SE-12 Series

Electrocardiograph

Version 3.2

User Manual

CE 0123

EDAN

About this Manual

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Statement

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

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The user shall understand that nothing in this manual grants him, expressly or implicitly, any right or license to use any of the intellectual properties of EDAN.

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

Product Information

Product Name: Electrocardiograph

Model: SE-12, SE-12 Express, SE-1200, SE-1200 Express, SE-1201

Responsibility of the Manufacturer

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

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

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

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

Terms Used in this Manual

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

WARNING

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

CAUTION

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

NOTE

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

Table of Contents

Chapter 1 Safety Guidance

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

1.1 Indications for Use/Intended Use

The intended use of SE-12 series electrocardiograph is to acquire ECG signals from adult and pediatric patients (beginning at birth through 21 years of age) through body surface ECG electrodes. The electrocardiograph is 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 intracardiac use or direct cardiac application.
2. This equipment is not intended for home use.
3. This equipment is not intended for treatment or monitoring.
4. This equipment is intended for use on adult and pediatric patients only.
5. The results given by the equipment should be examined based on the overall clinical condition of the patient, and they cannot substitute for regular checking.

1.2 Warnings and Cautions

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

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

1.2.1 Safety Warnings

WARNING

1. The electrocardiograph is intended to be used by qualified physicians or personnel professionally trained. They should be familiar with the contents of this user manual before operation.
2. Only qualified service engineers can install this equipment, and only service engineers authorized by the manufacturer can open the shell. Otherwise, safety hazards may happen.
3. **EXPLOSION HAZARD** - Do not use the electrocardiograph in the presence of flammable anesthetic mixtures with oxygen or other flammable agents.
4. **SHOCK HAZARD** - The power receptacle must be a hospital grade grounded outlet. Never try to adapt the three-prong plug to fit a two-slot outlet. This equipment must only be connected to a supply mains with protective earth.
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 cannot be guaranteed.
9. The use of patient cable and other accessories not supplied by the manufacturer may result in increased emissions or decreased immunity of the equipment.
10. The electrocardiograph has been safety tested with the recommended accessories, peripherals, and leads, and no hazard is found when the electrocardiograph is operated with cardiac pacemakers or other stimulators.
11. Make sure that all electrodes are connected to the patient correctly before operation.
12. Ensure that the conductive parts of electrodes and associated connectors, including neutral electrodes, do not come in contact with earth or any other conducting objects.

WARNING

13. Disposable electrodes must be used during defibrillation.
14. Electrodes of dissimilar metals should not be used; otherwise it may cause a high polarization voltage.
15. The disposable electrodes can only be used for one time.
16. Do not touch the patient, bed, table or the equipment while using the ECG together with a defibrillator.
17. Do not touch accessible parts of non-medical electrical equipment and the patient simultaneously.
18. Do not touch the signal input or output connector and the patient simultaneously.
19. 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.
20. If WIFI technology is used, in order to maintain compliance with the FCC RF exposure guidelines, WIFI should be installed and operated with a minimum distance of 20cm between the radiator and the human body. There should be no shield in or around the room where WIFI is used.
21. Fix attention on the examination to avoid missing important ECG waves.
22. **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.
23. **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.
24. Do not connect any equipment or accessories that are not approved by the manufacturer or that are not IEC/EN 60601-1 approved to the electrocardiograph. The operation or use of non-approved equipment or accessories with the electrocardiograph is not tested or supported, and electrocardiograph operation and safety are not guaranteed.
25. Any non-medical equipment (such as the external printer) is not allowed to be used within the patient vicinity (1.5m/6ft.).

WARNING

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

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

28. Do not use the additional multiple portable socket-outlet or extension cord in the medical electrical system, unless it's specified as part of the system by manufacturer. And the multiple portable socket-outlets provided with the system shall only be used for supplying power to equipment which is intended to form part of the system.

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

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

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

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

31. All the accessories connected to system must be installed outside the patient vicinity, if they do not meet the requirement of IEC/EN 60601-1.

32. You should purchase computer, printer, treadmill, ergometer and BP monitor from the manufacturer. Otherwise, the manufacturer will not be held responsible for the maintenance of the PC hardware, operating system and other accessories.

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

WARNING

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

1.2.2 Li-ion Battery Care Warnings

WARNING

1. Improper operation may cause the internal li-ion battery (hereinafter called battery) to

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

2. Only qualified service engineers authorized by the manufacturer can open the battery compartment and replace the battery, and batteries of the same model and specification as manufacturer configuration should be used.
3. **DANGER OF EXPLOSION** -- Do not reverse the anode and the cathode when installing the battery.
4. Do not heat or splash the battery or throw it into fire or water.
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. Federal (U.S.) law restricts this device to sale by or on the order of a physician.
2. Avoid liquid splash and excessive temperature. The temperature must be kept between 5 ºC and 40 ºC during operation, and it should be kept between -20 ºC and 55 ºC during transportation and storage.
3. Do not use the equipment in a dusty environment with bad ventilation or in the presence of corrosive.

4. 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.
5. Ruptured fuse must only be replaced with that of the same type and rating as the original.
6. The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal. Batteries are hazardous waste. Do NOT dispose of them together with house-hold garbage. At the end of their lives hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or battery, please contact your local Civic Office, or the shop where you purchased the product.

1.2.4 Protecting Personal Information

Protecting personal health information is a major component of security strategy. To protect the personal information and ensure the proper device performance, the user should take necessary precautions in accordance with local laws and regulations and institution's policies. EDAN recommends health care organizations or medical institutions to implement a comprehensive and multifaceted strategy to protect the information and systems from internal and external security threats.

To ensure the patients' safety and protect their personal health information, the user should implement practices or measures that include:

1. Physical safeguards - physical safety measures to ensure that unauthorized personnel do not have access to the electrocardiograph.
2. Operational safeguards - safety measures during operation.
3. Administrative safeguards - safety measures in management.
4. Technical safeguards - safety measures in technical field.

CAUTION

1 The access/operation of the electrocardiograph is restricted to authorized personnel only. Assign only staff with a specific role the right to use the electrocardiograph.

2 Ensure that all device components maintaining personal information (other than removable media) are physically secure (i.e. cannot remove without tools).

3 Ensure that the electrocardiograph is connected only to the device authorized/approved by EDAN. Users should operate all EDAN deployed and supported electrocardiographs within EDAN authorized specifications, including EDAN approved software, software configuration, security configuration, etc.

4 Protect all the passwords to prevent unauthorized changes. Only the manufacturer's service personnel are allowed to modify the **System Maintenance Setup**.

5 Anti-virus measures such as USB device virus scanning should be carried out prior to using USB flash drive.

6 When building the networking environment: 1) If a wireless router is used, please turn on the MAC address filtering function of the wireless router and add the MAC address of the electrocardiograph to the rule list. The wireless router only allows devices in the rule list to access the wireless network. 2) It is suggested to build a VLAN, assign the LAN ports where the approved switch port, electrocardiograph and data management software are into the same VLAN, and isolate it from other VLANs.

7 When the electrocardiograph is returned for maintenance, disposed of, or removed from the medical institution for other reasons, it is necessary to ensure that all patient data are removed from the electrocardiograph (Refer to Chapter 9 *Managing Files*).

8 Please protect the privacy for the information and the data displayed on the screen, and for the information and the data stored in the electrocardiograph.

9 Web service is disabled by the electrocardiograph.

1.2.5 Preparation and Operation Warnings (for SE-12 Express Exercise ECG)

WARNING

1. Test the safety stop (mushroom type) and safety stop (cord type) of the treadmill before using the system.

2. During the exercise test, ensure that such tests are supervised by properly trained technician who meets competency requirements for exercise test supervision, fully trained in cardiopulmonary resuscitation, and is supported by a physician skilled in exercise testing or emergency medicine who is in close proximity for pretest

assessment or compliance that may raise.

3. Make sure that there is necessary valid first-aid equipment such as defibrillators, blood-pressure meters etc, and necessary valid medication in the exercise test room.
4. Turn off the system power and disconnect the power cord from the wall outlet after using the system.
5. Make sure that the power is turned off and the power cord is disconnected from the AC socket before defibrillation.
6. Keep the four feet of the machine on the ground and make sure that it's stably working.
7. The treadmill must be powered by the specific power outlet.
8. Examine the treadmill/ergometer carefully before using it.
9. The patient undergoing the exercise test should wear suitable clothes and shoes.
10. Keep hands, hair, jewelry, and loose clothing away from moving parts.
11. Don't let the patient stand on the running belt when starting the treadmill. The patient should stand on the foot rails and hold the handrails during start-up. Wait until the running belt is moving before placing feet on the belt.
12. To avoid the static electricity, the patient should not wear loose clothing or clothing (such as nylon) that easily produces static electricity.
13. Stop exercising immediately when the patient feels uncomfortable or something abnormal in the operation.
14. Press down the safety stop (mushroom type) or pull out the safety stop (cord type) to stop the treadmill immediately when an emergency happens.

1.2.6 Contraindications (for SE-12 Express Exercise ECG)

Absolute Contraindications:

1. Acute MI (within 2 days)
2. High-risk unstable angina
3. Hemodynamic compromise caused by uncontrolled cardiac arrhythmia
4. Symptomatic severe aortic stenosis

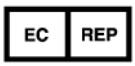
5. Heart failure with clinic episode uncontrolled
6. Acute pulmonary embolus or pulmonary infarction
7. Acute myocarditis or pericarditis
8. The patient opposes the test.

Relative Contraindications:

1. Left main coronary stenosis
2. Moderate stenotic valvular heart disease
3. Serum Electrolyte abnormalities
4. Severe hypertension (systolic blood pressure >200 mmHg or diastolic blood pressure >110 mmHg)
5. Tachyarrhythmias or bradyarrhythmias
6. Hypertrophic cardiomyopathy
7. Patients cannot cooperate because of mental impairment or physical disability
8. High-degree AV block

1.3 List of Symbols

No.	Symbol	Description
1		Output
2		Input
3		DEFIBRILLATION-PROOF TYPE CF APPLIED PART
4		Caution
5		Consult operating instructions
6		Equipotentiality

7		Patient Cable Socket
8		USB socket
9		SD Card slot
10		Computer network
11		Alternating Current
12		Battery check
13		Battery recharging indicator
14		Power On/Off key
		
15		General symbol for recovery/recyclable
16	P/N	Part Number
17		SERIAL NUMBER
18		Date of manufacture
19		MANUFACTURER
20		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
21		CE marking

22	Rx Only	Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.
23		Disposal method
24		Refer to instruction manual/booklet (Background: Blue; Symbol: White)
25		General warning sign (Background: Yellow; Symbol&Outline: Black)
26*		Non- ionizing electromagnetic radiation
27*	Contains FCC ID: YOPGS2011MIZ	Federal Communications Commission: Contains FCC ID: YOPGS2011MIZ
28		MR Unsafe
29		Conforms to AAMI Std. 60601-1, IEC Std. 60601-2-25 Certified to CSA Std. C22.2 No 60601-1,CSA Std. C22.2 No 60601-2-25
30		This way up
31		Fragile, handle with care
32		Keep dry
33		Stacking limit by number

34		Handle with care
35		Do not step on
36		Front

NOTE:

1. 26*/27*: Apply to devices with wireless functions.
2. The user manual is printed in black and white.

Chapter 2 Introduction

SE-12 series electrocardiograph 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 VCG (only configurable for SE-12 Express, SE-1200 Express, and SE-1201) mode can be chosen freely.

For SE-12 Express, the exercise ECG function is configurable. When a patient with coronary heart disease runs, the added heart load will cause myocardium hypotension, and then the ECG will change abnormally. Therefore, the exercise ECG function of SE-12 Express can be used to diagnose concealed coronary heart disease and atypical angina pectoris, prescribe the workload for patients with myocardial infarction before they leave hospital, and assess the effect of the treatment.

SE-12 series electrocardiograph can be powered by the mains supply or battery.

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

NOTE:

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

2 This manual takes pictures and interfaces of SE-12 Express as an example, and they may look slightly different from your model.

