Preface

Welcome to use Digital Multi-Channel Electrocardiograph Machine (hereinafter referred to as ECG machine, also referred to as “product”, “device”, or “unit”). In order to enable you to skillfully operate the ECG machine as soon as possible, we provide you this accompanying manual with specific instructions for use. Please read it carefully when you install and use this device for the first time. Be sure to keep this manual aside the device, if damaged or lost, please contact the manufacturer for purchase.

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The User Manual Version Number：6.0

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Product Information:

Name:	**Digital Multi-Channel Electrocardiograph**
Type:	**iMAC 300, iMAC 300pro**
Manufacturer:	**Wuhan Zoncare Bio-medical Electronics Co., Ltd**
Registered Address:	**#380, High-tech 2nd road, Eastlake high-tech district, Wuhan, Hubei, P. R. China**
Production Address:	**#380, High-tech 2nd road, Eastlake high-tech district, Wuhan, Hubei, P. R. China**
Production Date:	**See the label**
Operating Life:	**10 years**
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Manufacturer's Responsibility

Zoncare is responsible for the safety, reliability and performance of hardware supplied by Zoncare only if the following conditions are met:

- Assembly operations, expansions, readjustments, modifications or repairs are performed by persons authorized by Zoncare.
- The electrical safety of the room where the unit is installed complies with the requirements of appropriate local, state, and other government regulations.
- The unit is used in accordance with operation requirements.

Safety Conventions in this manual

A Hazard is a source of potential injury to a person, property, or the system.

This manual uses the term WARNING, CAUTION, and NOTICE to point out hazards and to designate a degree or level of seriousness. Familiarize yourself with the following definitions and their significance.

Safety Convention	Definition
⚠ **WARNING**	◆ It indicates a potential hazard or unsafe practice, which, if not avoided, could result in death or serious injury.
⚠ **CAUTION**	◆ It indicates a potential hazard or unsafe practice, which, if not avoid, could result in moderate or minor injury.
⚠ **NOTICE**	◆ It indicates a potential hazard or unsafe practice, which, if not avoided, could result in the loss or destruction of property or data. .
	◆ Follow the operating instructions Note: "Follow the instruction manual" on the device

Contents

Chapter 1 Safety Information and Introduction

1.1 Security Information

1.1.1 Hazards

This product does not involve any information of hazard level.

1.1.2 Warning

WARNING

- *This ECG machine can only be operated on one single patient at one time.*
- *The unit, its accompanying cables and accessories shall be checked prior to use in order to guarantee that they work normally and safely.*
- *Explosion hazard. Do not use the ECG machine in the presence of flammable anesthetics, gases or chemicals. Otherwise it will incur explosion or fire.*
- *The unit can only be connected to AC power outlet with grounding protection. If proper grounding cannot be guaranteed, you shall operate the unit on built-in rechargeable battery instead of AC power. The unit shall also be well grounded to avoid the risk of electric shock. Please place the unit where is easy for proper grounding.*
- *The ECG machine is to work in an environment free from interferences caused by high-voltage cable, X-ray machine, Ultrasound scanner, and Electrotherapeutic equipment. Do not use the unit in an environment with high static electricity. Otherwise the unit might be affected by electromagnetic interference.*
- *Do not open the unit cover, or there might be risk of electrical shock. Only service personnel trained and authorized by the manufacturer can repair or upgrade the unit.*
- *Keep the ECG machine away from water. Do not install or store the unit in*

the place where chemicals are stored or ventilation is poor. Keep the unit away from excessive humidity, temperature, dust, salt, and sulphate.

- *The ECG machine should be placed gently on a stable platform and be protected from tilting, excessive vibration, and/or shocking in the process of transportation.*
- *Since excessive leakage current in total will harm the patient, only EN 60601-1 class I equipment is allowed to be connected to the ECG machine. Therefore, the manufacturer of connected equipment shall hold relevant responsibility for leak current monitoring. When the unit is being used together with other instruments, attention shall be paid to good connections so as to avoid incorrect diagnosis. If necessary, you shall consult a professional technician for advice.*
- *Electrodes and connectors can only be in touch with the patient, but shall not be in touch with other conductor parts, including the earth.*
- *The operators shall not leave the exam room when the ECG machine is in operation. They shall keep careful observation on the patient and, if necessary, turn off the power or disconnect the electrodes to assure patient safety. If an accident happens during operation, please power off the unit immediately and check it*
- *Chemicals from a broken LCD display panel are toxic when ingested. Be cautious when handling an ECG machine with a broken display panel.'*
- *According to Standard EN 60601-1, this ECG machine belongs to type CF defibrillation-proof equipment, therefore its applied part can be connected conductively to human heart.*
- *Used together with a defibrillator, the unit's defibrillator protection is only guaranteed with the manufacturer recommended defibrillator protected electrodes and cables (for specifications, see chapter 11-Accessories). If the defibrillation takes more than 5 seconds or the unit is used with the high*

WARNING

frequency equipment, please use standard disposable electrodes so as to prevent metal electrodes from burning the patient's skin. While used together with other electrical stimulator, the unit shall be operated under instructions from professionals at present.

- *Do not touch the patient during defibrillation. Otherwise it will incur serious injury or death.*
- *ECG signal acquisition may be affected by special environment, incorrect operation of ECG machine and patient condition. For safety information, please refer to the corresponding chapter in this manual.*
- *Using unspecified patient cable, limb clamp, and suction bulb may degrade anti-interference performance of ECG machine. Connectivity of patient cable should be checked periodically, at least once a month.*
- *It is advised to use the unit with paper suggested by the manufacturer, as this is the only way the printer head life time and clear ECG waveform can be guaranteed.*
- *The ECG machine is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms. Physiological waveform and parameters displayed in this ECG machine are for the doctors' reference only, and cannot be used as the basis for clinical treatment.*

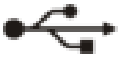
1.1.3 Cautions

CAUTION

- *Please used the accessories specified in this manual.*
- *When the unit and accompanying will exceed their life time, dispose of them in accordance with relevant local laws and regulations or the regime of local hospitals.*
- *Electromagnetic field will affect the performance of this unit. Therefore other equipment used in the vicinity of this unit must comply with relevant EMC requirements.*
- *Before connecting the unit to an AC power outlet, please verify its power voltage and frequency comply with the label on the unit or the requirements specified in this manual.*
- *Please properly install and carry this unit to prevent it from dropping, collision, strong oscillation or damage by other external mechanical forces.*
- *Please install the unit in the place available to observe, operate and maintain.*
- *Place this manual near the unit so that it is available when necessary.*
- *In order to describe and record electrocardiographs more accurately, the ECG machine should be placed and used in a quiet and comfortable environment.*

1.2 Device Symbols

The following table describes symbols or icons that may be on your device and its packaging.

Symbol	Description	Symbol	Description
	Attention! Consult accompanying documentation		On/Off
	DC power supply		AC power supply
	Charging battery		SD card
	Type CF Equipment equipped with protector against defibrillation.		Equipotential terminal
	Ethernet port		USB port
	Manufacturing date		Serial number
	Indoor use		WellKangLtd(www.CE-marking.eu) Enterprise Hub,NW Business Complex,1 Beraghmore Road,Derry,BT48 8SE,Northern Ireland
	Follow the operating instructions Note: "Follow the instruction manual" on the device		CE Certification
	It indicates this device contains electronic or electrical components that must not be disposed of as unsorted municipal was te but collected separately. Contact an authorized representative of the manufacturer for information concerning the decommissioning of your device.		Environment-friendly Use period

	Nonionizing electromagnetic radiation		Manufacture address
	Indicates the item is a madical device		

CAUTION

- *Do not damage any label on the unit.*
- *These labels provide important information for the safety and operation of the unit. Damaging or moving the labels may lead to disoperation.*

1.3 Introduction

1.3.1 Precautions

You are required to read through the operating instructions before use the ECG machine so as to ensure proper operation of the unit.

1.3.2 Product model division

Model	iMAC 300	iMAC 300pro
Hierarchical gain	Equipped	Equipped
Period sampling	No	Equipped

1.3.3 Product Performance

Power voltage: AC 100V-240V；

Power frequency: 50/60Hz±1Hz，75VA；

Continuous operation time: more than 7h；

Front-end acquisition mode: A/D sampling. A/D digits are not less than 24 digits. The effective sampling is not less than 32000 samples per second (or 32000Hz/channel);

Gain: the equipment is available in 40mm/mV, 20mm/mV, 10mm/mV, 5mm/mV and 2.5mm/mV and automatic six gears.; Gain accuracy is ±3%；

Paper speed: the equipment is available in 5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s, and 50mm/s. Accuracy is ±3%；

General safety for the product should conform to IEC 60601-1-2:2014 standard.

Particular safety for the product should conform to IEC 60601-2-25:2011 standard.

1.3.4 Product Composition

The ECG machine is mainly composed of the host, patient cable, limb electrodes, and chest electrodes.

1.3.5 Intended Application

The intended use of iMAC 300pro 12-lead electrocardiograph (hereinafter called iMAC 300pro) is to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. However, the interpreted ECG with measurements and interpretive statements is offered to clinicians on an advisory basis only.

1.3.6 Applicable people

Adult and pediatric patients.

1.3.7 Contraindication

None.

1.3.8 Side effects

No side effects.

1.3.9 Theory of Operation

Schematics:

Only qualified field service engineer will be provided schematics and spare parts list for the ECG machine.

Theory of Operation:

The ECG machine acquires a microvolt level signal from human body surface via patient cable and electrodes. It amplifies the signal by the Amplification Module before Analog to Digital (A/D) converting. Following A/D conversion, the signal is processed by the CPU of the Keyboard Control Module. The CPU outputs the signal to the thermal printer. Precision control program from the Keyboard Control Module is used to drive the stepping motor so as to make the recording paper run at a constant speed. By controlling temperature of the above mentioned thermal emitting components, relevant ECG trace and character could be printed out on the thermal recording paper. In addition, the Keyboard Control Module also processes the keyboard signal, and controls the trace display, the real time clock, and etc. The Power Supply Module provides other modules of the ECG machine with power sources, of which AC power is of priority to the rechargeable battery. When the ECG machine is powered by AC power, battery is charged provided there is no operation of the unit.

1.3.10 Main Features

- It adopts high-resolution thermal array printout system, uses recording paper of 80 mm in width, and records clear accurate ECG waveform and information about lead marks, gain, time reference (or paper speed), filter status etc.;
- It adopts a unique high-precision digital filter to prevent baseline drift and other interference without causing waveform distortion. It enhances the ability of anti-baseline drift, which is easy for waveform interpretation;
- Support English input with more complete information;
- Support various file output formats, and meet the needs of clinical information;
- Color LCD display, which can clearly record 12-lead ECG waveform and information;
- Classification function for different age group;
- External USB disk and SD card are supported to store as many reports as possible;
- Standby mode, reduces power consumption and prolongs LCD life;

- It is designed according to the safety standard of IEC class I type CF. ECG amplifier is fully floated with good safety performance;

- It has both AC and DC power supply modes. Rechargeable environmentally-friendly lithium-ion battery is installed in the machine and is easy to replace. And it has a dedicated battery charging circuit, a perfect battery management and protection system.

1.3.11 Intended Places and Users

- It can be used as measuring instrument in relevant hospital sections or patient rooms.
- It can be used for mass exam.
- ECG signal measurement is intended for users of different ages, but for the children, if there is crying and other uncoordinated factors, it will cause interference and ECG artifacts, which should be based on the diagnosis of the clinician.
- When use the unit on a pacemaker patient, please activate the PACE Detection with reference to *Section 4.2.2*.

WARNING

- *Wherever the ECG machine is used, you must verify that it is connected with reliable dedicated grounding wire.*

1.3.12 Safety Standards and Requirements

- Strictly in accordance with EN 60601-1:2006+A1:2013 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance; IEC60601-2-25 Medical electrical equipment-Part1-2:General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility-
  Requirements and tests. The security type is type I CF.
- Power supply conditions for the room where the ECG machine is to work shall be suitable for standard three-plug socket with the grounding plug properly grounded. Otherwise, you are required to ground the unit using the accompanying grounding cable, with one end connected to the grounding post and the other end to the ground.

WARNING

◆ *Grounding shall be performed in accordance with relevant standards or under the guidance of experienced electricians.*

- When the unit is used in combination with other medical devices, you are required to connect the grounding cable together with that of the others so as to protect the patient from possible shock.
- Connect one end of the grounding cable to the equipotential post of the ECG machine and other end to the ground. Avoid using water piping or other piping as a grounding conductor, otherwise the precautions for grounding protection of the unit shall lose effectiveness and the patient may has the risk of electrical shock.
- The ECG machine is an instrument of continuous operation and ordinary equipment. Avoid ingress of liquids into the unit. Explosion hazard. Do not use the unit in the presence of flammable anesthetics or gases.

Classification：

Type of protection against electrical shock	Class I internally powered equipment
Degree of protection against electrical shock	Type CF defibrillation-proof applied part
Degree of protection against harmful ingress of liquids	Ordinary equipment (enclosed equipment without protection against ingress of liquids).
Degree of safety of application in the presence of flammable gas	Equipment is not appropriate for use in the presence of flammable gas.
Signal input and output：	With input and output parts
Mode of operation	Continuous operation

Chapter 2 Structure Identification

2.1 Identification of Front Panel, Buttons, Symbols and Expansion Slot

2.1.1 Top View

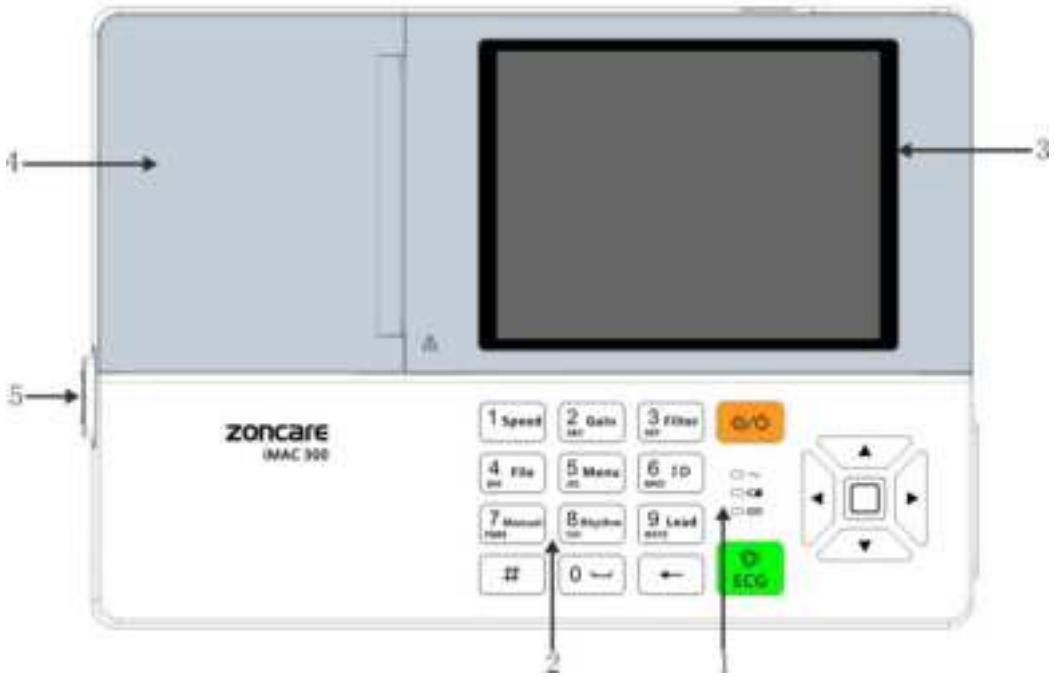
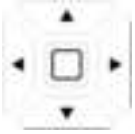
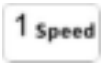
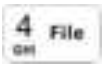
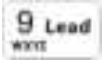


Fig. 2.1 Top View

1. Indicator Light: Indicating power supply status and battery charge status; for details, see the table below.
2. Operation Panel: Operation keys; for details, see the table below.
3. LCD Screen: Displaying ECG parameters and waveforms, patient and system information; for more interface information, please see section 2.3.
4. Printer Door: To contain the recording paper.
5. Printer Door Switch: To open the printer door.

Identification of Function Keys	
Key	**Function**
	Power switch, press this key to turn on/off ECG machine.

Identification of Function Keys	
Key	**Function**
	Printing Key.
	When perform settings, us e direction key to select among the items, Press" □ "key for selection confirmation, for details please see chapter 4.1.
	Character input key, shortcut function: Adjusting paper speed in main menu.
	Character input key, shortcut function: Adjusting gain in main menu.
	Character input key, shortcut function: Adjusting filter parameter in main menu.
	Character input key, shortcut function: Entering into File Management interface.
	Character input key, shortcut function: Entering into Application interface.
	Character input key, shortcut function: Entering into Patient Info interface.
	Character input key, shortcut function: Recording ECG waveforms in Manual/Auto mode.
	Character input key, shortcut function: Rhythm data analysis.
	Character input key, shortcut function: Changing Leads in manual mode.
	Character input key, shortcut function: None.
	Input key, changing input methods.

	Backspace key
Identification of Indicator Light	
Indicator Light	**Function**
	AC power indicator light On: AC power connected Off: AC power disconnected
	DC power indicator light On: Power supplied by battery Off: Power not supplied by battery, or no battery installed
	Charging status indicator light On: Battery being charged Off: No battery installed or battery fully charged

2.1.2 Side View

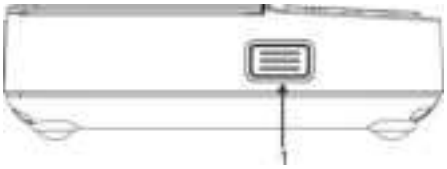


Fig. 2.2 Left Side View

1. Printer Door Switch: To open the printer door.

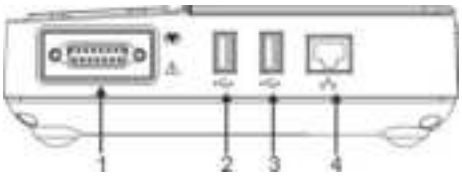


Fig. 2.3 Right Side View

1. ECG Cable Port: Connecting ECG cable.
2. USB Port: Connecting external USB devices.
3. USB Port: Connecting external USB devices.
4. LAN Port: Connecting internet, it's used when connecting with other devices

2.1.3 Rear View

Fig. 2.4 Rear View

1. AC Power Port: Connecting AC power, supply AC power to the ECG machine.
2. Equipotential Terminal： When the ECG machine is used together with other devices, users shall connect its equipotential terminal with those of other devices so as to eliminate the potential difference (PD) among different devices thus ensuring safety.

2.1.4 Bottom View

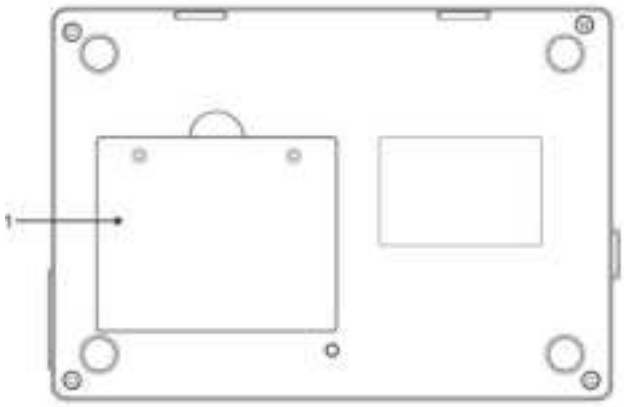


Fig. 2.5 Bottom View

1. Battery Compartment: To contain the battery.

2.2 Operation Mode

2.2.1 Standard Mode

After the ECG machine is turned on, it enters into standard mode automatically. Then you can perform ECG signal acquisition, measure, record measured results, perform system settings, export data and perform configuration management under this mode.

