OPERATOR'S MANUAL

V2.0C63

Fingertip Pulse Oximeter

CE 0123

MD300C63

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.

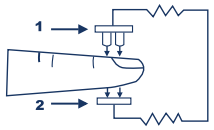
The fingertip pulse Oximeter features small size, low power consumption, convenient operation and portability. It is only necessary for a patient to put one of his fingers into the fingertip photoelectric sensor for diagnosis, and a display screen will show oxygen saturation. It has been proven in clinical 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.
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, 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.
11. Significant levels of dysfunctional hemoglobins (such as carbonxy- hemoglobin or methemoglobin)
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
15. Venous pulsations
16. Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
17. The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia
18. The patient is in cardiac arrest or is in shock.
19. 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.
4. 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

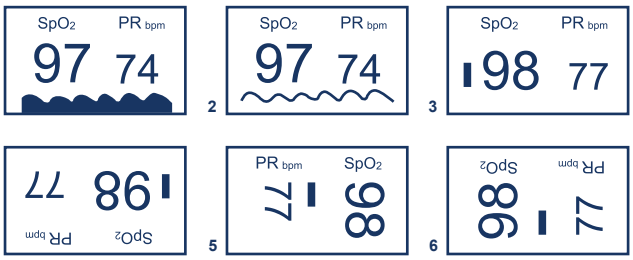
Fingertip PULSE OXIMETER is a portable non-invasive, spot-check, oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult and pediatric patient at home, and hospital (including clinical use in internist/surgery, Anesthesia, intensive care monitoring etc). It's not for continuously monitoring.

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

Operation Instructions

1. Installing two AAA batteries correctly.
2. Nip the clamp as diagram.
3. Insert one finger into rubber hole of the Oximeter fully.
4. Press the switch button once on front panel.
5. Your finger and body do not tremble during measuring.
6. Read corresponding data from display screen.
7. Six display modes

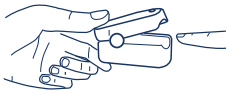
After turning on the Oximeter, each time you press the power switch, the Oximeter will switch to another display mode. There are 6 display modes shown as follows:



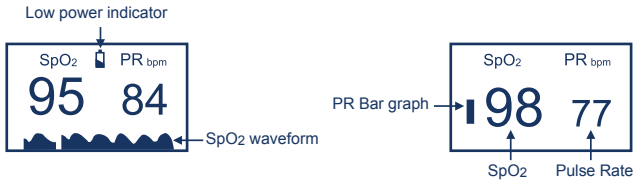
When you press the power switch for a long time (more than one second), the brightness of the Oximeter will be changed by degrees, there are 10 levels on brightness; the default is level four.

NOTE: Please use the medical alcohol to clean the rubber touching the finger inside of Oximeter, and clean the test finger using alcohol before and after each use. (The rubber inside of the Oximeter belongs to medical rubber, which has no toxin and no harm to the skin of human being).

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



Brief Description of Front Panel



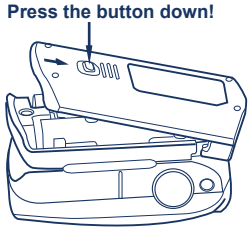
The PR Bar graph displays corresponding with the patient's pulse beat. The height of the bar graph shows the patient's pulse strength.

Product Accessories

1. One lanyard
2. Two batteries
3. One user manual

Battery Installation

1. Put the two AAA batteries into battery cassette with correct polarities.
2. Press the button down on the rear panel and push the battery cover horizontally along the arrow shown as below:



Notes:

- Battery polarities must be correctly installed. Otherwise, damage might be caused to device.
- Please put or remove batteries in right order, or is likely to damage the device bracket.
- Please remove batteries if the Oximeter will not be used for a long time.

Lanyard Installation

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

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 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 temperature –20°C~55°C and humidity is <93% (no condensation).
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 batteries.

Calibration

1. The functional tester cannot be used to assess the accuracy of the Oximeter.
2. Index 2 that made by Bioteck company is a function tester. Set Tech to 1, R curve to 2, and then a user can use this particular calibration curve to measure the Oximeter.
3. 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.

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.

Detailed descriptions of product functions

1. Display Type: OLED display

2. SpO_2:
Measurement range: 70-100%
Accuracy: 70%-100%, ±3%; ≤69% no definition.

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

4. Power Requirements:
Two AAA alkaline Batteries
Power consumption: Less than 30mA
Low power indication:
Battery Life: Two AAA 1.5V, 800mAh alkaline batteries could be continuously operated as long as 30 hours.

5. Dimension:
Length: 58mm
Width: 32mm
Height: 37mm
Weight: 33g (without batteries)

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

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 0.6%.

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

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

Guidance and manufacture's declaration – electromagnetic emission

The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer of the user of the Pulse Oximeter should assure that it is used in such and 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.

Symbol Definitions

Symbol	Definition	Symbol	Definition
	Type BF applied part		Low power indication
	Attention, consult accompanying documents.	SpO_2	Not for continuous monitoring
SpO_2%	Oxygen saturation	SN	Serial No.
BPM	Heart rate (BPM)		

Possible Problems and resolutions

Problems	Possible reason	Solution
SpO_2 or PR is not displayed.	1. Finger is not plugged correctly 2. Patient's SpO_2 value is too low to be measured.	1. Retry by plugging the finger 2. Try some more times, If you can make sure about no problem existing in the product. Please go to a hospital timely for exact diagnosis
SpO_2 or PR reading is unstable.	1. Finger is not inserted correctly. 2. Excessive patient movement.	1. Re-insert the finger. 2. Restrict patient/ oximeter movement.
The Oximeter can not be powered on.	1. No battery or low power of battery.l 2. Batteries might be installed incorrectly 3. The Oximeter might be damaged	1. Replace batteries. 2. Reinstall batteries. 3. Contact with local customer service centre.
Display suddenly turns off.	1. The oximeter will automatically power off when no signal is detected longer than 8 seconds. 2. Battery power is low.	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 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" is displayed on screen	1. Low power 2. Emission tube damaged. 3. Current control circuit malfunction.	1. Please change battery 2. Please contact with local customer service center 3. Please contact with local customer service center

Applicable models

MD300C63	MD300C631	MD300C632	MD300C633	MD300C634	MD300C635
MD300C636	MD300C637	MD300C638	MD300C639	MD300C630	MD300C63A
MD300C63B	MD300C63C	MD300C63D	MD300C63E	MD300C63F	MD300C63H
MD300C63I	MD300C63J				

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