**General Description**

Oxygen Saturation is a percentage of Hemoglobin (HbO2) capacity, compounded with oxygen, by all combinative hemoglobin (Hb) capacity in blood. In other words, it is consistency of Hemoglobin 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 brain. Additionally, the following factors can reduce oxygen saturation: Automatic regulation of organ dysfunction caused by Anesthesia, Intensive Postoperative Trauma, injured caused by some medical examinations. That situation might result in light-headness, 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 finger into the photodiode sensor for diagnosis and the pulse rate and oxygen saturation will appear on the display. It has been proved 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 Hemoglobin (HbO2) in glow and near-infrared zones. Operation principle of the instrument: Photoelectric Oxymetry Inspection Technique is adopted in accordance with Capability 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 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 Receptacle 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 pulse 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 intended 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 60901-1-2:2007 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.

Rx only: “Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.”

**Inaccurate measurements may be caused by**

1. Significant levels of dysfunctional hemoglobin (such as carbon - hemoglobin or methemoglobin).
2. Intravascular dyes such as indocyanine green or methyl blue.
3. High ambient light. Shield the sensor area if necessary.
4. Excessive patient movement;
5. High-frequency electro-ocular interference and defibrillations.
6. Venous pulsations;
7. Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravenous line;
8. The patient has hypotension, severe vasocostriction, severe anemia, or hypothermia;
9. The patient is in cardiac arrest or in shock;
10. Finger nail polish or false fingernails;
11. Weak pulse quality (low perfusion);
12. Low hemoglobin;

**Product Properties**

1. Operation of the product is simple and convenient.
2. The product is small in volume, light in weight and convenient to carry.
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 when battery voltage is low and normal operation of the oximeter might be influenced.
5. The product will automatically power off when there is no signal for longer than 8 seconds.

**Intended Use**

Fingertip pulse oximeter is a portable non-invasive device intended for spot-checking of oxygen saturation of arterial oxygen (SaO2) and pulse rate of adult and pediatric patient at home, and hospital (including clinical use in intramuscular, Anesthesia, intensive care etc.). It is not for continuous monitoring.

The fingertip pulse oximeter requires no routine calibration or maintenance other than replacement of batteries.

**Operation Instructions**

1. Install two AAA batteries according to the Battery Installation instructions listed above in the right column.
2. Open the clamp as illustrated in the picture below.
3. Fully insert one fingertip into the silicone hole of the oximeter before releasing the clamp.
4. Press the button on front panel.
5. Read corresponding data from display screen.
6. Press the button again to toggle between two display modes.

After turning on the Oximeter, each time you press the power switch, the Oximeter will switch to another display mode. There are 2 display modes shown as follows:

1. Pulse Column
2. SP02

Holding the power switch for longer than one second, will adjust the brightness of the oximeter. There are 10 levels of brightness. The default level is level four.

**Battery Installation**

1. Install two AAA batteries into the battery compartment. Match the plus (+) and minus (-) signs in the compartment. If the polarities are not matched, damage may be caused to the oximeter.
2. Slide the battery door cover horizontally along the arrow shown as the picture.

**Using the Lanyard**

1. Thread thinner end of the lanyard through the hanging hole.
2. Thread thicker end of the lanyard through the threaded end before pulling it tightly.

**Warnings!**

- Keep the oximeter away from young children. Small items such as the battery door, battery, and lanyard are choking hazards.
- Do not hang the lanyard from the device’s electrical wire.

**Maintenance and Storage**

1. Replace the batteries in a timely manner 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 if the oximeter is not operated for a long time.
4. It is best to store the product in 0°C – 55°C, and <30% humidity.
5. Keep in a dry place. Extreme moisture may affect oximeter lifetime and may cause damage.
6. Dispose of battery properly; follow any applicable local battery disposal laws.

**Cleaning the fingertip pulse oximeter**

Please use medical alcohol to clean the silicone touching the finger inside of oximeter with a soft cloth dampened with 70% isopropyl alcohol. Also clean the being tested finger using alcohol before and after each test.

Do not pour or spray liquids onto the oximeter, and do not allow any liquid to enter any openings in the device. Allow the oximeter to dry thoroughly before reuse.

