

Fingertip Pulse Oximeter

MD300C63

USER MANUAL

Ver5.0C63

General Description

Oxygen Saturation is a percentage of Oxyhemoglobin (HbO₂) capacity, compounded with oxygen, by all combinative hemoglobin (Hb) capacity in blood. In other words, it is consistency of Oxyhemoglobin in blood. It is a very important parameter for the Respiratory Circulation System. Many respiratory diseases can result in oxygen saturation being lowered in human blood. Additionally, the following factors can reduce oxygen saturation: Automatic regulation of organ dysfunction caused by Anesthesia, Intensive Postoperative Trauma, injuries caused by some medical examinations. That situation might result in light-headedness, asthenia, and vomiting. Therefore, it is very important to know the oxygen saturation of a patient so that doctors can find problems in a timely manner.

The fingertip pulse oximeter features low power consumption, convenient operation and portability. Place one fingertip into the photoelectric sensor for diagnosis, and the pulse rate and oxygen saturation will appear on the display. It has been proven in clinical experiments that it also features high precision and repeatability.

Measurement Principle

Principle of the oximeter is as follows: A mathematical formula is established making use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin (RHb) and Oxyhemoglobin (HbO₂) in red and near-infrared zones. Operation principle of the instrument: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm red and 940nm near infrared light) can be focused onto a human nail tip through a clamping finger-type sensor. A measured signal obtained by a photosensitive element, will be shown on the oximeter's display through process in electronic circuits and microprocessor.

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. The fingertip 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 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 60601-1-2:2007 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.

Rx only: "Caution: Federal law restricts this device to sale by or on the order of a physician."

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 Properties

1. Simple to operate and convenient to carry.
2. Special battery cover for more durability
3. Small volume, light weight and low power consumption.
4. Dual color OLED displays SpO₂, PR, Pulse bar and waveform.
5. Level 1-10 adjustable brightness.
6. 6 display modes.
7. 2pcs AAA-size alkaline batteries; battery-low indicator.
8. When no signal or low signal is detected, the pulse oximeter will power off automatically in 8 seconds.

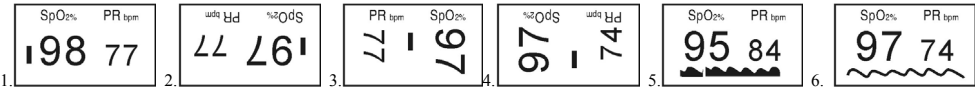
Intended Use

Fingertip pulse oximeter is a portable non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate of adult and pediatric patients in hospitals and hospital-type facilities.

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.
6. Press the button again to toggle between six display modes.

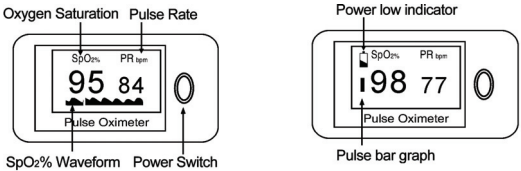
After turning on the Oximeter, each time you press the power switch, the Oximeter will switch to another display mode. There are 6 display modes shown as follows:



Holding the power switch for longer than one second, will adjust the brightness of the oximeter. There are 10 levels of brightness. The default level is level four.

Front Panel

ChoiceM Med



The height of the bar graph indicates of the pulse and signal strength. The bar should be greater than 30% for a proper reading.

Product Accessories

1. One lanyard
2. Two AAA batteries
3. One instruction manual

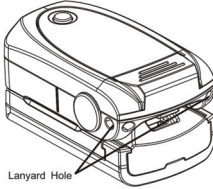
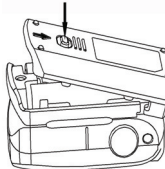
Battery Installation

1. Press the button down on the rear panel and push the battery cover horizontally along the arrow shown in the following picture.
2. 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.

Note:

- ✧ 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.

Press the button down !



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!

1. Keep the oximeter away from young children. Small items such as the battery door, battery, and lanyard are choking hazards.
2. Do not hang the lanyard from the device's electrical wire.
3. 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 timely 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 -20°C ~ +55°C 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 finger being tested 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 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.

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 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.

Specifications

1. Display Type

OLED display

2. SpO₂

Measurement range: 70%~100%

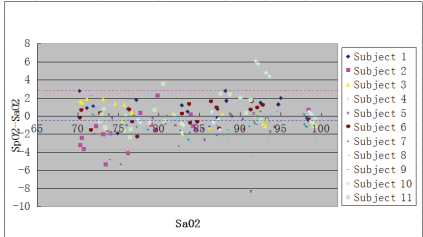
Accuracy: 70%~100%: ±2%; 0%~69% no definition

Resolution: 1%

ARMS Value Analysis

Testing Range	Data Points	Bias	ARMS	Specification
70--<80	81	-0.70	1.82	±2
80--<90	71	-0.60	1.52	±2
90--100	84	-0.15	1.78	±2
70--100	236	-0.47	1.72	±2

Bland-Altman graphical plot of all sampled data points as below



3. Pulse Rate

Measure range: 30bpm~235bpm

Accuracy: 30bpm~99bpm, ±2bpm; 100bpm~235bpm, ±2%

Resolution: 1BPM

4. Probe LED Specifications

	Wavelength	Radiant Power
RED	660 ± 2nm	1.8mW
IR	940 ± 10nm	2.0mW

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

5. Power Requirements

Two AAA alkaline Batteries

Power consumption: Less than 30mA

Battery Life: Two AAA 1.5V, 800mAh alkaline batteries could be continuously operated as long as 30 hours.

