ECG Recorder

Instruction Manual

Product Model: YK-ER3

Version: V1.0

Contents

Contents

1.Safety Information

1.1 Safety Notices

This instruction manual describes the device's purpose, functions, and safe operating procedures. Before using this device, please read and fully understand the contents of this instruction manual to ensure correct use and the safety of the patient and the operator.

⚠ Notice

1. When Bluetooth is disconnected, the application cannot connect to the ECG monitoring device via Bluetooth to view the ECG.
2. When the ECG monitoring device leads become detached, the application will display a lead detachment notification.
3. This product is not suitable for users with physical disabilities or those who are unable to understand the instructions for use.
4. Users may encounter the following critical defects: software crashes and server downtime. If you encounter the above situations and cannot recover on your own, please contact an engineer for assistance.
5. The product may cause adverse events, such as discrepancies between the electrocardiogram (ECG) diagnosis results and the doctor's diagnosis. The doctor should make a judgment based on their clinical ECG expertise and experience.
6. Please use the matching electrocardiogram (ECG) acquisition device. The acquisition device must be able to provide data that conforms to the data interface standard of this product.
7. Heart rate calculation method: HR=60×1000/RR interval (RR interval unit: ms).
8. If the heart rate value drops significantly suddenly or becomes an invalid value, and no heartbeat waveform is displayed, cardiac arrest may occur. Immediate attention must be paid to this situation.
9. No modifications of this product are permitted.
10. This product is not permitted to be used in conjunction with defibrillators, high-frequency surgical equipment, electrosurgical equipment, diathermy devices, pacemakers, electrical stimulators, or CT or MRI equipment.
11. Please keep this product dry, avoid getting it wet, and avoid strong impacts.

12. Do not use this product in strong magnetic fields, as this may affect the measurement results.
13. If you experience heart discomfort or irregular heartbeats, please contact your doctor immediately for treatment.
14. Do not squeeze the product forcefully. If the outer shell cracks, please stop using it.
15. Do not place this product near a fire source to avoid damaging the product or causing the battery to explode;
16. If the main unit's electrode plates are contaminated with foreign matter or dust, please clean them with a soft cloth before taking measurements.
17. When the battery of this product is low, please charge it in time by connecting it to a power source using a Type-C data cable.
18. Improper disposal of products and accessories at the end of their lifespan can harm the natural environment and human health. In such cases, they should be disposed of in accordance with the relevant environmental protection regulations of the city and should not be discarded at will.
19. Please use this product within the temperature and humidity range specified in the instruction manual, and within a space with good heat dissipation. Extremely cold, hot, or humid environments will affect the performance and lifespan of the product, so please avoid using it in such environments.
20. Bluetooth requirements: Bluetooth 5.0 and compatible versions, with a transmission rate of ≥80KB.
21. This recorder belongs to the CF type application section (the application section includes metal electrodes and a plastic housing) and internal power supply device, with a liquid ingress protection rating of IP22;
22. This recorder is a device that cannot be used in the presence of flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide.
23. Recorder repairs must be performed by professional technicians from our company or our designated repair centers. Unauthorized personnel are prohibited from disassembling the recorder; otherwise, the manufacturer will not be liable for any damage or consequences. For repair inquiries, please contact our company or our designated repair centers (circuit

diagrams, component lists, annotations, calibration details, and othervs The relevant technical documents required for repairs can be obtained from our company by our designated repair centers.

24. The physiological waveforms, parameters, and prompts displayed by this product are for reference only and should not be used as a basis for clinical diagnosis or treatment.
25. For a better user experience, please update your application version promptly.
26. Disposable ECG Only custom-made electrodes (electrode patches) provided by our company must be used. Do not replace or modify disposable ECG electrodes at will. Care must be taken to prevent electrode oxidation; otherwise, the measurement results will be affected.
27. Unauthorized personnel are prohibited from replacing the internal battery. Our company will not be responsible for any equipment damage or safety issues caused by unauthorized battery replacement.
28. This product is for adults only.
29. This product should be properly stored away when not in use to prevent damage from pets, insects, or children

1.2 Definitions of Symbols

	CF type		warn		Fragile items, handle with care.
	Validity period		Manufacturer		Production date
	Temperature Limit		Humidity Limit		Afraid of rain
	Sunscreen		up		Class II equipment
	Follow the operating instructions		Non-ionizing radiation		
IP 22	Enclosure protection rating: Protects against entry of particles with an outer diameter of 12.5 mm; protects against vertical water drop.		The symbol is a pollution control mark for electronic information products. This indicates that the product has an environmentally friendly lifespan of 5 years and can be recycled; it should not be discarded at will ; dry cell batteries are not included.		

2. Product Overview

This product is a wearable three-lead electrocardiogram recorder. Users can collect, observe, and store dynamic electrocardiogram signal data by attaching disposable electrocardiogram electrodes to the corresponding positions on the chest as required.

2.1 Scope of Use

This product is suitable for detecting ECG waveforms and heart rate in medical institutions or home settings. It can provide a reference for medical professionals in their diagnostic process.

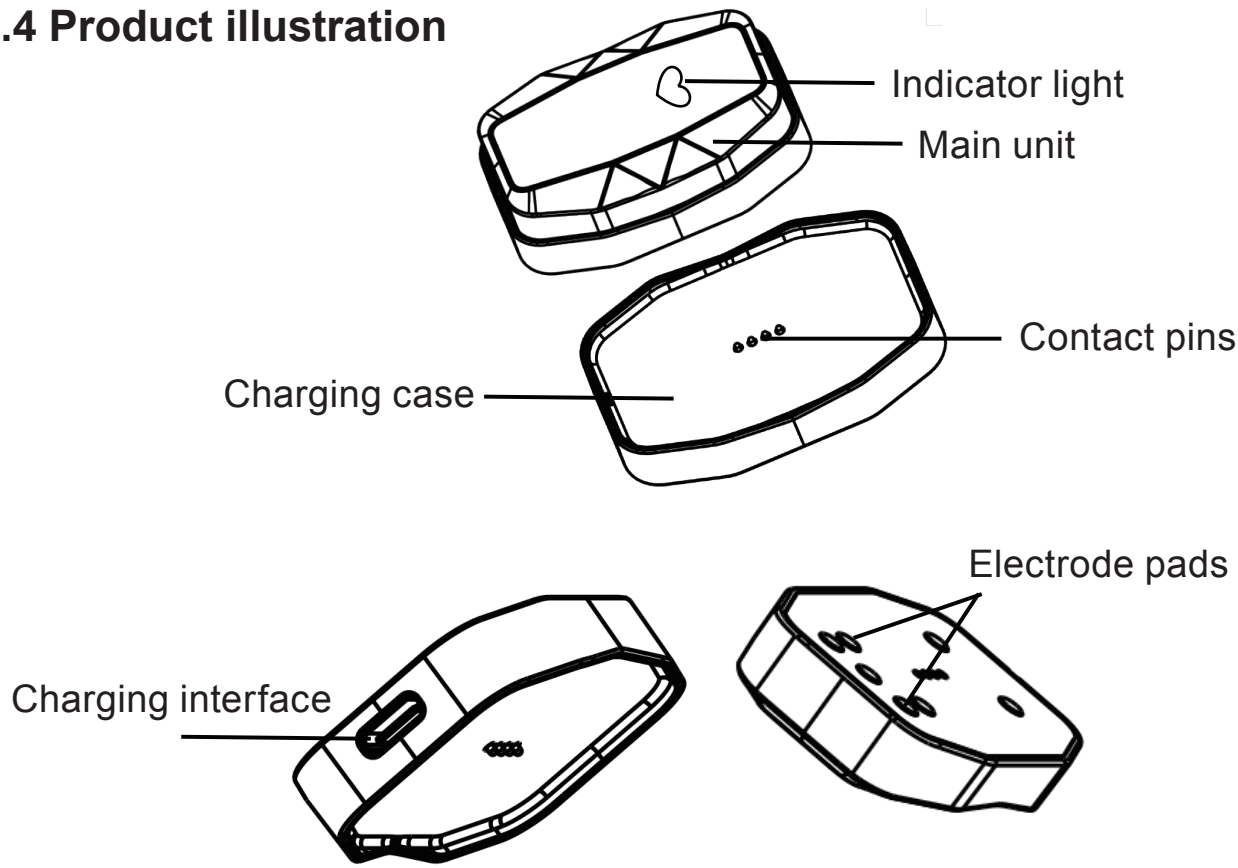
2.2 Contraindications

This product is not suitable for patients with pacemakers or other implanted devices. Patients with broken skin in the testing area should also not use this product.

