SE-18 Series

Electrocardiograph

Version 2.1

User Manual

CE 0123

EDAN

About this Manual

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Statement

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

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

Product Information

Product Name: Electrocardiograph

Model: SE-18, SE-15

Responsibility of the Manufacturer

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

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out

by persons authorized by EDAN, and

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

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

Terms Used in this Manual

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

WARNING

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

CAUTION

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

NOTE

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

Contents

Chapter 1 Safety Guidance

This chapter provides important safety information related to the use of SE-18 and SE-15.

1.1 Indications for Use/Intended Use

The SE-18/SE-15 18-lead electrocardiograph is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. However, the interpreted ECG with measurements and interpretive statements is offered to clinicians on an advisory basis only.

WARNING

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

1.2 Warnings and Cautions

To use the system safely and effectively, firstly be familiar with the operation method of Windows and read the user manual in detail to be familiar with the proper operation method for the purpose of avoiding 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 Safety Warnings

WARNING

1. **The electrocardiograph is intended to be used by qualified physicians or personnel professionally trained. They should be familiar with the contents of this user manual before operation.**
2. **Only qualified service engineers can install this equipment, and only service engineers authorized by the manufacturer can open the shell. Otherwise, safety hazards may happen.**
3. **EXPLOSION HAZARD - Do not use the electrocardiograph in the presence of flammable anesthetic mixtures with oxygen or other flammable agents.**
4. **SHOCK HAZARD - The power receptacle must be a hospital grade grounded outlet. Never try to adapt the three-prong plug to fit a two-slot outlet.**
5. **Make sure that the power is turned off and the power cord is disconnected from the AC socket before connecting or disconnecting equipment. Otherwise, electrical shock or other injuries may happen to the patient or operator.**
6. **If the integrity of the external protective conductor is in doubt, the equipment should be powered by an internal li-ion rechargeable battery.**
7. **Do not use this equipment in the presence of high static electricity or high voltage equipment which may generate sparks.**
8. **Only the patient cable and other accessories supplied by the manufacturer can be used. Or else, the performance and electric shock protection cannot be guaranteed.**
9. **The use of patient cable and other accessories not supplied by the manufacturer may result in increased emissions or decreased immunity of the equipment.**
10. **The electrocardiograph has been safety tasted with the recommended accessories, peripherals, and leads, and no hazard is found when the electrocardiograph is operated with cardiac pacemakers or other stimulators.**
11. **Make sure that all electrodes are connected to the patient correctly before operation.**

WARNING

12. **Ensure that the conductive parts of electrodes and associated connectors, including neutral electrodes, do not come in contact with earth or any other conducting objects.**
13. **If reusable electrodes with electrode gel are used during defibrillation, the electrocardiograph recovery will take more than 10 seconds. The manufacturer recommends the use of disposable electrodes at all times. When disposable electrodes are used, the defibrillation time of the electrocardiograph will be less than 10 seconds.**
14. **Electrodes of dissimilar metals should not be used; otherwise it may cause a high polarization voltage.**
15. **The disposable electrodes can only be used for one time.**
16. **Do not touch the patient, bed, table or the equipment while using the ECG together with a defibrillator.**
17. **Do not touch accessible parts of electrical equipment and the patient simultaneously.**
18. **The use of equipment that applies high frequency voltages to the patient (including electrosurgical equipment and some respiration transducers) is not supported and may produce undesired results. Disconnect the patient data cable from the electrocardiograph, or detach the leads from the patient prior to performing any procedure that uses high frequency surgical equipment.**
19. **If WIFI technology is used, in order to maintain compliance with the FCC RF exposure guidelines, WIFI should be installed and operated with a minimum distance of 20cm between the radiator and the human body. There should be no shield in or around the room where WIFI is used.**
20. **Fix attention on the examination to avoid missing important ECG waves.**
21. **SHOCK HAZARD - Don't connect non-medical electrical equipment, which has been supplied as a part of the system, directly to the wall outlet when the non-medical equipment is intended to be supplied by a multiple portable socket-outlet with an isolation transformer.**
22. **Any non-medical equipment (such as the external printer) is not allowed to be used within the patient vicinity (1.5m/6ft.).**

WARNING

23. **SHOCK HAZARD - Don't connect electrical equipment, which has not been supplied as a part of the system, to the multiple portable socket-outlet supplying the system.**
24. **Do not connect any equipment or accessories that are not approved by the manufacturer or that are not IEC/EN 60601-1 approved to the electrocardiograph. The operation or use of non-approved equipment or accessories with the electrocardiograph is not tested or supported, and electrocardiograph operation and safety are not guaranteed.**
25. **Do not exceed the maximum permitted load when using the multiple portable socket-outlet(s) to supply the system.**
26. **Multiple portable socket-outlets shall not be placed on the floor.**
27. **Do not use the additional multiple portable socket-outlet or extension cord in the medical electrical system, unless it's specified as part of the system by manufacturer. And the multiple portable socket-outlets provided with the system shall only be used for supplying power to equipment which is intended to form part of the system.**
28. **Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the standard IEC/EN 60601-1. Therefore anybody, who connects additional equipment to the signal input or output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC/EN 60601-1. If in doubt, consult our technical service department or your local distributor.**
29. **The potential equalization bar can be connected to that of other equipment when necessary. Make sure that all the equipment is connected to the potential equalization terminal.**
30. **The electrocardiograph shall not be serviced or maintained while in use with a patient.**

WARNING

31. **Connecting any accessory (such as external printer) or other device (such as the computer) to this electrocardiograph makes a medical system. In that case, additional safety measures should be taken during installation of the system, and the system shall provide:**
    a) **Within the patient environment, a level of safety comparable to that provided by medical electrical equipment complying with IEC/EN 60601-1, and**
    b) **Outside the patient environment, the level of safety appropriate for non-medical electrical equipment complying with other IEC or ISO safety standards.**
32. **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.**
33. **If multiple instruments are connected to a patient, the sum of the leakage currents may exceed the limits given in the IEC/EN 60601-1 and may pose a safety hazard. Consult your service personnel.**
34. **The appliance coupler or mains plug is used as isolation means from supply mains. Position the electrocardiograph in a location where the operator can easily access the disconnection device.**
35. **The medical electrical equipment needs to be installed and put into service according to Appendix 2 EMC information.**
36. **The equipment should not be used adjacent to or stacked with other equipment, refer to the recommended separation distances provided in Appendix 2 EMC Information.**
37. **Portable and mobile RF communications equipment can affect medical electrical equipment, refer to the recommended separation distances provided in Appendix 2 EMC Information.**
38. **Assembly of the electrocardiograph and modifications during actual service life shall be evaluated based on the requirements of IEC 60601-1.**

1.2.2 Protecting Personal Information

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

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

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

CAUTION

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

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

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

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

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

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

CAUTION

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

8 **When the system is returned for maintenance, disposed of, or removed from the medical institution for other reasons, it is necessary to ensure that all patient data are removed from the system.**

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

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

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

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

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

1.2.3 Li-ion Battery Care Warnings

WARNING

1. **Improper operation may cause the internal li-ion battery (hereinafter called battery) to be hot, ignited or exploded, and it may lead to the decrease of the battery capacity. It is necessary to read the user manual carefully and pay more attention to warning messages.**
2. **Only qualified service engineers authorized by the manufacturer can open the battery compartment and replace the battery, and batteries of the same model and specification as manufacturer configuration should be used.**
3. **DANGER OF EXPLOSION -- Do not reverse the anode and the cathode when installing the battery.**
4. **Do not heat or splash the battery or throw it into fire or water.**
5. **Do not destroy the battery; Do not pierce battery with a sharp object such as a needle; Do not hit with a hammer, step on or throw or drop to cause strong shock; Do not disassemble or modify the battery.**
6. **When leakage or foul smell is found, stop using the battery immediately. If your skin or cloth comes into contact with the leakage liquid, cleanse it with clean water at once. If the leakage liquid splashes into your eyes, do not wipe them. Irrigate them with clean water first and go to see a doctor immediately.**
7. **Properly dispose of or recycle the depleted battery according to local regulations.**
8. **Only when the device is off can the battery be installed or removed.**
9. **Remove the battery from the electrocardiograph when the electrocardiograph isn't used for a long time.**
10. **If the battery is stored alone and not used for a long time, we recommend that the battery be charged at least once every 6 months to prevent overdischarge.**

1.2.4 General Cautions

CAUTION

1. **Avoid liquid splash and excessive temperature. The temperature must be kept between 5 ºC and 40 ºC during operation, and it should be kept between -20 ºC and 55 ºC during transportation and storage.**
2. **Do not use the equipment in a dusty environment with bad ventilation or in the presence of corrosive.**
3. **Make sure that there is no intense electromagnetic interference source around the equipment, such as radio transmitters or mobile phones etc. Attention: large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment etc. is likely to bring electromagnetic interference.**
4. **Ruptured fuse must only be replaced with that of the same type and rating as the original.**
5. **The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal. Batteries are hazardous waste. Do NOT dispose of them together with house-hold garbage. At the end of their lives hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or battery, please contact your local Civic Office, or the shop where you purchased the product.**
6. **Federal (U.S.) law restricts this device to sale by or on the order of a physician.**

1.3 List of Symbols

No.	Symbol	Description
1		Input/output
2		DEFIBRILLATION-PROOF TYPE CF APPLIED PART
3		Caution
4		Consult operating instructions
5		Socket for DE18 sampling box
6		Equipotentiality
7		Patient cable socket (example) on DE 18
8		ECG mark/ Start ECG acquisition button on DE18
9		USB socket
10		SD card slot
11		Computer network

12		VGA socket
13		Serial port
14		Alternating Current
15		Battery check
16		Battery recharging indicator
17		Power On/Off key
18		General symbol for recovery/recyclable
19	P/N	Part Number
20	SN	Serial Number
21		Date of Manufacture
22		Manufacturer
23	EC REP	Authorized Representative in the European Community
24	CE 0123	CE marking
25	Rx Only	Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.
26		Disposal method

27		Refer to instruction manual/booklet (Background: Blue; Symbol: White)
28		General warning sign (Background: Yellow; Symbol & Outline: Black)
29*		Non-ionizing electromagnetic radiation symbol
30	FCC ID： SMQSE18EDAN	Federal Communications Commission: FCC ID：SMQSE18EDAN
31		Conforms to AAMI Std. 60601-1, IEC Std. 60601-2-25 Certified to CSA Std. C22.2 No 60601-1,CSA Std. C22.2 No 60601-2-25
32		Warning: Mind Your Fingers (Background: Yellow; Symbol & Outline: Black)
33		Medical Device
34		Unique Device Identifier

NOTE:

1. For details about buttons of the keyboard, refer to section 2.2.
2. 29*: Apply to devices with wireless functions.
3. The user manual is printed in black and white.

Chapter 2 Introduction

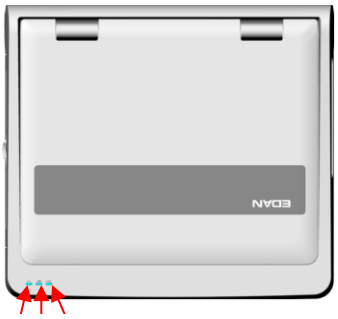
The SE-18/SE-15 18-lead electrocardiograph adopts a 15" LCD screen with a resolution of 1024×768. Its major components include the main unit, power cord, patient cable, electrodes, ECG sampling box, battery, and recorder. It is mainly used by healthcare facilities to acquire ECG signals from patients for clinical diagnosis and research.

NOTE:

1. The pictures and windows in this manual are for reference only.
2. The only difference between SE-15 and SE-18 is that 18-lead ECG is configurable for SE-15. Therefore, only SE-18 is described in the subsequent chapters.

2.1 Top Panel

Figure 2-1 SE-18 Top Panel



A
B
C

	Symbol	Name	Explanation
A	∼	Mains supply indicator	When the device is powered by the mains supply, this indicator is lit.
B	▭	Battery check	When the device is powered by the battery, this indicator is lit.

