Fingertip Pulse Oximeter MD300C208

USER MANUAL

Ver2.0

ChoiceMMed

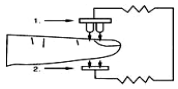
General Description

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 SpO_2. A pulse oximeter also measures and displays the pulse rate at the same time it measures the SpO_2 level.

Measurement Principle

Principle of the oximeter is as follows: The pulse oximeter works by applying a sensor to a pulsating arteriolar vascular bed. 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 Emission Tube
2. Red and Infrared-ray Receipt Tube

Precautions For Use

1. Before use, carefully read the manual.
2. Operation of the fingertip pulse oximeter may be affected by the use of an electrosurgical unit (ESU).
3. Pulse Oximeters require sufficient blood flow to obtain proper readings. Poor blood circulation can result in inaccurate readings. If your hands are cold or you have poor circulation, warm your hands by rubbing them together or use another method before attempting to obtain a reading. A tourniquet, blood pressure cuff or other blood flow hindrances may also result in inaccurate readings.
4. Do not use the fingertip pulse oximeter in an MRI or CT environment.
5. Do not use the fingertip pulse oximeter in situations where alarms are required. The device has no alarms. It is not for continuous monitoring.
6. Do not use the fingertip pulse oximeter in an explosive atmosphere.
7. The fingertip 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.
13. This equipment is not intended for use during patient transport outside the healthcare facility
14. This equipment should not be used adjacent to or stacked with other equipment.
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. These materials that contact with the patient's skin contain medical silicone and ABS plastic enclosure are all pass the ISO10993-5 Tests for invitro cytotoxicity and ISO10993-10 Tests for irritation and delayed-type hypersensitivity.
17. When the signal is not stable, the reading may inaccurate. Please do not reference.

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

Contraindication

It is not for continuous monitoring.

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

1 Simple to operate and convenient to carry.
2 Small volume, light weight and low power consumption.
3 Dual color OLED
4 2 display direction.
5 2pcs AAA-size alkaline batteries; battery-low indicator.
6 Wireless Bluetooth for data transmission.
7 When no or low signal is detected, the pulse oximeter will power off automatically
8 Compatible with iOS or Android App

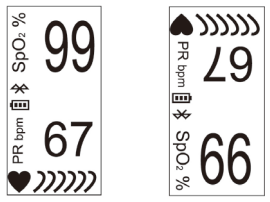
Intended Use

The Fingertip Pulse Oximeter is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO_2) and Pulse Rate of adult, adolescent and child 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

After turning on the Oximeter, each time you press the power switch, the Oximeter will switch to another display mode. There are 2 display directions shown as follows:



Notes:
1. Short press the power button to switch the screen display orientation.

Data Transmission

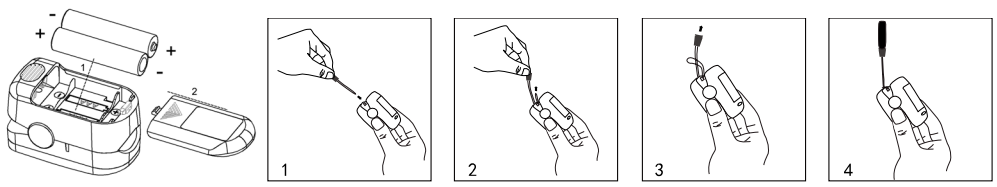
1. Turn on the device, the Bluetooth icon is flashing. After sync successfully, the Bluetooth icon is light on. Or else the Bluetooth icon still in the flashing status. When you turn off the device, the Bluetooth will break automatically.
2. The current measurement will transmit to the App automatically. After data transmission successfully, the measurement flashing for 8s, then the device will power off automatically power off. If there is no Bluetooth connection over 1min, the device will power off automatically and the data will not be stored.
3. If there is no digit appear, the device will power off automatically.

Notes:
1. With the Bluetooth 4.0 to transmit the data to App.
2. The transmission distance is 10m at most.

Battery Installation

1. Install two AAA batteries into the battery compartment. Match the plus (+) and minus (-) signs in the compartment. If the polarities are not matched, damage may be caused to the oximeter.
2. Slide the battery door cover horizontally along the arrow shown as the picture.

Notes:
- ✧ Please remove the batteries if the pulse oximeter will not be used for long periods of time.
- ✧ Please replace the battery when the power indicator starting flickering.



Using the Lanyard

1. Thread thinner end of the lanyard through the hanging hole.
2. Thread thicker end of the lanyard through the threaded end before pulling it tightly.

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

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

Cleaning the fingertip pulse oximeter

Please use medical alcohol to clean the silicone touching the finger inside of oximeter with a soft cloth dampened with 70% isopropyl alcohol. Also clean the being tested finger using alcohol before and after each test.
Do not pour or spray liquids onto the oximeter, and do not allow any liquid to enter any openings in the device. Allow the oximeter to dry thoroughly before reuse.
The fingertip pulse oximeter requires no routine calibration or maintenance other than replacement of batteries.

