Product Information

- Product Model: E65
- Product Name: Electrocardiograph
- Manufacturer Name: Guangdong Biolight Meditech Co., Ltd.
- Contact Information:

  Address: No.2 Innovation First Road, Technical Innovation Coast, Hi-Tech Zone Zhuhai, P.R. China

  Post code: 519085

  Fax: +86-756-3399919

  Toll-free consultation hot line: +86-400-8818-233

Revision History

This manual has a revision number. This revision number changes whenever the manual is updated due to software or technical specification change. Contents of this manual are subject to change without prior notice.

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CE mark

CE 0123

EC Representative Name:

Shanghai International Holding Corp. GmbH (Europe)

EC Representative Address:

Eiffestrasse 80, 20537 Hamburg Germany

Statement

- Manufacturer holds the copyright of this manual, and we are also entitled to deal with this manual as confidential files. This manual is only used for operation, maintenance and service of product, someone else can not publish the manual.
- This manual contains exclusive information protected by copyright laws and we reserve its copyright. Without written approval of manufacturer no parts of this manual shall be photocopied, Xeroxed or translated into other languages.
- The contents contained in this manual are subject to amendments without notification.

Manufacturer's Responsibility

Only under the following circumstances will manufacturer be responsible for the safety, reliability and performance of the instrument:

- All the installation, expansion, readjustment, renovation or repairs are conducted by the personnel certified by manufacturer.
- The storage condition, operation condition and electrical status of the instrument conform to the product specification.
- The instrument is used in accordance with the user's manual.

About this manual

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any question, please contact us.

This manual is an integral part of the product. It should always be kept close to the equipment so that it can be obtained conveniently when needed.

The manual is geared for clinical professionals who are expected to have a working knowledge of medical procedures, practiced and terminology as

required for monitoring patients.

All illustrations in this manual serve as examples only. They may not necessarily reflect the setup or data displayed on your product.

Conventions:

- ***Bold Italic*** text is used in this manual to quote the referenced chapter or sections.
- 【】is used to enclose screen texts.
- → is used to indicate operational procedures.

Signs in this manual:

Warning: Indicates a potential hazard or unsafe practice that, if not avoided, will result in death or serious injury.

Caution: Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.

Note: Provides application tips or other useful information to ensure that you get the most from your product.

Content

Chapter 1 General Introduction

1.1 Intended use

The electrocardiograph is used to extract the human body's ECG waves for contour and rhythm analysis, the results of analysis can be used for clinical diagnosis and research.

Electrocardiograph must be used under guidance of professionals, and is not suitable for family use.

Warning:

- **The cardiograph is intended for use only by clinical professionals or under their guidance. It must only be used by persons who have received adequate training in its use. Anyone unauthorized or untrained must not perform any operations on it.**
- **The patient is an intended operator. The patient can use and maintain the device and its accessories according to this manual.**

1.2 Contraindications

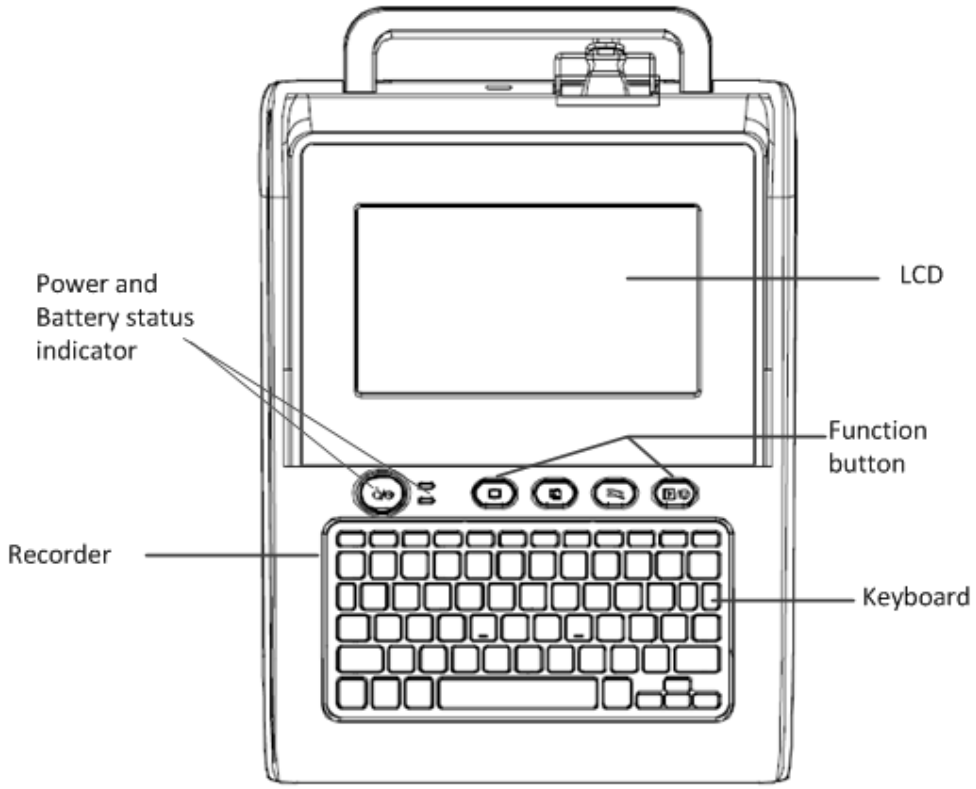
Temporary no found.

1.3 Product Components

Electrocardiograph is mainly composed of mainframe, ECG cables and electrodes.

1.4 Main Unit

1.4.1 Top View



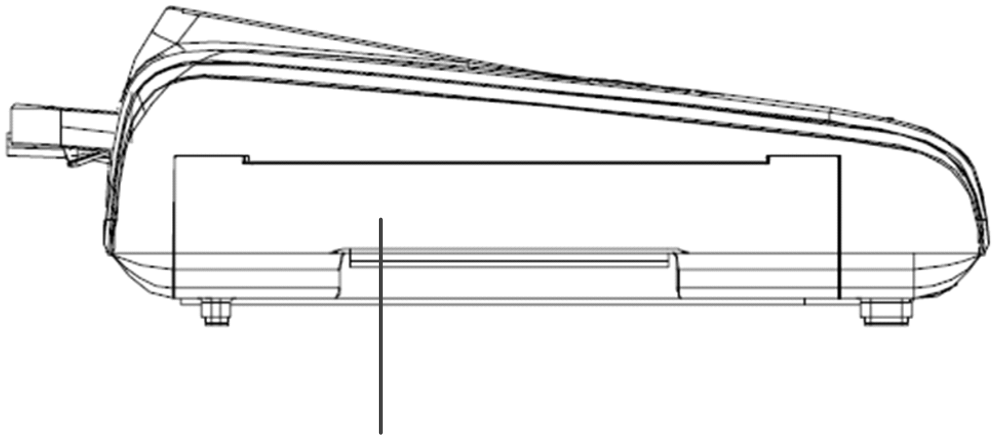
NO.	Name	Note
①	Power button ⏻/⊙	Turn on/off the device.
②	AC power or battery indicator	Green light turns on if with AC power. Orange light turns on if battery is recharging. No lights turn on if no battery is charging or without AC power.
③	Battery charging indicator	Orange light turns on if battery is recharging. The orange light will be off if battery charging finished or no battery in box.
④	Working modes switch button	Press this button to switch the current working modes. **Caution: Only when the user has selected the "Working modes" in "Working modes setting" window can the button be used to switch the working modes.**

⑤	Calibration /copy button 	Press the button will print out 1mV calibration signal in Manual mode. And review the latest ECG data recorded in Auto or Rhythm mode.
⑥	Paper feed button 	Press the button will make the report paper go to the next black grid, at this time, press it again will stop paper feed. **Caution: The button can only work in the interface of main, freeze, files, or files review.**
⑦	Record button 	Press this button to stop or start record.

1.4.2 Front View

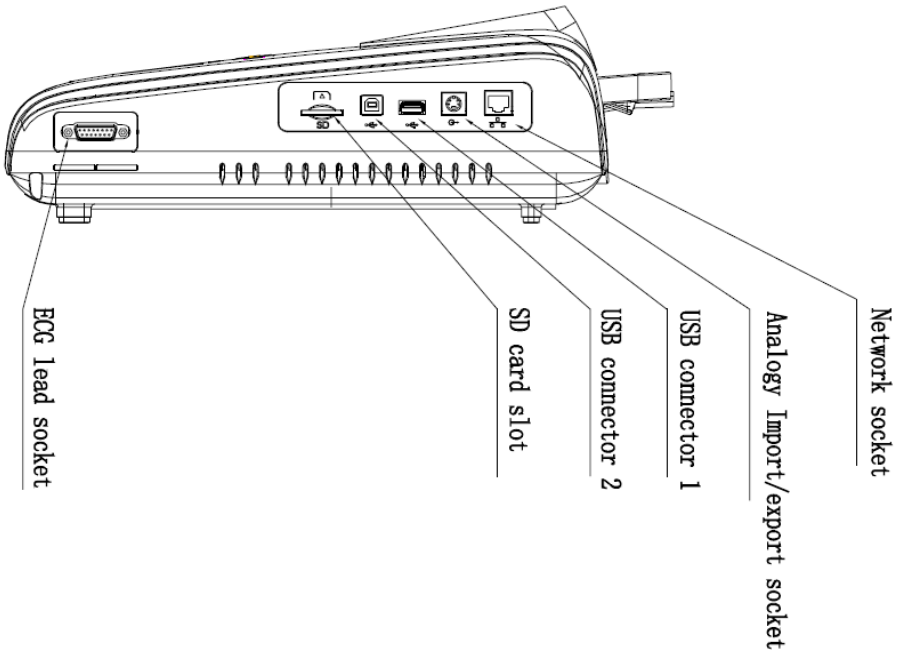
1.4.3 Side View

Left:



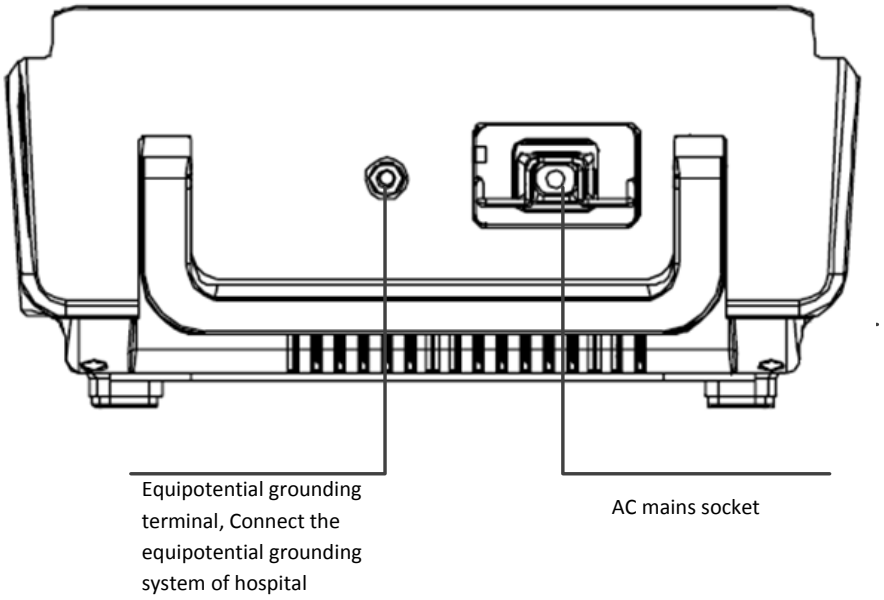
Recorder box

Right :



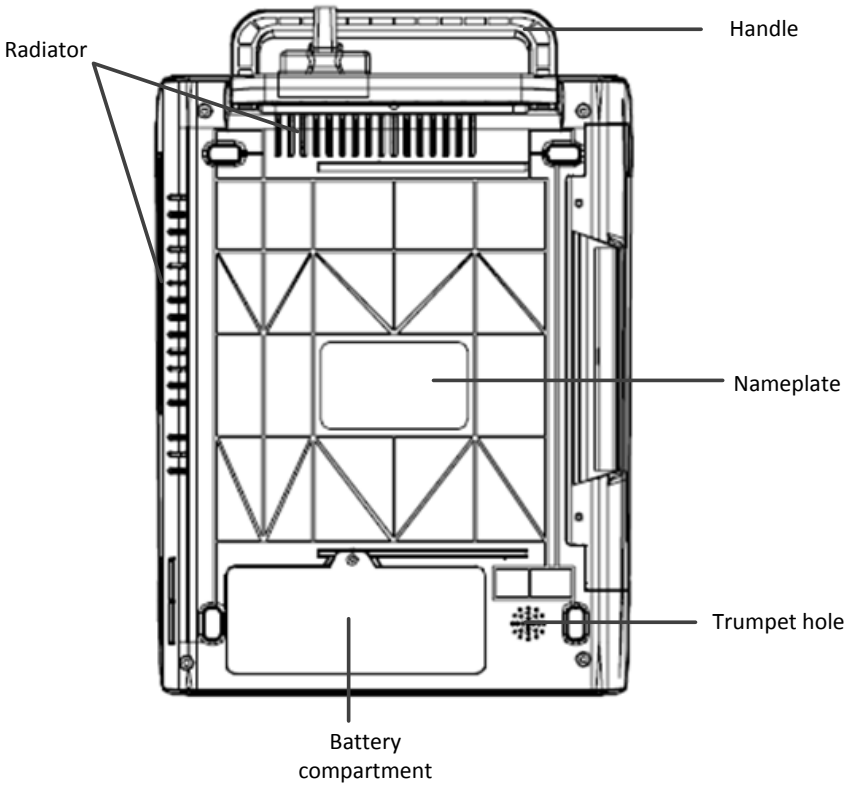
NO.	Name	Note
1	Network socket	Standard RJ45 socket, can be connected to the internet.
2	Analogy Import/export socket	Reserved function
3	USB connector 1	Standard USB connector, can be connected to USB disk, USB printer and barcode scanner. It can also be used to software upgrade.
4	USB connector 2	Standard USB connector, can be connected to PC computers.
5	SD card slot	Can be inserted in SD memory card to store the ECG data.
6	ECG lead socket	Connect to patient cables to collect the ECG data.

1.4.4 Back View



NO.	Name	Note
1	AC mains socket	Connect to AC power
2	Equipotent grounding terminal	Connect to the Equipotential grounding system of hospital

1.4.5 Bottom View



1.5 Keyboard

The keyboard of Cardiograph is designed to be user-friendly and easy to operate, and it supports entry in Chinese. According to functions, keys are divided into single function key, dual function key and combined function key. Below are the key layout and notes on keys:

◆ **Single function key**

NO.	Key	Note
1.	 Gender switch button	When the gender is been chose in the window of patient info setting , click the gender switch key on the keyboard can switch the patient's gender.
2.	 Age group switch button	When the age input style is set up to be Age group in the window of patient info setting, click the Age group switch key on the keyboard can switch the patient's Age group.
3.	 Del button	Delete the character entered
4.	 Enter button	Confirm operation
5.		Can switch the input methods style

	Input methods switch	
6.	 4 directions	Move cursor
7.	 Screen Brightness+	Increase the brightness of the screen
8.	 Screen Brightness -	Decrease the brightness of the screen
9.	 Tab	Window switchover key
10.	 Fn	Reserved function
11.	Space	Insert space while entering characters
12.	 Ctrl	Combined function key
13.	 ESC	Cancel operation, having the function of Return.
14.	 Shift	Second function keys
15.	 Caps	Switch capitalized and lowercase letters

◆ **Dual function key**

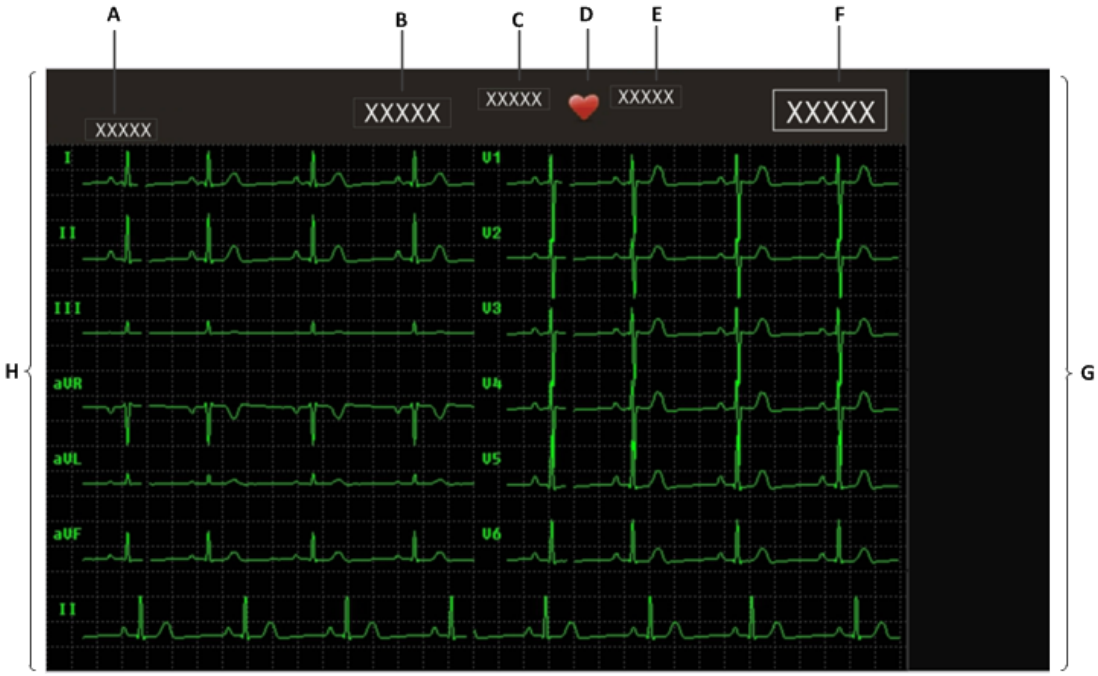
Key	Note
A-Z	Switch capitalized and lowercase letters while press Caps.

