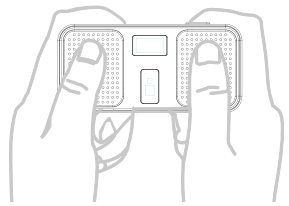
ChoiceMMed

Multi-parameters
Health Examination System

User Manual



INTRODUCTION

Thank you for purchasing *Multi-parameters Health Examination System*. 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.

SpO_2 measurement principle

SpO_2 measurement works by applying a sensor to a fingertip. The sensor contains a dual light source and photo detector. The one wavelength of light source is 660nm, which is red light; the other is 905nm, which is infrared-red light. Skin, bone, tissue and venous vessels normally absorb a constant amount of light over time. The photo detector in finger sensor collects and converts the light into electronic signal which is proportional to the light intensity. The arteriolar bed normally pulsates and absorbs variable amounts of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO_2.

Diagram of Operation Principle

1. Red and Infrared-ray Detector 2. Red and Infrared-ray Light Source

Intended use

The *Multi-parameters Health Examination System* 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.
The device can also be used as a pulse oximeter to spot check blood oxygen saturation (in %SpO_2) and pulse rate for wellness only and the values are not intended to diagnosis any medical condition or to be used in medical applications.

Contraindication

Contraindicated in persons with pacemakers.

Product features

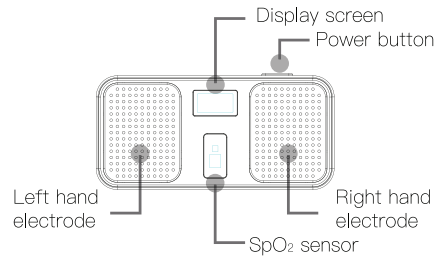
- Pocket size, easy to carry
- Both ECG and blood oxygen could be measured
- Support real-time and offline mode measurement

PRECAUTIONS FOR USE

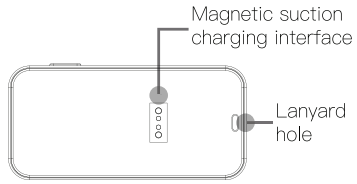
1. Before use, carefully read the manual.
2. Operation of the the device may be affected by the use of an electrosurgical unit (ESU).
3. The the device must be able to measure the pulse properly to obtain an accurate SpO_2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO_2 measurement.
4. Do not use the device in an MRI or CT environment.
5. Do not use the device in situations where alarms are required. The device has no alarms. It is not for continuous monitoring.
6. Do not use the device in an explosive atmosphere.
7. Do not use the device with a cardiac pacemaker or defibrillator.
8. Do not use the device near flammable anesthetics, or near pressurized oxygen such as in a hyperbaric chamber, ultraviolet sterilizer or oxygen tent.
9. Do not use the device near strong electromagnetic forces.
10. 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.
11. Do not expose the device to static electricity. Disperse static electricity from your body before handling the device.
12. Do not operate the device after it has been immersed in liquid.
13. 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.
14. In order to ensure correct sensor alignment and skin integrity, the maximum application time at a single site for our device should be less than half an hour.
15. Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components.
16. This equipment complies with IEC 60601-1-2:2014 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.
17. 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.
18. This equipment is not intended for use during patient transport outside the healthcare facility. Do not take measurements in a moving vehicle.
19. The patient is an intended operator. The patient can safely use all functions of the device.
20. 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
21. 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.
22. 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.
23. 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.
24. When the signal is not stable, the reading may be inaccurate. Please do not refer to it.
25. The equipment is calibrated to display functional oxygen saturation.
26. Do not take measurements when there are drops of water on your skin, such as from sweat or after bathing.

DEVICE DESCRIPTION

Front



Back

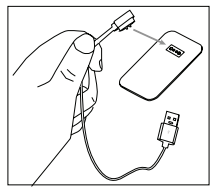


Charging the device

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

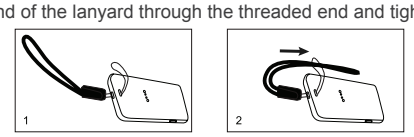
* The screen will display "Charging" in the charging process.

* Low batteries may affect the HR measurement accuracy. Charge the device when the screen displays "".

* The device will turn off when batteries are too low for normal operation.

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.



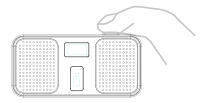
Warnings!

** 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

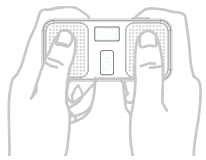
Follow these instructions carefully for use. Failure to comply with any of these instructions will result in an inaccurate measurement.

■ *Power on*

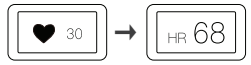


Press the **Power Button** to turn the unit on.
The display will show current date and time first and then the ECG symbol.

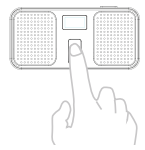
■ *ECG measurement*



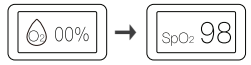
1. Place two fingers from each hand on the two electrodes (*you may hold the device as the figure*).
2. The device will start a 30s' recording after a countdown of 3s. Hold still until it completes.
3. Read the data *(The measurement will be saved automatically)*.



