

Pulse Oximeter

USER MANUAL

ChoiceMMed

General Description

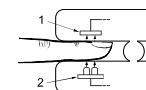
Oxygen binds to hemoglobin in red blood cells when moving through the lungs. It is transported throughout the body as arterial blood. A pulse oximeter uses two frequencies of light (red and infrared) to determine the percentage (%) of hemoglobin in the blood that is saturated with oxygen. The percentage is called blood oxygen saturation, or SpO₂. A pulse oximeter also measures and displays the pulse rate at the same time it measures the SpO₂ level.

Measurement Principle

Principle of the oximeter is as follows: The pulse oximeter 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 SpO₂.

Diagram of Operation Principle

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



Precautions for Use

1. Before use, carefully read the manual.
2. Operation of the pulse oximeter may be affected by the use of an electrosurgical unit (ESU).
3. The pulse oximeter must be able to measure the pulse properly to obtain an accurate SpO₂ measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO₂ measurement.
4. Do not use the pulse oximeter in an MRI or CT environment.
5. Do not use the pulse oximeter in situations where alarms are required. The device has no alarms. It is not for continuous monitoring.
6. Do not use the pulse oximeter in an explosive atmosphere.
7. The pulse oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
8. 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.
9. Do not sterilize the device using autoclaving, ethylene oxide sterilizing, or immersing the device in liquid. The device is not intended for sterilization.
10. Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
11. 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.
12. 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.
13. This equipment is not intended for use during patient transport outside the healthcare facility.
14. The patient is an intended operator. All functions of the device can be safely used by the patient.
15. 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
16. 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.
17. 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.
18. 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.
19. When the signal is not stable, the reading may be inaccurate, please do not refer.
20. The material of the device has no nature latex.
21. The pulse oximeter equipment is calibrated to display functional oxygen saturation.
22. The waveform we provide is normalized.
23. Do not modify this equipment without authorization of the manufacturer.
24. 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.
25. Stop using and contact local service center if one of the following cases occurs:
 - Any of the problems in the *Possible Problems and solutions* cannot be solved.
 - The oximeter cannot be powered on in any case and not the reasons of battery.
 - There is a crack on the oximeter or damage on the display resulting readings cannot be identified; the spring is invalid; or the key is unresponsive or unavailable.
26. Aging infrared-ray detector or insufficient battery level may affect the equipment performance. Please follow the instructions in the manual to maintain the device.
27. Please contact the manufacturer for any question about the usage or maintenance.

Rx only: "Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner."

Contraindication

Not yet found.

Inaccurate 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.

Product Features

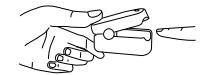
- Simple to operate and convenient to carry.
- Small volume, light weight and low power consumption.
- Dual color LCD displays SpO₂, PR, PI, and Pulse bar.
- 7 display modes.
- Level 1-5 adjustable brightness.
- 2pcs AAA-size alkaline batteries; real-time battery status indication.
- Wireless Bluetooth for data transmission.
- The device will power off automatically in 8 seconds when "Finger out" is displayed.
- Compatible with iOS or Android App.

Intended Use

The Pulse Oximeter is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO₂) and Pulse Rate of adult, adolescent, child and infant patients in hospitals, hospital-type facilities and homecare.

Operation Instructions

1. Install two AAA batteries according to the Battery Installation instructions.
2. Place one of your fingers into the rubber opening of the pulse oximeter.
3. Press the switch button one time on front panel to turn the pulse oximeter on.
4. Keep your hands still for the reading. Do not shake your finger during the test. It is recommended that you do not move your body while taking a reading.
5. Read the data from the display screen.

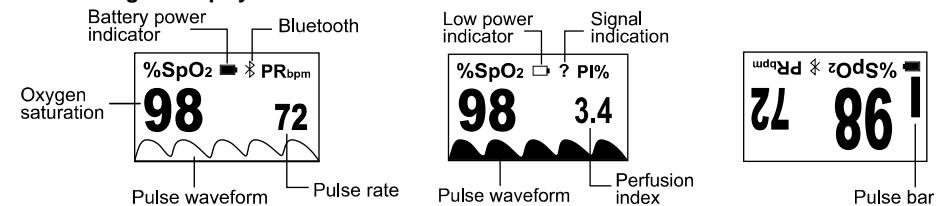


The oximeter is designed with 7 display modes, as below, the first one is the default mode.

Short press on the power button to switch between the 7 modes when the device is powered on.



Understanding the display:



DATA TRANSMISSION: transfer measurements to iChoice APP

1. Download iChoice APP from the APP marketplace in your smartphone and install the APP.
2. Register a user account in the APP and log in.
3. Connect the APP with the device via Bluetooth (select "Pulse Oximeter" on the APP homepage>choose device model>tap "Connect the device").
4. Upload your measurement data to the APP (tap "..." in the upper-right corner and read "How to Use" for detailed steps to use the APP).

