

SE-1200 Pro&SE-1201 Pro
Electrocardiograph
Version 1.1

User Manual

CE₀₁₂₃


EDAN

About this Manual

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Statement

This manual will help you understand the operation and maintenance of the product better. It reminds us that the product shall be used strictly in complying with this manual. The user's process failing to adhere to this manual may result in malfunction or accident for which EDAN INSTRUMENTS, INC. (From now on called EDAN) cannot be held liable. EDAN owns the copyrights of this manual. Without the prior written consent of EDAN, any materials contained in this manual shall not be photocopied, reproduced, or translated into other languages.

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

Product Information

Product Name: Electrocardiograph

Model: SE-1200 Pro and SE-1201 Pro

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 following the instructions for use.

Terms Used in this Manual

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

WARNING

A WARNING label advises against specific 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 helpful information regarding a function or a procedure.

Table of Contents

Chapter 1 Safety Guidance	1
1.1 Indications for Use/Intended Use	1
1.2 Precautions for Use.....	1
1.3 Warnings and Cautions	2
1.3.1 Protecting Personal Information.....	7
1.3.2 Battery Care Warnings	9
1.3.3 General Cautions	10
1.4 List of Symbols.....	12
Chapter 2 Product Information	14
2.1 Front View	14
Chapter 3 Operation Preparations.....	16
3.1 Preparing the Patient.....	16
3.1.1 Instructing the Patient.....	16
3.1.2 Cleaning the Skin	16
3.2 Attaching Electrodes to the Patient.....	17
3.2.1 Electrode Placement.....	17
3.2.2 Attaching the Reusable Electrodes	19
3.2.3 Attaching the Disposable Electrodes.....	20
3.3 Inspection Before Power-On	20
3.4 Turning On/Off the Electrocardiograph	21
3.5 Loading Recorder Paper	22
Chapter 4 Basic Operation Guidance	24
4.1 Login.....	24
4.2 ECG recording.....	24
4.3 Patient Tab	26
4.4 New Patient Information	27
4.4.1 Manually Entering Patient Information.....	27
4.4.2 Scanning a Barcode (Option)	27
4.4.3 Barcode scanner	28
4.5 Retrieving Orders from Server	28
4.6 Editing Patient Information	29
4.7 Deleting Patient Information	29
4.8 Searching Patient information	29
4.9 Sorting/Queuing Patient Information	29
4.10 WIFI and Bluetooth.....	30
4.11 Switching to another User Account.....	30
Chapter 5 ECG File Management	31
Chapter 6 Editing ECG	33
6.1 ECG View.....	33
6.2 ECG Measurement	33
6.3 Auto Measurement.....	34
6.4 Auto Diagnosis	34
6.5 Modifying Measurement Parameters.....	34

6.6 Modifying Diagnosis	35
6.7 Re-analysis	35
6.8 Averages View	35
6.9 Comparing ECGs.....	36
Chapter 7 Printing ECG Reports	37
Chapter 8 Transmitting and Exporting ECGs	38
Chapter 9 System Setup.....	40
9.1 Sampling Setting	40
9.2 Print and Storage Setting	41
9.3 Patient Information Setting.....	42
9.4 Filter Setting	44
9.5 Transmission Setting	44
9.6 Parameter Setting.....	45
9.7 User Setting	47
9.8 Others	47
9.9 System Update.....	48
9.10 System Maintenance.....	48
Chapter 10 Error Messages.....	49
Chapter 11 Cleaning, Care, and Maintenance	50
11.1 General Points	50
11.2 Cleaning	50
11.3 Disinfection	51
11.4 Care and Maintenance	52
11.4.1 Recharge and Replacement of Battery	52
11.4.2 Recorder Paper	54
11.4.3 Visual inspection	54
11.4.4 Maintaining Main Unit and ECG Cable	54
Chapter 12 Accessories	57
Chapter 13 Warranty and Service.....	59
13.1 Warranty	59
13.2 Contact information.....	59
Appendix 1 Technical Specifications	60
A1.1 Safety Specifications	60
A1.2 Environment Specifications	61
A1.3 Physical Specifications.....	61
A1.4 Power Supply Specifications.....	61
A1.5 Performance Specifications.....	62
Appendix 2 EMC Information.....	65
Appendix 3 Abbreviations	73
Appendix 4 Installation instructions	74

Chapter 1 Safety Guidance

1.1 Indications for Use/Intended Use

The SE-1200 Pro&SE-1201 Pro 12-lead electrocardiographs are intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiographs are 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 device cannot be directly applied to the heart.
 2. Non-domestic devices.
 3. This device is not intended for treatment or monitoring.
 4. This device is intended for use on adult and pediatric patients only.
 5. The result of reports should combine with the patient's clinical situation, which cannot replace regular examinations.
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1.2 Precautions for Use

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

1.3 Warnings and Cautions

WARNING

1. The system is intended to use 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 system in the presence of flammable anesthetic mixtures with oxygen or other volatile agents.
 4. Ensure 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.
 5. If the integrity of the external protective conductor is in doubt, the equipment should be powered by an internal Li-ion rechargeable battery.
 6. Do not use this equipment in the presence of high static electricity or high voltage equipment which may generate sparks.
 7. Only the manufacturer's ECG cable and other accessories can be used. Or else, the performance and electric shock protection cannot be guaranteed. The system has been safety tested with the recommended supplements, peripherals, and leads, and no hazards are found when the system is operated with cardiac pacemakers or other stimulators.
 8. Make sure that all electrodes are connected to the patient correctly before operation.
 9. Ensure that the conductive parts of electrodes and associated connectors, including neutral electrodes, do not contact the earth or any other conducting objects.
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WARNING

10. **Electrodes of dissimilar metals should not be used; otherwise, they may cause a high polarization voltage.**
11. **The disposable electrodes can only be used for one time.**
12. **Do not touch the patient, bed, table, or device while using the ECG and a defibrillator.**
13. **Do not touch accessible parts of electrical equipment and the patient simultaneously.**
14. **Disposable electrodes must be used during defibrillation.**
15. **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 before performing any procedure that uses high-frequency surgical equipment.**
16. **This device complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. This device must operate with a minimum distance of 20 cm between the radiator and user body.**
17. **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.**
18. **Pay close attention to the examination to avoid missing necessary ECG waveforms.**
19. **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 provided by a multiple portable socket-outlet with an isolation transformer.**

WARNING

- 20. SHOCK HAZARD - Don't connect electrical equipment, which has not been supplied as a part of the system, to the multiple portable socket-outlet providing the system.**
- 21. Do not connect any equipment or accessories that are not approved by the manufacturer or that are not IEC/EN 60601-1 approved in the system. The operation or use of non-approved equipment or accessories with the system is not tested or supported, and system operation and safety are not guaranteed.**
- 22. Any non-medical equipment (such as the external printer) is not allowed to be used within the patient's vicinity (1.5m/6ft.).**
- 23. Do not exceed the maximum permitted load when using the multiple portable socket-outlet (s) to supply the system.**
- 24. Multiple portable socket-outlets shall not be placed on the floor.**
- 25. Do not use the additional multiple portable socket-outlet or extension cord in the medical electrical system unless specified as part of the system by the manufacturer. And the multiple portable socket outlets provided with the system shall only be used for supplying power to equipment that is intended to form part of the system.**
- 26. Accessory equipment connected to the analog and digital interfaces must be certified according to 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 valid version of the system standard IEC/EN 60601-1. If in doubt, consult our technical service department or your local distributor.**
- 27. All the accessories connected to the system must be installed outside the patient vicinity if they do not meet the requirement of IEC/EN 60601-1.**
- 28. The electrocardiograph shall not be serviced or maintained while using a patient.**

WARNING

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

- a) Within the patient environment, a level of safety comparable to that offered 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 complies with other IEC or ISO safety standards.**

30. 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.**

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.

WARNING

- 32. All the accessories connected to the system must be installed outside the patient vicinity if they do not meet the requirement of IEC/EN 60601-1.**
- 33. The appliance coupler or mains plug is used as isolation means from supply mains. Position the electrocardiograph where the operator can easily access the disconnecting device.**
- 34. The electrocardiograph should be placed on a flat surface or EDAN's trolley. Avoid it dropping down to cause a strong shock.**
- 35. When the touchscreen is damaged or broken, please contact the manufacturer for repair or replacement.**
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1.3.1 Protecting Personal Information

Protecting personal health information is a significant component of security strategy. To protect personal information and ensure the proper device performance, the user should take necessary precautions by local laws and regulations and institutional policies. EDAN recommends health care organizations or medical institutions 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 does not have access to the device.
2. Operational safeguards - safety measures during operation.
3. Administrative safeguards - safety measures in management.
4. Technical safeguards - safety measures in the technical field

CAUTION

1. The access/operation of the electrocardiograph is restricted to authorized personnel only. Assign only staff with a specific role the right to use the electrocardiograph.
 2. Ensure that all device components maintaining personal information (other than removable media) are physically secure (i.e., cannot remove without tools).
 3. Users should make a backup of data periodically.
 4. Ensure that the electrocardiograph is connected only to the device authorized/approved by EDAN. Users should operate all EDAN deployed and supported electrocardiographs within EDAN allowed specifications, including approved software, software configuration, security configuration, etc.
 5. Protect all the passwords to prevent unauthorized changes.
 6. Before using a USB flash drive, anti-virus measures such as USB device virus scanning should be carried out.
 7. Firewalls and other security devices should be between the medical system and any externally accessible systems. It's recommended to use a Windows defender firewall or any other firewall that can defend against Dos and DDoS attacks and keep it up to date. Add the master computer software to the whitelist.
 8. Dos and DDoS protection of the router or switch must be turned on to defend against attacks.
 9. 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 and electrocardiograph are in the same VLAN, and isolate it from other VLANs.
 10. Do not install in SE-1200 Pro&SE-1201 Pro ECG the other APPs or software that the manufacturer does not configure.
 11. When the device is returned for maintenance, disposed of, or removed from the medical institution for other reasons, it is necessary to ensure that all patient data are removed from the electrocardiograph.
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CAUTION

12. Please protect patients' information displayed on the screen and the data stored in the electrocardiograph.
 13. The manufacturer or its authorized personnel can only upgrade the operating system of SE-1200 Pro&SE-1201 Pro ECG. If the user reinstalls SE-1200 Pro&SE-1201 Pro ECG with other operating systems not authorized by EDAN, the user shall bear the resulting security risks and losses. Possible security risks are stolen user information, sending SMS automatically, and locating your location.
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1.3.2 Battery Care Warnings

