# Mobile & Wireless ECG Systems

## Model: WOOTOP-P001

## Instructions for Use


Edition of the Instructions:

**Manufacturer/After-sales Service: Shenzhen Qianhai MDE Medical Technology Co., Ltd.**
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**Address of Manufacturing Site: Floor 6, Block B, Building 6, Baoneng Science & Technology Park, Qinghu Industrial Zone, Qingxiang Road, Longhua Office, Longhuan New Zone, Shenzhen**
**Tel: 0755-23972355 Fax: 0755-23972355 Website: http: //www.wootop.cn**
**Registration Certificate for Medical Apparatus and Technical Specification of Product:**
**License for Manufacture of Medical Apparatus and Instruments:**

# Contents

# I. General

WOOTOP-P001 is a Mobile & Wireless ECG Systems (hereinafter referred to as "ECG Systems") independently developed by Shenzhen Qianhai MDE Medical Technology Co., Ltd. (hereinafter referred to as MEDICAL). All parts of this ECG Systems, including any software and hardware, belong to and are exclusive properties of MEDICAL and shall not be reproduced, copied and plagiarized by any individual or group unless otherwise authorized by MEDICAL.

This product is manufactured as per Medical Device Registration Standards and fully complies with the precise requirements of national and professional standards.

You are welcome to use this product!

* To correctly and safely use this product, please be sure to carefully read the instructions of product prior to use;

* Please properly keep this Instructions after reading, in case of future reference.

* Please do not lose the warranty card attached to this document.

# II. Warning Information ⚠

1. Never use this ECG Systems in magnetic resonance imaging (MRI) room or hyperbaric oxygen chamber.

2. Electromagnetic interference - ensure there is no strong electromagnetic interference source, e.g. radiotelegraphic transmitter, in the service environment of this ECG Systems.

3. This ECG Systems is a sophisticated medical instrument. Do not impose such actions as throwing, hitting, beating, tamping and knocking, as well as dragging and twisting on the equipment.

4. Maintenance of this ECG Systems **must** be performed by the agencies and professionals authorized by the manufacturer, or in written form by the manufacturer.

5. Poor contact of electrode (for example, foreign matters on skin or frequent removal and placement) may cause disordered waveform and data jig. Therefore, to acquire strong electrocardiosignal, the contact between electrode and skin must be in good condition. It is recommended to clean the skin surface and wipe the skin with 75% alcohol on the positions where electrodes are to be placed.

6. Expired electrodes or electrodes without market entry license will directly affect the accuracy of measurements.

7. **Never** use this ECG Systems on skin present with such symptoms as injury, inflammation, blister and allergy (which, if caused by electrode, please replace the electrode and use this ECG Systems after the skin is recovered).

8. **Pay attention to** the anode and cathode of electrode. Place the electrode with its anode + oriented to heart.

9. Electrocardiogram monitoring is not recommended after strenuous exercises.

10. For those whose body weight is less than or equal to 10kg, this ECG Systems shall not apply or be used upon doctor's advice.

# III. Description of Product

**1. Basic Information**

Product name: Mobile & Wireless ECG Systems (hereinafter referred to as "ECG Systems")

Model: WOOTOP-P001

**2. Performance of the Product**

**2.1 Working conditions**

a) Ambient temperature: 5℃~40℃;

b) Relative humidity: 10%~95%;

c) Atmospheric pressure: 86kPa~106kPa;

d) Battery: 3.7V rechargeable polymer battery, 710mA;

e) Power: 56mW;

f) Charging way: exclusive safe-charging base.

**2.2 Technical parameters**

a) Overall dimensions of affix: 129×42.2×11.2(mm),
Overall dimensions of charger box: 158.5×97×36(mm);

b) Weight: 45g;

c) Memory space: 4GB;

d) Operating system: PC computer or system higher than Android 4.3 or IOS 4;

e) Bluetooth transmission: Bluetooth 4.0 (BLE);

f) Power endurance: 100μA in standby mode power consumption, 24 hours of continuous electrocardiogram monitoring (at maximum power consumption state);

g) Protection class: IPX4;

h) Material: silica gel at both ends, ABS for the enclosure and keys.