2.3 Structural Components

It consists of a main unit, a charging case, disposable ECG electrodes, a Type-C data cable, an OTG connector, and an application.

2.4 Product illustration



1. Electrode pads: Used in conjunction with disposable ECG electrodes for signal acquisition.
2. Charging port: When charging, connect the ECG recorder to the charging case via the contact pins. Connect the Type-C charging cable to the device and adapter, and then plug it into a power source to start charging.
3. Charging indicator light: After the power is connected, the green light flashes and remains on when fully charged.

3. Instructions for Use

3.1 Unpacking and Inspection

Before opening the box, please carefully inspect the packaging. If any damage is found, please contact the carrier or our company immediately. If the packaging is intact, please unpack it correctly and carefully remove the equipment and other components from the box. Check the equipment for any mechanical damage and ensure all items are present. If you have any questions, please contact our company immediately.

⚠ warn

- Please keep the packaging box and packaging materials safe for future use during transportation or storage.
- Please keep the warranty card safe for warranty purposes.
- When handling packaging materials, local regulations or hospital waste disposal procedures must be followed, and packaging materials must be kept out of reach of children.
- The equipment may be contaminated with microorganisms during storage, transportation, and use. Please check that the packaging is intact before use, especially for disposable accessories. If any damage is found, please do not use it.
- The product's production date and expiration date are shown on the label.

3.2 Downloading and Installing the APP

Apple (iOS) users, scan the QR code below to open it in your browser or WeChat.

Download path for Android users: Scan the QR code below. (This can only be opened with a browser.)

3.3 APP Operating Environment Requirements

Equipment	Minimum configuration requirements
Software environment	■ Android: Android 5.0 and compatible versions;
	■ Apple: iOS 8.0 and compatible versions .
Hardware configuration	■ Android version: Screen display resolution of 1920x1080px or higher , RAM of 8GB or higher , storage of 32GB or higher, screen size of 7 inches or higher ; ■ Apple iOS version: minimum screen resolution of 1920x1080px or higher , RAM of 2GB or higher , storage of 32GB or higher, and screen size of 7 inches or higher .
Network conditions	■ Cellular network, WIFI

3.4 APP Usage Restrictions

The app needs to be used in conjunction with our company's specified model of electrocardiogram recorder.

The app requires a specific software runtime environment; see "App Software Runtime Environment" for details.

3.5 Maximum Concurrency

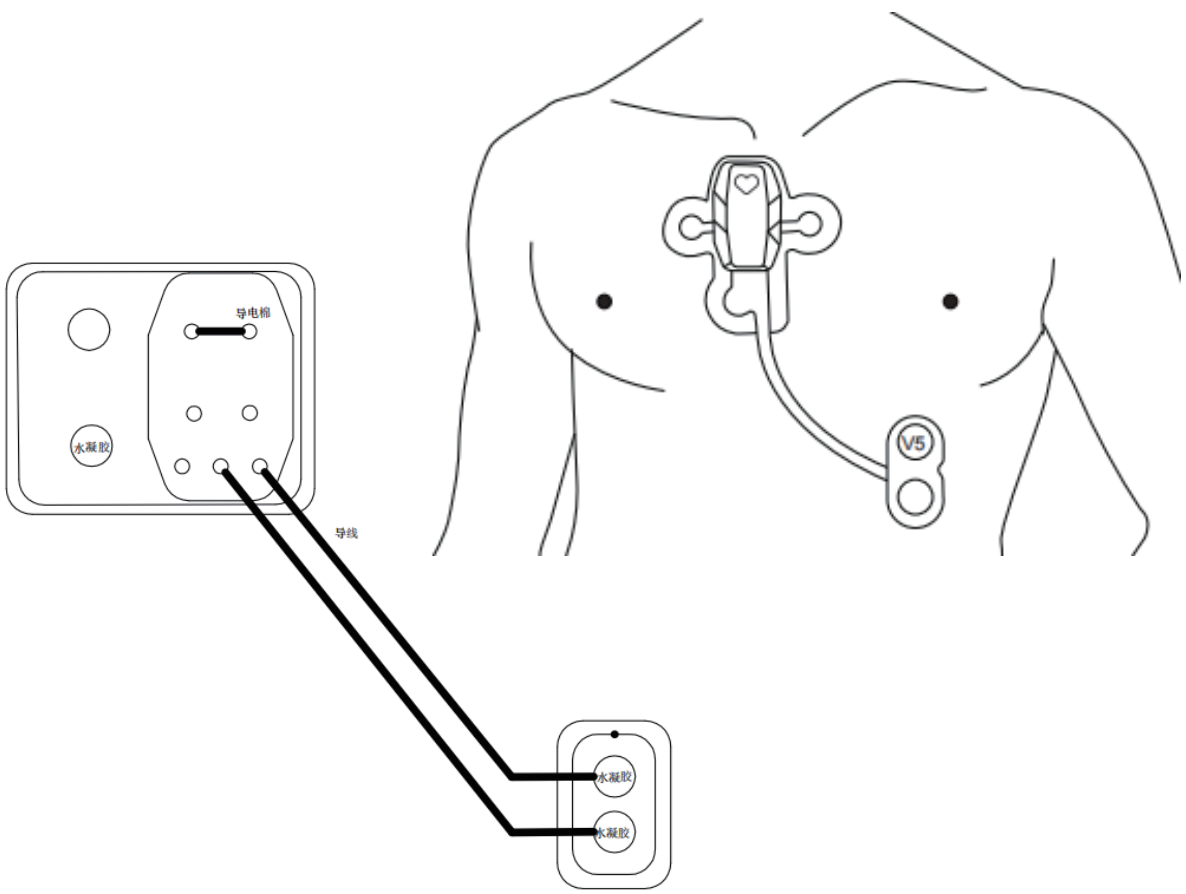
Maximum concurrency: 1, response time <10s.

3.6 Software Operation

3.6.1 Applying the Recorder

After connecting the dashcam and the app (see "Add Device" for connecting the dashcam):

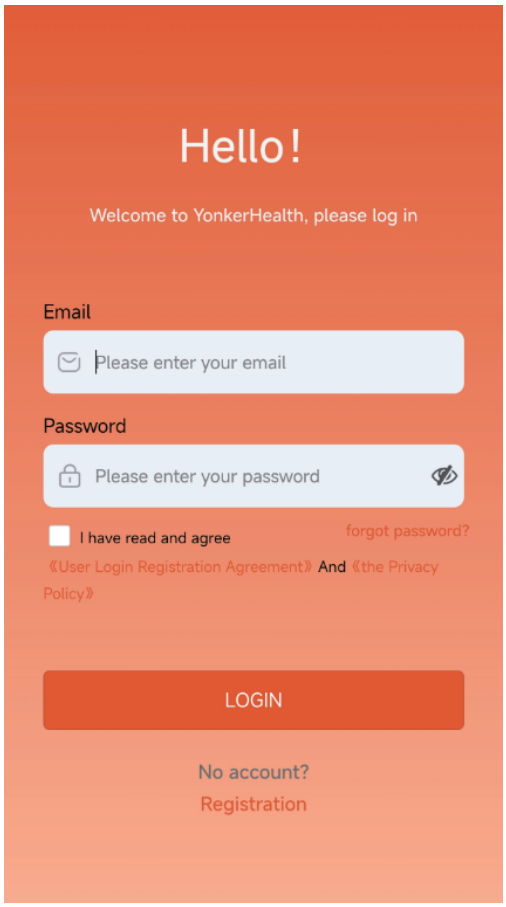
Align and attach the disposable ECG electrodes and the electrode pads on the ECG recorder in the correct positions, and attach them to the corresponding parts of the body as shown in the diagram below.

