

ECG Recorder

(Model: E-H09)

About this instruction

1 .Description of this instruction

This instruction is a description of the function, safety and operation of the ECG recorder. In order to ensure that you can use the dynamic ECG correctly and safely, please read all sections of this instruction carefully before using this product.

The manufacturer shall not bear any responsibility for the unauthorized parts.

2.Version information

Version of this instruction: REV 1.1

Date of revision: December 2017

The version number of this instruction may be upgraded due to changes in software or technical specifications. We will try to modify it as much as possible, but it may not be consistent with some descriptions. Please kindly understand.

3.Copyright

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Without permission, any copy or modification of the content of this document is illegal.

4.Applicable objects

This instruction is applicable to all users of this product.

5.Product information

Product name: ECG recorder

Product model: E-H09

Product Registration Certificate No.: No. 2211254 of JiangSu Food and Drug Supervision (Quasi) Word 2014

Product Technical Requirement Number: No. 2211254 of JiangSu Food and Drug Supervision (Quasi) Word 2014

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6. Patent

The patent of the ECG shall be owned by Nanjing Xijian Information Technology Co., Ltd.

7. Responsibility of manufacturer

Only in the following cases, the manufacturer shall be responsible for the impact of the safety, reliability and performance of the equipment:

- All of the assembly, installation, commissioning, modification or maintenance shall be carried out by the personnel approved by the manufacturer;
- The electrical facilities in the room shall be in accordance with the relevant requirements.
- The equipment shall be used in accordance with the requirements of this instruction.

8. Guarantee

Nanjing Xijian Information Technology Co., Ltd. shall reserve the right to modify this instruction and the products described.

If the product specifications are changed, we will not be able to notify you at that time, please understand.

Neither the content of this instruction involves proposals, warranties, commitments or contractual terms, nor should it be considered such projects.

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Chapter 1 Security

1.1 Brief introduction



Danger

Prompt that a direct risk that cannot be avoided will immediately cause death or serious injury.



Warning

Prompt that a potential risk that cannot be avoided may immediately cause death or serious injury.



Caution

Prompt that potential danger or unsafe operations that cannot be avoided may cause mild or moderate damage, injury, or financial loss.



Notice

Emphasize important matters of attention, provide instructions or explanations for better use of this product.

1.2 Overall security information



Danger

The ECG recorder does not involve information of danger level.



Warning

- **Do not use this product in an environment with flammable anesthetic gases, oxygen or nitrogen oxides.**
- **This product is not allowed to be modified in any way.**
- **This product is not allowed to be used with defibrillator devices.**
- **This product is not allowed to be used together with electrosurgical instruments.**
- **This product is not allowed to be used with CT or MRI equipment.**
- **Do not subject the product to high temperature, high pressure, gas fumigation or liquid immersion. Shut down the product before cleaning or disinfecting.**
- **The physiological waveforms, physiological parameters and prompts displayed in this product are for reference only and cannot be directly used as the basis for clinical treatment.**
- **Do not squeeze the product hard, if the shell is broken, please stop using it.**
- **Waste (including the product itself scrapped) in accordance with the relevant laws and regulations for processing.**
- **During use, do not charge the intelligent display device connected with the product.**
- **To keep the ECG recorder away from fire, do not heat it, otherwise the internal**

battery may explode.

- **Please keep the ECG recorder out of the reach of children.**



Caution

- **Do not use, maintain and repair the ECG recorder before reading the manual in detail.**
- **Keep the dynamic ECG recorder dry, and avoid strong collision.**
- **The ECG recorder should be far away from the strong magnetic field, because it may affect the accuracy of the test. If the ECG recorder accidentally gets wet, turn off the power immediately, dry the shell of the ECG before use, and contact the supplier.**



Notice

- **The user should avoid excessive and vigorous exercise, especially avoid excessive movement of upper limbs.**
- **Bluetooth transmission distance : Mobile phones and ECG Recorder in the absence of barriers, transmission distance of 5 meters -10 meters range**
- **This product cannot be used for baby monitoring records weighing less than 10kg.**



FCC Notice

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. (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.

WARNING: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Chapter 2 An Introduction to ECG Recorder

2.1 Scope of application

This product's real-time transmission and display of ECG information and waveform signals.

