Fingertip Pulse Oximeter

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, asthma, 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 fingertips 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 fingertips 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 (Hb) 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 Reception 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 SpO2 alarms; it is not for continuous monitoring.
9. Prolonged use or the patient’s condition may require changing the sensor site
10. Inaccurate measurements may be caused by autodrying, ethylene oxide sterilizing, or immersing the sensors in liquid.
11. Significant levels of dysfunctional hemoglobins (such as carbonyl- hemoglobin or methemoglobin) may cause inaccurate readings.
12. Intraocular dyes such as indocyanine green or methylene blue.
13. SpO2 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. Venous pulsations may cause inaccurate readings.
16. High-frequency electrosurgical interference may cause inaccurate readings.
17. Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravenous 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 SpO2 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 (SpO2) 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 compartment correctly.
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 once on the 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:

- SpO2
- PR
- 95 84
- 97 74
- 198 77
- 97 74

When you press and hold 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.

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

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

Brief Description of Front Panel

Oxygen Saturation Pulse Rate Power Low Indicator

- SpO2
- PR
- 95 84
- 97 74
- 198 77

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 best.
- Please remove the batteries if the Oximeter will not be used for a long time.
**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 SpO₂ accuracy is clinical testing. The oximeter used to measure the arterial hemoglobin 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°C~55°C 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: OLED
2. SpO₂:
   - Measurement range: 70-99%
   - Accuracy: 80%-99%, ±2%, 70%-80%, ±3%, <69% no definition.
3. Pulse Rate:
   - Measure range: 30-235 BPM
   - Accuracy: ±0.5 BPM, ±1 BPM, ±2 BPM, ±4 BPM
4. Power Requirements:
   - Two AAA alkaline Batteries
   - Power consumption: Less than 40mA
   - Low power indication: 

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°C
   - Storage Temperature: -20~55°C
   - Ambient Humidity: <80%, no condensation, except when the oximeter is used for more than 40°C or <85% when in such an environment.

**Possible Problems and resolutions**

<table>
<thead>
<tr>
<th>Problems</th>
<th>Possible reason</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>SpO₂ or PR can not be shown normally</td>
<td>1. Finger is not correctly inserted. 2. Patient's hemoglobin oxygen value is too low to be measured.</td>
<td>1. Try 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.</td>
</tr>
<tr>
<td>SpO₂ or PR is shown unstably</td>
<td>1. Finger might not be inserted deep enough. 2. Finger is tumbling or patient's body is in movement.</td>
<td>1. Try by inserting the finger. 2. Try not to move</td>
</tr>
<tr>
<td>The Oximeter can not be powered on</td>
<td>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.</td>
<td>1. Please replace batteries. 2. Please reinstall the batteries. 3. Please contact local customer service center.</td>
</tr>
<tr>
<td>Indication lamps are suddenly off</td>
<td>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.</td>
<td>1. Normal. 2. Replace the batteries.</td>
</tr>
<tr>
<td>&quot;Error3&quot; or &quot;Error4&quot; is displayed on screen</td>
<td>1. Low power. 2. Receiving tube being shielded or damaged together with broken connector. 3. Mechanical Mispalce for receive-emission tube. 4. Amp circuit malfunctions.</td>
<td>1. Change batteries. 2. Please contact local customer service center. 3. Please contact local customer service center. 4. Please contact local customer service center.</td>
</tr>
<tr>
<td>&quot;Error7&quot; is displayed on screen</td>
<td>1. Low power. 2. Emission tube damaged. 3. Current control circuit malfunctions.</td>
<td>1. Please change battery. 2. Please contact local customer service center. 3. Please contact local customer service center.</td>
</tr>
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**Symbol Definitions**

<table>
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<tr>
<td>Type BF applied part.</td>
<td>Attention, consult accompanying documents.</td>
</tr>
<tr>
<td>Oxygen saturation</td>
<td>Heat rate (BPM)</td>
</tr>
<tr>
<td>Not for continuous monitoring</td>
<td></td>
</tr>
<tr>
<td>Serial No.</td>
<td></td>
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**Applicable models**

- MD300C2
- MD300C20
- MD300C23
- MD300C24
- MD300C21
- MD300C21C
- MD300C21-P
- MD300C22
- MD300C23
- MD300C24
- MD300C25
- MD300C26
- MD300C28
- MD300C29
- MD300C20
- MD300C2A
- MD300C2B
- MD300C2D
- MD300C2E

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

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