

# **Wearable ECG Recorder**

## **Model: WM-3000**

### **User manual**

# Instruction

Thanks for purchased Mr. Wear Wearable ECG Recorder

Please read the contents of this instruction manual carefully before using the product in order to use the product correctly.

Please keep this instruction manual after reading so that you can check it whenever you need it.

Specification model:	WM-3000
Product name:	Wearable ECG Recorder
Registration Certificate Number:	
Product technical requirement number:	
Production license number:	皖 Food and Drug Administration Production No. 20150055
Application scope of products:	The product consists of a wearable ECG recorder, an ECG sensor and a mobile platform ECG application software.
Registrant / manufacturer name:	Daming Industrial (Suzhou) Co., Ltd.
Registrant / Production Enterprise Residence:	Suhuai west Road, Economic and Technological Development Zone, Suzhou City, Anhui Province
Manufacturing date :	at the back of product
Period of validity:	Reusable 500 times
Date of publication of this user manual :	June 2018

## Intellectual property

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It is a registered trademark of Daming Company.

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

Assembly operations, expansion, re-adjustment, improvement and repair are carried out by professionals recognized by Daming Company;

All repairs involving replacement parts and accessories and consumables used are all original (original) or approved by Daming Company;

The relevant electrical equipment complies with the national standards and the requirements of this instruction manual;

Product operation is carried out in accordance with these instructions.

## **Warranty and repair services**

The warranty period of the purchased product is subject to the sales contract. Consumables refer to disposable consumables that need to be replaced after each use or regularly replaced consumables, the consumables are not warranted.

The warranty period begins with the "installation date" on the <equipment warranty card> attached to the product. The <equipment warranty card> is the only certificate for calculating the warranty period. In order to protect your rights and interests, please fill in the card after the installation of the equipment, and hand over the second card of the insurance card ("Da Ming company retention") to the installer or mail back to the customer service department of Daming Company.

Please note that the following conditions will not be covered by the warranty:

The customer did not fill in and return the <equipment warranty card> within 30 days after the completion of the installation acceptance;

The serial number of the equipment provided by the customer is incorrect (our company confirms the warranty with the equipment serial number).

During the warranty period, the products can enjoy free after-sales service; however, please note that even if the product needs to be repaired due to the following reasons during the warranty period, Daming will implement the fee-based repair service, you need to pay the maintenance fee and accessories fee. :

Man-made damage;

misuse;

Irresistible natural disasters;

Replace or use parts, accessories, consumables that have not been approved by Da Ming Company, or be repaired by a non-Da Ming company authorized personnel;

Other failures caused by non-products themselves.

After the expiration of the warranty period, Daming Company can continue to provide fee-based repair services. If you do not pay or delay the payment of the repair service fee, Da Ming will temporarily suspend the repair service until you pay.

## **After sales service office**

Company name :	Daming Industrial (Suzhou) Co., Ltd.
Address :	Suhuai west Road, Economic and Technological Development Zone, Suzhou City, Anhui Province
Postal code:	234099
Website:	<a href="http://www.dmsyjt.com">http://www.dmsyjt.com</a>
24 hours service hotline:	4001819566
Tel:	+86 557 3152888
Fax:	+86 557 3698899

# Foreword

## Instruction

This manual describes in detail the use, function and operation of the product. Before using this product, please read and understand the contents of this manual to ensure the correct use of this product and to ensure the safety of patients and operators.

This manual describes the product in its most complete configuration, so some of the content may not be applicable to the product you purchased. If you have any questions, please contact us.

Keep this manual near the product so that it can be easily and timely obtained when needed.

## Suitable

This manual is intended for professional clinical staff to read.

## Illustration

All illustrations provided in this manual are for reference only, and the settings or data in the illustrations may not exactly match the actual display you see on the product.

## Convention

***Italic*** This section uses bold italics to indicate the quoted chapter.

The terms “danger”, “warning”, “caution” and “attention” are used in this manual to indicate the hazard information and its severity.

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# Safety

## Safety information

This section lists basic safety information that users should be aware of and follow when using the product. Other safety information that is the same, similar, or related to the specific operation will appear in each chapter.

