GIMA

PROFESSIONAL MEDICAL PRODUCTS

PM10 PALM ECG MONITOR

Gima 33246

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PEOPLE'S REPUBLIC OF CHINA
Made in China

CE 0123

REF **PM10**

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Foreword

Thank you very much for purchasing the PM10 Portable ECG Monitor.
This user manual introduces detail product information about its character, requirement, structure, performance, specification, appropriate methods of transportation, usage, operation, repair, maintenance and storage, and safety measures of how to protect the operator and product. Please read details in the following chapters.
Please read the user manual carefully before using the product and strictly follow its regulations to operate. The user manual indicates the operations that users need to pay much attention to, that may lead to abnormality, or may danger to the device or human body during using. Our company will not response the security, reliability and performance for any abnormality or device and human body damage caused by not following this user manual to use, maintain and store, nor provide free service for any situations above.
We apologize for the content in the manual is subject to change according to product upgrades without notice.
The product is reusable as a medical instrument.
Federal law restricts the device to sale by or on the order of a physician.
Please read the user manual carefully prior to use.

Warning:

- The reliability depends on whether users are following the operation and maintenance in the user manual or not.
- Our company's website: http://www.contecmed.com is the unique route for downloading APP software and PC software, also the updates of firmware, if user download software and firmware updates from other unauthorized channels , it will cause the risks associated with cyber security, our company will not take responsibility for the consequence it may cause.
- All servicing and future upgrade to the device must be carried out by personnel trained and authorized by our company, replacing batteries with insufficiently trained personnel can lead to hazards(such as overtemperature, fire, or explosion) and using the original fittings for maintenance.The schematic diagram and component list can only be provided to the service station or maintenance personnel designated by our company.No modification of this equipment is allowed.
- User should be aware of life-circle of battery, discard the battery in accordance with local laws when the life-circle of battery expire.
- This product contains silicone, TPU, ABS materials, which have been biocompatible tested in accordance with the requirements of ISO 109931 "Biometric Evaluation of Medical Devices" Part 1"Evaluation and Testing", and it has passed the recommened biocompatibility test in accordance with the ISO 109931-1 standard. Users who are allergic to silicone, TPU, TPE, and ABS should not use this product.
- MR-unsafe!
  Do not expose the device to a magnetic resonance (MR) environment.
  - The device may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnet core.
  - Thermal injury and burns may occur due to the metal components of the device that can heat during MR scanning.
  - The device may generate artifacts in the MR image. The device may not function properly due to the strong magnetic and radiofrequency fields generated by the MR scanner.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
- Issue date: see label.

This user manual contains proprietary information, which is protected by copyright. All rights reserved. Reproduction, adaption or translation, for any part of the manual without prior written permission, is prohibited.
Our company takes the responsibilities as follows:

1. To provide qualified products according to enterprise standard for users.
2. To provide services of requirement, debugging and training according to the contract.
3. To provide one year warranty and product maintenance after warranty period according to the contract.
4. To respond user's requests in time.

Chapter 1 Notice

1.1 Generic Notice

1) Do not use the device in locations subject to high temperatures or humidity. Use in the temperature within 5～40 ˚C and humidity within 25 %～80 % RH.
2) Do not wash the device with water.
3) Pre-set up time is within 30mins, at condition of:
   - warm from the minimum storage temperature until it is ready to use at ambient temperature of 20 °C.
   - cool from the maximum storage temperature until it is ready to use at temperature of 20 °C.
4) Do not use or store the device in the following ambient conditions:
   - Near fires or open flames
   - Locations exposed to strong vibration
   - Locations exposed to strong electromagnetic fields
5) Do not disinfect the device in autoclave or gas sterilizer.
6) Such as skin allergies or skin damage, do not use this device.
7) The device service lift is 3 years. Do not throw away the device and accessories when they can't work. If the device needs to dispose, it should meet the local laws and regulations requirement.
8) Lay responsible organization must contact its local authorities to Determine the proper method of disposal of potentially bio hazardous parts and accessories.
9) Please don't use multiple wireless devices connected to the product at the same time.
10) This device is no contraindication.
11) The parameters displayed by ECG should be interpreted by professional physician.
12) Please don't use the device for infants weighing less than 10 kg.
13) The device contains some tiny components that may be put into the mouth by children, which will cause asphyxia or damage to organs (including esophagus and stomach), so please keep it out of reach of children.