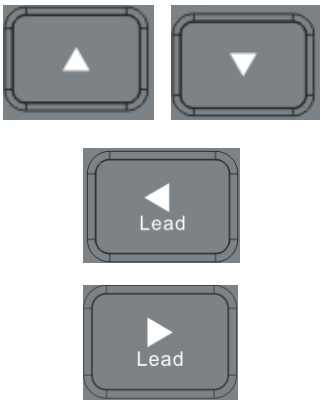
C		Battery recharging indicator	When the device is in sleeping status, this indicator flashes. When the battery is being recharged, this indicator is lit.

2.2 Keyboard and Keys

Figure 2.2 SE-18 Keyboard

NOTE: Only if the stress ECG function is activated, can keys in region ① be available.

Key	Description
	Press to delete characters.
	Press to quickly select the gender for the patient when **Gender** is selected in the **Patient Information Setup** window.
	Press to quickly select the age group on the main screen when you set **Age** to **Age Group** in the **Patient Information Setup** window.

	Press to select a working mode among the auto, manual, pharma study, and HRV modes. **NOTE:** Only if a working mode is selected in the **Work Mode Setup** window, can the working mode be selected by pressing the **MODE** key when the main screen is displayed.
	Press to confirm information.
Tab	Press to move the cursor. Pressing **Tab** can move the cursor forward, and pressing **Shift** + **Tab** can move the cursor backward.
	Press **Fn** and a letter key to type special characters.
	Press to move the cursor. In the manual mode or on the previewingscreen, press the Left or Right arrow to switch the lead groups. Pressing **Shift** + Up/Down can turn pages on the **Order Manager** screen and the **File Manager** screen.
	Press to start or stop printing reports Pressing **Shift** + **START/STOP** can quickly enable or disable the print out function in the AUTO mode.
	In the manual mode, pressing the **1mV/COPY** key can insert a 1mV calibration mark during the printing course. In the auto or rhythm mode, pressing the **1mV/COPY** key can print the ECG report which was printed out last time.
	Press to feed paper. If **Paper Marker** is set to **On (EDAN)** or **On (Other)**, pressing

	Tab can advance the recorder paper to the next black marker; if **Paper Marker** is set to **No,** pressing **Tab** can advance the paper for 2.5cm. Pressing **Tab** again can stop advancing the paper.
	During the resting test, press this key Pre-simple to sample 10s data and print out the ECG report of the sampled 10s data.
	Long press this key to turn on/off the electrocardiograph. Short press this key to enter or exit sleeping status.
Spacebar	Press to add a space between typed characters or select/deselect a checkbox.
	Press to cancel operation.
	If **Caps Lock** is disabled, pressing **Shift** + **P** can type a capital **P**.If **Caps Lock** is enabled, pressing **Shift** + **P** can type a lowercase **p**.

2.3 Rear Panel

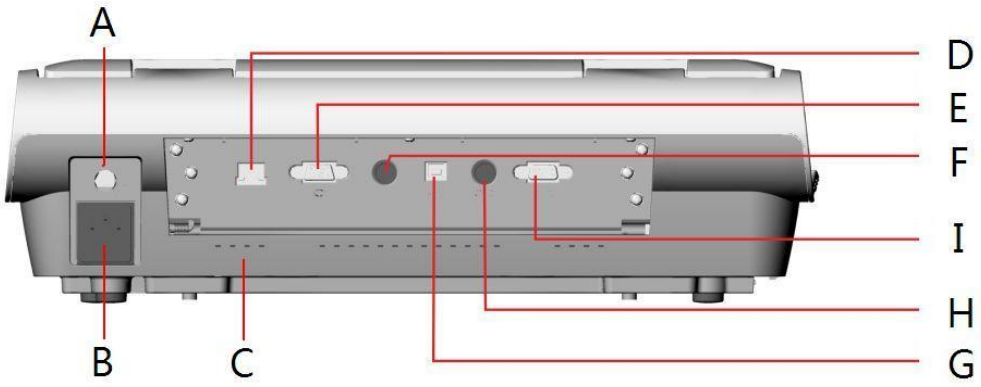


Figure 2-3 SE-18 Rear Panel

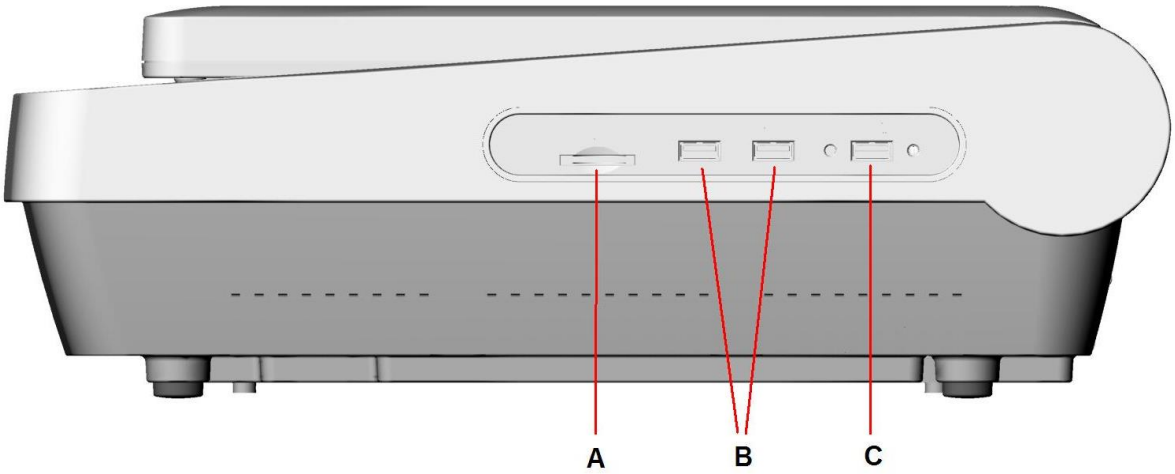
No.	Name	Explanation
A	Potential Equalization	Potential equalization conductor provides a

	Conductor	connection between the unit and the potential equalization bus bar of the electrical installation.
B	Mains Supply Socket	~ AC SOURCE: alternating current supply socket
C	Heat Emission Hole	Path for internal heat emission
D	Net Port	
E	VGA Socket	Connecting to display devices
F	External Input/Output Socket	
G	USB Socket	Connecting to a PC
H	Serial Port 1	Connecting to a BP monitor (Reserved)
I	Serial Port 2	Connecting to the treadmill/ergometer during exercise test (Reserved)

2.4 Right Panel

WARNING

1. Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the standard IEC/EN 60601-1. 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.
2. If multiple instruments are connected to a patient, the sum of the leakage currents may exceed the limits given in the IEC/EN 60601-1 and may pose a safety hazard. Consult your service personnel.



	Name	Explanation
A	SD Card Slot	Connecting to an SD card.
B	USB Socket 1	Standard USB socket, connecting to a U disk, a barcode reader or a USB printer recommended by the manufacturer
C	DE18 Socket	Connecting to the DE18 sampling box.

2.5 Bottom Panel

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

2.6 Features

- Supporting AC and DC power supply modes, internal rechargeable li-ion battery with professional battery powered circuit, battery management and protection systems
- Supporting multi-language
- Providing touch screen and full alphanumeric keyboard
- Correct detection for failure electrodes
- Convenient operation of recording by pressing the **START/STOP** key with high efficiency
- High resolution thermal recorder
- Supporting external USB printer
- Supporting accurate digital filter to decrease the polarization voltage and other interferences
- Supporting folded paper recorded with high resolution waveforms, calibration mark, gain, speed and filter
- Multiple work modes can be chosen freely, including auto, manual, HRV, VCG&SAECG, etc.
- Flexible printing formats
- Supporting ECG waves displaying with grid
- Convenient operation of system setup and file management
- Multiple file formats: DAT, PDF, BMP, JPG, TIFF, and configurable formats (SCP, FDA-XML, DICOM)
- Measurement function and interpretation function
- Supporting barcode reader
- ECG data can be transmitted to the PC software through the net cable or WIFI
- Supporting order function

Chapter 3 Operation Preparations

WARNING

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

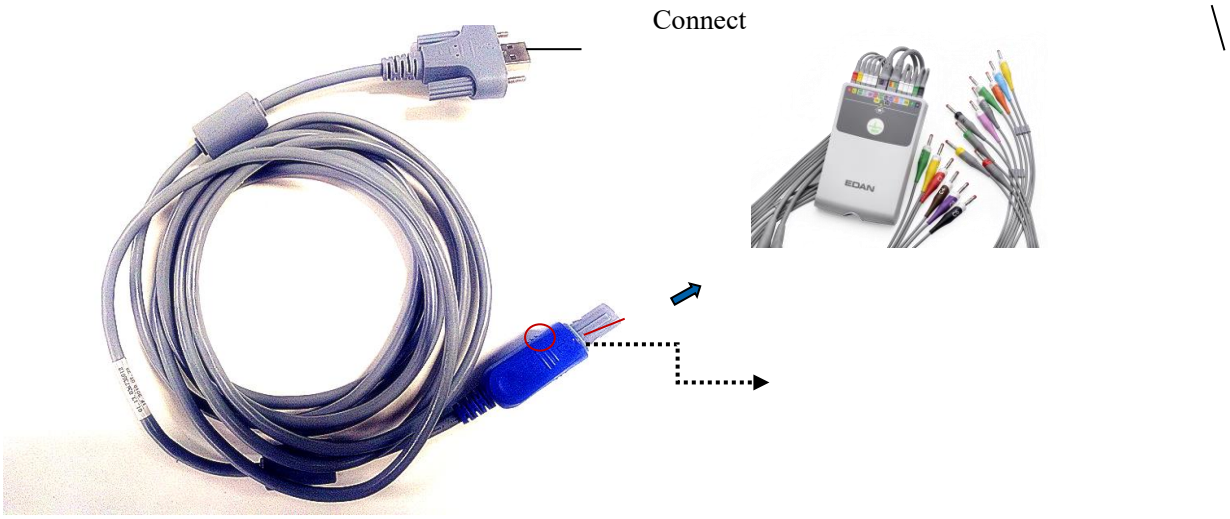
3.1 Connecting the Patient Cable to the Electrocardiograph and Electrodes

WARNING

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

3.1.1 Connecting the Patient Cable to the Electrocardiograph

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



DE18 cable DE18 sampling box and lead wires

3.1.2 Connecting the Patient Cable to Electrodes

Align all lead wires of the patient cable to avoid twisting, and connect the lead wires to the reusable electrodes or the clip/snap/banana socket adaptors. Firmly attach them.

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

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

IEC		AHA	
Electrodes	**Color Code**	**Electrodes**	**Color Code**
R	Red	RA	White
L	Yellow	LA	Black
N/RF	Black	RL	Green
F	Green	LL	Red
C1	White/Red	V1	Brown/Red
C2	White/Yellow	V2	Brown/Yellow
C3	White/Green	V3	Brown/Green
C4	White/Brown	V4	Brown/Blue
C5	White/Black	V5	Brown/Orange
C6	White/Violet	V6	Brown/Violet
C3R	White/Pink	V3R	Brown/Yellow
C4R	White/Gray	V4R	Brown/Red
C5R	White/Green	V5R	Brown/Green
C7	White/Orange	V7	Brown/Black
C8	White/Blue	V8	Brown/Blue
C9	White/Yellow	V9	Brown/Yellow
H	Light blue/Violet/	H	Orange/Violet
E	Light blue/ Yellow	E	Orange/Yellow
I	Light blue/ Red	I	Orange/ Red
M	Light blue/ Black	M	Orange/Black

3.2 Preparing the Patient

3.2.1 Instructing the Patient

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

3.2.2 Cleaning the Skin

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

To Clean the Skin

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

Wash the area thoroughly with soap and water.