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### Danger

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**Indicates an imminent danger that, if not avoided, could result in death, serious personal injury or property damage.**

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### caveat

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**Prompt for potentially dangerous or unsafe practices that, if not avoided, could result in death or serious personal injury or property damage.**

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### Caution

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**Indicates a potentially hazardous or unsafe operation that, if not avoided, could result in minor personal injury, product malfunction, damage, or property damage.**

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### Attention

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**Emphasize important considerations, provide instructions or explanations to better use the product.**

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## Danger

There are no safety information for hazard levels in this manual.

## Warning

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 **Warning**

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**This product is not suitable for infants weighing less than 10Kg.**

**Before using this product, the user must check the product and its accessories to ensure that they work properly and safely.**

**Skin is allergic to the accessory of this product**

**Do not use this product in an environment where flammable or explosive materials such as anesthesia are placed to prevent fire or explosion.**

**The product has a built-in battery and must not be opened to the outer casing of the product. Repairs or upgrades to the product must be performed by service personnel trained and authorized by the company.**

**This product does not have anti-defibrillation capability. When defibrillation, the wearable ECG recorder must be disconnected from the patient. Otherwise, the device may be damaged.**

**This product may not be used in conjunction with electrosurgical equipment. When using electrosurgical equipment, the device and the patient must be disconnected as this may result in equipment damage.**

**When handling packaging materials, you must comply with local regulations or the hospital's waste disposal system. Packaging materials must be placed out of reach of children.**

**This product generates RF radiation energy and, if not installed and used in accordance with the methods given in this manual, may cause conflicts in RF communications.**

**This product transmits wireless signals through space. During signal transmission, the signal may be interfered by multiple sources of RF interference. Although this product has a certain anti-interference ability, transmission failure may occasionally occur.**

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## Warning

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 **Warning**

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**When using this product, it is important to ensure that the environment in which it is used meets the environmental specifications claimed by the product.**

**To ensure the safety of the user, please use the accessories specified in this manual.**

**Disposable of devices can only be used once, and repeated use can result in performance degradation or cross-contamination.**

**When this product and its accessories are about to expire, they must be disposed of in accordance with the relevant local regulations or the hospital's system. If you have any questions, please contact us.**

**Electromagnetic fields can affect the performance of the product, so equipment used near the product must meet the appropriate EMC requirements. Mobile phones, X-ray or MRI equipment are all possible sources of interference because they emit high-intensity electromagnetic radiation.**

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## Attention

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**Attention**

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**Keep this manual near this product so that it can be easily and promptly obtained when needed.**

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## Device symbol

	Warning See random data (In this manual)
	Date of manufacturing
	Serial number
	Environmental protection life of electronic products (20 years)
<b>IPX7</b>	Waterproof rating is 7
	Reference manual or random information
	CF type application part
	Non-ionizing radiation symbol

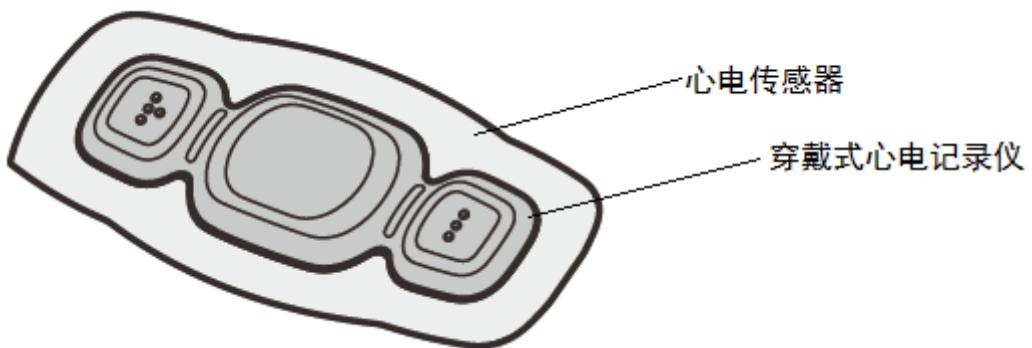
# Overview

## Product introduction

The wireless single-lead ECG collecting and recorder is composed of a wearable electrocardiograph (hereinafter referred to as an electrocardiograph), an electrocardiograph sensor and a mobile platform ECG application software. The ECG recorder collects the ECG signal through the ECG sensor. The collected signal is stored in the recorder and can be transmitted to the protocol-compatible device via Bluetooth. The acquired signal can also be displayed on the mobile platform ECG application software.