2.2.2 Standby Mode

If the user does not have any operation within the set time, the ECG machine automatically enters the standby state.

Follow the steps below to set the time to automatically enter standby mode:

1. On Waveform Acquisition interface, click“ 

”key to enter Application interface.；

2. Click the direction key“  ”to select“  ”and then press“  ”key to enter Machine interface.

3. Click“  ”direction key，select the standby item on the setting interface；

4. Set the time to automatically go to standby mode；

5. After setting, click“  ”direction key to move the cursor to the upper right corner“  ”, click“  ”to close the current interface and go back to the system application interface，continue to repeat this action will return to the waveform acquisition interface. Or just click the“  ”on the panel to go back to system application interface，continue to repeat this action will return to the waveform acquisition interface。

Turn off the display in standby mode, can reduces power consumption and extends display life.

2.2.3 Demo Mode

In this mode, the ECG can demonstrate some features of the machine without connecting the patient cable and accessories. Click the " 

" to enter system application interface. Click “  ”direction key to select“ 

”, click“  ”to enter analysis setting interface→click direction key“◀ ”or“▶” to select “  ”→ click direction key “▲”or“▼”to select【Demo mode】,click  ” to confirm, then click direction key “▲”or“▼”to select turn this mode on or off. Finally click “  ” to confirm. After setting is done, click direction key“▲”or“▼”to move the cursor to the upper right corner“  ”,click“  ” to close the current interface and return to the system application interface, continue to repeat this action will close the system application interface to enter demo mode. Or just click the “  ” on the panel to complete the operation.

In the demo mode, there is a demo waveform for demonstration, which can be printed.

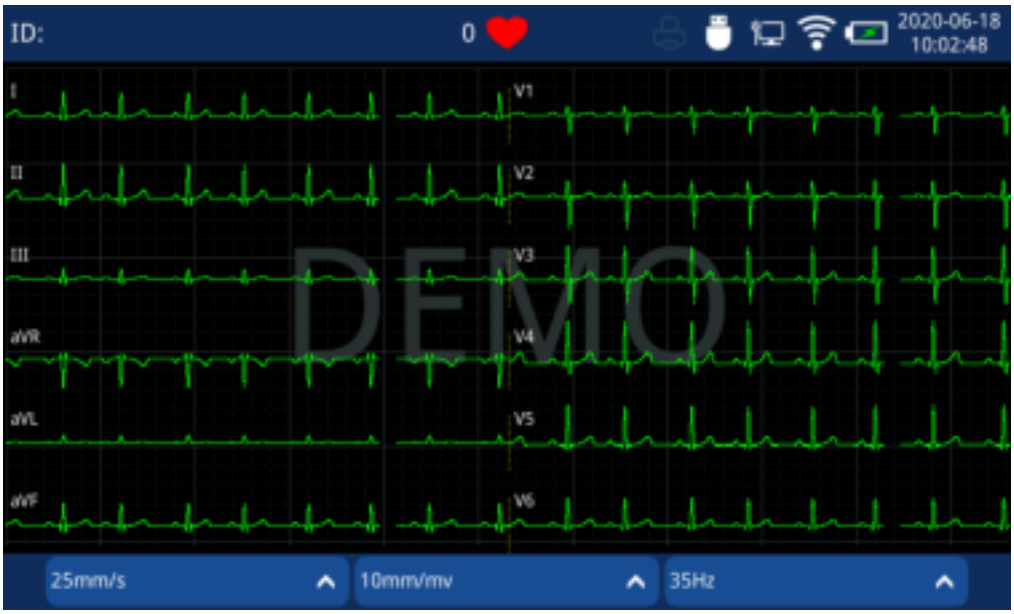


Fig. 2.6 Demo Mode

WARNING

- *Demo function is mainly used to display the machine performance and provide training for users. When the machine is connected to the patient in clinical practice, it's prohibited to use the Demo function in case that the medical staff shall mistake the demo waveform as the patient's, thus affecting the patient's measurement and delaying his or her treatment. Before use, the user must check the unit, its cables and accessories in order to make sure that all of them will work safely and properly.*

CAUTION

- *Once entering into the Demo Mode, the system cannot exit automatically. Even the ECG machine is Reboot after shutdown, it is still in demo mode. You need to click the "*  *" button to enter [Record Analyze] to close the demo mode.*

2.3 Interface Display

2.3.1 Waveform Acquisition Interface

Waveform Acquisition Interface show 6x2 layout only.

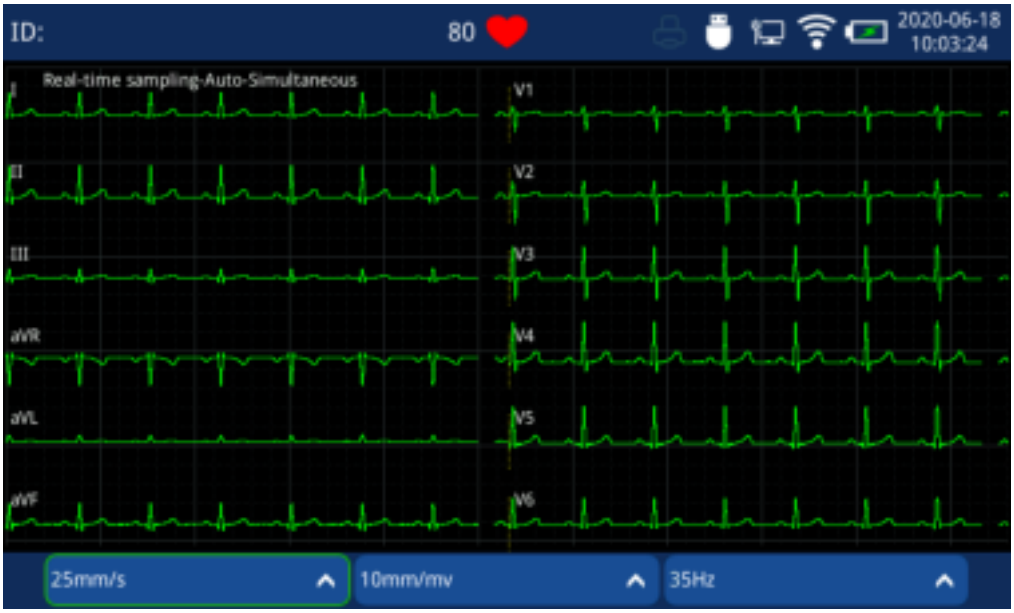


Fig. 2.7 Waveform Acquisition Interface

1 Patient and system information zone:

a  Patient ID;

b  Heart Rate Indication (tachycardia/bradycardia);

c  External printer indication. The icon being dark indicates that it is not connected;

d  Storage information;

e  LAN connection state; Dark icon indicates network disconnection;

f  WIFI connection state; Dark icon indicates network disconnection;

g  Battery Information. The white bar indicates the battery level;

h  Time display; Click it and quick set the date and time.

2 Waveform zone: Displaying ECG waveform. Red lead indicates the lead falls off, while white indicates the lead is well connected;

3 Shortcuts zone:

a 

Paper speed, press“1 Speed”key to change the value; options: 5mm/s, 6.25mm/s, 10 mm/s, 12.5mm/s, 25mm/s, 50mm/s。

b 

Gain amplitude, press“2 Gain”key to change the value, options: 2.5mm/mv, 5 mm/mv, 10mm/mv, 20 mm/mv, 40 mm/mv, auto.

c 

Filter settings, press“3 Filter” key to change the value, options: OFF、25、35、45、75、100、150、250、350;

d 

Sampling mode, press“7 Manual”key to change manual/auto mode (this function only support real-time sampling mode);

e 

Patient ID, press“6 ID”key to enter patient information input interface.

2.3.2 Patient Info Interface

In the waveform acquisition interface, you can press“ 6 ID ”key to enter the patient information page, finish patient basic information input. Press “▲”or “▼”direction key to select different items，press “#”to change between Number, English and Symbol，and then input through the keyboard.（input method please refer section 4.1）.System will generate ID automatically when you enter patient info interface. After the input is completed, press direction key to select“ Confirm ”，then press“ ☐ ”to save and return to waveform acquisition interface. Press“ Previous ” to automatically generate the last patient information.

Fig. 2.8 Patient Info Interface

Click the " " button in the Patient information interface, enter the server's IP address, port and path (for details, please consult your network administrator). You can synchronize the patient information data in the server, and directly import the patient information into the list. Click on one of the patients to automatically generate patient information. Before importing data, please test whether it can be connected.

If the automatic list synchronization function is enabled, the system will automatically synchronize the server data each time you enter the list interface.

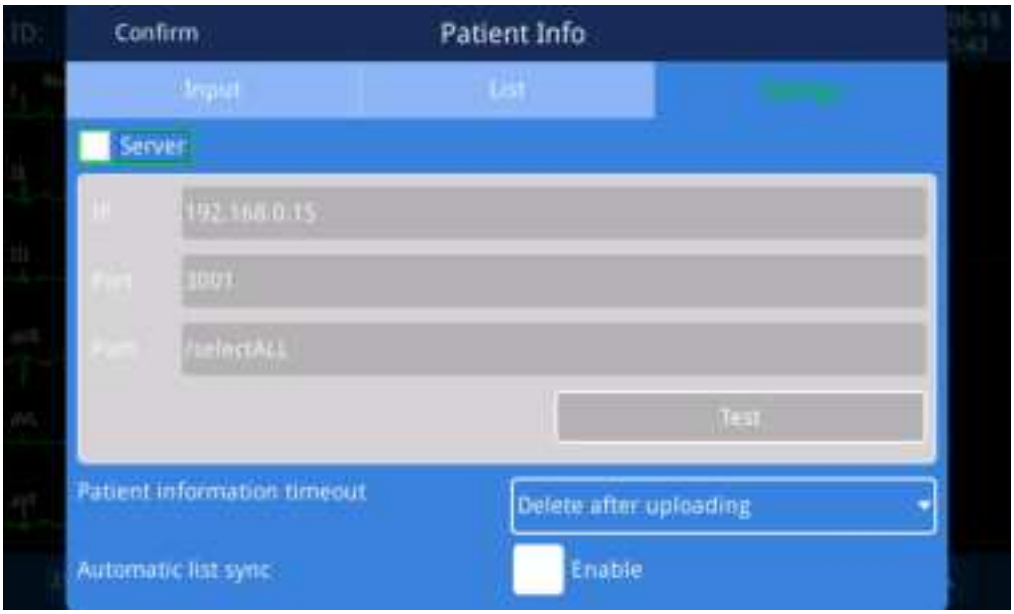


Fig. 2.9 Patient Information Interface – Settings

Fig. 2.10 Patient Information Interface - List

2.3.3 Report Management Interface

In the waveform acquisition interface directly clicks the “4 File”button to enter the report management interface. See Chapter 7, Report Management for details.

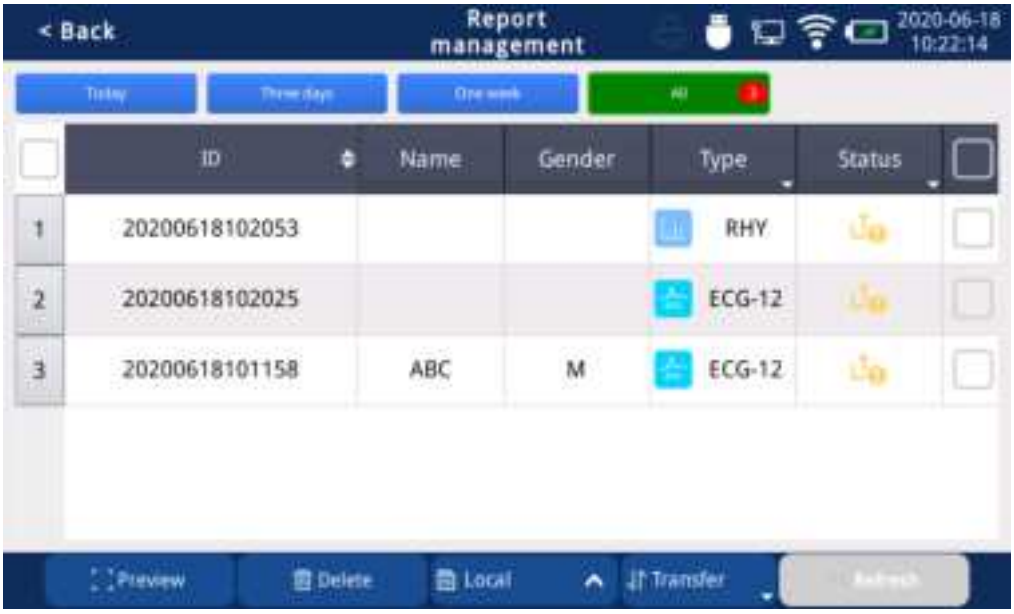


Fig. 2.11 Report Management Interface

2.3.4 Application Interface

On Waveform Acquisition interface, directly click the key “5 Menu” to enter the Application Interface.

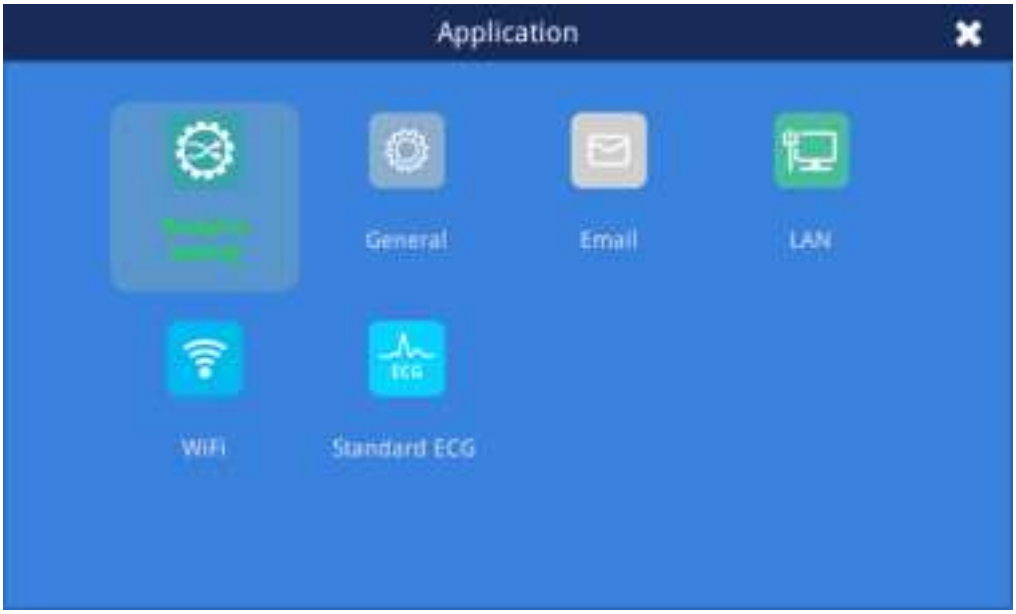


Fig. 2.12 Application Interface

Chapter 3 Installation

3.1 Preparation for Installation

CAUTION

- *This device shall be installed by the personnel authorized by the manufacturer.*
- *Don't open the device cover. Otherwise there might be risk of electrical shock. Only the service personnel authorized and trained by the manufacturer can maintain or update the device.*
- *This device includes software protected by copyright and international laws, all right reserved to the manufacturer, No part of the device may be modified, reproduced or transmitted in any form or by any means, without prior written permission from the manufacturer.*
- *All the analog digital devices connected to this device must be approved by the designated standard (such as EN 60601-1 Safety of Medical Electrical Equipment). And all equipment must be connected in accordance with the valid version of the system standard IEC60601-1-1. The person who is in charge of connecting the additional devices to the input and output signal ports shall be responsible for whether the system conforms to the standard IEC60601-1-1 or not. For any questions, please contact the manufacturer.*
- *When this device and another electrical device are connected into a conjunction with certain function, if it cannot be determined whether this conjunction is hazardous (for example, electrical shock caused by leakage current crowding) or not in terms of each device's specification, please contact the manufacturer or related experts in hospitals in order to guarantee that safety of all devices will not be breached.*

3.1.1 Open-package Inspection

Before opening the package box, carefully inspect it. If any damage is found, please contact the shipping company immediately.

Please open the package in a correct way. Carefully remove the device and other components from the box and check them one by one per the packing list. Check whether the device is damaged mechanically, or the goods are complete. For any questions, please contact the manufacturer immediately.

WARNING

- *Keep packaging materials out of reach of children. When dispose of the packaging materials, please follow local laws and regulations or regime of medical waste disposal in local hospitals.*
- *The device may be contaminated by microbes during storage, transportation and usage. Please verify that the package is intact before use, especially disposable accessories. If any damage is found, please stop using.*

CAUTION

- *Well keep the packaging boxes and materials for future shipment or storage.*

3.1.2 Environment Requirements

This device must be used in an environment complying with environment specifications in this manual.

- *Reasonably avoid using the device in the presence of noise, vibration, dust, corrosive or flammable and explosive substances. If the device is installed in a box, please make sure that the front and back space is enough for operation, maintenance and service. In order to allow unimpeded air circulation for a good cooling effect, at least 5cm space should be saved around the device*
- *During the process of device movement from one environment to another, it might cause condensation due to differences in temperature or humidity. At this moment, you can use it until the condensation disappears.*

WARNING

- *Please ensure that the device works under required specified environment. Otherwise it will not comply with the technical specifications alleged in this manual, which may lead to unpredictable consequences (damaging the device, etc.).*
- *Do not use the device in oxygen-rich environment, or the presence of flammable or explosive substances (anesthetics, etc.) in case of fire or explosion.*
- *Electromagnetic fields can affect the performance of this unit. Therefore other devices used in the vicinity of the unit must comply with EMC requirements. Mobile phone, X-ray or MRI equipment are potential interference sources, because they could emit electromagnetic radiation of high intensity.*
- *Power plug is used to separate the ECG circuit from power mains. Do not put the ECG machine in a place where is difficult to handle the plug.*
- *Be sure to connect the AC power cord to a hospital-grade three-core socket with a ground wire to guarantee reliable grounding*
- *Before the unit is connected to the AC power, please verify that the power's voltage and frequency comply with its label or the requirements specified in this manual.*

CAUTION

- *If strong electromagnetic radiation exists in surroundings, it will produce different levels of interference to the ECG machine. Please make sure there are no high-voltage lines and heavy-load power cables passing-by near the unit and patient bed.*
- *While examining the patient, prevent irrelevant individuals from contacting the machine or the patient in case that interference affects the interpretations.*

3.2 Power Selection

This ECG machine can work by 100V-240V AC power or lithium-ion rechargeable battery power.

3.2.1 Connecting to the AC Power

Plug one end of accompanying three-core power cord into the power jack at the back of the machine, and the other end into the three-core socket with a grounding cable, then the AC input light is on, which indicates that AC power has been connected.

WARNING

- *Use the dedicated adapter power cord provided by the manufacturer only. If the power cord is damaged, please contact the manufacturer to buy a new one for replacement.*
- *If proper grounding cannot be guaranteed, you shall operate the device with the built-in rechargeable battery. Otherwise it may incur electrical shock to the patient and operator.*

3.2.2 Battery Power

The ECG machine has a built-in rechargeable lithium battery pack that can be used to power the unit during transport or when AC power is not available. For battery use and maintenance, please refer to the related contents in *Section 9.3* of this manual.