**2.3 Performance indexes:**

a) Normal sensibility: 10mm/mV, error ≤±5%;

b) Working input voltage: 3.7V;

c) Sampling frequency: 250Hz;

d) Internal noise: ≤30μV(Peak-to-valley value);

e) Input impedance: ≥10MΩ;

f) Common mode rejection ratio: ≥80dB;

g) Frequency response: 0.5Hz~100Hz;

h) Measuring range of heart rate: 30bpm~300bpm.

**2.4 Parameters of bluetooth module:**

a) Protocol: Bluetooth 4.0 low power consumption (BLE)

b) Serial port: support RS232 serial port

c) Working frequency: 2.4 GHz ISM frequency band

d) Modulation: GFSK

f) Input sensitivity: ≤-93dBm

g) Security mode: Encryption supported

**3. Working Principle**

As this product is used following the placement modes, the electrocardiogram sensor will acquire the biologic signals regarding the heart's electrical potential, heart rate and identified motion state of the body, which, after data processing, are real-time send to and displayed on or stored in PC interface/mobile device App software, and the real-time received primary data, after subjected to intelligent algorithm, are expressed as the related diagnostic result and present on PC interface/App interface.

**4. Primary Structure**

This ECG Systems is composed of the host, polymer battery, charger base and USB leads, including data management software. This ECG Systems must run with disposable electrode (as electrodes are excluded from the registered unit, this Instructions does not cover any description of the electrodes. See Figure I for the primary components.

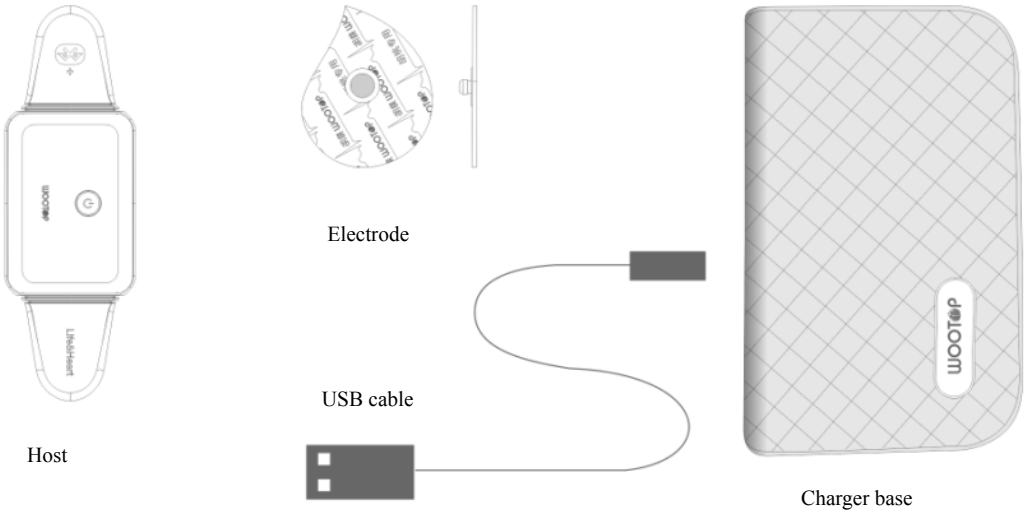



**Figure I**

**5. Intended Use and Features**

(1) Intended use: to record and analysis 24-hour dynamic electrocardiosignals of human body for the purpose of clinical diagnosis and study.