Wearable electrocardiograph recorder

electrocardiograph sensor



## Scope of use

For human body dynamic single-lead ECG data acquisition, recording and storage, does not include automatic analysis and diagnosis.



warning

**A single wearable ECG recorder can only monitor a single user.**

## Contraindications

1. This product is not suitable for infants weighing less than 10Kg;
2. The skin is allergic to this product;
3. Do not use this product in an environment where flammable or explosive materials such as anesthetic are placed.
4. This product cannot be used together with electrosurgical equipment.

## Product composition

The wireless single-lead ECG collecting and recorder is composed of a wearable electrocardiograph (hereinafter referred to as an electrocardiograph), an electrocardiograph sensor and a mobile platform ECG application software.

## Product exterior



Picture 0-1 Front of product



Picture 0-2 Back of product

# Installation and maintenance

## Installation

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### Warning

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**The copyright of the software of this product belongs to the company. Any organization or individual may not tamper with, copy or exchange any infringement by any means or form without permission.**

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### **open box to check**

Before unpacking, please check the box carefully to determine if the product is damaged during transportation. If you find any damage, please contact the carrier or the company immediately.

If the packaging is intact, please unpack the package in the correct way, carefully remove the product and other components from the box, and check the packing list one by one. Check the product for any mechanical damage and complete items. If you have any questions, please contact our Customer Service Department immediately.

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### Warning

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**The user should place the packaging materials out of reach of children; when handling packaging materials, they must comply with local regulations or the hospital's waste disposal system.**

**The equipment may be contaminated by microorganisms during storage, transportation and use. Please confirm that the packaging is in good condition before use, especially the one-time use accessories. If damage is found, please do not use it.**

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## Environmental requirements

The environment in which this product is used must comply with the environmental specifications in Appendix B, Product Specifications.

## Power requirement

The power supply used in this product should meet the power supply specifications in Appendix B Product Specifications.

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### Warning

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**Please ensure that the product works within the specified environmental requirements and power requirements, otherwise it will not meet the technical specifications stated in the Appendix B product specifications, and may lead to unforeseen consequences such as equipment damage.**

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### Installation method

For the installation of the wearable ECG recorder, see Chapter 4, Operating Instructions.

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## Cleaning and disinfection

The clean and disinfection is only for ECG recorders. The accessories are single-use single use, no need to clean and disinfect.

### Cleaning

The product should be cleaned before and after use. Please consult or understand the hospital's regulations on equipment cleaning, disinfection and sterilization before cleaning.

When cleaning the surface of the product, use a clean, soft cloth, sponge or cotton ball to absorb the non-erosion cleaner, wring it out and gently wipe it. The following cleaning agents are available:

Water

(70%) Ethanol (70%)

(70%) Isopropanol (70%)

To prevent damage to the device, please observe the following rules:

Some clean agent need to be diluted before use. Please dilute the clean agent in strict accordance with the manufacturer's instructions;

After cleaning, use a dry cloth to dry excess detergent;

Do not immerse the device in water or any cleaning agent, or spill water or detergent on the surface of the device;

Do not use abrasive materials (such as steel wool or silver polish), and any strong solvents (such as acetone or detergents containing acetone);

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 **Warning**

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**Failure to follow those instructions may result in corrosion, wear or blurring of the casing or label, or may result in equipment failure.**

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### Disinfection

Disinfection may result in a degree of damage to the equipment. Therefore, this equipment is not recommended for customers to disinfect.

