SE-301

Electrocardiograph

Version 1.7

User Manual

CE 0123

About this Manual

P/N: 01.54.456811

MPN: 01.54.456811017

Release Date: December 2018

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 the manufacturer. (hereinafter called the manufacturer) cannot be held liable.

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

Product Information

Product Name: Electrocardiograph

Model: SE-301

Responsibility of the Manufacturer

The manufacturer 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 the manufacturer, and

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

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

Terms Used in this Manual

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

WARNING

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

CAUTION

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

NOTE

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

Table of Contents

Chapter 1 Safety Guidance

This chapter provides important safety information related to the use of the 3-Channel Electrocardiograph.

1.1 Indications for Use/Intended Use

The intended use of the 3-Channel Electrocardiograph is to acquire ECG signals from adult and pediatric patients (beginning at birth through 21 years of age) through body surface ECG electrodes. The electrocardiograph is intended to be used only in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the 3-Channel Electrocardiograph can help users to analyze and diagnose heart disease. However the ECG with measurements and interpretive statements is offered to clinicians on an advisory basis only.

WARNING

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

1.2 Warnings and Cautions

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

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

1.2.1 Safety Warnings

WARNING

1. The electrocardiograph is provided for the use of 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. The EQUIPMENT is protected against malfunction caused by electrosurgery.
4. **EXPLOSION HAZARD** - Do not use the electrocardiograph in the presence of flammable anesthetic mixture with oxygen or other flammable agents.
5. **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.
6. If the integrity of the external protective conductor is in doubt, the equipment should be operated by using the built-in 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 can not be guaranteed.
9. The use of patient cable and other accessories not supplied by the manufacturer may result in increased emissions or decreased immunity of the equipment.
10. The electrocardiograph has been safety tested with the recommended accessories, peripherals, and leads, and no hazard is found when the electrocardiograph is operated with cardiac pacemakers or other stimulators.
11. Make sure that all electrodes are connected to the patient correctly before operation.
12. Ensure that the conductive parts of electrodes and associated connectors, including neutral electrode, do not come into contact with earth or any other conducting objects.

WARNING

13. To avoid a polarization or DC offset voltage, use non-polarizing electrodes(which will not form a DC offset voltage when subjected to a DC current) such as silver/silver-chloride types if there is a situation where there is a likelihood that a defibrillation procedure will be necessary.
14. There is no danger for patients with pacemakers. However, if a pacemaker is used, the results given by the equipment may be invalid, or lose the clinical significance.
15. Disposable electrodes must be used during defibrillation.
16. Electrodes of dissimilar metals should not be used; it may cause a high polarization voltage.
17. The disposable electrodes can only be used for one time.
18. Do not touch the patient, bed, table or the equipment while using the ECG together with a defibrillator.
19. Do not touch accessible parts of electrical equipment and the patient simultaneously.
20. 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.
21. If WIFI technology is used, in order to maintain compliance with the FCC RF exposure guidelines, the wireless should be installed and operated with a minimum distance of 20cm between the radiator and the human body. Use the supplied antenna only. There should be no shield in or around the room where WIFI is used.
22. Fix attention on the examination to avoid missing important ECG waves.
23. **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.
24. **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.

WARNING

25. 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.
26. Any non-medical equipment (such as the external printer) is not allowed to be used within the patient vicinity (1.5m/6ft.).
27. Multiple portable socket-outlets shall not be placed on the floor.
28. Do not use the additional multiple portable socket-outlet or extension cord in the medical electrical system, unless it's specified as part of the system by manufacturer. And the multiple portable socket-outlets provided with the system shall only be used for supplying power to equipment which is intended to form part of the system.
29. Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the standard IEC/EN 60601-1. Therefore anybody, who connects additional equipment to the signal input or output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC/EN 60601-1. If in doubt, consult our technical service department or your local distributor.
30. Connecting any accessory (such as external printer) or other device (such as the computer) to this electrocardiograph makes a medical system. In that case, additional safety measures should be taken during installation of the system, and the system shall provide:
    a) Within the patient environment, a level of safety comparable to that provided by medical electrical equipment complying with IEC/EN 60601-1, and
    b) Outside the patient environment, the level of safety appropriate for non-medical electrical equipment complying with other IEC or ISO safety standards.
31. All the accessories connected to system must be installed outside the patient vicinity, if they do not meet the requirement of IEC/EN 60601-1.

WARNING

32. 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.
33. The potential equalization conductor can be connected to that of other equipment when necessary, to make sure that all these devices are connected to the potential equalization bus bar of the electrical installation.
34. The electrocardiograph shall not be serviced or maintained while in use with a patient.
35. 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.
36. The medical electrical equipment needs to be installed and put into service according to Appendix 2 EMC Information.
37. 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.
38. Portable and mobile RF communications equipment can affect medical electrical equipment, refer to the recommended separation distances provided in Appendix 2 EMC Information.
39. Assembly of the electrocardiograph and modifications during actual service life shall be evaluated based on the requirements of IEC60601-1.
40. The device is MR unsafe. It is not intended for use in an MRI environment.
41. Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the device comply with the relevant EMC requirements. X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.

1.2.2 Lithium Battery Care Warnings

WARNING

1. Improper operation may cause the lithium battery (hereinafter called battery) to be hot, ignited or exploded, and it may lead to the declination of the battery capacity. It is necessary to read the user manual carefully and pay more attention to warning messages.
2. Only qualified service engineer 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 is not used for a long time.
10. If the battery is stored alone and not used for a long time, we recommend that the battery should be charged at least once every 6 months to prevent over-discharge.

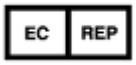
1.2.3 General Cautions

CAUTION

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

1.3 List of Symbols

No.	Symbol	Description
1		DEFIBRILLATION-PROOF TYPE CF APPLIED PART

2		Caution
3		Operating instructions
4		Equipotential grounding
5		Power key
6		Print/Stop key
7		Casing Button
8		General symbol for recovery/recyclable
9	P/N	Part Number
10		SERIAL NUMBER
11		Date of manufacture
12		MANUFACTURER
13		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
14		CE marking
15		Disposal method

16		SD card slot
17		USB socket
18		Net port
19	19V ⎓	Power adapter port
20	Rx Only	Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician
21		Refer to User Manual (Background: Blue; Symbol: White)
22		Warning (Background: Yellow; Symbol&Outline: Black)
23*	FCC ID: SMQSE301EDAN	Federal Communications Commission: FCC ID: SMQSE301EDAN
24*		Non- ionizing electromagnetic radiation
25		MR Unsafe–Keep away from magnetic resonance imaging (MRI) equipment
26	ETL CLASSIFIED C ETL US Intertek 4005997	Conforms to UL Std. 60601-1, IEC Std. 60601-2-25 Certified to CSA Std. C22.2 No 601.1,CSA Std. C22.2 No 60601-2-25

NOTE:

1. * Applicable to the Electrocardiograph configured with WIFI or 4G module.
2. For details about buttons of the keyboard, refer to Chapter 2.
3. The user manual is printed in black and white.