(2) Product features:

a) This ECG Systems allows testing/displaying your electrocardiogram data at any time and can record and maintain these data.

b) The function of continuous electrocardiogram monitoring over the complete sleeping period allows automatic and continuous monitoring of electrocardiogram data throughout the sleeping period, real-time diagnosis monitoring, and historical data recording.

c) The function of 24-hour uninterrupted monitoring on motion allows uninterrupted monitoring of your motion state, as well as analysis and recording.

d) Cloud storage and cloud analysis of health data, allows the acquired electrocardiogram and motion data being stored at cloud terminal. In this way the cloud terminal server can run automatic tracking/analysis

of data, and then give health report and recommendation.

e) The associated user function allows tracing/searching of the user's health data at any time as well as analysis and conclusion.

f) The bluetooth allows data to be sent to the user who in turn can deliver the data to cloud terminal.

g) Local SD card data storage function. When the equipment is not hooked up with the bluetooth host, once an electrocardiogram leads connected status is detected by the host, local data storage will run automatically. Bluetooth playback function is supported.

h) Self-contained local clock function, allows synchronization of the equipment clock via cellphone. When the equipment is switched off, the clock is powered by the polymer or back-up battery. In terms of the automatic data recording by SD card, the moment at which the data is recorded will be recorded automatically.

## IV. Instructions for Use and Operation

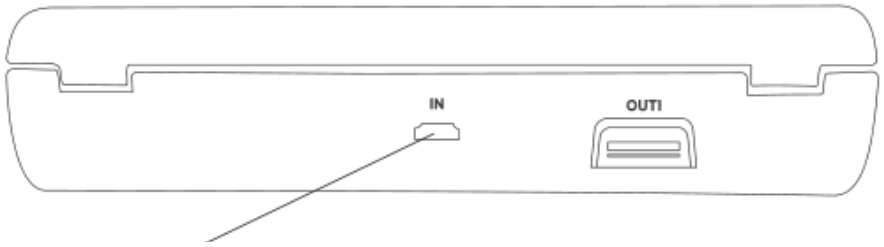
### 1. Charging

1) For first use of this ECG Systems, please charge with the charger base.

2) To connect the charger base to power supply, connect the USB terminal to the charger base and the other terminal to the adapter (power input: 4.8-5.5V) or computer USB output. In this case, the green indicator light is illuminated on the charger base, indicating ready to charge the ECG Systems.

3) The red indicator light illuminated on the equipment means the ECG Systems is charging and will turns to green as the charging process is finished.

4) It will take about 1.5 hours for the ECG Systems to be charged from low level to full.




Charging socket

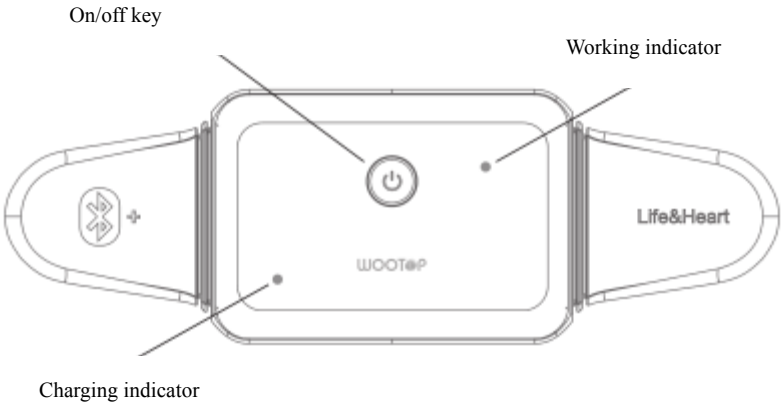
### 2. Turning on/off

1) Long-press the on/off key on ECG Systems for 3 seconds until the green light is constant illuminated, to turn on the ECG Systems.

2) Long-press the on/off key until the red light is constant illuminated, keep for 3 seconds to turn off the ECG Systems.

3) In case of low battery, the red light will flicker every 3 seconds to prompt the user of the current low battery.

4) When the internal polymer battery's voltage drops to below 3.3V, the battery will be exhausted after 10 minutes and the system will shut down automatically.




### 3. Software Installation and Hooking-up

1) To operate the ECG Systems, a PC computer or cellphone/App terminal with at least Android 4.3 system or IOS 4 system is required. Please confirm that the equipment support BLE Bluetooth 4.0.

2) Download and install the ECG Systems health management software on the PC/mobile equipment terminal (for downloading, please scan the two-dimension code or resort to the official MEDICAL website).

