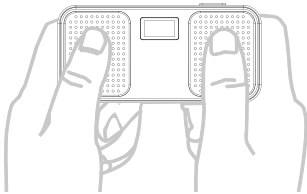


Card ECG Monitor

User Manual MD100C



INTRODUCTION

Thank you for purchasing *Card ECG Monitor*. Please read this manual carefully before use the device. Failure to follow the instructions may cause measurment abnormalities or equipment damage.

ChoiceMMed (the “Company”) assumes no responsibility for personal injury or device damage sustained by or through the use of this product. No part of this instructions may be copied, reproduced or translated into another language without prior written consent of the Company. The Company reserves the right to revise this guide at any time without prior notice.

Intended use

The *Card ECG Monitor* is a handheld non-invasive device intended for checking of electrocardiogram (ECG) and heart rate and for use by healthcare professionals, patients with known or suspected heart conditions and health conscious individuals in hospitals, hospital-type facilities and homecare. It is not intended for pediatric use.

Contraindication

Contraindicated in persons with pacemakers.

Product features

- Pocket size, easy to carry
- Support real-time and offline mode measurement

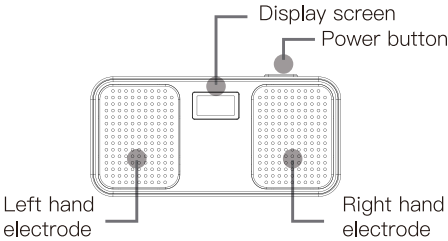
PRECAUTIONS FOR USE

1. Before use, carefully read the manual.
2. Operation of the the device may be affected by the use of an electrosurgical unit (ESU).
3. Do not use the device in an MRI or CT environment.
4. Do not use the device in situations where alarms are required. The device has no alarms. It is not for continuous monitoring.
5. Do not use the device in an explosive atmosphere.
6. Do not use the device with a cardiac pacemaker or defibrillator.
7. Do not use the device near flammable anesthetics, or near pressurized oxygen such as in a hyperbaric chamber, ultraviolet sterilizer or oxygen tent.
8. Do not use the device near strong electromagnetic forces.
9. Do not use the device in areas with extreme temperatures or humidity. Avoid using the device immediately after a significant change in temperature or humidity.
10. Do not expose the device to static electricity. Disperse static electricity from your body before handling the device.
11. Do not operate the device after it has been immersed in liquid.
12. The the device is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
13. Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components.
14. This equipment complies with IEC 60601-1-2 for electromagnetic compatibility for medical electrical equipment and/or systems. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device.
15. Portable and mobile RF communications equipment can affect medical electrical equipment. The portable and mobile RF communications equipment should be used no closer than 30cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
16. This equipment is not intended for use during patient transport outside the healthcare facility. Do not take measurements in a moving vehicle.
17. The patient is an intended operator. The patient can safely use all functions of the device.
18. It may be unsafe to:
 - use accessories, detachable parts and materials not described in the instructions for use
 - interconnect this equipment with other equipment not described in the instructions for use
 - disassemble, repair or modify the equipment
19. The material that contact with the patient’s skin has passed the ISO10993-5 Tests for invitro cytotoxicity and ISO10993-10 Tests for irritation and delayed-type hypersensitivity.
20. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

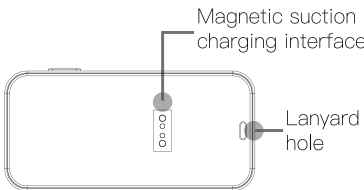
21. The use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
22. Do not take measurements when there are drops of water on your skin, such as from sweat or after bathing.
23. The manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist the user’s appropriately trained personnel to repair those parts of the equipment designated by the manufacturer to be repairable.

DEVICE DESCRIPTION

Front



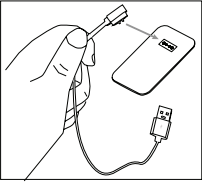
Back



Charging the device

Connect the device with the power adapter by the attached magnetic charging cable:

1. Connect the standard USB plug to a power adapter and then contact the magnetic connector with the magnetic suction charging interface of the device.
2. Plug the power adapter into a power outlet.

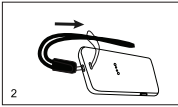
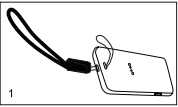


Notes:

- * The screen will display “Charging” in the charging process.
- * Low batteries may affect the HR measurement accuracy. Charge the device when the screen displays “”.
- * The device will turn off when battery power is too low for normal operation.
- * **Charge the battery every six months if the unit is not required for long periods of time.**
- * **The adapter should meet medical grade regulation.**

Using the Lanyard

1. Thread the thinner end of the lanyard through the hanging hole.
2. Thread thicker end of the lanyard through the threaded end and tighten.



