

Non-living support devices and systems

Guide and manufacturer's statement – electromagnetic immunity			
This product is intended for use in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in such an electromagnetic environment.			
Immunity test	IEC60601 Test level	Compliance level	Electromagnetic environment - guide
Radio frequency conduction GB/T 17626.6	3 V (rms) 150 kHz~80 MHz	3 V (rms)	<p>Portable and mobile RF communications equipment should not be used closer to any part of the equipment (system or system) than the recommended isolation distance, including cables. This distance is calculated by a formula corresponding to the transmitter frequency. Recommended isolation distance:</p> <p>$d = 1.2Vp$</p> <p>$d = 1.2Vp 80 MHz~800 MHz$</p> <p>$d = 2.3Vp 800 MHz~2.5 GHz$</p> <p>In the formula :</p> <p>p=Watts (W) based on the transmitter's maximum rated output power from the transmitter manufacturer ;</p> <p>d=Recommended isolation distance in meters (m).</p> <p>The field strength of a fixed RF transmitter is determined by the survey a of the electromagnetic field, and each frequency range b should be lower than the compliance level. Interference p may occur near devices marked with the following symbol.</p> 

Remark 1 : Adopt formula of higher frequency bands at 80MHz and 800MHz frequencies.

Remark 2 : These guidelines may not be suitable for all situations, and electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human bodies.

a: Fixed transmitters, such as base stations for wireless (cellular/cordless) phones and terrestrial mobile radios, amateur radios, AM and FM radio broadcasts, and television broadcasts, are not theoretically predictable. In order to assess the electromagnetic environment of a fixed RF transmitter, the survey of the electromagnetic field should be considered. If the measured field strength of the location where the device or system is located is above the applicable RF compliance level, it should be observed (device or system) to verify that it is functioning properly. Additional measures may be necessary if abnormal performance, such as reorienting (device or system) direction or location, is observed.

b: The field strength should be less than 3V/m over the entire frequency range from 150kHz to 80MHz..

Wearable dynamic ECG Recorder DL4310/03

User' s Manual

Date of the manual :

2018.06.22 A1

Product description

Thank you for purchasing a wearable dynamic ECG Recorder (hereafter referred to as ECG Recorder). This product can collect and record your ECG signals, and display real-time ECG and historical ECG records on your mobile phone.

This product needs to work with your mobile device to test, track and share your ECG data. The measurement results of this product are for reference only. If you find that the measurement result is out of the normal range, please consult a professional doctor or go to the hospital for a checkup.

Please read this manual carefully before starting to use the ECG recorder to understand the basic functions and correct use of the ECG recorder. Otherwise, it may cause damage to the user or the instrument.

Package list

1. Recorder body 1
2. Wristband 1
3. Chest stickers 1
4. Charging Cable 1
5. Disposable electrode (Gifts) 2 packs
6. Manual 1

Manufacture Information

Registrant/manufacturing company: Anhui Huami Healthcare Co.,Ltd

Manufacture: Anhui Huami Healthcare Co.,Ltd

Address: 1204, Building A4, National Animation Industry Base, No.800 Wangjiang West Road, Hefei City, Anhui Province , China

Factory address: 12th Floor, Building A4, National Animation Industry Base, No.800 Wangjiang West Road, Hefei City, Anhui Province, China

Phone : 400-8850-817

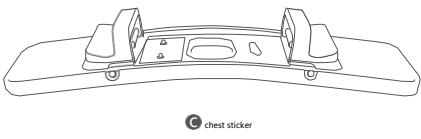
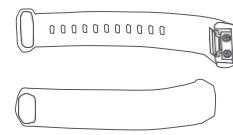
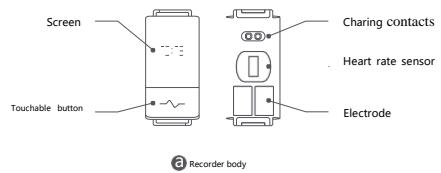
Service company: Anhui Huami Healthcare Co.,Ltd

After-sales service: 400-8850-817

After sales time : Monday to Sunday 8:00~18:00 (Except national statutory holidays)

Product structure and components

This product consists of the main body of ECG recorder, chest sticker, wrist strap, software and charging cable. Software includes external standalone software (version : V1.0.0) and embedded software (version : V2.0.7.7) . Disposable electrodes used in chest-paste mode need to be purchased.



