Fingertip Pulse Oximeter

MD300C15D-H

USER MANUAL

Ver2.0C15D-H

ChoiceMMed

General Description

Oxygen Saturation is a percentage of Oxyhemoglobin (HbO_2) 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.

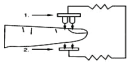
The fingertip pulse oximeter features low power consumption, convenient operation and portability. Place one fingertip into the photoelectric sensor for diagnosis and the pulse rate and oxygen saturation will appear on the display. It has been proven in clinical experiments that it also features high 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 (HbO_2) 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 905nm 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 SpO_2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO_2 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 4 fours.
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 should not be used adjacent to or stacked with other equiopment.
14 This equipment is not intended for use during patient transport outside the healthcare facility.
15 Do not disassemble, repair or modify the equipment without authority.
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 (USA) restricts this device to sale by or on the order of a licensed practitioner."

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 LCD screen display SpO_2, PR, and Pulse bar.
4 2pcs AAA-size alkaline batteries; battery-low indicator.
5 When no 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 (SpO_2) and pulse rate of adult and pediatric patients in hospitals, hospital-type facilities, and home environments. It is not for continuous monitoring.

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.

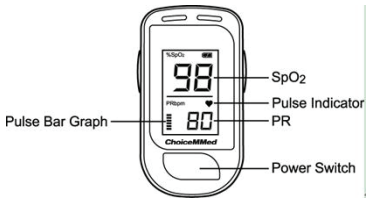


Product Accessories

1. One lanyard
2. Two AAA batteries
3. One user's manual

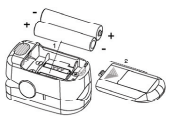
Front Panel

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



Battery Installation

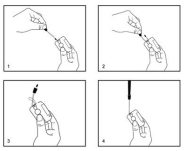
1. Install two AAA batteries into the battery compartment. Match the plus (+) and minus (-) signs in the compartment. If the polarities are not matched, damage may be caused to the oximeter.
2. Slide the battery door cover horizontally along the arrow shown as the picture.



Notes:
Please remove the batteries if the pulse oximeter will not be used for long periods of time.

Using the Lanyard

1. Thread thinner end of the lanyard through the loop.
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.

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 -20℃～+55℃ 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.

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.

Specifications

1. Display Type
LCD display

2. SpO_2
Display range: 35%～100%
Measurement range: 70～100%
Accuracy: 70-100%±2digits; 0%～69% no definition
Resolution: 1%

3. Pulse Rate
Display range: 30～250BPM
Measure range: 30～250 BPM
Accuracy: 30～99bpm, ±2bpm; 100～250bpm, ±2%
Resolution: 1BPM

4. Probe LED Specifications

	Wavelength	Radiant Power
RED	660±2nm	1.8mW
IR	905±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 25mA

Power indication:

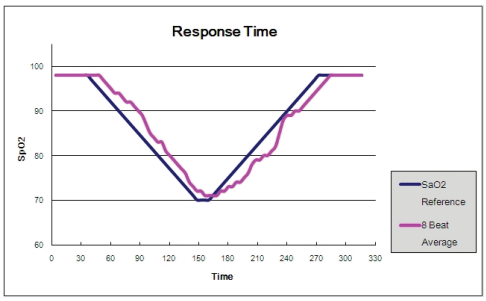
Battery Life: Two AAA 1.5V, 800mAh alkaline batteries could be continuously operated as long as 24 hours.

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

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As shown in the following figure.
Response time of slower average is 12.4s.



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;
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

Guidance and Manufacturer's declaration - electromagnetic emission		
The MD300C15D-H Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of MD300C15D-H Pulse Oximeter should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic Environment – guidance**
RF emissions CISPR 11	Group 1	The MD300C15D-H 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.
RF emissions CISPR 11	Class B	The pulse Oximeter (MD300C15D-H) 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.
Harmonic emissions IEC 61000-3-2	Not Applicable	
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 MD300C15D-H Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the MD300C15D-H 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%.
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.

Guidance and Manufacturer's declaration – electromagnetic immunity-
For all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and Manufacturer's declaration - electromagnetic immunity			
The MD300C15D-H Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the MD300C15D-H 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 Pulse Oximeter (MD300C15D-H), 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 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 station 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 Pulse Oximeter (MD300C15D-H) should be observed to verify normal operation. If abnormal performance is observed, additional measurements may be necessary, such as reorienting of the relocating the Pulse Oximeter (MD300C15D-H).
b Over the frequency range 150 kHz to 80 MHz, fields strengths should be less than 3 V/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 *Pulse Oximeter (MD300C15D-H)*
The *Pulse Oximeter (MD300C15D-H)* is intended for use in electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *Pulse Oximeter (MD300C15D-H)* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *Pulse Oximeter (MD300C15D-H)* as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power 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	0.1167	0.2334
0.1	0.3689	0.7378
1	1.1667	2.3334
10	3.6893	7.3786
100	11.6667	23.3334

For transmitters rated at a maximum output power not listed above, the recommended separation distanced 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 can not be shown normally	1. Finger is not inserted correctly 2. Patient's Oxyhemoglobin value is too low to be measured	1.Retry by inserting the finger 2. 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. Finger is trembling or patient's body is in movement status.	1. Retry by inserting the finger 2. Try not to move
The oximeter can not be powered on	1. Power of batteries might be inadequate or not be there at all. 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. Power quantity of the batteries is started being inadequate	1. Normal 2. Replace the batteries

Symbol Definitions

Symbol	Definition
	Type BF applied part.
	Caution
	Follow operating instructions
IPX1	Protected against dripping water.
%SpO_2	Oxygen saturation
PRbpm	Pulse rate (BPM)
	Low power indication
SpO_2	No SpO_2 Alarm
SN	Serial No.
	Storage temperature and relative humidity
	Manufacturer's information
	Date of Manufacture

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.

Manufactured by:
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Issue Date: 20/December 2012

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