



#### Overview 8

- ◆ Simultaneously 12 leads Acquisition
- ◆ Applicable people: Adult and pediatric
- 13 ◆ Built-in protection against defibrillator
- ◆ 10.4"HD LED Full Touch Screen with standard grid background
- ◆ Sampling Modes:  
Real-time/Pre-sampling/Trigger sampling/ Period sampling
- 4.1 ◆ Manual/Auto/Rhythm Modes
- ◆ 3x4, 3x4+1R, 3x4+3R, 6x2, 6x2+1R, 6x2+3R and 12x1 display and simultaneously printing.
- ◆ Support Multiple Languages
- ◆ Electrode Disconnection Alarm
- 3 ◆ Automatic measurement & analysis
- ◆ Support PACE detection
- ◆ Max 60 s waveform freezing and review function. 4.2
- ◆ 1 min – 5 minutes Rhythm Analysis.
- ◆ ZQECG/PDF/PNG/XML/HL7/DICOM-WAVEFORM/DICOM-IMAGE/DICOM-PDF/GDT format report transfer.
- ◆ Support to connect with scanner, USB mouse, USB keyboard, card reader and so on peripheral products.
- ◆ Support WiFi and LAN cable connecting to the third party ECG network system, like: HIS, EMR and PACS system without ECG workstation.
- 11.5 ◆ Transfer method:  
FTP/HTTP/Samba/DICOM etc.
- ◆ Full alphanumeric capability QWERTY keyboard.

#### Technique Specification

**Sampling rate:** 32000Hz (pcs)

**Pace Sample Rate:** 32000Hz

**Sample frequency of signal analysis and storage:** 1000 samples/second/channel

**Frequency Response:** 0.01 ~ 350Hz

**CMRR:**  $\geq 130\text{dB}$

**Patient Leakage Current:**  $< 10\mu\text{A}$

**Input Circuit:**  $< 50\mu\text{A}$

**RTI, peak-to-valley value:**  $\leq 15\mu\text{V}$

**Sensitivity valve:**  $20\mu\text{V}$

**DC bias voltage range:**  $\pm 950\text{mV}$

**Calibration Voltage:**  $1\text{mV}$

**A/D conversion:** 24 bit

**Input Impedance:**  $\geq 60\text{M}\Omega(10\text{Hz})$

**Sensitivity:** 2.5, 5, 10, 20, 40, Auto mm/mV 7

**Paper Speed:** 5, 6.25, 10, 12.5, 25, 50mm/s 5

6 **Recording Mode:** Thermal array printer  
8 dot/ mm (Vertical), 40 dot/ mm (Horizontal)

**Paper Type:** Z-Fold Paper

**Paper Size:** 210mm/216mm×140mm~20m  
210mm/216mm×150mm (A4)~20m (Option)

**Filter Setting:** AC: off/50/60Hz.

EMG: off/25/35/45/75/100/150/250/350Hz

Baseline Drift: off/0.01/0.05/0.3/0.6Hz

**Heart Rate Range:** 30-350 bpm

**WiFi Security Standards:**

WEP

WPA/WPA2 PSK

WPA2-Enterprise / ieee802.1x

11.1 Compliant to IEEE 802.11b/g/n

#### Physical Specification

**Dimension & weight:**

Equipment: 285mm\*360mm\*94mm 3.7kg

Package: 345mm \*195mm \*430mm 6.2kg

**Monitor:**

10.4 inch(L\*W=21.13cm\*15.85cm,

Diagonal: 26.42cm) HD Color LED.

2 Full Touch Screen

1024\*768 pixel resolution

**Electrical Power:**

AC: 100-240V, 50Hz/60Hz, 120VA 14.1

DC: Built-in rechargeable battery

**Battery Capacity:** 14.52V/5200mAh 14.2

**Continuous Operating:** DC  $\geq 10.5\text{h}$

15

**Recharge time:** The battery is charged to 90% for no more than 3 hours, and charged to 100% for no more than 3.5 hours

**Data Storage:**

12 > 1500 reports(sampling time 10s, 6\*2)  
> 2000 reports(sampling time 2.5s, 6\*2)

#### Environmental Conditions:

Transportation Temperature:  $-20^{\circ}\text{C}\sim+55^{\circ}\text{C}$

Relative Humidity: 10%~95%

Atmospheric Pressure: 500hPa~1060hPa

Operation Temperature:  $+5^{\circ}\text{C}\sim+40^{\circ}\text{C}$

Relative Humidity: 25%~85%

Atmospheric Pressure: 570hPa~1060hPa

#### System Inputs & Outputs

2\*USB2.0/ LAN/ SD Interface

#### Standard Package

16.1 iMAC 120 ECG Machine (with battery)

16.2 Patient Cable

16.3 Chest Electrodes

16.3 Limb Electrodes

16.5 Thermal Printing Paper

Power Cord

Grounding Wire

User Manual

#### Optional Accessories

Series Electrodes

Thermal Printing Paper

SD Memory Card

Lithium Battery

Workstation Software

Trolley

Cable Arm for trolley

Soft bag

Laser Printer

Scanner

Card Reader

16.4 ECG Gel

## Advanced Function

- |  |  |
|--|--|
| ● External laser printer to output the A4 report   | <b>Comply with</b>                               |
| ● Scanner, card reader and other patient information input devices   | <b><i>93/42/EEC As amended by 2007/47/EC</i></b> |
| ● Wireless WiFi function   | EN ISO 13485:2016                                |
| ● DICOM function (Worklist, Storage, MPPS, Storage Commit)   | EN ISO 14971:2012                                |
| ● QTc formula:   | EN ISO 15223-1:2016                              |
| Hodge, Bazett, Fridericia, Framingham  | EN 1041:2008                                     |
| ● Measurement Matrix   | ISO 10993-1:2009                                 |
| ● Average Template   | ISO 10993-5:2009                                 |
| ● R-R histogram, R-R chart   | ISO10993-10:2010                                 |
| ● Bradycardia and Tachycardia range adjustable   | IEC60601-1:2005/A1:2012                          |
| ● Lead System: Standard, Posterior wall, Right chest, Right chest posterior wall, Prev. intercostal space, Next intercostal space, CABRERA, Custom   | EN 60601-1-2:2015                                |
| ● GLASGOW ECG Algorithm can make precise diagnosis according to patient age, gender, racial, taking medicine history, etc., especially for AMI, Ventricular Fibrillation, Ventricular Tachycardia, quarterly Bradycardia, malignant arrhythmia, etc. | IEC 60601-2-25:2011                              |
|  | EN 62304:2006/A1:2015                            |
|  | EN 62366-1:2015                                  |
|  | EN 60601-1-6:2010/A1:2015                        |

## Certificates

### Quality Standards

ISO9001

ISO13485

CE

### NOTE:

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Dec. 2021

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## **Product Information:**

**Name:** Digital Multi-Channel Electrocardiograph Machine

**Type:** iMAC 120

**Manufacturer:** Wuhan Zoncare Bio-medical Electronics Co., Ltd

**Registered Address:** #380, High-tech 2<sup>nd</sup> road, Eastlake high-tech district,  
Wuhan, Hubei, P. R. China

**Manufacture Address:** #380, High-tech 2<sup>nd</sup> road, Eastlake high-tech district,  
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**Production Date:** See the label

**Operating Life:** 10 years

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**Post Code:** 430206

**After-sale Service by:** Wuhan Zoncare Bio-medical Electronics Co., Ltd.

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- All illustrations in this manual are provided as examples only. Depending on system configuration, screens in the manual may differ from the screens on your system.

## **Responsibility of the Manufacturer**

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 device.

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
 <b>WARNING</b>	◆ It indicates a potential hazard or unsafe practice, which, if not avoided, could result in death or serious injury.
 <b>CAUTION</b>	◆ It indicates a potential hazard or unsafe practice, which, if not avoid, could result in moderate or minor injury.
 <b>NOTICE</b>	◆ It indicates a potential hazard or unsafe practice, which, if not avoided, could result in the loss or destruction of property or data. .
	◆ Mandatory to refer to this manual for equipment use.

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# Chapter1 Safety Information and Introduction

## 1.1 Safety Information

### 1.1.1 Hazards

This product does not involve any information of hazard level.