2.1 Top Panel

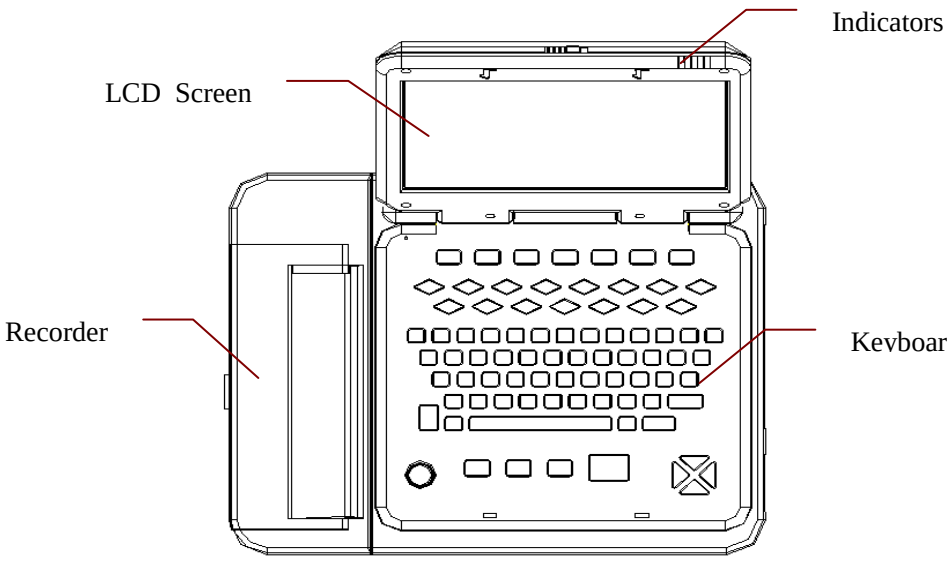


Figure 2-1 SE-12 Express

2.2 Keyboard and Keys

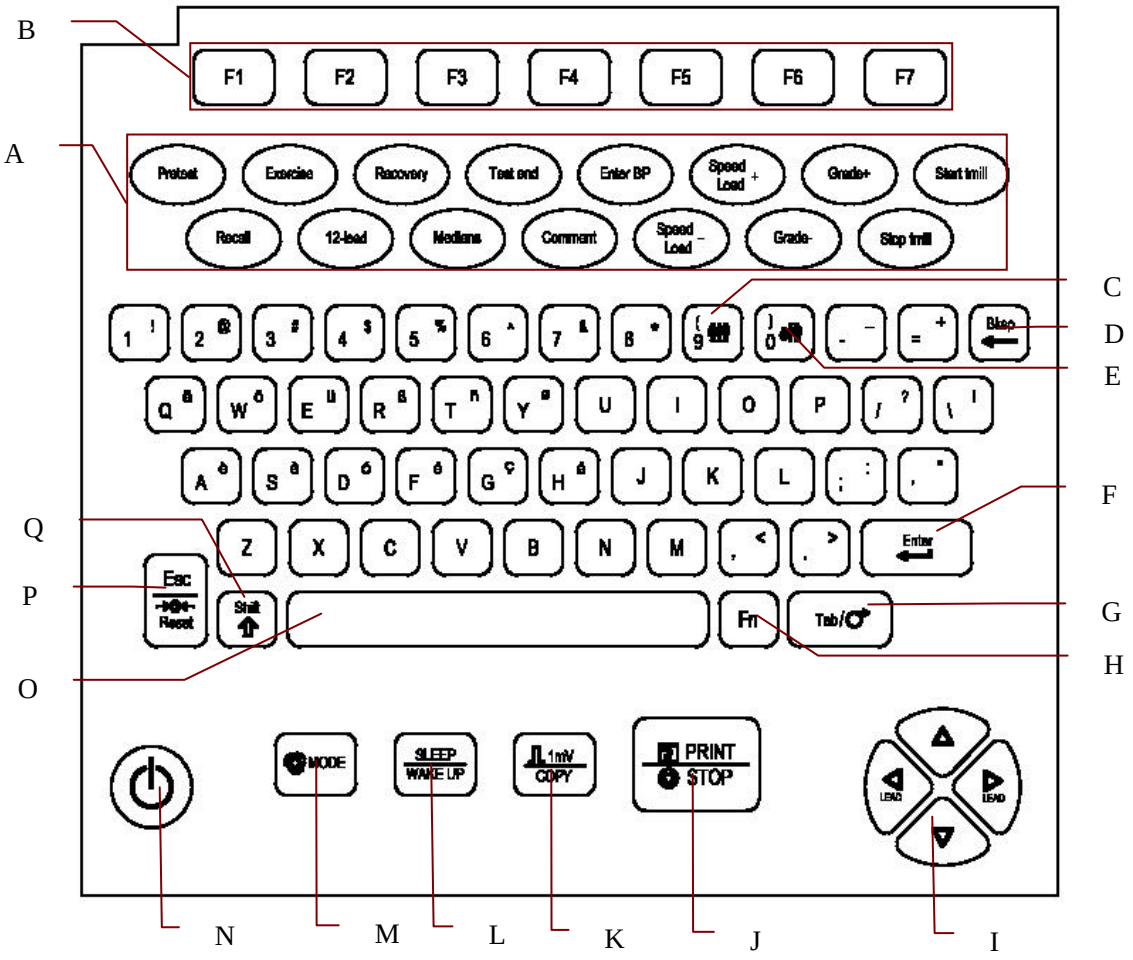


Figure 2-2 SE-12 Express Keyboard

	Name	Explanation
A	**NOTE:** Only if the stress ECG function is activated, can these keys be available.	
	Pretest	When the main screen is displayed, press this key to display the main screen of the exercise test. When the main screen of the exercise test is displayed, press this key to enter the pretest phase. The length of the pretest phase is not fixed. When the main screen of the exercise test is displayed and the exercise test is terminated, press this key to enter the no testing state.
	Exercise	Press to enter the exercise phase. In the exercise phase, press this key to enter the next stage of the exercise phase.

	Name	Explanation
	Recovery	Press to enter the recovery phase. In the recovery phase, press this key to enter the next stage of the recovery phase.
	Test end	Press to display a pop-up dialog box, and then you can decide whether the exercise test should be terminated.
	Enter BP	Press to display the **Input BP** dialog box, and then enter the BP values manually.
	Recall	During the exercise test, press this key to review 10s data and print out the 12-channel ECG report of the reviewed 10s data.
	12-lead	During the exercise test, press this key to sample 10s data and print out the 12-channel ECG report of the sampled 10s data.
	Medians	During the exercise test, press this key to print out the average template report.
	Comment	Press to display the **Comment** dialog box, and then you can annotate in the dialog box. The annotations will be displayed in the summary report.
	Speed Load +/-	Press **Speed Load +/-** to change the speed of the treadmill during the exercise phase. Press **Speed Load +/-** to change the power of the ergometer during the exercise phase. **NOTE:** The two keys are available for the customized protocol only.
	Grade +/-	Press **Grade +/-** to change the grade of the treadmill during the exercise phase. **NOTE:** The two keys are available for the customized protocol only.
	Start/Stop tmill	Before the exercise test, press the **Start tmill** key to test the connection between the electrocardiograph and the treadmill, and then press the **Stop tmill** key to stop the connection test. During the exercise test, press the **Stop tmill** key to stop the test temporarily, and then press the **Start tmill** key to restart the test. **NOTE:** Pressing the **Stop tmill** key cannot add the timing of the current phase during the exercise test.
B	Function Key	Press to select menu functions on the screen.

	Name	Explanation
C	Gender Key	Press to quickly select the gender for the patient when **Gender** is selected in the **Patient Information Setup** window.
D	Delete Key	Press to delete characters.
E	Age Group Key	Press to quickly select the age group on the main screen when you set **Age** to **Age Group** in the **Patient Information Setup** window.
F	Enter	Press to confirm operation.
G	Tab/Feed paper	Press to move the cursor: Pressing **Tab** can move the cursor forward, and pressing **Shift** + **Tab** can move the cursor backward. Press to feed paper: If **Paper Marker** is set to **Yes**, pressing **Tab** can advance the recorder paper to the next black marker; if **Paper Marker** is set to **No,** pressing **Tab** can advance the paper for 2.5cm. Pressing **Tab** again can stop advancing the paper. For SE-1201, press FEED to feed paper.
H	Fn	Press **Fn** and a letter key to type special characters. Pressing **Fn** + **a** can type **è**.
I	Arrow Keys	Press to move the cursor or switch between options.
J	PRINT/STOP	Press to start or stop printing reports Pressing **Shift** + **PRINT/STOP** can quickly enable or disable the print out function in the auto or rhythm mode.
K	1mV/COPY	In the manual mode, pressing the **1mV/COPY** key can insert a 1mV calibration mark during the printing course. In the auto, rhythm or VCG mode, pressing the **1mV/COPY** key can print the ECG report which was printed out last time.
L	SLEEP/WAKE UP	Press to rest/waken the electrocardiograph
M	MODE	Press to select a working mode among the auto, manual, rhythm, R-R analysis and VCG 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.
N	Power On/Off	Power-on/Power-off

	Name	Explanation
O	Spacebar	Press to add a space between typed characters or select/deselect a checkbox
P	Esc/Reset	Press to cancel operation **NOTE:** A large polarization voltage may cause baseline drift. On the main screen, pressing **Esc** can decrease the polarization voltage and draw the baseline to zero quickly.
Q	Shift	Press **Shift** + **Tab** to move the cursor backward. Press **Shift** and a number key to input the special character in the top right corner of the key. If **Caps Lock** is set to **Off**, pressing **Shift** + **P** can type a capital **P**. If **Caps Lock** is set to **On**, pressing **Shift** + **P** can type a lowercase **p**.

2.3 Front Panel

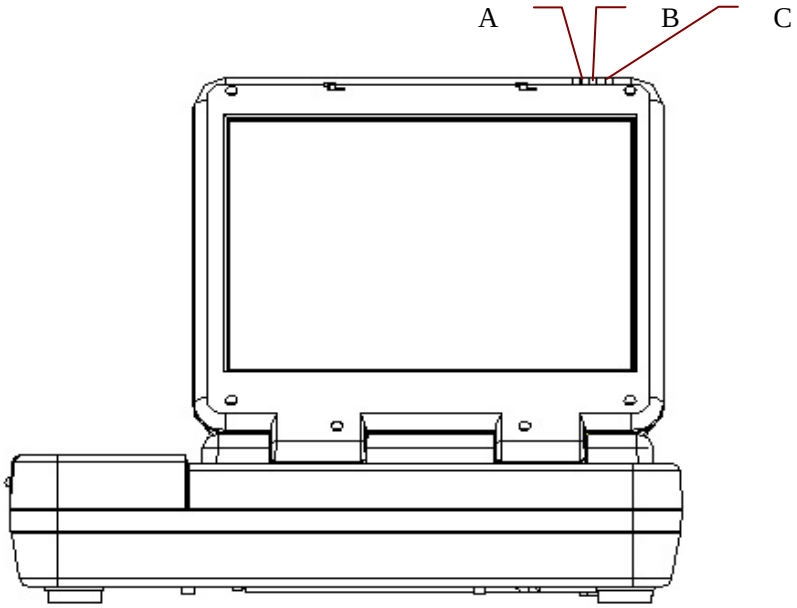


Figure 2-3 SE-12 Express Front Panel

	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 battery, this indicator is lit.

	Symbol	Name	Explanation
C		Battery recharging indicator	When the battery is being recharged, this indicator is lit.

2.4 Rear Panel

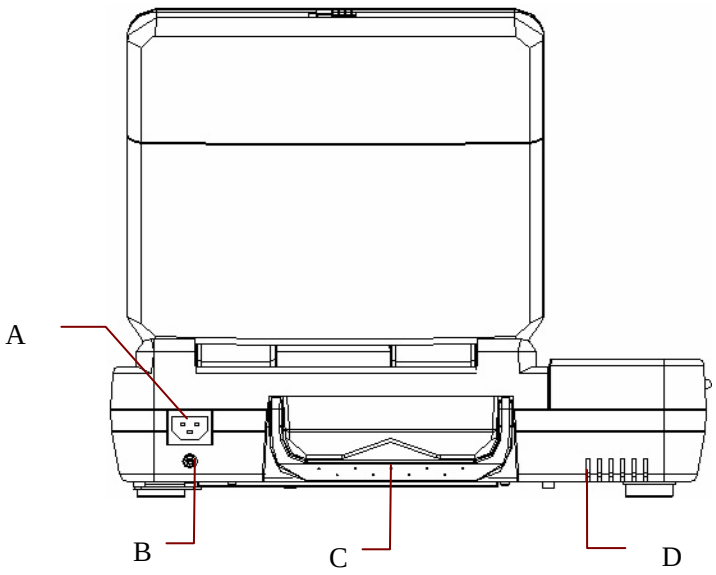


Figure 2-4 SE-12 Express Rear Panel

	Name	Explanation
A	Mains Supply Socket	AC SOURCE: alternating current supply socket
B	Potential Equalization Conductor	Potential equalization conductor provides a connection between the unit and the potential equalization bus bar of the electrical installation.
C	Handle	Part for people to hold
D	Heat Emission Hole	Path for internal heat emission

2.5 Right Panel

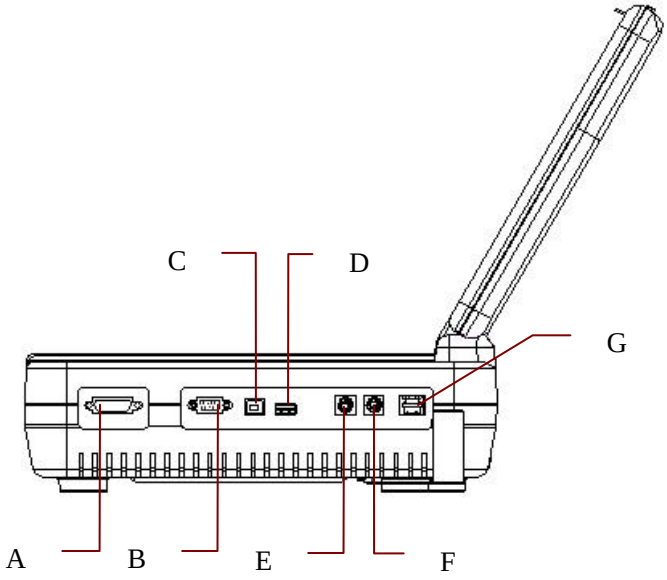


Figure 2-5 SE-12 Express Right Panel

	Name	Explanation
A	Patient Cable Socket	Connecting to the patient cable
B	Serial Port 1	Connecting to a PC In the exercise test, only the treadmill/ergometer recommended by the manufacturer can be connected.
C	USB Socket 1	Standard USB socket, connecting to a PC
D	USB Socket 2	Standard USB socket, connecting to a U disk, a bar code reader or a USB printer recommended by the manufacturer
E	External Input / Output Socket	Connecting to the external signal device
F	Serial Port 2	In the exercise test, only the BP Monitor recommended by the manufacturer can be connected.
G	Net port	Standard net port, connecting to a PC

CAUTION

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

2.6 Bottom Panel

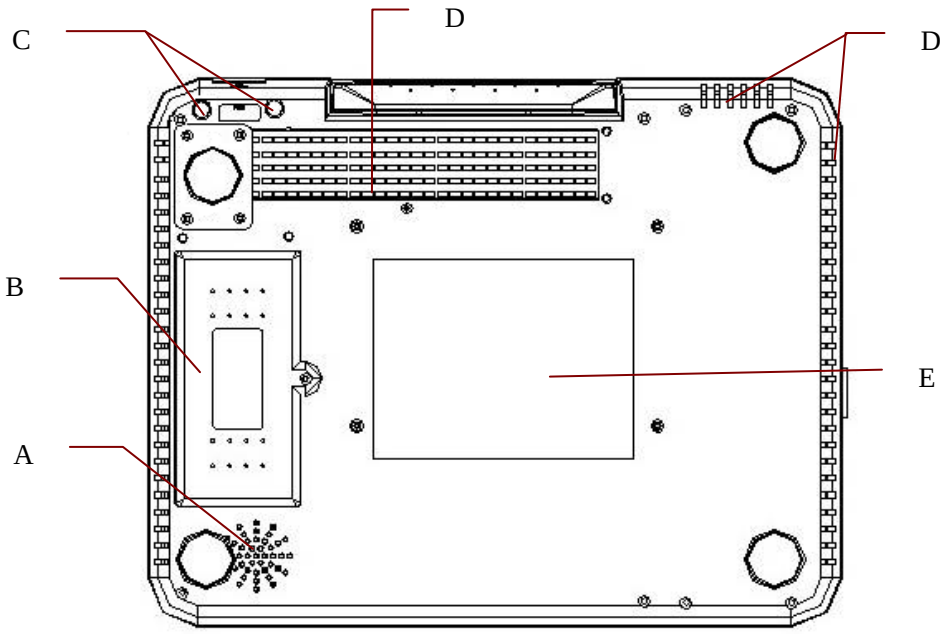


Figure 2-6 SE-12 Express Bottom Panel

	Name	Explanation
A	Speaker Hole	Path for sound from speaker
B	Battery Compartment	Compartment for battery
C	Fuse	The specification is: T3.15AH250V, Ø5×20mm T1AL250VP, Ø5×20mm (for UL device)
D	Heat Emission Hole	Path for internal heat emission
E	Label	Position for product information label