◆ **Combined function key**

Key	Note
Shift+letter	Switch the entry mode

1.6 Screen Display

The following is the main interface of electrocardiograph:

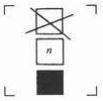


No.	Display	Note
A.	Patients' info	The patients' info (ID, gender, age and so on) will be displayed.
B.	prompt info	The current prompt info (no paper, lead fall-off and so on) will be displayed.
C.	Working mode	The current working mode is displayed, i.e. Auto, Manual, Rhythm.
D.	HR indicating	Heart beat measuring symbol is displayed.
E.	HR measurement	Heart rate values are displayed.
F.	System info area	Including: Internet and USB connecting status, system time, battery power status and so on.
G.	Function shortcut area	Can display: **Patient**: To input patient's ID and Name, at the same time, you can set Age. **Freeze**: To freeze the waveform of screen display.

		5mm/mV：To adjust the waveform gain. Optional: Auto, 2.5mm/mV, 5mm/mV, 10mm/mV, 20mm/mV, 40mm/mV,10/5mm/mV, AGC. **25mm/s**: To adjust the waveform scanning speed and the paper moving speed of recorder. Optional: 50mm/s, 25mm/s, 12.5mm/s, 10mm/s, 6.25mm/s or 5mm/s. **25HZ**: To adjust the bandwidth of filter to be 200Hz, 150Hz, 100Hz, 75Hz, 45Hz, 35Hz or 25Hz. **Files**：Can go to the interface of file manage. **Order**: Can go to the interface of order manage. **System setting**: Can go to the interface of system setting.
H.	Waveform display area	ECG waveform is displayed.

1.7 Equipment Sign

Sign	Note	Sign	Note
	USB printer		Dangerous voltage
	CE mark		
	Battery status indicator light		Internal protection earth terminal
	Non-ionizing radiation		Equipotential grounding
	USB socket		Manufacture date
	Simulate in-out connector		Manufacturer
	Refer to this user's manual.		SD Memory card slot

SN	Serial number		Network connector
IPX0	Degree of protection against ingress of liquid		Patient Cable slot
	Frangibility, Be careful		Avoid drench, Keep dryness
	Stacking layer limit. Same packing maximum stacking layers, N represents the number of layers limit. (N is 6).		This end keep upward while moving or storing
	Indicator of U flash disk		Indicator of SD card connect
	Indicator of battery capability		Indicator of Alternating current
	No battery or battery breakdown indicator		The AC power is off
	General warning sign. Warning the user that the protection of the ME EQUIPMENT against the effects of the discharge of a cardiac defibrillator is dependent upon the use of appropriate cables.		
	Type CF applied part, defibrillation protected The unit displaying this symbol contains an F-Type isolated (floating) applied part providing a high degree of protection against shock, and is defibrillator-proof.		
	Symbol for the marking of electrical and electronics devices according to Directive 2002/96/EC.		
	Fragile. Show transport package contents fragile, so handling should be handled with care.		
	Upward. It shows the correct position of the transport package is upright.		

Chapter 2 Safety

2.1 Safety Information

Warning:

- **Do not posit the equipment to make it difficult to operate the power plug which uses to isolate the equipment circuits electrically form the supply mains**
- **Before putting the system into operation, verify that the Cardiograph, connecting cables and accessories are in correct working order and operating condition.**
- **Use only accessories specified by our company. Using other accessories may cause damage to the Cardiograph.**
- **Do not open the Cardiograph housings; electric shock hazard may exist. All servicing and future upgrades must be carried out by the personnel trained and authorized by manufacturer only.**
- **To avoid explosion hazard, do not use the Cardiograph in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.**
- **To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth**
- **Don't use this device where exists high voltage device or high static electricity, or else, there is fire because of spark.**
- **Please connect the Cardiograph to a socket with protective earth. If the socket does not have protective earth conductor, please do not use the socket and use battery to provide power to the Cardiograph.**
- **To avoid burning, when using the ESU device, make sure those electrodes is far away from electro to me.**
- **Do not come into contact with the patient during defibrillation. Otherwise serious injury or death could result.**
- **To insure patient safety, leakage current summation caused can't exceed admit value.**

- **Please insure all electrodes connected and connect to the right position. Put electrodes and patient away from other electric parts and the earth.**
- **To avoid inadvertent disconnection, route all cables in a way to prevent a stumbling hazard. Wrap and secure excess cabling to avoid risk of entanglement or strangulation by patient or personnel.**
- **Keep the packing materials out of children's reach. Disposal of the packing materials should observe the applicable waste control regulations.**
- **Although safe request is considered during device design, but operator must not ignore device status and observing patient. Please especially notice device and patient can't be moved during device working.**
- **Device connected to digital and stimulant connector must be validated with each IEC standards (e.g. data processing equipment standard: IEC950, Medical electrical equipment: IEC60601-1), and all the configurations must comply with availability version of IEC60601-1. So the medical system must comply with availability version of IEC60601-1.**
- **The electrocardiograph can be directly applied to heart.**
- **For patient who is implanted the pacemaker, the device may explain and record the pacemaker pulse to be QRS complex waves, please check the recorded ECG waves carefully.**
- **The device's connector (including USB, network and so on) can only be connected to the matched accessories and network server. The misuse of them may cause damage to the device.**
- **Do not touch the Signal I/O ports if in contact with the patient, otherwise patient injury may result**
- **No modification of this equipment is allowed. Do not modify this equipment without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment**
- **The device is protected against malfunction caused by electrosurgery.**

Caution:

- **At the end of its service life, the cardiograph, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have any questions concerning disposal of the cardiograph, please contact us.**
- **Magnetic and electrical fields are capable of interfering with the proper performance of the cardiograph. For this reason make sure that all external devices operated in the vicinity of the cardiograph comply with the relevant EMC requirements. Mobile phone, X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.**
- **Before connecting the cardiograph to the power cord, check that the voltage and frequency ratings of the power cord are the same as those indicated on the cardiograph's label or in this manual.**
- **Always install or carry the cardiograph properly to avoid damage caused by drop, impact, strong vibration or other mechanical force.**

Note:

- **Put the cardiograph in a location where you can easily see the screen and access the operating controls.**
- **Keep this manual in the vicinity of the cardiograph so that it can be obtained conveniently when needed.**
- **The software was developed in compliance with IEC 60601-1. The possibility of hazards arising from software errors is minimized.**
- **This manual describes all features and options. Your cardiograph may not have all of them.**

2.2 General Safety

Warning: The cardiograph is neither a therapeutic instrument nor a device that can be used at home.

1. Safety precautions for installation

- Connect the power cord to a properly grounding socket. Avoid putting the socket used for it in the same loop of such devices as the air conditioners, which regularly switch between on and off.
- Avoid putting the cardiograph in the locations where it easily shakes or wobbles.
- Enough space shall be left around the cardiograph so as to guarantee normal ventilation.
- Make sure the ambient temperature and humidity are stable and avoid the occurrence of condensation in the operation process of the cardiograph.

Warning: Never install the cardiograph in an environment where flammable anesthetic gas is present.

2. Cardiograph conforms to the safety requirements of IEC 60601-1. This cardiograph is protected against defibrillation effects.

3. Notes on symbols related to safety

Type CF applied part, defibrillation protected

The unit displaying this symbol contains an F-Type isolated (floating) applied part providing a high degree of protection against shock,

The type CF applied parts provide a higher degree of protection against electric shock than that provided by type BF applied parts. and is defibrillator-proof.

Attention! Please refer to the documents accompanying this cardiograph (this manual)!

4. When a defibrillator is applied on a patient, the cardiograph may have transient disorders in the display of waveforms. If the electrodes are used and placed properly, the display of the cardiograph will be restored within 10s. During defibrillation, please note to remove the electrode of chest lead and

move the electrode of limb lead to the side of the limb. The electrode of the defibrillator should not come into direct contact with the electrodes. Please ensure the cardiograph is reliably grounded and the electrodes used repeatedly should be kept clean.

5. To guarantee the safe operation of the cardiograph, the cardiograph is provided with various replaceable parts, accessories and consuming materials (such as sensors and their cables, electrode pads). Please use the products provided or designated by the manufacturer.

6. The device connected to cardiograph must comply with IEC 60601-1 and IEC950. If the cardiograph is connected to other undesignated electrical equipment or devices, safety hazards may occur for causes such as the cumulating of the leakage current.

7. To guarantee the normal and safe operation of the cardiograph, a preventive check and maintenance should be conducted for the cardiograph and its parts every 6-12 months (including performance check and safety check) to verify the instrument can work in a safe and proper condition and it is safe to the medical personnel and the patient and has met the accuracy required by clinical use.

8. The system error and frequency of the device is tested according to the ANSI/AAMI EC11, for details you can consult the related information in ANSI/AAMI EC11 Clause 4.2.7.1 and 4.2.7.2.

Caution: The electrocardiograph does not contain any parts for self-repair by users. The repair of the instrument must be conducted by the technical personnel authorized by manufacturer.

2.3 Important Notes for Safety

- **Patient Number**

The electrocardiograph can only be applied to one patient at one time.

- **Interference**

Do not use mobile phone in the vicinity of the electrocardiograph. High level of electromagnetic radiation emitted from such devices may result in strong interference with the electrocardiograph performance.

■ **Protection against ingress of liquid**

To avoid electric shock or device malfunction, liquids must not be allowed to enter the device. If liquids have entered the device, take it out of service and have it checked by a service technician before it is used again.

■ **Accuracy**

If the accuracy of any value displayed on the electrocardiograph or printed on a printout paper is questionable, determine the patient's vital signs by alternative means. Verify that the equipment is working correctly.

■ **Before Use**

Before putting the system into operation, please visually inspect all connecting cables for signs of damage. Damaged cables and connectors must be replaced immediately.

Before using the system, the operator must verify that it is in correct working order and operating condition.

Periodically, and whenever the integrity of the product is in doubt, test all functions.

■ **Cables**

Route all cables away from patient's throat to avoid possible strangulation.

■ **Disposal of package**

Dispose of the packaging material; please observe the applicable waste control regulations and keeping it out of children's reach.

■ **Explosion hazard**

Do not use this equipment in the presence of flammable anesthetics, vapors or liquids.

■ **Leakage current test**

When interfacing with other equipment, a test for leakage current must be performed by qualified biomedical engineering personnel before using with patients.

■ **Battery**

The device is equipped with a battery. The battery discharges even when the device is not in use. Store the device with a fully charged battery and take out the battery, so that the service life of the battery will not be shortened.

■ **Disposal of accessories and device**

Disposable accessories are intended for single use only. They should not be reused as performance could degrade or contamination could occur.

The service life of this electrocardiograph is 5 years. At the end of its service life, the electrocardiograph, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have questions concerning disposal of products, please contact manufacturer or its representatives.

- **EMC**

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 electrocardiograph 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. Also, keep mobile phones or other telecommunication equipment away from the electrocardiograph.

- **Instruction for use**

For continuous safe use of the electrocardiograph, it is necessary that listed instructions were followed. However, instructions listed in this manual in no way can supersede established medical practices concerning patient care.

- **Loss of data**

Should the electrocardiograph at any time temporarily lose patient data, close patient observation or alternative monitoring devices should be used until electrocardiograph function is restored.

If the electrocardiograph does not automatically resume operation within 60s, restart the electrocardiograph using the power switch. Once monitoring is restored, you should verify correct monitoring state.

- **Intended for use in conjunction with other medical devices**

The electrocardiograph can be used together with defibrillators, and can not be used with high-frequency burns.

- **Prompt**

The machine can give prompts of abnormal status arising from excessive polarization voltage of ECG electrode.

For any question, contact us or native agent.

2.4 Safe Operation Conditions

Methods of sterilization or disinfection recommended by the manufacturer	Sterilization: not applicable Disinfection: Refer to ***Maintenance and Cleaning*** Chapter
Electromagnetic interference	No mobile telephone nearby
Electrosurgical interference damage	No damage
Diathermy instruments influence	Displayed values and prints may be disturbed or erroneous during diathermy
Defibrillation shocks	The electrocardiograph specifications fulfill the requirements of IEC 60601-2-25.

Chapter 3 Getting Started

3.1 Unpacking and Checking

1. Unpacking

Before unpacking, examine the packing case carefully for signs of damage. If any damage is detected, contact the carrier. If the packing case is intact, open the package.

2. Remove the electrocardiograph and accessories carefully.

3. Keep all the packaging materials for future use in transportation or storage.

4. Check the electrocardiograph and accessories

Check the electrocardiograph and its accessories one by one in accordance with the packing list. Check to see if the parts have any mechanical damages. In case of problems, please contact us or our agent.

Warning:

- **Keep the packing materials out of children's reach. Disposal of the packing materials should observer the applicable waste control regulations.**
- **The electrocardiograph might be contaminated during storage and transport. Before use, please verify whether the packages, especially the package of disposable accessories are intact. In case of any damage, do not apply it to the patient.**
- **Please ensure the electrocardiograph is working under specified Conditions; otherwise, the technical specifications mentioned in this manual will not be met, thus possibly leading to damage of equipment and other unexpected results.**

Caution: Please put a electrocardiograph onto a horizontal and stable supporting plane. Avoid putting the electrocardiograph in the locations where it easily shakes or wobbles. Enough space shall be left around the electrocardiograph so as to guarantee normal ventilation.

3.2 Power Supply

3.2.1 AC Power Supply

- AC power: AC 100V-240V, 50Hz/60Hz.
- Take out the accessory power cord, and insert the plug of output end into the AC power socket at back panel of Electrocardiograph, and insert the plug of input end into a grounded three-phase power socket (a specialized socket of hospital is required) , and ground the machine via ground wire (protective grounding) of power cord.
- If AC power is ON, the AC power indicator on Electrocardiograph will turn on, showing the status of AC power. If the battery status indicator is ON in orange, it shows that rechargeable battery is being recharged.
- After turning on the machine startup button, the equipment running indicator on Electrocardiograph will turn on; indicator in green glitters in startup process or standby status; indicator in green will be always ON if the machine has started normal running.

Caution:

- **The electrocardiograph does not have mains switch. The electrocardiograph is switched completely only by unplugging the power cable from the AC power source.**
- **Connect electrocardiograph to equipotential grounding system. Use the green/yellow equipotential grounding cable and connect it to the terminal labeled with the ⏚ symbol.**

3.2.2 Battery Power Supply

- Electrocardiograph is equipped with recharge battery for power supply to Electrocardiograph in case of AC power interruption.
- Please charge up battery before use. No external charger is provided. Rechargeable battery can be charged up when Electrocardiograph is connected to AC power. To ensure full charging of battery for use at any time, we suggest keeping Electrocardiograph connected to AC power socket at all times.
- When many AC disturbances are found during test, the mode of battery power supply may be adopted to maintain the equipment operation. In

this way, the impact of AC disturbances may be reduced.

- For the power supply period of battery, see the product specification. For battery maintenance, please refer to the section of ***Battery.***

3.3 Placing Cables

Insert patient cable pin into patient cable socket on the right side, and tighten the screw.

3.4 Placing Electrodes

3.4.1 Skin Preparation for Electrode Placement

Good electrode-to-skin contact is important for a good ECG signal, as the skin is a poor conductor of electricity. It is necessary to deal with the skin properly before placing the electrodes. The steps are shown as follows:

1. Select sites with intact skin, without impairment of any kind.
2. Clip or shave hair from sites as necessary.
3. Gently abrade the skin to remove dead skin cells to improve the conductivity of the electrode site.
4. Wash sites thoroughly with soap and water, leaving no soap residue.
   (We do not recommend using ether or pure alcohol, because this dries the skin and increases the resistance.)
5. Dry skin thoroughly.

3.4.2 Placing Electrode

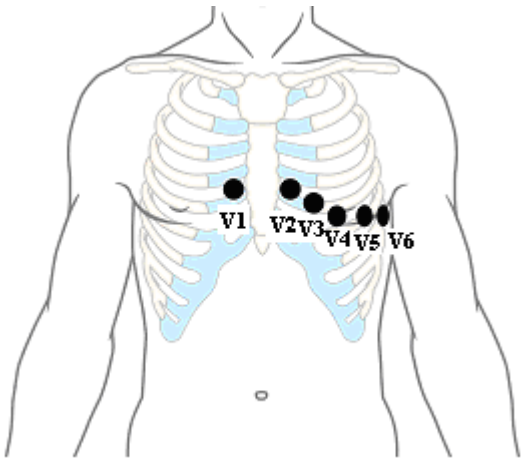
The following table shows the ECG electrode label to identify each electrode and its associated color of AAMI and IEC standards.

Electrode labels (IEC)	**Electrode colors (IEC)**	**Electrode labels (AAMI)**	**Electrode colors (AAMI)**	**Position**
R	Red	RA	White	sword arm (Inside)
L	Yellow	LA	Black	Left arm (Inside)

N	Black	RL	Green	Right leg (On crus, midpoint between knee and ankle.)
F	Green	LL	Red	Left leg (On crus, midpoint between knee and ankle)
C1	Red	V1	Red	On the fourth intercostal space at the right sternal border
C2	Yellow	V2	Yellow	On the fourth intercostal space at the left sternal border
C3	Green	V3	Green	Midway between the V2 and V4 electrode positions
C4	Brown	V4	Blue	On the fifth intercostal space at the left midclavicular line
C5	Black	V5	Orange	On the left anterior axillary line, horizontal with the V4 electrode position
C6	Violet	V6	Violet	On the left midaxillary line, horizontal with the V4 electrode position

◆ **Emplacing of chest electrodes**

In general, 6 electrodes are placed on chest based on the intervals of ribs. Taking the American standard as an example, the emplacing positions of electrodes V1-V6 are shown in the figure below:



Please refer to the following steps at the time of connecting chest electrodes:

1. Check whether the electrodes are clean and intact;

2. Clear up lead wire to avoid twisting, and firmly connect the electrode connector to electrodes;
3. Wipe up with alcohol the skin where electrodes will be placed;
4. Evenly spread the conductive paste in a diameter of about 25mm at each position on chest where electrodes will be placed;
5. Evenly spread a thin layer of conductive paste at the edges of chest electrode suction balls;
6. Place the electrodes on skin and squeeze the rubber balls, and then loosen the rubber balls, so the electrodes will be adsorbed on the corresponding positions on chest.

