SE-1202

Electrocardiograph

Version 1.1

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

Product Information

Product Name: Electrocardiograph

Model: SE-1202

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.

Contents

Chapter 1 Introduction

1.1 Product Information

1.1.1 Product Overview

The SE-1202 electrocardiograph features a 10.1" LCD touch screen, an operation panel, user-programmable reports, and the ability to operate on either battery or AC power. It is capable of simultaneous acquisition, display, and print of 12-lead ECG. It uses algorithm to generate measurements, data presentations, graphical presentations and interpretative statements.

NOTE: All illustrations in this manual are provided as examples only.

1.1.2 Indications for Use/Intended Use

The SE-1202 12-lead electrocardiograph is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. However, the interpreted ECG with measurements and interpretive statements is offered to clinicians on an advisory basis only.

WARNING

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

1.1.3 Features & Benefits

Full touch screen & operation panel

Enter patient information, data, and program the system easily and quickly.

Battery operation

Use the electrocardiograph almost anywhere. On battery power, the electrocardiograph can print at least 250 ECGs of 3x4+1R in the Auto work mode.

User-definable ECG report formats

Customize the report format for efficient reporting

Optional operation scenarios

Select the scenario (outpatient/inpatient, physical examination, and cardiology) to simplify the daily routine.

Compatibility with workstation software

Store and manage data electronically by transferring the data to an EDAN ECG workstation via Ethernet, WIFI, or 4G network

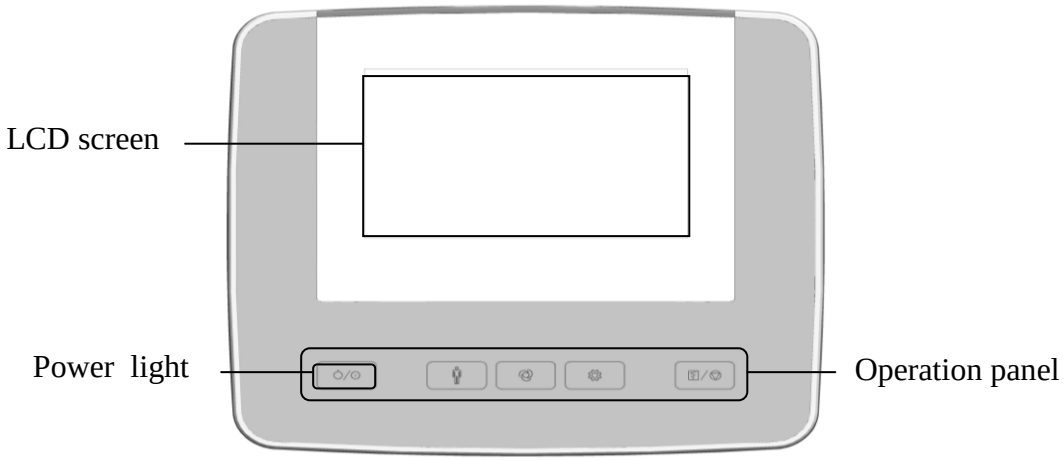
Compatibility with external printer

Connect an external USB printer to the electrocardiograph.

1.1.4 Controls, Indicators, and Connectors

This section describes the controls, indicators, and connectors that are part of the electrocardiograph.

Figure 1 Top



The keys on operation panel are as follows.

	Symbol	Name	Description
1		On/Off	• To power on, press the On/Off button when the device is off. • When the device is on: To enable power-save, press and hold this button in 1 second or To power off, press and hold this button for 3 seconds. • When the device is not responding, press and hold this button for 6 seconds to power off.
2		Patient	To open the patient information dialog box in the Resting ECG Test screen. To exit, press this button again.
3		Mode	To switch operation mode in the Resting ECG Test screen.
4		Setting	To configure the system setting in the Resting ECG Test screen. To exit, press this button again.
5		Print/Stop	• To start printing report(s). • To stop print when report(s) is being printed. • To stop paper feeding.
6	/	Power light	• Green indicates the system is connected to AC power. • Blue indicates the system is connected to battery power. • Orange indicates the system is connected to both the AC power and battery, and the battery is not full.

Figure 2 Left

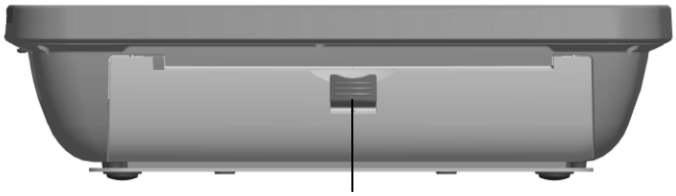
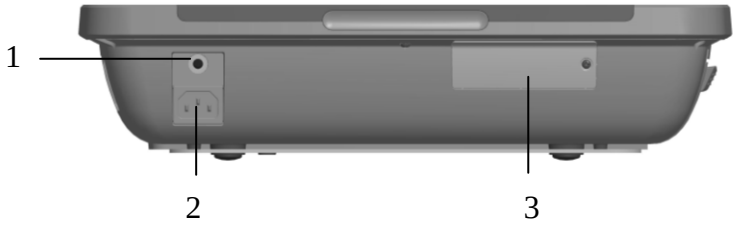
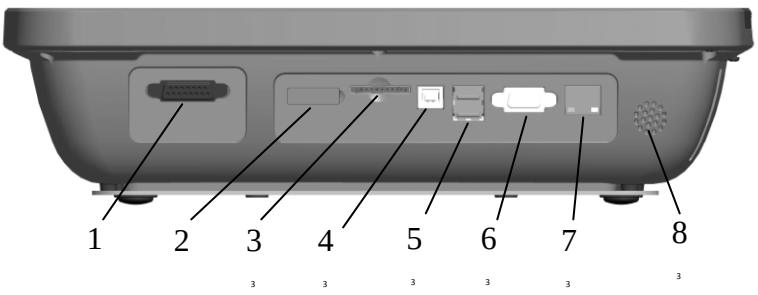


Figure 3 Back



	Name	Description
1	Ground lug	Connects to non-grounded peripheral devices to ensure equipotential.
2	Main AC power	Connects the system to an AC power supply via power cable.
3	Battery compartment	Contains a battery to supply power when the unit is not connected to AC power. Recharge the battery when the LCD screen prompts you battery is low.

Figure 4 Right



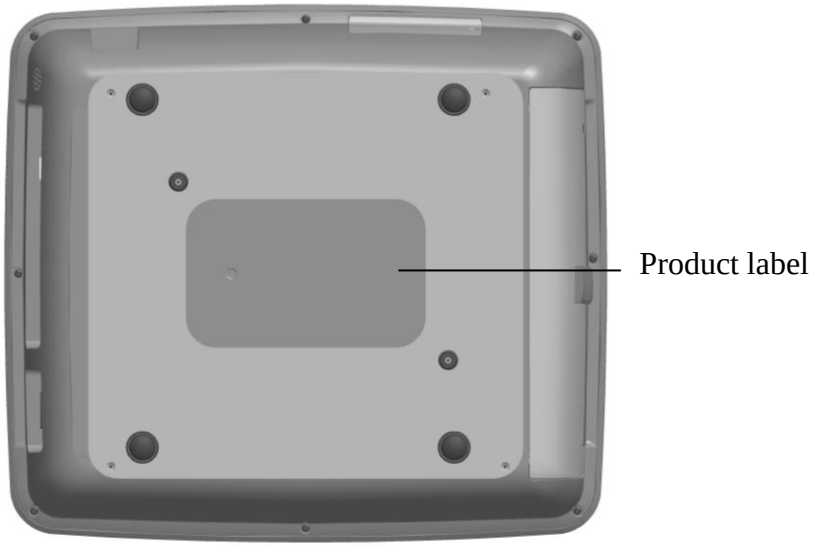
	Name	Explanation
1	ECG cable socket	Connects to the ECG cable.

2	SIM card slot	Insert a SIM card for data transmission.
3	SD card slot	Insert a SD card for data transmission and external storage.
4	USB device port	Reserved
5	USB interfaces	Connects to your PC, USB storage device, USB printer, and barcode scanner.
6	Serial Port	Reserved
7	LAN port	Connects to a LAN cable.
8	Speaker hole	/

CAUTION

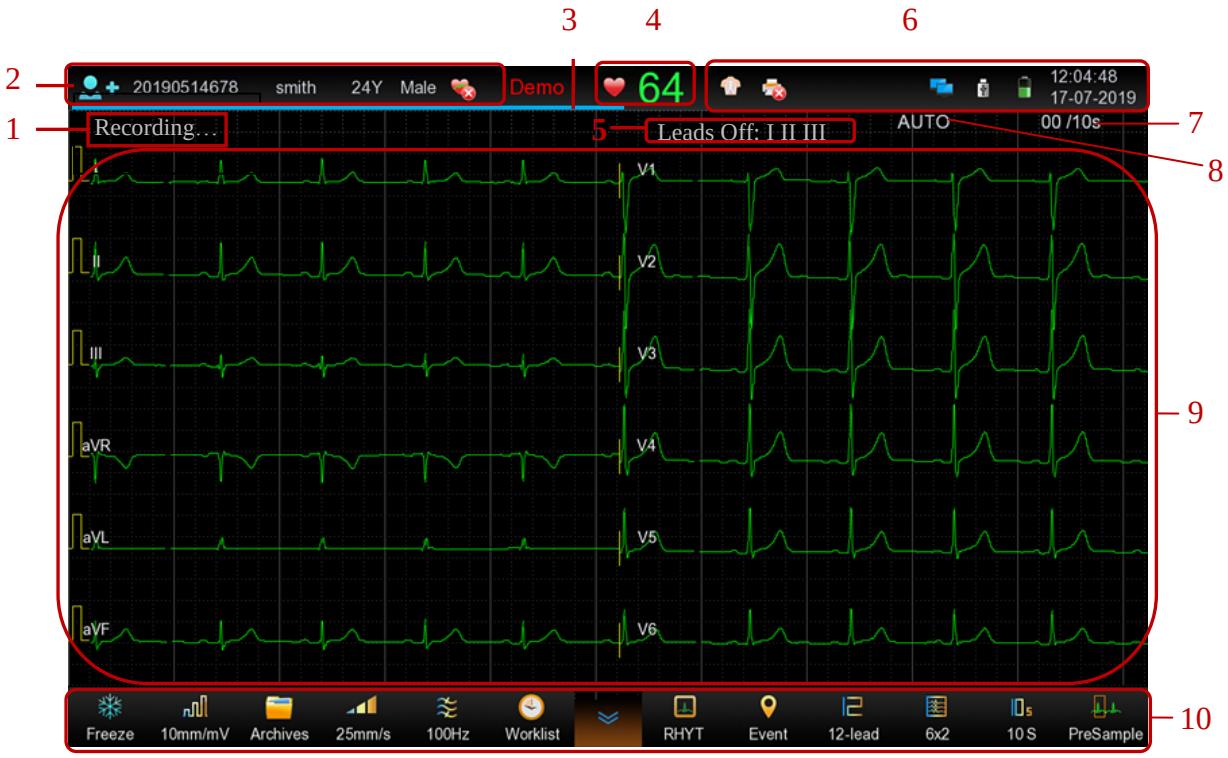
Only the USB devices recommended by the manufacturer can be connected to the USB interface.

Figure 5 Bottom

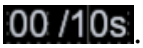


1.1.5 Resting ECG Test Screen

The resting ECG test screen appears when SE-1202 is powered on.



	Name	Description
1	System condition	Indicates the system working condition, such as low battery, no paper, paper error, or memory full. When doing the resting ECG test, it will tell you it is acquiring, analyzing, or recording ECGs.
2	Patient information	Displays patient ID, name, gender, age, and pacemaker. ● Tap on this portion, the patient information dialog box will pop up for manual entry. ● identifies male and female. Tap on this icon to change patient gender. ● : pacing spike OFF. Not to display the pacing spike when the electrocardiograph detects a pace signal. If you want to see the blue pacing spike, tap on this icon to turn it on..
3	Progress bar	Indicates the progress of ECG acquiring.
4	Real-time heart rate	Displays the patient's real-time heart rate.
5	System message	Provides error or other information such as leads off, muscle noise interference etc. when ECG signal is poor.