# Use instructions

Wearable ECG recorder operation flow

The operational flow chart of the wearable ECG recorder is as follows:

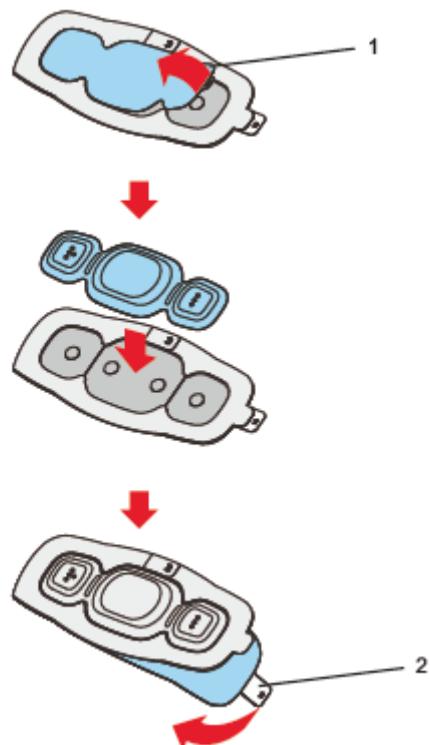
**Figure 0-1 Operational flow chart of the wearable ECG recorder**

## Attention

**The wearable ECG recorder is waterproof IPX7 and can be used in the shower and soaking in a short time.**

## Mounting accessories

When you start using the wearable ECG recorder, you need to attach the recorder to the accessory. The operation mode is shown in Figure 0-2.



**Figure 0-2 Attachment installation diagram**

The installation steps are as follows:

1. Uncover the adhesive backing of the upper part of the attachment.
2. Paste the host to the attachment.
3. Remove the lower backing of the attachment.
4. Paste the product onto the human body.
5. Remove the paper backing from the front of the attachment.

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## Attention

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**Do not use the accessory if it is found to be damaged or not.**

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## Paste the recorder to the measurement site

The quality of the dynamic ECG depends on the quality of the electrical signals obtained by the electrodes on the accessory. In order to ensure the quality of the electrical signal, proper treatment of the skin at the patient's placement electrode is necessary.

The steps for installing and pasting the pads are as follows:

1. Prepare the recorder with the attached accessories and put them next to them.
2. If necessary, remove the chest hair and wipe the skin with 75% alcohol to remove the oil.
3. If necessary, use a medical sandpaper to properly polish the skin where the recorder is attached.
4. Attach the recorder to the cleaned skin according to the specified location.

For the installation location of the recorder, please refer to Figure 0-3:

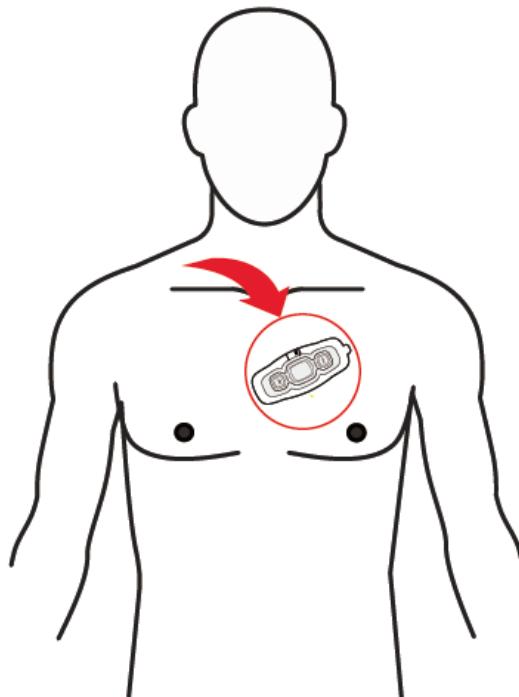


Figure 0-3 Recorder installation diagram when using a single-channel accessory

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## Attention

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**When placing the electrode or connecting the cable, make sure that it is not in contact with any other conductive parts or ground. In particular, ensure that all ECG electrodes, including neutral electrodes, are attached to the patient to prevent them from coming into contact with conductive parts or ground.**

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## Start recorder

The recorder is installed and attached to the anthropometric part, and the recorder will wake up. If the recorder is low, it needs to be charged before it can wake up.

