OPERATOR'S MANUAL

V4.0C1

Fingertip Pulse Oximeter

CE 0123

MD300C1

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.

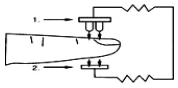
The fingertip pulse Oximeter features small size, low power consumption, convenient operation and portability. It is only necessary for a patient to put one of his fingers into the fingertip photoelectric sensor for diagnosis, and a display screen will show oxygen saturation. It has been proven in clinical 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 glow 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 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 the Oximeter's display through process in electronic circuits and microprocessor shown on the Oximeter's display through electronic circuits and a microprocessor.

Diagram of Operation Principle

1. Red and Infrared-ray Emission Tube
2. Red and Infrared-ray Receipt Tube



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. The device has no alarms.

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 manual.

8 The pulse oximeter has no SpO_2 alarms; it is not for continuous monitoring.

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.

11 Significant levels of dysfunctional hemoglobins (such as carbonxy- hemoglobin or methemoglobin) may affect the readings.

12 Intravascular dyes such as indocyanine green or methylene blue

13 SpO_2 measurements may be adversely affected in the presence of high ambient light. Shield the sensor area (with a surgical towel, or direct sunlight, for example) if necessary.

14 Excessive patient movement may cause inaccurate readings.

15 High-frequency electrosurgical interference may cause inaccurate readings.

16 Venous pulsations may cause inaccurate readings.

17 Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.

18 The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.

19 The patient is in cardiac arrest or is in shock.

20 Fingernail polish or false fingernails may cause inaccurate SpO_2 readings.

Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.

Product Properties

1 Operation of the product is simple and convenient.

2 The product is small in volume, light in weight and convenient in carrying.

3 Power consumption of the product is low and the two AAA batteries can be operated continuously for 30 hours.

4 A low voltage warning will be indicated in visual window when battery voltage is so low that normal operation of the oximeter might be influenced.

5 The product will automatically be powered off when no signal is in the product for longer than 8 seconds.

Product Operation Scope

Fingertip PULSE OXIMETER is a portable non-invasive, spot-check, oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult and pediatric patient at home, and hospital (including clinical use in internist/surgery, Anesthesia, intensive care etc). It is not for continuously monitoring.

The PULSE OXIMETER requires no routine calibration or maintenance other than replacement of batteries.

Operation Instructions

1 Install two AAA batteries into battery cassette before closing its cover.

2 Place clamp over finger nail as the following diagram.

3 Insert one finger into rubber hole of the Oximeter fully.

4 Press the switch for one time on front panel.

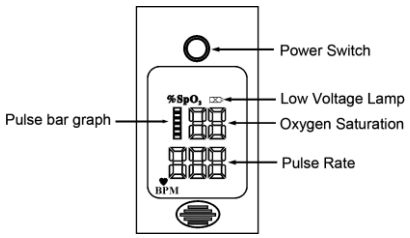
5 Finger and body should not tremble during measuring.

6 Read corresponding data on the display screen.

Note: Please use medical alcohol to clean the rubber, inside the Oximeter, that touches the finger. Also, clean the test finger with alcohol before and after each test. (The rubber inside of the Oximeter is medical rubber, which has no toxins, and is not harmful to the skin).

When your finger is inserted into the Oximeter, your nail surface must be upward.

Operation Instructions



The Pulse bar graph displays corresponding with the patient's pulse beat. The height of the bar graph shows the patient's pulse strength.

Product Accessories

1. One strap
2. Two batteries
3. One user's manual

Battery Installation

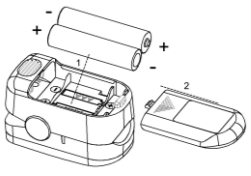
1. Put the two AAA batteries into battery compartment in correct polarities.
2. Push the battery cover horizontally along the arrow shown as below:

Notes:

✧ Battery polarities should be correctly installed. Otherwise, damage may be caused to the device.

✧ Please put in or remove batteries in right order, or may cause damage to the device bracket.

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



Strap Installation

1. Thread thinner end of the strap through the loop.
2. Thread thicker end of the strap through the threaded end before pulling it tightly.

Calibrating the pulse oximeter

1. The functional tester cannot be used to assess the accuracy of the oximeter.
2. The test methods used to establish the SpO_2 accuracy is clinical testing. The oximeter used to measure the arterial haemoglobin oxygen saturation levels and these levels are to be compared to the levels determined from arterial blood sampling with a CO-oximeter.
3. Index 2 made by Bioteck company is a function tester. Set Tech to 1, R curve to 2, then user can use this particular calibration curve to measure the oximeter.

Maintenance and Storage

1. Replace the batteries in time 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 inside the battery cassette if the Oximeter will not be operated for a long time.
4. It is best to preserve the product in a place where ambient temperatures is -20℃～55℃(-4～131℉) and relative humidity is ≤93%.
5. 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.
6. Please follow the law of the local government to deal with used battery.

Detailed descriptions of product functions

1. Display Type: LED

2. SpO_2:
Measurement range: 70-99%
Accuracy: 80%-99%, ±2%; 70%-80%,±3%; ≤69% no definition.

3. Pulse Rate:
Measure range: 30-235 BPM
Accuracy: 30~99bpm, ±2bpm; 100~235bpm, ±2%
Pulse Intensity: Bargraph Indicator

4. Power Requirements:
Two AAA alkaline Batteries
Power consumption: Less than 40mA
Low power indication: 
Battery Life: Two AAA 1.5V, 600mAh alkaline batteries could be continuously operated as long as 30 hours.

5. Dimension:
Length: 56mm～62mm
Width: 32mm～38mm
Height: 34mm～38mm
Weight: 45g～60g (including two AAA batteries)

6. Environment Requirements:
Operation Temperature: 5～40℃
Storage Temperature: -20～55℃
Ambient Humidity: ≤80%, no condensation in operation.
≤93%, no condensation in storage

7. Measurement Performance in Low Perfusion Condition: required the test equipment (BIO-TEK INDEX Pulse Oximeter tester) the pulse wave is available without failure when the simulation pulse wave amplitude is at 6%.

8. Interference Resistance Capacity against Ambient Light: Device works normally when mixed noise produced by BIO-TEK INDEX Pulse Oximeter tester.

Declaration

EMC of this product complies with IEC60601-1-2 standard.

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

Guidance and manufacturer's declaration – electromagnetic emissions-for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emission

The *Pulse Oximeter* is intended for use in the electromagnetic environment specified below. The customer or the user of the *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 *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 emission CISPR 11	Class B	The *Pulse Oximeter* 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.

Possible Problems and resolutions

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 is existing 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
"Error3" or "Error4" is 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 malfunctions.	1. Change batteries 2. Please contact local customer service center 3. Please contact local customer service center 4 Please contact local customer service center
"Error7" is displayed on screen	1. Low power 2. Emission tube damaged. 3. Current control circuit malfunctions.	1 Please change battery 2 Please contact local customer service center 3 Please contact local customer service center

Symbol Definitions

Symbol	Definition
	Type BF applied part.
	Attention, consult accompanying documents.
% SpO_2	Oxygen saturation
BPM	Heart rate (BPM)
	Low power indication
	No SpO_2 Alarm
	Power switch
SN	Serial No.

Applicable models

MD300C1 MD300C1C MD300C12 MD300C12-P MD300C13 MD300C14
MD300C1-E MD300C15 MD300C16 MD300C17 MD300C18 MD300C19
MD300C10 MD300C1A MD300C1B MD300C1D MD300C1E

Note：The illustration used in this manual may differ slightly from the appearance of the actual product.

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