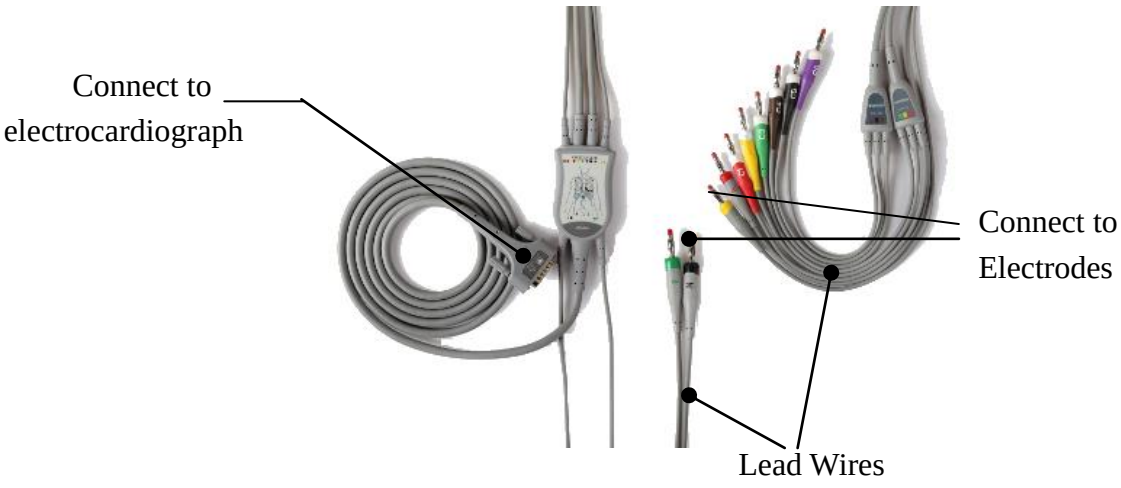
6	System information	●  : displays lead placement. ●  : print disabled. Tap on this icon to enable or disable the print function. This is the same as the "Print report" in the basic setup. ● Displays the icons of USB storage device, SD card, USB printer, USB scanner, ID card or social insurance card reader when they are inserted. ●  : mobile network disconnected. This icon is available when mobile network is used. It indicates the signal strength. ●  : WIFI disconnected. This icon indicates the WIFI signal strength when WIFI is used. Tap on it to configure its setting. ●  : displays the battery power. When the battery is low, the icon turns orange or red. ●  : displays the system time. Tap on this portion to configure the date and time setting.
7	ECG acquisition time	 . The "00" indicates the time taken to acquire ECG data. The "10s" indicates the predefined acquisition time. In real-time recording, tap on this portion to configure the setting.
8	Work mode	 indicates the current work mode. Tap on it to switch from one mode to another as preset in the Work Mode setup. Alternatively, you can touch the  key on the operation panel to change the work mode.
9	Waveforms	Displays the ECG waveforms of the leads that are selected for test. ● Auto (rhythm mode): displays waveforms of 1 or 3 rhythm leads. ● Auto arrhythmia detection (when enabled): in Auto mode, the system will detect arrhythmia automatically and display the ECGs in which arrhythmia is detected in red. The ECGs are also stored in the **Freeze Waveform** screen, Auto Analysis

		screen or Rhythm Analysis screen. For types of arrhythmias, see Appendix 3 *List of Arrhythmias*. ● HRV (heart rate variability): displays waveforms of 1 rhythm lead. ● VCG/SAECG: displays the X, Y, Z waveforms, and the vector loops of QRS/P/T waves in the frontal, horizontal, and sagittal planes.
10	Function icon	There are 12 function icons by default. ●  : freezes the waveform. Tap on it to open the **Freeze Waveform** screen. ●  : opens the **Order Manager** screen. ●  : displays the gain setting of the ECG. Tap on it to change the setting. ●  : displays the speed setting of the ECG. Tap on it to change the setting. ●  : displays the filter setting of the ECG. Tap on it to change the setting. ●  : prints, edits, displays, transmits, and deletes stored ECG data. Tap on it to open the **Archives** screen. ●  : initiates the recording of rhythm leads and displays waveforms of the leads in this resting ECG test screen. When recording finishes, the system will save the rhythm data in the Archives and print rhythm report. The system returns to the previous work mode. ●  : adds a vertical line to the current ECG. For more, see section 5.2 *Capturing an Event*. ●  : displays the lead configuration. Tap on it to select different lead configurations. The default configuration is 6x2 in the 12-lead resting ECG test and 6+3 in the pediatric

		resting ECG test. ●  : displays the current lead mode. There are two lead modes, 9-lead and 12-lead. Tap on it to change the lead mode and lead sequence. ●  : displays the setting of time for real-time ECG acquisition. Tap on it to change the setting. In Manual mode, this displays the lead group setting. ●  : initiates the acquisition of ECG data as soon as the ECG cables are connected to a patient. The system begins to acquire ECG data without waiting for the user to tap on the  button. The latest 10 seconds of ECG data will be analyzed and printed. ●  : initiates paper feeding till reaching the nearest black marker. Note: Changing gain, speed, and filter settings in the Resting ECG Test screen will have an effect only on the current ECG recording.
11	Grid	Initiates the display of grid lines or not on the screen. See section 11.9.1 *Basic Setup*.

1.1.6 ECG Cable and Lead Wires

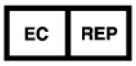
The ECG cable processes the patient's ECG data and transmits it to the electrocardiograph.



1.1.7 Symbols

The symbols illustrated on the following pages may appear on the electrocardiograph, on the packaging, on the shipping container, or in this manual.

No.	Symbol	Description
1		DEFIBRILLATION-PROOF TYPE CF APPLIED PART
2		Caution
3		Consult operating instructions
4		Equipotentiality
5		ECG cable socket
6		USB socket
7		SD card slot
8		SIM card slot
9		Computer network
10		On/Off button
11		Patient button

12		Mode button
13		Setting button
14		Print/Stop button
15		General symbol for recovery/recyclable
16	P/N	Part number
17		Serial number
18		Date of manufacture
19		Manufacturer
20		Authorized 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 symbol
27		This way up
28		Fragile, handle with care
29		Keep dry
30		Stacking limit by number
31		Handle with care
32		Do not step on
33		Front
34	Contains FCC ID: SMQ9113EDAN	Federal Communications Commission: Contains FCC ID: SMQ9113EDAN

NOTE:

1. The right angle bracket “>” in this manual is a concise method to indicate a sequence of menu selections.
2. 26*: Apply to devices with wireless functions.
3. The user manual is printed in black and white.

1.2 Safety Information

This section provides important information on the safe use of SE-1202. Familiarize yourself with this information and read and understand all instructions before attempting to use this

device.

1.2.1 General Warnings

WARNING

1. The electrocardiograph is intended to be used by qualified physicians or personnel professionally trained. They should be familiar with the contents of this user manual before operation.
2. Only qualified service engineers can install this equipment, and only service engineers authorized by the manufacturer can open the shell. Otherwise, safety hazards may happen.
3. **EXPLOSION HAZARD** - Do not use the electrocardiograph in the presence of flammable anesthetic mixtures with oxygen or other flammable agents.
4. **SHOCK HAZARD** - The power receptacle must be a hospital grade grounded outlet. Never try to adapt the three-prong plug to fit a two-slot outlet.
5. Make sure that the power is turned off and the power cord is disconnected from the AC socket before connecting or disconnecting equipment. Otherwise, electrical shock or other injuries may happen to the patient or operator.
6. If the integrity of the external protective conductor is in doubt, the equipment should be powered by an internal li-ion rechargeable battery.
7. Do not use this equipment in the presence of high static electricity or high voltage equipment which may generate sparks.
8. Only the ECG 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 ECG 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 tasted 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.

13. If reusable electrodes with electrode gel are used during defibrillation, the electrocardiograph recovery will take more than 10 seconds. The manufacturer recommends the use of disposable electrodes at all times. When disposable electrodes are used, the defibrillation time of the electrocardiograph will be less than 10 seconds.
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 electrical equipment and the patient simultaneously.
18. 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.
19. 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.
20. Fix attention on the examination to avoid missing important ECG waves.
21. **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.
22. **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.
23. 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.

24. Any non-medical equipment (such as the external printer) is not allowed to be used within the patient vicinity (1.5m/6ft.).
25. Do not exceed the maximum permitted load when using the multiple portable socket-outlet(s) to supply the system.
26. Multiple portable socket-outlets shall not be placed on the floor.
27. 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.
28. 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.
29. Connecting any accessory (such as external printer) or other device (such as the computer) to this electrocardiograph makes a medical system. In that case, additional safety measures should be taken during installation of the system, and the system shall provide:
    a) Within the patient environment, a level of safety comparable to that provided by medical electrical equipment complying with IEC/EN 60601-1, and
    b) Outside the patient environment, the level of safety appropriate for non-medical electrical equipment complying with other IEC or ISO safety standards.
30. 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.
31. 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.
32. 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.

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

34. 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.

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

36. 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.

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

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

39. 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.

40. 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.

41. The electrocardiograph should be placed on a flat surface or EDAN's trolley. Avoid it dropping down to cause strong shock.

1.2.2 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. Manufacturer 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 system.
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 system is restricted to authorized personnel only. Assign only staff with a specific role the right to use the system.

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 system is connected only to the device authorized/approved by manufacturer. Users should operate all system deployed and supported by manufacturer within specifications authorized by manufacturer, including the software, software configuration, security configuration, etc. approved by manufacturer.

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

5 Anti-virus measures such as virus scanning should be carried out on the USB storage device before using it for software upgrade or other purposes.

6 When connecting the system to a shared network, data security issues of the network topology and configuration must be considered. Since the patient sensitive data are not encrypted and might be transmitted from the system to the network, the medical institution should be responsible for the network security. Firewalls and/or other security devices should be in place between the medical system and any externally accessible systems. It's recommended to use Windows defender firewall or any other firewall that can defend against Dos and DDos attacks, and keep it up to date.

7 Dos and DDos protection of the router or switch must be turned on for defensing against attacks.

8 When the system 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 system.

9 For security, disable all unused USB and network ports.

10 When deploying the network, it is recommended to isolate the network and the Intranet system of the hospital by using VLAN so as to ensure the network security. Only trusted devices are allowed to join the VLAN network.

11 Make sure networking function is used in a secure network environment.

12 Please protect the privacy for the information and the data displayed on the screen, and for the information and the data stored in the system and external storage devices.

13 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 ECG workstation are into the same VLAN, and isolate them from other VLANs.

1.2.3 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 powered off can the battery be installed or removed.
9. Remove the battery from the electrocardiograph when the electrocardiograph is not in use 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.

1.2.4 General Cautions

CAUTION

1. Avoid liquid splash and excessive temperature. The temperature must be kept between 5 ºC and 40 ºC during operation, and it should be kept between -20 ºC and 55 ºC during transportation and storage.
2. Do not use the equipment in a dusty environment with bad ventilation or in the presence of corrosive.
3. Make sure that there is no intense electromagnetic interference source around the equipment, such as radio transmitters or mobile phones etc. Large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment etc. is likely to bring electromagnetic interference.
4. 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.
5. Federal (U.S.) law restricts this device to sale by or on the order of a physician.

Chapter 2 Setting Up the Electrocardiograph

WARNING

Before use, the equipment, ECG 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.

2.1 Inspecting the Electrocardiograph

In order to avoid safety hazards and get quality ECG recordings, 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) **ECG Cable:**

Make sure that the ECG 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 ECG 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.

2.2 Connecting the ECG cable

WARNING

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

1. Connecting the ECG cable to the electrocardiograph

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

2. Connecting the ECG cable to electrodes

Make sure that all lead wires align without twisting. Connect the lead wires to the reusable electrodes or the multi-functional electrode adaptors firmly.

2.3 Loading the Thermal Chart Paper

1. Squeeze the latch. Pull the paper door to the left. If any paper remains in the tray, remove it.
2. Remove the outer packaging, including the cardboard bottom, from a new pack of paper. Pull the top sheet back so that the paper's grid side faces up.
3. Slide the paper into the tray. Lay the top sheet over the paper door. Push the door to the right until it clicks.
4. Paper feed. When you print an ECG report, if Paper Marker is set to **On**, the electrocardiograph can identify the black markers and stop at the crease of paper for convenience of tearing. If Paper Marker is set to **Off**, you can tap the paper feeding button to make the paper move forward by 2.5 cm. Press the button to stop moving.

   For paper marker setting, see section 11.4.1 *Basic Setup*.

NOTE:

1. Paper Style in the Record Info setup should be consistent with that of the paper used.

2. When using the paper of 215mm in width, the movable part 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 of the paper.

CAUTION

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

2.4 Powering 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 run on AC or the battery power.

To power on the Electrocardiograph:

- When operating on AC power

  Make sure that the AC power meets the requirements (refer to A1.4 Power Supply Specifications) before power-on. Press and hold the ⏻ button on the operation panel. The power light is green, and the EDAN logo will be displayed on the LCD screen. The electrocardiograph is ready for use.

  When the battery capacity is low, leave the electrocardiograph connected to AC power. The battery will be automatically recharged. The power light is green.

- When operating on battery power

  Press and hold the ⏻ button on the operation panel. The power light is blue. After the EDAN logo is displayed on the LCD screen, the electrocardiograph is ready for use.

  Because of the consumption during storage and transport, the battery capacity may not be full. Please recharge the battery before first use. If the battery has been fully

recharged but its continuous use is greatly reduced, replace the battery.

CAUTION

1. If the electrocardiograph is turned off because of low battery capacity or unexpected power failure, the settings configured or the ECGs being recorded may not be saved.
2. The electrocardiograph cannot print an ECG report when the battery has low capacity.
3. The use of electrocardiograph accessories (such as barcode scanner) 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

  Press and hold the ⏻ button. The message *System is shutting down…*is displayed. The electrocardiograph will be off in a few seconds. Remove the plug from the outlet.

- When operating on battery power

  Press and hold the ⏻ button. The message *System is shutting down…*is displayed. The electrocardiograph will be off in a few seconds.

NOTE:

1. When turning off the device, follow the above sequence strictly, or else there may be something wrong on the screen.
2. Stop holding the ⏻ button when the message *System is shutting down…* is displayed.

2.5 Using Touch Screen or Operation Panel

You can touch the LCD screen or operation panel (see section 1.1.4) to operate the electrocardiograph.

CAUTION

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

When a dialog box needs input, the system will provide you with an alphanumeric keyboard shown below.

To close pop-up windows, tap on in the upper right corner.

2.6 Connecting an External USB Printer (Option)

If desired, you can connect an external printer. No special software is required.

To connect a USB printer

Connect one end of a USB cable to the printer's USB interface, and connect the other end to the electrocardiograph's USB interface. For interface location, see Figure 4 *Right*.

To enable the USB printer in the settings, see section 11.4.1 *Basic Setup*.

Chapter 3 Preparing the Patient

3.1 Instructing the Patient

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

3.2 Cleaning the Skin

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

To Clean the Skin

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

Wash the area thoroughly with soap and water.

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

3.3 Attaching Electrodes to the Patient

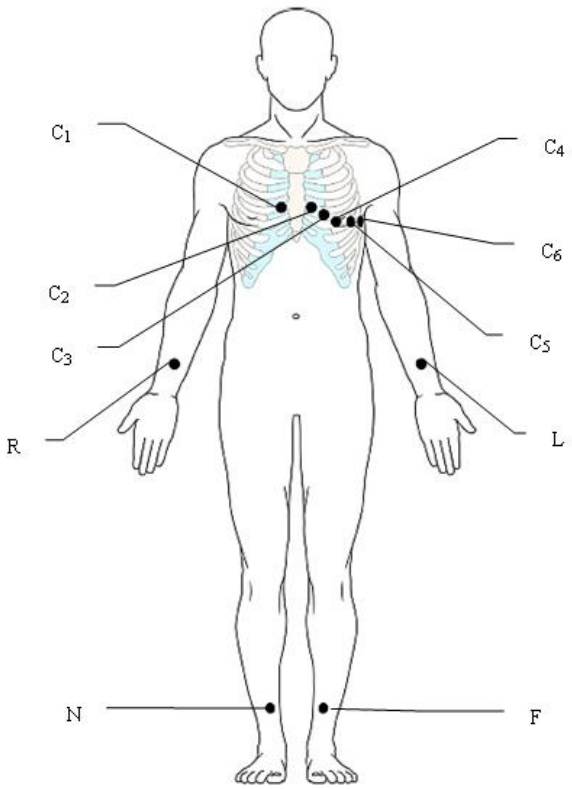
WARNING

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.

