



GIMA PM10 Palm ECG Monitor Owner's Manual

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GIMA PM10 Palm ECG Monitor



Product Information

Professional Medical Products – Tragbaren EKG-Monitors PM10

The Tragbaren EKG-Monitors PM10 is a professional medical device designed to monitor and record electrocardiogram (EKG) waveforms. It is portable and suitable for use in various medical settings.

Specifications

- Device Type: Portable EKG Monitor
- Measurement Method: Electrodes
- Power Source: Battery or AC adapter
- Display: LCD screen
- Data Storage: Internal memory or external storage device
- Connectivity: USB, Bluetooth
- Operating Temperature: 10-40°C
- Operating Humidity: 30-85%

Product Usage Instructions

Chapter 1: Note

In this chapter, you will find important information regarding the usage of the Tragbaren EKG-Monitors PM10.

Measurement Note

1. If your skin is dry, rub it with disinfectant alcohol or electrostatic charge 200 to detect EKG waveforms.
2. Ensure proper electrode placement and connection for accurate measurements.
3. Follow the recommended guidelines for electrode placement to obtain reliable results.
4. The device can measure QRS intervals and VEB (Ventricular Ectopic Beats).

Chapter 3: Normal Operating Conditions

This chapter provides information about the normal operating conditions for the Tragbaren EKG-Monitors PM10.

Operating Environment

1. Ensure that the device is operated within the recommended temperature range of 10-40°C.
2. Maintain the operating humidity between 30-85% for optimal performance.

FAQ

- **Q: How long does the battery last?**

A: The battery life of the Tragbaren EKG-Monitors PM10 depends on the usage and settings. On average, the battery can last up to 8 hours of continuous use.

- **Q: Can I transfer the recorded data to a computer?**

A: Yes, the Tragbaren EKG-Monitors PM10 supports data transfer via USB or Bluetooth. You can connect it to a computer or other compatible devices to transfer and analyze the recorded data.

- **Q: Is it suitable for home use?**

A: While the Tragbaren EKG-Monitors PM10 is primarily designed for professional medical use, it can also be used at home under the guidance of a healthcare professional.

Foreword

Thank you very much for purchasing the PM10 Portable ECG Monitor.

This user manual introduces detail product information about its character, requirements, structure, performance, specification, appropriate methods of transportation, installation, 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, which may lead to abnormality or may danger to the device or human body during use. Our company will not respond 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.

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 modification of this equipment is allowed.

- User should be aware of the life-cycle of battery, and discard the battery by local laws when the life-cycle of the battery expire.
- This product contains silicone, TPU, ABS materials, which have been biocompatible tested by the requirements of ISO 109931 “Biometric Evaluation of Medical Devices” Part 1” Evaluation and Testing”, and it has passed the recommended biocompatibility test by 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.

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1. To provide qualified products according to enterprise standard for users.
2. To provide services of installation, 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.

SAFETY NOTICE

Indication for Use

The device is a handheld, personal electrocardiograph unit, that can measure electrical activities of the heart easily and conveniently. It is immediately available at any time to manually record transient cardiac events, suitable for home health care use, which can detect, display and store ECG signal, and if possible, provide average heart rate message after ECG measurement. The users can use it themselves to check their heart condition. It is suitable for adult users, who suffers from cardiovascular diseases, or adult people who are caring about their heart working conditions during their daily life. This device is not intended for use as a conventional diagnostic tool, but use as a healthcare tool that can provide doctor the recorded data as references. The product is not a conventional diagnostic tool.

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 the condition of:
 - warm from the minimum storage temperature until it is ready to use at an ambient temperature of 20 °C
 - cool from the maximum storage temperature until it is ready to use at a 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 an autoclave or gas sterilizer.
 6. Such as skin allergies or skin damage, do not use this device.
 7. The device service life is 3 years. Do not throw away the device and accessories when they can't work. If the device needs to be disposed, it should meet the local laws and regulations requirement.
 8. The 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 has no contraindications.
 11. The parameters displayed by ECG should be interpreted by a 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 the esophagus and stomach), so please keep it out of reach of children.

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.