3) Turn on the bluetooth in App terminal and automatically search nearby bluetooth equipment.

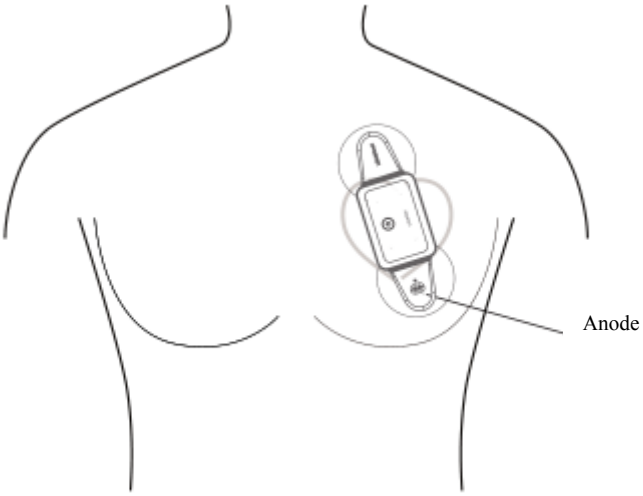
4) Turn on the ECG Systems, and as the App terminal shows the ECG Systems, click to pair.

5) The App terminal software will show the paired equipment once the pairing is completed.

**Two-Dimension Code to Download App**

### 4. Placement of Electrode

During placement, pay attention to the anode and cathode. To place the electrode, the anode shall be oriented to the heart ("+" sign, together with the bluetooth symbol , is provided at the anode).




## 5. Placement Modes

There are several placement modes:

As shown in Figure II, orient the end with "+" sign and bluetooth symbol ᛒ to the heart.

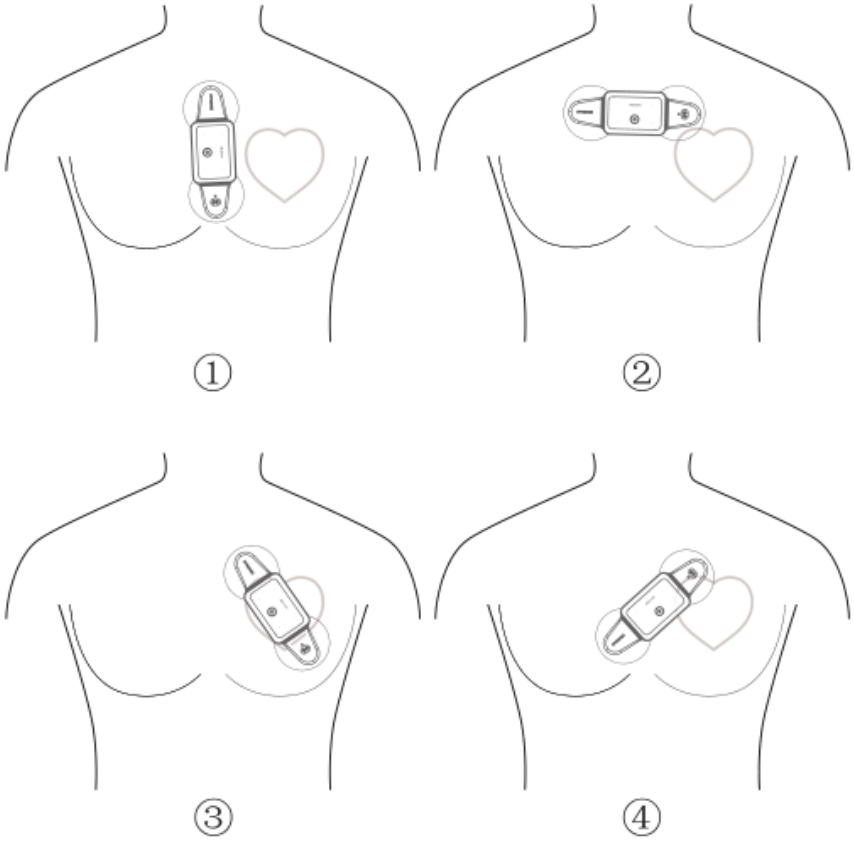



**Figure II**

## 6. Single-Pass Electrocardiogram Monitoring

1) Clean the skin and place the electrodes according to the positions to be acquired.

