Pulse Oximeter 50-102-003-L

Date of Issue: 2019.05, Version: V1.0

Precautions

- Do not attempt to repair the Oximeter unless you are professional engineers. Only professionals with maintenance qualification are allowed to perform interior maintenance as necessary.
- Change the contact position between the Oximeter probe and the finger periodically if you are monitoring your SpO_2 levels and pulse rate for a long time (no more than 2 hours).
- Stop immediately if you have broken skin or the blood circulation of your finger is affected during prolong use.
- This product is not designed to be used by newborn babies.

Seek medical care if the measured value goes beyond the normal range and you are sure that the instrument is not malfunctioning.

- The pulse oximeter uses infrared light (invisible to your eyes) to measure your SpO_2 levels. Hence, please do not stare at the light-emitting components of the Oximeter, as that could cause harm and/or potentially blind your eyes.
- This pulse oximeter is not intended to diagnose or treat any medical condition or disease. It is intended for non-medical use in healthy people to monitor their pulse and blood oxygen levels during sports and/or aviation only.

People who need SpO_2 and pulse rate measurements because of a medical condition should not use the oximeter and should consult with their physician.

- For details about clinical limitations and contraindications, please carefully consult relevant medical literatures.

The following factors may affect the accuracy of the measurement:

- The Oximeter should not be used in an environment involving high-frequency devices, such as high-frequency electric knives and CT apparatuses.
- Please avoid direct exposure to strong light (such as beams from operating lamps or sunlight) during measurement.
- Do not place probe of the Oximeter on the same arm that a blood pressure cuff arterial duct or intravenous injection occurs.
- The user suffers from hypotension, severe vascular atrophy, severe anemia, or low oxygen.
- The user is in sudden cardiac arrest or shock state.
- The user is wearing nail polish or artificial nails.
- Do not combine old and new batteries, or different brands of batteries.

Warnings

Warning: Do not use the Oximeter in an environment with any flammable gases, flammable anesthetic, or other flammable substances.

Warning: Keep unit and lanyard away from children's mouths as the included lanyard may present an entanglement or choking hazard to small children. Adult supervision required; never leave children unattended with unit or lanyard

Warning: Do not throw the batteries into fire, as that could cause an explosion.

Warning: Do not attempt to charge the included batteries, as that could cause leakage, fire disaster, or even explosion. Dispose the used batteries in accordance with local laws and regulations.

Warning: Do not use the Oximeter in an MRI or CT environment.

Warning: Caution: Do not operate the Oximeter if it is wet. Avoid moving the oximeter from a cold to a hot and humid environment.

Warning: Install the batteries properly before powering on the Oximeter for normal use. Please remove the batteries if you are not planning to use the Oximeter for a long time.

Warning: Close the battery cover when the instrument is in use.

Symbols

Symbol	Meaning
	Type BF applied part
	Caution: Please see this manual.
% SpO_2	Symbol of oxygen saturation
bpmPR	Symbol of pulse rate
	No SpO_2 alarms.
	Consult the instructions for use.
IP22	The degree of protection against harmful ingress of water and particulate matter
	When end users abandon this product, they must send the product to proper collection place for recycling.

Overview

Oxygen saturation is the percentage of oxyhemoglobin (HbO2) that is combined with oxygen against all combinable hemoglobin (Hb). It is an important physiological parameter involved in respiration and circulation. The oxygen saturation of arterial blood in a normal human body is 98%. Oxygen saturation is an important indicator of the oxygen condition in the human body. In general, the normal values of oxygen saturation shall not be lower than 94%. If the measured value of oxygen saturation is lower than 94%, an insufficient supply of oxygen is indicated.

The pulse rate is the number of pulse beats per minute. Normally, the pulse rate is consistent with the heart rate. In general, the typical pulse rate is 60 to 90 beats per minute.

