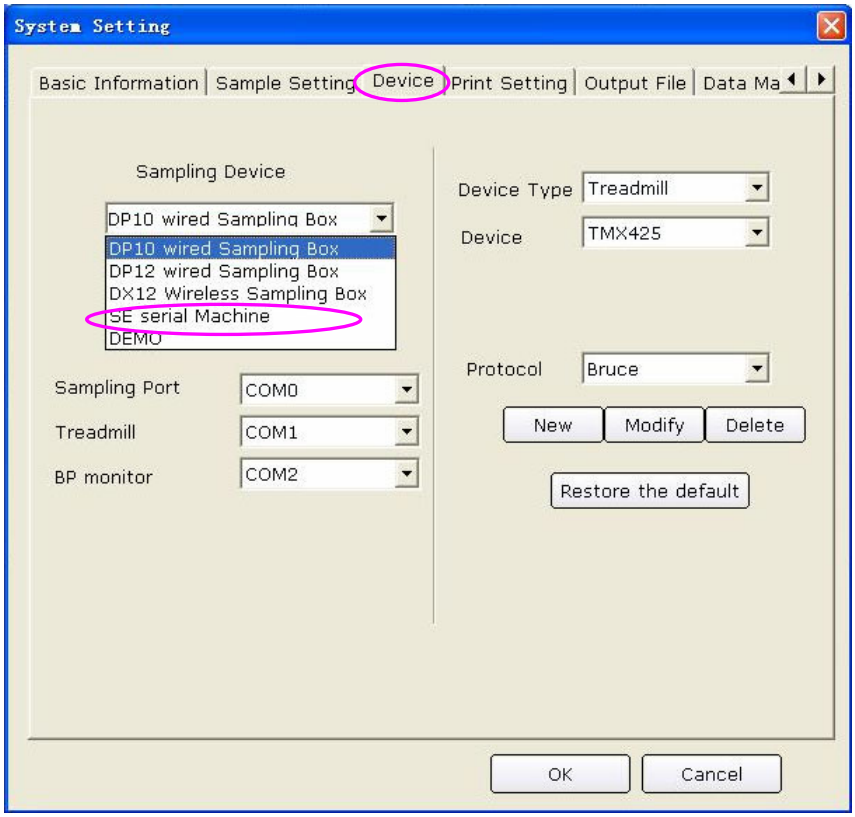


4. In the auto or rhythm mode, ECG data will be transmitted through the net cable automatically after an ECG report is printed out. In the off mode, 10s ECG data sampled after pressing the **PRINT/STOP** key will be transmitted through the net cable automatically.

7.2 Real-time Transmission to PC ECG

NOTE: For the real-time transmission, the PC ECG software of the manufacturer must be installed in the PC.

1. Run the PC ECG software and configure it for the real-time transmission.



1) Double-click on the shortcut icon 

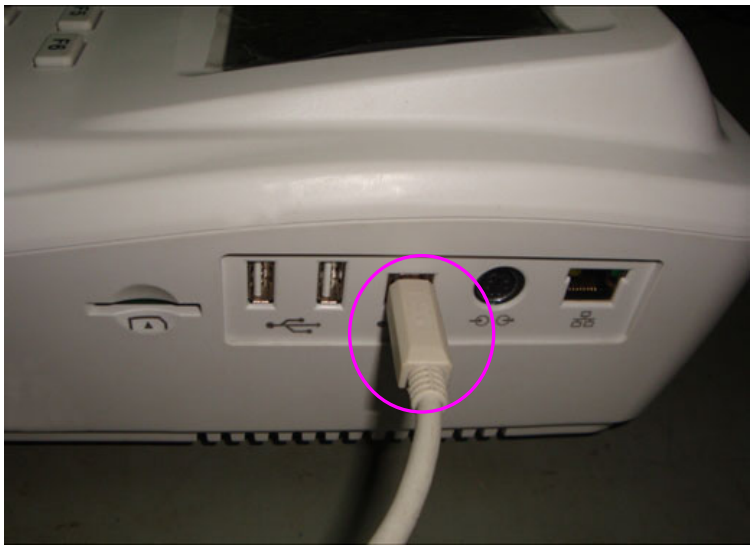
on the desktop to start up the PC ECG software.

2) Click on the **System Setting** button to open the **System Setting** screen, and then click on the **Device** tab.

3) Select **SE Serial Machine** from the **Sampling Device** drop-down list in the **Device** window.

4) After setup, click on the **OK** button to confirm.

2. Connect USB socket 3 of the electrocardiograph to the USB socket of the PC by using the high-speed USB cable.



For details, please contact the manufacturer or the local distributor.

3. Start the real-time transmission

The electrocardiograph transmits to the PC the ECG signals acquired from the patient. Acquisition and transmission are simultaneous. The ECG signals are displayed on the PC monitor and eventually analyzed. For more details, refer to the user manual of the PC ECG software.

In the real-time transmission, the function of the electrocardiograph is the same as that of the ECG sampling box.

Chapter 8 Managing Orders

NOTE: To use the order function, the Smart ECG Viewer software of the manufacturer must be installed in the PC.

Select **Order** on the main screen2 to open the **Order Manager** screen.

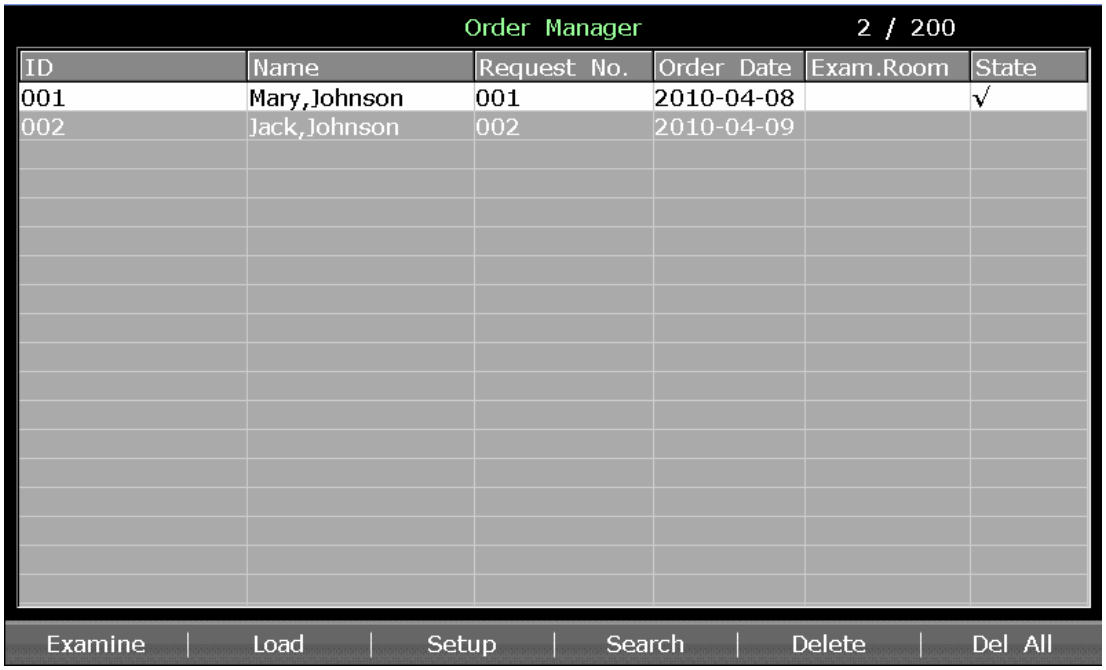


Figure 8-1 Order Manager Screen

8.1 Loading Orders

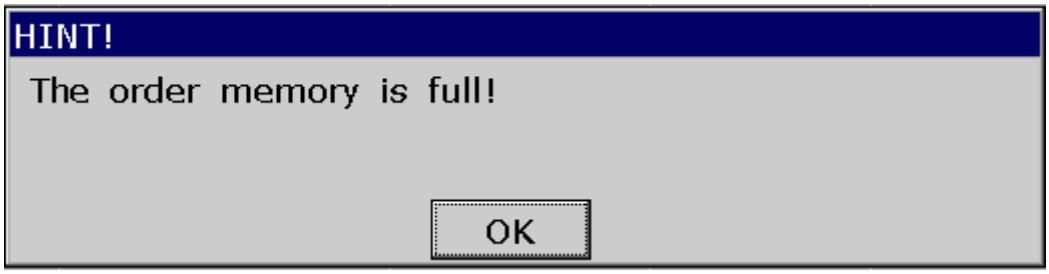
Before loading orders, please configure on the **Order Setup** screen. For details, please refer to Section 8.5 “Setting Orders”.

Operation procedures are as follows:

1. Connect the electrocardiograph to the PC installed with the Smart ECG Viewer software by using an Ethernet cable recommended by the manufacturer.
2. Set **Remote IP**, **Local IP**, **Gateway** and **Subnet Mask** in the **Transmission Setup** window. For details, please refer to Section 7.1.1 “Transmitting ECG Data in DAT Format through Net Cable”.
3. Select **Order** on the main screen2 to open the **Order Manager** screen.
4. Select **Load** on the **Order Manager** screen to load orders from the Smart ECG Viewer software, and then a hint will be displayed as follows.

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

5. If you select **Exam.Room Filter** on the **Order Setup** screen, orders will be filtered after you press **Load**. For details, please refer to Section 8.5 "Setting Orders".
6. If 200 orders already exist on the **Order Manager** screen, the following hint pops up after you press **Load**.



8.2 Examining Orders

Select an order on the **Order Manager** screen, and then select **Examine** or press **Enter** to return to main screen1 for starting an examination.

NOTE: If you select **Delete After Examination** on the **Order Setup** screen, the order will be deleted from the **Order Manager** screen after you examine the selected order. Otherwise, the order will be marked by √ mark on the **Order Manager** screen after you examine the selected order.

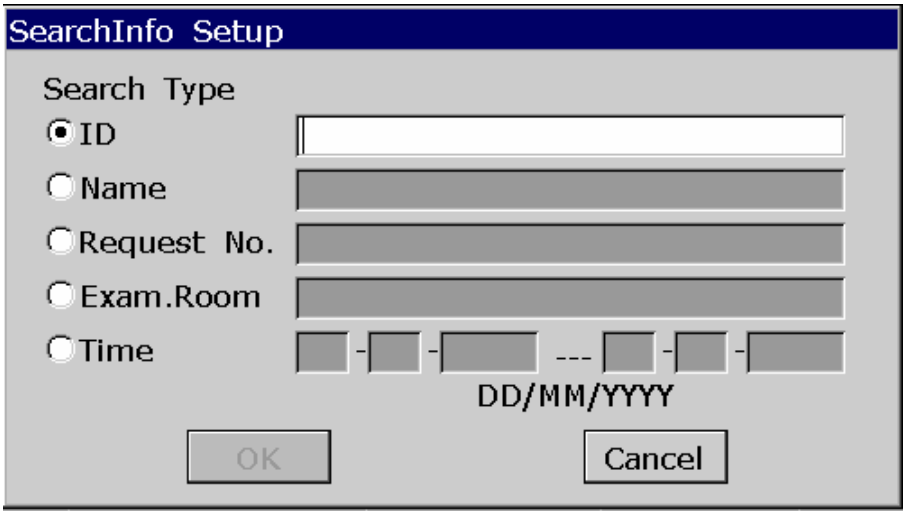
8.3 Deleting Orders

Pressing **Del All** on the **Order Manager** screen can delete all the orders from the electrocardiograph.

Or, you can select an order on the **Order Manager** screen, select **Delete,** and then press **Enter** to delete the selected order from the electrocardiograph.

8.4 Searching Orders

Select **Search** on the **Order Manager** screen to display the following window.



Select the search type, such as ID, Name, Request No., Exam. Room, Time, enter the search information, and then press **Enter** to confirm. All the orders which meet the requirements will be searched and displayed on the **Order Manager** screen.

NOTE: The time mode in the **SearchInfo Setup** window is the mode you select in the **Date & Time Setup** window.

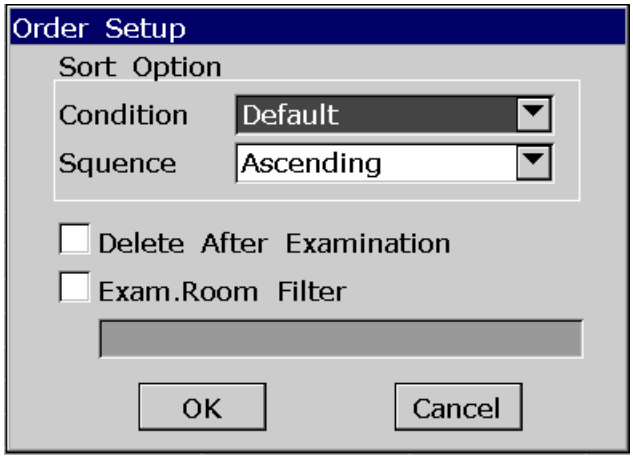
8.5 Setting Orders

8.5.1 Factory Defaults of Orders

Items	Default
Condition	Default
Sequence	Ascending
Delete After Examination	Deselect
Exam. Room Filter	Deselect

8.5.2 Order Setup

Select **Setup** on the **Order Manager** screen to make settings of orders.



Item	Description
Condition	Choose from: **Default**, **ID, Order Date, Request No.** or **State** Select **Default**, orders will be displayed in sequence of the time when the orders are loaded from the Smart ECG Viewer software. Select **ID, Order Date, Request No.** or **State**, orders will be displayed in sequence of the selected condition on the **Order Manager** screen.
Sequence	Choose from: **Ascending** or **Descending** Select **Ascending**, orders will be displayed in ascending sequence based on the option you select from the **Condition** list box. Select **Descending**, orders will be displayed in descending sequence based on the option you select from the **Condition** list box. **NOTE:** 1. When **Condition** is set to **State** and **Sequence** is set to **Ascending**, orders without examination will be displayed on the top of the **Order Manager** screen. 2. When **Condition** is set to **State** and **Sequence** is set to **Descending**, orders with examination will be displayed on the top of the **Order Manager** screen.
Delete After Examination	Choose from: Select or Deselect Select this item, the order will be deleted from the **Order Manager** screen after the order is examined. Deselect this item, the order will be marked by √ on the **Order Manager** screen after the order is examined.