Chapter 2 Introduction

SE-301 3-channel electrocardiograph gathers ECG signals of 12 leads simultaneously. It displays the operation menu, ECG parameters as well as electrocardiograms.

3-channel ECG waves can be viewed on the LCD screen and printed out by using a high-quality thermal recorder.

The AUTO, MANU, RHYT, and R-R modes can be chosen freely.

SE-301 can be powered by the mains supply or a built-in rechargeable lithium battery. WIFI and 4G are configurable for SE-301.With a 32-bit processor and a large-capacity memorizer, SE-301 has advanced performance and high reliability.

Configuration: main unit, power cord, earth wire, patient cable, electrodes, and lithium battery

2.1 Top Panel

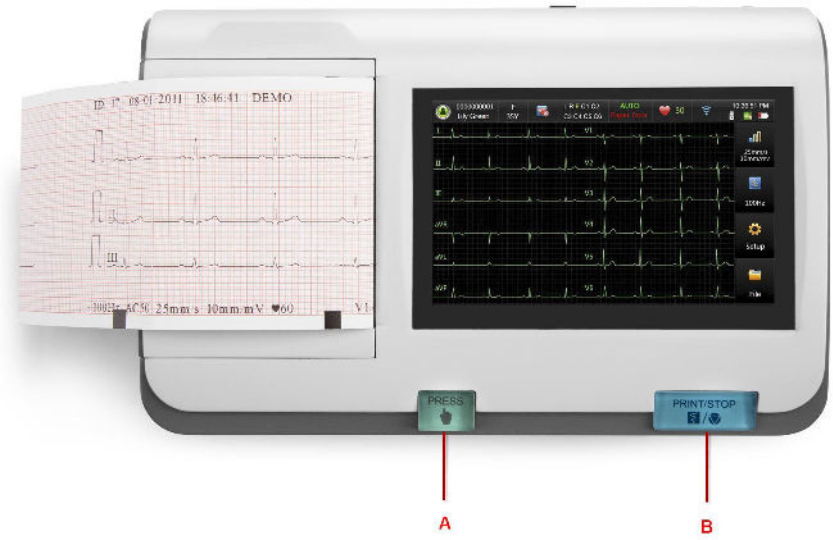


Figure 2-1 SE-301

No.	Description
A	Press to release the recorder casing
B	Press to start/stop ECG sampling

2.2 Bottom Panel

The silk screen on the battery compartment indicates the rated voltage.

4G SIM card can be inserted after taking out the battery, as shown on the picture above.

NOTE: The 4G function is currently not available in the U.S.

2.3 Right Panel

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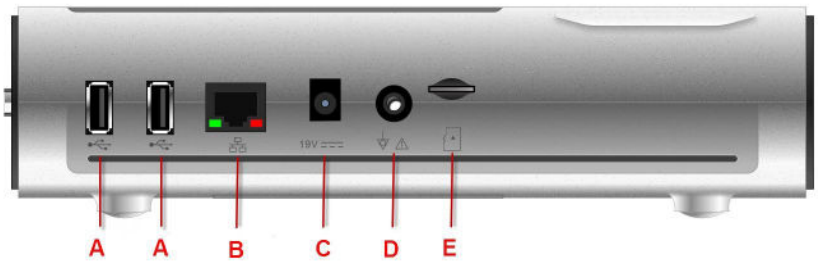
No.	Description
A	Patient cable socket
B	Power key (Long press: switch on/off; short press: sleep mode) Color when using the mains supply: Green Color when using built-in battery: Blue Color when recharging: Orange

2.4 Back Panel



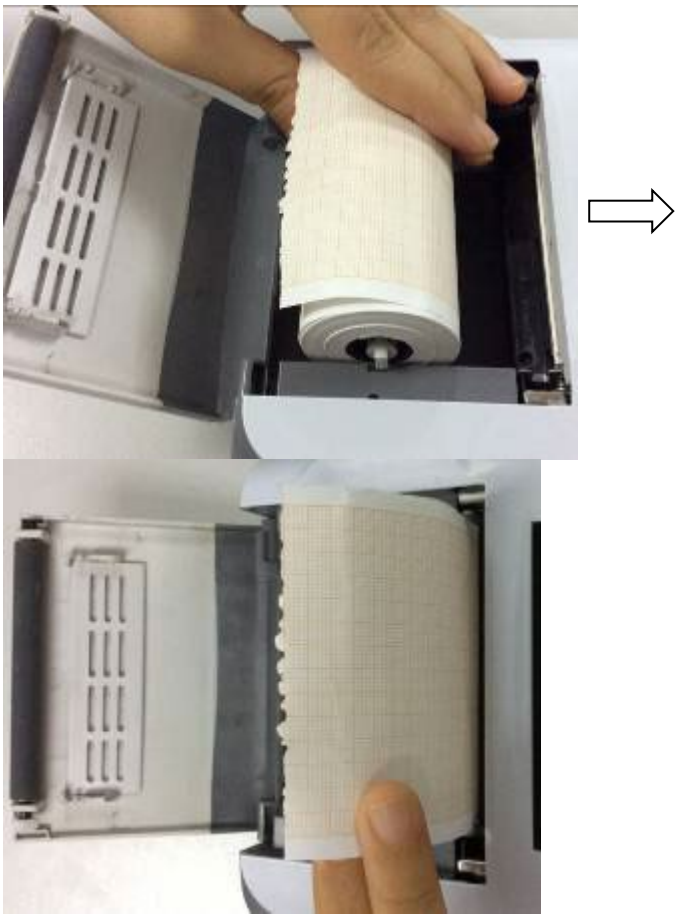
No.	Description	No.	Description
A	USB socket	D	Equipotential grounding
B	Net port	E	SD card slot
C	Power adapter port	-	-

Chapter 3 Operation Preparations

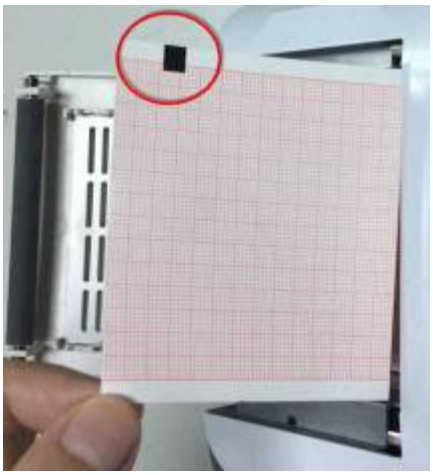
3.1 Loading/Replacing Recorder Paper

NOTE:

1. When the folded thermal paper is used, the paper roller is unnecessary and must be taken out.
2. The grid side of the paper should face the thermal print head, and the black marker on the paper should face the black marker detecting area.



Loading/Replacing Process of Rolled Thermal Paper



Loading/Replacing Process of Folded Thermal Paper

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.

