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Ver1.0

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Content

1. INTRODUCTION

1.1 Brief Introduction

Thank you for purchasing the Pulse Oximeter. The main functions of the device are to measure Haemoglobin Saturation (SpO_2) and Pulse Rate (PR) value of single patient and transmit data by GPRS or USB. Please read the instruction manual carefully before using the device.

Note: The illustrations used in this manual may differ slightly from the actual product.

1.2 Safety Information

Conception of Warning, Caution and Note

The Warning, Caution and Note in this document are special information in favor of users' operation.

★ **Warning**

Indicate that maybe some potential hurt or damage to patients or device.

★ **Caution**

Make user take a serious attitude toward the incorrect operation, which are likely to incur some life-threatening incidents.

★ **Note**

Serve as a pivotal notice to avoid preventable incidents during application of this equipment.

⚠ **Warnings!**

Before use, please read the manual directions, all precautions and specifications carefully. Our company will assume no warranty for using the device improperly.

The user must check that the device functions safely and ensure that it is in proper working

conditions.

Do not use the pulse oximeter in the presence of flammable anesthetics, vapors or liquids.

Do not use the pulse oximeter in an MRI or CT environment which is the source of some electric noise to influence the accuracy of the equipment and following measurement.

This equipment is intended only as an adjunct in patient assessment, and the measurement results only serve as a reference for any relevant treatment.

Prolonged use of the probe/sensor or the patient's condition may require changing the sensor site periodically. Change the sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours. Prolonged use may cause blisters, skin deterioration, and discomfort.

Connect the sensor correctly; please follow the directions for use of any accessories.

The sensor is a sensitive device so please strictly follow the sensor application instructions.

Use only the SpO_2 sensors supplied by our company. Use of sensors not intended for the device may cause wrong alarm.

The malfunction of sensor may cause inaccurate measurement result.

The disposable accessories should not be cycled.

The device does not require periodic calibration and maintenance, except replacing batteries.

When connecting this equipment to other peripherals, make sure that you are qualified operator to operate this device. Any peripherals must be certified according to the protocol of IEC 950 and IEC 60601-1-2. Any input/output device should be following the protocol of IEC 60601-1-2.

Cautions

This device is intended for use by persons trained in professional health care. The operator must be

thoroughly familiar with the information in the manual before using the device.

The surface of the device can be wiped with alcohol gently. The device is strictly forbided to contact with strong acid or alkali.

Unplug the sensor from the pulse oximeter before cleaning or disinfecting to prevent the sensor or pulse oximeter from being damaged, and also to protect the user under safety situation.

Clean the probe with an H_2O solution and a neutral detergent.

Don't submerge the device or probe into any liquid. Do not use the device in autoclave (sterilizer).

The materials that contact with human bodies are all non-toxic.

If the specification or function of the device is abnormal during measuring, stop measuring immediately and consult us.

Federal Law (U.S.A) restricts this device to sale by or on the order of a physician.

Notes

Application of this device in the background of electromagnetic areas may influence the measurement accuracy such as electro-surgery environment.

SpO_2 measurement may be adversely affected in the presence of strong ambient light. Shield the sensor area (with a surgical towel, for example) if necessary.

Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, and fluorescein, may adversely affect the accuracy of the SpO_2 measurement.

Any condition that restricts blood flow, such as using a blood pressure cuff or extremes in systemic vascular resistance, may cause a failure to detect the accurate SpO_2 value and pulse rate.

Remove fingernail polish or artificial fingernails before applying SpO_2 probes. Fingernail polish or artificial fingernails may lead to inaccurate SpO_2 readings.

Optical cross talk can occur when two or more probes are located in adjoining area. It can be eliminated by covering each site with opaque material. Optical cross talk may adversely affect the accuracy of the SpO_2 readings

Obstructions or dirt on the sensor's emission or receiving windows may cause a sensor failure. Make sure there are no obstructions and the sensor is clean.

Hazards arising from software errors have been minimized. Hazard analysis conforms to meet ISO14971: 2000 and EN60601-1-4: 1996. Significant levels of dysfunctional hemoglogins, such as carboxyhemoglogin or methhemoglobin, will spawn an affection of the accuracy of the SpO_2 measurement.

For routine equipment maintenance, please refer to the service procedures at the specific sections as indicated in the manual.

The circuit diagrams, the list of components, the illustration of diagrams, and the detailed rules of calibration, are provided exclusively to professional personnel authorized by our company.

Dispose of the device or its accessories end of life in accordance with the local ordinances and regulations, otherwise, discarding them as you like may cause pollution to the environment.

