1. Measurement principle

The oximeter is calibrated to display functional oxygen saturation. The principle of the oximeter is as follows: A data processing formula is established using the Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin(R Hb) and Oxyhemoglobin (O2 Hb) in glow and near-infrared zones. The operation principle of the instrument is Photoelectric Oxyhemoglobin Inspection Technology, which is adopted in accordance with Capacity Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm glow and 940nm near infrared light) can be focused onto human nail tip through a perspective clamp finger-type sensor. A measured signal is obtained by a photosensitive element. This information is shown on two groups of LEDs after being processed through electronic circuits and microprocessor.

2. Specifications for use

- Before use, carefully read the manual
- The operation of Pulse Oximeter may be affected by the use of an electrocautery unit (ESU)
- To ensure the Pulse Oximeter is able to obtain an accurate SpO2 measurement, verify nothing is interfering with the pulse measurement before recording the SpO2 result.
- Do not use the Pulse Oximeter in an MRI or CT environment
- Do not use the Pulse Oximeter in situations where alarms are required. The device has no alarms.
- Explosion hazard: Do not use the Pulse Oximeter in an explosive atmosphere.
- 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.
- Check the Pulse Oximeter Sensor application site frequently to determine the positioning of the sensor and circulation and skin sensitivity of the patient.
- Do not stretch the adhesive tape while applying the Pulse Oximeter Sensor. This may cause inaccurate readings or skin blisters.
- The Pulse Oximeter has no SpO2 alarms, it is not for continuous monitoring, as indicated by the symbol.
- 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.

3. Inaccurate measurements may be caused by

- Sterilization efforts. The device is not intended for sterilization. Use of an autoclave, ethylene oxide immersion or immersion in any liquid may cause inaccurate readings.
- Significant levels of dysfunctional hemoglobins (such as carboxyhemoglobin or methemoglobin)
- Intravascular dyes such as indocyanine green or methylene blue
- Use in high ambient light. SpO2 measurements may be adversely affected in the presence of high ambient light. When in use, the sensor should be shielded if exposed to direct sunlight or intense lighting
- Excessive patient movement
- High frequency electrosurgical interference and defibrillators
- Venous pulsations
- The placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- Patient conditions of hypotension, severe vasoconstriction, severe anemia, or hypothyromia
- Cardiac arrest or shock
- Fingernail polish or false fingernails

4. Technical Specifications

- Display type: OLED display
- Data update time: < 15 s
- PR display range: 30-200 BPM
- SpO2 display range: 0-100%
- SpO2 alarm range: <93% or >107%
- SpO2 waveform: two AAA batteries could be continuously operated as long as 30 hours.
- Optional power source: Two AAA 1.5V alkaline batteries could be continuously operated as long as 30 hours.

5. Product Features

- Power consumption of the product is low and the two originally-equipped two AAA batteries can be operated continuously for 30 hours.
- Low voltage warning will be indicated in visual window when battery voltage is so low that normal operation of the Oximeter might be influenced.
- The product will automatically be powered off when no signal is detected for more than 8 seconds.

6. Product Intended Use

The Pulse Oximeter is a portable non-invasive, spot-check, oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult or pediatric patient at home, or hospital (including clinical use in internal/surgery, anesthesia, intensive care). This oximeter is not intended for continuous monitoring.

The Pulse Oximeter requires no routine calibration or maintenance other than replacement of batteries.

7. Operation Instructions

- Install two AAA batteries into battery cassette before covering its cover.
- Open the clamp as illustrated in the picture below.
- Insert one finger into the rubber tube of the Oximeter (it is best to insert the finger thoroughly) before releasing the clamp.
- Press the switch button once on the front panel.
- Do not move fingers while using the Oximeter.
- Read the data from the display screen.
- Display modes

8. Brief Description of Front Panel

- SpO2
- PR signal intensity Bar graph
- Power Switch
- PR indicator

9. Product Accessories

- Two AAA batteries
- One instruction manual
- One hangable lanyard
- One handstrap
- OneSENSOR

10. Battery Installations

- Put the two AAA batteries into battery cassette in correct polarities.
- Push the battery cover horizontally along the arrow shown as below.

11. Hanging Lace Installations

- Thread thinner end of the lace through the hole and pull tightly.