WARNING

1. Improper operation may cause the internal Li-ion battery (from now on called a battery) to be hot, ignited, or explode. It may lead to a decrease in 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 the 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 the battery with a sharp object such as a needle. Do not hit with a hammer; step on, throw, or drop to cause a strong shock. Do not disassemble or modify the battery.
 6. Properly dispose of or recycle the depleted battery, according to local regulations.
 7. The battery can be installed or removed only when the device is powered off.
 8. Please remove the battery from the electrocardiograph when you have not used it for a long time.
 9. If the battery is stored alone and not used for a long time, we recommend that the battery be charged at least once every six months to prevent over-discharge.
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1.3.3 General Cautions

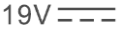












CAUTION










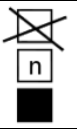



1. **Avoid liquid splash and excessive temperature. The temperature must be kept between 5 °C and 40 °C during operation, and it should be kept between -20 °C and 55 °C during transportation and storage.**
 2. **Do not use the equipment in a dusty environment with inadequate ventilation or in the presence of corrosive.**
 3. **Ensure that there is no intense electromagnetic interference source around the equipment, such as radio transmitters or mobile phones. Large medical electrical equipment is likely to bring electromagnetic interference such as electrosurgical, radiological, magnetic resonance imaging, etc.**
 4. **Make sure that there is no intense electromagnetic interference source around the equipment, including RF emitters (e.g. radio transmitters, diathermy, electrocautery, and RFID) 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.**
 5. **Electromagnetic Interference - Ensure that the environment in which the electrocardiograph is installed is not subject to any source of strong electromagnetic interference, such as CT, radio transmitters, mobile phone base stations, etc. Even though other devices are in accordance with national standard radiation requirements, the electrocardiograph may be interfered.**
 6. **Electromagnetic Interference - ECG parameters are sensitive measurements involving small signals, and the recording equipment contains very sensitive high gain front-end amplifiers. Immunity levels for radiated RF electromagnetic fields and conducted disturbances induced by RF fields are subject to technological limitations. To ensure that external electromagnetic fields do not cause erroneous measurements, it is recommended to avoid the use of electrically radiating equipment in close proximity to these measurements.**
 7. **Electromagnetic Interference - The electrocardiograph should not be used adjacent to or stacked with other equipment, refer to section Appendix 2 EMC Information for recommended separation distances.**
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CAUTION

8. The medical electrical equipment needs to be installed and put into service according to Appendix 2 EMC Information.
 9. The device and accessories must 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 household garbage. At the end of their lives, hand the batteries to the appropriate collection points for the recycling of waste batteries. For more detailed information about recycling this product or battery, don't hesitate to contact your local Civic Office or the shop where you purchased the product.
 10. **Federal (U.S.) law restricts this device to sale by or on the order of a physician.**
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1.4 List of Symbols

No.	Symbol	Description
1	19V 	Direct current
2		DEFIBRILLATION-PROOF TYPE CF APPLIED PART
3	PATIENT	ECG cable socket
4		Caution
5		Consult operating instructions
6		USB socket
7		SIM card/ SD card slot
8		Computer network
9		Power On/Off
10		Patient
11		Mode
12		Setting
13		Print/Stop
14		The general symbol for recovery/recyclable

15		Dispose of method
16		Serial number
17		General warning sign (Background: Yellow; Symbol & Outline: Black)
18		Refer to the instruction manual/booklet (Background: Blue; Symbol: White)
19*		Non-ionizing electromagnetic radiation symbol
20		Environmentally friendly use period
21		This way up
22		Fragile, handle with care
23		Keep dry
24		Stacking limit by number
25		Handle with care
26		Do not step on
27		Front
28	Contains FCC ID: SMQSE120XPRO	Federal Communications Commission: Contains FCC ID: SMQSE120XPRO

NOTE:

The user manual is printed in black and white.



Chapter 2 Product Information




SE-1200 Pro&SE-1201 Pro ECG is new generation series of high-end smart electrocardiographs with a light body, which can meet the needs of multi-scenario and multi-service use. It consists of the following components: main unit, ECG cable, chest electrode suction ball, limb electrode clip, power cord (national standard, European standard, and American standard), power adapter, lithium battery, and system software.





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

2.1 Front View



Symbol	Name	Description
	Power on/off Power light	<ul style="list-style-type: none"> ● Press the On/Off button when the device is off to power on. ● When the device is on: To enable power-save, press and hold this button for 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. ● Green indicates the system is connected to AC power. ● Blue suggests the system is connected to battery power. ● Orange means the system is charging.
	Patient	To open the patient information dialog box in the Resting ECG Test screen. To exit, press this button again.

Symbol	Name	Description
	Mode	To switch operation mode in the Resting ECG Test screen.
	Setting	To configure the system setting in the Resting ECG Test screen. To exit, press this button again.
	Print/Stop	<ul style="list-style-type: none"> ● To start printing report(s). ● To stop print when report(s) is being printed. ● To stop paper feeding.

Symbol	Name	Description
PATIENT	Patient Cable Socket	Connecting to the patient cable
 SIM/SD	SIM/SD slot	The symbol indicates that a SIM/SD card can be inserted for data communication and storage.
	USB port	Standard USB port connecting to a U disk, a bar code reader, or a USB printer recommended by the manufacturer
	Type-C port	For factory debugging only, not rechargeable.
	Computer network	Standard net port, connecting to a PC

Chapter 3 Operation Preparations

3.1 Preparing the Patient

3.1.1 Instructing the Patient

Before attaching the electrodes, greet the patient and explain the procedure. It can decrease the patient's anxiety. Reassure the patient that the operation is painless. Privacy is critical for the patient to relax. 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.

3.1.2 Cleaning the Skin

Thorough skin preparation is critical. The skin is a poor conductor of electricity and frequently creates artifacts that distort the ECG signals. By performing systematic skin preparation, you can significantly 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 epidermis cells, oils, and dirt.

To Clean the Skin

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

3.2 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 contact the earth or any other conducting objects.

NOTE: The quality of the ECG waveform will be affected by the contact resistance between the patient and the electrode. Proper skin preparation (abrasion if necessary), proper electrodes, and patient cables in a fixed position are essential for good signal quality.

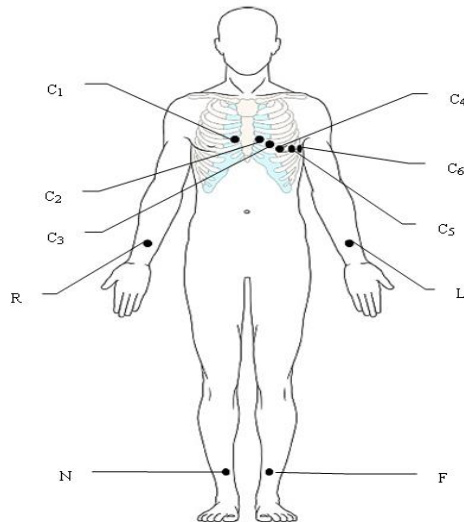
The identifiers and color codes of electrode connectors comply with IEC/EN requirements. Avoid incorrect connections; the identifiers and color codes are specified in Table 3-1. Moreover, the equivalent codes according to AHA requirements are also given in Table 3-1.

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

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

3.2.1 Electrode Placement

Standard 12 lead placement

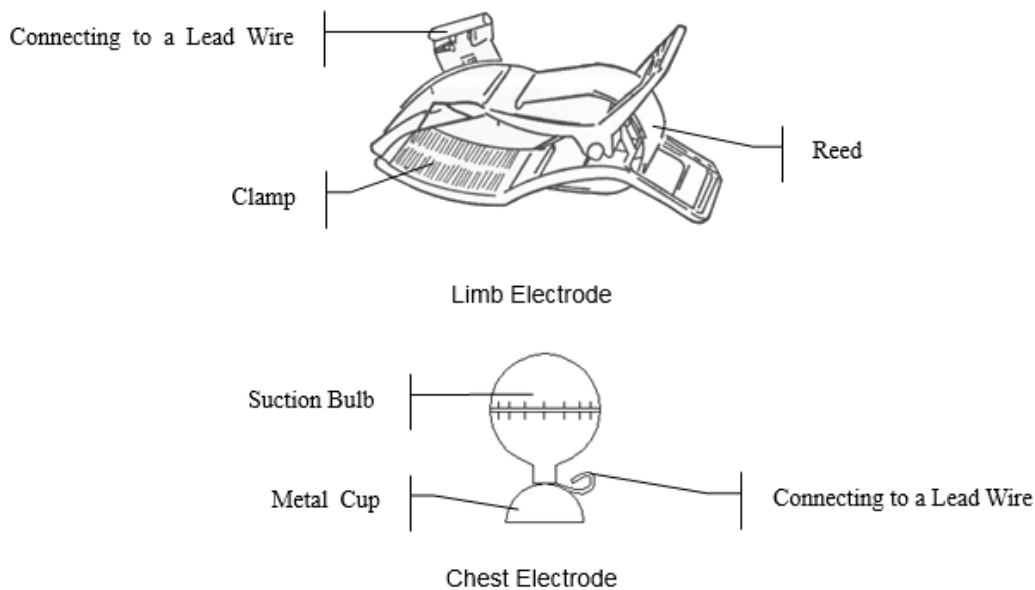


Electrodes		Locations
IEC	AHA	
C1 White/Red	V1 Brown/Red	Fourth intercostal space at the right border of the sternum
C2 White/Yellow	V2 Brown/Yellow	Fourth intercostal space at the left border of the sternum
C3 White/Green	V3 Brown/Green	Fifth rib between C2 and C4
C4 White/Brown	V4 Brown/Blue	Fifth 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	The left mid-axillary line at the horizontal level of C4
L Yellow	LA Black	Left-arm
R Red	RA White	Right arm

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

3.2.2 Attaching the Reusable Electrodes

Attaching Electrodes



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

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

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

3.2.3 Attaching the Disposable Electrodes

Disposable Electrode Connection (Clip Style)

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

CAUTION

The disposable electrodes can only be used for one time.

3.3 Inspection Before Power-On

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

1) Environment:

- ◆ Ensure no electromagnetic interference source around the equipment and extensive medical electrical equipment such as electrosurgical equipment, radiological equipment, magnetic resonance imaging equipment, etc. Turn off these devices when necessary.
- ◆ Keep the examination room warm to avoid muscle tremor voltages in ECG signals caused by cold.

2) Power Supply:

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

3) Patient Cable:

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

4) Electrodes:

- ◆ Ensure that all electrodes are connected to the lead wires to the patient cable correctly.
- ◆ Ensure that the chest electrodes do not in contact with each other.