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, the 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 and electrify per three months.
3. Do not use the device in the environment placed inflammable 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;

EMC Notice

1. Please note the effect from EMC when using the device, because it can be influenced by portable or movable high electromagnetic compatibility RF devices.
2. This equipment needs to be installed and put into service by 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 1-2:2014.

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, under 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 by 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.

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.

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 prevented.

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.

Introduction

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.

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

Application

1. Occasion: family, medical clinic and hospital. The device can't be used as a general electrocardiogram for clinical examination.
2. Object: people under high pressure and workload for long time, heart disease patients, middle-aged and aged people, sub-health people
3. Purpose: The device is only used for heart rate record. Operation method is simple and less requirement for the operating personnel.

Primary Technical Orders

Normal Work Environment

1. Operation environment

1. **Temperature:** +5°C~+40°C
2. **Relative humidity:** 25%~80%
3. **Atmospheric pressure:** 70 kPa~106 kPa
4. **Power supply:** built-in rechargeable lithium battery, voltage: 3.7 V

2. Transportation and storage environment

1. **Temperature:** -40°C~+55°C
2. **Relative humidity:** ≤95%
3. **Atmospheric pressure:** 50 kPa~106 kPa

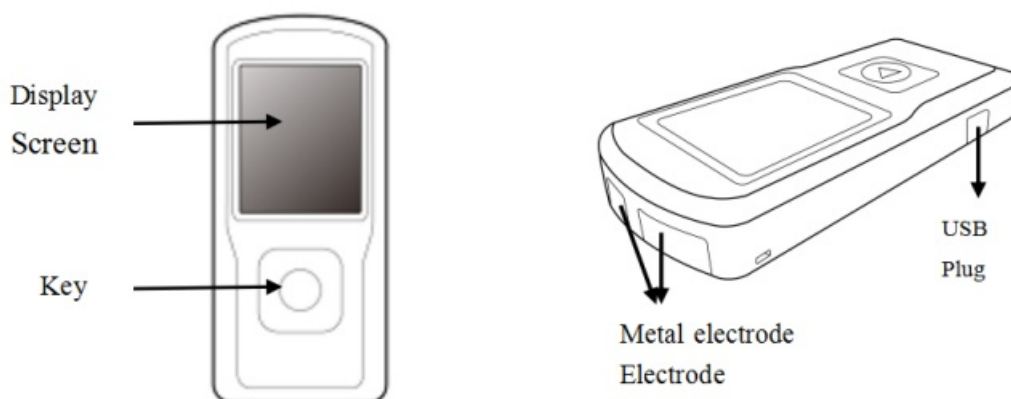
Basic Parameters

1. **Lead:** Standard 3 leads, I II III
2. **Calibration voltage:** 1 mV±5%
3. **Standard sensitivity:** 10 mm/mV±5%
4. **Amplitude frequency characteristic:** standard: 10 Hz; 1 Hz~20 Hz; (+0.4 dB, -3 dB)
5. **Noise level:** ≤30 μV
6. **Input impedance:** ≥50 MΩ
7. **CMRR:** ≥60 dB
8. **Scanning speed:** 25 mm/s±5%
9. **Sampling rate:** 250 dots/s

10. **HR measurement range:** 30 bpm~300 bpm, error: ± 1 bpm or 1%
11. **Battery Voltage:** DC 3.7 V
12. **Type of protection against electric shock:** Internal power device
13. **Degree of protection against electric shock:** Type BF applied part
14. **Degree of waterproof:** IP22
15. **Display:** 1.77" color TFT-LCD
16. **Size:** 100 mm (L)*45 mm (W)*15 mm (H)
17. **Weight:** about 60 g
18. **Bluetooth specifications:**
 - **Bluetooth protocol:** Bluetooth V4.0, Classic and Low Energy
 - **Operating frequency:** 2.4 GHz ISM band
 - **Modulation:** GFSK (Gaussian Frequency Shift Keying)
 - **Transmitting power:** <10 dBm, Class 1
 - **Sensitivity:** -92 dBm at BER <.001 with DH5
 - **Transfer rate:** 1.5 Mbps data throughput
 - **Safety features:** Authentication and encryption
 - **Support Services:** Bluetooth SPP/IAP/HID/OBEX
 - **Effective RF Radiated Power Output:** <10 dB
 - **Operating Range:** 2400 MHz – 2485 MHz
 - **Bandwidth of Receiving Section:** 85 M
19. **FCC ID:** 2AB0GPM10

