OPERATOR'S MANUAL

V1.0CF3

Fingertip Pulse Oximeter

CE 0123

MD300CF3

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 Receiving Tube

Precautions for use

1. Do not use the pulse oximeter in an MRI or CT environment or in the presence of a FLAMMABLE ANAESTHETIC MIXTURE.
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 may cause inaccurate readings.
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 affect the readings.
15. Venous pulsations may affect the readings.
16. High-frequency electrosurgical interference may affect the 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 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 originally-equipped 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 and 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 correctly.
2. Place clamp over finger nail per diagram.
3. Insert one finger into rubber hole of the Oximeter fully.
4. Press the switch button once on front panel.
5. Finger and body should not tremble during measuring.
6. Read correspondent 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 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.

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

8. **PR tone modulation function**
9. **Adjustable brightness**
10. **Alarm**

Alarm range:
SpO_2:<90
Pulse rate: <60 or >100

Visual alarm: The measuring value will be flashing when it is through over the alarm limitation.

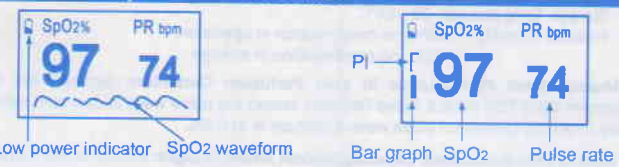
Audio alarm: The audible alarms can be heard if there is no silence. The buzzer will beep shortly for two times when the value exceeds the alarm limitation.

Alarm silence:
When the audio alarm occurs, press the button and then the Oximeter will enter into the "alarm silence mode" for 30 seconds, and then there is only the visual alarm. This silence operating has only effect on the alarm sound not on the pulse rate sound.
In the silence mode, press the button, and then the display mode will be changed.
It will exit the silence mode automatically when a new alarm occurs or the value is in the normal range again.

NOTE:

- Please use the medical alcohol to clean the rubber touching the finger inside of Oximeter, and clean the test sensor using alcohol before and after operation. (The rubber inside of the Oximeter is medical rubber, which has no toxin, and no harm to the skin).
- The internal spring provides the correct pressure; additional pressure may cause inaccurate readings.
- If you are not getting a pulse rate reading and your pulse quality is weak, warm the finger or reposition to another finger.
- It is not recommended that measure when the power low icon appears. The measurement accuracy will be affected when measuring at low power.

Brief Description of Front Panel



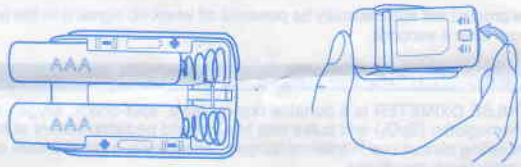
The PR Bar graph displays corresponding with the patient's pulse beat. The height of the bar graph shows the patient's pulse strength.

Product Accessories

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

Battery Installation

1. Put the two AAA batteries into battery cassette 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 batteries if the Oximeter will not be used for a long time.

Hang Lace Installation

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

Maintenance and Storage

1. Replace the batteries timely 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 from 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 -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.

Calibrating the pulse oximeter

1. The functional tester cannot be used to assess the accuracy of the oximeter. And the pulse oximeter requires no calibration or periodic maintenance other than battery replacement.
2. 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.
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.

Detailed descriptions of product functions

1. Display Type: OLED display

2.Data update time: <15s

3.LED Wavelengths:

	Wavelength	Radiant Power
RED	660±2nm	1.8mW
IR	940±10nm	2.0mW

4. SpO_2:

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

5. Pulse Rate:

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

6. Power Requirements:

Two AAA alkaline Batteries
INTERNALLY POWERED EQUIPMENT
Power capacity: 800mAh
Power consumption: Less than 40mA
Battery Life: about 15 hours
Low power indication: (Battery Voltage <2.3V)

7. Dimension:

Length: 60mm
Width: 35mm
Height: 34mm
Weight: 35g (without batteries)

8. Environment Requirements:

Operation Temperature: 5~40℃
Storage Temperature: -20~55℃
Relative humidity: ≤80%, no condensation in operation.
≤93%, no condensation in storage

9. 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%.

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

NOTE: The specifications are subject to changes without prior notice.

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 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 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 plugged correctly 2. Patient's Oxyhemoglobin value is too low to be measured	1. Retry by plugging 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 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 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	Symbol	Definition
	Type BF applied part.		Attention, consult accompanying documents.
SpO_2%	Arterial Oxygen saturation	PR bpm	Pulse Rate (bpm)
	Low power indication		No SpO_2 alarm
	CATEGORY NON-AP EQUIPMENT		Date of Manufacture
SN	Serial Number	IPX1	Drip-proof

Applicable models

MD300CF3 MD300CF31 MD300CF32 MD300CF33

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

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