

iSE Series

Electrocardiograph

Version 1.4

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

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

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

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

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

Terms Used in this Manual

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

WARNING

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

CAUTION

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

NOTE

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

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Chapter 1 Introduction

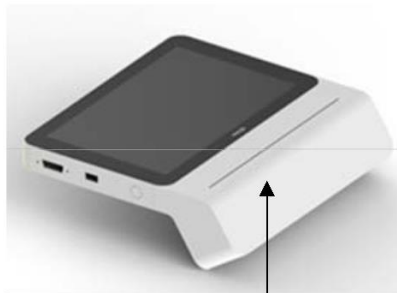
1.1 Product Information

1.1.1 Product Overview

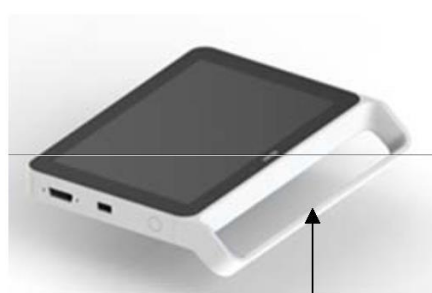
The iSE series electrocardiograph features intuitive user interface with simple workflow, clinical-quality ECG recorder, and convenient design. For more features, see section 1.1.3 *Features & Benefits*.

The device consists of the following components: main unit, ECG cable, electrodes, electrode adapters, power cord and power adapter, battery, and iSE software.

There are two models, iSE-1210 and iSE-1810. iSE-1210 uses DE12 for ECG acquisition while iSE-1810 uses DE18 sampling box. For the performance difference between DE12 and DE18, see A1.5 *Performance Specifications*. For each model, there are three styles. See the following illustrations.



With thermal printer



With handle but no thermal printer



No thermal printer or handle

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

1.1.2 Indications for Use/Intended Use

The iSE series electrocardiograph is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. However, the interpreted ECG with measurements and interpretive statements is offered to clinicians on an advisory basis only. The electrocardiograph is capable of network communications and supports the informatized management of workflows in hospital and healthcare facilities.

WARNING

1. This system is not designed for intracardiac use or direct cardiac application.

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

1.1.3 Features & Benefits

Fingerprint Access

Log in to the electrocardiograph easily and quickly.

Touch screen operation based on Android operating system

Easy to use, intuitive interface.

Small (1.2 kg±0.3 kg minimum), at least 8 hours of continuous usage on Li-ion battery

Use the electrocardiograph in a wide variety of care environments.

Easy communication and synchronization with EDAN's SE-1515 PC ECG

Communicate with the server via WIFI or mobile network.

Large storage capacity

Minimum of 16 GB local memory, allows you to extend the device's storage capacity by using an external Secure Digital (SD) card.

Support standard 9/12/15/16/18-lead ECGs

You can easily switch between acquisition modules for ECG acquisition.

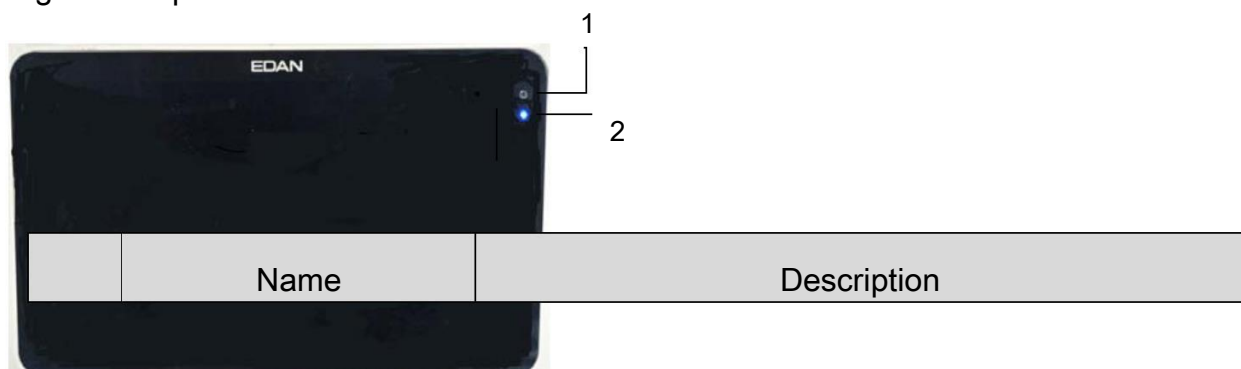
Compatibility with external printer

You can connect an external APP printer or a printer with infrastructure WIFI

1.1.4 Controls, Indicators, and Connectors

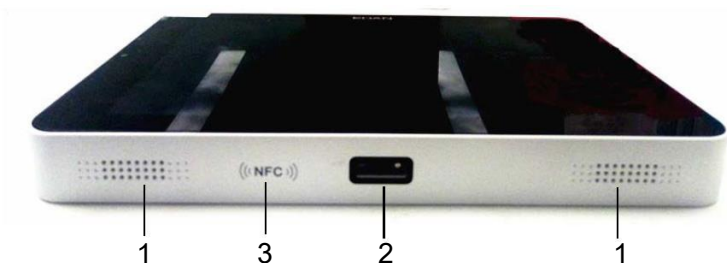
This section describes the controls, indicators, and connectors that are part of the electrocardiograph.

Figure 1 Top



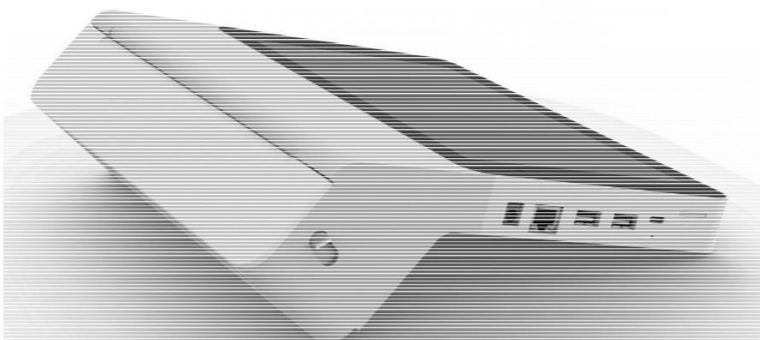
1	Camera	Reserved.
2	Power light	Indicates power usage in different colors: Blue: the electrocardiograph is powered by battery. Green: the electrocardiograph is connected to AC power. Or when the electrocardiograph is connected to both the battery and AC power, the battery is full. Orange: the electrocardiograph is connected to both the battery and AC power, and the battery is recharging.

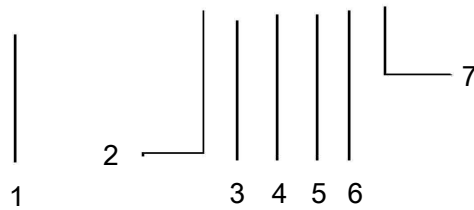
Figure 2 Front



	Name	Description
1	Speaker holes	/
2	Infrared scanner	Scans one-dimensional or two-dimensional codes. NOTE: When you use the infrared scanner, DO NOT look straight at it.
3	NFC reader	Reads contactless tags on your devices like smartphones or tablets.

Figure 3 Left





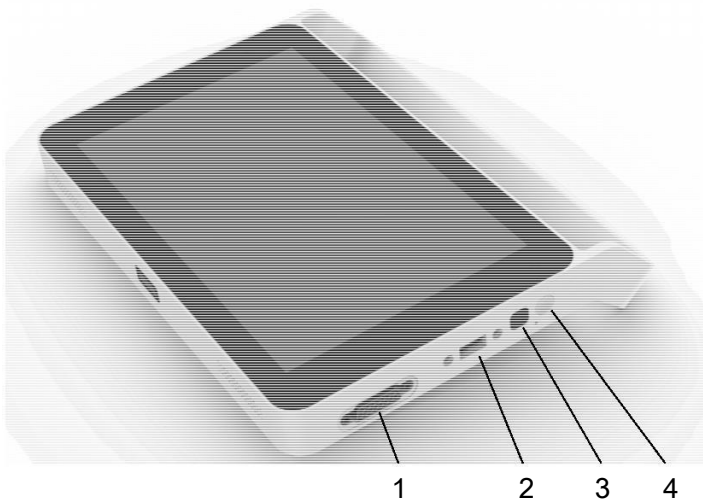
	Name	Description
1	Paper tray switch	Pull down the switch to open the paper tray. To close the tray, close the door directly. NOTE: This is only applicable to electrocardiographs with thermal printer.
2	Mains AC power	Connects the system to an AC power supply via power cable.
3	LAN port	Connect to a LAN cable.
4	USB interface	Connect to your keyboard, mouse, U disk, USB printer, and code scanner. NOTE: Only FAT32 format is supported by the USB storage devices.
5		
6	Type-C interface	Used only by the manufacturer. NOT for recharging.
7	SIM and SD cards two-in-one slot	Insert SIM card and SD card for data transmission and storage.

Figure 4 Back



	Name	Description
1	Paper tray (option)	Contains thermal chart paper roll.
2	Handle (option)	/

Figure 5 Right



	Name	Description
1	ECG cable socket	Connects to the ECG cable.
2	DE18 socket	Connects to the DE18 connection cable.
3	Fingerprint identifier	Identifies user fingerprint for login to the electrocardiograph.
4	On/Off button	To power on, press and hold the On/Off button when the device is off. When the device is on:

		<p>Press and hold the button. A menu pops up, providing the following options: restart, power off, and screenshot.</p> <p>To enable power-save, gently press the button.</p>
--	--	--

Figure 6 Bottom



	Name	Description
1	Battery	Contains a battery to supply power when the unit is not connected to AC power.
2	Battery compartment switch	Pull the switch left to make the battery pop out.
3	Product label	Contains product information.

1.1.5 Software Overview

This section provides an overview of the system software. It describes the basic screen layout and main menu functions. Familiarize yourself with these features before attempting to use iSE.