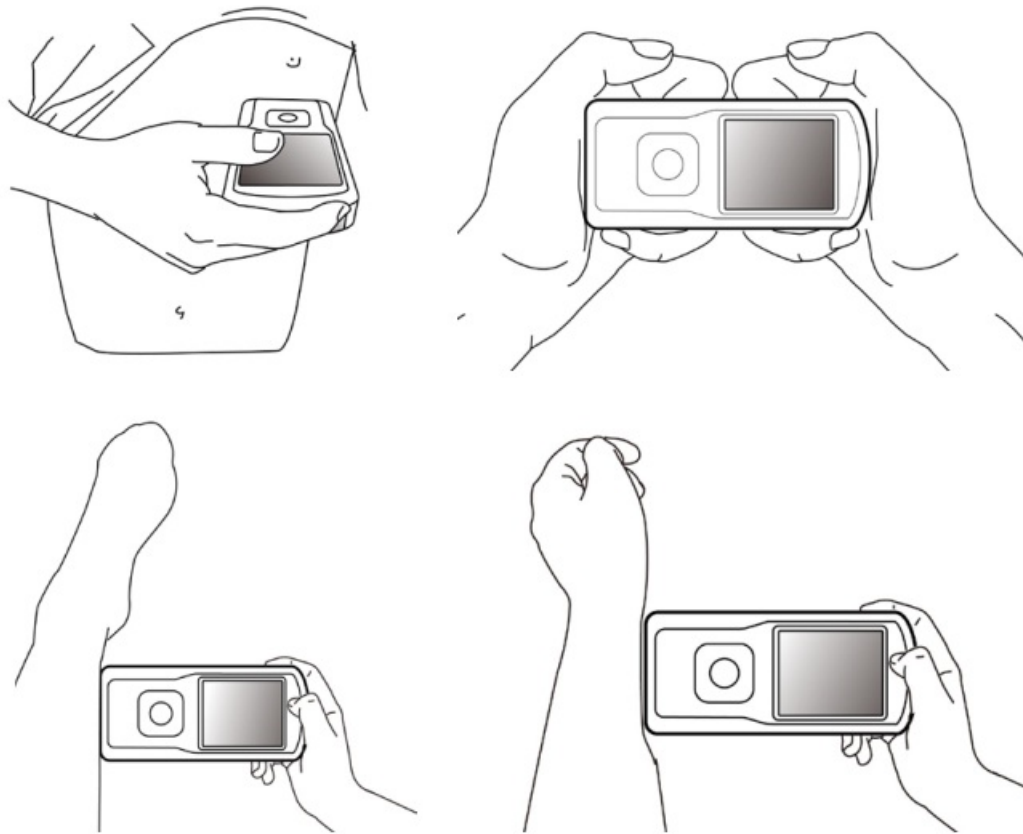
Operation Directions

The Sketch Map and Components Name



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.

