ENG

INSTRUCTION MANUAL

Fingertip Pulse Oximeter model MD300C23

Little Doctor®

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

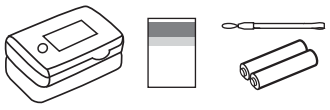


Fig. 1

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.

Diagram of Operation Principle

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

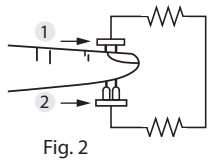


Fig. 2

INTENDED USE

The Fingertip 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 and child patients in hospitals, hospital-type facilities and homecare.

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.
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 to the measurement.
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.

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

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).

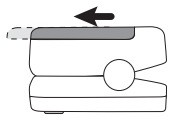


Fig. 3a

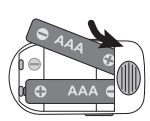


Fig. 3b

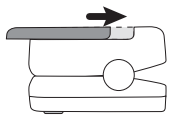


Fig. 3c

⚠ WARNING!

Replace batteries when low power indncator "▭" 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 measuremrnt

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.

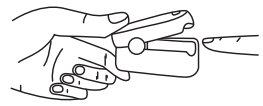
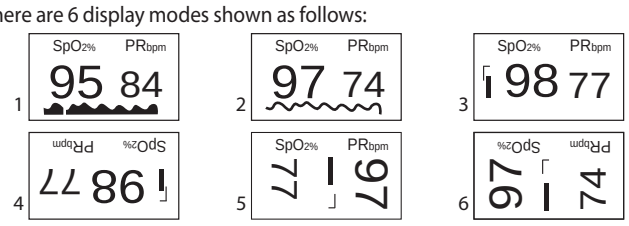


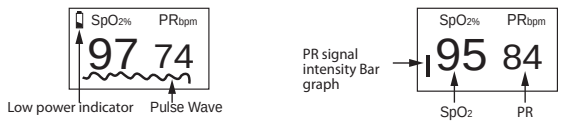
Fig. 4

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:



BRIGHTNESS ADJUSTMENT

When you press the power switch for a long time (more than one second), the brightness of the oximeter will be changed by degrees, there are 10 levels on brightness; the default level is level four.

HANG LACE INSTALLATION

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

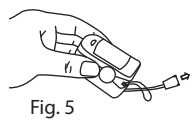


Fig. 5

MAINTENANCE AND STORAGE

Replace the batteries timely when indncator "▭" 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 -20-55r 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 govern ment 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 Relative humidity	 5ºC ~ 40ºC <80%
Storage and transportation environment: Temperature Relative humidity	 -20 ºC ~ 55ºC < 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:

SYMBOL	DEFINITION	SYMBOL	DEFINITION
	Type BF applied part.		Conformity to WEEE Directive
IP22	Protected against dripping water.		Attention
PR bpm	Pulse rate (BPM)	**%SpO2**	Oxygen saturation
	No SpO2 Alarm		Low power indication
	Storage temperature and relative humidity	SN	Serial No.
	Date of Manufacture		Follow instructions for use
CE 0123	European Union approval	EC REP	Authorized representative in the European community
	Sign of type approval of measuring instruments		Manufacturer's information

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.

Manufactured under control and for Little Doctor International (S) Pte. Ltd., 7500A, Beach Road, 11-313 The Plaza 199591, Singapore. Yishun Central P.O. Box 9293 Singapore 917699.

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GUARANTEE

We grant 2 years guarantee on the product commencing on the date purchase. The guarantee only comes info 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.

TROUBLESHOUTING

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 centre
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

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	10 V/m 80% AM 1kHz
	380 – 390 MHz	27 V/m Pulse mod. 18Hz
	430 – 470 MHz	28 V/m FM±5Hz deviation 1kHz sine
	704 – 787 MHz	9 V/m Pulse mod. 217Hz
	800 – 960 MHz	28 V/m Pulse mod. 18Hz
	1.7 – 1.99 GHz	28 V/m Pulse mod. 217Hz
	2.4 – 2.57 GHz	28 V/m Pulse mod. 217Hz
	5.1 – 5.8 GHz	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.		

For more information please visit
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CE 0123

GUARANTEE CARD

MD300C23 *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*

E595/2111/4_ENG