WARNING

- *Make sure that the ECG machine is powered by dedicated rechargeable battery. Before use, please refer to the contents in Section 9.3 of this manual. Safe and proper use of the battery shall be guaranteed to prevent current leakage, heat or explosion.*
- *Battery replacement shall be carried out by the manufacturer authorized service engineer. For battery replacement, please contact the service engineer authorized by the manufacturer.*

CAUTION

- *To prevent data loss caused by accidental AC power interruption, a battery must always be installed in ECG machine.*
- *Whenever the unit is connected to AC power and AC power is on, the battery is being charged. Therefore, it is recommended that the unit remain connected to AC power when not in use. This will ensure a fully-charged battery whenever it is needed.*

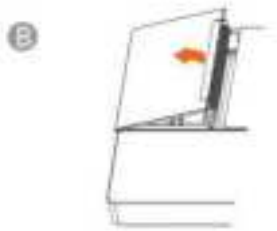
3.3 Installing the Recording Paper

This ECG machine is designed to use Roll or Zip-fold thermal recording paper of 80mm in width.

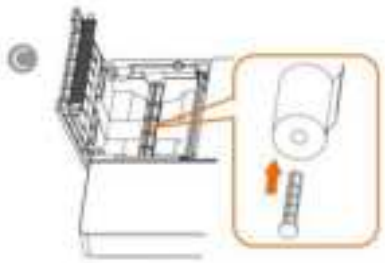
1. Steps of installing Roll paper:

A. Press the printer door switch on the left side of ECG machine;

B. Open the printer door;



C. Take out paper roll and fit in new paper, please verify that the printing side(or grid side) faces to printer head;



D. Put roll paper into paper warehouse, and verify that both sides are located in warehouse groove. Open the starting point of paper;

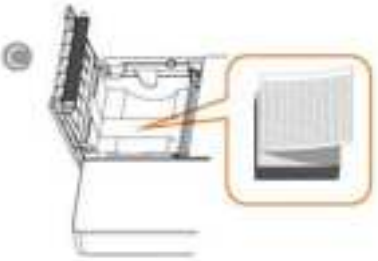
E. Close the printer door.

2. Steps of installing Folding paper:

A. Press the printer door switch on the left side of ECG machine;

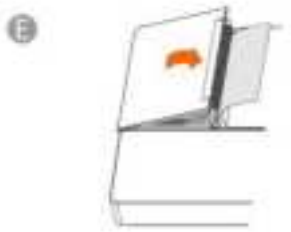
B. Open the printer door switch;

C. Put the folding paper on the plastic pull-tab, please verify that the printing side (or grid side) faces to printer head;



D. Unfold the first page of the folding paper;

E. Close the printer door.



- *The black-marked end of recording paper should stay close to the black-marked detecting end of the recorder.*
- *The grid side of recording paper should face up to the printer head.*
- *The end page of recording paper is marked red. Make sure it is placed on the bottom.*
- *Recording paper should be placed above the plastic pull tab.*
- *Place the recording paper naturally while installing. Keep the lower edge of recording paper close to that of the printer door. Don't center it deliberately.*
- *When close the printer door, parallel the vertical grid line of recording paper to the tearing margin as possible in case of the paper jam caused by huge placement deviation while printing.*
- *Please use the paper recommended by the manufacturer.*

3.4 Connecting the Patient Cable

Correctly connect the ECG cable to the lead connector at the right side of the machine.

Tighten the screws on patient cable connector and attach the cable to the ECG machine.

The other end of the cable shall be connected to the patient via electrodes. For more details, please refer to *Chapter 5*.

CAUTION

- *Please use the dedicated patient cable configured by the manufacturer. If the cable is damaged, please contact the manufacturer in time to purchase a new one for replacement.*

3.5 Power on

3.5.1 Checks before Power on

In order to ensure safe examination and stable printout of electrocardiogram, you are required to make the above-mentioned checks before operating of the ECG machine.

- Checks on Operation Environment

Verify that the ground wire is well connected, the ground bolt is tight, and ground wire and its connector are properly connected.

Operation environment of the machine should be free of X-ray equipment, short wave devices, and the like, which may impose interference on the ECG machine. The machine shall be operated in warm indoors (room temperature should be no less than 18℃) so as to avoid myoelectric interference caused by coldness.

Verify that the power cord is properly connected, and disentangled with other cables.

- Checks on Power Supply

When the machine is to operate on AC power, please check whether the power voltage is the same as local voltage used and whether the power cord is firmly connected with the machine. Please use a properly grounded AC outlet. If a battery is used, please check whether it is fully charged.

- Checks on Patient Cable

Check whether the patient cable is firmly connected with the ECG machine.

Verify that the patient cable plugs are correctly and reliably connected with related electrodes.

- Checks on Recording Paper

Verify that recording paper is sufficient and properly installed.

CAUTION

- *If the device is damaged or does not work, it cannot be used to acquire and record the patient ECG. Please contact the service personnel or the manufacturer immediately.*

3.5.2 Power on

After installation and checks, connect the power cable and turn on the ECG machine, then start to acquire and record the patient's ECG.

3.6 ECG Machine Setting

There are some settings need to be done for the first time use, such as time, report storage modes etc. During ECG waveform acquisition and measurement, you need to set such parameters as recording modes, printing duration, gain, paper speed, filter etc. For more details, please refer to *Section 2.3* and *Chapter 4*.

3.7 Power Off

Please follow the steps below to power off the ECG machine:

1) Verify that the patient ECG acquisition and recording can be ended.

2) Disconnect the ECG electrodes with the patient.

3) Press the power switch to power off the ECG machine.

CAUTION

- *If you cannot shut down the machine normally, or special circumstances arise, please long press the power switch for 10 seconds to force a shutdown. Forced shutdown may incur ECG data loss, thus not recommended usually except in special circumstances.*

Chapter 4 System Application

4.1 Enter into main menu

In waveform acquiring interface, press “ 

”to enter into system application interface. Please refer to chapter 2.3.4 for system application interface layout. By pressing the arrow button of “  ” and “  ”to confirm the target option.(Operation requires the combination use of arrow button and confirm button)

4.1.1 Button operation method

- Press “ 

” while in waveform acquiring interface to enter into system application interface
- Press the arrow button of “  ” to shift options of application interface, then press “  ” to enter into next interface
- Press the arrow button of “  ” to shift the options of the interface, then press“  ” to confirm the option. After setting completing, move the cursor to “  ”at the top right corner of the screen and then press “  ”to exit the current interface and enter into system application interface, the repetitive operation will enter into waveform acquiring interface.

  Or press “  ”at the input board to enter into system application interface, the repetitive operation will enter into waveform acquiring interface.

4.1.2 Input method

Under input mode, press “#”to shift input method. When entering digital input, “#”has no function. Press the arrow button of “  ” to choose the needed option or shift the pages; then press the button with corresponding digit to confirm, and press “  ” to delete the input.

4.2 Application interface illustration

4.2.1 Analysis Setting-Standard ECG

Select “  ”, then select Standard ECG to enter standard ECG setting interface.

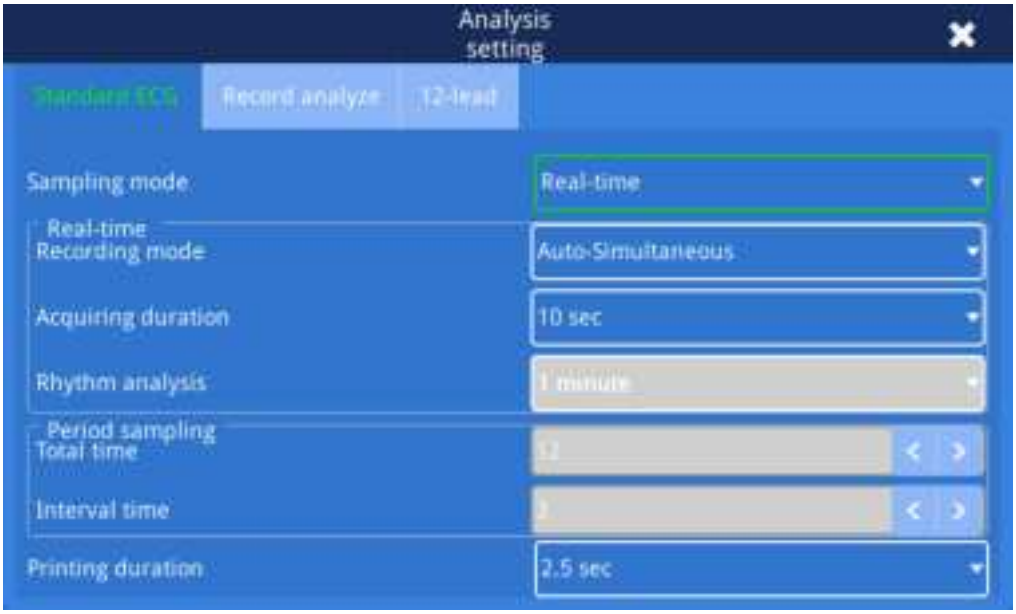


Fig. 4.1 Standard ECG interface

Standard ECG			
Menu	**Menu operation**	**Default**	**illustration**
Sampling mode	Real time Pre-sampling Triggered sampling Periodic sampling	Real time	Real time: Acquiring and measuring ECG signal in real time; Pre sampling: Acquisition starting 10 seconds before recording. Triggered sampling: In triggered sampling mode, acquisition starting 2 seconds before confirmation Periodic interval sampling.

Standard ECG			
Menu	**Menu operation**	**Default**	**illustration**
Real-time sampling	Auto-simultaneous Auto-sequential Manual Rhythm	Auto-simultaneous	Auto: When recording the ECG waveform, the system automatically records each lead according to the sampling time and automatically switches the record; Simultaneous: record the ECG waveform of the 12-lead at the same time; Sequential: The 12-lead is divided into 4 averaging periods according to the record format layout (such as 3×4), and recorded in the lead sequence. The lead recording time of each column is set by the “printing duration” item; Manual: Manually change the recording when recording ECG waveform. Manual recording is only available in real time sampling; External printer is not supported in manual mode; Only sequential recording is available in manual mode; Rhythm: Record a single rhythm lead waveform.
Real time Sampling time	10sec 、 20 sec、30 sec、 40 sec 、 50 sec、60 sec	10sec	Sampling mode: Auto-Sync, Auto-Sequence, time for each lead acquisition
Real time Rhythm analysis	1-5 min	1 min	Single rhythm lead sampling time setting

Standard ECG			
Menu	**Menu operation**	**Default**	**illustration**
Periodic sampling Total time	3-100 min	12 min	Periodic sampling total time setting
Periodic sampling Interval time	3-100 min	3 min	Each sampling period sampling time setting
Printing duration	2.5s、5 s 、7 s、10 s	2.5 sec	Sampling mode: Auto-Sync, Auto-Sequence, time for each lead acquisition

CAUTION

- *When the sampling mode is pre-sampling, triggering sampling or periodic sampling, the recording mode defaults to auto-simultaneous with no auto-sequential option.*

4.2.2 Analysis Setting-Record Analyze

Select “  ”, then select Record analyze to enter into record analyze setting interface.

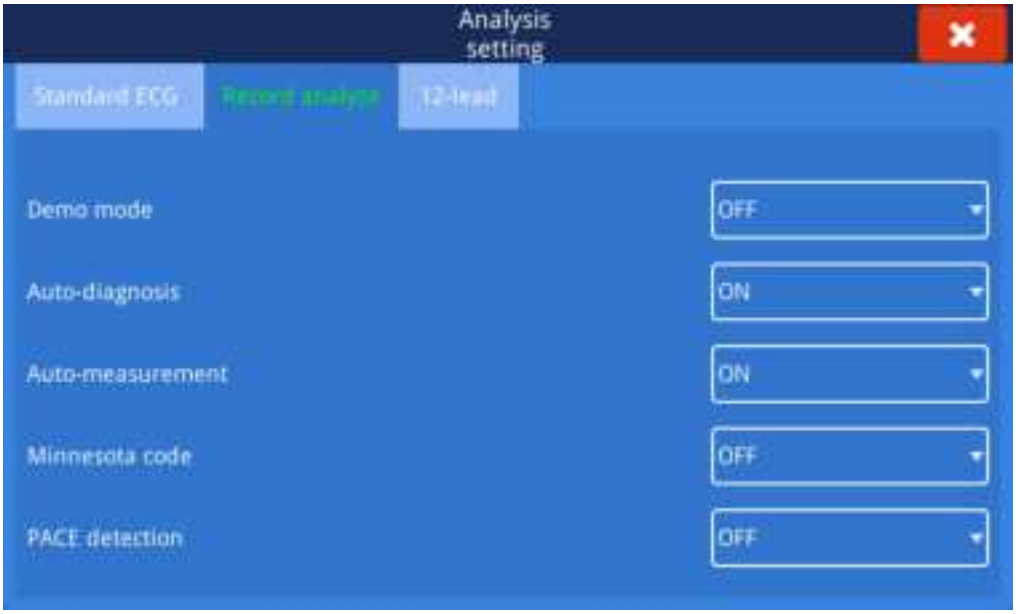
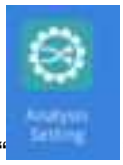


Fig. 4.2 Record analyze interface

Recording analyze			
Menu	**Menu option**	**Default**	**illustration**
Demo mode	Off/On	Off	On/Off demo mode
Auto diagnosis	Off/On	On	On/Off auto diagnosis Under off mode, ECG report does not show diagnosis results
Auto measurement	Off/On	On	On/Off auto diagnosis Under offer mode, ECG report does not show diagnosis parameters
Minnesota code	Off/On	Off	On/Off Minnesota code Under offer mode, Minnesota code cannot be received, ECG report does not show Minnesota code
PACE detection	Off/On	Off	On/Off PACE detection

4.2.3 Analysis Setting-12 lead

Select “  ” option and then select 12 lead, click and enter into setting interface

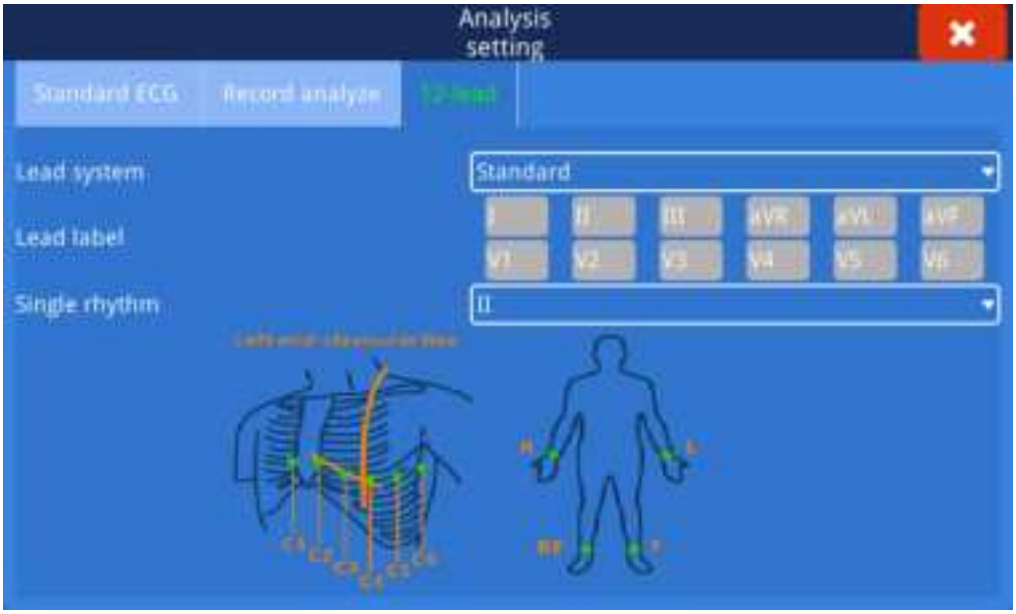


Fig. 4.3 12 lead interface

Lead System	
Menu Item	**Lead Label**
Standard	Ⅰ, Ⅱ, Ⅲ, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Posterior Wall	Ⅰ, Ⅱ, Ⅲ, aVR, aVL, aVF, V1, V2, V3, V7, V8, V9
Right Chest	Ⅰ, Ⅱ, Ⅲ, aVR, aVL, aVF, V1, V2, V3, V3R, V4R, V5R
Right Chest Posterior Wall	Ⅰ, Ⅱ, Ⅲ, aVR, aVL, aVF, V3R, V4R, V5R, V7, V8, V9
Previous Intercostal Space	Ⅰ, Ⅱ, Ⅲ, aVR, aVL, aVF, V`1, V`2, V`3, V`4, V`5, V`6
Next Intercostal Space	Ⅰ, Ⅱ, Ⅲ, aVR, aVL, aVF, V.1, V.2, V.3, V.4, V.5, V.6
CABRERA	aVL, Ⅰ, -aVR, Ⅱ, aVF, Ⅲ, V1, V2, V3, V4, V5, V6
Custom	Ⅰ, Ⅱ, Ⅲ, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6

4.2.4 General-Machine Setting

Fig. 4.4 General-Machine setting interface

Machine setting			
Menu	**Option**	**Default**	**illustration**
Brightness	10~100	70	Adjust display screen backlight intensity
Standby	Off, 5min, 10min, 15min,20min,25min, 30min	Off	Set the time when the ECG machine automatically enters standby mode. If there is no user operation within the set standby time, the ECG machine enters the standby state. When entering standby mode, the screen is turned off. The standby time you set cannot be longer than the automatic shutdown time.
Power off	Off, 5 min, 10 min, 15 min, 20 min, 25 min, 30 min	Off	Set the auto power off time. If the user does not perform any operation during the set auto power off time, the ECG will automatically shut down.

Language	Simplified Chinese, traditional Chinese, English, Ukrainian, Turkish, Russian, French, Portuguese, Spanish, German, Italian, polish, Romanian, Bulgarian, Croatian, Thai, Czech	English	Select the interface language.
Date and time	/	/	Set the date and time of the machine.
Factory settings	Restore Factory settings	/	To restore Factory settings
Burn verification	Burn verification	/	Burn verification is used to verify that the current version is successfully burned.
ECG Workstation (optional)	Support		Support ECG Workstation.

CAUTION

- *Once factory settings are restored, the ECG machine will reboot automatically.*
- *If the ECG machine is not used for a long time or the battery power is seriously low, which leads to shutdown, please confirm whether the system time needs to be reset before use.*

4.2.5 General-Report Setting

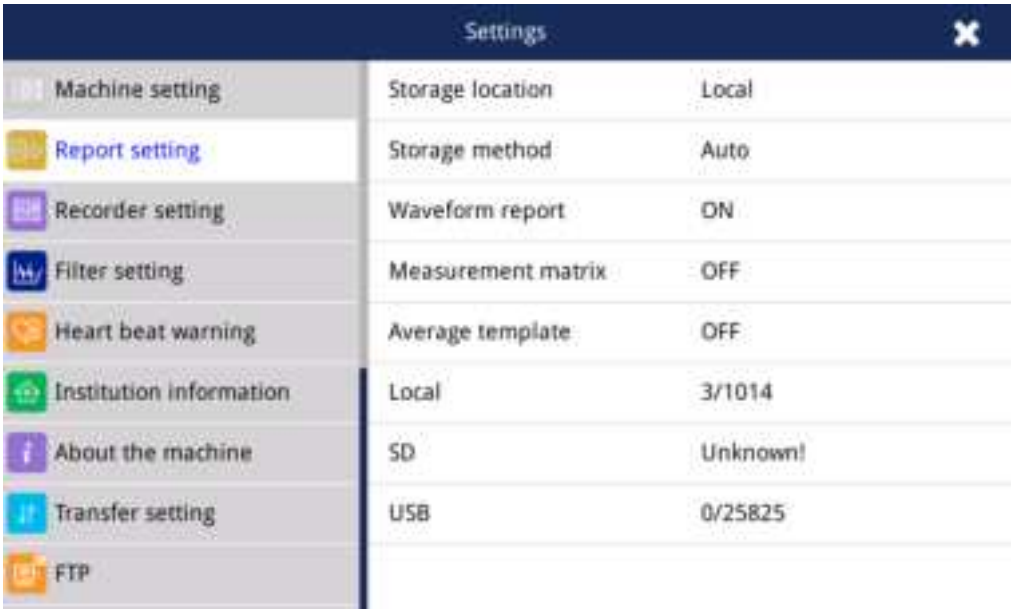


Fig. 4.5 General-Report setting

Report Setting			
Menu Item	**Option**	**Defaults**	**Illustration**
Storage location	Local/ SD / USB	Local	See section 6.3.1 for details.
Storage method	Auto/Manual	Auto	See section 6.3.2 for details.
Report template	On/off	On	After turn on report template, report will show ECG waveform
Measurement matrix	On/off	Off	When turn on Measurement matrix, ECG reports shows Measurement matrix, in printing, horizontal direction shows 12 leads while vertical direction shows the parameter of each lead, including PQRST waveform beginning point, ending point, and interval of P、QRS、T Waveform.