Exam.Room Filter	Choose from: Select or Deselect Select this item, a check mark √ appears in the box before **Exam.Room Filter**. You can enter an exact exam.room in the textbox, such as Electrocardiograph. If the room you entered exists in the Smart ECG Viewer software, all the related information will be searched and displayed on the Order Manager screen. Deselect this item or enter nothing in the textbox, all the loaded information will be searched and displayed on the **Order Manager** screen.

Chapter 9 Managing Files

If you want to save the ECG data in the electrocardiograph, you should set **Auto Save** to **to ECG** in the **File Setup** window. Then the ECG data in the auto, off or rhythm mode will be saved on the **File Manager** screen automatically. For details, please refer to Section 10.10 “File Setup”.

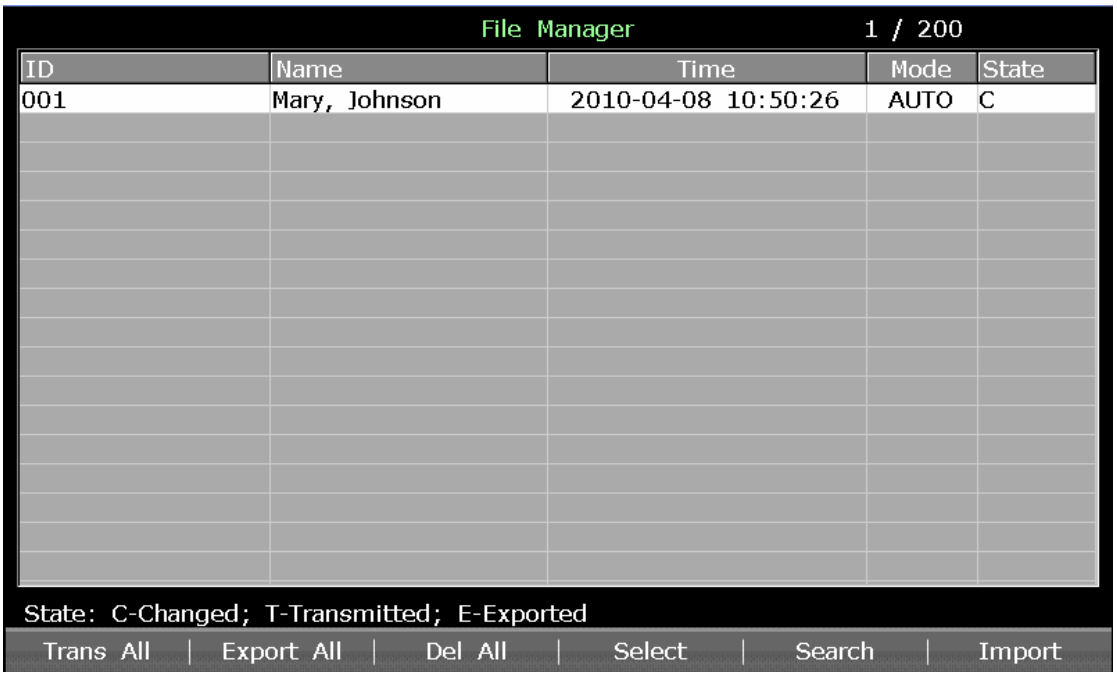


Figure 9-1 File Manager Screen1

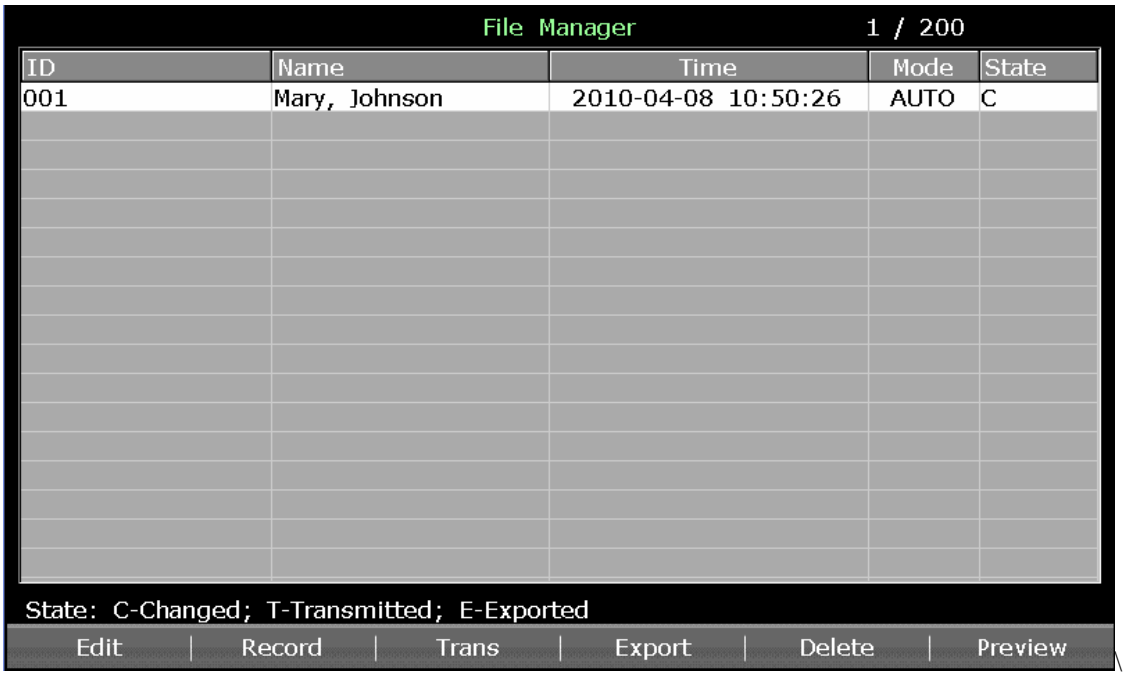
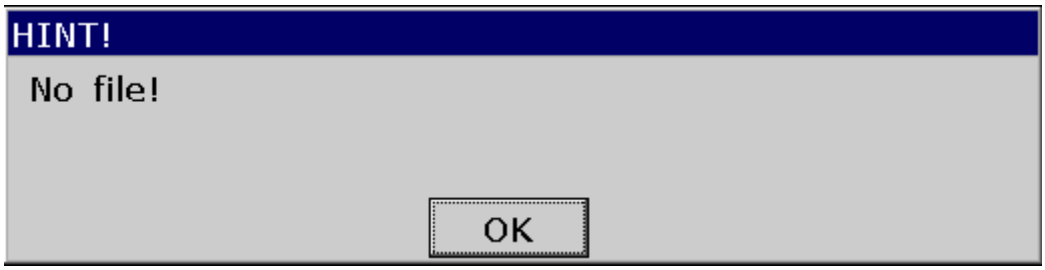


Figure 9-2 File Manager Screen2

On the **File Manager** screen, files can be printed, transmitted, exported, displayed, edited searched or deleted. SE-1201 can accommodate 200 files.

If there is no file on the **File Manager** screen, the following dialog box will pop up when you press function keys.



CAUTION

1. When files are being printed, transmitted, deleted or exported, you can not turn off the electrocardiograph.
2. Do not cut off the mains supply directly when no battery is installed in the device, or else, the stored data may be lost.

9.1 Transmitting Files

Make configuration in accordance with Section 7.1 “Transmitting ECG Data” before you transmit files.

Pressing **Trans All** on the **File Manager** screen1 can transmit all the files from the electrocardiograph.

Or, you select a file on the **File Manager** screen1, and then press **Select** to display the **File Manager** screen2. Select **Trans** on the **File Manager** screen2, and then press **Enter** to transmit the selected file from the electrocardiograph.

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

9.2 Exporting Files

1. Connect the U disk or SD card recommended by the manufacturer to the electrocardiograph.
2. Select **DAT/SCP/FDA-XML/PDF** from the **File Format** list box in the **File Setup** window.
3. Select **Export All** on the **File Manager** screen1 to export all the files to the directory of ***ECGDATA\ECG-X\Export\Export Date and Time*** of the U disk or SD card.
4. Or select a file on the **File Manager** screen1, and then press **Select** to display the **File Manager** screen2. Select **Export** on the **File Manager** screen2 to export the selected file to the directory of ***ECGDATA\ECG-X\Export\Export Date and Time*** of the U disk or SD card.

CAUTION

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

NOTE:

1. Please insert the U disk or SD card recommended by the manufacturer. Please set the format to **FAT** or **FAT32** when formatting the U disk or SD card.
2. X in the directory of ***ECGDATA\ECG-X\Export\Export Date and Time*** can be set in the **Device No.** textbox in the **Transmission Setup** window.
3. If you select **Delete After Trans. Or Export** in the **File Setup** window, the files will be deleted from the **File Manager** screen after they are exported.

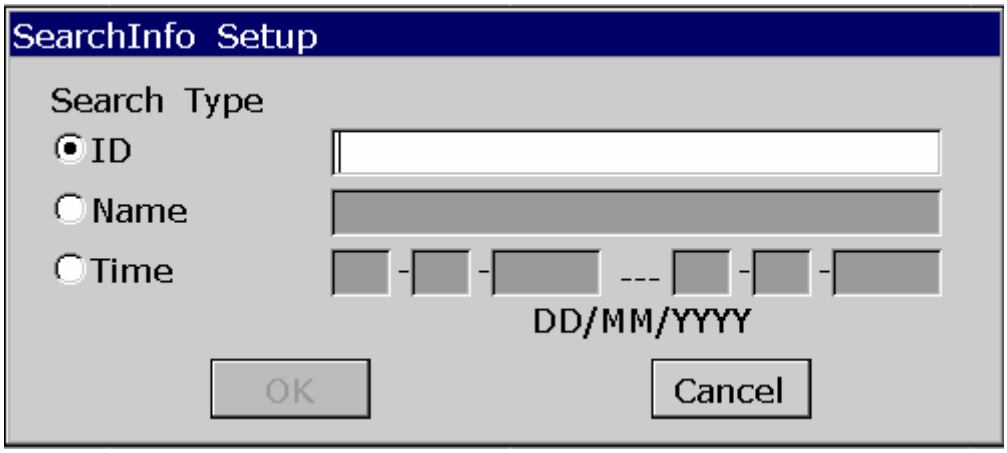
9.3 Deleting Files

Pressing **Del All** on the **File Manager** screen1 can delete all the files from the electrocardiograph.

Or, you select a file on the **File Manager** screen1, and then press **Select** to display the **File Manager** screen2. Select **Delete** on the **File Manager** screen2, and then press **Enter** to delete the selected file from the electrocardiograph.

9.4 Searching Files

Select **Search** on the **File Manager** screen1 to display the following window.



Select the search type, such as ID, Name, Time, enter the search information, and then press **Enter** to confirm. All the files which meet the requirements will be searched and displayed on the **File Manager** screen.

NOTE: The time mode in the **SearchInfo Setup** window is the mode you select in the **Date & Time Setup** window.

9.5 Importing Files

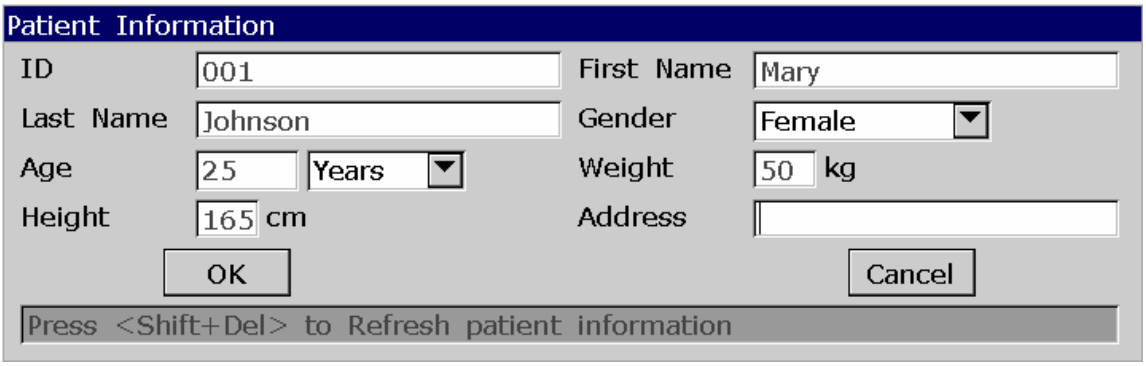
Operation procedures are as follows:

1. Connect the U disk or SD card recommended by the manufacturer to the electrocardiograph.
2. Save files to the directory of ***ECGDAT\Import*** of the U disk or SD card.
3. Select **File** on the main screen2 to open the **File Manager** screen1.
4. Select **Import** on the **File Manager** screen1 to import files from the directory of ***ECGDAT\Import*** of the U disk or SD card to the electrocardiograph.

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

9.6 Editing Patient Information

Press **Select** on the **File Manager** screen1 to display the **File Manager** screen2, and then select **Edit** to open the **Patient Information** window.



NOTE: The **Address** item can be defined in the **User-defined** text box in the **Patient Information Setup** window. For details, please refer to Section 10.5 “Patient Information Setup”.