2.2 Principle of this product

Through human contact, this product carries out the measurement and record of the ECG information, and the ECG information is transferred to the intelligent display device via blue tooth, and then the display and storage of the ECG data and waveform may be completed in the display device, which has the function of waveform display, heart rate display, data storage, trend charts and prompt, in addition, it can generate PDF for the data and send it to share.

2.2.1 The calculation method of heart rate value: $60 \times 1000 / \text{RR interphase}$.

2.2.2 Breathing identification method: $\text{RR interphase} \geq \text{optional absolute threshold}$.

2.3 Applicable population and contraindication

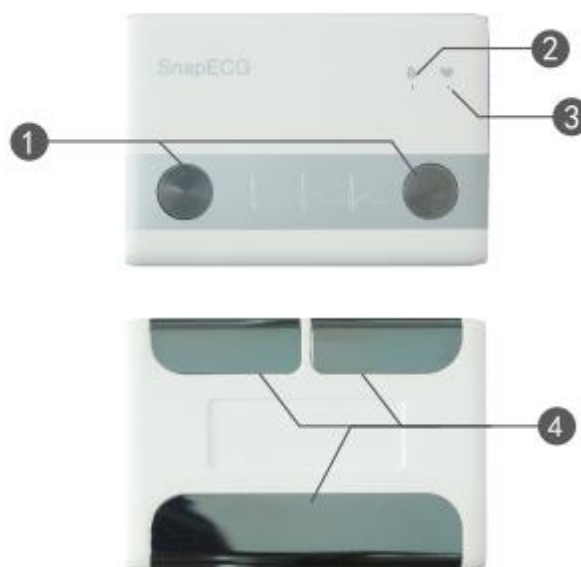
Applicable population: all groups of people (except for infants underweight 10kg).

Contraindication: None

2.4 Structure composition:

Product composition: The ECG recorder consists of a ECG recorder and ECG analyser software.

Among them, the structure of ECG recorder is shown in the following figure.



E-H09

No.	Symbol Name	Meaning

1	Circular Electrodes	Used in measurement
2	Charging Indicator	Light on in charging, and light off when power is fully charged.
3	Status Indicator	Fast blink indicates that the connection has not succeeded; slow blink indicates that the connection is successful
4	Long Electrodes	Used in measurement

2.5 Identification

Identification	Description for identification	Identification	Description for identification
	Fragile; be careful		Batch code
	Fear of Rain; Avoid Rain		Recycle
	Manufacturer		Authorized representative in the European community
	date of manufacture		Term of Use
	Product Sequence Number		Environmental Protection Service Life is 10 Years
	Waste Disposal Should Conform to WEEE Standard		CF Application Domain
	Attention ! Refer to the Attached Files		consult instructions for use

Chapter 3 Installation and debugging

3.1 Unpacking

Open the packing box and carefully remove the ECG recorder and accessories. Please check if the item is complete or damaged. If there is any missing piece or damage, please contact the supplier immediately.



Notice

- electrical schematic and components list only provide qualified maintenance station or personnel confirmed by manufacturer.
- The production date and expiry date can be seen in the external package.

3.2 Download and installation of software

The ECG shall be used in conjunction with the intelligent display device. The Bluetooth for the system of intelligent display device shall be Version 4.2 or above.

Handheld ECG software download and installation steps:

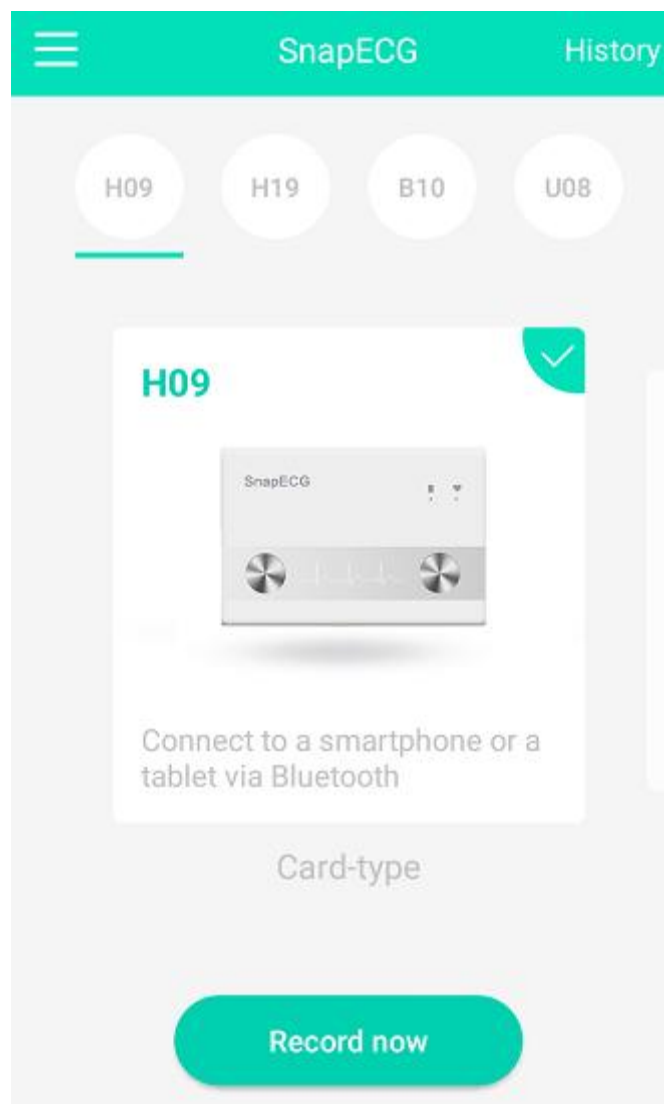
- (1) Installation package download: you can login the related webpages of the palmtop ECG official website www.mhealth365.com/en/, or scan the two-dimensional code on the back of the package, and then download the installation package from these prompts .
- (2) Click on the installation package downloaded and complete the installation of the software according to the prompt.

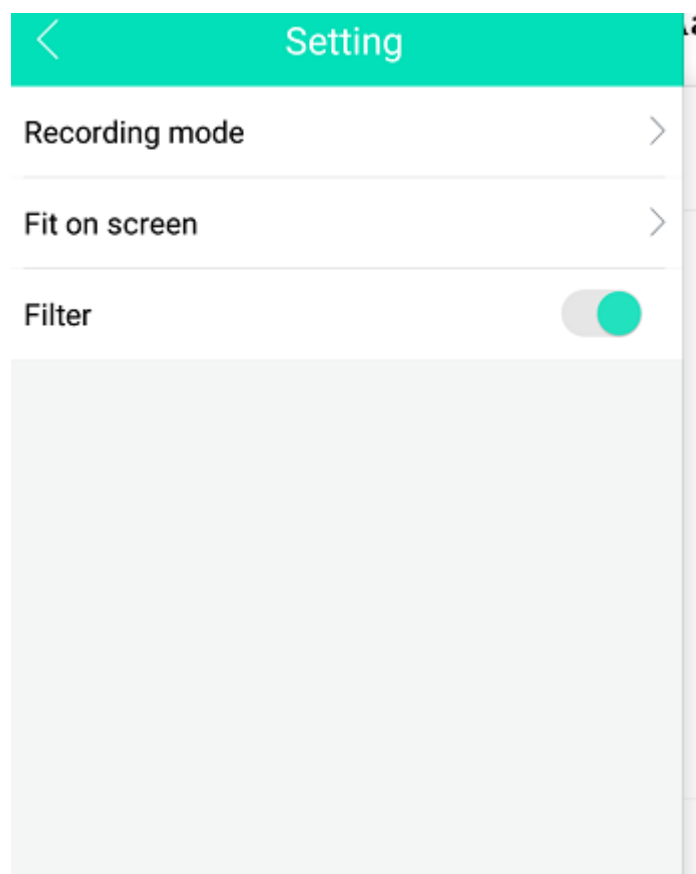


Caution: if the software version has been upgraded, please use the latest version.

3.3 Instruction

- (1) Search for ECG recorder: follow the prompts on the software page, turn on the Bluetooth, make sure it is in the Bluetooth search state, and then touch the front dual electrodes of the dynamic ECG with your fingers to start the product, the product's indicator should flash quickly.





