Wearable ECG Recorder

User Manual

Shenzhen Xinyan Medical Technology Co., Ltd.

Content

About this manual

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This manual is only used as a reference material for the use and maintenance of the corresponding product. Before using the product, please read this manual carefully to ensure correct use. Please follow the safety precautions provided in the manual.

Xinyan Medical has the right of final interpretation of this instruction manual.

 This manual can be obtained by contacting Xinyan Medical.

Revision history

Version	ECN/PCN/TCN/CR	Doc. No.	Release date
A0	/		

After-sales service information

After sales unit:	Shenzhen Xinyan Medical Technology Co., Ltd.
Address:	1st Building, 501-1 & 501-2, Mitehua&Pukyo Bio Science Park, No. 9 Jinxiu East Road,Laokeng Community, Longtian Street, Pingshan District, Shenzhen
Email:	ymheart@xinyancare.cn
Website:	www.xinyancare.cn

Symbols

⚠Warning

Warning of potential hazards or unsafe operations that could lead to death or serious personal injury or property damage if not avoided.

⚠Caution

Warning of potential hazards or unsafe operations that could lead to minor personal injury, product malfunction, damage, or property loss if not avoided.

Safety information

This section lists the basic safety information that users should pay attention to and comply with when using the product. The same, similar, or other operationspecific safety information will appear in subsequent sections.

⚠Warning

- This product is not suitable for infants or young children under 10 kg.

- This product has an average power of 10 mW, with ABS structural shell which is non-fireproof.
- Do not squeeze the accessible part (contact, battery).
- Check the product and its accessories before use, ensuring that they work normally and safely.
- Individuals with skin allergies to this product's accessories should not use it.
- Do not operate the device in the presence of flammable or explosive liquids, such as anesthetics, Otherwise, it might result in fire or explosion.
- The product contains a built-in battery (model CR2450), which is located inside the wearable ECG sensor. The battery is replaced simultaneously when the sensor is replaced. Do not disassemble the product. Repairs or upgrades to the product must be carried out by maintenance personnel who have been trained and authorized by the manufacturer.
- This product is not defibrillation-resistant. It is essential to disconnect the ECG recorder from the patient during defibrillation. Otherwise, it may cause device damage.
- This product should not be used in conjunction with electrosurgical equipment. When using electrosurgical equipment, the product must be disconnected from the patient to prevent potential device damage.
- Dispose of the electrodes and packaging materials by following local regulations or waste disposal rules of the hospital. The device and packaging materials must be stored out of reach of children.
- This product emits radio frequency radiation energy. Failure to install and use the product according to the methods provided in this manual may cause interference with radio frequency communications.
- Only the data box specified by the manufacturer can be used, which complies with IEC 60601-1-2:2014+A1:2020.
- Dispose of the expired sensor and battery in accordance with relevant local regulations or hospital rules. If you have any doubts, contact the manufacturer.
- Do not delete or modify any files of the ECG management software on your own, as it may lead to data loss.

Sensor:

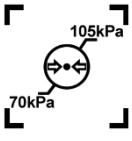
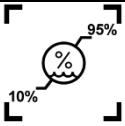
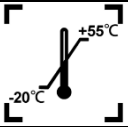
- When using this product, please use the sensors specified in this chapter(models: ECG Sensor-010、ECG Sensor-011、ECG Sensor-030~ECG Sensor-039、ECG Sensor-060、ECG Sensor-090、ECG Sensor-120~ECG Sensor-134).
- All sensors are for single-patient, single-use only. Using sensors of other models may damage the product.
- If there are damages to the sensor packaging or the sensor itself, do not use that sensor.

 **Caution**

- When using this product, ensure that the usage environment meets the environmental specifications required.
- To ensure user safety, please use the sensors specified in this chapter(models: ECG Sensor-010、ECG Sensor-011、ECG Sensor-030~ECG Sensor-039、ECG Sensor-060、ECG Sensor-090、ECG Sensor-120~ECG Sensor-134).
- Disposable sensors are intended for single use only. Reusing them may result in performance degradation or cross-infection.
- When the product and its accessories are nearing their expiration date, dispose of them in accordance with relevant local regulations or hospital rules. If you have any doubts, contact the manufacturer.
- Electromagnetic fields can affect the performance of the product, so any equipment used near the product must comply with the relevant EMC requirements. Mobile phones, X-ray, or MRI equipment are potential sources of interference as they emit high-intensity electromagnetic radiation.
- Do not place the device in areas with excessive cotton or dust to prevent damage from accumulated dirt.
- Avoid placing the device in direct sunlight to prevent accelerated aging of the casing or components, reduced performance of sensors and electrodes, and loosening of electrode adhesion.
- Store the device out of reach of children or pets.

- Prevent children or pets from swallowing small parts such as batteries.

Symbols

Serial No.	Item	About this manual	Serial No.	Item	About this manual
1		Product Model	11		manufacturer
2		General waning sign	12		Batch code
3		Date of manufacture	13		Class II medical device
4		Serial number	14		Indicate separate collection for electrical and electronic equipment (WEEE)
5	**IP27**	Dust-proof level 2, Water-proof level 7	15		EU representative
6	**IP21**	Dust-proof level 2, Water-proof level 1	16		CE certification
7		Consult instructions for use	17		Cannot be used a second time
8		Type CF applied part	18		FCC ID
9		Non-ionizing radiation	19		Storage pressure range
10		Storage humidity range	20		Storage temperature range

About the product model

YMHeart XY-12, where YMHeart XY is the product feature code, and 12 is the product improvement serial number.

Model	Main functional differences	
	acquisition channel	Host color
YMHeart XY - 03	Acquisition and storage of 1- and 3-lead waveforms	milky white
YMHeart XY - 0301	Acquisition and storage of 1- and 3-lead waveforms	beige
YMHeart XY - 0302	Acquisition and storage of 1- and 3-lead waveforms	grayish white
YMHeart XY - 0303	Acquisition and storage of 1- and 3-lead waveforms	light grey
YMHeart XY - 12	Acquisition and storage of 1, 3, 6, 9 and 12 lead waveforms	milky white
YMHeart XY - 1201	Acquisition and storage of 1, 3, 6, 9 and 12 lead waveforms	beige
YMHeart XY - 1202	Acquisition and storage of 1, 3, 6, 9 and 12 lead waveforms	grayish white
YMHeart XY - 1203	Acquisition and storage of 1, 3, 6, 9 and 12 lead waveforms	light grey

Chapter 1 Product introduction

1.1 Structural composition

The product consists of Wearable ECG recorder host, Wearable ECG Sensor, Data Box, USB cable, and ECG Management Software (Release version V01).

Figure 0- 1 Structural composition

Working Principle:

The wearable ECG sensor is installed on the wearable ECG recorder host and adhered to the human body surface. The wearable ECG recorder sample ECG signal through the wearable ECG sensor. After the sample completed, he wearable ECG recorder is placed in the data box, and the USB cable of the data box is plugged into the computer. The data stored in the wearable ECG recorder host is displayed on the computer in the form of a USB flash drive, and ECG management software can display, measure and print the collected ECG date. ECG management software can also communicate via Bluetooth to display ECG waveforms from wearable ECG recorders in real time.

1.2 Purpose of use

Intended use

The product is intended for the collection and storage of ECG data during 24-hour human activity.
NOTE: A single ECG recorder can only monitor a single user at a time.

Application scope

It is designed for the dynamic collection, recording, and storage of 1-lead, 3-lead, 6-lead, 9-lead, 12-lead, ECG data from the human body, excluding automatic analysis and diagnostic functions.

Applicable Population

Except for infants and young children weighing less than 10 kg.

Intended user

- Medical professionals such as doctors, nurses, and physiotherapists who have statutory professional knowledge.
- Caregivers and patients who are guided by medical professionals.
- Individuals who possess the ability to understand the general operation and the content of the user manual for the wearable ECG recorder.

Application part

Both the wearable ECG sensor and the wearable ECG recorder main unit may come into contact with the human body, both are considered application parts.

Contraindications

The product is not suitable for use on individuals with skin damage or chest deformities that make it unsuitable to wear this product.

Environment

This product is specifically designed and manufactured for use in medical facilities such as hospitals, clinics, and nursing homes, as well as in general household indoor settings.

Date of manufacture

See the back of the main unit.

Service life

- The wearable ECG sensor has a service life of 7 days (i.e., 168 hours).
- Please use it immediately after opening to avoid loss of moisture from the hydrogel.
- The wearable ECG recorder has a service life of 5 years from the date of manufacture.

Storage period

The wearable ECG sensor has a service life of 2 years from the date of manufacture

1.3 Product specifications

LED status

Status	Description
Powered on	Flash once every 2 s, with a constant on-time of 1 s
During storage	Flash every 10 s, with a constant on-time of 8 ms
Low battery	Flash every 0.5 s
Lead off	Flash once every second, with a constant on-time of 8 ms

Batter specifications

Item	Description
Rated Voltage	2.7V-3.3V
Battery type	CR2450, Lithium-manganese coin cell battery, not rechargeable
Duration	≥168 h

Recorder specifications

Item	Description
Host dimensions	Length：50.5±1.0mm Width：34.7±1.0mm Height：10.5±1.0mm
Weight	≤ 25g

Recording and storage specifications

Item	Description
Recording type	Real-time recording
Storage method	Chip storage
Communication method	Supports USB 2.0 and BLE 5.3
Storage capacity	⩾168h storage time