1) Battery Compartment

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

2) Fuse

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

WARNING

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

2.7 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 (For SE-12 Express/SE-1200 Express/SE-1201, touch screen is available)
- 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 ≤300Hz
- Supporting external USB printer
- Supporting accurate digital filter to decrease the polarization voltage and other interferences
- Despite that SE-1201 only supports folded paper, the other models can support both rolled and folded paper recorded with high resolution waveforms, calibration mark, gain, speed and filter
- The auto, manual, rhythm, R-R analysis and VCG (only configurable for SE-12 Express/SE-1200 Express/SE-1201) 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, PDF and configurable formats (SCP/FDA-XML/DICOM)
- Measurement function and interpretation function
- Supporting bar code reader
- ECG data can be transmitted to the PC software through the serial cable, net cable, or WIFI (configurable for SE-12 Express/SE-1200 Express/SE-1201)
- Real-time transmission to ECG data management software
- Supporting order function
- Ability to disable USB ports, which can enhance security of ECG data and lower the potential of distribution of computer viruses
- Supporting QTcFd and QTcFm formulae

The following features are only for the exercise test function of SE-12 Express (configurable)

- Real-time analysis, ST segment and trend are applied while sampling
- Real-time display and print of 12-lead simultaneous ECG waveforms with average template
- ST segment analysis while sampling; ST position is adjustable while sampling;
- Providing average templates of three rhythm leads in every stage to observe the change of ST segments between every two stages
- Automatically forming elaborate reports, including Summary Report, ST Scope Report, Summary Average Template Report and Trend Graph Report
- Supporting magnifying or minifying the average templates
- Providing saving PDF files to U disk and transmitting PDF files to the server by implanting FTP protocol.
- Providing classical exercise protocols; exercise protocols can be edited and created
- Providing 30 exercise stages at most in a user-defined protocol
- Automatically controlling and adjusting the speed and grade of the treadmill or the power of the ergometer
- Supporting multi-types of treadmill or ergometer

Chapter 3 Operation Preparations

WARNING

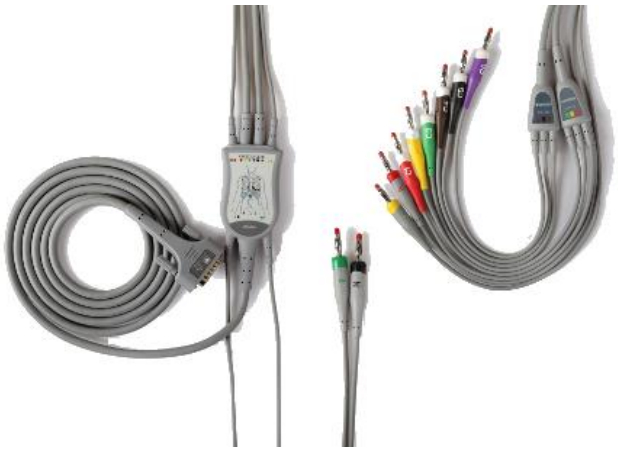
Before use, the equipment, patient cable and electrodes should be checked. Replace them if there is any evident defectiveness or aging which may impair the safety or the performance, and make sure that the equipment is in proper working condition.

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.



Patient Cable for Resting ECG

Patient Cable for Exercise ECG

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

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 AHA requirements are given in Table 3-1 too.

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

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

3.2 Preparing the Patient

3.2.1 Instructing the Patient

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

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

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

Wash the area thoroughly with soap and water.

Dry the skin with a gauze pad to increase capillary blood flow to the tissues and to remove the dead, dry skin cells and oils.

3.3 Attaching Electrodes to the Patient

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

WARNING

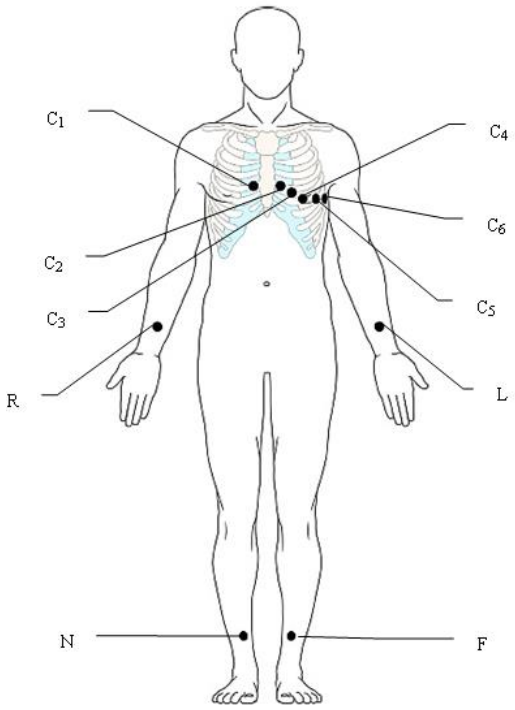
1. Make sure that all electrodes are connected to the patient correctly before operation.
2. Ensure that the conductive parts of electrodes and associated connectors, including neutral electrodes, do not come in contact with earth or any other conducting objects.

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

3.3.1 Electrode Placement (for Resting ECG)

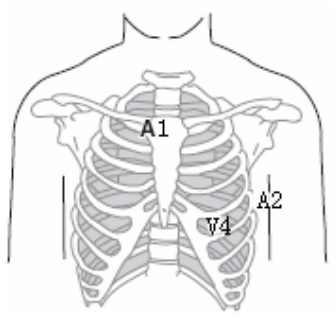
The electrodes' positions on the body surface are shown in the following tables and figures.

Standard 12-Lead Placement



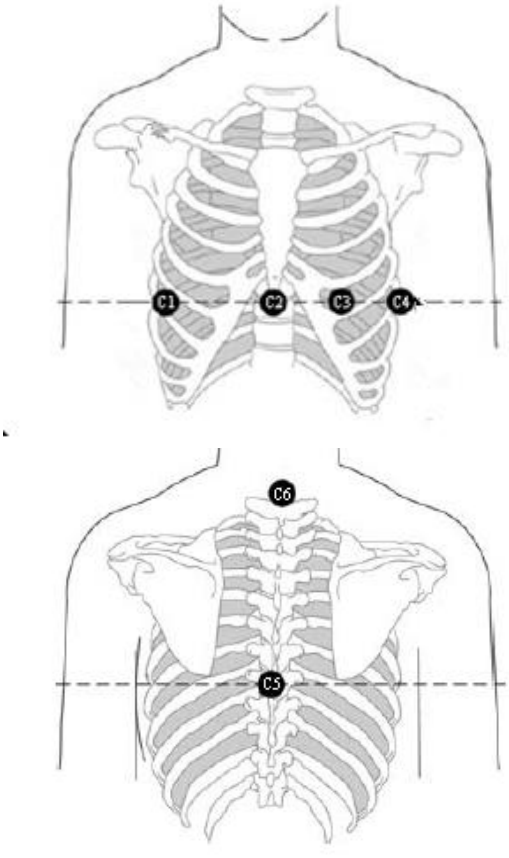
IEC	AHA	Electrode Placement
C1	V1	Fourth intercostal space at the right border of the sternum
C2	V2	Fourth intercostal space at the left border of the sternum
C3	V3	Fifth rib between C2 and C4
C4	V4	Fifth intercostal space on the left midclavicular line
C5	V5	Left anterior axillary line at the horizontal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

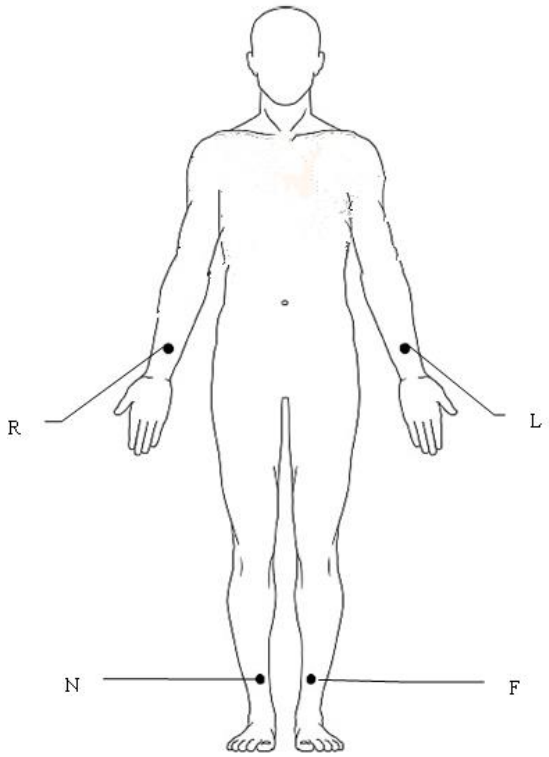
NEHB Placement



IEC	AHA	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

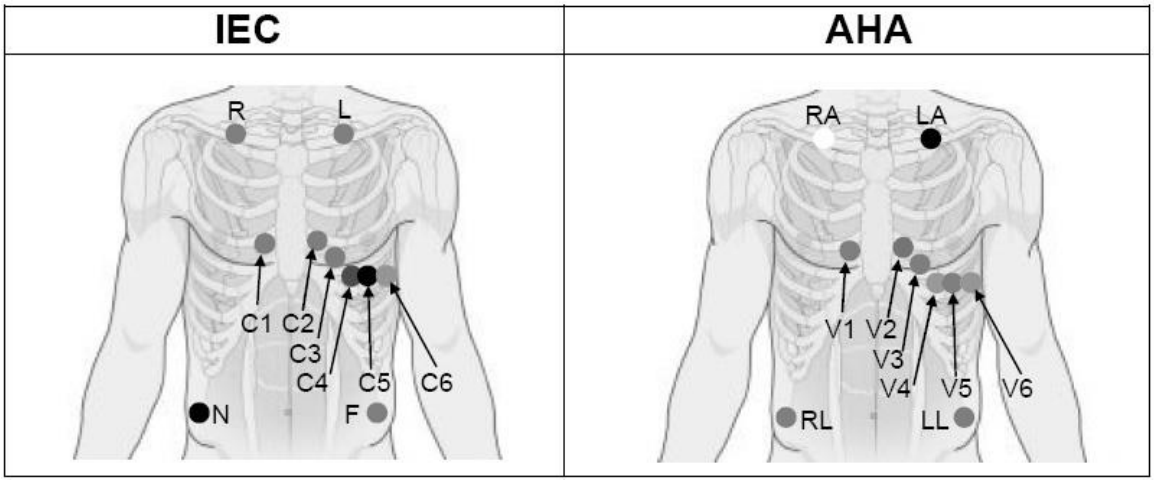
Frank Lead Placement (for VCG)





IEC	AHA	Electrode Placement
C1	V1	Right mid-axillary line on the same horizontal level as C3 and C4
C2	V2	Sternum at the level of C3 and C4
C3	V3	Mid-clavicular line in the fifth intercostals space
C4	V4	Left mid-axilary line on the same horizontal level as C3
C5	V5	Center of spine on the same horizontal level as C3 and C4
C6	V6	Neck, avoid carotid artery and jugular vein
L	LA	Left arm
R	RA	Right arm
F	LL	Left leg
N	RL	Right leg

3.3.2 Electrode Placement (for Exercise ECG)



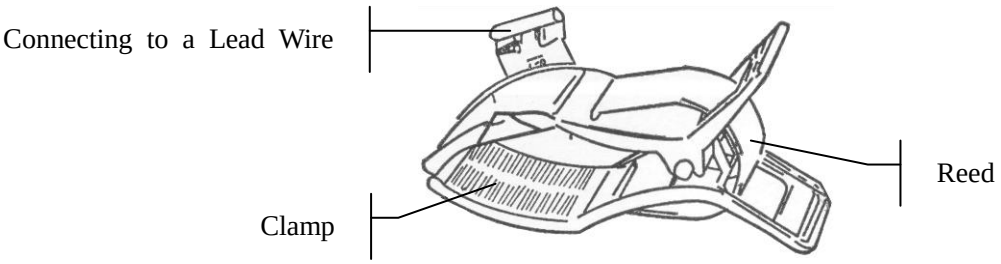
The Precordial Electrodes' Positions on Body Surface:

IEC	AHA	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

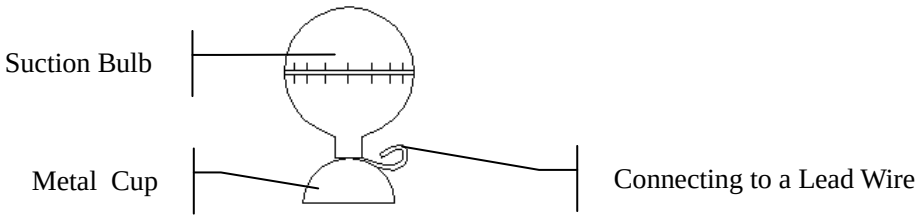
The Extremity Electrodes' Positions on Body Surface:

IEC	AHA	Electrode Placement
R / L	RA / LA	Below the right/left clavicle
N / F	RL / LL	Below the right/left rib

3.3.3 Attaching the Reusable Electrodes (for Resting ECG)



Limb Electrode



Chest Electrode

1) Ensure that the electrodes are clean;
2) Clean the electrode area which is a short distance above the ankle or the wrist with 75% alcohol;
3) Daub the electrode area on the limb with gel evenly;
4) Place a small amount of gel on the metal part of the limb electrode clamp or on the brim of the chest electrode's metal cup;
5) Attach the electrodes in place.

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

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

3.3.4 Attaching the Disposable Electrodes

CAUTION

The disposable electrodes can only be used for one time.

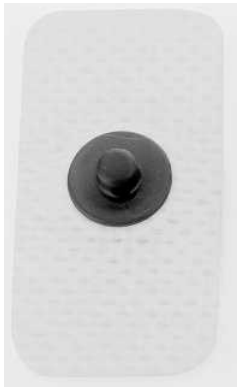
Disposable Electrode (clip style):

Clip/Snap/Banana Socket Adaptors

Disposable Electrode Connection (Clip Style)

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

Snap/Banana Socket Adapters



Disposable Electrode (Snap Style)

Disposable Electrode Connection (Snap Style)

1) Align all lead wires of the patient cable to avoid twisting, and connect Snap/Banana Socket Adapters to connector of patient cable.
2) Clean the electrode areas on the body surface with 75% alcohol.
3) Attach the disposable electrodes to the electrode positions on the body surface.
4) Connect Snap/Banana Socket Adapters to the disposable electrodes.