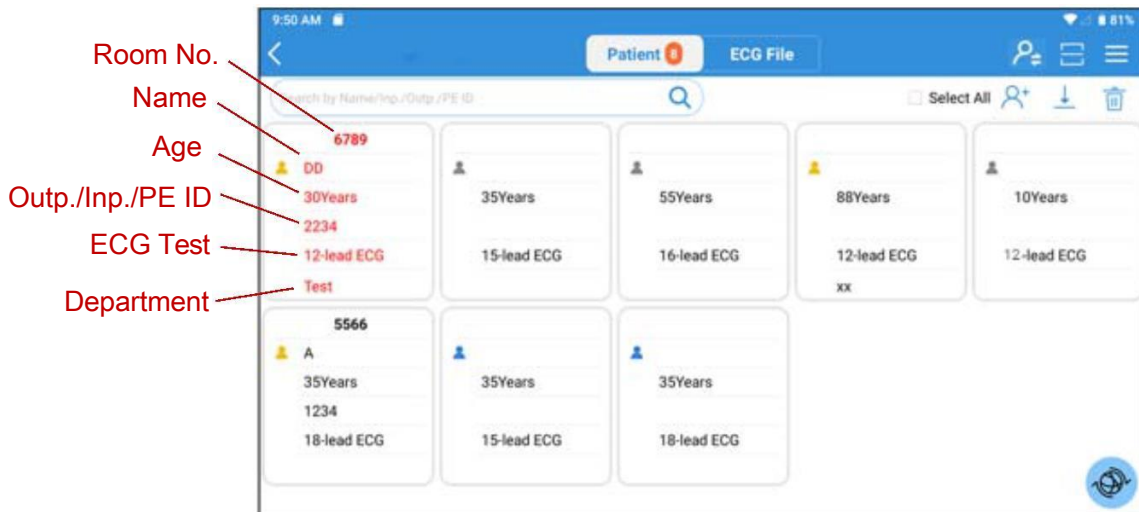
Figure 7 Main Menu














Submenu	Description
Patient	Displays patients that have ordered an ECG test and contains a number of operations you can perform on patient information.
ECG File	Stores ECGs that have been recorded and contains a number of operations you can perform on ECGs.
System Setting	Review or change system settings.
STAT ECG	STAT mode bypasses patient data entry. A temporary ID number is assigned to the patient to identify stat tests.
EDAN Cloud	Reserved

Figure 8 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 displayed in red.



Button/Icon	Description
	Return to the <i>Main Menu</i> .
	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 at a time.





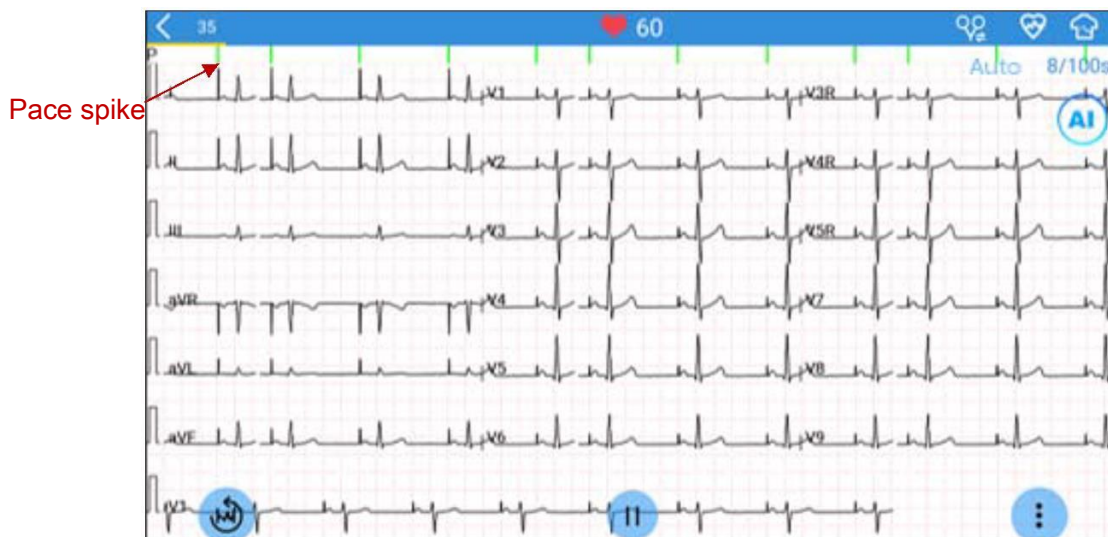




	Activate iSE's infrared scanner to scan the barcode so as to retrieve the Outpatient / Inpatient / PE ID. Tap this icon again to stop scanning.
	Download the specific patient information from the PC. You need to enter the default key word for order querying so that the information with the order can be downloaded. For details, see section 4.3 <i>Retrieving Orders from Server</i> .
	Disable the filter when it is used to filter the patient information.
	STAT ECG. For more information, see Figure 7.

Figure 9 ECG recording screen



Button/Icon	Description
	Real-time heart rate. It automatically updates during ECG recording.
	Display the pacing spike when the iSE 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.
	Intelligent ECG sampling. This icon is displayed when you enable intelligent sampling in the setting. NOTE: This option is available in the Auto mode of standard ECG recording.


















	Start or stop ECG recording. NOTE: iSE can record up to 1,800-second ECGs.
	Re-acquire ECGs.
Auto	Recording mode, including Auto and Manual. Tap on it to toggle between the two modes. In the Auto mode, the system will acquire ECGs at the set time and then print a report. If the user stop recording before the time, the system will print the last 10s of ECG. In the Manual mode, the system will not stop recording or printing ECGs until you tap the stop button.
	This icon provides the following setting options: gain, filter, speed, and lead mode. Tap the icon again to hide these options.
	Gain. Options are: 1.25 mm/mV, 2.5 mm/mV, 5 mm/mV, 10 mm/mV, and 20 mm/mV. The default gain is 10mm/mV.
	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.
	Speed. Options are: 5 mm/s, 12.5 mm/s, 25 mm/s, and 50 mm/s. The default speed is 25mm/s.
	Lead mode. <ul style="list-style-type: none"> • If DE12 is used, options are: pediatric mode, 12 lead (Standard or Cabrera). The default setting is 12 lead (Standard). • If DE18 is used, options are: pediatric mode, 12 lead (Standard or Cabrera), 15 lead, 16 lead, and 18 lead. The default setting is 18 lead.
	Record rhythm ECGs. To toggle between single-lead and three-lead rhythm strips, swipe the screen left or right.
	Return to the previous menu.

Figure 10 ECG file tab

Serial No.	Name	Gender	Age	Department	Exam. Type	Inpatient ID	Registration Time
1	ECG001	Male	36Years	ZHJK001	18-lead ECG	11011	2020/03/18 11:10:03
2	ECG002	Male	35Years	ZHJK001	12-lead ECG	11012	2020/03/18 11:10:53
3	ECG003	Male	35Years	ZHJK001	15-lead ECG	1103	2020/03/18 11:11:18
4	ECG004	Male	35Years	ZHJK001	16-lead ECG	1104	2020/03/18 11:11:33
5	ECG005	Male	14Years	ZHJK001	12-lead ECG	1105	2020/03/18 11:11:50
6	ECG006	Female	25Years	ZHJK001	Pediatric ECG	1106	2020/03/18 11:12:19
7	ECG007	Female	30Years	ZHJK001	18-lead ECG	1107	2020/03/18 11:12:35
8	ECG008	Female	21Years	ZHJK001	12-lead ECG	1108	2020/03/18 11:12:50

Summary: All(16) | To Upload(8) | Diagnosed(4) | To Print(16)

Button/Icon	Description
	Search for ECGs that have been recorded. Enter the key word for 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 from server the latest ECG measurements and diagnosis for all ECG files in this tab.
	Get or update signature. You can download doctors' electronic signatures from the server. With this button, you can also update doctors' signatures stored in your electrocardiograph.
	Export ECGs to USB memory device. You can select the file format for export. See section 10.3 <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.
Print	Print a report for an ECG file. You can select the APP or WIFI printer. Press and hold an ECG file. This button will appear.

Edit	<p>Modify the patient information of an ECG file. You can modify all patient information except ID and exam item. Press and hold an ECG file. This button will appear.</p> <p>NOTE:</p> <p>If patient information such as names or gender are modified, the information elsewhere with the same ID number will be updated.</p>
Sync	<p>Retrieve diagnosis and doctor's signature for an ECG file. Press and hold an ECG file. This button will appear.</p>
Urgent	<p>Send a notification to the server to take priority over other ECGs. The ECG will be highlighted in red and listed on top. Press and hold an ECG file. This button will appear.</p>
All (16)	<p>The number of ECGs stored in the electrocardiograph is 16.</p>
To Upload (8)	<p>The number of ECGs to be uploaded to server is 8.</p>
Diagnosed (4)	<p>The number of ECGs of which diagnosis is retrieved from the server is 4.</p>
To Print (16)	<p>The number of ECGs to be printed is 16.</p>
	<p>Return to the main menu.</p>

1.1.6 ECG Cable and Lead Wires

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

WARNING

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

Figure 11 ECG cable and lead wires for DE12



Figure 12 DE18 sampling box, DE18 cable, and lead wires
















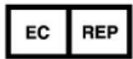


DE18 sampling box,
Cable connector











Electrode connector

DE18 cable

1.1.7 Symbols

No.	Symbol	Description
1		DEFIBRILLATION-PROOF TYPE CF APPLIED PART
2	19V 	Direct current
3		Caution

4		Consult operating instructions
5		Near-field communication
6		USB interface
7		SIM and SD cards slot (two-in-one)
8		Computer network
9		On/Off switch
10		General symbol for recovery/recyclable
11	P/N	Part Number
12		SERIAL NUMBER
13		Date of manufacture
14		MANUFACTURER
15		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
16		CE marking
17		Disposal method

18	Rx Only	Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.
19		Refer to instruction manual/booklet (Background: Blue; Symbol: White)
20		General warning sign (Background: Yellow; Symbol & Outline: Black)
21*		Non-ionizing electromagnetic radiation
22		This way up
23		Fragile, handle with care
24		Keep dry
25		Stacking limit by number
26		Handle with care
27		Do not step on
28		Front
29*	Contains FCC ID: SMQISEEDAN	Federal Communications Commission: Contains FCC ID: SMQISEEDAN

NOTE:

1. The user manual is printed in black and white.

2. The right angle bracket “>” is a concise method to indicate a sequence of menu selections.
3. *: Apply to devices with wireless functions.

1.2 Safety Information

This section provides important safety information related to the use of iSE.

To use the system safely and effectively, firstly be familiar with the operation method of Android and read the user manual in detail to be familiar with the proper operation so as to avoid the possibility of system failure. The following warnings and cautions must be paid more attention to during the operation of the system.