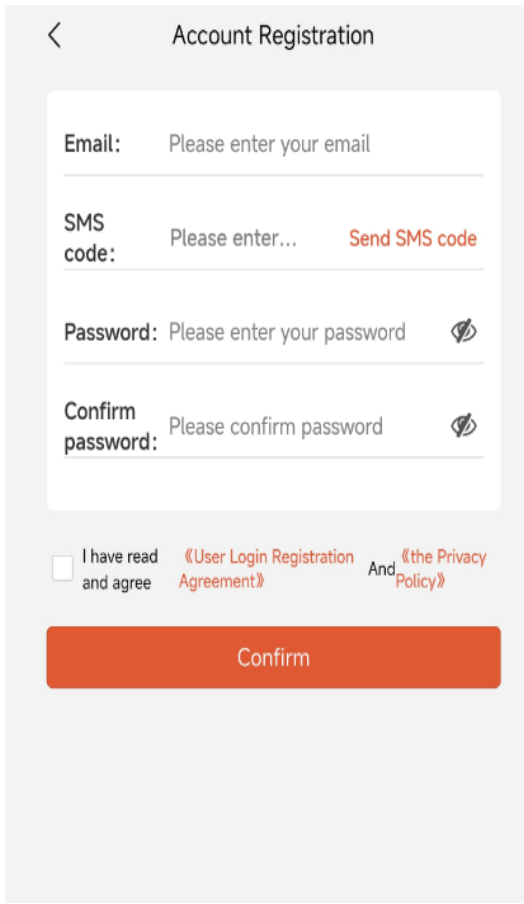


1. Before measurement, gently wipe the area where the disposable ECG electrodes are attached and the skin area to be measured with saline or clean water ;
2. After putting on the device, avoid strenuous exercise during the data collection process. Try not to raise your arms or expand your chest, and do not touch the device or electrode patches.
3. The power indicator displayed by the software shows the current battery level. It is recommended to charge the battery in time when the power is low to avoid affecting its use.
4. When the ECG recorder's battery is low, the yellow light will flash for 10 seconds, after which the device will automatically shut down.
5. Automatic shutdown: The device will automatically shut down 3 minutes ± 5 seconds after the electrode detaches from the recorder .

3.7 Software Operation

3.7.1 Registration and Login

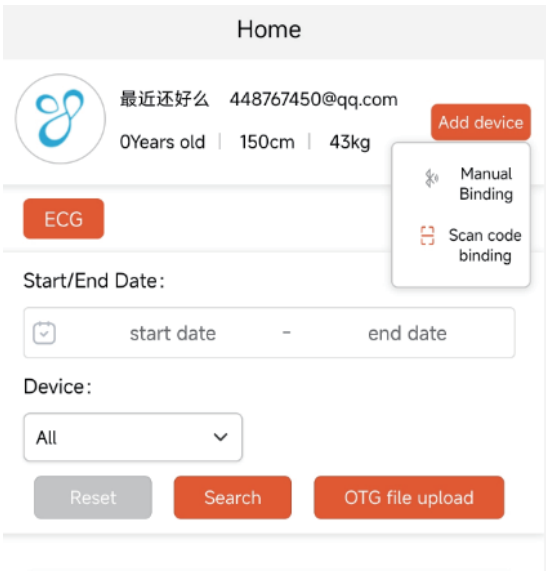


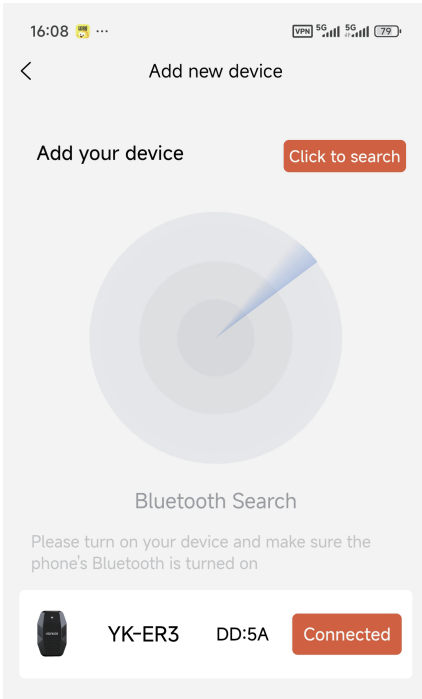


1. Turn on your phone's Bluetooth
2. New users can click "Register" to register an account, enter the "Account Registration" page, fill in the information, and start the registration process.
3. After successful account registration, you will be returned to the login page to log in.

3.7.2 Add Device

After attaching the electrode pads to the recorder , power it on. The blue "+" symbol on the recorder screen will remain lit. Open the mobile app homepage (as shown in the image below), tap "Add Device" in the upper right corner, and manually bind the device. Then, go to the search page.





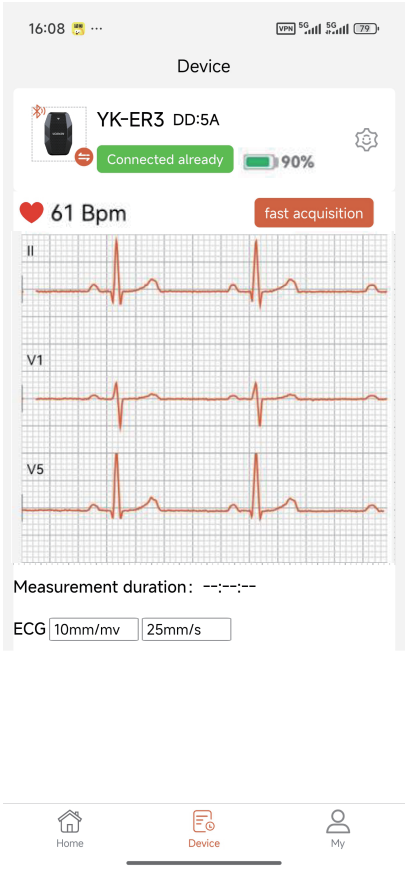
The blue light will flash when ECG data collection begins (as shown in the picture).

⚠ Notice

If the device is not turned on, the page will display a message indicating that no device was found.

When other devices are open, one or more devices will be found. Select the device you want to bind.

3.7.3 Equipment Setup



This page displays the ECG waveform and heart rate data in real time.

When acquiring ECG signals, if you click " Quick Acquisition " on the interface, the mobile app will display a message saying, "Please keep the ECG duration within 30 minutes. Recording will automatically end and save if it exceeds this time." If the acquisition time is less than 30 seconds, clicking the acquisition time will display a message saying, "Record at least 30 seconds of data." If the acquisition time is more than 30 seconds, clicking the acquisition time will display a message saying, "ECG data recording complete."

When a pop-up window displays "Device disconnected," it means that the device has been disconnected and needs to be reconnected.