3.4 Inspection Before Power-On

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

WARNING

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

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 Recorder Paper

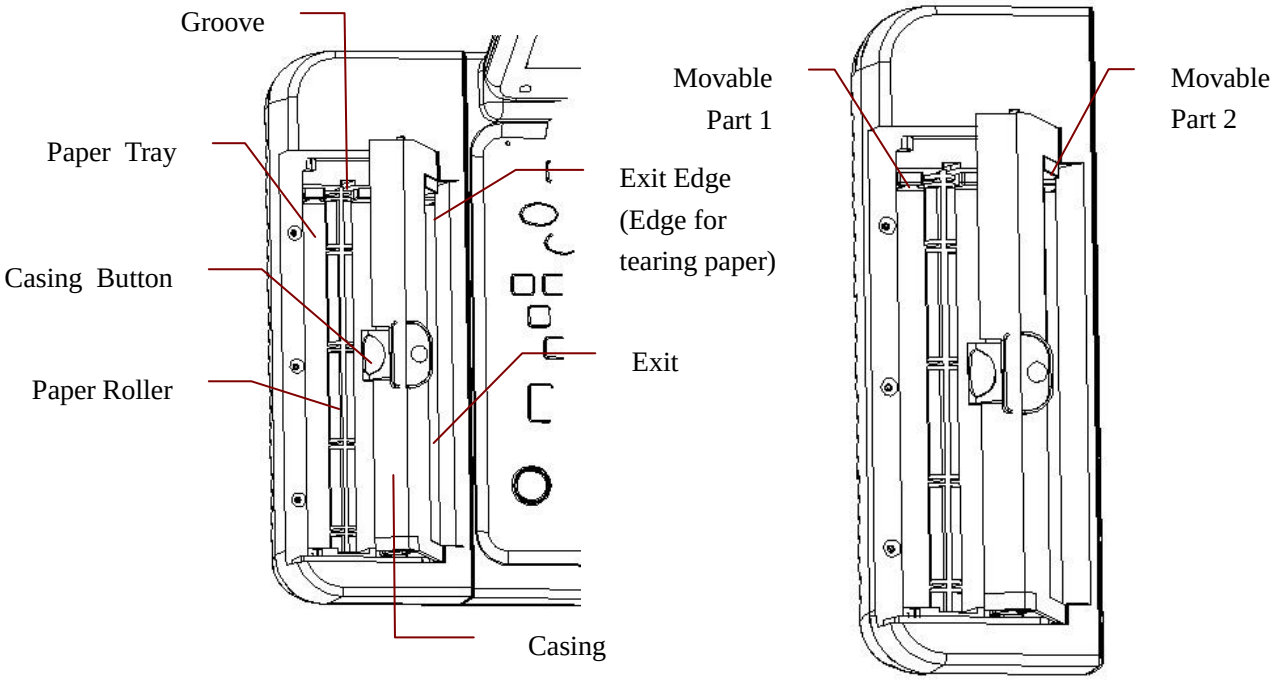
NOTE:

1. When the folded thermal paper is used, the paper roller is unnecessary and must be taken out.
2. When using the paper of 215mm in width, the two movable parts should be removed.
3. The exit edge can help you tear the recorder paper.
4. If the paper with black markers is used, make sure that the markers are on the bottom.

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.



SE-12/SE-12 Express/SE-1200/SE-1200 Express:

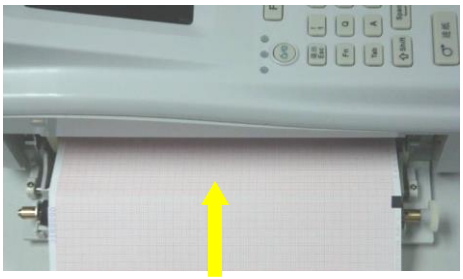
Step 1 Step 2 Folded paper / Rolled paper Step 3

1) Press the casing button downwards and remove the casing to open the recorder.
2) Take off the wrapper of the new folded paper, and then put it in the paper tray.
3) Pull the paper out with the grid side facing the thermal print head, and replace the casing on the recorder.

   If rolled paper is used, Place the paper and the roller gently in the recorder with the roller pin clicking into the groove. Pull the paper out with the grid side facing the thermal print head.
4) Press down the recorder casing firmly.

SE-1201 A5 paper：

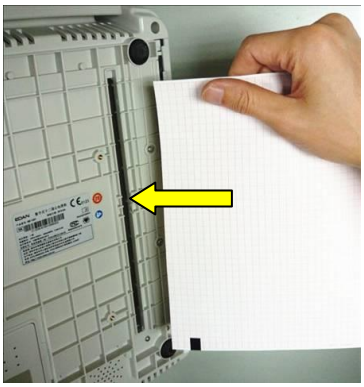
Step 1



Step 2

1) Press the casing button downwards to open the recorder.
2) Take off the wrapper of the new folded paper, and then put it in the paper tray with the grid side facing the thermal print head.
3) Close the recorder casing firmly.

SE-1201 A4 paper:



Step 1

Step 3

1) Tilt the electrocardiograph and put the record paper to the paper tray through the opening on the bottom panel with the grid side facing the thermal print head.
2) Press the casing button downwards to open the recorder.
3) Pull the paper out with the grid side facing the thermal print head, and close the recorder casing firmly.

After loading paper,

1) Set **Paper Marker** to **No** in the **Record Info Setup1** window.
2) Advance the recorder paper.

When the main screen is displayed, you can press Tab/♂ to advance the paper for 2.5cm. Press Tab/♂ again to 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 (configurable).

CAUTION

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

4.1 Basic Operation

Operation	Keys
To select options on the bottom panel of the screen	Corresponding functional keys
To move the cursor	**Tab** or **Shift + Tab**
To erase the typed information	**Bksp**
To input special characters	**Shift** + numeric key
To switch between upper case and lower case	**Shift** +letter key
To select or deselect an item	**Space**
Switch between options	Up and down arrow keys
To confirm and entering a screen	**Enter**
To cancel operation; return to the upper level	**ESC**
refresh all patient information except for the **Gender**, **Age Group**, **Exam.Room**, **Physician** and **Technician** information after you print an ECG report	**Shift** + **Bksp**

4.2 About the Main Screen

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

Figure 4-1 SE-12 Express Main Screen1

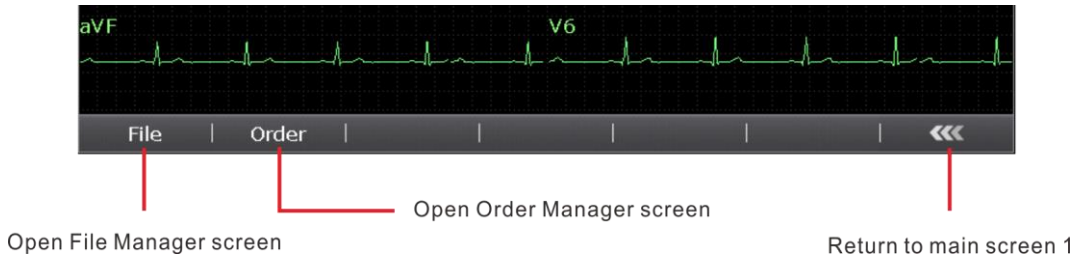


Figure 4-2 SE-12 Express Main Screen2

NOTE:

1. The modification of filter, gain, or speed on the main screen is only effective for the current patient.
2. When the leads are off, the lead names will be highlighted.
3. Work mode can be selected by pressing the **MODE** key when the main screen is displayed.

4.3 Work Mode Description

There are five work modes in SE-12 series electrocardiograph.

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

MANU: In the manual mode, you can determine the lead group to be displayed and printed. Pressing 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.

VCG Only configurable for SE-12 Express/SE-1200 Express/SE-1201

In the VCG mode, X, Y, Z waves and frontal, horizontal, sagittal planes can be displayed. 10s sampled ECG data can be analyzed, and vector waves, vector loops, measure information, diagnosis information can be printed.

.

Chapter 5 Entering Patient Information

5.1 Entering Patient Information Manually

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

   For details, please refer to Section 10.4 "Patient Information Setup".

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

5.2 Entering Patient Information by Using a Reader (Configurable)

1. Configure the bar code

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

2. Connect the bar code/social security card/ID card 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/social security card/ID card reader, and then the patient information will appear in the corresponding region.

NOTE: Recommended social security card reader: T6-ULD-I, USB socket;
Recommended ID card reader: GTICR100-02, USB socket.

5.3 Entering Patient Information by Acquiring Orders

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

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

2. Log into the DMS.

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

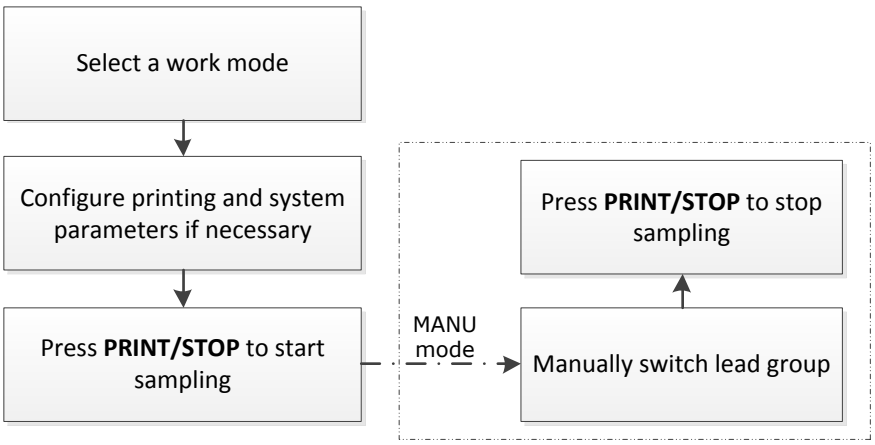
4. Select **Order Acquired** function in **Setup-> Patient Info**

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

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

Chapter 6 Printing ECG Reports

The operation procedure is as follows:



NOTE:

1. The working mode cannot be changed during the printing course. Stop printing reports before changing the working mode.
2. Within three seconds after returning to the main screen, if you press the **PRINT/STOP** key to print an ECG report in the auto quick mode or the manual mode, the recorder will not respond.
3. If **Print Out** is set to **Off** in the **Record Info Setup1** window, the ECG report can be saved and transmitted, but cannot be printed out by pressing the **PRINT/STOP** key in the auto and rhythm modes.
4. Please consult with physician or medical professional regarding diagnosis produced by VCG test if you have any questions or concerns about your results.

Chapter 7 Transmitting ECG Data

WARNING

1. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
   a) this device may not cause harmful interference, and
   b) this device must accept any interference received, including interference that may cause undesired operation.
2. If the FTP user name and password are compromised, then transmitted data may be compromised.
3. The patients' basic and health information embedded in SCP, FDA-XML and DICOM files is not encrypted to allow for portability, therefore the user is responsible for ensuring security of these files, otherwise PHI(Projected Health information)may be compromised when transmitting SCP, FDA-XML or DICOM files.
4. Data that is transmitted to a web browser is not encrypted, therefore it is the user needs to ensure network security to ensure that patients' basic and health information is not compromised when using a web browser.
5. Data transmitted between the device and order server is not encrypted, therefore the user needs to ensure network security to ensure that patient information is not compromised when querying orders from the server.
6. Beware that the SE-12 series do not have built in anti-malware protection. Any USB devices connected to the SE-12 series should be verified as not being infected before being connected to the SE-12 series.

   Note that the system can be used without USB by utilizing alternative methods, namely:
   - An external barcode reader would not be available, but patient information can be entered manually through keyboard.
   - USB printers would not be available, but the onboard thermal printer, which is standard configuration, can be used.
   - USB disk would not be available, but Ethernet/Wi-Fi can be used to transmit data.
7. As a cyber security precaution, the SE-12 series will only read and download files that follow a specific EDAN format. These files are encoded in a manner for the SE-12 to conduct checks to ensure file integrity, but note that to allow for portability, the files are not encrypted.

NOTE:

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

7.1 Transmitting ECG Data to the PC

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

CAUTION

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

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

1. Log into the FTP receiving software.
2. Configure the **Transmission Setup** window.
   1) Press **Shift+F1** in the **Transmission Setup** window to open the **Basic Setup** window.
   2) Set **Auto Transmission** to **On** and **Transmission Mode** to **Net Port** or **Wireless**.
   3) Set the **Server IP** item to the IP of the PC.

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

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

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

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

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

3. Set **File Format** in the **File Setup** window.
4. In the auto or rhythm mode, ECG data will be transmitted through the network automatically after an ECG report is printed out.

NOTE: If the message *Transmitting Fails* appears on the system screen, then there has been an error in network communication of the data. Please check the network connection, move the device where the wireless signal is stronger or directly use a U disk to transfer data.

7.2 Real-time Transmission to the DMS

In real-time transmission, the electrocardiograph functions as an ECG sampling box to the DMS software.

NOTE: To use the real-time transmission function, the ECG data management software (DMS) of EDAN must be installed in the PC.

1. Start the DMS.
2. In the **Sampling Setting** window, set **Device Model** to **SE12**.
3. Connect USB socket 1 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.

4. Start real-time transmission

The sampling box 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 DMS software.

Chapter 8 Managing Orders

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

Operation procedures are as follows:

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

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

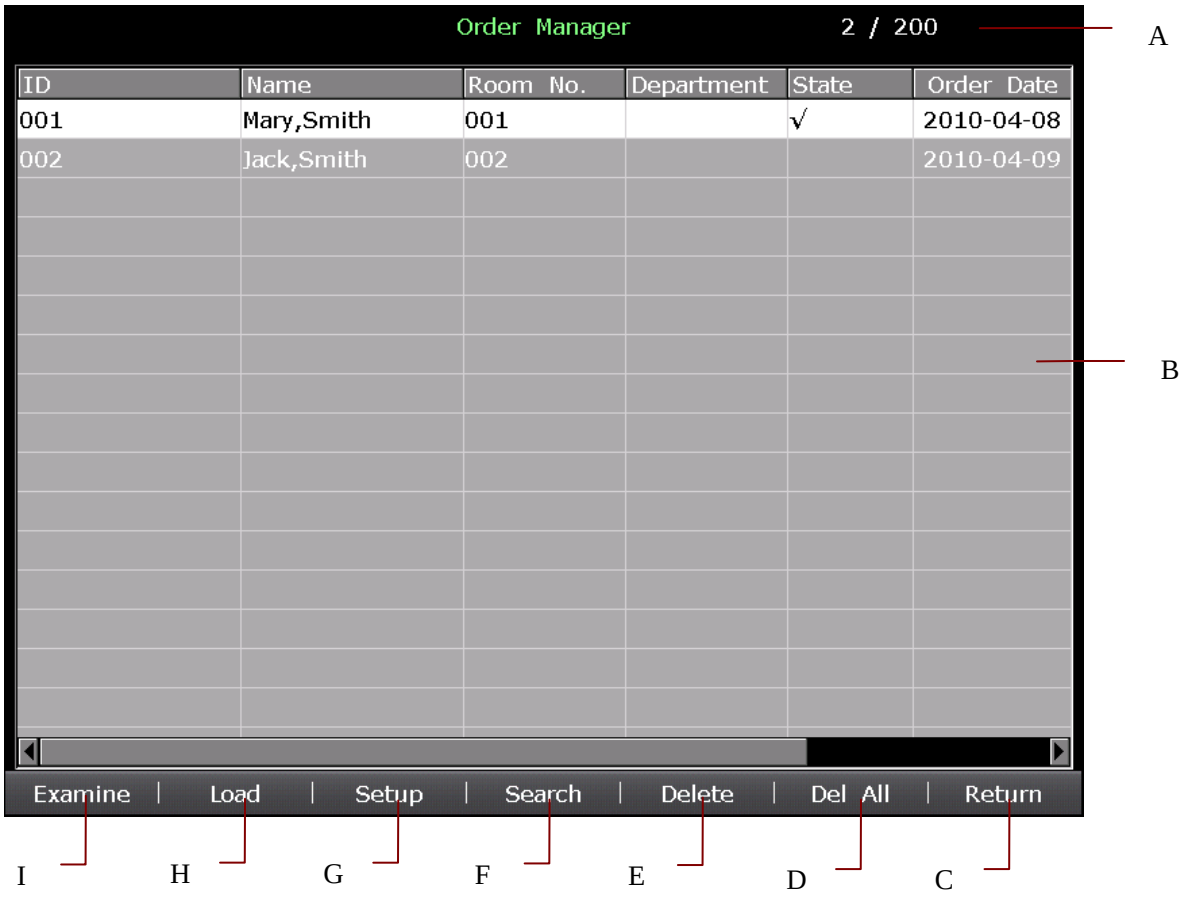


Figure 8-1 Order Manager Screen

	Name	Explanation
A	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.
B	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: √ indicates an order with examination No mark indicates an order without examination.
C	Return	Press to return to the main screen1.
D	Del All	Press to delete all the orders from the electrocardiograph.
E	Delete	Press to delete the selected order from the electrocardiograph.
F	Search	Press to search for orders on the Order Manager screen.
G	Setup	Press to make the related settings.
H	Load	Press to load orders to the electrocardiograph.
I	Examine	Press to return to main screen1 for starting examination of the selected order.