1.2.1 General Warnings

WARNING

1. The system is intended to be used by qualified physicians or personnel professionally trained. They should be familiar with the contents of this user manual before operation.
2. Only qualified service engineers can install this equipment, and only service engineers authorized by the manufacturer can open the shell. Otherwise, safety hazards may happen.
3. EXPLOSION HAZARD - Do not use the system in the presence of flammable anesthetic mixtures with oxygen or other flammable agents.
4. Only the ECG cable and other accessories supplied by the manufacturer can be used. Or else, the performance and electric shock protection cannot be guaranteed. The system has been safety tested with the recommended accessories, peripherals, and leads, and no hazard is found when the system is operated with cardiac pacemakers or other stimulators.
5. Make sure that all electrodes are connected to the patient correctly before operation.
6. Ensure that the conductive parts of electrodes and associated connectors, including neutral electrodes, do not come in contact with earth or any other conducting objects.
7. Disposable electrodes must be used during defibrillation.
8. Electrodes of dissimilar metals should not be used; otherwise it may cause a high polarization voltage.

9. The disposable electrodes can only be used for one time.
10. Do not touch the patient, bed, table or the equipment while using the ECG together with a defibrillator.
11. Do not touch accessible parts of electrical equipment and the patient simultaneously.
12. The use of equipment that applies high frequency voltages to the patient (including electrosurgical equipment and some respiration transducers) is not supported and may produce undesired results. Disconnect the patient data cable from the electrocardiograph, or detach the leads from the patient prior to performing any procedure that uses high frequency surgical equipment.
13. Pay close attention to the examination to avoid missing important ECG waveforms.
14. Do not connect any equipment or accessories that are not approved by the manufacturer or that are not IEC/EN 60601-1 approved to the 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.
15. The use of patient cable and other accessories not supplied by the manufacturer may result in increased emissions or decreased immunity of the equipment.
16. Any non-medical equipment (such as the external printer) is not allowed to be used within the patient vicinity (1.5m/6ft.).
17. Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configuration shall comply with the valid version of the standard IEC/EN 60601-1. Therefore anybody, who connects additional equipment to the signal input or output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC/EN 60601-1. If in doubt, consult our technical service department or your local distributor.
18. Connecting any accessory (such as external printer) or other device (such as the computer) to this system makes a medical system. In that case, additional safety measures should be taken during installation of the system, and the system shall provide:
 - a) Within the patient environment, a level of safety comparable to that

- provided by medical electrical equipment complying with IEC/EN 60601-1, and
- b) Outside the patient environment, the level of safety appropriate for non-medical electrical equipment complying with other IEC or ISO safety standards.
19. All the accessories connected to system must be installed outside the patient vicinity, if they do not meet the requirement of IEC/EN 60601-1.
20. 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.
21. Connecting to other devices may decrease the antistatic gradation of the system during operation.
22. Make sure that there is no intense electromagnetic interference source around when using the wireless system of iSE.
23. The device shall not be serviced or maintained while in use with a patient.
24. The medical electrical equipment needs to be installed and put into service according to Appendix 2 *EMC information*.
25. Portable and mobile RF communications equipment can affect medical electrical equipment, refer to the recommended separation distances provided in Appendix 2 *EMC Information*.
26. The equipment should not be used adjacent to or stacked with other equipment, refer to the recommended separation distances provided in Appendix 2 *EMC Information*.
27. Assembly of the ECG workstation and modifications during actual service life shall be evaluated based on the requirements of IEC60601-1.
28. Check the gain and speed of the report thoroughly when confirming diagnosis.
29. Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the device comply with the relevant EMC requirements. X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.
30. The electrocardiograph should be placed on a flat surface or EDAN's trolley. Avoid it dropping down to cause strong shock.
31. 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.

32. 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.
- Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- FCC Radiation Exposure Statement

This device complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

- This device must operate with a minimum distance of 20 cm between the radiator and user body.
-
-

1.2.2 Protecting Personal Information

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

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

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

CAUTION

1. The access/operation of the electrocardiograph is restricted to authorized personnel only. Assign only staff with a specific role the right to use the electrocardiograph.
2. Ensure that all device components maintaining personal information (other than removable media) are physically secure (i.e. cannot remove without tools).
3. Ensure that the electrocardiograph is connected only to the device authorized/approved by EDAN. Users should operate all EDAN deployed and supported electrocardiographs within EDAN authorized specifications, including EDAN approved software, software configuration, security configuration, etc.
4. Protect all the passwords to prevent unauthorized changes.
5. Anti-virus measures such as USB device virus scanning should be carried out prior to using USB flash drive.
6. Firewalls and/or other security devices should be in place between the medical system and any externally accessible systems. Firewalls and/or other security devices should be in place between the medical system and any externally accessible systems. It's recommended to use Windows defender firewall or any other firewall that can defend against Dos and DDos attacks, and keep it up to date. Add the master computer software to the whitelist.
7. Dos and DDos protection of the router or switch must be turned on for defending against attacks.
8. 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 into the same VLAN, and isolate it from other VLANs.
9. When the electrocardiograph is returned for maintenance, disposed of, or removed from the medical institution for other reasons, it is necessary to ensure that all patient data are removed from the electrocardiograph.
 10. Please protect the privacy of the information and data displayed on the screen, and those information and the data stored in the electrocardiograph.
 11. Users should make a backup of data on a periodic basis.
 12. Disable unnecessary services from the operating system and reduce vulnerabilities.
 13. It is recommended that you disable the Administrator and Guest accounts.
 14. Destroy the sensitive information in the idle or scrapped device.
 15. Sharing patient data or data storage folders on the network is not supported by the iSE system and may cause irreversible data lost or corruption.
 16. For proper running, the iSE system has access to user's NFC, Bluetooth, WIFI, system setup, storage, location, and system time setup without prior permission.
 17. Do not install in iSE the other APPs or software that are not configured by the manufacturer.
 18. The operating system of iSE can only be upgraded by the manufacturer or its authorized personnel. If the user reinstall iSE with other operating system not authorized by EDAN, the resulting security risks and losses shall be borne by the user. Possible security risks are user information stolen, sending SMS automatically, locating your location.
-

1.2.3 Battery Care Warnings

WARNING

1. Improper operation may cause the internal battery to be hot, ignited or exploded, and it may lead to the decrease of the battery capacity. It is necessary to read the user manual carefully and pay more attention to warning messages.
2. Batteries of the same model and specification as manufacture configuration should be used.
3. DANGER OF EXPLOSION -- Do not reverse the anode and the cathode when

installing the battery.

4. Do not heat or splash the battery or throw it into fire or water.
 5. Do not destroy the battery; do not pierce battery with a sharp object such as a needle; do not hit with a hammer, step on or throw or drop to cause strong shock; do not disassemble or modify the battery.
 6. When leakage or foul smell is found, stop using the battery immediately. If your skin or cloth comes into contact with the leakage liquid, cleanse it with clean water at once. If the leakage liquid splashes into your eyes, do not wipe them. Irrigate them with clean water first and go to see a doctor immediately.
 7. Properly dispose of or recycle the depleted battery according to local regulations.
 8. Remove the battery from the transmitter if the system won't be used for a long time.
 9. Recharge the battery at least once every 6 months. Conduct checks and maintenance on the battery every 3 to 6 months.
-

1.2.4 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 bad ventilation or in the presence of corrosive.
3. Make sure that there is no intense electromagnetic interference source around the equipment, such as radio transmitters or mobile phones etc. Attention: large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment etc. is likely to bring electromagnetic interference.
4. The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal. Batteries are hazardous waste. Do NOT dispose of them together with house-hold garbage. At the end of their lives hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about

recycling of this product or battery, please contact your local Civic Office, or the shop where you purchased the product.

5. Federal (U.S.) law restricts this device to sale by or on the order of a physician.

Chapter 2 Setting Up the Electrocardiograph

WARNING

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

2.1 Inspecting the Electrocardiograph

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

WARNING

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

1) Environment

Make sure that there is no electromagnetic interference source around the equipment, especially large medical electrical equipment such as electrosurgical equipment, radiological equipment, magnetic resonance imaging equipment etc. Turn off these devices when necessary.

Keep the examination room warm to avoid muscle tremor voltages in ECG signals caused by cold.

2) Power Supply

If the mains supply is used, please check whether the power cord is connected to the unit well. The grounded three-slot outlet should be used.

When the battery capacity is low, recharge the battery before use.

3) ECG Cable

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

4) Electrodes

Make sure that all electrodes are connected to ECG lead wires correctly.

Ensure that the chest electrodes do not contact with each other.

5) Patient

The patient should not come into contact with conducting objects such as earth, metal parts etc.

Ensure that the patient is warm and relaxed, and breathes calmly.

2.2 Connecting the ECG Cable

1. Connecting to the electrocardiograph

In the case of DE12, connect the ECG cable to the socket on the right side of the electrocardiograph. Secure with two screws. (See Figure 11.)

In the case of DE18, connect the DE18 sampling box to the DE18 cable, which is connected to the socket on the right side of the electrocardiograph. Secure with two screws. (See Figure 12.)

2. Connecting to the electrodes

Align all lead wires of the ECG cable to avoid twisting, and connect the lead wires to the reusable electrodes or the electrode adaptors. Firmly attach them.

2.3 Loading the Thermal Chart Paper (Option)

The electrocardiograph uses thermal paper roll.

CAUTION

Make sure that the recorder paper is placed in the center of the recorder, and the paper edge is parallel with the recorder edge in the advancing direction to avoid paper offset or extrusion.

Loading/Replacing paper roll:

1. Press down the switch to open the paper door.
2. Remove the remaining paper from the paper tray if necessary.
3. Remove the outer packaging from a new pack of paper, and put the paper into the tray.
4. Pull the paper out with the grid side facing the thermal print head.
5. Close the door securely.

NOTE:

The exit edge can help you tear the recorder paper.

2.4 Connecting an External APP/WIFI Printer (Option)

1. Slide the top of the iSE screen down. The notification bar is displayed
2. Turn the WLAN on. WIFI pairing starts.
3. Select the printer model for pairing. Enter the password to activate the printer.
4. Select Print and Storage Setting > Recording Device > External Printer.
5. Select Print via App before you print an ECG.

To connect an external printer with infrastructure WIFI:

1. Slide the top of the iSE screen down. The notification bar is displayed
2. Turn the WLAN on. WIFI pairing starts.
3. Select the printer model for pairing. Enter the password if available.
4. Select Print and Storage Setting > Recording Device > External Printer.
5. Select Print via WIFI before you print an ECG.

Refer to Chapter 7 *Printing an ECG Report* for the recommended APP and WIFI printers.

2.5 Powering the Electrocardiograph

WARNING

If the integrity of the external protective conductor is in doubt, the equipment should be powered by the battery.

Use the AC-DC power adapter provided by the manufacturer.

The electrocardiograph can run on AC or the battery power.