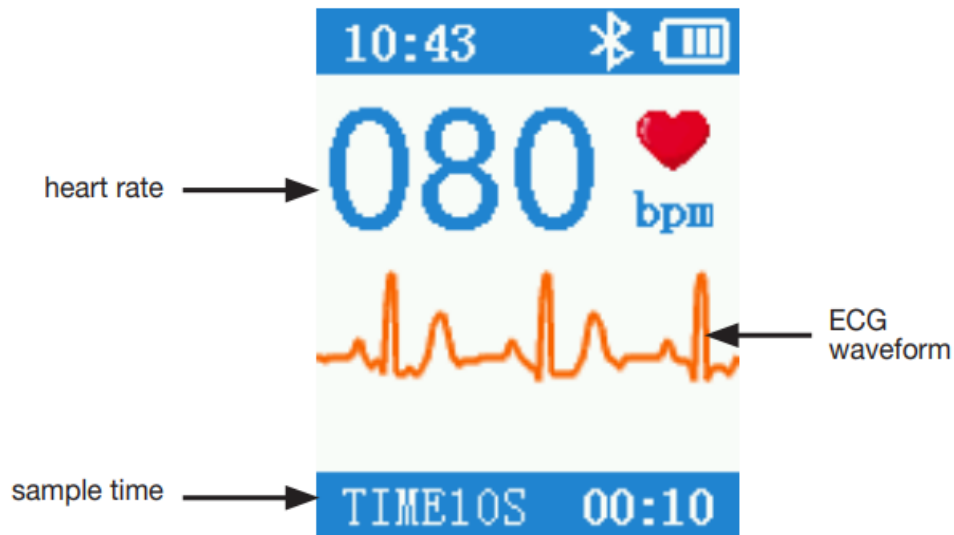
Menu Operations

1. Start-up

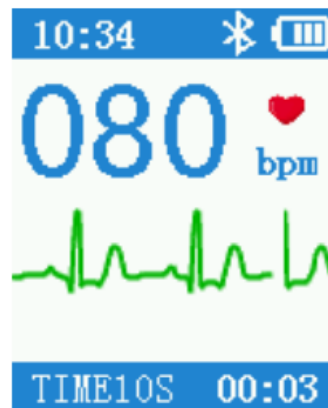
Long press the on/off key for 3 seconds, you will hear a beep sound and see the screen lighting. The device will keep level off when not measuring.

2. Start measurement

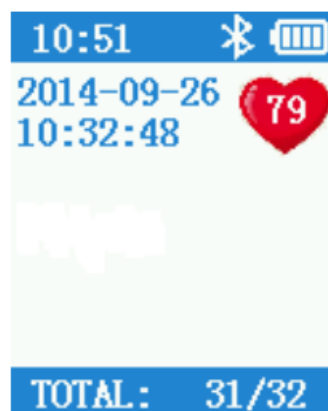
After start-up, the device will enter into the pre-sample interface. Please use the correct measurement method as guided, the ECG waveform and heart rate will displayed on the screen, as shown in Figure 4.1. The calculation method of heart rate: number of heartbeats without interference in ECG fragment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



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.



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.
- **(c)** 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.



Figure 4.4

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.

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. 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.

3. Software Installation

Run the setup software, and you can see a window as follows, Click the button "OK".



Figure 4.5

Click the button “Next”, and the dialog box in Fig.4.6 shows up, then if you click “Browse...”, you can set the installation path, otherwise the default installation path is “C:\ PM10”. Click the button “Next” again, and the dialog box showed in Fig.4.7 shows up.