◆ **Emplacing of electrodes on limbs**

Limb electrodes shall be placed at the positions with close contact with skin such as upper side of wrist and upper inner side of ankle. Please refer to the following steps at the time of connecting limb electrodes:

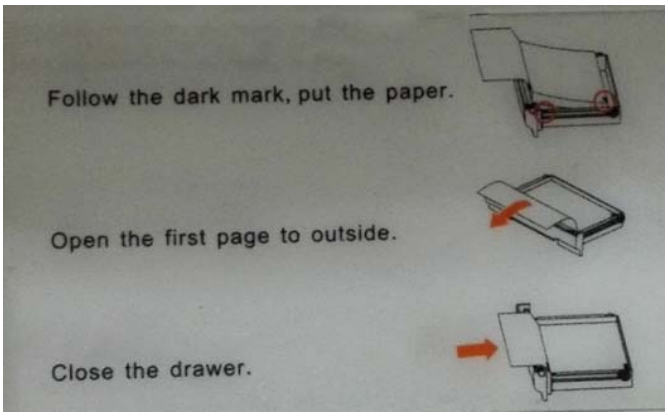
1. Check whether the electrodes are clean and intact;
2. Clear up lead wire to avoid twisting, and firmly connect the electrode connector to electrodes;
3. Wipe up with alcohol the skin where electrodes will be placed;
4. Evenly spread the conductive paste on skin;
5. Evenly spread a thin layer of conductive paste on the surface of limb electrodes;
6. Properly place the electrodes on skin.

Caution:

- **The conductive paste shall not be used excessively and the spreading layers shall be separated; otherwise, electrode short-circuit will be caused, resulting in ECG signal record error.**
- **Patients and the machine can be connected via lead and electrode only.**
- **Install the lead wire in shut-off status as far as possible.**
- **If ECG waveform does not appear during long period, please confirm whether electrodes are in good contact with skin.**
- **The electrodes should not contact any other conductive parts including earth.**

3.5 Install the chart paper

When the chart paper is not installed or is used up, "no paper" will be shown on the display screen of Electrocardiograph to remind the users of installing or replacing the chart paper. Folded thermosensitive printing papers are used for the Electrocardiograph. There is an illustration about how to install the chart paper in the paper box as follows:



◆ **Install the folded thermosensitive printing paper:**

1) Grasp the edge of box cover with the one hand, lift the wrench and open outward the cover of recorder with a little force, and take out the remaining folded paper from the paper slot;

Fig. 3-1: Install folded paper

2) Remove the packaging of new chart paper, and place the chart paper into paper slot. Caution: The grid surface shall be upwards at the time of inserting the prepared Z-shaped printing paper, and the first fold shall be toward the paper cartridge;

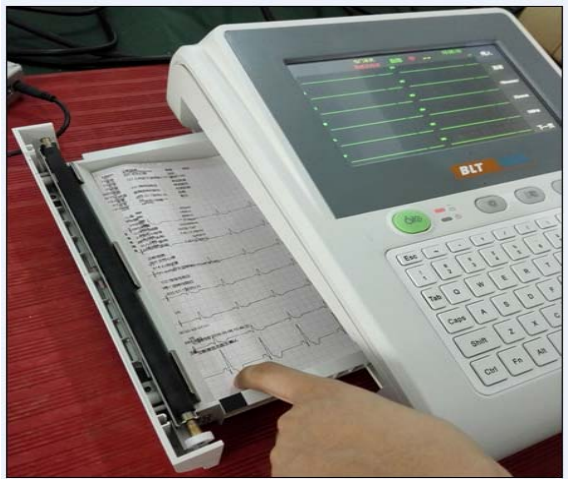


Fig. 3-2 Install folded paper

3) Pull out about 2cm chart paper from the paper outlet of recorder, and close the cover of recorder. At this time, the installation is completed.

Fig. 3-3 Install folded paper

Caution:

- **The storage of chart paper shall meet the following requirements:**
- **Chart paper shall be stored at a dry cool place to prevent from high temperature, humidity and direct sunlight.**
- **Do not overlap for long period the chart paper with recorded**

waveform; otherwise, the recorded waveforms will blot each other.

- **Printing may start only after ECG waveform appears on screen.**
- **Please use the chart paper provided by the manufacturer; otherwise, the lifespan of thermosensitive recording head of printer will be shortened.**

3.6 Inspecting Before Starting

Please read the manual carefully before using the electrocardiograph, be familiar with the function, operations and notes. Check the following contents before starting up.

1. Environment

Make sure the electrocardiograph will not be interfered by electromagnetic radiation. Mobile phones, X rays or MRI equipment are all possible interference sources, because they can produce high-intensity electromagnetic radiation. The room temperature should be kept warm (above 18℃) to avoid ECG interfere caused by cold.

2. Power supply

Please check whether power cord and device connect well before using AC power.

3. Grounding

Please check the grounding line connected well.

4. Cable

Please check the cable pin connected firmly, and avoid cable close to AC power cord. Check the cable connects to the corresponding electrodes.

5. Electrode

Please check electrode placed firmly. And insure the chest electrodes are not contact each other.

6. Recording paper

Please check the recording paper enough and be putted right.

7. Patient

Make sure patient doesn't contact the metal part of the bed. The room temperature should be comfortable and the patient should be relaxed.

Chapter 4 Operation Instruction

This manual is based on the maximum configuration, you can choose the configurations you need. Therefore some contents may not apply to your product which will display gray on your product and are useless for users.

4.1Turn On/Off

◆ **Using AC power supply:**

——Turn on: Press the power button after connecting the power cord. the screen displays the start menu, and then enter work mode.

——Turn off: Press power button, and screen will display "The device is shutting off.", when the prompt info is over, the device is power off. Then unplug the power pin.

Note: When powering off is not work, pressing power button lasting 5s can force to turn off.

◆ **Using battery:**

——Turn on: Press the power button, the screen displays start menu, and then entering work mode.

——Turn off: Press power button, and screen will display "The device is shutting off.", when the prompt info is over, the device is power off.

Warning:

- **Advert to status of patient and device at any moment;**
- **If the electrocardiograph is mechanically damaged, or if it is not working properly, do not use it for any monitoring procedure on a patient. Contact your service personnel.**

4.2 Patient Setup

Click【**Patient**】in main interface to enter 【**Patient info input**】interface. In this interface, you can use the keyboard to input patient's ID, Name and Age, at the same time, you can select Gender and Pacemaker (has or not). When you selected 【**Name/Family**】,【**Weight**】and other patient information in the window of 【**Patient info**】, these selected information will display in the 【**Patient info input**】interface.

4.3 Freeze

By use of waveform freezing function, operators can browse, record and save waveforms so as to easily analyze and process the ECG waveforms selected and export reports in various modes.

Caution: Freezing is allowed only after 10s data collection of Electrocardiograph.

Click 【**Freeze**】in main interface to enter freeze interface. In the interface, you may conduct the following operations:

——Select【**Pre page**】: Display waveform last page.

——Select【**Next page**】: Display waveform next page.

——Select【**Pre sec**】: Display waveform last second.

——Select【**Next sec**】: Display waveform next second.

——Select【**2.5mm/mV**】: can set up the waveform gain to be 2.5mm/mV.

——Select【**5mm/mV**】: can set up the waveform gain to be 5mm/mV.

——Select【**10mm/mV**】: can set up the waveform gain to be 10mm/mV.

——Select【**20mm/mV**】: can set up the waveform gain to be 20mm/mV.

——Select【**10/5mm/mV**】: can set up the waveform gain to be 10/5mm/mV.

——Select【**Return**】: Return to the main interface.

4.4 10mm/mV Gain

In the main interface, you can change the waveform's gain from 10mm/mV to 5 mm/mV, 20mm/mV, 40mm/mV,10/5mm/mV or AGC.

Caution:

- **The setup is only useful for the current patient.**
- **Only when the 40mm/mV is chosen in Config of Others setting, the 40mm/mV gain change can be achieved in the main interface.**

4.5 25mm/s Speed

In the main interface, you can change the paper moving speed of recorder from 25mm/s to 50mm/s、12.5mm/s、10mm/s、6.25mm/s or 5mm/s.

Caution:

- **The speed can only be set up to be 50mm/s or 25mm/s in Auto and Rhythm mode.**
- **The speed can only be set up to be 25mm/s in R-R mode.**
- **The setup is only useful for the current patient.**

4.6 100Hz EMG filter

In the main interface, you can change the EMG filter from 100Hz to 25Hz, 35Hz, 75Hz, 100Hz, 150Hz, 200Hz or 45Hz.

Caution:

- **EMG filter: can select 25Hz, 35Hz, 45Hz, Close.**
- **Lowpass filter: can select 75Hz, 100Hz, 150Hz, 200Hz, Close.**
- **The setup is only useful for the current patient.**

4.7 Files

Electrocardiograph can store and manage more than 800 shares of patient data. It can review, edit, record, delete or transmit patient data in file management window. Data stored contains ECG waveform in xml format; analyze conclusion and ECG report with patient info.

Click 【**Files**】 in main interface to enter file management interface.

In the above interface you can see the ID, Name, Date, Time.

In the down interface, you may conduct the following operations:

——Select【**Transmit all**】: Transmit all the files to computer.

——Select【**Export all**】: Export all the files to SD card or U disk.

——Select【**Delete all**】: Can delete file or content selected. After you choosing a patient data, press this key, the system can spring a dialog box, and then you choose【**OK**】 can delete the data.

——Select【**Search**】: Search the setup information.

——Select【**Pre page**】:Turn up one page of contents displayed by interface.

——Select【**Next page**】:Turn down one page of contents displayed by interface.

——Select【**Return**】: Return to the main interface.

4.8 Order

The user can use the order function after installed the specific software.

After the Electrocardiograph has successfully connected to the CENTRAL, click 【**Order**】can enter the order setting interface. In this interface, you may conduct the following operations:

——Select【**Check**】: Check the booked patient.

——Select【**Load**】: Load the information of the booked patient.

——Select【**Setup**】: Set up the information of the booked patient.

——Select【**Search**】: Search the booked patient setup .

——Select【**Delete All**】: Delete all the booked information.

——Select【**Pre page**】:Turn up one page of contents displayed by interface.

——Select【**Next page**】:Turn down one page of contents displayed by interface.

——Select【**Return**】: Return to the main interface.

4.9 System Setting

4.9.1 Working mode Setting

Click 【**System setting**】→【**Working mode**】in main interface can enter working mode setting interface. Shown as the following:

——Select【**Manual style**】: Can select 3CH, 6CH, 12CH.

——Select【**Auto style**】: Can select 3×4、3×4+1R、3×4+3R、6×2、6×2+1R、12×1.

——Select【**Mode options**】: Can select Manual, Auto, Rhythm, R-R, Close.

——Select【**Rhythm style**】: Can select Single lead, Three lead.

——Select【**R-R style**】: Can select 1minute, 3minutes.

After setup of filter, select【**OK**】.

4.9.1.1 Manual Mode

The manual mode means the user can manually control the ECG collecting or printing time. In this mode, users may select lead group according to actual needs, and conduct different setups of recording parameters or other parameters for different lead groups.

Refer to the following steps to operate:

1. Before recording, enter the patients' info.
2. Click the 【**System setting**】to enter the 【**Working mode setting**】interface ,and select the Manual mode to set up the "Manual style", then click the "OK" to exit.
3. Enter the 【**Leads&sampling**】interface select the "Lead order".
4. Carry on other parameters' settings based on your own need, and exit the 【**System setting**】when you finished the settings.
5. Press"  "key on keyboard to start recording. You can press "  "key on keyboard to stop recording in the process of recording.

4.9.1.2 Auto Mode

Auto mode is a common mode of the ECG to automatically sample and print about 10s' waves.

During ECG recording in Auto mode, the lead group will switch over

automatically in order, i.e. after the recording of ECG signals of leads in a group is completed within the specified period, the machine will switch over automatically to the next lead group and begin to record the ECG signals of the next lead group. Before recording ECG signals, 1mV calibration is conducted automatically, and mark is added on chart paper. For the operations in details, please refer to the following steps:

1. Before recording, enter the patients' info.
2. Click the 【**System setting**】to enter the 【**Working mode setting**】 interface ,and select the "Auto mode", set up the "Auto style ".
3. Enter the 【**Leads&sampling**】interface select the "Lead order".
4. Enter the 【**Recorder**】interface ,set the" Recording style" and "Recording mode".
5. Carry on other parameters' settings based on your own need, and exit the 【**System setting**】when you finished the settings.
6. Press "  " key on keyboard to start recording. The machine will stop automatically after a complete ECG diagram is recorded.
7. Press"  "key on keyboard to start recording. You can press "  "key on keyboard to stop recording in the process of recording,

4.9.1.3 Rhythm Mode

The Rhythm mode needs a long time to sample or print the waves of a single lead or three leads. It can be used to observe the Arrhythmia.

In Rhythm mode, users may select lead according to actual needs, and record the rhythm waveform of single lead within 60s or rhythm waveforms of 3 leads within 20s each.

Operating refers to the following steps:

1. Before recording, enter the patients' info.
2. Enter the 【**Working mode setting**】interface ,and select the Press the "Rhythm mode", set the "Rhythm style".
3. Enter the 【**Leads&sampling**】interface select the "lead order".
4. Carry on other parameters' settings based on your own need, and exit the 【**System setting**】when you finished the settings.
5. Press "  " key on keyboard, the prompt info area will display "Sampling", and timing the sample time. It will start to draw when the

time reaches 60s or 20s.

6. The machine will stop automatically after a complete rhythm diagram is recorded. You can press "  " key on keyboard to stop recording in the process of recording,

4.9.1.4 R-R Mode

The related indicators of HRV can be obtained under the analysis mode of R-R. In R-R analysis mode, the user can select lead in accordance with requirement, and record R-R intervals histogram, R-R intervals trend diagram and compress waveform figure 60s or 180s, which belong to this lead.

Please refer to the following steps:

1. Before recording, enter the patients' info.
2. Enter the **【Working mode setting】**interface ,and select the "R-R mode".
3. Enter the **【Leads&sampling】** interface select the "Rhy_".
4. Carry on other parameters' settings based on your own need, and exit the **【System setting】** when you finished the settings.
5. Press "  " key on keyboard, the prompt info area will display "Sampling", and timing the sample time. It will start to draw when the time reaches 60s or 180s. The machine will stop automatically after a complete rhythm diagram is recorded.
6. You can press "  " key on keyboard to stop recording in the process of recording.

Caution: The speed of the record is fixed to be 5mm/s or 12.5mm/s in R-R mode, users can't set up the speed. The speed of printing the record is 5mm/s or 12.5mm/s. For the waves had been compressed to be 1/5 or 1/2 of the origin waves in R-R mode , the report shows a 5mm/s or 12.5mm/s speed (actually is 25 mm/s).

4.9.1.5 Close mode

The waves information can be saved and transmitted, which can realize no paper recording in Close mode.

4.9.2 Filter

Set the filter parameters of Electrocardiograph to improve ECG anti-disturbance performance. Filters include power frequency filter, baseline drift filter, EMG filter and Lowpass.

- Baseline drift filter: Resist drift of baseline to ensure that ECG signal is on baseline at the time of recording.
- EMG filter: Resist interference to ECG signal caused by strong muscle fibrillation. When EMG filter is in use, lowpass is "Off".
- Lowpass: Restrict the bandwidth of input signal and attenuate the signals higher than the cut-off frequency. When lowpass is in use, EMG filter is "Off".
- Power frequency filter: Resist interference of AC power to prevent attenuation or distortion of ECG signal.

In the **【Filter setting 】**interface, you may conduct the following operations:

——Select **【Baseline drift filter】**: Select On/Off to turn on/off the baseline drift filter. When the instability of baseline is found, it is suggested to open the baseline drift filter in order to eliminate the drift of baseline or the other interference without any distortion of ECG wave, greatly enhance the ability of resist the drift of baseline and also convenient for the interpretation of the waveform, DFT will shown in the chart paper when the baseline drift filter is on, the frequency of baseline drifter filter with the value of 0.05Hz will displayed when the baseline drift filter is off.

——Select **【EMG filter】**: Cut-off frequency is optional. Options: Close, 25Hz, 35Hz or 45Hz.

——Select **【Lowpass filter】**: Cut-off frequency is optional. Options: Close, 75Hz, 100Hz, 150Hz or 200 Hz.

——Select **【AC filter】**: Select On/Off to turn on/off the status of power frequency filter. According to the frequency of network, the Factory Default Setting can be set to "50Hz"or "60Hz".

After setup of filter, select **【OK】**.

Caution:

- **The setups of EMG filter and Lowpass are mutually exclusive, i.e. only one setup is effective at the same time.**
- **Open the EMG filter can filter the disturbance of the EMG, but it may cut down the bandwidth and change the ECG waves.**
- **The baseline drift filter can restrain most of the baseline drift disturbance and keep the ST segment normal.**
- **The AC filter is recommended to be opened all the time, except it really needs to be closed.**
- **The device has distortion test.**

4.9.3 Recorder

Click 【**System setting**】→【**Recorder**】in main interface can enter recorder setup interface. Shown as the following:

In the interface, you may conduct the following operations:

——Select 【**Recording style**】: can select 3×4、3×4+1R、3×4+3R、6×2、6×2+1R、12×1 、12×1_V6.

——Select【**Recording mode**】: can select Fast, Save paper. This function can only be achieved in Real-time sampling.

——Select 【**Recording waves**】: can select 5s, 10s. This selection only use to record the waves for 12x1 recording style.

——Select 【**Recording machine**】: can select "Thermal recorder" or "HP LazerJet 1010, Brother HL-2250DN, HP LaserJet 1020 Plus and HP LaserJet Pro M202" as the position of ECG record export.

——Select 【**Recording Info**】: can select Patient Info, Analysis result, Measurements.

After setup of Info, select【**OK**】.

Caution:

- **The report printed by the USB printer may exist the circumstance of inaccurate time scale plate due to different printer.**
- **The transferred ECG report as a PDF can only be browsed through computer screen, it can't be seen directly on the Electrocardiograph.**

Caution:

- **Select save paper pattern: Press the  button in the main interface of auto mode, the ECG report will be recorded 10s later. And patient info, measurement info, diagnosis info and ECG waves will all be recorded on the same patient report.**
- **Select fast pattern: Press the  button in the main interface, the ECG report will be recorded immediately. And Patient info, measurement info, diagnosis info and ECG waves will be recorded on the different patient report respectively.**
- **The fast pattern will be effective when the sample mode is set up as real time sample in auto mode.**
- **The save paper pattern will be effective only when the Recording style is set up as "3x4","3×4+1R"or "3×4+3R".**
- **The"12x1" Recording style can be effective when the fast pattern is chosen.**

4.9.4 Patient Info.

Click【**System setting**】→【**Patient Info**.】in main interface can enter recorder setup interface. Shown as the following:

In the interface, you may conduct the following operations:

——Select【**Name/Family**】: If select Name/Family, it will be seen in the interface of 【**Patient info input**】 and after input the actual information, it will be displayed in patient's ECG report.