Storage space	256MB

Sensor specifications

ECG Sensor model	Main Functional Differences	Tolerance
ECG Sensor-010	1-Lead, size 142mm*56mm*7.0mm	±20%
ECG Sensor-011	1-Lead, size 134mm*48mm*7.0mm	±20%
ECG Sensor-030	3-Lead, size 180mm* 400 mm*7.0mm	±20%
ECG Sensor-031	3-Lead, size 180mm* 390 mm*7.0mm	±20%
ECG Sensor-032	3-Lead, size 180mm* 380 mm*7.0mm	±20%
ECG Sensor-033	3-Lead, size 180mm* 370 mm*7.0mm	±20%
ECG Sensor-034	3-Lead, size 180mm* 360 mm*7.0mm	±20%
ECG Sensor-035	3-Lead, size 180mm* 350 mm*7.0mm	±20%
ECG Sensor-036	3-Lead, size 180mm* 340 mm*7.0mm	±20%
ECG Sensor-037	3-Lead, size 180mm* 330 mm*7.0mm	±20%
ECG Sensor-038	3-Lead, size 180mm* 320 mm*7.0mm	±20%
ECG Sensor-039	3-Lead, size 180mm* 310 mm*7.0mm	±20%
ECG Sensor-060	6-Lead, size 380mm* 290mm* 7.0mm	±20%
ECG Sensor-090	9-Lead, size 380mm* 340mm* 7.0mm	±20%
ECG Sensor-120	12-Lead, size 400mm* 380mm* 7.0mm	±20%
ECG Sensor-121	12-Lead, size 400mm* 375mm* 7.0mm	±20%
ECG Sensor-122	12-Lead, size 400mm* 370mm* 7.0mm	±20%
ECG Sensor-123	12-Lead, size 400mm* 365mm* 7.0mm	±20%
ECG Sensor-124	12-Lead, size 400mm* 360mm* 7.0mm	±20%
ECG Sensor-125	12-Lead, size 400mm* 355mm* 7.0mm	±20%
ECG Sensor-126	12-Lead, size 400mm* 350mm* 7.0mm	±20%
ECG Sensor-127	12-Lead, size 400mm* 345mm* 7.0mm	±20%
ECG Sensor-128	12-Lead, size 400mm* 340mm* 7.0mm	±20%
ECG Sensor-129	12-Lead, size 400mm* 335mm* 7.0mm	±20%
ECG Sensor-130	12-Lead, size 400mm* 330mm* 7.0mm	±20%
ECG Sensor-131	12-Lead, size 400mm* 325mm* 7.0mm	±20%
ECG Sensor-132	12-Lead, size 400mm* 320mm* 7.0mm	±20%
ECG Sensor-133	12-Lead, size 400mm* 315mm* 7.0mm	±20%
ECG Sensor-134	12-Lead, size 400mm* 310mm* 7.0mm	±20%

Wearable ECG recorder model, compatible with the following sensors:

Wearable ECG recorder model	Compatible sensors
YMHeart XY-03、YMHeart XY-0301、 YMHeart XY-0302、YMHeart XY-0303	ECG Sensor-010、ECG Sensor-011、 ECG Sensor-030~ECG Sensor-039
YMHeart XY-12、YMHeart XY-1201、 YMHeart XY-1201、YMHeart XY-1201	ECG Sensor-010、ECG Sensor-011、 ECG Sensor-030~ECG Sensor-039、 ECG Sensor-060、ECG Sensor-090、 ECG Sensor-120~ECG Sensor-134

Performance specifications

ECG specifications	
Item	**Description**
Lead system	Supports 1/3/6/9/12lead
Sampling rate	250Hz
Dynamic input range	With superimposed ±300 mV DC bias voltage, the input signal range is not less than ±5 mVpp
CMRR	Power frequency: ● Electrical network frequency (50Hz and 60Hz) ≥100dB. ● Twice the electrical network frequency (100Hz and 120Hz) ≥80dB.
Frequency response (-3dB to +3dB)	0.5 Hz to 45 Hz @250 Hz sampling rate
Input impedance	≥15 MΩ @10 Hz
AD accuracy	24-bit sampling
Noise	<25 μVpp (within 10 s)
Polarization voltage tolerance	≥±300 mV
Timing accuracy	<30 s within 24 h
Pacing signal detection	Supports pacing detection, pulse width 0.1 ms to 2.0 ms, amplitude ±2 mV to ±200 mV

Safety specifications

Item	Description
EC Directive	
Electrical shock protection type	Button cell power supply
Electrical shock protection class	CF type (No defibrillation resistance)
Operating mode	Continuous operation
Explosion protection class	General equipment, no explosion protection provided
IP code	IP27, to be used in conjunction with the wearable ECG sensor
Device type	Portable device
EMC grouping	Group I, Class B

Safety classification for use with flammable anesthetic gases mixed with air or with oxygen or nitrous oxide	Non-AP/APG type

1.4 Operating environment requirements

Item	Description
Operating temperature	5℃ - 45℃
Operating humidity	10% - 95%, non-condensing
Operating atmospheric pressure	80 kPa - 105 kPa
Storage temperature	-20℃ - 55℃
Storage humidity	10% - 95%, non-condensing
Storage atmospheric pressure	70 kPa - 105 kPa
Altitude	≤2000 m

1.5 Packing list

No.	Name	Service life	Storage period	Note
1	Wearable ECG recorder	5 years	5 years	1 packaging box can hold 1 to 5 main units.
2	Wearable ECG sensor (1-lead，ECG Sensor-010、ECG Sensor-011)	7 days	2 years	Optional
3	Wearable ECG sensor (3-lead，ECG Sensor-030~ECG Sensor-039)	7 days	2 years	Optional
4	Wearable ECG sensor (6-lead，ECG Sensor-060)	7 days	2 years	Optional
5	Wearable ECG sensor (6-lead，ECG Sensor-090)	7 days	2 years	Optional
6	Wearable ECG sensor (9-lead，ECG Sensor-120~ECG Sensor-134)	7 days	2 years	Optional
7	ECG Management Software	Long-term	Long-term	

Chapter 2 Installation and usage

Unpacking inspection

Before unpacking, please carefully inspect the packaging to determine if the product has been damaged during transportation. If you notice any damage, please contact the carrier or our company immediately.
If the packaging appears intact and undamaged, please open it using the correct method. Carefully remove the product and other components from the box, and check them against the packing list one by one. Inspect the product for any mechanical damage and ensure that all items are present. If you have any questions or concerns, please contact our customer service department immediately.

⚠Warning

- Store the packaging materials out of reach of children. Dispose of the packaging by following local regulations or waste disposal rules of the hospital.
- The device may be susceptible to microbial contamination during storage, transportation, and use. Please check if the packaging is intact before use, especially for single-use accessories. If any damages are found, do not use them.

Environmental requirements
The usage environment for this product must comply with the specifications mentioned in section 1.4.

Power supply requirements
The power supply used for this product must comply with the specifications mentioned in section 1.3.

⚠Warning

Ensure that the product operates within the specified environmental and power supply requirements. Otherwise, it may not function properly and may lead to unforeseen consequences such as device damage.

2.1 Function

2.1.1 Wearable ECG Recorder

Workflow of the wearable ECG recorder

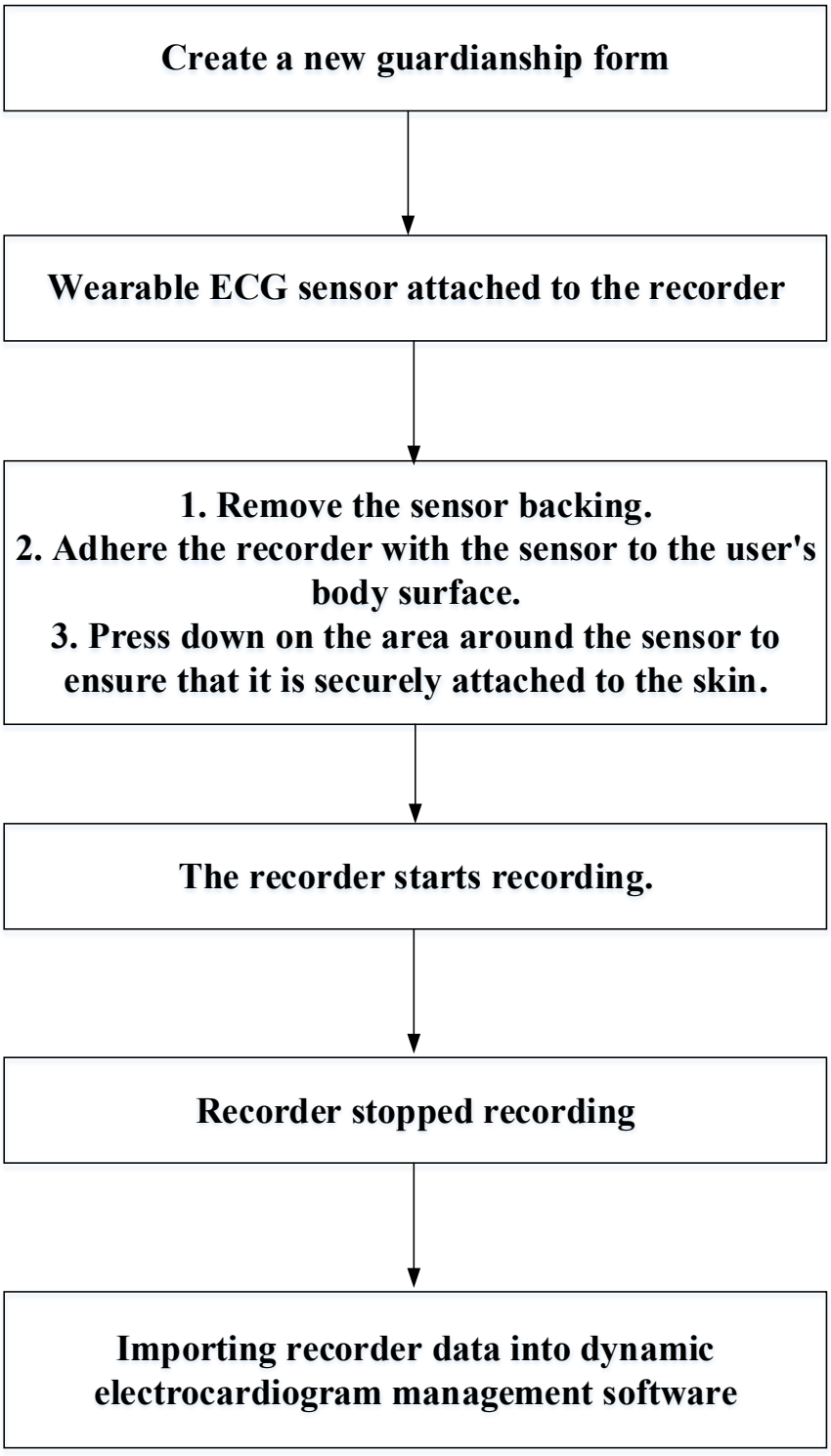
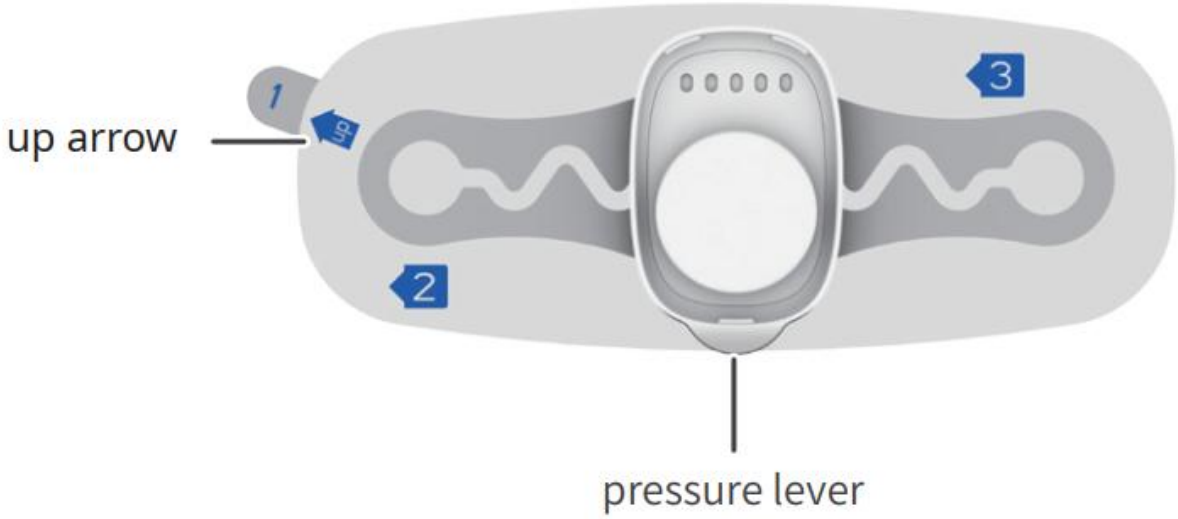
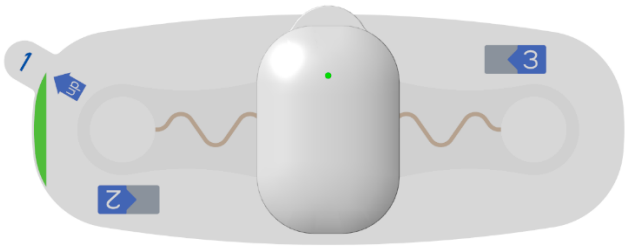