A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor. Clinical testing is used to establish the SpO2 accuracy. The measured arterial hemoglobin saturation value (SpO2) of the sensors is compared to arterial hemoglobin oxygen (SaO2) value, determined from blood samples with a laboratory CO-oximeter. The accuracy of the sensors in comparison to the CO-oximeter samples measured over the SpO2 range of 70 – 100%. Accuracy data is calculated using the root-mean-squared (Arms value) for all subjects, per ISO 9191:2005, Medical Electrical Equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.

The use life of the device is five years when it is used for 15 measurements every day and 10 minutes per one measurement. Stop using and contact local service center if one of the following cases occurs:

- An error in the Possible Problems and solutions is displayed on screen.
- The oximeter cannot be operated in any case and not the reasons of battery.
- There is a crack on the oximeter or damage on the display resulting readings cannot be identified; the spring is invalid; or the key is unresponsive or unavailable.

**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
   - Measure range: 30-235 BPM
   - Accuracy: ±0.3BPM; ±2%; 100~235BPM, ±2%
   - Resolution: 1BPM
4. LED Wavelengths
   - Wavelength: 660±2, 940±10nm
   - Radiant Power: 1.8mW; 2.0mW
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.
   - It is equipped with a function switch, through which the oximeter can be powered off in case no finger is the oximeter longer than 8 seconds.
6. Outline Dimension
   - Length: 58mm
   - Width: 32mm
   - Height: 34mm
   - Weight: 50g (including two AAA batteries)
7. Environment Requirements
8. Equipment Response Time

Response time of slower average is 12.4s.

9. 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

The Pulse Oximeter (MD300C201) is intended for use in electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Pulse Oximeter (MD300C201) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pulse Oximeter (MD300C201) 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>$d = \frac{3.5}{\sqrt{P}}$</td>
</tr>
<tr>
<td>800 MHz to 2.5 GHz</td>
<td>$d = \frac{7}{\sqrt{P}}$</td>
</tr>
</tbody>
</table>

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 cannot be shown normally</td>
<td>1. Finger is not inserted correctly</td>
<td>1. Put finger firmly on the monitoring surface</td>
</tr>
<tr>
<td></td>
<td>2. Patient’s SpO2 value is too low to be measured</td>
<td>2. Increase pressure</td>
</tr>
<tr>
<td>SpO2 or PR is shown unexpectedly</td>
<td>1. Finger might not be inserted deep enough</td>
<td>1. Put finger firmly on the monitoring surface</td>
</tr>
<tr>
<td></td>
<td>2. Excessive patient movement</td>
<td>2. Increase pressure</td>
</tr>
<tr>
<td>The oximeter can not be powered on</td>
<td>1. No battery or low power of battery</td>
<td>1. Replace the battery</td>
</tr>
<tr>
<td></td>
<td>2. Batteries might be installed incorrectly</td>
<td>2. Replace the batteries</td>
</tr>
<tr>
<td></td>
<td>3. The oximeter might be damaged</td>
<td>3. Please contact local service centre</td>
</tr>
<tr>
<td>Indication lamps are suddenly off</td>
<td>1. The product is automatically powered off.</td>
<td>1. Check the red emission LED</td>
</tr>
<tr>
<td></td>
<td>2. The battery power is too low to work.</td>
<td>2. Check the infra-red emission LED</td>
</tr>
<tr>
<td>Error 1</td>
<td>1. Err 1 means the red emission LED is damaged</td>
<td>1. Check the red emission LED</td>
</tr>
<tr>
<td>Error 2</td>
<td>2. Error 2 means the screen is damaged</td>
<td>2. Check the infra-red emission LED</td>
</tr>
<tr>
<td>Error 3</td>
<td>3. Err 3 is displayed on screen</td>
<td>3. Check the emission LED and reception diode.</td>
</tr>
</tbody>
</table>

Recommended separation distances between portable and mobile RF communications equipment and the Pulse Oximeter (MD300C201)

Recommended separation distances between portable and mobile RF communications equipment and Pulse Oximeter (MD300C201)