The use life of the device is five years when it is used for 15 measurements every day and 10 minutes per one measurement. Stop using and contact local service center if one of the following cases occurs:

- An error in the *Possible Problems and solutions* is displayed on screen.
- The oximeter cannot be powered on in any case and not the reasons of battery.

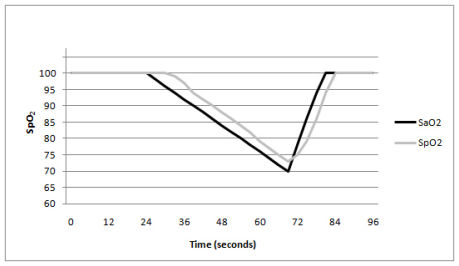
- There is a crack on the oximeter or damage on the display resulting readings cannot be identified; the spring is invalid; or the key is unresponsive or unavailable.

Specifications

1. Display Type
OLED display
2. SpO_2
Measurement range: 70%~100%
Accuracy: 70%~100%: ±2%; 0%~69% no definition
Resolution: 1%
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 SpO_2 accuracy. The measured arterial hemoglobin saturation value (SpO_2) of the sensors is compared to arterial hemoglobin oxygen (SaO_2) 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 SpO_2 range of 70%~100%. Accuracy data is calculated using the root-mean-squared (Arms value) for all subjects, per ISO 9919:2005, Medical Electrical Equipment – Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.
A functional tester is used to measure how accurately Fingertip Pulse Oximeter is reproducing the specified calibration curve and the PR accuracy.
The model of functional tester is Index2 FLUKE simulator and the version is 2.1.3.
3. Pulse Rate
Measure range: 30bpm~250bpm
Accuracy: 30bpm~99bpm, ±2bpm; 100~250bpm, ±2%
Resolution: 1bpm
5. Probe LED Specifications

	Wavelength	Radiant Power
RED	660±3nm	3.2mw
IR	905±10nm	2.4mw

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
Operation Temperature: 5℃~40℃
Storage Temperature: -25℃~+70℃
Ambient Humidity: 15%~93% no condensation in operation; ≤93% no condensation in storage/transport
Atmosphere pressure: 70kPa~106kPa
8. Equipment Response Time
As shown in the following figure.
Data update period of slower average is 8s.



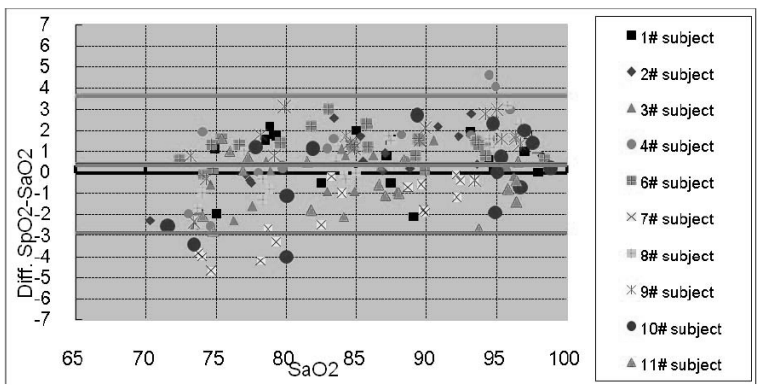
9. Classification
According to the type of protection against electric shock: INTERNALLY POWERED EQUIPMENT;
According to the degree of protection against electric shock: TYPE BF APPLIED PART, (applied part: the rubber hole of the device);
According to the degree of protection against ingress of water: IP22
According to the mode of operation: CONTINUOUS OPERATION

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

FCC Declaration

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.
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.
Note: This product 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 product 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 product 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.

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 exists 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 calmness
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 with local customer service centre
Indication lamps are suddenly off	1. The product is automatically powered off when no signal is detected longer than 8 seconds 2. The battery power is too low to work	1. Normal 2. Replace the batteries
"Error7" is displayed on screen	Err 7 means all the emission LED or reception diode is damaged.	Please contact with local customer service centre

Symbol Definitions

Symbol	Definition	Symbol	Definition
	Type BF applied part.		Attention
IP22	Protected against dripping water	SpO_2%	Oxygen saturation
PR bpm	Pulse rate (BPM)		Low power indication
SpO_2	No SpO_2 Alarm	SN	Serial No.
+70℃ max, -25℃ min, RH≤93% non-condensing	Storage temperature and relative humidity		Follow instruction for use
	Manufacturer's information		Date of Manufacture
	Bluetooth indication		Indicate the signal is not stable
CE 0123	European union approval	EC REP	Authorized representative in the European community
	Waste electrical and electronic equipment		

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

Applicable Models

MD300C208, MD300C228

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