——Select【**Weight** 】: If select Weight, it will be seen in the interface of 【**Patient info input**】and after input the actual information, it will be displayed in patient's ECG report.

——Select【**Pacemaker**】: If select Pacemaker, it will be seen in the interface of 【**Patient info input**】and after select the actual information(has or not), it will be displayed in patient's ECG report.

Caution: We don't advise to select the "pacemaker" when most of the patients need no ECG inspection.

——Select 【**Nature**】: If select Race, it will be seen in the interface of 【**Patient info input**】and after select the actual information, it will be displayed in patient's ECG report.

——Select【**Gender**】: If select Gender, it will be seen in the interface of 【**Patient info input**】and after select the actual information, it will be displayed in patient's ECG report.

——Select 【**NIBP**】: If select NIBP, it will be seen in the interface of 【**Patient info input**】and after input the actual information, it will be displayed in patient's ECG report.

——Select【**Medications**】: If select Medications, it will be seen in the interface of 【**Patient info input**】 and after input the actual information, it will be displayed in patient's ECG report.

——Select【**Technician**】: If select Technician, it will be seen in the interface of 【**Patient info input**】and after input the actual information, it will be displayed in patient's ECG report.

——Select【**Application Doc.**】: If select Application Doc., it will be seen in the interface of 【**Patient info input**】and displayed after input the actual information, it will be in patient's ECG report.

——Select【**Doctor**】: If select Application Doc., it will be seen in the interface of 【**Patient info input**】 and after input the actual information, it will be displayed in patient's ECG report.

——Select 【**Height**】: If select Application Doc., it will be seen in the interface of【**Patient info input**】and after input the actual information, it will be displayed in patient's ECG report.

——Select【**Application dept**】: Application dept If select Application Doc., it will be seen in the interface of 【**Patient info input**】and after input the actual information, it will be displayed in patient's ECG report.

——Select【**Bed NO.**】: If select Application Bed NO., it will be seen in the interface of 【**Patient info input**】 and after input the actual information, it will be displayed in patient's ECG report.

——Select【**Examine dept**】: If select Examine dept, it will be seen in the interface of 【**Patient info input**】 and after input the actual information, it will be displayed in patient's ECG report.

——Select 【**Clear Patient Info.**】: Can select "on" or "off", after select "on"

the patient information will be cleared..

——Select【**ID generate**】:Can select "Add", "Time", "Input".

——Select【**Age input mode**】: Can select "Birth date", "Age group", "Age".

——Select【**Height &weight unit**】: May select unit of Height &weight unit "cm/kg" or "inch/lb".

——Select【**NIBP unit**】: Can select "kPa" or "mmHg".

——Select【**USER-DEFINED**】: User can input the additional information.

After setup of Info, select【**OK**】.

Caution:

- **Select "Input", the patient's ID(less than 14 ASCII) must be manually input.**
- **Select "Time", "Add", the patient's ID can't be manually input.**

Caution:

- **In case of interfere with other USB device, including USB keyboard, please use the barcode scanner provided or designated by the manufacturer.**
- **Please check whether the switch of scanner is open before start the barcode scanner. Only the Barcode Scanner is effective can you enter the patient ID automatically.**
- **No matter where the current cursor is in the Patient info setting dialog box, when you use the barcode scanner, the Patient ID will be filled in automatically. The ID will not accumulate when repeated scanning occurs.**

4.9.5 Communication

Click 【**System setting**】→【**Communication**】in main interface can enter recorder setup interface. Shown as the following:

In the interface, you may conduct the following operations:

——Select【**FTP user name**】: Can set up FTP user's name.

——Select【**FTP path**】: Can set up FTP path.

——Select【**FTP password**】: Can set up FTP password.

——Select【**Server Port**】: Can check server port.

——Select【**Server AE**】: Can check server AE.

——Select【**Client AE**】:C an check client AE.

——Select【**Machine NO.**】: Can check the machine number.

——Select【**Server IP**】: Can set up the device's Server IP.

——Select【**Local IP**】: Can set up the device's Local IP

——Select【**Subnet mask**】: Can set up the device's Subnet mask

——Select【**Gateway**】: Can set up the device's Gateway

After setup of Info, select【**OK**】.

4.9.6 Leads &Sampling

Click 【**System setting**】→【**Lead &Sampling**】in main interface can enter Lead &Sampling setup interface. In the interface, you may conduct the following operations:

——Select 【**Sampling mode**】: Optional: Pre-sampling, Real-time sampling and Trigger sampling, Cyc-sample.

1. When "Pre-sampling" is selected, the ECG data will be stored as soon as the device started up. Press "  " key, the recorder will print the latest 10s collected ECG data. If the ECG data is collected less than 10s, the record will not work.
2. When "Real-time sampling" is selected, press "  " key, ECG data collected within 10s will be printed out;
3. When "Trigger sampling" is selected, if the user presses"  "key, the interface will prompt" learning ", and the Electrocardiograph starts to analysis the data, then collect it. An automatically "Trigger sampling" will be triggered when arrhythmia occurs during the collection.
4. When "Cyc-sample" is selected, press "  "key, if the interface shows " measuring ", it means the device is running the "Cyc-sample", at this time, if the sample period is set up to 10min and the sample interval is set up to 2min, the record will start the first printing, after the printing, the interface shows "measuring " again, 2min later ,the record will start the second printing.

5. The data produced in the process of "Cyc-sample" can't be copied and stored.

——Select【**Lead order**】: Can select Standard, Cabrera.

Lead order	Lead1	Lead 2	Lead 3	Lead 4
Standard	I, II, III	aVR, aVL, aVF	V1,V2,V3	V4,V5,V6
Cabrera	aVL, I, aVR	II, aVF, III	V1,V2,V3	V4,V5,V6

——Select【**Lead name**】: Can select lead name displayed as "AAMI" or "IEC".

——Select【**Sample period(min)**】:Can input arbitrary number in 000-999 using keyboard.

——Select【**Sample interval(min)**】:Can input arbitrary number in 00-99 using keyboard.

——Select【**Rhy1**】: Can select I, II, III, AVR, AVL, AVF, V1~V6.

——Select【**Rhy2**】: Can select I, II, III, AVR, AVL, AVF, V1~V6.

——Select【**Rhy3**】: Can select I, II, III, AVR, AVL, AVF, V1~V6.

After setup of Info, select【**OK**】.

Caution:

- **In Auto mode: The RHY lead of Rhy1 will be recorded when 3x4+1R or 6x2+1R auto style has been selected in the process of recording; The RHY lead of Rhy1, Rhy2 and Rhy3 will all be recorded when 3x4+3R auto style has been selected in the process of recording;**
- **In Rhythm mode: A 60s's rhythm waves of the RHY lead of Rhy1 will be recorded when single lead has been selected in the process of recording; A 20s's rhythm waves of the RHY lead of Rhy1, Rhy2 and Rhy3 will be recorded respectively when three lead has been selected in the process of recording.**

4.9.7 Display&Voice

Click 【**System setting**】→【**Display&Voice**】in main interface can enter Display &Voice setup interface. Shown as the following:

——Select【**Key volume**】: Set the volume of key sound. Options: Low, Middle, High or close. When "Close" is selected, Electrocardiograph will not give off any sound at the time of key pressing.

——Select 【**Prompt volume**】: Set the volume of prompt sound. Options: Low, Middle, High or close. When "Close" is selected, Electrocardiograph will not give off any sound at the time of giving prompt.

——Select【**QRS volume**】: Set the volume of QRS sound. Options: Low, Middle, High or close. When "Close" is selected, Electrocardiograph will not give off any sound of QRS.

——Select【**Black grid**】: May select "ON" or "OFF" to turn the background of the wave form from black to grid.

——Select【**Icon color**】: Can select the icon color.

——Select【**Brightness**】: May setup the brightness of display: 1~5.

After setup of Info, select【**OK**】.

4.9.8 Date&Time

Click 【**System setting**】→【**Date&Time**】in main interface can enter Date&Time setup interface. Shown as the following:

—Select【**Date**】: The users may select the format of date display according to actual needs.

——Select 【**Time**】: The users may select the format of time display according to actual needs.

——Select【**Date style**】: Can select DDMMYY, YYMMDD or MMDDYY.

——Select【**Time style**】: Can select 12hours and 24hours. When choose 12hours, you can adjust the related AM or PM.

After setup of Info, select【**OK**】.

4.9.9 File

Click【**System setting**】→【**File**】in main interface can enter File setup interface. Shown as the following:

——Select【**Auto delete**】: Can select "on" or "off". Select "on", the files will be automatically deleted when they are been transmitted.

——Select【**Auto cover**】: Can select "on" or "off". Select "on", the most original files will be automatically covered when the storage space is full.

——Select【**Auto save**】: Can select "on" or "off". When select "on", the report will be automatically saved.

——Select【**Export medium**】: Can select USB disk or SD card to export the data.

——Select【**Medium selection**】: Can select Flash, USB disk or SD card to store the data.

——Select【**File format**】: Can select the format of DAT, PDF, Dicom(optional), Xml(optional).

After setup of Info, select【**OK**】.

Caution:

- **Only when Dicom or Xml is chosen in Config of Others setting, Dicom or Xml can be achieved in the File format of File Setting.**

4.9.10 System maintenance

Click【**System setting**】→【**System maintenance**】in main interface can enter System maintenance setup interface. Shown as the following:

——Select【**Export system config**】: Can Export system configuration to USB disk.

——Select【**Loading backup config**】: Can load the local backup configuration.

——Select【**Backup system config**】: Can backup the local system configuration.

——Select【**Recover factory config**】: Can recovery the device's factory configuration.

——Select【**Calibration**】: Calibrate the touch screen.

——Select【**Machine Info.**】: Can look over the machine's information about

Kermel, Root, Analysis library, APP and so on.

——Select【**Import system config**】: Can import the external configuration to the device system.

——Select【**Factory maintenance**】To maintain the machine by the professional person after entering the password. In the maintenance interface, you can select the AC filter, Save Raw Waves, Standby time, ECG Barcode Scanner and so on.

After setup of Info, select【**OK**】.

Note: 【Factory maintenance】can only operated by the maintainer authorized by the manufacturer.

4.9.11 Others

Click 【**System setting**】→【**Others**】in main interface can enter others setup interface. Shown as the following:

——Select【**Demo**】: Can select "ON","OFF". When select ON, the screen will turn to demo style.

——Select【**Language**】: The users may select the language of electrocardiograph displaying or using for ECG recording according to be English, Chinese and so on.

——Select【**Medical institutions**】: Can input the medical institutions information.

——Select【**Config**】: Can select Standby, Network, Dicom, Xml, 40mm/mV, Replay, BarcodeScan or Sample Time when you need.

After setup of Info, select【**OK**】.

Note:

- **Standby: Can close the LED regularly to save electric quantity.**
- **Network: Support for E6000 ECG management software.**
- **Dicom or Xml: Is a supported ECG data storage format.**
- **40mm/mV: Is a supported gain type.**
- **Replay: Can observe the frozen ECG waveform through playback, which can support at most 300s.**

- **BarcodeScan: Support for bar-code scanner function.**
- **Sample Time: The "record time" shown on the ECG report is the ECG sample time, not the machine acquiescent report printing time.**

4.9.12 Return

Click 【**return**】to go back to the main interface.

Chapter 5 Read the Printed ECG Report

5.1 Examples and notes of Record Report

The formats of printed reports usable for E65 electrocardiograph are described in this section.

5.1.1 Auto Mode

This chapter contains following examples in auto mode (Fig. 5-1, Fig. 5-2 , Fig. 5-3 , Fig. 5-4, Fig. 5-5).