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

3.3 Attaching Electrodes to the Patient

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

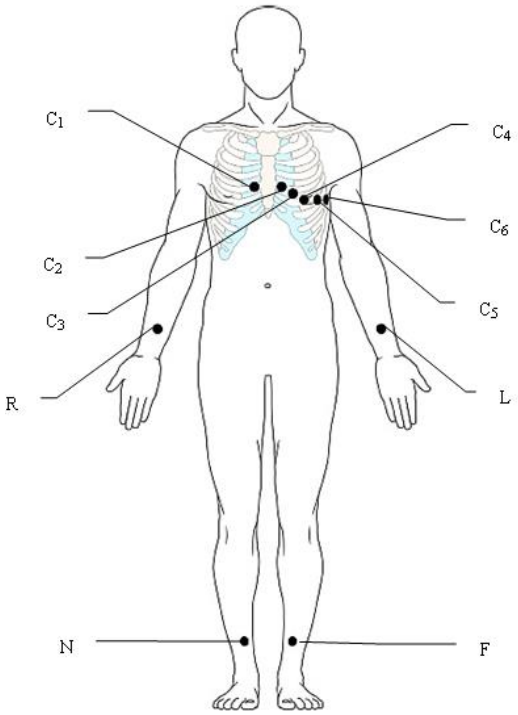
WARNING

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

3.3.1 Electrode Placement

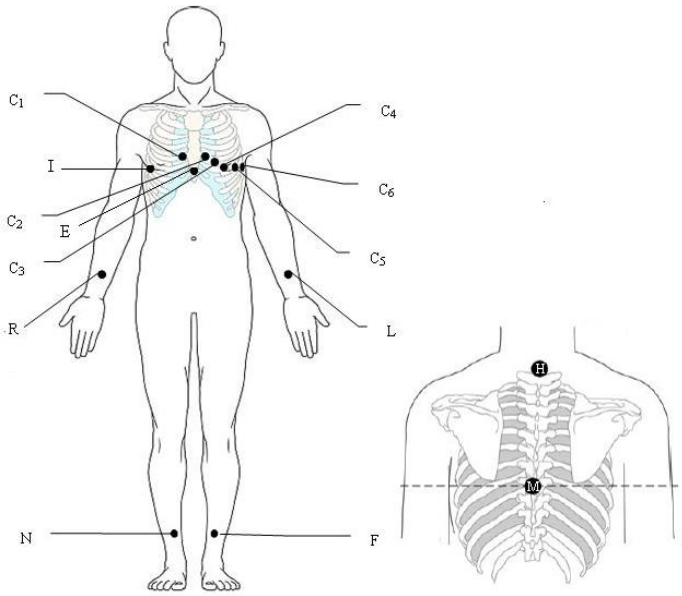
The electrodes' positions on the body surface are shown in the following table and figure.

Standard 12-Lead Placement



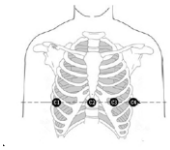
IEC	AHA	Electrode Placement
C1	V1	Fourth intercostal space at the right border of the sternum
C2	V2	Fourth intercostal space at the left border of the sternum
C3	V3	Fifth rib between C2 and C4
C4	V4	Fifth intercostal space on the left midclavicular line
C5	V5	Left anterior axillary line at the horizontal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

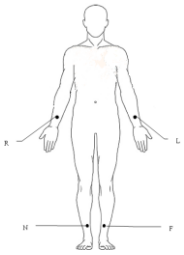
◆ **Standard + XYZ**

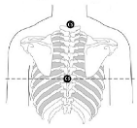


IEC	AHA	Electrode Placement
C1	V1	Fourth intercostal space at the right border of the sternum
C2	V2	Fourth intercostal space at the left border of the sternum
C3	V3	Fifth rib between C2 and C4
C4 (C)	V4 (C)	Fifth intercostal space on the left midclavicular line
C5	V5	Left anterior axillary line at the horizontal level of C4
C6 (A)	V6 (A)	Left midaxillary line at the horizontal level of C4
L	LA	Left arm
R	RA	Right arm
F	LL	Left leg
N	RL	Right leg
H	H	Back of neck, avoid the carotid artery and jugular vein.
E	E	Mid-sternum on the same horizontal level as C4 and C6.
I	I	Right mid-axillary line on the same horizontal level as C4 and C6.
M	M	Center of spine on the same horizontal level as C4 and C6

◆ Frank Lead Placement (for VCG)



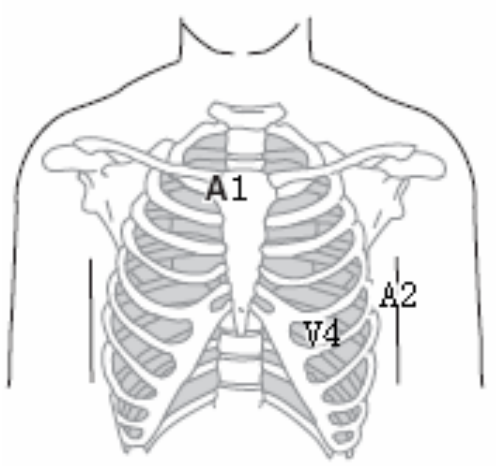




IEC	AHA	Electrode Placement
C1 (Corresponding to I)	V1 (Corresponding to I)	Right mid-axillary line on the same horizontal level as C3 and C4
C2 (Corresponding to E)	V2 (Corresponding to E)	Sternum at the level of C3 and C4
C3 (Corresponding to C)	V3 (Corresponding to C)	Mid-clavicular line in the fifth intercostals space
C4 (Corresponding to A)	V4 (Corresponding to A)	Left mid-axilary line on the same horizontal level as C3
C5 (Corresponding to M)	V5 (Corresponding to M)	Center of spine on the same horizontal level as C3 and C4
C6 (Corresponding to H)	V6 (Corresponding to H)	Neck, avoid carotid artery and jugular vein
L	LA	Left arm
R	RA	Right arm

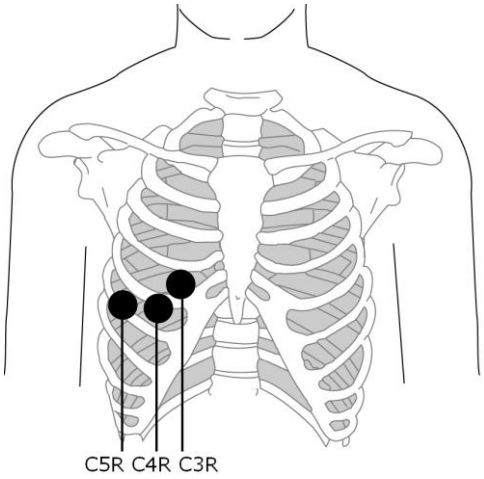
F	LL	Left leg
N	RL	Right leg

◆ **NEHB Placement**



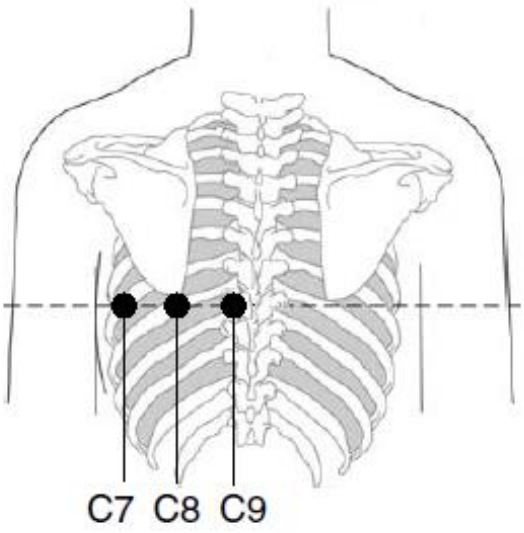
IEC	AHA	Electrode Placement
N_{st}	A1	Attachment point of the second rib to the right sternal edge
N_{ax}	A2	Fifth intercostal space on the left posterior axillary line
N_{ap}/C4	V4	Left mid-clavicular line in the fifth intercostal space

V3R+V4R +V5R (Right)



IEC	AHA	Electrode Placement
C3R	V3R	Right anterior chest opposite of C3
C4R	V4R	Right anterior chest opposite of C4
C5R	V5R	Right anterior chest opposite of C5

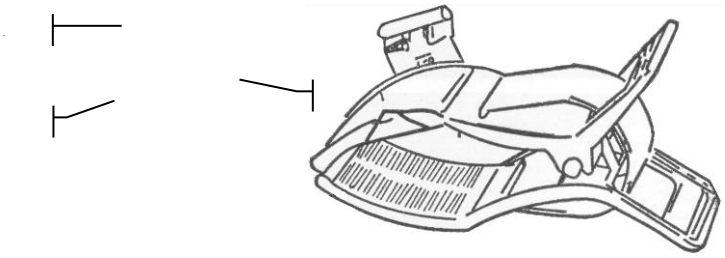
◆ **V7+V8+V9 (Back)**



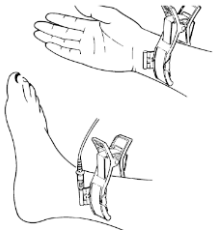
IEC	AHA	Electrode Placement
C7	V7	Left posterior axillary line on the same horizontal level as C4 and C6
C8	V8	Left midscapular line on the same horizontal level as C4 and C7
C9	V9	Left paraspinal border on the same horizontal level as C4 and C8

3.3.2 Attaching the Reusable Electrodes (for Resting ECG)

3.3.2.1 Attaching the Limb Electrodes



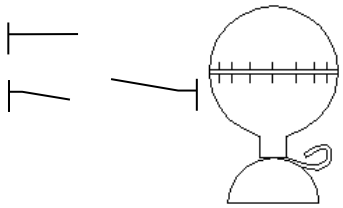
Limb Electrode



Limb Electrode Connection:

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

3.3.2.2 Attaching the Chest/Back Electrodes



Chest Electrode

Chest/Back Electrode Connection:

1) Ensure that the electrodes are clean;
2) Clean the electrode area on the chest surface with 75% alcohol;

3) Daub the round area of 25mm in diameter on each electrode site with gel evenly;

4) Place a small amount of gel on the brim of the chest electrode's metal cup;

5) Place the electrode on the chest electrode site and squeeze the suction bulb. Unclench it and the electrode is adsorbed on the chest;

6) Attach all chest electrodes in the same way.

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

3.3.3 Attaching Disposable Electrodes

Disposable Electrode (clip style):

Clip/Snap/Banana Socket Adaptor

Disposable Electrode Connection (Clip Style)

1) Align all lead wires of the patient cable to avoid twisting, and connect the clip/snap/banana socket adaptors to the patient cable.

2) Clean the electrode areas on the body surface with 75% alcohol.

3) Attach the disposable electrodes to the electrode positions on the body surface.

4) Clip the disposable electrodes with the clip/snap/banana socket adaptors.

Snap/Banana Socket Adapters

Disposable Electrode (Snap Style)

Disposable Electrode Connection (Snap Style)

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

WARNING

The disposable electrodes can only be used for one time.

3.4 Inspection Before Power-On

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

WARNING

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

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

signals caused by cold.

2) **Power Supply:**

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

3) **Patient Cable:**

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

4) **Electrodes**:

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

5) **Patient**:

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

3.5 Turning On/Off the Electrocardiograph

WARNING

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

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

To turn on the Electrocardiograph:

- When operating on AC power

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

  If the battery is weak when the mains supply is used, it will be recharged

automatically at the same time. Both the mains supply indicator (∿) and the battery recharging indicator (⇥▭) will be lit.

♦ When operating on battery power

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

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

CAUTION

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

To turn off the Electrocardiograph:

- When operating on AC power

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

- When operating on battery power

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

NOTE:

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

3.6 Loading/Replacing Recorder Paper

The electrocardiograph uses the folded thermal paper.

NOTE:

1. Paper Style set in Record Info setup should be consistent with that of the paper used.
2. When using the paper of 215mm in width, the movable part should be removed.
3. The exit edge can help you tear the recorder paper.
4. If the paper with black markers is used, make sure that the markers are on the bottom.

CAUTION

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

Loading/Replacing Process of Folded Paper:

1. Press the recorder button downwards to open the recorder.
2. Remove the remainder paper from the paper tray if necessary.
3. Take off the wrapper of the new folded paper, and then put it in the paper tray.
4. Pull the paper out with the grid side facing the thermal print head, and replace the casing on the recorder.
5. Press down the recorder casing firmly.
6. Advance the recorder paper.

   When the main screen is displayed, if **Paper Marker** is set to **On**, you can press 

to advance the recorder paper to the next black marker; if **Paper Marker** is set to **Off,** you can press 

to advance the paper for 2.5cm. Press 

again to stop advancing the paper.

Chapter 4 Basic Operation Guidance

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

You can operate the electrocardiograph by using the touch screen.

CAUTION

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

4.1 Navigation Tips

4.1.1 Entering Data

To enter data, follow the typical procedures of how to enter a patient name in the patient information window:

1. Turn on the electrocardiograph and the ECG sampling screen will be displayed. Click the patient icon on the upper left corner to open the patient information window.
2. Click the **Name** textbox.