Notes:

- ◊ The Bluetooth icon stops flashing and stay still on the display when the oximeter is connected with APP.
- ◊ The Bluetooth communication range is 10 meters at most.
- ◊ The "?" appears on the display when the signal is not stable. The readings are potentially incorrect. Please keep your hand still and retry.
- ◊ The display will show "Finger out" if no finger is detected.
- ◊ Automatic shutdown happens after no operation for 8 seconds.

Settings

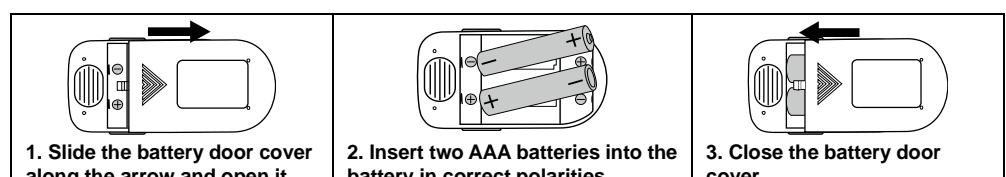
1. Press and hold the power button to enter **Settings** menu when the unit is powered on.
2. Press the power button to select between the setting items, and then press and hold the power button to select the option behind the selected item.

Work Mode: to set up the work mode of Bluetooth as Real-time or Spot-check.
-Spot-check: The stable readings are transferred to the App automatically. The measurements will flash for 8s and then the device will automatically power off.
-Real-time: The data are uploaded to the App in real-time. The device will power off automatically in 8 seconds when "Finger out" is displayed.

Language: to change the display language to English or Chinese
Brightness: to adjust screen brightness from 1-5. Level 5 is the default.
Reset: to restore default settings
Exit: to return to measuring interface.

* Without any operation, the device automatically enters measurement mode in 8 seconds.

Battery Installation



Notes:

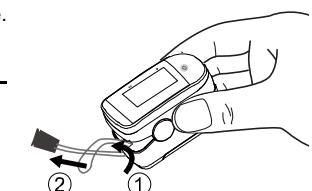
- ◊ Please make sure the battery polarities are matched with the +/- signs on the compartment.
- ◊ Please remove the batteries if the pulse oximeter will not be used for a long time.
- ◊ Please replace the battery when the low power indicator starts flickering.

Using the Lanyard

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

Warnings!

- ◊ Keep the oximeter away from young children. Small items such as the battery door, battery, and lanyard are choking hazards.
- ◊ Do not hang the lanyard from the device's electrical wire.
- ◊ Please notice that the lanyard which is tied to the oximeter may cause strangulation due to excessive length.



Maintenance and Storage

- Replace the batteries in a timely manner when low voltage lamp is lighted.
- Clean surface of the oximeter before it is used in diagnosis for patients.
- Remove the batteries if the oximeter is not operated for a long time.
- It is best to store the product in -25°C~+70°C and ≤93% humidity.
- Keep in a dry place. Extreme moisture may affect oximeter lifetime and may cause damage.
- Dispose of battery properly; follow any applicable local battery disposal laws.

Cleaning and disinfecting the device

- It is recommended to clean and disinfect the silicone touching the finger inside of device with a soft cloth dampened with recommended alcohol of 70% isopropyl or 70% ethanol before and after each use.
- 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.

Caution: Never use EtO (ethylene oxide) or formaldehyde for disinfection.

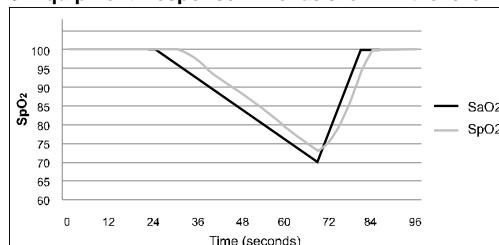
The use life of the device is five years when it is used for 15 measurements every day and 10 minutes per one measurement. The Oximeter requires no routine calibration or maintenance other than replacement of batteries.

Specifications

1. Display Type	LCD display
2. SpO ₂	<p>Measurement range: 70%~100%</p> <p>Accuracy: 70%~100%: ±2%; ≤69% no definition</p> <p>Resolution: 1%</p>
<p><i>Note: A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor. Clinical testing is used to establish the SpO₂ accuracy. The measured arterial hemoglobin saturation value (SpO₂) of the sensors is compared to arterial hemoglobin oxygen (SaO₂) value, determined from blood samples with a laboratory CO-oximeter. The accuracy of the sensors in comparison to the CO-oximeter samples measured over the SpO₂ range of 70%~100%. Accuracy data is calculated using the root-mean-squared (Arms value) for all subjects, per ISO 80601-2-61, Medical Electrical Equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.</i></p> <p><i>A functional tester is used to measure how accurately Pulse Oximeter is reproducing the specified calibration curve and the PR accuracy.</i></p> <p><i>The model of functional tester is Index2 FLUKE simulator and the version is 2.1.3.</i></p>	
3. Pulse Rate	<p>Measure range: 30bpm~250bpm</p> <p>Accuracy: 30bpm~99bpm, ±2bpm; 100~250bpm, ±2%</p> <p>Resolution: 1bpm</p>
4. Perfusion Index	Measure range: 0.3%~20.0%
5. Probe LED Specifications	<p>RED Wavelength: 660±3nm Radiant Power: 3.2mw</p> <p>IR Wavelength: 905±10nm Radiant Power: 2.4mw</p>