1.2 Measurement Notice

1) If your skin is dry, wipe them with disinfectant alcohol or electric salve to strengthen the electric capability.
2) You are better to comfortably sit, draw yourself up, begin to measure when the heart rate level off.
3) When measuring, the finger and chest electrodes should touch your skin exactly, roundly and well.

1.3 Safety Notice

1) No sampling in the battery-charging. (sampling means acquiring ECG data of patient in the designated anatomical areas.) When the battery is charging, the device will not record ECG. The following symbol will present on the use interface to remind the charging state, device cannot be operated in battery charging state.
2) Lay the device in shady and cool environment when you are not going to use it for a long period of time, and 99electrify per three months.
3) Do not use the device in the environment placed inflammables objects, such as anesthetic.
4) Other equipment connected with it must meet national safety standards.
5) That conductive parts of ELECTRODES and associated connectors for TYPE BF APPLIED PARTS including the NEUTRAL ELECTRODE, should not contact other conductive parts including earth.

1.4 EMC Notice

1) Please note the effect from EMC when using the device, because it can be influenced by portable or movable high electromagnetic compatity RF devices.
2) This equipment needs to put into service in accordance with the information provided in the accompanying documents.
3) Wireless communications equipment can affect me equipment and should be kept at least a distance d away from the equipment. The distance d is calculated by the manufacturer from the 800 MHz to 2,5 GHz column of Table 5 or Table 6 of IEC 60601-1-2.

1.5 RF Instruction

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
A. This device may not cause harmful interference;
B. 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.
Some electronic devices are susceptible to electromagnetic interference sent by this equipment if inadequately shielded. Please use this equipment at least 20 cm or as far as you can from TV set, radio and other automated office equipment so as to avoid interference.
This device is a radio transmitter and receiver. It is designed and manufactured not to exceed limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission (FCC) of the U.S. Government. These limits are part of comprehensive guidelines and establish permitted levels of RF energy for the general population. The guidelines are based on standards that were developed by independent scientific organizations through periodic and thorough evaluation of scientific studies. The standards include a substantial safety margin designed to assure the safety of all persons, regardless of age or health.
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 equipment. This equipment generates, uses and can radiate radio frequency energy and, if not 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 use. 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:
A. Reorient or relocate the receiving antenna.
B. Increase the separation between the equipment and receiver.
C. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
D. Consult the dealer or an experienced radio/ TV technician for help.
⚠ A minimum separation distance of at least 0.2 m between this equipment and all persons shall be guaranteed to satisfy the RF exposure compliance.

1.6 Quality of Service and Security

The device assures timely, reliable, accurate, and secure data and wireless information transfer by the following design.
When you want to establish wireless connection with the portable ECG monitor, you must input correct communication instruction. Therefore, unauthorized access to the ECG data is prevent.

1.7 Manufacture Information

Name of manufacturer: Contec Medical Systems Co., Ltd
Address of manufacturer: No.112 Qinhuang West Street, Economic & Technical Development Zone, Qinhuangdao, Hebei Province, PEOPLE'S REPUBLIC OF CHINA
Website: http: //www.contecmed.com
Tel: +86-335-8015430
Fax: +86-335-8015588
Technical support: +86-335-8015431
E-mail: cms@contecmed.com.cn
Website: http://www.contecmed.com

1.8 Intended Operator

Lay Person, with the following requirements:

1. Be able to read and understand the content in the user manual;
2. Be able to distinguish the following anatomic sites: chest, left /right palm, upper extremity and low extremity.

Chapter 2 Introduction

2.1 Instruction for Use

The portable ECG monitor is designed for family and individual users. It is a good helper for family members to prevent from cardiovascular disease. The device can record and display user's ECG waveform and heart rate anytime at anyplace with easy operation.

