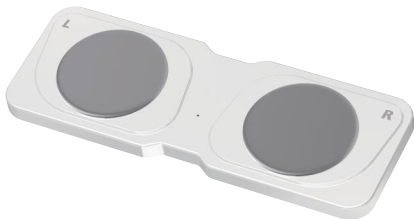


Portable ECG Monitor **PM10**

User Manual



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Preface

1. Description of the Manual

This manual serves as a comprehensive guide to the functions, safety precautions, and operational procedures of the portable ECG monitor. To ensure that you can use the portable ECG monitor correctly and safely, please peruse all sections of this manual carefully before using this product. The manufacturer bears no responsibility for any unauthorized modifications or parts.

2. Version Information

Manual Version: REV1.1

Revision Date: 2024-08-08

The version number of this manual may be upgraded due to changes in software or technical specifications. We will try our best to make modifications, but there may still be some inconsistencies in certain descriptions. Your understanding is appreciated.

3. Intended Audience

This manual is applicable to all users of this product.

4. Product Information

Trade/Device Name: Portable ECG Monitor

Regulation Name: Electrocardiograph

Regulatory Class: Class II

Product Code: DPS

Model: PM10

Lead: Lead I

Measurement parameters: Heart rate

Registrant: Quanzhou Kangju Medical Equipment Co., Ltd.,

ADD: Unit 203, 160 Qiyun Road, Renfeng Industrial Zone,
Donghu Subdistrict, Fengze District, Quanzhou City,
Fujian Province, China.

5 Manufacturer's Liability

The manufacturer shall be liable for the impact on the safety, reliability, and performance of the equipment only under the following circumstances:

- Assembly, addition, commissioning, modification or repair are carried out by personnel approved by the

manufacturer;

- The electrical facilities in the relevant rooms meet the relevant requirements;
- The equipment is used in accordance with the requirements of the user manual.

6 Warranty

If there are any changes to the product specifications, we will not be able to notify you separately. Your understanding is appreciated.

Nothing in this user manual involves proposals, guarantees, commitments or contract terms, nor should it be regarded as such items.

1. Safety

1.1 Legends, Warning Symbols and Their Meanings:

Table 1-1

Symbol	Meaning
	The symbol indicates attention (including warnings and dangers). The specific attention content is represented by words or pictures. The left picture indicates "Beware of electric shock".
	Warning symbol. There may be personal injury and property loss when used incorrectly.
	Emphasize important precautions, provide descriptions or explanations for better use of this product.
	CF type applied part, equipment directly applied to the heart.
	Non-ionizing radiation, electromagnetic waves with energy below 10 electron volts.
	Contains batteries inside. It is prohibited to discard or burn it at will.

- 1) Do not squeeze the product forcefully. If the casing is cracked, please stop using it.
- 2) Waste materials (including the scrapped product itself)

shall be disposed of in accordance with relevant laws and regulations.

3) During the use process, do not charge the smart display device connected to the product.

4) Keep the device away from fire sources and never heat it.

5) The intended users of the device are adults above 20 years old. It is not suitable for newborns and children.

Please keep the device out of the reach of children.

 Attention

1) Do not use, maintain or repair this portable electrocardiogram recorder before reading the manual in detail.

2) Keep the portable ECG monitor dry, avoid getting wet by water, and avoid strong collisions.

3) The use of the device should be kept away from strong magnetic fields, as it may affect the accuracy of the test. If the device is accidentally wet, please take out the battery in time, stop using it, and contact the supplier.

1.2 General Safety Information

 **The portable ECG monitor does not involve information on hazard levels.**

Warnings

- 1) Do not use this product in an environment with flammable anesthetic gases, oxygen or nitrogen oxides.
- 2) Any form of modification to this product is not allowed.
- 3) This product is not allowed to be used together with defibrillator equipment.
- 4) This product is not allowed to be used together with electrosurgical instruments.
- 5) This product is not allowed to be used together with CT or MRI equipment.
- 6) Do not subject this product to high temperature, high pressure, gas fumigation or liquid immersion. The product must be turned off before cleaning or disinfecting.
- 7) The physiological waveforms, physiological parameters and prompt information displayed by this product are only for reference and cannot be directly used as the basis for clinical treatment.