To power on the electrocardiograph:

When operating on AC power

Make sure that the AC power meets the requirements (refer to A1.4 Power Supply Specifications) before power-on. Press and hold the On/Off button on the right side of the electrocardiograph. The power light turns light blue, and the EDAN logo will be displayed on the LCD screen. The electrocardiograph is ready for use.

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

When operating on battery power

Press and hold the On/Off button on the right side of the electrocardiograph. The power light turns deep blue. After the EDAN logo is displayed on the LCD screen, the electrocardiograph is ready for use.

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

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

CAUTION

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

To power off the electrocardiograph:

When operating on AC power

Press and hold the On/Off button. Select Power off from the pop-up menu. The message *System is shutting down...* is displayed. The electrocardiograph will be off in a few seconds. Remove the plug from the outlet.

When operating on battery power

Press and hold the On/Off button. Select Power off from the pop-up menu. The message *System is shutting down...* is displayed. The electrocardiograph will be off in a few seconds.

NOTE:

When turning off the device, follow the above sequence strictly, otherwise there may be something wrong on the screen.

2.6 Logging in to the Electrocardiograph

After iSE is powered on, you need to log in by password or fingerprint. You can also disable them by unselect the User Login in User Setting.



Using fingerprint (if enrolled before)

Tap Fingerprint Identification. Press your finger on the fingerprint reader on the right side of iSE.

Using user account and password

Enter your user name and password. Tap Log in.

No matter which way you choose, the Patient tab will open after login.

NOTE:

Do not run other applications if available when running iSE, otherwise the system response will slow down.


2.7 Configuring the Ethernet

To configure the Ethernet for data transmission:

1. Slide the top of the iSE screen down. The notification bar is displayed.
2. Press and hold Ethernet from the bar.
3. Turn Ethernet on.
4. Configure the settings of Ethernet.
5. Tap Save.

2.8 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 3 Preparing the Patient

3.1 Instructing the Patient

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

3.2 Preparing the Skin

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

To prepare the skin

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

NOTE: Rub the skin with a gauze pad to increase capillary blood flow if you don't have enough time for the steps above.

3.3 Attaching Electrodes to the Patient

WARNING

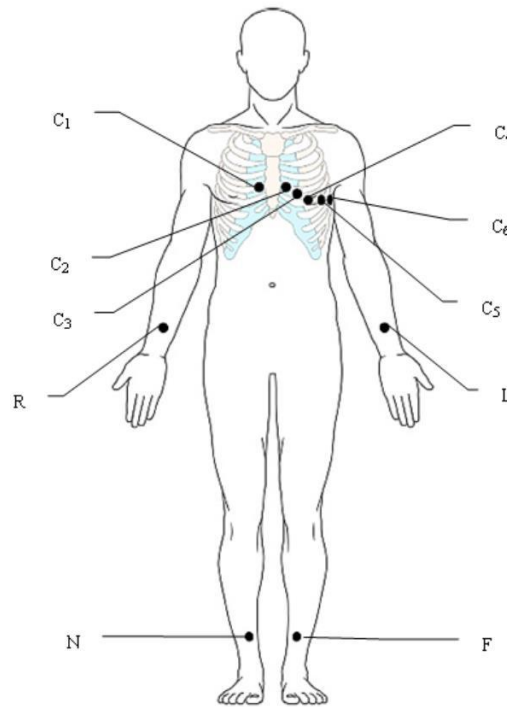
Make sure that all electrodes are connected to the patient correctly before operation.

Ensure that the conductive parts of electrodes and associated connectors, including neutral electrodes, do not come in contact with earth or any other conducting objects.

Electrode Placement

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

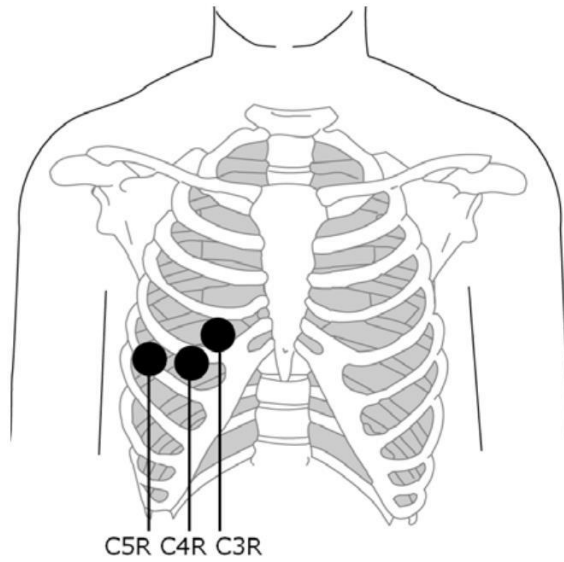
Figure 13 Standard 12 lead placement



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

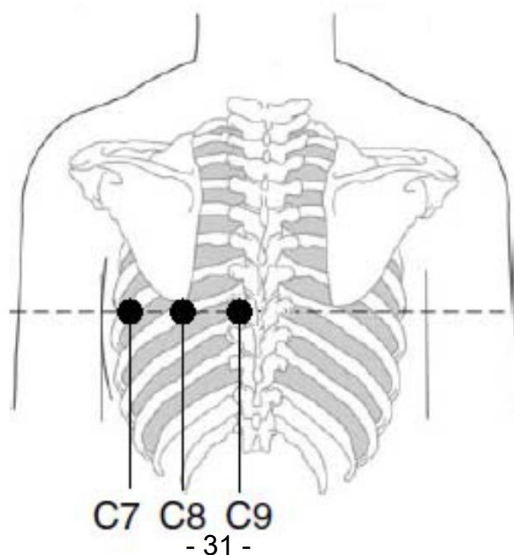
Green	Red	
N Black	RL Green	Right leg

Figure 14 C3R+C4R +C5R (Right)



Electrodes		Locations
IEC	AHA	
C3R White/Pink	V3R Brown/Yellow	Right anterior chest opposite of C3
C4R White/Gray	V4R Brown/Red	Right anterior chest opposite of C4
C5R White/Green	V5R Brown/Green	Right anterior chest opposite of C5

Figure 15 C7+C8+C9 (Back)



Electrodes		Locations
IEC	AHA	
C7	V7	Left posterior axillary line on the same horizontal level as C4 and C6
White/Orange C8	Brown/Black V8	
White/Blue C9	Brown/Blue V9	Left paraspinal border on the same horizontal level as C4 and C8
White/Yellow	Brown/Yellow	

Attaching Electrodes

1. Ensure that the electrodes are clean.

2. For reusable electrodes:

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

Apply electrodes to the prepared locations.

For disposable electrodes:

Apply electrodes to the prepared locations.

Clip or connect electrode adaptors to electrodes.

NOTE:

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


Proper skin preparation (abrasion if necessary), proper electrodes, and ECG cables in fixed position are very important for a good signal quality.

CAUTION

The disposable electrodes can only be used for one time.

Chapter 4 Entering Patient Information

4.1 Manually Entering Patient Information

Tap  in the Patient tab. 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.


If you want to record an ECG immediately after you enter the information, turn Sample now on in the New Patient window.

NOTE:

Patient ID is a must when entering patient information. You can use the number generated by the system or enter an ID manually (see System Setting > Patient Information Setting > Patient ID). Patient ID can only be English numbers and letters.

4.2 Scanning a Barcode (Option)



Infrared (IR) scanning

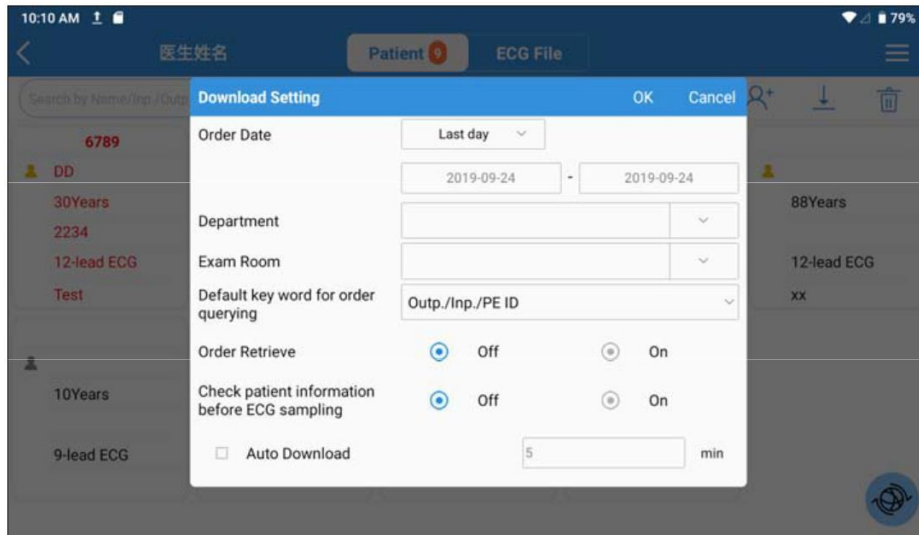
Tap  in the New Patient window. The electrocardiograph will load the Outp./Inp./PE ID.

Scanning a barcode



Connect the barcode scanner to the USB port on the left side of the electrocardiograph. For each new patient, scan the barcode in the Patient tab or the New Patient window. The patient data will be loaded and displayed in the Patient tab. To get the right data, you have to configure the barcode before scanning. For information, see 10.2 *Patient Information Setting*.

4.3 Retrieving Orders from Server


1. Tap  In the Patient tab. Select Order Server. Enter 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 key word 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 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 key word 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 update.

NOTE:

To retrieve orders from server, you need to purchase and install EDAN's data management software in your PC.

Use the recommended barcode scanner. For one-dimensional barcode, the recommend scanner is Zebra DS2208, and 1900GSR-2 for QR code.

The distance for barrier-free data transmission via Bluetooth is 5 meters.



4.4 Modifying and Deleting Patient Information



To modify patient information:

Tap and hold the patient information you want to modify. Select Edit from the pop-up menu. When finished, tap OK to save your modification. Or you can tap Cancel to cancel your modification.

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 information 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.

To cancel selection:

Tap on the patient information of which the outer square is blue. The outer square now turns grey. The information becomes unselected.

To exit the deletion:

You need to unselect all the patient information first, that is all the outer squares of patient information are grey. Then tap .

4.5 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.

NOTE:

Fuzzy search is supported in the search bar.

4.6 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. Two sequences are available, up and down, which means ascending and descending.
3. When you are done, tap OK. Patient information is displayed in your desired order.