2.1.1 Intended purpose

The device is used to monitor and record the user's ECG waveform and HR, it can be used in home.

2.1.2 Intended users

Home and personal user.

2.1.3 Patient population

Adults.

2.1.4 Clinical indication

It is suitable for the adult users who suffer from cardio-vascular diseases, or who are caring about their heart working conditions during their daily life.

2.1.5 Contraindication

Not found.

2.1.6 Product principle

The resting ECG signal is extracted from human body through ECG electrodes. Via amplifying and filtering, the signal is converted into a digital ECG signal, which is sent to memory and display to record and display ECG waveform.

2.2 Characteristic

1) Handsome shape, handy operation, convenient tote.
2) Record real-time heart rate anytime and anywhere.
3) Built-in large capability rechargeable lithium battery, continuously sample 200 ECG waveform after charged once.
4) QRS intervals and VEB measurement.

Chapter 3 Primary Technical Orders

3.1 Normal Work Environment

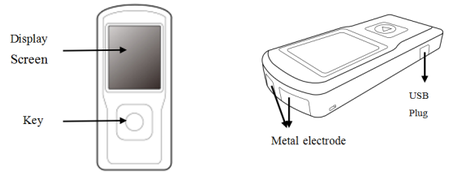
1) Operation environment
   - Temperature: +5 ℃～+40 ℃
   - Relative humidity: 25%～80%
   - Atmospheric pressure: 70 kPa～106 kPa
   - Power supply: built-in rechargeable lithium battery, voltage: 3.7 V
2) Transportation and storage environment
   - Temperature: -20 ℃～+55 ℃
   - Relative humidity: ≤95%
   - Atmospheric pressure: 50 kPa～106 kPa

3.2 Basic Parameters

1) Calibration voltage: 1 mV±5%
2) Standard sensitivity: 10 mm/mV±5%
3) Amplitude frequency characteristic: standard: 10 Hz; 1 Hz～20 Hz; (+0.4 dB, -3 dB)
4) Noise level: ≤30 μV
5) CMRR: ≥60 dB
6) Scanning speed: 25 mm/s±5%
7) Sampling rate: 250 dots/s
8) HR measurement range: 30 bpm～300 bpm, error: ±1 bpm or 1%
9) Battery Voltage: DC 3.7 V
10) Type of protection against electric shock: Internal power device
11) Degree of protection against electric shock: Type BF applied part
12) Degree of waterproof: IP22
13) Software release version: V1.7
14) FCC ID: 2AB0GPM10

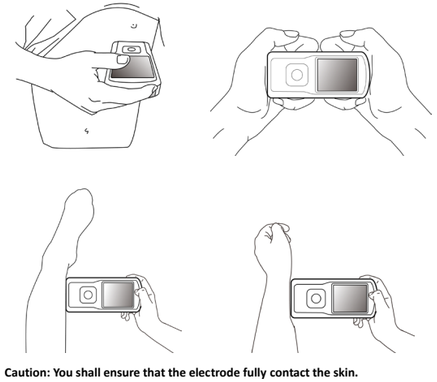
Chapter 4 Operation Directions

4.1 The Sketch Map and Components Name



4.2 How to Use

There are several measurement methods as shown in the following pictures



Caution: You shall ensure that the electrode fully contact the skin.

4.3 Menu Operations

1) Start-up

Long press the on/off button, you will hear a beep sound and see the screen lighting. The device will keep level off when not measuring.

2) Start measurement

After start-up, the device will enter into pre-sample interface. Please use the correct measurement method as guided, the ECG waveform and heart rate will displayed on the screen, as shown in Figure 4.1. The calculation method of heart rate: number of heart beats without interference in ECG fragment is set as N, then the calculation formula of heart rate is as follows:
HR=60000/(Sum of R-R intervals during numbers(N) of heart beats/N)

Figure 4.1 Pre-sample Interface

When the waveform becomes stable, the device will start formal sampling automatically, sample time countdown on the bottom right corner begins until finished one time sample and the color of sample time turns to red. See Figure 4.2. The device will enter into case review interface after completed sampling. Case review interface displays the sampling start time and heart rate. See Figure 4.3.