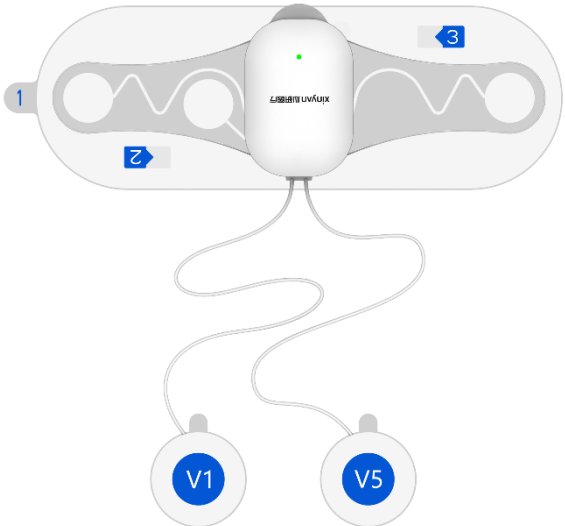
Figure 0- 2 Workflow of the wearable ECG recorder



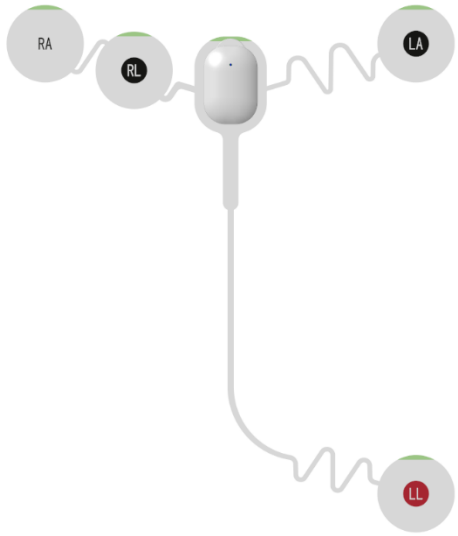
ECG Sensor-010~ ECG Sensor-011 schematic diagram



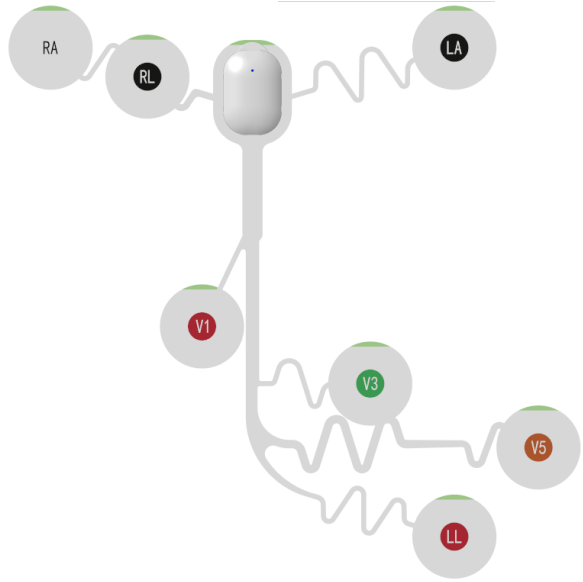
ECG Sensor-030~ ECG Sensor-039 schematic diagram



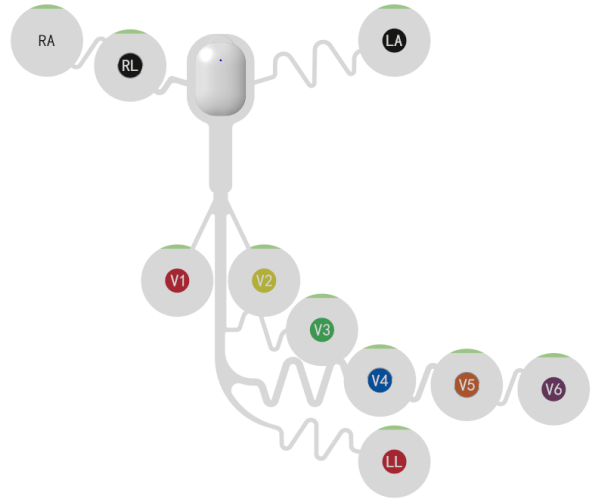
ECG Sensor-060 schematic diagram



ECG Sensor-090 schematic diagram



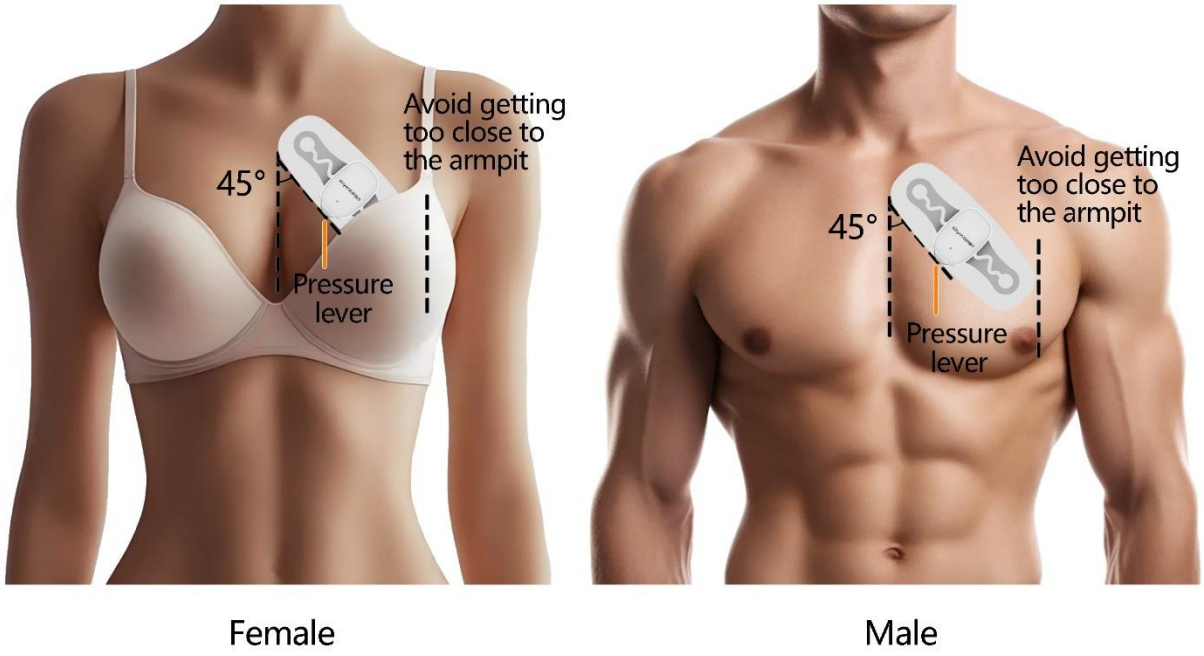
ECG Sensor-120~ ECG Sensor-134 schematic diagram



NOTE

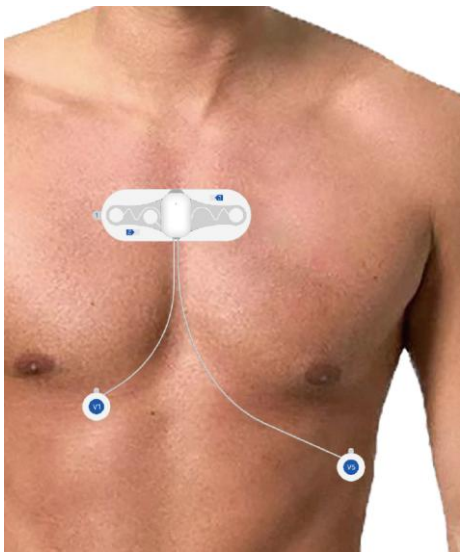
- If you notice any signs of damage to the sensor packaging or the sensor itself, do not use the sensor.