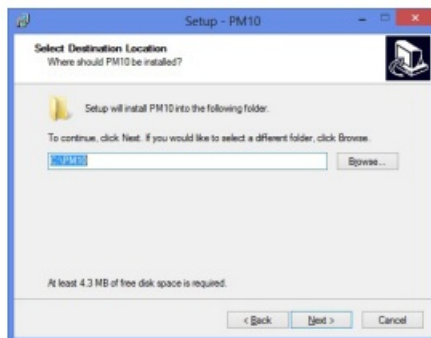


Figura 4.6

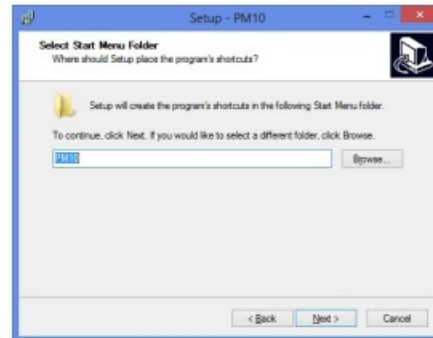


Figura 4.7

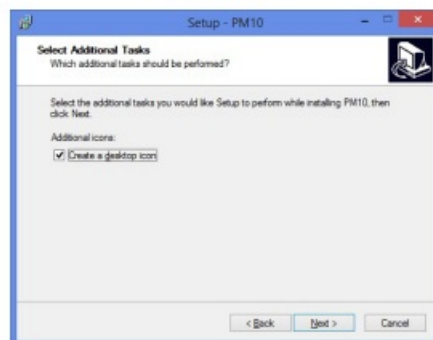


Figura 4.8

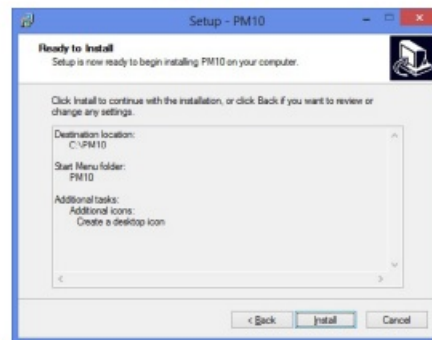


Figura 4.9

Click “Browse...”, you can reset the apellation in Startup Menu folder, the default folder will be “PM10”. Click “Finish” to end installation.

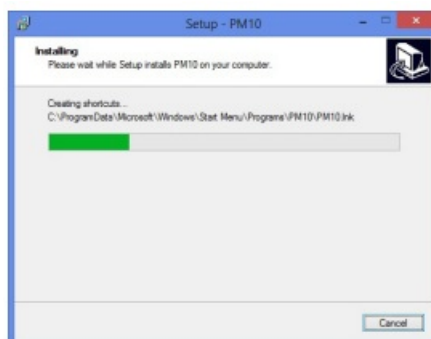


Figura 4.10



Figura 4.11

4. Data Communication

Start the software under the circumstance of no device connected, it will enter to the following interface shown as Figure 4.12. Turn on the device, insert to USB port, click “New search”, then the software starts to search the device, shown as Figure 4.13.



Figura 4.12



Figura 4.13

After searching, device information will be displayed in “List” form, including: cases ID, time length, check time, heart rate, shown as Figure 4.14. Click the button “?”, you can get help from the operation

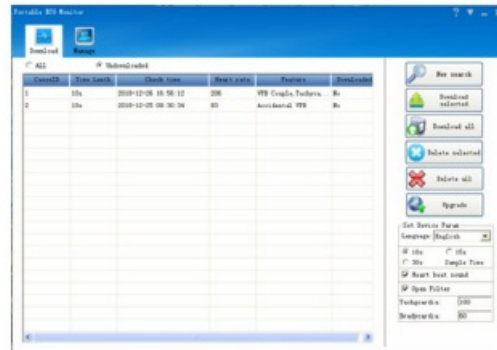


Figura 4.14

5. 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.

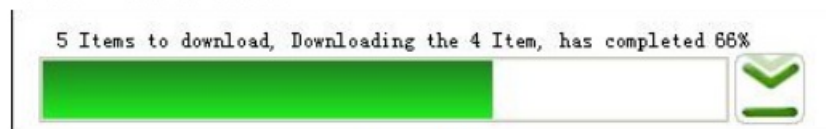


Figura 4.15

- **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”..



Figura 4.16

- **Firmware upgrade:** click “Upgrade”, select a firmware (naming rules: file name_version.bin, for example: xxx_USB_Vxxx.bin). If the firmware needs to upgrade from low to high version, then click “OK”. Otherwise “Force Upgrade” should be selected firstly, then click “OK”. During upgrading, please keep connection state between the computer and the device.