Basic parameters

Name : Wearable dynamic ECG Recorder DL4310/03

Model : DL4310/03

Manufacturing license number of medical equipment: 皖食药监械生产许 20180012号

Number of registration certificate of medical equipment : 皖械准许 20182210012

Serial number of product technical requirements : 皖械准许 20182210012

Recorder body size : 41.79*19*11.17mm

Chest stickers size : 102*25*4.5 mm

Adjustable length of wrist buckle : 160mm ~ 214mm

Product performance index

Dynamic input range : 10mVpeak-trough

Input resistance : > 10MΩ

System noise : <50μV (input reference value)

Minimum signal : 50μV

Common mode rejection : ≥60dB

-3dB frequency response : 0.67Hz ~ 40Hz

Power : internal power, DC 3.8V, Lithium battery

Intended use and scope of use

Wearable dynamic ECG Recorder for measurement, acquisition and storage of adult single-lead ECG waveforms, but not for clinical analysis, diagnosis or screening.

Contraindications

1. Disabled for allergic to disposable ECG electrodes

2. Disabled with a pacemaker installed,

3. Disabled for allergic reactions to this product.

Precautions

1. Avoid electromagnetic interference above 3V/m during measurement. Possible sources of interference: microwave ovens, X-rays, etc.

2. Do not use the product for a long time, please store the battery fully and recharge it every 2 months to prevent the battery from being over-discharged.

3. ECG measurement records cannot be made while the product is charging.

4. If the product is used or stored outside the temperature and humidity range specified in this manual, it may cause product safety and performance failure, or even damage. For the specified temperature and humidity range, please refer to "Working Conditions" and "Transport Storage Conditions" in the manual.

5. Please avoid sharing this product with others to avoid cross infection.

6. Before and after using the product, use medical alcohol to gently wipe the parts that contact with the skin to clean and disinfect the product.

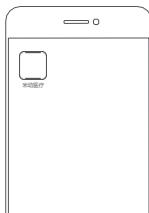
7. Please contact the service center if the user is not able to collect valid ECG signals when the skin is dry and the fingers are defective.

Installation and usage instructions

The wearable dynamic ECG recorder is placed in the package. First, open the package, remove the bracelet, chest sticker, charging cable, disposable electrode pad, manual, check the completeness according to the product list before use, and check there is no obvious damage to the appearance of the product.

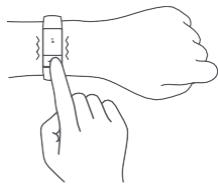
01 Download the App

Install 米动医疗 App on your mobile phone. Please make sure your mobile device is Android 4.4 or iOS 9.0 and above that support Bluetooth 4.0.



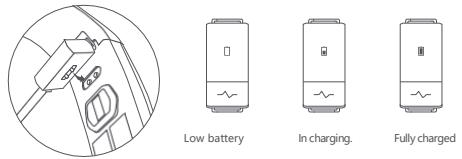
02 Connect to iOS or Android devices via Bluetooth

Start the client on the phone, follow the prompts to add the bracelet, when the bracelet vibrates and the prompt animation appears on the screen, please touch the touch button of the bracelet to complete the binding of the bracelet and the phone.



03 Charging

Charge the bracelet before using it for the first time. As shown, the magnetic contacts on one end of the charging cable are attached to the charging contacts on the back of the bracelet. Then connect the USB plug to the phone charger or the computer's USB port to charge. The charging progress animation is displayed on the screen of the bracelet when charging starts.



Precaution

1. Do not use when charging the product.

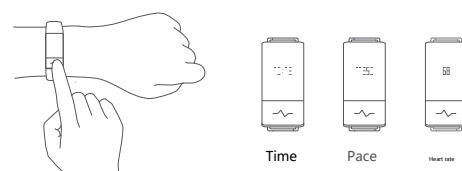
2. Please connect the charger with certificate output voltage of 5V and avoid charging the product under too high or too low temperature conditions.

3. Please do not overcharge or over discharge the battery, which may cause the battery life to decrease or even fail. The user should charge the battery when the battery is lower than 25%, and disconnect the charging line after the charging is completed.

4. Do not open the unit to replace the battery. If the battery does not charge properly, please contact customer service.

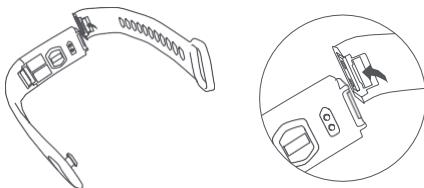
04 Wearing the recorder

In order to make the measurement more accurate, please wear the bracelet in the position of the wrist to avoid the carpal bone. Then adjust to the appropriate tightness, neither too loose to free to shake or too tight, resulting in no blood flow to the wrist. Touch the touch button on the bracelet to see the current time, the number of steps and the current heart rate.

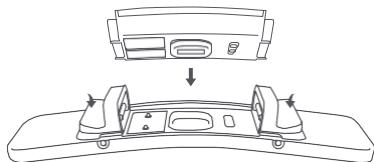


05 chest sticker installation

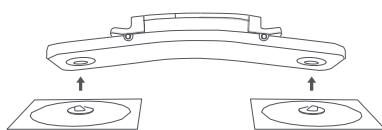
1. Disassemble the main body of the wristband and the wristband. Use the thumb to press the elastic piece at the joint of the wristband as shown in the figure. At the same time, slowly push the wristband upwards and remove the wristband from both sides of the product body.