### 1.1.2 Warning

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#### **WARNING**

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- ◆ *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*
-



## **WARNING**

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*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 IEC 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 IEC 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**

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## **CAUTION**

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- ◆ *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
	China Metrology Accreditation		EU authorized representative
	Indoor use		CE Certification
	Refer to this manual for equipment use		Environment-friendly use period
	It indicates this device contains electronic or electrical components that must not be disposed of as unsorted municipal waste but collected separately. Contact an authorized representative of the manufacturer for information concerning the decommissioning of your device.		



## **CAUTION**

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- ◆ *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 Performance**

Power voltage: AC100V-240V ;

Power frequency: 50/60Hz $\pm$ 1Hz , 75VA;

Continuous operation time: more than 10.5 h;

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 32000 Hz/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  $\pm$ 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  $\pm$ 3%;

General safety for the product should conform to IEC 60601-1-2:2012 standard.

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

### **1.3.3 Product Composition**

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

### **1.3.4 Intended Application**

The unit is intended to extract ECG wave group from human body for its morphological and rhythm analysis.

### **1.3.5 Applicable people**

Adult and Children

### **1.3.6 Contraindication**

None

### **1.3.7 Side effects**

No side effects.

### **1.3.8 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.

### **1.3.9 Main Features**

- It adopts high-resolution thermal array printout system, uses thermal Zip fold paper of 216mm or 210mm in width, and records clear accurate ECG waveform and information about lead marks, gain(sensitivity), 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 convenient to interpret the waveform.
- It has man-machine interaction interface, independent full alphanumeric keyboard and full touchscreen. Also it can be connected with mouse and keyboard externally. It operates flexibly and easily, reduces workload, and improves working efficiency.
- Support English input with more complete information;
- Support various file output formats, and meet the needs of clinical information.
- Color LCD display, which can record 12-channel ECG waveform and information.
- Real-time waveform freezing;
- Age grading function;
- External USB disk and SD card are supported to store as many patient reports as possible;
- Standby mode, reduces power consumption and extends LCD life ;
- It is designed according to the safety standard of IEC class I type CF. ECG amplifier is fully floated and has 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 and a perfect battery management and protection system.

### 1.3.10 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 under 2 years old, the interpretations may have deviation.
- When use the unit on a pacemaker patient, please activate the PACE Detection with reference to *Section 2.3.2.2*.



#### **WARNING**

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

### 1.3.11 Safety Standards and Requirements

- Strictly in accordance with IEC 60601-1:2012 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 - Collateralstandard: 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

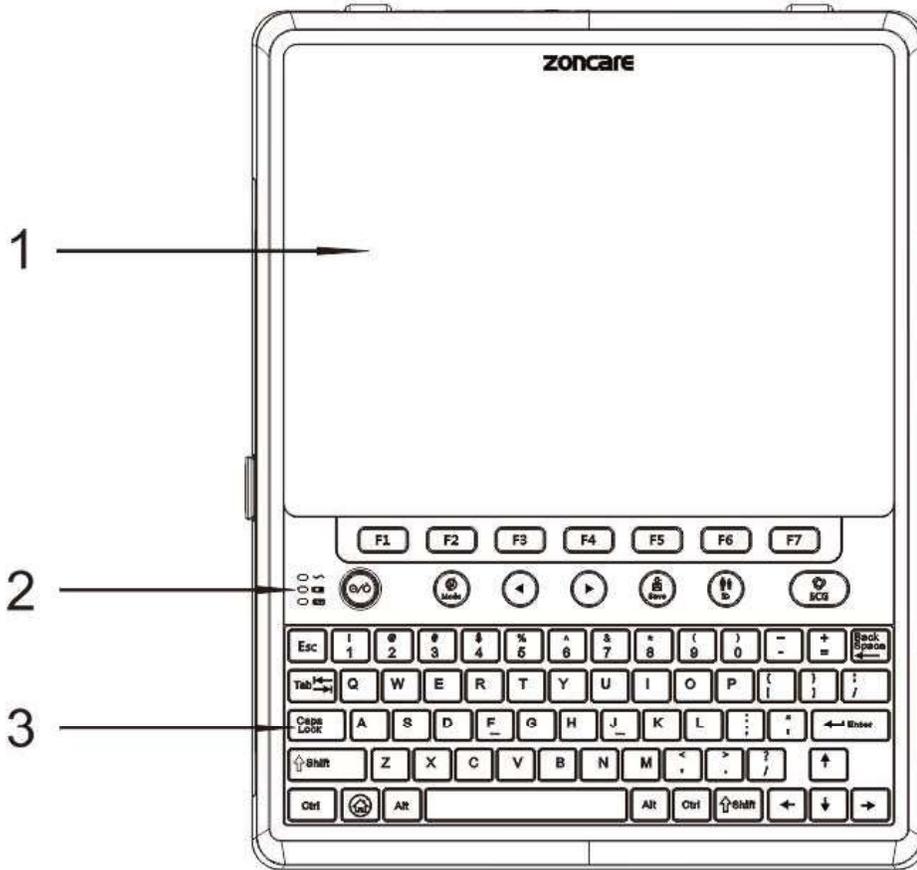


Fig. 2.1 Top View

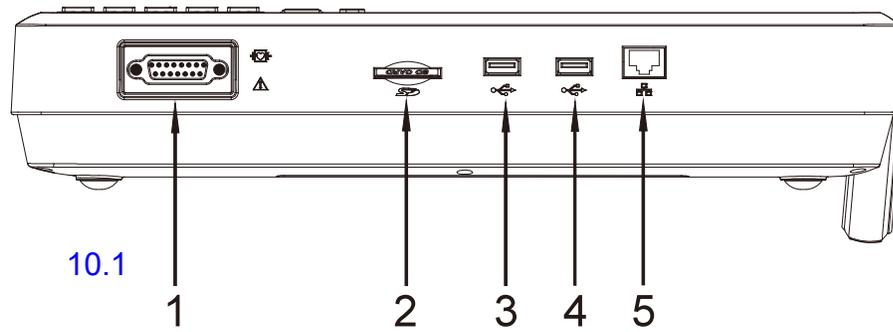
1. Touch Screen: Displaying ECG parameters and waveforms, patient and system information; for more interface information, please see *Section 2.3*.
2. Indicator Light: Indicating power supply status and battery charge status; for details, see the table below.
3. Operation Panel: Operation keys; for details, see the table below.

Identification of Front Panel Keys	
Key	Function
	“ON/OFF”: Provided the unit is powered on, key “ON/OFF” could be used to change its condition between “ON” and “OFF”.

Identification of Front Panel Keys	
Key	Function
F1~F7	Real-time function keys, which correspond to the hotkeys displayed at the bottom of the screen
	“Mode”: For switch over the unit’s operation mode between Automatic and Manual.
	Switching leads in manual mode
	Switching leads in manual mode
	Quickly save the ECG
	“Patient ID”: Provided on Waveform Acquisition interface, key “Patient ID” could be used to quick enter into Patient Info interface.
	“ECG” could be used to print the ECG trace.
Keyboard	Composite keyboard for information input and some function keys

Identification of Front Panel Buttons	
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



10.1

1

2

3

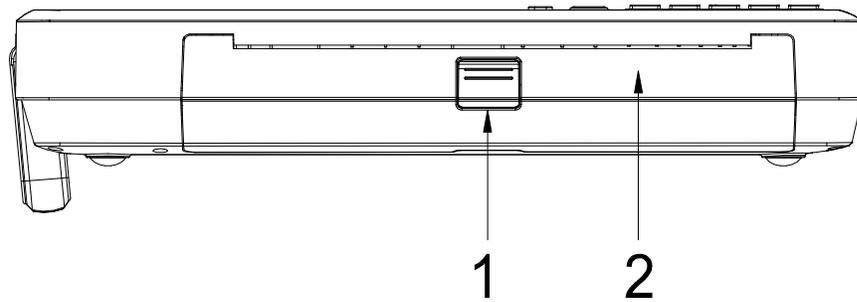
4

5

Fig. 2.2 Right Side View

1. Patient Cable Connector: For connection with the patient cable.
2. SD Card Slot: External SD storage.
3. USB Port: To connect external USB devices.
4. USB Port: To connect external USB devices.
5. LAN Connector: For Network connection.