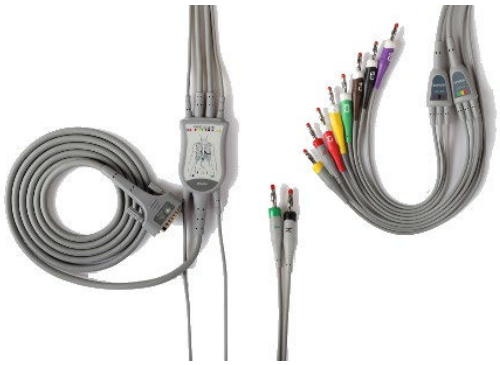
3.2.2 Cleaning the Skin

Thorough skin preparation is very important. The skin is a poor conductor of electricity and frequently creates artifact that distorts the ECG signal. By performing methodical skin preparation, you can greatly reduce the possibility of the 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

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

3.3 Connecting the Patient Cable to the Electrocardiograph and Electrodes



WARNING

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

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.

2. Connecting the Patient Cable to Electrodes

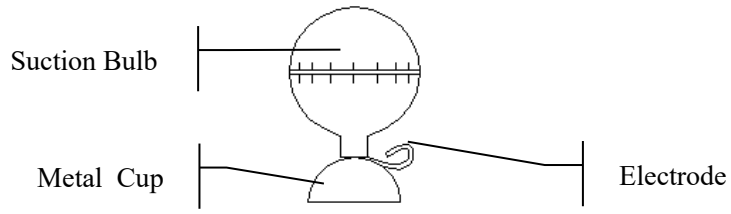
Align all lead wires of the patient cable to avoid twisting, and connect the lead wires to the corresponding electrodes according to the colors and identifiers. Firmly attach them.

3.4 Attaching Electrodes to the Patient

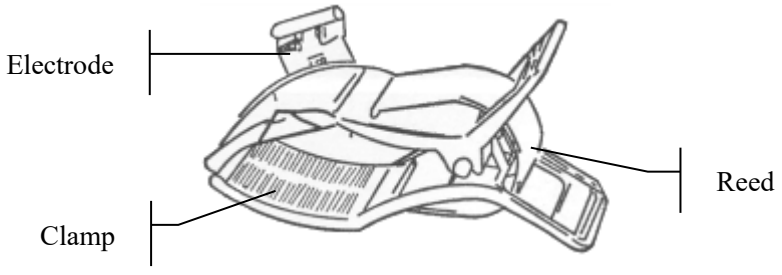
There are two types of electrode for you to choose, one is the reusable electrodes, and the other is the disposable electrodes. The uses of the two types of electrode are as shown below:

3.4.1 Reusable Electrodes

Reusable Electrodes is divided into Limb electrode and Chest Electrode, as the following figure shows:



Chest Electrode



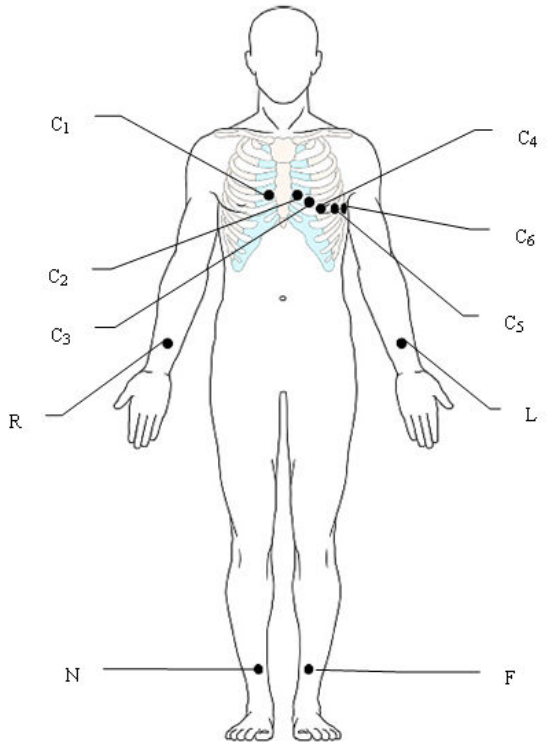
Limb Electrode

The identifiers and color codes of electrodes used comply with IEC/EN requirements. In order to avoid incorrect connections, the electrode identifiers and color codes are specified in Table 4-1. Moreover the equivalent codes according to American requirements are given in Table 4-1 too.

Table 3–1 Electrodes and Their identifiers and color codes

	European		American	
Electrodes	**Identifier**	**Color code**	**Identifier**	**Color code**
Right arm	R	Red	RA	White
Left arm	L	Yellow	LA	Black
Right leg	N or RF	Black	RL	Green
Left leg	F	Green	LL	Red
Chest 1	C1	White/red	V1	Brown/red
Chest 2	C2	White/yellow	V2	Brown/yellow
Chest 3	C3	White/green	V3	Brown/green
Chest 4	C4	White/brown	V4	Brown/blue
Chest 5	C5	White/black	V5	Brown/orange
Chest 6	C6	White/violet	V6	Brown/violet

As the following figure shows, the positions of chest electrodes on the body surface are



C1: Fourth intercostal space at the right border of the sternum

C2: Fourth intercostal space at the left border of the sternum

C3: Fifth rib between C2 and C4

C4: Fifth intercostal space on the left midclavicular line

C5: Left anterior axillary line at the horizontal level of C4

C6: Left midaxillary line at the horizontal level of C4

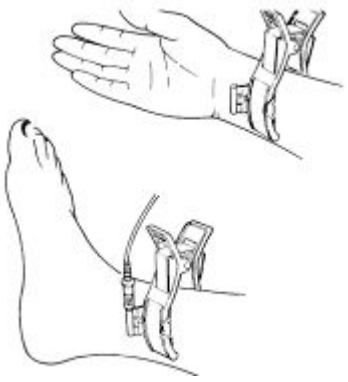
Chest Electrode Connection:

1) Ensure that the electrodes are clean;
2) Align all lead wires of the patient cable to avoid twisting, and connect the lead wires to the corresponding electrodes according to the colors and identifiers;
3) Clean the electrode area on the chest surface with 75% alcohol;
4) Daub the round area of 25mm in diameter on each electrode site with gel evenly;
5) Place a small amount of gel on the brim of chest electrode's metal cup;
6) Place the electrode on the chest electrode site and squeeze the suction bulb. Unclench it and the electrode is adsorbed on the chest;
7) 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 small children or patients with delicate skin, squeeze the suction ball lightly.

Limb Electrode Connection:

2) Ensure that the electrodes are clean;
3) Align all lead wires of the patient cable to avoid twisting, and connect the lead wires to the corresponding electrodes according to the colors and identifiers;
4) Clean the electrode area which is a short distance above the ankle or the wrist with alcohol;
5) Daub the electrode area on the limb with gel evenly;
6) Place a small amount of gel on the metal part of the limb electrode clamp;



7) 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;
8) Attach all limb electrodes in the same way.

3.4.2 Disposable Electrodes

Disposable Electrode

Clip/Snap/Banana Socket Adaptor

Disposable electrode must be used together with the clip/snap/banana socket adaptor.