Chapter 9 Managing Files

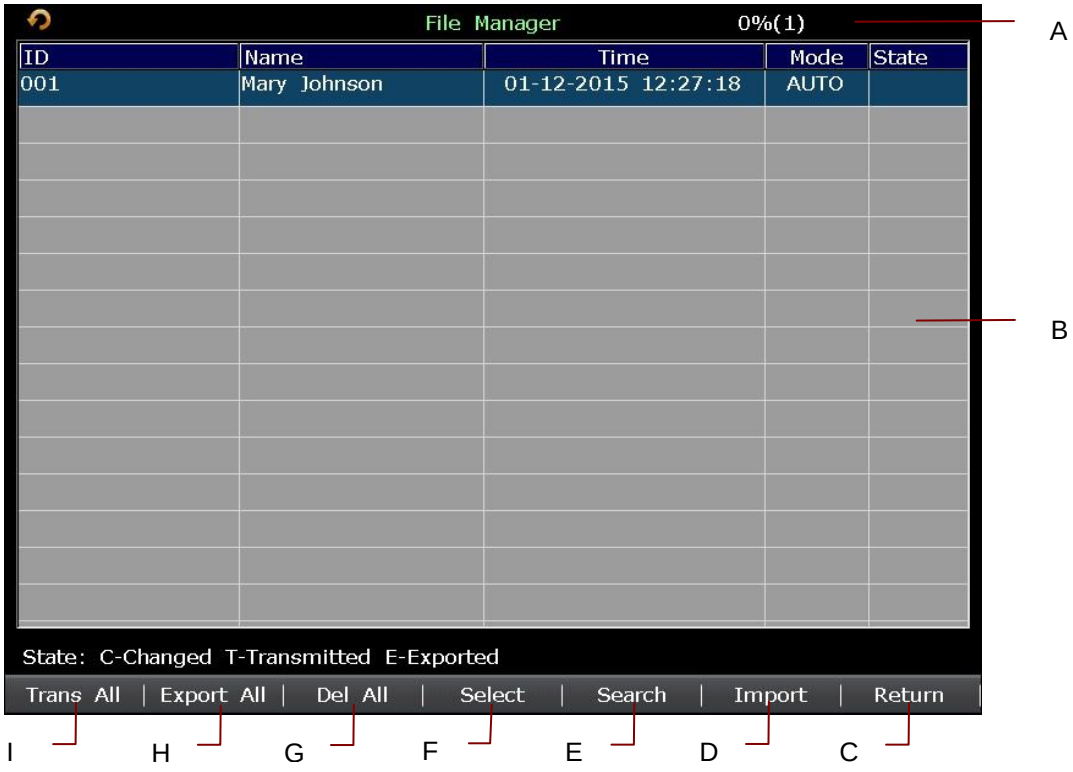


Figure 9-1 File Manager Screen1

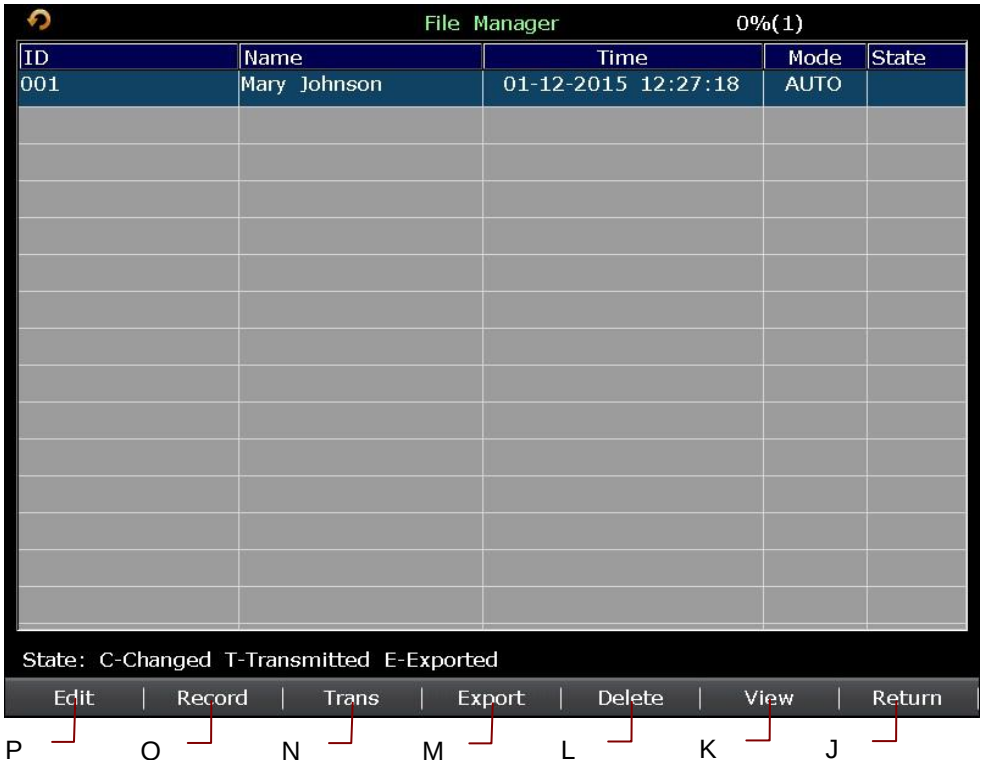


Figure 9-2 File Manager Screen2

	Name	Explanation
A	File Count	For example, 0% (1) 0% is space occupancy of the files stored in the electrocardiograph. 1 is the current number of files stored in the electrocardiograph. For 10s AUTO data, the upper storage limit is 800.
B	File List	Files will be loaded and displayed in the file list. The file information includes ID, Name, Time, Mode and State. State includes: No mark T indicates the file is transferred successfully. E indicates the file is exported successfully. C indicates the file has been edited. **NOTE**: A file can be displayed in more than one state at the same time.
C	Return	Press to return to the main screen.
D	Import	Press to import files from the U disk to the electrocardiograph.
E	Search	Press to open the SearchInfo Setup window.
F	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.
G	Del All	Press to delete all the files from the electrocardiograph.
H	Export All	Press to export all the files from the electrocardiograph to the U disk.
I	Trans All	Press to transmit all the files to the PC.
J	Return	Press to return to the File Manager screen1.
K	Preview	Press to open the file preview screen.
L	Delete	Press to delete the selected file from the electrocardiograph.
M	Export	Press to export the selected file from the electrocardiograph to the U disk.
N	Trans	Press to transmit the selected file to the PC.
O	Record	Press to print the selected file.
P	Edit	Press to open the Patient Information window. Then you can edit the patient information.

Export file path: ***ECGDATA\ECG-Device No.\Export\ Export Date and Time***
Import file path: ***ECGDATA***

CAUTION

1. When files are being printed, transmitted, deleted or exported, you cannot 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.
3. It is forbidden to connect or disconnect a U disk or a USB printer during the transmission course.

NOTE:

1. Please insert the U disk recommended by the manufacturer. Please set the format to **FAT** or **FAT32** when formatting the U disk.
2. 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.
3. For SE-12 and SE-1200, Rhythm data cannot be previewed.
4. Only the ECG files in DAT format produced by the electrocardiograph of the manufacturer can be imported.

Chapter 10 System Setup

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

10.1 Work Mode Setup

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

10.2 Filter Setup

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

NOTE:

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

10.3 Record Info Setup

10.3.1 Setup 1

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

NOTE:

1. If the time period is longer than 10s, the ECG data sampled will be stored, and the last 10s of data will be analyzed.
2. Record sequence of lead groups include **Sequential** and **Simultaneous** which can be set by user according to different kinds of clinic situation.

Item	Description
Record Device	Choose from: **Thermal, HP1010/1510**, **HP M401**, **HP 1020/1020PLUS/1106** HP 2010/1050/2000, HP 2015/2035, and HP 1525 are also compatible. You should connect the corresponding USB printer to the electrocardiograph.

WARNING

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

CAUTION

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

NOTE:

1. During the USB printing course, pressing the **PRINT/STOP** key again cannot stop printing ECG reports.
2. USB printing is ineffective in the auto periodic sampling mode, manual mode, VCG mode, and R-R analysis mode.

10.3.2 Setup 2

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

10.3.3 Setup 3

Items	Default	Default (Only in the U.S.)
XYZ Wave / Measure / Analysis	Off	Off
QRS Gain	20mm/mV	20mm/mV

NOTE:

1. Only if the VCG function is activated, can the **Record Info Setup3** window appear. For details on activating the VCG function, please contact the manufacturer or the local distributor.
2. Pressing **F2** twice in the **Record Info Setup** window can display the **Setup3** window.

10.4 Patient Information Setup

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

Item	Description
Patient Options	Select the item displayed in the **Patient Information** window. **Child Mode** is available only when Glasgow algorithm is used. In the Child Mode, lead V3 is used to sample ECG signals of V4R. The lead sequence of the Child Mode is: I, II, III, aVR, aVL, aVF, V4R, V1, V2, V4, V5, V6. **NOTE:** 1. **Pacemaker** appears in the **Patient Information** window after it is selected in the **Patient Information Setup** window. Set **Pacemaker** to **Yes** in the **Patient Information** window, and the **Pacemaker** information will be displayed on the report printed out. 2. **Pacemaker** is recommended to be set to **No** unless it is known that the majority of the electrocardiograph usage will be on patients with pacemakers. 3. Glasgow algorithm is a configurable advanced function. Password is required to enter the Advanced Setup screen. To activate it, please contact the local distributor.

10.5 Transmission Setup

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

10.5.1 Basic Setup

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

10.5.2 WIFI Setup (Configurable)

NOTE:

1. The WIFI transmission function is only available for the machine configured with the WIFI module.
2. Data transmission through Wi-Fi is not supported during ECG sampling.

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

Item	Description
SECURITY	The encryption type for the connected wireless network. **NOTE**: While SE-12 Express supports WEP encryption, we do not recommend the usage of WEP given the known security issues with the WEP protocol. The recommended WIFI encryption modes are WPA or WPA2.

10.6 Lead Setup

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

Item	Description
Lead Sequence	Choose from: **Standard** or **Cabrera** **Standard**: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 **Cabrera**: aVL, I, -aVR, II, aVF, III, V1, V2, V3, V4, V5, V6
Nehb	Choose from: **On** or **Off**. Lead Sequence: I, II, III, ND, NA, NI **NOTE:** If you set **Nehb** to **On**, the working mode is fixed to be manual.

10.7 Display&Sound Setup

Items	Default	Default (Only in the U.S.)
Brightness	10	10
Key Volume	Medium	Medium
Hint Volume	Medium	Medium

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

10.8 Date&Time Setup

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

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

10.9 File Setup

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

Item	Description
Auto Save	Choose from: **Off, To ECG** or **To External Memory** Select **Off**, ECG data will not be saved. Select **To ECG**, ECG data in the auto or rhythm mode will be saved in the ECG automatically. Select **To External Memory**, ECG data in the auto or rhythm mode will be automatically saved to the directory of ***ECGDATA\ECG-X\Store\Examination Date*** of the external memory after an ECG report is printed out. **NOTE:** X in the directory of ***ECGDATA\ECG-X\Store\Examination Date*** can be set in the **Device No.** textbox in the **Transmission Setup** window.

10.10 System Maintenance Setup

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

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

10.11 Other Setup

Items	Default	Default (Only in the U.S.)
External Input	Off	Off
External Output	Off	Off
Caps Lock	Off	Off

Item	Description
External Output	The external output socket is equipped in the electrocardiograph, through which the electrocardiograph can send rhythm lead signals to the external equipment. Choose from: **Off, Standard** or **Triggered** Select **Standard**, the electrocardiograph sends ECG signals of rhythm lead 1. Select **Triggered**, the electrocardiograph sends pulses with the height of 5V and the width of 45ms, based on the data of rhythm lead 1.

Chapter 11 Operation Instructions for Exercise ECG (Configurable for SE-12 Express)

Exercise ECG test contributes to discover myocardial ischemia, including the treadmill test and the ergometer test. The patients with stable chest pain or unstable chest pain but drug controlled, the heart blood reserve function and myocardial ischemia existence to be estimated after myocardial infarction or coronary artery reconstruction surgery need to do exercise test. Please consult with physician or medical professional regarding diagnosis produced by Exercise ECG test if you have any questions or concerns about your results.

Diagnosis of exercise test contributes to:

1. Diagnose the coronary artery ischemic disease
2. Estimate the severity, fatalness and prognosis of the known or suspicious coronary heart disease
3. Provide early fatalness evaluation of the acute myocardial infarction before discharge
4. Evaluate the heart status of patients in different age groups and genders with other heart diseases or coronary artery reconstruction.

11.1 About the Main Screen of Exercise ECG

NOTE: Some keys are used in operating SE-12 Express, please refer to Section 2.2 "Keyboard and Keys" for details.

