PM10

Portable ECG Monitor

User Manual

Contec Medical Systems Co., Ltd.

Contents

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, 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, 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.

Warning:

- The product is not a examination device applied in clinical medicine, and its results can not serve as the basis for diagnosis, but can be used as a reference for patient to take further medical treatment and reference for doctor to diagnose.
- The reliability depends on whether users are following the operation and maintenance in the user manual or not.
- All servicing and future upgrade to the device must be carried out by personnel trained and authorized by our company, and using the original fittings for maintenance.

Our company takes the responsibilities as follows:

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.

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 to 40˚C and humidity within 25% to 80%RH.

2) Do not wash the device with water.

3) 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

4) Do not disinfect the device in autoclave or gas sterilizer.

5) Such as skin allergies or skin damage, do not use this device.

6) 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.

7) lay responsible organization must contact its local authorities to determine the proper method of disposal of potentially bio hazardous parts and accessories.

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 waveform 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.

2) Lay the device in shady and cool environment when you are not going to use it for a long period of time, and electrify per three months.

3) Do not use the device in the environment placed inflammables objects, such as anesthetic.

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 compatibility RF devices.

2) This equipment needs to be installed and 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 60601-1-2:2007.

Chapter 2 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, for it can monitoring patients ECG anytime at anyplace with easy operation. The device can record, analysis and display user's ECG waveform, capturing the pathological ECG waveform when user happen to heart attack or other unpleasant symptoms. The ECG monitor can be conducted not limited in the hospital, which saves money from the physical check-up for users. After connected with a computer, users can print their ECG waveform, providing data reference for doctors.

2.1 Characteristic

1) Handsome shape, handy operation, convenient tote.

2) Monitor and record real-time ECG waveform and HR anytime and anywhere.

3) Built-in large capability rechargeable lithium battery, continuously sample 200 ECG waveform after charged once.

4) The applied part is the electrode

2.2 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 ECG monitoring and data storage. It is NOT a therapy equipment. Operation method is simple and less requirement for the operating personnel.

Chapter 3 Primary Technical Orders

3.1 Normal work environment

1) Operation environment

- Temperature: +5℃~+40℃
- Relative humidity: 25%～80%
- Atmospheric pressure:70kPa～106kPa
- Power supply: built-in rechargeable lithium battery, voltage: 3.7V

2) Transportation and storage environment

- Temperature: -40℃～+55℃
- Relative humidity: ≤95%
- Atmospheric pressure:50kPa～106kPa