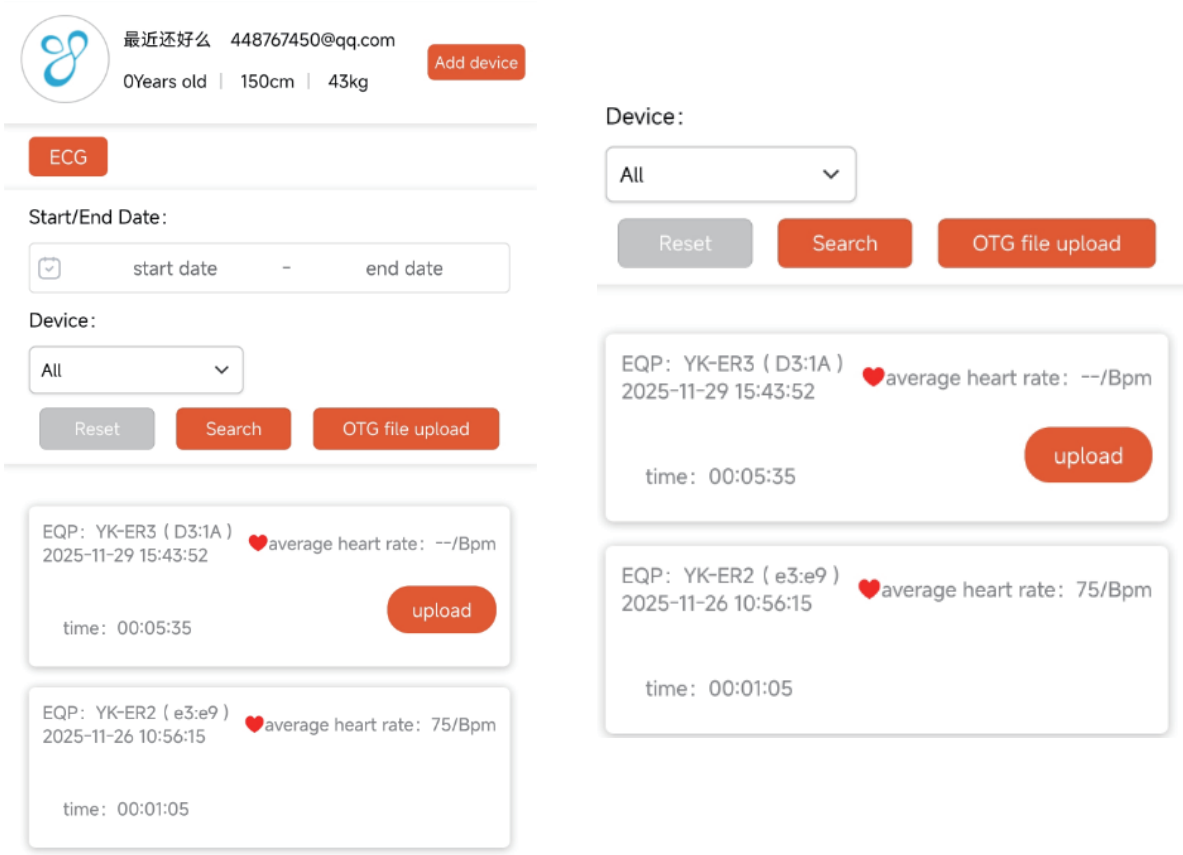
YK-ER3	Equipment Model
	Current device power
	The current device connection status can be displayed as either not connected or connected.
	Current heart rate
	After collecting data for a period of time, the "Quick Collection" window will display the collection duration.

The switchable parameters in the software are shown in the table below.

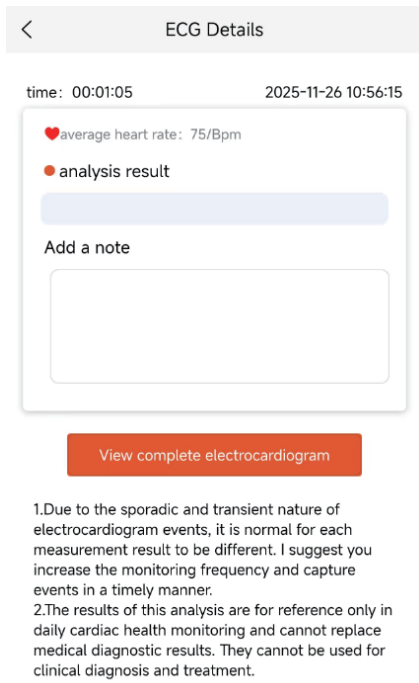
Gain control	5 mm/mv
	10 mm/mv
	20 mm/mv
Paper feeding management	25 mm/s
Electrocardiogram	Three-lead Electrocardiogram

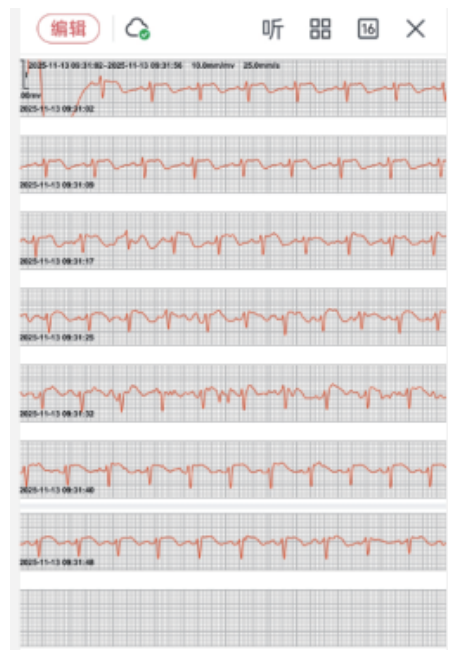
3.7.4 Measurement Record

1. After the measurement is completed, you can view the measurement results on the homepage.
2. The "Home" dropdown menu displays historical measurement data, including specific device model, measurement date, measurement time, and heart rate, as shown in the image below:



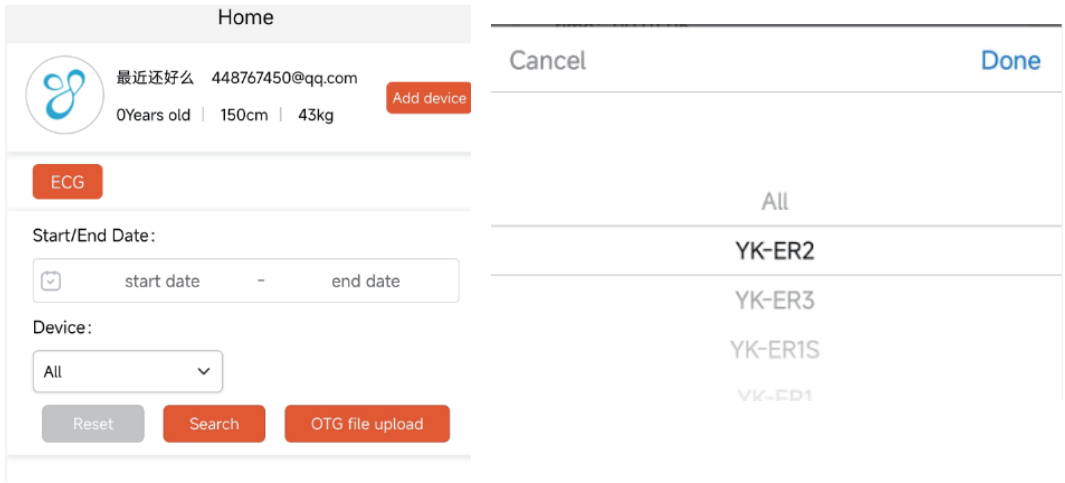
3.Clicking on any data point below will take you to the page shown in the image. Clicking "View Full ECG" will then take you to the ECG page. Swipe the progress bar left and right to view the complete ECG, as shown in the image below:





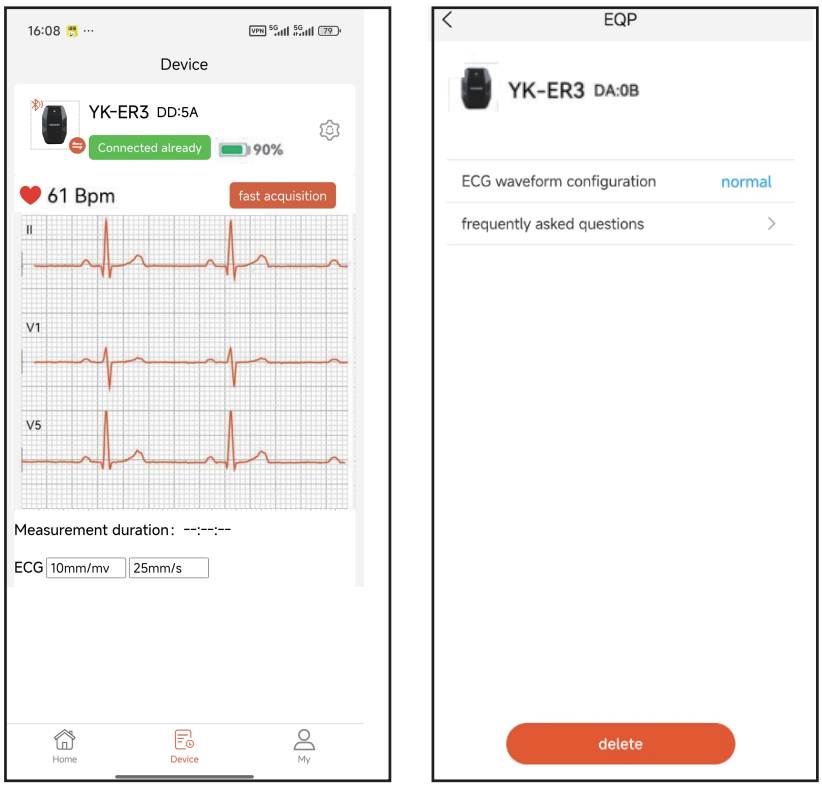
3.7.5 Page Search

Select the start/end date, and use the dropdown menu " All " to search by product model, as shown in the image below:

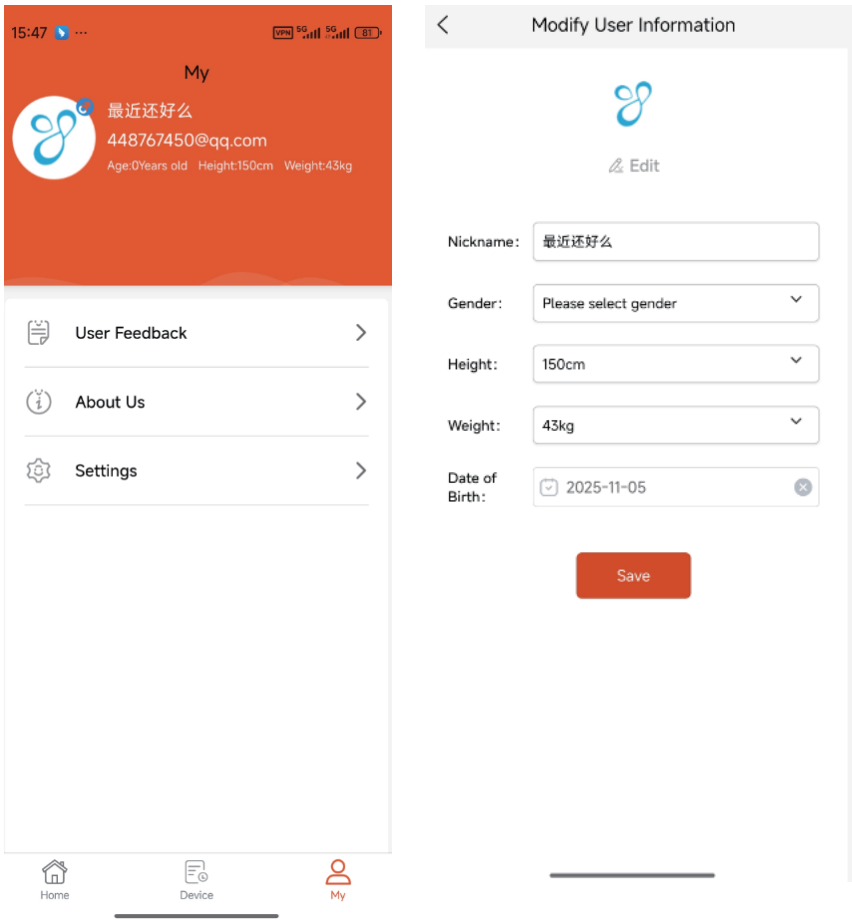


3.7.6 Device Removal

On the bound device page, click the " " in the upper right corner to enter the device management page, click "Delete" at the bottom of the interface, and a pop-up window will ask "Confirm whether to unbind this device". Select "Confirm" to delete the bound device.



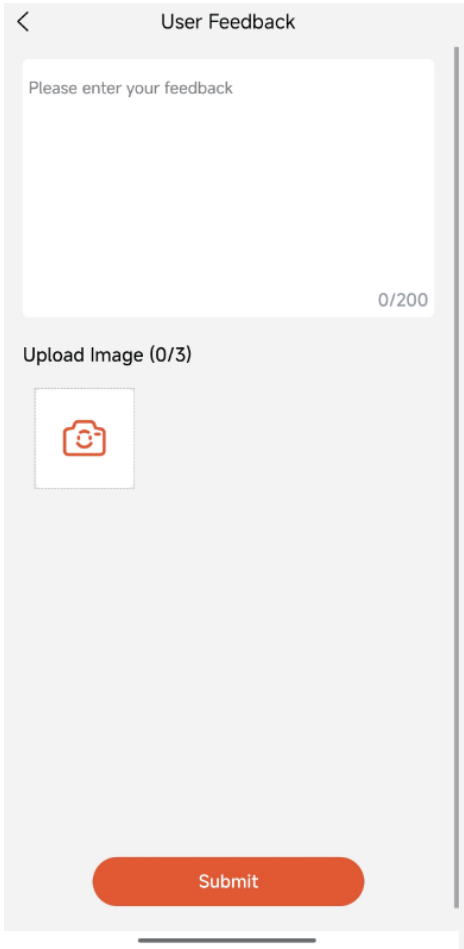
3.7.7 Personal Information Settings



After logging in, your personal information will be displayed on the "My" page. Clicking on your avatar will take you to the page shown in the image, where you can set the following information: avatar, nickname, gender, height, weight, and date of birth.

3.7.8 User Feedback

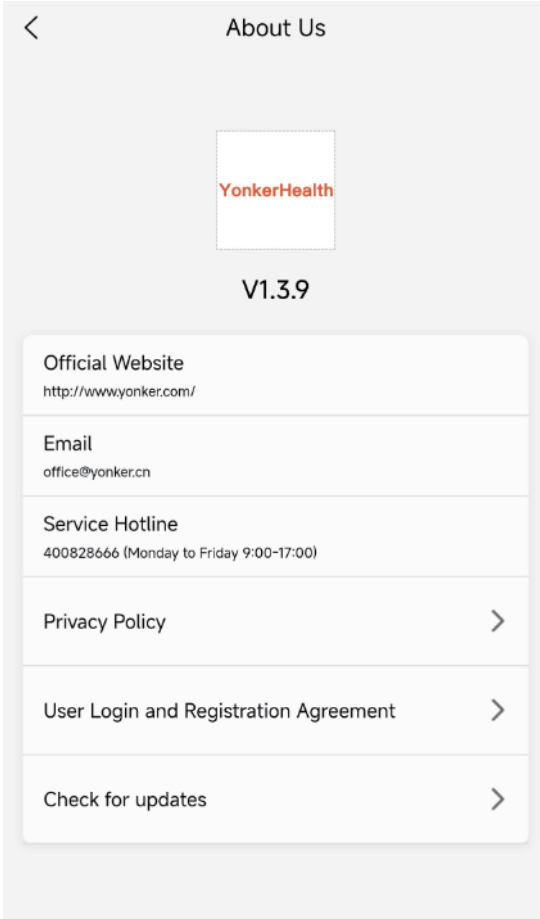
If you have any other issues you'd like to report to our company or our backend system, you can go to the "My" page, click "User Feedback," edit the text content of your feedback,  or click to upload an image. Click "Submit" at the bottom of the page to complete your feedback.



3.7.9 About Us

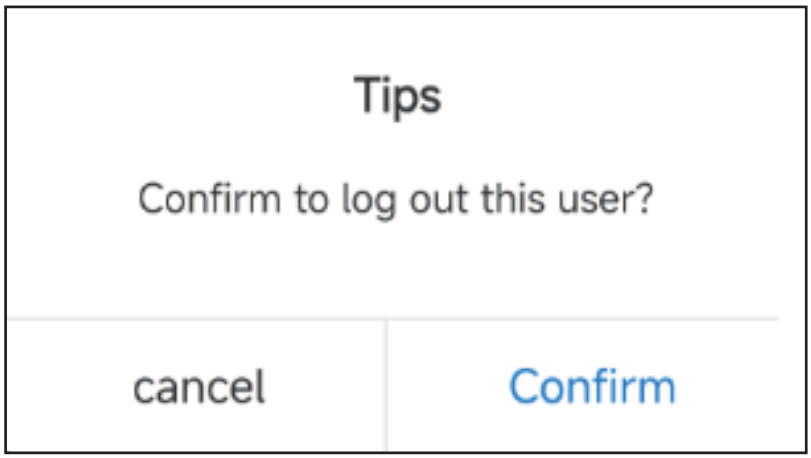
Clicking "About Us" will display the following information: current software version number, official website, email address, service hotline, service hours, privacy policy, user login agreement, and check for new version.