■ *SpO_2 measurement*



1. Press the **Power Button** to switch to SpO_2 measurement (*the display will show the* SpO_2 *symbol*).
2. Place a finger (*the index/middle finger is recommended*) on the SpO_2 sensor. Read the data. *(The measurement will be saved automatically)*.

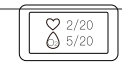


■ *Real-time ECG/SpO_2 measurement by APP & Data transmission*

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.

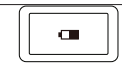
■ *Check records*

Press the **Power Button** for 2s to check measurements records.
Latest 20 ECG and 20 SpO_2 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 or SpO_2 sensor 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.

Inaccurate SpO_2 measurements may be caused by

1. Significant levels of dysfunctional hemoglobin (such as carbonyl - hemoglobin or methemoglobin).
2. Intravascular dyes such as indocyanine green or methylene blue.
3. High ambient light. Shield the sensor area if necessary.
4. Excessive patient movement.
5. High-frequency electrosurgical interference and defibrillators.
6. Venous pulsations.
7. Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
8. The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
9. The patient is in cardiac arrest or is in shock.
10. Fingernail polish or false fingernails.
11. Weak pulse quality (low perfusion).
12. Low hemoglobin.

⚠ 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 (-40°C ~55°C/-40°F~131°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.

TROUBLE SHOOTING

Problem	Cause	Solution
The device can not be powered on	1. The battery power is exhausted. 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.
SpO_2 can not be shown normally	1. The finger is not in good contact with the SpO_2 sensor. 2. User's SpO_2 value has variations or inaccurate.	1. Try some more times. 2. There is excessive illumination. 3. Lightly press the sensor
SpO_2 is shown unstably	1. The finger might touch the sensor too hard. 2. Excessive user movement	1. Try some more times. 2. Be calm. 3. Lightly press the sensor

SYMBOL DEFINITION

Symbol	Meaning	Symbol	Meaning
SpO_2	Oxygen saturation	HR	Heart rate (bpm: beat per minute)
	Type CF applied part		Low battery voltage
	Attention		Follow instructions for use
SN	Serial Number		Date of manufacture
	Manufacturer's information		Fragile or handle with care
	Keep dry or keep away from rain	+70℃ max, -25℃ min, RH≤93% non-condensing	Storage temperature and relative humidity
IP22	Protected against dripping water		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 measurement

Sampling Rate: 500Hz
ECG Bandwidth: 0.67Hz~40Hz
Measurement Range: 30bpm~250bpm
Resolution: 1bpm
Accuracy: 30bpm~99bpm; ±2bpm, 100bpm~250bpm; ±2%

SpO_2 measurement

Measurement Range: 70%~100%
Resolution: 1%
Accuracy: 70%~100%, ±2%; ≤69%, no definition

Probe LED specifications

	Wavelength	Radiant Power
RED	660±2nm	3.2mW
IR	905±10nm	2.4mW

NOTE: The information about wavelength range can be especially useful to clinicians.

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, ≤80% (no condensation)
Storage/transport environmental conditions: -40~55°C, ≤93% (no condensation)
Atmosphere pressure: 70kPa~106kPa

Equipment data update period

The average data update period is 8s.

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
Safety: IEC 60601-1

Packing list

- One User Manual
- One charging cable

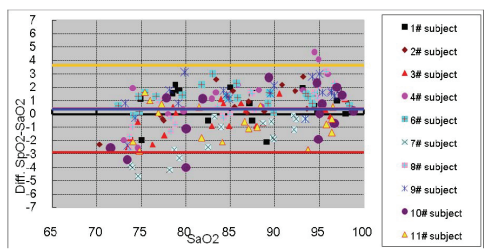
CLINICAL STUDY SUMMARY

The following details are provided to disclose actual performance observed in the clinical validation study of healthy adult volunteers. The ARMS value analysis statement and Bland-Altman plot of data is shown as following:

ARMS Value Analysis Statement

Item	90--100	80--<90	70--<80
#pts	78	66	63
Bias	1.02	0.40	-0.48
ARMS	1.66	1.46	1.93

Bland-Altman Plot Graphic



ELECTROMAGNETIC COMPATIBILITY

The device conforms to IEC60601-1-2:2014 Electromagnetic Compatibility (EMC) standard.

Essential performance is defined as SpO_2 accuracy and heart rate accuracy or an indication of abnormal operation. Accuracies may be affected as a result of exposure to electromagnetic disturbances that are outside of the environments listed in the intended use. If issues are experienced, move the device away from the source of electromagnetic disturbances.

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: WWIMD100CPRO

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 Pro
Version: Ver1.0
Issue date: April 07, 2021

Beijing Choice Electronic Technology Co., Ltd.

2nd Floor, 3rd Floor and Room 410-412 4th Floor,
No. 2 Building, No. 9 Shuangyuan Road, Shijingshan District,
100041 Beijing, PEOPLE'S REPUBLIC OF CHINA