2. Fix the main body of the product on the chest stick base through the buckle on the chest. Please pay attention to the direction of the product when installing. Make sure that the electrode piece on the back of the product is aligned with the metal contact on the base of the chest to ensure that the installation is in place without shaken or loosen.



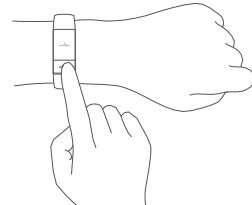
3. Attach the disposable electrode sheets to the ends of the bottom of the chest by a snap fastener.



06 Measuring posture

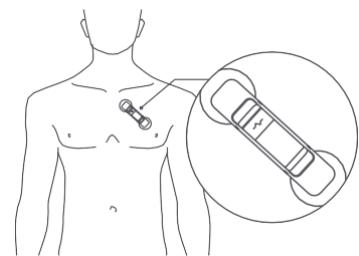
1. Using the bracelet to measure

Lift the arm of the wristband horizontally, and press the index finger on the metal button at the bottom of the screen. Press the button down naturally to start the measurement. Keep the arm stable during the measurement process to ensure good contact between the bracelet and the skin.



2. Use chest stickers to measure

After installing the main body and the disposable electrode piece on the chest sticker according to the instructions, tear off the film on the surface of the disposable electrode piece and stick it on the left side of the chest according to the position shown. Please wear it in strict accordance with the direction of the product shown. Confirm the touch button points to the middle of the body, keep the angle oblique upward and ensure that the disposable electrode sheets are firmly attached. After wearing it, use the mobile phone software to connect the product, open the chest sticker mode and start measuring.



⚠️ Precautions

1. Before the measurement, ensure that the surface of the metal electrode of the product body is clean. If the measurement fails several times, use alcohol to wipe the measuring contacted skin and fingers.
2. Try to keep it as quiet as possible during the test, otherwise the measurement data may be inaccurate.
3. Please correct the position of the electrode sheet before measurement to avoid inaccurate measurement data.
4. A disposable ECG electrode with a medical device product registration certificate must be used for measurement and used with this product.
5. Please keep the Bluetooth connection between the product and the mobile phone when measuring. If the interruption is found, please reconnect the device in time.
6. Please make sure that the phone has enough storage space before measuring, otherwise the measurement data may not be stored.
7. Do not uninstall and reinstall the software, as this may result in loss of history.
8. The measurement software automatically saves the user's measurement data during measurement.
9. If you encounter software crash or termination during measurement, please restart the software and measure again.
10. Changes in the memory of the mobile terminal (such as plugging and unplugging, replacing the SD card, etc.) may cause the program to malfunction and may even result in the loss of historical data.
11. Do not use it with life-sustaining equipment such as defibrillators to avoid equipment and personnel damage.
12. Do not use this device during nuclear magnetic resonance (MRI) or CT examinations.
13. During the measurement, the electrode pads and connectors must not be in contact with other conductive parts including the ground.
14. Do not use this product on babies weighing less than 10 kg.
15. Parts contained in the product may be swallowed by children. Please avoid contact with children.
16. Insufficient power will affect the normal operation of the product. Please use it after it is fully charged.
17. Once the disposable electrode is used as medical waste, it should be disposed in accordance with national laws and regulations, and should not be discarded at will, so as not to pollute the environment.

07 Software features

For details on the operation of the software functions, please refer to the operating instructions in the software page.

08 Stop measuring

If you are no longer measuring, please quit the app.

Trouble shooting

1. Can't search the device: First check if the device has power; secondly, please close the device to the phone as much as possible. If after the above operation, the device still can't be connected, please try to switch the phone Bluetooth once or restart the phone.
2. The device cannot collect data: dry skin will affect the signal collection. It is recommended to apply some water to the skin contacting the electrode or replace it with a new disposable electrode.
3. Data upload failure: Data upload is related to the network environment. Try to change the network environment (switch WiFi/cellular data).

Wearable dynamic ECG Recorder performance fault table

Name	performance fault
Recorder body	The functions listed in the manual are invalid; The screen is not displayed/has typo/misses picture; Vibration is invalid; Unable to sync with the specified device; Damage to the case due to structural or material factors;
chest stickers	Cannot be measured after the product body and electrode pads are properly installed
Charging cable	Can't be charge properly

Symbols explanation



Attention: consult ACCOMPANYING DOCUMENTS



Type CF APPLIED PART



Fragile, handle with care; Keep dry; Recyclable



The symbol is a pollution control sign for electronic information products, indicating that the product has an environmentally friendly use period of 10 years and can be recycled and should not be discarded at will.