   Keyboard operation: Press **Tab** to move the cursor.
3. Click "←" or Press **Backspace** on the keyboard to erase the typed information.
4. Press the letters and numeric keys to input a name.

   To input the special character in the upper right corner of a numeric key, press **Shift** and the numeric key.

   To input the special character in the upper right corner of a letter key (**Q/W/E/R/T/Y/A/S/D/F/G/H**), press **Fn** and the letter key.
5. If **Caps Lock** is disabled, pressing **Shift** + **P** can type a capital **P**. If **Caps Lock** is set to **On**, pressing **Shift** + **P** can type a lowercase **p**.
6. Press **Enter** to confirm, or press **Tab** to move the cursor to the **OK** button, and then press **Enter** to confirm.
7. Press **Esc** to cancel the operation, or press **Tab** to move the cursor to the **Cancel** button, and then press **Enter** to cancel the operation.

4.1.2 Selecting an Item

The electrocardiograph is equipped with a touch screen. You can touch any region for further operation.

To use the keyboard, you can:

1. Press **Tab** or **Shift + Tab** to move the cursor among different check boxes.
2. Press spacebar to select a check box.
3. Press the Up/Down arrow keys to move the cursor to a list box or dropdown list.
4. Press **Enter** to confirm, or press **Tab** or **Shift + Tab** to move the cursor to the **OK** button, and then press **Enter** to confirm.
5. Press **Esc** to cancel the operation, or press **Tab** or **Shift + Tab** to move the cursor to the **Cancel** button, and then press **Enter** to cancel the operation.

4.2 Configuring the Electrocardiograph

For details on configuring the system settings and the order settings, please refer to Chapter 10"System Setup" and section 10.9.2.1 "Worklist".

4.3 About the Main Screen

After the electrocardiograph is turned on, the main screen for resting ECG will be displayed.

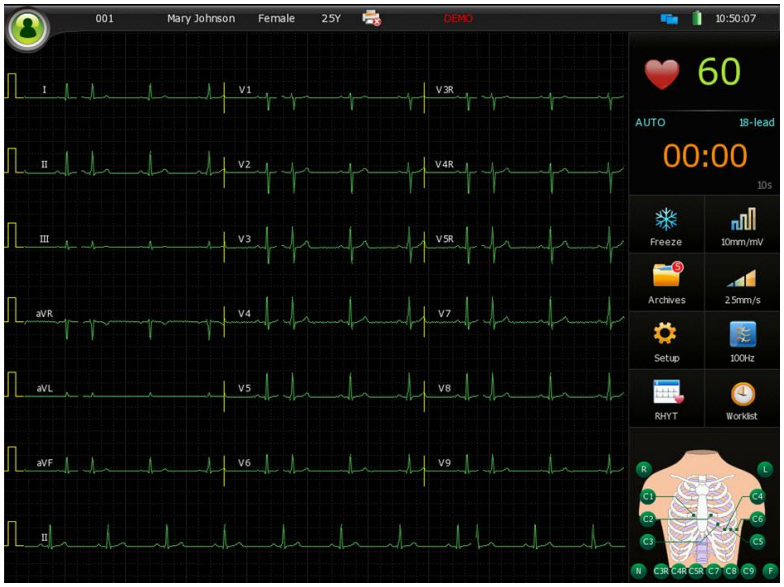


Figure4-1 Main Screen

Item	Description
Patient Information	Information including the patient ID, patient name, gender, age, pacemaker, etc. You can: ● click on the gender region to set the gender. ● click on the pacemaker icon to set the pacemaker. ● click on other patient information to open the **Patient Information** window.
System Status	Symbols indicating the system working status are displayed, including the battery capacity, network status, time, etc. ● Caps lock symbol: displayed when **Caps Lock** is activated. ● Network symbol: click to enter the **Transmission** setup screen. ● Time: click to enter the Date & Time setup screen. ● When a USB memory stick, SD card, USB printer, or USB scanner is connected to the electrocardiograph, corresponding symbols will be displayed.
Waveform	Display waveforms of all leads.
Function Panel	Items including the heart rate, sampling time, function keys, electrode indicators, etc.
Background Grid	The background grid can be configured on the Display & Sound setup screen.

Chapter 5 Entering Patient Information

You can enter the patient information by:

1. using the keyboard of the electrocardiograph
2. using an external keyboard and mouse
3. using the soft keyboard
4. acquiring orders
5. using a reader, including one-dimension or two dimension barcode readers

5.1 Entering Patient Information Manually

Operation procedures are as follows:

1. Configure the **Patient Info** setup window. (Configurable)

   1) Select the desired items.

   2) Select an ID generating mode.

   For details, please refer to Section10.5 “Patient Information Setup”.

2. Click the patient icon on the main screen to open the patient information window.
3. Enter data in a desired textbox.
4. Press **Enter** to confirm or press **Esc** to return to the main screen.

First Name	Within 30 ASCII characters
Last Name	Within 30 ASCII characters
Age	Age Unit: **Years**, **Months**, **Weeks** or **Days**
Gender	Patient Gender
BP	Patient Systolic Blood Pressure/Diastolic Blood Pressure
Race	Patient Race
Pacemaker	Select **Yes** to detect very small pacemaker pulses. However, when **Pacemaker** is set to **Yes**, the system is very sensitive, and should not be close to equipment emitting high frequency radiation. High frequency radiation can interfere with pacemaker pulse detection and

	normal ECG acquisition. **NOTE: Pacemaker** is recommended to be set to **No** unless it is known that the majority of the electrocardiograph usage will be on patients with pacemakers.

NOTE: The total number of supported characters may be fewer if special Latin characters are entered.

5.2 Entering Patient Information by Using a Barcode Reader

Operation procedures are as follows:

1. Configure the barcode

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

2. Connect the barcode reader to USB socket 2 on the right panel of the electrocardiograph.
3. When the main screen is displayed, scan the patient's barcode with the barcode reader, and then the patient information will appear in the corresponding box.

NOTE: Only bar code readers recommended by the manufacturer can be used.

5.3 Entering Patient Information by Acquiring Orders

✧ FTP Server

1. Choose **Transmission** > **FTP Setup** and configure the parameters.

   For details, please refer to *Chapter 7 "Transmitting ECG Data"*.

2. In **Patient Information > Other Setup**, select **Order Acquired** and set **Order Source** to **EDAN Server**.
3. Connect the electrocardiograph to the FTP Server via network.
4. Click the patient icon on the main screen to open the patient information window.
5. Enter the patient ID manually in the **ID** textbox or connect a barcode reader, click **Worklist**, and then the matched order will be loaded from Smart ECG Viewer

software and the order information will be displayed in the corresponding textboxes.

✧ DICOM Worklist/HL7

1. Activate the DICOM Transmission/HL7 function in **Maintenance**>**Advanced Setup**>**Function**.
2. Choose **Transmission**>**DICOM Setup/HL7 Setup**, and configure the parameters.
3. In **Patient Info**>**Other Setup**, select **Order Acquired** and set **Order Source** to **DICOM Worklist/HL7**.
4. Connect the electrocardiograph to the server via network.
5. Click the patient icon on the main screen to open the patient information window.
6. Enter the patient ID manually in the **ID** textbox or connect a barcode reader, click **Worklist**, and then the matched order will be loaded from software and the order information will be displayed in the corresponding textboxes.

Chapter 6 Printing ECG Reports

The electrocardiograph can print ECG reports in the following modes: auto (including the quickly mode and save paper mode), manual, pharma study, HRV, and VCG/SAECG modes.

USB report is also supported.

NOTE:

1. The working mode cannot be changed during the printing course. Stop printing reports before changing the working mode.
2. Within three seconds after returning to the main screen, if you press the **START/STOP** key to print an ECG report in the auto quick mode or the manual mode, the recorder will not respond.
3. If **Print Out** is deselected in the **Record Info** setup window, the ECG report can be saved and transmitted, but cannot be printed out by pressing the **START/STOP** key. In the Manual Mode, if **Manual Mode Save** in the File setup screen is not set to **Off**, you can print reports normally.
4. When the main screen is displayed, click on the work mode display region or press the MODE key to select a working mode.

6.1 Printing an ECG Report

This section takes printing an ECG report in the AUTO mode for example.

The AUTO mode is the most common electrocardiograph usage and is applied to normal ECG test. ECG data can be sampled, analyzed, and printed by pressing the **PRINT/STOP** key.

Operation Method:

1) On the main screen, click **Setup**, in the **Work Mode** setup screen, select **AUTO** in **Mode Options**, and set the display style, sampling mode, and whether to preview.
2) In the Record Info setup screen, set the auto record style and record sequence.
3) In the Lead setup screen, set the lead mode.
4) Configure other parameters if necessary, and then exit the system setup screen.
5) Print an auto ECG report.

On the VCG report, VCG loops and Front/Horizontal/Sagittal Partial loops are printed.

Front/Horizontal/Sagittal Partial: 30ms of the vector loop onset and offset are selected and expanded by double the QRS gain.

6.2 Copy Printing

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

6.3 Freezing ECG Waves

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

Operation Method:

1) Click **10mm/mV**, **100Hz** on the main screen to set the gain and filter.
2) Click **Freeze** to enter the freezing screen.

   In the auto, manual, and pharma study mode, the **Freeze Auto** screen will be displayed by default. Click **Freeze RHYT** and the **Freeze RHYT** screen.

   In the HRV mode, the **Freeze RHYT** screen will be displayed by default. Click **Freeze AUTO** and the **Freeze AUTO** screen.
3) Click **Print** on the screen or press the **START/STOP** button to print the report.

Chapter 7 Transmitting ECG Data

WARNING

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

ECG data can be transmitted to the PC through the net cable or wireless network.

WARNING

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

1) this device may not cause harmful interference, and

2) this device must accept any interference received, including interference that may cause undesired operation.

FCC Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates 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.

NOTE:

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

CAUTION

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

7.1 FTP

1. Log into the FTP receiving software.
2. Configure the **Transmission** setup screen.

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

   1) Open **Transmission**> **Basic Setup**, set the transmission mode.

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

   2) Select **Auto Transmission**.

   3) Set the IP address of the electrocardiograph.

      For details, please refer to Section 10.6.1 "Basic Setup".

3. On the electrocardiograph, set **Transmission Protocol** to FTP.
4. In **Transmission**>**FTP Setup**, set the **FTP User Name**, **FTP Password** and **FTP Path**.

   1) The user name and the password you input in the **FTP User Name** and **FTP**

Password items must be available for FTP server.

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

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

5. Set the file format in the **File** setup screen.
6. Return to the main screen.
7. ECG data will be transmitted through the network automatically after an ECG report is printed out.

7.2 DICOM Storage

1. Activate the DICOM Transmission function in **Maintenance>Advanced Setup>Function**.
2. In **Transmission>Basic Setup**, set **Transmission Protocol** to **DICOM**.
3. In **Transmission>DICOM Setup**, set the **DICOM Storage** parameters.

   Set the server IP, server port, and server AE to those of the server.

   You can click **ECHO** to check whether the connection is successful.
4. Return to the main screen.
5. When an ECG report is confirmed on the report analysis screen, it will be transmitted to the server automatically if **Store when making diagnosis** is selected in **DICOM Setup**.

7.3 HL7

1. Activate the HL7 function in **Maintenance**>**Advanced Setup**>**Function**.
2. In **Transmission**>**Basic Setup**, set **Transmission Protocol** to HL7.
3. In **Transmission**>**HL7 Setup**, set the HL7 parameters.

   Set the server IP and server port to those of the server.
4. Return to the main screen.
5. After an ECG report is printed, upload the data to the server.