10.4



1

2

Fig. 2.3 Left Side View

1. Printer Door Switch: Toggle the printer door upwards to open it.
2. Printer Door: To close the printer.

### 2.1.3 Back View

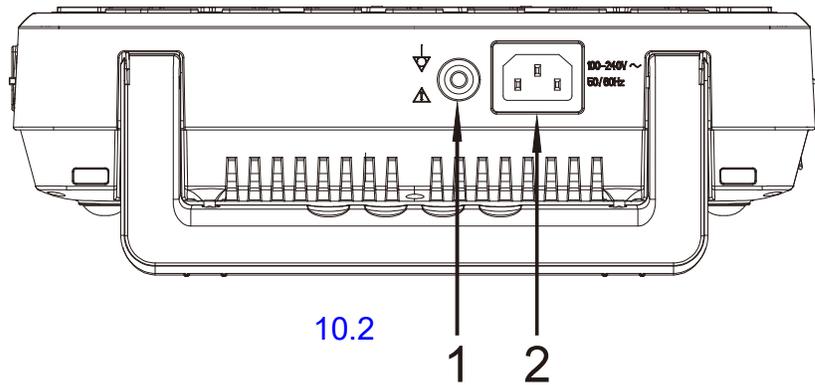


Fig. 2.4 Back View

1 Equipotential terminal: When other equipment is used together with the electrocardiograph, the other equipment and the equipotential terminal of the electrocardiograph should be connected by wires to eliminate the potential difference between different devices to ensure safety.

2 AC power connector: Connect the power cable to provide AC power to the ECG.

### 2.1.4 Bottom View

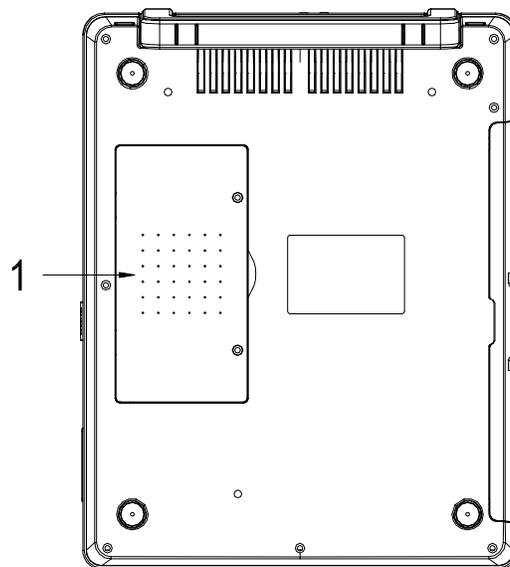


Fig.2.5 Bottom View

Battery Compartment: To contain the battery.

## 2.2 Operation Mode

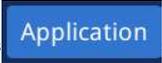
### 2.2.1 Standard Mode

Automatically enters the standard ECG mode after power on. In this mode you can perform ECG measurements, record waveform and measured value results. You can also perform system setup, export data and perform configuration management.

### 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. Directly click “” on Waveform Acquisition interface to enter into Application interface;



2. Click “” to enter the general interface;
3. Select “machine setting”;
4. The display turns off in standby mode, which reduces power consumption and extends display life. Click the “” button in the upper left corner of the screen to return to the system application interface, and continue to click the “” button to return to the normal mode.

### 2.2.3 Demo Mode

In this mode, the ECG can demonstrate features of the machine without connecting the patient cable and accessories. Click the "☰" button in the upper left corner to enter [Record Analyze] → [Demo Mode] → [ON], click the "✕" button to return to enter the demo mode.

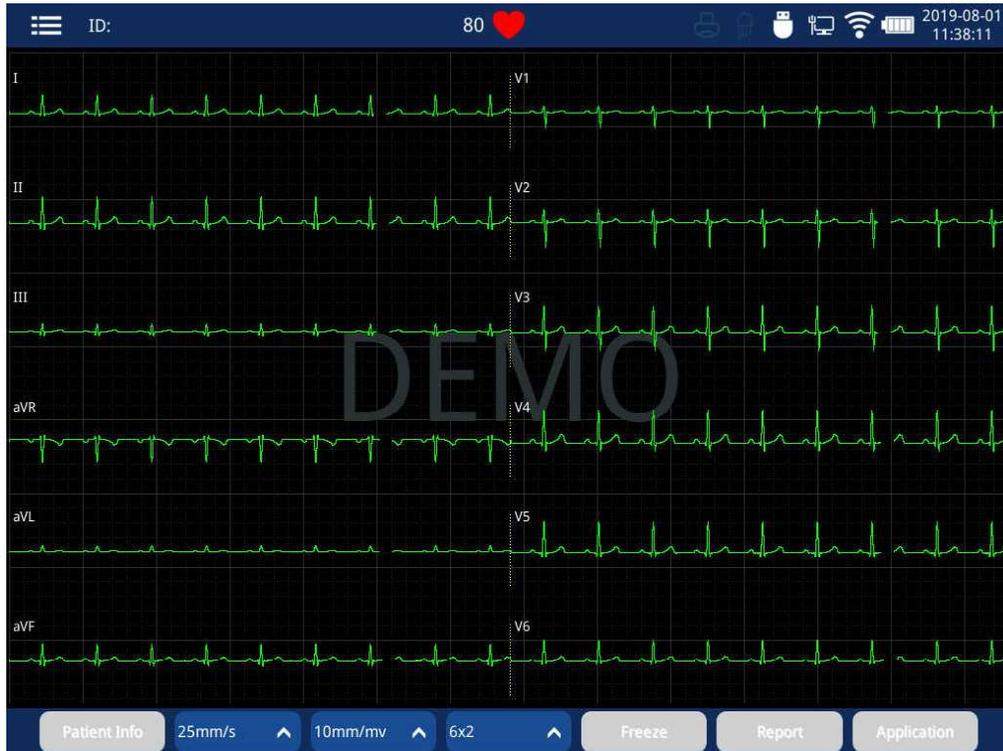


Fig. 2.6 Demo mode

In the demo mode, there are demonstration waveforms for demonstration, which can be printed. Click the "☰" button in the upper left corner to enter [Record Analyze] → Demo Mode → Off. Click the "✕" button to exit the 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 in the upper left corner to enter [Record Analyze] to close the demo mode.
- 

## 2.3 Interface Display

### 2.3.1 Waveform Acquisition Interface

There is locking function in this interface. After pressing the keyboard, press the key combination "CTRL+ALT+L". A lock dialog box will pop up, which can lock the paper feed speed, gain, layout and report printing functions. After locking, the option button is gray; if you need to change the option settings, press the key combination "CTRL+ALT+L" again to unlock the option.

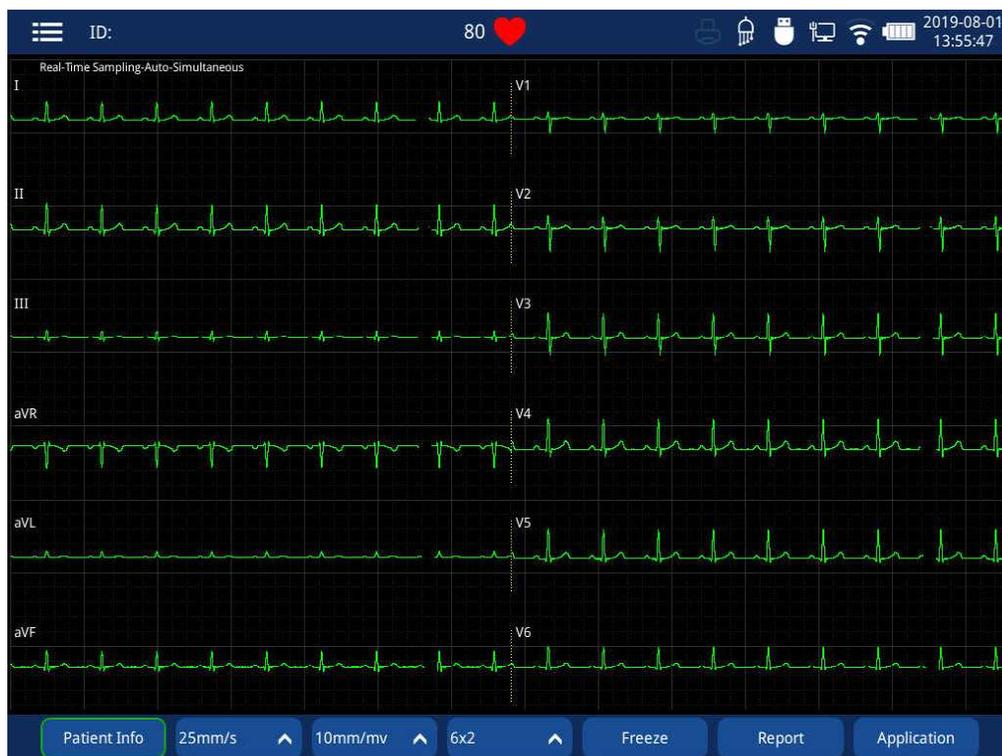
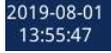