As to other attentions, please carefully look through the specific chapter in this instruction manual.

1.3 Intended Use

This pulse oximeter is a portable, non-invasive device intended for continuous monitoring or spot checking, displaying and transmitting functional arterial oxygen saturation (SpO_2) and pulse rate of single adult and pediatric (greater than 3 years of age) patients in hospital and home care. The device is reusable. The application site is finger.

1.4 Electromagnetism Interference

This pulse oximeter is designed and tested in compliance with the EMC standard, complying with the international standard for the EMC of the electronic medical device - IEC 60601-1-2. However, because of the proliferation of radio frequency transmitting equipment and other sources of electrical noise in the health-care and home environments (e.g. cellular phones, mobile two-way radios, electrical appliances) it is possible that high levels of such interference due to close proximity or strength of a source, may result in disruption of performance of this device.

This apparatus complies with the IEC 60601-1-2 international standard. The requirements of this international standard are: CISPR11, GROP1, and CLASS B.

1.5 Explanation of Symbols

Symbol	Meaning
	Attention, consult the accompanying documents.
	Type BF applied part
	Prevent from rain
	Storage temperature and relative humidity
IPX1	Protected against dripping water
SN	Serial number
	Date of Manufacture

SpO_2	Haemoglobin Saturation
PR	Pulse Rate
	Battery power indication
	Brightness Setting
	Battery Setting
	Reading ID Setting
	Version Information
	Return

1.6 Product Features

Simple to use and easy to operate.

Portable and compact in design.

Long-distance data transmission by GPRS.

OLED display screen.

Power off automatically after 30s if no operation and measure are carried out.

Low power consumption: the backlight will turn off automatically when there is no operation in 30s.

Prompt information for low battery.

2. GENERAL DESCRIPTION

2.1 Appearance

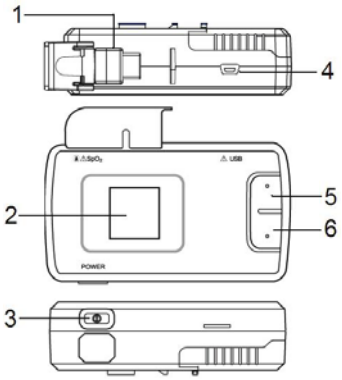

Fig.2-1

Description of Fig.2-1

(1) SpO_2 Socket: used for connecting SpO_2 probe;

(2) DisplayScreen;

(3) Power Button: Press and hold this button for about 3 seconds to power the device on, and for about 4 seconds to turn the device off.

When there is no measurement and no press on keys for 30 seconds, “Auto Power Down” displays on the screen. And then it will power off automatically.

(4) USB Interface: used for data transmission and power charging;

(5) Menu Button: You can enter the menu interface by press this button in the measuring screen, press this button to enter the selected menu item and conform your setting;

(6) Adjust Button: press this button to select different menu item and adjust its corresponding value;

2.2 Power Supply

The device can be powered by Lithium-ion rechargeable battery. The Lithium-ion rechargeable battery with capacity 1500mAh can support the device working for 10 hours.

Battery Installation:

(1) Use your thumb to slide the battery cover in the direction of the mark, and lift the end of the cover upwards.

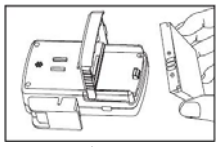

Fig.2-2

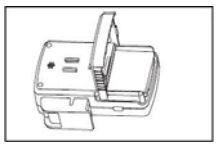

Fig.2-3

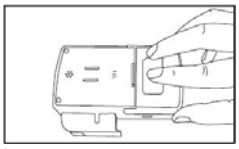

Fig.2-4

(2) Put the battery into the battery compartment with correct polarity.

(3) Carefully re-position the battery cover. Do not force the cover into other place; it fits well only when positioned properly.

Notes:

Keep away from source of fire and/or heat;

Do not disassemble battery and/or battery pack;

Do not connect the positive and negative pole directly using conductive metal; avoid short circuit;

Do not put the battery into water or damp it;

Do not cut the battery;

Do not strike or needle the battery;

Charge the battery using specified chargers;

Do not solder the battery directly;

Do not use the battery in un-specified application;

Battery Charging:

Power low alarm: When the battery indicator becomes a frame with display of "Power low" information,

the unit will power off a time later. You should charge the battery in time.

You can charge the battery by connecting the device to a computer through a USB cable.

3. TAKE A MEASUREMENT

3.1 Sensor Installation

Before measuring, connect the sensor/probe to the pulse oximeter as shown in the following figure.