Average template	On/Off	Off	After turn on Average template, ECG report will show ECG Average template (In printing, multiple periodic waveform of each lead will generate one comprehensive single waveform and then print out)
Local/USB/SD Card	/	/	Display storage capacity

CAUTION

- *Under real time sampling mode, the internal printer can only support waveform report*
- *Other sampling model support waveform report, matrix measurement and average template while turning on with internal printer or ECG preview printing*
- *Standard ECG external printing report supports waveform report, matrix measurement and average template whether all turn on or one turn on based on printer model*
- *At least one from waveform report, matrix measurement and average template shall turn on, otherwise, waveform will show as default.*

4.2.6 General-Recorder Setting

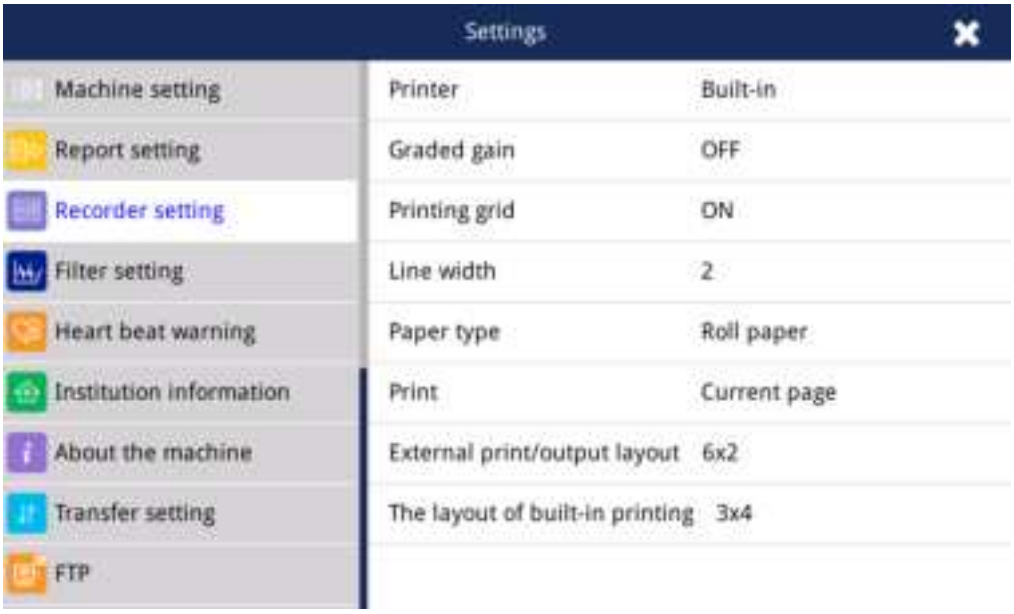


Fig. 4.6 General-Recorder setting

Recorder Setting			
Menu Item	**Options**	**Default Value**	**Illustration**
Printer	Built-in/ external/ paperless	Built-in	In paperless mode, click ECG key, the system will acquire and save ECG waveforms. No matter there is recording paper in the printer or not, it will not print the waveforms.
Graded gain	Off/On	Off	When set to On, the gain amplitude of the first six leads is twice the gain of the last lead. For example, when the gain amplitude is set to 20 mm/mv, the first six-lead gain amplitude is 20 mm/mv, and the last lead

Recorder Setting			
Menu Item	**Options**	**Default Value**	**Illustration**
			amplitude is 10 mm/mv. If the waveform acquisition interface selects automatic gain, the gain amplitude of each lead is automatically assigned.
Printing Grid	Off/On	On	Set the grid when export PDF reports. When it is set “On”, the waveform zone and footer zone will display grid background. When set “Off”, no grid will appear on the report. Printing grid is only available for an External printer.
Line width	1/2/3	2	The width of the waveform line displayed on the thermal paper.
Paper type	Roll/fold paper	Roll paper	Select the appropriate type of printing paper.
Printing	Current page/All	Current page	Preview the contents of the print when it is in built-in printer.
External print/output layout	3×4，3×4+1，6×2，6×2+1，12×1	6×2	Select the lead layout for the external printing

Recorder Setting			
Menu Item	**Options**	**Default Value**	**Illustration**
Supported printer models	/	/	Supported printer models: HP Dest_Jet P1102 /HP Dest_Jet P1108/ HP Dest_Jet P1008（Only support one type choose from waveform report, measurement matrix and average template） LaserJet Pro M202n（support waveform report, measurement matrix and average template） If the report template is multi-selected, the connection only supports external printers that report single-selection, and the waveform report is printed by default.
Built-in print layout	3×4，3×4+1，1×12	3×4	Select the lead layout for the built-in printing

4.2.7 General-Filter Setting

Fig. 4.7 General-Filter setting

Filter setting			
Menu Item	**Options**	**Default Value**	**Illustration**
Baseline drift（Hz）	OFF、0.01、0.05、0.3、0.6	0.6	Select the baseline drift filter (BDR) frequency. Baseline drift filter rejects most of the baseline drift interference and makes the ST segment undistorted. Baseline drift filtering is not performed when set to [Off]. (This filter is high-pass filtering)
AC Filter（Hz）	OFF、50、60	50	Select whether to turn on the AC filter to filter out AC power interference. AC Filter should always be turned on, unless it is necessary to turn it off.

EMG（Hz）	OFF、25、35、45、75、100、150、250、350	35	Set the frequency of EMG. Turning on the EMG filter can filter out EMG interference, but it may reduce the bandwidth and cause the ECG waveform shape to change. The EMG filter is low-pass filtering. Signals with a frequency higher than the set value will be filtered out. When set to 35 Hz, the system only displays signals below 35 Hz and below 35 Hz, and signals beyond 35 Hz will be filtered out.

CAUTION

- *The settings of the baseline drift filter and the EMG filter affect the frequency response range of the electrocardiograph. If the baseline drift filter setting value is too high and the EMG filter setting value is too low, it will affect the accuracy of the ECG machine for waveform restoration. For example, when the baseline drift filter frequency is set to 0.6 Hz and the EMG filter frequency is set to 25 Hz, the system frequency response range is 0.6 Hz to 25 Hz.*

4.2.8 General-Heartbeat Warning

Fig. 4.8 Heartbeat Warning Interface

Heartbeat Warning			
Menu Item	**Options**	**Default Value**	**Illustration**
Bradycardia	40-80	60	Set the bradycardia threshold.
Tachycardia	81-140	100	Set the tachycardia threshold.

4.2.9 General-Institution Information

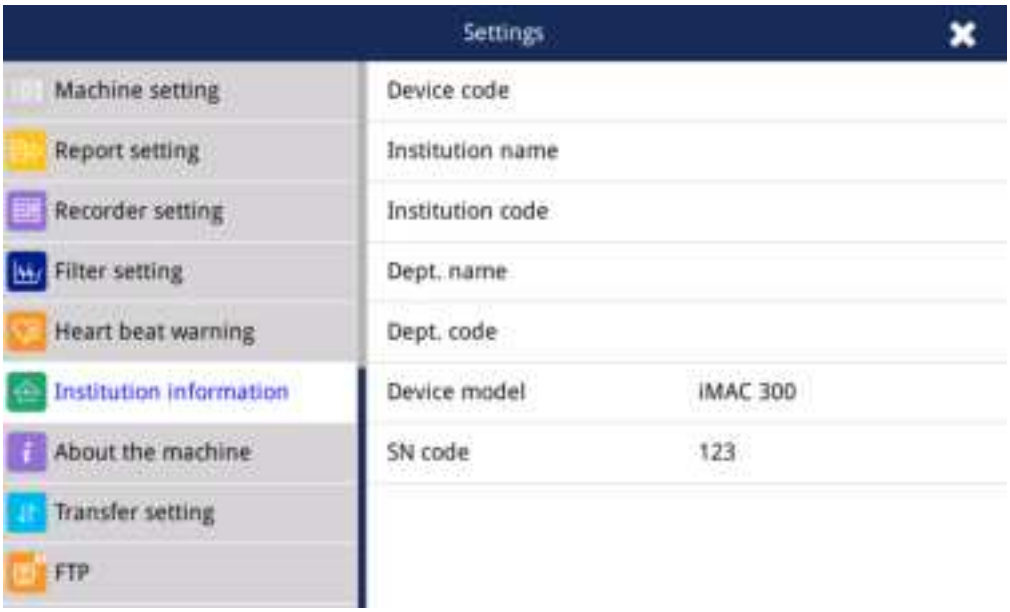


Fig. 4.9 Institution Information Interface

4.2.10 General-About the Machine

Fig. 4.10 About the Machine Interface

4.2.11 General-Transfer Setting

Fig. 4.11 General–Transfer Setting

Transfer Setting			
Menu Item	**Options**	**Default Value**	**Illustration**
Report transmission format	ZQECG、PDF、PNG、JPG、XML、HL7、DICOM-WAVEFORM、DICOM-IMAGE、DICOM-PDF、GDT	ZQECG	Transmission format of ECG file.
Auto transfer	OFF/FTP/SAMBA /HTTP/DICOM	OFF	When it is OFF, you can manually select the ECG report transmission on the [Report Management] interface. When it is on, the report can be transmitted in real time in the FTP/SAMBA/HTTP/DICOM transmission mode when the ECG report is printed and frozen.

			(You should ensure that the network is properly connected and the FTP/SAMBA/HTTP/DICOM transmission mode is successfully enabled) Note: The corresponding button will only be highlighted if the FTP/SAMBA/HTTP/DICOM transfer mode is enabled, otherwise it will be grayed out.

4.2.12 General-FTP setting

Fig. 4.12 General-FTP setting

Transfer Setting			
Menu Item	**Options**	**Default Value**	**Illustration**
FTP setting	Enable, IP address, port number,	OFF	1) The FTP username and password that you set must be the username and password that

	directory, username, password, FTP test		can be logged into the FTP server. 2) The FTP path that you set must be a subdirectory that already exists in the root directory of the FTP server. Note: For more information about the FTP server, please consult your network administrator. 3) After setting, you can click the "FTPTest" button to check if it can be connected. 4) After the test is passed, check the "" button to enable it. (Note: It can only be used in the transmission of the [Report Management] interface after it is enabled.)

4.2.13 General-HTTP setting

Fig. 4.13 General-HTTP setting

Transfer Setting			
Menu Item	**Options**	**Default Value**	**Illustration**
HTTP setting	Enable, IP address, port number, directory, username, password, HTTP test	OFF	1) The HTTP username and password that you set must be the username and password that can be logged into the HTTP server. 2) The HTTP path that you set must be a subdirectory that already exists in the root directory of the HTTP server. Note: For more information about the HTTP server, please consult your network administrator. 3) After setting, you can click the "HTTPTest" button to check if it

			can be connected. 4) After the test is passed, check the “ ” button to enable it. (Note: It can only be used in the transmission of the [Report Management] interface after it is enabled.)

4.2.14 General-Remote diagnosis settings

Fig. 4.14 General-Remote diagnosis settings

Transfer setting			
Menu Item	**Options**	**Default Value**	**Illustration**
Remote diagnosis setting	Enable, IP address, port number, directory, username, password,	OFF	1) The remote diagnosis username and password that you set must be the username and password that can be logged into the remote diagnosis server. 2) The remote diagnosis path

	Reload test		that you set must be a subdirectory that already exists in the root directory of the remote diagnosis server. Note: For more information about the remote diagnosis server, please consult your network administrator. 3) After setting, you can click the "ReloadTest" button to check if it can be connected. 4) After the test is passed, check the "☐" button to enable it. (Note: It can only be used in the transmission of the [Naming Rule] interface after it is enabled.)

4.2.15 General-SAMBA setting

Fig. 4.15 General-SAMBA settings

Transfer Setting			
Menu Item	**Options**	**Default Value**	**Illustration**
SAMBA setting	Enable, IP address, directory, Workgroup username, password, SAMBA test	OFF	1) The SAMBA username and password that you set must be the username and password that can be logged into the SAMBA server. 2) The SAMBA path that you set must be a subdirectory that already exists in the root directory of the SAMBA server. Note: For more information about the SAMBA server, please consult your network administrator. 3) After setting, you can click the "SAMBATest" button to check if it

			can be connected. 4) After the test is passed, check the “ ” button to enable it. (Note: It can only be used in the transmission of the [Report Management] interface after it is enabled.)

4.2.16 General-DICOM (IHE)

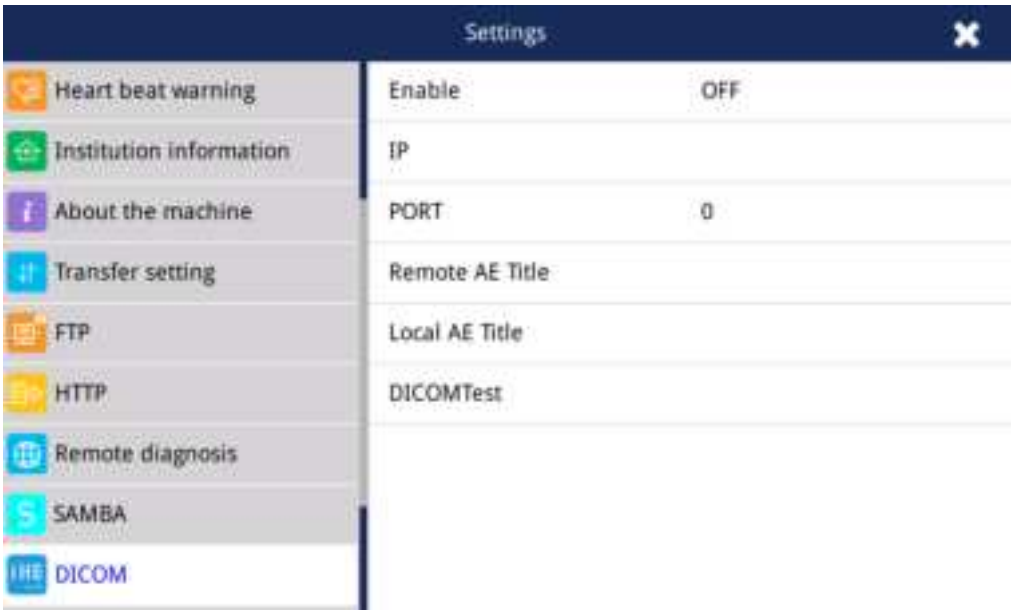


Fig. 4.16 General-DICOM

IHE (Integrating the Healthcare Enterprise) - DICOM SETTING			
Menu Item	**Options**	**Default Value**	**Illustration**
Dicom upload configuration	Enable, IP address, remote port number, remote AE title, local AE title, DICOM test	OFF	The ECG file is uploaded to this server in the "dicom" transfer format. 1) After setting, you can click the “DICOMTest” button to check if it can be connected.

			2) After the test is passed, check the “ ” button to enable it. (Note: It can only be used in the transmission of the [Report Management] interface after it is enabled.)

4.2.17 General-MPPS (IHE)

Fig. 4.17 General-MPPS

IHE (Integrating the Healthcare Enterprise) –MPPS Setting			
Menu Item	**Options**	**Default Value**	**Illustration**
MPPS Server Configuration	Enable, IP address, remote port number, remote AE title, local AE title, DICOM test	OFF	The ECG machine will send three states of acquisition, start the acquisition, complete the acquisition, and cancel the acquisition, to this server. 1) After setting, you can click the “DICOMTest” button to check if it

			can be connected. 2) After the test is passed, check the “ ” button to enable it.

4.2.18 General-STOCOM (IHE)

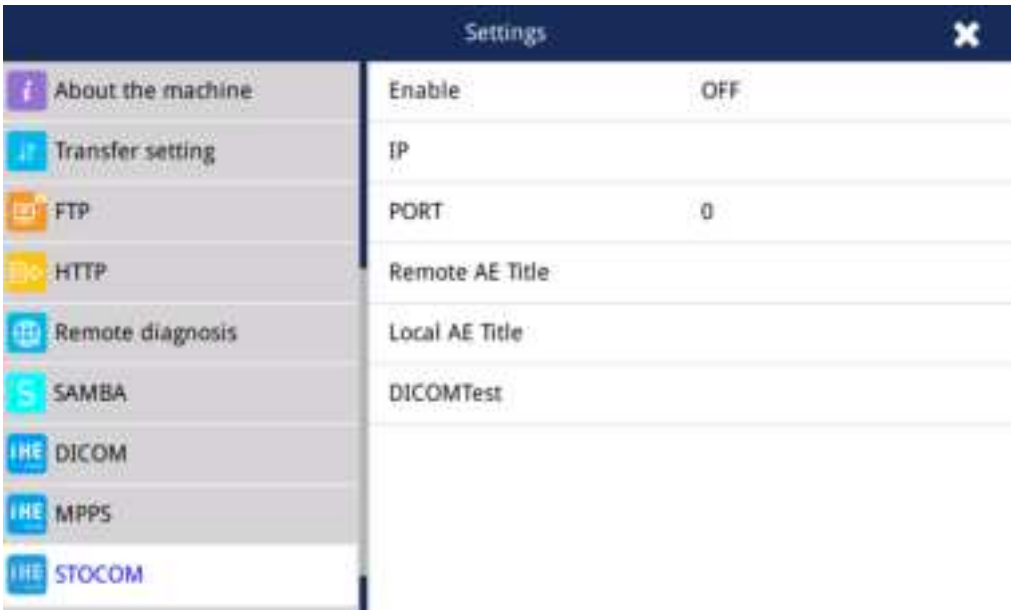


Fig. 4.18 General-STOCOM

IHE (Integrating the Healthcare Enterprise) – STOCOM Setting			
Menu Item	**Options**	**Default Value**	**Illustration**
STOCOM (Storage Server Configuration)	Enable, IP address, remote port number, remote AE title, local AE title, DICOMTest	OFF	A server that confirms whether the ECG file has been uploaded. 1) After setting, you can click the “DICOMTest” button to check if it can be connected. 2) After the test is passed, check the “ ” button to enable it.

4.2.19 General-WORKLIST (IHE)

Fig. 4.19 General-WORKLIST

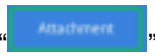
IHE (Integrating the Healthcare Enterprise) – WORKLIST			
Menu Item	**Options**	**Default Value**	**Illustration**
Worklist Server Configuration	Enable, IP address, remote port number, remote AE title, local AE title, Modality, Search, DICOMTest	OFF	The ECG machine imports patient information data from this server. 1) After setting, you can click the "DICOMTest" button to check if it can be connected. 2) After the test is passed, check the "☐" button to enable it.

4.2.20 E-Mail setting

1、 Click the "  " button to open the mail dialog. Note: For more information on configuring your network and interfaces, please consult your network administrator. Use wired Ethernet or WIFI transmission:

1）Manually add the sender, recipient's account number, server address and port number.

2）Select and confirm the appropriate sender, recipient.

3）Click the "  " button to check the files you want to upload.

4）Click the "  " button to send the mail.

2、Recipients can view ECG files in png format by Email.