The electrodes' positions on body surface are as the following table and figures:

American label	European label	Electrode placement
RA	R	Right deltoid
LA	L	Left deltoid
RL	N or RF	Above right ankle (Alternate placement, upper leg as close to torso as possible)
LL	F	Above left ankle (Alternate placement, upper leg as close to torso as possible)
V1	C1	Fourth intercostals space at right border of sternum
V2	C2	Fourth intercostals space at left border of sternum
V3	C3	Fifth rib between V2 and V4
V4	C4	Fifth intercostals space on left midclavicular line
V5	C5	Left anterior axillary line at the horizontal level of V4
V6	C6	Left midaxillary line at the horizontal level of V4

Disposable Electrode connection

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

The quality of ECG waveform will be affected by the contacting resistance between the patient and the electrode. In order to get a high-quality ECG, the skin-electrode resistance must be minimized when you attach electrodes to patients.

CAUTION

The disposable electrodes can only be used for one time.

WARNING

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

3.5 Inspection Before Power On

In order to avoid safety hazards and get good ECG records, the following inspection procedure is recommended before power-on and 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. Switch off these devices when necessary.
- ♦ Keep the examination room warm to avoid muscle action 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-phase outlet should be used.
- ♦ When the battery capacity is low, recharge the battery before use.

3) **Patient Cable**:

- ♦ Check whether the patient cable is connected to the unit firmly, and keep it far away from the power cord.

4) **Electrodes**:

- Check whether all electrodes are connected to lead wires of the patient cable correctly.
- Ensure that the chest electrodes do not contact.

5) **Recorder Paper**:

- Ensure that there is enough recorder paper loaded correctly.

6) **Patient**:

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

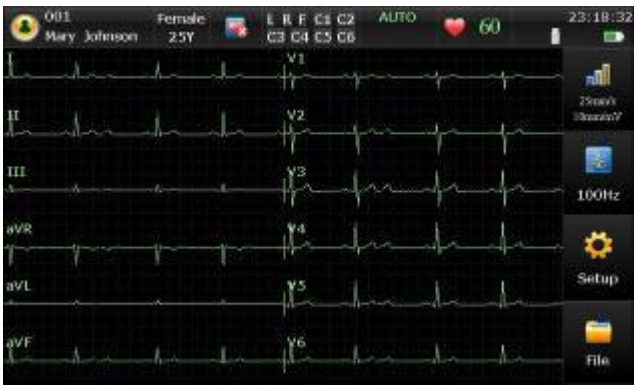
WARNING

The electrocardiograph is provided for the use of qualified physicians or personnel professionally trained, and they should be familiar with the contents of this user manual before operation.

Chapter 4 Sampling and Printing ECG

4.1 Entering Patient Information

4.1.1 Entering Patient Information Manually



On the main screen, the following information is displayed: patient information, system hints, heart rate, waveforms, current time, battery capacity, WIFI/4G signal (configurable), and functional keys.

Click the patient symbol to enter the patient information window, enter the patient information, or you can configure the patient information items in system setup first.

Item	Description
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:

1. The patient information cannot be set or changed during the printing course.
2. The lead notation area may cut the peaks of the waveform in display when the peak goes through the lead notation during changing the HR value on the main screen correspondingly, but the rest of the waveform is displayed normally. Therefore, this does not affect the user's normal judgment.

4.1.2 Entering Patient Information by Acquiring Orders

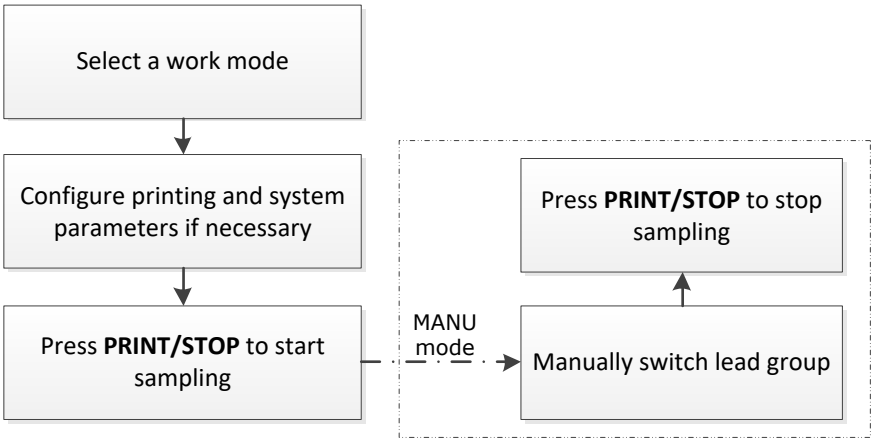
NOTE: To use the order function, the data management software (DMS) of the manufacturer must be installed in the PC.

Operation procedures are as follows:

1. Connect the electrocardiograph to the PC through the network.
2. Log into the DMS.
3. Set **Remote IP**, **Local IP**, **Gateway** and **Subnet Mask** in the **Transmission Setup** window.
4. Click the patient symbol on the main screen to open the patient information window, and then click **Order** to open the **Order** screen.
5. Click **Load** to download order records from the server.
6. Select an order and click **Examine** to enter the presampling screen.

4.2 Printing ECG Reports

The operation procedure is as follows:



NOTE:

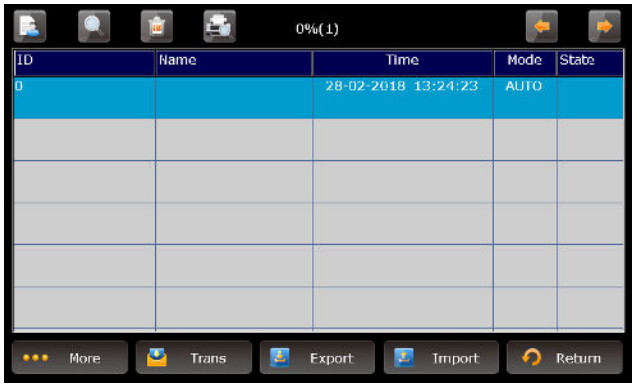
1. The printing mode cannot be changed during the printing course. Stop printing reports before changing the printing mode.
2. In the MANU mode, press the 1mV/COPY key to print out 1mV mark in the ECG reports
3. When switching from the system setting or file management screen to the main screen, the heart rate value will be shown after a 3-second delay for calculation. If

you print immediately, the heart rate value will be 0 on the printed report while the value in the diagnosis area is normal. In this case, please wait more than 3 seconds before printing.

Chapter 5 Managing ECG Records

If you want to save the ECG records, you should set the **Auto Save** to **To ECG** or **Ext. Memory**. The default value is **To ECG**. Then the ECG records will be saved in the File Manager or in the external memory automatically.

Click **File** on the main screen to enter the file manager screen.



The File Manager allows records to be stored, deleted, printed and transmitted. When there is no space for more records to be stored in the File Manager, the message *MemFull* will be displayed.

5.1 Transmitting ECG Records to the PC

NOTE: To transmit ECG records to the PC, data management software (DMS) of the manufacturer (Smart ECG Viewer or SE-1515) must be installed in the PC. You should log into the DMS before the transmission.