To update the software, click "Check for new versions". If an update is available, click to update. If the current version is already the latest, a pop-up window will appear saying "This is already the latest version".



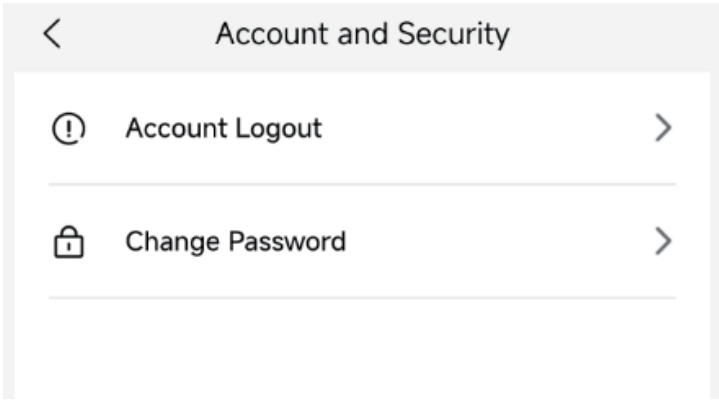
3.7.10 Account Deletion

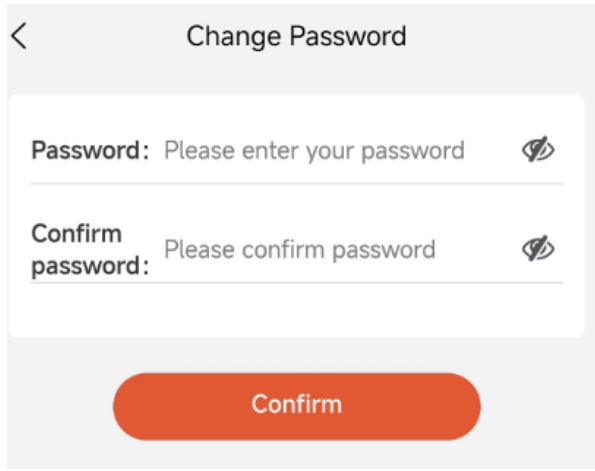
On the "My" page, click "Settings" → "Account and Security" → "Account Deregistration" → "Logout". A pop-up window will appear prompting "Confirm deregistration of this user". Click "OK" to complete the deregistration process.



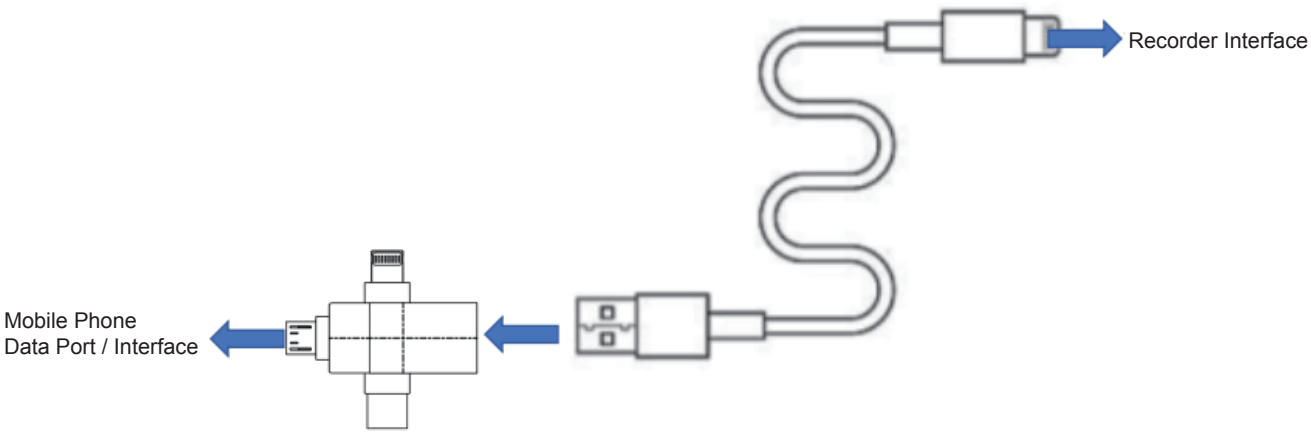
3.7.11 Change Password

On the "My" page, click "Settings" → "Account and Security" → "Change Password". Enter your password twice and click "Confirm" to complete the password change.





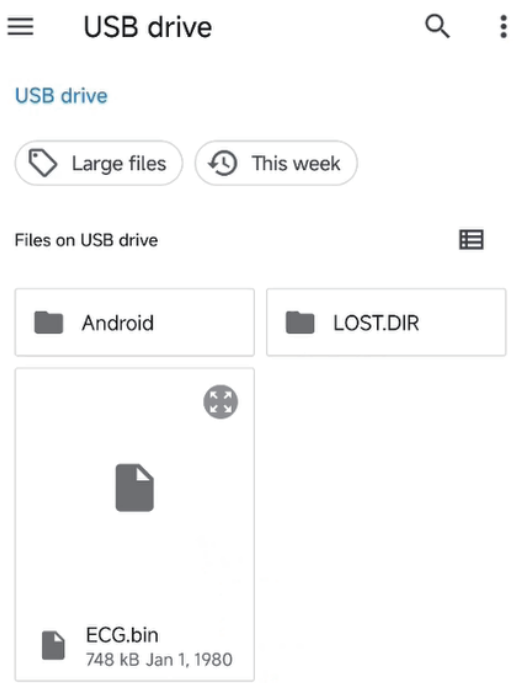
3.7.12 OTG Data Upload



Use the OTG connector and data cable that come with this product to connect the mobile phone and the host.

1. Place the dashcam in the charging case and connect it to the charging case using the included data cable.
2. Connect the USB port of the data cable to the USB port of the OTG cable.
3. Select the OTG and phone-compatible interface, and connect the phone.

After the connection is established, use the mobile device to click "OTG Upload File" to enter the file selection interface (as shown in Figure 3-16), and select the file to upload. The results can be viewed in "3.6.4 Measurement Record".



4. Charging Instructions

To charge, connect the ECG recorder to the charging case contacts. Connect the Type-C charging cable to the device and adapter, and then plug it into a power source to begin charging.

⚠ Notice:

1. When the ECG recorder is charging, the indicator light on the device will flash green; when fully charged, the indicator light on the device will remain solid green.
2. When the dashcam's battery is low, the indicator light will flash yellow for 10 seconds and then automatically shut down. Please charge it promptly to avoid affecting its use. The battery level will be displayed on the app screen after connection.
3. If the device is not to be used for an extended period (more than 3 months), please fully charge it before storing it.

4. This equipment requires a Class II adapter that meets the requirements of IEC 60601-1 or GB 9706.1-2020 standards, and the adapter must meet the 2 MOPP insulation requirement.

5. Maintenance And Upkeep

5.1 Maintenance

5.1.1 Daily cleaning and disinfection

- When dust or dirt appears on the product surface, please wipe it with a dry, clean, soft cloth.
- When the main unit is heavily soiled, wipe it with a soft cloth dampened with water or neutral detergent, wrung out thoroughly. After wiping away the dirt, wipe it again with a dry, soft cloth.
- If the electrodes are heavily soiled, wipe them with a soft cloth dampened with alcohol disinfectant.
- Please use a clean cloth that will not produce lint.
- Do not use abrasives.
- If there is a temperature difference between the place of use and the place of storage, please let it sit for 30 minutes before use.

⚠ Notice!

- When multiple people are using the product, please disinfect it with 75% medical alcohol before use. Be careful not to let water or alcohol seep into the product.
- Do not store the computer in the following places:
    1. Places where water is likely to splash.
    2. Places with high temperature, humidity, direct sunlight, high dust, and high salt content.
    3. Tilt, places that will vibrate or impact.
    4. Places where chemicals or corrosive gases are stored.
- Disposal Recommendation: Please dispose of the main unit, accessories, and separately sold items in accordance with the relevant environmental protection regulations of the city.

