

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 small size, low power consumption, convenient operation and portability. It is only necessary for a patient to put one of his fingers into the fingertip photoelectric sensor for diagnosis, and a display screen will show oxygen saturation.

PARTS LIST

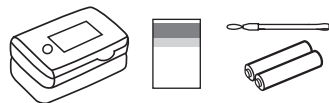


Fig. 1

Complete set (fig. 1):
Main Unit – 1 pcs.,
Instruction Manual with Warranty Card – 1 pcs.,
Hang Lace – 1 pcs.,
batteries – 2 pcs.

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 glow and near-infrared zones.

Operation principle of the instrument is 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 glow 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 OLED display through process in electronic circuits and microprocessor shown.

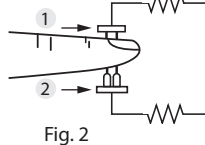


Fig. 2

Diagram of Operation Principle

1. Red and Infrared-ray Receipt Tube.
2. Red and Infrared-ray Emission Tube. (fig.2)

PRECAUTIONS FOR USE

1. Do not use the pulse oximeter in an MRI or CT environment.
2. Do not use the pulse oximeter in situations where alarms are required.
3. Explosion hazard: Do not use the pulse oximeter in an explosive atmosphere.
4. 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.
5. Check the pulse oximeter sensor application site frequently to determine the positioning of the sensor and circulation and skin sensitivity of the patient.
6. Do not stretch the adhesive tape while applying the pulse oximeter sensor. This may cause inaccurate readings or skin blisters.
7. Before use, carefully read the Instruction manual.
8. The pulse oximeter has no SpO2 alarms; it is not for continuous monitoring, as indicated by the symbol.
9. Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.
10. Inaccurate measurements may be caused by:
 - autoclaving, ethylene oxide sterilizing, or immersing the sensors in liquid may cause inaccurate readings.
 - significant levels of dysfunctional hemoglobins (such as carbonxy- hemoglobin or methemoglobin)
 - intravascular dyes such as indocyanine green or methylene blue
 - high ambient light. Shield the sensor area (with a surgical towel, or direct sunlight, for example) if necessary.
 - excessive patient movement
 - high-frequency electrosurgical interference
 - venous pulsations
 - placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
 - hypotension, severe vasoconstriction, severe anemia, or hypothermia
 - fingernail polish or false fingernails may cause inaccurate SpO2 readings.
 - the patient is in cardiac arrest or is in shock.
11. The pulse oximeter can be used before or after sports. Operation in sport procedure is not recommended)
12. Please follow the law of the local government to deal with used battery.

BATTERY INSTALLATION

1. Shift the bottom panel and then open it (fig.3a).
2. Put the two AAA batteries into battery cassette in correct polarities (fig. 3b).
3. Close the bottom panel (fig. 3c).

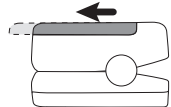


Fig. 3a

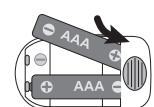


Fig. 3b

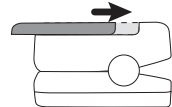


Fig. 3c

WARNING!

Replace batteries when low power indicator " " is lit or if after pressing Power button there is no indication on display.

Please remove the battery if the Oximeter will not be used for a long time.

Do not use re-chargable batteries.

HOW TO USE

WARNING! Do not tremble the hand with oximeter during measurement

1. Open the clamp (fig. 4)
2. Plug one of fingers into rubber hole of the oximeter (it is best to plug the finger thoroughly) before releasing the clamp.
3. Press the button once on front panel.

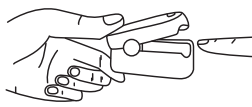
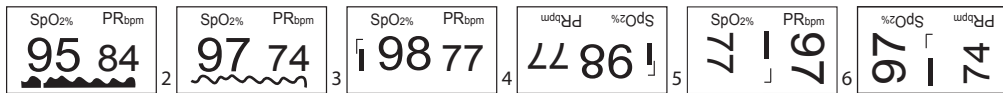


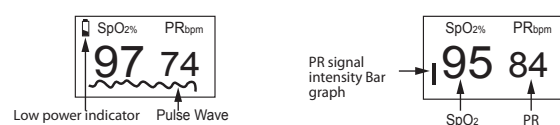
Fig. 4

DISPLAY MODES.

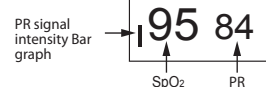
After turning on the oximeter, each time you press the power switch, the oximeter will switch to another display mode, there are 6 display modes shown as follows:



4. Read correspondent data from display screen:



Low power indicator Pulse Wave



PR signal intensity Bar graph

HANG LACE INSTALLATION

1. Thread thinner end of the hang lace through the hanging hole (fig. 5).
2. Thread thicker end of the lace through the threaded end before pulling it tightly.