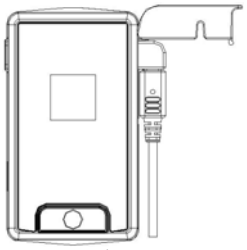

Fig.3-1

3.2 Take a Measurement

(1) First plug the sensor into the interface of the pulse oximeter.

Ensure that the sensor is plugged correctly and firmly.

(2) Secondly fix the sensor on your finger correctly as shown in Fig.3-2. Be sure to make the finger touches the bottom of the probe and the nail surface is facing upwards.

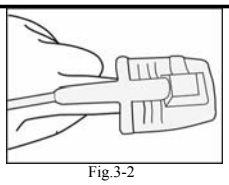

Fig.3-2

(3) After several seconds the following interface will appear.

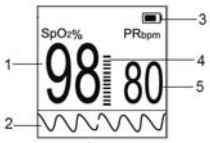

Fig.3-3

Description of Fig.3-3

(1) SpO_2 value measured;

(2) Blood Oxygen plethysmogram;

(3) Power quality indicator;

(4) Pulse Bar;

(5) Pulse rate value measured;

3.3 Factors That May Affect The Measurement

Proper sensor placement is critical for good performance. The following factors may degrade the performance of the pulse oximeter.

Inaccurate measurements may be caused by:

1.Incorrect sensor application or use;

2.Excessive patient movement;

3.Significant levels of dysfunctional hemoglobins (e.g.,carboxyhemoglobin or methemoglobin);

4.Exposure to excessive light such as xenon light sources, bilirubin lamps or direct sunlight (should this occur, cover the sensor and application site with opaque material);

5.Intravascular dyes such as indocyanine green or methylene blue.

Loss of pulse signal may be caused by:

1. Patient is in cardiac arrest or shock;

2. Applying the sensor too tightly;

3. Inflating a blood pressure cuff on the extremity where the sensor is attached;

4. Patient who has hypotension, severe vasoconstriction, severe anemia or hypothermia;

5. An arterial occlusion proximal to the sensor;

6. Excessive illumination.

Potential adverse events:

The following potential risks may be associated with the use of pulse oximetry sensors. The frequency and severity of these adverse events can vary, and may necessitate additional medical intervention, including surgery.

1. Swelling or reddening of skin;

2. Burns;

3. Blisters;

4. Pressure sores;

5. Skin removal.

3.4 Applying The Belt

The longer belt is applied to secure the oximeter around the user's waist and the shorter one is for securing it around the user's wrist.

Please use the following steps to apply the belt securely and comfortably around the user's waist or wrist:

(1). Thread one terminal of the belt through one hole of the bracket, make sure the even side faces the oximeter and hook-and-loop fastener back to it.

(2). One the already-threaded terminal of the belt, press the hook side onto the loop side to fix them, refer to Fig.3-4.

(3) Thread the other terminal of the belt through the other hole of the bracket, refer to Fig.3-5.

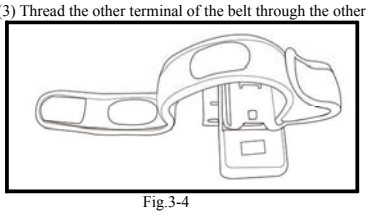

Fig.3-4

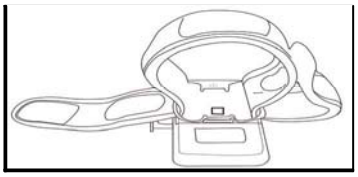

Fig.3-5

4. SETTINGS

Press and hold this button for about 3 seconds to power the device on, and then press the Menu button to enter the menu interface as shown in the following interface.

Fig.4-1

4.1 Brightness Setting

In the menu interface as shown in Fig.4-1 press the Adjust button to select the brightness icon , and then press the Menu button to enter the brightness set interface, you can change the brightness level by pressing the Adjust button. The setting range is 1~7.

4.2 Battery Setting

In the menu interface as shown in Fig.4-1 press the Adjust button to select the battery icon , and then press the Menu button to enter the battery set interface, you can set the Power Save mode on or off.

Power Save Mode: The screen will darkle in case of no press on keys for 20 seconds; The light of backlight will be restored whenever there is a key-press.

4.3 Reading ID Setting

In the menu interface as shown in Fig.4-1 press the Adjust button to select the Reading ID icon  , and then press the Menu button to enter the Reading ID set interface, you can set patient ID in this interface.

4.4 Version Information

In the menu interface as shown in Fig.4-1 press the Adjust button to select the version icon  , and then press the Menu button to enter the version information interface, you can check the information on version of software.

4.5 Return

You can return to the measurement screen by performing this item.