Chapter 8 File Receiving

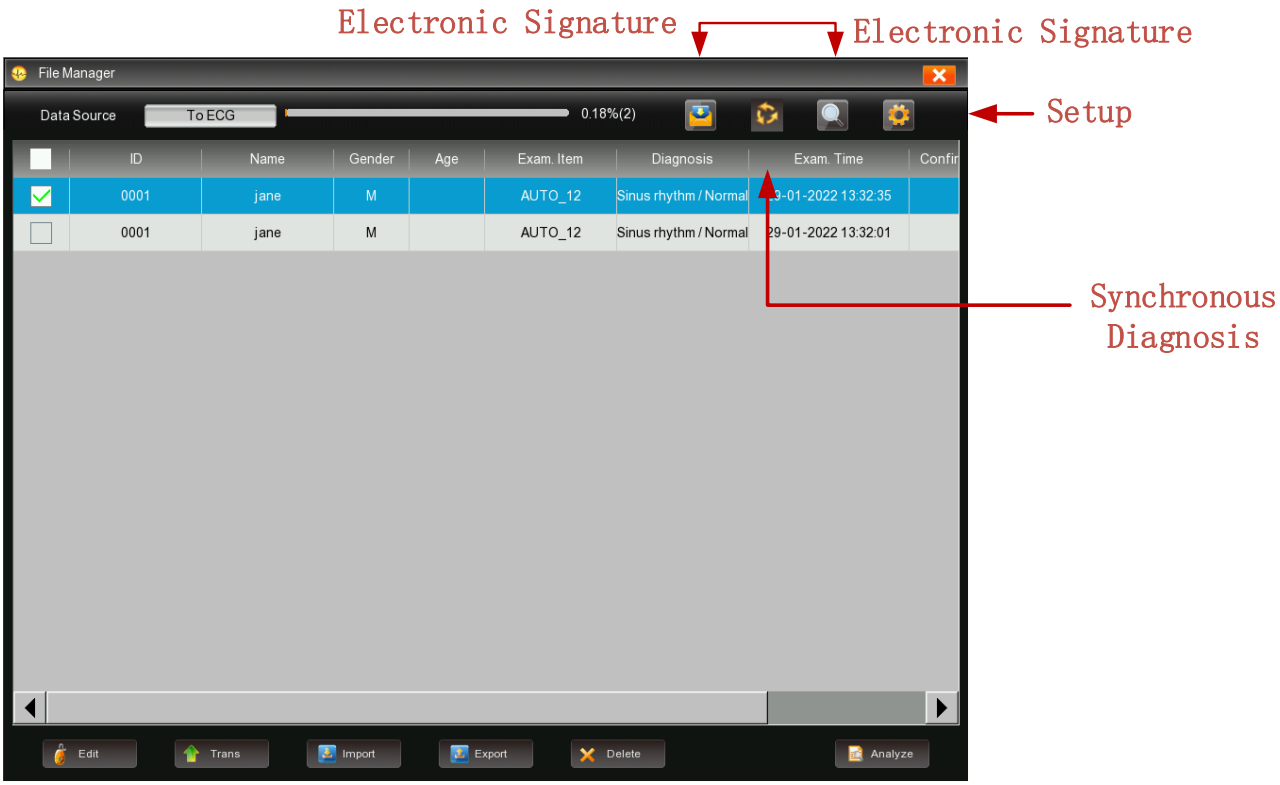
Reserved function

Chapter 9 File Management

On the main screen, click **Archives** to open the **File Manager** screen.

On this screen, you can perform operations including data transmission, import and export, print, search, delete, synchronization, and analysis.

If you have set a password for the **File Manager** screen in **Maintenance**>**Basic Setup**>**File Password**, the password is required to enter the **File Manager** screen.



Item	Description
Electronic signature	Click to enter the Electronic signature **screen**, you can update the electronic signature.
Synchronous diagnosis	After selecting data, click Synchronize Diagnosis to synchronize the diagnosis results and measurement information of the selected data.
Search symbol	Click to enter the **SearchInfo** Setup **screen** and set the search criteria.
Setup	Configure the items to be displayed in the **File Manager** screen.

symbol	
File count	For 10s Auto data, the upper storage limit is 1000.
Edit	Edit the basic patient information of the selected record.
Trans	Click to transmit the selected data to the server.
Import	Click this button and the system will automatically import data from the U disk connected.
Export	Click this button and the system will export the selected data to the external memory.
Delete	Click to delete the selected data.
Analyze	Click to enter the analysis screen of the selected data.

Figure 9-1 Analysis screen in the AUTO mode

Figure 9-2 ST View

No.	Item	Description
A	**Waveform**	Display the ECG waveform. You can view the waveform, and the measurement and diagnosis information.
B	**Display Settings**	Change the lead configuration, gain, or speed.
C	**Inversion**	After it is found that the electrodes are reversed, the electrode inversion setting can be performed.
D	**ST View**	Check the amplitude and morphology of the ST segments of all leads. ST View is available for resting ECG data of 9 leads (Pediatric), 12 leads (Standard, Pediatric mode), 15 leads (Standard+Right, Standard+Back, and Pediatric mode), and 18 leads (Standard+Right+Back).
E	**Comparison**	Compare the waveforms and templates of the examination records at different times of the same patient ID. 5 records in the AUTO mode can be compared simultaneously at most.

Chapter 10 System Setup

Click **Setup** on the main screen to enter the system setup screen, c

10.1 Work Mode Setup

Item	Description
Mode Options	Options: **AUTO, MANU, HRV, Pharma, VCG&SAECG**
Lead Configuration	Options: 12-lead: **12×1, 3×4, 3×4+1R, 3×4+3R, 6×2, 6×2+1R**. 15-lead: **15×1, 3×5, 3×5+1R, 3×5+3R, 6+6+3, 6+6+3+1R, 6+9**. 9-lead: **9×1, 3×3, 3×3+1R, 3×3+3R, 6+3**. 18-lead: **6×3+1R**
Sampling Mode	Options: **Real-time Sample, Triggered Sample, Periodic Sample.**
REC Time	Set the time period to acquire ECG signals in real time. Options: **10s, 20s, 30s, 1min, 3 min, 5 min, 10 min, 15 min, 30 min**
Real-time Sample Timing Advance	● In the **Save Paper** mode: The timing advance can be 0-10s, and the default value is 0s. When Sampling Mode is set to Real-time Sample and Real-time Sample Timing Advance is set to n seconds, data sampled and stored will begins at n seconds before pressing the START/STOP key. ● In the **Quickly** mode: Data sampled and stored begins at 10 seconds before pressing the START/STOP key.
Periodic Sample Duration	It can be set to a value between 0-60 min. The default value is 60 min.
Periodic Sample Interval	It can be set to a value of 0-60 min. The default value is 1 min.

	This interval must be no longer than the periodic sample duration.
Rhythm Style	Options: **Single Lead, Three Leads**
Rhythm Mode	Options: **Save Paper, Quickly** Select **Save Paper**, an ECG report is printed after the ECG data sampling when you pressing the **PRINT/STOP** key on the main screen in the rhythm mode. Select **Quickly**, an ECG report is printed immediately after pressing the **PRINT/STOP** key on the main screen in the rhythm mode.
Rhythm Sample Duration	Options: **20s**, **1 min**, **3 min**, **5 min**, **10 min**, **15 min**, **30 min**
Preview	Enable or disable the report preview function. It's disabled by default
Auto Arrhythmia Detection	After enabled, if arrhythmia is detected in the AUTO mode, a hint will pop up to ask you whether to print an extra rhythm report. It's disabled by default

NOTE: The underlined values are system default values.

10.2 Filter Setup

Item	Description
AC Frequency	It can be enabled or disabled. **NOTE:** AC frequency can be set to **50Hz** or **60Hz** in **Maintenance**>**Advanced Setup**>**Other** according to local mains supply specifications.
DFT Filter	DFT Filter greatly reduces the baseline fluctuations without affecting the ECG signals. The purpose of this filter is to keep the ECG signals on the baseline of the printout. Options: **0.01Hz**, **0.05Hz**, **0.32Hz**, or **0.67Hz**

	The set value is the lower limit of the frequency range.
EMG Filter	EMG Filter suppresses disturbance caused by strong muscle tremor. The cutoff frequency can be set to **Off**, **25Hz**, **35Hz** or **45Hz**.
Lowpass Filter	Lowpass Filter restricts the bandwidth of input signals. The cutoff frequency can be set to **75Hz**, **100Hz**, **150Hz, 270Hz, 300Hz,** or **350Hz**. **NOTE:** Only when **EMG Filter** is set to **Off**, can the setting of **Lowpass Filter** be effective.

NOTE: To pass the distortion test, the electrocardiograph has to be configured with the highest bandwidth in filter settings. Otherwise, ECG signal may be distorted.

10.3 Lead Setup

<table>
<tr><th>Item</th><th>Description</th></tr>
<tr><td>Lead Mode</td><td>Options provided are 9-lead, 12-lead, 15-lead, and 18-lead.</td></tr>
<tr><td>Lead Sequence</td><td>Except from choosing the following lead sequence, customization of lead sequence is also supported.
Under the 9-lead mode, you can choose Pediatric mode.
<table>
<tr><th>Lead</th><th>Lead Group</th></tr>
<tr><td>PE mode</td><td>I, II, III, aVR, aVL, aVF, V1, V3, V5</td></tr>
</table>
Under the 12-lead mode, you can choose from Standard and Cabrera.
<table>
<tr><th>Lead</th><th>Lead Group</th></tr>
<tr><td>Standard</td><td>I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6</td></tr>
<tr><td>Cabrera</td><td>aVL, I, -aVR, II, aVF, III, V1, V2, V3, V4, V5, V6</td></tr>
<tr><td>Pediatric</td><td>I, II, III, aVR, aVL, aVF, V4R, V1, V2, V4, V5, V6</td></tr>
</table>
NOTE: Pediatric mode is available only when Glasgow algorithm is used. In the Pediatric Mode, lead V3 is used to sample ECG signals of V4R.
Under the 15-lead mode, you can choose from Standard+Right, Standard+Back, Standard+NEHB, Standard+XYZ, and Pediatric</td></tr>
</table>

<table>
<tr><td></td><td>mode.
<table>
<tr><th>Lead Sequence</th><th>Lead Group</th></tr>
<tr><td>Standard+Right</td><td>I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6, V3R, V4R, V5R</td></tr>
<tr><td>Standard+Back</td><td>I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6, V7, V8, V9</td></tr>
<tr><td>Standard+NEHB</td><td>I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6, ND, NA, NI</td></tr>
<tr><td>Standard+XYZ</td><td>I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6, X, Y, Z</td></tr>
<tr><td>Pediatric mode</td><td>I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6, V3R, V4R, V7</td></tr>
</table>
Under the 18-lead mode, you can choose Standard+Right+Back.
<table>
<tr><th>Lead Sequence</th><th>Lead Group</th></tr>
<tr><td>Standard+Right</td><td>I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6, V3R, V4R, V5R, V7, V8, V9</td></tr>
</table></td></tr>
<tr><td>NEHB</td><td>It is disabled by default.
Lead sequence: I, II, III, ND, NA, NI</td></tr>
<tr><td>Electrode Inversion Hint</td><td>It is enabled by default.
If it is enabled, sample ECG data in the AUTO mode, and the system will automatically check whether the electrodes need inversion before report preview or printing.</td></tr>
<tr><td>Rhythm Lead1/2/3</td><td>Options: I, II,III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6, V3R, V4R, V5R, V7, V8, V9
NOTE:
1. Rhythm lead 1/2/3 cannot be the same.
2. When Rhythm Lead is set to V3R/V4R/V5RV7/V8/V9, if you activate the pacemaker function, the system detects pace signals</td></tr>
</table>

	in lead II by default.
Lead Off Hint	It is disabled by default. If it is enabled, after pressing the REVIEW button, the system will automatically check whether any lead falls off in the sampled data. If any lead falls off, a hint will be displayed.

10.4 Record Information Setup

Click **Record Info** to open the record information setup screen.