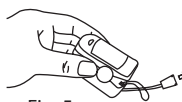


Fig. 5

MAINTENANCE AND STORAGE

Replace the batteries timely when indicator " " is lit.

Clean surface of the fingertip oximeter before it is used in diagnosis for patients.

Remove the batteries inside the battery cassette if the Oximeter will not be operated for a long time.

It is best to preserve the product in a place where ambient temperatures -20-55° and humidity is <93%.

It is recommended that the product should be kept in a dry environment anytime. A wet ambient might affect its lifetime and even might damage the product.

Please follow the law of the local government to deal with used battery.

SPECIFICATION

Model	MD300C23
Display	OLED display
SpO ₂	
measurement range	70% - 100%
accuracy	±2%
Pulse Rate	
measurement range	30 - 250 bpm
accuracy	30 - 99 bpm - ±2 bpm; 100 - 250 bpm - ±2%
Measurement wavelengths	
red	660 nm
infrared	905 nm
Power source	2 x 1,5V AAA (LR03)
Battery set operating period	> 30 hrs.
Max. power consumption	0.075 W
Applicable finger circumference	20-75 mm
Operating conditions:	
Temperature	5°C ~ 40°C
Relative humidity	<80%
Storage and transportation environment:	
Temperature	-25°C ~ 70°C
Relative humidity	< 93%
Net Weight (without batteries)	31g
External dimension	58 (L) x 30 (W) x 34 (H) mm.
Date of manufacturing	Manufacturing Date printed on sticker
Country of Origin	PRC
Symbol Definitions	<p> The equipment type is BF</p> <p> Read User manual before use</p> <p> Not for continuous monitoring</p> <p> No critical SpO2 alarm</p> <p> CE marking in conformity with EC directive 93/42/EEC</p>

DECLARATION

This device complies with EMC (IEC 60601-1-2:2001, CISPR 11/A2:2002

(Group 1, Class B), IEC 61000-4-2:2001, IEC 61000-4-3:2002, IEC 61000-4-8:2001).

The materials which user can come into contact have no toxicity and no action on tissues, complying with ISO10993-1,-5,-10.

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GUARANTEE

We grant 2 years guarantee on the product commencing on the date purchase. The guarantee only comes into force if the data of purchase is confirmed by the dealer's stamp and signature on Guarantee Card.

This warranty does not extend to, and will be void in respect of any products which have been subjected to misuse, neglect, fire, improper modification, use in violation of the instructions furnished by us repaired by an unauthorized third party.

TROUBLESHOOTING

Problems	Possible reason	Solution
SpO ₂ or PR can not be shown normally	1. Finger is not plugged correctly 2. Patient's Oxyhemoglobin value is too low to be measured	1. Retry by plugging the finger 2. Measure other patients to make sure that no problem exists in the product. Go to a hospital in a timely manner for an exact diagnosis.
SpO ₂ or PR is shown unstably	1. Finger might not be plugged deep enough 2. Finger is trembling or patient's body is in movement status	1. Retry by plugging 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 center
Indication lamps are suddenly off	1. The product is automatically powered off when no signal is detected longer than 8 seconds 2. Power is too low.	1. Normal 2. Replace the batteries
"Error3" or "Error4" Displayed on screen	1. Low power 2. Receiving tube being shielded or damaged together with broken connector. 3. Mechanical Misplace for receive-emission tube 4. Amp circuit is malfunction.	1. Change new battery 2. Please contact with local customer service center 3. Please contact with local customer service center 4. Please contact with local customer service center
"Error7" displayed on screen	1. Low power 2. Emission tube damaged. 3. Current control circuit is malfunction.	1. Change battery 2. Contact with local customer service center 3. Contact with local customer service center

TECHNICAL DESCRIPTION FOR ELECTROMAGNETIC DISTURBANCES

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS-FOR ALL EQUIPMENT AND SYSTEMS

Guidance and Manufacturer's declaration - electromagnetic emission		
The MD300C23 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of MD300C23 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 MD300C23 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 (MD300C23) 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 MD300C23 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the MD300C23 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	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic 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 MD300C23 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the MD300C23 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 (MD300C23), 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, 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 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 (MD300C23) 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 (MD300C23).			
b Over the frequency range 150 kHz to 80 MHz, field 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 (MD300C23)		
The Pulse Oximeter (MD300C23) is intended for use in electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Pulse Oximeter (MD300C23) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pulse Oximeter (MD300C23) as recommended below, according to the maximum output power of the communications equipment.		
Rated maximum out put 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 distance 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.		

For more information please visit
WWW.LITLEDOTOR.SG



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GUARANTEE CARD		
MODEL	Serial №	
Name and address of retailer		Retailer stamp
I confirm that surface appearance and complete set of device is OK:		
Date of Purchase	Purchaser sign	Purchaser sign

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