Pulse Oximeter

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 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 user so that doctors can find problems in a timely manner. The fingertip pulse Oximeter features small size, low power consumption, convenient operation and portability. It is only necessary for a user to put one of his fingers into the fingertip photoelectric sensor for diagnosis, and a display screen will show oxygen saturation. 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 glow and near-infrared zones. Operation principle of the instrument. Photoelectric Oxymyglogin Inspection Technology is adopted in accordance with Capacity 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 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 user so that doctors can find problems in a timely manner. The fingertip pulse Oximeter features small size, low power consumption, convenient operation and portability. It is only necessary for a user to put one of his fingers into the fingertip photoelectric sensor for diagnosis, and a display screen will show oxygen saturation. It has been proven in clinical experiments that it also features high precision and repeatability.

Diagram of Operation Principle
1. Red and Infrared-ray Emission Tube
2. Red and Infrared-ray
3. Receipt Tube

Precautions for use
1. Do not use the pulse oximeter in an MRI or CT environment.
2. Do not use the pulse oximeter in situations where alarms are required. The device has no alarms.
3. Explosion hazard: Do not use the pulse oximeter in an explosive atmosphere.
4. The pulse oximeter is intended only as an adjunct in user assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
5. Check the pulse oximeter sensor application site frequently to determine the positioning of the sensor and circulation and skin sensitivity of the user.
6. Do not stretch the adhesive tape while applying the pulse oximeter sensor. This may cause inaccurate readings or skin blisters.
7. Before use, carefully read the manual.
8. The pulse oximeter has no SPO₂ alarms; it is not for continuous monitoring.
9. Prolonged use or the user’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.
10. Inaccurate measurements may be caused by autoclaving, ethylene oxide sterilizing, or immersing the sensors in liquid.
11. Significant levels of dysfunctional hemoglobin (such as carboxyhemoglobin or methemoglobin) may cause inaccurate readings.
12. Intravascular dyes such as indocyanine green or methylene blue.
13. SPO₂ measurements may be adversely affected in the presence of high ambient light. Shield the sensor area (with a surgical towel, or direct sunlight, for example) if necessary.
14. Excessive user movement may cause inaccurate readings.
15. Venous pulsations may cause inaccurate readings.
16. High-frequency electrosurgical interference may cause inaccurate readings.
17. Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
18. The user has hypotension, severe vasoconstriction, severe anemia, or hyperthermia.
19. The user is in cardiac arrest or is in shock.
20. Fingernail polish or false fingernails may cause inaccurate SPO₂ readings.

Product Properties
1. Operation of the product is simple and convenient.
2. The product is small in volume, light in weight and convenient in carrying.
3. Power consumption of the product is low and the two AAA batteries can be operated continuously for 24 hours.
4. A low voltage warning will be indicated in visual window when battery voltage is so low that normal operation of the oximeter might be influenced.
5. The product will automatically be powered off when no signal is in the product for longer than 16 seconds.

Product Operation Scope
Fingertip PULSE OXIMETER is a portable non-invasive, spot-check oxygen saturation of arterial hemoglobin (SPO₂) and pulse rate of adult and pediatric user at home, and hospital (including clinical use in internist/surgery, Anesthesia, intensive care etc). It is not for continuously monitoring.

Operation Instructions
1. Install two AAA batteries into battery compartment correctly.
2. Place clamp over finger nail as the following diagram.
3. Insert one finger into rubber hole of the Oximeter fully.
4. Press the switch once on the front panel.
5. Finger and body should not tremble during measuring.

Notes:
- When your finger insert into the Oximeter, your nail surface must be upward.
- The results may be wrong if you did not plug the finger thoroughly in the Oximeter.
- Please use medical alcohol to clean the rubber touching the finger inside of Oximeter, and clean the test finger using alcohol before and after each test. (The rubber inside of the Oximeter belongs medical rubber, which has no toxic and no harmful to the skin).