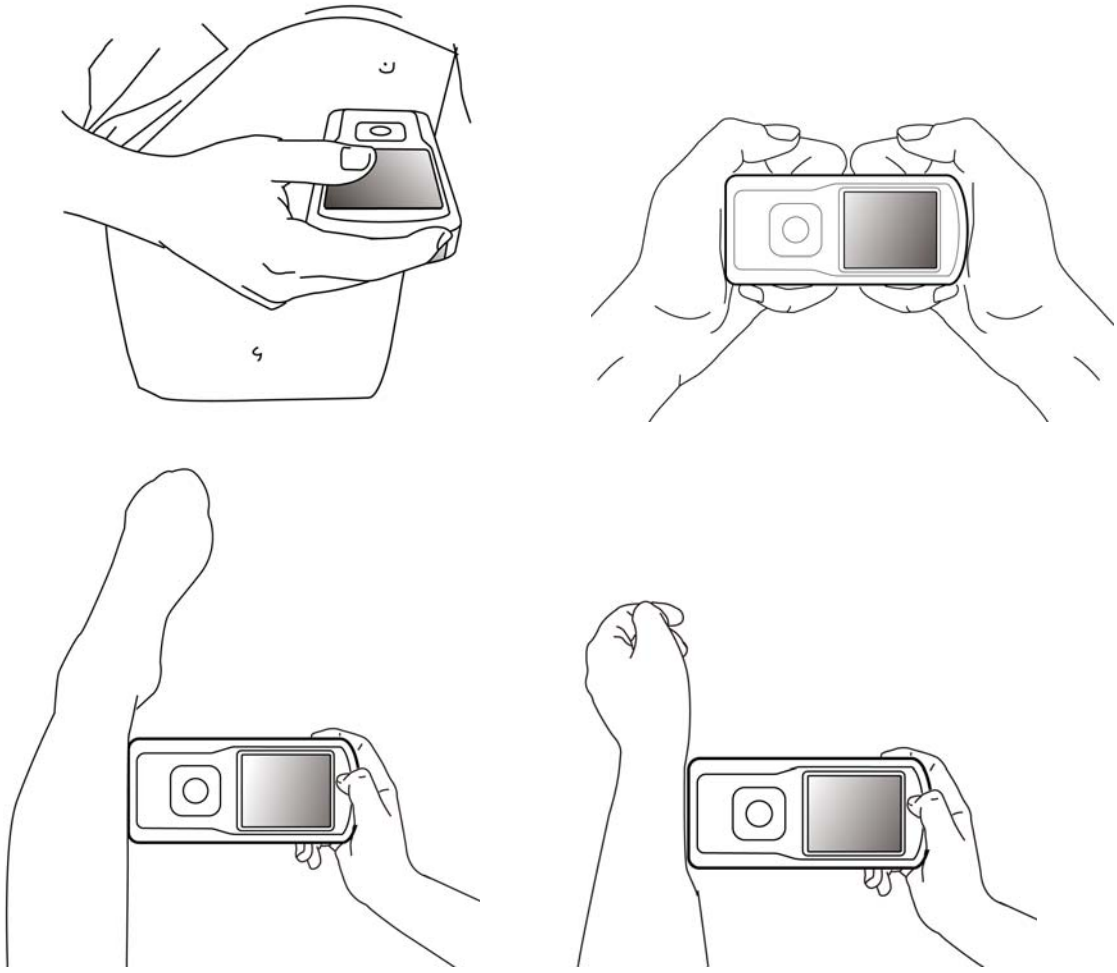
3.2 Basic parameters

1) Calibration voltage: 1mV±5%
2) Standard sensitivity: 10mm/mV±5%
3) Amplitude frequency characteristic: standard: 10Hz; 1Hz～20Hz; (+0.4dB，-3dB)
4) Noise level: ≤30μV
5) CMRR: ≥60dB
6) Scanning speed: 25mm/s±5%
7) Sampling rate: 250 dots/s
8) HR measurement range: 30bpm～300bpm, error: ±1bpm or 1%
9) Battery Voltage: DC 3.7V 530mAh
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

Chapter 4 Operation Directions

4.1 How to use

There are several measurement methods as shown in the following pictures.



4.2 Menu operations

1) Start-up

Long press the on/off key for 2 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 pre-sample interface. Please use the correct measurement method as guided, the ECG waveform will displayed on the screen, as shown in Figure 4.1.

Figure 4.1 Pre-sample Interface

When the waveform becomes stable, the device will start formal sampling automatically, the color of waveform turns to green, sample time countdown on the bottom right corner begins until finished one time sample. See Figure 4.2:

Figure 4.2 Formal Sample Interface

The device will enter into case review interface after completed sampling. Case review interface displays the sampling start time, heart rate and diagnosis. The diagnosis including normal and different kinds of heart rate abnormal, please refer to Figure 4.3 and Figure 4.4.

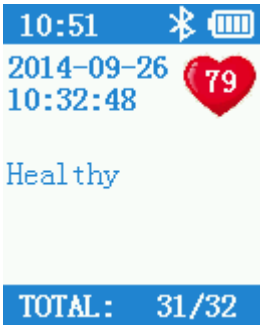


Figure 4.3 Case Review Interface (Normal)

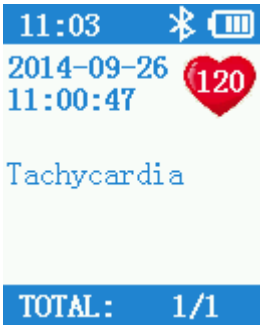


Figure 4.4 Case Review Interface

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 99 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

4) Li-battery

Battery Voltage: DC 3.7V 530mAh. The device can continuously work for more than 4 hours when battery is completely charged.The cycle life of the battery up to 300 times.

Two method for charging:

(a) Connect the device with a computer by using Micro USB cable, charging completed after about 2~4 hours.

(b) Use a Micro USB to connect the device with a power adapter (output current＞ 500mA, 5V), charging completed after about 2 hours.

(c) The connected power supply shall be in compliance with IEC 60950-1standard.

(d) 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.

5) Auto power off

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

4.3 Sync software operations

Users can operate in the PC synchronous software according to necessary, which including sample mode and time setting, upload case, case review, measurement, print, etc. Please refer to operation directions of PC synchronous software for details.

4.4 accessories list

No.	Description	Quantity
1	Host	1
2	USB cable	1

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 key	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 waveform 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.

Chapter 6 Maintenance&Transportation&Storage

6.1 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.

If for single patient use, the cleaning frequency is before use.

If for multiple patients use, the cleaning frequency should be between use. The disinfection frequency is 1time/week.

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.

6.3 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 -40℃～+55℃, relative humidity no more than 95%, atmospheric pressure 500hPa～1060hPa, no corrosion gas and well-ventilated room.

Chapter 7 The Explanation of Symbols

Signal	Description	Signal	Description
	Refer to instruction manual/booklet		Type BF
	Pulse rate (bpm)		Bluetooth
	power button/function button	IP22	International Protection
	USB (only for battery charging)		WEEE (2002/96/EC)
	Humidity limitation		Atmosperic pressure limitation
CE 0123	This item is compliant with Medical Device Directive 93/42/EEC of June 14, 1993, a directive of the European Economic Community.		Temperature limitation

Chapter 8 Packing List

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

*Note:

FCC WARNING

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, includinginterference that may cause undesired operation.
Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
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

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