2. Overview of the Portable ECG Monitor PM10

2.1 Indications for Use (Describe)

The Portable ECG Monitor PM10 is intended to record and store Lead 1 ECG signals, and display heart rate for home health care use.

2.2 Contraindications and Precautions

Please use this product under the guidance of professionals.

The intended users are adults above 20 years old.

This device is not intended to substitute for a hospital diagnostic ECG device.

Users with implanted pacemaker are not recommended to use this device.

Patients with life-threatening heart diseases who need to be monitored in the hospital should go to the hospital for diagnosis and treatment immediately.

Users who are considered by doctors to need medical treatment should follow the doctor's advice and seek medical treatment.

2.3 Product Composition

The product consists of an ECG detector, a built-in button battery, and mobile software for the ECG detector.

3. Use and Operation

3.1 Appearance Inspection

Open the packaging box and take out the portable electrocardiogram recorder and its accessories. Please check whether the items are complete or damaged. If there are any missing items or damages, please contact the supplier immediately.

3.2 Battery Installation

- 1) Remove the battery cover and insert the battery into the battery compartment. Pay attention to aligning the contacts on the battery with the corresponding contacts on the battery slot.
- 2) Put the battery cover back on.
- 3) The battery specification used by the portable electrocardiogram recorder is: **CR2016 3V** lithium battery.

The **Panasonic CR2016 3V** lithium battery is recommended.



Note: When removing the battery cover, be careful not to hurt your fingernails. When installing the battery, be careful not to damage the contacts on the battery slot.

3.3 Download and Install Software

The portable electrocardiogram recorder is used in conjunction with Android or Apple smart display devices. The minimum configuration requirements for the display devices are as follows:

- 1) **Android** client running environment: **Android 5.1**.
- 2) **iOS** client running environment: **iOS 12**.
- 3) Hardware configuration requirements: **dual-core CPU**; **2GB RAM**; resolution above **1080 x 1920**; support for multi-touch.
- 4) Security software:
 - a) The verification tool built into the Android Open Source Project.

- 5) The portable electrocardiogram recorder uses Bluetooth to transmit data with smart devices.
- 6) One mobile phone number or email address represents one account, and one account is only allowed to view and edit the test records under that account.
- 7) Software update mechanism: If there is an update, the software will automatically prompt the user to update.

4.Maintenance

4.1 Daily Maintenance

- 1) After use, it should be stored in a clean and dry place.
- 2) When the low battery prompt appears, the battery should be replaced promptly before use.
- 3) Clean the electrode patches frequently to obtain better detection data. For the cleaning method, it is recommended to use a damp cloth and neutral detergent to wipe off the oil stains on the electrode surface. If disinfection is required, use 70% - 80% medical alcohol to wipe it twice and let it act for 3 minutes. During the wiping process, avoid letting the alcohol drip or flow into the product. Plastic parts should not be wiped with alcohol.



Note:

- a) Medical alcohol is a flammable product. Please keep it away from open flames when using it!
 - b) It cannot be sterilized or autoclaved.
 - c) Cleaning and disinfection with substances other than alcohol may damage the equipment, shorten its service life or lead to safety risks.
 - d) Do not use gasoline, thinner or similar organic solvents to clean any part of this product. Never use radiation, steam, ethylene oxide or other methods for disinfection, otherwise the product will be damaged.
 - e) Those who are allergic to alcohol should use ethanol disinfectant with caution.
 - f) Plastic products will become hard after long-term contact with alcohol-based disinfectants. Residual disinfectants should be removed in a timely manner after disinfection.
 - g) If users use peroxide or chlorine-containing disinfectants for disinfection, make sure that the disinfectant solution does not touch the metal parts.
- 4) If it will not be used for a long time, please take out the battery.