Fig. 2.7 Waveform Acquisition Interface

1 Patient and system information zone :

- a  Mode setting, press it to quickly enter the mode setting dialog window;
- b  Patient ID;
- c  Heart Rate Indication (tachycardia/bradycardia); Click it to quick enter into Heart Rate Indication menu;
- d  External printer indication. The icon being dark indicates that it is not connected;
- e  Lead indication: light-on icon indicates that the patient cable is wellconnected. Click it to quick enter into Lead Indication menu;
- f  Storage information; Click it to quick check the storage device;
- g  LAN connection state; Dark icon indicates network disconnection, click it to set LAN connection;
- h  WIFI connection state; Dark icon indicates network disconnection, click it to set WIFI connection;
- i  Battery Information. The white bar indicates the battery level; Click it to enter Power Management menu;
- j  Time display; Click it and quick set the date and time;

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

3 Hot keys zone: Displaying real-time function keys, which respectively correspond to F1~F7 keys. Each key's function is listed in the table below:

Name	Key	Function Illustration
F1		Enter into Patient Info interface
F2		Change the paper speed
F3		Change the gain amplitude
F4		Change the lead layout
F5		Freeze to generate the report (for details, please see <i>Chapter 6</i> )
F6		Enter into Report Management interface
F7		Enter into Application interface

## 2.3.2 “Standard ECG”, “Record Analyze”, “Lead System” Interface

On Waveform Acquisition interface, click “” at upper left of screen to quick enter into “Standard ECG”, “Record Analyze”, or “Lead System” interface.

### 2.3.2.1 Standard ECG

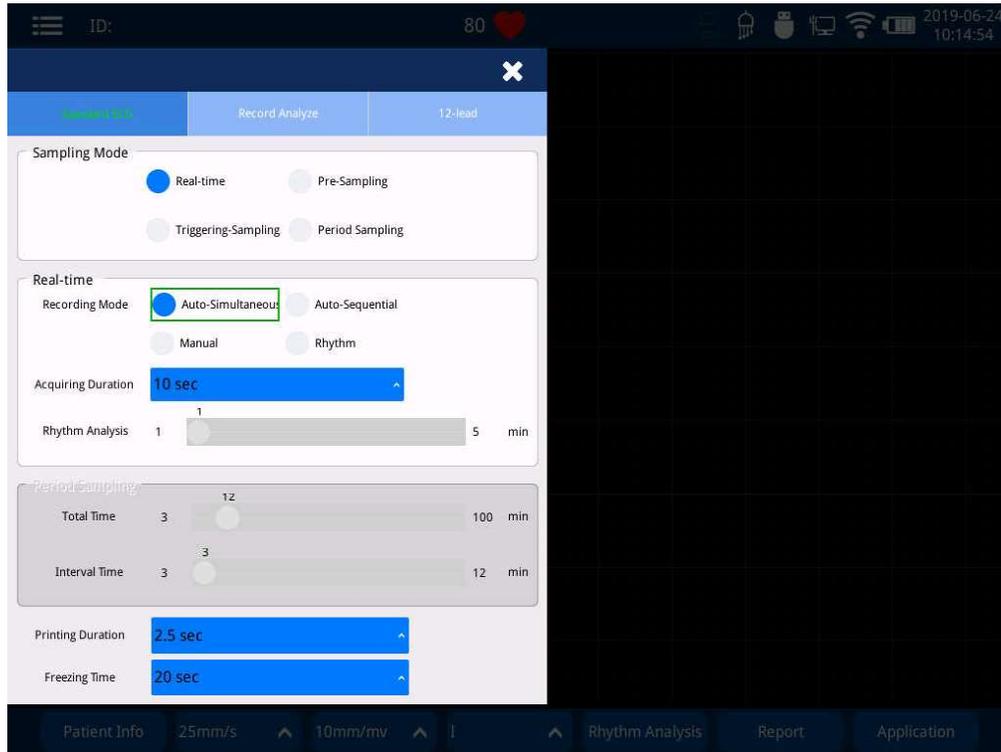


Fig. 2.8 Standard ECG Interface

Standard ECG			
Menu	Drop-down Menu	Defaults	Illustration
Sampling mode	Real-time Pre-sampling Trigger Sampling Period Sampling	Real-time	Real-time: real-time acquisition and measurement of ECG signals; Pre-sampling: Start acquisition several seconds before you decide the start point of recording. If the time of recording signals before the start point is insufficient, the signals can be supplemented by those acquired after the start point. Trigger sampling: Once triggered by preset

Standard ECG			
Menu	Drop-down Menu	Defaults	Illustration
			<p>conditions, start acquisition 2 seconds before the start point.</p> <p>Period sampling: sampling in periodic intervals</p>
Real-time sampling	Auto-simultaneous Auto-sequential Manual Rhythm	Auto-simultaneous	<p>Auto: When recording the ECG waveform, the system automatically records each lead according to the sampling time and automatically switches the record;</p> <p>Simultaneous: record the ECG waveform of the 12-lead at the same time;</p> <p>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;</p> <p>Manual: Manually change the recording when recording ECG waveform. Manual recording is only available in real time sampling;</p> <p>External printer is not supported in manual mode.;</p> <p>Only sequential recording is available in manual mode;</p> <p>Rhythm: Record a single rhythm lead waveform.</p>
Real-time rhythm analysis	1-5 min	1min	Set the single rhythm lead sampling time.
Periodic sampling	3-100min	12min	Set the total sampling time.

Standard ECG			
Menu	Drop-down Menu	Defaults	Illustration
total time			
Periodic sampling interval	3-100min	3min	Set the sampling time for each cycle
Printing duration	2.5 sec、 5 sec 、 7 sec、 10 sec, Two pages, Three pages, Four pages	Two pages	The time of each lead being recorded when the recording mode is auto-simultaneous, auto-sequential
Freezing time	20 sec、 30 sec、 60 sec	20 sec	The ECG signal waveform is frozen 20 seconds before the button is pressed to observe the measurement result. If the time is not enough, only take the effective time.