Chapter 5 Recording an ECG

The method for recording an ECG 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), pharmaceutical study, VCG and SAEKG, and heart rate variability (HRV). Except standard ECG, the other methods need to be purchased and enabled.

Standard ECG acquisition is classified into real-time sample and pre-sample. You can configure pre-sample in System Setting > Sampling Setting.

The iSE detects pacemaker pulse when recording the standard ECG in the Auto mode. Once a pacemaker pulse was detected, it will ask users to display pacing spikes in the ECG traces or not. If you don't want such a message, disable the intelligent pace detection in the setting. While in the Manual mode, the acquired ECGs are not stored or transmitted. The system will not stop printing the report until you tap the stop button.

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


5.1 Real-Time Recording

To acquire real-time ECGs, you have four ways:

Turn Sample now on in the New Patient window. When you have entered patient information and tap Save, the ECG recording screen opens. You can start recording an ECG.


Tap the patient you want to test in the Patient tab (

Figure 8 Patient tab). The ECG recording screen opens. You can start recording an ECG.


Tap  in the Main Menu (Figure 7 Main Menu) or the Patient tab. The ECG recording screen opens. You can start recording an ECG.

Turn Intellectual Sampling on in System Setting > Sampling Setting. The electrocardiograph automatically records an ECG when it detects no poor ECG signals in 5 seconds. iSE electrocardiograph can be configured to upload ECGs to the server after recording. To configure, select System Setting > Transmission Setting > Auto Upload.

5.2 Pre-Sample Recording

Pre-sample initiates the acquisition of ECG data before users tap . The latest 10 seconds of ECG data will be recorded. If less than 10 seconds, the system will continue to acquire ECG until it reaches 10s.

To carry out pre-sample recording:

1. Select System Setting > Sampling Setting > Sampling Mode > Pre-sample.
2. Tap . ECG recording screen opens. The system automatically checks if 10s ECG has been acquired. If no, the system will continue to acquire ECG till reaching 10s. If yes, the system records and analyzes the ECG.

NOTE:

Gain, filter, and speed are not allowed to change during ECG recording.

To change the lead configuration e.g. 6×2+1R, slide the ECG traces left or right.


5.3 Rhythm ECG

In this sampling mode, rhythm strips from 10s to 30 min can be recorded. You can select the leads to display and record in the rhythm strips. To configure, see system setting > sampling setting > rhythm leads. Stop recording whenever you want by tapping the stop button. Rhythm strips allow storage, transmission, and printing.

5.4 Pharmaceutical Study

Up to 30 min ECGs can be recorded for pharmaceutical study. The acquired ECGs allow storage, transmission, and printing. During the experiment, you can stop recording or printing by tapping the stop button. To configure the recording time and ECG report, see system setting > printing and storage setting > pharma study record info.

5.5 VCG and SAECG

The VCG converts the P/QRS/T into spatial loops in the transverse, right sagittal, and frontal planes. Each plane displays coverage percentile of the P/QRS/T loop in the four quadrants. The mark  is used to indicate the orientation of loop movement by its round head. Tap on the P/QRS/T gain to change. The gain of P loop and T loop will be synchronized. VCG can be recorded up to 5 minutes. The VCG allow storage, transmission, and printing.

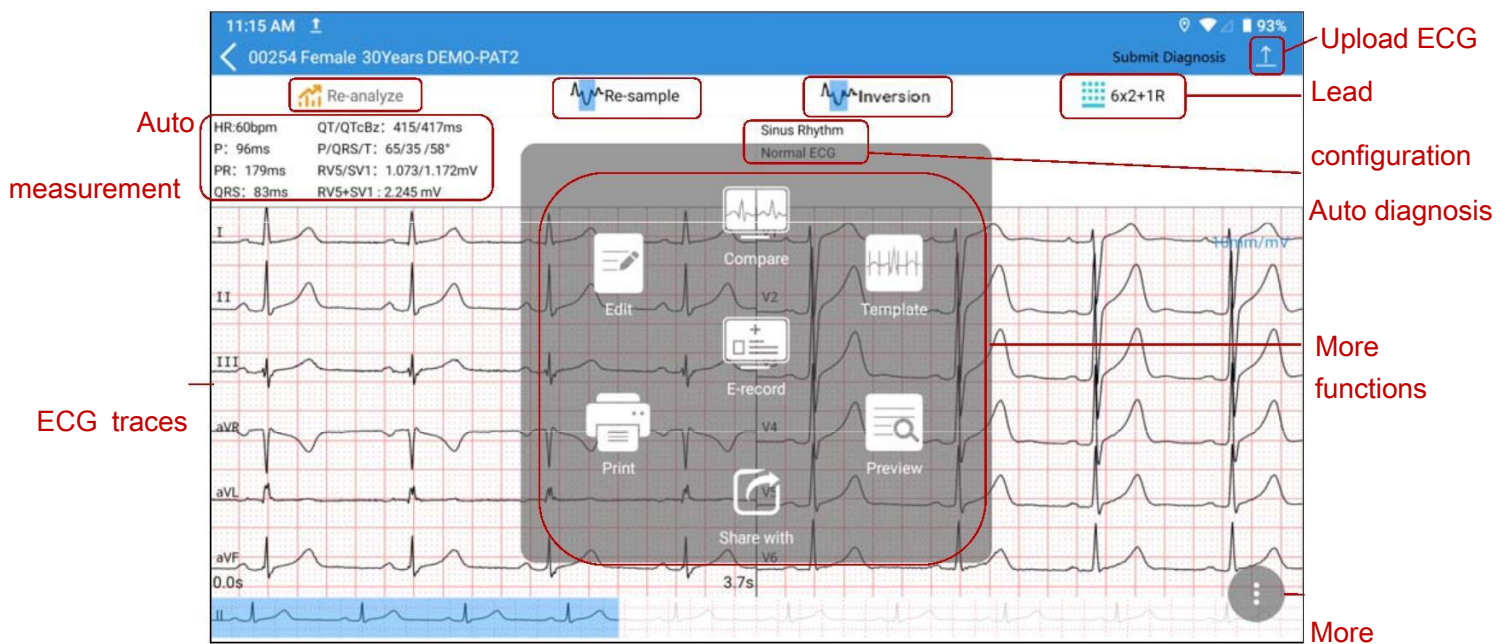
5.6 HRV

HRV is measured based on 12-lead ECGs. Five minutes of ECGs are recorded by default. You can select the leads to display in this test by tapping the lead name. Stop recording when you want to. The acquired ECGs allow storage, transmission, and printing.

Chapter 6 Editing ECGs

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

Figure 16 ECG analysis screen



6.1 ECG View

To switch lead configuration, tap the configuration e.g. 6×2+1R on the top right of the screen.

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



To zoom in the waveform, double tap on the waveform of a lead. The magnification page opens. Double tap the page, continue to zoom in. The ECG waveform can be magnified up to 5 times. When reaching its maximum, double tap the page to return to one-time size. To exit magnification, tap on 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/Diagnosis

Manual Measurement

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

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

To use manual ruler, zoom in/out the waveforms in the magnification page. Move this ruler up/down or left/right to measure amplitude and interval.

To change gain, tap on it.

Auto Measurement

iSE 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.


Auto Diagnosis

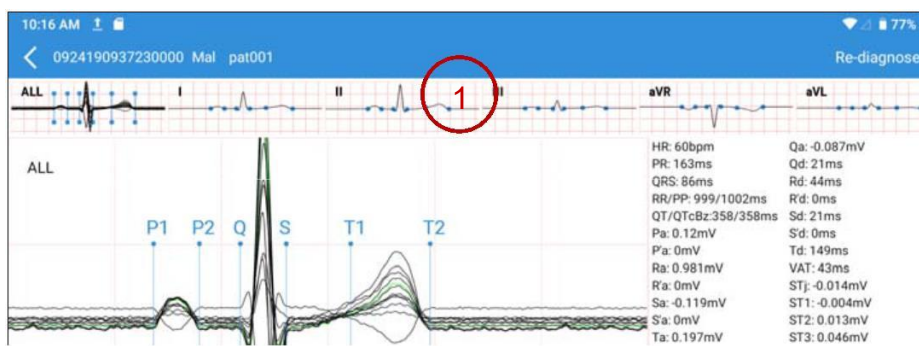
iSE provides auto diagnosis of ECG in the Analysis screen. Slide the diagnosis portion up and down to see all. If serious diseases are diagnosed, they will be displayed in red.

Re-analysis

ECG can be re-analyzed only when more than 10s ECG is recorded. Tap Re-analyze. The 10s ECG waveforms from the present onset will be re-analyzed. Auto measurements and diagnosis will be automatically updated.

Averages View

iSE 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 Analysis screen. Select Template from the pop-up menu. The Averages screen is opened as below.



2

3

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 in **2**.

2 Magnified averages

There are six measurement lines matching six measurement points. They are P1 (onset of P wave), P2 (offset of P wave), Q (onset of QRS complex), S (offset of 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. To save measurements after moving these lines, tap Re-diagnose in Averages screen. The measurements and diagnosis will be automatically updated.

Double-tap this portion, 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.

6.3 Editing Measurements/Diagnosis

Editing Measurements

To edit auto measurements, tap on it. The Modify Measurements window opens. Enter the values, and tap OK to save your modifications. The measurements 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 (°)	Axis of P wave, QRS complex, and T wave in the frontal plane
RV5/SV1 (mV)	Amplitude of R wave of V5 lead/the amplitude of S wave of V1 lead
RV5+SV1 (mV)	Amplitude of R wave of V5 lead plus the amplitude of S wave of V1 lead
RV6/SV2 (mV)	Amplitude of R wave of V6 lead/ Amplitude of S wave of V2 lead
RR/PP	This is visible only when enabled. RR interval / PP interval This is visible only when enabled.

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 statements to the textbox. The list allows you to add or delete diagnostic statements.
3. When you exit the analysis screen, select to save your modification or not. You can also upload the diagnosis to server by tapping "Submit Diagnosis" in the upper right corner.


6.4 Retrieving Diagnosis

To retrieve diagnosis for an ECG file:

1. Open the ECG File tab.
2. Tap and hold the ECG file you want.
3. Select Sync from the pop-up menu.
4. The diagnosis (if available) is obtained for this ECG file. The ECG is now diagnosed.


6.5 Reviewing Electronic Medical Record

iSE allows you to review the medical records of the patient.

1. Open the Analysis screen.
2. Tap . Select E-record from the menu.
3. You can review the patient's electronic medical records from the server.

6.6 Comparing ECGs


iSE 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.