5) Patient:

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




3.4 Turning On/Off the Electrocardiograph

WARNING

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

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

To turn on the Electrocardiograph

- When operating on AC power
Ensure that the mains supply meets the requirements (refer to A1.4 Power Supply Specifications) before powering on, and then press  to turn on the Electrocardiograph. Suppose the battery is weak when the mains supply is used. In that case, it will be recharged automatically at the same time.
- When operating on battery power
Press  on the keyboard to turn on the Electrocardiograph, and then the battery indicator will be lit, and the battery symbol will be displayed. The logo will be displayed on the LCD screen.
Because of the consumption during the storage and transport of cars, the battery capacity may not be full. If the symbol  and the hint information *Battery Weak* are displayed, the battery capacity is low; please recharge the battery first.

CAUTION


1. When using a new battery, after the first charge is fully charged, it can be charged for another 20-30 minutes to reach full capacity.
2. When using a new battery for the electrocardiograph, it needs to be charged and discharged for a cycle before the fuel gauge can accurately display the battery level.

CAUTION


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

To turn off the Electrocardiograph:


- When operating on AC power

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

- When operating on battery power

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

NOTE:

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

3.5 Loading Recorder Paper

SE-1200 Pro&SE-1201 Pro use folded thermal recording paper. When the paper is not installed or when the paper is used up, the system will prompt No Paper, reminding the user to install or replace the recording paper. For more details, see chapter 9, *Error Messages*.

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 paper pack. 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 entrance 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 the paper for the convenience of tearing.

NOTE:

1. When the folded thermal paper is used, the paper roller is unnecessary and must be taken out.
2. The two moving parts should be removed when using paper of 215mm in width.
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

Ensure that the recorder paper is installed in the center of the recorder. The paper edge is parallel with the casing edge in the direction of the advancing paper to avoid paper deviation or damage to the paper edge.

Chapter 4 Basic Operation Guidance

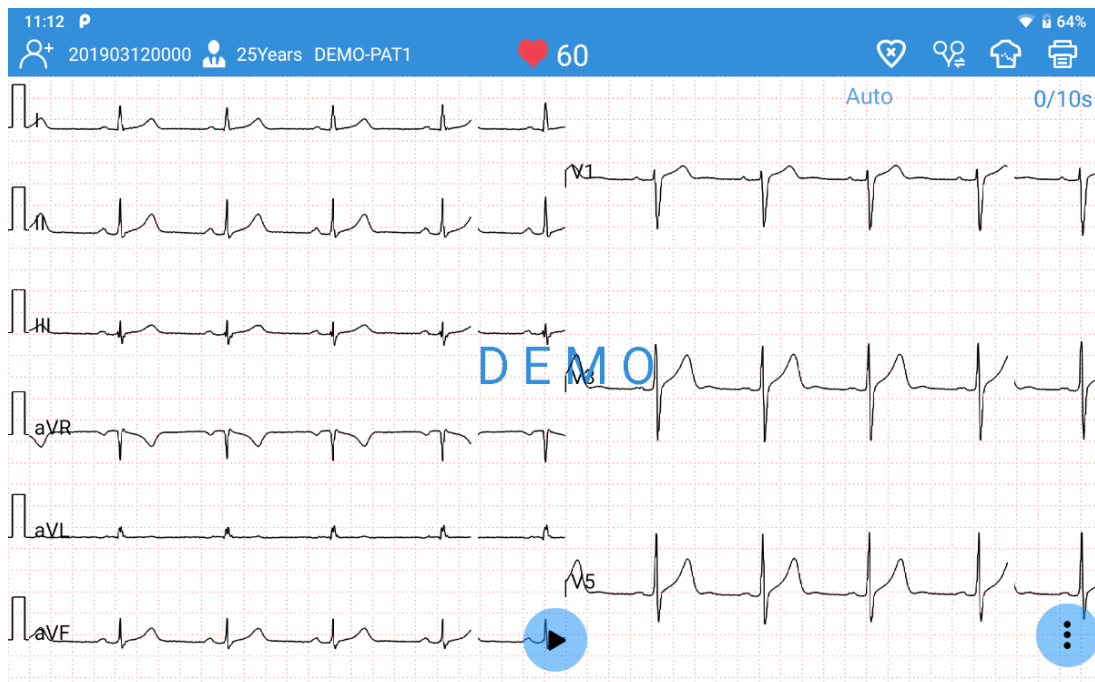
4.1 Login

If you have set a user name and login password, see the 8.7 user settings for details. After powering on, you need to enter the user name and password on the login interface. If you do not set up a user log-in, you will enter the reservation interface directly after powering on.









4.2 ECG recording

The recording method varies depending on the type of ECG to be recorded. This chapter describes how to record the following ECG types: standard ECG (including rhythm ECG).

ECG recording screen

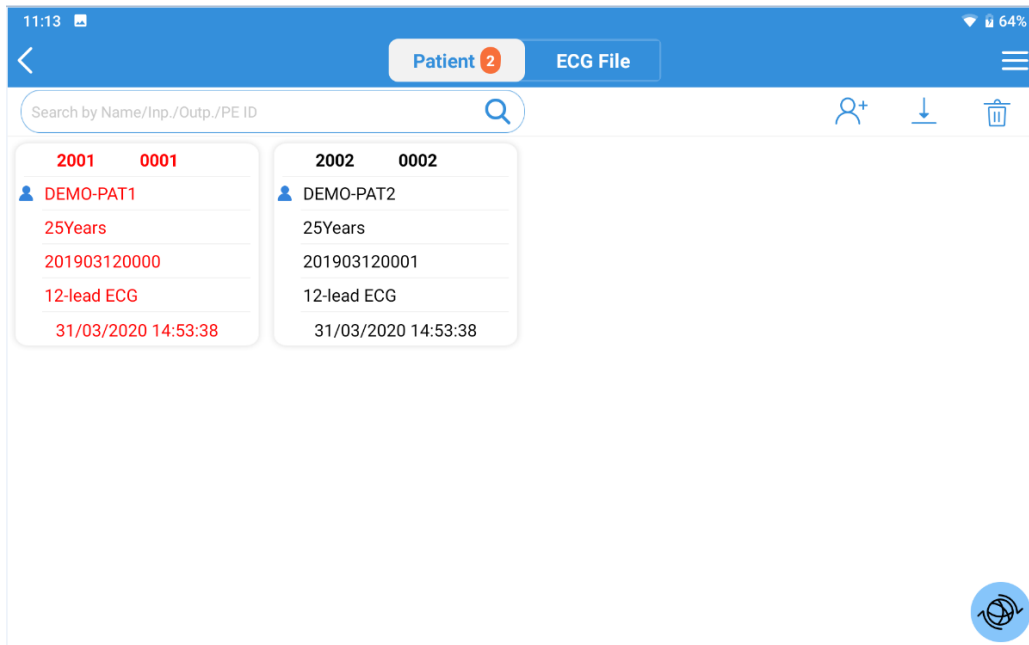










Button/Icon	Description
	Real-time heart rate. It automatically updates during ECG recording.
	Display the pacing spike when the SE-1200 Pro&SE-1201 Pro ECG detects a pacemaker pulse. If you don't need to see the pacing spike, tap on this icon to turn it off.
	Electrode placement locations.








	<p>Start or stop ECG recording.</p> <p>NOTE: SE-1200 Pro&SE-1201Pro can record up to 1,800-second ECGs.</p>
	<p>Re-acquire ECGs.</p>
Auto	<p>Recording mode, including Auto and Manual. Tap on it to toggle between the two modes.</p> <p>In the Auto mode, the system will acquire ECGs at the set time and then print a report. If the user stops recording before the time, the system will print the last 10s of ECG.</p> <p>The system will not stop recording or printing ECGs until you tap the stop button in the Manual mode.</p>
	<p>This icon provides eight setting options. Tap the icon again to hide these options.</p>
	<p>Gain.</p> <p>Options are: 1.25 mm/mV, 2.5 mm/mV, 5 mm/mV, 10 mm/mV, 10/5mm/mV and 20 mm/mV. The default gain is 10mm/mV.</p>
	<p>Filter. Options are: 25 Hz, 35 Hz, 45 Hz, 75 Hz, 100 Hz, 150 Hz, 270 Hz, 300 Hz, and 350 Hz. The default filter is 100Hz.</p>
	<p>Speed. Options are: 5 mm/s, 12.5 mm/s, 25 mm/s, and 50 mm/s. The default speed is 25mm/s.</p>
	<p>12 lead (Standard or Cabrera).</p>
	<p>Record rhythm ECGs. Swipe the screen left or right to toggle between single-lead and three-lead rhythm strips.</p>

4.3 Patient Tab

The **Patient** tab displays all the patients that have ordered an ECG test. If patients' priority is urgent, they will be listed at the top, and their information will be displayed in red.




Button/Icon	Description
	Return to the previous menu.
	Display the on-screen number of patients to be tested. This number updates in real-time.
	This icon provides the following options: sequence setting, filtering setting, download setting, and order server.
	Switch to another user account. This button is visible when user login is enabled in system setting > user setting.
	Male
	Female
	Gender unknown
	Search for a patient. Fuzzy search is supported.

	Enter new patient information.
	Delete patient information.
	Download batches of patient information from the PC. NOTE: A maximum of 200 latest orders can be downloaded from the server.
	Activate SE-1200 Pro&SE-1201Pro ECG's infrared scanner to scan the barcode to retrieve the Outpatient / Inpatient / PE ID. Tap this icon again to stop scanning.
	Download the specific patient information from the PC. You need to enter the default keyword for order querying to download the information with the order. For details, see section 4.5, <i>Retrieving Orders from Server</i> .
	Disable the filter when it is used to filter the patient information.
	STAT ECG.


4.4 New Patient Information

4.4.1 Manually Entering Patient Information

Tap  in the **Patient** tab. A **new Patient** window will open. Enter patient information, select an ECG test, and set the priority. Tap **Save**. The patient is available now in the **Patient** tab.

4.4.2 Scanning a Barcode (Option)

Infrared (IR) scanning

Tap  in the **New Patient** window. The electrocardiograph will load the Outp./Inp./PE ID.

Note: 1200Pro does not support infrared scanning.

Scanning a barcode

Connect the barcode scanner to the USB port on the left side of the electrocardiograph. Scan the barcode in the Patient tab or the New Patient window for each new patient. The

patient data will be loaded and displayed in the **Patient** tab. You have to configure the barcode before scanning to get the correct data. For information, see 7.3 *Patient Information Setting*.



4.4.3 Barcode scanner



1. Configure the barcode scanner.
2. For information about configuring the barcode scanner, please contact the manufacturer or your local distributor.
3. Connect the barcode scanner to the USB interface on the right of the electrocardiograph.
4. Open the Patient Information dialog box, and scan the patient's barcode with the barcode scanner. The patient information will appear in the text box.

