Fingertip Pulse Oximeter

USER MANUAL
Ver.1.0C

General Description
Oxygen Saturation is a percentage of Hemoglobin (HbO2) capacity, compounded with oxygen, by all combinative hemoglobin (Hb) capacity in blood. It is very important parameter for the respiratory circulation system. Therefore, it is very important to know the oxygen saturation.

The fingertip pulse oximeter features low power consumption, convenient operation and portability. Place one fingertip into the photosensitive sensor for diagnosis and the pulse rate and oxygen saturation will appear on the display.

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 Reflective hemoglobin (HbR) and Oxygenhemoglobin (HbO2) in glow and near infrared zones. Operation principle of the instrument: Photoelectric Oxymeter 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 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 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 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 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. Check the pulse oximeter sensor application site every 4 hours to determine the positioning of the sensor and circulation and skin sensitivity of the patient.
9. Do not use the device using alcohol, 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 60601-2-2:2007 for electromagnetic compatibility. 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 the 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 user 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 intravenous line;
8. The user has hypotension, severe vasovagal syncope, severe anemia, or hypothermia;
9. The user is in cardiac arrest or is in shock;
10. Fingernail 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 an portable non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate.

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.

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:

Front Panel

Product Accessories
1. One lanyard
2. Two AAA batteries
3. One instruction manual

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
1. Keep the oximeter away from young children. Small items such as the battery door, battery, and lanyard are choking hazards.
2. 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 -20°C ~ -55°C and 15%~35% 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.

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:
1. An error in the Possible Problems and solutions is displayed on screen.
2. The oximeter cannot be powered on in any case and the reasons of battery.
3. 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: 5-254BPM
   Measure range: 30-235 BPM
   Accuracy: 30-99bpm, ±2bpm; 100-235bpm, ±2%
   Resolution: 1BPM
4. Probe LED Specifications
<table>
<thead>
<tr>
<th>Wavelength</th>
<th>Radiant Power</th>
</tr>
</thead>
<tbody>
<tr>
<td>RED 660±2nm</td>
<td>1.8mW</td>
</tr>
<tr>
<td>IR 940±10nm</td>
<td>2.0mW</td>
</tr>
</tbody>
</table>
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
6. Weight: 55g (including two AAA batteries)

7. Environment Requirements
   Operation Temperature: 5 ~ 40°C
   Storage Temperature: -20 ~ -55°C
   Ambient Humidity: 5%~80% in operation
   ≤93% 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 method(s) of sterilization or disinfection recommended by the manufacturer: Equipment with method(s) of sterilization or disinfection recommended by the manufacturer;
According to the degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE: EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE.
According to the degree of output of protection against interference: TYPE BF.
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 MQ3200 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the MQ3200 Pulse Oximeter should ensure that it is used in such an environment.

Emission test Compliance Electromagnetic Environment – guidance
RF emissions CISPR 11 Group 1 The MQ3200 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 (MQ3200) is suitable for use in all establishment, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Voltage fluctuations/ flicker emissions 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 MQ3200 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the MQ3200 Pulse Oximeter should ensure that it is used in such an environment.

Immunity test IEC 60601-1 test level Compliance Level Electromagnetic Environment – guidance
Electrostatic Discharge (ESD) IEC 61000-4-2 +/- 8kV contact +/- 8kV air +/- 8kV air Flors should be wood, concrete or ceramic tile. If floor 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 characteristics of a typical location in a typical commercial environment.

Possible Problems and Solutions

Problem Possible reason Solution
SpO2 or PR can not be shown normally
1. Finger is not inserted correctly
1. Retry by inserting the finger
2. Patient’s SpO2 value is too low to be measured
2. There is excessive illumination
3. Try not to remove

The oximeter can not be powered on
1. No battery or low power of battery
1. Please replace batteries
2. Batteries might be installed incorrectly
2. Please reinstall the batteries
3. The oximeter might be damaged
3. Please contact with local customer service centre

Indication lamps are suddenly off
1. The product is automatically powered off when no signal is detected longer than 8 seconds
1. Normal
2. The battery power is too low to work
2. Replace the batteries

Error 3 or Error 4 is displayed on screen
1. Err 3 means the red emission LED is damaged
1. Check the red emission LED
2. Err 4 means the infra-red emission LED is damaged
2. Check the infra-red emission LED

Error 6
Err 6 means the screen is failure
Change the screen

Error " is displayed on screen
Err 7 means all the emission LED or reception diodes is damaged.
Check the emission LED and reception diode.

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>SP</td>
<td>According, consult accompanying documents.</td>
</tr>
<tr>
<td>IX</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>No SpO2</td>
<td>Low power indication</td>
</tr>
<tr>
<td>SN</td>
<td>No SpO2 Alarm</td>
</tr>
<tr>
<td>EC REP</td>
<td>Serial No.</td>
</tr>
<tr>
<td>Storage temperature and relative humidity</td>
<td></td>
</tr>
<tr>
<td>Manufacturer’s information</td>
<td></td>
</tr>
<tr>
<td>Date of Manufacture</td>
<td></td>
</tr>
<tr>
<td>European union approval</td>
<td></td>
</tr>
<tr>
<td>Authorized representative in the European community</td>
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</tbody>
</table>

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

Manufactured for:

P.O. Box 1599
Bluffton, SC 29910
(888) 404.5666

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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 (MQ3200C2)

The Pulse Oximeter (MQ3200C2) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Pulse Oximeter (MQ3200C2) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pulse Oximeter (MQ3200C2) as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output Separation distance according to frequency of transmitter (m)

<table>
<thead>
<tr>
<th>Power of transmitter (W)</th>
<th>80 MHz to 800 MHz</th>
<th>800 MHz to 2.5 GHz</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.01</td>
<td>0.1167</td>
<td>0.2334</td>
</tr>
<tr>
<td>0.1</td>
<td>0.3689</td>
<td>0.7378</td>
</tr>
<tr>
<td>1</td>
<td>1.1667</td>
<td>2.3334</td>
</tr>
<tr>
<td>10</td>
<td>3.6693</td>
<td>7.376</td>
</tr>
<tr>
<td>100</td>
<td>11.6667</td>
<td>23.334</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.

\[ d = \frac{3.5}{\sqrt{P}} \text{ meters} \]

\[ d = \frac{7}{\sqrt{P}} \text{ meters} \]

\[ d = \frac{8.3}{\sqrt{P}} \text{ meters} \]

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 from structures, objects and people.