## Wireless transmission

This product has the wireless transmission function of data, compatible with Android system version 4.3 and above, iOS system version 7.1 and above, and built-in Bluetooth 4.0 version and above mobile communication equipment

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# Handling of common problems

## Handling of common problems

Fault phenomenon	Possible reason	Solutions
After booting, the display shows low battery	Low power	Charge the recorder
Recording time is not enough, it may only be a few hours or a few minutes	Low power There is a problem with the recorder itself.	Use after charging; Return it to the manufacturer or contact the factory service personnel for processing.
Bluetooth connection is not available	Low power There is a problem with the recorder itself. Mobile platform ECG application software Bluetooth is not turned on	Use after charging; Return it to the manufacturer or contact the factory service personnel for processing. Turn on the Bluetooth of Mobile platform ECG application

# Battery

The wearable ECG recorder has a built-in rechargeable lithium battery as the working power source for the recorder.

When the battery is below 10%, the wearable ECG will flash a red light and the battery should be charged.

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## Warning

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**The built-in lithium battery cannot be replaced.**

**Keep the product out of the reach of children when charging.**

**Only use the charger specified by the manufacturer, the charger should meet GB 9706.1-2007.**

**In order to increase the battery life, please charge it when prompted low battery or low battery.**

**Charge the ECG recorder to more than 80% before long-term storage and charge it once a month.**

**When the battery is about to exceed its lifespan, it must be disposed of in accordance with relevant local regulations or hospital regulations. If you have any questions, please contact us.**

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# Accessory

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## Warning

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**When using this product, please use the accessories specified in this chapter. The attachments are single-use for a single patient. Using other types of accessories may reduce product performance or damage the product.**

**Do not use the accessory if it is found to be damaged or not.**

**The accessories in this chapter are in compliance with biocompatibility requirements and meet the standard YY/T 0196-2005.**

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## Accessory

name	Model / material code	Type	Manufacturer
ECG single lead ECG sensor	EPA001	Dispose user	Daming Industrial (Suzhou) Co., Ltd.

# Product specifications

## Safety specification

Parameter	specification
China National Food and Drug Supervisory Authority Classification	Class II
Electric shock protection type	Internal power supply
Electric shock protection level	CF type
Work model	continuously working
Explosion protection rating	
IP protection level	IPX7
Equipment type	Portable
Safety when using flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide	Equipment that cannot be used in the presence of flammable anesthetic gases mixed with air or flammable anesthetic gases mixed with oxygen or nitrous oxide

## Environmental specifications

Parameter	Specification
Working temperature	0~45°C
Working humidity	10~95%, Non-condensing
Working altitude	86~106kPa
Storage temperature	-20~45°C
Storage humidify	10~95%, Non-condensing
Storage altitude	57~107kPa

## Power specification

Parameter	Specification
Battery voltage input range	3-4.2V
Type of battery	Rechargeable built-in lithium battery (rated voltage 3.7V)
Life time (continuous measurement typical value)	≥30hours

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## Wearable recorder specification

Parameter	Specification
Size	length : $87 \pm 5$ mm Width : $32 \pm 3$ mm Height: $6 \pm 1$ mm
Weight	$10 \pm 1$ g
Interface	Standard interface with lead signal and Bluetooth signal

## Recording and storage specification

Parameter	Specification
Recording method	Real-time recording
Storage method	Chip storage
Storage capacity	Storage time 30 hours

## ECG Specification

ECG	
Lead system	Support I lead
Sampling Rate	125Hz
Dynamic input range	Input signal range is not less than $\pm 8$ mV with $\pm 500$ mV DC bias voltage superimposed
PACE detection capability	Has the ability to detect the following pacing pulses and correctly display the ECG signal: Pulse amplitude: 2~200mV Pulse pulse width: 0.1~2.0ms
Common mode rejection ratio	$\geq 96$ dB
Bandwidth (-3dB)	When the sampling rate is 125Hz, the bandwidth is 0.05~40Hz.
Gain setting	Error $\leq \pm 5\%$
Wave speed	Error $\leq \pm 5\%$
Input resistance	$\geq 20M\Omega$ @10Hz

# EMC and radio management compliance

## EMC

This device complies with EMC standard YY 0505. All accessories listed in the attached chapter of this manual comply with the requirements of YY 0505 when used in conjunction with this equipment.