NOTE:


- Only bar code readers recommended by the manufacturer can be used.
- One-dimensional scanner: Motorola LS4208 and ZEBRA DS2208-HC0000BZZRW.
- Two-dimensional scanner: Honeywell Xenon1900GSR, Honeywell 1950GSR-2-INT, Newland NLS-HR22+, and Newland NLS-HR32-SR.

4.5 Retrieving Orders from Server

1. Tap  In the **Patient** tab. Select **Order Server**. Enter the IP or URL of the server and tap **OK**.
2. Tap  again. Select **Download Setting**. The following window opens.
 - a) Turn **Order Retrieve** on.
 - b) Select the **Default keyword for order querying** from the drop-down menu.
 - c) Type the **Order Date**, **Department**, or **Exam Room** as appropriate.
 - d) If needed, configure these settings: **Auto-Download** and the downloading interval, **Check the patient information before ECG sampling**, **Order Date**, **Department**, **Exam Room**.
 - e) When finished, tap **OK**.
3. Single download:

Tap  , and the **New Patient** window opens. Enter the keyword for order querying you have set up in step 2. Tap  the system will download patient data with the order from the server. The patient data is now available in the **Patient** tab.

 - Alternatively, batch download:

Tap  to download a batch of orders from the server. After download, patient data with the orders will be listed in the **Patient** tab. You can also slide down the tab for an update.

NOTE:





- To retrieve orders from the server, you need to purchase and install EDAN's data management software on your PC.
- Use the recommended barcode scanner.

4.6 Editing Patient Information

On the patient tab, select patient information that you want to edit and then click Edit to edit patient information.

4.7 Deleting Patient Information

To delete patient information:

- Tap and hold the patient information you want to delete. Select Delete from the pop-up menu. The selected one is deleted.
- Alternatively, tap  in the Patient tab. Tap on one or more patients' information you want to delete. Once selected, the square around the patient data will turn blue. Tap  again. The selected ones are deleted.
- If you want to delete all the available patient information at a time, Tap  first and then All. Tap  again.

4.8 Searching Patient information

1. Enter one of the following wholly or partially into the search bar:
 - Patient name
 - Outpatient ID
 - Inpatient ID
 - Physical examination ID
 - ID number
2. Tap. Patient information that meets the search criteria is displayed.

4.9 Sorting/Queuing Patient Information

To sort out patient information:

1. Tap  in the **Patient** tab. Select **Filtering Setting** from the pop-up menu.




2. Configure the setting.
3. Enter the sorting criteria, e.g., Outp./Inp./PE ID, name, request ID, etc. Tap **OK**.
4. Patient information that meets the criteria is displayed. To cancel sorting, tap ↶
Patient information before sorting is displayed.

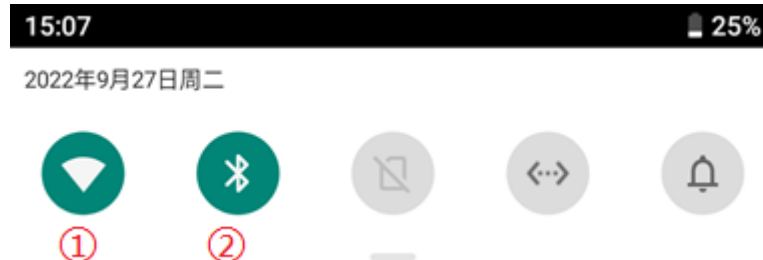
To queue patient information:

1. Tap ☰ in the Patient tab. Select Sequence Setting from the pop-up menu.
2. Configure the setting. The queuing criteria include order date and patient name. Up and down, two sequences are available, which means ascending and descending.
3. When you are done, tap OK. Patient information is displayed in your desired order.

4.10 WIFI and Bluetooth

To open and close the function of WIFI and Bluetooth, the steps are as follow:


1. After sliding down the top of the screen, you can choose what you want to open, see the ①WIFI  (open) and ② Bluetooth  (open). click  again, it will turn gray, besides, long press the icon will enter the relevant setting interface.



2. After WIFI connection, patient information can be downloaded from ECG server and ECG data can be transmitted to ECG server.
3. After Bluetooth connection, you can share the report at the form of PDF, JPG, BMP and PNG at the analyzing interface.

4.11 Switching to another User Account

If two or more user accounts have been set up, you may need to switch to another user account.





1. Open the Patient tab.
2. Tap on the icon  in the upper right corner of the tab.
3. A message prompts you to log out. Select OK.
4. The login window opens. Enter the user name and password to log in.






Chapter 5 ECG File Management

Click the **ECG File** tab to manage the patient's ECG data. After the ECG data is recorded, it will be saved to the **ECG File** regardless of whether it is immediately analyzed. The **ECG File** of the SE-1200 Pro&SE-1201 Pro can store the data of 10s DAT examination with files larger than 10W.

The screenshot shows a mobile application interface for ECG file management. At the top, there is a blue header with a back arrow, a search bar, and two tabs: 'Patient' and 'ECG File'. Below the header is a search bar with the placeholder text 'Search by Name/Inp./Outp./PE ID' and a magnifying glass icon. To the right of the search bar are several icons: a funnel (filter), a cloud with an arrow (retrieve diagnosis), a pen (signature), a document with a checkmark (download), an upload arrow, and a trash can. Below the search bar is a table with the following columns: Serial No., Patient ID, Name, Age, Gender, Department, Exam. Type, and Exam. Time. The table contains two rows of data. At the bottom of the interface, there are four filter buttons: 'All(2)', 'To Upload(2)', 'Diagnosed(2)', and 'To Print(2)'. The 'All(2)' button is currently selected.

Serial No.	Patient ID	Name	Age	Gender	Department	Exam. Type	Exam. Time
1	202003311452330001	DEMO-PAT2	30Years	Female		12-lead ECG	31/03/2020 14:53:38
2	202003311502290002	DEMO-PAT1	25Years	Male		12-lead ECG	31/03/2020 15:04:26

Button/Icon	Description
	Search for ECGs that have been recorded. Enter the keyword to search, and the system will display the ECGs that meet the criteria. Fuzzy search is supported.
	Filter ECGs. You can filter ECGs by using the criteria such as uploaded or not, diagnosed or not, printed or not, and the exam time.
	Retrieve diagnosis. You can get the latest ECG measurements and diagnoses for all ECG files in this tab from the server.
	Get or update your signature. You can download doctors' electronic signatures from the server. You can also update doctors' signatures stored in your electrocardiograph with this button.

	Import ECGs from U disk.
	Export ECGs to the USB memory device. You can select the file format for export. See section 8.2 <i>Print and Storage Setting</i> .
	Upload ECGs to the server. You can choose one or more or even all ECGs to upload at a time.
	Delete ECGs. You can choose one or more or even all ECGs to delete at a time.
Edit	<p>Modify the patient information in an ECG file. You can modify all patient information except the ID and exam items.</p> <p>Press and hold an ECG file. This button will appear.</p> <p>NOTE:</p> <p>If patient information such as names or gender is modified, the information elsewhere with the same ID number will be updated.</p>
Print	<p>Print a report for an ECG file. You can select the APP or WIFI printer.</p> <p>Press and hold an ECG file. This button will appear.</p>
Sync	<p>Retrieve diagnosis and doctor's signature for an ECG file.</p> <p>Press and hold an ECG file. This button will appear.</p>
All (2)	The number of ECGs stored in the electrocardiograph is 2.
To Upload (2)	The number of ECGs to be uploaded to the server is 2.
Diagnosed (2)	The number of ECGs of which diagnosis is retrieved from the server is 2.
To Print (2)	The number of ECGs to be printed is 2.
	Return to the main menu.

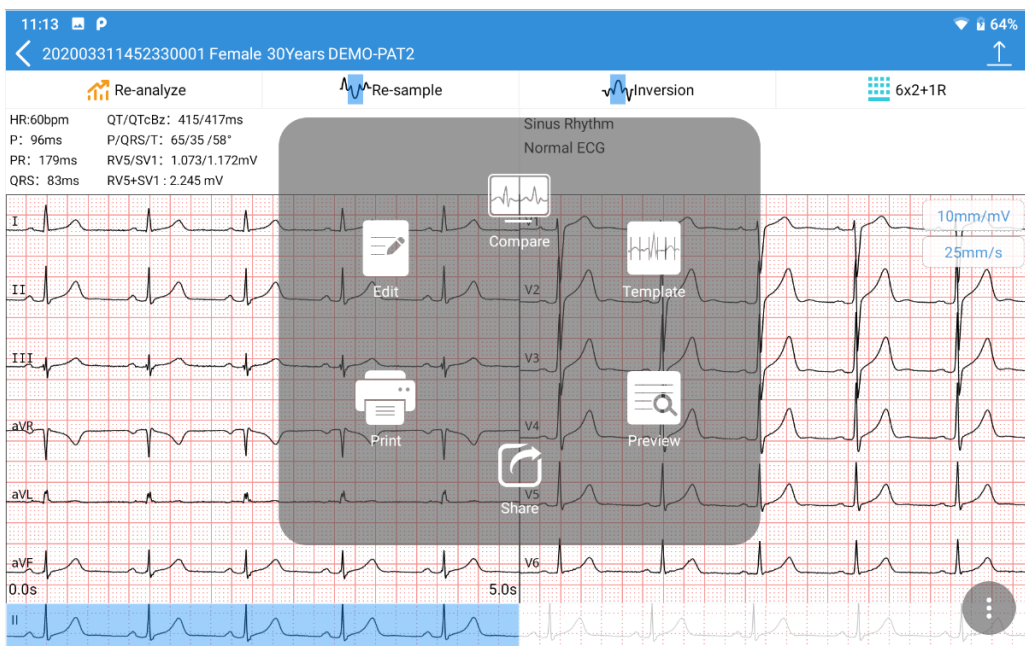
Chapter 6 Editing ECG

The system can be configured to analyze ECGs after recording automatically. To manually activate ECG data analysis, tap an ECG in the **ECG File** tab. Then the ECG Analysis screen is displayed. You can edit, measure, diagnose, and compare ECGs on this screen. The analysis screen is varied according to the ECG type. The following figure shows the analysis screen of standard ECG as an example.

NOTE: The instructions in this chapter assume that the patient has been adequately prepared and the electrodes have been placed correctly for the selected ECG test.

6.1 ECG View

To switch lead configuration, tap the configuration, e.g., **6x2+1R**, on the top right of the screen.



Slide the ECG traces left or right to view the 10s waveform. The time below the ECG traces indicates the onset and offset of the on-screen waveform.