The installation location of the ECG Sensor-010 to ECG Sensor-011 sensors is shown in the figure below：



Female　　Male

The installation location of the ECG Sensor-030 to ECG Sensor-039 sensors is shown in the figure below：

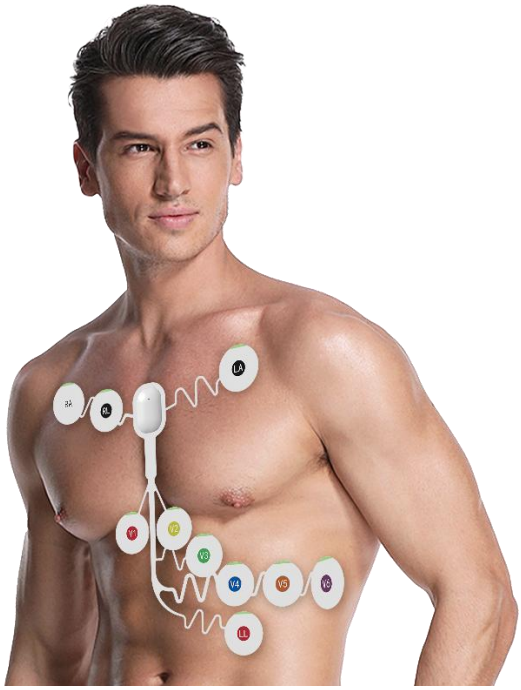


3-channel dynamic electrocardiogram electrode placement:
The 3-channel leads are bipolar leads with 5 electrode patches. It is generally recommended to select simulated V1 and V5.

1、 Simulated V1 (CM1, MV1): The positive electrode is placed at the V1 position (black), and the negative electrode is placed on the left side of the sternal notch (brown), recording an electrocardiogram similar to V1.

2、 Analog V5 (CM5, MV5): The positive electrode (red) is positioned at the V5 location, and the negative electrode (white) is positioned on the right side of the sternal notch. This configuration records an ECG similar to V5.

The corresponding electrode positions for the 6-lead sensor (ECG Sensor-060), 9-lead sensor (ECG Sensor-090), and 12-lead sensors (ECG Sensor-120 to ECG Sensor-134) are shown in the figure below:



Paste location:

European standard	American standard	Electrode placement
Red R	White RA	(Right arm) Below the clavicle, near the right shoulder;
Yellow L	Black LA	(Left arm) Below the clavicle, near the left shoulder;
Black N	Green RL	Reference electrodes
Green F	Red LL	(Left leg) Located above the lowest rib on the left side
Red C1	Red V1	Located on the right side between the fourth ribs, near the right edge of the sternum
Yellow C2	Yellow V2	Located on the left side between the fourth ribs, near the left edge of the sternum
Green C3	Green V3	Located between V2 and V4
Brown C4	Blue V4	Located on the midclavicular line of the left clavicle, at the fifth intercostal space
Black C5	Orange V5	Located on the anterior axillary line of the left axilla, at the same level as V4

Purple C6	Purple V6	Located on the mid-axillary line of the left axilla, at the same level as V4

Remove the sensor:
Remove the recorder from the sensor. The correct method is to hold the side opposite the tongue depressor with one hand, hold the tongue depressor with the other hand, press down firmly on the tongue, and the main unit will pop out of the sensor, allowing you to remove the recorder.

NOTE

When placing electrodes or connecting cables, ensure that there is no contact with any other conductive parts or the ground. Particularly, it should be ensured that all ECG electrodes, including the neutral electrode, are attached to the patient's body to prevent them from coming into contact with conductive parts or the ground.

Start recoding:

After the sensor is installed, the recorder automatically begins to operate, stating data sampling.

Stop recoding:

1、 Remove the sensor, and the main unit will automatically stop working, thereby ending the data sampling.
2、 To remove the recorder from the sensor, use one hand to grip the opposite side of the pressure lever and the other hand to grip the pressure lever itself. Press firmly on the pressure lever, and the recorder will pop out from the sensor, allowing you to remove it.

Importing data:

This product supports USB data export function. Place the recorder main unit on the data box, then connect the data box to a computer via a USB cable. The data stored in the device will appear on the computer as a USB flash drive, allowing you to read the data contained within.

The main unit of the recorder must be used with the original ECG management software.

2.2 ECG management software

2.2.1 Download

Scan the QR code to download the software installation package and install it:HolterSetup-Vxxx.zip：

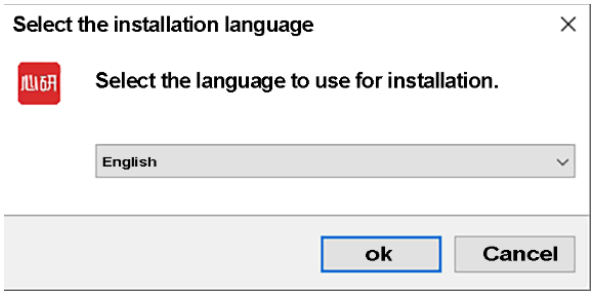
2.2.2 Installation and Uninstallation

a) Host CPU: Intel(R) Core(M) i5-4460 CPU @ 3.20GHz or higher
b) RAM: 16GB or more
c) Hard drive: 512GB or more
d) Software environment: Windows 10 or compatible versions
e) Supports USB 2.0 protocol and BLE 5.3 protocol
f) Network requirements: No internet connection required

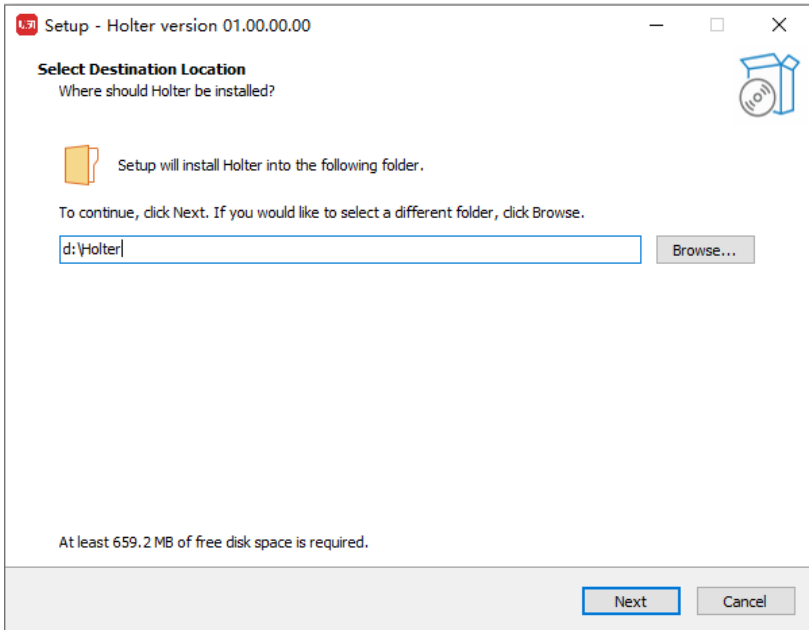
2.2.2.1 Install

Double-click the installation package file HolterSetup-Vxxxx.exe to enter the installation interface.

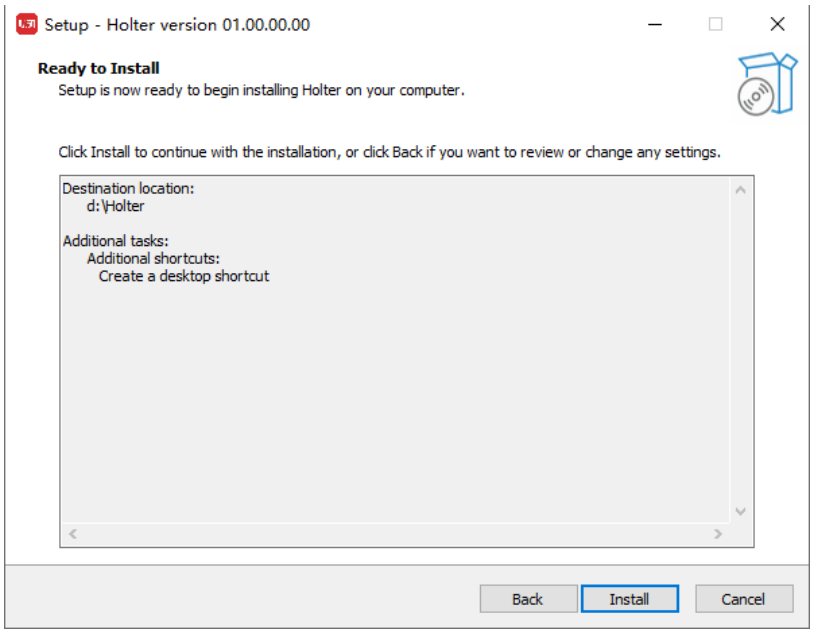
Step 1: Select the installation language



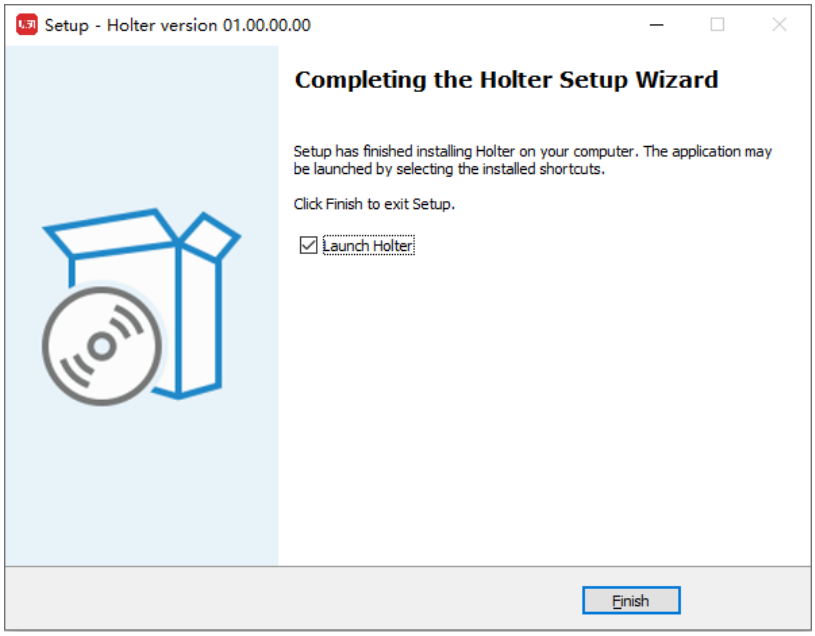
Step 2: Select the installation path



Step 3: Then click Next and Install.