Note: The system returns to the measurement screen as shown in Fig.3-3 in case of no press on keys for 10 seconds.

5. MAINTENANCE AND CLEANING

Warning!

The advanced circuit inside the oximeter does not require periodic calibration and maintenance, instead of replacing the batteries. Don't open the cover of oximeter or repair electronic circuits.

Its open will cause the damage of the device and the annulment of the warranty.

5.1 Equipment Maintenance

Use only the substances approved by us and methods listed in this chapter to clean or disinfect

your equipment. Warranty does not cover damage caused by unapproved substances or methods.

We make no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control infection, consult your hospital's Infection Control Officer or Epidemiologist. Keep your equipment and accessories free of dust and dirt. To avoid damage to the equipment, follow these rules:

Always dilute according the manufacturer's instructions or use lowest possible concentration.

Do not immerse any part of the equipment into liquid.

Do not pour liquid onto the equipment or accessories.

Do not allow liquid to enter the case.

Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).

Caution: If you spill liquid on the equipment or accessories, contact us or your service personnel.

Note: To clean or disinfect reusable accessories, refer to the instructions delivered with the accessories.

5.2 Battery Maintenance

Warning!

Dispose of all used batteries in a proper waste disposal according to local applicable regulations.

For detailed information about battery maintenance please refer to chapter *2.2 Power Supply.*

5.3 Preventive Maintenance

The following simple preventive maintenance tasks should be performed monthly to ensure

continued performance of the device at maximum capacity, and to reduce the possibility of a failure.

Mechanical Inspection

Check for splits, cracks or imperfections in the case. If you have any questions or doubts, call your service provider.

Do not make any repairs by yourself

Do not attempt to open or disassemble your oximeter, if so you may run the risk of electric shock and void the limited warranty. No user-serviceable parts are inside. Only authorized service personnel may repair the product.

5.4 Cleaning

Your equipment should be cleaned on a regular basis. If there is heavy pollution or lots of dust and sand in your place, the equipment should be cleaned more frequently. Before cleaning the equipment, consult your hospital's regulations for cleaning the equipment.

Recommended cleaning agents are:

Mild soap (diluted)
Ammonia (diluted)
Sodium hypochlorite bleach (diluted)
Hydrogen peroxide (3%)
Ethanol
Isopropanol (70%)

To clean your equipment, follow these rules:

1. Shut down the pulse oximeter and take the batteries out of the battery compartment.

2. Clean the display screen using a soft, clean cloth dampened with a glass cleaner.

3. Clean the exterior surface of the equipment using a soft cloth dampened with the cleaner.

4. Wipe off all the cleaning solution with a dry cloth after cleaning if necessary.

5. Dry your equipment in a ventilated, cool place.

Cautions:

Do not allow any liquid to enter the case, and avoid pouring water or other liquid on the device while cleaning.

Never use abrasives such as wire wool or metal polish.

During cleaning, make sure you do not expose the device to temperature excess of 40°C.

Please take out batteries before cleaning the oximeter.

Warnings!

To reduce the chance of shock or injury, do not use your oximeter in or near water or wet locations.

Keep your oximeter away from sources of liquids, such as drinks, wash basins, bathtubs, shower stalls, and so on.

Protect your oximeter from direct sunlight and rain or other moisture.

Take care not to spill any food or liquid on oximeter. If you do, unplug oximeter before cleaning up the spill.

Depending on what you spilled and how much of it got into your equipment, you may have to send your equipment to Apple for service.

Environment

Keep away from extreme heat. Do not leave it on the dashboard of a car or near a heater. Do not leave it in any place that is extremely damp or dusty.

As this product is not waterproof, do not use it or store it where fluids such as water can splash onto it. Raindrops, water spray, juice, coffee, steam, perspiration, etc. may also cause a malfunction.

Keep accessories that might be swallowed away from children.

6. TROUBLESHOOTING

Trouble 1: When the probe is not inserted or the probe is faulted, the system may prompt user by the information “Probe Off”.

Solution 1: Reinsert the sensor or change to a new available sensor.

Trouble 2: When the finger is not inserted into the probe or the probe can not detect any signal, the system may prompt user by the information“Finger Off”.

Solution 2: Pull your finger out and reinsert it to make your finger fully contact the inner detector of probe or rub your hands to warm them if your hands are too cool.

When encountering other troubles, please contact our service department.

7. WARRANTY AND REPAIR

7.1 Service Method

a）Maintenance responding time: 9:00am～17:30pm, Monday to Friday

b）Service support: Our company will offer user telephone and e-mail support and parts change.