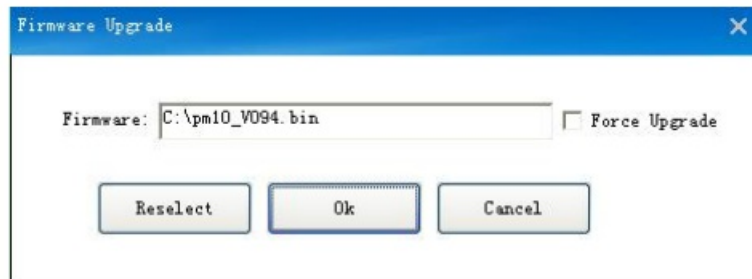


Figura 4.17

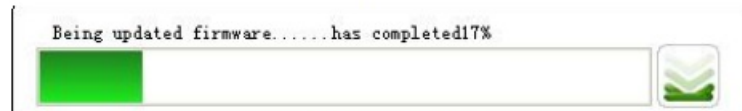


Figura 4.18

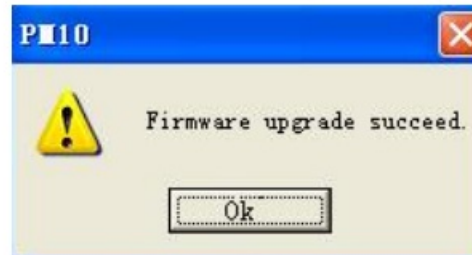


Figura 4.19

- **Set device parameters:** Languages and sample time can be set by user. The interface for setting success is shown as.



Figura 4.20

6. PC management software can be operated in WIN8/WIN 10 operation system, hereafter list the requirements of hardware of PC to run WIN10/WIN 8 operation system

1. Hardware Specifications for the WIN 10 Operation System

- **Processor:** 1.0 GHz or faster
- Screen: above 800×600 resolution
- Firmware: UEFI 2.3.1, support safety start
- Start memory: 2 GB(64 bit), 1 GB(32 bit)
- Hard disk space: no less than 16 GB(32 bit), no less than 20 GB(64 bit)
- Graphic card: support Direct X9 tablet

2. Hardware specification for WIN 8 operation system

1. Windows 8 PC (32 bit ,64 bit)

- 32 bit (x86)

Windows 8 32 bit system hardware requirements			
	Minimum configuration	Suggested configuration	Optimum configuration
Central processor	1 GHz (support PAE, NX and SSE2)	2 GHz (support PAE, NX and SSE2)	2 GHz multi-core processor
Memory	1 GB	2 GB	2 GB DDR3
Graphics card	Microsoft Direct X 9 graphics device with WDDM driver program	Direct X 10 graphics device with WDDM driver program, with 128 MB memory	Direct X 11 graphics device with WDDM driver program, with 256 MB memory
Residual space of hard disk	16 GB	30 GB above	64 GB SSD hard disk

- 64 bit (x64)

Windows 8 32 bit system hardware requirements			
	Minimum configuration	Suggested configuration	Optimum configuration
Central processor	2 GHz (support PAE, NX and SSE2)	2 GHz (support PAE, NX and SSE2)	2 GHz multi-core processor
Memory	2 GB	4 GB	4 GB DDR3
Graphics card	Microsoft Direct X 9 graphics device with WDDM driver program	Direct X 10 graphics device with WDDM driver program, with 128 MB memory	Direct X 11 graphics device with WDDM driver program, with 256 MB memory
Residual space of hard disk	20 GB	45 GB above	128 GB SSD hard disk

- Windows 8 tablet computer

Architecture	ARM, x86 and x86-64
Central processor	NVIDIA Tegra/Qualcomm/Texas Instructment TI ARM, AMD x86/x64 and Intel x86/x64
Memory	Suggest above 4G
Graphics card	Adopt WDDM 1.2 or DirectX10 graphics device with higher version driver program

Hard disk/NAND Flash	10 GB Memory capacity or above after installation of system
Push button	“n/off”, “rotation lock “, “Windows key”, “increase volume”, “decrease volume”
Touch screen	at least 5 points touch controlled capacitor screen, the resolution higher than 1366×768, the screen must be 10 inch or above
Screen resolution	Resolution 1280 × 720
USB 2.0	At least one outlets
Connection with internet	Wi-Fi and bluetooth 4.0
System starting firmware	UEFI
Others	Speaker, microphone ,gyroscope, gravity sensor

Mobile Application Operation and Communication

1. The intended use of mobile application: Mobile application is intended to download and display case data from PM 10, it will not control PM 10 and will not alter any setting of PM10
2. Software Installation Run the setup software, and you can see a window as follows, Click the button “install”.
3. Mobile application can be installed in mobile phone installed Android system, currently, Mobile applicable is not suitable for mobile phone installed Apple system.
4. 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.
5. **Data Communication**
 - Start the software, turn on the device, then the software starts to search the device, click “PM10”
 - Device information will be displayed, including: time length, check time, heart rate.