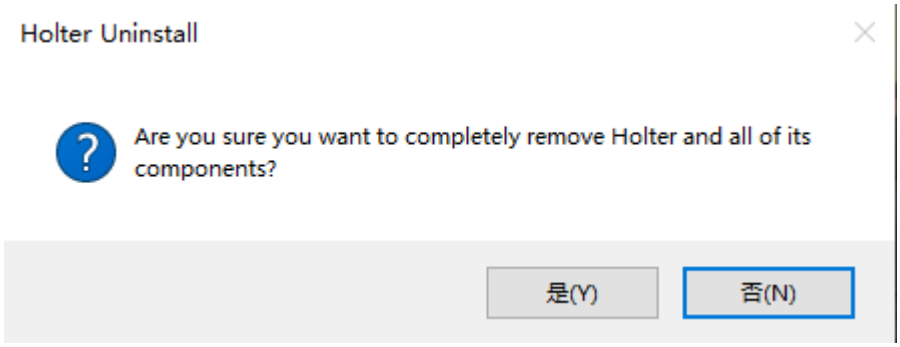


Step 4: Complete the installation



2.2.2.2Uninstallation

Select the unins000.exe file in the software installation directory, double-click to bring up the prompt box, select Yes, and the software will be uninstalled.



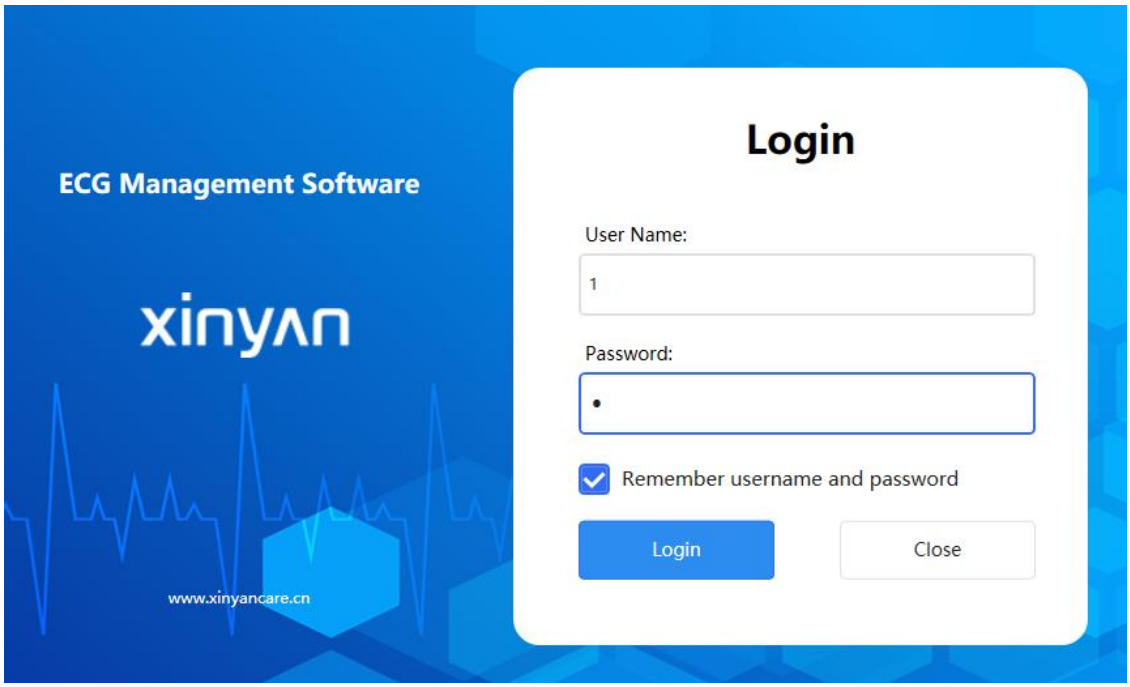
2.2.2.3 Software upgrade

Reinstall HolterSetup-Vxxxx.exe to complete the software upgrade.

2.2.3 Authorization and Login

Only the designated account and password can log in to this software. Unauthorized accounts and passwords cannot log in.
Accounts and passwords are assigned by our company's sales department, and both accounts and passwords are generated offline by our company.

The software has a password protection feature, and the password is displayed as ● when entered.

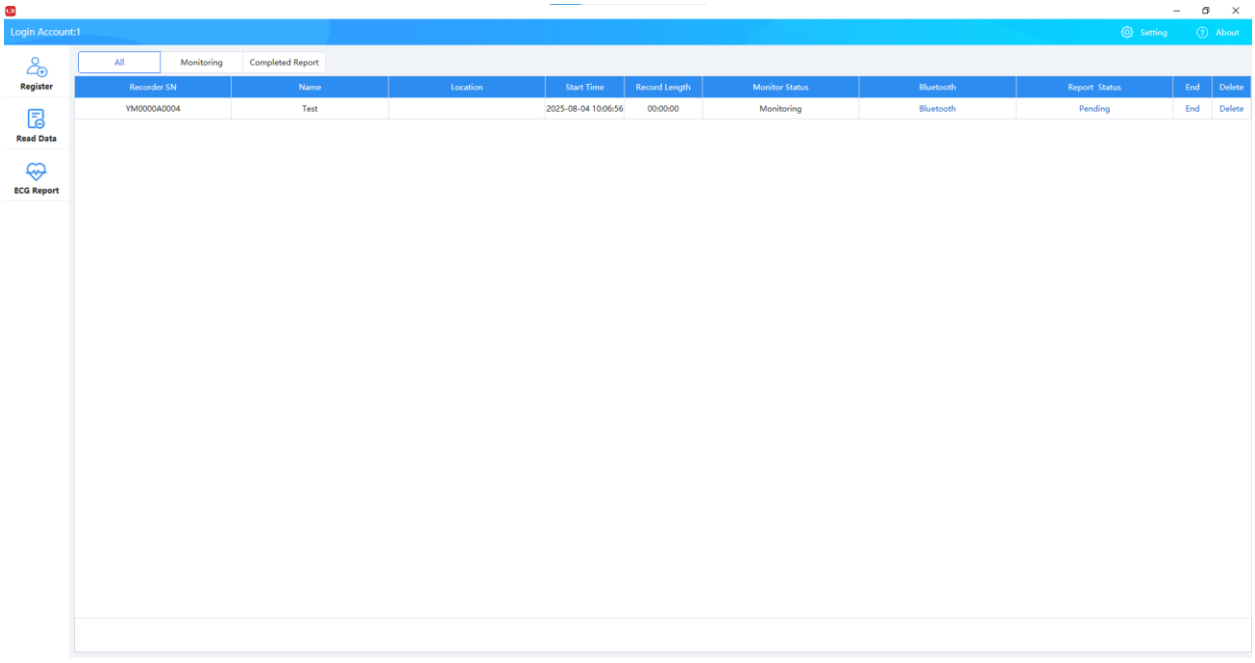


2.2.4 Data Management

Warning

Please do not delete or modify the software files themselves.

2.2.4.1 Data Management Interface



As shown in the figure above,

- **Create a new monitoring record**

Register user information such as name, age, gender, phone number, pacemaker, and other relevant information.

- **Read data**

The ECG management software reads data from the wearable ECG recorder via a USB interface.

- **Display historical ECG waveforms**

Displays the ECG waveforms collected by the wearable ECG recorder and supports PDF report printing.

- **Real-time ECG Waveform Display**

In the main menu, select Bluetooth to enter the real-time waveform display interface.
The wearable ECG recorder supports Bluetooth communication. The ECG management software displays ECG data collected by the wearable ECG recorder in real-time via Bluetooth. The system has remote ECG monitoring functionality.

- **Report Printing**

In the historical ECG display interface, select a waveform to complete PDF report printing.

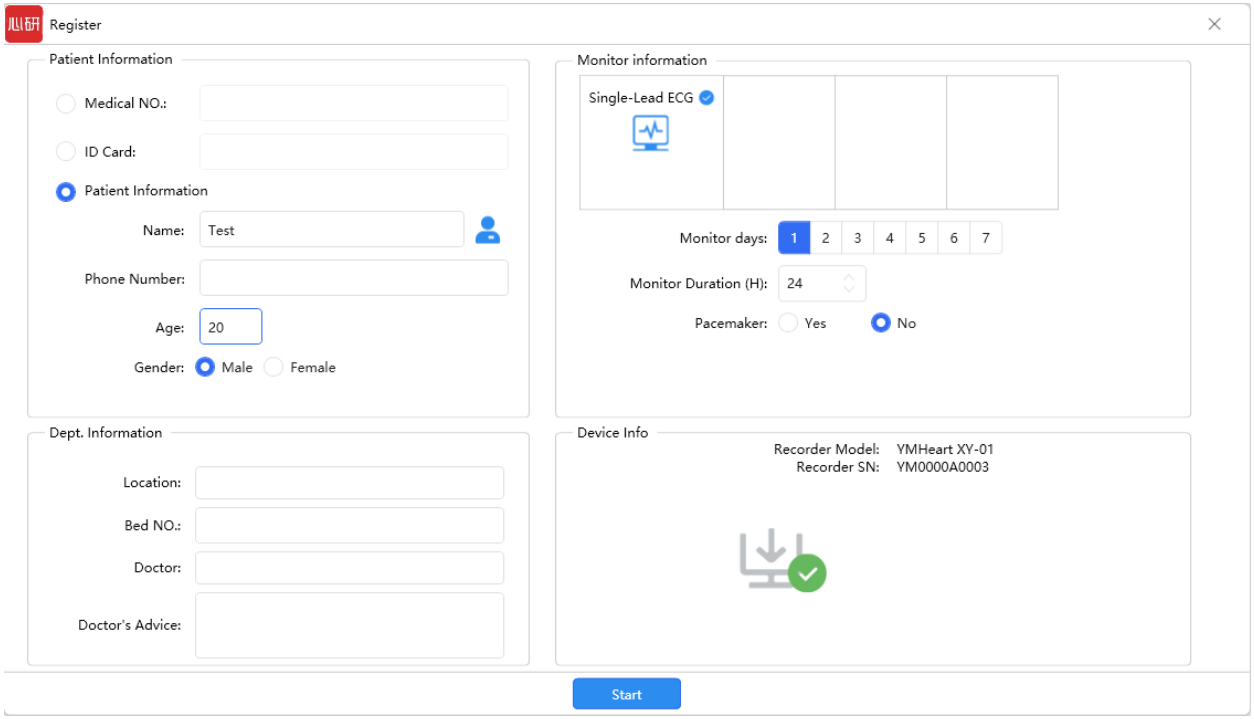
- **Messages**

1. Select a data entry, click “End,” and enter the pending reports.
2. In the software main interface, select a data entry, click “Delete,” and a prompt will appear asking if you want to delete the monitoring record. Click ‘Confirm’ to delete the monitoring record, or click “Cancel” to keep it.