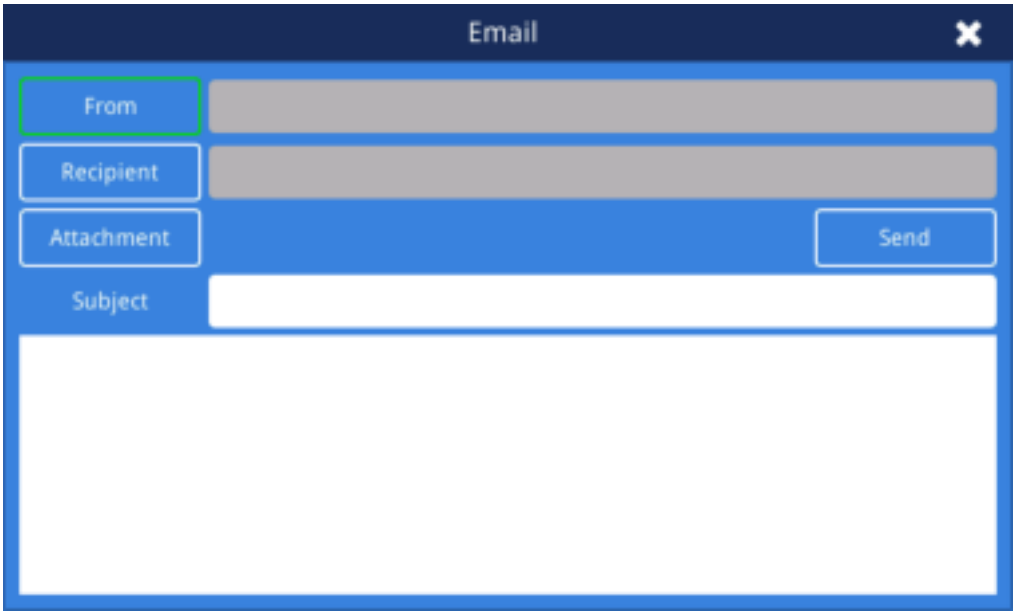


Fig. 4.20 Email Interface

4.2.21 LAN setting

Click the "  " button to open the Wired Settings dialog box to make the appropriate network settings (Note: For details on configuring the network, please consult your network administrator). After setting, click the "  " button to save and take effect. You can automatically obtain the local IP address or manually enter the local IP address.

Fig. 4.21 LAN Interface

4.2.22 WIFI setting

Click the "  " button to open the Wireless Settings dialog box, you can choose to turn WiFi on or off. Click the "  " button to manually connect hidden WiFi and support WEP encryption type hotspots.

Fig. 4.22 WIFI Interface

4.2.23 Standard ECG setting

Click the " 

" button to enter the waveform acquisition interface.

4.2.23.1 Auto mode

The automatic mode refers to the automatic acquisition and printing of wave forms by the electrocardiograph. It is a common mode of the electrocardiograph and is used for routine electrocardiogram examination. The user simply presses the " 

" button to automatically capture and print the waveform. (Does not include pre-sampling mode).

Specific operation method:

1. In the waveform acquisition interface, set the gain, and paper speed according to actual needs;

2. In the【Recorder Setting】Interface，set the layout according to actual needs;

3. Enter the system application interface, Click the "  "then select【Standard ECG】to enter the [Standard ECG] setting interface, select the auto-simultaneous or auto-sequential recording mode, set the sampling mode, and printing duration;

4. Enter the [12-lead] interface and select the lead system and the single-ratio lead label;

5. According to your own needs, set other parameters, and exit the [Standard ECG] interface after the setting is completed.

6. Click the “ 

” button on the panel to print the automatic mode ECG report.

CAUTION

- *When the ECG signal is just connected or the device receives the overload noise, the waveform will be disordered, the baseline drift is serious, and the signal waveform amplitude may exceed the maximum display width. At this time, wait for the device connection and the patient as well as the waveform to stabilize. Then start measuring and recording.*
- *When the ECG is overloaded or any part of the amplifier is saturated, the ECG machine is in an abnormal working state. At this time, the interface only displays the baseline. In order to obtain accurate measurement results, wait for the device connection and the patient as well as the waveform to stabilize. Then start measuring and recording.*
- *If the waveform becomes cluttered or unstable during the patient's ECG signal acquisition, see Chapter 8.*

4.2.23.2 Manual mode

Manual mode means that the user can manually control the duration of the ECG machine to collect and print the ECG. It is generally used by the user to collect and print ECG waveform of any length according to clinical needs.

Specific operation method:

1. In the waveform acquisition interface, set the gain, and paper speed according to actual needs;

2. In the 【Recorder Setting】Interface，set the layout according to actual needs;

3. Enter the system application interface, Click the “  ”then select 【Standard ECG】to enter the [Standard ECG] setting interface, select the auto-simultaneous or manual recording mode;

4. Enter the [12-lead] interface and select the lead system and the single-ratio lead label;

5. According to your own needs, set other parameters, and exit the [Standard ECG] interface after the setting is completed.

6. Click the “  ”button on the panel to print the manual mode ECG report.

Caution：Manual mode does not support external printing.

Fig. 4.23 Manual mode waveform acquisition Interface

4.2.23.3 Rhythm mode

The rhythm mode is for user to collect and print a single lead for a long time to observe and capture sporadic or frequent arrhythmia.

Specific operation method:

1. Enter the system application interface, Click the “ ”then select【Standard ECG】to enter the [Standard ECG] setting interface, select the real-time sampling mode, rhythm recording mode and rhythm analysis time;

2. Click the “ 9 Lead ” button and select rhythm lead label. Or enter the [12-lead] interface and select the single-ratio lead label;

3. After setting, click the “ 8 Rhythm ” button on the screen, the sampling time countdown will appear. A complete rhythm waveform will be recorded after the countdown ends. During the recording process, press the “ 8 Rhythm ” button to stop recording if necessary.

4. Click the “ ECG ” button on the panel, and the sampling time countdown will appear. A complete rhythm waveform will be printed after the countdown ends. During the recording process, press the “ ECG ” button to stop recording or stop printing the rhythm analysis report if necessary.

Fig. 4.24 Rhythm Analysis waveform acquisition Interface

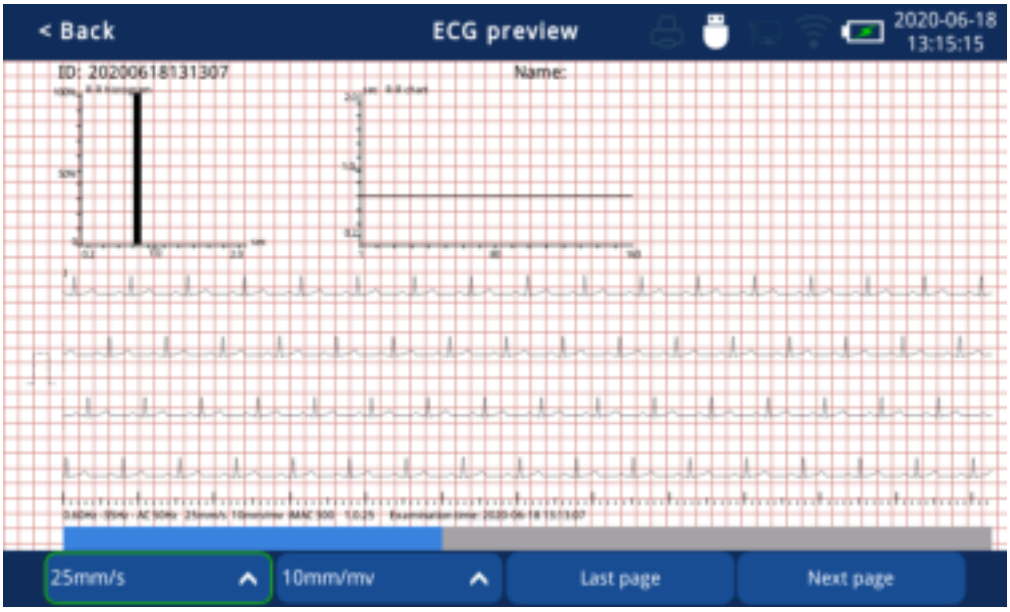


Fig. 4.25 2 minute rhythm analysis report Interface

4.3 Machine Setting

4.3.1 First Time Setup

When using the ECG for the first time or use it after repair or update, be sure to check and improve the following settings:

- Fill in the relevant device information in [Institution Information] for the convenience of centralized management and maintenance.
- Set the date and time in [Machine Settings] to ensure accurate date and time for the convenience of patient number generation and report management.
- Set the backlight brightness in [Machine Setting].
- Set the standby time in [Machine Setting]
- Set the language type in [Machine Setting].
- Set the report save location and save mode in [Report Setting].

CAUTION

- *When the equipment is repaired or upgraded, the equipment settings will usually be restored to the factory values and need to be reset at that time.*

4.3.2 Setup before Use

When using the ECG for the first time or use it after repair or update, be sure to check and improve the following settings:

In the [12-lead] interface, select the lead system and the single rhythm lead label;

In the [General-Filter Setting] setting interface, set the filter frequency;

In the waveform acquisition interface, set the layout, gain, and paper speed according to actual needs;

In the [Standard ECG] setting interface, select sampling mode, printing time, freezing time and other parameters according to actual needs.

CAUTION

- *In the measurement, the paper speed, gain, layout, etc. can be quickly set by the real-time shortcut key. For details, see section 2.3.*

Chapter 5 Connecting ECG Cable

- *During defibrillation, don't touch the patient, electrodes, patient cable and lead terminals. Otherwise it may result in serious injury or death.*
- *For a pacemaker patient, ECG machine may interpret and record the pacemaker pulse as the QRS complex wave. Please carefully inspect the ECG waveform recorded by ECG machine.*
- *For a pacemaker patient, pacemaker detection should be activated when set the machine. Please refer to Section 4.2.2 for details.*
- *Please verify that all electrodes are connected to the correct sites on patient body. Avoid electrodes (including neutral electrodes) and the patient contacting the ground or any other electric conductors.*
- *As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.*
- *Suction ball of chest electrodes contains natural rubber, which may cause allergy. Please pay close attention to the skin placed with electrodes, if allergy occurs, please change other types of electrodes.*
- *Automatic measurement and diagnosis are for the doctors' reference only, and cannot be directly used as the basis for clinical treatment.*

5.1 Environmental Requirements

- It is required to keep warm indoors in winter, and the room temperature is no lower than 18 ℃ so as to avoid EMG interference caused by coldness. In summer, open the air conditioner to control room temperature and to prevent insecure placement of electrodes cause by the patient's sweating.
- AC power outlet must be connected with dedicated and reliable ground wire. .
- When place the ECG machine, try to keep its power cord away from the patient's bed and patient cable. Do not place other appliances or power cord near the bed.

- The patient's bed should be of suitable size to ensure that the patient can naturally lie down, with hands and feet stretching naturally.

5.2 Preparation

To acquire accurate ECG signals, the patient should be explained about the following information.

- Before ECG examination, the patient should not do strenuous exercise, drink alcohol, smoke, have full meal, have tea, have uncooked and cold food.
- Inform the patient of preparation for ECG examination, and make a good explanation to him or her so as to eliminate his or her mental nervousness.
- Before examination, the patient should have a good rest and stay calm.
- During examination, the patient should lie down naturally, relax, and breathe calmly and evenly.
- During examination, the patient should not move or turn over casually, with hands and feet no touching metal objects, such as metals at the bed edges.
- Open the ECG machine to warm it up, and then set its parameters. For startup and system setup, please refer to *Chapter 3* and *Chapter 4*. Power off the ECG machine when connecting the patient cable and electrodes.

5.3 Electrode Selection and Usage

5.3.1 Examinee's Skin Preparation

When environmental factors are correct and the examinee is ready for the exam, place electrodes on examinee body. To obtain accurate ECG signals, properly prepare the examinee's skin to be placed with electrodes.

Remove body hair on intended sites.

Wipe the intended sites with alcohol to degrease and remove dead skin cells.

Dry each site with a dry cotton ball.

5.3.2 Electrode Selection

The ECG machine is equipped with reusable chest bulbs and limb clamps. For your convenience, you can also purchase disposable electrode slices from the manufacturer. Use chest bulbs or disposable electrode slices to connect the chest leads (C1 ~ C6), while use limb clamps or disposable electrode slices to connect the limb leads (R, F, L, RF).

5.3.2.1 Chest Bulb

The chest bulb is composed of suction bulb and metal electrode. There is a connection hole on metal electrode, which is used to connect the lead wire of Φ4.0 mm connector.

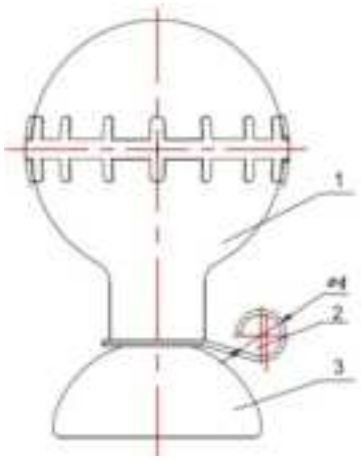


Fig. 5.1 Chest Bulb

1. Suction bulb;
2. Connection hole (Φ4.0mm);
3. Metal electrode;

Placing Chest Electrodes

- Check the chest electrodes, and verify that they are clean;
- Respectively connect 6 chest electrodes with its corresponding lead wire. Straighten out the lead wires, and avoid twisting and twining;
- Unsnap the patient's chest button to expose electrode sites;
- Prepare the skin;
- Apply a thin layer of conductive cream on the surface of electrode sites.
- Evenly apply a thin layer of conductive cream on the edges of chest bulbs,;

- Well place the electrodes: squeeze the chest suction bulb to make the lower edge of the metal electrode tightly connected with the skin. Loosen the bulb to make the electrode adsorbed on the patient's skin;
- Ensure that the ECG machine and its cable, electrodes and lead wires are firmly connected.

5.3.2.2 Limb Clamp

The limb clamp is composed of the clamp and metal electrode. There is a connection hole on the metal electrode, which is used to connect the lead wire of Φ4.0 mm connector.

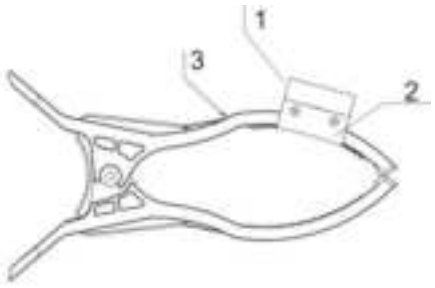


Fig. 5.2 Limb Clamp

1. Connection hole (Φ4.0mm);
2. Metal electrode;
3. Clamp

Placing Limb Clamps

Limb electrodes should be placed above the forearm wrist joint and the calf ankle joint medial to make them closely contact with skin, bypassing the bones.

- Check the electrodes to verify that they are clean,
- The four limb electrodes are respectively connected with the corresponding lead wire. Straighten out the lead wires, and avoid twisting,
- Roll up sleeves and trousers to expose electrode sites.
- Prepare the skin,
- Apply a thin layer of conductive cream on the surface of electrode sites;
- Apply a thin layer of conductive cream on metal electrodes,
- Well place the electrodes: clamp the prepared sites by limb clamps;

- Ensure the ECG machine and its patient cable, the electrodes and the lead wires are firmly connected.

5.3.2.3 Disposable Electrode Slice

Disposable electrode slices are not accompanied with this ECG machine. Please contact the manufacturer or authorized representatives if needed.

Steps of placing disposable electrode slices:

- Roll up the patient's sleeves and trousers, and loosen his or her chest button to expose electrode sites,
- Prepare the skin,
- Attach the electrodes in correct position. Limb electrodes should be placed above the forearm wrist joint and the calf ankle joint medial to make them closely contact the skin, bypassing the bones.
- Straighten out the lead wires, and avoid twisting and twining. Connect the lead wires with electrode slices;
- Ensure the ECG machine and its patient cable, the electrodes and lead wires are firmly connected.

- *Please don't mix up electrodes of different types and brands. Otherwise it may cause large baseline drift or longer baseline recovery after defibrillation.*
- *Disposable electrodes can be used only once, repeated use may result in performance degradation or cross infection.*
- *Reusable electrodes must be cleaned and disinfected before use.*
- *Suction bulb of chest electrode contains natural rubber, which may cause allergy. Please pay close attention to the electrode sites, if allergy occurs, please change another type of electrodes.*
- *If reusable electrodes are damaged after long-term use, please contact our after-sale service in time for purchase and replacement. We receive order of*

electrodes only by set. Old and new electrodes cannot be mixed up.

CAUTION

- *In order to achieve satisfactory ECG recording results, metal electrodes must be closely contacted with the skin evenly.*
- *Metal electrodes must be clean. And the prepared sites contacting metal electrodes must be clean, free of grease and perspiration.*
- *When placing chest electrodes, don't let metal electrodes contact with each other, or the conductive cream zone of adjacent electrodes overlap.*
- *When placing the four limb electrodes, don't injury the patient' hands and feet. After placement, check whether the electrodes are too loose or too tight.*
- *Frequent plugging and unplugging may cause the metal plates of limb electrodes moving or loosening, which need adjustment during use.*
- *Reusable electrodes should be immediately cleaned after each use.*
- *It is not allowed to use different metal electrodes.*

5.4 Electrode Placement

5.4.1 ECG Patient Cable

Contrast Table of Electrodes and Lead Wires:

Placement	Symbol	Color Code
Right Arm	R	Red
Left Arm	L	Yellow
Left Foot	F	Green
Right Foot	RF	Black
Chest	C1	Red
Chest	C2	Yellow

Chest	C3	Green
Chest	C4	Brown
Chest	C5	Black
Chest	C6	Purple

5.4.2 Limb Lead Placement

R ——Right Arm

L ——Left Arm

RF——Right Foot

F ——Left Foot

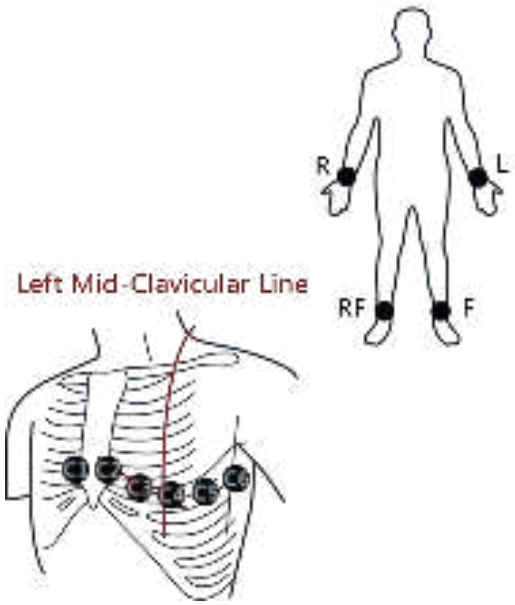


Fig. 5.3 Chest & Limb Lead Electrode Placement

5.4.3 Chest Lead Placement

C1: Fourth intercostal space at the right sternal border.

C2: Fourth intercostal space at the left sternal border

C3: Midway between location C2 and C4.

C4: Left mid-clavicular line in the fifth intercostal space.

C5: Left anterior axillary line on the same horizontal level as C4.

C6: Left mid-axillary line on the same horizontal level as C4.

5.4.4 Pediatric Electrode Placement

When acquiring pediatric ECG, C3 lead should be placed in C4R position rather than the site where standard C3 lead is placed, as shown in right figure.