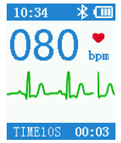


Figure 4.2 Formal Sample Interface

Figure 4.3 Case Review Interface

When the device enters into case review interface, it will display the latest sampled case. Click the button to review other cases information. The device can store 100 pieces of cases at most. If reaches to the limit, new stored case will cover the original case, the one that stored at the earliest, piece by piece.
The device will automatically turn to sampling interface to continue if the user holding the electrode at both ends again when the device is under the case review interface.

3) Battery Operation Notes

The device can continuously work for more than 2 hours when battery is completely charged.The cycle life of the battery up to 200 times.
Two method for charging:
(a) Connect the device with a computer by using Micro USB cable, charging completed after about 2 hours.
(b) Use a Micro USB to connect the device with a power adapter (output current＞500 mA, 5 V), charging completed after about 2 hours.
When the battery is charging, the device will not record ECG. The following symbol will present on the use interface to remind the charging state, device can not be operated in battery charging state.
Battery display

No.	Indicator	Description
a		full power
b		capacity: 3/4
c		capacity: 1/2
d		capacity: 1/4
e		Using battery, low power, it is recommended to recharge the battery.The device will automatically shut down.

4) Auto power off

The device will automatically shut down after no operations within 1 minutes.

4.4 PC Sync Software Operation and Communication

1) The intended use of PC software:

PC Management software is intended to be used as supportive software for portable ECG device, Functions include setting of device parameters (language setting and acquisition types setting, etc), downloading ECG data from portable ECG device, data management.

2) Security advice：

To ensure the safety of our patients and to protect their personal health information, we give the following security advice:

a. Auto-lock screen:
   Set the screen saver to display the login screen when it resumes, shorten the interval between automatic logoffs when the system is idle, and advise users to log off or shut down the computer when they leave.
b. Windows user and password:
   - Set complex passwords, change them regularly, and we recommend that you activate the Windows password policy;
   - Disable administrator and user accounts; each user should have a unique identity.
c. Install security software, anti-virus software, and activate firewalls and automatic updates. Run anti-virus software regularly.
d. Ensure that all device components (other than removable media) that save personal information are physically secure (i.e., can't be removed without tools).
e. The analysis software contains personal health information and medical record data that need to be protected and kept confidential. Do not copy patient health information and medical record data to removable storage media, and if you do, always ensure the physical security of the media.
f. Take anti-virus measures, such as virus scanning of USB devices, before using USB storage devices.
g. Turn off Windows' default services such as Remote Desktop, Telnet, and File Sharing.
h. Secure environment:

By design, this product should be used in an environment with the following expected privacy and security safeguards:

- The computer on which the dynamic cardiac analysis software is installed should be physically protected to eliminate access by non-established users;
- External media containing patient data, reports and logs should be protected. When no longer in use, data should be securely deleted and/or media should be securely unplugged;
- The monitor of the computer on which the Portable ECG Monitor software is installed should be placed in a position that restricts the user's ability to see the contents of the screen.

3) PC software :

Users can operate in the PC synchronous software according to necessary, which including sample mode and time setting, upload case, case review, measurement, etc.

4) Software Installation

Run the setup software, and you can see a window as follows, Click the button "OK". Click the button "Next", then if you click "Browse...", you can set the installation path, otherwise the default installation path is "C:\ Portable ECG Monitor". Click the button "Next" again, and the dialog box showed in Fig.4.5 shows up. Click "Browse...", you can reset the apellation in Startup Menu folder, the default folder will be "Portable ECG Monitor".

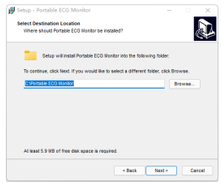


Figure 4.4

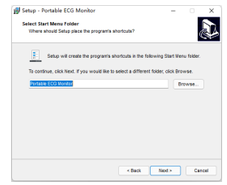


Figure 4.5

Click the button "install", and the software will be installed at the appointed position. When the installation finished, click "Finish" to end installation, shown as Figure 4.6.