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< About us

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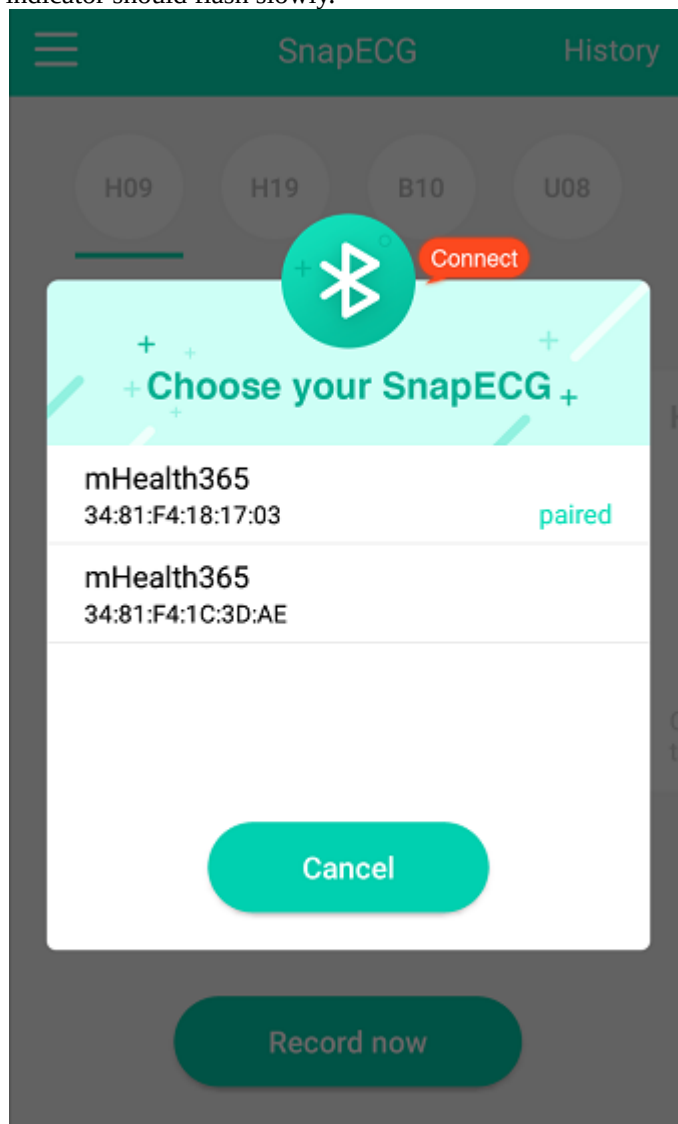
European Representative name

