Fingertip Pulse Oximeter

USER MANUAL
Ver.1.0C2

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 body. 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 fingertip pulse oximeter features low power consumption, convenient operation and portability. Place one fingertip into the photoelectric sensor for diagnosis and the pulse rate and oxygen saturation will appear on the display. 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 red 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 wavelengths of light (660nm red 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 electronic circuits and microprocessor shown on the oximeter's display through electronic circuits and a microprocessor.

Diagram of Operation Principle
1. Red-Infared ray Emission Tube
2. Red and Infared-ray Reception Tube

Precautions For Use
1. Before use, carefully read the manual.
2. Operation of the fingertip pulse oximeter may be affected by the use of an electrosurgical unit (ESU).
3. The fingertip pulse oximeter must be able to measure the pulse properly to obtain an accurate SpO2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO2 measurement.
4. Do not use the fingertip pulse oximeter in an MRI or CT environment.
5. Do not use the fingertip oximeter in situations where alarms are required. The device has no alarms. It is not for continuous monitoring.
6. Do not use the fingertip pulse oximeter in an explosive atmosphere.
7. The fingertip 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.
8. In order to ensure correct sensor alignment and skin integrity, the maximum application time at a single site for our device should be less than 4 hours.
9. Do not sterilize the device using autoclaving, ethylene oxide sterilizing, or immersing the device in liquid. The device is not designed for sterilization.
10. Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
11. This equipment complies with IEC 6601-1:2007 for electromagnetic compatibility for medical electrical equipment and/or systems. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device.
12. Portable and mobile RF communications equipment can affect medical electrical equipment.
13. This device is not intended for use during the procedures for which the device facility is being used.
14. This equipment should not be used adjacent to or stacked with other equipment.
15. Do not disassemble, repair or modify the equipment without authority.
16. These materials that contact with the patient’s skin contain medical silicone and ABS plastic enclosure are all pass the ISO10993-5 Tests for invitro cytotoxicity and ISO10993-10 Tests for irritation and delayed-type hypersensitivity.

Inaccurate measurements may be caused by:
1. Significant levels of dysfunctional hemoglobin (such as carboxy - hemoglobin or methemoglobin).
2. Intravascular dyes such as indocyanine green or methylene blue.
3. High ambient light. Shield the sensor area if necessary.
4. Excessive patient movement.
5. High-frequency electrosurgical interference and defibrillators.
6. Venous pulsations.
7. Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
8. The patient has hypertension, severe vasodistraction, severe anemia, or hypothermia.
9. The patient is in cardiac arrest or is in shock.
10. Fingernail polish or false fingernails.
12. Low hemoglobin.

Product Features
1. Simple to operate and convenient to carry.
2. Small volume, light weight and low power consumption.
3. Dual color OLED displays SpO2, PR, Pulse bar, and waveform.
4. Level 1-10 adjustable brightness.
5. 6 display modes.
6. 2pc AAA-size alkaline batteries; battery-low indicator.
7. When no or low signal is detected, the pulse oximeter will power off automatically in 8 seconds.

Intended Use
Fingertip pulse oximeter is a portable non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult and pediatric patients in hospitals, hospital-type facilities, and home environments. It is not for continuous monitoring.

Operation Instructions
1. Install two AAA batteries according to the Battery Installation instructions.
2. Place one of your fingers into the rubber opening of the pulse oximeter.
3. Press the switch button one time on front panel to turn the pulse oximeter on.
4. Keep your hands still for the reading. Do not shake your finger during the test. It is recommended that you do not move your body while taking a reading.
5. Read the data from the display screen.
6. Press the power switch for longer than one second, will adjust the brightness of the oximeter. There are 10 levels of brightness. The default is level four.

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:

Specifications
1. Display Type
   OLED display
2. SpO2
   Display range: 0-99%
   Measurement range: 70-99%
   Accuracy: 70%-99%: ±3%, 0%-69%: no definition
   Resolution: 1%
3. Pulse Rate
   Display range: 0-254BPM
   Measurement range: 30-235 BPM
   Accuracy: ±50bpm, ±30bpm; 100-235bpm: ±2%
   Resolution: 1BPM
4. Probe LED Specifications
   Wavelength: 660±20nm
   Radiant Power: 1.9mW
   IR: 940±10nm
   2.0mW

NOTE: The information about wavelength range can be especially useful to clinicians.
5. Power Requirements
   Two AAA alkaline Batteries
   Power consumption: Less than 30mA
   Battery Life: Two AAA 1.5V, 600mAh alkaline batteries could be continuously operated as long as 30 hours.
6. Environment Requirements
   Operation Temperature: 5~40°C
   Storage Temperature: -20~65°C
7. Equipment Response Time

As shown in the following figure.

Response time of slower average is 15.4s.

8. Classification

According to the type of protection against electric shock: INTERNALLY POWERED EQUIPMENT; according to the degree of protection against electric shock: TYPE BF APPLIED PART; according to the degree of protection against ingress of water: IPX1 according to the mode of operation: CONTINUOUS OPERATION

Declaration

Guidance and Manufacturer’s declaration – electromagnetic emissions - For all EQUIPMENT and SYSTEMS

Guidance and Manufacturer’s declaration - electromagnetic emission
The MD300C2 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the MD300C2 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 MD300C2 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 emissions CISPR 11  Class B          The pulse Oximeter (MD300C2) 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.
Harmatic emissions IEC 61000-3-2 Not Applicable
Voltage fluctuations / interferences IEC 61000-3-3 Not Applicable

Guidance and Manufacturer’s declaration – electromagnetic immunity - For all EQUIPMENT and SYSTEMS

Guidance and Manufacturer’s declaration - electromagnetic immunity
The MD300C2 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the MD300C2 Pulse Oximeter should assure that it is used in such an environment.

