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 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 (HbR) 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 light of different wavelengths (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.

### Diagram of Operation Principle

1. Red and Infrared-ray Emission Tube
2. Red and Infrared-ray Receipt 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 four 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. The device complies with IEC 60601-1-2:2007 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.

### Inaccurate measurements may be caused by:

1. Significant levels of dysfunctional hemoglobin (such as carbonyl - 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 hypotension, severe vasoconstriction, 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 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 eight seconds.

### Intended Use

The Fingertip Pulse Oximeter is a portable non-invasive device intended for spot-checking of oxygen saturation of arteriolar hemoglobin (SpO2) and pulse rate of adult and pediatric patients at home and in hospital (including clinical use in internist/surgery, anesthesia, intensive care, etc). It is not for continuous monitoring.

### 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 switch button once on front panel.
5. Keep your finger still during measurement.
6. Read corresponding data from display screen.
7. Press the button again to toggle between six display modes.

### 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.

### 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 -20°C——+55°C and 33% 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 finger being tested 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 9919:2005, Medical Electrical Equipment – Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.

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

### 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 ~ 235bpm
   - Accuracy: 0% ~ ±99bpm, ±2bpm; 100 ~ ±235bpm, ±2b%
   - Resolution: 1bpm

### Probe LED Specifications

<table>
<thead>
<tr>
<th>Wavelength</th>
<th>Radiant Power</th>
</tr>
</thead>
<tbody>
<tr>
<td>RED</td>
<td>660 ±2nm</td>
</tr>
<tr>
<td>IR</td>
<td>940 ±10nm</td>
</tr>
</tbody>
</table>
5. Power Requirements
Two AAA alkaline batteries
Power consumption: Less than 30mA
Battery Life: Two AAA 1.5 V, 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 if no finger is present in the oximeter for longer than eight seconds.

6. Outline Dimensions
Length: 59mm
Width: 32mm
Height: 34mm
Weight: 50g (including two AAA batteries)

7. Environment Requirements
Operation Temperature: 5 ~ 40°C
Storage Temperature: -20 ~ +55°C
Ambient Humidity: ≤90% no condensation in operation
≤93% no condensation in storage

8. Equipment Response Time
As shown in the following figure. 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 mode of operation: CONTINUOUS OPERATION

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

Guidance and Manufacturer’s declaration – electromagnetic emissions
The MD300C25 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the MD300C25 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 MD300C25 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 (MD300C25) is suitable for use in all establishments, including domestic establishments and those directly or indirectly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2 | Not Applicable | Not Applicable
Harmonic emissions IEC 61000-3-3 | Not Applicable | Not Applicable

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

Guidance and Manufacturer’s declaration – electromagnetic immunity
The MD300C25 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the MD300C25 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 | +/- 8kV contact +/- 8kV air | +/- 8kV contact +/- 8kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3A/m | 3A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEMS – For all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and Pulse Oximeter (MD300C25)

The Pulse Oximeter (MD300C25) is intended for use in electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Pulse Oximeter (MD300C25) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pulse Oximeter (MD300C25) as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W) | Separation distance according to frequency of transmitter (m)
--- | ---
0.01 | 0.1167 80 MHz to 800 MHz
0.1 | 0.3689 800 MHz to 2.5 GHz
1 | 1.1667 800 MHz to 2.5 GHz
10 | 3.6893 7.3786
100 | 11.6667 23.334

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.

Symbol Definitions

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type BF applied part</td>
<td>No SpO2 Alarm</td>
</tr>
<tr>
<td>Attention, consult accompanying documents</td>
<td>Storage temperature and relative humidity</td>
</tr>
<tr>
<td>Protected against dripping water</td>
<td>Serial No.</td>
</tr>
<tr>
<td>Manufacturer’s information</td>
<td>Date of Manufacture</td>
</tr>
</tbody>
</table>

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

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