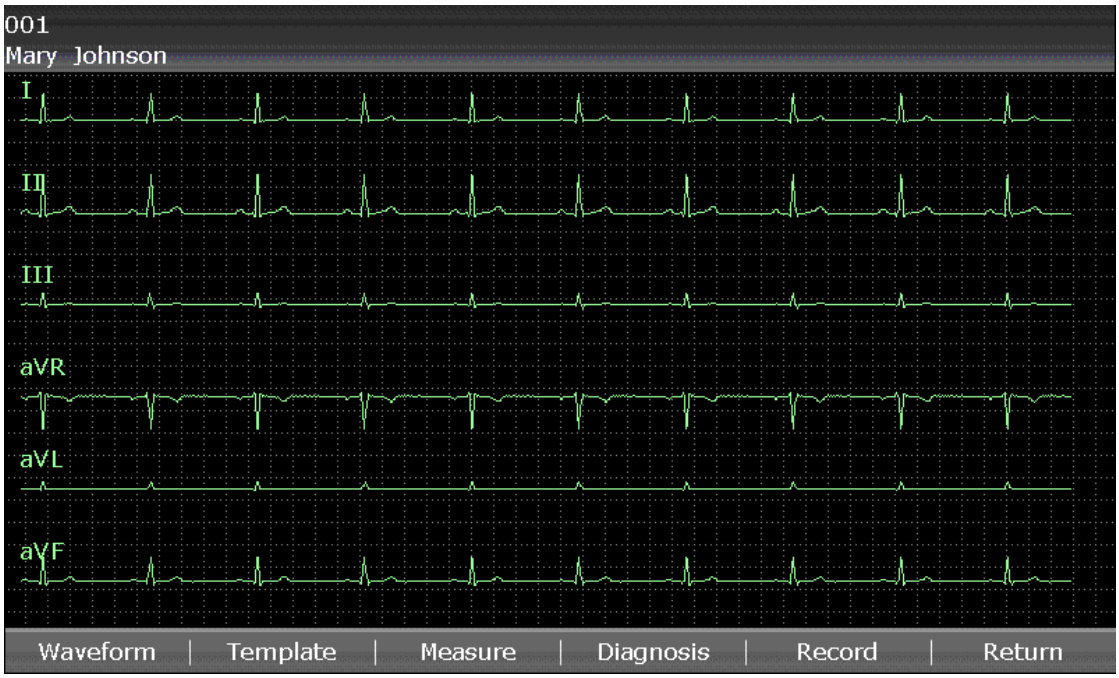
For details on inputting data, please refer to Section 4.1.2, “Entering Data”.

9.7 Printing Files

You can press **PRINT/STOP** on the File Manager screen1/2 or the preview screen to print ECG reports. For details, please refer to Section 6.4 “Printing a Stored ECG Report”.

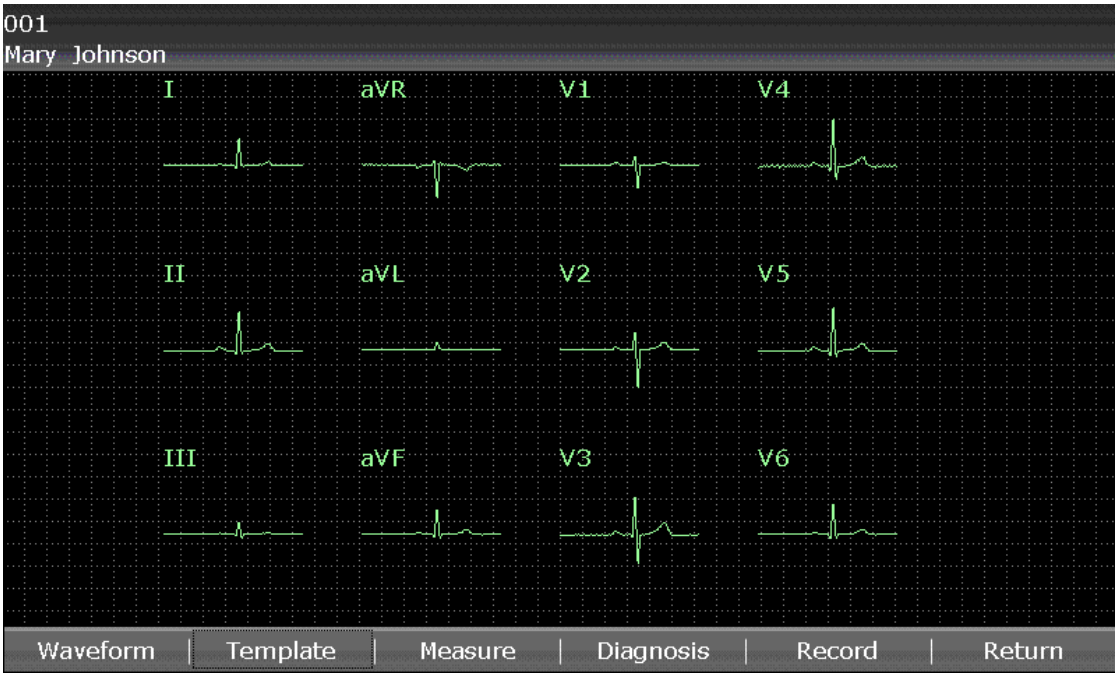
9.8 Previewing a File

1. Select **Preview** on the **File Manager** screen2 to open the file preview screen.
2. Select **Waveform** to display the waveform screen.

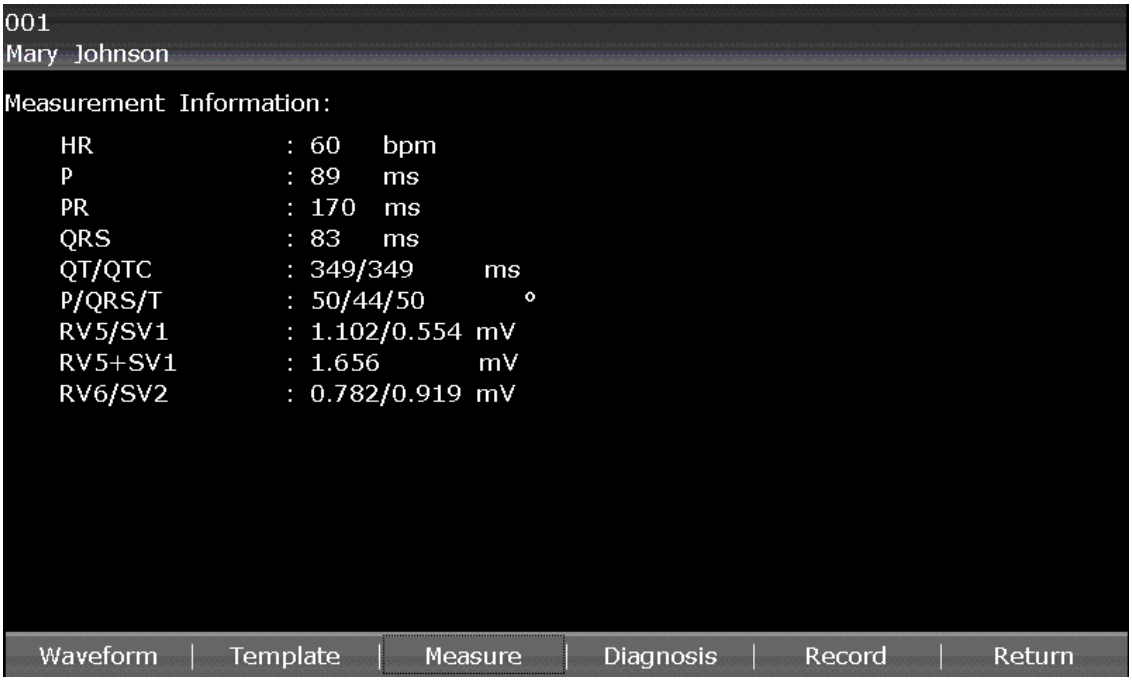


You can press the Left or Right arrow to switch between the lead groups when previewing a file on the waveform screen.

3. Select **Template** to display the template screen.



4. Select **Measure** to display the measure screen which shows the measurement information.



5. Press **PRINT/STOP** or select **Record** on the preview screen to print the selected file.Or, press **PRINT/STOP** again to stop printing the file.
6. Select **Diagnosis** to show Minnesota Code and Diagnosis Information.

Chapter 10 System Setup

Select **Setup** on the main screen 2 to display the **System Setup** screen.

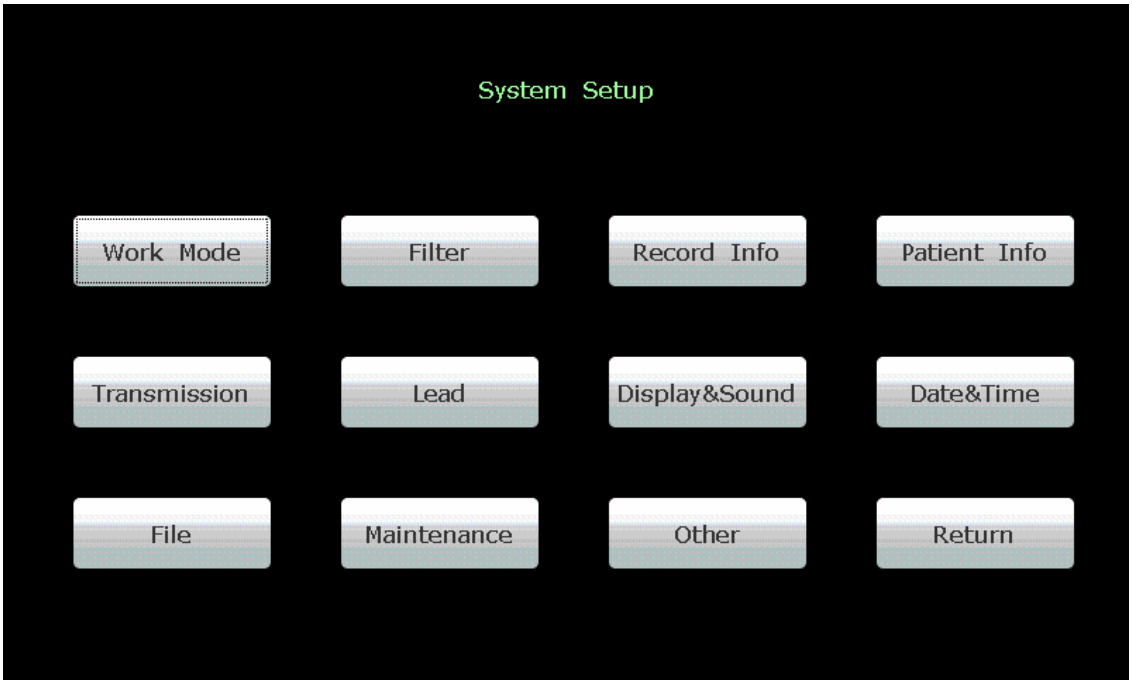


Figure 10-1 System Setup Screen

10.1 Factory Defaults

Table 10-1 Factory Defaults

Work Mode Setup	
Items	**Default**
Mode Options	Auto, Manual, Rhythm
Manual Style	6 channels
Auto Display Style	6×2
Rhythm Style	Three Leads
Sampling Mode	Real-time Sample
Duration (Periodic Sample)	60 min
Interval (Periodic Sample)	1 min
Auto Extend Record	Off

Filter Setup	
Items	**Default**
AC filter	On
EMG filter	Off
DFT filter	0.67Hz
Lowpass filter	100Hz
Record Info Setup-Setup1	
Items	**Default**
Record Style	6×2
Record Mode	Save Paper
Record Sequence	Sequential
Gain	10mm/mV
Record Device	Thermal
Speed	25mm/s
Paper Marker	Yes
Paper Style	210×140mm
Sample Time	10s
Record Info Setup-Setup2	
Items	**Default**
Template \ Measure \ Analysis	On
Position Marker \ Minnesota Code	Off
Baseline Adjustment	Horizontal
RR Interval List	Off
Grid of Thermal Report	Off
Grid of USB Report	On
Patient Information Setup	
Items	**Default**
Gender \ Pacemaker	On
First/Last Name \ BP \ Race \Height \Weight\ Medication \ Room No.\ Department \ Physician \ Technician \ Ref-Physician \ Exam. Room	Off

ID Mode	Auto
ID Hint	On
Age Mode	Age
H/W Unit	cm/kg
BP Unit	mmHg
Prompt	Confirmed By
Patient Information Refreshed	On
Order Acquired	Off
User-defined	Cleared
Transmission Setup	
Items	**Default**
Auto Transmission	Off
FTP User Name/FTP Password/ FTP Path	Cleared
Lead Setup	
Items	**Default**
Lead Sequence	Standard
Nehb	Off
Rhythm Lead 1	II
Rhythm Lead 2	V1
Rhythm Lead 3	V5
Display & Sound Setup	
Items	**Default**
Brightness	16
Display Colors	Option 1
Antialiasing	Off
Grid	On
QRS Volume	Off
Hint Volume	Medium

Key Volume	Medium
Notify Volume	Medium
Date & Time Setup	
Items	**Default**
Date Mode	DD-MM-YYYY
Time Mode	24 Hours
Power Off/ LCD Off	Cleared
File Setup	
Items	**Default**
Auto Save	To ECG
File Format	DAT
Delete After Trans. Or Export	Off
Replace When Memory Full	Off
SCP File Compression (after being activated)	On
Maintenance Setup	
Items	**Default**
System Password	Cleared
Other Setup	
Items	**Default**
External Input	Off
External Output	Off
Caps Lock	Off

10.2 Work Mode Setup

Select **Work Mode** on the **System Setup** screen, and then press **Enter** to open the **Work Mode Setup** window.