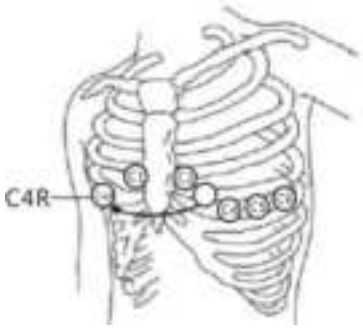


Fig. 5.4 Pediatric Chest Lead Electrode Placement

5.5 Electrode Connection

Plug chest lead wires and limb lead wires respectively into connection holes of the chest electrode bulbs and limb electrode clamps. Adjust the contact sites to guarantee compact connection. Pay attention to the electrode placement.

- *During defibrillation, don't touch the patient, electrodes, patient cable and lead terminals. Otherwise it may lead to serious injury or death.*
- *For a patient with pacemaker, ECG machine may interpret and record the pacemaker pulse as the QRS complex wave. Please inspect the ECG waveform carefully recorded by ECG machine.*
- *For a patient with pacemaker, PACE detection should be activated when setting the machine. Please refer to Section 4.2.2 for details.*
- *Please verify that all electrodes are connected to the correct points on the patient body. Prevent the electrodes (including neutral electrodes) and the patient from contacting the ground or any other electric conductors.*
- *As with all medical equipment, pls clear the patient cabling up carefully to reduce the possibility of entanglement or strangulation.*
- *Suction balls of chest electrodes contain natural rubber, which may cause allergy. Please pay great attention to the skin placed with electrodes, if allergy*

occurs, please change other types of electrodes.

- *Automatic measurement and interpretations are for doctors' reference only, and cannot be directly used as the basis for clinical treatment.*

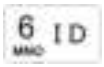
5.6 Electrode Connection

Plug chest lead wires and limb lead wires respectively into connection holes of the chest electrode bulbs and limb electrode clamps. Adjust the contact sites to guarantee compact connection. Pay attention to the electrode placement.

5.7 Lead-off Handling

When the electrode is loose, or the electrode is not properly connected to the lead wire, or the ECG cable is loose from the machine side, the lead name on the ECG display will be red.

5.8 Entering Patient Information

Prior to ECG acquisition, you must verify patient information for better report management. On Waveform Acquisition interface, click 

key to enter Patient Info interface and fill in relevant information as required. For details, please refer to *Section 4.2*.

Chapter 6 ECG Acquisition and Recording

6.1 Acquisition Preparation

To secure the patient and to record stable accurate electrocardiogram (ECG), please carefully check the following items before you power on the machine for measurement.

1）Check whether the exam room is appropriate;

- Whether there are apparatuses such as X-ray machine, ultrasound system and so forth in the patient room, as they may interfere with each other;
- Whether the ground is well connected;
- Whether room temperature and humidity are suitable; temperature would better be in the range of 20 ~ 25℃, ambient humidity would better be in the range of 30% ~ 60%.

2） Whether the power is well connected.

- Whether the power plug is loose;
- Whether the power cord is intertwined;
- Whether the power is sufficient if supplied by battery.

3）Whether the lead wires are well connected.

- Whether the plug is loose;
- Whether the patient cable stays too close to the power cord;
- Whether the lead wires and electrodes are well connected;
- Whether electrodes are installed loosely, or adjacent electrodes have contact with each other.

4）How is the patient?

- Whether the patient is too nervous; whether he or she moves or talks
- Whether the patient’s hands or feet contact metal objects such as bed edges.

5）Whether instruments are in good condition.

- Whether the ECG machine is damaged;
- Whether ECG machine is inspected and maintained regularly:
- Whether recording paper is sufficient.

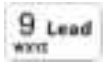
6.2 Acquisition and Recording

6.2.1 Recording Setting

After the checks are all right, power on the ECG machine, it enters into Waveform Acquisition interface, and then you can observe the waveform when they become stable. With reference to *Chapter 4 System Setting* set the sampling mode, layout, gain, and paper speed on actual needs, and then press 

key to print ECG waveform. The system will automatically acquire the waveform and generate the patient report.

On Waveform Acquisition interface, press shortcut keys 

to set paper speed, gain, and filter. In manual mode, press 

key to change leads. For other settings, refer to *Section 4.2.* If the layout is selected with rhythm lead, set it in **[12-lead]**. For details, please refer to *Chapter 4*.

CAUTION

- *When ECG signal is just connected or the machine receives overload noise, waveform will be chaotic, baseline drift will be severe, and waveform amplitude may exceed the maximum width. At this moment, please wait until the machine is connected, the patient calms down, and waveform displayed on the interface become stable, then start measuring and recording.*
- *When the ECG machine is overloaded or any part of the amplifier is saturated, or ECG machine works abnormally, at this moment, only baseline is displayed on the interface. In order to achieve accurate results, please wait until the machine is connected, the patient calms down, and waveform displayed on the interface become stable, then start measuring and recording.*

◆ *During the process of ECG signal acquisition, if waveforms become cluttered or unstable, please refer to chapter 8.*

6.2.2 ECG Report

The following are the reports printed in real-time auto-simultaneous mode:

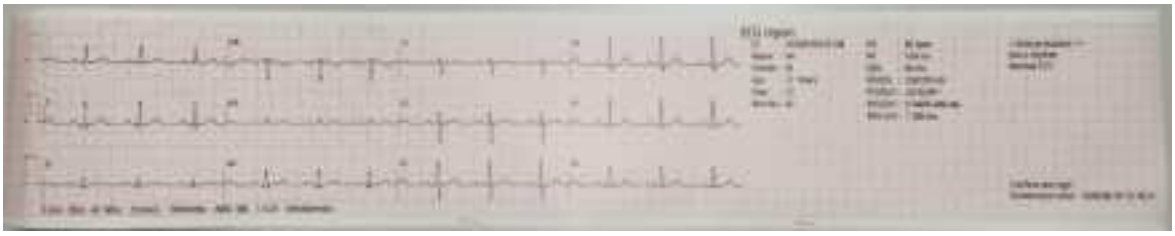


Fig. 6.1 ECG Report (a)

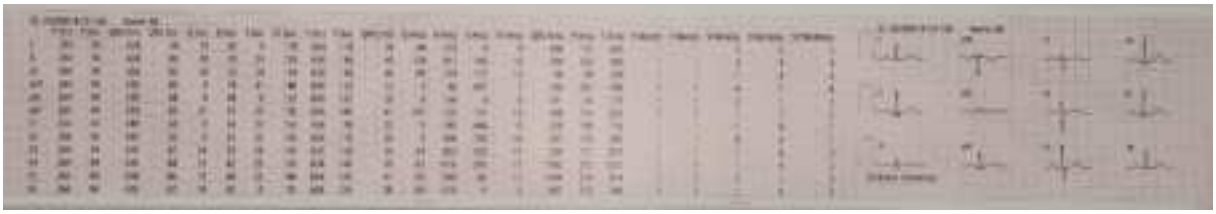


Fig. 6.1 ECG Report （b）

The ECG report above consists of two parts (a) and (b) with a print layout of 3×4.

This ECG report contains the following information:

The ECG waveform 3×4 layout, patient information, date of inspection, and measurement information.

Measurement information:

HR: heart rate

P duration: average value of the P-wave duration of the average heartbeat of each lead

PR interval: average value of the PR interval of the average heartbeat of each lead

QRS duration: average value of the QRS duration of the average heartbeat of each lead

QT/QTc interval: average/normalized value of the QT interval of the average heart beat per lead of each lead

P/QRS/T electric axis: the dominant direction of the average integrated ECG vector on the frontal plane.

RV5/SV1 amplitude: the maximum amplitude of the R and R' waves in the average heart beat on the lead V5 / The maximum value of the absolute amplitude of the S and S' waves in the average heart beat on the lead V1

RV5+SV1 amplitude: RV5 and SV1 sum

Minnesota code (optional) ECG code

Average template (optional): multiple periodic waveform for each lead will be combined into an average of a single periodic waveform

Measurement matrix (optional): the horizontal display shows 12 leads; the vertical display shows the parameters of each lead, such as PQRST wave start and end points, P, QRS, T wave group interval, etc.

The dotted line on the ECG waveform is the position marker, which marks the start and end points of the P wave, the start and end points of the QRS wave, and the T wave end point.

Diagnostic results: the diagnostic results show the results of the automated diagnosis.

Top information; name of medical institution

Bottom information: 0.6~35Hz (0.6Hz baseline drift filter, 35Hz low pass filter)

AC 50Hz (AC filter)

25mm/s (paper feed speed)

10mm/mV (gain)

iMAC 300 (machine model)

1.0.25 (software version)

Simultaneous (recording order)

Inspection date

Confirm report and sign

WARNING

- *Auto-measurement precision of this machine conforms to the measurement standards of ECG machine (refer to the appendixes in this manual). Diagnostic structure is derived from measuring relevant parameters of each band. The interpretations are for physicians' reference only, but cannot be used as the basis of clinical treatment.*

6.2.3 ECG Waveform Description

Standard ECG waveform is shown as follows:

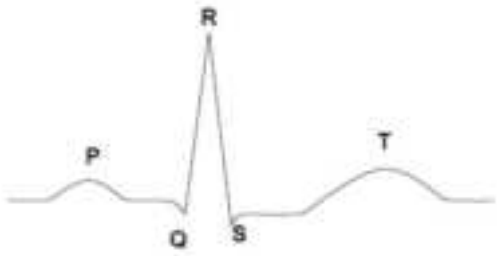


Fig. 6.2 Standard ECG Waveform

Meaning and description of each segment of ECG waveform:

- P wave is of blunt round shape, and its amplitude is lower than T wave's.
- PR interval: time from the start point of P wave to the start point of QRS wave group. It represents the depolarization time from atrial to ventricle. The older the patient is or the slower the heart rate is, the longer PR interval will be. Abnormally-prolonged PR interval indicates atrioventricular conduction disturbance.
- QRS waveform group: it indicates the changes of potential and time during ventricular muscle depolarization. R wave is high and narrow without notch, and its segments are completely above or below the base point.
- S-T segment: a horizontal line from the end point of QRS wave group (J point) to the start point of T wave is called S-T segment. Down deviation of any normal lead's S-T segment should not exceed 0.05mV. When S-T segment's down deviation exceeds the standard range, it is common in myocardial ischemia or strain. Normally, if S-T segment deviates upwards, limb lead and precordia leads of V4-6 should not exceed 0.1mV and precordia leads of V1-3 should not exceed 0.3mV. When S-T segment's up deviation exceeds the standard range, it is common in acute myocardial infarction or pericarditis.
- T wave is of blunt round shape. Its amplitude is lower than 1/3 of R wave's. But it takes longer time. The direction of T wave is usually the same as that of the main wave of QRS wave group. Ⅰ,Ⅱ, V4-6 leads are upright while aVR is upside down. Other leads can be upright, bidirectional or upside down. If V1 is upright, V3 could not be upside down. In the leads of QRS wave group whose main wave is up, when T wave is low and smooth or

upside down, it is common in myocardial ischemia or hypokalemia.

CAUTION

- *Here is a simple description of ECG waveforms. For details, please see relevant references.*

6.3 Report Storage

6.3.1 Report Storage Location

Configure the report storage location in Application→ Convention→ General with options such as Local/SD card/USB.

Local: When sampling time is 10s, and layout is 3×4, you can store no less than 1500 reports.

When sampling time is 2.5s, and layout is 3×4, you can store no less than 2000 reports.

USB (SD card): you can select USB (SD card) only when it is inserted. Reports are stored in .ECG format and can be viewed from this ECG Machine or dedicated software workstation.

CAUTION

- *Local storage has limited capacity, thus* USB *(SD card) is recommended to store the reports.*

6.3.2 Report Storage Mode

Configure the report storage mode with options of Manual / Auto.

Auto Storage

In auto recording mode, after each measurement, the system will automatically store the current report to designated location.

When freezing the ECG waveform, the system will automatically generate the report and store it in designated location.

CAUTION

- *In auto recording mode, the system will store the report only when the measurement is finished. If it stops recording abnormally, the report will not be saved.*

Manual Storage

When the save mode is set to manual, when the recording ends, the system will pop up the "Save the ECG file?" dialog box.

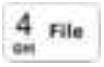
Chapter 7 Report Management

7.1 Report Storage

The report is default to be saved locally, but the local storage capacity is limited. It is recommended to use USB storage. The USB has large storage capacity, which is convenient for category management and storage.

To avoid damage or loss of external storage devices, you can back up the reports in the storage device to a dedicated computer server.

7.2 Report Management

On Waveform Acquisition interface, press 

key to enter Report Management interface, for whose layout, please refer to Section 2.3.3.

7.2.1 Selecting Reports

Ways of selecting reports:

- Select a storage device to view the reports in it.
- Select the direction with “  ”, and confirm with “  ”, or with external keyboard.
- Select all reports on the current page;
- Check the Select All button to select all reports.

7.2.2 Searching Reports

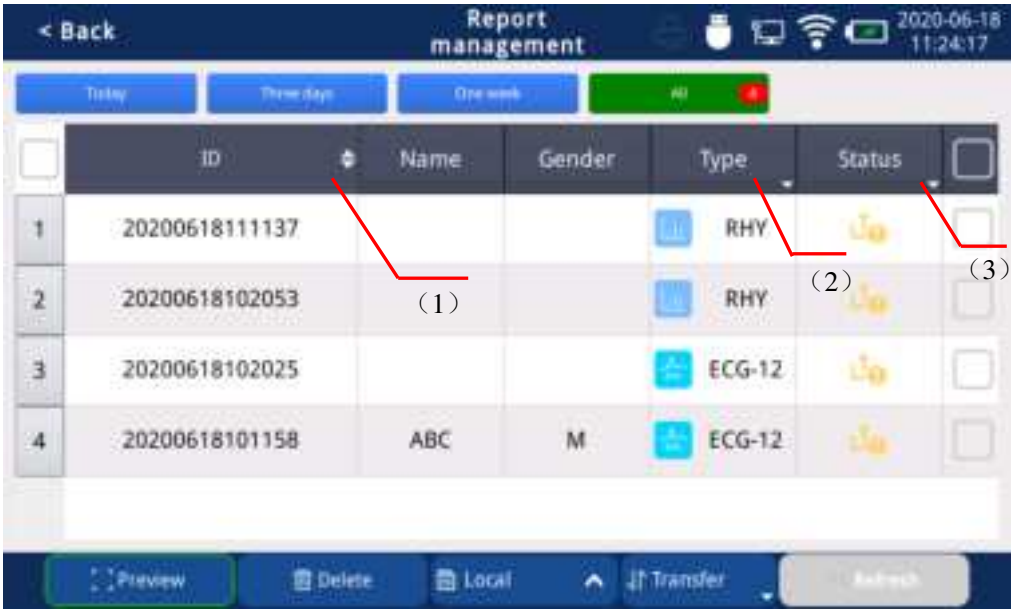


Fig. 7.1 Searching Reports

Searching Reports:

(1) Click the up arrow next to the “ID” button, all reports will be sorted in ascending order by ID number; click the down arrow, all reports will be sorted by ID number in descending order; click the “ID” button, all reports will be sorted in descending order of report modification time.

(2) Click the “Type” button to filter the report by report type. They are: all, standard 12 leads, rhythm, etc.

(3) Click the “Status” button to filter the report by report upload status. They are: all, not uploaded, uploaded, failed to upload, diagnosed, etc.

Operation method：Select the direction with “ ”, and confirm with “ ”, or with external keyboard.

7.2.3 Previewing reports

Choose report with“ Preview , then you can check the all the reports. You can click “ Last Second ”or “ Next Second ” to preview the ECG wave in different time. The preview can only be shown in “6x2”.

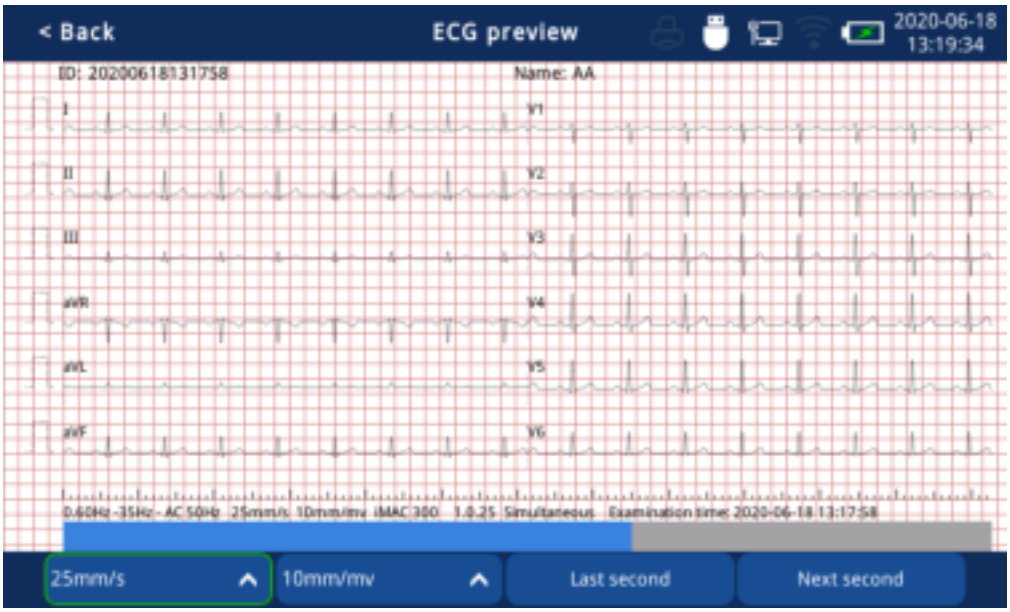


Fig. 7.2 ECG Preview

CAUTION

- *When preview and edit the report, you can select only one report.*

7.2.4 Printing Reports

When previewing a report, you can print it with “ ECG ” key.

CAUTION

- *When previewing and editing the report, you can only select one report.*

7.2.5 Deleting Reports

Select a report and press the key  to delete it.

(1) Check to select all the reports in [Report Management]

(2) Check to select all the reports in the current page.

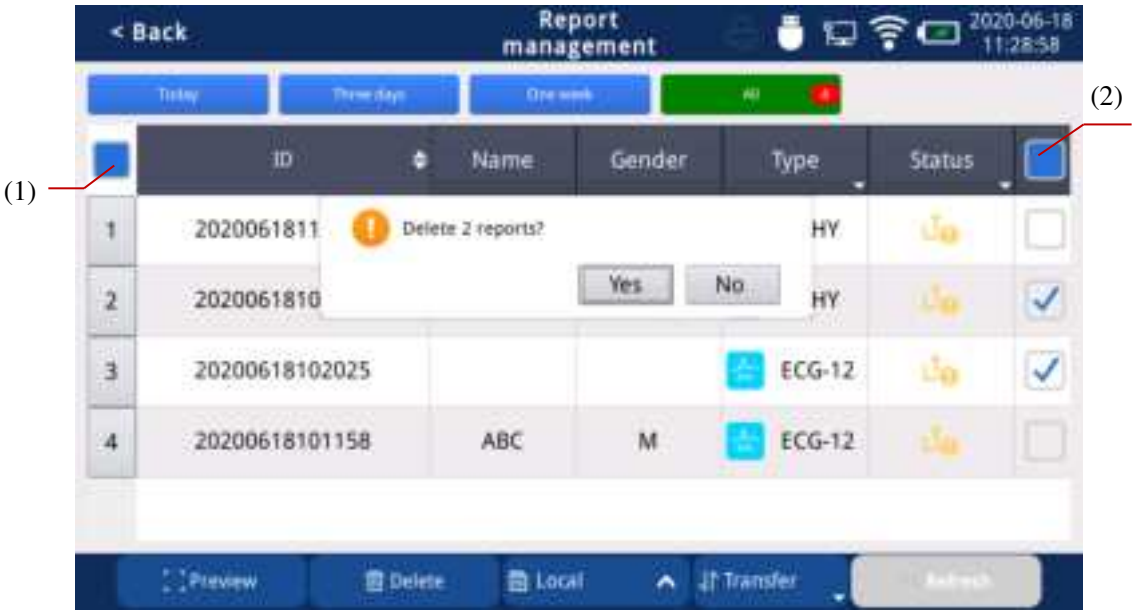


Fig. 7.3 Delete Reports

7.3 Report Transmission

Here are steps of transmitting reports:

1. Click the key  at bottom of Report Management interface.
2. Select a time option (today, three days, one week, all)
3. Select the report to be transmitted
4. Click the “  ” button on the report transmission interface to select the transfer mode (FTP/HTTP/SAMBA/DICOM/USB/SD card/local); (see Chapter 4 The transfer mode FTP/HTTP/SAMBA/DICOM can only be used in the [Report Management] interface transmission after the settings interface is enabled.)
5. Continue to click the “  ” button to complete the report transmission. (Support multi-page PDF transmission. For example, if the report template is set to select all, upload the report PDF document, the first page displays the waveform, the second page displays the

measurement matrix, and the third page displays the average template. The PNG format only supports a single report template options.)