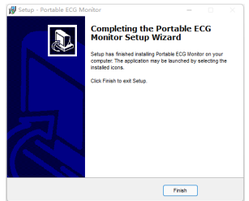


Figure 4.6

5) Use the Software

① PC-side synchronization software operation and communication

To protect the security of patients' personal health information, we provide the following security advice:

- Automatic screen lock: Set up a screen saver that displays the login interface when resumed, shorten the automatic logout interval when the system is idle, and recommend that users log out or shut down the computer when leaving;
- Users can use Windows user accounts and passwords, or the secure login provided by this software (see the User Management section). If using Windows user accounts and passwords, please note the following two points:
  - Set complex passwords and change them regularly. We recommend enabling Windows password policies;
  - Disable administrator and guest accounts. Each user should have a unique identity.
- Install security software and antivirus software, and enable the firewall and automatic updates. Run antivirus software regularly;
- Ensure the physical security of all devices storing personal information (excluding removable media), meaning they cannot be removed without tools;
- This software contains personal health information and medical records that require protection and confidentiality. Do not copy patient health information and medical records to removable storage media. If copied, ensure the physical security of the medium at all times;
- Take antivirus measures before using USB storage devices, such as scanning the USB device for viruses;
- Disable default services such as Windows Remote Desktop, Telnet, and file sharing;
- Secure environment:
  This product is designed to be used in an environment with the following expected privacy and security safeguards:
  - Computers on which this software is installed should be physically protected to prevent access by unauthorised users;
  - External media containing patient data, reports, and logs should be protected. When no longer in use, data should be securely deleted and/or the media should be safely removed;
  - The display of computers on which this software is installed should be positioned so that only authorised users can view the screen content.

② Welcome for using the software

When the software is run for the first time, a "Welcome" window pops up for prompt. If secure login is not enabled, click the Continue button in the welcome window to enter the main interface of the software. If secure login is enabled, clicking the Continue button will take you to the user management function interface (see the User Management section). Click the Exit button to exit the software.

③ User Management

This section applies to situations where secure login is enabled.

a. Administrators

When the software is run for the first time, a "Administrators" window is displayed by default, which is used for administrator account login and password modification.

◆ Administrator login:

Input administrator password and click the “Log in” button. Default administrator password: user2025.

Error Prompt: When the password input is incorrect, a prompt “Password error, please re-enter” will appear.

◆ Modifying administrator password:

Click the “Modify” button, then the “New password” and “Confirm password” edit boxes become available, where you can input the new password, and the “Log in” button changes to “Confirm” button.

Input the old password in the “Password” edit box, the new password in the “New password” and “Confirm password” edit boxes, and click “Confirm” to complete administrator password modification and log in the administrator account.

Note: the password is 8-16 characters long and must be composed of letters and numbers.

Error Prompt:

No.	Prompt	Error
1	Password cannot be empty!	No old password is input.
2	Password error, please re-enter.	The old password is input incorrectly.
3	The new password cannot be empty!	No new password is input.
4	Please enter a confirmation password!	No confirmation password is input.
5	The confirmation password you entered is incorrect. Please re-enter it!	The confirmation password is not consistent with the new password.

b. User Management

After the successful login of administrator account, a “User Management” window appears, which is used for adding and deleting users.

◆ **Add New User**:

Input account information in corresponding locations and click the “Save” button. When the “Success” is prompted, the new user is added successfully.

“Account” limit: 1-32 characters, composed of letters or numbers.

“Password” and “Confirm password” limit: 8-16 characters, composed of letters and numbers.

Error Prompts:

No.	Prompt	Error
1	Please enter an account and try again.	No account is input.
2	Password cannot be empty!	No password is input.
3	Please enter a confirmation password!	No confirmation password is input.
4	The confirmation password you entered is incorrect. Please re-enter it!	The confirmation password is not consistent with the new password.

◆ **Modify User Information**:

When the account input already exists, click the “Save” button to modify user information.

◆ **Delete User**:

Select the account to be deleted in the account pull-down list, and click “Delete” to delete it.