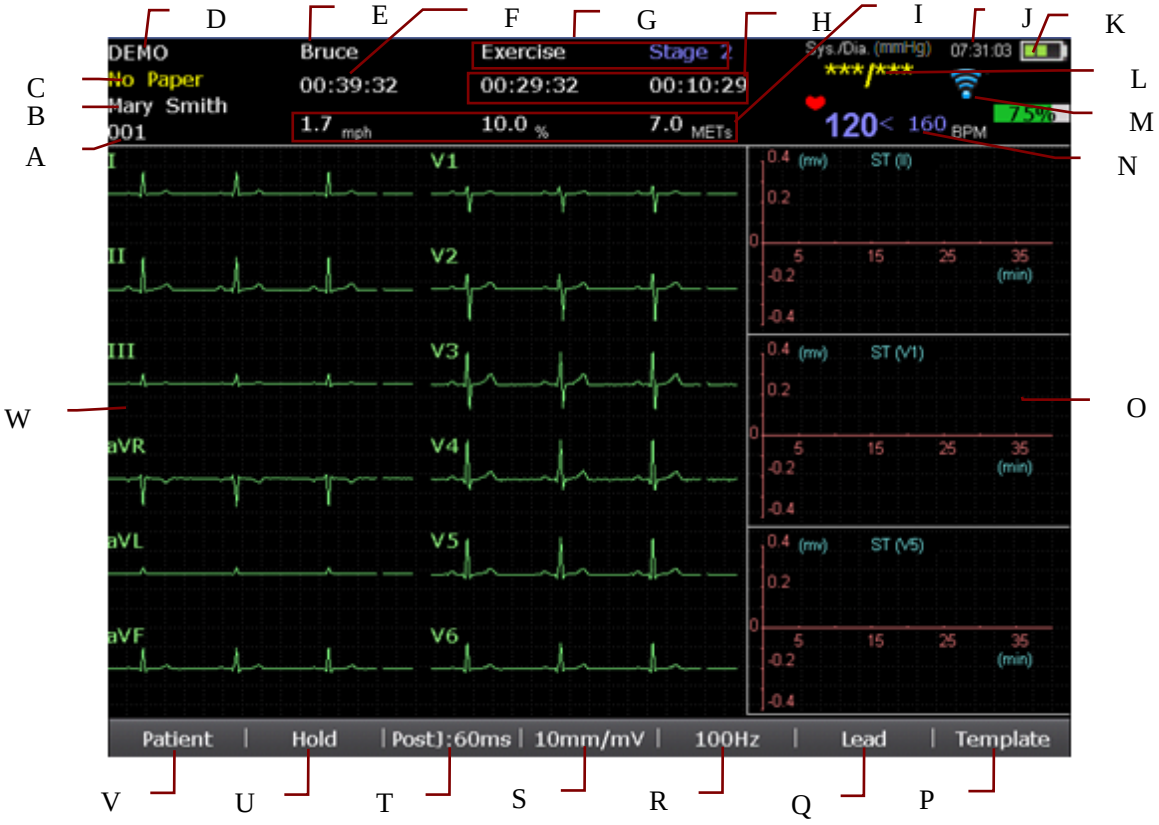


Figure 11-1 Main Screen of ST Trend

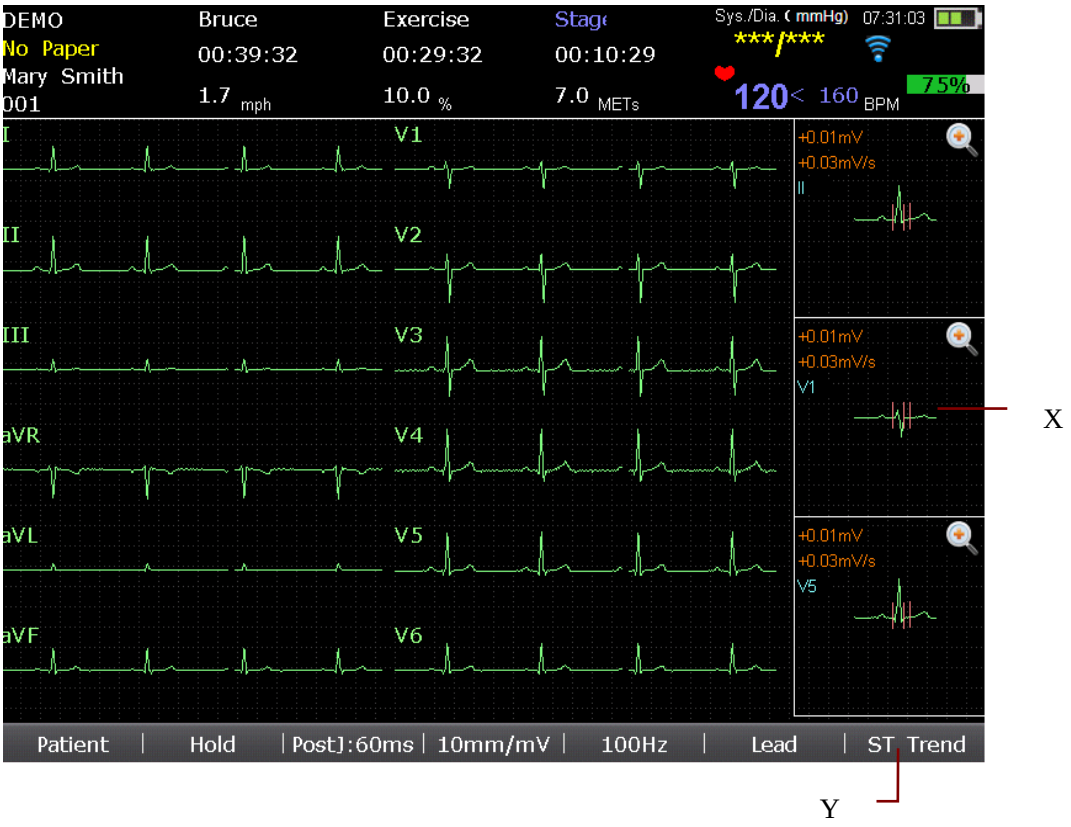


Figure 11-2 Main Screen of Template

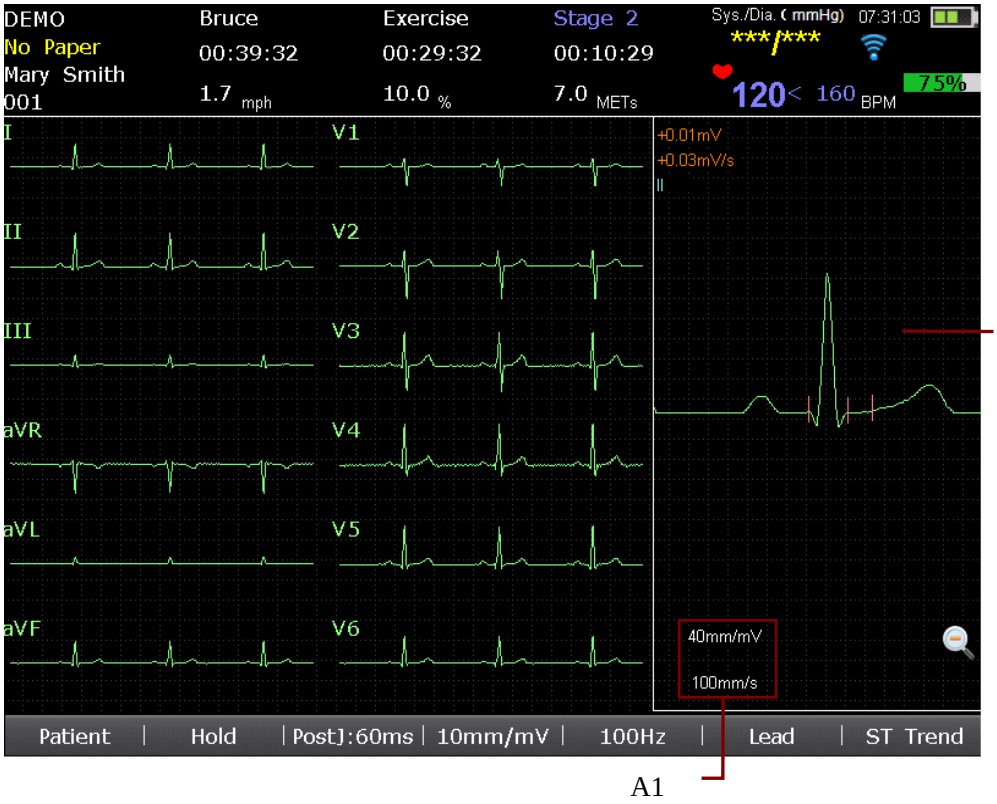


Figure 11-3 Closeup View of Template

A	ID	When **ID Mode** is set to **Manual**, the length of the patient ID plus the length of the default 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 **Pretest** key to start an exercise test. Entering the patient ID manually is not supported.
B	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
C	Hint Information1	***HR Overrange!***, ***Sys. Overrange!***, ***Dia. Overrange!***, ***Saving***, ***No Paper***, ***Paper Error***, ***U disk***, ***USB Scanner, Security Reader, ID Card Reader.*** **NOTE:** 1. The above hint information is listed in a priority-ranked sequence. ***HR Overrange!***, ***Sys. Overrange!*** and ***Dia. Overrange!*** have the same priority to be displayed. 2. If more than one fault occurs, the hint information which has the same priority will be displayed in a circulative mode.

		3. If more than one fault occurs, only the hint information with a higher priority will be displayed.
D	Hint Information2	***Lead X Off***, ***DEMO***, ***Module Error***, ***Overload***, TM-400 Treadmill hint information (including ***Lanyard Off***, ***Transmission Communication Error***, ***Transducer Error***, ***Incline Error***, ***Great Interference***, ***No Speed Signal***, ***Abnormal Speed***, ***UART Error***) **NOTE:** 1. *Lead X Off* has a high priority to be displayed. The other hint information of Hint Information2 has a normal priority to be displayed. 2. If more than one fault occurs, the hint information which has the same priority will be displayed in a circulative mode. 3. If more than one fault occurs, the hint information which has a high priority will be displayed.
E	Current Protocol	The selected protocol name
F	Total Time	The total time counted from the beginning of the pretest phase to the end of the exercise test.
G	Current Phase and Stage	The current phase and stage of the exercise test **NOTE:** Before or after the exercise test, state name is displayed.
H	Total Exercise Phase Time and Stage Time	The left number is the total exercise phase time, which is counted from the beginning to the end of the exercise phase. The right number is the stage time, which shows the running time of the current stage.
I	Current Speed or Rotation Speed, Grade or Power, Workload	When the treadmill is used, the current speed, grade and workload of the treadmill will be displayed on the main screen; When the ergometer is used, the current rotation speed and power of the ergometer will be displayed on the main screen.
J	Current Time	Current examination time.
K	Battery Symbol	Identify the current capacity of the battery
L	Systolic Blood Pressure and Diastolic Blood Pressure	The left number is the systolic blood pressure, and the right number is the diastolic blood pressure.
M	WIFI	If a wireless network is connected successfully, an icon appears on the main screen.  : Poor signal (-85dBm ＜transmit power ≤-70dBm);

		 : Good signal (-70dBm ＜transmit power ≤-50dBm);  : Great signal (-50dBm ＜transmit power) **NOTE**: For successful data transmission, please transmit data when the WIFI signal is good or great.
N	Current Heart Rate and Target Heart Rate	The left number is the current heart rate, and the right number is the target heart rate. **75%** is the percentage of the current heart rate to the target heart rate.
O	ST Trend	Display 3-lead ST trends.
P	Template Button / Exit	**During the exercise test or when the test is terminated:** This button changes into **Template** on the ST Trend screen, press it to display the 3-lead average templates; **No testing:** This button changes into **Exit**, press it to exit the main screen of the exercise test.
Q	Lead / Setup	**During the exercise test or test is terminated:** This button changes into **Lead**, press it to open the **Lead Setup** window. **No testing:** This button changes into **Setup**, press it to open the **System Setup** screen.
R	Filter	EMG Filter: Off, 25Hz, 35Hz or 45Hz Lowpass Filter: 75Hz, 100Hz, 150Hz, 270Hz or 300Hz
S	Gain	2.5 mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV, 10/5 mm/mV
T	Post J: 80ms	Post J is the length after J point of ST segment. Press to set Post J to 0, 20ms, 40ms, 60ms or 80ms. **NOTE**: J point is the connection point between the end of QRS complex and the start of ST segment. It is the standard point to fix the position of ST segment. Please select a proper option based on the patient's actual ECG waves.
U	Hold / Trans	**During the exercise test:** This button changes into **Hold**, press it to keep the current speed and grade until it is pressed again. **NOTE:** The test cannot enter the next stage automatically in **Hold** state.

		No testing: This button changes into **Hold**, and it does not respond to any operations. **Test is terminated:** This button changes into **Trans**, press it to transmit the file to the PC.
V	Patient	Press to open the **Patient Information** window. It is invalid in the exercise test.
W	ECG waveforms	Display real-time ECG waveforms.
X	Average Template	Press to display the 3-lead average template waves which are updated every 10 seconds and the positions of the calibration lines. The **Template** button will change into the **ST Trend** button. The 3 leads can be selected in the **Lead Setup** window of the exercise test. Press  or  to magnify or minify the selected lead average wave.
Y	ST Trend Button / Exit	**During the exercise test:** This button changes into **ST Trend** on the Average Template screen, press it to display the 3-lead ST trends. **No testing or test is terminated:** This button changes into **Exit**, press it to exit the main screen of the exercise test.
Z	Closeup View of Waveforms	Closeup view of the selected lead.
A1	Gain and Speed	Press to set the gain to **20mm/mV** or **40mm/mV**. Press to set the speed to **50mm/s** or **100mm/s**.

11.2 Operation Preparations

1. Turn on the electrocardiograph

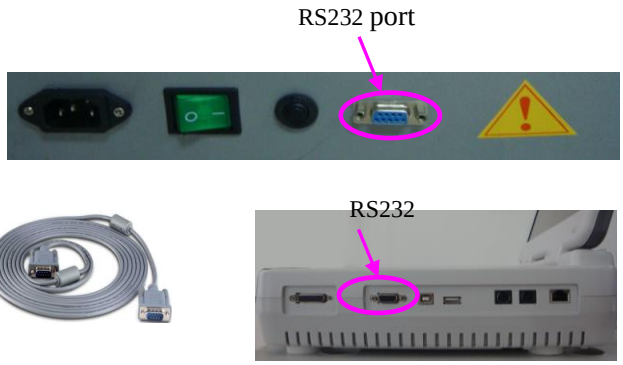
NOTE: Turn on the electrocardiograph before connecting the treadmill or the ergometer; or else, the start-up of the electrocardiograph may be abnormal.

2. Connect the electrocardiograph to the treadmill or the ergometer.

CAUTION

Only the treadmill/ergometer recommended by the manufacturer can be connected to Serial Port 1 and Serial Port 2.