6. Status bar:  means not uploaded;

 means upload successful;

 means upload failed;

 means report reload successful;

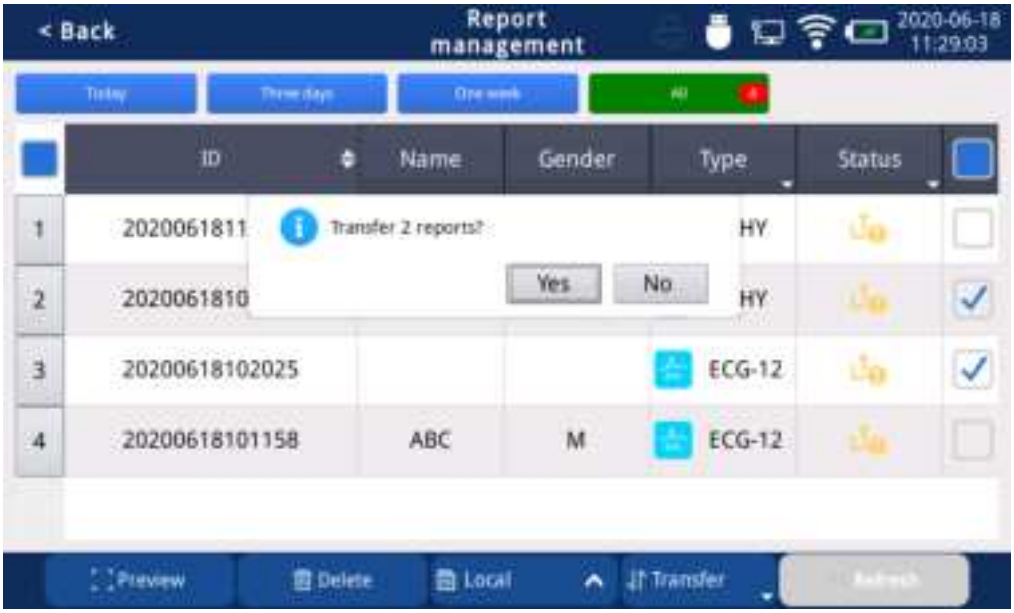


Fig. 7.4 Report Transmission

7.4 Report Refresh

Report brush operation steps:

1) Successfully enable HTTP and remote diagnosis on the [General Settings - Transfer Settings] screen. (For details, see Chapter 4 [General Settings - Transfer Settings]);

2) Select the report that needs to be transmitted;

3) Click the "  " button on the report management interface to select the HTTP transmission mode;

4) Continue to click the "  " button to complete the report transmission.

5) After the remote diagnosis is completed, click the "  " button to return the ECG report after the diagnosis has been updated.

Chapter 8 Troubleshooting

To record a stable and accurate ECG, when a failure occurs, please find out its cause, and solve it with effective solutions.

WARNING

- *ECG machine cover should be opened only by qualified service personnel. There are no user-serviceable parts inside the ECG machine.*

8.1 Interference Problem

During use, ECG machine will inevitably be disturbed by the environment, itself, human static electricity etc. The ECG machine is desired with functions of myoelectric filter, baseline drift filter, and frequency filter. As the filter band is limited, interference signals cannot be filtered out completely. Therefore, please avoid the interferences caused by the environment or non-standard operation during use.

8.1.1 AC Interference

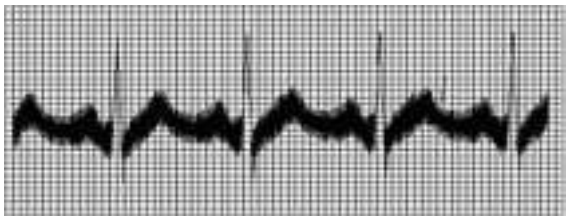


Fig. 8.1 ECG with AC interference

1）Environment Cause:

- Both ECG machine and metal bed are properly grounded.
- Avoid electrical devices of large power working in the vicinity of the ECG machine, such as X-Ray machine or ultrasound instrument etc.

2）Patient Cause:

Inform the patient of no touching the wall or metal bed edges. Don't let other people contact the patient.

3）Electrode Cause:

- Check whether the electrodes or lead wires are connected correctly,

Electrodes and skin are well applied with conductive cream, clean the patient's electrode

sites with medical alcohol, apply conductive cream on the sites evenly, conductive cream on each electrode can't be cross-linked

- Check whether the patient cable is too close to or intertwined with the power cord.
- Check whether the metal part on the connection of lead wire and electrode is rusty or dirty, if it is, please clean it.
- Check whether the patient cable has poor contact, please replace a new cable and try again.

If the interference can't be cleared out by the solutions above, please make sure whether frequency filter is activated.

8.1.2 EMG Interference

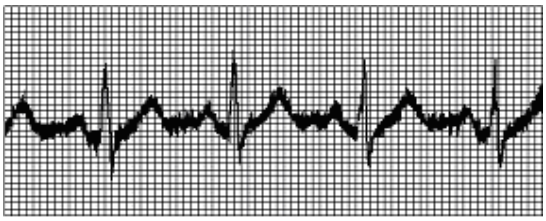


Fig. 8.2 EMG Interference

1）Environment Cause:

- Check whether the exam room is comfortable,
- Check whether the indoor temperature is too low,
- Check whether the bed is small and narrow.

2）Patient Cause:

- Explain to the examinee that ECG examination is very simple, which will not injury his or her body, or have sequelae;
- Make the patient relax physically and mentally, and breathe gently.
- Do not let the patient move or talk.

3）Electrode Cause:

- Check whether limb electrodes are installed too tightly, which makes the patient feel uncomfortable,
- Check the metal part on the connection of the lead wire and electrode is rusty or dirty, if it is, please clean it.

8.1.3 Baseline Drift

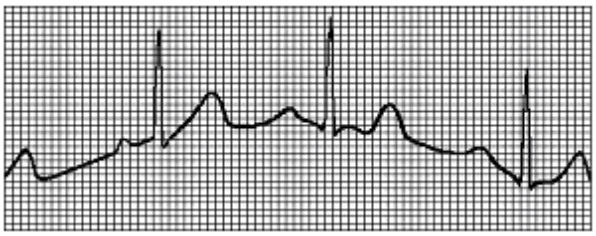


Fig. 8.3 Baseline Drift Waveform Graph

1）Environment Cause:

- Check whether the exam room is comfortable,
- Check whether the indoor temperature is too low,
- Check whether the bed is small and narrow.

2）Patient Cause:

- Explain to the patient that ECG examination is very simple, which will not injury his or her body, or have sequelae;
- Make the patient relax physically and mentally, and breathe gently.
- Let the patient not move or talk.

3）Electrode Cause:

- Check whether limb electrodes are installed too tightly, which makes the patient feel uncomfortable,
- Check whether the electrode is loose or poorly connected.
- Check whether the metal part on the connection of the lead wire and electrode is rusty or dirty.
- Make sure that all electrodes are of the same specification; mixed use of new and old batteries will also cause interference.

If the interference can't be cleared out by the solutions above, please make sure whether frequency filter is activated.

8.2 Recorder Failure

Failure	Possible Cause	Solutions
The paper feeds slowly and unevenly.	As the paper-feeding device has been used for a long time, its transmission ability is degraded by worn gear or loose connector.	Tighten the transmission unit, and apply some lubricating oil on the gear and both ends of paper shaft.
	As the paper-feeding device has been used for a long time, its transmission resistance increases.	Contact our service department for maintenance or replacement.
	The recorder is deformed by external force collision, thus affecting the paper speed.	Contact our service department for maintenance or replacement.
	The paper is out of specification, thus the resistance becomes over-large.	Select and use the specified paper.
	The paper has been installed for a long time, it gets heated or moistened, which makes local viscosity increase, thus affecting the paper speed.	Replace the paper
	ECG machine is not well cleaned and maintained. The recorder's transmission unit is dusty, thus degrading the transmission ability.	Inspect and clean the ECG machine to remove moisture and dust.
The paper doesn't feed, while paper is detected.	The motor is damaged.	Contact our service department for replacement.
	Main control board failure.	Return to depot maintenance.
The printer works with noises but the paper doesn't feed.	Transmission gear is stuck by some hard object.	Clear out the hard object
	Transmission gear teeth are damaged.	Contact our service department for replacement.
It's detected lack of paper.	Recording paper is not well placed or the recorder's printer door is not well closed.	Place the paper again and well close the printer door.
	Paper detector transducer is dusty.	Clear the transducer with Anhydrous ethanol.

Failure	Possible Cause	Solutions
It prints unclear or with breakpoints	Recording paper is out of specification.	Replace it with our paper or with better paper of the same specification.
	Paper shaft is dusty.	Clean the paper shaft.
	Print head is dusty.	Clean the print head.
After pressing "Stop", the recorder still works, but prints nothing.	Recording paper is installed backwards. Black label direction is wrong	Reinstall the recording paper.
	Recording paper is out of specification.	Select the recording paper with black label.
	Black label detection sensor head is dusty.	Clean the transducer head with a cotton swab dipped in medical alcohol.
It prints empty	Recording paper is installed backwards	Properly install the recording paper, with grid side right facing to the print head.

The solutions above can solve common printing failures. If there are still some issues unsolved, please contact our service department, or return the ECG machine to us for maintenance or replacement.

Chapter 9 Maintenance

9.1 Cleaning and Disinfection

Please keep the ECG machine and accessories clean. And in order to avoid damaging the ECG machine, please follow the regulations below:

- Please dilute the cleaner and disinfectant according to the manufacturer's instructions, or use the cleaner and disinfectant whose concentration is as low as possible;
- Please don't submerge the ECG machine into the liquid,
- Please don't pour any liquid on the ECG machine or accessories,
- Please don't allow any liquid to enter the ECG machine,
- Please don't use abrasive materials (such as steel wool or silver polisher), and any strong solvents (such as acetone or acetone detergent).

- *You must turn off the power, and disconnect the power cord and the outlet before cleaning and disinfecting the machine.*

WARNING

- *The ECG machine can be cleaned or disinfected only by the materials and methods listed in this chapter. We will not provide warranty for any damage or accident caused by using other materials or methods;*
- *We will not assume any responsibility for the effectiveness of using the listed chemicals or methods as infection control ways. For ways of infection control, please consult the infection prevention department in hospitals or epidemiologists.*

CAUTION

- *If you accidentally dump liquid onto the equipment or its accessories, cause damage, please contact our service department.*

9.1.1 Cleaning

Available detergents for cleaning the host are listed as follows:

Ethanol (75%)

It is recommended to clean the accessories with 75% ethanol.

Cleaning the host:

The ECG machine should be cleaned regularly. In those areas where the environment is seriously polluted or the sand blows heavily, it should be cleaned more frequently. Please consult or know about the hospital regulations for cleaning the ECG machine before you clean it.

When clean the machine:

- *Turn off the power. Disconnect the power cord, accessories and other devices connected to this ECG machine before cleaning;*
- *Use a soft cotton ball to wipe the LCD screen with some detergents;*
- *Use a soft cloth to clean the surface of the machine with some detergents. Avoid the ports at the sides and rear of the machine;*
- *Wipe off the remaining detergents with a dry cloth if necessary;*
- *Put the machine in a place with cool ventilation to dry it naturally.*

Cleaning ECG cables and lead wires:

- *Please remove the cables from ECG machine before cleaning them and the lead wires.*
- *Use a soft cloth with some 75% ethanol to wipe the surface of the cables and lead wires. Avoid the metal connection parts;*
- *Wipe off the remaining detergent with a dry cloth if necessary;*
- *Put the cables and lead wires in a place with cool ventilation to dry them*

naturally.

Cleaning reusable electrodes:

- *Reusable electrodes must be cleaned after each use.*
- *Use a soft cloth with some 75% ethanol to wipe the surface of the electrodes;*
- *Wipe off the remaining detergent with a dry cloth if necessary;*
- *Put the electrodes in a place with cool ventilation to dry them naturally.*

Cleaning the recorder head:

Stains and dirt on the surface of thermal recorder head will influence the record's definition. Therefore the recorder head should be cleaned regularly (at least once a month). If you find that characters on the report are light or the recorder doesn't work, it indicates that the recorder head needs cleaning.

Please follow the steps below to clean the recorder head:

- *Turn off the ECG machine;*
- *Push the button to open the print door, and take out the paper;*
- *Clear out the stains and dirt on the surface of thermal recorder head with a cotton swab dipped with 75% alcohol;*
- *Dry the recorder head gently with a clean cotton swab;*
- *Dry the recorder head naturally, reinstall the recording paper and close the printer door.*

CAUTION

- *Please don't clean the recorder head immediately after recording as the head might be extremely hot at this time.*

9.1.2 Disinfection

Disinfection may cause some damage to the ECG machine or its accessories. It's recommended to perform disinfection only when it is necessary for the service plan in your hospital. Perform cleaning before disinfection.

The recommended disinfectant for host and accessories is: 75% ethanol.

Please use 75% alcohol cotton ball to wipe the surface of the suction cup when disinfecting the chest electrode. After disinfecting, use soft cotton cloth or cotton ball to clean the residual liquid on the suction cup. Do not use boiling method to clean and disinfect it.

When disinfecting the limb electrode, please use 75% alcohol cotton ball to wipe the inner side of the limb clamp and the surface of the electrode piece. After disinfecting, use soft cotton cloth or cotton ball to clean the residual liquid on the limb clamp. Do not use boiling method to clean and disinfect it.

9.1.3 Sterilization

It is not recommended to sterilize the ECG machine and its accessories unless otherwise required in the manual for accessories.

9.2 Routine Inspection and Test

9.2.1 Daily Inspection

Before the first use each day, the machine appearance should be inspected. Once the ECG machine is found damaged, please stop using it immediately, and contact the engineers in your hospital or our maintainers.

Inspection items include:

- No stain is on ECG machine shell; the panel and LCD screen is not broken or damaged;
- All buttons are in good condition;
- Ports, plugs and cables are not damaged or twined;
- The power cord and ECG cable are firmly and respectively connected with the machine;
- The recording paper is installed correctly, and sufficient for use;

- The battery is installed and fully charged;
- Chest bulbs are free of cracks, and limb clamps clamp well with adequate force.

9.2.2 Regular Inspection

When used continuously for 6 to 12 months, or after maintenance or upgrading, the ECG machine should be tested completely by the qualified service personnel, ensuring that the ECG machine works normally.

Inspection items are listed as follows:

- The environment and power meet the requirements;
- The ECG machine and it accessories are not mechanically damaged;
- The power cord, ECG cable and lead wires are not worn;
- The battery performance is in good condition;
- Function test: used for inspecting the inside of the ECG machine. This test needs to be performed by our professionals or by the authorized personnel under the guidance of our technicians.
- Sensitivity test: measure the (1 ± 1%) mV impulse response at each gain setting, and verify whether the peak deviation is within ± 3 of the ideal value to evaluate the sensitivity.

CAUTION

- *For accidents or equipment damage caused by lack of necessary maintenance, we will not assume any responsibility.*

9.2.3 Test of system error and frequency response

9.2.3.1 System error

The system error is evaluated by the following steps:

a. Set the gain to 10 mm/mV, then apply a 5Hz sinusoidal signal to the appropriate patient electrode connection to obtain a full-scale deflection of 50mm (40mm for those with limited equipment).

b. Measure the amplitude of the input signal and calculate the gain by output/input. The calculated gain must be within ± 5% of the nominal 10mm/mV.

c. Deflect the output of 40mm, 30mm, 20mm, 10mm and 5mm, and repeat steps a and b.

d Repeat steps a, b, and c for all available sensitivities without exceeding an input signal of ± 5mV.

e. The calculated gain value in each test must be within ± 5% or ± 40μV of the nominal value.

9.2.3.2 Frequency and impulse response

For all experiments, the gain was set to 10 mm/mV. The test steps of Method A, Method B and Method C are as follows:

a. Connect the appropriate patient electrode to a 10Hz sinusoidal signal, and then adjust the signal amplitude to get a 10mm (peak-to-valley) output. Without changing the input amplitude, change the signal frequency within the range of 0.01 Hz to 0.67 Hz.

b. At least 10 cycles, verify that the output amplitude is maintained within ± 30% of the amplitude recorded at 10 Hz.

c. Connect the appropriate patient electrode to a 10Hz sinusoidal signal, and then adjust the signal amplitude to obtain a 10mm (peak-to-valley) output. Without changing the input amplitude, the signal frequency can be changed within the range of 0.67 Hz to 40 Hz.

d. At least 10 cycles, verify that the output amplitude is within ± 5% of the amplitude recorded at 10 Hz.

e. Adjust the input amplitude to get a 5mm (peak-valley) output at 10Hz. Without changing the input amplitude, change the signal frequency within the range of 40 Hz to 100 Hz.

f. At least 10 cycles, verify that the output waveform amplitude is within + 5% and -20% of the amplitude recorded at 10 Hz.

g. Adjust the input amplitude to get a 2.5mm (peak-to-valley) output at 10Hz. Without changing the input amplitude, change the signal frequency within the range of 100Hz ~ 150Hz.

h. At least 10 cycles, verify that the output waveform amplitude is maintained within +5% and -30% of the amplitude recorded at 10 Hz.

i. Adjust the input amplitude to get a 5mm (peak-valley) output at 10Hz. Without changing the input amplitude, change the signal frequency within the range of 150Hz ~ 350Hz.

j. At least 10 cycles, verify that the output waveform amplitude remains within + 5% and -30% of the amplitude recorded at 10 Hz.

k. Adjust the input amplitude to get a 5mm (peak-valley) output at 10Hz. Without changing the input amplitude, the signal frequency can be changed within the range of 350 Hz to 500 Hz.

l. At least 10 cycles, verify that the output waveform amplitude is within + 5% and -100% of the amplitude recorded at 10 Hz.

m. Repeat these seven steps for each setting of the lead selector.

CAUTION

- *Due to the asynchrony of sampling characteristics, sampling rate and signal rate, the digital system will produce a perceptible modulation effect from one cycle to the next, especially for children's ECG measurement.*

9.3 Battery Usage & Maintenance

9.3.1 Overview

ECG machine is configured with rechargeable lithium-ion battery so as to ensure that it works normally while moving in the hospital or when the power fails. When the power fails suddenly, the system will automatically enable the battery to supply the ECG machine, thus the machine won't stop working.

CAUTION

- *In order to prevent the machine from working interruption caused by sudden power failure, we suggest the user always install a full-charged battery in it.*
- *When ECG machine is supplied by battery, if the battery is short of power, the machine will crash with black screen. This is a normal phenomenon, which could be eliminated by connection with AC power or charging the battery.*

Battery icons on the screen indicate its status:

Those two icons   indicate that the battery works normally. The white grid shows the power capacity.