◆ **Return to "User Login"**:

After the user management is completed, click the “OK” button to return to the “User Login” interface.

c. User Login

After adding the account, proceed to the “User Login” function.

Select the login account, and input the password, then click “Log in”.

Click the “Administrators” button to recall the “Administrator Login” function.

Click the “Exit” button to close the software.

d. Software settings

After entering the software interface, click the button“ ”,in the upper right corner of the interface to enter the software settings interface. In the software settings interface you can set the user login and running prompt two options.

Enable running prompt: check this option to display the welcome window after turning on the software.

Enable user login: check this option to enable the user management and user login functions.

Note: when checking or unchecking two options above, a “Administrators Verification” dialog box will pop up, then input the correct password and click “OK” to complete the operation.

6) Data Communication

Start the software under the circumstance of no device connected, it will enter to the following interface shown as Figure 4.7. Turn on the device, insert to USB port, click "New search", then the software starts to search the device, shown as Figure 4.8.

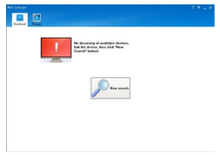


Figure 4.7

Figure 4.8

After searching, device information will be displayed in "List" form, including: cases ID, time length, check time, heart rate, shown as Figure 4.9. Click the button "?", you can get help from the operation.

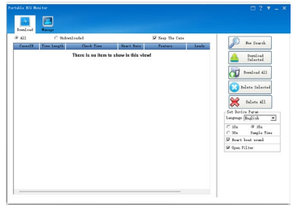


Figure 4.9

7) Operation

- Download case: double-click a case selected to download, or select multi-case, then click "Download selected" to download these cases, or click "Download all" to download all cases.
- Delete case: select a case or multi-case, then click "Delete selected" to delete the case selected, or click "Delete all" to delete all cases. To prevent mistake, before deleting, the system will prompt user, the system will delete the records after selecting "Yes".
- Set device parameters: Languages and sample time can be set by user. The interface for setting success is shown as Figure 4.10.

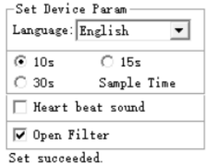


Figure 4.10

8) PC management software can be operated in WIN10/WIN11 operation system, hereafter list the requirements of hardware of PC to run WIN10/WIN 11 operation system.

	Windows10 system hardware requirements	**Windows11 system hardware requirements**
	Minimum configuration	
Central processor	1 GHz or faster	1GHz or faster
Memory	2 GB(64 bit), 1 GB(32 bit)	4GB
Graphics card	support Direct X9 tablet	support Direct X12
Residual space of hard disk	no less than 16 GB(32 bit), no less than 20 GB(64 bit)	64GB
Firmware	UEFI 2.3.1, support safety start	UEFI、support safety start

4.5 Mobile Application Operation and Communication

1) Mobile App has the following functions:
   - Connect with PM10 via Bluetooth
   - Download case data(date, time, measuring duration and average heart rate)
   - Display store and review the case data.
2) Data Communication
   - Start the software, turn on the device, then the software starts to search the device, click "PM10XXXX".
   - Device information will be displayed, including: time length, check time, heart rate.
3) Mobile APP can be installed in mobile phone installed Android or iOS system.

Chapter 5 Trouble Shooting and Solution

If the device has a problem account, please look up the following sheet for solutions first, if not included in the following issues and you can not solve either, please contact with the customer service.

Problem	**Cause**	**Solution**
Start-up failure after long press the on/off button	The batteries are worn out.	Please recharge the batteries.
Automatically shut down in using process	The batteries are worn out.	Please recharge the batteries.
The noise is too big or the heart rate is random in ECG sample process.	Your skin is dry.	Wipe them with disinfectant alcohol or electric salve
	There is unwanted movement in sample process	Please comfortably sit, draw yourself up to carry on sample
	The sample environment has strong electromagnetic noise.	Please close interference source or resample in no strong electromagnetic noise environment.
Wireless communication failure	Unable to send or receive data	1.Restart the device. 2.Check whether the bluetooth adapter, or mobile phone bluetooth normally
	The sample environment has strong electromagnetic noise.	Please close interference source or resample in no strong electromagnetic noise environment.