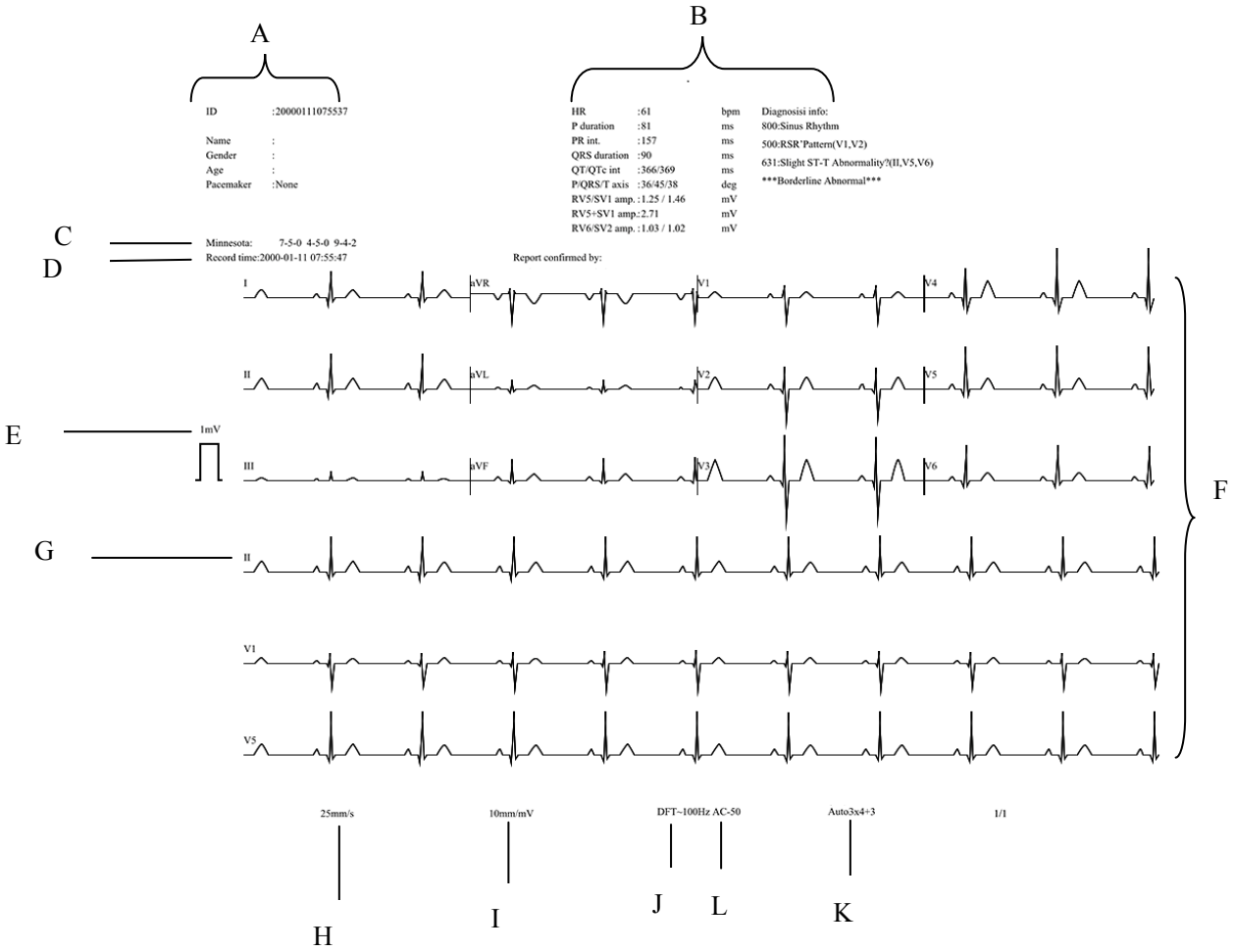


Fig. 5-1: Auto mode 3x4+3 report

A. Patient info (include: name, ID, age and gender)

B. HR and other monitoring info

C. Minnesota

D. The time recording report

E. 1mV calibration signal

F. Waveform info

G. Leads info

H. Speed

I. Gain

J. Baseline drift filter (Off) and lowpass filter frequency

K. Work mode

L. AC filter status

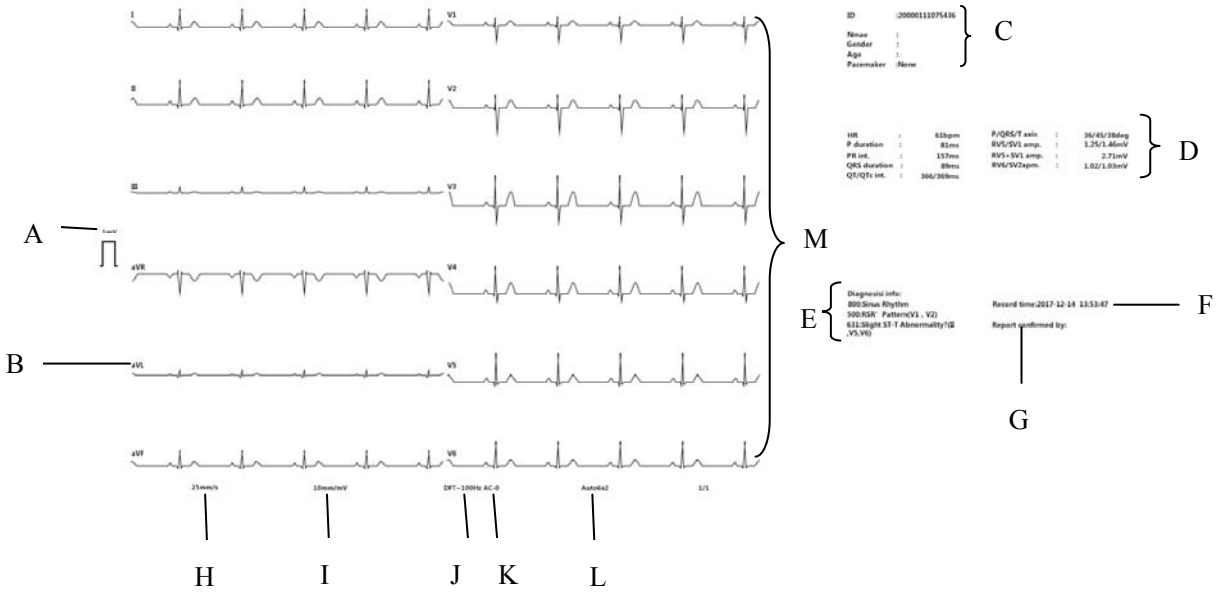


Fig. 5-2: Auto mode 6x2report

A. 1mV calibration signal

B. Leads info

C. Patient info (include: name, ID, age and gender)

D. HR and other monitoring info

E. Diagnosis info.

F. The time recording report

G. Doctor sign place

H. Speed

I. Gain

J. Baseline drift filter (Off) and lowpass filter frequency

K. AC filter status

L. Work mode

M. Waveform info

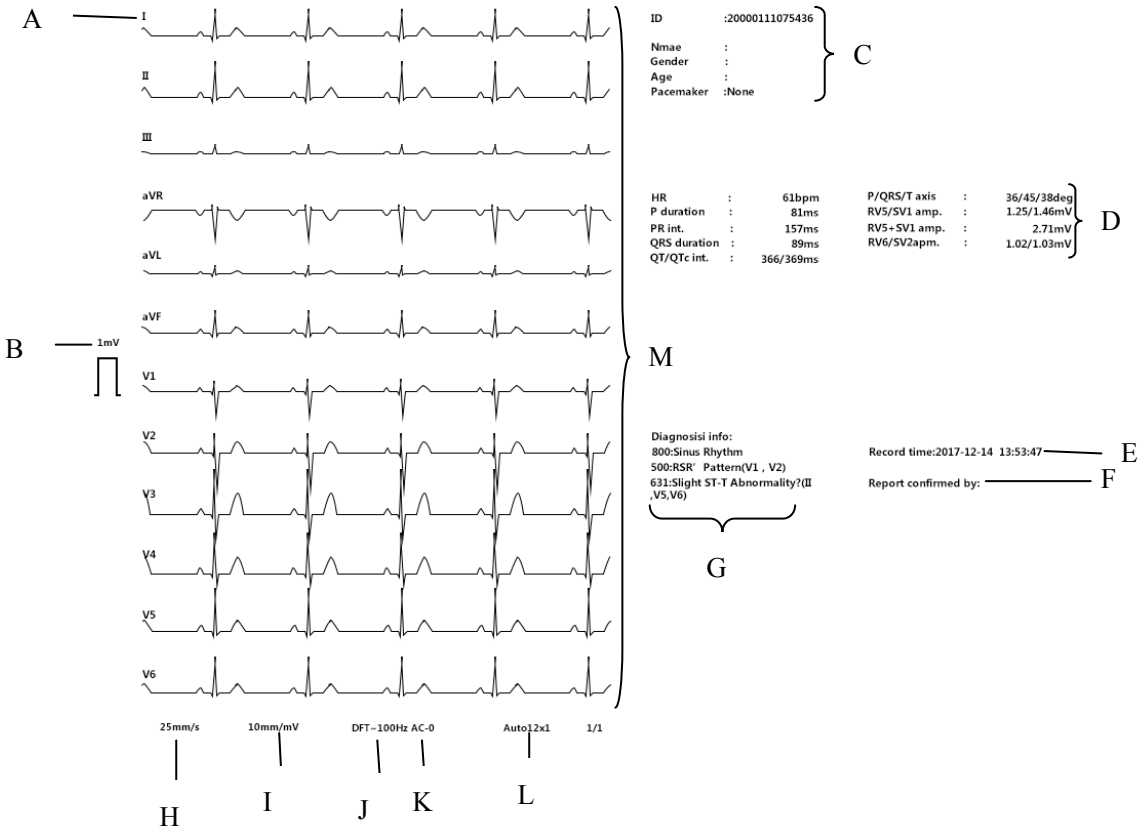


Fig. 5-3: Auto mode 12x1 (5s) report

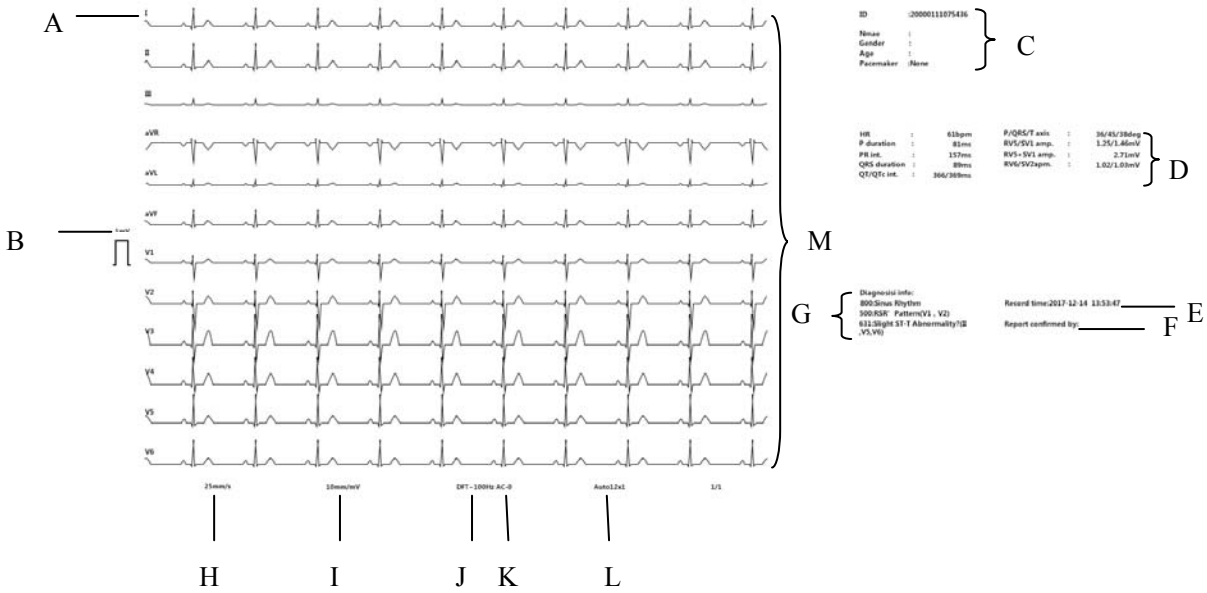


Fig. 5-4: Auto mode 12x1(10s) report

A. Leads info

B. 1mV calibration signal

C. Patient info (include: name, ID, age and gender)

D. HR and other monitoring info

E. The time recording report

F. Doctor sign place

G. Diagnosis info.

H. Speed

I. Gain

J. Baseline drift filter (Off) and lowpass filter frequency

K. AC filter status

L. Work mode

M. Waveform info

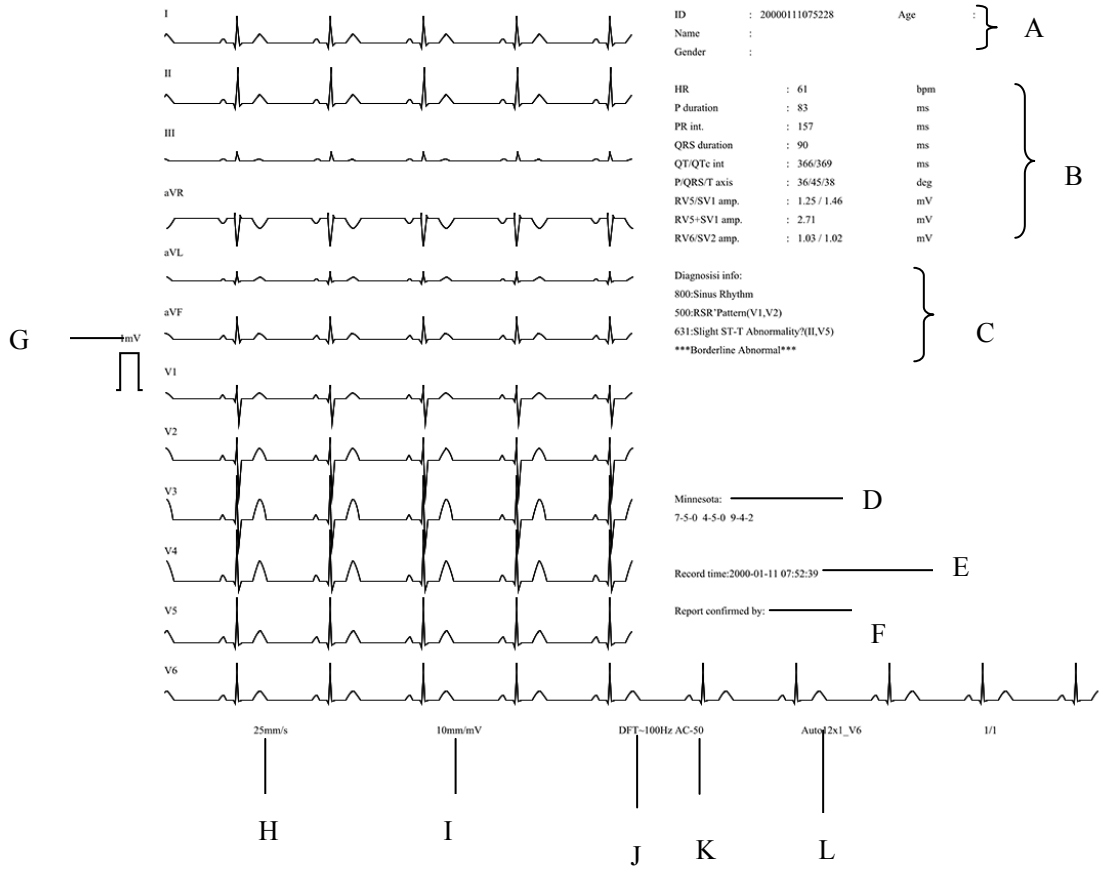


Fig. 5-5: Auto mode 12x1_V6 report

A. Patient info (include: name, ID, age and gender)

B. HR and other monitoring info

C. Diagnosis info

D. Minnesota

E. The time recording report

F. Doctor sign place

G. 1mV calibration signal

H: Speed

I. Gain

J. Baseline drift filter (Off) and Lowpass filter frequency

K. AC filter status

L. Work mode

Note: Only after the Minnesota and so on is chosen in factory maintain of system maintenance, they can be seen in the report.

5.1.2 Manual Mode

In manual mode, real-time recording of ECG waveform is conducted manually according to the requirements of users, and start and stop of

recording are controlled via keys. The figure below shows 12-channel ECG record report in manual mode.

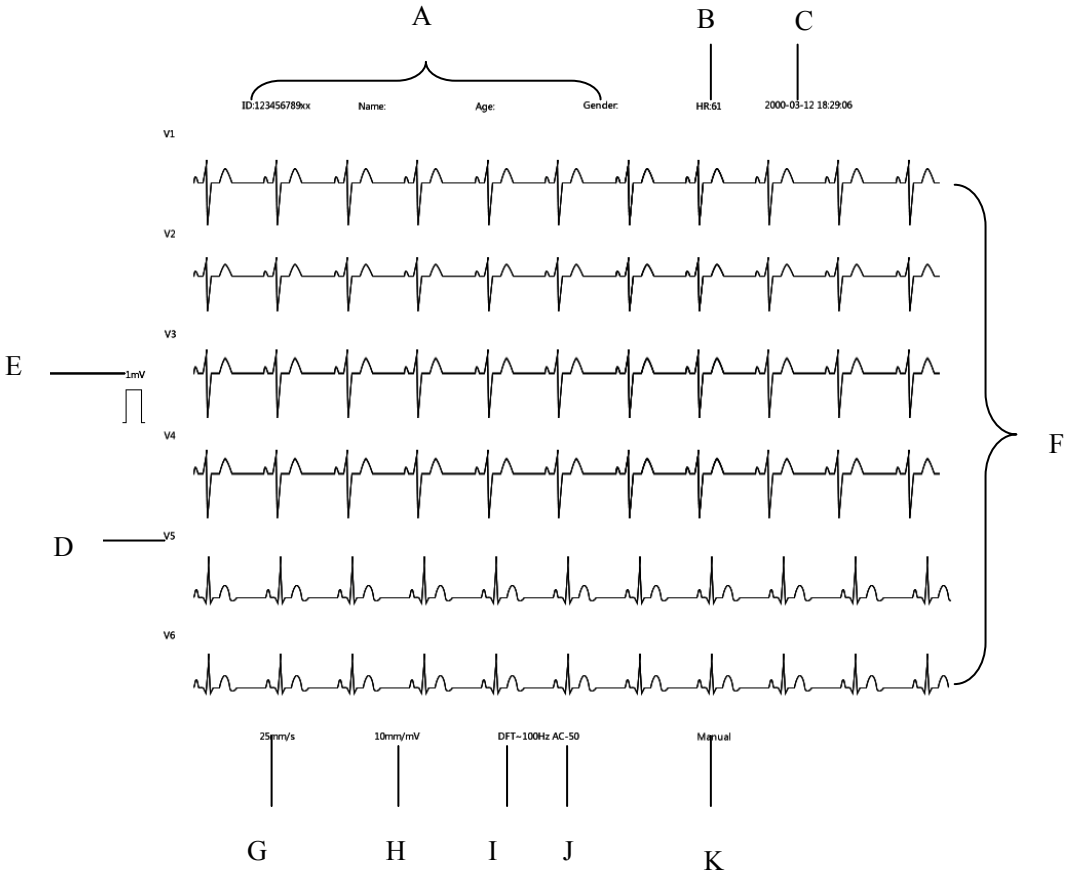


Fig. 5-6: Manual mode report

A: Patient info (include: name, ID, age and gender)

B: HR

C: The time recording report

D: Leads info

E: 1mV calibration signal

F: Waveform info

G: Gain

H: Speed

I: Baseline drift filter (On) and lowpass filter frequency

J: AC filter status

K: Work mode

5.1.3 Rhythm Mode

In Rhythm mode, specific lead rhythm is analyzed. The machine supports single-rhythm lead mode and 3-rhythm lead mode. In single-rhythm lead mode, the waveform data of 60s are collected; in 3-rhythm lead mode, the waveform data of 20s are collected.