To zoom in on the waveform, double tap on the waveform of a lead. The magnification page opens. Double-tap the page, and continue to zoom in. The ECG waveform can be magnified up to 5 times. Double-tap the page to return to a one-time size when reaching its maximum. To exit magnification, tap on the **X** in the upper right corner.

If the ECG waveform is not satisfactory, tap **Re-sample** to acquire ECG again.

If a lead is in the wrong location, tap **Inversion** to correct it.

6.2 ECG Measurement

Zoom in on an ECG

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

Manual Measurement

To measure the 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 the measurement.

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

6.3 Auto Measurement

SE-1200 Pro&SE-1201 Pro ECG provides auto measurements of HR, P wave duration, PR interval, QRS complex duration, QT/QTc, frontal P/QRS/T axis, RV5/SV1, and RV6/SV2 on the ECG Analysis screen. Any measurement out of the specified range will be displayed in red.

6.4 Auto Diagnosis

SE-1200 Pro&SE-1201 Pro ECG provides an auto diagnosis of the ECG in the Analysis screen. Slide the diagnosis portion up and down to see all. If serious diseases are diagnosed, they will be displayed in red.

6.5 Modifying Measurement Parameters

To edit auto measurements, tap on it. The Modify Measurements window opens. Enter the values, and tap OK to save your modifications. The measures will be automatically updated.

The measuring parameters are listed below.

Parameter	Description
HR (bpm)	Heart Rate
P (ms)	P wave duration
PR (ms)	P-R interval
QRS (ms)	QRS complex duration
QT/QTc (ms)	Q-T interval / Normalized QT interval

	For calculation of QTc, select System Setting > Parameter Setting > QTc Formulas. The default formula is Bazett. You can change the formula, but this takes effect only for the ECG analysis done after this change.
P/QRS/T (°)	The axis of the P wave, QRS complex, and T wave in the frontal plane
RV5/SV1 (mV)	The amplitude of the R wave of V5 lead/the amplitude of the S wave of V1 lead
RV5+SV1 (mV)	The amplitude of the R wave of V5 lead plus the amplitude of the S wave of V1 lead
RV6/SV2 (mV)	The amplitude of the R wave of V6 lead/ Amplitude of the S wave of V2 lead It is visible only when enabled.
RR/PP	RR interval / PP interval It is visible only when enabled.

6.6 Modifying Diagnosis

Editing Diagnosis


To edit auto diagnosis:

1. Tap on the auto diagnosis portion. The Auto Diagnosis window opens.
2. Select the diagnostic statement you want from the list, or manually enter comments in the textbox. The list allows you to add or delete diagnostic messages.
3. When you exit the analysis screen, select whether to save your modification or not. You can also upload the diagnosis to the server by tapping “Submit Diagnosis” in the upper right corner.

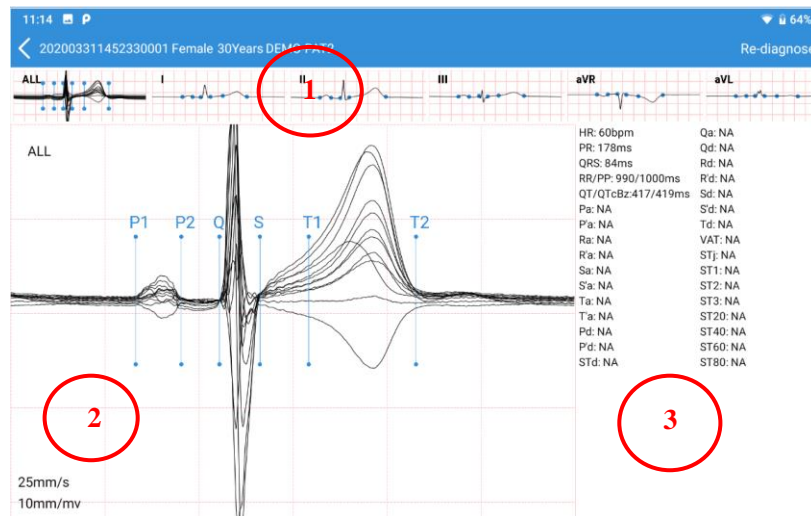
6.7 Re-analysis

Tap **Re-analyze**. The 10s ECG waveforms from the present onset will be re-analyzed. Auto measurements and diagnosis will be automatically updated.

6.8 Averages View

SE-1200 Pro&SE-1201 Pro ECG provides a Template (averaged complexes) to analyze ECG waveforms. To open Template, tap on the  icon (three vertical dots) at the right lower corner of the Analysis screen—select Template from the pop-up menu. The

Averages screen is opened as below.



① Averages thumbnail

The averaged complexes of standard leads and ALL are displayed. Slide the thumbnail to switch from one lead to another. Tap on one lead to display its magnified averages

② Magnified averages


Six measurement lines are matched to six measurement points. They are P1 (onset of P wave), P2 (offset of P wave), Q (onset of the QRS complex), S (offset of the QRS complex), T1 (onset of T wave), and T2 (offset of T wave). Tap and slide a measurement line of an averaged complex, and the same line of other averages will be automatically moved. After moving these lines, tap Re-diagnose on the Averages screen to save measurements. The measurements and diagnosis will be automatically updated. Double-tap this portion, and a measurement pane will pop up. Slide the pane lines to get real-time QRS duration, amplitude, and HR.

③ Detailed measurements of one lead.


Slide left to display the measurement results of all leads.





6.9 Comparing ECGs

SE-1200 Pro&SE-1201 Pro ECG allows you to compare ECGs with the same patient ID.

1. Open the Analysis screen.
2. Tap . Select **Compare** from the menu.
3. Select the ECGs you want to compare from the pop-up window.
4. Tap **Compare**. You can compare the ECG waveforms or averaged complexes.

Chapter 7 Printing ECG Reports

Tap  on the Analysis screen, and select **Print** from the menu. After clicking print, the system will automatically print. Before printing for the first time, you need to set up the printer connection. The USB direct-connected printers are recommended to use HP 1112, HP2132, HP Desk Jet 4729, HP Desk Jet 3638, HP LaserJet Pro M202DW, HP M401, HP LaserJet P2035, HP 1020P, HP LaserJet Pro M403D. WIFI printing is recommended to use HP LaserJet Pro M202dw and, HP Desk Jet 3638, Samsung Xpress M2021w.



In manual mode, click the /  in the Analysis screen, and the system will automatically print a report. Click the button /  again and the system will stop printing the report.

NOTE:

- WIFI and APP printers work only under network connection.
- Do not change the default print direction if you choose a WIFI printer. Otherwise, ECG waveforms may appear distorted and compressive.
- Contact the manufacturer or your local distributor for information on setting up the WIFI connection with the printer.
- Ensure that the printer connected is the type you select in the setting. Otherwise, an error may occur.

Chapter 8 Transmitting and Exporting ECGs

To transmit ECGs to server:



1. Log in to the FTP receiving software (including EDAN's SE-1515) on your PC.
2. Turn on electrocardiograph.
3. Configure the transmission setup.
 - 1) Find **Ethernet Setting** shortcut in the drop-down menu.
 - 2) Turn on the **Ethernet** switch
 - 3) Set **Local IP**, **Gateway**, and **Subnet Mask**. Or alternatively, select **Auto Get IP**.
 - 4) Save Settings
4. Configure SFTP server in System Setting > Transmission Setting > Server Setting.
 - 1) Set the **Order Server**, **Server Address**, **Port number**.
 - 2) Set the **SFTP Server**, **Server Address**, **Port number**, SFTP User Name, **SFTP Password**.
 - The **SFTP User Name** and **SFTP Password** should allow access to the FTP server.
 - The **SFTP Path** should lead to the subdirectory available under the FTP root directory.
5. Return to ECG File tab.
6. Tap . Select the ECGs you want to transmit. Or tap **Select All** to select all the ECGs.
7. Tap  again to upload the ECGs to the server.

NOTE:

1. You can transmit ECGs to the server with TCP/IP protocol via Ethernet, WIFI or mobile network (4G).
2. Ethernet is the primary transmission method. When the wired network is not available, you can choose WIFI or 4G to transmit ECGs.
3. Correct sever Setting are a prerequisite for transmitting ECGs.
4. For more information about FTP server, consult your network administrator.
5. Please refer to A1.5 Performance Specifications for WIFI and 4G specifications.
6. Do not talk on the phone or send messages when you are using your 4G card for ECG upload. Otherwise ECG transmission will be affected.
7. If the server is unavailable, the ECGs transfer will fail, and ECGs that fail to transmit will be flagged. The ECGs saved in device can be transmitted again after the server is

restored.



To export ECGs to a USB storage device:

1. Connect a USB disk to the left side of electrocardiograph.
2. Open ECG File tab.
3. Tap . Select the ECGs you want to export. Or tap **Select All**.
4. Tap  again to export the ECGs to the USB storage device.

Chapter 9 System Setup

To set up the SE-1200 Pro&SE-1201 Pro ECG system, tap System Setting in the Main Menu. Options underlined are default settings. You need to tap Save in each setting window to save your changes if available.

9.1 Sampling Setting

Item	Description
Sampling Mode	Choose from: <u>Real-time sampling</u> or Pre-sampling Select Pre-sample to initiate the acquisition of ECG data before you tap  . The latest 10 seconds of ECG data will be recorded. Select a Real-time sample to initiate the acquisition of ECG data after you tap  .
Sampling Time	Set the duration for real-time acquisition, single-lead or three-lead rhythm ECG acquisition. Enter a value between 10s and 1,800s. The default is 10s for real-time acquisition, the 60s for single-lead rhythm, and 20s for three-lead rhythm ECG. NOTE: The pre-sampling time is fixed at 10s.
Intellectual Sampling	If selected, the electrocardiograph automatically acquires ECGs when it detects no poor ECG signals in 5 seconds. The default setting is Off . NOTE: This option applies to the Auto mode of standard ECG.
AI Detection	Pace If selected, the system asks you if to display the pacing spike or not when it detects a pacemaker pulse. NOTE: This option applies to the Auto mode of standard ECG.
Enter the Analysis screen when sampling finishes	If selected, the system automatically opens the ECG Analysis screen when sampling finishes. The default setting is On .
Preview	If selected, the system opens the report preview page when the ECG analysis finishes. The default setting is Off .
Lead Mode	Choose from: Pediatric mode , <u>12-Lead</u>
Rhythm Leads	Select the leads to be recorded for rhythm strips. The default is lead

II for RHYT1, lead V1 for RHYT2, and lead V5 for RHYT3.

Reverse Electrode Hint If selected, the system prompts you if the electrodes are connected in the opposite position. The default setting is **On**.