Electrode Placement

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

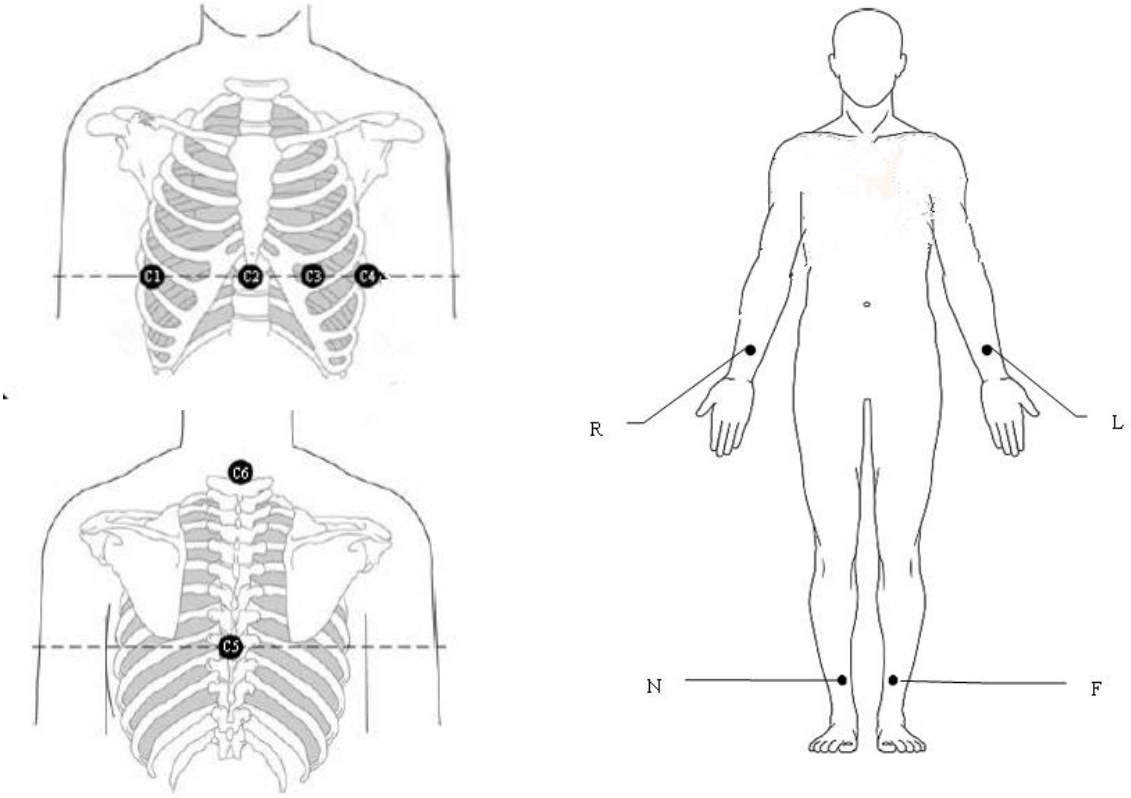
Figure 6 Standard 12 lead placement



Electrodes		Locations
IEC	AHA	
C1 White/Red	V1 Brown/Red	Fourth intercostal space at the right border of the sternum
C2 White/Yellow	V2 Brown/Yellow	Fourth intercostal space at the left border of the sternum
C3 White/Green	V3 Brown/Green	Fifth rib between C2 and C4
C4 White/Brown	V4 Brown/Blue	Fifth intercostal space on the left midclavicular line
C5 White/Black	V5 Brown/Orange	Left anterior axillary line at the horizontal level of C4
C6 White/Violet	V6 Brown/Violet	Left midaxillary line at the horizontal level of C4
L Yellow	LA Black	Left arm
R	RA	Right arm

Red	White	
F Green	LL Red	Left leg
N Black	RL Green	Right leg

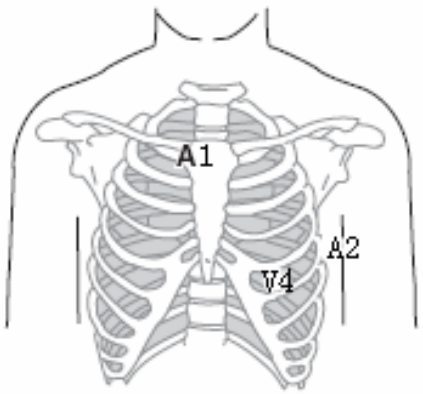
Figure 7 Frank lead placement (for VCG & SAECG)



Electrodes		Locations
IEC	AHA	
C1 (Corresponding to I) White/Red	V1 (Corresponding to I) Brown/Red	Right mid-axillary line on the same horizontal level as C3 and C4
C2 (Corresponding to E) White/Yellow	V2 (Corresponding to E) Brown/Yellow	Sternum at the level of C3 and C4
C3 (Corresponding to C)	V3 (Corresponding to C)	Mid-clavicular line in the fifth intercostals space

White/Green	Brown/Green	
C4 (Corresponding to A) White/Brown	V4 (Corresponding to A) Brown/Blue	Left mid-axilary line on the same horizontal level as C3
C5 (Corresponding to M) White/Black	V5 (Corresponding to M) Brown/Orange	Center of spine on the same horizontal level as C3 and C4
C6 (Corresponding to H) White/Violet	V6 (Corresponding to H) Brown/Violet	Neck, avoid carotid artery and jugular vein
L Yellow	LA Black	Left arm
R Red	RA White	Right arm
F Green	LL Red	Left leg
N Black	RL Green	Right leg

Figure 8 NEHB Placement



Electrodes		Locations
IEC	AHA	
N_{st}/C3R White/Pink	A1/V3R Brown/Yellow	Attachment point of the second rib to the right sternal edge
N_{ax}/C4R White/Gray	A2/V4R Brown/Red	Fifth intercostal space on the left posterior axillary line
N_{ap}/C4 White/Brown	V4 Brown/Blue	Left mid-clavicular line in the fifth intercostal space

Attaching Electrodes

1. Ensure that the electrodes are clean.
2. For reusable electrodes:

   Daub the electrode location with gel evenly. The electrode gel must cover an area the size of the electrode but no larger, especially on the chest.

   Apply electrodes to the prepared locations.

- For disposable electrodes:

  Apply electrodes to the prepared locations. Clip or connect electrode adaptors to electrodes.

Chapter 4 Entering Patient Information

4.1 Manually Entering Patient Information

1. Configure the Patient Information setup window.

   For details, please refer to Section 12.5 *Patient Information*.

2. Tap on the patient information portion on the Resting ECG Test screen (See section 1.1.5). The patient information dialog box will pop up for manual entry. Alternatively, tap on the  button on the operation panel to open the patient information dialog box.

3. Enter the patient information as appropriate. Tap **OK**.

4.2 Scanning a Barcode/Reading a Patient Card (Option)

1. Configure the barcode scanner.

   For information about configuring the barcode scanner, please contact the manufacturer or your local distributor.

2. Connect the barcode scanner or card reader to the USB interface on the right of the electrocardiograph (See Figure 4).

3. Open the Patient Information dialog box, scan the patient's barcode with the barcode scanner or alternatively reading a patient card. The patient information will appear in the text box.

NOTE:

1. Only bar code readers recommended by the manufacturer can be used. Zebra DS2208 is recommended for one-dimensional scanner and Honeywell Xenon1900GSR for two-dimensional scanner.
2. T6-ULD-I is recommended for reading patient’s social insurance card and GTICR100-02 for reading patient’s ID card.

4.3 Entering Orders

SE-1202 offers two methods for entering orders. This section describes both methods for entering orders and provides instructions for order query and setup.

4.3.1 Retrieving Orders from Server (Option)

SE-1202 can receive orders via the following protocols of which the settings are varied. Order can be retrieved through Ethernet, WIFI, and mobile network.

Receiving orders from EDAN server

1. Connect the electrocardiograph to your PC with Ethernet cable or via WIFI/mobile network.
2. Log in to the data management software on your PC.
3. Set the **Local IP**, **Gateway**, and **Subnet Mask** in Transmission > Basic Setup. Or alternatively, select **Auto Get IP**.
4. Set **Order Source** to **EDAN server** by tapping the icon in the Worklist (Order Manager).
5. Turn **Order Acquired** on in Patient Information Setup> Other Setup. Proceed to step 6, 7.
   - Alternatively, in the Order Manager, tap on the icon to set order query criteria. Tap **OK**. The orders are retrieved and displayed in the Order Manager.
6. Open the Patient Information dialog box.
7. Enter the patient ID. Tap **Acquire**. Information from the order will be displayed in the corresponding text boxes.

NOTE:

To use the EDAN server, install EDAN's data management software in your PC and set up the server for connection.

Receiving orders via DICOM or HL7 protocol

1. Follow the steps 1 and 2 in "**Receiving orders from EDAN server**".
2. Activate DICOM or HL7 in Maintenance > Advanced Setup > Function.
3. In the case of DICOM protocol, configure **DICOM Worklist** in Transmission > DICOM setup. In the case of HL7 protocol, configure **Get Patient Information Setup** in Transmission > HL7 setup.
4. Set **Order Source** to **DICOM worklist** or **HL7** in Patient Information > Other Setup.
5. Set **Protocol** to **DICOM** or **HL7** by tapping the icon in the Worklist (Order Manager).
6. Turn **Order Acquired** on in Patient Information > Other Setup.

- Alternatively, in the Order Manager, tap on the icon to set order query criteria. Tap **OK**. The orders are now available in the Order Manager.

7. Open the Patient Information dialog box.
8. Enter the patient ID. Tap **Acquire**. Information from the order will be displayed in the corresponding text boxes.

NOTE:

If you choose to receive orders via DICOM protocol, activate DICOM and select DICOM worklist as order source. If you choose to receive orders via HL7 protocol, activate HL7 and select HL7 as order source.

4.3.2 Manually Entering Orders

If you do not have the data management software, or cannot connect to the PC for some reason, you can manually create the order directly on SE-1202 using the following procedure.

1. Tap **Worklist** The Order Manager screen opens.
2. Tap **Add**. The Add Order window opens.
3. Enter the order information as appropriate.
4. When you are done, tap **OK**.

The new order is now available in the Order Manager.

4.3.3 Searching Orders

To search an order:

1. Tap on the button.
2. Enter one of the following wholly or partially into the search bar:

- patient ID
- patient name
- accession number
- order date
- department

- exam room
- priority.

3. Tap **OK**. A window will pop up to tell you how many order(s) or no order is found.
4. Tap **OK**. The order(s) that meets the search criteria is displayed.
5. To exit order searching, tap the  icon. The system returns to the order list.

NOTE:
Fuzzy search is supported in the search bar.

Chapter 5 Recording an ECG

This chapter describes how to record the following ECG types:

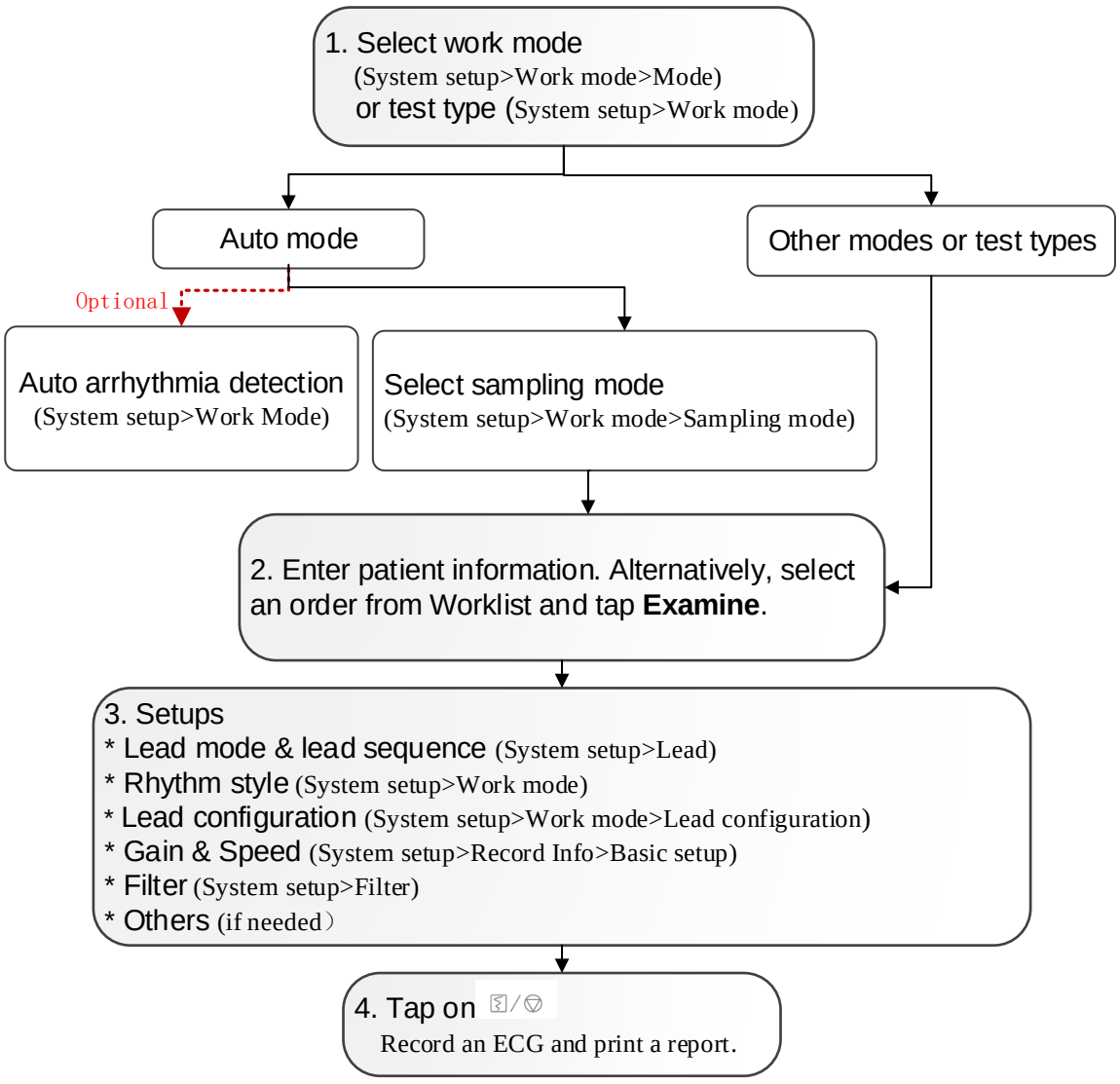
- Standard resting ECG (including pharmaceutical study)
- HRV (heart rate variability)
- VCG (vector cardiogram) & SAECG (for ventricular late potentials)

Among which HRV, VCG & SAECG have to be purchased and enabled first.