1) Connect the electrocardiograph to the treadmill



NOTE: The position of the RS232 port may be different on different treadmills.

2) Connect the RS232 port of the ergometer to the RS232 port of the electrocardiograph with an RS232 cable.

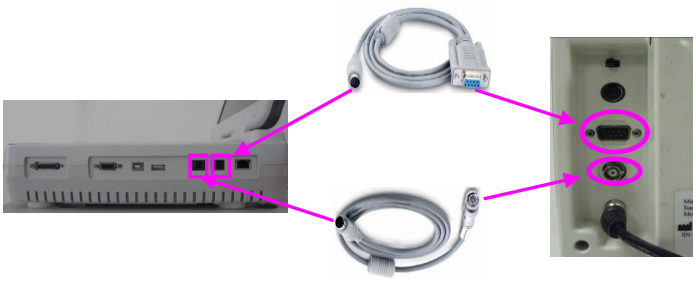
NOTE: The position of the RS232 port may be different on different ergometers.

3) Connect the electrocardiograph to the ergometer

4) Connect the RS232 port of the ergometer to the RS232 port of the electrocardiograph with an RS232 cable.

NOTE: The position of the RS232 in port may be different on different ergometers.

3. Connect the electrocardiograph to the stress BP monitor



4. Connect the power cords, and connect the earth wire (when necessary)
5. Load the recorder paper
6. Turn on the stress BP monitor and treadmill/ergometer
7. Set the electrocardiograph
   1) Activate the stress ECG function.

      For details, please contact the manufacturer or the local distributor.
   2) After turning on the electrocardiograph, press **Pretest** on the keyboard to open the main screen of the exercise test.
   3) Select **Setup** on the main screen1 to open the **System Setup** screen.
   4) Configure the **System Setup** screen.

      For details, please refer to Chapter 10 "System Setup".
8. Set the treadmill or the ergometer for external control
   1) For TM-400 treadmill

      It is ready for external control and needn't be set.
   2) For Lode Treadmill Valiant

      Hold down the following two keys for 10 seconds, and then you will enter the service menu of the Valiant.

      By default, the Valiant is shipped with the Lode RS232 communication protocol. It should be set to the Trackmaster RS232 protocol. You can change the communication protocol by following the procedures below:
      a) Select **Prot id** and select the second RS232 protocol which is the Trackmaster communication protocol
      b) Select **Baudrate** and set this to **4800 Baud**
      c) Press the red button to leave the service menu
      d) Turn off the Valiant
   3) For Lode ergometer

      By default, the Corival ergometer is shipped with the LODE RS232 communication protocol. It should be set to the ERGOLINE P4 protocol. You can change the RS232 protocol by following the procedures below:
      a) Turn on the ergometer and press **Enter**
      b) You will be in **MAINMENU**

c) Select, by using the Up/Down keys, the menu **SYSTEM PARAMETER** and press **Enter**

d) Select, by using the Up/Down keys, the menu **SETTINGS** and press **Enter**

e) Select, by using the Up/Down keys, the menu **RS232 PROTOCOL** and press **Enter**

f) Select, by using the Up/Down keys, **ERGOLINE P4** and press **Enter**

g) Save the selected RS232 protocol or restore the default RS232 protocol, which is also the LODE PROTOCOL.

h) Turn off the ergometer

4) For controlling the Lode ergometer by SE-12 Express

The ergometer should be set in the **ANALOG** mode. The **ANALOG** mode should be selected as follows.

a) Turn on the ergometer and press **Enter**

b) You will be in **MAINMENU**

c) Select, by using the Up/Down keys, the menu **SYSTEM PARAMETER** and press **Enter**

d) Select, by using the Up/Down keys, the menu **SETTINGS** and press **Enter**

e) Press **Enter** to confirm the menu **DEFAULTSTARTMENU** and press **Enter**

f) The Lode ergometer is now ready for external control

NOTE: You can also let the ergometer start up in the **ANALOG** mode every time you turn on the ergometer, by using the default start menu.

If you turn off the ergometer, it will start up in the **ANALOG** mode every time the ergometer is turned on again. For details on setting other models for external control, please refer to the connection instruction of the models.

9. Select **Patient** on the main screen1 to open the **Patient Information** window, and then enter the patient information. For details on entering patient information, please refer to Chapter 5, "Entering Patient Information".

NOTE: If you do not enter the patient age or the birthday before pressing the **Pretest** key to begin the exercise test, a hint will pop up to remind you to input the patient age.

11.3 Exercise Test

The following method is recommended when operating SE-12 Express electrocardiograph connected with a treadmill.

Operation Method:

1. Instruct the patient, attach the disposable electrodes to the patient, and then apply the stress BP monitor to the patient. For details, please refer to Chapter 3 Operation Preparations.
2. Instruct the patient to lay on the bed, oberserve the ECG waveforms and the supine blood pressure.
3. Select a protocol for the patient and configure the **System Setup** screen.

   NOTE: You cannot change the settings of the **System Setup** screen after staring an exercise test.
4. Press the **Pretest** key to begin the pretest phase.
5. Press the **Exercise** key to enter the exercise phase, and then observe the ECG waveforms, heart rate, blood pressure, the patient's state and ST trend during the exercise test. If the stress BP monitor is connected, the patient's blood pressure is measured once at a phase, and you should print or save an ECG report after the main screen displays the BP value.
6. When the target value is reached, such as the target heart rate, press the **Recovery** key to enter the recovery phase, and then instruct the patient to walk on the treadmill for 1 minute. Observe the ECG waveforms, heart rate, blood pressure and the patient's state during the recovery stage.
7. Instruct the patient to sit on the bed, and then observe the ECG waveforms and the blood pressure for 6～8 minutes.
8. When the patient's heart rate resumes the normal value, press the **Test end** key to terminate the exercise test. Press the **PRINT/STOP** key to print the final report. Select **Trans** on the main screen of excersice screen to tranmist the report to the PC.
9. Take off the patient cable and electrodes, press the **Pretest** key to exit the test, and then prepare for the next patient.

WARNING

1. During the exercise test, ensure that such tests are supervised by properly trained technician who meets competency requirements for exercise test supervision, fully trained in cardiopulmonary resuscitation, and is supported by a physician skilled in exercise testing or emergency medicine who is in close proximity for pretest assessment or compliance that may raise.
2. Remind patients to take care not to fall down from the treadmill.
3. Press down the emergency stop switch of the treadmill before defibrillating to avoid the hazard to the patient and the operator.

11.4 Factory Defaults of Exercise ECG

General Information Setup		
Items	**Default**	**Default (Only in the U.S.)**
Display Style	6×2	3×4+1R
Speed Unit	mph	mph
Post J	60ms	60ms
Device Style	Treadmill	Treadmill
Treadmill Model	TMX425	TMX425
Ergometer Model	Ergoline	Ergoline
BP Monitor	Tango	Tango
Normal BP Range (Sys./Dia.) Maximum 220/90 mmHg Minimum 110/60 mmHg Max Predicted HR=220-Age Target HR= Max Predicted HR*85%		
Filter Setup		
Items	**Default**	**Default (Only in the U.S.)**
AC filter	On	On
EMG filter	Off	Off
DFT filter	0.67Hz	0.67Hz
Lowpass filter	100Hz	100Hz
Recorder Setup		
Items	**Default**	**Default (Only in the U.S.)**
Gain	10mm/mV	10mm/mV
Paper Marker	Yes	Yes
Record Info Setup		
Items	**Default**	**Default (Only in the U.S.)**
12-Lead Report: Record Style	6×2+1	3×4+1R
12-Lead Report: ST Info	On	On

Manual Report	Print	Print
Pretest Report	Print	Print
Exercise Report: Auto Report	Print	Print
Exercise Report: Print Time	Late Stage	Late Stage
Recovery Report: Auto Report	Print	Print
Recovery Report: Start Time	20s	20s
Recovery Report: Interval	2min	2min
Final Report: Summary / ST Scope / Trend Graph / Summary Template Report	Print	Print
Final Report: Edit Conclusion	Off	Off
Transmission Setup		
Items	**Default**	**Default (Only in the U.S.)**
Transmit After Saving	Off	Off
FTP User Name/FTP Password	EDANDAT	EDANDAT
FTP Path	Cleared	Cleared
Transmission - WIFI Setup (with WIFI configured)		
Items	**Default**	**Default (Only in the U.S.)**
Enable WIFI	Disabled	Disabled
Auto Get IP	Off	Off
Lead Setup		
Items	**Default**	**Default (Only in the U.S.)**
Lead Sequence	Standard	Standard
Rhythm Lead 1	II	II
Rhythm Lead 2	V1	V1
Rhythm Lead 3	V5	V5

NOTE:

1. Pressing the Up or Down arrow can switch the display style during the exercise test. When the display style is 3×1, pressing the Left or Right arrow can switch the lead group.
2. Except for the **General Information Setup** window, the **Record Information Setup** window and the **Protocol Manager** screen, the changes of the System Setup screen are synchronous in both Resting and Exercise ECG tests.

3. You should test whether the treadmill is controlled by SE-12 Express well when SE-12 Express is connected to the treadmill for the first time.
4. Do not stand on the treadmill when testing it for the first time.
5. Before the exercise test, be sure to be familiar with the user manual of the treadmill or the ergometer.
6. If you have any questions about the operation, please contact us or your local distributor.

11.5 Managing Protocols

Select **Protocol** on the **System Setup** screen, and press **Enter** to open the **Protocol Manager** (treadmill or ergometer) screen.

NOTE: The Protocol Manager (treadmill or ergometer) screen can be displayed according to the **Device Type** setting you configure in the **General Information Setup** window. Managing treadmill protocols is taken for an example in this manual; therefore there is no further description for managing ergometer protocols.

1. Adding Protocols

Select **Add** on the **Protocol Manager** screen to display the **Edit Protocol** dialog box.

Enter the new protocol name in the **Protocol Name** textbox, and then enter the stage information of every stage, including the time, speed and grade. After that, press **Enter** to confirm.

NOTE:

1) When Time of a stage in the exercise phase is set to 00, this stage and its following stages in the exercise phase will not be carried out.
2) "1/3" in the **Add Protocol** window stands for "the current page/ the total pages".
3) Pressing **Shift** + Left/Right can turn pages in the on the **Add Protocol** window.

2. Editing Protocols

Select a protocol on the **Protocol Manager** screen by pressing the Up or Down arrow, and select **Edit** to display the **Edit Protocol** dialog box.

Edit the protocol name or the stage information of every stage, including the time, speed and grade. After that, press **Enter** to confirm.

NOTE: For the Bruce or Modified Bruce protocol, only the stage information of the pretest and recovery phases can be edited.

3. Setting Default Protocols

Select a protocol on the **Protocol Manager** screen by pressing the Up or Down arrow, and press **Select** to set the selected protocol as the default protocol.

4. Deleting Protocols

Pressing **Del All** on the **Protocol Manager** screen can delete all the protocols from the electrocardiograph.

Or, you select a protocol on the **Protocol Manager** screen, select **Delete**, and then press **Enter** to delete the selected protocol from the electrocardiograph.

NOTE: Only the customized treadmill protocol can be deleted.

5. Restoring Protocols

Pressing **Restore** on the **Protocol Manager** screen can restore the factory settings.

6. Return

Pressing **Return** on the **Protocol Manager** screen can return to the **System Setup** screen for the exercise test.

Chapter 12 Error Messages

Hint information and the corresponding causes provided by the electrocardiograph are listed in Table 12-1.

Table 12-1 Error Messages and Causes for Resting ECG

Message	Cause
Lead off	Electrodes fall off the patient or the patient cable falls off the unit, or a high polarization voltage occurs.
Battery Weak	The battery is weak.
No Paper	Recorder paper runs out or is not loaded.
Testing	The ECG data is being sampled periodically.
Paper Error	When **Paper Marker** is set to **Yes**, the electrocardiograph advances the recorder paper to the next black marker. If it advances the paper for 300mm and cannot 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 or serial cable in the auto or rhythm mode.
Transmitting fails	Data fails to be transmitted through Ethernet or WIFI.
Loading Order…	Orders are being loaded to the electrocardiograph.
Memory Full	There is no space for saving more records.
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.

Message	Cause
U Disk / USB Printer / USB Scanner / Reader	A U disk, a USB printer or a bar code reader / security reader / ID card reader is connected to the USB interface.

Table 12-2 Hint Information and Causes for Exercise ECG

Message	Cause
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 for 300mm and cannot find the next black marker, the hint *Paper Error* is displayed.
Module Error	There is something wrong with the signal sample module.
DEMO	The system is in the demonstration mode.
Lead X off	Electrodes fall off the patient or the patient cable falls off the unit.
Overload	The direct current offset voltage on an electrode is too high.
HR Overrange!	Heart rate exceeds the normal range.
Sys. Overrange!	Systolic blood pressure exceeds the normal range.
Dia. Overrange!	Diastolic blood pressure exceeds the normal range.
Lanyard Off	The safety stop (mushroom type) is revolved and the safety stop (cord type) is pulled out.
Trans.Comm Err	The transducer and the main control board lines are not connected well.
Transducer Err	The transducer doesn't work well or is not connected well.
Incline Err	The incline motor doesn't work well or is not connected well.
Great Interference	There is great magnetic interference around the transducer.
No Speed Signal	The speed sensor doesn't work well or is not connected well.

Message	Cause
Abnormal Speed	The speed set in the electrocardiograph is different from the actual speed of the running belt; the signal cable is not connected well, parts, the speed sensor are loose, or great magnetic field exists.
UART Error	The serial cable is not connected well.

Chapter 13 FAQ

1. Operating Problems

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

A1: Actually, the system provides a method for fast moving: pressing **Shift** + **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, you can set **Print Out** to **Off** in the **Record Info Setup1** window. Or, in the auto or rhythm mode, you can directly press **Shift** + **PRINT/STOP** to enable or disable the print out function. The ECG data will be collected and saved without printing. In the same way, if the transmission settings are configured, the ECG data could be transmitted to the PC without printing.

Q4: The screen of SE-12 series electrocardiograph 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.

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.

Q6: ***Memory Full*** is displayed on the main screen; Or, the hint ***Memory full! Replace the earliest file?*** pops up every time when I save an ECG report to the electrocardiograph. What am I supposed to do?

A6: ***Memory Full*** is used to remind you that the amount of stored file reaches the upper limit.

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

Select **Off** from the **Replace When Memory Full** list box, when the amount of stored files reaches the upper limit and you save an ECG report to the electrocardiograph, the hint ***Memory full! Replace the earliest file****?* pops up.

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

You can deal with the hint as follows:

1) You can just delete several stored files from the electrocardiograph to ensure the amount of stored file not to reach the upper limit.
2) When ***Memory Full*** is displayed on the main screen, you can set **Auto Save** to **To U Disk** to save the added ECG reports. However, the amount of stored files in the electrocardiograph still reaches the upper limit.