Immunity test       IEC 60601 test level       Compliance Level       Electromagnetic Environment – guidance
Electrostatic Discharge (ESD) IEC 61000-4-2 +/- 6kV contact +/- 8kV air +/- 6kV contact +/- 8kV air Power is on or off. Power is on or off. Power is on or off. Power is on or off. Power is on or off. Power is on or off. Power is on or off. Power is on or off.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 3A/m 3A/m Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.

Guidance and Manufacturer’s declaration – electromagnetic immunity - For all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and Manufacturer’s declaration - electromagnetic immunity
The MD300C2 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the MD300C2 Pulse Oximeter should assure that it is used in such an environment.

Immunity test       IEC 60601 test level       Compliance Level       Electromagnetic Environment – guidance
Radiated RF IEC 61000-4-3  3 V/m            3 V/m Portable and mobile RF communications equipment should be used no closer to any part of the Pulse Oximeter (MD300C2), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance

\[ d = \frac{1.2}{P} \] 

80 MHz to 800 MHz

\[ d = \frac{2.3}{P} \] 

800 MHz to 2.5 GHz

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with following symbol:

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

Recommended separation distances between portable and mobile RF communications equipment and Pulse Oximeter (MD300C2)

Recommended separation distances between portable and mobile RF communications equipment and Pulse Oximeter (MD300C2)

The Pulse Oximeter (MD300C2) is intended for use in electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Pulse Oximeter (MD300C2) can prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pulse Oximeter (MD300C2) as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter (W)</th>
<th>Separation distance according to frequency of transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>80 MHz to 800 MHz</td>
<td>( d = \frac{1.2}{P} )</td>
</tr>
<tr>
<td>800 MHz to 2.5 GHz</td>
<td>( d = \frac{2.3}{P} )</td>
</tr>
<tr>
<td>0.01</td>
<td>0.1167</td>
</tr>
<tr>
<td>0.1</td>
<td>0.3689</td>
</tr>
<tr>
<td>1</td>
<td>1.1667</td>
</tr>
<tr>
<td>10</td>
<td>3.6693</td>
</tr>
<tr>
<td>100</td>
<td>11.667</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance 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.

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.

Possible Problems and Solutions

<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>Finger is not inserted correctly</td>
<td>1. Correctly insert your finger.</td>
</tr>
<tr>
<td>Patient’s SpO2 value is too low to be measured</td>
<td></td>
<td>2. There is excessive illumination</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Try some more times.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. If you can make sure no problem exist in the product, please go to a hospital timely for exact diagnosis.</td>
</tr>
<tr>
<td>SpO2 or PR is shown instable</td>
<td>Finger might not be inserted deep enough</td>
<td>1. Correctly insert your finger</td>
</tr>
<tr>
<td></td>
<td>Excessive patient movement</td>
<td>2. Be calmness</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. The oximeter might be damaged</td>
</tr>
<tr>
<td>The oximeter cannot be powered on</td>
<td>No battery of power or battery</td>
<td>1. Please replace battery</td>
</tr>
<tr>
<td></td>
<td>Batteries might be installed incorrectly</td>
<td>2. Please reinstall the batteries</td>
</tr>
<tr>
<td></td>
<td>The oximeter might be damaged</td>
<td>3. Please contact local customer service centre</td>
</tr>
</tbody>
</table>

Indication lamp is suddenly off

1. The product is automatically powered off when no signal is detected longer than 8 seconds.
2. The battery power is too low to work.
3. Please replace battery
4. Replace the batteries
5. Contact the local customer service centre

Error4 and Error3 is displayed on screen

1. Error 4 means the red emission LED is damaged.
2. Error 3 means the red emission LED is damaged.
3. Check the red emission LED
4. Replace the batteries
5. Contact the local customer service centre

Error2 is displayed on screen

1. Error 2 means the screen is failure
2. Please contact local customer service centre

Symbol Definitions

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>BF</td>
<td>Type BF applied part.</td>
</tr>
<tr>
<td>SP02</td>
<td>Attention, consult accompanying documents.</td>
</tr>
<tr>
<td>Pr</td>
<td>Protected against dripping water.</td>
</tr>
<tr>
<td>IPX</td>
<td>Oxygen saturation</td>
</tr>
<tr>
<td>PR</td>
<td>Pulse rate (BPM)</td>
</tr>
<tr>
<td>RPM</td>
<td>Low power indication</td>
</tr>
<tr>
<td>No SP02 Alarm</td>
<td></td>
</tr>
<tr>
<td>SN</td>
<td>Storage temperature and relative humidity</td>
</tr>
<tr>
<td>EN</td>
<td>Manufacturer’s information</td>
</tr>
<tr>
<td>CE</td>
<td>Date of Manufacture</td>
</tr>
<tr>
<td>EEC</td>
<td>European union approval</td>
</tr>
<tr>
<td>SN</td>
<td>Authorized representative in the European community</td>
</tr>
</tbody>
</table>

Notes:

1. The illustrations used in this manual may differ slightly from the appearance of the actual product.
2. The specifications are subject to change without prior notice.

*In collaboration with ChoiceMed

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