NOTE:

The instructions in this chapter assume that the patient has been properly prepared and the electrodes have been placed correctly for the selected ECG type.

5.1 Recording Procedure



5.2 Capturing an Event

When a chest pain or arrhythmia occurs during ECG recording, you can tap on the **Event** icon. The system will insert a mark (a vertical line) to the ECG waveform. You can also add a description of the event. To enable text input, select **System Setup** > **Patient Info** > **Personal Setup > Comment when marking an event**. The system can keep up to 27 events. To review the events, see section 7.1 *ECG View*.

NOTE:

This function is available only in Auto ECG, Manual ECG, Pharmaceutical study, and HRV.

5.3 Freezing Waveforms

By freezing the waveform, users can review up to 30 min ECGs recorded, print 10s ECGs, and review events if available. Tap on the **Freeze** icon when at least 10s ECG is recorded. There are three types of freeze waveform: Auto, Rhythm, and Vector. They are applicable to different work modes.

NOTE:

The data in Freeze Waveform screen will be lost when you switch from the Resting ECG Test screen to the System Setup or Archives or Order Manager screens.

Chapter 6 Printing an ECG Report

6.1 Printing Standard Report

SE-1202 will automatically print a report after an ECG test. If you don't need a print, turn **Print Out** off in **System Setup** > **Record Info** > **Basic Setup**.

In Auto ECG and Rhythm ECG tests, you may print a report after ECG recording (called paper-save), or print during ECG recording (called quickly). Choose one of them in **System Setup** > **Record Info** > **Basic Setup** > **Record Mode**. In other tests or work modes, only paper-save printing is applied.

Preview before print

You can preview the ECGs when analysis is completed but the report is yet to print. To enable, select **System Setup** > **Work Mode** > **Preview**.

Auto gain control (AGC)

AGC is used to reduce waveform overlap or crowding problem on the ECG report. It can only reduce the gain when the amplitude is big, but cannot increase the gain. AGC is not applicable to HRV or VCG tests.

Baseline adjustment

This function applies for ECG reports in all work modes except HRV and VCG. For details, see section 11.4.1 *Basic Setup > Baseline Adjustment*.

Report setting

You can determine what is displayed in the ECG report. For details, see section 11.4.2 *Report Setup*.

NOTE:

1. If **Print Out** is **Off** in the Record Info setup, ECG reports can still be saved and transmitted though not printed out when you tap on the button. However, when **Manual Mode Save** or **Pharmaceutical study Save** is set to **Off**, ECG reports still print even if **Print Report** is **Off**.

2. You can print an ECG report over unlimited time in the Manual mode. Once printing starts, it will not stop until you tap on the button.

6.2 Printing Arrhythmia Report

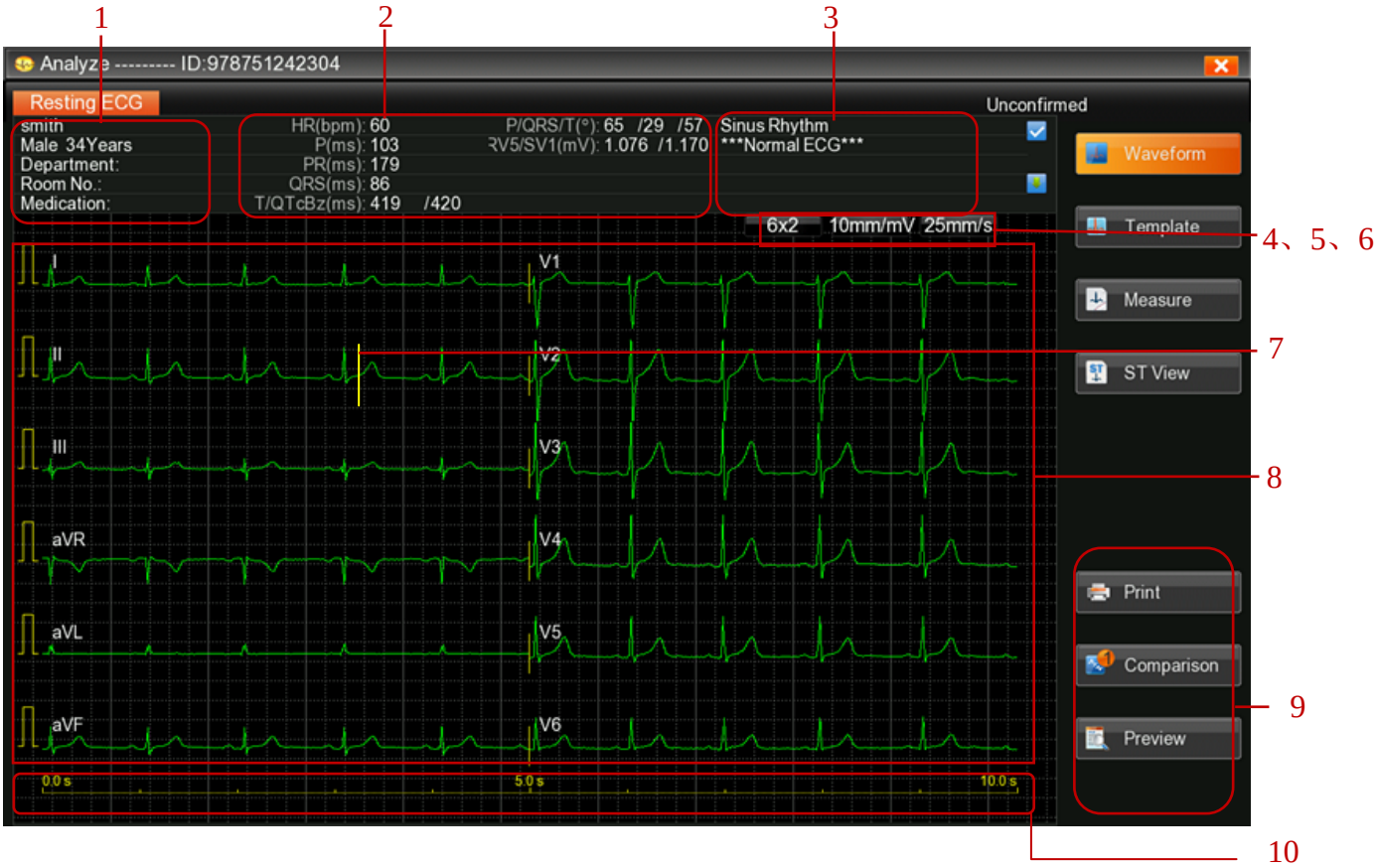
You can print an arrhythmia report if **Auto Arrhythmia Detection** is enabled. The system will ask you whether to print the arrhythmias whenever it detects arrhythmia diagnostic statements in the diagnosis. For arrhythmia diagnostic statements, see Table 2 in Appendix 3 *List of Arrhythmias*. The arrhythmia data can also be saved and transmitted.

Chapter 7 Editing ECGs

ECG analysis applies for Auto, Manual, Rhythm, VCG, and SAECG tests. To activate ECG analysis, tap **Archives** in the Resting ECG Test screen. Enter the password if set before. Select the ECG you want and tap **Analyze**.

7.1 ECG View

In the ECG analysis screen, you can edit, measure, diagnose, and compare ECGs.



	Name	Description
1	Patient information	Displays patient ID, name, gender, age etc. Tap to edit such information.
2	Auto measurements	Provides automatic measurements of HR, P wave duration, PR interval, QRS complex duration, QT/QTc, frontal P/QRS/T axis, and RV5/SV1. Other parameters like RV5+SV1, RV6/SV2, and RR/PP will be displayed if enabled in **System Setup** > **Maintenance** > **Advanced Setup** > **Parameter Setup**. To edit the value of the above parametes, tap on the

		parameter. A parameter out of measurement range is identified in red. For the measurement range, see Appendix 4 *Abnormal Measurements and Diagnosis*.
3	Auto diagnosis	Provides automatic diagnosis of ECG and identify serious diseases in red. Tap the arrows to move up and down to see all diagnosis. Tap on this portion to enter and edit diagnostic statements, or add statements to diagnosis list. For serious diseases, see Appendix 5 *List of Serious Diseases*.
4	Lead configuration	Tap to switch to another lead configuration.
5	Gain	Tap to change the gain setting.
6	Speed	Tap to change the speed setting.
7	Event mark	A mark manually inserted during an ECG test to indicate an event.
8	Waveform	10s ECG waveforms can be viewed by using the scroll bar at the bottom of the screen. ECGs in which an arrhythmia is detected are displayed in red. To zoom in and measure the ECG wavefrom, tap the waveform and hold down. For more operations, see section 7.2 *ECG Measurement*. Lead timing is sequential by default. For setup, go to **Record Info** > **Basic Setup** > **Record Sequency**.
9	Function icon	**Print**: Prints an ECG report according to the report setting. **Re-analyze**: Re-analyzes the 10s waveforms on-screen. After re-analysis, the measurement results, diagnosis, and averaged ECG template will be automatically updated. **Event review**: Reviews the arrhythmias or other events you mark or detected by the electrocardiograph. **Measure**: Displays the measurement results of all leads. **Comparison**: See section 7.3 *Comparing ECGs*. **Confirmed**: Saves the change to diagnosis or measurements. Once this icon is tapped, the corresponding ECG updates its status to confirmed. The name and electronic signature of the physician

		are saved to the file. **Preview**: To preview the ECG report. **Inversion**: To set the electrode to its opposite position so that it is unnecessary to re-acquire ECG data. After inversion, The measurements and diagnosis will be updated. **Template**: see **Averages View** in section 7.2 *ECG Measurement*. **ST view**: see section 7.4 *ST View*.
10	Time scale	Displays the start time and end time of the waveform on-screen.

7.2 ECG Measurement

Zoom in on an ECG

To zoom in the waveform, press and hold the waveform of a lead. The ECG waveform can be magnified up to 5 times by tapping ⊕. To exit magnification, tap on **X** in the upper left corner.

Manual Measurement

To measure ECG waveform, open the waveform magnification page. Tap on the ruler in the right lower corner. A measurement pane will be displayed. Tap on the ruler once more to exit measurement.

To move the four pane lines, tap on it and use the arrow keys. Move up and down to measure amplitude (in mV), and left and right to measure interval (in ms). Amplitude, interval, and heart rate are synchronous with line movement.

Averages View

SE-1202 provides a template to analyze ECG waveforms. The template displays 10s averaged complexes for ECG leads. To open the template, tap **Template** in the Analysis screen.

- To highlight one averaged complex, tap the lead in the upper left corner. The measurements of highlighted lead are displayed on the right.
- To view averaged complexes of all leads that are not overlapped, not select **Superimposed Display**.

There are five markers in the template to indicate where in the QRS complex the measurement reference points have been set. These reference points are automatically calculated, but they can be modified. You can use a marker as a starting point for your observation or measurements. Markers can only be displayed in the averaged complex.

SE-1202 shows markers at the following points (from left to right):

- P1 onset of P wave
- P2 offset of P wave
- Q onset of QRS complex
- S offset of QRS complex
- T offset of T wave

You can make measurements between two points:

1. Tap on a marker and move it to the starting point of your measurement by using the arrow keys.
2. Tap on another marker and move it to the end point of your measurement by using the arrow keys.
3. SE-1202 updates the measurements.

7.3 Comparing ECGs

SE-1202 allows you to compare ECGs with the same patient ID. Tap **Comparison**. Select the ECG files you want to compare. Tap **OK**.

This function is available only in the Auto mode.

7.4 ST View

ST view uses histograms to represent ST values. Different colors of histogram identify normal ST, ST elevation and depression. One histogram corresponds to one lead.

NOTE:

This function applies for standard resting ECGs (excluding rhythm ECG and user-defined lead sequence).

7.5 VCG and SAECG

The following sections describes analysis of VCG, Temporal VCG, and SAECG.

7.5.1 VCG

The VCG converts the P/QRS/T into spatial loops in the transverse, right sagittal, and frontal planes. Each plane displays coverage percentile of the P/QRS/T loop in the four quadrants. The mark ⟵ is used to indicate the orientation of loop movement by its round head. Tap on the

P/QRS/T gain to change. The gain of P loop and T loop will be synchronized.

X, Y, Z complexes are the averaged ECGs of each lead. When the complexes are re-analyzed, the vector loops and measurements automatically update.

To view the original ECGs of X, Y, Z leads, tap **Waveform**.

To get detailed measurements of vector loops, tap **Measure**.

7.5.2 Temporal VCG

The temporal VCG displays X,Y, Z lead ECGs, X-Y loops, X-Z loops, and Z-Y loops.

- X-Y loop: chronologically displays the vector loops for P wave, T wave and QRS in the frontal plane in cardiac cycles. Each cardiac cycle is identified by a vector loop.
- X-Z loop: chronologically displays the vector loops for P wave, T wave and QRS in the transverse plane in cardiac cycles. Each cardiac cycle is identified by a vector loop.
- Z-Y loop: chronologically displays the vector loops for P wave, T wave and QRS in the sagittal plane in cardiac cycles. Each cardiac cycle is identified by a vector loop.

7.5.3 SAECG

SAECG analyzes the late potential in QRS offset by time-domain method.

Two ECGs are displayed. One is standard ECG without filtering and the other is ECG with IIR filter. Both of them have markers to identify QRS onset and offset. Move the marker, the measurements on the right will update. A horizontal line across the filtered ECGs indicates 40uV.

Chapter 8 Transmitting ECGs

SE-1202 can be configured to transmit ECGs to your PC through a LAN cable, wireless network, or mobile network. Most methods transmit ECGs in EDAN's DAT format, but you can also choose to transmit ECGs in PDF, JPG, BMP, SCP, FDA-XML, DICOM, DICOM encapsulated PDF, or TIFF formats.