2) Turn on the ECG Systems, run the health management software and click the testing icon.

3) Keep monitoring until a stable diagram presents, after adequate data are acquired (>30 seconds), remove the ECG Systems and exit the software.

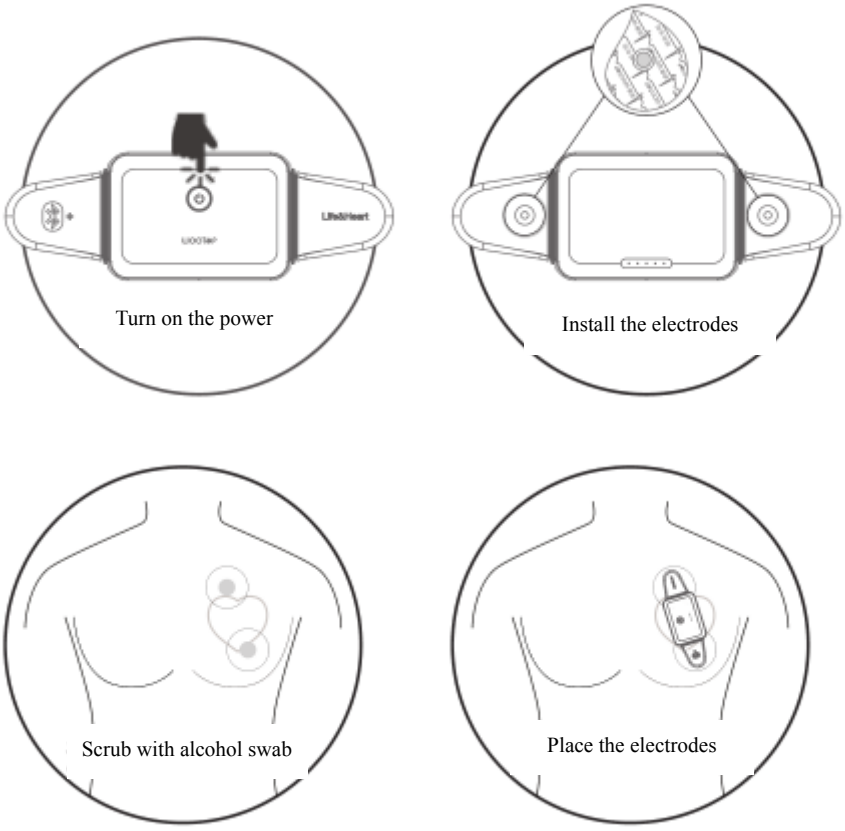
## 7. Continuous Electrocardiogram Monitoring

The continuous electrocardiogram monitoring function, at one time, allows continuous monitoring and preservation of electrocardiogram data for 24 hours at maximum.

1) Clean the skin and place the electrodes according to the leads to be acquired.

2) Turn on the ECG Systems, run the health management software and click the testing icon.

3) Keep monitoring until a stable diagram presents, after adequate data are acquired (>30 seconds), remove the ECG Systems and exit the software.




## 8. Data Retrieval

1) Enable the health management software. After the PC/App terminal is hooked up with the ECG Systems, real-time retrieval of the electrocardiogram data stored by the ECG Systems is enabled.

2) The ECG Systems has a memory space of 4G. When the equipment bluetooth is not enabled (after the equipment bluetooth is enable, data will be automatically upload to cloud terminal), there is an automatic data recording for 30 fields at maximum and only the electrocardiogram data of the latest month is recorded.