9.2 Print and Storage Setting

Item	Description
Print Report	Print ECG report after recording. The default setting is Off.
Auto Measure	If selected, the system provides you with auto measurements after ECG recording. The default setting is On.
Auto diagnosis	If selected, the system provides you with auto diagnosis after ECG recording. The default setting is On.
File Format	Choose from: SCP, FDA-XML, DICOM (Encapsulated PDF), DICOM (ECG Waveform), PDF, JPG, BMP, PNG, and TIFF . Determine the format of ECG files that are transmitted to the server. If not selected, ECG files in DAT format will be transferred.
Storage Location	Choose from: <u>Local memory</u>, External SD card .
External storage is forbidden	Choose from: <u>On</u>, Off .
Report Format	Choose from: Pediatric mode: 3x3, <u>6+3</u>, 9x1 12-lead: 3x4+1R, <u>6x2+1R</u>, 12x1 . NOTE: In the case of an external printer, only the default report formats are available.
Report Channel	Print Define the channels to be printed in the ECG report. The options are varied depending on the lead mode. 12-lead: 3 Channels, 6 Channels, 12 Channels, and Customize. 9-lead: 3 Channels, 6 Channels, 9 Channels, and Customize. When you select "Customize", you can choose the leads for 3 or 6 channels.

Recording Sequence	Choose from: Sequential , Simultaneous . “Simultaneous” prints ECG data captured simultaneously for all lead groups. “Sequential” prints ECG data captured at sequential intervals for each lead group in turn.
Recording Device	Choose from: Thermal printer , WIFI printer , USB printer . If a thermal printer is not configured, you can connect an external printer.
Speed	Choose from: 5mm/s、6.25mm/s、10mm/s、12.5mm/s、25 mm/s、50 mm/s。
Gain Setting	Choose from: 1.25 mm/mV , 2.5 mm/mV , 5 mm/mV , 10 mm/mV , 20 mm/mV , 10/5 mm/mV .
AGC	If selected, the gain will be automatically adjusted. The default setting is Off.
Baseline Adjustment	Choose from: <u>Horizontal</u> , <u>Auto</u> , Off
Paper Marker	Choose from: Off, <u>ON</u>

9.3 Patient Information Setting

Item	Description
Patient Source ID	Choose from: Inpatient ID , Outpatient ID , Physical Examination ID .
Patient ID	Choose from: Auto , Manual Select Auto , and the system automatically generates a patient ID according to the test date. Select Manual , and you can manually enter a patient ID in the New Patient window.
Default Patient ID	Enter four or fewer English letters or numbers as the prefix of patient ID. The default setting is blank.
First/Last Name	If selected, first name and last name will be displayed in two columns in the New Patient window. If not selected, only the name is displayed in this window. It is the default setting.
Age/Birthdate	Choose from: Manual , Birthdate Select Manual , and you need to enter the patient's age in the

		textbox.
		Select Birthdate . You can slide the box to select the birth year, month, and day. The system will automatically calculate the age of the patient.
Height/Weight		Choose from: Off , cm/kg , inch/lb .
BP		Choose from: Off , mmHg , Kpa
Hide patient data viewable		Choose from: Off , On If On , patient name, age, and gender will be encrypted in the Patient tab and ECG File tab. Only the first letter of the first name is displayed, age is shown as “*”, and gender is unknown.
Other Settings	Display	You can determine whether the New Patient window displays the following options. Selected means to show. ID: Selected by default. Race: Not selected by default. Medical History: Not selected by default. Medication: Not selected by default. Ward: Not selected by default. Department: Selected by default. Room No.: Selected by default. Request ID: Selected by default. Exam Room: Selected by default. Exam Item: Selected by default. Technician: Not selected by default. Physician: Selected by default. Clinical Diagnosis: Not selected by default. Customize: You can add what you want to display in the New Patient window.

Barcode Setting	<p>Configure the start and end addresses, the male and female codes, an encoding mode, and then tap Save.</p> <p>NOTE:</p> <p>If not configured, the results of barcode scanning may be incorrect.</p>
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9.4 Filter Setting

Item	Description
Baseline Filter	<p>ECG traces can contain some baseline wander caused by movement. You can reduce this wander of the baseline by applying a baseline filter. When you use this filter, the recorded signal is not changed.</p> <p>Choose from: 0.01Hz, 0.05Hz, 0.32Hz or <u>0.67Hz</u>.</p> <p>This setting is the lower limit of the frequency range. The higher the settings, the more the filter smooths out the wandering baseline. When the P wave duration exceeds this setting, the system will prompt you to P wave widen.</p>
EMG Filter	<p>Muscle noise in an ECG signal hides low amplitude signals that may be important for interpreting an ECG. You can remove this noise with an EMG filter.</p> <p>Choose from: <u>Off</u>, 25Hz, 35Hz, or 45Hz.</p> <p>ECG signal whose frequency is higher than this setting will be attenuated.</p>
Low pass Filter	<p>This filter controls the bandwidth of input signals.</p> <p>Choose from: 75Hz, <u>100Hz</u>, 150Hz, 270Hz, 300Hz, or 350Hz.</p> <p>ECG signal whose frequency is higher than this setting will be attenuated.</p> <p>NOTE: The low pass filter is effective only when the EMG Filter is Off.</p>
AC Filter	<p>This filter removes any AC interference from the ECG.</p> <p>Choose from: Off, <u>50Hz</u>, 60Hz.</p>

9.5 Transmission Setting

Item	Description
Device ID	Enter the device ID with up to 30 English numbers or letters.

Auto Upload	Choose from: On , Off . When On , the system will automatically transmit ECG files to the server when the recording finishes.
Delete file after uploading	Choose from: On , Off . When On, the system will automatically delete ECG files from local memory when the files are automatically or manually transmitted to the server.
Time Synchronization	Choose from: On , Off . When "On", the system will send a synchronization request to the server, and the electrocardiograph retrieves orders from the server simultaneously. And the time sent by the server is taken as the current system time.
Encrypted Transmission	Choose from: On , Off . When On, the system will use encryption protocol during ECG transmission. SFTP and SSL protocols will be employed for such transmission. Don't hesitate to contact the manufacturer if you need to import another certificate for encrypted transmission.
MAC Address	View the MAC address of the device.
Server Setting	Order Server: set the address and port number of the server that provides orders for the system. The port number allows a maximum of five numbers for entry. FTP or SFTP Server: set the address, port No., user name, and server password that receives ECG files from the system. The communication port allows a maximum of five numbers for entry. Connection test: checks if the server is connected. NOTE: For information on how to configure the network, consult your network administrator.
Transmission Commitment	Choose from: On , Off . When On, the server will respond whether it has received ECG files or not to the system in each upload. This option is at the bottom of the server setting mentioned above.

9.6 Parameter Setting

Item	Description
Axis calculation method	Choose from: Area Method or <u>Amplitude Method</u> .
Tachycardia (greater than)	Enter a heart rate. The default value is 100 bpm.
Bradycardia (less than)	Enter a heart rate. The default value is 60 bpm.
P Wave Normal Duration	Choose from: 110ms or <u>120ms</u> . When the P wave duration exceeds this setting, the system will prompt you to P wave widen.
Algorithm Sensitivity	Choose from: <u>Normal</u> or Weak . 30us~2.0ms
Serious Diseases Hint	Choose from: <u>On</u> , Off . When On, diagnosis with severe illnesses will be marked with “▶◀” in the ECG report.
QTc Formulas	Choose from: <u>Bazzet</u> , Fridericia , Framingham , Hodges , and QRS . Bazzet, Fridericia, Framingham, Hodges, and QRS are displayed in the ECG report as QTcBz, QTcFd, QTcFm, QTcHd, and QTcQRS, respectively.
RV5+SV1	This measuring parameter will be displayed in auto measurements, and ECG reports if selected. It is selected by default.
RV6/SV2	This measuring parameter will be displayed in auto measurements, and ECG reports if selected. It is not determined by default.
RR/PP	This measuring parameter will be displayed in auto measurements, and ECG reports if selected. This is not determined by default.
Pacemaker	Choose from: <u>Low</u> , High .

 Detection Rate

Maximum Signal Choose from: **±5 mV**, **±10 mV**, **±20 mV**.
Range

9.7 User Setting

You have to enter a password before configuring the user setting.

Item	Description
User Login	Choose from: <u>On</u> , Off . User login is selected by default.
Add User	Please enter the user's real name, define their user name and password for login to SE-1200 Pro&SE-1201 Pro ECG. The user can also be given the authority to diagnose by ticking the check box before the diagnostic power.
Modify User	Modify user name and (or) password. Select a user from the user list for modification. You can also update user information by tapping Sync .

9.8 Others

Item	Description
DEMO Mode	Choose from: <u>Off</u> , Normal ECGs , Abnormal ECGs . Patient information can neither be deleted nor retrieved from the server when enabled. ECG data acquired is not stored. You need to enter the password "006363" to open the DEMO mode.
Hospital Name	Enter up to 90 English letters to define the hospital name. This name will appear in the title of the ECG report. File formats such as PDF, JPG, BMP, PNG, and TIFF are supported.
Administrator Password	Define the password required to access System Setting , the Patient tab (if selected), and the ECG File tab (if selected). Blank by default. Enter up to 13 letters or numbers or a combination of them to define the password.
Restore default factory settings	Clears the current settings and returns to the default. You need to enter the password to configure this setting.

Function Activation	Activate DICOM, SCP, FDA-XML, communications. Select the one you want to activate and enter the activation code. Communications here means retrieving orders from the server and uploading ECG data to the server.
Set System Time	Set or change the system time.
Language	Set the language according to your needs.

9.9 System Update


Item	Description
Device Model	Displays the model of the electrocardiograph.
Software Version	Displays the version of the software. You can upgrade the software if a new version is available...
System Version	Displays the version of the system. You can upgrade the system if a new version is available.
ECG Board Version	Displays the version of the ECG board.
SEMIP Version	Displays the version of the algorithm.
Upgrade APP by USB	Upgrade the software by connecting to a USB storage device. Please refer to the service manual or contact the manufacturer for more information.
Upgrade ECG Board by USB	Upgrade the ECG board by connecting to a USB storage device. Please refer to the service manual or contact the manufacturer for more information.
Upgrade system by U Disk	Support external U disk to upgrade system software.

9.10 System Maintenance

For the configuration of this setting, contact the manufacturer's maintenance personnel or your local distributor. Password is required to access this setting.