In addition to automatically transmitting ECGs, you can manually transmit stored ECGs at any time. Whatever way you choose, you need to follow this chapter to select a transmission protocol and configure transmission settings prior to ECG transmission.

WARNING

1. FTP user name and password may leak out when using FTP to transmit ECG files.
2. Patients' basic and health information may leak out when transmitting SCP, FDA-XML or DICOM files.
3. Sensitive application data and configuration files may be modified when logging in through Telnet.
4. Patients' basic and health information may leak out when using a web browser.
5. Patient information may leak out when querying orders from the server.

NOTE:

1. The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate this equipment.
2. To transmit ECG data in SCP/FDA-XML/DICOM ECG Waveform/DICOM Encapsulated PDF format, you should activate corresponding functions in **System Setup** > **Maintenance** > **Advanced Setup** > **Functions**. For details about how to activate the functions, please contact the manufacturer or local distributor.

CAUTION

1. It is forbidden to connect or disconnect a USB storage device or a USB printer during data transmission.
2. Do not power off the electrocardiograph when you are working with the ECGs in Archives.

8.1 Transmitting via FTP Protocol

To automatically transmit ECGs:

1. Log into the FTP receiving software on your PC.
2. Turn on SE-1202 electrocardiograph.
3. Configure the **Transmission** setup.
   1) Open Transmission > Basic Setup, set the transmission mode.

      If **Wireless** is selected, you need to configure WLAN setting and connect to a wireless network.

      The option **Mobile Network** will appears only when a SIM card is inserted and identified.
   2) Select **Auto Transmission**.
   3) Set the **Local IP**, **Gateway**, and **Subnet Mask**. Or alternatively, select **Auto Get IP**.
   4) Set **Transmission Protocol** to **FTP**.
4. Set the **FTP User Name**, **FTP Password**, **FTP Path**, and **Server IP** in Transmission > FTP Setup.
   - The **FTP User Name** and **FTP Password** should allow access to the FTP server.
   - The **FTP Path** should lead to the subdirectory available under the FTP root directory.

   NOTE: For more information about FTP server, consult your network administrator.
5. Set the file format in System Setup > Archives.
6. Return to the Resting ECG Test screen.
7. ECG data will be automatically transmitted to your PC when recording completes.

To manually transmit ECGs:

1. Follow the above step 1 to 6, but DO NOT select **Auto Transmission**.
2. Tap **Archives** in the Resting ECG Test screen. The Archives screen opens.
3. Select the ECG file(s) to be transmitted.
4. Tap **Trans**.

8.2 Transmitting via DICOM Protocol

1. Follow steps 1, 2 of “Receiving orders via DICOM or HL7 protocol” in section 4.3.1. If the

settings have been configured, skip to step 2 in this section.

2. In Transmission > Basic Setup, set **Transmission Protocol** to **DICOM.**
3. In Transmission > DICOM Setup, set the **DICOM Storage** parameters.

   Click **ECHO** to check whether the connection is successful.

   For configuration, see section 11.6.6 *DICOM Setup*.
4. When an ECG report is confirmed on the report analysis screen, it will be transmitted to your PC automatically if **Store when making diagnosis** is selected in **DICOM Setup**.
   - Alternatively, open the Archives screen. Select the ECG(s) to be transmitted. Tap **Trans**.

8.3 Transmitting via HL7 Protocol

1. Follow steps 1, 2 of "Receiving orders via DICOM or HL7 protocol" in section 4.3.1. If the settings have been configured, skip to step 2 in this section.
2. In Transmission > Basic Setup, set **Transmission Protocol** to HL7
3. In Transmission > HL7 Setup, configure the **Back Trans File Setup**.

   For more information, see section 11.6.5 *HL7 Setup*.
4. ECG data will be automatically transmitted to your PC when an ECG is recorded.

Chapter 9 Importing and Exporting ECGs

Importing ECGs

You can transfer ECGs from a USB storage device or SD card to SE-1202, up to 1000 ECGs at a time. However, only DAT files generated by EDAN's electrocardiograph can be imported. The import directory is \ECGDATA.

1. Tap **Archives** in the Resting ECG Test screen.
2. Tap **Import.** A progress bar is displayed.
3. A message is prompted when completed. The ECGs are now available in Archives.

   But if you want to stop during importing, tap **Cancel**. Remaining ECGs will not be imported.

Exporting ECGs

You can transfer ECGs from SE-1202 to a USB storage device or SD card. The files are exported to: \ECGDATA\ECG-Device No.\Export\export date and time.

1. Tap **Archives** in the Resting ECG Test screen.
2. Select the ECG(s) to be sent.
3. Tap **Export.** The ECGs are now available in the USB storage device or SD card.

NOTE:

Use the USB storage device provided by the manufacturer. Choose FAT16 or FAT32 for SD card formatting.

Chapter 10 Deleting ECGs and Orders

SE-1202 can be configured to delete ECGs and orders. You can also choose to manually delete them.

10.1 Deleting ECGs

To automatically delete ECGs:

Select **Delete After Trans. Or Expor**t in the Archives setup. ECGs will be automatically deleted when they are transmitted or exported. Once deleted, they are unable to be restored any longer. Be cautious about it.

To manually delete ECGs:

1. Tap **Archives**.

   A list of ECGs opens.

2. Select the ECG report(s) you want to delete.

3. Tap **Delete**.

   The following message is displayed:

   You will delete selected file(s). Sure?

4. Do one of the following:

   - To delete the select ECG report(s), tap **OK**.
   - To cancel the deletion and select different reports, tap **Cancel**.

10.2 Deleting Orders

To automatically delete orders, select **Delete After Examination** by tapping on the icon in the Order Manager.

To manually delete orders:

1. Tap **Worklist**.

   A list of orders opens.

2. Select the order(s) you want to delete.

3. Tap **Delete**.

   The following message is displayed:

You will delete selected order(s)! Are you sure?

4. Do one of the following:
   - To delete the select order(s), tap **OK**.
   - To cancel the deletion and select different orders, tap **Cancel**.

Chapter 11 System Setup

To open the system setup, tap ⚙ on the operation panel or tap the system information portion on the Resting ECG Test screen. The options with underlines are the default setting.

11.1 Work Mode

Item	Description
Mode Options	Options: **AUTO, MANU, HRV, Pharma, VCG&SAECG.** HRV, Pharma, and VCG & SAECG are visible if activated.
Lead Configuration	Options: 12-lead: **12×1, 3×4, 3×4+1R, 3×4+3R, 6×2, 6×2+1R**. 9-lead: **9×1, 3×3, 3×3+1R, 3×3+3R, 6+3**.
Sampling Mode	Options: **Real-time Sample, Triggered Sample, Periodic Sample.**
REC Time	Set the time period to acquire ECG signals in real time. Options: **10s, 20s, 30s, 1 min, 3 min, 5 min, 10 min, 15 min, 30 min.**
Real-time Sample Timing Advance	● In the **Save Paper** mode: The timing advance can be 0-10s, and the default value is 0s. In the Real-time ECG acquisition, you can set the time how much earlier the advance sampling is carried out than you press the START/STOP key. ● In the **Quickly** mode: Advance sampling is carried out 10 seconds earlier than you press the START/STOP key.
Periodic Sample Duration	It can be set to a value between 0-60 min. 60 min by default.
Periodic Sample Interval	It can be set to a value of 0-60 min. 1 min by default. This interval must be no longer than the periodic sample duration.
Rhythm Style	Options: Single Lead, Three Leads.
Rhythm Mode	Options: **Save Paper, Quickly.** Select **Save Paper**, a rhythm ECG report is printed when the

	acquisition is finished. Select **Quickly**, the printing of rhythm ECG report is simultaneous with ECG recording.
Rhythm Sample Duration	Options: **20s, 1 min, 3 min, 5 min, 10 min, 15 min, 30 min.**
Preview	Enable or disable previewing the report before print. Disabled by default.
Auto Arrhythmia Detection	If enabled, when an arrhythmia diagnostic statement is detected in the Auto ECG report, the notification is triggered for you to print an arrhythmia report or not. Disabled by default.

11.2 Filter

Item	Description
AC Filter	It can be enabled or disabled. **NOTE:** AC frequency can be set to 50Hz or 60Hz in Maintenance > Advanced Setup > Other according to local mains supply specifications.
DFT Filter	DFT Filter greatly reduces the baseline fluctuations without affecting the ECG signals. The purpose of this filter is to keep the ECG signals on the baseline of the printout. Options: **0.01Hz, 0.05Hz, 0.32Hz,** or **0.67Hz.** The set value is the lower limit of the frequency range.
EMG Filter	EMG Filter suppresses disturbance caused by strong muscle tremor. The cutoff frequency can be set to **Off, 25Hz, 35Hz or 45Hz**.
Lowpass Filter	Lowpass Filter restricts the bandwidth of input signals. The cutoff frequency can be set to **75Hz, 100Hz, 150Hz, 270Hz, 300Hz,** or **350Hz**. **NOTE:** Only when EMG Filter is set to Off, can the setting of Lowpass Filter be effective.

NOTE: To pass the distortion test, the electrocardiograph has to be configured with the

highest bandwidth in filter settings. Otherwise, ECG signals may be distorted.

11.3 Lead

Item	Description
Lead Mode	Options: **9-lead, 12-lead**.
Lead Sequence	9-lead: **Pediatric mode, Customize 9 leads**. In the pediatric mode, the sequence is I, II, III, aVR, aVL, aVF, V1, V3, V5. 12-lead: **Standard, Cabrera, Customize 12 leads**. The standard sequence is I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6. The Cabrera sequence is aVL, I, -aVR, II, aVF, III, V1, V2, V3, V4, V5, V6.
NEHB	Lead sequence: I, II, III, ND, NA, NI. Disabled by default.
Electrode Inversion Hint	Enable a notification if users attempt to preview or print an ECG report but the system have detected that the R and L leads were reversed in the AUTO mode. Enabled by default.
Rhythm Lead1	Options: **I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6**. **NOTE**: Rhythm lead 1/2/3 cannot be the same.
Rhythm Lead2	Options: **I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6**.
Rhythm Lead3	Options: **I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6**.
Lead-Off Hint	Enable a notification if users attempt to print a report but the system have detected disconnected leads in 10s ECG pre-sampling. Disabled by default.

11.4 Record Info

11.4.1 Basic Setup

Item	Description

Auto Record Style	Determines how to print the Auto ECG waves. Options: 12-lead: **12×1**, **3×4**, **3×4+1R**, **3×4+3R**, **6×2**, **6×2+1R** 9-lead: **9×1**, **3×3**, **3×3+1R**, **3×3+3R**, **6+3**
Manual Record Style	Determines how to print the Manual ECG waves. Options: 12-lead: **3 channels**, **6 channels**, **12 channels**, **Customize.** 9-lead: **3 channels**, **6 channels**, **9 channels**, **Customize**.
Record Mode	Options: **Save Paper**, **Quickly** **Save Paper** means printing report after ECG recording. **Quickly** means the printing of report is simultaneous with ECG recording. **NOTE**: 1. The option *Quickly* is effective only when Sampling Mode is set to "Real-time Sample" for Auto ECG. 2. Only the option *Quickly* is available when the Auto Record Style is set to N×1.
Record Sequence	Options: **Sequential**, **Synchronous** Select **Sequential**, the lead groups are refreshed one by one in order. Select **Simultaneous**, all leads are refreshed simultaneously.
Print Out	If enabled, the ECG report can be printed out by pressing the **PRINT/STOP** key. When disabled, the ECG report can be saved or transmitted, but cannot be printed out by pressing the **PRINT/STOP** key. Enabled by default. **NOTE**: 1. This function is unavailable in the periodic sampling mode. 2. If this function is disabled and ECG are set to be not stored in the Manual ECG or Pharmaceutical Study, the system will still print the ECG report.
Record Device	Options: **Thermal**, **USB Printer** When "USB Printer" is selected, and a USB printer is connected and

	turned on, reports will print by the USB printer. For details, see section 2.6 *Connecting an External USB Printer (Option)*. USB printers supported are: HP 1510 HP 1020P HP 1112 HP 2132 HP DeskJet 4729 HP DeskJet 3638 HP M401 HP LaserJet P2035 HP 1010 HP Laserjet Pro M403D HP LaserJet pro M202DW

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 USB storage device or a USB printer during the transmission course.

NOTE:

1. During the USB printing course, pressing the **START/STOP** key again cannot stop printing ECG reports.
2. Make sure that paper is loaded in the USB printer before printing. Error may occur if no paper is loaded in the printer.

Gain	Options: **1.25mm/mV, 2.5mm/mV, 5mm/mV, 10mm/mV**, **20mm/mV** or **10/5mm/mV**. The setting **10/5mm/mV** displays limb leads at **10mm/mV** and precordial leads at **5mm/mV**.
Speed	This setting varies depending on the test type. Manual ECG: **5mm/s**, **6.25mm/s**, **10mm/s**, **12.5mm/s**, **25mm/s**, **50mm/s** Auto ECG/Pharmaceutical Study: **25mm/s**, **50mm/s**

	Rhythm ECG: **5mm/s**, **25mm/s**, **50mm/s** HRV: **25mm/s**
AGC	When selected, the gain can be automatically adjusted according to actual signals. Disabled by default.
Baseline Adjustment	Options: **Horizontal**, **Auto** or **Off** You can set the baselines of ECG waves on the printed report. Select **Horizontal**, the baselines are adjusted according to the maximum amplitude of the leads in a horizontal line. The greater the amplitude, the larger portion the line takes up. But leads in a horizontal line will have the same baseline. Select **Auto**, the baseline is adjusted according to the amplitude of each lead. The greater the amplitude, the larger portion the lead takes up. But leads in a horizontal line may have different baselines. Select **Off**, the portion of each lead is equal and leads in a horizontal line have the same baseline.
Paper Marker	**Paper Marker** is used to identify the start point at each page of the recorder paper. Options: **Off**, **On (EDAN)**, **On (Other)**. Select **On (EDAN)** or **On (Other)** if the paper with black markers on the bottom is used. So the device can identify the start point at each page of the recorder paper while printing ECG reports.
Paper Style	Options: **A4 (210*295mm), Letter (215*280mm)**.
Print after diagnosis	When selected, If users attempt to print an ECG report that has not been diagnosed by the doctor in the **Archives**, the system will prompt you to confirm before print. Disabled by default

11.4.2 Report Setup

Item	Description
Auto Record Info	Select the item to be printed in the Auto ECG report. Options: **Waveform**, **Template**, **Rhythm Lead Report**, **Position**

	Marker, **Minnesota Code, VCG Calculat. Report, Basic Measures, Detailed Measures**. Some options may not be displayed if have been set up elsewhere.
Auto Analysis	Options: **On**, **Off**, **Normal ECG only** Select **Normal ECG only**, only the normal diagnosis results will be stored and printed. Select **Off**, no diagnosis result will be stored or printed. Only the title "Diagnosis Information:" will be printed. Select **On**, all diagnosis results will be stored and printed.
Copies	Set the number of copies printed after Auto ECG sampling. It can be set to 1-5 copies. 1 copy by default.
HRV Record Info	Options: **RR waveform**, **RR Interval List**. Visible if HRV is activated. Select which information will be printed in the HRV report.
Other Record Info	Select **Thermal Report Grid**. The background grid will be printed when using the thermal printer. Select **Time Scale,** time scale will be printed on the ECG waveforms. Selected by default. Select **USB Report Grid**, background grid will be displayed on the reports printed by the USB printer. Selected by default. Select **Device No.**, the device number will be displayed on the printed reports.