◆ **single-rhythm lead mode:**

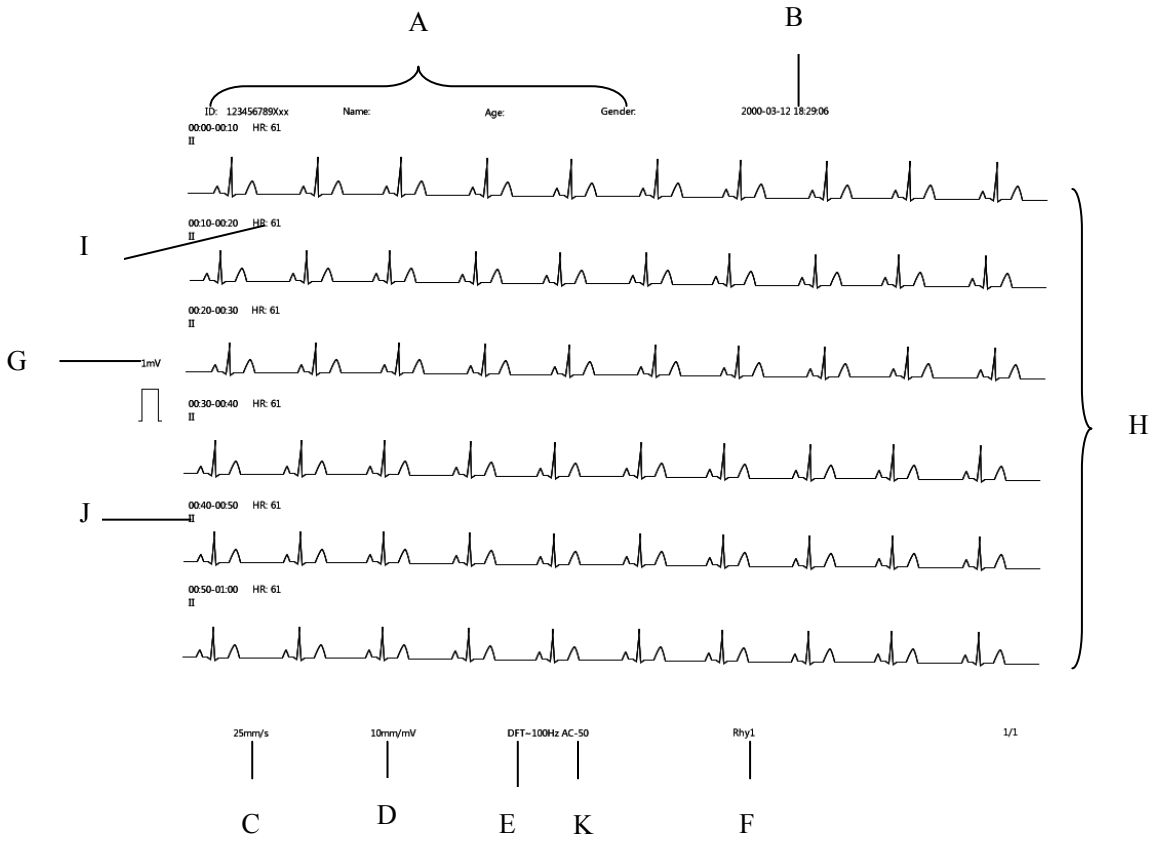


Fig. 5-7: single-rhythm lead mode

◆ **3-rhythm lead mode:**

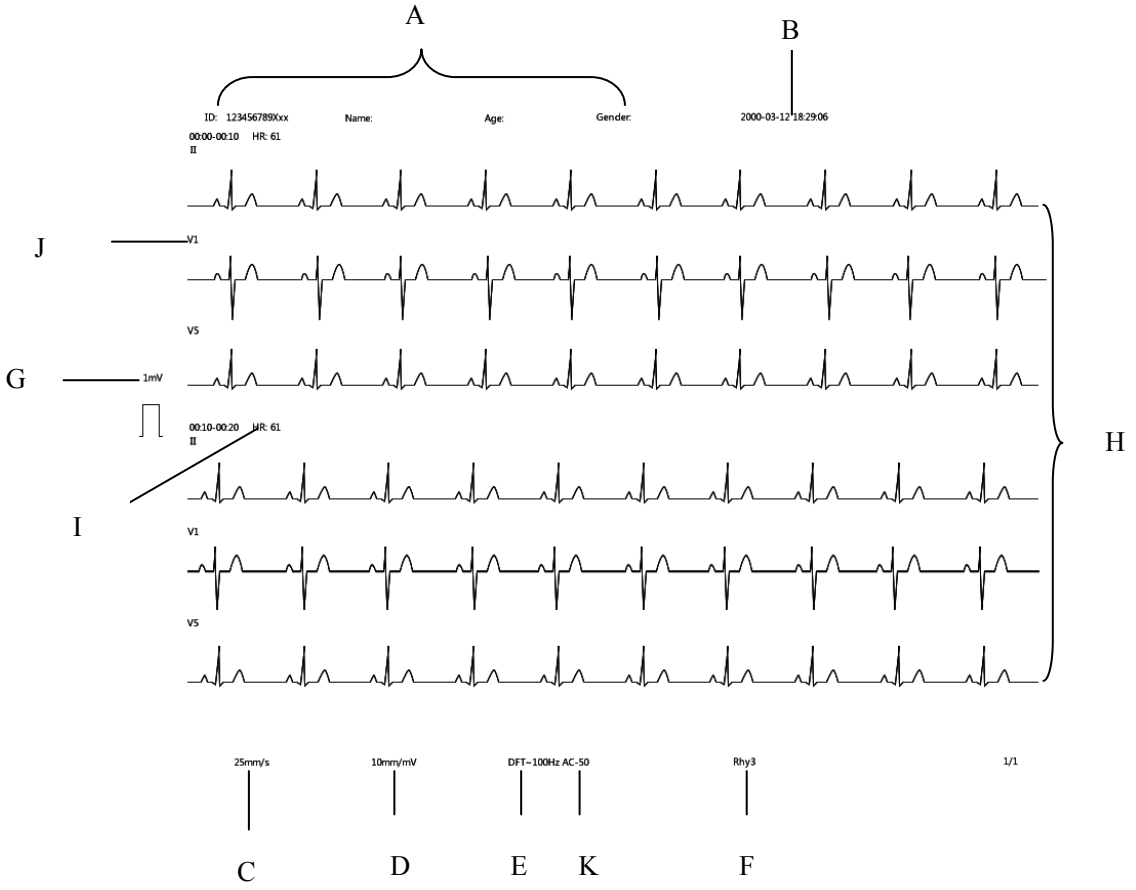


Fig. 5-8: 3-rhythm lead mode

A. Patient info (include: name, ID, age and gender)

B. The time recording report

C. Speed

D. Gain

E. Baseline drift filter (Off) and lowpass filter frequency

F. Work mode

G. 1mV calibration signal

H. Waveform info

I. HR and other monitoring info

J. Leads info

K. AC filter status

5.1.4 R-R Mode

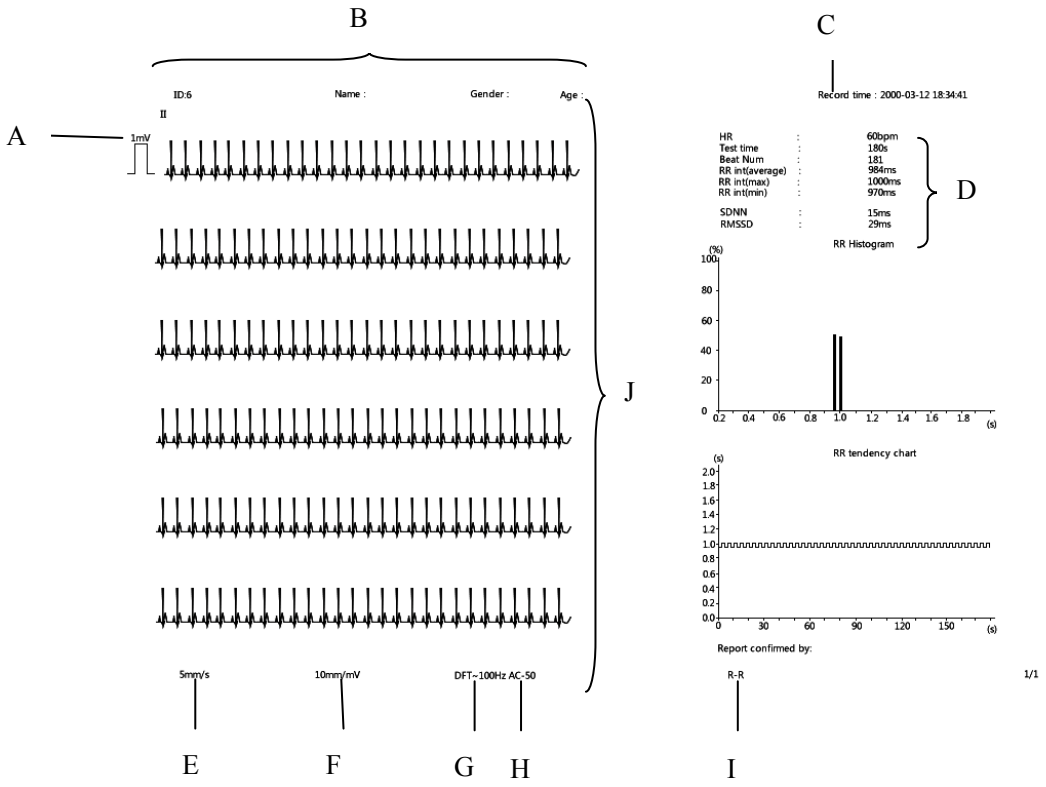


Fig. 5-9: R-R mode (3minutes)

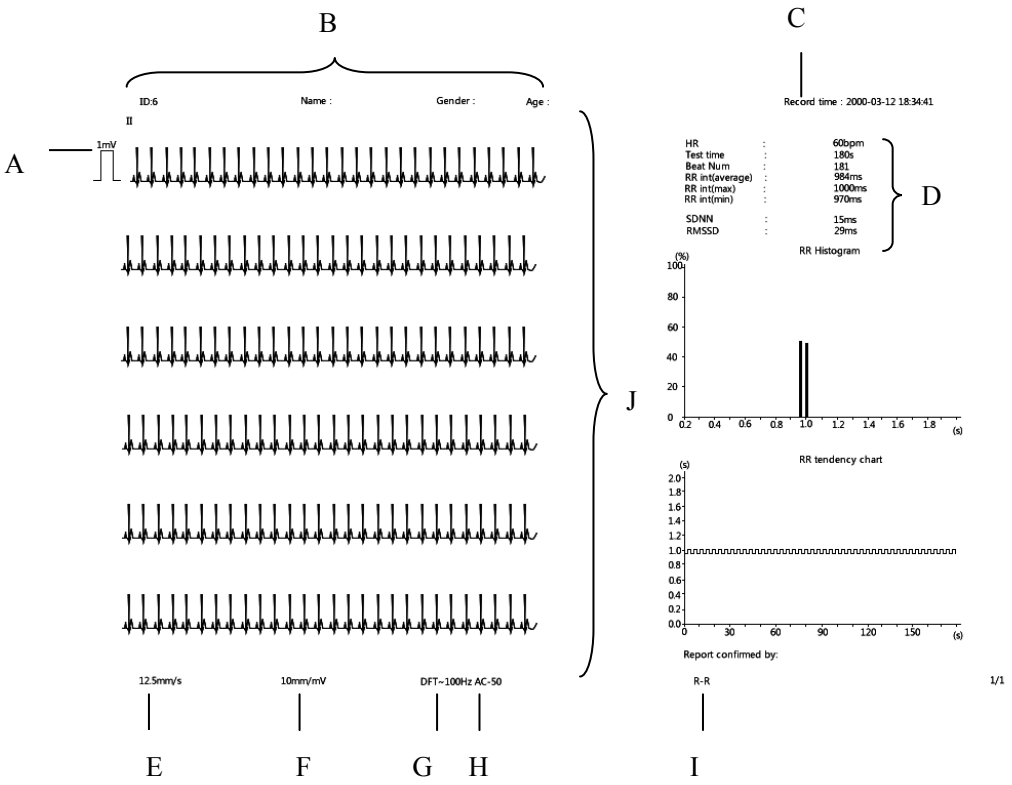


Fig. 5-10: R-R mode (1minute)

A: 1mV calibration signal

B: Patient info (include: name, ID, age and gender)

C: The time recording report

D: HR and other monitoring info

E: Speed

F: Gain

G: Baseline drift filter (On) and lowpass filter frequency

H: AC filter status

I: Work mode

J: Waveform info

Chapter 6Battery

6.1 Introduction

The electrocardiograph can be fitted with rechargeable battery to ensure its continuous work after the failure of alternating current power supply, and it needs no special maintenance under the normal condition. While the electrocardiograph connecting with alternating current power, no matter whether the electrocardiograph is operating or not, the battery always can be charged. In the event of sudden being powered off, the electrocardiograph will automatically get power supply from battery without interruption of monitoring work.

Indicative message on top left corner of the screen will display battery states:

 Indicates that the battery is fully charged.

 Indicates that the battery is almost fully charged.

 Indicates that the battery is half charged.

 Indicates that the battery is low charged.

 Indicates that the battery is almost depleted and need to be charged immediately.

The battery icon will flash while charging.

Caution: Remove the batteries prior to shipping or if the electrocardiograph is not likely to be used for an extended period of time.

Warning:

- **Use only batteries specified in this manual.**
- **Keep the batteries out of children's reach.**
- **The battery must be checked regularly to guarantee its normal function.**
- **When the battery's service life is reached, a new one must be installed.**

6.2 Install battery

The battery box is at the bottom of Electrocardiograph. Please refer to the following steps at the time of installing or replacing battery:

1. Power off the Electrocardiograph, and disconnect the power cord and other connecting wires;
2. Screw off the fixing screws above the battery cover with screwdriver, and open the battery cover (as shown in Figure 6-1) ;

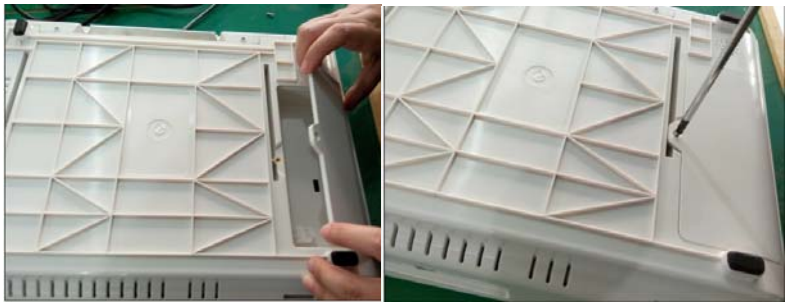


Fig. 6-1 Install battery

3. Place new battery into the battery box according to the direction of mark, and press down the battery to ensure close contact of battery;

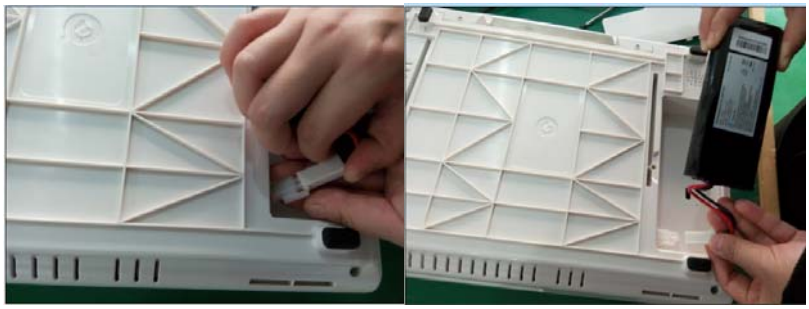


Fig. 6-2 Install battery

4. Mount the battery cover properly as shown in the figure below;

Fig. 6-3 Install battery

5. Connect the Electrocardiograph to AC power, and check whether the battery status indicator of the Electrocardiograph is in good status.

Warning:

- **The positive pole and negative pole of battery shall be connected correctly; otherwise, it is possible to result in explosion.**
- **Do not directly contact the positive pole and negative pole of battery with wire; otherwise, there will be risks of fire.**
- **Only the person be trained or having a good understand of the device can take apart the battery compartment and replace the battery.**
- **Lithium battery shall be plugged or pulled in turn-off status; otherwise, white screen and system halt, etc. will be caused.**

6.3 Optimizing Battery Performance

A battery needs at least two optimizing cycles when it is put into use for the first time. A battery cycle is one complete, uninterrupted charge of the battery, followed by a complete, uninterrupted discharge of the battery. A battery should be conditioned regularly to maintain its useful life. Condition a battery once when it is used or stored for two months, or when its run time

becomes noticeably shorter.

To optimize a battery, follow this procedure:

1. Disconnect the electrocardiograph from the patient and stop all monitoring and measuring procedures.
2. Place the battery in need of optimizing into the battery compartment to the electrocardiograph.
3. Place the electrocardiograph in the charger stand and connect the AC mains. Allow the battery to be charged uninterruptedly for above 6 hours.
4. Remove the AC mains and allow the electrocardiograph to run from the battery until it shuts off.
5. Replace the electrocardiograph in the charger stand and connect the AC mains. Allow the battery to be charged uninterruptedly for above 6 hours.
6. The optimizing of the battery is over.

6.4 Checking Battery Performance

The performance of a battery may deteriorate over time. To check the performance of a battery, follow this procedure:

1. Disconnect the electrocardiograph from the patient and stop all monitoring and measuring procedures.
2. Place the electrocardiograph in the charger stand and connect the AC mains. Allow the battery to be charged uninterruptedly for above 6 hours.
3. Disconnect AC mains and allow the electrocardiograph to run on the battery until it shuts off.
4. The operating time of a battery reflects its performance directly.

6.5 Disposing Batteries

Batteries that are damaged or depleted should be replaced and discarded properly. Dispose of used batteries according to local regulations.

Caution: The service life of battery depends on the service time and frequency. This electrocardiograph battery can be charged and discharged for 300 times generally.

Warning:

- **Do not random remove battery, place battery at a place with open flame or cause short circuit of battery. Combustion or explosion of battery or leak of battery electrolyte is possible to result in personal injuries.**
- **In case built-in rechargeable battery reaches the time limit of service life or is damaged, the user shall timely contact the local maintenance engineer or manufacturer for replacing with new battery;**
- **In case of leak of battery electrolyte or unpleasant smell, the user shall immediately go away from the battery; in case battery electrolyte drips onto clothes or skin, the user shall immediately rinse with clean water; in case battery electrolyte enters into eye, the user shall immediately rinse with clean water and see a doctor instead of rubbing the eye.**
- **Do not cut battery with metal chisel, hammer or knock battery or otherwise damage battery; otherwise, there will be risks due to heating, smoking, distortion or combustion of battery.**

Chapter 7 Clean and Maintenance

7.1 Summarize

Keep your equipment and accessories free of dust and dirt. To avoid damage to the equipment, follow these rules:

1. Always dilute according the manufacturer's instructions or use lowest possible concentration.
2. Do not immerse part of the equipment in the liquid.
3. Do not pour liquid onto the equipment or accessories.
4. Do not allow liquid to enter the case.
5. Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).

Warning: Be sure to shut down the system and disconnect all power cables from the outlets before cleaning the equipment.

Caution: If you spill liquid onto the equipment or accessories, contact us or your service personnel.

7.2 Cleaning of the Electrocardiograph

- Common detergent and non-corrosive disinfectant used in hospital can be applied to clean electrocardiograph, however you must be aware that many kinds of detergents must be diluted prior to utilization, and please use it according to the instruction of detergent manufacturer.
- Avoid the use of alcohols, amino or acetonyl detergent.
- The enclosure and screen of electrocardiograph shall be free of dust, and they can be wiped with lint-free soft cloth or sponge soaked in detergent. While cleaning, be careful and do not spill liquid onto the instrument and keep any liquid out of it. When wiping the side panel of electrocardiograph, you must be especially careful to keep water out of all kinds of cable and outlet on the panel.

▭ Do not use abrasive material including wire brush or metal brightener during cleaning because this material will damage the panel and electrocardiograph screen.

▭ Do not submerge the electrocardiograph in liquid.

▭ While cable or plug of attachment accidentally gets wet, please rinse it with distilled water or deionized water and dry it in the environment of temperature 40℃ to 80℃ for at least one hour.

Caution:

- **Avoid high temperature.**
- **Avoid sunshine, dust or bump, and avoid shaking acutely while moving.**

7.3 Cleaning and Disinfection of Accessories

1. ECG cable

The recommended disinfectors include glutaric dialdehyde solution and 10% decolourant solution.

a) Please clean cable prior to disinfection.

b) Clean the cable surface with soft cloth bedewed with some fresh water or neutral soapy water.

c) Scrub cable with soft cloth bedewed with some disinfector.

d) Wipe off the disinfector remaining on cable by soft cloth bedewed with fresh water.

e) Put cable in a shady and cool environment for airing.

Caution:

- **Do not sterilize lead wire with high-pressure, radioactive or steam device.**
- **Do not directly submerge lead wire in liquid.**
- **To avoid long-time harm to cable, it is suggested that disinfection to the product be conducted only when necessary according to the regulation of your hospital.**
- **Do not clean and reuse disposable electrode.**

2. Chest electrode and limb electrode

a) Please clean chest electrode and limb electrode before disinfection.

b) Wipe off the conductive paste on surface of electrode with soft cloth;

c) Take apart the electrode plate and clamp of limb electrode as well as rubber ball and metal cup of chest electrode;

d) Put electrode into clean warm water (not higher than 35℃) and clean it to ensure no residue of conductive paste;

e) Air dries the electrode at a shady and cool place.

Caution:

- **Electrode shall be timely cleaned after use;**
- **Rubber ball of chest electrode shall be prevented from direct sunlight; otherwise, aging will be caused;**
- **Electrode with eroded surface shall be timely replaced with new electrode.**

Caution:

- Do not disinfect cable and lead wire with high voltage, radial or steam.
- Do not dip cable or lead wire directly in liquid.
- To prevent long-term damage to cable, it is suggested that the product be disinfected only when your hospital regulation deems it as necessary.
- Do not clean or reuse disposable electrode.

Warning:

- **Do not use EtO, phenyl, amido or iodo for disinfection of the machine.**
- **The device and accessories are to be disposed of according to local regulations after their service lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal**

Caution: Disinfection possibly causes damage to Electrocardiograph to some extent. It is suggested that disinfection be conducted only when your hospital maintenance plan deems it as necessary. The equipment shall be cleaned before disinfection.

Note: Electric schematic diagram and list of components are provided to the qualified maintenance station or personnel certified by the manufacturer only.

7.4 Cleaning and Maintenance of Recorder

To prevent stain on surface of thermosensitive printing head due to excessive long period of use of printer and clarity of recording is adversely affected, the users shall regularly (at least once every month) clean the surface of recording head:

- Open the box cover of recorder;
- Take out the remaining chart paper;
- Gently wipe the surface of recording head by use of clean soft cloth dipped with small quantity of diluted alcohol;
- Air dry the recorder at a cool and ventilated place;
- Place the chart paper properly, and close the box cover of recorder.

