Fingertip Pulse Oximeter
Model: 459

General Description
Oxygen binds to hemoglobin in red blood cells when moving through the lungs. It is transported throughout the body as arterial blood. A pulse oximeter uses two frequencies of light (red and infrared) to determine the percentage (%) of hemoglobin in the blood that is saturated with oxygen. The percentage is called blood oxygen saturation, or SpO2. A pulse oximeter also measures and displays the pulse rate at the same time it measures the SpO2 level.

Measurement Principle
Principle of the oximeter is as follows: The pulse oximeter works by applying a sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and photo detector. The one wavelength of light source is 660nm, which is red light; the other is 905nm, which is infrared-red light. Skin, bone, tissue and venous vessels normally absorb a constant amount of light over time. The photo detector in finger sensor collects and converts the light into electronic signal which is proportional to the light intensity. The arterial bed normally pulsates and absorbs variable amounts of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO2.

Diagram of Operation Principle
1. Red and Infrared-Ray Emission Tube
2. Red and Infrared-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 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 half an hour.
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 60601-1-2-2014 for electromagnetic compatibility for medical electrical equipment and 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 equipment is not intended for use during patient transport outside the healthcare facility.
14. This equipment should not be used adjacent to or stacked with other equipment.
15. It may be unsafe to—
   —use accessories—detachable parts and materials not described in the instructions for use—
   —interconnect this equipment with other equipment not described in the instructions for use—
   —disassemble, repair or modify the equipment.
16. These materials that contact the patient’s skin contain medical silicone and ABS plastic enclosure are all pass the ISO10993-5 Tests for in vitro cytotoxicity and ISO10993-10 Tests for irritation and delayed-type hypersensitivity.
17. When the signal is not stable, the reading may be inaccurate. Please do not reference.

Contraindication
It is not for continuous monitoring.

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 Features
1. High brightness LED/LCD display SpO2, PR, and Pulse bar.
2. Two display modes. (NOTE: except for LCD series)
3. 2 pcs AAA-size alkaline batteries, battery-low indicator.
4. When no operation or low signal is detected, the pulse oximeter will power off automatically in 8 seconds.

Intended Use
The Fingertip Pulse Oximeter is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate of adult, adolescent and child patients in hospitals, hospital-type facilities and homescare.

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. There are two display modes. After turning on the pulse oximeter, each time you press the power switch, the pulse oximeter will switch to another display mode. (NOTE: only for the LED series).

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.

Note:
✦ Please remove the batteries if the pulse oximeter will not be used for long periods of time.
✦ Please replace the battery when the power indicator starting flickering.

Maintenance and Storage
1. Replace the batteries in a timely manner when low voltage lamp is lighted.
2. Clean the 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 -25°C ~ 70°C and ≤93% 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 storage.
The fingertip pulse oximeter requires no routine calibration or maintenance other than replacement of batteries.

The use life of the device is five years when it is used for 15 measurements every 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 powered on 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 unavaliable.

Disinfecting
The applied parts touching the patients’ body are required to be disinfected once after each use. The recommended disinfectants include: ethanol 70%, isopropyl alcohol 70%, glutaraldehyde-type 2% liquid disinfectants.
Disinfection may cause damage to the equipment and is therefore not recommended for this pulse oximeter unless otherwise indicated in your hospital’s servicing schedule. Clean the pulse oximeter before disinfecting it.

CAUTION: Never use EO or formaldehyde for disinfection.

Specifications
1. Display Type
   LED/LCD display
2. SpO2
   Display range: 0%~100%
   Measurement range: 70%~100%
   Accuracy: 70%~100%
   Resolution: 1%

Note: 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.
A functional tester is used to measure how accurately Fingertip Pulse Oximeter is reproducing the specified calibration curve and the PR accuracy.

The model of functional tester is Index2 FLUKE simulator and the version is 2.1.3.

3. Pulse Rate
   Display range: 60bpm~250bpm
   Accuracy: ±2bpm

4. Probe LED Specifications
   WaveLength: 660nm, 905nm
   Radiant Power: 1.3mW, 2.4mW

Note: The information about wavelength range can be especially useful to clinicians.

5. Power Requirements
   Two AAA alkaline batteries
   Battery life: Two AAA 1.5V, 20mAh alkaline batteries could be continuously operated as long as 15 hours.

6. Environmental Requirements
   Operation Temperature: 5°C~40°C
   Storage Temperature: -25°C~70°C
   Ambient Humidity: 15% ~ 93% non-condensation in operation; ≤93% no condensation in storage/transport
   Atmospheric pressure: 70kPa~106kPa
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

The Pulse Oximeter (MD300C1) is intended for use in electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Pulse Oximeter (MD300C1) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pulse Oximeter (MD300C1) 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 2.5 GHz</td>
<td></td>
</tr>
<tr>
<td>0.01</td>
<td>$d = 1.2 \sqrt{P}$</td>
</tr>
<tr>
<td>0.1</td>
<td>$d = 2.3 \sqrt{P}$</td>
</tr>
<tr>
<td>1</td>
<td>$d = 1.2 \sqrt{P}$</td>
</tr>
<tr>
<td>10</td>
<td>$d = 2.3 \sqrt{P}$</td>
</tr>
<tr>
<td>100</td>
<td>$d = 1.2 \sqrt{P}$</td>
</tr>
<tr>
<td>11.6867</td>
<td>7.378</td>
</tr>
<tr>
<td>23.334</td>
<td>7.378</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.

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### Possible Problems and Solutions

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Reason</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>SpO2 or PR cannot be shown normally</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Finger is not inserted correctly. 
Patient's Oxymoglobin value is too low to be measured. | 
Try not to move. 
Try to measure. | 
Wait until the measurement is possible. |
| SpO2 or PR is shown instably | | | |

### Symbol Definitions

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type BF applied part</td>
<td>Attention</td>
</tr>
<tr>
<td>IP22</td>
<td>The degree of protection against ingress of water</td>
</tr>
<tr>
<td>S</td>
<td>Oxygen saturation</td>
</tr>
<tr>
<td>BPM</td>
<td>Pulse rate (BPM)</td>
</tr>
<tr>
<td>No SPo2 Alarm</td>
<td>Power switch</td>
</tr>
</tbody>
</table>

### Box Content

1. Finger tip pulse oximeter
2. One lanyard
3. Two AAA batteries
4. One instruction manual

### Applicable Models

Model 459

### 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.