NOTE:

You can compare 9- or 12-lead waveforms of up to two ECGs or averaged complexes of up to five ECGs on the same screen.

Chapter 7 Printing an ECG Report

To preview, print and share an ECG report, tap  in the Analysis screen. Select Preview, Print, or Share from the menu.

You can choose thermal printer (if configured) or external printer. In the case of thermal printer, the system will automatically print an ECG report. For external printer, you can connect a printer to the electrocardiograph by a USB cable, or connect an external APP printer or a printer with infrastructure WIFI. The recommended models are HP DeskJet 2332, HP DeskJet 4729, HP DeskJet 1212, and HP DeskJet M3638 with USB connection, HP LaserJet Pro M202dw with WIFI connection, and Xpress M2021w for APP printing. You need to configure the connection of external printer prior to the first print.

iSE allows you to share the ECG report via its Bluetooth module. The file formats provided are PDF, JPG, BMP, and PNG.

NOTE:

WIFI and APP printers work only under network connection.



If you choose WIFI printer, do not change the default print direction. Otherwise, ECG waveforms may appear distorted and compressive.

Contact the manufacturer or your local distributor for information on how to configure the WIFI connection with the printer.

Make sure that the printer connected is the type you select in the setting. Otherwise, error may occur.

Chapter 8 Transmitting and Exporting ECGs



To transmit ECGs to server:

1. Configure SFTP server in System Setting > Transmission Setting > Server Setting.
2. Open ECG File tab.
3. Tap . Select the ECGs you want to transmit. Or tap Select All to select all the ECGs.
4. Tap  again to upload the ECGs to the server.

NOTE:



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.

To export ECGs to a USB storage device:

1. Connect a USB disk to the left side of iSE 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 Deleting ECGs



To delete ECGs:

1. Open the ECG File tab.
2. Tap . Select the ECG report(s) you want to delete. Or tap Select All to select all the ECGs.
3. Tap  again. The following message is displayed:
Are you sure to delete the data?
4. Do one of the following:
 - To delete the selected ECG report (s), tap OK.
 - To cancel the deletion and select different reports, tap Cancel.

Chapter 10 System Setting

To set up the iSE system, tap System Setting in the Main Menu. Options underlined are default settings. In each setting window, you need to tap Save if available to save your changes.

10.1 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 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, 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 is applicable 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 ECG analysis finishes. The default setting is Off.
Sampling Device	Choose from: DE18 or <u>DE12</u>
Lead Mode	Choose from: DE12: Pediatric mode, <u>12-Lead</u> DE18: Pediatric mode, 12-Lead, 15-Lead, 16-Lead, <u>18-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	If selected, the system prompts you if the electrodes are connected

Electrode Hint	in the opposite position. The default setting is On.
Intelligent Pace Detection	If selected, the system asks you if to display the pacing spike or not when it detects a pacemaker pulse. NOTE: This option is applicable to the Auto mode of standard ECG.

10.2 Patient Information Setting

Item	Description
Patient Source ID	Choose from: <u>Inpatient ID</u> , Outpatient ID, Physical Examination ID.
Patient ID	Choose from: <u>Auto</u> , Manual Select Auto, the system automatically generates a patient ID according to the test date. Select Manual, you can manually enter a patient ID in the New Patient window.
Default Patient ID	Enter four or less 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 name is displayed in this window. This is the default setting.
Age/Birthdate	Choose from: <u>Manual</u> , Birthdate Select Manual, you need to enter the age of patient in the textbox. Select Birthdate, you can slide the box to select birth year, month, and day. The system will automatically calculate the age of patient.
Hide patient data viewable	Choose from: <u>Off</u> , On If On, patient name, age, and gender will be encrypted in Patient tab and ECG File tab. Only the first letter of first name is displayed, age are displayed as “*”, and gender is unknown.
Other Display Settings	You can determine whether the following options are displayed in New Patient window. Selected means to display.
ID	Selected by default.
Race	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.
Priority	Selected by default.
Medical History	Not selected by default.
Height/Weight	Choose from: <u>Off</u> , cm/kg, inch/lb.
BP	Choose from: <u>Off</u> , mmHg, Kpa
Customize	You can add what you want to display in the New Patient window.

Barcode Setting	Configure the start and end addresses, the male and female codes and encoding mode, and then tap Save. NOTE: If not configured, the results of barcode scanning may be incorrect.
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10.3 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 transmit to the server. If not selected, ECG files in DAT format will be transmitted. NOTE:

	In DICOM (Encapsulated PDF) files and DICOM (ECG Waveform) files, the value of QTc is always calculated by the Bazget formula.
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. 15-lead: 3x5+1R, <u>6+9</u> , 15x1 18-lead: <u>6x3+1R</u> , 18x1 NOTE: In the case of external printer, only the default report formats are available.
Recording Sequence	Choose from: <u>Sequential</u> , Simultaneous. "Simultaneous" prints ECG data that was captured simultaneously for all lead groups. "Sequential" prints ECG data that was captured at sequential intervals for each lead group in turn.
Recording Device	Choose from: <u>Thermal printer</u> , WIFI printer, USB printer. If a thermal printer is not configured, you can connect an external printer. For more about the external printer, see Chapter 7 <i>Printing an ECG Report</i> .
Speed	Choose from: 1.25 mm/s, 5 mm/s, 6.25 mm/s, 10 mm/s, 12.5 mm/s, <u>25 mm/s</u> , and 50 mm/s.
AGC	If selected, the gain will be automatically adjusted. The default setting is Off.
Storage Location	Choose from: <u>Local memory</u> , External SD card.
Gain Setting	Choose from: 1.25 mm/mV, 2.5 mm/mV, 5 mm/mV, <u>10 mm/mV</u> , 20 mm/mV, 10/5 mm/mV.
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, <u>6 Channels</u> , 12 Channels, and Customize. 15-lead: 3 Channels, <u>6 Channels</u> , 15 Channels, and Customize. 16-lead: 3 Channels, <u>6 Channels</u> , 16 Channels, and Customize. 9-lead: 3 Channels, <u>6 Channels</u> , 9 Channels, and Customize. 18-lead: 3 Channels, <u>6 Channels</u> , 18 Channels, and Customize. When you select "Customize", you can select the leads for 3 or 6 channels.
VCG Calculation	If selected, you can get a printout of VCG calculation report in

Report	addition to an automatic ECG printout.
VCG (visible when activated. Settings are displayed according to the functions activated.)	
Record Time	Choose from: <u>10s</u> , 1 min, 3 min, 5 min.
Report Type	Choose from: VCG Report, TVCG Report, SAECG Report.
X/Y/Z Wave	Choose from: <u>Off</u> , On. If On, print X, Y, and Z waves on the VCG report.
Analysis	Choose from: <u>Off</u> , On. If On, print the diagnosis on the VCG and SAECG report.
VCG Parameters	Choose from: <u>Off</u> , On. If On, print the detailed measurements on the VCG report.
QRS Gain	Choose from: 10, <u>20</u> , 40, and 80 mm/mV. Change the gain of QRS loop, the gain of P loop and T loop will be synchronized.
SAECG Filter	Choose from: <u>25-250 Hz</u> , 40-250 Hz.
VCG Analysis	Choose from: X, Y, Z. Display the real-time heart of the lead you choose on the recording screen.
HRV Report (visible when activated)	
RR Waveform	Choose from: <u>Off</u> , On. If On, print the compressed waveforms on the HRV report.
RR Interval List	Choose from: <u>Off</u> , On. If On, print the RR interval list on the HRV report.
Pharma Study Record Info (visible when activated)	
Auto Save	Choose from: <u>Off</u> , On. If On, the system stores the ECGs recorded for the pharmaceutical study.
Record Time	Choose from: <u>0-1-3-5-10-15 (Minute)</u> , 0-1-3-5-7-9 (Minute), 0-2-4-6-8-10 (Minute), Customize. This setting is related to the setting of report type below.
Report Type	Choose from: All-Lead ECG Report, <u>Single-Lead ECG Report</u> . If All-Lead ECG Report is selected, the system will print out a 9-lead or 12-lead ECG report at the set N minute. If <u>Single-Lead ECG Report</u> is selected, the system will acquire <u>10s single-lead waveforms at the set N minute</u> and at the end of recording put all the acquired waveforms to a rhythm printout.

10.4 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 wandering baseline.</p>
EMG Filter	<p>Muscle noise in an ECG signal hides low amplitude signals that may be important for the interpretation of 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>
Lowpass 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 lowpass 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>

10.5 Transmission Setting

Item	Description
Device ID	Enter the device ID with up to 30 English numbers or letters.
Auto Upload	<p>Choose from: On, <u>Off</u>.</p> <p>When On, the system will automatically transmit ECG files to the server when recording finishes.</p>
Delete file after uploading	<p>Choose from: On, <u>Off</u>.</p> <p>When On, the system will automatically delete ECG files from local memory when the files are automatically or manually transmitted to</p>

	the server.
Time Synchronization	<p>Choose from: <u>On</u>, Off.</p> <p>When On, the system will send a synchronization request to the server each time the electrocardiograph is powered on or retrieves orders from server. And the time sent by the server is taken as the current system time.</p>
Encrypted Transmission	<p>Choose from: <u>On</u>, Off.</p> <p>When On, the system will use encryption protocol during ECG transmission. SFTP and SSL protocols will be employed for such transmission. If you need to import another certificate for encrypted transmission, please contact the manufacturer.</p>
Receive push notifications	<p>Choose from: On, <u>Off</u>.</p> <p>When On, the electrocardiograph can receive notifications of ECG diagnosis from the server in real time.</p> <p>When Off, the electrocardiograph will not receive such notifications.</p>
MAC Address	View the MAC address of the device.
Server Setting	<p>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.</p> <p>FTP or SFTP Server: set the address, port No., user name, and password of the server that receives ECG files from the system. The communication port allows a maximum of five numbers for entry.</p> <p>Connection test: checks if the server is connected.</p> <p>NOTE:</p> <p>For information on how to configure the network, consult your network administrator.</p>
Transmission Commitment	<p>Choose from: <u>On</u>, Off.</p> <p>When On, the server will give a response 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.</p>

10.6 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, system will prompt you P wave widens.
Algorithm Sensitivity	Choose from: <u>Normal</u> or Weak.
Serious Diseases Hint	Choose from: On, <u>Off</u> . When On, diagnosis with serious illnesses will be marked with "▶" in the ECG report.
RV5+SV1	If selected, this measuring parameter will be displayed in auto measurements and ECG report. This is selected by default.
RV6/SV2	If selected, this measuring parameter will be displayed in auto measurements and ECG report. This is not selected by default.
RR/PP	If selected, this measuring parameter will be displayed in auto measurements and ECG report. This is not selected by default.
Maximum Signal Range	Choose from: <u>±5 mV</u> , ±10 mV, ±20 mV.
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.
Pacemaker Detection Rate	Choose from: Low, <u>High</u> .