The software saves user data to the local disk on the computer, ensuring data preservation and recovery.

2.2.4.2Create a new guardianship form

Record user-related information in a wearable ECG recorder using ECG management software:



NOTE

Clicking on “Monitoring Days” displays 24 hours. Each additional day of monitoring increases the monitoring duration by 24 hours. The pacemaker can be worn or not worn.

- **Message**

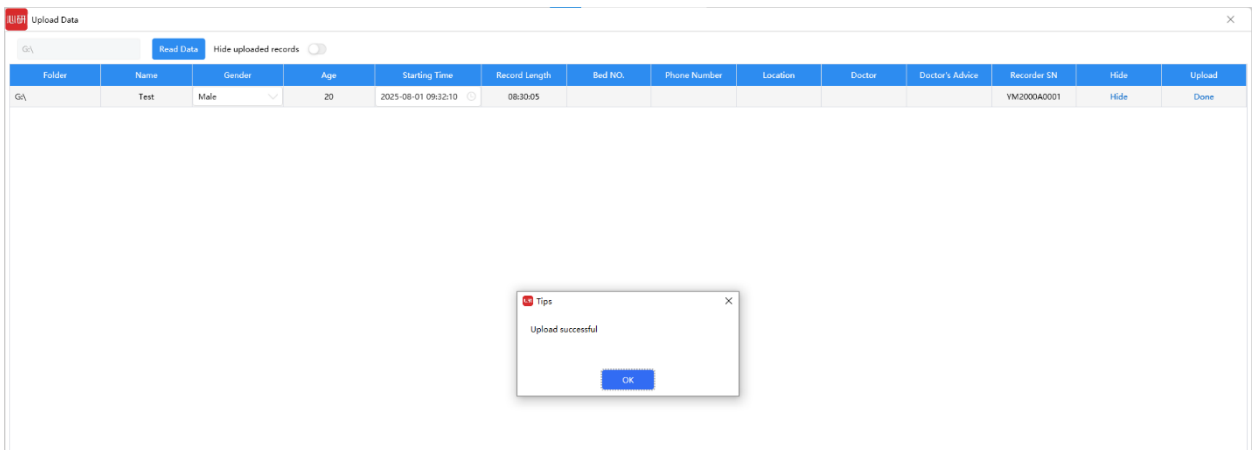
1、 When creating a new monitoring record, if the wearable ECG recorder is not connected to the computer, the system prompts “Please insert the main unit” before proceeding;

2、 When creating a new monitoring record, if the patient's name is not entered, clicking the “Start Monitoring” button displays a prompt: “Please enter the patient's name”;

3、 If the patient's age is entered as greater than 200, the system prompts “Please enter the correct age”.

2.2.4.3 Read data

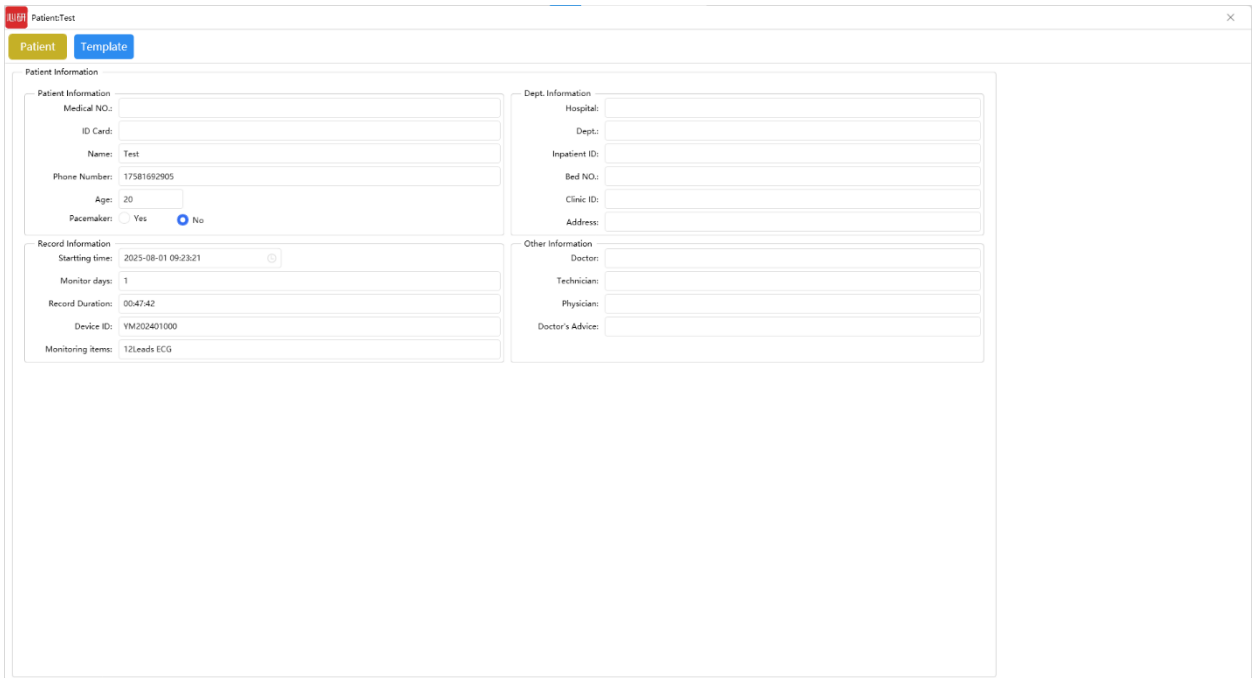
After data collection is complete, import the data from the wearable ECG recorder into the ECG management software, as shown in the figure below:



2.2.4.4 ECG waveform display & printing

- **Patient Information**

Double-click on the patient information to enter the case information interface, which displays the name, mobile phone number, age, pacemaker, and recorded information.



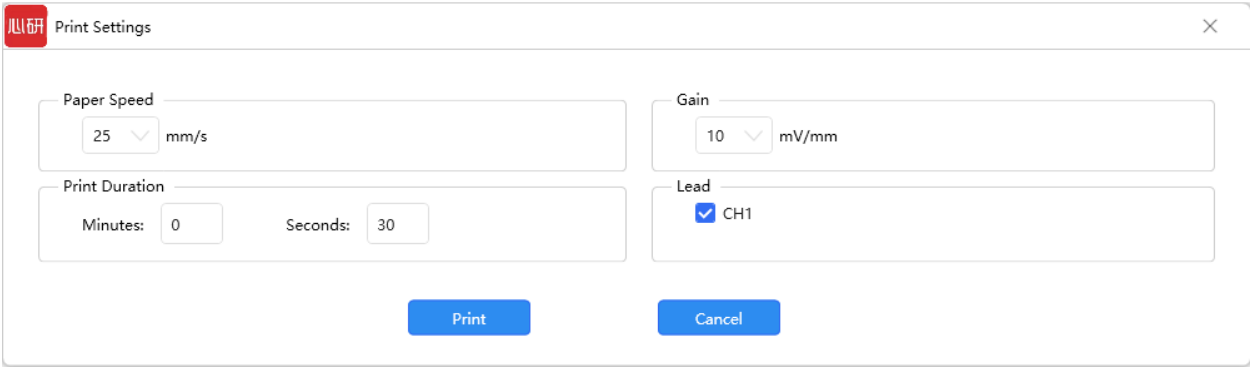
- **Template**

Double-click on the patient information to enter the template interface, which displays 1-lead, 3-lead, 6-lead, 9-lead, and 12-lead ECG waveforms (no waveform acquisition, straight lines), waveform display gain, walking speed, and print options.

walking speed：5mm/s、10mm/s、25mm/s、50mm/s、100mm/s、200mm/s、400mm/s
gain：2.5mV/mm、5mV/mm、10mV/mm、20mV/mm、40mV/mm、80mV/mm、160mV/mm
Select different gear speeds and gains, and the ECG waveform will change accordingly.

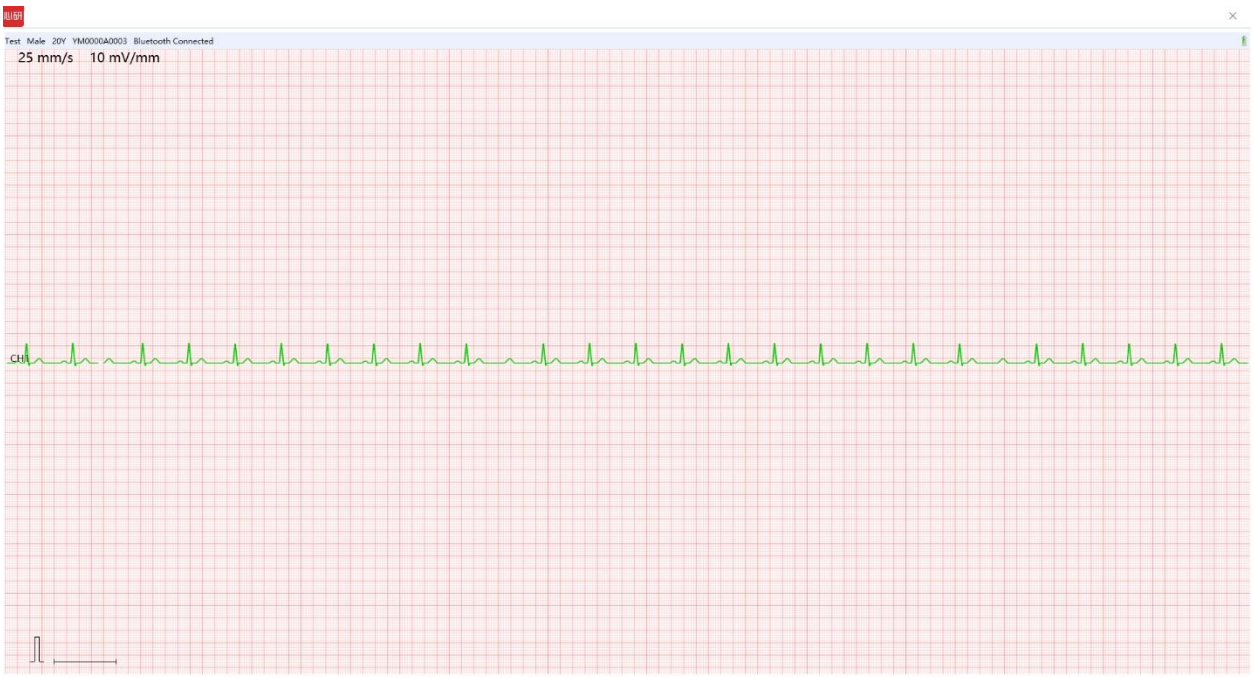
- **Historical data display and printing**

ECG waveforms can be selected, viewed, and printed by doctors for the entire recording period.