12. Maintenance and Storage

- Replace the batteries when the low battery voltage indicator is lighted.
- Clean surface of the oximeter after each use.
- Remove the batteries if the Oximeter will not be operated for a long period of time.
- Do not preserve the product in a place where ambient temperatures are between -10-40°C (14-104°F) and humidity is between10%-80%.
- It is recommended that the product should be kept in a dry environment at all times. Moisture could affect the product life and might damage the product.
- Follow local ordinances and recycling instructions regarding disposal or recycling of the batteries.
Cleaning the Pulse Oximeter

Please clean the rubber touching the finger inside of the Oximeter with a soft dampened cloth with 70% isopropyl alcohol, and clean the test finger using alcohol before and after each test. Do not pour or spray any liquids onto the Oximeter, and do not allow any liquids to enter any openings in the device. Allow the Oximeter to dry thoroughly before reusing.

13. Possible Problems and Resolutions

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible reason</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>SpO2% or pulse rate is not displayed normally</td>
<td></td>
<td>1. Finger is not inserted in correctly</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Patient’s SpO2 value is too low to be measured</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Excessive ambient light</td>
</tr>
<tr>
<td>SpO2% or pulse rate is unstable</td>
<td></td>
<td>1. Finger might not be inserted deep enough</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Excessive patient movement</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The Monitor cannot be powered on</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Display powers off</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. The oximeter is automatically powered off when no signal is detected</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. The battery power is too low</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Error 3 or “Error” displayed on screen</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Error 6 means the crytal is failure</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Error 7 means the emission LED or reception dioxide is damaged</td>
</tr>
</tbody>
</table>

14. Declaration

Guidance and Manufacture’s declaration – electromagnetic emissions

- For all EQUIPMENT and SYSTEMS

<table>
<thead>
<tr>
<th>Emission test</th>
<th>Compliance</th>
<th>Electromagnetic Environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>The Pulse Oximeter uses very low RF energy and is not likely to cause interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
<td>The Pulse Oximeter is suitable for use in all establishments, including homes directly connected to a public low-voltage power supply network.</td>
</tr>
<tr>
<td>Voltage fluctuations/</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>flicker emissions</td>
<td>IEC 61000-3-2</td>
<td></td>
</tr>
</tbody>
</table>

Guidance and Manufacture’s declaration – electromagnetic immunity

- For all EQUIPMENT and SYSTEMS

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic Discharge</td>
<td>IEC 61000-4-2</td>
<td>+/- kV contact BUV air</td>
<td>Electrostatic Discharge guidance</td>
</tr>
<tr>
<td>Microwave exposure</td>
<td>IEC 61000-4-8</td>
<td>3A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

15. Symbol Definitions

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
<th>Symbol</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>⚠️</td>
<td>The equipment type is BF</td>
<td>📡</td>
<td>Low battery voltage indicator</td>
</tr>
<tr>
<td>📥</td>
<td>Refer to user manual before application</td>
<td>🛑</td>
<td>Heart rate (BPM)</td>
</tr>
<tr>
<td>SN</td>
<td>Hemoglobin saturation</td>
<td>🌈</td>
<td>Not for continuous monitoring</td>
</tr>
<tr>
<td>BPM</td>
<td>Address</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Manufacturer: Beijing Choice Electronics Technology Co., Ltd
Rm.1127-1128, Bailangyuan Building 8A36 Fuxing Road, Beijing 100039, P.R.China
Tel: 86-10-88203551 88203520
Fax: 86-10-88204632

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Goleta, CA 93117 USA
Tel: 877-446-6436

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended separation distances between portable and mobile RF communications equipment and the Pulse Oximeter

For all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

- For all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

- For all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the Pulse Oximeter

The Pulse Oximeter is intended for use in electromagnetic environment in which radiated RF disturbances are controlled. The user of the Pulse Oximeter may help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pulse Oximeter as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output of the transmitter (W)</th>
<th>Separation distance according to frequency of transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.01</td>
<td>9.2334</td>
</tr>
<tr>
<td>0.1</td>
<td>0.7378</td>
</tr>
<tr>
<td>1</td>
<td>2.3334</td>
</tr>
<tr>
<td>10</td>
<td>7.3786</td>
</tr>
<tr>
<td>100</td>
<td>23.333</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distances in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

\[
\text{Recommended separation distance} = \frac{10}{\sqrt{P}} 
\]

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.