10.7 User Setting

You have to enter password before configuring the user setting.

Item	Description
User Login	If selected, you have to enter user name and password for login to iSE. You can also input the user's fingerprint for login. User login is selected by default.
Add User	Enter the user's real name, define his/her user name and password, and (or) input his/her fingerprint for login to iSE. The user can also be given the authority to diagnose by ticking the check box before diagnostic authority.
Modify User	<p>Modify user name and (or) password. Select a user from the user list for modification. You can also update user information by tapping Sync.</p> <p>NOTE:</p> <ol style="list-style-type: none"> Users may have different permission to operate iSE: <ul style="list-style-type: none"> ECG test: all the iSE operations except modifying ECG measurements and diagnosis. ECG diagnosis: all the iSE operations including modifying ECG measurements and diagnosis. User permission is set up in the server. The users added from your electrocardiograph only has permission to do ECG test.

10.8 Others

Item	Description
DEMO Mode	<p>Choose from: <u>Off</u>, Normal ECGs, Abnormal ECGs.</p> <p>When enabled, patient information can neither be deleted nor retrieved from the server. ECG data acquired is not stored.</p> <p>You need to enter the password "006363" to open the DEMO mode.</p>
Hospital Name	Enter up to 90 English letters to define the hospital name. This name will appear in the title of ECG report. File formats such as PDF, JPG, BMP, PNG, and TIFF are supported.
Function Activation	Activate DICOM, SCP, FDA-XML, communications, 18-lead ECG, VCG, VCG Calculation, HRV, SAECG, and TVCG. Select the one you want to activate and enter the activation code. Communications here means to retrieve orders from the server

and upload ECG data to the server.

Administrator Password	Define the password required to access System Setting, the Patient tab (if selected), and ECG File tab (if selected). Blank by default. Enter up to 6 letters or numbers or combination of them to define the password.
Restore default factory settings	Clears the current settings and returns to the default factory settings. You need to enter the password to configure this setting.
Set System Time	Set or change the system time.

10.9 System Update

Item	Description
Device Model	Displays the model of the electrocardiograph.
Software Version	Displays the version of 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 ECG board.
SEMIP Version	Displays the version of algorithm.
Upgrade APP by USB	Upgrade the software by connecting to a USB storage device. For more information, please refer to the service manual or contact the manufacturer.
Upgrade ECG Board by USB	Upgrade the ECG board by connecting to a USB storage device. For more information, please refer to the service manual or contact the manufacturer.


10.10 System Maintenance

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

Chapter 11 System Message

System messages and the corresponding causes are listed below.

Table 11-1 System messages and causes

System Message	Causes
Lead off:	Electrodes fall off the patient or the lead wires are disconnected to the ECG sampling box.
Network unavailable!	4G, WIFI, and Ethernet are off.
Network connection timeout! Please check the network.	The network signal is poor and network connection is failed.
Order server connection failed!	IP address is wrong or the server is off.
FTP connection failed!	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.

Chapter 12 Cleaning, Care and Maintenance

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

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

12.1 General Points

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

Use only the recommended cleaning agents and disinfectants listed in this manual. Others may cause damage (not covered by warranty), reduce product lifetime or cause safety hazards.

Always dilute according to the manufacturer's instructions.

Unless otherwise specified, do not immerse any part of the equipment or any accessories in liquid.

Do not pour liquid onto the equipment.

Do not allow liquid to enter the case.

Never use abrasive material (such as steel wool or silver polish).

Inspect the sampling box and reusable accessories after they are cleaned and disinfected.

CAUTION

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

12.2 Cleaning

WARNING

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

If the device or accessories has been in contact with the patient, clean and disinfect them after each use.

1. Power off the device. Take out its battery. In the case of DE18 sampling box, disconnect it from the DE18 cable and the lead wires.
2. Wipe the exterior of the device and accessories, including the main unit, DE18 sampling box, ECG cable, reusable electrodes and etc., using a clean soft cloth dampened with cleaning solution until no visible contaminants.
3. Remove residual cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning solution.
4. Air dry the device and accessories in a ventilated and cool place.

The validated cleaning agents for the electrocardiograph, sampling box, and ECG patient cables are:

Mild near neutral detergent

Ethanol (75%)

Isopropanol (70%)

The validated cleaning agent for reusable electrodes is:

Mild near neutral detergent

CAUTION

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

12.3 Disinfection

To avoid permanent damage to the device, it is recommended that disinfection is performed only when it is considered as necessary according to your hospital' 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 DE18 sampling box, disconnect it from the DE18 cable and the lead wires.

2. Wipe the exterior of the device and accessories, including the main unit, DE18 sampling box, ECG cable, reusable electrodes and 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. Do not use high-temperature, high-pressure vapour or ionizing radiation as disinfection methods.
 2. Do not use chloric disinfectant such as chloride, sodium hypochlorite etc.
 3. Clean and disinfect reusable electrodes after each use.
-

12.4 Care and Maintenance

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


CAUTION


1. Besides the maintenance requirements recommended in this manual, comply with local regulations on maintenance and measurement.
 2. Do not open the casing. Once the device is opened, all warranties will lapse.
 3. The maintenance operations like software upgrade of the device can only be completed by EDAN-qualified service personnel.
 4. Operate the cardiograph, charge or store the battery at a temperature of 40°C (104°F) or lower. Exposure to higher temperature may reduce battery life, damage the battery, and degrade cardiograph performance.
-

12.4.1 Recharging and Replacing the Battery

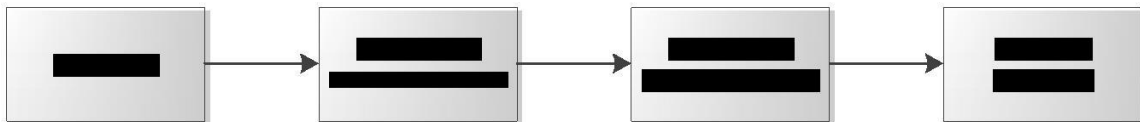
Recharging the battery

iSE series electrocardiograph is equipped with a recharge control circuit together with the battery. Because of consumption during storage and transportation, the battery capacity decreases. Recharge the battery prior to the first use.

When the unit is connected to the mains supply, the battery will be recharged automatically. The power light turns red and the recharge indicator  appears on the display. The battery capacity is indicated by the percentage in the top right corner of the

display. When the battery capacity is lower than 20%, the icon  will appear and the following message will be displayed: ***Battery is low. Please recharge!***

Recharging process:



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

CAUTION

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

Replacing the battery

If you have recharged the battery and the electrocardiograph still does not turn on when unplugged, or if the battery loses its charge quickly, or foul smell and leakage are found, replace the battery as follows.

1. Unplug the electrocardiograph from AC power if connected.
2. Turn the electrocardiograph upside-down.
3. Switch on the battery compartment. The battery will pop out.
4. Place a new battery into the battery compartment. You will then hear a click as the battery are stuck into the compartment.

WARNING

1. Replace a battery with a new one that is the same model and specification provided by the manufacturer.
2. Danger of explosion -- Do not reverse the anode and the cathode when installing the battery.
3. Discard the old battery appropriately. Contact your local authorities concerning

disposal and recycling.

4. Remove the battery from the electrocardiograph that is not in use for a long time.
 5. If the battery is not used for a long time, we recommend that the battery be recharged at least once every 6 months to prevent over-discharge.
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-

12.4.2 Thermal Chart Paper

Tips for handling thermal paper:

Store in a dry, dark and cool place.

Avoid exposure to excessive temperature, humidity and sunshine.

Avoid exposure to fluorescence for a long time.

Do not store with polyvinyl chloride or other chemicals, which will lead to color change of the paper.

Store thermal paper separately to avoid the thermal traces trans-printing each other.

NOTE:

Use the thermal chart paper provided by the manufacturer. Otherwise the thermal print head may not survive its expected lifespan. Illegible ECG traces and unsmooth paper feeding may occur.

12.4.3 Visual inspection

Perform a visual inspection of 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/touch screen for cracks or other damage.

Regularly inspect all plugs, cords, cables, and connectors for fraying or other damage.

Verify that all cords and connectors are securely seated.

Inspect keys and controls for proper operation.

12.4.4 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 properly as described in the instructions for use.
- e) Test the protection earth resistance according to IEC/EN 60601-1: Limit: 0.1 ohm.
- f) Test the earth leakage current according to IEC/EN 60601-1: Limit: NC 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 essential performance according to IEC/EN 60601-2-25, or methods recommended by the hospital or local distributor.

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

WARNING

1. Failure on the part of the responsible individual hospital or institution employing this equipment to implement a satisfactory maintenance schedule may cause undue equipment failures and possible health hazards.
 2. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
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Main unit and sampling box

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

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 in 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

Electrodes must be cleaned after use and make sure there is no gel left on them.

Keep suction bulbs of chest electrodes away from sunshine and excessive temperature.

After long-term use, the surfaces of electrodes will be oxidized because of erosion and other causes. By this time, electrodes should be replaced to achieve high data quality.