Chapter 8 Accessories

Warning:

- **Use only accessories specified in this manual. Using other accessories may cause damage to the electrocardiograph.**
- **Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.**

Accessories list:

NO.	Name	Specification	PN
1.	Standard chest electrode	One set comprises 6 electrodes	1.15.62-0001-01-00
2.	Standard chest electrode	Optional (children)	1.15.62-0002-01-00
3.	Standard limb electrode(IEC)	One set comprises 4 electrodes (2 large and 2 small)	1.15.61-0004-01-00
4.	Standard limb electrode(IEC)	Optional (children)	1.15.61-0005-02-00
5.	Standard limb electrode (AAMI)	Optional, One set comprises 4 electrodes (2 large and 2 small)	1.15.61-0004-03-00
6.	Thermosensitive reel chart paper	210mm*140mm *20m	1.21.00-000024-050
7.	15PIN Type AAMI standard integrated 12-lead ECG cable	Optional, With 10K defibrillation resistance，ESD	1.15.52-0035-02-12
8.	15PIN Type IEC standard integrated 12-lead ECG cable	With 10K defibrillation resistance，ESD	1.15.52-0035-02-10
9.	ECG extend cable (10/set)	Optional (adult)	1.15.52-0065-01-00

10.	Disposal electrode pad	Optional (adult)	1.15.61-0001-02-00
11.	ECG extend cable(10/set)	Optional (children)	1.15.52-0065-01-00
12.	Disposal electrode pad	Optional (children)	1.15.61-0001-03-00
13.	Conductive cream	Optional	1.21.00-000003-001
14.	SD card	optional，4G	1.16.00-000083-001
15.	Barcode scanner	optional，FG2100	1.16.00-000023-001
16.	USB printer	optional，HP LaserJet P2055d	1.16.22-000002-001

Appendix A Product Specifications

A.1 Safety Specifications

According to the MDD 93/42/EEC, the electrocardiograph is Type Ⅱa equipment. Classified according to the IEC60601-1 is as follows:

Classification of protection against electric shock	Class I, internally and externally powered equipment.
Degree of protection against electric shock	Type CF applied part（ECG module）, and is defibrillator-proof.
Degree of protection against ingress of liquid	IPX0
Degree of protection against hazards of explosion	Equipment is not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.
Mode of operation	Continuous
Electromagnetism compatible	Group I Class A

A.2 Environmental Specifications

Operating	
Temperature	5℃～40℃
Relative humidity	25%～95% (non condensing)
Atmospheric pressure	700hPa～1060hPa
Transportation and storage	
Temperature	-20℃～+55℃
Relative humidity	25%～95% (non condensing)
Atmospheric pressure	500hPa～1060 hPa

A.3 Physical Specifications

Size (W×H×D)	360mm×276mm×130mm
Weight	4.2Kg
Display	8″, 800×600 TFT LCD

A.4 Power Specifications

A.4.1 AC Power

Rated Voltage	100V-240V AC
Rated Frequency	50Hz/60Hz
Input Power	100VA
Earth leakage current	<0.3 mA
Standard	Comply with IEC 60601-1 and IEC 60601-1-2
Fuse	T 4AH/250V, integrated in the power module

A.4.2 DC Power (Battery)

Type	Rechargeable lithium ion battery
Rated Voltage	11.1V
Capability	4400mAH
Operating time	Used continuously for 5 hours (print 500 shares of cardiogram)
Charge time	At most 6 hours
Charge flow	800~1300mA
Discharge stop Voltage	9.5V±0.3V
Charge voltage	12.6V±0.05V
Charge mode	Constant voltage/constant current charged
Circle times	≥300 times ≥80% leave

Indication of battery capability	With
Shutdown delay	5 min-15 min (after the first low power prompt information occurs)

A.5 Hardware Specifications

A.5.1 Recorder

Assembly component Mode	PT2161 Thermosensitive core
Main assembly component	Thermosensitive core , stepping motor
Thermosensitive core	
Style	Horizontal Thermosensitive recorder
Dot density	8 dots/mm
Recording speed	5 mm/s,6.25 mm/s,10 mm/s,12.5 mm/s,25 mm/s,50 mm/s, error: ±3%.
Print width	216mm(the effective record width of the device is 210mm)
Paper	210mm×140mm×20m (Z type)
Paper type	Folded thermosensitive printing paper
Recording precision	0.125mm
Recording type	Can carry out more than 10 kind of printing methods. (Auto:3×4,3×4+1R,3×4+3R,6×2,6×2+1R,12×1, 12×1_V6;Manual : 3 path, 6path, 12path, Rhythm: single-lead, three-leads , R-R: R-R) .
Stepping motor	
Type	PM
Driving voltage	DC24V
Driving current	500mA/phase
Phase	2

A.5.2 Mainframe LED

AC Power/ Battery status indicating lamp	1 (Green/Orange) Green: It lights green when powered with AC only. Orange: It lights orange when powered with battery only. When it extinguishes, there is no power on the device.
Battery charging indicating lamp	1 (Orange) It lights Orange when the battery is in recharging. It extinguishes when the battery is fully recharged or no battery in the slot.

A.6 Measure and Diagnosis of ECG Waveform

HR range	30bpm -300bpm
HR precision	±1bpm (10s average)
Coefficient error	≤5%, 0.333
Measure info of ECG waveform	P time limit, PR interphase, QRS time limit, QT interphase, QTC interphase, RV5swing, SV1swing, RV6swing, SV2swing, RV5+SV1swing, P axis, QRS axis , T axis.
Coding of diagnosis info	Coding of diagnosis info (Factory default)
Diagnosis analyze	≥140 kinds

A.7 Display of ECG Collection

Signal input	12-Lead, defibrillator-proof, Pacemaker pulse rejection
Degree of protection against electric shock	4000V, Type CF applied part
Electrode offset potential	≥±600mV d.c

Response to frequency **Baseline filter** **EMG filter** **Lowpass filter** **AC filter**	0.05Hz -200Hz (-3dB) On/Off 25Hz,35Hz,45Hz, Close 75Hz,100Hz,150Hz, 200Hz,Close On/Off
Gain selection	2.5,5,10,20, 40,10/5,AGC (mm/mV)
Gain accuracy	±5%
Time base selection	5 mm/s,6.25 mm/s,10 mm/s,12.5 mm/s,25mm/s, 50mm/s
Input impedance	≥50MΩ
Current of input loop	≤15 n A
System Noise	≤12.5 μ V
Patients leakage current	<10 μ A
CMR	≥89dB
CMRR	≥110dB (with AC filter open)
Time constant	≥3.2s
Time for response to wave displaying	≤5s
Time for baseline recovered after switching leads	≤1s
Defibrillator-proof	5000V 360J Recovering time for defibrillator-proof ≤5 s Energy reduced ≤10% Voltage transfer ≤1V

Pacemaker pulse display capability: **Pacemaker Pulse width:** **Rise time of the pacemaker pulse:** **pacemaker pulse frequency:**	±2mV-±700mV 0.1ms-2.0ms; ≥5V/s; ≤100 pulses/min
Standard complied with	IEC 60601-2-25: 2011

A.8 Input/Output Specification

Keyboard	USB keyboard
Touch screen	Standard touch-screen connector (4 lines)
Shortcut key	4 shortcut keys 1 power key
Network connector	RJ-45 (one) TCP/IP; Web function;
Analogy Import/export socket	Reserved function
USB connector	USB Host (one) connects U disk, scanner ,and printer. USB Device (one) connects PC computer
SD card connector	Standard SD card (one) , use to export the ECG data.
ECG lead connector	DB15(one) connects patient's ECG cable for ECG data sampling

A.9 Storage Specification

Fixed Memory	800 groups of ECG data
Optional Memory	Flash, SD card or U disk
Storage mode	Background storage automatically
Storage format	PDF and DAT, Dicom（optional）、FDA-XML（optional）file is supported

A.10 Function

Recording function	According to setup, the machine can complete reports of ECG, real-time waveform, rhythm waveform, saving review and freezing analysis; It can provide reports in multiple formats such as :auto 3×4, 3×4+R, 3×4+3R, 6×2, 6×2+1R, 12×1, 12×1_V6, manual 3-channel, manual 6-channel, manual 12-channel, single-lead rhythm and 3-lead rhythm, R-R;
Operation function	It can conduct function of mode switch , calibration symbol, reviewing record printing, paper feed positioning it also has a function of stop or start record; It supports operations on touch screen.
Input function	Use the keyboard to input the related information The patients' information can be entered in both Chinese and English; The patients' information can be entered via scanner;
Maintenance function	Software can be upgraded by means of USB flash disk
Storage function	Data management of 800 groups is supported; Data saving of Flash, SD card and USB flash disk is supported; Export of data are allowed.
PDF file function	Convert the ECG report into PDF file.

Appendix B Factory Default Setting

This chapter lists some important factory default settings of electrocardiograph. Users can not change them, but electrocardiograph can be recovered to factory default setting according to actual need.

NO.	Item	Factory Default Setting
Working Mode default setting		
1.	Mode options	Auto ,Manual, Rhythm
2.	Manual style	6CH
3.	Auto style	6x2+1R
4.	Rhythm style	Three lead
5.	R-R style	1minute
Filter default setting		
6.	AC filter	On(50Hz)
7.	Baseline drift filter	On
8.	EMG filter	Off
9.	Lowpass filter	100Hz
Recorder default setting		
10.	Work Mode	Fast
11.	Recording style	6x2+1R
12.	Recorder machine	Thermal recorder
13.	Patient Info	Display
14.	Measurements	Display
15.	Recording waves	10s
Patient info default setting		
16.	Pacemaker	Display
17.	Gender	Display
18.	Clear Info.	On
19.	ID generate	Add
20.	Age mode	Age
21.	Ht&Wt unit	cm/kg

NO.	Item	Factory Default Setting
22.	NIBP unit	mmHg
Leads &sampling default setting		
23.	Sample mode	Realtime sample
24.	Lead Sequence	Standard
25.	Lead name	AAMI
26.	Sample period	1min
27.	Sample interval	1min
28.	RHY lead CH 1	Ⅱ
29.	RHY lead CH 2	V1
30.	RHY lead CH 3	V5
Display & Voice default setting		
31.	Brightness	4
32.	Key volume	Middle
33.	Prompt volume	Middle
34.	QRS volume	Middle
35.	Back grid	On
36.	Icon color	Grey
Date &Time default setting		
37.	Date style	YYMMDD
38.	Time style	24hours
File default setting		
39.	Auto delete	Off
40.	Exported medium	USB disk
41.	Medium selection	Flash
42.	Auto Covered	Off
43.	File format	*.dat
44.	Auto save	Off
Others default setting		
45.	Language	English
46.	Demo	Off

Appendix C Trouble shooting

Possible Trouble	Possible Reason	Trouble Shooting
Starting up failure	1、The device is not turned on 2、External power supply failure 3、No battery or the power wire is not connected 4、The quantity of the battery is not enough to provide energy	1、Open the device 2、Make sure the external power supply system works normally. 3、Connect the power wire and fit on the battery. 4、Connect the device to AC power supply, recharge the battery.
Blank screen	1、The device is not turned on 2、The device is in standby mode	1、Turn on the device. 2、Press any button on the device to illumine the screen.
No response from keyboard input	Software failure	Turn off the device then start it again.
Wrong input character	Wrong selection of the input character	Switch the input character to correct mode.
Recorder doesn't work	1、The device is in close mode. 2、The paper is not placed. 3、The paper slot is not closed well. 4、The recorder is too hot.	1、Exit the close mode by pressing the mode switch button. 2、Place the paper according to the require of the user's manual or the sketch map. 3、Close the paper slot well. 4、Start the operation again after the recorder turns cool.
Recorder paper can't be orientated	1、Specified paper is not used. 2、The paper is wrongly	1、Use the correct paper. 2、Place the paper according to the require of the user's manual or

	placed. 3、Software failure	the sketch map . 3、Turn off the device then start it again.
Recorder paper jam	1、Specified paper is not used. 2、The paper is installed wrongly .	1、Use the correct paper. 2、Place the paper according to the requirement of the user's manual or the sketch map.
No wave display for lead	1、The cable is badly contacted. 2、 The electrode is badly contacted. 3、The cable is worn out or broken.	1、Connect the cable again. 2、 Place the electrode correctly 3、Use new cable.
Lead baseline drift	1、Specified electrode is not used. 2、The preparation of the skin is not enough. 3、The electrode is badly contacted or invalid.	1、Use new right electrode. 2、Prepare the patient's skin 3、Place the electrode again or use a new electrode.
Unacceptable disturbance wave exist	1、The patient is moving during the ECG test 2、No preparation of the patient's skin. 3、The electrode is badly contacted or invalid. 4、EMG filter is set wrongly. 5、Equipotent grounding terminal of the device is not connected with the Equipotential grounding system. 6、There is disturbance	1、Make the patient calm down during test. 2、Prepare the patient's skin. 3、Place the electrode again or use a new electrode. 4、Reset the EMG filter. 5、Use the ground electrode to connect the device and the Equipotential grounding system again. 6、Turn off the external AC power or move the device to a place where no disturbance exist or reset the AC filter.

	from the external AC power or the AC filter is set wrongly.	
The scanner can't work	1、The scanner is not connected to the device or they are badly contacted. 2、The scanner breakdown	1、Connect the scanner with the main USB, and make sure their connection is fine. 2、Change the scanner to normal one
The USB printer can't work	1、The USB printer is not selected in software 2、The USB printer is not connected to the device or they are badly contacted. 3、The USB printer breakdown	1、Enter *the* ***system setting*** – ***recorder*** to select corresponding style 2、Connect the USB printer with the main USB, and make sure the connection is fine. 3、Change the USB printer to normal one.
The device is automatically shutdown	The quantity of the battery is not enough to provide energy	Connect the device to AC power supply to recharge the battery

Appendix D Prompt Information

Prompt information	Cause
Sampling	Data collection.
No paper	Record paper is not installed or record paper is used up.
File review	The selected data are being reviewed.
Low battery	The battery has a very low energy.
Transmitting , please wait	The device is transmitting data.
Demo	The system is in demonstration status.
Leads missed	Electrode and lead wire fall off or are disconnected.
Lead fall-off	Electrode falls off from the patient.
Analyzing	Data are being analyzed.
Learning	The self-study process of arrhythmia algorithm in sampling mode is triggered.
Recording	ECG data are being recorded.
Sampling now	Data are being collected.
Testing	The device is in Cyc-sampling mode
Position	It is positioning the record paper.
Position failed	The black grid is wrong.
The disk space is not enough	The patient data has already reached to 800 or the space of the storage medium is not enough.
	Connect the USB printer.
	Insert the SD card.
	Insert the USB interface medium (U disk or USB scanner).
Too hot	The head of the recorder is too hot.

Appendix E Diagnosis Info Mark

E.1 Otherwise

Diagnosis Info Mark	Terms
111	Unsatisfactory Record
112	Arm leads Reversed?
121	Counter Clock Wise Rotation
122	Clock Wise Rotation
131	Low Voltage (Limb Leads)
132	Low Voltage (Chest Leads)
133	Low Voltage
141	QT Prolongation
142	Short QT
151	Dextrocardia (Re-examination)?
161	High T
171	ST Elevation

E.2 Electrical Axes Deviation

Diagnosis Info Mark	Terms
201	Indeterminate Axis
202	Mild Left Axis Deviation
203	Right Axis Deviation
204	Marked Right Axis Deviation
205	Left Axis Deviation
206	S1, S2, S3 Pattern

E.3 Ventricular Hypertrophy and Atrial Enlargement

Diagnosis Info Mark	Terms
301	High Voltage (Left Ventricle)
302	Positive T in V1
303	Right Ventricular Hypertrophy? (RVH)
304	Left Ventricular Hypertrophy? (LVH)
305	LVH (Probably Normal for This Age)
306	Right Ventricular Hypertrophy
307	Left Atrial Enlargement (LAE)
308	Right Atrial Enlargement (RAE)
309	Right Ventricular Hypertrophy (Pulmonary Disease)
310	LAE+RAE
311	RVH+RAE
312	RVH+LAE
313	LVH+LAE
314	LVH+RVH
315	Left Ventricular Hypertrophy
316	Excessive Overload of Left Atrium

E.4 Atrial/Ventricular Block

Diagnosis Info Mark	Terms
401	Short PR Interval
402	WPW Syndrome
403	WPW Syndrome (A)
404	WPW Syndrome (B)

Diagnosis Info Mark	Terms
405	WPW Syndrome
406	WPW Syndrome (A)
407	WPW Syndrome (B)
410	PR Prolongation
412	AV Block 2 (Wenckebach)
413	AV Block 2 (Mobitz)
414	2:1 AV Block
415	Complete AV Block
420	Artificial Pacemaker Rhythm (A)
421	Artificial Pacemaker Rhythm (V)
422	Artificial Pacemaker Rhythm (D)
424	Pacemaker Function Normal
425	Capture Failed
426	Export Failed
427	Perception Adverse
428	Perception Excessive

E.5 Ventricular Conduction Block

Diagnosis Info Mark	Terms
500	RSR' Pattern
501	IRBBB (Incomplete Right Bundle Branch Block)
502	IVCD (Intraventricular Conduction Block)
504	CRBBB (Complete Right Bundle Branch Block)
505	CLBBB (Complete Left Bundle Branch Block)

Diagnosis Info Mark	Terms
506	ICLBBB (Incomplete Left Bundle Branch Block)
510	Suspect Left Anterior Hemi Block
511	LAH (Left Anterior Hemi Block)
512	LPH (Left Posterior Hemi Block)
521	BBBB (Bifascicular Bundle Block)
532	TBBB (Trifascicular Bundle Block)
541	Peri-Infarction Block

E.6 ST-T Morphology Statements

Diagnosis Info Mark	Terms
611	Flat T
621	Negative T
631	Slight ST-T Abnormality?
632	Slight ST-T Abnormality
633	ST-T Abnormality
636	Early Repolarization Syndrome

E.7 Myocardial Infarction

Diagnosis Info Mark	Terms
701	Poor R Progression
711	Abnormal Q
721	Subendcardial Infarction
731	Suspect Anterior Infarction?
741	Possible Anterior Infarction