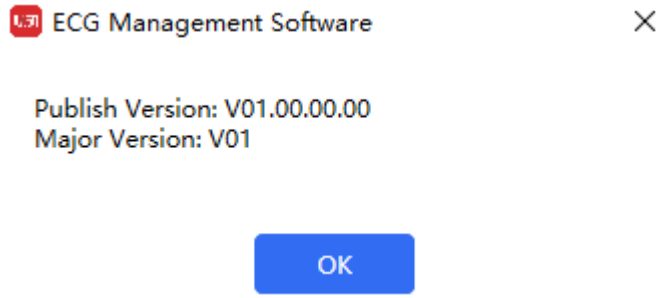
- **Real-time waveform display function**

Through Bluetooth signals, the ECG management software can display the waveforms collected by the wearable ECG recorder in real time.



2.2.5 Software name, specifications, model number

Software Name: ECG Management Software
Model Specifications: YMheartXY-12
Release Version: V01
Full Version: V01.00.00.00
ECG Management Software. You can view the software version information in the “About” section of the menu bar.



2.2.6 Intended Use

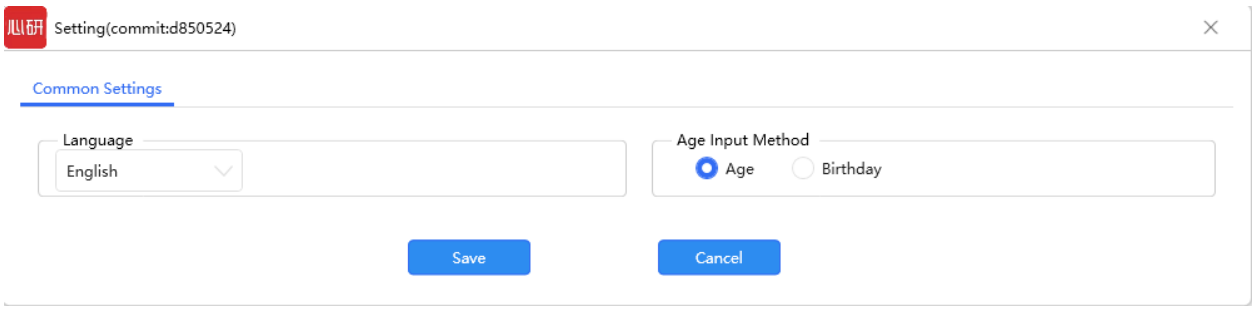
ECG Management Software for reading data from wearable ECG recorders, followed by electrocardiogram display, measurement, and printing.

2.2.7 Software operating environment

a) Host CPU: Intel(R) Core(M) i5-4460 CPU @ 3.20GHz or higher
b) RAM: 16GB or more
c) Hard drive: 512GB or more

d) Software environment: Windows 10 or compatible versions
e) Supports USB 2.0 protocol and BLE 5.3 protocol
f) Network requirements: No internet connection required

2.2.8 System Settings



1、 Language can be selected as Simplified Chinese or English. Select English, and the software will prompt “Please restart the program for the language settings to take effect”.
2、 Age input method: You can choose between age and date of birth, with two formats available.

2.3、Software Technical Specifications

2.3.1、Installation and Uninstallation

2.3.1.1、Installation

ECG Management Software, designed for use on Windows 10 and compatible versions, with the following specific system requirements:
Minimum hardware configuration:
g) Host CPU: Intel(R) Core(M) i5-4460 CPU @ 3.20GHz or higher
h) RAM: 16GB or more
i) Hard drive: 512GB or more
j) Software environment: Windows 10 or compatible versions
k) Supports USB 2.0 protocol and BLE 5.3 protocol
l) Network requirements: No internet connection required

2.3.1.2、Uninstallation

See section “2.2.2.2”.

2.3.1.3、Software upgrade

See section “2.2.2.3”.

2.3.2、Performance efficiency

Software runtime environment, meeting the conditions specified in 2.3.1:

1、 The maximum number of concurrent users logging into and using the software is 1;
2、 Data import time for the ECG management software: For 24-hour patient data, the time taken to import the data into the software is ≤ 100 seconds;
3、 The timer starts when the software is logged in, and stops when the main interface is reached; the login duration must be ≤3 seconds;
4、 The software's CPU resource usage must not exceed 1%, and memory usage must not exceed 10MB.

2.3.3、Compatibility

2.3.3.1、 Software Interface

The software outputs PDF format files, which require office software such as Adobe PDF Reader for viewing.

2.3.3.2、 Hardware Interface

1、 The data interface between the software and hardware uses the USB 2.0 protocol for communication.
2、 Bluetooth interface, which can connect to wearable ECG recorders to display electrocardiograms in real time.

2.3.3.3、 Coexistence

In the environment described in the operating environment section, this software can coexist with common antivirus software including Kingsoft Antivirus and 360 Antivirus; it can also coexist with common office software such as Office and WPS.

2.3.4、Usability

This document is intended for software users who have received professional training, system maintenance personnel, software administrators, software implementation engineers, and others.

This software must be used after training by company professionals. Users must be familiar with the basic operations of the Windows operating system.

To prevent user errors, the software includes the following prompts:
1. Entering an incorrect username or password will display the prompt “Username or password is incorrect”;
2. When creating a monitoring report and the wearable ECG recorder is not connected to the computer, proceeding to the next step will display the prompt “Please connect the main unit”;
3. When deleting patient data in the data management folder, the prompt “Are you sure you want to delete the monitoring report?” will appear.

2.3.5、Usage Restrictions

Log in using the account and password provided by the manufacturer.

2.3.6、Portability

- **Adaptability:**

The software can run normally under the hardware and software environments described in Section 2.2.7.

- **Ease of Installation:**

The software can be installed and used normally under the hardware and software environments described in Section 2.2.7, and users can perform related operations.

- **Replaceability:**

Under the hardware and software environments specified in Section 2.2.7, the software can be uninstalled normally.

2.3.7、Maintenance

Software operation logs are stored in the installation folder, recording operation status;
If users encounter any issues or have suggestions during software use, they may contact the manufacturer via the contact information provided in this document for guidance, or request assistance from the local distributor.

2.3.8、Reliability

The software has undergone comprehensive testing and verification and is capable of meeting all usage requirements in the compatible environment.
The software includes recovery mechanisms and runtime logs: Runtime logs are stored in the installation folder and record runtime status.
The software runs locally, and user data is stored on the local disk of the computer. If the software crashes or freezes, a prompt box will pop up with three options: cancel, retry, or ignore.

User data will not be lost. Simply reopen the software or uninstall and reinstall it to ensure data is saved and restored.

The ECG management software has the following usage restrictions to enhance software reliability:
1. You must use a company-authorized account and password to log in to the ECG management software;
2. When entering information, required fields such as name, phone number, and age must be filled in; otherwise, a prompt will appear asking you to enter the information;
3. If the patient's age is entered as greater than 200, a prompt will appear asking you to enter the correct age;

2.3.9、Information Security

The copyright protection of this software is ensured through control of visibility permissions for the source code, thereby guaranteeing the software's security and integrity.

2.3.9.1 Confidentiality

This software provides user login authentication. Only authorized users with valid accounts and passwords can log in and access the system. After logging in, users can perform read and write operations on data.

2.3.9.2 Integrity

All user data is verified according to a private protocol to ensure data integrity and consistency, preventing tampering by external programs.

2.3.9.3 Non-repudiation

The software has a logging mechanism that records local logs; in case of an accident, it can be restored to a specific point in time.

2.3.9.4 Auditability

When using the software for the first time, authorized users must log in using the correct username and password;
Users can interpret software logs on their own or with the assistance of the supplier. The log files in the software installation directory contain the login account ID of the application operator and records of their main operations.

2.3.9.5 Authenticity

The software requires offline certification by the company during its initial use, along with authorization of the software account and password. During certification, users must submit their valid ID, contact information, and medical qualifications for review and approval by the company.

2.3.9.10 User Error Prevention

When deleting patient data, a confirmation prompt “Are you sure you want to delete the monitoring record?” appears.

2.3.9.11 Copyright Protection

Software copyright protection is achieved through control of source code visibility permissions. The manufacturer provides the software installation package, username, and password to ensure the software's security and integrity.

2.3.10、Essential Software and Hardware

The wearable ECG recorder must be used in conjunction with the ECG management software (version V01).

2.3.11、Maximum Concurrent Users

The maximum number of concurrent users is 1; the software can only be logged in with one username and password at a time.

2.3.12、Input/Output

Input: Data is transmitted via the USB protocol.
Output: The ECG management software can export PDF reports.

2.3.13、Important Notes

NOTE

- This software is intended for use by medical professionals with knowledge of electrocardiograms.
- This software will not cause harm or damage to patients or users.
- The software interface provides information in Chinese and is intended for use by users

who can read Chinese.

Chapter 3 Product maintenance

NOTE

- The device must not be modified without authorization from the manufacturer.
- Heating the device from its minimum storage temperature to a usable state takes approximately 10 minutes. Cooling the device from its maximum storage temperature to a usable state takes about 10 minutes(when the ambient temperature is 20°C).

3.1 Product maintenance

The warranty period for the purchased product is subject to the sales contract. Consumables, which are single-use disposable materials or replaceable wearing materials that need to be changed after each use or regularly, are not covered by the warranty.

The warranty period is calculated from the “Installation date" filled in the accompanying "Warranty Card," which is the sole proof for calculating the warranty period. To protect your rights and interests, please fill in the warranty card after the device is installed, and hand over the second copy (the "Xinyan Medical Retention" copy) to the installation personnel or deliver it back to the Xinyan Medical User Service Department.