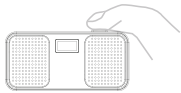
Warnings!

- * Keep the device away from young children. Small items such as the lanyard are choking hazards.
- * Please notice that the lanyard may cause strangulation due to excessive length.

TAKE A MEASUREMENT

Follow these instructions carefully for use. Failure to comply with any of these instructions will result in an inaccurate measurement.

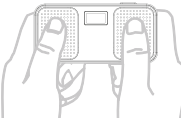
■ Power on



Press the **Power Button** to turn the unit on. The display will show current date and time first and then the ECG symbol .



■ ECG measurement



1. Place two fingers from each hand on the two electrodes (*you may hold the device as the figure*).

2. The device will start a 30s’ recording after a countdown of 3s. Hold still until it completes.

3. Read the data (*The measurement will be saved automatically*).



■ Real-time ECG measurement by APP & Data transmission

Connect the unit with iChoice APP via Bluetooth. Real-time measurements will be transferred to the APP automatically. You can view the result analysis from the APP as well as historical record and trend. You can upload offline measurements to the APP and view the result analysis.

■ Check records

Press the **Power Button** for 2 seconds to check measurements records.

Latest 20 ECG measurements can be saved.



■ Power off

Press the **Power Button** until the battery indocator appears, then the device will power off.



Notes:

- * Do not take measurements with overly wet skin.
- * Do not take a recording if the electrodes are dirty. Clean them first.
- * Too dry skin will cause weak ECG signal, please measure after moisturizing skin.
- * When measuring ECG, keep your fingers and arms in a relaxed position for full duration of the measurement. If the device senses poor contact-the device will indicate "Lead off" or the measurement is interrupted by a hand adjustment, you will need to repeat the recording.
- * Make sure your left and right fingers placed on right electrodes for ECG measuring.
- * Make sure the electrodes is in direct contact with your skin. DO NOT press firmly.
- * The device will automatically shut off in 8 seconds with no any operation.
- * After each use, carefully disinfect the contact electrodes only with a disinfectant swab or equivalent.

⚠ CAUTION!

- * The device is for monitoring purposes only. It is not intended to substitute a hospital diagnostic device and should not be used as a basis for starting or modifying medical treatment. Do NOT make diagnosis or treat decision by yourself according to the measurement and analysis results. Always consult your physician if you have any questions or if you believe you have abnormal measurements.
- * The values displayed by the device are the ones derived at the time of measurement. Medical conditions can change suddenly. If you notice any change in your condition, consult your physician, regardless of the measured results.
- * The device is not intended for simultaneously recording and transmitting a user’s Heart Rhythm.

MAINTANENCE AND STORAGE

- Do not drop or hit this device.
- Do not disassemble, repair, or modify the unit.
- Do not expose the device to strong shocks or vibrations.
- Keep out of reach of small children and people who cannot express their consent.
- This device does not require calibration during the expected life cycle.
- This device is designed to be compliant with the rules and regulations where it is sold and will be labeled as required.
- Any change or modification to this device, not expressly approved by the manufacturer, will void the user’s authority to operate the equipment.
- The life of the device is 5 years.
- The environment temperature for transport or storage of the packaged device is -25°C ~70°C/-13°F~158°F, and the humidity is ≤93%, no condensation.
- Avoid extreme changes in temperature and humidity. Do not use this device in locations subject to high or low temperatures or humidity. Use it at a temperature within 5°C~40°C/ 41°F~104°F and ≤80% RH.
- Do not store the device in ambient conditions: exposed to direct sunlight, with high temperatures and/or high humidity, that are wet or damp or where water may get on the device, that are dusty near fires or open flames or exposed to strong vibration, or strong electromagnetic fields.

Clean and disinfect the device

- The applied parts touching the patients’ body are required to be disinfected once after each use.
- Use a medical disinfectant swab only to clean the device electrodes. Do not use water, or substances such as benzene, gasoline, paint thinner, concentrated alcohol, or detergents. Do not clean other parts of the device with any liquid.
- Excessive disinfection may cause damage to the device and is therefore not recommended for this device unless otherwise indicated in your hospital’s servicing schedule.
- Do not pour or spray liquids onto the device and do not allow any liquid to enter any openings in the device. Allow the device to dry thoroughly before reuse.
- Do not sterilize this device in an autoclave, ultraviolet sterilizer or gas sterilizer (EOG, formaldehyde, high density ozone, etc.). The device is not intended for sterilization.