11.4.3 Advanced Setup

Item	Description
Pharma Study Record Info	
Pharma Study Record Time	Set the time points of printing the reports. Options: **0-1-3-5-10-15 min, 0-1-3-5-7-9 min, 0-2-4-6-8-10 min, Customize**.
Pharma Study Mode	Options: **Single-Lead ECG Report, All-Lead ECG Report.**
Auto Save	Only when this function is enabled will the system store the acquired ECG data in the Pharmaceutical Study. Disabled by default.

VCG Record Info	
Record Time	Options: **10 s, 1 min, 3 min, 5 min.** Set the acquisition time of VCG.
Report Style	Options: **VCG Report, TVCG Report, SAECG Report.** Select which report to be printed after recording or in the Archives. The options are displayed only if the functions are activated.
XYZ Wave	Prints X, Y, and Z waveforms in the VCG report. Not selected by default.
Analysis	Displays auto diagnosis in the analysis screen of VCG and prints them out in the VCG report. Not selected by default.
VCG Parameters	Prints the detailed measurements in the VCG report. Not selected by default.
QRS Gain	Options: **10 mm/mV**, **20 mm/mV**, **40 mm/mV**, **80 mm/mV.** Set the gain of QRS loop. The gain of P and T loops will be changed simultaneously.
VCG Analysis	Options: **X, Y, Z.** Select the lead to calculate the real-time heart rate and display it in the Resting ECG Test screen.
SAECG Filter	Options: **25-250 Hz**, **40-250 Hz**.

11.5 Patient Information

Click **Patient Information** to enter the patient information setup screen.

Item	Description
Personal Setup	
First name/Last Name	If selected, the first name and last name of a patient are separated for entry. If not selected, only name is provided for entry.
Gender, Height, Weight, BP, Race, Technician, Pacemaker, Medication, Room No., Physician, Department, Ref-Physician,	Select the item you want to display in the patient information dialog box so that users need to enter the information. All the items except Gender are not selected by default.

Exam Room, Accession Number	
Priority	If selected, this item will be displayed in the patient information dialog box and provides two options: general and urgent. Not selected by default.
Customize_1	Enter a title you want to display in the patient information dialog box. Users need to input information under this title. The title allows a maximum of 20 letters for entry.
Customize_2	Enter another title you want to display in the patient information dialog box. Users need to input information under this title. The title allows a maximum of 20 letters for entry.
Medication Customization	Enter medications for you to select in the patient information dialog box.
Comment when marking an event	If selected, you can make comments in a pop-up box when you mark an event. If not, no box will pop up for you to make comments. Not selected by default.
Customize Comment	Enter the comments you usually make so that you don't need to type every time when you mark an event. You can select one comment from the drop-down list. This setting allows you to add or delete the comments shown in the drop-down list.
Other Setup	
ID	Options: **Auto, Time** or **Manual** Select **Manual**, the patient ID needs to be input manually. Select **Auto**, the patient ID is automatically generated in numerical order. Select **Time**, the patient ID is automatically generated based on system time.
ID Hint	Enables a notification if users attempt to record Auto ECG, Rhythm ECG, or VCG but the patient ID is set to **Manual** and not input yet.
Age Mode	Options: **Age**, **D.O.B** or **Age Group** Select **Age**, you enter the patient age manually in the Patient Information dialog box. Select **D.O.B**, the **D.O.B** text box appears in the **Patient Information** window. You enter the birthday of the patient, and the system will calculate the patient age automatically. Select **Age Group**, the **Age Group** text box appears in the **Patient**

	Information window. You select an age group from the drop-down list.
H/W Unit	The unit of height and weight. Options: **cm/kg** or **inch/lb.**
BP Unit	Options: **mmHg** or **kPa.**
Pacemaker Setup	When selected, the shortcut setup symbol of the pacemaker will be displayed on the main screen. Selected by default.
PatInfo Refreshed	When selected, the patient information will be refreshed after the ECG report is printed out and all the leads are off. Selected by default.
Order Acquired	When selected, the **Acquire** button will be displayed in the **Patient Information** window. With this option, you can retrieve orders from the server. Not selected by default.
Report Hint	Options: **Confirmed By**, **Unconfirmed**, **Null** Select **Unconfirmed**, Unconfirmed Report is printed in the ECG reports. Select **Confirmed By,** the physician's name is printed in the ECG reports if it is input in the **Patient Information** window. Select **Null**, no hint information will be printed in the ECG reports.

11.6 Transmission

11.6.1 Basic Setup

Item	Description
Device No.	Users can enter up to 30 letters or numbers. Nine random numbers by default. This number will be stored in the DAT, SCP, FDA-XML, and DICOM files.
Auto Transmission	Automatically transmits the ECG test data to the server when a test is completed. Disabled by default.
Transmission Mode	Options: **Wired, Wireless, Ethernet.** Select which way to transmit the ECG data to the server.
Auto Get IP	If selected, **Local IP, Gateway** and **Subnet Mask** will be acquired

	automatically if the wireless connection is successful. **NOTE:** To use **Auto Get IP**, DHCP function needs to be enabled on the router.
Local IP	It can be set to a value within the range of 0 to 255. The format is: XXX.XXX.XXX.XXX. The default IP is 192.168.1.135.
Gateway	It can be set to a value within the range of 0 to 255. The format is: XXX.XXX.XXX.XXX. The default gateway is 192.168.1.1.
Subnet Mask	It can be set to a value within the range of 0 to 255. The format is: XXX.XXX.XXX.XXX. The default subnet mask is 255.255.255.0
Transmission protocol	Options: **FTP**, **DICOM**, **HL7**. Select the protocol to transmit ECGs to your PC. DICOM and HL7 are displayed only if activated.

11.6.2 FTP Setup

Item	Description
FTP User Name	It allows entry of up to 20 English letters or numbers. EDANDAT by default.
FTP Password	It allows entry of up to 20 English letters or numbers. EDANDAT by default.
FTP Path	It allows entry of up to 20 English letters or numbers. Blank by default. This path is the next level directory to store files on the FTP server.
Server IP	It can be set to a value within the range of 0 to 255. The format is: XXX.XXX.XXX.XXX. The default IP is 192.168.1.187.
FTP Mode	Options: **Positive Mode, Passive Mode.**
Control Port	It allows entry of up to 3 numbers. 21 by default.

Data Port	It allows entry of up to 5 numbers. Blank by default. This port can be configured only when the positive mode (FTP mode) is selected.

11.6.3 Mobile Network

Item	Description
APN	Enter the access point name.
Proxy	Enter the proxy address.
Port	Enter the port number.
MCC	Enter the mobile country code.
MNC	Enter the mobile network code.
APN type	Options: **Default, SUPL.**
User Name	Users can enter up to 20 English letters or numbers.
Password	Users can enter up to 20 English letters or numbers.

11.6.4 WLAN Setup (Option)

Item	Description
On/Off	Turns WLAN on or off.
Scan	Click to search wireless networks nearby.
Connect	Click to connect to the selected network.
Add network	If the network is on closed broadcasting, you can add it manually. Click **Add network** to open the Add network dialogue box, enter the SSID (name of the searched wireless network) and set the security type, and click **OK**. If the network is detected, it will appear in the network list. If not, a message indicating connection error will be displayed.
MAC Address	Click to acquire the MAC address of the WIFI module.

11.6.5 HL7 Setup

The HL7 setup is available only if it has been activated in the **Maintenance** > **Advanced Setup** > **Function.**

Item	Description
Get Patient Information Setup	
Server IP	It can be set to a value within the range of 0 to 255. The format is: XXX.XXX.XXX.XXX. The default IP is 192.168.1.187.
Port	It can be set to a value within the range of 0 to 65535.
Listen	Retrieves orders from the server.
Back Trans File Setup	
Server IP	It can be set to a value within the range of 0 to 255. The format is: XXX.XXX.XXX.XXX. The default IP is 192.168.1.187.
Port	It can be set to a value within the range of 0 to 65535.

11.6.6 DICOM Setup

The DICOM setup is available only if it has been activated in the **Maintenance** > **Advanced Setup** > **Function.**

Before use, you should set the server IP, server port, and server AE to those of the server. Server AE and client AE allow entry of up to 60 numbers. Server port allows entry of up to 5 numbers.

Item	Description
DICOM Worklist	With this option, you can retrieve a single order or batches of orders from the server. For more, see "Receiving orders via DICOM or HL7 protocol" in section 4.3.1 *Retrieving Orders from Server (Option).* The server IP is 192.168.1.187 by default. Server port and server AE are blank by default.
DICOM Storage	With this option, you can transmit DICOM files with ECG data to the server. If **Store when making diagnosis** is selected, a DICOM file will be generated automatically when an ECG is diagnosed and then transmitted to the server.

	The server IP is 192.168.1.187 by default. Server port, server AE, and client AE are blank by default.

11.7 Archives

Item	Description
Auto Save	Options: **Off, To ECG** or **Ext. Memory** Select **Off**, ECG data will not be saved. Select **To ECG** or **Ext. Memory**, ECG data in the auto (exclude periodic sample mode), rhythm, or HRV mode will be saved automatically, while ECG data in the pharma study mode or manual mode can be saved manually.
File Format	Select a file format of the data to be exported or transferred. Options: DAT, PDF, JPG, BMP, TIFF, SCP, FDA-XML, DICOM ECG Waveform, DICOM Encapsulated PDF. **NOTE**: To select SCP, FDA-XML, DICOM ECG Waveform, DICOM Encapsulated PDF, you should first activate the SCP, FDA-XML, and DICOM function in Maintenance > Advanced Setup > Function. For details, please contact the manufacturer or the local distributor.
Delete After Trans. Or Export	When selected, the files will be automatically deleted from the **Archives** screen after they are transmitted to the PC or exported to the external memory.
Replace When Memory Full	When selected, if the amount of stored files reaches the upper limit of the Flash memory, the files will replace the earliest one automatically.
Manual Mode Save	Options: **Off**, **Manual Save**, **Auto Save**. Select **Off**, ECG data will not be saved. Select **Manual Save**, ECG data needs to be saved manually in the manual mode. Select **Auto Save**, ECG data will be saved automatically at the set interval in the manual mode.
Manual Mode Save	Set the length of ECG data to be stored before you stop recording in

Time	the Manual work mode. It can be set to an integer within 1-30 min. 5 min by default.

11.8 Maintenance

You need to enter the password before configuring the maintenance setup.

11.8.1 Basic Setup

Item	Description
Export Setup	Exports the system setup to the root directory of an external storage device. The export file is "SetupFile.xml".
Import Settings	Imports the system setup from the root directory of an external storage device. The import file is "SetupFile.xml".
Backup Settings	Makes a backup of the system setup and store it in the local memory of the electrocardiograph.
Load Backup Settings	Imports the system setup from the local memory of the electrocardiograph.
Record System Settings	Prints all system setups using the thermal printer.
Load Factory Setting	Clears the current setups and returns to the default factory settings.
User Password	Define the password to access the Worklist, Archives, ECG analysis screen, and system setup. Blank by default. Enter up to 6 numbers and (or) letters to define the password. You can choose which access mentioned above needs the password. The access to ECG analysis screen means permission to modify ECG measurements and diagnosis. You can also change the password.

11.8.2 Advanced Setup

You need to enter the password before configuring the advanced setup.

Item	Description
Demo	Set the type of ECG waves displayed in DEMO mode. Options: **Off, Normal, Frequent PVCS, ST 0.8, 2ND DEG BLOCK, SINUS ARRHYTHMIA, L BNDL BR BLOCK, R BNDL BR BLOCK, ARTIAL FIB COARSE**.
Function	Activate the functions. Options: **SCP, FDA-XML, DICOM, VCG, TVCG, SAECG, VCG calculation, HL7, DICOM Transmission, Glasgow, HRV**.
Upgrade	The system supports upgrading the software, language, LOGO, Bootloader, and ECG board using an external memory, which helps the service personnel or distributor to maintain the device. Options: **Upgrade All, Upgrade ECG Board Only**.
Device Info	View the software serial number, device model, software version, ECG board version, and SEMIP version.
Barcode	Set the barcode information. • ID: enter a value between 0 and 255. • First Name: enter a value between 0 and 255. 0-0 by default. • Last Name: enter a value between 0 and 255. 0-0 by default. • Gender: enter a value between 0 and 255. 0-0 by default. 13-13 by default. • Year of Birth: enter a value between 0 and 255. 0-0 by default. 14-17 by default. • Month of Birth: enter a value between 0 and 255. 0-0 by default. 18-19 by default. • Day of Birth: enter a value between 0 and 255. 0-0 by default. 20-21 by default. • Male Code: enter a value between 0 and 99. 1 by default. • Female Code: enter a value between 0 and 99. 2 by default.