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

6. Power Requirements	Two AAA alkaline Batteries
	Power consumption: Less than 40mA
7. Environment Requirements	<p>Operation Temperature: 5°C~40°C</p> <p>Storage Temperature: -25°C~+70°C</p> <p>Ambient Humidity: 15%~93% no condensation in operation; ≤93% no condensation in storage/transport</p> <p>Atmosphere pressure: 70kPa~106kPa</p>
	<i>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.</i>
8. Equipment Response Time:	as shown in the following figure, average data update period is 8s.



9. Classification

According to the type of protection against electric shock: Internally powered equipment

According to the degree of protection against electric shock: Type BF applied part (applied part: the rubber hole of the device)

According to the degree of protection against ingress of water: IP22

According to the mode of operation: continuous operation

Possible Problems and Solutions

Problems	Possible reason	Solution
SpO ₂ or PR cannot be shown normally.	1. Finger is not inserted correctly. 2. Patient's SpO ₂ value is too low to be measured.	1. Retry by inserting the finger. 2. There is excessive illumination. 3. Try some more times. If you can make sure no problem exist in the product, please go to a hospital timely for exact diagnosis.
SpO ₂ or PR is shown unstably.	1. Finger might not be inserted deep enough. 2. Excessive patient movement.	1. Retry by inserting the finger. 2. Be calm.
The oximeter cannot be powered on.	1. No battery or low power of battery. 2. Batteries might be installed incorrectly. 3. The oximeter might be damaged.	1. Please replace batteries. 2. Please reinstall the batteries. 3. Please contact local customer service center.
Indication lamps are suddenly off.	1. The product is automatically powered off when no signal is detected longer than 8s. 2. The battery power is too low to work.	1. Normal. 2. Replace the batteries.
"Err 7" is displayed on screen.	Err 7 means all the emission LED or reception diode is damaged.	Please contact local customer service center.

Symbol Definitions

Symbol	Definition	Symbol	Definition
	Type BF applied part		Attention
IP22	Protected against dripping water	%SpO₂	Oxygen saturation
PR bpm	Pulse rate (BPM)		Low power indication
	No SpO ₂ Alarm	SN	Serial No.
	Storage temperature and relative humidity		Follow instruction for use
	Manufacturer's information		Date of Manufacture
	Bluetooth indication		Indicate the signal is not stable
	Waste electrical and electronic equipment	MD	Medical device

Electromagnetic Compatibility

The device conforms to IEC60601-1-2:2014 Electromagnetic Compatibility (EMC) standard. Essential performance is defined as SpO₂ accuracy and pulse 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 380 – 390 MHz 430 – 470 MHz 704 – 787 MHz 800 – 960 MHz 1.7 – 1.99 GHz 2.4 – 2.57 GHz 5.1 – 5.8 GHz	10 V/m 80% AM 1kHz 27 V/m Pulse mod. 18Hz 28 V/m FM±5Hz deviation 1kHz sine 9 V/m Pulse mod. 217Hz 28 V/m Pulse mod. 18Hz 28 V/m Pulse mod. 217Hz 28 V/m Pulse mod. 217Hz 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: WWMD300C228

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:

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

Box Content

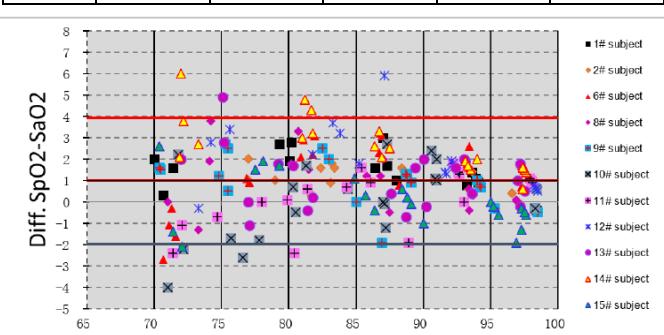
- One pulse oximeter
- One lanyard
- Two AAA batteries
- One instruction manual

Applicable Models

MD300C208 MD300C228

Notes:

- The illustrations used in this manual may differ slightly from the appearance of the actual product.
- The specifications are subject to change without prior notice.



Bland-Altman Plot Graphic



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