Chapter 10 Error Messages

Table 9-1 Error Messages and Causes

Message	Cause
Lead off	Electrodes fall off the patient, the patient cable falls off the unit, or a high polarization voltage occurs.
Network unavailable!	4G, WIFI, and Ethernet are off.
Network connection timeout! Please check the network.	The network signal is poor, and the network connection is failed.
Order server connection failed!	An IP address is wrong, or the server is off.
FTP connection failed!	An IP address is wrong, or the server is off.
Are you sure to stop sampling?	Tap  during the acquisition of ECG data.
Overload	The direct current offset voltage on an electrode is too high.
Inversion	Reversal of left and right arm electrodes?
No Paper	Recorder paper runs out or is not loaded.
Battery Weak	The battery is weak.
Transmitting fails	Data fails to be transmitted through Ethernet or WIFI.
Memory Full	There is no space for saving more records.

Chapter 11 Cleaning, Care, and Maintenance

Use only the EDAN-approved substances and methods listed in this chapter to clean or disinfect your equipment. The 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 healthcare professional's responsibility to ensure that the instructions are followed to ensure adequate cleaning and disinfection.

11.1 General Points

Keep your electrocardiograph and accessories free of dust and dirt. To prevent the device from being damaged, 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 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 hospitals, but cleaning agents or disinfectants that are not listed in this manual are not recommended. For example, dodecyl dimethyl ammonium bromide, which contains quaternary ammonium salt, may corrode the equipment and accessories.
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11.2 Cleaning

If the equipment or accessory has contacted the patient, cleaning and disinfection are

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.

WARNING

Before cleaning, unplug the electrocardiograph from AC power if connected. Disconnect with the ECG cables.

1. Wipe the device's exterior and accessories, including the main unit, sampling box, ECG cable, reusable electrodes, etc., using a clean, soft cloth dampened with a cleaning solution until no visible contaminants.
2. Remove residual cleaning solution with a fresh cloth or towel dampened with tap water until there is no visible cleaning solution.
3. Air-dry the device and accessories in a ventilated and cool place.

CAUTION

Any remainder of the cleaning solution should be removed from the device, sampling box, and ECG cable after cleaning.

11.3 Disinfection

To avoid permanent damage to the device, it is recommended that disinfection is performed when it is considered necessary according to your hospital's regulations. Clean the device and reusable accessories before they are disinfected.

1. Unplug the device from AC power if connected. Take out its battery. Disconnect the ECG cables. In the case of the sampling box, disconnect it from the DE18 cable and the lead wires.
2. Wipe the device's exterior and accessories, including the main unit, sampling box, ECG cable, reusable electrodes, etc., using a soft cloth dampened with diluted disinfectant.

3. Remove the remaining disinfectant if appropriate with a dry cloth.

4. Air-dry the main unit/sampling box/ECG cable/reusable electrodes for at least 30 minutes in a ventilated and cool place.

The validated disinfectants for the main unit, sampling box, and ECG cables are:

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

The validated disinfectant for the reusable electrodes is:

- Isopropanol (70%)

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

CAUTION

1. As for disinfection methods, do not use high-temperature, high-pressure vapor, or ionizing radiation.
2. Do not use a chloric disinfectant such as chloride, sodium hypochlorite, etc.
3. Clean and disinfect reusable electrodes after each use.

WARNING

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

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

11.4 Care and Maintenance

CAUTION

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

11.4.1 Recharge and Replacement of Battery

1) **Capacity Identification**

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

2) **Recharge**

The electrocardiograph is equipped with a recharge control circuit together with the battery. When the unit is connected to the main 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 used for the first time. Battery recharge should be considered before the first use. When using a new battery, after the first charge is fully charged, it can be charged for another 20-30 minutes to reach full capacity.

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 battery's useful life 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. The battery of the same model and specification provided by the manufacturer must be used.
 2. The danger of explosion -- Do not reverse the anode and the cathode when installing the battery.
 3. When the battery's useful life is over, contact the manufacturer or the local distributor for disposal or disposal of the battery according to local regulations.
 4. Remove the battery from the electrocardiograph when the electrocardiograph isn't used for a long time.
 5. If the battery is stored alone and not used for a long time, we recommend that the battery be charged at least once every six months to prevent over-discharge.
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CAUTION

Consider a replacement if the battery has been fully charged and requires recharging after printing only a few ECGs.

11.4.2 Recorder Paper

NOTE: Recorder paper provided by the manufacturer should be used. Other papers 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 the 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.
- The thermal head may need to be cleaned if stains appear on the printed ECG report.

11.4.3 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.
- ◆ 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.

11.4.4 Maintaining Main Unit and 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 as described in the instructions for use.
- e) Test the protection earth resistance according to IEC/EN 60601-1: Limit: 0.1 ohms.
- f) Test the earth leakage current according to IEC/EN 60601-1: Limit: NC 500 μ A, SFC 1000 μ A.
- g) Test the enclosure leakage current according to IEC/EN 60601-1: Limit: NC 100 μ A, SFC 500 μ A.
- h) Test the patient leakage current according to IEC/EN 60601-1: Limit: NC a.c. 10 μ A, d.c. 10 μ A; SFC a.c. 50 μ A, d.c. 50 μ A.
- i) Test the patient auxiliary current according to IEC/EN 60601-1: Limit: NC a.c. 10 μ A, d.c. 10 μ A; SFC a.c. 50 μ A, d.c. 50 μ A.
- j) Test the patient leakage current under single fault condition with mains voltage on the applied part according to IEC/EN 60601-1: Limit: 50 μ A (CF).
- k) Test the actual 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. Checks should be recorded in an equipment log. If the equipment is not functioning correctly or fails any of the above tests, the equipment has to be repaired.

WARNING

1. Failure from the responsible individual hospital or institution employing this equipment to implement a satisfactory maintenance schedule may cause undue equipment failures and possible health hazards.
 2. Any severe incident concerning the device should be reported to the manufacturer and the Member State's competent authority in which the user and patient are established.
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Main unit

- ◆ Avoid excessive temperature, sunshine, humidity, and dirt.

- ◆ Put the dustproof coat on the main unit and sampling box after use and prevent shaking them violently when moving to another place.
- ◆ Prevent any liquid from seeping into the equipment; otherwise, the safety and the performance of the electrocardiograph and sampling box cannot be guaranteed.

ECG cable

- ◆ The 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. Hold the plug instead of the cable when connecting or disconnecting the patient cable.
- ◆ Align the ECG cable to avoid twisting, knotting, or crooking at a closed angle.
- ◆ Store the lead wires appropriately to prevent any people from stumbling.
- ◆ Once damage or aging of the ECG cable is found, replace it with a new one immediately.

Reusable electrodes

1. Electrodes must be cleaned after use and ensure no gel is left on them.
2. Keep suction bulbs of chest electrodes away from sunshine and excessive temperature.
3. After long-term use, the surfaces of electrodes will be oxidized because of erosion and other causes. By this time, electrodes should be replaced to achieve high data quality.
4. While usage will impact, it is expected that the electrocardiograph will be in service for ten years. Replace the ECG cable and reusable electrodes according to your actual use. It is recommended that you replace them once every year.

CAUTION

The device and accessories must be disposed of according to local regulations at the end of their service lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal.

Chapter 12 Accessories

Table recommend11-1Standard Accessories List

Accessory	Part Number
Power cord	01.13.036638
	01.13.037122
ECG Cable, Patient Cable (European)	01.57.471500
ECG Cable, Patient Cable (IEC)	01.57.471499
Adult Chest electrodes	01.57.040163
Adult Limb electrodes	01.57.040162
Recorder Paper	01.57.472248
Rechargeable Li-ion Battery, TWSLB-005	21.21.064149
AC-DC Adapter	21.21.064244

Table 11-2 Optional Accessories List

Accessory	Part Number
ECG Cable, Patient Cable (European)	01.57.471500
	01.57.107581
	01.57.107583
ECG Cable, Patient Cable (IEC)	01.57.471499
	01.57.107582
	01.57.107584
Bar Code Reader (One-Dimension)	01.23.068023
Bar Code Reader (Two-Dimension)	21.18.052311
LAN Cable	01.13.020096
Micro SD Card	01.17.052452

U Disk	01.18.052245
Conductive Paste	01.25.078047
ECG Lead Adapter	01.57.471866
Dusting Cloths	01.57.471026
Pediatric Chest Electrodes	01.57.040168
Pediatric Limb Electrodes	01.57.040169
Electrode Adapters	01.57.040172
Snap/Banana Socket Adapters	01.57.471864
MT-201 Trolley	83.61.361191
CA-100 Lead Wire Bracket	02.04.245388
	02.04.245398
Disposable Electrodes	01.57.471858
	01.57.471859
	01.57.471860
	01.57.471863

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

Chapter 13 Warranty and Service

13.1 Warranty

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

Suppose 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. In that case, EDAN will, at its discretion, repair or replace the defective part(s) free of charge. EDAN will not provide a substitute product when the defective product is being repaired.

13.2 Contact information

Contact your local distributor if you have any questions about maintenance, technical specifications, or malfunctions of devices.

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

Appendix 1 Technical Specifications

A1.1 Safety Specifications

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

Essential Performance

The main performance features are defined as:

- Defibrillation protection as specified in IEC60601-2-25;
- Amplitude and interval measurements as specified in IEC60601-2-25;
- Filters (including line frequency interference filters) as specified in IEC60601-2-25

A1.2 Environment Specifications

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

A1.3 Physical Specifications

Dimensions	SE-1201Pro: 298mm×258mm×82.5mm, ±5mm
Weight	SE-1201Pro: 4kg(excluding battery and recorder paper), ±0.3kg
Display	SE-1201Pro: 10.1" LCD full-touch screen, at a resolution of 1920x1200

A1.4 Power Supply Specifications

Mains Supply	Operating Voltage: AC 100~240V
	Operating Frequency: 50Hz/60Hz
	Output Power: 19V, 2.53A
Li-ion Battery	Typical Capacity: 2500 m Ah
	Recharge Time: ≤ 3 h
	Rated Voltage: 14.8V
	When the battery is fully charged, the SE-1200 Pro&SE-1201 Pro electrocardiograph can work for ≥4 H in auto mode (printing a report once every 2 minutes), the SE-1200 Pro&SE-1201 Pro electrocardiograph can work for ≥ 2 H in manual mode, and print 3*4+1R copies of reports automatically ≥ 250 copies. The battery takes just under 2 hours to charge from empty to 90%.