Wellkang Ltd

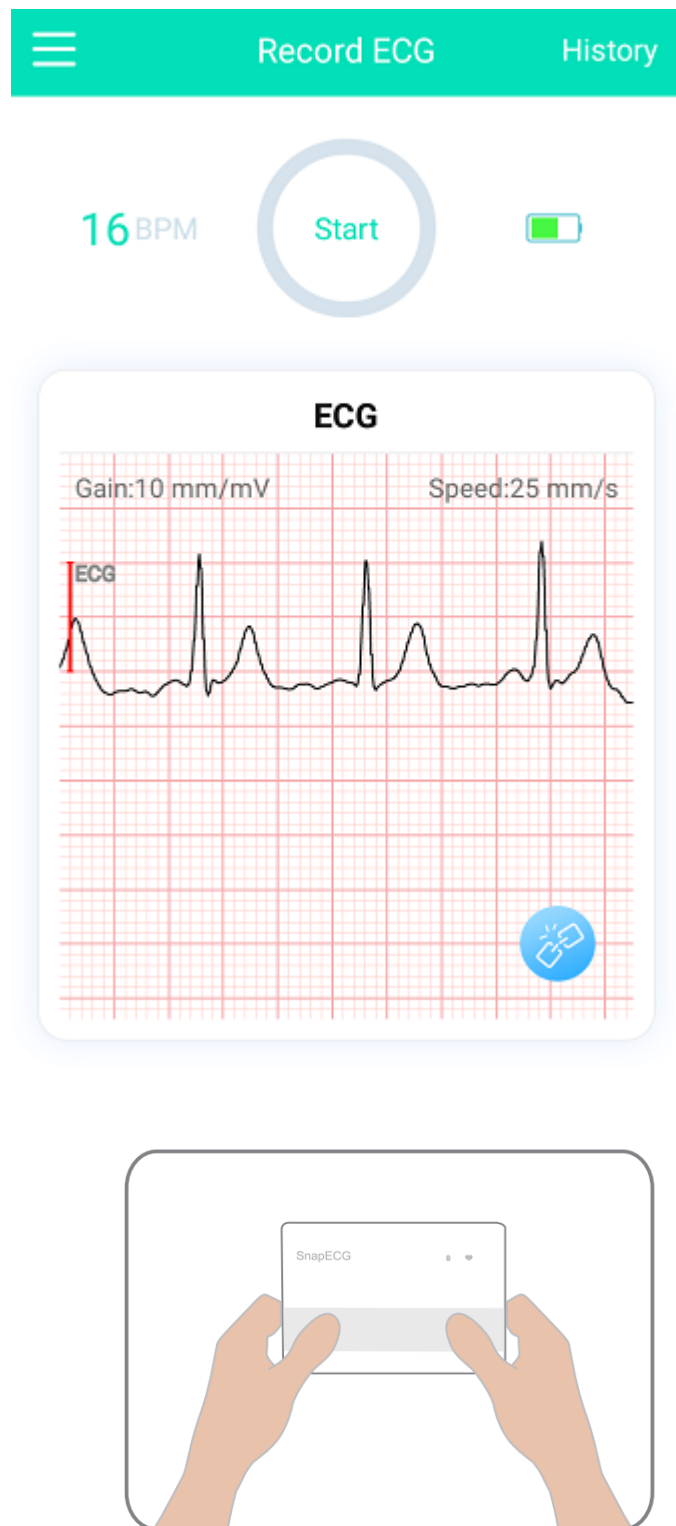
European Representative address

699-18 Xuanwu Avenue,Nanjing,China

(2) Connect the ECG recorder: On the software's Bluetooth search page, select the device whose name begins with mhealth365 for Bluetooth connection. After the connection is successful, the indicator should flash slowly.

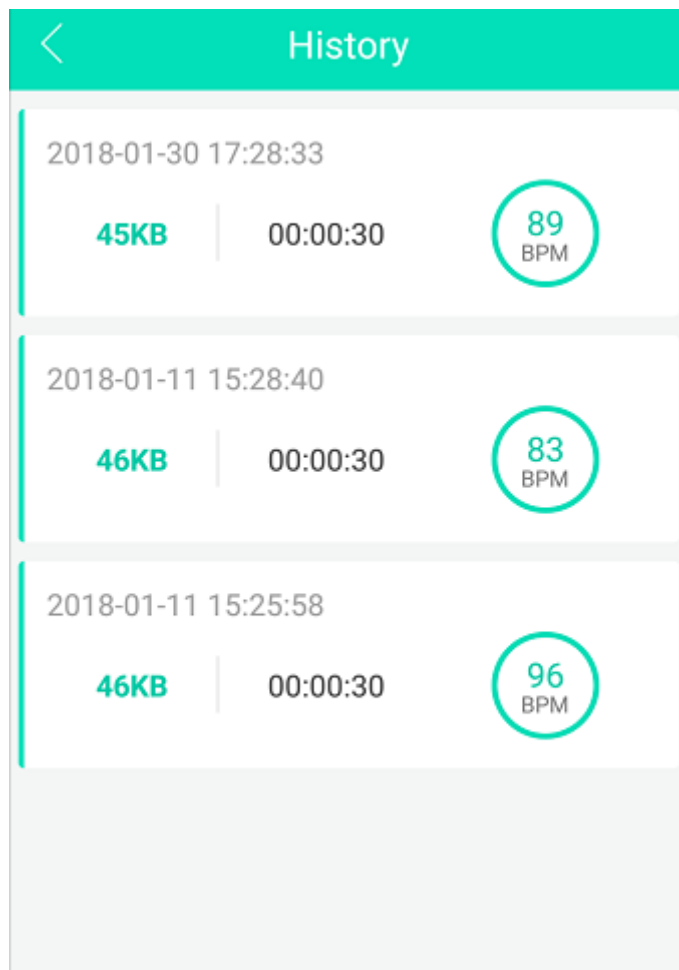


(3) Measure and record the ECG: On the software page, follow the prompts and click it to start the measurement. Hold the ECG recorder with both hands and press the electrode with your thumb (refer to the figure below). At this time, keep the words "SnapECG" up. After the measurement, the software will prompt and generate a health report, from which you can view the record measured in the software.