Please note that the following situations are not covered by the warranty:

1、 You do not fill out and return the equipment warranty card within 30 days after the completion of the installation acceptance.
2、 The equipment serial number provided is incorrect (we use the equipment serial number to confirm warranty coverage).

Within the warranty period, our products are entitled to free after-sales service. However, please note that even within the warranty period, Xinyan Medical will charge for repair services if the product requires repair due to the following reasons:

1、 Human-induced damage.
2、 Improper use.
3、 Irresistible natural disasters.
4、 Replace or use of parts, accessories, consumables not recognized by Xinyan Medical, or repair by unauthorized personnel.
5、 Other malfunctions not caused by the product itself.

After the warranty period expires, Xinyan Medical can continue to provide paid repair services. If you do not pay or delay payment for the charged repair services, Xinyan Medical will temporarily suspend the repair services until full payment is made. Xinyan Medical is

responsible for the safety, reliability, and performance of the product only if all the following requirements are met:

1、 Assembly operations, expansions, readjustments, improvements, and repairs are carried out by professionals authorized by Xinyan Medical. All replaced parts and accompanying accessories, consumables used in repairs are either original Xinyan Medical parts or approved by Xinyan Medical.
2、 The electrical equipment complies with Chinese national standards and the requirements of this user manual.
3、 The product operation is conducted in accordance with this user manual.

3.2 Cleaning, disinfection, and maintenance

NOTE

- Cleaning and disinfection of this product applies only to the wearable ECG recorder. The wearable ECG sensors are for single-patient, single-use, and do not require cleaning or disinfection.
- Ceaning and disinfection of this product must be performed under the storage temperature, humidity, and altitude conditions specified in section 1.4 Environmental requirements.
- We recommend that you clean the product before each use and disinfect it once a month.
- Because the wearable ECG recorder may be used for data collection from multiple patients, we recommend that you clean it before each use.

3.2.1 Cleaning

The product should be cleaned before and after each use. Before cleaning, please consult or understand the hospital regulations regarding equipment cleaning, disinfection, and sterilization.

When cleaning the surface of the product, use a clean, soft cloth, sponge, or cotton ball, dampen it with non-corrosive cleaning agent, wring out excess liquid, and gently wipe the surface. Recommended cleaning agents are as follows:

- Water
- 70% ethanol
- 70% isopropanol

To prevent damage to the equipment, please follow the following requirements:Some cleaning agents need to be diluted before use. Please strictly follow the manufacturer's instructions to dilute the cleaning agents properly.
After cleaning, use a dry cloth to wipe any excess cleaning agent.
Do not immerse the device in water or any cleaning agents, nor should you splash water or cleaning agents on the surface of the device.
Do not use abrasive materials (such as steel wool or silver polish), nor any strong

solvents (such as acetone or cleaning agents containing acetone).

Caution

Non-compliance with the above requirements may result in corrosion, wear, or illegibility of the casing or labels, or even device malfunction.

3.2.2 Disinfection

To prevent long-term damage to the product, we recommend that you disinfect the product only when your hospital's procedures consider it necessary, and that you clean the product first before disinfection.

The recommended disinfectants are as follows:

- 75% ethanol
- 70% isopropanol

Before disinfection, the main unit and data box of the wearable ECG recorder must be powered off and the USB cable must be disconnected.

Use a soft, clean, lint-free cloth to absorb an appropriate amount of disinfectant and wipe the exterior surfaces of the main unit and data box of the wearable ECG recorder. If necessary, use a dry cloth to remove any residual disinfectant.

Caution

- Do not use high-temperature, high-pressure steam, or ionizing radiation methods for disinfection.
- Avoid using chlorine-based disinfectants such as bleaching powder or sodium hypochlorite.

3.2.3 Maintenance

To ensure the proper functioning of the product, we recommend that hospital professionals perform maintenance on the equipment once every month.

Visual inspection

The product should be checked regularly or be visually inspected before each use. If any problems occur, please contact the maintenance personnel.

- Check the casing for cracks or other damages.
- Regularly inspect connectors for wear or other damages.
- Ensure that all cables and connectors are properly connected.

Maintaining the main unit

Place the main unit into the data box, then connect to the computer, and confirm if it is connected successfully. If any problems occur, please contact the maintenance personnel.

3.3 Troubleshooting and maintenance

No.	Problem	Cause analysis	Solution
1	The device cannot power on.	The battery is run out.	Replace the sensor.
2	The recorder is showing a straight line.	The recorder is not properly connected to the sensor. The sensor is not in good contact with the skin.	Reconnect the recorder and the sensor. Replace the sensor and reattach it properly.
3	The software cannot start normally.	The software package has been uninstalled. Software error.	Reinstall the software.

Since this recorder is a precision instrument, other malfunctions that are not mentioned above can only be handled by professionals. Therefore, in case of other malfunctions, please contact the manufacturer or authorized after-sales service promptly.

Xinyan Medical can provide circuit diagrams, component lists, annotations, calibration guidelines, or other materials that help maintenance personnel repair the device designated by Xinyan Medical upon request. Only maintenance personnel designated by Xinyan Medical can repair this device.

Appendix

Compliance information

① IEC 60601-2-47:2012 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems

② IEC 60601-1:2005/AMD2:2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

③ IEC 60601-1-2:2014+A1:2020 Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance -Collateral Standard: Electromagnetic disturbances-Requirements and tests

④ IEC 60601-1-11:2015+A1:2020 Medical electrical equipment –Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Electromagnetic compatibility (EMC)

This device, as well as all accessories mentioned in the manual when used in conjunction with this device, comply with the EMC standards tested in accordance with the relevant clauses of the following:

- IEC 60601-1-2:2014+A1:2020 Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance -Collateral Standard: Electromagnetic disturbances-Requirements and tests
- IEC 60601-2-47:2012 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
- IEC 60601-1-11:2015+A1:2020 Medical electrical equipment –Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

NOTE

- Use of accessories, sensors, and cables other than those specified may result in increased emission or decreased immunity of device.
- The device should not be used adjacent to or stacked with other equipment. Device should be observed to verify normal operation in the configuration in which it will be used.
- The device needs special precauttions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- Even if other equipment complies with CISPR emission requirements, they may still cause interference with the device.
- Operation of device when the patient physiological signal is lower than the minimum amplitude specified in the product specifications, might cause inaccurate results.
- Portable and mobile RF communications equipment can affect device.
- Other devices with RF radio frequency transmission may affect this equipment. For example, mobile phones, tablets, computers with wireless functions.

Guidance and manufacturer's declaration **– electromagnetic emissions**
The model ECG recorder is intended for use in the electromagnetic environment specified

below. The customer or the user of the model ECG recorder should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The model ECG recorder uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The model ECG recorder is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	n.a.	
Voltage fluctuations/ flicker emissions IEC 61000-3-3		

Recommended separation distances between portable and mobile RF communications equipment and the A&D unit

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150kHz to 80MHz $d = [\frac{3.5}{V1}]\sqrt{P}$	80MHz to 800MHz $d = [\frac{3.5}{E1}]\sqrt{P}$	800MHz to 2.7GHz $d = [\frac{7}{E1}]\sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.37	0.12	0.23
1	1.17	0.35	0.70
10	3.70	1.11	2.22
100	11.70	3.50	7.00

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.

Recommended separation distances between RF wireless communications equipment

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

Frequency MHz	Maximum Power W	Distance	IEC60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
385	1.8	0.3	27	27	RF wireless communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $E = [\frac{6}{d}]\sqrt{P}$ Where P is the maximum output power rating of the ransmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
450	2	0.3	28	28	
710	0.2	0.3	9	9	
745					
780					
810	2	0.3	28	28	
870					
930					
1720	2	0.3	28	28	
1845					
1970					
2450					
5240	0.2	0.3	9	9	
5500					
5785					

Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration – electromagnetic immunity

The model ECG recorder is intended for use in the electromagnetic environment specified below. The customer or the user of The model ECG recorder should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC61000-4-6 Radiated RF IEC61000-4-3	3Vrms 150kHz to 80MHz 10V/m 80MHz to 2.7GHz	N/A 10V/m	Portable and mobile RF communications equipment should be used no closer to any part of The model ECG recorder, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3.5}{V1}]\sqrt{P}$ $d = [\frac{3.5}{E1}]\sqrt{P}$ 80MHz to 800MHz $d = [\frac{7}{E1}]\sqrt{P}$ 800MHz to 2.7GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres(m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a, should be less than the compliance level in each frequency range b, Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

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

B, The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

C, 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 whichThe model ECG recorder is used exceeds the applicable RF compliance level above, Themodel ECG recordershould be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating The model ECG recorder.

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

Guidance and manufacturer's declaration – electromagnetic immunity

The model ECG recorder is intended for use in the electromagnetic environment specified below. The customer or the user of The model ECG recorder 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	± 8 kV contact ± 2 kV， ± 4 kV， ± 8kV， ± 15kV air	± 8 kV contact ± 2 kV， ± 4 kV， ± 8 kV， ± 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	n.a.	n.a.
Surge IEC61000-4-5	± 1 kV line to line ±2 kV line to earth	n.a.	n.a.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T 0,5cycle At 0°,45°,90°,135°,180°,225°,270°and 315°, 0% U_T 1cycle and 70% U_T	n.a.	n.a.

	25/30 cycles Single phase:at 0°		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m, 50/60Hz	30A/m,50/60Hz	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 AC mains voltage prior to application of the test level.			

Wearable ECG Recorder

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CE 0051

FCC Statement

15.105

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

KDB447498 D01 v05r02 (P5)

FCC Radiation Exposure Statement

This device complies with FCC radiation exposure limits set forth for an uncontrolled environment and it also complies with Part 15 of the FCC RF Rules. This equipment must not be co-located or operating in conjunction with any other antenna or transmitter. End-users and installers must be provided with antenna installation instructions and consider removing the no-collocation statement.

FCC Warnning

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1)This device may not cause harmful interference, and
(2)this device must accept any interference received,
including interference that may cause undesired operation.
Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does

cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-Reorient or relocate the receiving antenna.

-Increase the separation between the equipment and receiver.

-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-Consult the dealer or an experienced radio/TV technician for help.

The device has been evaluated to meet general RF exposure requirement.

The device can be used in portable exposure condition without restriction.