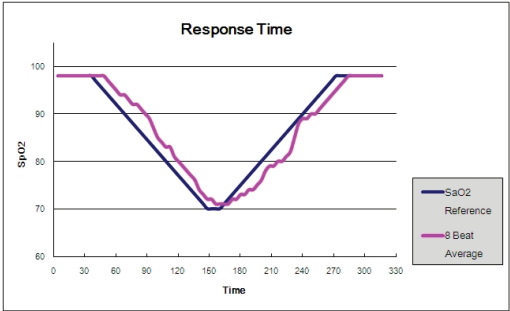
6. Environment Requirements

Operation Temperature: 5℃~40℃
Storage Temperature: -20℃~+55℃
Ambient Humidity: ≤80% no condensation in operation; ≤93% no condensation in storage
Atmosphere pressure: 86kPa~106kPa

7. Equipment Response Time

As shown in the right figure.

Response time of slower average is 12.4s.



8. 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;

According to the degree of protection against ingress of water: IPX1

According to the mode of operation: CONTINUOUS OPERATION

Declaration

Guidance and Manufacturer's declaration – electromagnetic emissions-For all EQUIPMENT and SYSTEMS			
1	Guidance and Manufacturer's declaration - electromagnetic emission		
2	The MD300C63 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of MD300C63 Pulse Oximeter should assure that it is used in such an environment.		
3	Emission test	Compliance	Electromagnetic Environment – guidance
4	RF emissions CISPR 11	Group 1	The MD300C63 Pulse Oximeter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The pulse Oximeter (MD300C63) is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
5	RF emissions CISPR 11	Class B	
6	Harmonic emissions IEC 61000-3-2	Not Applicable	
7	Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and Manufacturer's declaration – electromagnetic immunity-For all EQUIPMENT and SYSTEMS			
Guidance and Manufacturer's declaration - electromagnetic immunity			
The MD300C63 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the MD300C63 Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic Environment – guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 6kV contact +/- 8kV air	+/- 6kV contact +/- 8kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic transient / burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 sec	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MD300C63 Pulse Oximeter requires continued operation during power mains interruptions, it is recommended that the MD300C63 Pulse Oximeter be powered from an un-interruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.

NOTE UT is the a. c. mains voltage prior to application of the test level.

Guidance and Manufacturer's declaration – electromagnetic immunity – For EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING			
Guidance and Manufacturer's declaration - electromagnetic immunity			
The MD300C63 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the MD300C63 Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic Environment – guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the MD300C63 Pulse Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations, Electromagnetic propagation is affected by absorption and reflection structures, objects and people.

- a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MD300C63 Pulse Oximeter is used exceeds the applicable RF compliance level above, the MD300C63 Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the MD300C63 Pulse Oximeter.
- b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEMS - For all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING		
Recommended separation distances between portable and mobile RF communications equipment and the MD300C63 Pulse Oximeter		
The MD300C63 Pulse Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MD300C63 Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MD300C63 Pulse Oximeter as recommended below, according to the maximum output power of the communications equipment		
Rated maximum output of transmitter (W)	Separation distance according to frequency of transmitter (m)	
	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	7.3
100	12	23

For transmitters rated at a maximum output power not listed above the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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 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
"Error3" or "Error4" is displayed on screen	1. Err 3 means the red emission LED is damaged 2. Err 4 means the infra-red emission LED is damaged	1. Check the red emission LED 2. Check the infra-red emission LED
Error 6	Err 6 means the screen is failure	Change the screen
"Error7" is displayed on screen	Err 7 means all the emission LED or reception diode is damaged.	Check the emission LED and reception diode.

Symbol Definitions			
Symbol	Definition	Symbol	Definition
	Caution		No SpO ₂ Alarm
	Type BF applied part.		Protected against dripping water.
SN	Serial No.		Storage temperature and relative humidity
PR bpm	Pulse rate (BPM)		Oxygen saturation
	Low power indication		Date of Manufacture
	Manufacturer's information		European union approval
	Authorized representative in the European community		Follow instruction for use

Applicable Models

MD300C63 MD300C631 MD300C632 MD300C633 MD300C634 MD300C635 MD300C636 MD300C637
MD300C638 MD300C639 MD300C630 MD300C63A MD300C63B MD300C63F MD300C63H MD300C63I
MD300C63J

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.

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