### **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.*
- 
-

### 2.3.2.2 Record Analyze

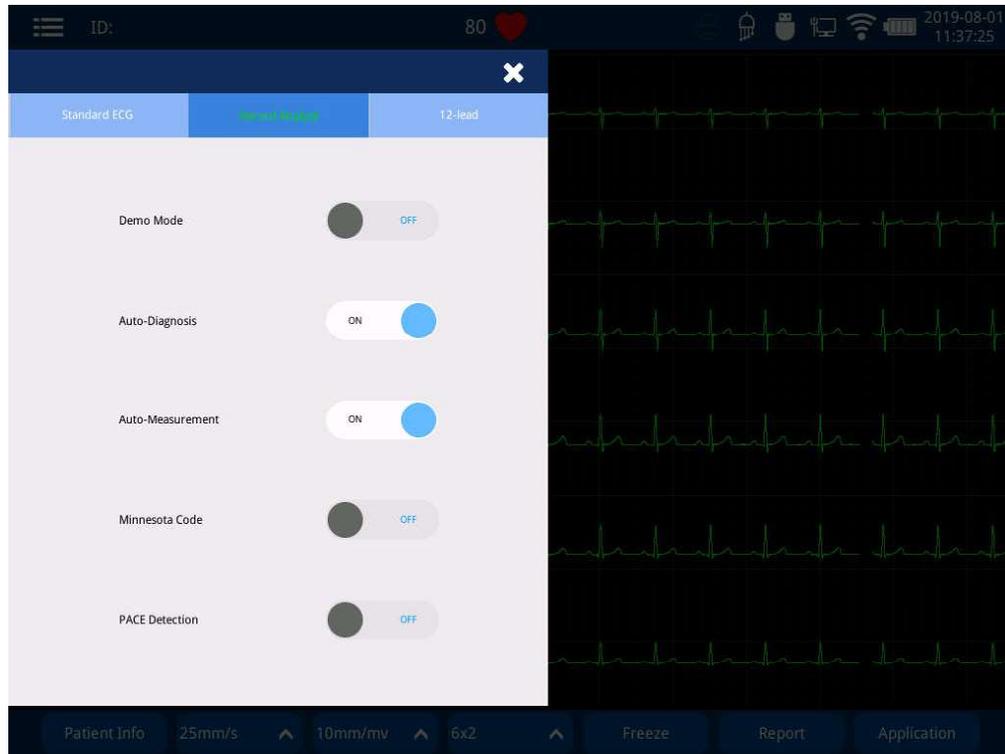


Fig. 2.9 Record Analyze Interface

Record Analyze			
Menu Item	Drop-down Menu	Defaults	Illustration
Demo Mode	Off / On	Off	Turn on/off the Demo mode.
Auto Diagnosis	Off / On	On	Turn on/off the Auto Diagnosis After turning off, the ECG report does not show the diagnosis conclusion
Auto Measurement	Off / On	On	Turn on/off the Auto Measurement. After turning off, the ECG report does not show the diagnosis parameters.
Minnesota Code	Off / On	On	Turn on/off the Minnesota Code. If it is turned off or can not acquire the code, the ECG report does not show the Minnesota Code
PACE Detection	Off / On	On	Turn Off / On the PACE Detection

### 2.3.2.3 Lead System

Lead system can freely change among Standard, Posterior Wall, Right Chest, Right Chest Posterior Wall, Previous Intercostal Space, Next Intercostal Space, CABRERA, and Custom.

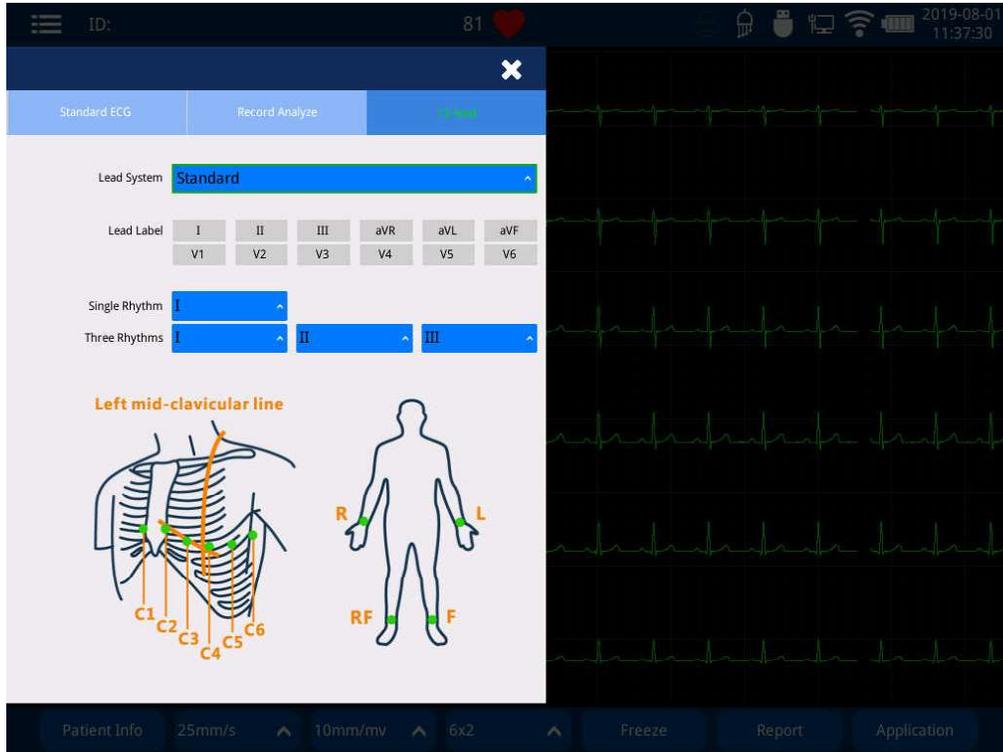


Fig. 2.10 Lead System Interface

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

### 2.3.3 Patient Info Interface

In the waveform acquisition interface, you can click **F1** key on panel or the “**Patient Info**”

or “” button at the bottom of the touch screen to enter the patient information interface and then enter the information by keyboard. After the input is completed, click the “**Confirm**” button to save and return. Click the “**Previous**” button to automatically generate the last patient information.

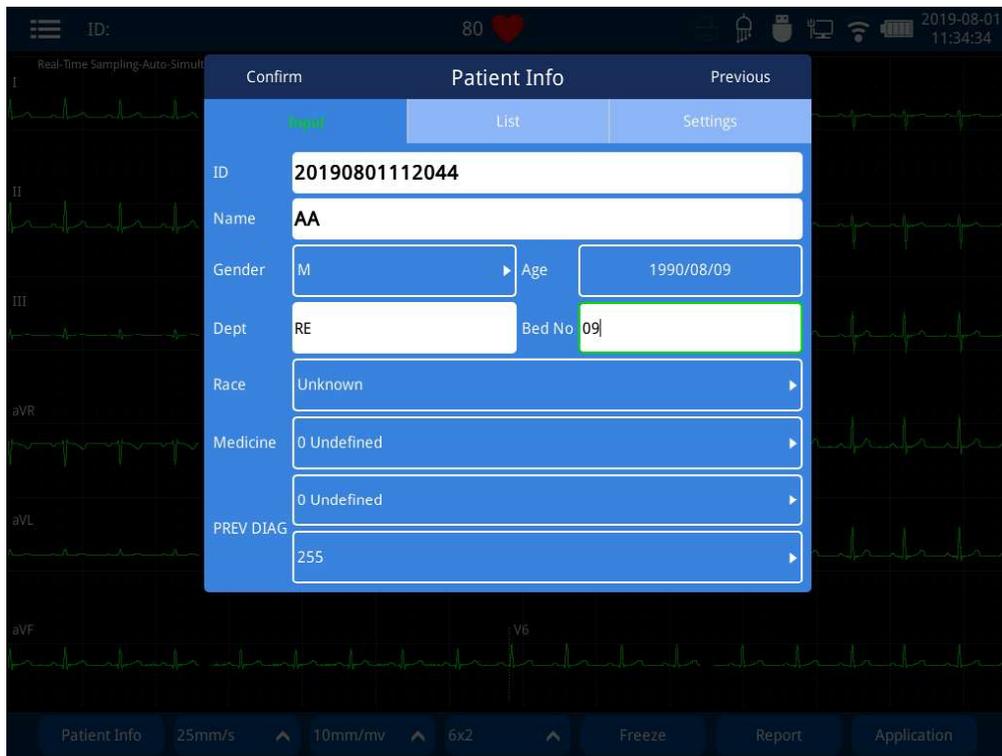


Fig. 2.11 Patient Info Interface

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. After the test is successful, click the “Save” button, and then click the “Sync” button.

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

If the function of the ID card module is enabled, and the resident ID card reading machine can be connected to the electrocardiograph through the USB interface, the patient ID is automatically generated by brushing the patient ID card.