5.1.1 Transmitting ECG Records through the Network

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

- **Auto Transmission:**

1. Choose **Setup** > **Transmission** to enter the Transmission Setup window.
2. Set **Auto Transmission** to **On** and set **Transmission mode** to **Ethernet.**
3. Set the **Server IP** to the IP of the DMS.

4. Set the first three numbers of the **Local IP** according to the first three numbers of the IP of the DMS. The last number of the **Local IP** item can be set at random, but it can't be the same as the last number of the IP of the DMS.
5. In the **AUTO** or **RHYT** mode, ECG data can be transmitted through the net automatically after an ECG report is printed out.

- **Manual Transmission:**

1. Choose **Setup** > **Transmission** to enter the Transmission Setup window.
2. Set **Auto Transmission** to **Off** and set **Transmission mode** to **Ethernet.**
3. For IP address setting, refer to step 3 and 4 for auto transmission.
4. To transmit all the data files to the PC, choose **More** > **Trans All** in the file management window.

   To transmit a single file, select it and click **Trans**.

NOTE: The transmission process is long, and please be patient to wait.

5.1.2 Transmitting ECG Records through WIFI/4G Network (Configurable)

If the WIFI module or 4G SIM card is configured, ECG records can also be transmitted through WIFI/4G 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.

NOTE:

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

5.2 Copying ECG Records between the ECG Machine and External Memory

1. Connect the external memory to the electrocardiograph.
2. Click **File** to open the File Manager screen.
3. Choose **More > Trans All**, and click **OK**, all the records will be transmitted to the external memory automatically.

   During the transmission, if something wrong happens, the electrocardiograph will give the error information. Then you should check whether the external memory is connected to the electrocardiograph well.
4. If you want to import records from the **ECGDATA** folder of the external memory to the electrocardiograph, click the **Import** button, the extended-name of imported records should be ".dat".

NOTE: To import records from the external memory to the electrocardiograph, there should be some records in the folder named ECGDATA in the external memory. The folder name ECGDATA must be capital letters. You should not change the name of records in the **ECGDATA** folder.

5. If you want to export only one record, choose the patient record in the table and click **Export**.

NOTE:

1. The transmission process is long, please be patient to wait.
2. During the transmission, the external memory should not be pulled out.
3. Only FAT or FAT32 format can be used when formatting the external memory.
4. The storage of the external memory should not exceed 16G.

5.3 Deleting Patient Records

1. Open the File Manager screen.
2. If you want to delete all the records, click **More** and select the **Del All** button, and then click **OK**.
3. If you want to delete a record, choose the patient record in the table, and then click the delete symbol on the top.

5.4 Printing a Patient Record in the File Manager screen

1. Open the File Manager screen.
2. If you want to print the patient record, choose the patient record in the list, and then press **PRINT/STOP**.

NOTE: If you use USB printer to print the patient record, when the **PRINT/STOP** key is pressed, the electrocardiograph begins to analyze data. Then the USB printer begins to print the ECG record after 8 seconds.

Chapter 6 Settings

Click **Setup** on the main screen to display the **System Setup** screen.

NOTE: The underlined values are system default values.

6.1 Work Mode

Item	Description
Sampling Mode (Only available in the AUTO mode)	Choose from: **Pre-Sample**, **Real-time Sample**, **Triggered Sample**, and **Periodic Sample**. Select **Pre-Sample**, 10s ECG data sampled before pressing the **PRINT/STOP** key will be printed out. **NOTE:** When **Sampling Mode** is set to **Pre-Sample**, if you press the **PRINT/STOP** key before the electrocardiograph samples for 10s, the recorder will not respond.
Periodic Sample Setup	**Duration** can be set to a value between 0-60 min. The default value is 60 min. Interval can be set to a value of 0-60 min. The default value is 1 min. This interval must be shorter than the periodic sample duration.
Display Mode	Choose from: 3×4+1R, 6×2, and 6×2+1R
Preview	When enabled, you can preview AUTO or RHYT data after sampling.
Auto Arrhythmia Detection	When enabled, if arrhythmia is detected in the AUTO mode, a hint will pop up to ask you whether to print an extra rhythm report after the 12-lead ECG report.

6.2 Filter

Item	Description
AC Filter	Choose from: **On** or **Off** AC filter is used to suppress interference of AC power supply. **NOTE:** AC frequency can be set to **50Hz** or **60Hz** on the **Advanced Setup** screen according to local mains supply specifications.

DFT Filter	Choose from: **0.01Hz, 0.05Hz**, **0.32Hz**, or **0.67Hz** 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. The set value is the low limit of the frequency range.
EMG Filter	The cutoff frequency can be set to **25Hz**, **35Hz**, **45Hz** or **Off** EMG Filter suppresses disturbance caused by strong muscle tremor.
Lowpass Filter	The cutoff frequency can be set to **75Hz**, **100Hz**, **150Hz**, **270Hz** or **300Hz** Lowpass Filter restricts the bandwidth of input signals. All the input signals whose frequency is higher than the set cutoff frequency will be attenuated. **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.

6.3 Record Info Setup

6.3.1 Setup 1

Item	Description
Print Out	Choose from: **On**, **Off** Select **Off** to disable the print function in the AUTO or RHYT mode.
Speed	Choose from: **5mm/s**, **6.25mm/s**, **10mm/s**, **12.5mm/s**, **25mm/s** and **50mm/s** **NOTE**: The speed is corresponding with the work mode.
Gain	Choose from: **1.25mm/mV, 2.5mm/mV**, **5mm/mV**, **10mm/mV**, **20mm/mV**, **10/5mm/mV and 20/10mm/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**.

Auto Record Style	● When using the thermal recorder, choose from: 3×4, 3×4+1R, 3×2+2×3 ● When using a USB printer, choose from: 3×4, 3×4+1R, 3×4+3R, 6×2, 6×2+1R or 12×1
Sample Time	Set the sampling duration.
Prompt	Choose from: **Unconfirmed** and **Report Confirm**. Select **Unconfirmed**, **Unconfirmed Report** will be printed in the ECG reports. Select **Report Confirm,** the physician's name will be printed in the ECG reports if it is input in the **Patient Information** window.
Record Sequence	Choose from: **Sequential** or **Synchronous** Select **Sequential**, the lead group is printed one by one in a certain sequence. The start time of a lead group is just the end time of the previous lead group. Select **Synchronous**, the lead group is printed one by one in a certain sequence. All leads are printed with the same start time.
AGC	**AGC** means auto gain control. Choose from: **On** or **Off** Select **On**, the gain can be automatically adjusted according to actual signals.
Record Length	Choose from: **Short (2.5s)**, **Medium (5s)** and **Long (10s)** **NOTE:** 1. It's configurable only when **Record Device** is set to **Thermal**, **Record Sequence** to **Sequential, Sample Time** to **10s**, and **Auto Record Style** to **3×2+2×3** or **3×4.** 2. The device acquires ECG signals from patients undergoing short-term resting test. The time range can be 2.5s, 5s or 10s.