Tips: when measuring, please keep quiet in an undisturbed environment. Don't exercise and talk.

(4) Consult professional ECG services: On the software page, you can browse the history report.



(5) Login registration: When you send a health report, the palmtop ECG software will automatically jump to the login page, and then you may complete the account registration according to the page prompt, and log in to your personal account; you can log in directly in case that you already have an account.

×

SIGN UP

LOGIN IN

Email

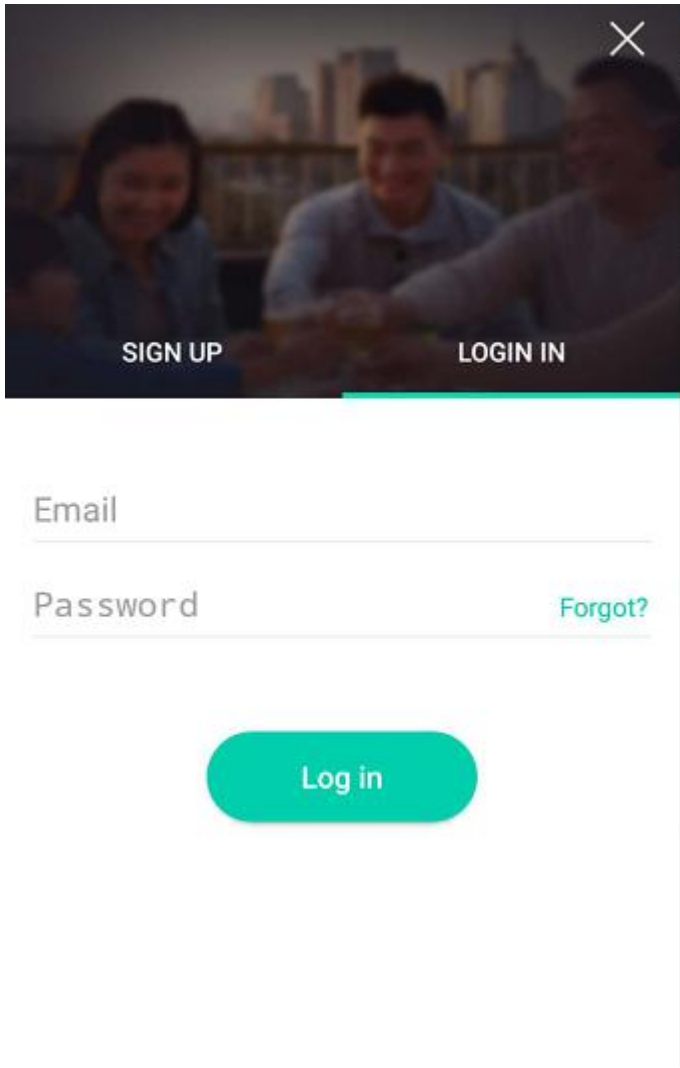
Password

Input code

[Get code](#)

☒ I agree to your privacy policy

Confirm

The image shows a user interface for a login and sign-up system. At the top, there is a header image of three people smiling, with a close button (X) in the top right corner. Below the header, there are two buttons: "SIGN UP" and "LOGIN IN". Underneath these buttons, there are input fields for "Email" and "Password". To the right of the "Password" field, there is a link labeled "Forgot?". Below the input fields, there is a large, rounded, teal-colored button labeled "Log in".

SIGN UP LOGIN IN

Email

Password [Forgot?](#)

Log in

(6) After the measurement is completed, exit the software and both hands leave the electrode of ECG recorder for more than 3 seconds to shut down automatically.

3.4 Charging description

E-H09 is powered by an internal 3.7V rechargeable battery, and the battery is not detachable. Before use, please fully charge the battery to meet the needs of record time. When the power of the equipment is low, the indicator will turn off automatically after the light flicker quickly. Please plug in the USB charging line to charge the device. When charging, please choose the 5V output adapter. When charging, the charging indicator is always bright; after full electricity, the indicator lights out automatically.