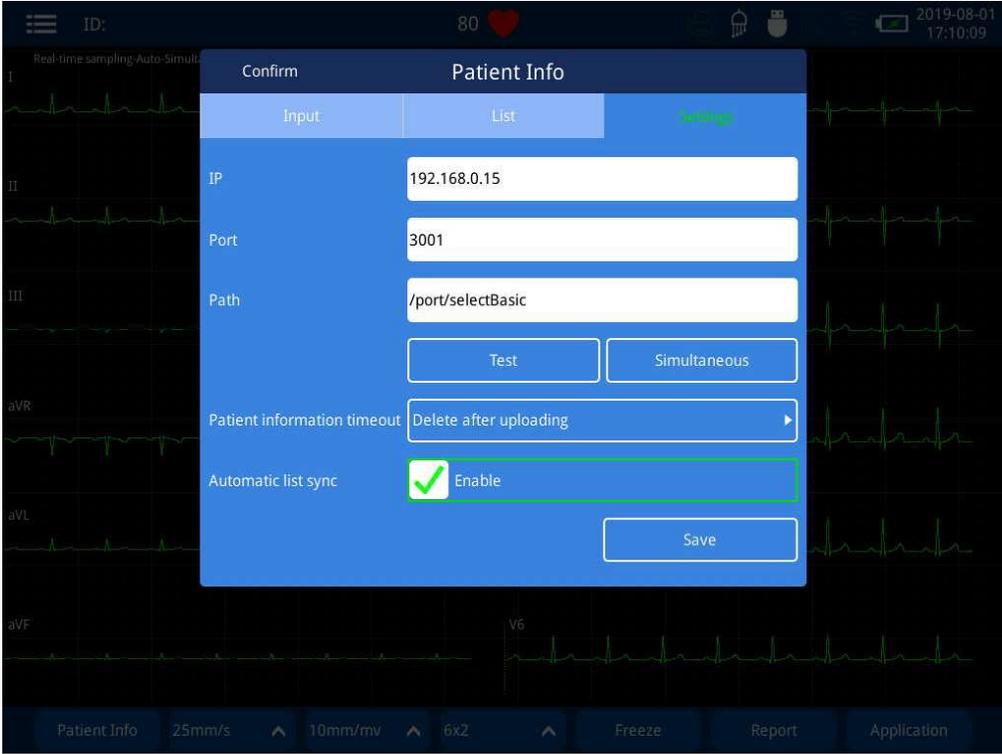


Fig 2.12 Patient Information Interface - Settings

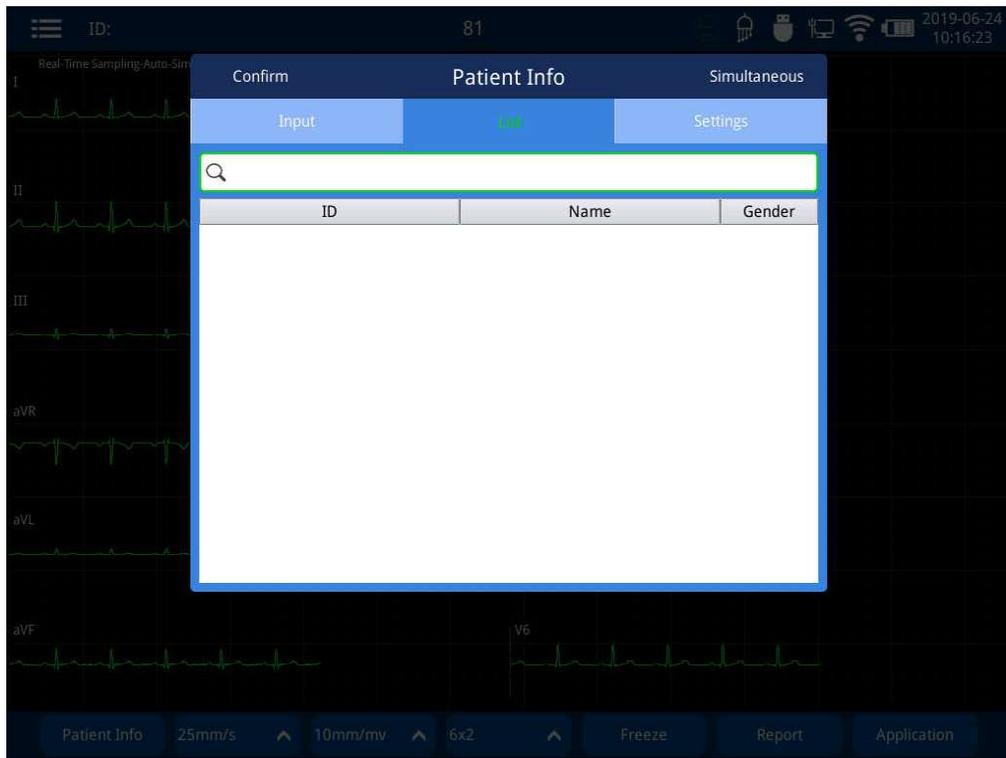


Fig 2.13 Patient Information Interface - List

### 2.3.4 Paper Speed Interface

On Waveform Acquisition interface, touch the key **25mm/s** or click the F2 key on the panel to change the paper speed. Paper speed can be selected among 5mm/s , 6.25mm/s , 10 mm/s , 12.5mm/s , 25mm/s , 50mm/s.

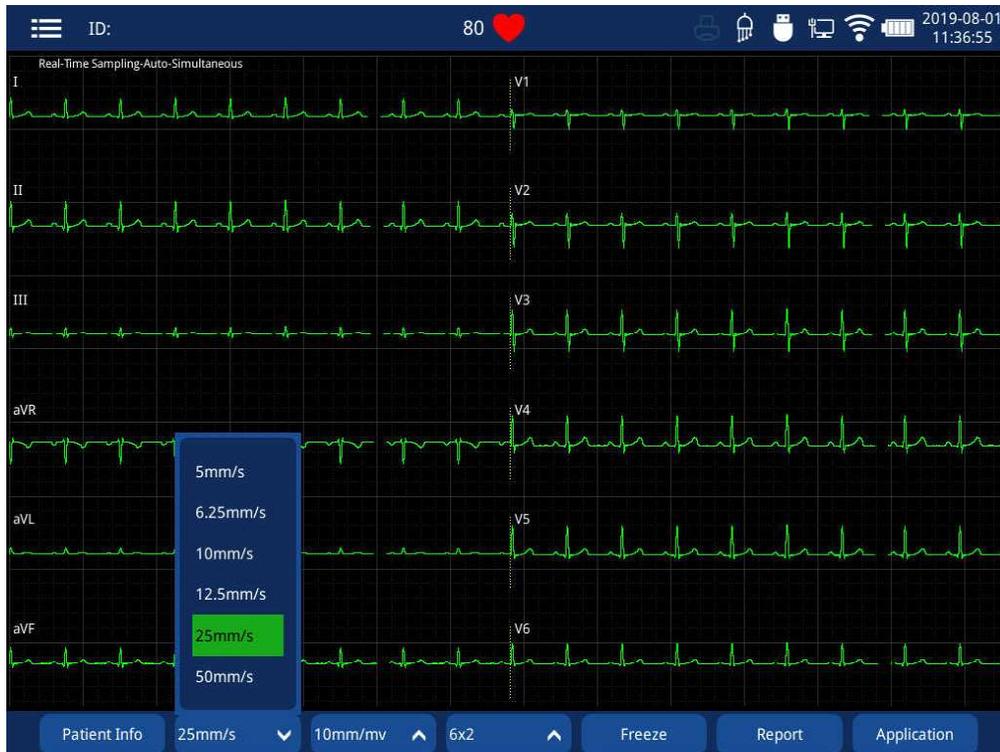


Fig. 2.14 Paper Speed Interface

### 2.3.5 Gain Amplitude Interface

On Waveform Acquisition interface, touch the key **10mm/mv** or click the F3 key on the panel to change the gain amplitude. Gain amplitude can be selected among 2.5mm/mv, 5mm/mv, 10mm/mv, 20 mm/mv, 40 mm/mv and Auto.