Record Device	Choose from: **Thermal, HPM401/2035, HP1106/1020P, HP1106/1020P, HP4729/3638, HPM202D/M403d**, and **HP3638/4729.** You should connect the corresponding USB printer to the electrocardiograph before printing with the selected record device. **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 an external memory or a USB printer during the transmission course. **NOTE**: 1. During the USB printing course, pressing the **PRINT/STOP** key again cannot stop printing ECG reports. 2. USB printing is ineffective in the AUTO mode and RHYT 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. 4. Make sure the type of USB printer connected matches the type you choose in the Record Device. Error may occur if the USB printer type is not matched.
Manual Style	Choose from **3 channels** and **1 channels** Select a style to print the ECG waves in the manual mode.
Rhythm Record Mode	Choose from: **Save Paper** or **Quickly** Select **Save Paper**, 10s after pressing the **PRINT/STOP** key on the main screen, an ECG report is printed in the RHYT mode. Select **Quickly**, pressing the **PRINT/STOP** key on the main screen to begin printing an ECG report immediately in the RHYT mode.
Paper Marker	**Paper Marker** is used to identify the start point of each page of the recorder paper. Choose from: **Yes** or **No** Select **Yes** 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.

WARNING

Under some extreme circumstance, for example the input signal is 5mV which is almost impossible during clinical application, the AGC function may adjust the gain (sensitivity) to an inappropriate value which cause overlap or gap between waveforms. Besides, you can adjust the sensitivity manually to get a better display.

6.3.2 Setup 2

Item	Description
Measure	Choose from: **On** or **Off** When it is set to **On**, the Measure information will be printed in the ECG report.
Analysis	Choose from: **On** or **Off** When it is set to **On**, the Analysis information will be printed in the ECG report.
Template	Choose from: **On** or **Off** When it is set to **Off**, the template will not be printed in the ECG report
Position Marker	Choose from: **On** or **Off** When it is set to **Off**, the template printed in the ECG report will not have position marker.
Minnesota Code	Choose from: **On** or **Off** When it is set to **On**, the Minnesota Code will be printed in the ECG report.
Device No.	Choose from: **On** or **Off** When it is set to **On**, the Device No. will be printed in the ECG report.
Baseline Adjustment	Choose from: **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.
Grid of Report	Choose from: **On** or **Off** When it is set to **On**, the grid will be printed while printing ECG reports with the thermal recorder or USB printer.

6.4 Patient Information Setup

Item	Description
ID	Choose from: **Auto**, **Time** or **Manual**
ID Hint	Choose from: **On** or **Off** In the AUTO or RHYT mode, when **ID** is set to **Manual** and **ID Hint** is set to **On**, if you do not input the patient ID before pressing the **PRINT/STOP** key, a hint will pop up to remind you to input the patient ID.
Age	Choose from: **Age**, **D.O.B** or **Age Group**
H/W Unit	Choose from: **cm/kg** or **inch/lb**
BP Unit	Choose from: **mmHg** or **kPa**
PatInfo Refreshed	Choose from: **On** or **Off** Select **On**, the patient information will be refreshed after the ECG report is printed out and all the leads are off.
Order Acquired	Choose from: **On** or **Off** Select **On**, the **Order** item will be displayed in the **Patient Information** window and you can acquire orders by clicking it.
User-defined	Add new items.
First/Last Name	Choose from: **On** or **Off** When it is set to **On**, patient name will be divided into first name and last name.
Other patient options	Select information to be displayed in the Patient Information window.
Pacemaker	Select to detect very small pacemaker pulses. However, when **Pacemaker** is selected, 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 disabled unless it is known that the majority of the electrocardiograph usage will be on patients with pacemakers.

6.5 Transmission Setup

NOTE:

1. To transmit ECG data to the PC, the DMS produced of the manufacturer must be installed in the PC. You should log into the DMS before transmission.
2. If the power supply suddenly breakdown during data storage or transmission, file system error may occur. In this case, the file system should be formatted.

6.5.1 Basic Setup

Item	Description
Device No.	Enter Device No., it should be within 7 ASCII characters.
Auto Transmission	Choose from: **On** or **Off** Select **On**, ECG data will be transmitted automatically after an ECG report is printed out in the AUTO or RHYT mode.
Transmission Mode	Choose from: **Ethernet**, **Wireless** or **Mobile Network.**
FTP Information	Enter data in the **FTP Path**, **FTP User Name** textboxes.
IP Addresses	Set **Server IP, Local IP,** Set **Gateway,** Set **Subnet Mask** For details, please refer to Section 5.1: "*Transmitting ECG Records to the PC*".

6.5.2 WIFI Setup (Configurable)

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

6.6 Lead Setup

<table>
<tr><th>Item</th><th>Description</th></tr>
<tr><td>Rhythm Lead1/2/3</td><td>Choose from: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, or V6, the default
NOTE: Rhythm Lead 1/2/3 must be different from each other.</td></tr>
<tr><td>Lead Sequence</td><td>Choose from: Standard or Cabrera
<table>
<tr><th>Lead Sequence</th><th>Lead group 1</th><th>Lead group 2</th><th>Lead group 3</th><th>Lead group 4</th></tr>
<tr><td>Standard</td><td>I, II, III</td><td>aVR, aVL, aVF</td><td>V1, V2, V3</td><td>V4, V5, V6</td></tr>
<tr><td>Cabrera</td><td>aVL, I, -aVR</td><td>II, aVF, III</td><td>V1, V2, V3</td><td>V4, V5, V6</td></tr>
</table></td></tr>
<tr><td>Lead off hint</td><td>When it is set to On and lead off waves are detected in the presampled waves, a lead off hint message will be displayed.</td></tr>
</table>

6.7 File Setup

Item	Description
Auto Save	Choose from: **Off, <u>To ECG</u>** or **Ext. Memory** Select **Off**, ECG data will not be saved. Select **To ECG**, ECG data in the AUTO or RHYT mode will be saved in the ECG automatically. Select **Ext. Memory**, ECG data in the AUTO or RHYT mode will be automatically saved to the directory of ***ECGDATA\ECG-X\Store\Examination Date*** of the external memory after an ECG report is printed out. **NOTE:** 1. Please insert the external memory recommended by the manufacturer. Please set the format to **FAT** or **FAT32** when formatting the external memory. 2. X in the directory of ***ECGDATA\ECG-X\Store\Examination Date*** can be set in the **Device No.** textbox in the **Transmission Setup** window.

File Format	Choose from: **DAT, PDF, SCP, FDA-XML** and **DICOM** To select **SCP/FDA-XML/DICOM**, you should first activate the SCP/FDA-XML/DICOM function on the **Advanced Setup** screen. For details, please contact the manufacturer or the local distributor.
Del. After Trans. Or Export	Choose from: **On** or **Off** Select **On**, 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	Choose from: **On** or **Off** Select **On**, if the number of stored files reaches 800, the files will replace the earliest one automatically.