10.4.1 Basic Setup

Item	Description
Auto Record Style	Select a style to print the ECG waves in the AUTO mode. Options: 12-lead: **12×1**, **3×4**, **3×4+1R**, **3×4+3R**, **6×2**, **6×2+1R** 15-lead: **15×1**, **3×5**, **3×5+1R**, **3×5+3R**, **6+6+3**, **6+6+3+1R**, **6+9** 9-lead: **9×1**, **3×3**, **3×3+1R**, **3×3+3R**, **6+3** 18-lead: **6×3+1R**, **6×2+6×1, 6×2+6×1+2R, 12×1+6x1**
Manual Record Style	Select a style to print the ECG waves in the manual mode. Options: 12-lead: **3 channels**, **6 channels**, **12 channels**, **Customize** 15-lead: **3 channels**, **6 channels**, **12 channels**, **Customize** 9-lead: **3 channels**, **6 channels**, **9 channels**, **Customize** 18-lead: **3 channels**, **6 channels**, **Customize**
Record Mode	Options: **Save Paper**, **Quickly** Select **Save Paper**, an ECG report is printed after ECG data sampling when you pressing the **PRINT/STOP** key on the main screen in the AUTO mode. Select **Quickly**, an ECG report is printed immediately after pressing

	the **PRINT/STOP** key on the main screen in the AUTO mode. NOTE: 1. The Quickly mode is effective only when "Sampling Mode" is set to "Real-time Sample" in the AUTO mode. 2. Only Quickly mode is available when "Auto Record Style" is in N×1 format.
Record Sequence	Options: **Sequential**, **Synchronous** Select **Sequential**, the lead groups are refreshed one by one in order. Select **Synchronous**, all leads are refreshed simultaneously.
Record Device	Options: Thermal, USB Printer To select USB record, you should connect the corresponding USB printer to the electrocardiograph. USB printers supported are: HP 1010、HP1510、HP M401、HP 1020P、HP LaserJet P2035、HP Laserjet Pro M403D、HP LaserJet pro M202DW、HP DeskJet 4729、HP DeskJet 3638、HP1112 and HP2132.

WARNING

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

CAUTION

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

NOTE:

1. During the USB printing course, pressing the **START/STOP** key again cannot stop printing ECG reports.
2. USB printing is ineffective in the auto periodic sampling mode, auto 11~24s sampling

mode, manual mode and HRV mode.

3. Make sure that paper is installed in the USB printer before printing. Error may occur if no paper is loaded in the USB Printer.

Print Out	It is enabled by default. When selected, the ECG report can be printed out by pressing the **PRINT/STOP** key. When disabled, the ECG report can be saved or transmitted, but cannot be printed out by pressing the **PRINT/STOP** key. **NOTE**: 1. This function is unavailable under the periodic sampling mode. 2. If this function is disabled when **Manual Mode Save** or **Auto Save** for Pharma study is set to **Off**, the system will still print the ECG report.
Paper Marker	**Paper Marker** is used to identify the start point of each page of the recorder paper. Options: **Off**, **On (EDAN)**, **On (Other)**. Select **On (EDAN)** or **On (Other)** if the paper with black markers on the bottom is used, and the device can identify the start point of each page of the recorder paper while printing ECG reports.
Print after diagnosis	It is disabled by default. When selected, press REVIEW in the **File Manager** screen, if the system detects the diagnosis result of the record has not been confirmed, a hint will be displayed.
Gain	You can set the indicated height of 1mV ECG on the paper. Options: **2.5mm/mV, 5mm/mV, 10mm/mV**, **20mm/mV** or **10/5mm/mV**. **10/5mm/mV** means that the gain of limb leads is set to **10mm/mV**, while the gain of chest leads is set to **5mm/mV**.
Speed	Manual mode: **5mm/s**, **6.25mm/s**, **10mm/s**, **12.5mm/s**, **25mm/s**, **50mm/s**

	Auto/Pharma Study mode: **25mm/s**, **50mm/s** Rhythm mode: **5mm/s**, **25mm/s**, **50mm/s** HRV mode: **25mm/s**
Baseline Adjustment	Options: **Horizontal**, **Auto** or **Off** Select **Horizontal**, the baselines of the lead groups are adjusted simultaneously, and the baselines of the leads in the same row are on the same line. Select **Auto**, the baselines of the lead groups are adjusted respectively. Select **Off**, the baselines of the lead groups are adjusted equally in the ECG reports.
AGC	It is disabled by default. When selected, the gain can be automatically adjusted according to actual signals.

10.4.2 Report Setup

Item	Description
Auto Record Info	Select the item printed in the ECG reports.
Auto Analysis	Options: **All**, **Off**, **Normal ECG only** Select **Normal ECG only**, only the ECG reports with normal diagnosis results will be printed. Select **Off**, no diagnosis result will be printed. Only the title "Diagnosis Information:" will be printed.
Copies	Set the number of copies printed after sampling in AUTO mode. It can be set to 1-5 copies. The default value is 1 copy.
HRV Record Info	Select **RR waveform** or **RR Interval List**, corresponding information will be printed in the report.
Other Record Info	Select **Thermal Report Grid** and background grid will be printed when using the thermal printer. Select **Time Scale** and time scale will be printed under the

	waveforms. Select **USB Report Grid** and background grid will be printed when using the USB printer. Select **Device No.** and the device number will be printed on the thermal reports or USB reports.

10.4.3 Advanced Setup

Item	Description
Pharma Study Record Info	● Pharma Study Record Time Set the time points of printing the reports. ● Pharma Study Mode Options: Single-Lead ECG Report, All-Lead ECG Report ● Auto Save Only when this function is enabled will the system save the sampled data in the Pharma Study mode.
VCG Record Info	● Set the record time, report style ● Select items to be printed on the report ● Set the QRS gain and SAECG filter

10.5 Patient Information Setup

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

10.5.1 Personal Setup

On this screen, you can select/deselect and customize items to be displayed on the patient information window. You can also choose to enable the **Comment when marking an event** function.

10.5.2 Other Setup

Item	Description
ID	Options: **Auto, Time** or **Manual** Select **Manual**, the patient ID needs to be input manually.

	Select **Auto**, **ID** can be automatically generated accumulatively. Select **Time**, the patient ID can be automatically generated according to the time when you press the **START/STOP** key to print an ECG report.
ID Hint	In the auto or rhythm mode, when **ID** is set to **Manual** and **ID Hint** is enabled, if you do not input the patient ID before pressing the **START/STOP** key, a hint will pop up to remind you to input the patient ID.
Age Mode	Options: **Age**, **D.O.B** or **Age Group** Select **Age**, you can enter the patient age manually in the **Patient Information** window. Select **D.O.B**, the **D.O.B** textbox appears and the **Age** textbox becomes unavailable in the **Patient Information** window, you can enter the birthday of the patient, and the system will calculate the patient age automatically. Select **Age Group**, the **Age Group** textbox appears in the **Patient Information** window and the **0** key (or **Age Group** key) can be available.
H/W Unit	Options: **cm/kg** or **inch/lb**
BP Unit	Options: **mmHg** or **kPa**
Report Hint	Options: **Confirmed By**, **Unconfirmed**, **Null** Select **Unconfirmed**, **Unconfirmed Report** is printed in the ECG reports. Select **Confirmed By,** the physician's name is printed in the ECG reports if it is input in the **Patient Information** window. Select **Null**, no hint information will be printed in the ECG reports.
Pacemaker Setup	When selected, the shortcut setup symbol of the pacemaker will be displayed on the main screen.
PatInfo Refreshed	When selected, the patient information will be refreshed after the ECG report is printed out and all the leads are off.

Order Source	Select the server for downloading orders.
Oder Acquired	When selected, the **Acquire** item will be displayed in the **Patient Information** window and you can acquire orders by clicking it.

10.6 Transmission Setup

Click **Record Info** to open the record information setup screen.

10.6.1 Basic Setup

Item	Description
Sampling Device	DE18
Auto Transmission	It is disabled by default.
Transmission Mode	Options: **Wired, Wireless**
IP	Options: IPV4、IPV6
Transmission Protocal	Options: FTP、DICOM、HL7
Synchronize with a time server	Options: **EDAN server、NTP server**
Auto Get IP	Select this item, addresses of **Local IP, Gateway** and **Subnet Mask** will be acquired automatically after the wireless network is connected successfully. **NOTE:** 1. Only if WIFI is disabled, can **Auto Get IP** option be available. 2. To use **Auto Get IP**, DHCP function needs to be enabled on the router.
Local IP/Gateway/Subnet Mask	It can be set to a value within 0-255. The format is: XXX.XXX.XXX.XXX ● Set the local IP address: For the cross-network transmission, a) Set the first two sections of the **Local IP** item to the first two

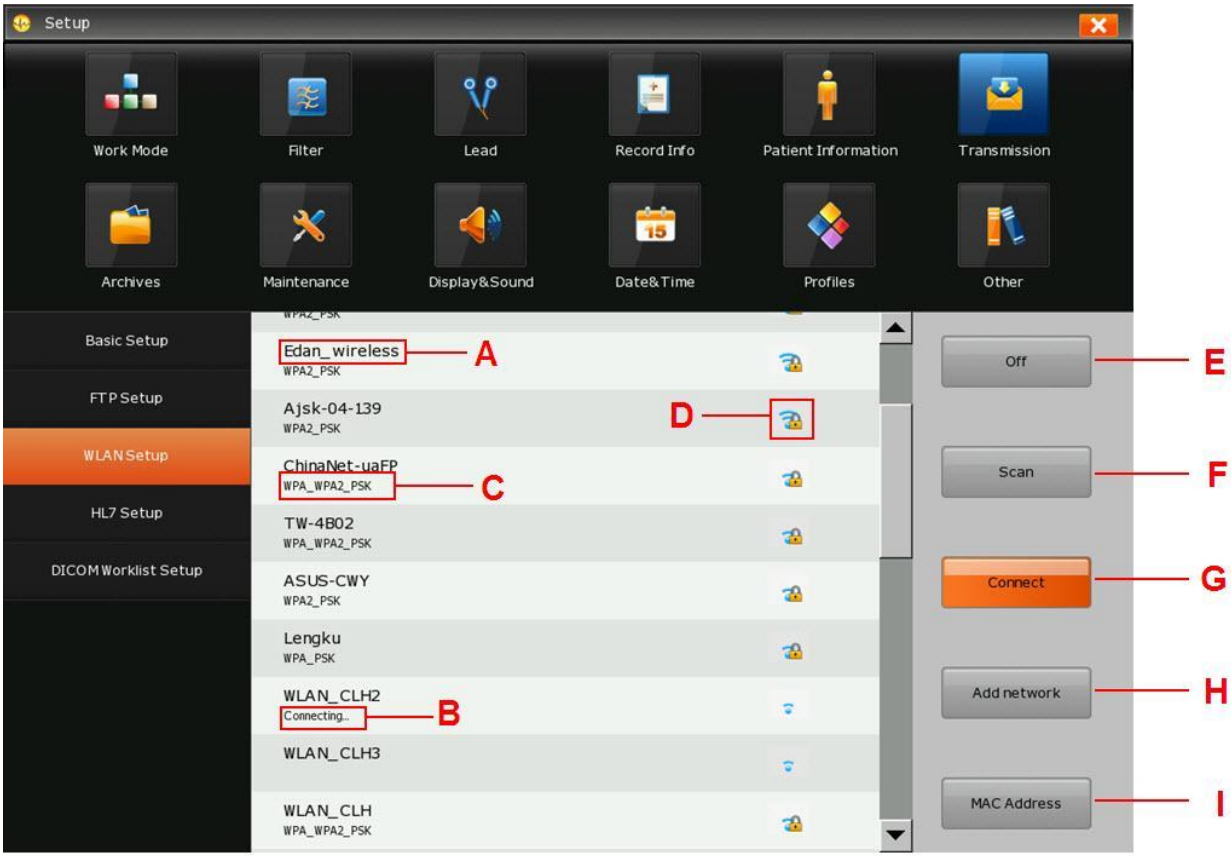
	sections of the IP of the PC. b) Set the third section of the **Local IP** item to the network segment of the electrocardiograph which depends on the configuration of Router. c) The last section of the **Local IP** item can be set at random. For the same network transmission, a) Set the first three sections of the **Local IP** item to the first three sections of the IP of the PC. b) The last section of the **Local IP** item can be set at random, but it can't be the same as the last section of the IP of the PC. ● Set the first three sections of the subnet mask to the first three sections of the local IP, and set the last section to 001. ● Set the Subnet Mask to 255.255.255.000.
Device No.	Type the Device No., within 7 ASCII characters

10.6.2 FTP Setup

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

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

10.6.3 WLAN Setup



Item	Description
SSID	The name of the searched wireless network.
STATE	The connection status for the searched wireless network.
SECURITY	The encryption type for the connected wireless network.
RSSI	The signal quality of the wireless network
Scan	Click to search wireless networks nearby.
Connect	Click to connect to the selected network.
Add network	If the network is on closed broadcasting, you can add it manually. Click **Add network** to open the **Add network** dialogue box, enter

	the SSID and set the security type, and click **OK**. If the network is detected, it will appear in the network list. If not, a hint indicating connection error will be displayed.
MAC Address	Click to acquire the MAC address of the WIFI module.