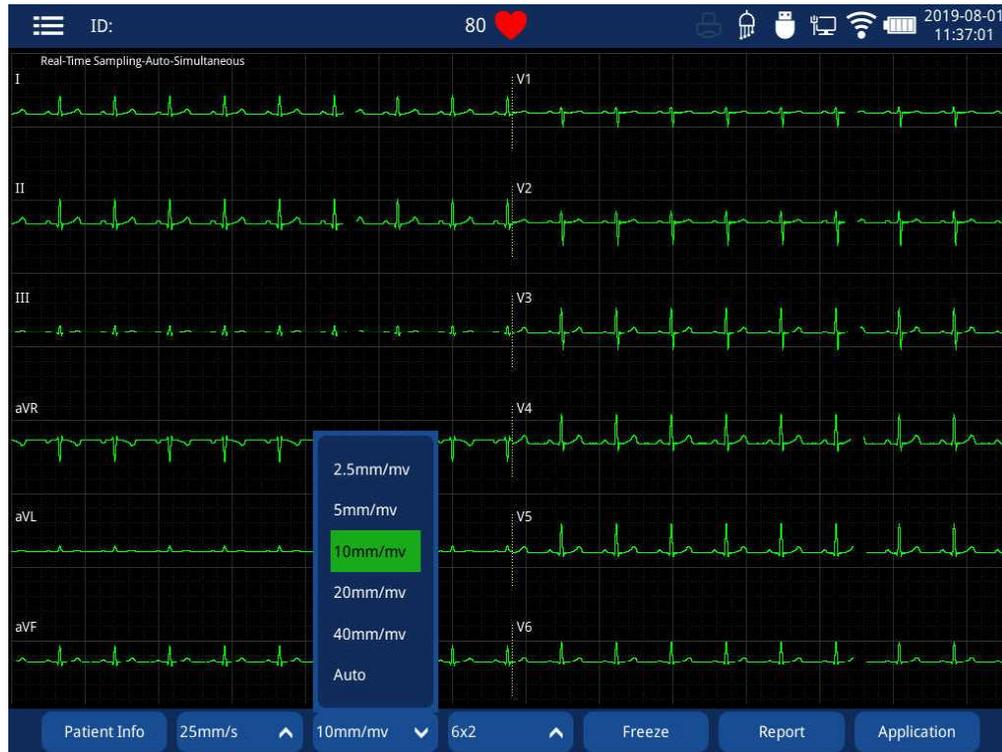


Fig. 2.15 Gain Amplitude Interface

### 2.3.6 Lead Layout Interface

In the waveform acquisition interface, you can directly click the "6x2" button on the touch screen or click the F4 key on the panel to switch the lead layout. Lead layout options are: 3x4 , 3x4+1 , 3x4+3 , 6x2 , 6x2+1 , 12x1 , 6x2+3. Take 3x4+1 for example, When printing, the 12-lead ECG waveform is arranged in a 3-row, 4-column format with a rhythm lead below when printing. (The lead layout will be saved after shutdown.)

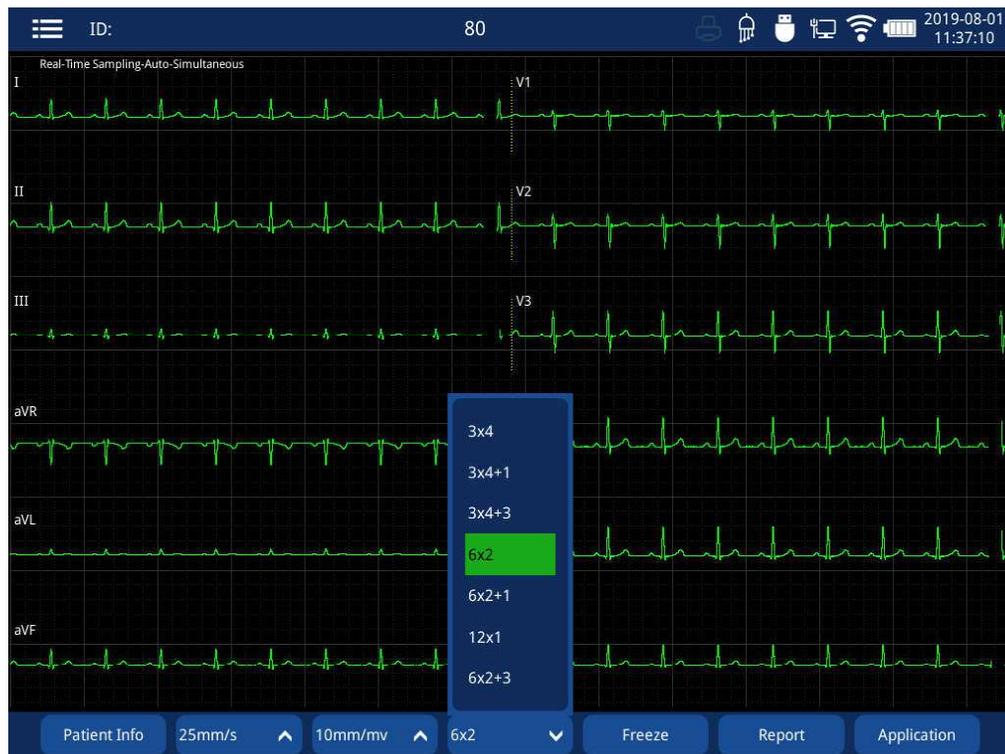


Fig. 2.16 Lead Layout Interface

## 2.3.7 Report Management Interface

In the waveform acquisition interface directly clicks the "Report" button on the touch screen or click the F6 key on the panel to enter the report management interface. See Chapter 7, Report Management for details. This interface has locking function. After the external keyboard is pressed, press the key combination "CTRL+ALT+L", a lock dialog box will pop up, and the report printing, report transmission and report deletion functions can be locked. After locking, the option button is grayed out; if you need to change the option settings, press the key combination "CTRL+ALT+L" again to unlock the option.

The screenshot displays the 'Report management' interface. At the top, there is a navigation bar with a '< Back' button and the title 'Report management'. Below this, there are filter buttons for 'Today', 'Three days', 'One week', and 'All' (with a red '3' notification). A search bar labeled 'Query ID/name' is also present. The main content area is divided into two columns. The left column shows patient information: ID: 20190801085813, Name: AA, Gender: M, Age: 29 Years. Below this are sections for 'Diagnostic parameters' (HR: 80 bmp, PR: 166 ms, QRS: 82 ms, QT/QTc: 354/389 ms, P/QRS/T: 21/16/20°, RV5/SV1: 1.107/0.488 mv, RV5+SV1: 1.595 mv), 'Diagnostic result' (Normal ECG, Sinus rhythm), 'Report information' (Inspection time: 2019-08-01 08:58:49, Reporting time: 10 s, Lead type: 12Lead), and 'Status description' (Not uploaded). The right column contains a table with columns: ID, Name, Gender, Type, Status, and a checkbox. The table lists three reports, with the second one (ID: 20190801085813, Name: AA, Gender: M, Type: ECG-12) highlighted in green. The bottom of the interface features a navigation bar with buttons for 'Preview', 'Last page', 'Next page', 'Delete', 'Local', 'Transfer', and 'Refresh'.

ID	Name	Gender	Type	Status	
1	20190801085922		ECG-12	📄	<input type="checkbox"/>
2	20190801085813	AA	M	ECG-12	📄
3	20190801084820		ECG-12	📄	<input type="checkbox"/>

Fig. 2.17 Report Management Interface

### 2.3.8 Application Interface

On Waveform Acquisition interface, directly touch the key  or click the F7 key on the panel to enter the Application interface.

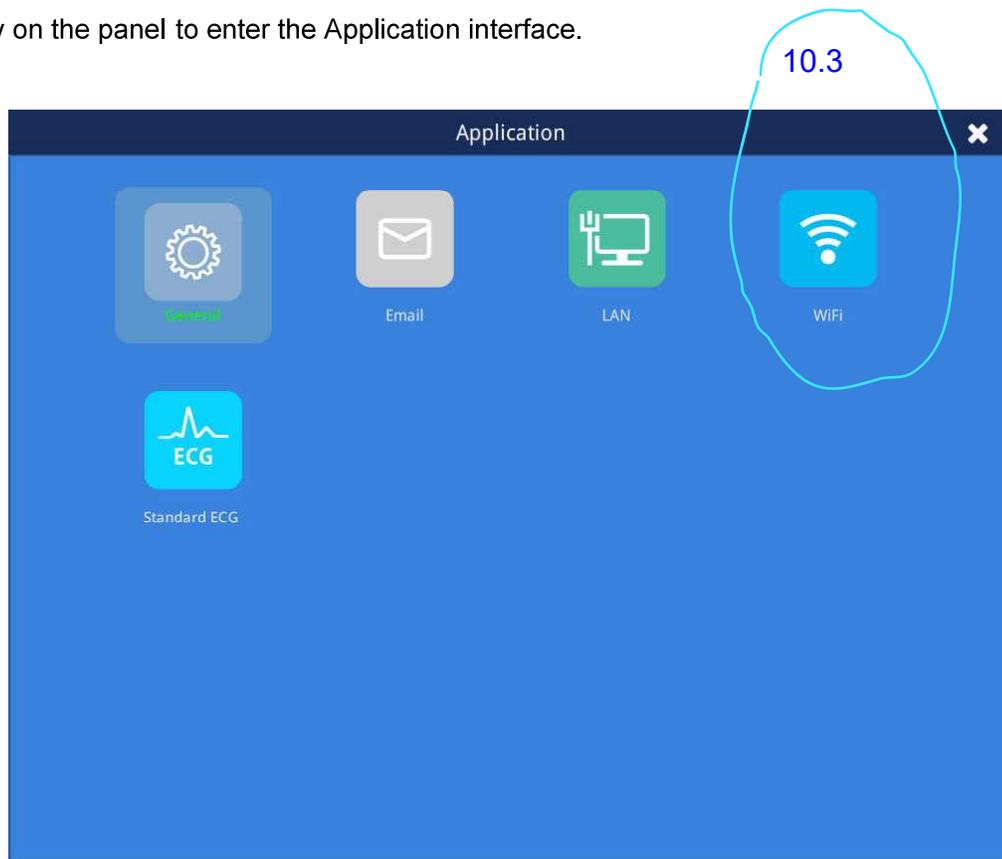


Fig. 2.18 Application Interface

## Chapter 3 Installation

### 3.1 Preparation for Installation

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#### **CAUTION**

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- ◆ *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 IEC60601-1 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**

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- ◆ *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**

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- ◆ *We'll 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.