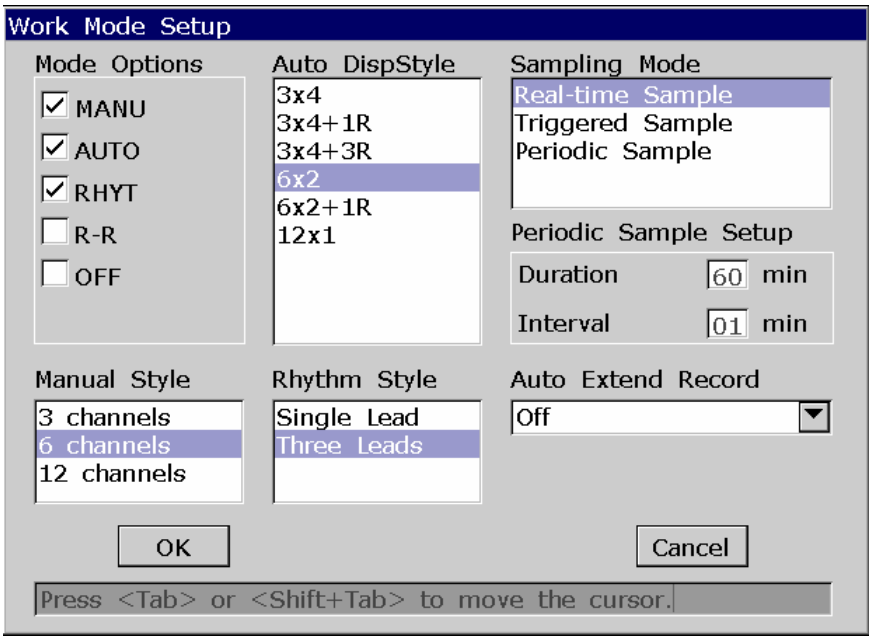


Figure 10-2 Work Mode Setup Window

Item	Description
Mode Options	Choose from: **AUTO**, **MANU**, **RHYT, R-R**, or **OFF** **NOTE:** Only if a work mode is selected in the **Work Mode Setup** window, can the work mode be selected by pressing the **MODE** key when the main screen is displayed. Select **MANU**, you can determine the lead group to be displayed and printed. Select **AUTO**, the lead groups are switched automatically according to the lead sequence during the printing course. After the ECG waves of one lead group are printed within a certain time, the system switches to print ECG waves of another lead group automatically. Select **RHYT**, you can select rhythm leads to print 60s or 20s rhythm-lead ECG waves. Select **R-R**, you can select a lead to print its R-R histogram, R-R trend chart, 180s compressed ECG waveform and all the R-R interval values. Select **OFF**, the lead groups are switched automatically according to the lead sequence. When the main screen is displayed, after pressing the **PRINT/STOP** key, the sampled ECG data can be saved and transmitted, but can not be printed.

Item	Description
Auto DispStyle	Choose from: **3×4**, **3×4+1R**, **3×4+3R**, **6×2**, **6×2+1R** or **12×1** Select **3×4** to display ECG waves of 12 leads in 4 groups of 3. Select **3×4+1R** to display ECG waves of 12 leads in 4 groups of 3 with the ECG wave of one rhythm lead on the bottom. Select **3×4+3R** to display ECG waves of 12 leads in 4 groups of 3 with ECG waves of three rhythm leads on the bottom. Select **6×2** to display ECG waves of 12 leads in 2 groups of 6. Select **6×2+1R** to display ECG waves of 12 leads in 2 groups of 6 with the ECG wave of one rhythm lead on the bottom. Select **12×1** to display ECG waves of 12 leads on one screen simultaneously.
Manual Style	Choose from: **3 channels**, **6 channels** or **12 channels** Select **3 channels** to display ECG waves of 3 leads. Select **6 channels** to display ECG waves of 6 leads. Select **12 channels** to display ECG waves of 12 leads.
Rhythm Style	Choose from: **Single Lead** or **Three Leads** Select **Single Lead** c to print 60s ECG waves of the appointed single rhythm lead. Select **Three Leads** to print 20s ECG waves of three appointed rhythm leads.
Sampling Mode	Choose from: **Real-time Sample**, **Triggered Sample** or **Periodic Sample** Select **Real-time Sample**, 10s ECG data sampled after pressing the **PRINT/STOP** key will be printed out. Select **Triggered Sample**, after pressing the **PRINT/STOP** key, if Arrhythmia ECG data, including Asystole, Ventricular Fibrillation/Ventricular Tachycardia, 5>PVCS>=3, Paired PVCS, Bigeminy, Trigeminy, R ON T, single PVC and Missed Beat, is detected during the learning course, the printing will be triggered automatically. **NOTE:** ID and patient information will not be changed while carrying out the periodic printing.
Duration & Interval	In the auto mode, when **Sampling Mode** is set to **Periodic Sample**, if **Interval** is set to **2 min**, **Duration** is set to **24 min**, after pressing the **PRINT/STOP** key, the printing will be performed every two minutes and come to 12 times.
Auto Extend Record	Choose from: **On** or **Off** Select **On**, if arrhythmia is detected in the auto or off mode, a hint will pop up to ask you whether to print an extra rhythm report after the 12-lead ECG report.

10.3 Filter Setup

Select **Filter** on the **System Setup** screen, and then press **Enter** to open the **Filter Setup** window.

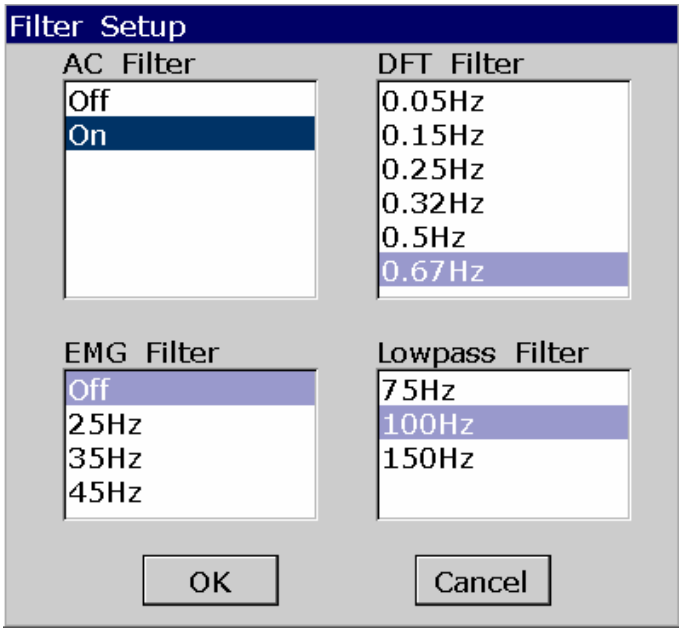


Figure 10-3 Filter Setup Window

Item	Description
AC Filter	Choose from: **On** or **Off** **NOTE:** AC frequency can be set to **50Hz** or **60Hz** on the **Advanced Setup** screen according to local mains supply specifications.
DFT Filter	DFT Filter greatly reduces the baseline fluctuations without affecting the ECG signals. The purpose of this filter is to keep the ECG signals on the baseline of the printout. Choose from: **0.05Hz**, **0.15Hz**, **0.25Hz**, **0.32Hz**, **0.5Hz** or **0.67Hz** (The set value is the low limit of the frequency range.)
EMG Filter	EMG Filter suppresses disturbance caused by strong muscle tremor. Choose from: **25Hz**, **35Hz, 45Hz** or **Off** The cutoff frequency can be set to **25Hz**, **35Hz** or **45Hz**. Select **Off** to turn off the function.
Lowpass Filter	Lowpass Filter restricts the bandwidth of input signals. The cutoff frequency can be set to **150Hz**, **100Hz** or **75Hz**. All the input signals whose frequency is higher than the set cutoff frequency will be attenuated. **NOTE:** Only when **EMG Filter** is set to **Off**, can the setting of **Lowpass Filter** be effective.

10.4 Record Info Setup

Select **Record Info** on the **System Setup** screen, and then press **Enter** to open the **Record Info Setup** window.

10.4.1 Setup 1

Press **F1** to switch to the **Setup 1** window.

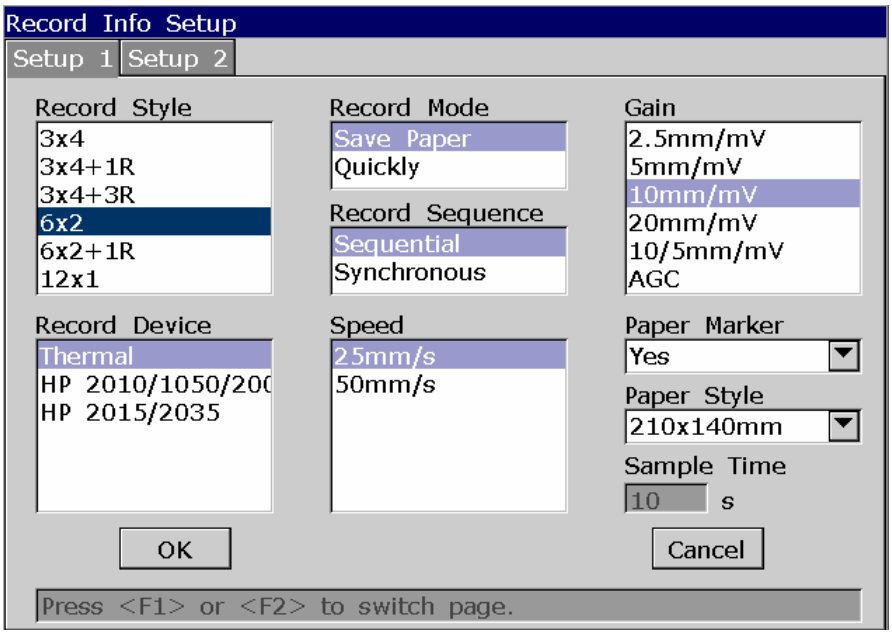


Figure 10-4 Record Info Setup1

Item	Description
Record Style	Choose from: 3×4, 3×4+1R, 3×4+3R, 6×2, 6×2+1R or 12×1 Select **3×4** to print ECG waves of 12 leads in 4 groups of 3. Select **3×4+1R** to print ECG waves of 12 leads in 4 groups of 3, with the ECG wave of one rhythm lead on the bottom of the ECG reports. Select **3×4+3R** to print ECG waves of 12 leads in 4 groups of 3, with the ECG waves of three rhythm leads on the bottom of the ECG reports. Select o **6×2** to print ECG waves of 12 leads in 2 groups of 6. Select **6×2+1R** to print ECG waves of 12 leads in 2 groups of 6, with the ECG wave of one rhythm lead on the bottom of the ECG reports. Select **12×1** to print ECG waves of 12 leads simultaneously.

Item	Description
Record Mode	Choose from: **Save Paper** or **Quickly** Select **Save Paper**, 10s after pressing the **PRINT/STOP** key on the main screen, an ECG report is printed. The patient information, measure information, interpretation and ECG waves are printed at the same time. Select **Quickly**, pressing the **PRINT/STOP** key on the main screen to begin printing an ECG report immediately, the patient information, measure information, interpretation and ECG waves are printed on the different pieces of paper. **NOTE:** 1. In the auto mode, only when **Sampling Mode** is set to **Real-time Sample**, **Quickly** is available. 2. When **Record Style** is set to **3×4**, **3×4+1R** or **3×4+3R**, only **Save Paper** is available. When **Record Style** is set to **12×1,** only **Quickly** is available
Record Sequence	Choose from: **Sequential** or **Synchronous** Select **Sequential**, the lead group is printed one by one in a certain sequence. The start time of a lead group is just the end time of the previous lead group. Select **Synchronous**, the lead group is printed one by one in a certain sequence. All leads are printed with the same start time.
Gain	You can set the indicated height of 1mV ECG on the paper. Choose from: **10mm/mV**, **20mm/mV**, **10/5mm/mV**, **AGC**, **2.5mm/mV** or **5mm/mV**. **AGC** means auto gain control. When ECG signals vary greatly, **AGC** can be selected to adjust the gain automatically according to actual signals. **10/5mm/mV** means that the gain of limb leads is set to **10mm/mV**, while the gain of chest leads is set to **5mm/mV**.
Record Device	Choose from: **Thermal**, **HP 2010/1050/2000** or **HP 2015/2035** You should connect the corresponding USB printer **HP 2010/1050/2000** and **HP 2015/2035** to the electrocardiograph.

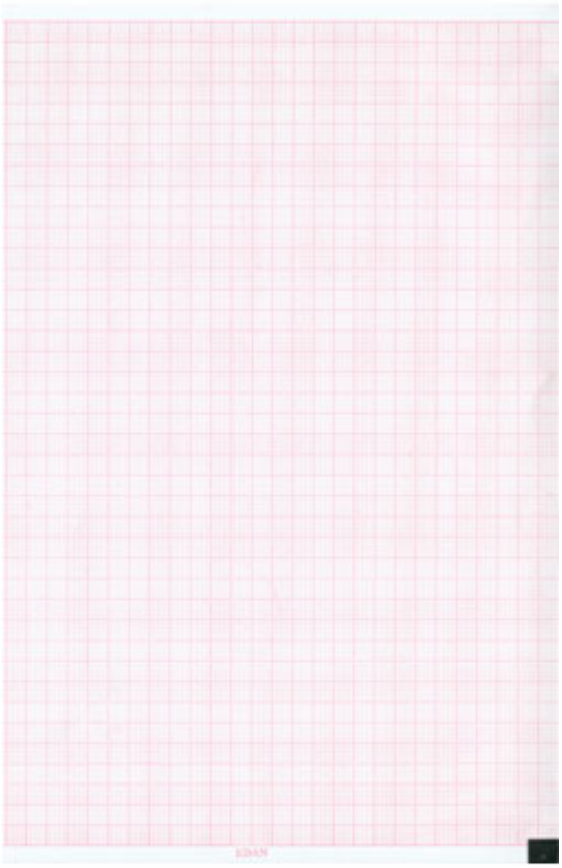
WARNING

If the printer used is not the type listed above, additional safety measures (such as applying an isolation transformer to supply the medical system) should be taken when the safety of the medical system has not been evaluated. If in doubt, consult our technical service department or your local distributor.