Short press to switch among the settings, long press to change the current settings of sounds and alarm limits.

Battery Indicator
- Functional oxygen saturation of arterial hemoglobin
- Power On
- Pulse Rate
- Plethysaogram
- Bargraph

The Pulse bar graph displays corresponding with the user’s pulse beat. The height of the bar graph shows the user’s pulse strength.

Product Accessories
1. Lanyard
2. Two batteries
3. One user manual
Battery Installation
1. Put the two AAA batteries into battery compartment in correct polarities.
2. Push the battery cover horizontally along the arrow shown as below:

Notes:
- Battery polarities should be correctly installed. Otherwise, damage may be caused to the device.
- Please put in or remove batteries in right order, or may cause damage to the device bracket.
- Please remove the batteries if the Oximeter will not be used for a long time.

Strap Installation
1. Thread thinner end of the strap through the loop.
2. Thread thicker end of the strap through the threaded end before pulling it tightly.

Maintenance and Storage
1. Replace the batteries in time when low voltage lamp is lighted.
2. Clean surface of the fingertip oximeter before it is used in diagnosis for users.
3. Remove the batteries inside the battery cassette if the oximeter is continuously operated as long as 24 hours.
4. It is best to preserve the product in a dry environment.
5. Avoid exposure to direct sunlight.
6. Avoid excessive radioactive infrared rays or ultraviolet rays.
7. Please follow the law of the local government to deal with used battery.

Technical Specification
1. Display Type: Color OLED display, 4 display directions
2. SPO2: Measurement range: 0%-100%
   Resolution: 1%
   Accuracy: 70%-100%, ±2%; 0%-69% no definition.
3. Pulse Rate: Measure range : 25BPM -250 BPM
   Resolution: 1bpm,
   Accuracy : 2bpm
   Pulse Intensity: Bargraph Indicator
4. Power Requirements:
   Two AAA alkaline Batteries
   Power consumption: 30mA(Normal)
   Low power indication:
   Battery Life: Two AAA 1.5V, 600mAh alkaline batteries could be continuously operated as long as 24 hours.
5. Dimension:
   Length: 64mm
   Width: 35mm
   Height: 34mm
   Weight: 57g (including two AAA batteries)
6. Environment Requirements:
   Operation Temperature: 5°C ~ 40°C
   Storage Temperature: -10°C ~ 50°C
   Ambient Humidity: 15%-80%, no condensation in operation.
   10%-93%, no condensation in storage
7. Measurement Performance in Low Perfusion Condition:0.3%

Declaration
EMC of this product complies with IEC60601-1-2 standard.
The materials which the user can come into contact have no toxicity and no action on tissues comply with ISO10993-1, ISO10993-5 and ISO10993-10.

Guidance and manufacturer’s declaration – electromagnetic emissions for all EQUIPMENT and SYSTEMS

<table>
<thead>
<tr>
<th>Emission test</th>
<th>Compliance</th>
<th>Electromagnetic environments – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>HF emissions</td>
<td>Group 1</td>
<td>The 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.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td>Class B</td>
<td>The Pulse Oximeter 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.</td>
</tr>
</tbody>
</table>

Possible Problems and resolutions

<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>1. Finger is not inserted correctly</td>
<td>1. Retry by inserting the finger correctly.</td>
</tr>
<tr>
<td></td>
<td>2. User’s Oxyhemoglobin value is too low to be measured</td>
<td>2. Try some more times, if you can make sure no problem is existing in the product. Please go to a hospital timely for exact diagnosis.</td>
</tr>
<tr>
<td>SPO2 or PR is shown unstably</td>
<td>1. Finger might not be inserted deep enough.</td>
<td>1. Retry by inserting the finger correctly.</td>
</tr>
<tr>
<td></td>
<td>2. Finger is trembling or</td>
<td>2. Try not to move.</td>
</tr>
</tbody>
</table>

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