All the maintenance above can be performed by the patient.

TROUBLE SHOOTING

Problem	Cause	Solution
The device can not be powered on	1. The battery power is exhusted. 2. The device might be broken.	1. Charge the device. 2. Please contact the local service center.
The device fails to measure heart rate	1. The electrodes are not making good contact with your fingers. 2. The user does not keep still during measurement. 3. Electromagnetic interference. 4. The signal is too weak.	1. Place the electrode correctly. 2. Keep motionless and avoid moving when measuring. 3. keep away from electromagnetic interference. 4. Try to take another measurement.
Unstable ECG waveform	1. The skin is dry. 2. The electrodes are not making good contact with your body. 3. Too nervous.	1. If your skin is very dry, use a moisturizer. 2. Place the electrode correctly. 3. Please relax and keep calm.
The battery can not charge.	1. No power supply. 2. The battery is damaged.	1. Charge the device correctly and check the power source. 2. Contact local service center.

SYMBOL DEFINITION

Symbol	Meaning	Symbol	Meaning
HR	Heart rate (bpm: beat per minute)		Low battery voltage
	Type CF applied part		Attention
IP22	Protected against dripping water		Follow instructions for use
	Serial Number		Date of manufacture
	Manufacturer's information		Fragile or handle with care
	Keep dry or keep away from rain		Storage temperature and relative humidity
	Conformity to WEEE Directive		

TECHNICAL SPECIFICATIONS

Notes: Specifications may be changed without prior notice.

Weight: ≈80g

Dimension: 80mm(L) X 38mm(W) X 8mm(H)

Heart Rate

Sampling Rate: 500Hz
ECG Bandwidth: 0.67Hz~40Hz
Measurement Range: 30bpm~240bpm
Resolution: 1bpm
Accuracy: 30bpm~100bpm; ±2bpm, 101bpm~240bpm; ±4bpm

Power requirement

Power supply: one built-in rechargeable lithium battery (3.7V/150mAh)
The battery will last up to 2 months if it is used for 5 measurements in one day.

Environment requirements

Operating environmental conditions: 5°C~40°C (41°F~104°F), ≤80% (no condensation)
Storage/transport environmental conditions: -25°C~70°C (-13°F~158°F, ≤93% (no condensation)
Atmosphere pressure: 70kPa~106kPa

Notes: When the ambient temperature is 20°C, it is required 6 hours for the equipment to warm from the minimum storage temperature or 4 hours to cool from the maximum storage temperature between uses until it is ready for its intended use.

Classification

Type of protection: Internally powered equipment
Degree of protection: CF type (the application part are electrodes)
According to the degree of protection against ingress of water: IP22
According to the mode of operation: Continuous operation

Packing list

- One User Manual
- One charging cable

ELECTROMAGNETIC COMPATIBILITY

The device conforms to IEC60601-1-2:2014 Electromagnetic Compatibility (EMC) standard.
Table 1: Electromagnetic Emissions Limits and Compliance

Emissions Test	Compliance
RF Emissions CISPR 11	Group 1, Class B
Note: Harmonic Emissions (IEC 61000-3-2), Voltage Flicker Emissions (IEC 61000-3-3) are not applicable.	

Table 2: Electromagnetic Immunity

Immunity Test	Compliance	
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	
Rated power Frequency Magnetic Fields IEC 61000-4-8	30 A/m 50Hz and 60 Hz	
Radiated RF IEC 61000-4-3	80 MHz – 2.7 GHz	10 V/m 80% AM 1kHz
	380 – 390 MHz	27 V/m Pulse mod. 18Hz
	430 – 470 MHz	28 V/m FM±5Hz deviation 1kHz sine
	704 – 787 MHz	9 V/m Pulse mod. 217Hz
	800 – 960 MHz	28 V/m Pulse mod. 18Hz
	1.7 – 1.99 GHz	28 V/m Pulse mod. 217Hz
	2.4 – 2.57 GHz	28 V/m Pulse mod. 217Hz
	5.1 – 5.8 GHz	9 V/m Pulse mod. 217Hz
Note: Electrical Fast Transients (IEC 61000-4-4), Surge (IEC 61000-4-5), Voltage dips (IEC 61000-4-11), Conducted Immunity (IEC 61000-4-6) are not applicable.		

FCC Declaration

FCC ID: WWIMD100C

Please take attention that changes or modification not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) This device must accept any interference received, including interference that may cause undesired operation.

Model: MD100C
Version: Ver1.0
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