Diagnosis Info Mark	Terms
751	Anterior Infarction
761	Anterior Infarction (possibly recent)
771	Anterior Infarction (possibly acute)
734	Suspect Anteroseptal Infarction?
744	Possible Anteroseptal Infarction
754	Anteroseptal Infarction
764	Anteroseptal Infarction (possibly recent)
732	Suspect Lateral Infarction?
742	Possible Lateral Infarction
752	Lateral Infarction
762	Lateral Infarction (possibly recent)
772	Lateral Infarction (possibly acute)
733	Suspect Inferior Infarction?
743	Possible Inferior Infarction
753	Inferior Infarction
763	Inferior Infarction (possibly recent)
773	Inferior Infarction (possibly acute)
735	Suspect High-Post Infarction or CCW?
745	Possible High-Post Infarction

E.8 Arrhythmias

Diagnosis Info Mark	Terms
800	Sinus Rhythm
801	Coronary Sinus Rhythm

Diagnosis Info Mark	Terms
802	Suspect Left Atrial Rhythm?
803	AV junctional Rhythm
804	AV Dissociation
810	Marked Sinus Bradycardia
811	Sinus Bradycardia
812	Sinus Tachycardia
813	Tachycardia
814	Bradycardia
815	Extreme Tachycardia
816	Extreme Bradycardia
821	Sinus Arrhythmia
831	Escape Beat
841	PAC (Premature Atrial Construction)
845	Frequent PAC
847	PAC Bigeminy
843	PAC Trigeminy
842	PVC (Premature Ventricular Construction)
846	Frequent PVC
848	PVC Bigeminy
844	PVC Trigeminy
853	Pair PAC
854	Pair PVC
862	Runs of PAC
864	Runs of PVC

Diagnosis Info Mark	Terms
856	PVC (RonT)
851	SA Block or Marked Sinus Arrhythmia
852	Blocked PAC
861	Supraventricular Tachycardia
863	Ventricular Tachycardia
865	Ventricular Escape Rhythm
866	Ventricular Rhythm
871	Atrial Fibrillation
872	Atrial Flutter
873	Ventricular Fibrillation
881	Undefined Arrhythmia

E.9 Diagnosis Result

Diagnosis Info Mark	Terms
900	Normal Cardiogram
901	Approximately Normal Cardiogram
902	Possible Abnormity Cardiogram
903	Abnormity Cardiogram

E.10 Movement Test

Diagnosis Info Mark	Terms
0	Can Movement Test
1	Be Careful Movement Test
2	Can not Movement Test

E.11 Datum Value

Datum value used for classification of Minnesota Code and diagnosis information is based on age and gender according two methods as following:

(1)a（b1，b2）c d

a	Age of the male or the female not less than 19 years old
b1	Age of the male between 12 years old and 18 years old
b2	Age of the female between 12 years old and 18 years old
c	Age of the male or the female between 3years old and 11years old
d	Age of the male or the female not more than 2 years old

(2) a（b）c

a	Age of the male or the female not less than 19 years old
b	Age of the male between 12 years old and 18 years old
c	Age of the male or the female not more than 11 years old

Note: Default of age is 35 years old. Default of gender is male. Standard value unit: time (s); voltage amplitude (mV).

The value describes as "more than"/"less down" in this section is also included without exception.

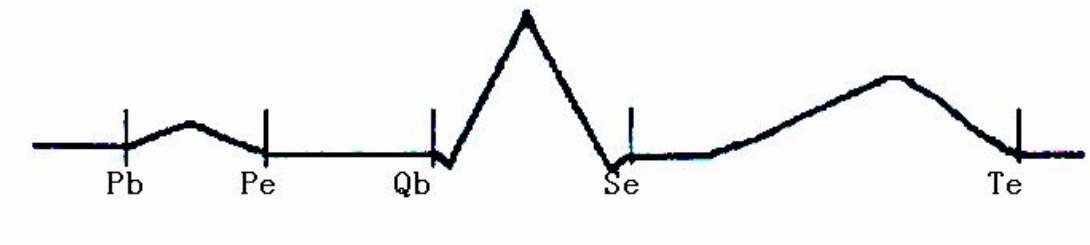
Appendix F Measurement

One predominant beat is selected from each 12 leads waveform. The 12 predominant beats are used by EMDI to locate the waveform boundaries (the onsets and ends of P, QRS, T wave) in multi-lead ECG signal (the 12 standard leads) and measure features of clinical importance (such as the amplitude and duration of the Q, R, S, R' and S' waves, the QT interval, the PR internal).

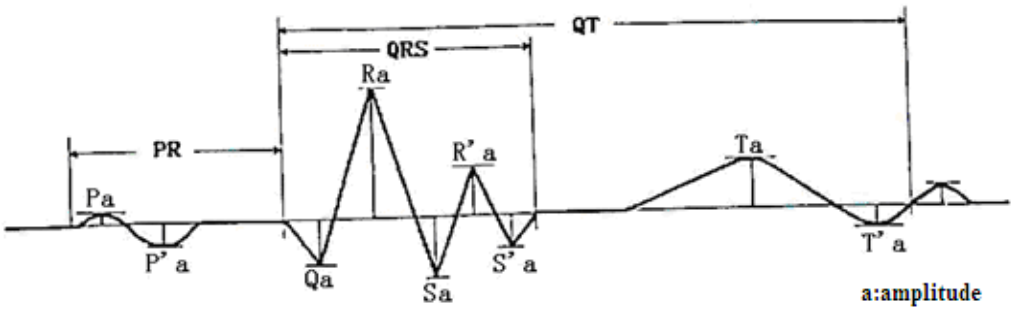
F.1 The Waveform Boundaries of 12 Leads

We adopt some scientific methods to determine multi-lead wave onset and end as follows:

Firstly, we detect and obtain, for each waveform boundary WB (including P end (Pe), P onset (Pb), QRS onset (QRSb), QRS end (QRSe), T end (Te)) , a set of waveform boundary positions WBj(i) belonging to beat I of lead j (j can take values from 1 to 12 (12 leads), except for values corresponding to the leads where no detection was made). The next step is the selection, from these WBj(i) positions, of the one WB(i) that will be considered as the real onset or end of waveform at the ith beat. Electrophysiologically, if all WBj(i) were correctly detected, we should select the earliest WBj(i) (j= 1,2,…,12) for the waveform onset and the latest for the waveform end, in order to recover the boundary from that lead where the electrical activity of the heart has the longest temporal project. However, due to noise or errors, misestimations could have occurred in the determination of some WBj(i), that may lead to erroneous final WBj(i) position. To reduce the risk of this occurrence, we apply the following multi-lead wave boundary detection rule for each ith beat: we calculate the mean and the standard deviation of WBj(i) (j=1,2,…,12), and we search the minimum time position (for onsets) or maximum time position (for ends) of WBj(i) (j=1,2,…,12). If the difference between the minimum or maximum WBj(i) position and the mean is bigger than three times the standard deviation, the minimum or maximum WBj(i) point is rejected as a possible noisy detection. After that we take the wave onsets (ends) as the minimum (maximum) of the remaining WBj(i) positions, obtaining the final WB(i).



F.2 Measurements of One Beat

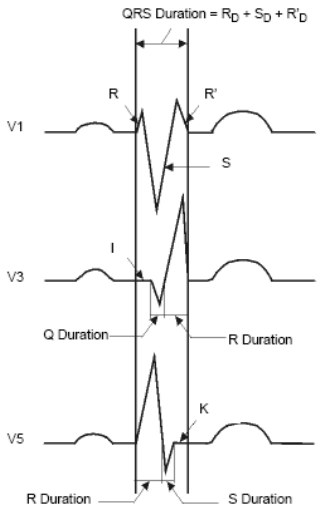


Parameter	Description	Measurement unit
Pa	Amplitude of the P wave	mV
P'a	Amplitude of the P' wave(in case of biphasic P wave)	mV
Qa	Amplitude of the Q wave	mV
Ra	Amplitude of the R wave	mV
Sa	Amplitude of the S wave	mV
R'a	Amplitude of the R' wave	mV
S'a	Amplitude of the S' wave	mV
Ta	Amplitude of the T wave	mV
T'a	Amplitude of the T' wave （in case of biphasic T wave）	mV
Pd	Duration of P wave	ms
P'd	Duration of P' wave	ms
PR	PR interval	ms
QRS	Duration of QRS	ms
QT	QT interval	ms

F.3 Isoelectric Segments

Between the global onset and offset of the QRS-complex, signal parts with a duration of more than 6 ms and amplitudes not exceeding 20μV for at least three samples should be defined as isoelectric segments – I-wave before the global QRS-ONSET and K-wave after the global QRS-OFFSET.

Isoelectric parts (I-wave) after global QRS-ONSET or before global QRS-OFFSET (K-wave) are excluded in the duration measurement of the respective adjacent waveform.



F.4 Stability of Measurements against NOISE

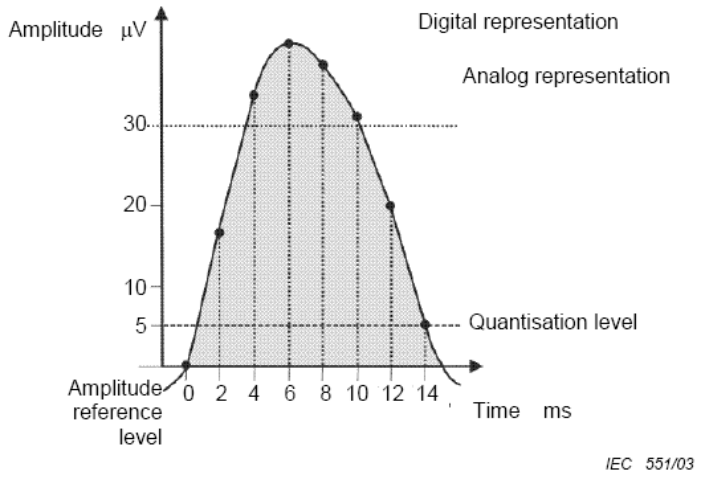
F.4.1 Acceptance of minimum waves

The labeling of the QRS waveforms depends by definition (since Einthoven) on the first detected wave. A tiny positive wave at QRS beginning is called r or R and may mask a true, following Q wave. Therefore the acceptance criteria of initial waveforms should be clearly defined and standardized.

The following rule for acceptance of minimum waves is used by wave detection:

a) The signal part under consideration shows clearly two opposite slopes with at least one turning point in between;

b) The signal part under consideration deviate at least 30μV from the reference level for duration of at least 6ms.



To be accepted because
duration above 30 µV ≥ 6 ms

F.4.2 Disclosed changes of measurements caused by NOISE on ECGs

Global measurement	Type of added NOISE	Disclosed differences		Remark
		Mean (ms)	Standard deviation	
		MA_	MA_	
P-duration	High	5.8	8.4	
	AC	0.2	7.2	50Hz
	AC	6.0	12.0	60Hz
	Baseline	5.6	8.4	
PR-interval	High	2.4	8.2	
	AC	-5.6	7.7	50Hz
	AC	1.6	6.7	60Hz
	Baseline	0.0	9.1	
QRS-duration	High	3.2	7.9	
	AC	2.2	6.4	50Hz
	AC	2.0	10.2	60Hz
	Baseline	2.2	9.5	
QT-interval	High	4.2	7.6	
	AC	7.4	7.9	50Hz
	AC	5.0	6.9	60Hz
	Baseline	3.6	8.7	

Appendix G Automated ECG interpretation accuracy

G.1 Automated ECG interpretation

Definition of accuracy measures for automated ECG interpretation

Reference	Test result	
	"Normal"	**"Pathologic"**
"Normal"	TN	FP
"Pathologic"	FN	TP

Calculating equations of *Sensitivity, Specificity, Positive predictive value (P+)* :

$$Sensitivity = \frac{TP}{TP+FN} \times 100\ \%$$

$$Specificity = \frac{TN}{TN+FP} \times 100\ \%$$

$$P^{+} = \frac{TP}{TP+FP} \times 100\ \%$$

G.2 The intended use of analysing electrocardiograph

Program in the analysing electrocardiograph can help the clinician to measure and interpret 12 leads synchronization tranquillization electrocardiogram. All the measuring and interpreting result must be confirmed by the clinician before use. Analyzing algorithm is intended for the general population, can apply to different age of male or female, e.g. adults, children, neonates.

The patient who is suffering from expiratory dyspnea, pectoralgia, fainting, cardiopalmus and other cardiac disease can check the electrocardiogram through the electrocardiograph.

The Electrocardiograph is intended to be used in various hospital rooms such as the electrocardiogram outpatient department，physical examination office, emergency ward, and inpatient department to provide ECG information to medical and nursing staff about the physiological condition of the patient.

Electrocardiograph must be used under guidance of professionals, and is not

suitable for family use.

The attributes of algorithm are as follows:

1. High-specificity for low-risk patients;
2. High-specificity and high-sensitivity for detecting sinus rhythm ,
3. High-specificity and high-sensitivity for detecting tachycardia or bradycardia.
4. High-specificity and high-sensitivity for detecting anterior, lateral, inferior infarction.

G.3 Accuracy of contour (morphology) diagnostic interpretative statements

G.3.1 Contour diagnostic ECG database

Table1 Use the CSE diagnostic ECG database to test the Accuracy of contour (morphology) diagnostic interpretative. The database is as follows:

COMPOSITION OF CSE DIAGNOSTIC LIBRARY DATASET 5 (1220 ECGs)

Diagnostic category	Number of cases
Normal (NL)	382
Left ventricular Hypertrophy (LVH)	183
Right ventricular Hypertrophy (RVH)	55
Biventricular Hypertrophy (BVH)	53
Anterior myocardial Infarction (AMI)	170
Inferior Myocardial Infarction (IMI)	273
Anterior and Inferior Myocardial Infarction (MIX)	73
Hypertrophy and Myocardial Infarction (VH+MI)	31
Total	1220

Table2 Population statistics

2.1 Gender distribution：

Gender	Number of subjects	Percentages
male	831	68.11%
female	389	31.89%

2.2 Age distribution：

Age(year)	Number of subjects	Percentages	Total
＜18	7	0.57%	1220
19 – 60	837	68.61%	
＞60	376	30.82%	

G3.2 Accuracy of diagnostic interpretative statements

Table3 Compare with the clinical analysing data

Diagnostic category	Number of ECGs tested	Sensitivity %	Specificity %	Positive predictive value%
NORM	382/1220	96.3	——	56.4
LVH	183/1220	40.2	99.1	88.6
RVH	55/1220	38.2	99.8	89.4
BVH	53/1220	22.6	100	100
AMI	170/1220	76.5	97.3	82.3
IMI	273/1220	62.8	97.7	88.9
MIX	73/1220	53.1	99.8	95.1
VH+MI	31/1220	38.7	100	100
HYPER	291/1220	36.6	98.8	89.9
MI	516/1220	65.7	93.4	89

Table4 Compare with the doctor analysing data

Diagnostic category	Number of ECGs tested	Sensitivity %	Specificity %	Positive predictive value%
NORM	382/1220	97.8	——	98
LVH	183/1220	56.9	95.7	96.6
RVH	55/1220	68.7	92.7	90.5
BVH	53/1220	48.9	98.3	95.8
AMI	170/1220	86.5	83.6	96.9
IMI	273/1220	74.4	78.9	92.7
MIX	73/1220	71.7	93.9	97.6
VH+MI	31/1220	64.9	100	100
HYPER1	291/1220	55.7	95.8	95.8
HYPER2	236/1220	55.6	97.1	97.1
HYPER3	108/1220	57.2	95.4	92.4
MI	516/1220	78.8	85.3	96.3
ABN	838/1220	71.9	90.1	95.1

G.4 Accuracy of rhythm interpretative statements

G.4.1 Rhythm ECG database

Rhythm ECG database has 1716 records of electrocardiogram, among them about 1220 records come from CSE diagnostic ECG database, 496 records come from MIT-BIH ECG database. The 1716 records of electrocardiogram include 1576

electrocardiograms and 113 electrocardiograms. The specialist about the electrocardiogram can analyzing the printed electrocardiogram of 12 leads or 2 leads , the reading results will be the real rhythm.

Population statistics

Gender distribution：

Gender	Number of subjects	percentages	Total
male	1113	64.86%	1716
female	603	35.14%	

Age distribution：

Age(Year)	Number of subjects	Percentages
＜18	23	1.36%
19 – 60	1115	64.98%
＞60	578	33.68%

G4.2 Accuracy of rhythm interpretative statements

Rhythm category	Number of ECGs tested	Sensitivity%	Specificity%	Positive predictive value%
Sinus Rhythm	1716	97.02	--	98.14
Atrial Fibrillation	1716	40.71	99.94	97.87
Atrial Fibrillation/Atrial Flutter	1716	73.17	99.94	98.90
Atrial Flutter	1716	50.00	97.75	11.36
Ventricular Rhythm	1716	42.86	100.00	100.00
Coronary Sinus Rhythm	1716	100.00	99.66	14.29

Appendix H Guidance and Manufacture's Declaration of EMC

Guidance and manufacture's declaration – electromagnetic emissions-
for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission		
The E65 Electrocardiograph is intended for use in the electromagnetic environment specified below. The customer of the user of the E65 Electrocardiograph should assure that it is used in such and 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 buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacture's declaration – electromagnetic immunity –
for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The E65 Electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of E65 Electrocardiograph should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 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 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 k V for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and	<5% UT (>95% dip in UT)	<5% UT (>95% dip in UT)	Mains power quality should be that of a typical commercial or hospital environment.

voltage variations on power supply input lines IEC 61000-4-11	for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	
Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity –for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture's declaration – electromagnetic immunity			
The *E65 Electrocardiograph* is intended for use in the electromagnetic environment specified below. The customer or the user of *E65 Electrocardiograph* should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V_{rms} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the *monitor* including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz 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 *monitor* is used exceeds the applicable RF compliance level above, the *monitor* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *monitor*

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

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the V6 *monitor*

The *E65 Electrocardiograph* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *E65 Electrocardiograph monitor* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *monitor* 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 2.5 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 metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

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

Warning:

- **This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.**
- **Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.**

Caution:

- **This unit has been thoroughly tested and inspected to assure proper performance and operation.**
- **This machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.**

Product name: Electrocardiograph

Product type: E65

Manufacturer: Guangdong Biolight Meditech Co., Ltd.

Address: No.2 Innovation First Road, Technical Innovation Coast, Hi-Tech Zone Zhuhai, Guangdong, P.R. China

Fax: +86-756-3399919

Post code: 519085

Toll-free consultation hot line: +86-400-8818-233

PN: 22-064-0003