A1.5 Performance Specifications

Recording	Recorder	Thermal dot-matrix recorder
	Printing Density	8 dots per mm / 200 dots per inch (amplitude axes) 40 dots per mm / 1000 dots per inch (time axes, @ 25 mm/s)
	Recorder Paper	Folded thermal paper: 210 mm×140 mm
	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 Calculator	HR Range	30 bpm~300 bpm
	Accuracy	±1 bpm
ECG Unit	Filter	AC Filter: 50Hz / 60Hz / Off
		DFT Filter: 0.01Hz / 0.05Hz / 0.32Hz / 0.67Hz
		EMG Filter: 25Hz / 35Hz / 45Hz / Off
		Low pass Filter: 350Hz / 300Hz / 270Hz / 150Hz / 100Hz / 75Hz
	Leads Mode	9/12Lead
	Analog-to-Digital Converter	24 bits
	Sampling Frequency	64,000 /sec/channel
	Time Constant	≥5s
	Frequency Response	0.01Hz ~ 350Hz(-3dB)
	Gain	1.25, 2.5, 5, 10, 20, 10/5, AGC (mm/mV) (±5%)
	Speed	5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s, 50mm/s
	Input Impedance	≥100MΩ (10Hz)

	Input Circuit Current	$\leq 0.01\mu\text{A}$	
	Input Voltage Range	$< \pm 5\text{mVp-p}$	
	Calibration Voltage	$1\text{mV} \pm 1\%$	
	DC Offset Voltage	$\pm 960\text{mV}, \pm 5\%$	
	Noise	$\leq 12.5\ \mu\text{V p-p}$	
	Patient Leakage Current:	NC	$< 10\ \mu\text{A (AC)} / < 10\ \mu\text{A (DC)}$
		SFC	$< 50\ \mu\text{A (AC)} / < 50\ \mu\text{A (DC)}$
	Patient Auxiliary Current:	NC	$< 10\ \mu\text{A (AC)} / < 10\ \mu\text{A (DC)}$
SFC		$< 50\ \mu\text{A (AC)} / < 50\ \mu\text{A (DC)}$	
CMRR	$\geq 140\text{dB (AC ON)}$ $\geq 123\text{dB (AC OFF)}$		
Pacemaker Detection (single-channel)	Amplitude	$\pm 500\text{uV} \sim \pm 700\text{mV}$	
	Width	$30\text{us} \sim 2.0\text{ms}$	
	Sampling Frequency	80,000Hz, Rhythm Lead	
4G	Bands	FDD LTE: Band 2 , Band 4, Band 5, Band 7, Band 12, Band 17, all bands with diversity TDD LTE: Band 41, all bands with diversity	
WiFi	Radio Technology	802.11 a/ac/b/g/n	
	Modulation	DBPSK/DQPSK/CCK BPSK/QPSK/16QAM/64QAM,GFSK, $\pi/4$ -DQPSK,8-DPSK	
	Frequency Range	2.4GHz and 5 GHz 2412 MHz – 2462 MHz (2.4GHz) 5180 MHz – 5320 MHz (5GHz) 5745 MHz – 5825 MHz (5GHz)	

	Output Power	≤22 dBm (2.4GHz) ≤14 dBm (5GHz)
	Transmit rate	2.4GHz IEEE 802.11b: 1 Mbps to 11 Mbps DSSS IEEE 802.11g: 6 Mbps to 54 Mbps OFDM IEEE 802.11n: HT20 MCS7@17dB 5GHz IEEE 802.11a: 6 Mbps to 54 Mbps OFDM IEEE 802.11n: HT20 MCS0 to 7@16dB IEEE 802.11ac: VHT20 MCS8@15.5dB
Wi-Fi Quality of Service	Data security	WEP,WPA/WPA2 PSK,802.1x EAP encryption
	Application-layer delay	No requirement. It's not used in real-time.
	Application-layer reliability	No requirement. Application failure will be notified to the user immediately.
	Network interruption alarm	Network interruption and failure in the transmission is notified in Transfer interface.
Bluetooth	Modulation	GFSK, $\pi/4$ -DQPSK, 8-DPSK
	Frequency Range	2402 MHz – 2480 MHz
	Output Power	≤ 15 dBm

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

Appendix 2 EMC Information

Electromagnetic Emissions

Guidance and manufacturer's declaration - electromagnetic emission		
The SE-1200 Pro&SE-1201 Pro ECG is intended for use in the electromagnetic environment specified below. The customer or the SE-1200 Pro&SE-1201 Pro ECG user should ensure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The SE-1200 Pro&SE-1201 Pro ECG uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class A	The SE-1200 Pro&SE-1201 Pro ECG is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC/EN 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC/EN 61000-3-3	Complies	

NOTE:

The EMISSIONS characteristics of the system make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If used in a residential environment (for which CISPR 11 class B is usually required), the system might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Electromagnetic Immunity

Guidance and manufacturer's declaration - electromagnetic immunity			
The SE-1200 Pro&SE-1201 Pro ECG is intended for use in the electromagnetic environment specified below. The customer or the SE-1200 Pro&SE-1201 Pro ECG user should ensure 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	$\pm 2, \pm 4, \pm 6, \pm 8$ kV contact $\pm 2, \pm 4, \pm 8, \pm 15$ kV air	$\pm 2, \pm 4, \pm 6, \pm 8$ kV contact $\pm 2, \pm 4, \pm 8, \pm 15$ kV air	Floors should be wood, concrete or ceramic tile. If the floor is covered with synthetic material, the relative humidity should be 30%.
Electrical transient/burst IEC/EN 61000-4-4	AC port: ± 2 kV Signal port: ± 1 kV	AC port: ± 2 kV Signal port: ± 1 kV	The main power quality should be a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	± 0.5 kV, ± 1 kV for line to line ± 0.5 kV, ± 1 kV, ± 2 kV for line to ground	± 0.5 kV, ± 1 kV for line to line ± 0.5 kV, ± 1 kV, ± 2 kV for line to ground	The main power quality should be a typical commercial or hospital environment.
Power frequency (50 Hz / 60 Hz) magnetic field IEC/EN 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a specific location in a typical commercial or hospital environment.

<p>Voltage dips, short interruptions, and voltage variations on power supply input lines</p> <p>IEC/EN 61000-4-11</p>	<p>0 % U_T; 0.5 cycle</p> <p>At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°</p> <p>0 % U_T; 1 cycle</p> <p>and</p> <p>70 % U_T; 25/30 cycles)</p> <p>Single-phase: at 0°</p> <p>0 % U_T; 250/300 cycle</p>	<p>0 % U_T; 0.5 cycle</p> <p>At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°</p> <p>0 % U_T; 1 cycle</p> <p>and</p> <p>70 % U_T; 25/30 cycles)</p> <p>Single-phase: at 0°</p> <p>0 % U_T; 250/300 cycle</p>	<p>The main power quality should be a typical commercial or hospital environment.</p>
<p>NOTE U_T is the a. c. mains voltage before applying the test level.</p>			

Electromagnetic Immunity

Guidance and manufacturer's declaration - electromagnetic immunity			
The SE-1200 Pro&SE-1201 Pro ECG is intended for use in the electromagnetic environment specified below. The customer or the SE-1200 Pro&SE-1201 Pro ECG user should ensure 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 6V _{rms} ^{c)} in ISM bands between 0.15 MHz and 80 MHz	3V _{rms} 150 kHz to 80 MHz 6V _{rms} ^{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-1200 Pro&SE-1201 Pro ECG, including cables, than the recommended separation distance calculated from the equation applicable to the transmitter's frequency. Recommended separation distance $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC/EN 61000-4-3	3 V/m 80 MHz to 2.7 GHz See Table 1.	3 V/m 80 MHz to 2.7 GHz See Table 1.	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz $d = 6\sqrt{P} / E$ 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-1200 Pro&SE-1201 Pro ECG, including cables specified by the manufacturer). Otherwise, degradation of the performance of this equipment could result.


		<p>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 meters (m).</p> <p>As determined by an electromagnetic site survey, field strengths from fixed RF transmitters should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p>		
<p>Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts, and TV broadcasts, cannot be predicted theoretically with accuracy. An electromagnetic site survey should be considered to assess the electromagnetic environment for fixed RF transmitters. Suppose the measured field strength in the location in which the SE-1200 Pro&SE-1201 Pro ECG is used exceeds the applicable RF compliance level above. In that case, the SE-1200 Pro&SE-1201 Pro ECG should be observed to verify regular operation. If abnormal performance is monitored, additional measures may be necessary, such as reorienting or relocating the SE-1200 Pro&SE-1201 Pro ECG.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p> <p>^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.</p>		

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 A 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN,802.11 b/g/n, RFID 2450, LTE Brand 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation ^{b)}	0.2	0.3	9
5500						

5785			217 Hz			
<p>Note: If necessary, to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1m. The 1 m test distance is permitted by IEC/EN 61000-4-3.</p>						
<p>a) For some services, only the uplink frequencies are included.</p> <p>b) The carrier shall be modulated using a 50% duty cycle square wave signal.</p> <p>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 the worst case.</p>						

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

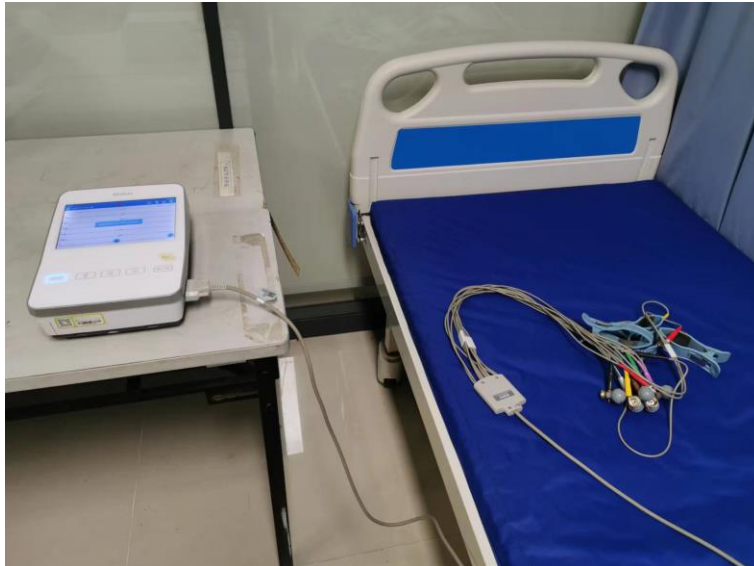
Recommended separation distances between portable and mobile RF communications equipment and the SE-1200 Pro&SE-1201 Pro ECG			
<p>The SE-1200 Pro&SE-1201 Pro ECG is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SE-1200 Pro&SE-1201 Pro ECG can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SE-1200 Pro&SE-1201 Pro ECG as recommended below, according to the maximum output power of the communications equipment.</p>			
The maximum output power rating of the transmitter (W)	Separation distance according to the frequency of the transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
<p>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.</p> <p>NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p>			

Appendix 3 Abbreviations

Abbreviation	Full Description
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

Appendix 4 Installation instructions

1. The specific use scenario and installation setting diagram of the product.



2. This device is fixed used and can not move by Non-professionals.
3. This device must operate with a minimum distance of 20 cm between the radiator and user body.

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