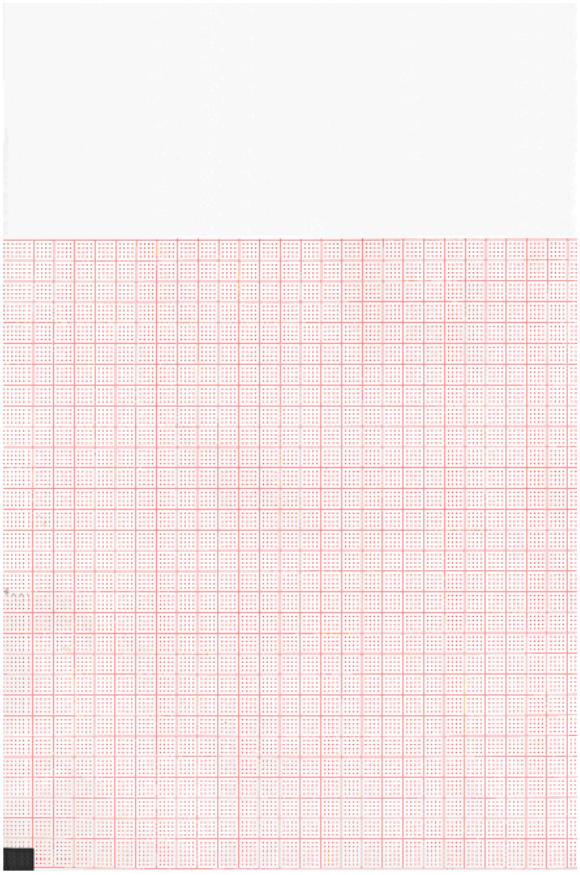
<table>
<tr><th>Item</th><th>Description</th></tr>
<tr><td>Record Device</td><td>
<table>
<tr><th>Options</th><th>Corresponding USB Printers</th></tr>
<tr><td rowspan="4">HP 2010/1050/2000</td><td>HP Deskjet 2010</td></tr>
<tr><td>HP Deskjet 1050</td></tr>
<tr><td>HP Deskjet 2000</td></tr>
<tr><td>HP Deskjet 2050</td></tr>
<tr><td rowspan="2">HP2035</td><td>HP Laserjet P2015</td></tr>
<tr><td>HP Laserjet P2035</td></tr>
</table>
NOTE:
1. During the USB printing course，pressing the PRINT/STOP key again can not stop printing ECG reports.
2. For details of the ECG report printed by the USB printer, please refer to Section 6.5.5, “ECG Reports Printed by the USB Printer”.
3. USB printing is ineffective in the auto periodic sampling mode, auto 11~24s sampling mode, manual mode and R-R analysis mode.
4. Make sure that paper is installed in the USB printer before printing. Error may occur if no paper is loaded in the USB Printer.
</td></tr>
<tr><td colspan="2"><u>CAUTION</u>
It is forbidden to connect or disconnect a U disk, an SD card or a USB printer during the transmission course.</td></tr>
<tr><td>Speed</td><td>Choose from: 5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s or 50mm/s
In the manual mode, select 5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s or 50mm/s.
Only 25mm/s and 50mm/s are available in the auto and rhythm modes.
Only 25mm/s is available in the R-R analysis mode.</td></tr>
<tr><td>Paper Marker</td><td>Paper Marker is used to identify the start point of each page of the recorder paper.
Choose from: Yes or No
Select Yes if the paper with black markers on the bottom is used, and the device can identify the start point of each page of the recorder paper while printing ECG reports.</td></tr>
</table>

Item	Description
Paper Marker	Select **No**, the device can not identify the start point of each page of the recorder paper while printing ECG reports.
Sample Time	If **Record Style** is set to **12×1**, you can set the time period. If the time period is set from 11 to 24 seconds, in the auto mode, after pressing the **PRINT/STOP** key, the ECG waves of the set time period are printed. **NOTE:** If the time period is set from 11 to 24 seconds, the ECG data sampled will not be analyzed or stored.
Paper Style	**Paper Style** is used to identify the style of the recorder paper. Choose from: **210×140mm, 216×140mm, A4 (210×295mm)** or **Letter (215×280mm)**

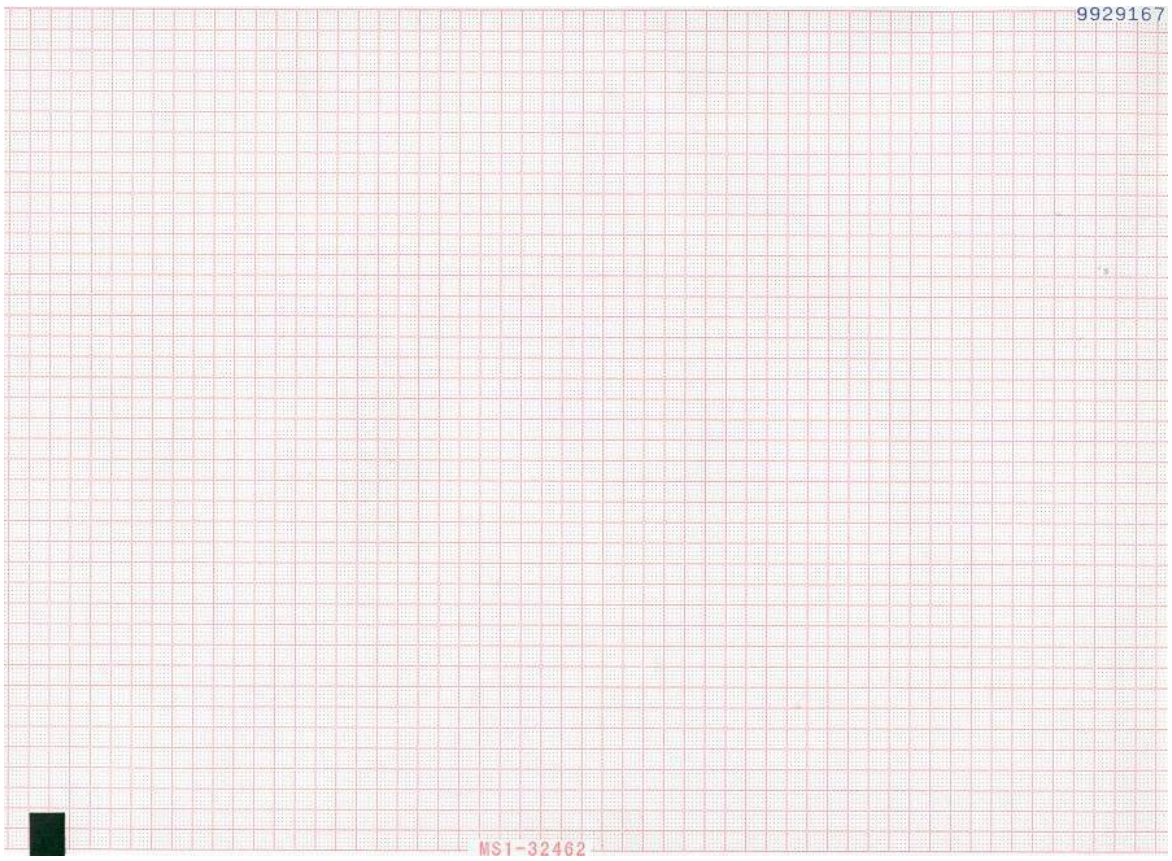
All the recorder paper related to the options of the **Paper Style** is shown below:



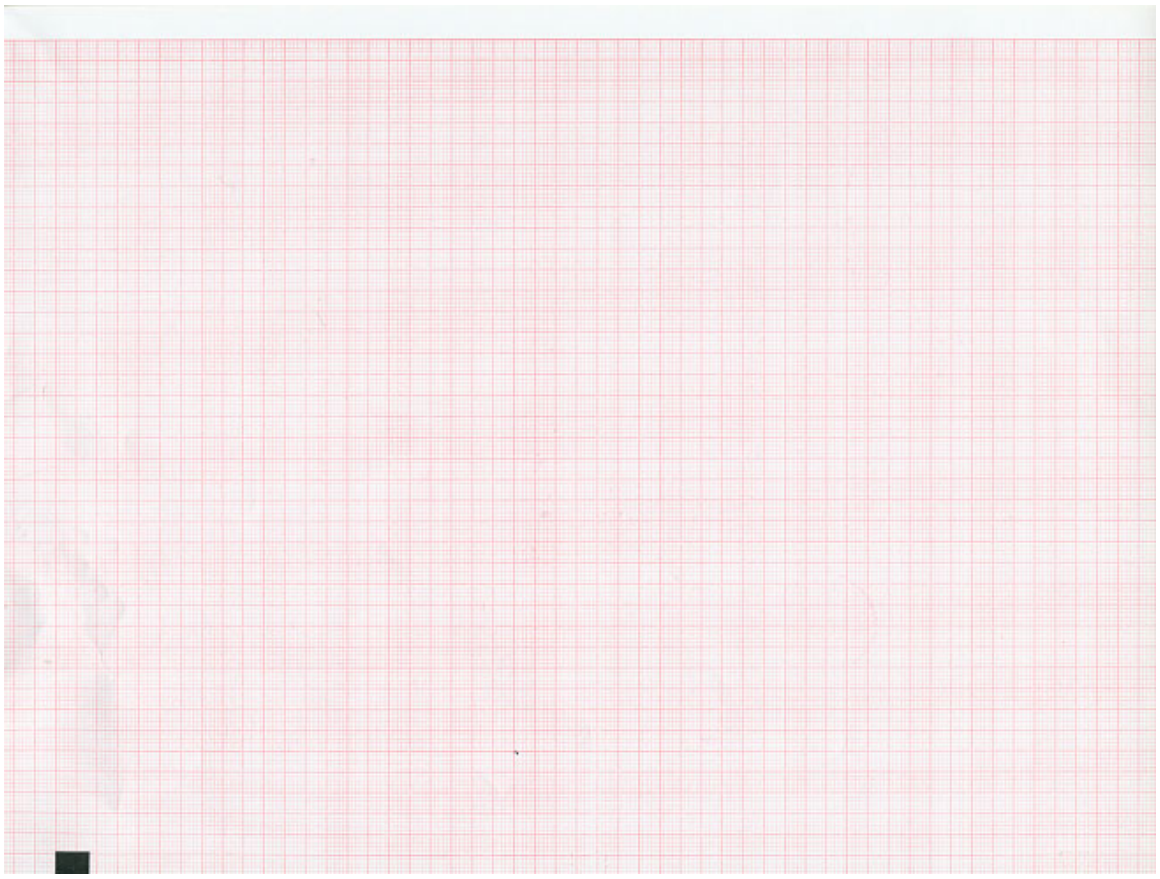
210×140mm



216×140mm



210×295mm



215×280mm

10.4.2 Setup 2

Press **F2** to switch to the **Setup 2** window.

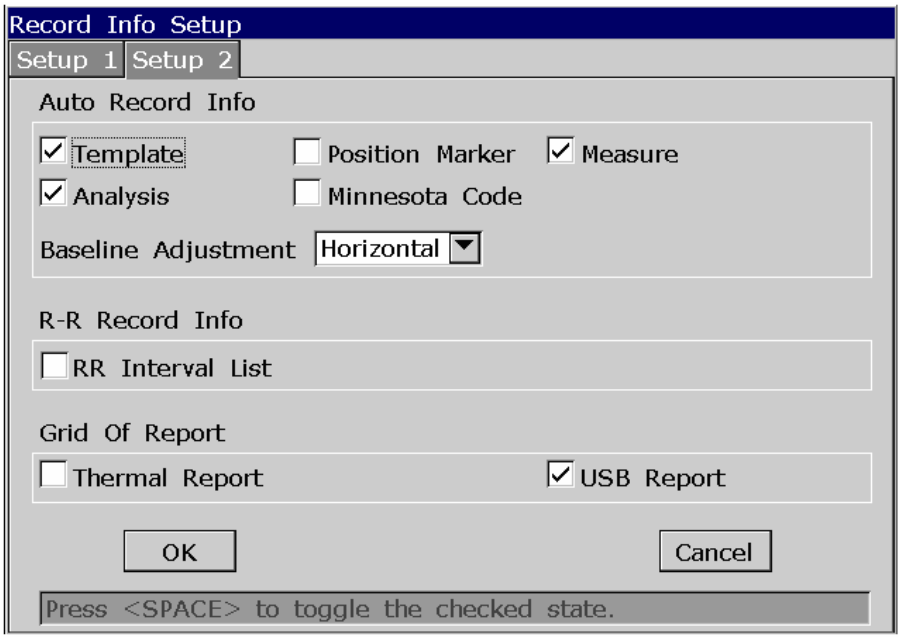


Figure 10-5 Record Info Setup2

Item	Description
Auto Record Info	Select **Position Marker**, **Analysis**, **Template**, **Measure** or **Minnesota Code**, the item will be printed in the ECG reports. Choose **Auto** or **Horizontal** from the **Baseline Adjustment** list box Select **Auto**, the baselines of the lead groups are adjusted respectively. Select **Horizontal**, the baselines of the lead groups are adjusted simultaneously, and the baselines of the leads in the same row are on the same line.
Auto Record Info	**NOTE:** 1. The items of **Auto Record Info** are available only in the auto mode, and Template and Position Marker do not work in the **Save Paper** mode. 2. To get more information about the above contents, please refer to Section 6.5.1, “ECG Reports in the Auto Mode”.
RR Record Info	Select **RR Interval List**, the item will be printed in the ECG reports.
Grid of Report	Select **Thermal Report**, the grid will be printed while printing ECG reports with the thermal recorder. Select **USB Report**, the grid will be printed while printing ECG reports with a USB printer.

10.5 Patient Information Setup

Select **Patient Info** on the **System Setup** screen, and then press **Enter** to open the **Patient Information Setup** window.