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.

Maintenance & Transportation & Storage

Cleaning and Disinfecting

Turn off the device before cleaning. Medical alcohol is available for the device disinfection, then air dry. Or just wipe it with a dry and clean cloth for cleaning. Do not allow any liquid to enter the device.









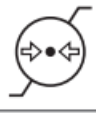














Maintenance

1. Non-maintenance personnel designated by our company, do not open the instrument case to avoid damage to internal components.
2. Any equipment maintenance and upgrades must be carried by 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 use.

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 $-40^{\circ}\text{C}\sim+55^{\circ}\text{C}$, relative humidity no more than 95%, atmospheric pressure 500 hPa~1060 hPa, no corrosion gas and a well-ventilated room.

The Explanation of Symbols

Signal	Description	Signal	Description
	Follow instructions for use		Type BF applied part
	Pulse rate (bpm)		Bluetooth
	Power button/function button	IP22	Covering protection rate
	USB		WEEE disposal
	Humidity limitation		Atmospheric pressure limitation
	Medical Device complies with Directive 93/42/EEC		Temperature limit
	Serial number		Manufacturer
	Date of manufacture		Caution: read instructions (warnings) carefully
	Keep away from sunlight		Keep in a cool, dry place
	Do not use this equipment in the MRI scan room		Product code
	Authorized representative in the European community		This side up
	Fragile, handle with care		Imported by

Packing List

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

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 or the user of the PM10 should assure that it is used in such an 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.

Guidelines 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.

Test di immunità	Livello test IEC 60601	Livello di conformità	Ambiente elettromagnetico – indicazioni
Scariche elettrostatiche (ESD) IEC 61000-4-2	±8 kV a contatto ±15 kV in aria	±8 kV a contatto ±15 kV in aria	Il pavimento deve essere di legno, cemento o piastrelle. Se il pavimento è ricoperto di materiale sintetico, l'umidità relativa deve essere almeno del 30%.
Frequenza campi magnetici (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	La qualità dell'alimentazione di rete dovrebbe essere quella di un tipico ambiente commerciale o ospedaliero.

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	<p>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.</p> <p>Recommended separation distance</p> $d = \left[\frac{3.5}{E^1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E^1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.7 \text{ GHz}$ <p>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, should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

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.

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 communication 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 $d = \underline{3.5} \sqrt{P E 1}$	800 MHz to 2,7 GHz $d = \underline{7} \sqrt{P E 1}$
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

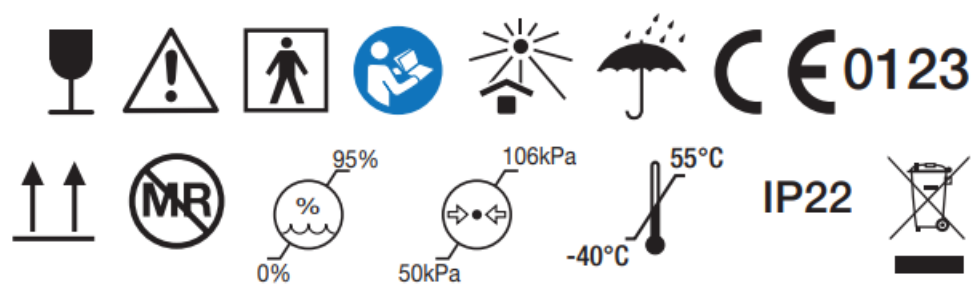
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter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



PM10 (Gima 33246)

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Documents / Resources

	<p>GIMA PM10 Palm ECG Monitor [pdf] Owner's Manual PM10 Palm ECG Monitor, PM10, Palm ECG Monitor, ECG Monitor, Monitor</p>
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References

-  [company.no in parked](#)
-  [CONTEC MEDICAL SYSTEMS CO.,LTD](#)
-  [Gima, articoli medicali, apparecchi per medicina, elettromedicali, endoscopi, misuratori medicali, arredo ambulatorio, elettrobisturi, articoli per il pronto soccorso, articoli per la sterilizzazione](#)
- [User Manual](#)