5) Please use the device in a clean, tidy environment free of corrosion and flammable substances. Do not use it when the temperature or humidity exceeds the requirements of the operating environment.

6) Do not immerse the device partially or completely in liquid, and avoid splashing liquid onto the recorder. If you find that the device is splashed wet or has condensed water, please immediately stop all operations, turn off the power and take out the battery.

4.2 Warranty and Repair

The warranty service is only applicable to non-artificial damage failures caused by product quality problems within the valid warranty period under normal use conditions.

1) The warranty period for the product is one year starting from the date of purchase.

2) When requesting warranty service, you need to present the warranty card and shopping voucher.

3) The warranty card and user manual shall not be altered, otherwise they will be regarded as invalid vouchers.

The following situations (but not limited to these situations) are not covered by the free warranty service:

- 1) The product is disassembled, repaired, processed or modified privately by non-designated warranty institutions or unauthorized maintenance personnel.
- 2) The product or its accessories are out of the warranty period.
- 3) Maintenance, repair or replacement of parts due to wear and tear caused by use.
- 4) Damage caused by failure to use, maintain or take care of the product as required by the product user manual.
- 5) Damage caused by usage errors such as dropping, squeezing or immersion in water.

5.Fault Analysis and Troubleshooting

When using the device, if you encounter the following problems, please try to solve them according to the provided methods. If the problems still cannot be solved, please contact our customer service staff. The common faults and corresponding solutions are shown in the following table:

E-mail: service_hasocare@hotmail.com

Fault	Possible Reasons	Solutions
The device cannot be turned on normally	1) The battery power is insufficient. 2) The battery is not installed correctly. 3) The device is damaged.	1) Please replace the battery. 2) Reinstall the battery. 3) Contact the customer service center.
Electrocardiogram software cannot be installed	1) The external software installation function is disabled on the mobile device. 2) There is insufficient storage space on the mobile device.	1) In the 'mobile device' security settings', open the 'unknown sources' setting option. 2) Uninstall some other application software

Fault	Possible Reasons	Solutions
The mobile device cannot connect to the recorder	1) The mobile device security software disables the Bluetooth connection function. 2) The Bluetooth on the mobile device is not turned on. 3) When some mobile devices are in flight mode, the wireless Bluetooth connection will be forcibly closed, resulting in the inability to open Bluetooth.	1) Refer to the mobile device user manual and open the Bluetooth usage permission in the corresponding security software. 2) Turn on the Bluetooth of the mobile device. 3) Turn off the flight mode (it should be done under the circumstances permitted by the surrounding environment regulations)
Abnormalities occur during the collection process	1) Insufficient cache on the mobile device. 2) The ClickECG conflicts with other software. 3) The power-saving mode of the mobile device reduces the operating ability or automatically closes the Bluetooth connection.	1) Turn off and restart the mobile device. 2) Refer to the mobile device user manual and stop some background running programs. 3) Turn off the power-saving mode of the mobile device.

Fault	Possible Reasons	Solutions
Electrocardiogram waveforms have noise, large interference or baseline drift	1) The skin is dry or greasy. 2) Poor contact between the electrodes and the human body. 3) Muscle tension and tremors.	1) Please clean the parts of the body in contact with the electrodes, and keep them clean, moist and free of grease. 2) Ensure reliable contact between the parts of the body and the electrodes. 3) Relax your body and appropriately relax the parts in contact with the electrodes.
R-wave inversion appears in the electrocardiogram waveform	1) The electrocardiogram electrodes are placed on the wrong sides (left and right). 2) Physiological condition, R-wave inversion.	1) This is caused by swapping the electrode patches on the left and right hands. Just swap them back. 2) Please consult a doctor.

Appendix A Product Performance

Safety Standard Number	
Safety Standard Number	GB 9706.1-2007
Electromagnetic Compatibility	YY 0505-2012
Product Classification	
Classification of Anti-electric Shock Type	Internal power supply equipment