### Attention

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Use of accessories, sensors and cables outside the specified range may increase the electromagnetic emissions of the device and/or reduce the electromagnetic immunity of the device.

This device cannot be used in close proximity or stacked with other devices. If necessary, observe the device closely to ensure it is functioning properly in the configuration used.

EMC is required to be specifically protected against this equipment and needs to be installed and repaired in an environment that meets the following EMC information.

Even if other devices meet the CISPR emission requirements, they may cause interference to the device.

When the input signal amplitude is lower than the minimum amplitude specified in the technical specifications, the measurement may be inaccurate.

Portable and mobile communication devices can affect the performance of this device.

Other devices that contain RF radio transmissions may affect the device (for example, mobile phones, PADs, wireless-enabled computers)

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Electromagnetic emission guidelines and statements		
Launch test	Compliance	Electromagnetic environment – guide
Radio frequency emission GB 4824	Group 1	This device uses RF energy only for its internal functions. Therefore, its RF emissions are low and there is little possibility of interference with nearby electronic equipment.

<b>Radio frequency emission</b> GB 4824	Class B	This equipment is suitable for use in all facilities, including domestic facilities and residential public low-voltage power supply networks that are directly connected to the home.
<b>Harmonic emission</b> GB 17625. 1	Not applicable	/
<b>Voltage fluctuations and flicker</b> GB 17625. 2	Not applicable	

This equipment provides the following basic features and remains safe in the guidelines and manufacturer's statement - electromagnetic immunity environment.

Operating mode  
Precision  
Function  
Attachment identification  
Data storage  
Prompt  
Connection detection (accessory)

<b>Electromagnetic Immunity Guidelines and Statements</b>			
<b>Immunity test</b>	<b>IEC60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guide</b>
<b>Electrostatic discharge (ESD)</b> GB/T 17626. 2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	The floor must be wood, concrete or tile. If the floor is covered with synthetic materials, the relative humidity is at least 30%
<b>Electrical Fast Pulse Group (EFT)</b> GB/T 17626. 4	±2 kV power cord ±1kV to input/output line	Not applicable	/
<b>Surge</b> GB/T 17626. 5	±1 kV differential mode voltage ±2 kV common	Not applicable	

	mode voltage		
<b>Voltage dips, short interruptions, and voltage changes</b> GB/T 17626. 11	<5% UT (drop > 95% UT) 0.5 cycle 40% UT (drop 60% UT) 5 cycles 70% UT (drop 30% UT) 25 cycles <5% UT (drop > 95% UT) 5 seconds	Not applicable	/
Power frequency magnetic field (150Hz/180Hz) GB/T 17626. 8	3 A/m	3 A/m	The power frequency magnetic field should have the characteristics of the power frequency magnetic field in a typical place in a typical commercial or hospital environment.

Note 1: UT refers to the AC network voltage before the test voltage is applied.

Electromagnetic Immunity Guidelines and Statements			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment – guide
Conducted immunity GB/T 17626. 6	3 Vrms 150k~80MHz	Not applicable	$d = 1.2 \sqrt{P}$ <p>Portable and mobile RF communications equipment must be used at specified distances from any component of the equipment and/or system, including the cable. This isolation distance is calculated by selecting the appropriate equation based on the transmitter frequency. The recommended calculation for the isolation distance is:</p> $d = 1.2 \sqrt{P}$
17626. 3	3V/m 80MHz~2. 5GHz	3 V/m	<p><i>The recommended calculation for the isolation distance is:</i></p> <p><i>80 MHz to 800 MHz:</i></p> $d = 1.2 \sqrt{P}$ <p><i>800MHz to 2. 5GHz:</i></p>

