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 light (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 SpO2 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 carboxy- hemoglobin or methemoglobin) may affect the readings.
12. Intravascular 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. 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 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 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

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 SpO2 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 Biotecnk 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.

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### 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 ({eq}4~131°F\) 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.

### Technical Specifications

1. Display Type: LED
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: 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 ~ 65g (including two AAA batteries)
6. Environment Requirements:
   - Operation Temperature: 5 ~ 40°C
   - Storage Temperature: -20 ~ 55°C
   - Ambient Humidity: <= 80%, no condensation in operation.
   - <= 93%, no condensation in storage
7. Measurement Performance in Low Perfusion Condition:
   - Measure range: 70-99%
   - Accuracy: 80%-99%, ±2%; 70%-80%, ±3%; ≤69% no definition.
8. Interference Resistance Capacity against Ambient Light:
   - Device works normally when mixed noise produced by BIO-TEK INDEX Pulse Oximeter tester.

### EMC

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.

### Possible Problems and resolutions

**SpO2 or PR can not be shown normally**

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible reason</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>SpO2 or PR</td>
<td>Finger is not inserted correctly.</td>
<td>Retry by inserting the finger</td>
</tr>
<tr>
<td></td>
<td>Patient’s Oxyhemoglobin value is too low to be measured.</td>
<td>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>
</tbody>
</table>

**SpO2 or PR is shown unstably**

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible reason</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>SpO2 or PR</td>
<td>Finger might not be inserted deep enough.</td>
<td>Retry by inserting the finger</td>
</tr>
<tr>
<td></td>
<td>Finger is trembling or patient’s body is in movement status.</td>
<td>Try to not move</td>
</tr>
</tbody>
</table>

### Symbol Definitions

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>♂</td>
<td>Type BF applied part.</td>
</tr>
<tr>
<td>% SpO2</td>
<td>Oxygen saturation</td>
</tr>
<tr>
<td>%HbO2</td>
<td>HbO2 saturation</td>
</tr>
<tr>
<td>BP</td>
<td>Heart rate (BPM)</td>
</tr>
<tr>
<td>X</td>
<td>Low power indication</td>
</tr>
<tr>
<td>☐</td>
<td>No SpO2 Alarm</td>
</tr>
<tr>
<td>☐</td>
<td>Power switch</td>
</tr>
<tr>
<td>☐</td>
<td>Serial No.</td>
</tr>
</tbody>
</table>

### Applicable models

MD300C1 MD300C1C MD300C12 MD300C1Z MD300C1E MD300C15 MD300C16 MD300C17 MD300C18 MD300C19 MD300C1-E MD300C15 MD300C16 MD300C17 MD300C18 MD300C19 MD300C1-E MD300C15 MD300C16 MD300C17 MD300C18 MD300C19 MD300C1-E MD300C15 MD300C16 MD300C17 MD300C18 MD300C19 MD300C1-E MD300C15 MD300C16 MD300C17 MD300C18 MD300C19 MD300C1-E

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

### Manufactured for

Fabrication Enterprises, Inc.”

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