6.8 Date&Time Setup

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

Item	Description
Date Mode	Choose from: **DD-MM-YYYY**, **MM-DD-YYYY** or **YYYY-MM-DD**
Time Mode	Choose from: **24 Hours** or **12 Hours**
Date&Time	Enter the current date and time displayed on the main screen and in the ECG reports.
Power off time	Set to 0-120 This function is only available when the electrocardiograph is powered by using the mains supply.
LCD off time	Set to 0-120

6.9 System Maintenance

- Import/export the system settings, backup the settings, or load the backup settings
- Load factory settings
- Set the password to access system settings

6.10 Other Setup

Item	Description
Institution	Input the institution name manually within 40 ASCII characters. **NOTE:** The total number of supported characters may be fewer if special Latin characters are entered.
Grid	When enabled, the waveforms on the main screen will be displayed with a background grid.
Language	Select the language displayed on the main screen and in the ECG reports.
Key Volume	When enabled, the electrocardiograph gives a short sound when you press keys.
Hint Volume	When enabled, the electrocardiograph gives a sound when a hint such as ***Lead Off***, ***Overload***, ***Battery Weak*** etc. is displayed.
QRS Volume	When enabled, the electrocardiograph gives a sound when an R wave is detected.
Notify Volume	When enabled, the electrocardiograph gives a sound after ECG report is printed.

6.11 Advanced Setup

View the device information, perform system test, etc.
Activate purchased advanced functions.

Item	Description
Demo Setup	Choose from: **Normal**, **abnormal** or **Off** When it is set to **Normal**, the main screen will display demo of normal ECG signal.

Chapter 7 Error Messages

Error messages provided by SE-301 and the corresponding causes are listed in Table 10-1.

Table 7–1 Error Messages and Causes

Error Message	Causes
Lead off	Electrodes fall off the patient or the patient cable falls off the unit.
Paper?	Recorder paper runs out or is not loaded.
PaperErr	The system doesn't detect any black signs while the paper style is set as "Folded" on the System Setup Screen.
BAT WEAK	The built-in battery is weak.
Demo	The system is in the demonstration mode.
Sampling/Analyzing/Recording	ECG signals are being sampled / analyzed / recorded.
Transmitting	ECG data is being transmitted from the electrocardiograph to the PC through the net or serial cable in the AUTO or RHYT mode.
Transmitting fails!	Transmitting ECG data fails.
MemoryFull	There is no space for saving more records.
USB Printer / USB Scanner	An external USB printer or a bar code reader is connected to the USB interface.

Chapter 8 Troubleshooting

1) Operating Problems

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

A1: Yes, in the Record Info setup, set **Print Out** to **Off**. In the same way, if the transmission settings have been configured, the ECG data could be transmitted to the PC without printing.

2) Printing Problems

Q1: There was double impression in printing when I printed ECG reports by using an ink-jet printer. What's wrong with it?

A1: It may be the result of the coexisting black and color ink cartridges. Taking out the color ink cartridge may solve the problem.

Q2: I was encountered with paper-jam, what was I supposed to do?

A2: 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 paper 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.

Q3: The hint PaperErr is displayed on the screen, what should I do?

A3: Check if the paper maker setting is right or might be the result of unsuccessful detection of the black markers, first open the paper casing so as to clear the error information, and then check whether the black marker is on the top 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.

Q4: The hint Paper? is displayed on the screen, what should I do?

A4: Check whether the paper runs out, or the black marker is just facing the black maker detection window on the thermal printing head.

Reload the paper in the paper tray, close the paper casing firmly. If the problem still exists, please contact the manufacturer or the local distributor for further disposal.

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

A5: Please check whether there is any error information displayed on the screen.

If the hint *Paper?* or *PaperErr* is shown on the screen, please deal with it according to the above-mentioned measures.

If the hint *Transfer* is shown 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 has been transmitted.

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

3) Transmitting Problems

Q1: The ECG doesn't respond to any keys after a long time of transmitting. It transmits nothing for there is no new data appearing on the interface 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 restart the ECG. If it doesn't work, please restart the PC.

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

4) Main Unit Problems

Q1: I was doing the examination when the machine suddenly gave out a sound and displayed the hint *Lead Off*. What should I do?

A1: The leads are not connected well. Please check whether the electrodes are 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 take effect, please contact the manufacturer or the local distributor for further disposal.

Q2: The touch screen is not sensitive after restoring to factory defaults. What should I do?

A2: Hold down the PRINT/STOP key while switching on the electrocardiograph, the system will enter the touch screen calibration screen. Operate as indicated on the screen.

Chapter 9 Cleaning, Care and Maintenance

Use only the manufacturer-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.

The manufacturer 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.

9.1 General Points

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

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

CAUTION

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

9.2 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.

9.2.1 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.

9.2.2 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.

9.2.3 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.

9.3 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's 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.

9.3.1 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.

9.3.2 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.

9.3.3 Disinfecting the Reusable Electrodes

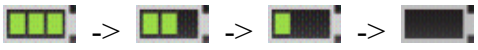
1. Wipe the suction bulbs of chest electrodes and the clamps of limb electrodes with a soft cloth dampened with the disinfectant solution.
2. Wipe off the disinfectant solution with a dry cloth after disinfection.
3. Leave the suction bulbs and clamps to air dry for at least 30 minutes.

9.4 Care and Maintenance

9.4.1 Recharge and Replacement of Battery

1) Capacity Identification

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

 -> -> ->

Capacity is from full to empty.

2) Recharge

SE-301 is equipped with the recharge control circuit together with the built-in rechargeable lithium battery. When the unit is connected to the mains supply, the battery will be recharged automatically. During the recharging course, the battery symbol flashes in the top right corner of the LCD screen. When the battery capacity is full, the symbol stops flashing.

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

NOTE: If the battery has not been used for more than two months, it should be recharged before use.

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

9.4.2 Recorder Paper

NOTE: Recorder paper provided by the manufacturer should be used. Other paper may shorten the life of the thermal print head. And the deteriorated print head may lead to illegible ECG reports and block the advance of 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 recorded paper for a long time, or else the ECG reports may trans-print each other.

9.4.3 Maintenance of the Main Unit, the Patient Cable and Electrodes

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 rated current and breaking characteristics.

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

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

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

1) Main Unit

- Avoid excessive temperature, sunshine, humidity or 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 performance of the electrocardiograph can not 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) 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 10 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 10-1 Accessories List

Accessory	Part Number
Power cord (IEC)	01.13.036638
Power cord(AHA)	01.13.037122
Patient Cable (IEC)	01.57.107402
	01.57.107581
	01.57.107583
	01.57.471613
Patient Cable (AHA)	01.57.110375
	01.57.107582
	01.57.107584
	01.57.471614
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 Resting Snap Electrodes	01.57.471858
Disposable Resting Snap Electrodes	01.57.471859
Disposable Resting Tab Electrodes	01.57.471863
Paper roller	01.51.19993
Thermal Recording Paper	01.57.78076
	01.57.78079

Rechargeable Li-ion Battery	21.21.064149
Snap/Banana Socket Adapters	01.57.471864
Clip/Snap/Banana Socket Adaptors	01.57.040172
Net Cable	01.13.20096
Grounding Wire	01.13.114214
U Disk	01.18.052275
Micro SD card	01.17.052452

SE-301 and accessories are available by contacting the manufacturer or your local distributor.