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			$d = 2.3\sqrt{P}$ Where $P$ is based on the transmitter's maximum output rated power, in watts (W), and $d$ is the recommended isolation distance in meters (m). The field strength of a fixed RF transmitter is determined by surveying the electromagnetic field $a$ , and each frequency range $b$ should be lower than the compliance level. Interference may occur near devices marked with the following symbols: 
Note 1: At 80MHz and 800MHz frequencies, the formula for the higher frequency band is used.			
Note 2: The above guidelines may not be applicable in all cases. Electromagnetic wave propagation is affected by absorption and reflection from buildings, objects and the human body.			
Note 3: This equipment is intended to receive RF electromagnetic energy and is free of basic performance requirements in the occupied frequency band (2400MHz–2483.5MHz), but remains safe.			
a.	Fixed launch emission is strong, such as: wireless (cellular / cordless) telephone and ground mobile radio base station, amateur radio, AM (amplitude modulation) and FM (frequency modulation) radio broadcast and television broadcast, etc., its field strength in theory can not accurately predict. In order to assess the electromagnetic environment of a fixed RF transmitter, an electromagnetic field survey should be considered. If the field strength of the location where the [device or system] is located is higher than the RF compliance level of the above application, the [device or system] should be observed to verify that it is functioning properly. If abnormal performance is observed, additional measures may be necessary, such as reorienting and relocating [device or system].		
b.	The field strength should be less than 3V/m over the entire frequency range from 150kHz to 80MHz.		

Recommended distance between wearable ECG recorders and portable/mobile RF communication devices			
This device can be used in an electromagnetic environment where RF interference is controlled. To avoid electromagnetic interference, the customer or user should maintain a minimum recommended distance between the device and the portable/mobile RF communication device.			
Transmitter rating	Calculate the isolation distance based on the frequency of the transmitter (m)		
Maximum output power (W)	150 kHz ~ 80 MHz	80 MHz ~ 800 MHz	800 MHz ~ 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$

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0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.80	3.80	7.30
100	12.00	12.00	23.00

For the rated maximum output power of the transmitter not listed above, the recommended isolation distance  $d$ , in meters (m), can be determined using the formula in the corresponding transmitter frequency column, where  $P$  is provided by the transmitter manufacturer. Transmitter maximum output rated power in watts (W).

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

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

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## EMC Wireless Management Compliance

### RF parameters

Items	Description
	Bluetooth low energy 4.1
Working frequency band (MHz)	2402 – 2480
Modulation	GFSK
Transmit power (mW)	≤2.5

This device with the Panlink II Wireless Module complies with Part 15 of the FCC Rules. The premise of this operation is that this device will not cause harmful interference.

FCC and Industrial Canada radio regulatory compliance for this device including the Panlink II wireless module: This device complies with Part 15 of the FCC Rules and RSS-210 of Industrial Canada. 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 modifications and alterations to this equipment not expressly approved by the company could cause harmful radio frequency interference and void your authority to operate the equipment.

The maximum allowed antenna gain is in accordance with the e. i. r. p. limit specified in RSS-210.

The maximum allowed antenna gain is in accordance with the e. i. r. p. limit specified for peer-to-peer work in RSS-210.

# Symbols and terms

## Unit list

Abbreviation	English
A	ampere
dB	decibel
g	gram
Hz	hertz
k	kilo
kPa	kilopascal
m	meter
mm	millimeters
ms	millisecond
mV	millivolt
mW	milliwatt
s	second
V	volt
$\Omega$	ohm
W	watt

## Symbol list

Symbol	English
—	minus
%	percent
/	per; divide; or
$\sim$	to
$^$	power
+	plus
=	equal to
<	less than
>	greater than
$\leq$	less than or equal to
$\geq$	greater than or equal to
$\pm$	plus or minus
$\times$	multiply
©	copyright

# Toxic or harmful substances or elements

Accessory name		Pb	Hg	Cd	Cr(VI)	PBB	PBDE
Main device	Casing	○	○	○	○	○	○
	PCBA	○	○	○	○	○	○
Package	Material of package	○	○	○	○	○	○
Battery	Lithium battery	○	○	○	○	○	○
Accessory	ECG accessories	○	○	○	○	○	○
Remarks	○ : Indicates that the content of this toxic and hazardous substance in all homogeneous materials of this part is below the limit requirement specified in SJ/T11363-2006. × : Indicates that the toxic or hazardous substance contains at least a certain homogeneous material content of the part exceeding the limit requirement specified in SJ/T11363-2006.						

## FCC Warning Statement

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

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.