	• Vendor ID: enter at most 8 letters or numbers which are hexadecimal. 0C2E by default. • Product ID: enter at most 8 letters or numbers which are hexadecimal. 090A by default. • Encode: **Unicode, UTF-8**.
Parameter Setup	• Output Measurement Info • Output Analysis Info • Serious Illness Hint • RV5+SV1 • RV6/SV2 • RR/PP • QTc Calculation: **QTc (Bazett), QTc (Fridericia), QTc (Framingham), QTc (Hodges), QTc (QRS)**. • Axis Calc Method: **Area Method, Amplitude Method**. • Tachycardia Criterion: The default value is 120 bpm (excluded). • Bradycardia Criterion: The default value is 60 bpm (excluded). • Algorithm Sensitivity: **Normal, Low**. • P Wave Normal Time: **110 ms, 120 ms**. • Pacing Sampling: **Low, High**. • Maximum Signal Range: **±5 mV, ±10 mV, ±20 mV.**
Other	• AC Frequency: **50 Hz, 60 Hz**. • Lead Electrode: **IEC, AHA**. • MAC Address: 00-XX-XX-XX-XX-XX. XX is two-digit characters. Enter numbers or English letters to define the address. . • PDF File Name: **Time-ID, Patient Name-ID-Time**. • Default ID Prefix: Enter four or less English letters or numbers as the prefix of patient ID. Blank by default. The change of this setting takes effect for the patient ID generated subsequently. • Localization: **General, North America**.

Cybersecurity Setting	• Encrypt patient info: If selected, the patient name, age, and gender will be hidden on the screen. Only the first letter of first name is displayed, age are displayed as "*", and gender is unknown. • Transmission verification: **On, Off.** When On, the server will give a response to the system whether it has received ECG files or not in each upload. • Encrypted transmission: **On, Off**. When On, the system will use encryption protocol during ECG transmission. SFTP and SSL protocols will be employed for such transmission. • Forbidden external memory: if selected, external storage device cannot be used for import, export, or software upgrade, but can be connected to printer, barcode scanner, keyboard, or mouse. Not selected by default. • Import certificate: enter the private key and select a certificate to import. This setting is for encrypted transmission. You can select an external USB storage device or SD card to import the certificate. • Net firewall: **On, Off**. • Access control: **On, Off**. If On, only the applications predefined can run in the system. • Trust all USB devices: **On, Off**. If On, all USB devices that are connected to the electrocardiograph do not need to authenticate. But if Off, all USB devices need users to authenticate when they are connected to the electrocardiograph in the first time.
System Test	Click **System Test** and enter the correct password to access the system test setup. The following tests are provided: display test, touch screen test, battery test, recorder test, and file system test. Refer to the Service Manual for more details.

11.9 Display and Sound

11.9.1 Basic Setup

Item	Description
Brightness	Adjust the brightness of display by sliding the bar from 1 (the dimmest) to 20 (the brightest). The default is 10. If Auto Brightness is enabled, the system will adjust the brightness automatically based on the current environment.
Volume	Set the key volume, QRS volume, hint volume, and notification volume.
Grid	Options: **On**, **Off.**
Antialiasing	When selected, the ECG waveforms displayed on the main screen will be smoother. Selected by default.
1mV Mark	When selected, the 1mV mark will appear before each line of the ECG waveforms on the main screen, preview screen, and freeze screen. Selected by default.

11.9.2 Main UI Configuration

On this screen, you can configure 12 function keys to be displayed on the main screen.
The functions keys are: **Freeze**, **Archives**, **Worklist**, **Gain**, **Speed**, **Filter**, **RHYT**, **REC Time** (or **Lead Group** in Manual mode), **Event**, **Lead Mode**, **Lead Config**, **Pre-sample**, **Paper Feed.**
To configure a function key, click on the key to be displayed and click on the one that you want to remove from the main screen.

11.10 Date and Time Setup

Item	Description
Date Mode	Options: **DD-MM-YYYY**, **MM-DD-YYYY**, **YYYY-MM-DD**
24-Hour Format	When selected, the system time will be displayed in 24-hour format. Otherwise, it will be displayed in 12-hour format.
Date	Enter a value between 2000 and 2037 as the year, 1 to 12 as the month,

	and 1 to 31 as the day.
Time	Enter a value between 0 and 23 as the hour, 0 to 59 as the minute, and 0 to 59 as the second.
LCD Off	Options: **Never**, **Battery**, **Always** ● Never: The LCD display never turns itself off after several idle minutes. ● Battery: The LCD display turns itself off after several idle minutes only when powered by the battery. ● Always: The LCD display always turns itself off after several idle minutes no matter powered by AC power or battery.
LCD-Off Time	Set an idle period so that power-save is enabled. Enter a value between 0-120 min. 5 minutes by default. To disable power-save, press any key on the screen or the operation panel.
Power Off	Options: **Never**, **Battery**, **Always** ● Never: The electrocardiograph never turns itself off after several idle minutes. ● Battery: The electrocardiograph turns itself off after several idle minutes only when powered by the battery. ● Always: The electrocardiograph turns itself off after several idle minutes no matter powered by AC power or battery.
Power-Off Time	Set an idle period so that power-off is enabled. Enter a value between 0-120 min. 5 minutes by default.

11.11 Profiles

Three scenarios of using the system are provided. They are Outpatient/Common Inpatient, Physical Exam, and Internal Medicine-Cardiovascular Dept.. The Outpatient/Common Inpatient scenario is configured by default as the factory settings.

The default configurations in the three scenarios are listed as follows:

1. Outpatient/Common Inpatient

Item	Description
Work Mode	AUTO, MANU
REC Time	10s
Lead Mode	12-lead
Lead Sequence	Standard
Record Mode	Save Paper
Auto Analysis	All
Main UI Configuration	RHYT, Freeze, Archives, Lead Mode, Gain, Speed, Filter, Worklist, Lead Config, Pre-sample, Event, REC Time
Algorithm Sensitivity	Normal

2. Physical Exam.

Item	Description
Work Mode	AUTO, MANU
REC Time	10s
Lead Mode	12-lead
Lead Sequence	Standard
Record Mode	Quickly
Auto Analysis	All
Main UI Configuration	RHYT, Freeze, Archives, Lead Mode, Gain, Speed, Filter, Worklist, Lead Config, Pre-sample, Event, REC Time
Algorithm Sensitivity	Low

3. Internal Medicine-Cardiovascular Dept.

Item	Description
Work Mode	AUTO, MANU, HRV, Pharma
REC Time	10s

Lead Mode	12-lead
Lead Sequence	Standard
Record Mode	Save Paper
Auto Analysis	Off
Main UI Configuration	RHYT, Freeze, Archives, Lead Mode, Gain, Speed, Filter, Worklist, Lead Config, Pre-sample, Event, REC Time
Algorithm Sensitivity	Normal

11.12 Other

Item	Description
Institution	Enter the institution name, 60 English letters or 20 Chinese characters at most. Blank by default. **NOTE:** The total number of supported characters may be fewer if special Latin characters are entered.
Language	Select the language used in the electrocardiograph and in the ECG reports. English, Chinese, French, German, Italian, Spanish, Russian, Polish, Finnish, Turkish, and Czech are provided.

11.13 Initialize System Setup

Configure this setting when you access to the system at the first time or right after default factory settings are restored.

Item	Description
Institution	See section 11.12 *Other*.
Profiles	See section 11.11 *Profiles*.
Lead Configuration	See section 11.1 *Work Mode*.
Record Mode	See section 11.4.1 *Basic Setup*.

Record Sequence	
AC Frequency	See section 11.8.2 *Advanced Setup*.
H/W Unit	See section 11.5 *Patient Information*.
BP Unit	
Date Mode	See section 11.10 *Date and Time Setup*.
24-Hour Format	

Chapter 12 System Message

System messages and the corresponding causes are listed below.

Table 12-1 System message and causes

System Message	Causes
Lead off	Electrodes fall off the patient or the ECG cable falls off the unit, or a high polarization voltage occurs.
Muscle artifact	Patient's muscle tremor or skin is not well prepared
Low Battery	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 **On**, 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.
Sampling/Analyzing/Recording	ECG signals are being sampled / analyzed / recorded.
Learning	The self-study process of arrhythmia arithmetic in the **Triggered Sample** mode.
Detecting	The examining process of arrhythmia data in the **Triggered Sample** mode.
Sending	ECG data is being transmitted from the electrocardiograph to the PC through the net in the auto or rhythm mode.
Loading Order…	Orders are being loaded to the electrocardiograph.
Memory Full	The amount of files reaches the upper limit of the Flash memory.
Module error	The signal sampling module has an error.
DEMO	The system is in the demonstration mode.
Overload	The direct current offset voltage on an electrode is too high.
U disk / USB printer / USB scanner / card reader	A U disk / USB printer / USB scanner / card reader is connected to electrocardiograph via the USB interface.

Chapter 13 Cleaning, Care and Maintenance

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

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

13.1 General Points

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

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

CAUTION

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

13.2 Cleaning

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

The validated cleaning agents for cleaning the electrocardiograph and ECG cable are:

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

The validated cleaning agent for cleaning the reusable electrodes is:

- Mild near neutral detergent

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

13.2.1 Cleaning the Main Unit

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 equipment 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 main unit in a ventilated and cool place.

13.2.2 Cleaning the ECG cable

1. Wipe the ECG cable with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
2. Wipe off the cleaning solution with a fresh cloth or towel dampened with tap water after cleaning until no visible cleaning agent remains.
3. Wipe off with a dry cloth to remove residual moisture.
4. Leave the ECG cable to air dry.

CAUTION

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

13.2.3 Cleaning the Reusable Electrodes

1. Wipe off with a soft cloth to remove residual gel.
2. Wipe the suction bulbs of chest electrodes and the clamps of limb electrodes with 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. Wipe off with a dry cloth to remove residual moisture.
5. Leave the suction bulbs and clamps to air dry.

13.3 Disinfection

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

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

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

The validated disinfectant for disinfecting the reusable electrodes is:

- 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.

13.3.1 Disinfecting the Main Unit

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 equipment 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 main unit for at least 30 minutes in a ventilated and cool place.

13.3.2 Disinfecting the ECG cable

1. Wipe the ECG cable with a soft cloth dampened with the disinfectant solution.
2. Wipe off the disinfectant solution with a dry cloth after disinfection.
3. Leave the ECG cable to air dry for at least 30 minutes.

13.3.3 Disinfecting the Reusable Electrodes

1. Wipe the suction bulbs of chest electrodes and the clamps of limb electrodes with a soft cloth dampened with the disinfectant solution.
2. Wipe off the disinfectant solution with a dry cloth after disinfection.
3. Leave the suction bulbs and clamps to air dry for at least 30 minutes.

13.4 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.

13.4.1 Recharge and Replacement of Battery

1) Capacity Identification

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

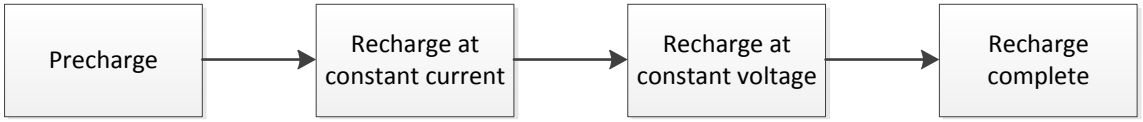
 Full capacity to low capacity (left to right)

2) Recharge

The 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. During the recharging course, the battery indicator flashes in the top right corner of the LCD screen. After the battery is fully recharged, the indicator stops flashing.

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

Recharging process:



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. 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.
4. 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.
5. Remove the battery from the electrocardiograph when the electrocardiograph isn't used for a long time.
6. If the battery is stored alone and not used for a long time, we recommend that the battery be charged at least once every 6 months to prevent overdischarge.

CAUTION

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

13.4.2 Recorder Paper

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

Storage Requirements:

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

13.4.3 Visual inspection

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

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

13.4.4 Maintenance of the Main Unit and the ECG cable

CAUTION

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

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

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

b) Inspect the safety related labels for legibility.

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

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

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

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

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

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

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

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

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

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

WARNING

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

The maintenance operations like software upgrade of the device can only be completed by EDAN-qualified service personnel.

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) ECG cable

- Integrity of the ECG cable, including the main cable and lead wires, should be checked regularly. Make sure that it is conductible.
- Do not drag or twist the ECG cable with excessive stress while using it. Hold the connector plug instead of the cable when connecting or disconnecting the ECG cable.
- Align the ECG 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 ECG 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. In this case, electrodes should be replaced so as to acquire high-quality

ECGs.

While usage will have an impact, it is expected the electrocardiograph will be in service for 10 years.

Replace the lead wires, electrodes and other accessories according to your actual use. It is recommended that you replace them once every year.

EDAN will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair those parts of the equipment that are designated by EDAN as repairable by service personnel.

CAUTION

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

Chapter 14 Accessories

WARNING

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

Table 14-1 Standard Accessories List

Accessory	Part number
Power Cord (AHA)	01.13.037122
Power Cord (IEC)	01.13.036638
ECG Cable, Patient Cable (IEC)	01.57.471500
ECG Cable, Patient Cable (AHA)	01.57.471499
Adult Chest Electrodes	01.57.040163
Adult Limb Electrodes	01.57.040162
Thermal Chart Paper	01.57.107371
	01.57.32462
	01.57.107451
Rechargeable Lithium Battery	01.21.064142
	01.21.064143

Table 14-2 Optional Accessories List

Accessory	Part Number
ECG Cable, Patient Cable (IEC)	01.57.107581 (Snap Style)
	01.57.107583 (Grabber Style)
ECG Cable, Patient Cable (AHA)	01.57.107582 (Snap Style)
	01.57.107584 (Grabber Style)
Pediatric Chest Electrodes	01.57.040168
Pediatric Limb Electrodes	01.57.040169

Accessory	Part Number
Snap/Banana Socket Adapters	01.57.471864
Clip/Snap/Banana Socket Adapter	01.57.040172
Grounding Wire	01.13.114214
USB Storage Device	01.18.052245
ECG Bag	01.56.465625
One-dimensional Scanner	01.23.068023
Two-dimensional Scanner	21.18.052311
LAN Cable	01.13.020096
Serial Cable	01.13.020117

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

Chapter 15 Warranty and Service

15.1 Warranty

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

The warranty is void in cases of:

a) Damage caused by mishandling during shipping.

b) Subsequent damage caused by improper use or maintenance.

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

d) Damage caused by accidents.