5.1.2 Routine Inspection

To record an accurate electrocardiogram, please perform the following checks :

1. Before use, please check whether the main unit has any abnormal appearance, such as deformation, damage, electrode corrosion, or dirt.
2. When recording an electrocardiogram, please make sure that the recording begins as soon as the electrodes touch the skin.
3. During use, please check for any unusual odors or noises.

5.1.3 Repairs

If you experience any abnormalities during use or routine checks, please stop using the product and contact our company for assistance.

5.2 Common Faults and Solutions

Fault phenomenon	Possible reasons	Solution
The phone cannot connect recorder	1. Low battery power 2. Turn off Bluetooth on your phone. 3. The recorder is damaged.	1. Charge the recorder 2. Turn on your phone's Bluetooth. 3. Contact customer service
The ECG waveform has large noise and the displayed waveform is abnormal.	1. Skin that is too dry or oily 2. There are excessively strong interference sources in the environment. 3. Excessive muscle t ension causes electromyographic interference . 4. The device is too far away from the mobile phone.	1. Clean the skin at the test site appropriately , making it moist but not oily. 2. Try using it in a different environment. 3. Relax your shoulders and body 4. Bring your phone close to the dashcam.

Historical data cannot be viewed on mobile phones	1. Insufficient phone storage space 2. Software issues	1. Clear the cache and delete useless data. 2. Contact customer service
The recorder cannot be turned on.	1. Low battery power 2. The recorder is damaged.	1. Charge the recorder 2. Contact our customer service.
Other issues	/	Contact our customer service

6. Electromagnetic Compatibility

The electromagnetic compatibility (EMC) specifications of the recorder (YK-ER3) fully comply with YY 9706.102-2021 and YY standards. Clause 202 of 9706.247-2023 stipulates that the verification method for electromagnetic compatibility indicators shall also be carried out in accordance with this standard.

When the recorder operates in the electromagnetic environment specified in this EMC technical datasheet, its basic performance is unaffected.

Basic performance of the recorder (YK-ER3): detection of the electrocardiogram waveform and heart rate.

Magnetic fields may interfere with the normal operation of the instrument. Furthermore, this recorder may cause electromagnetic interference to other electronic products. Therefore, please note the following points when the instrument is in operation:

⚠ Warn

- Purchasers or users of this device should use the recorder (YK-ER3) in the electromagnetic environment specified in Tables 1, 2, 3, and 4 (see YY 9706.102-2021); otherwise, the recorder (YK-ER3) may malfunction.
- Portable and mobile radio frequency communication devices may affect the normal use of the recorder (YK-ER3). Please use the recorder (YK-ER3) in the recommended electromagnetic environment.

- Using accessories and cables other than those provided by the recorder (YK-ER3) manufacturer may result in increased emissions or reduced immunity of the recorder (YK-ER3).
- The recorder (YK-ER3) should not be used near or stacked with other devices. If it must be used near or stacked, its proper functioning under the configuration in which it is used should be observed and verified.
- The following cables must be used to meet the requirements for electromagnetic emission and interference immunity:

Name	Cable length (m)	Should I block it
charging cable	1.0	no

Table 1

<table>
<tr><th colspan="3">Guidelines and Manufacturer's Statements—Electromagnetic Launch</th></tr>
<tr><td colspan="3">The recorder (YK-ER3) is intended for use in the electromagnetic environments specified below, and the purchaser or user shall ensure that it is used in such electromagnetic environments.</td></tr>
<tr><td>Launch test</td><td>Compliance</td><td>Electromagnetic Environment - Guide</td></tr>
<tr><td>Radio frequency transmission
GB 4824
(CISPR 11)</td><td>Group 1</td><td>The recorder (YK-ER3) uses RF energy for its internal functions. Therefore, its radio frequency radiation is very low and the possibility of interfering with nearby electronic equipment is minimal.</td></tr>
<tr><td>Radio frequency t ransmission
GB 4824 (CISPR 11)</td><td>Category B</td><td rowspan="3">The recorder (YK-ER3) is suitable for use in all facilities, including home facilities and those directly connected to the public low-voltage power grid of a residential home.</td></tr>
<tr><td>Harmonic emission
GB 17625.1</td><td>Category A</td></tr>
<tr><td>Voltage fluctuation/ scintillation emission
GB 17625.2
(IEC 61000-3-3)</td><td>conform to</td></tr>
</table>

Table 2

Guidelines and Manufacturer's Statements - Electromagnetic Immunity			
The recorder (YK-ER3) is intended for use in the electromagnetic environments specified below, and the purchaser or user shall ensure that it is used in such electromagnetic environments.			
Anti-interference test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic Environment - Guide**
electrostatic discharge GB/T 17626.2 (IEC61000-4-2)	±6kV contact discharge ±8kV air discharge	±6kV contact discharge ±8kV air discharge	The floor should be made of wood, concrete, or tile. If the floor is covered with a synthetic material, the relative humidity should be at least 30%.
Electric Fast Transient Second Charge Group GB/T 17626.4 (IEC61000-4-4)	±2kV power supply line ±1kV input/output lines	±2kV power supply line not applicable	The mains power supply should have the quality typically used in commercial or hospital environments.
surge GB/T 17626.5 (IEC61000-4-5)	± 1 kV line-to-line ± 2 kV line to ground	±1kV line-to-line not applicable	The mains power supply should have the quality typically used in commercial or hospital environments.

Voltage dips, short interruptions and voltage variations on power input lines GB/T 17626.11 (IEC61000-4-11)	< 5% U_T , lasting 0.5 cycles (>95% transient decrease in U_T) . 40% U_T , for 5 consecutive cycles (60% temporary decrease in U_T) . 70% U_T , lasting for 25 cycles (30% temporary drop in U_T) . <5% U_T , lasting 5 seconds (>95% transient decrease in U_T) .	< 5% U_T, lasting 0.5 cycles (> 95% sag on U_T) 40% U_T, for 5 consecutive cycles (60% sag on U_T) 70% U_T, for 25 consecutive cycles (30% sag on U_T). < 5% U_T, lasting 5 seconds (On U_T, >95% temporary descent)	The mains power supply should have the quality typical of commercial or hospital environments. If the user of the equipment needs continuous operation during power outages, it is recommended that the equipment be powered by an uninterruptible power supply (UPS) or batteries.
Power frequency magnetic field (50/60Hz) GB/T 17626.8	3 A/m	3 A/m	The power frequency magnetic field should have the power frequency magnetic field level characteristics of typical locations in a typical commercial or hospital environment.
Note: U_T refers to the AC mains voltage before the test voltage is applied .			

Table 3

Guidelines and Manufacturer's Statements - Electromagnetic Immunity			
The recorder (YK-ER3) is intended for use in the electromagnetic environments specified below, and the purchaser or user shall ensure that it is used in such electromagnetic environments.			
Anti-interference test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic Environment - Guide**
Radio frequency conduction GB/T 17626.6 (IEC61000-4-6) Radio frequency radiation GB/T 17626.3 (IEC61000-4-3)	3 V (RMS value) 150 kHz~80 MHz 3 V/m 80 MHz ~ 2.5 GHz	3 V (RMS value) 3 V/m	Portable and mobile radio frequency communication devices, including cables, should not be used closer to any part of the recorder (YK-ER3) than the recommended isolation distance . This distance should be calculated using a formula corresponding to the transmitter frequency. Recommended isolation distance d = $1.2\sqrt{P}$ d = $1.2\sqrt{P}$ 80 MHz to 800 MHz d = $2.3\sqrt{P}$ 800 MHz to 2.5 GHz In the formula: P—The maximum rated output power of the transmitter as provided

			by the transmitter manufacturer, in watts (W). d—Recommended isolation distance, in meters (m) The field strength of a fixed radio frequency transmitter is determined by electromagnetic field survey [a] , and should be lower than the compliance level in each frequency range [b] .  Interference may occur near devices marked with the following symbols .

Note 1: At the 80MHz and 800MHz frequencies, the formula for the higher frequency band is used.

Note 2: These guidelines may not be suitable for all situations, as electromagnetic propagation is affected by absorption and reflection from buildings, objects, and the human body.