Parts change: our company will change parts when necessary, free of charge during the warranty period.

User should send all defective parts back to our company if not specified otherwise.

c）Update the system software free of charge.

7.2 Warranty Limitations

a) Our company isn't responsible for such damage caused by force majeure. For example: fire, thunder flash, flood, cyclone, hail, earthquake, house collapse, commotion, plane crash and traffic accident, deliberate damage, lack of fuel or water, labor and capital bother, strike and stop-working etc.

b) No-service offer

The corresponding charge and insurance charge of disassembling, refurbishing, repackaging and moving the oximeter or the part of it.

The damage caused by the third party not authorized by our company to adjust, install, replace the parts of the oximeter.

The damage and failure caused by the user or its representative non-compliance with the operator's manual.

c) The oximeter is installed or connected with an external device (eg. printer, computer) without our company's permission and this leads to oximeter failure. In such case our company will charge for the maintenance.

d）Responsibility limitation

During the period of maintenance contract validity, if user changes any parts manufactured by other manufacturers without the permission of our company, our company is entitled to stop the contract.

7.3 User Guarantee

a) Please read the manual carefully before operation

b) The advanced circuit inside the oximeter does not require periodic calibration and maintenance, instead of replacing the batteries.

7.4 No-Warranty Principle

The annulment of the warranty will be caused by following instances:

There is physical damage to the oximeter and/or its accessories.

There are liquid leftovers and this has led to short circuit and plugboard failure.

The probe and accessories belong to consumption and will not be replaced free.

Damage of probe caused by mechanical force will not be replaced free.

Oximeter Maintenance seal has been removed.

Bad packaging leads to oximeter damage during the transportation.

Oximeter operation by non-professional or without reading the manual first leads to oximeter failure.

7.5 Warranty Period

Our warranty for oximeter complies with electronic product after-sale service standard regulated by national laws. The warranty period of mainboard is one year, and for all the accessories the period is three months.

7.6 Repackage

Take all the accessories and put them into plastic bag.

Try to use original package and packing materials. User will be responsible for such damage caused by bad package during transportation.

Please describe failure in detail

7.7 Storage and Transportation

Storage: Storage Temperature -20°C～55°C, Relative Humidity≤93%.

Transportation: Transport by air, train or vessel after packing according to request.

APPENDIX SPECIFICATIONS

Note: The specifications are subject to change without prior notice.

Display

Display Type: OLED

Display Parameter: SpO_2, pulse rate, pulse bar, SpO_2 plethysmogram, date and time, power quality indicator and other prompt information.

Data Update Time: <15s.

SpO_2

Display Range: 0%-100%

Measuring Range: 70%-100%

Measuring Accurate: 70%-100%±3%, ＜70% unspecified

Resolution: 1%

PR

Display Range: 0～255bpm

Measuring Range: 30～235bpm

Measuring Accurate: ±2bpm or 2% (the greater)

Resolution: 1bpm

Operating Conditions

Operating temperature: 5℃～40℃

Relative humidity: ≤80% (non-condensation)

Atmosphere pressure: 86kPa～106kPa

Package & Storage Conditions

Storage temperature: -20℃～55℃

Relative humidity: ≤93% (non-condensation)

Atmosphere pressure: 50kPa～106kPa

Power Support

A rechargeable Li-battery with the voltage of 4.2V and battery capacity 1500mAh.

Continuous working time: 10 hours.

Equipment Classification

According to the type of protection against Electrical shock:

Internal electrical power source equipment;

According to the degree of protection against Electrical shock:

Type BF equipment;

According to the degree of protection against harmful ingress of water:

IPX1;

According to the mode of operation:

Continuous operation;

Dimensions & Weight

Dimensions: 133mmX63mmX33mm (length×width×height)

Weight: 200g (including batteries)

FCC ID: WWIMD300W4

Model No.: MD300W4

Manufacturer: Beijing Choice Electronic Technology Co., ltd

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.

Any 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.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter. This equipment has been SAR-evaluated for use in hand. SAR measurements are based on a 0cm spacing from the body and that compliance is achieved at that distance.

The highest SAR value tested when properly worn on the body is 0.367 W/kg.

Standard Accessories

One SpO_2 Sensor (model: M-50G)

One lithium ion rechargeable battery (1500mAh)

One USB cable

One Operator's manual

One piece of wrist belt

One clip for wrist belt

Manufacturer address: Beijing Choice Electronic Technology Co.，Ltd.

Bailangyuan Building B

Rm. 1127-1128, Fuxing Road, A36

100039 Beijing

PEOPLE'S REPUBLIC OF CHINA