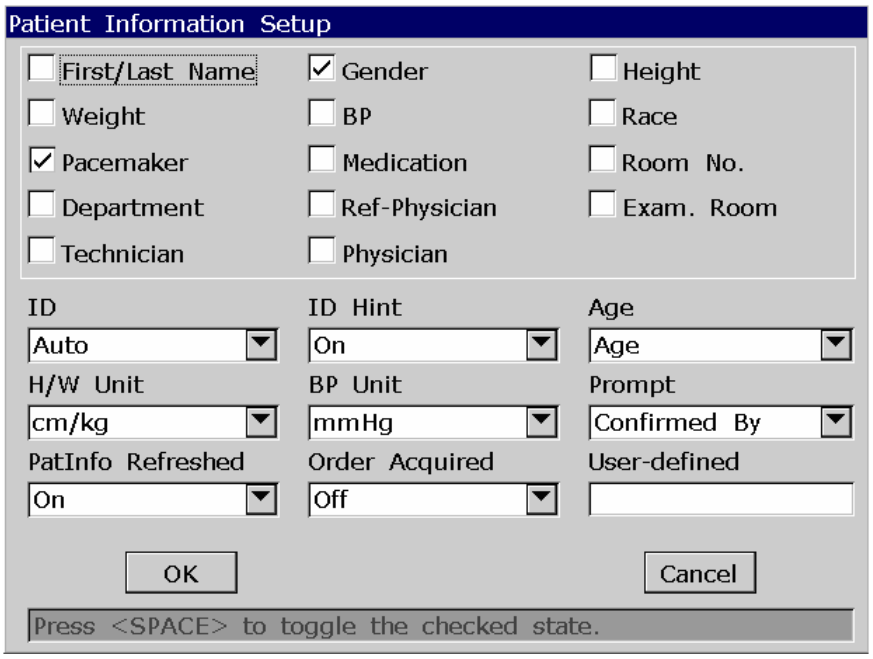


Figure 10-6 Patient Information Setup Window

Item	Description
Patient Options	Select **First/Last Name**, **Gender**, **Height**, **Weight**, **BP**, **Race**, **Pacemaker**, **Medication**, **Room No.**, **Department**, **Physician**, **Technician**, **Exam. Room** or **Ref-Physician**, the item will be displayed in the **Patient Information** window. **NOTE: Pacemaker** appears in the **Patient Information** window after it is selected in the **Patient Information Setup** window. Set **Pacemaker** to **Yes** in the **Patient Information** window, and the **Pacemaker** information will be displayed on the report printed out.
ID	Choose from: **Auto, Time** or **Manual** Select **Auto,** the patient ID can be automatically generated. The patient ID range is 0~1999, 999, 999. Select **Time**, the patient ID can be automatically generated according to the time when you press the **PRINT/STOP** key to print an ECG report. Entering the patient ID manually is not supported. Select **Manual**, you can enter the patient ID manually in the **Patient Information** window. (Only 30 ASCII characters can be input.)

Item	Description
ID Hint	Choose from: **On** or **Off** In the auto, rhythm or off mode, when **ID** is set to **Manual** and **ID Hint** is set to **On**, if you do not input the patient ID before pressing the **PRINT/STOP** key, a hint will pop up to remind you to input the patient ID.
Age	Choose from: **Age**, **D.O.B** or **Age Group** Select **Age**, you can enter the patient age manually in the **Patient Information** window. Select **D.O.B**, the **D.O.B** textbox appears and the **Age** textbox becomes unavailable in the **Patient Information** window, you can enter the birthday of the patient, and the system will calculate the patient age automatically. Select **Age Group**, the **Age Group** textbox appears in the **Patient Information** window and the **0** key (or **Age Group** key) can be available. For details, please refer to Section 2.2 “Keyboard and Keys”.
H/W Unit	Choose from: **cm/kg** or **inch/lb**
BP Unit	Choose from: **mmHg** or **kPa** Select **kPa**, two extra edit boxes will be displayed in the **Patient Information** window for inputting decimal fraction.
Prompt	Choose from: **Confirmed By** or **Unconfirmed** Select **Confirmed By,** the physician’s name is printed in the ECG reports if it is input in the **Patient Information** window. Select **Unconfirmed**, **Unconfirmed Report** is printed in the ECG reports.
PatInfo Refreshed	Choose from: **On** or **Off** Select **On**, the patient information will be refreshed after the ECG report is printed out and all the leads are off.
Order Acquired	Choose from: **On** or **Off** Select **On**, the **Order** item will be displayed in the **Patient Information** window and you can acquire orders by clicking it.
User-defined	Input customized information such as **Address**, the information will be displayed in the **Patient Information** window.

10.6 Transmission Setup

NOTE:

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

Select **Transmission** on the **System Setup** screen, and press **Enter** to open the **Transmission Setup** window.

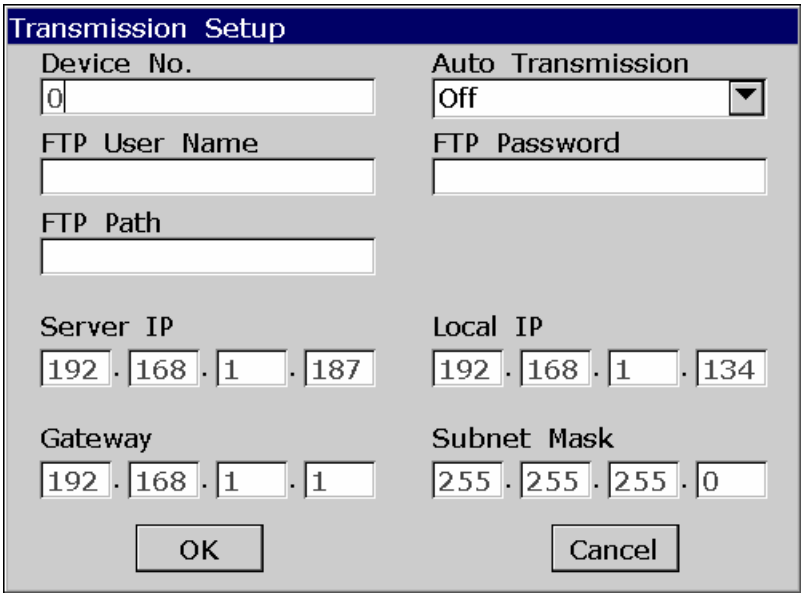


Figure 10-7 Transmission Setup Window

Item	Description
Device No.	If you input **0** in the **Device No.** textbox, after you save data to the U disk or SD card, the data will be in the directory of ***ECGDATA\ECG-0\Store\Examination Date*** of the U disk or SD card; after you export files from the electrocardiograph to the U disk or SD card, the files will be in the directory of ***ECGDATA\ECG-0\Export\Export Date and Time*** of the U disk or SD card.
Auto Transmission	Choose from: **On** or **Off** Select **On**, ECG data will be transmitted automatically after an ECG report is printed out in the auto or rhythm mode; in the off mode, 10s ECG data sampled before pressing the **PRINT/STOP** key can be saved and transmitted, but can not be printed.

Item	Description
FTP Information	Enter data in the **FTP Path**, **FTP User Name** textboxes.
IP Addresses	**Set Server IP, Local IP, Set Gateway, Set Subnet Mask** For details, please refer to Section 7.1.1 “Transmitting ECG Data in DAT Format through Ethernet Cable”.

10.7 Lead Setup

Select **Lead** on the **System Setup** screen, and press **Enter** to open the **Lead Setup** window.

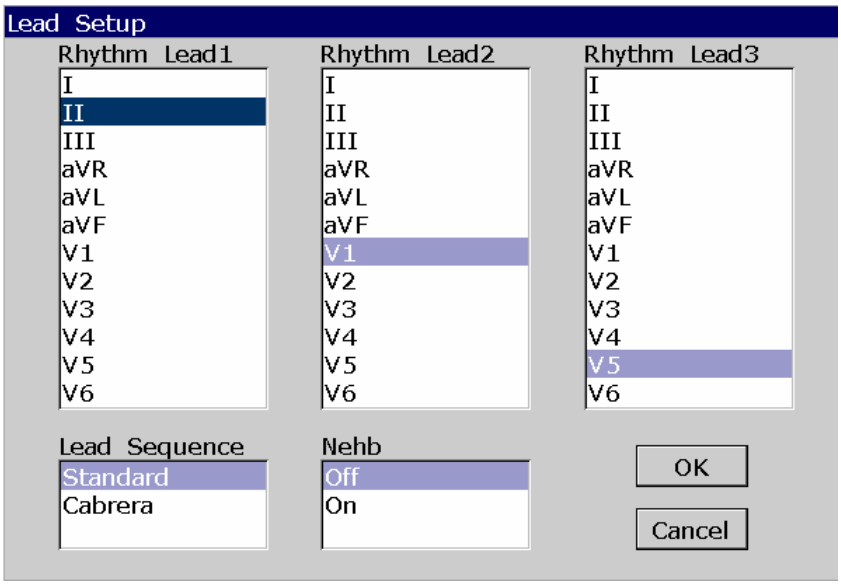


Figure 10-8 Lead Setup Window

Item	Description
Rhythm Lead1/2/3	Choose from: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, or V6 In the auto mode: When **Record Style** is set to **3×4+1R** or **6×2+1R**, the rhythm lead selected in the **Rhythm Lead1** list box will be printed in the ECG reports; When **Record Style** is set to **3×4+3R**, 3 rhythm leads selected respectively in the **Rhythm Lead1/2/3** list box will be printed in the ECG reports. In the rhythm mode: When **Rhythm Style** is set to **Single Lead**, 60s wave of the rhythm lead selected in the **Rhythm Lead1** list box will be printed in the ECG reports; When **Rhythm Style** is set to **Three Leads**, 20s waves of three rhythm leads selected respectively in the **Rhythm Lead1/2/3** list box will be printed in the ECG reports.

Item	Description
Rhythm Lead1/2/3	In the R-R analysis mode: The R-R analysis report of the rhythm lead selected in the **Rhythm Lead1** list box will be printed.
Lead Sequence	Choose from: **Standard** or **Cabrera**

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

Nehb	Lead Sequence: I, II, III, ND, NA, NI Choose from: **On** or **Off**. **NOTE:** If you set **Nehb** to **On**, the working mode is fixed to be manual.

10.8 Display&Sound Setup

Select **Display&Sound** on the **System Setup** screen, and then press **Enter** to open the **Display&Sound Setup** window.

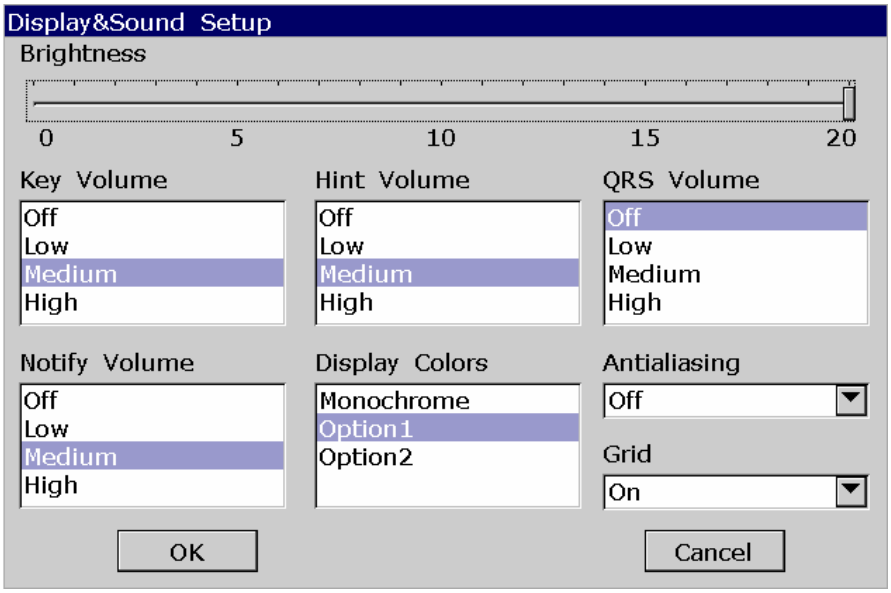


Figure 10-9 Display&Sound Setup Window

Item	Description
Brightness	Set the brightness within 0~20.
Key Volume	Choose from: **Low**, **Medium**, **High** or **Off** Select **Low**, **Medium** or **High,** the electrocardiograph gives a short sound when you press keys on the keyboard. Select **Off**, there is no sound.
Hint Volume	Choose from: **Low**, **Medium**, **High** or **Off** Select **Low**, **Medium** or **High**, the electrocardiograph gives a sound when a hint such as *Lead Off*, *Overload*, *Battery Weak* etc. is displayed. Select **Off**, there is no hint sound.
QRS Volume	Choose from: **Low**, **Medium**, **High** or **Off** Select **Low**, **Medium** or **High**, the electrocardiograph gives a sound when an R wave is detected. Select **Off**, there is no sound when an R wave is detected.
Notify Volume	Choose from: **Low**, **Medium**, **High** or **Off** Select **Low**, **Medium** or **High**, the electrocardiograph gives a sound after ECG report is printed. Select **Off**, there is no sound after ECG report is printed.
Display Colors	Choose from: **Monochrome**, **Option1** or **Option2**
Antialiasing	Reserved for future use.
Grid	Choose from: **On** or **Off** Select **On**, the waveforms will be displayed with a background grid. Select **Off**, the waveforms will not be displayed with a background grid.

10.9 Date&Time Setup

Select **Date&Time** on the **System Setup** screen, and press **Enter** to open the **Date&Time Setup** window.

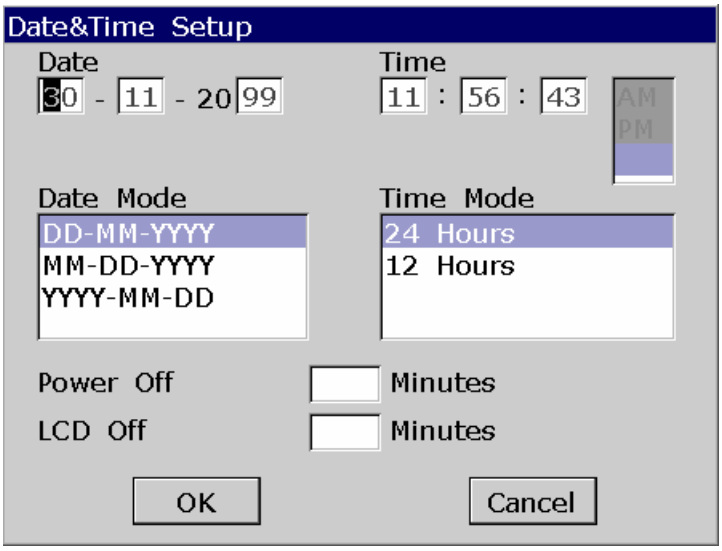


Figure 10-10 Date &Time Setup Window

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

Item	Description
Date&Time	Input the date or the time manually, the time will be displayed on the main screen, and the date and the time will be printed in the ECG reports.
Date Mode	Choose from: **DD-MM-YYYY**, **MM-DD-YYYY** or **YYYY-MM-DD** **NOTE:** Select **OK** in the **Date&Time Setup** window or press **Enter** to confirm. Then the new setup will become effective.
Time Mode	Choose from: **24 Hours** or **12 Hours**
Power Off Time	Input the power-off time manually. If you enter **0 Minutes** or nothing, this function will not be effective. **NOTE:** 1. Power-off time is counted from the time when you last press the keys on the keyboard. 2. Only when the device is powered by the battery, can the set automatic power-off time be effective.
LCD off Time	Input the LCD off time manually. If you enter **0 Minutes** or nothing, this function will not be effective. **NOTE:** LCD Off time is counted from the time when you last press the keys on the keyboard.