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

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

15.2 Contact information

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

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

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		Type CF 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 B
Patient Leakage Current	NC	<10μA (AC) / <10μA (DC)
	SFC	<50μA (AC) / <50μA (DC)
Patient Auxiliary Current	NC	<10μA (AC) / <10μA (DC)
	SFC	<50μA (AC) / <50μA (DC)

A1.2 Environment Specifications

	Transport & Storage	Working
Temperature	-20℃ (-4℉) ~ +55℃ (+131℉)	+5℃ (+41℉) ~ +40℃ (+104℉)
Relative Humidity	15% RH~95% RH Non-Condensing	15% RH~95% RH Non-Condensing
Atmospheric Pressure	70 kPa ~106 kPa	70 kPa ~106 kPa

A1.3 Physical Specifications

Dimensions	400 mm×360 mm×90 mm, ±2mm
Weight	≤6.5 kg (Excluding recorder paper and battery), ±0.3 kg
Display	10.1", 1280×800 multicolor LCD Screen. The display can be flipped 25 degrees clockwise.

A1.4 Power Supply Specifications

<table>
<tr><td rowspan="3">Mains Supply</td><td colspan="3">Operating Voltage = 100V-240V~</td></tr>
<tr><td colspan="3">Operating Frequency = 50Hz/60Hz</td></tr>
<tr><td colspan="3">Input Current = 0.9A ~ 0.4A</td></tr>
<tr><td rowspan="5">Internal Lithium Battery</td><td colspan="3">Rated Voltage = 14.8V</td></tr>
<tr><td colspan="3">Typical Capacity = 2,500 mAh or 5,000 mAh</td></tr>
<tr><td>Typical Capacity</td><td>100% Recharge Time</td><td>90% Recharge Time</td></tr>
<tr><td>2500 mAh</td><td>3 hours</td><td>2.5 hours</td></tr>
<tr><td>5000 mAh</td><td>6 hours</td><td>5 hours</td></tr>
<tr><td colspan="3">When the battery is fully charged and SE-1202 operates at 23℃ (±3℃), the performance is as follows.</td></tr>
</table>

	Typical Capacity	Normal Work Hours	Print Number and Duration	
			Auto Mode （3×4+1R）	Manual Mode (Continual)
	2500 mAh	≥ 4h	≥ 250	≥ 2h
	5000 mAh	≥ 8h	≥ 500	≥ 4h
Fuse	021502.5MXEP, 2.5A, 250V, 5x20mm			

A1.5 Performance Specifications

Recording	
Recorder	Thermal dot-matrix recorder
Printing Density	8 dots per mm / 200 dots per inch (amplitude axes) 40 dots per mm / 1000 dots per inch (time axes, @ 25 mm/s)
Recorder Paper	Folded thermal paper: 210 mm×295 mm×100 pages Folded thermal paper: 215 mm×280 mm×100 pages Folded thermal paper: 210 mm×295 mm×200 pages
Effective Width	210 mm
Paper Speed	5 mm/s, 6.25 mm/s, 10 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s (±3%)
HR Recognition	
HR Range	30 bpm ~300 bpm
Accuracy	±1 bpm
ECG Unit	
Leads	9 or 12 standard leads
Acquisition Mode	9 or 12 leads acquisition simultaneously
Analog-to-Digital Converter	Sampling Frequency: 64,000 /sec/channel
	A/D: 24 bits
	Resolution: 0.1192 μV/LSB
Time Constant	≥ 5s

Frequency Response	0.01~350Hz(-3dB)	
Gain	1.25 mm/mV, 2.5 mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV, 10/5 mm/mV, AGC (mm/mV), ±5%	
Input Impedance	≥100 MΩ (10Hz)	
Input Circuit Current	≤0.01 μA	
Input Voltage Range	≤±5 mVpp	
Calibration Voltage	1 mV±2%	
DC Offset Voltage	±900 mV, ±5%	
Minimum Amplitude	20 μVp-p (10Hz)	
Noise	≤12.5 μVp-p	
Multichannel crosstalk	≤0.5 mm	
Filter	AC Filter	50 Hz / 60 Hz / Off
	DFT Filter	0.01 Hz / 0.05 Hz / 0.32 Hz / 0.67 Hz
	EMG Filter	25 Hz / 35 Hz / 45 Hz / Off
	LOWPASS Filter	350 Hz / 300 Hz / 270 Hz / 150 Hz / 100 Hz / 75 Hz
CMRR	≥140 dB (AC filter on) ≥123 dB (AC filter off)	
Pacemaker Detection		
Amplitude	±500μV to ±700mV	
Width	30μs to 2.0ms	
Sampling Frequency	80,000 /sec/channel, Rhythm Lead	
WIFI (Option)		
Radio Technology	802.11 a/b/g/n	

Frequency Range	FCC: 2412 MHz ~ 2462 MHz, 5180 MHz ~ 5825 MHz CE: 2412 MHz ~ 2472 MHz, 5180 MHz ~ 5825 MHz
Modulation	DBPSK, DQPSK, CCK, BPSK, QPSK, 16-QAM, 64-QAM
Output Power	<20 dBm (CE requirement: detection mode - RMS) <30 dBm (FCC requirement: detection mode - peak power)
Transmit rate	IEEE 802.11b: 1 Mbps to 11 Mbps IEEE 802.11g: 6 Mbps to 54 Mbps IEEE 802.11n: 6.5 Mbps to 72.2 Mbps IEEE 802.11a: 6 Mbps to 54 Mbps
Bandwidth	2.4 GHz & 5 GHz 20 MHz
4G (Option)	
Bands	FDD LTE: Band 1, Band 2, Band 3, Band 4, Band 5, Band 7, Band 8, Band 20, all bands with diversity WCDMA/HSDPA/HSUPA/HSPA+:Band 1, Band 2, Band 5, Band 8, all bands with diversity GSM/GPRS/EDGE: 850 MHz/900MHz/1800 MHz/1900 MHz
Rate	GPRS: UL 85.6 kbit/s; DL 85.6 kbit/s EDGE: UL 236.8 kbit/s; DL 236.8 kbit/s WCDMA CS: UL 64 kbit/s; DL 64 kbit/s WCDMA PS: UL 384 kbit/s; DL 384 kbit/s HSPA+: UL 5.76 Mbit/s; DL 21.6 Mbit/s DC-HSPA+: UL 5.76 Mbit/s; DL 42 Mbit/s LTE FDD: UL 50 Mbit/s; DL 150 Mbit/s@20M BW cat4

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

EDAN's electrocardiographs with 4G are not sold in the U. S. A.

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 SE-1202 electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the SE-1202 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 SE-1202 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 B</td><td rowspan="3">The SE-1202 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 SE-1202 electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of SE-1202 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	0 % $U_{T;}$ 0.5 cycle At 0 °, 45 °, 90 °, 135 °, 180 °, 225 °, 270 °and 315 °	0 % $U_{T;}$ 0.5 cycle At 0 °, 45 °, 90 °, 135 °, 180 °, 225 °, 270 °and 315 °	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SE-1202 electrocardiograph

IEC/EN 61000-4-11	0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles) Single phase: at 0 ° 0 % U_T; 250/300 cycle	0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles) Single phase: at 0 ° 0 % U_T; 250/300 cycle	requires continued operation during power mains interruptions, it is recommended that the SE-1202 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 SE-1202 electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the SE-1202 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	3 V_{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 SE-1202 electrocardiograph, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF IEC/EN 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz

	See Table 1.	See Table 1.	$d = 2.3\sqrt{P}$ 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 SE-1202 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 SE-1202 electrocardiograph is used exceeds the applicable RF compliance level above, the SE-1202 electrocardiograph should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SE-1202 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.

Table 1 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 800/900,TETRA 800, iDEN	Pulse modulation[b)] 18 Hz	2	0.3	28
870						
930						

		820, CDMA 850, LTE Band 5				
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 SE-1202 Electrocardiograph			
The SE-1202 electrocardiograph is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SE-1202 electrocardiograph can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SE-1202 electrocardiograph as recommended below, according to the maximum output power of the communications equipment.			
Maximum output power rating of	**Separation distance according to frequency of transmitter(m)**		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**800 MHz to 2.7 GHz**

transmitter (W)	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
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 List of Arrhythmias

Table 1 Arrhythmia ECG signals that will trigger automatic ECG sampling when detected

Name	Description
Single premature ventricular contraction (PVC)	In a ventricular ectopic beat, QRS complex appears wide and bizarre and its duration is above 0.12s. T wave is wide and in the opposite direction from the QRS complex. One single ventricular ectopic beat appears among normal sinus beats. The cardiac rhythm is like N, N, N, V, N, N, N.
Ventricular couplet	Two ventricular ectopic beats appear in a row and the cardiac rhythm is like N, V, V, N.
Ventricular triplet or quadruplet	Three or four ventricular ectopic beats appear in a row and the cardiac rhythm is like N, V, V, V, N or N, V, V, V, V, N.
Runs of V-Tach	More than four ventricular ectopic beats appear in a row.
Ventricular Bigeminy	Each normal heart beat is followed by a ventricular ectopic beat. The cardiac rhythm is like N, V, N, V, N, V.
Ventricular Trigeminy	Every two normal heart beats are followed by a ventricular ectopic beat. The cardiac rhythm is like N, N,V, N, N,V, N, N,V.
R on T	A normal heart beat has a ventricular ectopic beat occurring in the position of T wave.
Missing beat	When heart rate is < 100, no heart beat is detected in the period calculated by 1.75 multiplying averaged RR interval. Or when heart rate is > 100, no heart beat is detected in a second.
Tachycardia	Heart rate is more than 120 beats per minute.
Bradycardia	Heart rate is less than 40 beats per minute.

Table 2 Arrhythmia diagnostic statements that will trigger extended arrhythmia ECG print

Marked Sinus Bradycardia
Sinus Bradycardia
Sinus Tachycardia
Tachycardia
Bradycardia
Marked Tachycardia

Marked Bradycardia
Sinus Arrhythmia
Sinus Bradycardia with Sinus Arrhythmia
Sinus Tachycardia with Sinus Arrhythmia
Premature Atrial Contraction
Frequent Premature Atrial Contraction
Premature Ventricular Contraction
Frequent Premature Ventricular Contraction
Premature Ventricular Contraction Bigeminy
Premature Ventricular Contraction Trigeminy
Runs of Premature Atrial Contraction
Runs of Premature Ventricular Contraction
Sino-Atrial Block
Pair Premature Ventricular Contraction
Supraventricular tachycardia
Ventricular tachycardia
Atrial Fibrillation
Atrial flutter

Table 3 Arrhythmia ECG waveforms that will be displayed in red

Occasional VE	In a ventricular ectopic beat, QRS complex appears wide and bizarre and its duration is above 0.12s. T wave is wide and in the opposite direction from the QRS complex. One single ventricular ectopic beat appears among normal sinus beats. The cardiac rhythm is like N, N, N, V, N, N, N.
VE couplet	Two ventricular ectopic beats appear in a row and the cardiac rhythm is like N, V, V, N.
VE trigeminy or quadrigeminy	Three or four ventricular ectopic beats appear in a row and the cardiac rhythm is like N, V, V, V, N or N, V, V, V, V, N.
VE runs	More than four ventricular ectopic beats appear in a row.
Ventricular bigeminy	Each normal heart beat is followed by a ventricular ectopic beat. The cardiac rhythm is like N, V, N, V, N, V.

Ventricular trigeminy	Every two normal heart beats are followed by a ventricular ectopic beat. The cardiac rhythm is like N, N,V, N, N,V, N, N,V.
R on T	A normal heart beat has a ventricular ectopic beat occurring in the position of T wave.

Appendix 4 Abnormal Measurements and Diagnosis

Table 1 Normal measurement range

Parameter	Normal Range
Heart rate	60 bpm - 100 bpm (including 60 and 100 bpm)
P wave duration	<120 ms by default, excluding 120 ms. This parameter can be configured in System Setup > Parameter Setup.
PR interval	120 ms – 200 ms (including 120 ms and 200 ms)
QRS complex duration	<120 ms (excluding 120 ms)
QT interval	320 ms – 440ms ((including 320 ms and 440 ms)

Table 2 Abnormal diagnostic statement

Diagnostic statement
Second-degree Atrioventricular Block (Mobitz type II)
Third-degree Atrioventricular Block
Marked ST Depression
Marked ST Elevation
Acute Anterior Myocardial Infarction
Acute High Lateral Myocardial Infarction
Acute Inferior Myocardial Infarction
Extensive Anterior Myocardial Infarction
Occlusion of the First Septal Branch of LACA
Occlusion of the Left Anterior Descending Coronary Artery (LACA)
Occlusion of the Left Main Coronary Artery Stenosis
Occlusion of the Right Coronary Artery (RCA)
Occlusion of Ostium Right Coronary Artery
Occlusion of the Left Circumflex Coronary Artery (LCx)
Atrioventricular Dissociation
Asystole
Ventricular Fibrillation
Marked Sinus Bradycardia
Ventricular Tachycardia

Appendix 5 List of Serious Diseases

Serious Diseases
Second-degree Atrioventricular Block (Mobitz type II)
Third-degree Atrioventricular Block
Marked ST Depression
Marked ST Elevation
Acute Anterior Myocardial Infarction
Acute High Lateral Myocardial Infarction
Acute Inferior Myocardial Infarction
Extensive Anterior Myocardial Infarction
Occlusion of the First Septal Branch of LACA
Occlusion of the Left Anterior Descending Coronary Artery (LACA)
Occlusion of the Left Main Coronary Artery Stenosis
Occlusion of the Right Coronary Artery (RCA)
Occlusion of Ostium Right Coronary Artery
Occlusion of the Left Circumflex Coronary Artery (LCx)
Atrioventricular Dissociation
Asystole
Ventricular Fibrillation
Marked Sinus Bradycardia
Ventricular Tachycardia

Appendix 6 Abbreviation

Abbreviation	Statement
LCD	Liquid Crystal Display
BP	Blood Pressure
ECG	Electrocardiogram/Electrocardiograph
HR	Heart Rate
AC	Alternating Current
USB	Universal Serial Bus
AGC	Auto Gain Control
NC	Normal Condition
SFC	Single Fault Condition
PDF	Portable Document Format
FDA-XML	Food and Drug Administration–Extensible Markup Language
DICOM	Digital Imaging and Communications in Medicine

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