## 9. Indicator Light Status

| Operating mode | Operating state | Indicator light status |
|---|---|---|
| Bluetooth ECG mode | Bluetooth connection, ECG collection | Green light flashes (once every 3s) |
| Startup & wait | Startup & wait (shut down automatically after startup & wait state continues for 10min) | Green light flashes (once every 1s) |
| Shutdown process | Red light keeps on (shut down by long-press for 3s) | Red light keeps on |
| Startup process | Green light keeps on (start up by long-press for 3s) | Green light keeps on |
| ECG mode | Bluetooth is out of connection, ECG collection | Blue light flashes (once every 3s) |
| SD card data playback | Bluetooth is out of connection and SD card data in playback | Blue light flashes (once every 1s) |

# V. Cleaning, Maintenance and Service

**1. Cleaning**

1) No soak cleaning; wipe the splotchy parts slightly with a dampish soft cloth until clean.

2) Please keep the ECG Systems in the box of charger base, if not to be used for a long time.

**2. Maintenance and Service**

1) The ECG Systems is a precise electronic product and its internals shall not be disassembled or repaired at your own discretion.

2) The ECG Systems shall not be used for long time in excessively damp and dusty places.

3) Such actions as throwing, hitting, beating, tamping and knocking, as well as dragging and twisting shall not be imposed on the ECG Systems.

4) Electrodes with guaranteed quality shall be used.

5) To extent battery life, please charge before total exhaustion of electricity.

# VI. Fault Analysis and Trouble-shooting

**1. Common Faults**

| No. | Fault | Cause analysis | Solution |
|---|---|---|---|
| 1 | Failure in starting up | ECG Systems battery runs out | Make it fully charged in the charging base |
| 2 | Unable to detect the ECG Systems | The ECG Systems is not well-connected with PC/APP terminal;<br>The operating system is abnormal. | Reconnect the ECG Systems to PC/APP terminal;<br>Restart operation or reinstall the operating system. |
| 3 | Software is unable to start | The software package is unloaded/the software system fails | Reinstall the software package and upgrade it timely. |

***As the ECG Systems is a sophisticated instrument, faults other than the above-mentioned shall not be handled by non-professions . Therefore, once any fault occurs, please contact with the manufacturer or the authorized after-sales service department.***

**2. Guarantee/Warranty Card**

From the date of purchase, this product will be provided with one-year warranty for free, except the following faults as follows:

1) Faults arising from unauthorized disassembling or refitting;
2) Faults arising from falling inadvertently in using and transport;
3) Faults caused by lack of appropriate maintenance;
4) Faults arising from operations without following the correct indications in the instructions for use.

# VII. Accessories and Packing List

| | |
|---|---|
| Dynamic electrocardiograph host (1) | Charger base (1) |
| Product instructions (1) | USB data cable (1) |
| Diagram for application (1) | Warranty card (1) |
| Certificate (1) | Electrodes (optional) |

## VIII. Signs and Symbols

| | | | |
|---|---|---|---|
|  | Warning information |  | No rain for the transport packages |
|  | BF-type application part |  | No unauthorized disassembly or repair |
| + | Anode |  | Bluetooth |
|  | RF emitter | | |

## IX. Storage and Transport

**1. Storage**

The packed ECG Systems shall be stored indoors at a temperature of -10℃~55℃, a relative humidity up to 95%, free from corrosive gas and well-ventilated.

**2. Transport**

The ECG Systems may be transported by general means, but must be protected from fierce impact, shake and rain & snow in the transport process.

## X. Production Information and After-sales Service

Manufacturer/After-sales Service: Shenzhen Qianhai MDE Medical Technology Co., Ltd.

Address: Room 201, Building A, Qianwan Yi Road No.1, Qianhai Shenzhen-Hong Kong Cooperation Zone, Shenzhen， Guangdong， P.R. China

Address of Manufacturing Site: Floor 6, Block B, Building 6, Baoneng Science & Technology Park, Qinghu Industrial Zone, Qingxiang Road, Longhua Office, Longhuan New Zone, Shenzhen

Expiration date: Eight years (from the date of production)

Manufacture date: See the product label

Tel.: 0755-23972355

Fax: 0755-23972355

Web: http: //www.wootop.cn

Registration Certificate for Medical Apparatus and Technical Specification of Product:

License for Manufacture of Medical Apparatus and Instruments:

*The Instructions is prepared or revised on August 28, 2015.*

# Annex: Description of Electromagnetic Compatibility

**Cautions:**

- The ECG Systems complies with the requirements related to electromagnetic compatibility in YY0505-2012.
- Users shall install and use the ECG Systems according to the information of electromagnetic compatibility in the accompanied documents.
- Portable and movable RF communication equipment may influence the ECG Systems performances; avoid strong electromagnetic interference (e.g. approaching the microwave oven) when using.
- The guide and the manufacturer's declaration are detailed in the attachments.

**Warnings:**

- The equipment or system shall not be used near or overlapped with other equipment; if unavoidable, observe and verify whether it is in normal operation under the used configuration.
- In addition to the transducer and cables sold by the equipment or system manufacturer as the spare parts of internal components, accessories, transducer and cables other than the specified ones may make the equipment or system emission increased or the immunity reduced.
- Using accessories, transducer or cables other than the specified ones together with the equipment and system may make the equipment or system emission increased or the immunity reduced.

**Federal Communications Commission (FCC) Statement**

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

**Note:** This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

●Reorient or relocate the receiving antenna.
●Increase the separation between the equipment and receiver.
●Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
●Consult the dealer or an experienced radio/TV technician for help.

**Warning:** Changes or modifications made to this device not expressly approved by **Shenzhen Qianhai MDE Medical Technology Co., Ltd.** may void the FCC authorization to operate this device.

**Note:** The manufacturer is not responsible for any radio or tv interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate the equipment.

| Guide and Manufacturer's Declaration - Electromagnetic Emission | | |
|---|---|---|
| The ECG Systems is intended to be used in the electromagnetic environment specified as follows; the purchaser or user shall guarantee that the ECG Systems is used under such electromagnetic environment: | | |
| **Emission test** | **Conformity** | **Electromagnetic environment - Guide** |
| GB4824<br>RF emission | Group 1 | The ECG Systems uses RF energy only for its internal functions, so its RF emission is very low and may not produce any interference to the neighboring electronic equipment. |
| Radio-frequency emission<br>GB 4824 | Category B | |

<table>
<tr><th colspan="4">Guide and Manufacturer's Declaration - Electromagnetic Immunity</th></tr>
<tr><td colspan="4">The ECG Systems is intended to be used in the electromagnetic environment specified as follows; the purchaser or user shall guarantee that the ECG Systems is used under such electromagnetic environment:</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Required level</th><th>Electromagnetic environment - Guide</th></tr>
<tr><td>ESD<br>GB/T 17626.2</td><td>±6kV contact discharge<br>±8kV air discharge</td><td>±6kV contact discharge<br>±8kV air discharge</td><td>The ground shall be woody, concrete or ceramic; if the ground is covered by synthetic materials, the relative humidity shall at least be 30%.</td></tr>
<tr><td>Power frequency magnetic field (PFMF) (50Hz/60Hz)<br>GB/T 17626.8</td><td>3A/m</td><td>3A/m</td><td>The PFMF must be the level in a typical place of a typical commercial or hospital environment.</td></tr>
<tr><td>RF emission<br>GB/T 17626.3</td><td>3V/m<br>80MHz~2.5GHz</td><td>3V/m</td><td>Portable and movable RF communication equipment must be used with a specified distance from any part of the equipment and/or system (including cables). The isolating distance is calculated by appropriate formulae selected according to the frequency of the emitter. The calculation formulae for isolating distance are recommended as follows:<br>$d = 1.2\times\sqrt{P}$<br>$d = 1.2\times\sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2.3\times\sqrt{P}$ 800 MHz to 2.5GHz<br>Where, P is the rated maximum output power of emitter, in W; d is the recommended distance, in m. The field intensity of RF emitter obtained by the measurement a of electromagnetic field must be less than the conformity grade in each frequency range b. Interference may occur around the equipment marked with the following symbol:<br>  </td></tr>
</table>