10.10 File Setup

Select **File** on the **System Setup** screen, and press **Enter** to open the **File Setup** window.

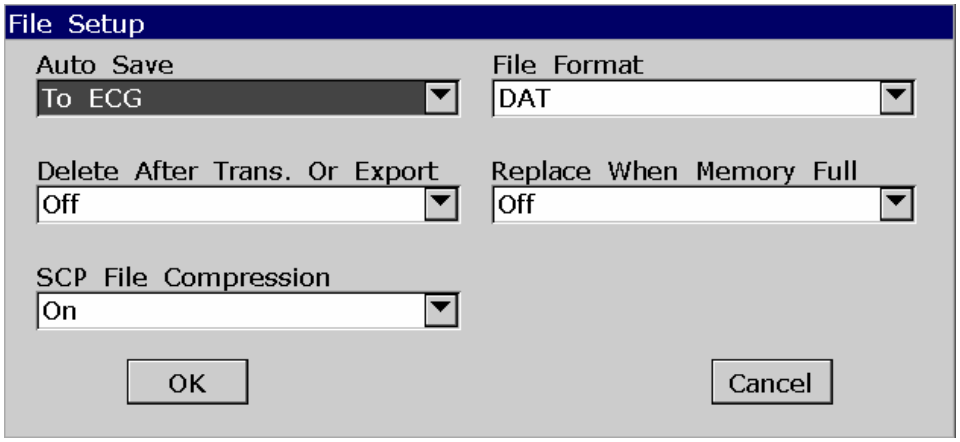
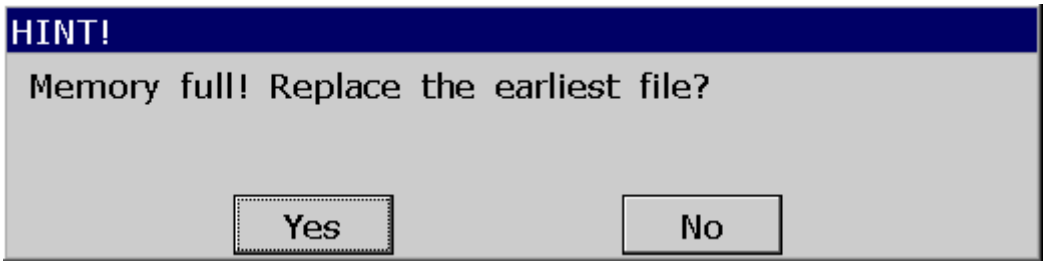


Figure 10-11 File Setup Window

Item	Description
Auto Save	Choose from: **Off, To ECG** or **To External Memory** Select **Off**, ECG data will not be saved. Select **ECG**, ECG data in the auto, rhythm or off mode will be saved in the ECG automatically. Select **To External Memory**, ECG data in the auto or rhythm mode will be automatically saved to the directory of ***ECGDATA\ECG-X\Store\Examination Date*** of the U disk or SD card after an ECG report is printed out. In the off mode, 10s ECG data sampled after pressing the **PRINT/STOP** key will be automatically saved to the directory of ***ECGDATA\ECG-X\Store\Examination Date*** of the U disk or SD card. **NOTE:** 1. Please insert the U disk or SD card recommended by the manufacturer. Please set the format to **FAT** or **FAT32** when formatting the U disk or SD card. 2. X in the directory of ***ECGDATA\ECG-X\Store\Examination Date*** can be set in the **Device No.** textbox in the **Transmission Setup** window.
File Format	Choose from: **DAT**, **SCP**, **FDA-XML** or **PDF** To select **SCP\FDA-XML**, you should first activate the SCP/FDA-XML function on the **Advanced Setup** screen. For details on activating the SCP/FDA-XML function, please contact the manufacturer or the local distributor.

Item	Description
Delete After Trans. Or Export	Choose from: **On** or **Off** Select **On**, the files will be automatically deleted from the **File Manager** screen after they are transmitted to the PC or exported to the U disk or SD card.
Replace When Memory Full	Choose from: **On** or **Off** Select **On**, if the stored files reaches 200, the files will replace the earlies one automatically. Select **Off**, if the stored files reaches 200, the following hint will be displayed. If you select **Yes**, the current file will replace the earliest file stored in the electrocardiograph. If you select **No**, the current file will not be saved.
	
SCP File Compression	Choose from: **On** or **Off** Select **On**, the SCP file will be compressed. After the SCP function is activated, **SCP File Compression** appears in the **File Setup** window. For details on activating the SCP function, please contact the manufacturer or the local distributor.

10.11 System Maintenance Setup

Select **Maintenance** on the **System Setup** screen, and press **Enter** to open the **System Maintenance** window.

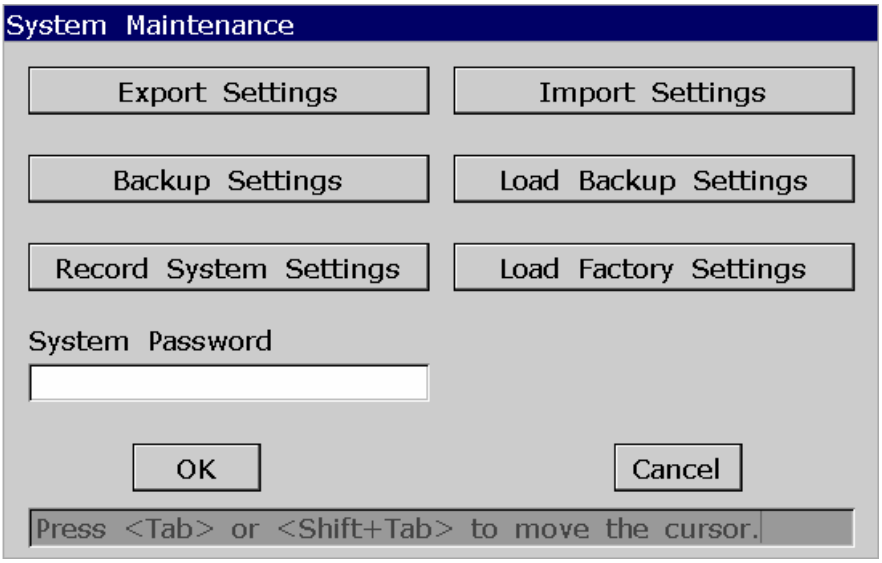


Figure 10-12 System Maintenance Window

Item	Description
Export Settings	Press to export the system settings to the U disk or SD card
Import Settings	Press to load the system settings from the U disk or SD card to the electrocardiograph.
Back up Settings	Press to back up the system settings to the ECG.
Load Backup Settings	Press to load the backup settings from the ECG.
Record System Settings	Press to print the system settings. Pressing this button again can stop printing system settings.
System Password	Enter the password. If you set the system password, after you press **F1** below **Setup** on the main screen2, the **System Password** window will pop up. After you enter the correct password, the **System Setup** screen will be displayed.
Load Factory Settings	Press to restore the factory settings.

10.12 Other Setup

Select **Other** on the **System Setup** screen, press **Enter** to open the **Other Setup** window.

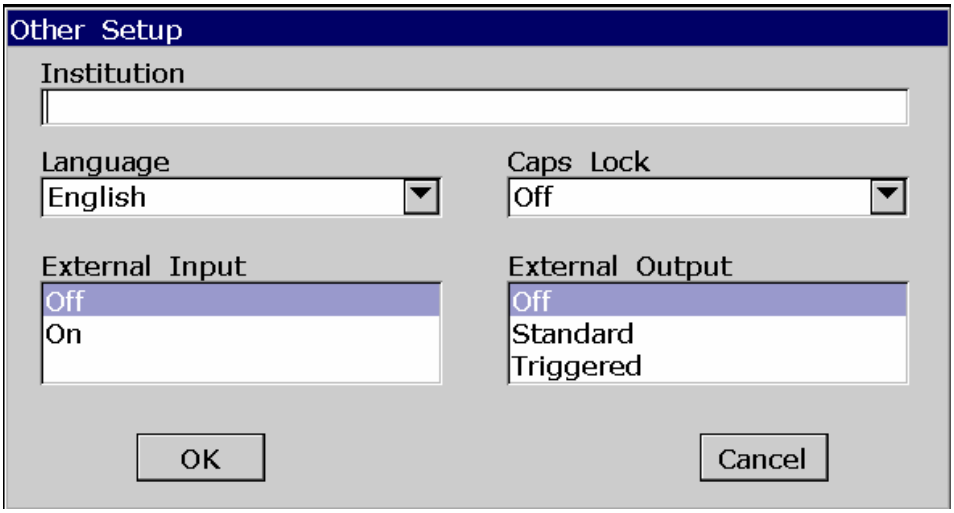


Figure 10-13 Other Setup Window

Item	Description
Institution	Input the institution name manually within 40 ASCII characters. **NOTE:** The total number of supported characters may be fewer if either special Latin characters or Chinese characters are entered.
Language	Select a language
Caps Lock	Choose from: **On** or **Off** Select **On**, the letters entered will be capital. Pressing **Shift** and a letter key can input a lowercase letter. Select **Off**, the letters entered will be lowercase. Pressing **Shift** and a letter key can input a capital letter.
External Input	The external input socket is equipped in the electrocardiograph, through which the electrocardiograph can receive signals from the external equipment. Choose from: **On** or **Off**

Item	Description
External Output	The external output socket is equipped in the electrocardiograph, through which the electrocardiograph can send signals to the external equipment. Choose from: **Off, Standard** or **Triggered** If **External Input** is set to **On**, and **External Output** is set to **Standard** or **Triggered**, the electrocardiograph sends the signals which it receives. If **External Input** is set to **Off**, and **External Output** is set to **Standard**, the electrocardiograph sends ECG signals of rhythm lead 1. If **External Input** is set to **Off**, and **External Output** is set to **Triggered**, the electrocardiograph sends pulses with the height of 5V and the width of 40ms, based on the data of rhythm lead 1.

Chapter 11 Hint Information

Hint information and the corresponding causes provided by the electrocardiograph are listed in Table 11-1.

Table 11-1 Hint Information and Causes

Hint Information	**Causes**
Lead off	Electrodes fall off the patient or the patient cable falls off the unit，or a high polarization voltage occurs.
Battery Weak	The battery is weak.
No Paper	Recorder paper runs out or is not loaded.
Paper Error	When **Paper Marker** is set to **Yes**, the electrocardiograph advances the recorder paper to the next black marker. If it advances the paper and can not find the next black marker, the hint *Paper Error* is displayed.
Testing	The ECG data is being sampled periodically.
Sampling/Analyzing/ Recording	ECG signals are being sampled / analyzed / recorded.
Learning	The self-study process of arrhythmia arithmetic in the **Trigger Sample** mode
Detecting	The examining process of arrhythmia data in the **Trigger Sample** mode
Transmitting	ECG data is being transmitted from the electrocardiograph to the PC through the net in the auto, rhythm or off mode.
Transmit Fail	ECG data fails to be transmitted from the electrocardiograph to the PC through the net in the auto, rhythm or off mode.
Memory Full	The amount of files on the **File Manager** screen of SE-1201 reaches 200.
Module Error	There is something wrong with the signal sample module.
DEMO	The system is in the demonstration mode.
Overload	The direct current offset voltage on an electrode is too high.
U Disk / SD Card / USB Printer / USB Scanner	A U disk, an SD card, a USB printer or a bar code reader is connected to the USB interface.

Chapter 12 Troubleshooting

1. Operating Problems

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

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

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

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

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

A3: Yes, the off mode could provide this convenience. The ECG data will be collected and saved without printing. In the same way, if the transmission settings are configured, the ECG data could be transmitted to the PC without printing.

Q4: The screen of SE-1201 is too shiny. Could it be possible to weaken the brightness of the screen?

A4: There is a setup item named brightness in the **Display & Sound Setup** window, you can press the **Left** or **Right** arrow to change the value, which would lead to the change of the brightness of the screen of SE-1201. For details, please refer to Section 10.8, “Display & Sound Setup”.

Q5: I want to input the patients’ phone number in the **Patient Information** window, but there is no such item. Can I add it manually?

A5: Yes, there is a user-defined item for entering patient information. It works in this way: first input the name of the item in the **User-defined** textbox in the **Patient Information Setup** window, e.g. Tel. Then return to the main screen1, and open the **Patient Information** window, the **Tel** item will be displayed in this window. Now it’s possible to input the phone number of the patient in the **Tel** textbox. For details, please refer to Section 10.5 “Patient Information Setup” and Section 4.1.2 “Entering Data”.

Q6: The hint *"Memory full! Replace the earliest file?"* pops up every time when I operate the electrocardiograph. What am I supposed to do?

A6: The hint is used to remind you that the amount of stored file reaches 200. You can just make a choice every time when the hint pops up. Or, you can prevent the display of the pop-up hint as follows:

Select **On** from the **Replace When Memory Full** list box in the **File Setup** window, if the amount of stored files reaches 200, the files will replace the earliest ones automatically.

Or, you can just delete several stored files from the electrocardiograph to ensure that the amount of stored file not to reach 200.

2. Printing Problems

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

A1: If it happened for the first time, it might be the result of an inappropriate placement of the paper. In this case, please open the recorder casing, pull the paper out of the paper tray, tear the pages with rumples, and then put the paper in the paper tray again, adjust the position of the paper carefully and close the casing.

If it happened several times, it might have something to do with your configuration. Please check the **Paper Marker** and **Paper Style** setting, and make sure that the settings match the loaded paper.