While usage will have an impact, it is expected that the electrocardiograph will be in service for 10 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 are to 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 13 Accessories

WARNING

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

Table 13-1 Standard accessory list

Accessory	Model	Part Number
Power Cord	FG-L23X-20150323-001	01.13.037122
Power Cord	FG-L23X-003-04	01.13.036638
ECG Cable	EC10DIBDS1A	01.57.471500
	EC10DISDS2	01.57.107581
	EC10DIGDS1	01.57.107583
	CI-0001	01.57.471876
ECG Cable	EC10DABDS1A	01.57.471499
	EC10DASDS2	01.57.107582
	EC10DAGDS1	01.57.107584
	CD205E	01.57.471877
ECG Cable	EL16DIB181	01.57.471394
	EL10DIB181	01.57.471686
	EL06DIB181	01.57.471688
ECG Cable	EL16DAB181	01.57.471393
	EL10DAB181	01.57.471687
	EL06DAB181	01.57.471689
ECG Sampling Box	DE18	02.01.215702
ECG Sampling Box	DE18	02.01.215703
Cable	CNT02	01.13.036736
Chest electrodes	ECG-FQX41	01.57.040163
	ECG-EQX41	01.57.040168
Limb electrodes	ECG-FJX42	01.57.040162

	ECG-EJ01	01.57.040169
Switching Power Adaptor	UE48-190253SPA3	21.21.064244

Table 13-2 Optional accessory list

Accessory	Model	Part Number
ECG Electrodes	H99SG	01.57.471858
	H124SG	01.57.471859
	L-00-S	01.57.471860
	Medi-Trace 200	01.57.471862
	Q-Trace Gold5500	01.57.471863
Electrode Adapters	98ME07GA454	01.57.040172
Socket Adapters	CK-03-752	01.57.471864
Thermal Chart Paper	/	01.57.472015
SD Card	/	01.17.052452
Scanner	LS4208-SR20007ZZR	01.23.068023
	1900GSR-2	21.18.052311
LAN Cable	/	01.13.020096

NOTE:

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

Chapter 14 Warranty and Service

14.1 Warranty

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

The warranty is void in cases of:

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

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

14.2 Contact information

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

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

Appendix 1 Technical Specifications

A1.1 Safety Specifications

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

A1.2 Environment Specifications

Temperature:	Transport & Storage -20°C (-4°F)~+55°C (+131°F)	Working +5°C (+41°F) ~ +40°C (+104°F)

Relative Humidity:	15%RH~95%RH Non-Condensing	15%RH~95%RH Non-Condensing
Atmospheric Pressure:	70 kPa ~106 kPa	70 kPa ~106 kPa

A1.3 Physical Specifications

Dimensions	No handle or thermal printer: 270mm(L)×170mm(W)×28mm(H), ±2mm With handle: 270mm(L)×230mm(W)×52mm(H), ±2mm With thermal printer: 274mm(L)×274mm(W)×90mm(H), ±2mm
Weight	1.2 kg±0.3 kg (excluding thermal printer, handle, and printer paper) 1.4 kg±0.3 kg (with handle, excluding thermal printer and printer paper) 2.3 kg±0.3 kg (with thermal printer, excluding handle and printer paper)
Display	About 10.1" LCD full-touch screen, at a resolution of 1920×1200

A1.4 Power Supply Specifications

Mains Supply	Operating Voltage = 100 V-240 V~
	Operating Frequency = 50 Hz / 60 Hz
	Power Adapter: Output Voltage = 19 V, Output Current = 2.53 A Input current=1.1 A
Li-ion Battery	Rated Voltage / Typical Capacity = 15.2 V / 3550 mAh
	When the battery is fully charged, iSE can work (without printing) continuously at least 8 hours. 100% recharge time: ≤ 5 hours 90% recharge time: < 4 hours
	Cycle life
	500 times

A1.5 Performance Specifications

HR Recognition

HR Range	30 bpm – 300 bpm
Accuracy	1 bpm
Filter	AC Filter: 50Hz / 60Hz / Off
	DFT Filter: 0.01Hz / 0.05Hz / 0.32Hz / 0.67Hz
	EMG Filter: 25Hz / 35Hz / 45Hz / Off
	Lowpass Filter: 350Hz / 300Hz / 270Hz / 150Hz / 100Hz / 75Hz
DE12 / DE18 Performance	
Leads Mode	DE12: 12 standard leads
	DE18: 18 standard leads
Acquisition Mode	DE12: Simultaneously 12 leads
	DE18: Simultaneously 18 leads
Analog-to-Digital Converter	A/D: 24 bits
	Resolution: 0.1192 uV/LSB
	Sampling Frequency: 64,000 /sec/channel
Time Constant	$\geq 5s$
Frequency Response	0.01 Hz – 350 Hz, -3 dB
Gain	1.25, 2.5, 5, 10, 20, 10/5, AGC (mm/mV) ($\pm 5\%$)
Input Impedance	$\geq 100 M\Omega$ (10Hz)
Input Circuit Current	$\leq 0.01 \mu A$
Input Voltage Range	$< \pm 5 mV_{p-p}$
Calibration Voltage	1mV $\pm 2\%$
DC Offset Voltage	$\pm 900 mV$, $\pm 5\%$
Minimum Amplitude	20 μV_{p-p}
Noise	$\leq 12.5 \mu V_{p-p}$
CMRR	$\geq 140 dB$ (AC filter on)
	$\geq 123 dB$ (AC filter off)
Pacemaker Detection (Single Channel Detection)	
Amplitude	DE12: $\pm 500 uV$ to $\pm 700 mV$

	DE18: ± 750 μ V to ± 700 mV
Width	DE12: 30 μ s to 2.0 ms
	DE18: 50 μ s to 2.0 ms
WIFI	
Transmitting Frequency	2.4 GHz and 5 GHz
Frequency Band	2412 MHz – 2472 MHz (2.4GHz) 5150 MHz – 5850 MHz (5GHz)
Modulation Type	DBPSK/DQPSK/CCK BPSK/QPSK/16QAM/64QAM,GFSK, $\pi/4$ -DQPSK,8-DPSK
Transmitting Power	≤ 17 dBm (2.4GHz) ≤ 17 dBm (5GHz)
Bluetooth	
Transmitting Frequency	2402 MHz – 2480 MHz
Modulation Type	GFSK, $\pi/4$ -DQPSK, 8-DPSK
Transmitting Power	≤ 15 dBm
4G	
Bands	FDD LTE: Band 1, Band 3, Band 8, all bands with diversity
	TDD LTE: Band 34, Band 38, Band 40, Band 41, all bands with diversity
Others	
NFC	13.56 MHz

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

Appendix 2 EMC Information

Electromagnetic Emissions

Guidance and manufacture's declaration - electromagnetic emission		
The iSE is intended for use in the electromagnetic environment specified below. The customer or the user of the iSE should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The iSE 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 B	The iSE 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 it is used in a residential environment (for which CISPR 11 class B is normally 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 manufacture's declaration - electromagnetic immunity

The iSE is intended for use in the electromagnetic environment specified below. The customer or the user of the iSE should assure that it is used in such an environment.

Immunity test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC/EN 61000-4-2	8 kV contact 15 kV air	8 kV contact 15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC/EN 61000-4-4	2 kV for power supply lines	2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	1 kV line to line 2 kV line to ground	1 kV line to line 2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (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 typical 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 At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°</p> <p>0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles) Single phase: at 0°</p> <p>0 % U_T; 250/300 cycle</p>	<p>0 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°</p> <p>0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles) Single phase: at 0°</p> <p>0 % U_T; 250/300 cycle</p>	<p>Mains power quality should be that of a typical commercial or hospital environment. If the user of the 18-lead electrocardiograph requires continued operation during power mains interruptions, it is recommended that the 18-lead electrocardiograph be powered from an uninterruptible power supply or a battery.</p>
<p>NOTE U_T is the a.c. mains voltage prior to application of the test level.</p>			

Electromagnetic Immunity

Guidance and manufacture's declaration - electromagnetic immunity			
The iSE is intended for use in the electromagnetic environment specified below. The customer or the user of the iSE should assure that it is used in such an environment.			
Immunity test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF	3 V _{rms} 150 kHz to 80 MHz	3V _{rms} 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the iSE, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
IEC/EN 61000-4-6	6V _{rms(c)} in ISM bands between 0.15 MHz and 80 MHz	6V _{rms(c)} in ISM bands between 0.15 MHz and 80 MHz	$d = 1.2 \sqrt{P} \quad 150 \text{ kHz to } 80 \text{ MHz}$
Radiated RF	3 V/m	3 V/m	
MHz IEC/EN 61000-4-3	80 MHz to 2.7 GHz	80 MHz to 2.7 GHz	$d = 1.2 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3 \sqrt{P} \quad 800 \text{ MHz to } 2.7 \text{ GHz}$
	See Table 1.	See Table 1.	$d = 6 \sqrt{P/E} \quad \text{at RF wireless communications equipment bands}$ equipment (including peripherals such as antenna cables and external antennas) should be used any part of the iSE, including cables specified by the manufacturer). (Portable RF communications

no closer than 30 cm (12 inches) to

Where P is the maximum output power rating of the transmitter in


		<p>watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</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>a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the iSE is used exceeds the applicable RF compliance level above, the iSE should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the iSE.</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 800, iDEN 820, CDMA 850, LTE	Pulse modulation ^{b)} 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	Band 5 GSM 1800; CDMA 1900; GSM 1900; DECT; LTE	Pulse modulation ^{b)} 217 Hz			
1845						
1970						
		UMTS Bluetooth,		2	0.3	28
2450	2400-2570	WLAN,802.11 b/g/n, RFID 2450, LTE Brand 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28
5240			Pulse modulation ^{b)}			
5500	5100-5800	WLAN 802.11 a/n	modulation ^{b)} 217 Hz			
5785						
				0.2	0.3	9

Note: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM maybe reduce to 1m. The 1 m test distance is permitted by IEC/EN 61000-4-3.

- a) For some services, only the uplink frequencies are included.
- b) The carrier shall be modulated using a 50% duty cycle square wave signal.
- c) As an alternative FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

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

Recommended separation distances between portable and mobile RF communications equipment and the iSE

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

Maximum output power rating of transmitter P (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.7 GHz $d = \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

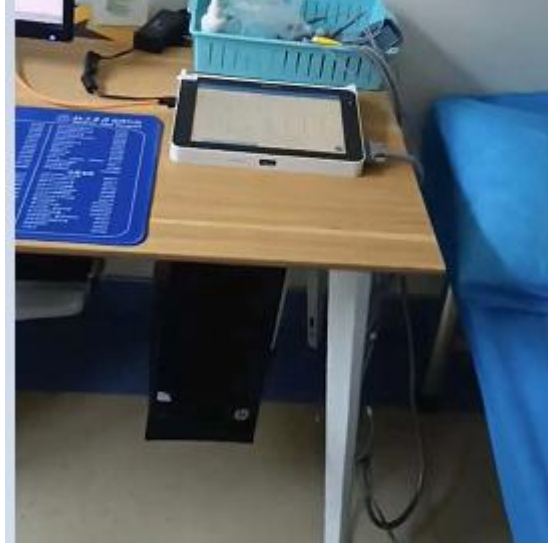
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix 3 Abbreviation

Abbreviation	Statement
LCD	Liquid Crystal Display
ECG	Electrocardiograph/Electrocardiogram
BP	Blood Pressure
HR	Heart Rate
AC	Alternating Current
ID	Identification
AC	Alternating Current
USB	Universal Serial Bus
AGC	Auto Gain Control
NC	Normal Condition
SFC	Single Fault Condition
NFC	Near field communication
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.

P/N: 01.54.458432

MPN: 01.54.458432014



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