This icon  indicates that the battery power is extremely low. When battery power is extremely low, the message “Extremely Low Power” will pop out from the ECG machine. When the battery is nearly exhausted, the message [The battery is low and the machine is about to shut down] will pop out from the ECG machine. At this moment, please immediately connect the machine with AC power to charge the battery. Otherwise the ECG machine will shut down automatically.

9.3.2 Battery Charging

When the ECG machine is connected with AC power, no matter it is turned on or off, the battery will be charged. When the battery is being charged, its light will be lit. Once fully charged, the light will go out

When charging the battery with the ECG machine turned off, in an environment with temperature range of 25℃±5℃, the battery is charged to 90% in no more than 3 hours, and charged to 100% in no more than 3.5 hours. After fully charged, it can work continuously for more than 6 hours.

9.3.3 Battery continuous working time

When the electrocardiograph is only powered by batteries, it can work continuously for 7 hours under the following conditions.

a) The battery is brand new and fully charged;

b) Input a sine wave signal with a peak-to-valley value of 1mV and a frequency of 10Hz without baseline drift into all channels of the electrocardiograph.

c) At standard sensitivity, the signal is continuously recorded electronically at a speed of 25 mm/s.

9.3.4 Battery Replacement

The battery installed in this ECG machine should be replaced by authorized service engineers. Please contact our service engineers if it is demanded for battery replacement.

9.3.5 Battery Usage Guide

The battery's life depends on its usage frequency and time. If the lithium-ion battery is properly maintained and stored, its life will last for about 2 years. If used improperly, its life will be shortened. We recommend replacing the battery every two years.

In order to guarantee the battery's life, please pay attention to the following guidance:

- Battery performance must be inspected once half a year. Besides, you also need to inspect the battery performance before maintenance of the ECG machine or when the battery is suspected to be faulty.
- When the battery has been used or stored for three months or when its working time obviously shortens, perform an optimization on it.
- Before the ECG machine is delivered or when it will not be used for more than 3 months, please take out the battery.
- If the ECG machine has not been used for a long time with the battery installed in it, the battery's life will shorten. The battery should be charged and discharged at least once every three months.
- When the lithium battery is laid aside with 50% of its full power, it can be stored for about 6 months. After 6 months, the battery must be charged again to full power, and then use it to supply ECG machine. When its power reduces to 50% of the full power, take it out of ECG machine and lay it aside again.
- When storing the battery, please make sure that its electrodes do not touch mental objects. If the battery needs to be stored for a long time, put it in a cool environment, which can delay battery aging. Ideally, the battery should be stored in a cool environment whose temperature is 15℃. If the battery is placed in high heat for a long time, its life will obviously shorten. Do not store the battery in the environment whose temperature is not within the range of -20℃～60℃.

CAUTION

- *Put the battery in a place out of children's reach.*
- *Only use the battery designated by the manufacturer.*

9.3.6 Battery Maintenance

Battery Performance Optimization

The battery should be optimized for its initial use. A complete optimization period is continuously charging the battery to full capacity. Then discharge it until the ECG machine is power off. During use, the battery should be optimized annually to sustain its life.

Please optimize the battery by following steps:

1. Disconnect ECG machine with the patient;
2. Connect ECG machine with AC power, continuously charge the battery to its full capacity, and then the indicator light goes out.
3. Disconnect AC power, and supply ECG machine with battery power until it is power off.
4. Connect ECG machine with AC power again, and continuously charge the battery to full capacity, then the light goes out.

CAUTION

- *As the time of using the battery increases, its actual power capacity will decrease. For the used battery, full-capacity icon indicates that neither its power capacity nor supply time could still meet the manufacturer's specification. When optimizing the battery, if you find that its supply time shortens obviously, please replace it.*

Battery Performance Inspection

Battery performance will degrade as times of using the battery increase, thus it should be inspected once a year. Besides, it also needs inspection before servicing the ECG machine or when the battery is suspected to be faulty.

Please inspect the battery performance according to the following steps:

1. Disconnect ECG machine with the patient

2. Connect ECG machine with AC power, and constantly charge the battery to full power, then the light goes out.

3. Disconnect AC power, supply ECG machine by battery until it is power off.

The Battery's supply time reflects its performance. After announced charging time, if its actual supply time is obviously lower than the time declared in specification, please contact the maintainer to replace the battery.

CAUTION

- *If the battery's supply time is too short after fully charged, it might be damaged or faulty. Its supply time depends on configuration and operation of the machine.*

9.3.7 Battery Recycling

If the battery is obviously damaged or cannot be charged, it should be replaced and recycled properly. When disposing of the used battery, please follow relevant laws and regulations.

WARNING

- *Do not disassemble the battery or throw it into fire or short it out. Its burning, explosion or leakage may cause personal injury.*

9.4 Usage and Maintenance of Recording Paper

Please follow the rules below when storing the recording paper：

- Store it in cool dry environment free from high temperature, humidity and direct sunlight.
- Do not put it in fluorescent light for a long time.
- Do not let it contact polyvinyl chloride (PCC), which will cause its color change.
- Do not overly the used paper while storing, which may cause its printout transferring with each other.
- Using the paper provided by the manufacturer or of specification dedicated by the manufacturer. Otherwise it may shorten thermal recorder head's life, recorded waveforms will become fuzzy and the paper will feed poorly.

9.5 Maintenance of Electrodes and Lead Wires

Conduction of each lead wire will directly affect ECG traces. If it conducts poorly (any one lead conducts poorly), it will cause virtual image of corresponding lead wire on ECG traces. Therefore the conduction must be inspected regularly, at least once a month.

Slightly bending or entangling the lead wire will shorten its life. Please put it in as good order as possible before use.

Electrodes must be properly stored. After long-term use, their surfaces may become oxidized and discolored because of corrosion, at this moment, it's better to replace them.

Chapter 10 After-sale Service

1. When users begin to use the ECG machine, they should fill the details in warranty card and send it back to the manufacturer by mail or email in time, the manufacturer will build the users' profiles and regularly contact them to know about the usage, which will help provide targeted first-rate services constantly.

2. During normal use per the manual and operation notes, once the machine breaks down, please contact the manufacturer's after-sale service center immediately. Users can enjoy free service within the stipulated time on warranty card since the purchase day.

3. The manufacturer after-sale service team or local support partners may fulfill its warranty promise by ways of visiting your place, telephone guidance or delivery back to the manufacturer.

4. Even within warranty period, the following services will be charged:

①Fault and damage caused by improper operation of users;

②Fault or damage caused by falling down while moving the machine after purchase;

③Fault and damage caused by repairing, transforming or decomposing the machine without the manufacturer's authorization.

④Fault and damage caused by fire or natural disaster after purchase;

⑤Fault and damage caused by using thermal paper unspecified by the manufacturer;

⑥Fault and damage caused by connection with other devices;

⑦Warranty seal is broken. Users privately alter and replace the serial numbers of the machine and lead wires.

5. The product has failed within three months. If it is not the reason of Article 4, the company will replace the main unit free of charge, but the accessories, wear parts and consumables will not be replaced.

6. The manufacturer will assume no responsibility for failure of other connected devices caused directly or indirectly by this machine's failure.

7. If warranty label is damaged, the manufacturer has rights to exempt free service within stipulated time on warranty card.

8. For chargeable services out of warranty period, it's recommended to continue "Service Contract Rules". For details, please consult the customer service center of the manufacturer.

Chapter 11 Accessories

WARNING

- *Use the accessories stipulated in this manual only. Other accessories may damage this ECG machine or cannot meet the specification declared in this manual.*
- *Disposable accessories can be used only once; Reuse will cause performance degradation or cross infection.*
- *If the accessories or their packages are found damaged, please do not use the accessories.*

Accessories:

Name	Type	Specification
Patient Cable	Pinning defibrillation-proof ECG cable	12 Lead: Φ4 10-pin banana plug wire
Chest Bulbs	ECG chest electrodes(ф4)	Adult: Compatible with diameteΦ4 (IEC) banana plug use; Pediatric: Compatible with diameteΦ4 (IEC) banana plug use.
Limb Electrodes	ECG limb electrodes (ф4)	Adult: Compatible with diameteΦ4 (IEC) banana plug use; Pediatric: Compatible with diameteΦ4 (IEC) banana plug use.
Power Cord	Power cord of European standard	16A 250V

Appendix I

I.1 Performance index

Performance Description	Min/Max	Unit	Min/Max Value
Input Dynamic Range:			
Linear working range of input signal	Min	mV	±5
Slew rate change	Min	mV/s	320
DC bias voltage range	Min	mV	±950
Allowable amplitude variation during DC bias	Max	%	±3
Gain control, accuracy and stability:			
Gain selection	At least	mm/mV	40,20,10,5, 2.5,Auto
Gain error	Max	%	±3
Manual reset of Auto gain control	Inapplicable	Inapplicable	Inapplicable
Gain change rate per minute	Max	%	±0.33
Overall gain change per hour	Max	%	±3
Time benchmark and accuracy			
Time benchmark selection	Min	mm/s	5, 6.25, 10,12.5, 25, 50
Time benchmark error	Max	%	±3
Output display:			

Display width	Min	mm	40
Track visibility (recording rate)	Max	mm/s	1600
Track width (Only for permanent record)	Max	mm	1
Aligned offset of time axis	Max	mm	0.5
	Max	ms	10
Pre-printed paper grids	Min	div/cm	10
Scale error	Max	%	±2
Time mark error	Max	%	±2

Accuracy of rebuilt input signal:

Total error of signals of ±5mV and 125mV/s	Max	%	±5
Frequency and pulse response:	Max	μV	±40
Rated input amplitude 1.0mV, frequency 0.01Hz～0.67Hz, sine wave	Range	%	±30[a]
Rate input amplitude 1.0mV, frequency 0.67Hz～40Hz, sine wave	Range	%	±5[a]
Rated input amplitude 0.5mV, frequency 40Hz～100Hz, sine wave	Range	%	+5,-20[a]
Rated input amplitude 0.25mV, frequency 100Hz～150Hz, sine wave	Range	%	+5,-30[a]
Rated input amplitude 0.5mV, frequency	Range	%	+5,-30[a]

150Hz～350Hz, sine wave Rated input amplitude 0.5mV, frequency 350Hz～500Hz, sine wave	Range	%	+5,-100[a]
Rated input amplitude 1.5mV, ≤1Hz,200ms, triangular wave	Range	%	+0,-10[b]
Lead weighting factor error	Max	%	±5
Lag behind 15mm baseline deflection	Max	Mm	0.5
Response to min signal(At 25mm/s time base and 10mm/mV gain Settings, a visible recording deflection of a minimum 10Hz sinusoidal signal is produced	Max	μV	20
Calibration voltage:			
Rated value	Inapplicable	mV	1.0
Rise time	Max	ms	1
Fall time	Min	s	100
Amplitude Error	Min	%	±2
DC current（arbitrary input lead）	Max	μA	0.1
CMRR	Min	dB	115
System noise:			
RTI，peak-to-valley value	Max	μV	15
Multichannel crosstalk	Max	%	2

Baseline control and stability:			
10s return time after reset	Max	s	3
Return time after lead change	Max	s	1
Baseline stability:			
Baseline drift rate RTI	Max	μV/s	10
Total baseline drift（2min cycle）	Max	μV	500
Overload protection:			
Apply differential voltage, 50Hz, 1V (peak-to-valley value), 10s，no damage	Min	V	1
No damage after discharge of analog defibrillator,			
Overload voltage	Inapplicable	V	5000
Energy	Inapplicable	J	360
Recovery time	Max	s	8
Energy loss of defibrillator impact	Max	%	10
Charge transfer via defibrillator shell	Max	μC	100
Where there is pace-marking pulse, there is visible pace-marking pulse indication:			
Amplitude	Range	mV	2~250
S pulse time	Range	ms	0.1~2.0[b]

Rise time	Max	μs	100
Frequency	Max	Pulses/min	100
Front–end acquisition mode			
Adopting A/D sampling bits	Min	bit	24
Valid sampling	Min	pcs	32000
	Min	Hz	32000
Time deviation of ECG axis channel	Max	μs	0.24
Amplitude quantification	Max	Ms/LSB	0.08

[a] Relative to 10Hz output.

[b] Relative to 200ms output.

I.2 Safety Index

Safety	Class I, type CF, with protective circuit of defibrillation and pace-making
Continuous operation time	more than 8 hours

I.3 Power Specifications

AC Power	100V-240V, 50Hz/60Hz, 75VA
Battery	Rechargeable li-ion battery (10.89V/2600mAh) Working continuously for more than 7 hours

I.4 Appearance Parameters

Size	(L × W × H) 260mm × 180mm × 55mm
Weight	about 1.05 kg(without battery) about 1.2 kg(with battery)

I.5 Environmental Conditions

Operation

Ambient Temperature	+ 5℃～ + 40℃
Ambient Humidity	20%~85%(no condensation)
Atmospheric Pressure	57kpa～106kpa

Shipment and Storage

Ambient Temperature	－20℃～+55℃
Ambient Humidity	10%～95%
Atmospheric Pressure	500hPa～1060hPa

I.6 Adherence to Standards

EN ISO 13485:2016	Medical devices-quality management system-Requirements for regulatory purpose;
EN ISO 14971:2012	Medical devices-Application of risk management to medical devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
ISO10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices-Part 10:Tests for irritation and skin sensitization
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN 60601-1:2006+A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-2-25: 2011	Medical Electrical Equipment - Part 2-25: Particular Requirements For The Basic Safety And Essential Performance of Electrocardiographs;
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance -Collateral standard: Electromagnetic compatibility-Requirements and tests;
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes
EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices
EN 60601-1-6:2010/2015	Medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability

Appendix II Electromagnetic (EMC)

Electromagnetic compatibility (EMC) is defined as the ability of a product, device, or system to function properly in its electromagnetic environment without posing unacceptable electromagnetic disturbances to anything in the environment.

Anti-electromagnetic interference is the ability of a product, device, or system to function properly in the presence of electromagnetic interference (EMI).

It is designed and manufactured in accordance with existing electromagnetic compatibility standards and related requirements. Use in the presence of an electromagnetic field may cause performance degradation such as output anomalies. If this happens frequently, it is recommended to check the environment in which the ECG is used to determine possible sources of disturbance. These harassments may come from other electrical equipment used in the same room or in a nearby room, or from portable and mobile RF communications equipment such as cell phones, walkie-talkies, or from nearby radios, televisions, or microwave transmission equipment. If electromagnetic interference (EMI) interferes with the ECG, it may be necessary to move the ECG to another location or take appropriate electromagnetic interference suppression measures.

This product complies with the requirements of the EMC standard EN 60601-1-2.

WARNING

- *It will not be used for the lead wire and power cord of the electrocardiograph for the electrocardiograph, which may result in an increase in the emission of the electrocardiograph or a decrease in the immunity.*
- *The electrocardiograph should not be used close to or stacked with other equipment. If it must be used close to or stacked, it should be observed that it will function properly in the configuration in which it is used.*

NOTE

- Medical equipment has special precautions for EMC and needs to be installed and used according to the EMC information provided in the documentation

provided with the ECG.

- This section includes information on electromagnetic radiation and immunity to electromagnetic systems. Ensure that the operation of the electrocardiograph meets the conditions specified in the reference information. Operating an electrocardiograph in an environment that does not meet these conditions may degrade the performance of the system.
- To ensure electromagnetic compatibility when installing and using an electrocardiograph, follow the information and warnings contained in this and other sections.

Description

- If you operate and use an electrocardiograph in the electromagnetic environment described in “Anti-Electromagnetic Interference” below, it will work safely and provide the following basic properties:

  1 button works normally;

  2 The host continuously collects signals and displays the waveform and measured value results on the display.

Approved accessories that meet electromagnetic standards

Accessories for electrocardiographs may affect their amount of radiation. The accessories listed in this section have been tested in accordance with international standards when used in electrocardiographs to confirm compliance with radiation standards. Please use only the attachments listed in this section.

When connecting the accessories to the ECG machine, the user should ensure the electromagnetic compatibility of the ECG machine. Unless otherwise stated, use only EMC-compliant equipment.

No.	Name	Cable length (m)	Shielding or Not
1	power cord	1.6	NO
2	Patient cable	< 3.2	NO

WARNING:

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this the iMAC 300 machine could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the iMAC 300 machine, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result

NOTE:

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

Guidance and manufacturer´s declaration – electromagnetic emission –
for all EQUIPMENT AND SYSTEMS

1	**Guidance and manufacturer´s declaration – electromagnetic emission**		
2	The iMAC 300 machine is intended for use in the electromagnetic environment specified below. The customer or the user of iMAC 300 machine should assure that it is used in such an environment.		
3	**Emissions test**	**Compliance**	**Electromagnetic environment - guidance**
4	RF emissions CISPR 11	Group 1	The iMAC 300 machine uses RF energy only for its internal function. There for, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
5	RF emissions CISPR 11	Class A	The iMAC 300 machine 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.
6	Harmonic emissions IEC 61000-3-2	Class A	
7	Voltage fluctuations flicker emissions IEC 61000-3-3	Complies	

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

Guidance and manufacturer´s declaration – electromagnetic immunity			
The iMAC 300 machine is intended for use in the electromagnetic environment specified below. The customer or the user of the iMAC 300 machine 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	± 8air kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply 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	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines	0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles	0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the iMAC 300 machine requires continued operation during power mains interruptions, it is recommended that the iMAC 300 machine be powered

IEC 61000-4-11	Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 250/300 cycle	from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer´s declaration – electromagnetic immunity –
for EQUIPMENT and SYSTEM

Guidance and manufacturer´s declaration – electromagnetic immunity			
The iMAC 300 machine is intended for use in the electromagnetic environment specified below. The customer or the user of the iMAC 300 machine should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the iMAC 300 machine, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF	3 V/m	3 V/m	$d = [\frac{3.5}{V_1}]\sqrt{P}$
IEC 61000-4-6	150 kHz to 80 MHz	150 kHz to 80 MHz	$d = [\frac{12}{V_2}]\sqrt{P}$
	6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	$d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF	3 V/m	3 V/m	$d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.7 GHz
IEC 61000-4-3	80 MHz to 2.7 GHz	80 MHz to 2.7 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).[b]
	385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless	385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a]

	communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	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 is affected by absorption and reflection from structures, objects and people.

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

[b] 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 theiMAC 300 machine is used exceeds the applicable RF compliance level above, the iMAC 300 machine should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the iMAC 300 machine.

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

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

Recommended separation distances between portable and mobile RF communications equipment and the iMAC 300 machine

The iMAC 300 machine is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the iMAC 300 machine can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the iMAC 300 machine as recommended below, according to the maximum output power of the communications equipment

Rated maximum output of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz outside ISM and amateur radio bands $d = [\frac{3.5}{V_1}]\sqrt{P}$	150 kHz to 80 MHz in ISM and amateur radio bands $d = [\frac{12}{V_2}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.20	0.035	0.07
0.1	0.38	0.63	0.11	0.22
1	1.2	2.00	0.35	0.70
10	3.8	6.32	1.10	2.21
100	12	20.00	35	70

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

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

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

Appendix III Environmental Statement

Names and Contents of Hazardous and Noxious Substances:

Name	Hazardous and Noxious Substances or Elements					
	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (CrVI)	PBB	PBDE
Built-in PCB	○	○	○	○	○	○
plug-in board	○	○	○	○	○	○
Metal parts	○	○	○	○	○	○
Shell	○	○	○	○	○	○
Display part	○	○	○	○	○	○
Package	○	○	○	○	○	○
Accessories	○	○	○	○	○	○
○: It indicates that contents of hazardous substances in the all homogeneous materials of the part are below the limits specified in SJ/T 11363-2006 standard.						

⚠ ***CAUTION***	The product and its spare parts should be disposed of in accordance with the local laws and regulations, and shall not be discarded as useless together with household waste.

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