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

A2: It might be the result of unsuccessful detection of the black markers, first open the recorder casing so as to clear the error information, and then check whether the black marker is on the bottom of the paper. Reload the paper in the paper tray. If it doesn't work, change the paper.

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

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

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

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

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

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

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

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

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

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

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

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

Q6: I pressed the **REVIEW** key, but the ECG didn't start printing, what's wrong with it?

A6: The system will not respond to the **REVIEW** key unless 10s data has been collected. Therefore, you have to wait for a few seconds, and then you should try again by pressing the **REVIEW** key.

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

Q7: I set the filter, speed and gain on the main screen1, but these settings were changed after printing.

A7: The filter, speed and gain which are set on the main screen1 will not be saved, and they are changed when you exit the main screen1 or after printing. If you want to save these settings, please set them in the **Record Info Setup** window and the **Filter Setup** window.

3. Transmitting Problems

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

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

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

4. Main Unit Problems

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

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

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

A2: The corresponding electrodes are not connected well. Please find out which lead is off by checking the Lead Name area on the main screen (please refer to Section 4.3.1, "About the Main Screen"). The lead whose name is highlighted is off. Please check whether the corresponding electrode of the lead is connected to the patient skin well, and then make sure that the patient cable socket is connected to the patient cable firmly.

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

Chapter 13 Cleaning, Care and Maintenance

CAUTION

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

13.1 Cleaning

CAUTION

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

13.1.1 Cleaning the Main Unit and the Patient Cable

To clean the cardiograph:

1. Unplug the AC power cord.
2. Wipe the external surfaces of the electrocardiograph with a soft cloth dampened in any of the approved cleaning solutions listed below.

To clean the patient cable:

1. Dampen a soft cloth with one of the disinfectants or cleaning agents listed below.
2. Wring excess moisture from the cloth before cleaning.

Recommended Cleaning Solutions

- ♦ Mild soap and water
- ♦ 75% alcohol

13.1.2 Cleaning the Reusable Electrodes

1. Remove the remainder gel from the electrodes with a clean soft cloth first.
2. Take suction bulbs and metal cups of chest electrodes apart, and take clamps and metal parts of limb electrodes apart.
3. Clean them in warm water and make sure there is no remainder gel.
4. Dry the electrodes with a clean dry cloth or air dry naturally.

CAUTION

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

13.1.3 Cleaning the Print Head

1. Open the recorder casing and remove the paper.
2. 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.
3. After air drying, load the recorder paper and shut the recorder casing.

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

CAUTION

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

13.2 Disinfection

Disinfection of the main unit is not necessary need in daily maintenance, it is only necessary in operating room. In that case, please use hospital standard disinfectant.

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

CAUTION

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

13.3 Care and Maintenance

CAUTION

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

13.3.1 Recharge and Replacement of Battery

1) Capacity Identification

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

 : Full capacity;

 : 3/4 capacity;

 : 1/4 capacity;

 : Low capacity

2) Recharge

SE-1201 electrocardiograph is equipped with the recharge control circuit together with the battery. When the unit is connected to the mains supply, the battery will be recharged automatically. Then the battery recharging indicator (⇥▭) and the mains supply indicator (∿) will be lit at the same time. During the recharging course, the symbol ▭ flashes in the top right corner of the LCD screen. After the battery is fully recharged, the symbol stops flashing, and the battery recharging indicator (⇥▭) is black.

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

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

CAUTION

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

3) Replacement

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

WARNING

1. Only qualified service engineers authorized by the manufacturer can open the battery compartment and replace the battery, and the battery of the same model and specification provided by the manufacturer must be used.
2. Danger of explosion -- Do not reverse the anode and the cathode when installing the battery.

WARNING

3. When the battery's useful life is over, contact the manufacturer or the local distributor for disposal or dispose of the battery according to local regulations.
4. Remove the battery from the electrocardiograph when the electrocardiograph isn't used for a long time.
5. If the battery is stored alone and not used for a long time, we recommend that the battery be charged at least once every 6 months to prevent overdischarge.

CAUTION

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

13.3.2 Recorder Paper

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

Storage Requirements:

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

13.3.3 Visual inspection

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

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

13.3.4 Maintenance of the Main Unit and the Patient Cable

CAUTION

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

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

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

b) Inspect the safety related labels for legibility.

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

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

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

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

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

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

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

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

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

WARNING

Failure on the part of the responsible individual hospital or institution employing this equipment to implement a satisfactory maintenance schedule may cause undue equipment failures and possible health hazards.

1) Main Unit

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

2) Patient Cable

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

3) Reusable Electrodes

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

CAUTION

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

Chapter 14 Accessories

WARNING

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

14.1 Standard Accessories

Table 14-1 Standard Accessory List

Accessory	Part Number
Power Cord (American)	11.13.36015
Power Cord (European)	01.13.36014
Patient Cable (American)	01.57.471017-11
Patient Cable (European)	01.57.471016
Adult Chest electrodes	01.57.040163
Adult Limb electrodes	01.57.040162-12
Thermal Recorder Paper	01.57.471182-10
Fuse	01.21.064144
Rechargeable Li-ion Battery	21.21.064149

14.2 Optional Accessories

Table 14-2 Optional Accessory List

Accessory	Part Number
Patient Cable (European)	01.57.107581 (Snap Style)
	01.57.107583 (Grabber Style)
Patient Cable (American)	01.57.107582 (Snap Style)
	01.57.107584 (Grabber Style)
Pediatric Chest Electrodes	01.57.040168
Pediatric Limb Electrodes	01.57.040169
Snap/Banana Socket Adapters	01.13.107449
Clip/Snap/Banana Socket Adapter	01.57.040172

Alligator Clip/Banana Socket Adapters	01.57.040173
Adult Disposable Adhesive Electrodes	11.57.471056
Pediatric Disposable Adhesive Electrodes	11.57.471057
Disposable Resting Tab electrodes (1 piece)	11.57.471031-10
Electrode gel	11.25.78047
Input/Output connector	11.13.19907
Grounding Wire	11.13.114114
Smart ECG Viewer	03.24.38952
	03.24.38953
Smart ECG Viewer Software Key	11.18.47116 (TINY-SPRO)
	12.01.47194 (USB)
Ethernet download cable	11.13.20096
High Speed USB Cable	11.13.36063
Wireless AP	11.17.047338
External Ink-jet Printer (HP Deskjet 1050)	01.18.052250
External Ink-jet Printer (HP Deskjet 2010)	01.18.052251
External Ink-jet Printer (HP Deskjet 2050)	01.18.052256
SD Card Reader	11.17.047324
ECG bag	11.56.78106
MT-201 Trolley	03.28.111847
12V Vehicle-carried Inverter	11.21.64056
Touch Screen	01.16.045063

Chapter 15 Warranty & Service

15.1 Warranty

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

The warranty is void in cases of:

a) damage caused by mishandling during shipping.
b) subsequent damage caused by improper use or maintenance.
c) damage caused by alteration or repair by anyone not authorized by EDAN.
d) damage caused by accidents.
e) replacement or removal of serial number label and manufacture label.

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

15.2 Contact information

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

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

Appendix 1 Technical Specifications

A1.1 Safety Specifications

Comply with:		IEC/EN 60601-1+A1+A2, IEC/EN60601-1-2+A1, IEC/EN60601-2-25, ANSI/AAMI EC11, IEC/EN 60601-2-51
Anti-electric-shock type:		Class I with internal power supply
Anti-electric-shock degree:		CF type with defibrillation-proof
Degree of protection against harmful ingress of water:		Ordinary equipment (Sealed equipment without liquid proof)
Disinfection/sterilization method:		Refer to the user manual for details
Degree of safety of application in the presence of flammable gas:		Equipment not suitable for use in the presence of flammable gas
Working mode:		Continuous operation
EMC:		Group I, Class A
Patient Leakage Current:	NC	<10μA (AC) / <10μA (DC)
	SFC	<50μA (AC) / <50μA (DC)
Patient Auxiliary Current:	NC	<10μA (AC) / <10μA (DC)
	SFC	<50μA (AC) / <50μA (DC)

A1.2 Environment Specifications

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

A1.3 Physical Specifications

Dimensions	361mm×262mm×135mm (91.6in×66.5in×34.3in)
Weight	Approx. 4.2 kg (1.9 lbs) (Excluding recorder paper and battery)
Display	800×480 TFT LCD Screen

A1.4 Power Supply Specifications

Mains Supply:	Operating Voltage = 100V-240V~
	Operating Frequency = 50Hz/60Hz
	Input Current = 0.9-0.4A
Li-ion Battery Pack:	Rated voltage = 14.8V
	Rated capacity = 2200mAh
	When the battery is fully charged, SE-1201 can work normally about 4 hours, and it can continually print about 1.5 hours in the **MANU** mode or print about 300 ECG reports of 3×4+1R in the auto mode.
	Charge mode: Constant current/voltage
	Charge current (standard) = 0.45 C_5A (1000mA)
	Charge voltage (standard) = 16.8V
	Final discharging voltage = 12V
	Necessary Charge time: 3 hours
	Cycle life ≥ 300 times
Fuse:	T3.15AH 250V Ø5×20

A1.5 Performance Specifications

Recording	
Recorder:	Thermal dot-matrix recorder
Printing Density	8 dots per mm / 200 dots per inch (amplitude axes) 40 dots per mm / 1000 dots per inch (time axes, @ 25 mm/s)
Recorder Paper:	Folded thermal paper: 210 mm×140 mm, 216 mm×140 mm, 210 mm×295 mm, 215 mm×280mm
Effective Width:	210mm
Paper Speed:	5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s, 50mm/s（±3%）
Accuracy of data:	±5% (x-axis), ±5%(y-axis)
HR Recognition	
Technique:	Peak-peak detection
HR Range:	30 BPM ~300 BPM
Accuracy:	±1 BPM
ECG Unit	
Leads:	12 standard leads
Acquisition Mode:	simultaneously 12 leads
A/D Resolution:	24 bits
Time Constant:	≥3.2s (0, +20%)
Frequency Response:	0.05Hz ~ 150Hz (-3dB)
Gain:	2.5, 5, 10, 20, 40, 10/5 mm/mV, AGC, ±5%
Input Impedance:	≥50MΩ (10Hz)
Input Circuit Current:	≤0.01μA
Input Voltage Range	≤±5 mVpp
Calibration Voltage:	1mV±2%
DC Offset Voltage:	±600mV
Noise:	≤12.5 μVp-p
Multichannel crosstalk	≤0.5mm

Filter	AC Filter: On/Off
	DFT Filter: 0.05Hz/0.15Hz/0.25Hz/0.32Hz/0.5Hz/0.67Hz
	EMG Filter: 25Hz/35Hz/45Hz/OFF
	LOWPASS Filter:150Hz/100Hz/75Hz
CMRR	≥115dB
Sampling Frequency	1000 Hz
Pacemaker Detection	
Amplitude	±2 to ±700 mV
Width	0.1 to 2.0 ms
Sampling Frequency	10,000/sec/channel
External Input/Output (Optional)	
Input	≥100kΩ; Sensitivity 10mm/V±5%; Single ended
Output	≤100Ω; Sensitivity 1V/mV±5%; Single ended

NOTE:

1. Test the accuracy of input signal reproduction according to the methods described in clause 4.2.7.2 in ANSI/AAMI EC11:1991/(R) 2001, and the result complies with the clause 3.2.7.2 in ANSI/AAMI EC11:1991/(R) 2001.
2. Overall System Error is tested using the method described in AAMI EC11 3.2.7.1. Overall System Error is not more than ±5%.
3. Frequency Response is tested using the method described in AAMI EC11 3.2.7.2 methods A and D.

Appendix 2 EMC Information

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

<table>
<tr><th colspan="3">Guidance and manufacture's declaration – electromagnetic emission</th></tr>
<tr><td colspan="3">The 12-channel electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the 12-channel electrocardiograph should assure that it is used in such an environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The 12-channel 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.</td></tr>
<tr><td>RF emission
CISPR 11</td><td>Class A</td><td rowspan="3">The 12-channel electrocardiograph is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC/EN 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC/EN 61000-3-3</td><td>Complies</td></tr>
</table>

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

Guidance and manufacture's declaration – electromagnetic immunity			
The 12-channel electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of 12-channel electrocardiograph should assure that it is used in such an environment.			
Immunity test	**IEC/EN 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC/EN 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC/EN 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	±1 kV line to line ±2 kV line to ground	±1 kV line to line ±2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50Hz/60Hz) magnetic field IEC/EN 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	<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)	<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)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 12-channel electrocardiograph requires continued operation during power mains interruptions, it is recommended that the 12-channel electrocardiograph be

	for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	powered from an uninterruptible power supply or a battery.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

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

Guidance and manufacture's declaration – electromagnetic immunity			
The 12-channel electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the 12-channel electrocardiograph should assure that it is used in such an environment.			
Immunity test	**IEC/EN 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC/EN 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3V_{rms}	Portable and mobile RF communications equipment should be used no closer to any part of the 12-channel electrocardiograph, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF IEC/EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in

			metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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 12-channel electrocardiograph is used exceeds the applicable RF compliance level above, the 12-channel electrocardiograph should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the 12-channel electrocardiograph.

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

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

Recommended separation distances between portable and mobile RF communications equipment and the 12-channel Electrocardiograph

The 12-channel electrocardiograph is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the 12-channel electrocardiograph can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 12-channel electrocardiograph as recommended below, according to the maximum output power of the communications equipment.

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

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

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

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

Appendix 3 Abbreviation

Abbreviation	Statement
LCD	Liquid Crystal Display
BP	Blood Pressure
ECG	Electrocardiogram/Electrocardiograph
HR	Heart Rate
aVF	Left Foot Augmented Lead
aVL	Left Arm Augmented Lead
aVR	Right Arm Augmented Lead
LA	Left Arm
LL	Left Leg
RA	Right Arm
RL	Right Leg
ID	Identification
AC	Alternating Current
USB	Universal Serial Bus
AGC	Auto Gain Control
NC	Normal Condition
SFC	Single Fault Condition

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