Refer to instruction manual

Term and abbreviation

IPX7: IEC 60529 degrees of protection provided by enclosures(IP code), 7 means protected against the effects of temporary immersion in water

APP means application

iOS means iPhone operating system

Android means Mobile operating system developed by Google Inc.

ECG means electrocardiogram

Operation and transportation conditions

1. Normal operation conditions

① Environment

a) Temp. : +10°C ~ +40°C ;
Humidity : 30%~75% , exclude condensation ;
Atmospheric pressure : 700hPa~1060hPa ;

② Power

Internal power supply: Internal power, DC 3.8V , lithium battery.

③ Classification

Electric shock: internal power supply equipment ;

Electric shock protection : CF applied part ;

Protection provided by enclosures : IPX7 ;

Safety when use under condition of flammable anesthetic mixture with air or oxygen or nitrous oxide : Neither AP nor APG

Operation mode : continuous operation

2. Transportation conditions

① Temp. : -10°C ~ +50°C [Storage temperature range is generally wider than operating temperature range]

② Humidity : 10% ~ 95% , exclude condensation

Packaged products can be transported using general transportation, but should be protected from violent shocks, vibrations, and rain and snow. Note: The company reserves the right to change specifications.

Maintenance

1. Avoid falling or strong collision

2. Avoid high temperatures or long periods of direct sunlight

3. Avoid water entering main body

4. Do not use for a long time, please follow the battery maintenance requirements

5. This product has no user-serviceable parts. The company can provide circuit diagrams, component lists, or materials necessary for qualified technicians to repair.

7. Duration of use: 2 years

Precaution

The disposable electrode piece is a random gift accessory. In the later use of the product, the user needs to purchase the disposable ECG electrode with the medical device product registration certificate and use it with the chest sticker.

Guarantee

After-sales service of wearable dynamic ECG recorders is strictly based on the Consumer Protection Law of the People's Republic of China and the Product Quality Law of the People's Republic of China. The service is as follows:

During the validity period of the three guarantees, you can enjoy the services of return, exchange and maintenance in accordance with this regulation. Repair, exchange and return shall be handled by invoice.

1. Within 7 days from the date of your receipt, if the wearable dynamic ECG recorder display the performance failures listed in the "Wearable dynamic ECG Recorder performance fault table" , after testing, you can enjoy return or exchange service for free (except for special provisions for the return of goods purchased by e-commerce platform);
2. From 8th to 15th of the day from the date of your receipt, if the wearable dynamic ECG recorder display the performance failures listed in the " Wearable dynamic ECG Recorder performance fault table ", after testing, you can enjoy exchange or maintenance service for free;
3. Within 12 months from the date of your receipt, if the wearable dynamic ECG recorder display the performance failures listed in the "Wearable dynamic ECG Recorder performance fault table" , after testing, you can enjoy the maintenance service for free.

Non-warranty regulations

1. Damage caused by wear and tear caused by use, and human factors such as exposure to chemical agents and contact with sharp objects;
2. Unauthorized repair, misuse, collision, negligence, abuse, fluid injection, accident, alteration, improper use of non-wearable dynamic ECG accessories, or tearing or altering labels or anti-counterfeiting marks;
3. The validity period of the three guarantees has been exceeded;
4. Damage caused by force majeure;
5. Does not meet the performance failures listed in the " Wearable dynamic ECG Recorder performance fault table ";

Electromagnetic compatibility information

Guide and declaration – electromagnetic emissions

It is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment:		
Emission test	Compliance	Electromagnetic environment – guide
Radio frequency emission GB 4824	Class 1	Use RF energy only for its internal functions. Therefore, the frequency/emission is very low and there is little interference to nearby electronic equipment.
Radio frequency emission GB 4824	Type B	Suitable for use in all facilities, including domestic facilities and direct connection to residential public low-voltage power supply networks.
Harmonic emission GB 17625.1	Type A	
Voltage fluctuation/flicker emission GB 17625.2	Pass	

Guide and declaration – Electromagnetic immunity

It is expected to be used in the electromagnetic environment specified below. The purchaser or user of this product should use it in such an electromagnetic environment.

Immunity test	IEC60601 Test level	Compliance level	Electromagnetic environment – guide
Electrostatic discharge (ESD) GB/T 17626.2	±6kV contact discharge ±8kV air discharge	±6kV contact discharge ±8kV air discharge	The floor should be wood, concrete or ceramic. If the floor is covered with synthetic material, the relative humidity should be at least 30%.
Power frequency magnetic field 50/60Hz GB/T 17626.8	3A/m	3A/m	The power frequency magnetic field should have the power frequency magnetic field level characteristics in a typical commercial or hospital environment.

Remark : UT means AC network voltage before applying test voltage

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.

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

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.

FCC RF warning statement:

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.