For fixed transmitters, such as base stations for wireless (cellular, cordless) telephones and terrestrial mobile radios, amateur radio, AM and FM radio broadcasting, and television broadcasting, the electromagnetic field strength cannot be accurately predicted in theory. To assess the electromagnetic environment of a fixed RF transmitter, an electromagnetic field survey should be considered. If the field strength at the location of the recorder (YK-ER3) is measured to be higher than the applicable RF compliance level, the recorder (YK-ER3) should be observed to verify its normal operation. If abnormal performance is observed, supplementary measures may be necessary, such as readjusting the orientation or position of the recorder (YK-ER3) .

b. The electric field strength should be less than 3V/m across the entire frequency range of 150kHz to 80MHz.

Table 4

Recommended isolation distance between portable and mobile radio frequency communication devices and recorders (YK-ER3)

The recorder (YK-ER3) is intended for use in electromagnetic environments where radio frequency radiated interference is controlled. Based on the maximum rated output power of the communication equipment, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile radio frequency communication equipment (transmitter) and the recorder (YK-ER3) as recommended below .

The transmitter's maximum rated output power W	Isolation distance (m) corresponding to different frequencies of the transmitter		
	150 kHz~80MHz $d = 1.2\sqrt{P}$	80MHz~800MHz $d = 1.2\sqrt{P}$	800MHz~2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters whose maximum rated output power is not listed in the table above, the recommended isolation d, in meters (m), can be determined using the formula in the corresponding transmitter frequency column. Here, P is the transmitter's maximum rated output power provided by the transmitter manufacturer, in watts (W).

Note 1: At the 80MHz and 800MHz frequencies, the formula for the higher frequency band is used.

Note 2: These guidelines may not be suitable for all situations, as electromagnetic propagation is affected by absorption and reflection from buildings, objects, and the human body.

7. Annexs

7.1 Product Package Lis

Serial Number	Name	quantity	Remark
1	Host	1	
2	Charging case	1	
3	Charging cable	1 item	
4	Manual	1 copy	
5	Certificate of Conformity	1	
6	Storage bag	1	
7	OTG adapter	1	

8. After-Sales Service

8.1 Warranty and Service Policy

1) The company provides users with a one-year free warranty and lifetime maintenance.
2) If the recorder malfunctions, do not attempt to disassemble or reassemble it yourself. Please contact the manufacturer's customer service center immediately. In special circumstances requiring repair by qualified technicians other than those from the manufacturer, our company can provide product circuit diagrams, component lists, etc. Please contact our customer service center for assistance.
3) The company is not responsible for free repair or replacement of any direct or indirect damage caused by improper use of the equipment. The user will be responsible for the repair costs (including transportation fees).

The following situations are not covered by the warranty:

1. Unable to produce a warranty card, invoice, or proof of purchase.
2. Damage caused by improper use or other human factors
3. Damage caused by unforeseen natural disasters

For products beyond the warranty period, we will provide paid repair services. Our company reserves the right to interpret this warranty information.

8.2 Manufacturer Information

Registrant Name/Manufacturer Name/After-Sales Service Provider Name: Xuzhou Yongkang Electronic Technology Co., Ltd.
Registered Address: No. 19, Yinshan Road, Xuzhou High-tech Industrial Development Zone
Production Address/After-sales Service Unit Address: 2nd&3rd floor of Building No.5, Block B, Huaihai Biomedical Industry Park, No. 5 Tengzhai North Road, Xuzhou High-tech Industrial Development Zone, 221000 Xuzhou, PEOPLE'S REPUBLIC OF CHINA
Production date: See product label
Service life: 5 years
Product Registration Certificate Number / Product Technical Requirements Number : Jiangsu Medical Device Registration Certificate
Production License Number:
Telephone: 0516-87892766
Fax: 0516-87892766-606
Postal code: 22100
Website: www.yonker.cn
Email: office@yonker.cn

Appendix A: Safety Requirements

Product Name	Electrocardiogram recorder
Product Model	YK- ER3
Protection level	IP22
Classification by level of protection against electric shock	CF type
Classification by type of electric shock protection	Class II, Internal power supply equipment
Classification by operating mode	Continuous operation equipment

Does the equipment have an application section that protects against defibrillation discharge effects?	This equipment does not have any application section for defibrillation discharge effect protection.	
Permanent installation equipment or non-permanent installation equipment	Non-permanent installation equipment	
Classified according to the level of safety when used in flammable anesthetic gases mixed with air or flammable anesthetic gases mixed with oxygen or nitrous oxide.	It cannot be used in the presence of flammable anesthetic gases mixed with air or flammable anesthetic gases mixed with oxygen or nitrous oxide.	
Charging power supply	External power supply: Input 100-240V; 50Hz/60Hz, Output DC 5V ⎓ 2A	
Electrical parameters	Operating voltage	Battery powered: DC 3.7V
	Battery capacity	400mAh
	Automatic shutdown	The device will automatically shut down if the electrocardiogram electrode detaches for 3 minutes ± 5 seconds.
Low voltage warning	When the voltage is 3.3V±0.1V , the indicator light will flash yellow for 10 seconds and then automatically shut down.	
Working hours	>72 hours	
Use period	5 years	

Appendix B: Environmental Requirements

Work environment	Ambient temperature	5ºC～45 ºC	1. If stored or used outside the temperature and humidity range specified by the manufacturer, the system may not achieve the claimed performance. 2. During transportation, avoid strong impacts, direct collisions, exposure to sunlight or rain . After packaging, the recorder should be stored in an environ-ment that meets the temperature, humidity and atmospheric conditions, free from corrosive gases and in a well-ventilated indoor environment .
	Relative humidity	10 %～ 95 % (Non-condensing)	
	Atmospheric pressure	70kPa～106kPa	
Transportation and storage environment	Ambient temperature	-20ºC～+55ºC	
	Relative humidity	≤ 95% (non-condensing)	
	Atmospheric pressure	70kPa～106kPa	

Appendix C: Product Specifications

Product Dimensions	Main unit: 55*36*12mm
	Charging case: 53*39*10mm
Product weight	Main unit: 17g
	Charging case: 12g
Number of leads	Three leads, three channels
Heart rate measurement range	30-300bpm

Heart rate measurement accuracy	±2bpm	
Input impedance	≥ 10MΩ	
System noise	<25μV (peak-to-valley value)	
Impulse response	overshoot <10%	
Frequency response	Sine wave signal 0.67Hz～40Hz (+3dB～-3dB)	
Rated input amplitude	Input frequency and waveform	amplitude changes
2.0mv	0.67Hz～40Hz, sine wave	140%～70% [a]
1.5mv	1Hz, triangular wave, 40ms bottom width	70 %～ 110 %[b]
a is the output amplitude relative to a 5 Hz sinusoidal input signal. b is the output amplitude relative to a triangular wave input signal with a bottom width of 200ms.		
Timing Accuracy	The error should not exceed 30 seconds within 24 hours .	
Gain Accuracy	With all possible gain settings, the output signal is equivalent to the input test signal, with a maximum amplitude error of ±10% .	
Gain Stability	Gain Stability: After the dynamic ECG recorder is powered on for 1 minute, the gain change shall not exceed 3% within 24 hours (under stable environmental conditions).	
Storage Dduration	>72 hours	
Light Indicator (Charging Case）	Green light	The green light flashes while charging; the green light stays on when fully charged.
	Blue light	The charging case's indicator light will remain constantly blue when charging from a mains power source.

indicator lights (Charging case)	Yellow light	When the battery is low, the yellow light will flash for 10 seconds before automatically shutting down.
Mobile software	Software Name	Dynamic electrocardiogram recorder software
	Model/Specification	YK-ER3
	Release version	V1
Embedded software	Software Name	ECG recording software
	Applicable models/ specifications	Yonker Health
	Release version	1
Communica-tion methods	Bluetooth connection	
Gain control	5 mm/mv , 1 0mm/mv , 2 0mm/mv	
Paper Speed	25mm/s	
Bluetooth module	Frequency	2402～2480MHz
	Modulation type	GFSK
	Effective radiated power	≤20dBm
Data export	OTG adapter + USB data cable	