Chapter 6 Maintenance&Transportation&Storage

6.1 Cleaning

Before cleaning, ensure good room ventilation, remove the inflammable and combustible materials around it, and avoid open flame and electrical power source, etc.

When cleaning, turn off the device and disconnect it from the power, then wipe the enclosure, protective screen and electrode respectively with a medical gauze dipped in isopropanol (70%) (note: isopropanol produced by any formal company can be used.) for about 1 minute.

Dry them naturally or clean them with a clean and dry cloth.

Determine whether the cleaning is adequate by visual inspection. If stains are found, please repeat the above steps.

6.2 Maintenance

1) Non-maintenance personnel designated by our company, do not open the instrument case so as to avoid damage to internal components.
2) Any equipment maintenance and upgrades must be carried by the professionals who are trained and authorized of the company.
3) Prevent any liquid from seeping into the device as it will affect the safety and performance of the device.
4) The device should avoid the use of violent shaking or impact.
5) Do not place objects on the device. This could damage the touch screen.
6) If you do not use the device for a long time, please charge the battery to full every 3 months, otherwise, it will cause permanent damage to the battery.
7) The device should not be maintained during being used.

6.3 Transportation and Storage

1) The device transportation adopts general transportation means or follows the contract requirements. Avoid violent shock, vibration, rain and snow splash during the process of transportation.

2) Store the packaged device in an environment with temperature -20 ℃~+55 ℃, relative humidity no more than 95%, atmospheric pressure 500 hPa~1060 hPa, no corrosion gas and well-ventilated room.

Chapter 7 The Explanation of Symbols

Signal	**Description**	**Signal**	**Description**
	Refer to instruction manual/booklet		Type BF
bpm	Pulse rate (bpm)		Bluetooth
	Battery capacity		Power button/Function button
	USB	IP22	International Protection
	Temperature limitation		WEEE (2012/19/EU)
	Humidity limitation		Atmosperic pressure limitation
SN	Serial number	EU REP	Authorized representative in the European Community
	Manufacture Date		Manufacturer
	Fragile, handle with care		This side UP
	Keep in a cool, dry place		Recyclable
MR	Do not use this equipment in the MRI scan room.	MD	Medical Device
REF	Product code		Imported by
CE 0123	This item is compliant with Regulation(EU)2017/745 of the European Parliament and of the Council of 5 April 2017.		

Chapter 8 Packing List

No.	**Description**	**Quantity**
1	Host	1
2	USB cable	1
3	User Manual	1

Chapter 9 Electromagnetic Compatibility and Interference

Guidance and manufacturer’s declaration – electromagnetic emissions- for all EQUIPMENT and SYSTEMS

Guidance and manufacturer’s declaration – electromagnetic emission

The PM10 is intended for use in the electromagnetic environment specified below. The customer of the user of the PM10 should assure that it is used in such and environment.

Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The PM10 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The PM10 is suitable for use in all establishments, including domestic and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

Guidance and manufacturer’s declaration – electromagnetic immunity

The PM10 is intended for use in the electromagnetic environment specified below. The customer or the user of PM10 should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±15 kV air	±15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Mains power quality should be that of a typical commercial or hospital environment.

NOTE

Guidance and manufacturer’s declaration – electromagnetic immunity –for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer’s declaration – electromagnetic immunity

The PM10 is intended for use in the electromagnetic environment specified below. The customer or the user of PM10 should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the PM10, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 Hz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PM10 is used exceeds the applicable RF compliance level above, the PM10 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PM10.

[b] In the frequency range of 150 kHz to 80 MHz, the field strength is less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the PM10

The PM10 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PM10 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PM10 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**	
	80 MHz to 800 MHz $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.7 GHz** $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.23
0.1	0.37	0.74
1	1.17	2.33
10	3.69	7.38
100	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

***Disposal**: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.*

GIMA WARRANTY terms

The Gima 12-month standard B2B warranty applies.