Chapter 4 Service and maintenance

1. When the product's surface is covered with dust or dirt, use dry, clean, and soft cotton cloth, or wet medical alcohol cotton ball to gently wipe it, but be sure to avoid alcohol drip or flew into the product.
2. The service life of the product is 5 years; the disposal of the products should comply with local laws and regulations.
3. When the product is not used for a long time, please put it in a dry and cool place according to the storage environment requirement.
4. the product needs to be charged every three months to ensure the charging performance of the internal battery.

 Warnings:

- Do not sterilize or autoclave.
- Using disinfectants other than alcohol may damage the device, shorten the service life, or cause a safety risk.
- Do not use gasoline, thinner or similar organic solvents to clean any part of this product. Do not use radiation, steam, ethylene oxide and other methods for sterilization, otherwise it will cause damage to the product.

Chapter 5 Fault and elimination

The failures that users may encounter and troubleshooting methods during the use process are shown in the following table.

Fault phenomenon	Possible causes	Solutions
Unable to boot	1.The battery power is insufficient or is dead. 2.The product may be damaged	1. Please reboot or replace the battery. 2. Please contact with the after-sales service personnel of the manufacturer
Unable to connect to the receiving device	1. The receiving device may be not supported 2. The machine may be damaged	1, Please reconnect 2, Please contact with the after-sales service personnel of the manufacturer
Abnormal electrocardiogram	1. The fingers are not in good contact 2. The machine may be damaged 3. The working environment of the machine is disturbed	1. Adjust the handheld posture 2. Please contact with the after-sales service personnel of the manufacturer 3. Far away from strong electromagnetic interference

Appendix A Product specification

Safety standards	
EN 60601-1: 2012	Medical electrical equipment-Part1: General requirements for basic safety and essential performance
EN 60601-1-2: 2014	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
Product classification	
Classification of anti-electric shock type	Internal power supply equipment
Classification of anti-electric shock degree	CF-type application part

The degree of protection of the incoming liquid	Common equipment
Classification of EMC	Class B of Group 1
Safety levels in situations where flammable anaesthetized gases, oxygen, or nitrogen oxides are mixed	Not suitable for use in cases containing flammable anaesthetized gases, oxygen, or nitrogen oxides
Operation mode	Continuous operation
Operating environment	
Working temperature	+10℃～+45℃
Working humidity	10%～95%RH (non-condensing)
Atmospheric pressure range	70kPa～106kPa
Transportation environment	
Temperature	-20℃～+55℃
Relative humidity	≤93%RH (non-condensing)
Atmospheric pressure range	50kPa～106kPa
Storage environment	
Temperature	-20℃～+50℃
Relative humidity	≤85%RH (non-condensing)
Atmospheric pressure range	50kPa～106kPa
Power Supply	
Working voltage	DC 3.7V(rechargeable internal battery)
Power	0.15VA
ECG part	
Gain accuracy	5mm/mV (X0.5), 10mm/mV (X1), 20mm/mV (X2), error range of + 10%
Scanning speed	12.5mm/s, 25mm/s, 50mm/s, error range of 10%
Measuring range	15～350bpm
Accuracy	+ 1bpm or + 1%, select the max value
Lead	Single lead

Appendix B Common sense of heart health

1. What is the heart rate trend?

The rate of heart rate changes in a period of time, normally, the heart rate of adults is 60 to 100 times per minute.

2. What is the heart rate distribution?

Normal heart rate for a period of time, the heart rate is slightly faster, slower, too fast, too slow.

3. What is the rhythm trend?

A change in the rhythm of the beating of the heart for a period of time.

4. What is the abnormal rhythm distribution?

The proportion of abnormal rhythms, such as arrhythmias, premature beats and atrial fibrillation during a period of time.

5. What is premature beat?

The beat of the normal heart is the rule, and the heartbeat interval is basically the same. If the heart beats suddenly earlier, it is called premature pulsation in medicine.

6. What is atrial fibrillation?

Atrial fibrillation referred to as atrial fibrillation, that is, the atrial produce up to 350-600 times per minute irregular impulses, atrial fibrillation in various parts of the very uncoordinated chaos fibrillation, which lost the effective contraction, the vast majority occurred in patients with heart disease Of patients such as rheumatic heart disease, coronary heart disease and hypertension.