2. Printing Problems

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

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

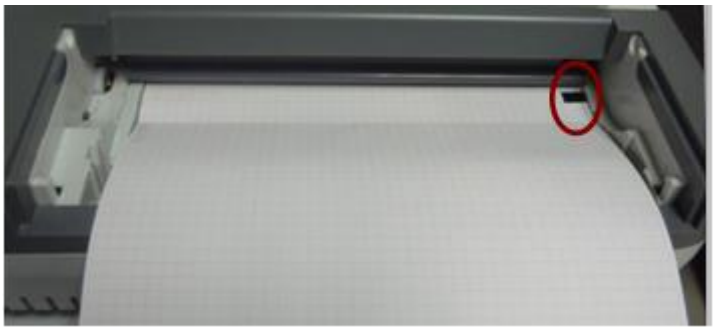
Q2: The hint ***Paper Error*** is displayed on the screen, what should I do?

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.

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

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

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

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

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

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

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

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

3. Transmitting Problems

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

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

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

4. Main Unit Problems

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

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

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

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

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

5. Exercise Test Problems

Q1: Before the exercise test, the treadmill cannot be started after I press the **Start tmill** key to test the connection. What should I do?

A1: Set **Device Type** to **Treadmill** and select a model from the **Device Model** list in the **General Information Setup** window. Then make sure the RS232 cable between the electrocardiograph and the treadmill is connected well, the treadmill is powered on and the power switch is switched to **On**.

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

Q2: I press the **Stop tmill** key to stop the test temporarily during the exercise test, but in a while, the treadmill cannot be started after I press the **Start tmill** key. What should I do?

A2: Press the **Stop tmill** key, 1 minute later press the **Start tmill** key to start the treadmill.

Chapter 14 Cleaning, Care and Maintenance

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

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

14.1 General Points

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

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

CAUTION

1. If you spill liquid on the equipment or accessories, or they are accidentally immersed in liquid, contact your service personnel or EDAN service engineer.
2. The equipment is chemically resistant to most cleaning agents, disinfectants and non-caustic detergents used in hospital, but cleaning agents or disinfectants that are not listed in this manual are not recommended. For example, didecyl dimethyl ammonium bromide, which contains quaternary ammonium salt, may corrode the equipment and accessories.

14.2 Cleaning

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

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

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

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

WARNING

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

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

CAUTION

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

14.3 Disinfection

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

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

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

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

CAUTION

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

disinfection methods.

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

WARNING

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

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

14.4 Care and Maintenance

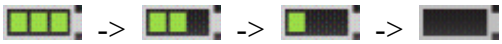
CAUTION

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

14.4.1 Recharge and Replacement of Battery

1) Capacity Identification

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

 -> -> ->

Capacity is from full to empty.

2) Recharge

SE-12 series electrocardiograph is equipped with the recharge control circuit together with the battery. When the unit is connected to the mains supply, the battery will be recharged automatically. Then the battery recharging indicator (⇥▭) and the mains supply indicator (∿) will be lit at the same time. During the recharging course, the symbol ▭ flashes in the top right corner of the LCD screen. After the battery is fully recharged, the symbol stops flashing, and the battery recharging indicator (⇥▭) is black.

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

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.
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.

14.4.2 Recorder Paper

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

Storage Requirements:

- Recorder paper should be stored in a dry, dark and cool area, avoiding excessive temperature, humidity and sunshine.
- Do not put the recorder paper under fluorescence for a long time.

- Make sure that there is no polyvinyl chloride or other chemicals in the storage environment, which will lead to color change of the paper.
- Do not overlap the recorder paper for a long time, or else the ECG reports may trans-print each other.

14.4.3 Visual inspection

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

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

14.4.4 Maintenance of the Main Unit and the Patient Cable

CAUTION

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

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

a) Inspect the equipment and accessories for mechanical and functional damage.
b) Inspect the safety related labels for legibility.
c) Inspect the fuse to verify compliance with the rated current and circuit-breaking characteristics.
d) Verify that the device functions properly as described in the instructions for use.
e) Test the protection earth resistance according to IEC/EN 60601-1: Limit: 0.1 ohm.
f) Test the earth leakage current according to IEC/EN 60601-1: Limit: NC 500μA, SFC 1000μA.
g) Test the enclosure leakage current according to IEC/EN 60601-1: Limit: NC 100μA, SFC 500μA.
h) Test the patient leakage current according to IEC/EN 60601-1: Limit: NC a.c. 10μA, d.c. 10μA; SFC a.c. 50μA, d.c. 50μA.
i) Test the patient auxiliary current according to IEC/EN 60601-1: Limit: NC a.c. 10μA, d.c. 10μA; SFC a.c. 50μA, d.c. 50μA.

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

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

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

WARNING

1. 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.
2. The maintenance operations like software upgrade of the device can only be completed by EDAN-qualified service personnel.
3. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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 cannot 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 15 Accessories

WARNING

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

15.1 Standard Accessories

Table 15-1 Standard Accessories List

Accessory	Part Number
Power cord (European)	01.13.036638
Power cord(American)	01.13.037122
ECG Cable, Patient Cable (European)	01.57.471500*
ECG Cable, Patient Cable (American)	01.57.471499*
Adult Chest electrodes	01.57.040163
Adult Limb electrodes	01.57.040162
Thermal Recorder Paper	01.57.107371
Rechargeable Li-ion Battery (SE-12), TWSLB-005	21.21.064149
Rechargeable Li-ion Battery (SE-12 Express), TWSLB-004	21.21.064146
Fuse	21.21.64073
	21.21.064172

15.2 Configurable Accessories

Table 15-2 Optional Accessories List

Accessory	Part Number
ECG Cable, Patient Cable (European)	01.57.107581 (Snap Style)
	01.57.107583 (Grabber Style)
ECG Cable, Patient Cable (American)	01.57.107582 (Snap Style)
	01.57.107584 (Grabber Style)
ECG Cable (Patient Cable) for Exercise ECG, European Standard	01.57.109850
ECG Cable (Patient Cable) for Exercise ECG,	01.57.109851

Accessory	Part Number
American Standard	
Grounding Wire	01.13.114214
Pediatric Chest Electrodes	01.57.040168
Pediatric Limb Electrodes	01.57.040169
Adult Disposable Adhesive Electrodes	01.57.471858
	01.57.471862
Pediatric Disposable Adhesive Electrodes	01.57.471859
Disposable Resting electrodes	01.57.471863
Disposable Exercise electrodes	01.57.471860
Snap/Banana Socket Adapters	01.57.471864
Clip/Snap/Banana Socket Adapter	01.57.040172
Thermal Recorder Paper (Rolled, 210mm×30m)	01.57.32461
Thermal Recorder Paper (Folded, 215mm×280mm×100P)	01.57.107451
BP Monitor	83.61.328019
ECG Bag	01.56.465625
MT-201 Trolley	83.61.111847
MT-801 Trolley	83.63.5600232
Belt for Exercise Test	01.57.106750
U Disk	01.18.052245
CA-100 Lead wire bracket	02.04.111902
	02.04.242639*
	02.04.242640*
Bar Code Reader (One-Dimension)	01.23.068023
Bar Code Reader (Two-Dimension)	21.18.052311

SE-12 series electrocardiograph and accessories are available at your request.

NOTE:

1 * Currently not available in the U.S.

2 The chest electrodes, limb electrodes, pediatric chest electrodes and pediatric limb electrodes are not available in the U.S.

3 The part name may vary depending on context, but the part number is constant.

Chapter 16 Warranty & Service

16.1 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.

16.2 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.

Appendix 1 Technical Specifications

A1.1 Safety Specifications

Comply with:		IEC 60601-1:2005/A1:2012 EN 60601-1:2006/A1:2013 IEC 60601-1-2:2014 EN 60601-1-2:2015 IEC/EN 60601-2-25
Anti-electric-shock type:		Class I with internal power supply
Anti-electric-shock degree:		CF type with defibrillation-proof
Degree of protection against harmful ingress of water:		Ordinary equipment (Sealed equipment without liquid proof)
Disinfection/sterilization method:		Refer to the user manual for details
Degree of safety of application in the presence of flammable gas:		Equipment not suitable for use in the presence of flammable gas
Working mode:		Continuous operation
EMC:		CISPR 11, Group 1, Class A
Patient Leakage Current:	NC	<10μA (AC) / <10μA (DC)
	SFC	<50μA (AC) / <50μA (DC)
Patient Auxiliary Current:	NC	<10μA (AC) / <10μA (DC)
	SFC	<50μA (AC) / <50μA (DC)

A1.2 Environment Specifications

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

A1.3 Physical Specifications

Dimensions	SE-12	420mm×330mm×105mm, ±2mm
	SE-12 Express	420mm×330mm×120mm, ±2mm
	SE-1200	420mm×330mm×120mm, ±2mm
	SE-1200 Express	420mm×330mm×120mm, ±2mm
	SE-1201	361mm×262mm×135mm, ±2mm
Weight	SE-12	≤ 5.0kg (Excluding recorder paper and battery)
	SE-12 Express	≤ 6.5kg (Excluding recorder paper and battery)
	SE-1200	≤ 5.0kg (Excluding recorder paper and battery)
	SE-1200 Express	≤ 5.0kg (Excluding recorder paper and battery)
	SE-1201	≤ 4.2kg (Excluding recorder paper and battery)
Display	SE-12	5.7", 320×240 LCD screen
	SE-12 Express	12.1", 800×600 LCD screen
	SE-1200	5.7", 320×240 LCD screen
	SE-1200 Express	8.0", 800×600 LCD screen
	SE-1201	7", 800×480 LCD screen

A1.4 Power Supply Specifications

Mains Supply:	Operating Voltage = 100V-240V~
	Operating Frequency = 50Hz/60Hz
	Input Current = 0.9-0.4A

<table>
<tr><td rowspan="4">Internal Li-ion Battery Pack:</td><td>Rated Voltage = 14.8V</td></tr>
<tr><td>Rated Capacity = 5000mAh or 2500mAh
5000mAh battery pack is configurable for SE-1200 Express and SE-12 Express only.</td></tr>
<tr><td>
<table>
<tr><th>Rated Capacity</th><th>100% Charge Time</th><th>90% Charge Time</th></tr>
<tr><td>2500mAh</td><td>3 hours</td><td>2 hours</td></tr>
<tr><td>5000mAh</td><td>6 hours</td><td>3.5 hours</td></tr>
</table>
</td></tr>
<tr><td>
<table>
<tr><th rowspan="2">Rated Capacity</th><th rowspan="2">Normal Work Hours</th><th colspan="2">Print Number and Duration</th></tr>
<tr><th>Auto Mode（3×4+1R）</th><th>Manual Mode (Continual)</th></tr>
<tr><td>2500mAh</td><td>≥ 4h</td><td>≥ 250</td><td>≥ 2h</td></tr>
<tr><td>5000mAh</td><td>≥ 8h</td><td>≥ 500</td><td>≥ 4h</td></tr>
</table>
</td></tr>
<tr><td>Fuse:</td><td>T3.15AH250V, Ø5×20mm;</td></tr>
</table>

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:	SE-12, SE-12Express, SE-1200, SE-1200 Express: Folded thermal paper: 210mm×295mm×100pages Folded thermal paper: 215mm×280mm×100pages (Configurable) Rolled thermal paper: 210mm×30m (Configurable) SE-1201: Folded thermal paper: 210mm×140mm×144 pages Folded thermal paper: 210mm×295mm×100 pages (Configurable) Folded thermal paper: 215mm×280mm×100 pages (Configurable)
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:	24 bits
Resolution:	0.1192uV/LSB
Sampling Frequency	64,000/sec/channel
Time Constant:	≥3.2s
Frequency Response:	0.01Hz～300Hz
Gain:	1.25mm/mV, 2.5mm/mV, 5mm/mV, 10mm/mV, 20mm/mV, 10/5mm/mV, AGC

Input Impedance:	≥100MΩ (10Hz)
Input Circuit Current:	≤0.01μA
Input Voltage Range	≤±5 mVpp
Calibration Voltage:	1mV±2%
DC Offset Voltage:	±600mV
Minimum Amplitude:	20 μVp-p
Noise:	≤12.5 μVp-p
Multichannel crosstalk	≤0.5mm
Filter	AC Filter: On/Off
	DFT Filter: 0.01Hz/0.05Hz/0.15Hz/0.25Hz/0.32Hz/0.5Hz/0.67Hz
	EMG Filter: Off/25Hz/35Hz/45Hz
	LOWPASS Filter: 300Hz/270Hz/150Hz/100Hz/75Hz
CMRR	≥140dB (AC ON) ≥123dB (AC OFF)
Pacemaker Detection	
Amplitude	±750uV to ±700 mV
Width	50μs to 2.0 ms
External Input/Output	
Input	≥100kΩ; Sensitivity 10mm/V±5%; Single ended
Output	≤100Ω; Sensitivity 1V/mV±5%; Single ended
WIFI (Configurable)	
Transmitting Frequency	2400-2497MHz

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

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

Appendix 2 EMC Information

Electromagnetic emissions

<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>

Electromagnetic immunity

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	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC/EN 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	±1 kV line to line ±2 kV line to ground	±1 kV line to line ±2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50Hz/60Hz) magnetic field IEC/EN 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	0 % $U_{T;}$ 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle	0 % $U_{T;}$ 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle	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

	and 70 % U_T; 25/30 cycles) Single phase: at 0° 0 % U_T; 250/300 cycle	and 70 % U_T; 25/30 cycles) Single phase: at 0° 0 % U_T; 250/300 cycle	power mains interruptions, it is recommended that the 12-channel electrocardiograph be powered from an uninterruptible power supply or a battery.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Electromagnetic immunity

Guidance and manufacture's declaration – electromagnetic immunity			
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 6Vrms[c)] in ISM bands between 0.15 MHz and 80 MHz	3V_{rms} 150 kHz to 80 MHz 6Vrms[c)] in ISM bands between 0.15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of 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	3 V/m	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz

61000-4-3	80 MHz to 2.7 GHz	80 MHz to 2.7 GHz	$d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz $d = 6\sqrt{P}/\mathrm{E}$ at RF wireless communications equipment bands (Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the 12-channel electrocardiograph, including cables specified by the manufacturer). Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
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.

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

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

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

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

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

Recommended separation distances between

portable and mobile RF communications equipment and 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 2.7 GHz** $d = 2.3\sqrt{P}$
0.01	**0.12**	**0.12**	**0.23**
0.1	**0.38**	**0.38**	**0.73**
1	**1.2**	**1.2**	**2.3**
10	**3.8**	**3.8**	**7.3**
100	**12**	**12**	**23**

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

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

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

Appendix 3 Abbreviations

Abbreviation	Full Description
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

P/N: 01.54.032423
MPN: 01.54.032423032

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