10.6.4 HL7 Setup

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

Before use, you should set the server IP, server port, and server AE to those of the server.

10.6.5 DICOM Setup

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

Before use, you should set the server IP, server port, and server AE to those of the server.

10.7 Archives Setup

Item	Description
Auto Save	Options: **Off, To ECG** or **Ext. Memory** Select **Off**, ECG data will not be saved. Select **To ECG** or **Ext. Memory**, ECG data in the auto (exclude periodic sample mode), rhythm, or HRV mode will be saved automatically, while ECG data in the pharma study mode or manual mode can be saved manually.
File Format	Select a file format of the data to be exported or transferred. NOTE: To select **SCP/FDA-XML/DICOM ECG Waveform/ DICOM Encapsulated PDF**, you should first activate the SCP/FDA-XML/DICOM function in **Maintenance**> **Advanced Setup>Function**. For details, please contact the manufacturer or the local distributor.
Delete After Trans. Or Export	When selected, the files will be automatically deleted from the **File Manager** screen after they are transmitted to the PC or

	exported to the external memory.
Replace When Memory Full	When selected, if the amount of stored files reaches the upper limit of the Flash memory, the files will replace the earliest one automatically.
Manual Mode Save	Options: **Off**, **Manual Save**, **Auto Save**. Select **Off**, ECG data will not be saved. Select **Manual Save**, ECG data needs to be saved manually in the manual mode. Select **Auto Save**, ECG data will be saved automatically at the set interval in the manual mode.
Manual Mode Save Time	Set the interval of automatically saving data in the manual mode. It can be set to an integer within 1-30 min.

10.8 System Maintenance Setup

Click **Maintenance** and enter the required password to enter the system maintenance setup screen.

10.9 Display and Sound Setup

10.9.1 Basic Setup

Item	Description
Brightness	Adjust the brightness of the screen display. If Auto Brightness is enabled, the system will adjust the brightness automatically based on the current environment.
Volume	Set the key volume, QRS volume, hint volume, and notify volume.
Grid	Options: **On**, **Off**
Antialiasing	When selected, the ECG waveforms displayed on the main screen will be smoother.
1mV Mark	When selected, the 1mV mark will appear before each line of the ECG waveforms on the main screen, preview screen, and freeze screen.

Arrhythmia Color Mark	When selected, arrhythmia detected will be marked with color.

10.9.2 Main Screen Configuration

On this screen, you can configure function keys that you want to be displayed on the main screen.

The functions keys which must be configured are: **Freeze**, **Archives**, **Setup**, **Worklist**, **Gain**, **Speed**, **Filter**, and **RHYT**.

Other keys that are available include **Event**, **Comparison**, **PRINT/STOP**, and **REVIEW**.

To configure a new function key, click on the key to be displayed and click on the one that you want to remove from the main screen.

10.9.2.1 Worklist

When configured, click **Worklist** on the main screen to enter the Order Manager screen.

NOTE: To use the order function, you must install the software that supports orders.

✧ Loading orders

Click **Load** on the **Order Manager** screen to load orders from the server.

✧ Examining orders

Select an order on the **Order Manager** screen, and then click **Examine** or press **Enter** to start an examination.

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

✧ Adding orders

Click **Add** to create new orders.

✧ Deleting orders

Click **Delete** to delete the selected orders.

✧ Searching orders

Click on the search symbol, select the search type, such as ID, Name, Request No., Exam. Room, Priority, or Order Date, enter the search information, and then click **OK** or press **Enter** to confirm. All the orders which meet the requirements will be searched and displayed on the **Order Manager** screen.

When Order Date is chosen as the search type, if you only input the start date, all the orders after the start date will be searched and displayed. If you only input the end date, all the orders before the end date will be searched and displayed.

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

✧ Setting orders

Item	Description
Condition	Options: **Default**, **ID, Order Date, Request No., STATE, Exam. Room, Department, Room No.** Select **Default**, orders will be displayed in sequence of the time when the orders are loaded from the server. Select other options, orders will be displayed in sequence of the selected condition on the **Order Manager** screen.
Sequence	Options: **Ascending** or **Descending** Select **Ascending/Descending**, orders will be displayed in ascending/descending sequence based on the option you select from the **Condition** list box. **NOTE:** 1. When **Condition** is set to **STATE** and **Sequence** is set to **Ascending**, orders without examination will be displayed on the top of the **Order Manager** screen. 2. When **Condition** is set to **STATE** and **Sequence** is set to **Descending**, orders with examination will be displayed on the top of the **Order Manager** screen.
Delete After	When selected, the order will be deleted from the **Order**

Examination	**Manager** screen after the order is examined.
Order Date Filter/Exam. Item Filter	The system will filter orders based on the set condition.
Exam Room Filter/Department Filter	When selected, enter an exact exam.room name or department name in the textbox, such as Electrocardiograph, and then click **Load**. All the orders which meet the requirements will be searched and displayed on the **Order Manager** screen. When selected, but no exact exam.room name or department name is entered, click **Load** and a list of departments will be displayed. Select the desire department and the system will load the related orders.
Auto Load Order	If selected, the system automatically loads orders from the server when you enter the order manager screen.

10.9.2.2 Comparison

When configured, click **Comparison** on the main screen, and you can compare ultimately 5 resting ECG records in the AUTO mode which has the same patient ID.

10.9.2.3 Rhythm

When configured, click **RYHT** on the main screen to enter the rhythm wave sampling screen.

10.9.2.4 Event

When configured, click **Event** during ECG sampling, you can add and edit an event.

10.9.2.5 Review

The review function is the same as the Pre-simple button on the keyboard.

10.9.3 User Management

Reserved function

10.10 Date and Time Setup

Item	Description
Date Mode	Options: **DD-MM-YYYY**, **MM-DD-YYYY**, **YYYY-MM-DD**
24-Hour Format	When selected, the system time will be displayed in 24-hour format. Otherwise, it will be displayed in 12-hour format.
LCD Off	Options: **Never**, **Battery**, **Always** ● Never: The LCD will not turn off automatically ● Battery: Effective when using battery as the power supply ● Always: Effective when using AC power and battery as the power supply
LCD Off Time	It can be set to a value within 0-120 min.
Power Off	Options: **Never**, **Battery**, **Always** ● Never: The electrocardiograph will not turn off automatically ● Battery: Effective when using battery as the power supply ● Always: Effective when using AC power and battery as the power supply
Power Off Time	It can be set to a value within 0-120 min.

10.11 Profile Mode Setup

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

The default values in different scenarios are listed as follows:

1. Outpatient/Common Inpatient

Item	Description
Work Mode	AUTO, MANU
REC Time	10s
Lead Mode	12-lead
Lead Sequence	Standard
Record Mode	Save Paper
Auto Analysis	All
Main UI Config	RHYT, Freeze, Setup, Archives, Gain, Speed, Filter,

	Worklist

2. Physical Examination

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

3. Internal Medicine-Cardiovascular Dept.

Item	Description
Work Mode	AUTO, MANU, HRV, Pharma
REC Time	10s
Lead Mode	12-lead
Lead Sequence	Standard
Record Mode	Save Paper
Auto Analysis	Off
Main UI Config	Freeze, Setup, Archives, Gain, Speed, Filter, Event, RHYT

10.12 Other Setup

Item	Description
Institution	Input the institution name manually, about 60 ASCII characters at most. **NOTE:** The total number of supported characters may be fewer if special Latin characters are entered.
Language	Select the language displayed on the main screen and in the ECG reports.
ECG Key	Options: **Forbidden**, **START/STOP**, **Event**

	● **Forbidden**: Press the ECG key and no response will be provided. ● **START/STOP**: Equals pressing the START/STOP key on the keyboard. ● **Event**: Equals clicking **Event** on the main screen.
Soft Keyboard	When selected, the soft keyboard will be displayed when clicking any textbox.
External Input	The external input socket is equipped in the electrocardiograph, through which the electrocardiograph can receive signals from the external equipment. When selected, the electrocardiograph will display the signals which it receives from external input port.
External Output	Options: **Off**, **Standard**, **Triggered**

Chapter 11 Hint Information

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

Table 11-1 Hint Information and Causes

Hint Information	Causes
Lead off	Electrodes fall off the patient or the patient cable falls off the unit, or a high polarization voltage occurs.
Battery Weak	The battery is weak.
No Paper	Recorder paper runs out or is not loaded.
Testing	The ECG data is being sampled periodically.
Paper Error	When **Paper Marker** is set to **Yes**, the electrocardiograph advances the recorder paper to the next black marker. If it advances the paper for 300mm and cannot find the next black marker, the hint *Paper Error* is displayed.
Testing	The ECG data is being sampled periodically.
Sampling/Analyzing/Recording	ECG signals are being sampled / analyzed / recorded.
Learning	The self-study process of arrhythmia arithmetic in the **Triggered Sample** mode
Detecting	The examining process of arrhythmia data in the **Triggered Sample** mode
Transmitting	ECG data is being transmitted from the electrocardiograph to the PC through the net in the auto or rhythm mode.
Loading Order…	Orders are being loaded to the electrocardiograph.
Memory Full	The amount of files reaches the upper limit of the Flash memory.
DEMO	The system is in the demonstration mode.
Overload	The direct current offset voltage on an electrode is too high.

Chapter 12 FAQ

1. Operating Problems

Q1: I want to save the ECG data without printing, could it be possible?

A1: Yes, you can deselect **Print Out** in the **Record Info** setup window. Or, in the auto or rhythm mode, you can directly press **Shift** + **START/STOP** to enable or disable the print out function. The ECG data will be collected and saved without printing. In the same way, if the transmission settings are configured, the ECG data could be transmitted to the PC without printing.

Q2: The screen the electrocardiograph is too shiny. Could it be possible to weaken the brightness of the screen?

A2: There is a setup item named brightness in the **Display & Sound** setup window, please refer to Section 10.9, "Display & Sound Setup".

Q3: I want to input the patients' phone number in the **Patient Information** window, but there is no such item. Can I add it manually?

A3: Yes, there is a customize item for entering patient information. It works in this way: first input the name of the item in the **Customize_1/2** textbox in the **Patient Info** setup window, e.g. Tel. Then return to the main screen, and open the **Patient Information** window, the **Tel** item will be displayed in this window. Now it's possible to input the phone number of the patient in the **Tel** textbox. For details, please refer to Section 10.5 "Patient Information Setup" and Section 4.1.1 "Entering Data".

Q4: ***Memory Full*** is displayed on the main screen; Or, the hint ***Memory full! Replace the earliest file?*** pops up every time when I save an ECG report to the electrocardiograph. What am I supposed to do?

A4: ***Memory Full*** is used to remind you that the amount of stored file reaches the upper limit of the Flash memory.

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

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

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

You can deal with the hint as follows:

1) You can just delete several stored files from the electrocardiograph.
2) When ***Memory Full*** is displayed on the main screen, you can set **Auto Save** to **To U Disk** to save the added ECG reports. However, the amount of stored files in the electrocardiograph is still the maximum.

2. Printing Problems

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

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

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

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

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

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

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

Reload the paper in the paper tray, close the recorder casing firmly. If the problem

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

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

A4: Please open the **Other Setup** window, and input the hospital name in the **Institution** textbox. The content you input in this textbox will be printed in the report. For details, please refer to Section10.12 "Other Setup".

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

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

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

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

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

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

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

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

3. Transmitting Problems

Q1: The ECG doesn't respond to any keys after a long time of transmission. It transmits

nothing for there is no new data appearing on the screen of the PC software. What should I do?

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

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

4. Main Unit Problems

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

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

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

A2: The corresponding electrodes are not connected well. Please find out which lead is off by checking the Lead Name area on the main screen (please refer to Section 4.3, "About the Main Screen"). The lead whose name is highlighted is off. Please check whether the corresponding electrode of the lead is connected to the patient skin well, and then make sure that the patient cable socket is connected to the patient cable firmly.