NOTE:

1. The adult chest electrodes, adult limb electrodes, pediatric chest electrodes and pediatric limb electrodes are not available in the U.S.
2. The part name may vary depending on context, but the part number is constant.

Chapter 11 Warranty and Service

11.1 Warranty

The manufacturer warrants that the manufacturer'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:

Damage caused by mishandling during shipping.

Subsequent damage caused by improper use or maintenance.

Damage caused by alteration or repair by anyone not authorized by the manufacturer.

Damage caused by accidents.

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, the manufacturer will, at its discretion, repair or replace the defective part(s) free of charge. The manufacturer will not provide a substitute product for use when the defective product is being repaired.

11.2 Contact information

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

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
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:	70kPa ~ 106kPa	70kPa ~ 106kPa

A1.3 Physical Specifications

Dimensions	224 mm×143 mm×54 mm, ±2 mm
Weight	< 1kg (Excluding recorder paper and battery)
Display	5", 800×480 LCD Screen

A1.4 Power Supply Specifications

Mains Supply:	Operating voltage =100V-240V~
	Operating frequency = 50Hz / 60Hz
	Power adapter output voltage: 19V, 2A
Built-in Lithium Battery Pack:	Rated voltage = 14.8V
	Rated capacity = 2500mAh
	When the battery is fully charged, the 3-channel electrocardiograph can work normally about 8.5 hours. It can continuously record about 5 hours in Manual mode, and record at least 500 reports at most in the AUTO mode.
	Necessary Charge time: ≤ 3.5 hours
	Cycle life ≥ 300 times

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, 80mm×70mm×200pages Rolled thermal paper, 80mm×20m
Effective Width:	72mm
Paper Speed:	5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s, 50mm/s (±3%)

Accuracy of data:	±5% (x-axis), ±5%(y-axis)
HR Recognition	
Technique:	Peak-Peak Detection
HR Range:	30 bpm ~ 300 bpm
Accuracy:	±1 bpm
ECG Unit	
Leads:	Standard 12 leads
Acquisition Mode:	simultaneously 12 leads
A/D:	24bits
Resolution:	0.1575 μV/LSB
Time Constant:	≥3.2s
Frequency Response:	0.01Hz ~ 300Hz (-3dB)
Sensitivity:	2.5mm/mV, 5mm/mV, 10mm/mV, 20mm/mV, 10/5mm/mV, 20/10mm/mV, AGC
Input Impedance:	≥50MΩ(10Hz)
Input Circuit Current:	≤0.01μA
Input Voltage Range	≤±5 mVpp
Calibration Voltage:	1mV±3%
DC Offset Voltage:	±600mV
Minimum Amplitude:	20 μVp-p
Noise:	≤12.5μVp-p
Multi-channel Crosstalk	≤0.5mm
Filter	AC Filter: On / Off
	DFT Filter: 0.01Hz, 0.05Hz, 0.32Hz, or 0.67Hz
	EMG Filter: 25Hz / 35Hz / 45Hz / OFF
	LOWPASS Filter:300Hz / 270Hz / 150Hz / 100Hz / 75Hz
CMRR	≥140dB (AC: ON) ≥110dB (AC: Off)

Sampling Frequency	16,000/sec/channel
Pacemaker Detection	
Amplitude	±2mV ~ ±700mV
Width	0.1ms ~ 2.0ms
Sampling Frequency	16,000/sec/channel
WIFI (Configurable)	
Transmitting Frequency	2.4GHz
Frequency Band	2.400 ~ 2.500GHz (2.4 GHz ISM band)
Modulation Type	OFDM with BPSK, QPSK, 16-QAM, and 64-QAM 802.11b with CCK and DSSS
Transmitting Power	17 dBm for 802.11b DSSS 17 dBm for 802.11b CCK 15 dBm for 802.11g/n OFDM
4G (Configurable)	
Bands	FDD LTE: Band 1, Band 2, Band 3, Band 4, Band 5, Band 7, Band 8, Band 20, all bands with diversity WCDMA/HSDPA/HSUPA/HSPA+:Band 1, Band 2, Band 5, Band 8, all bands with diversity GSM/GPRS/EDGE: 850 MHz/900MHz/1800 MHz/1900 MHz
Rate	GPRS: UL 85.6 kbit/s; DL 85.6 kbit/s EDGE: UL 236.8 kbit/s; DL 236.8 kbit/s WCDMA CS: UL 64 kbit/s; DL 64 kbit/s WCDMA PS: UL 384 kbit/s; DL 384 kbit/s HSPA+: UL 5.76 Mbit/s; DL 21.6 Mbit/s DC-HSPA+: UL 5.76 Mbit/s; DL 42 Mbit/s LTE FDD: UL 50 Mbit/s; DL 150 Mbit/s@20M BW cat4

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

Appendix 2 EMC Information

Electromagnetic emissions

Guidance and manufacture's declaration – electromagnetic emission		
The Electrocardiograph is intended for use in the electromagnetic environment specified below. The user of the Electrocardiograph should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The 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.
RF emission CISPR 11	Class A	The 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 building used for domestic purposes.
Harmonic emissions IEC/EN 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC/EN 61000-3-3	Complies	

Electromagnetic immunity

Guidance and manufacture's declaration – electromagnetic immunity			
The Electrocardiograph is intended for use in the electromagnetic environment specified below. The user of 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.
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 Electrocardiograph requires continued operation during power mains interruptions, it is recommended that the Electrocardiograph be powered from an uninterruptible power supply or a battery.
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.
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 Electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of Electrocardiograph should assure that it is used in such an environment.			
Immunity test	**IEC/EN 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the electrocardiograph, including cables, than the recommended

			separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC/EN 61000-4-6	3 V_{rms} 150 kHz to 80 MHz 6Vrms[c)] in ISM bands between 0.15 MHz and 80 MHz	3V_{rms} 150 kHz to 80 MHz 6Vrms[c)] in ISM bands between 0.15 MHz and 80 MHz	$d = 1.2\sqrt{P}$
Radiated RF IEC/EN 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 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 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 Electrocardiograph is used exceeds the applicable RF compliance level above, the Electrocardiograph should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Electrocardiograph.

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

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

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test Frequency (MHz)	Brand [a] (MHz)	Service [a]	Modulation [b]	Maximum Power(W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380-390	TETRA 400	Pulse modulation[b] 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [C] ±5 kHz deviation 1kHz sine	2	0.3	28
710	704-787	LTE Brand 13, 17	Pulse modulation[b] 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900,TETRA 800, iDEN 820, CDMA 850, LTE	Pulse modulation[b] 18 Hz	2	0.3	28
870						
930						

		Band 5				
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation[b)] 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN,802.11 b/g/n, RFID 2450, LTE Brand 7	Pulse modulation[b)] 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation[b)] 217 Hz	0.2	0.3	9
5500						
5785						
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 electrocardiograph

The electrocardiograph is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the electrocardiograph can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 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

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

P/N: 01.54.456811
MPN: 01.54.456811017

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