Appendix C Product pollution control sign

C.1 Environmental protection service life mark



The environmental protection service life mark is formulated in accordance with the control measures for pollution control of electronic information products and the requirements for pollution control identification of electronic information products (SJ/t11364-2006). It applies to the identification of electronic information products sold in China. As long as according to the safety and the use of the contents in the normal use of electronic information products, conditions, from the date of production, in this period of time the product contain toxic and harmful substances shall not leak or mutation, does not cause serious pollution to the environment or cause serious damage to the person or property. After the normal use of the product, it is necessary to discard the products that have been used in the environmental protection service years or the new years. Please take appropriate measures according to the national standards. In addition, this period is different from the warranty period of quality/function.

The term "environmental protection term" shall only be effective when the product is normally used in the normal circumstances described in this instruction.

C.2 Table of toxic and harmful substances or elements

Part name	The content of toxic or harmful substances or elements					
	Pb	Hg	Cd	Cr(VI)	(PBB)	(PBDE)
Plastic/polymer components	○	○	○	○	○	○
Metal parts	×	○	○	○	○	○
Circuit board components *	×	○	○	○	○	○
Cable and cable components	×	○	○	○	○	○
Welding flux	×	○	○	○	○	○
Battery	○	○	○	○	○	○
*: PCB components include printed circuit boards and their components, such as resistors, capacitors, inductors, semiconductor devices, connectors and so on. ○: Indicates that the content of the toxic and hazardous substance in all homogeneous materials of the part is below the limit requirement of SJ / T11363-2006 standard; ×: Indicates that the content of the toxic and hazardous substance in at least one homogeneous material of the part exceeds the limit requirement of SJ / T11363-2006. Note: this table indicates that the dynamic ECG recorder may contain these substances.						

Appendix D Guidance and manufacturer's declaration

–Electromagnetic compatibility

Guidance and manufacturer's declaration – electromagnetic emission		
The E-H09 ECG Recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the E-H09 ECG Recorder should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Group 1	The E-H09 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 CISPR11	Class B	The E-H09 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	N/A	

Guidance and manufacturer's declaration – electromagnetic immunity			
The E-H09 ECG Recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the E-H09 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 ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	0 % U_T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T ; 1 cycle and 70 % U_T ; 25/30 cycles Single phase: at 0° 0 % U_T ; 250/300 cycle	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the E-H09 ECG Recorder requires continued operation during power mains interruptions, it is recommended that the E-H09 ECG Recorder be powered from an uninterruptible power supply or a battery.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The E-H09 ECG Recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the E-H09 ECG Recorder should assure that it is used in such an environment.			
Immunity test	EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V _{rms} 150 kHz to 80 MHz 6 V _{rms} in ISM bands between 0,15 MHz and 80 MHz	3 V _{rms} 150 kHz to 80 MHz 6 V _{rms} in ISM bands between 0,15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the E-H09 ECG Recorder, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ 800 MHz to 2.7 GHz where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). ^b 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. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the E-H09 ECG Recorder is used exceeds the applicable RF compliance level above, The E-H09 ECG Recorder should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary,			

such as reorienting or relocating the E-H09 ECG Recorder.

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

Recommended separation distances between portable and mobile RF communications equipment and the E-H09 ECG Recorder			
The E-H09 ECG Recorder is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the E-H09 ECG Recorder can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the E-H09 ECG Recorder as recommended below, according to the maximum output power of the communications equipment			
Rated maximum output of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}] \sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}] \sqrt{P}$	800 MHz to 2.7 GHz $d = [\frac{7}{E_1}] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Appendix E Packing List

Packing List		
No.	Name	Number
1	ECG recorder	1 unit
2	Data cable	1 PCS
3	Instructions	1 copy
4	Warranty Card	1 copy
5	Certificate	1 copy

Note: The List is the standard packaging configuration for E-H09 Dynamic ECG recorder

Registered person / manufacturing enterprise: Nanjing Xijian Information Technology Co., Ltd.

Residence: (BDA,Jiangning) 3/F, No.4 Jinjulong Building,9 Gaohu Road, Jiangning District,Nanjing,China

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