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- ◆ *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**

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- ◆ *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 220V 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. Turn on the power switch at the back of the machine, 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*
-

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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.*
- 

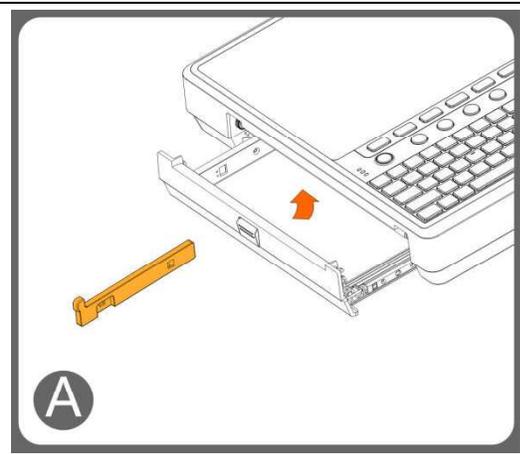
## **3.3 Installing the Recording Paper**

This ECG machine is designed to use Zip fold thermal recording paper of 216 mm or 210 mm in width.

### **3.3.1 Installing the Paper Block**

Prior to install the 216mm-wide paper, please install the accompanying paper block first.

A: Push the printer door switch, and pull out the door, then put in the paper block as shown.



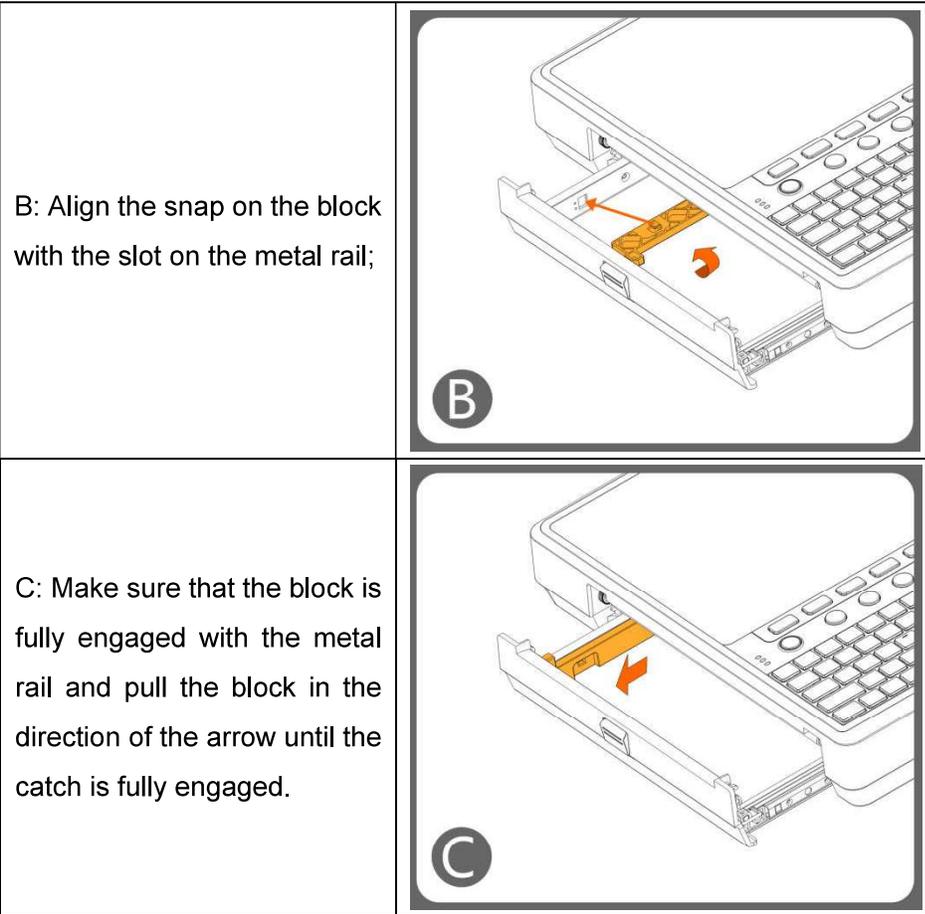


Fig. 3.1 Sketch of Installing the Recording Paper

**3.3.2 Installation of recording paper**

The method of installing the 216mm and 210mm wide Z-fold thermal recording paper is the same as the following figure:

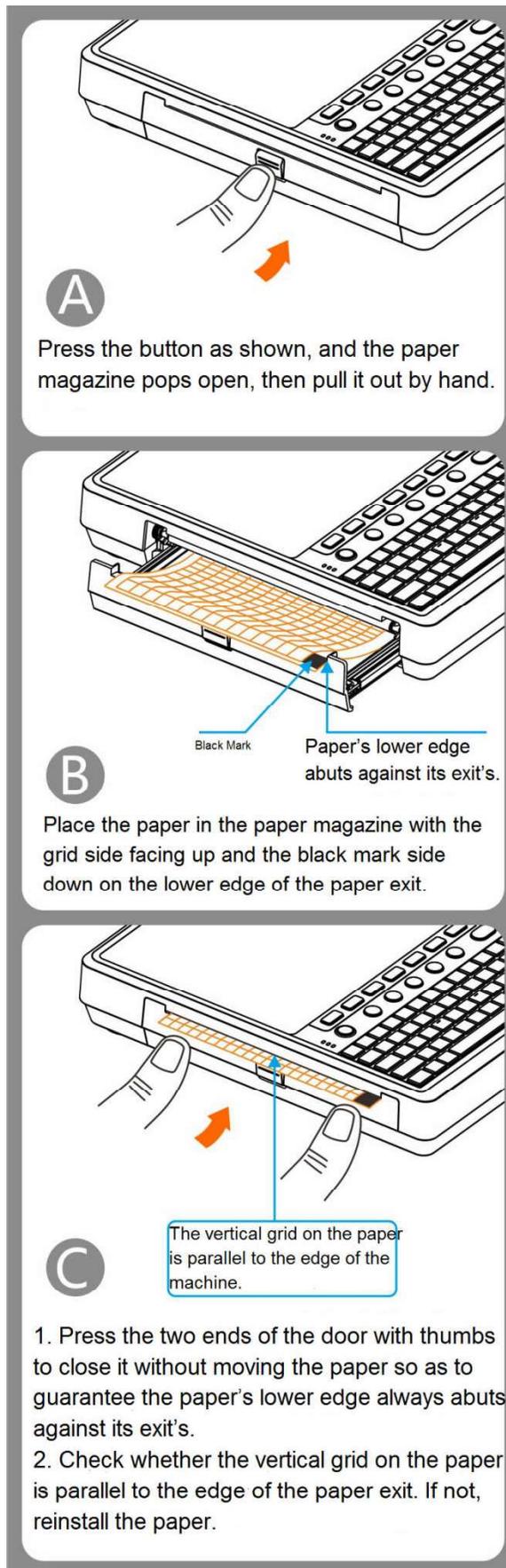


Fig 3.2 Schematic of Installing the Recording Paper



- ◆ 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

Properly connect the patient 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*.

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#### **CAUTION**

- ◆ *Please use the dedicated patient cable configured by the manufacturer. If the cable is damaged, please contact the manufacturer in time to replace or purchase a new one.*
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## **3.5 Power on**

### **3.5.1 Checks before Power on**

**In order to ensure safe exam and stable printout of ECG, 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 connector and grounding wire 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°C) in order 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 inspect 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 reliable connected with the related electrodes.

- **Checks on Recording Paper**

Verify that recording paper is sufficient and properly installed.

### **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.