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

Chapter 13 Cleaning, Care and Maintenance

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

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

13.1 General Points

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

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

CAUTION

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

13.2 Cleaning

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

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

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

The validated cleaning agent for cleaning the reusable electrodes is:

- Mild near neutral detergent

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

13.2.1 Cleaning the Main Unit

WARNING

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

1. Switch off the main unit and disconnect it from the power cord.
2. Wipe the exterior surface of the equipment using a soft cloth dampened with the cleaning solution until no visible contaminants remain.
3. Wipe off the cleaning solution with a fresh cloth or towel dampened with tap water after cleaning until no visible cleaning agent remains.
4. Dry the main unit in a ventilated and cool place.

13.2.2 Cleaning the Patient Cable

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

CAUTION

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

13.2.3 Cleaning the Reusable Electrodes

1. Wipe off with a soft cloth to remove residual gel.
2. Wipe the suction bulbs of chest electrodes and the clamps of limb electrodes with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
3. Wipe off the cleaning solution with a fresh cloth or towel dampened with tap water after cleaning until no visible cleaning agent remains.
4. Wipe off with a dry cloth to remove residual moisture.
5. Leave the suction bulbs and clamps to air dry.

13.3 Disinfection

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

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

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

The validated disinfectant for disinfecting the reusable electrodes is:

- Isopropanol (70%)

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

CAUTION

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

13.3.1 Disinfecting the Main Unit

WARNING

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

1. Switch off the main unit and disconnect it from the power cord.
2. Wipe the exterior surface of the equipment using a soft cloth dampened with the disinfectant solution.
3. Wipe off the disinfectant solution with a dry cloth after disinfection if necessary.
4. Dry the main unit for at least 30 minutes in a ventilated and cool place.

13.3.2 Disinfecting the Patient Cable

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

13.3.3 Disinfecting the Reusable Electrodes

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

13.4 Care and Maintenance

CAUTION

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

13.4.1 Recharge and Replacement of Battery

1) Capacity Identification

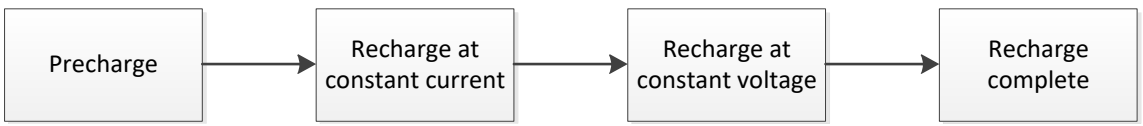
The battery capacity can be identified according to the battery symbol in the top right corner of the LCD screen.

2) Recharge

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

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

Recharging process:



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

CAUTION

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

3) Replacement

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

WARNING

1. Only qualified service engineers authorized by the manufacturer can open the battery compartment and replace the battery, and the battery of the same model and specification provided by the manufacturer must be used.
2. Danger of explosion -- Do not reverse the anode and the cathode when installing the battery.
3. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
4. When the battery's useful life is over, contact the manufacturer or the local distributor for disposal or dispose of the battery according to local regulations.
5. Remove the battery from the electrocardiograph when the electrocardiograph isn't used for a long time.
6. If the battery is stored alone and not used for a long time, we recommend that the battery be charged at least once every 6 months to prevent overdischarge.

CAUTION

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

13.4.2 Recorder Paper

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

Storage Requirements:

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

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

13.4.3 Visual inspection

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

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

13.4.4 Maintenance of the Main Unit and the Patient Cable

CAUTION

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

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

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

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

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

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

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

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

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

WARNING

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

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

1) Main Unit

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

2) Patient Cable

- Integrity of the patient cable, including the main cable and lead wires, should be checked regularly. Make sure that it is conductible.
- Do not drag or twist the patient cable with excessive stress while using it. Hold the connector plug instead of the cable when connecting or disconnecting the

patient cable.

- ♦ Align the patient cable to avoid twisting, knotting or crooking in a closed angle while using it.
- ♦ Store the lead wires in a big wheel to prevent any people from stumbling.
- ♦ Once damage or aging of the patient cable is found, replace it with a new one immediately.

3) Reusable Electrodes

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

CAUTION

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

Chapter 14 Accessories

WARNING

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

Table 14-1 Accessories List

Accessory	Part number
Power Cord (AHA)	01.13.037122
Power Cord (IEC)	01.13.036638
Patient Cable (AHA)	01.57.471393
Patient Cable (IEC)	01.57.471394
Patient Cable (IEC)	01.57.471686
Patient Cable (AHA)	01.57.471687
Patient Cable (IEC)	01.57.471688
Patient Cable (AHA)	01.57.471689
DE18 USB Cable	01.13.036736
Adult Chest electrodes	01.57.040163
Adult Limb electrodes	01.57.040162
Pediatric Chest Electrodes	01.57.040168
Pediatric Limb Electrodes	01.57.040169
Disposable Electrodes	01.57.471858
Disposable Electrodes	01.57.471859
Disposable Electrodes	01.57.471863
Disposable Electrodes	01.57.471860

Disposable Electrodes	01.57.471862
Snap/Banana Socket Adapters	01.57.471864
Clip/Snap/Banana Socket Adaptor	01.57.040172
Fuse	21.21.064172
Grounding Wire	01.13.114214
Rechargeable Lithium Battery	01.21.064143
Thermal Recorder Paper	01.57.107371
Thermal Recording Paper	01.57.107451
Thermal Recording Paper	01.57.032462
SD Card	01.17.102573

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

Chapter 15 Warranty and Service

15.1 Warranty

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

The warranty is void in cases of:

a) Damage caused by mishandling during shipping.

b) Subsequent damage caused by improper use or maintenance.

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

d) Damage caused by accidents.

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

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

15.2 Contact information

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

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

Appendix 1 Technical Specifications

A1.1 Safety Specifications

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

A1.2 Environment Specifications

	Transport & Storage	Working
Temperature:	-20ºC (-4ºF) ~ +55ºC (+131ºF)	+5ºC (+41ºF) ~ +40ºC (+104ºF)
Relative Humidity:	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	438mm×395mm×135mm, ±2mm
Weight	9.5kg,±0.3kg (Excluding recorder paper and battery)
Display	15", 1024×768 multicolor LCD Screen

A1.4 Power Supply Specifications

Mains Supply	Operating Voltage = 100V-240V~
	Operating Frequency = 50Hz/60Hz
	Input Current = 0.9A ~ 0.4A
Internal Li-ion Battery Pack:	Rated Voltage = 14.8V
	Typical Capacity = 5000mAh
	100% Charge time: 6 hours 90% charge time: 5 hours
	When the battery is fully charged, SE-18 can work normally about 6 hours, and it can continually print about 3 hours in the manual mode or print about 250 ECG reports of 6×3+1R in the AUTO mode.
Fuse	T3.15AH 250V Ø5×20mm

A1.5 Performance Specifications

Recording	
Recorder:	Thermal dot-matrix recorder
Printing Density	8 dots per mm / 200 dots per inch (amplitude axes) 40 dots per mm / 1000 dots per inch (time axes, @ 25 mm/s)
Recorder Paper:	Folded thermal paper: 210mm×295mm×100pages Folded thermal paper: 215mm×280mm×100pages Folded thermal paper: 210mm×295mm×200pages
Effective Width:	210mm
Paper Speed:	5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s, 50mm/s (±3%)
Accuracy of data:	±5% (x-axis), ±5%(y-axis)
HR Recognition	
HR Range:	30 bpm ~300 bpm
Accuracy:	±1 bpm
ECG Unit	
Leads:	18 standard leads
Acquisition Mode:	18 leads acquisition simultaneously
Sampling Frequency	64,000/sec/channel
A/D:	24bits
Resolution:	0.1192 μV/LSB
Time Constant:	≥5s
Frequency Response:	0.01~500Hz
Gain:	2.5, 5, 10, 20, 10/5, AGC (mm/mV)

Input Impedance:	≥100M Ω (10Hz)	
Input Circuit Current:	≤0.01μA	
Input Voltage Range	≤±5 mVpp	
Calibration Voltage:	1mV±2%	
DC Offset Voltage:	±900mV	
Minimum Amplitude:	20 μVp-p	
Noise:	≤12.5μVp-p	
Multichannel crosstalk	≤0.5mm	
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
CMRR	≥123dB (AC Off)	
Pacemaker Detection		
Amplitude	±750μV to ±700mV	
Width	50μs to 2.0ms	
External Input/Output		
Input	≥100kΩ; Sensitivity 10mm/V±5%; Single ended	
Output	≤100Ω; Sensitivity 1V/mV±5%; Single ended	
WIFI		

Radio Technology	802.11 a/b/g/n
Frequency Range	FCC: 2412 MHz ~ 2462 MHz, 5180 MHz ~ 5825 MHz CE: 2412 MHz ~ 2472 MHz, 5180 MHz ~ 5825 MHz
Modulation	DBPSK, DQPSK, CCK, BPSK, QPSK, 16-QAM, 64-QAM
Output Power	<20 dBm (CE requirement: detection mode - RMS) <30 dBm (FCC requirement: detection mode - peak power)
Transmit rate	IEEE 802.11b: 1 Mbps to 11 Mbps IEEE 802.11g: 6 Mbps to 54 Mbps IEEE 802.11n: 6.5 Mbps to 72.2 Mbps IEEE 802.11a: 6 Mbps to 54 Mbps
Bandwidth	2.4 GHz & 5 GHz 20 MHz

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

Appendix 2 EMC Information

Electromagnetic Emissions

<table>
<tr><th colspan="3">Guidance and manufacture's declaration – electromagnetic emission</th></tr>
<tr><td colspan="3">The 18-lead electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the 18-lead electrocardiograph should assure that it is used in such an environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The 18-lead electrocardiograph uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emission
CISPR 11</td><td>Class A</td><td rowspan="3">The 18-lead electrocardiograph is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC/EN 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC/EN 61000-3-3</td><td>Complies</td></tr>
</table>

Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity			
The 18-lead electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of 18-lead electrocardiograph should assure that it is used in such an environment.			
Immunity test	**IEC/EN 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC/EN 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC/EN 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	±1 kV line to line ±2 kV line to ground	±1 kV line to line ±2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50Hz/60Hz) magnetic field IEC/EN 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	0 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles) Single phase: at 0° 0 % U_T; 250/300 cycle	0 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles) Single phase: at 0° 0 % U_T; 250/300 cycle	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.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity			
The 18-lead electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the 18-lead electrocardiograph should assure that it is used in such an environment.			
Immunity test	**IEC/EN 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC/EN 61000-4-6	3 V_{rms} 150 kHz to 80 MHz 6Vrms[c)] in ISM	3 V_{rms} 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the 18-lead electrocardiograph, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation**

	bands between 0.15 MHz and 80 MHz	6Vrms[c)] in ISM bands between 0.15 MHz and 80 MHz	**distance** $d = 1.2\sqrt{P}$
Radiated RF IEC/EN 61000-4-3	3 V/m 80 MHz to 2.7 GHz See Table 1.	3 V/m 80 MHz to 2.7 GHz See Table 1.	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz $d = 6\sqrt{P}/\mathrm{E}$ at RF wireless communications equipment bands (Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the 18-lead electrocardiograph, including cables specified by the manufacturer). Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

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

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

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 18-lead electrocardiograph is used exceeds the applicable RF compliance level above, the 18-lead electrocardiograph should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the 18-lead electrocardiograph.

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

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

Table 1 Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test Frequency (MHz)	**Band [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-	GMRS 460,	FM [C)]	2	0.3	28

	470	FRS 460	±5 kHz deviation 1kHz sine			
710 745 780	704-787	LTE Brand 13, 17	Pulse modulation[b)] 217 Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900,TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b)] 18 Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation[b)] 217 Hz	2	0.3	28
2450	2400-2570	Bluetooth, WLAN,802.11 b/g/n, RFID 2450, LTE Brand 7	Pulse modulation[b)] 217 Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation[b)] 217 Hz	0.2	0.3	9
Note: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM maybe reduce to 1m. The 1 m test distance is permitted by IEC 61000-4-3.						
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50% duty cycle square wave signal. c) As an alternative FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.						

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

Recommended separation distances between portable and mobile RF communications equipment and the 18-lead Electrocardiograph

The 18-lead electrocardiograph is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the 18-lead electrocardiograph can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 18-lead electrocardiograph as recommended below, according to the maximum output power of the communications equipment.

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

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

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

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

Appendix 3 Abbreviation

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

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EDAN

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