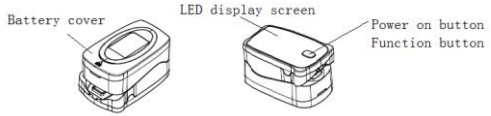
The Perfusion Index (PI) usually reflects the limb perfusion status of an examined patient, and shows the detection precision of the instrument as well; that is, examination can still be performed even in the low or weak perfusion condition. The PI of a normal human body is 3% or greater.

Working Principles and Usage

Based on full digital technology, the Finger Pulse Oximeter non-invasively measures the actual content (oxygen saturation) of oxyhemoglobin (HbO2) in arterial blood using the optical transmittance method.

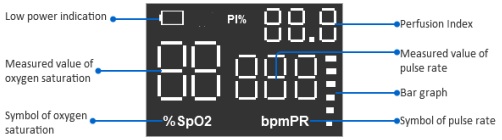
The Finger Pulse Oximeter measures the blood oxygen saturation and pulse rate of a human body via finger artery. It is applicable to a wide range of fields, such as families, clinics. Use this instrument for measurement before or after sports. You are not advised to use this instrument during sports activities. Do not use it for continuous care for patients.

Schematic Diagram of Display



Schematic Diagram of Display

The following figure shows the information display on the LED screen of the Oximeter in normal detection state:



Power-On button/Function Button Operations

Press the power-on/function button to turn on the oximeter. Once the unit is turned on, simply press or hold the button to perform corresponding operations.

Press: Press the button for less than 0.5 seconds.

Hold: Press the button for more than 0.5 seconds.

Brightness Setting

Hold the power-on button while the oximeter is in powered-on state. The oximeter shows a brightness setting interface (as "Interface 1" below shows, "br" represents brightness). Hold the button to adjust brightness. There are 3 brightness settings (1,2,3). 3 is the brightest.

Interface1

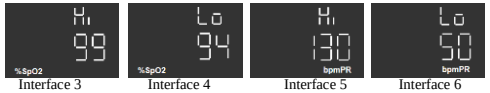
Alert Setting

After setting the brightness, press the power-on button to enter the alert setting interface (as "interface 2" below shows, "AL" represents alert). Then, hold the button to set "AL" to on or off. When "AL" is set to on and the measured values of the blood oxygen saturation and pulse rate go beyond the upper limit or lower limit, the oximeter will beep to alert.

Interface 2

Alert Range Setting

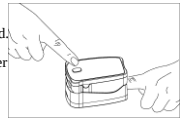
When "AL" is set to on, you can set the upper limit and lower limit of SpO_2 Alert and PR Alert. Press it to switch an option (SpO_2 upper limit, SpO_2 lower limit, PR upper limit and PR lower limit). Hold the power-on button to adjust the limits (as "Interface 3,4,5,6" below show, "Hi" represents upper limit, "Lo" represents lower limit) .



Interface 3 Interface 4 Interface 5 Interface 6

Operation Guide

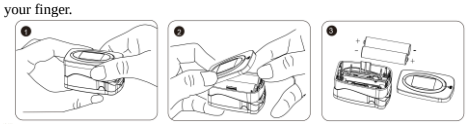
Stick one finger completely into the finger chamber of the oximeter. The fingernail should be facing upward. Release the clip and press the power-on button to power on the pulse oximeter.



⚠ If you do not insert your finger completely into the chamber, measurement will be inaccurate.

⚠ To keep your finger still during measurement. It is also not advisable to use this instrument during sports activities as movement may lead to inaccuracies. Once the reading stabilizes, read the measured values of oxygen saturation and pulse rate on the screen.

NOTE: The oximeter will automatically shut down 10 seconds after you remove your finger.



⚠ Replace the batteries when the batteries run out of power and the symbol ( ) flickers on the screen.

Install the two AAA dry batteries into the battery slot according to polarity indication and mount the battery cover.

Cleaning

Power off the instrument and remove the batteries before cleaning. Ensure that the appearance of the instrument is neat, dust-free, and dirt-free. Clean the outer surface of the instrument (including the LED screen) using a piece of dry soft cloth dipped with 75% medical alcohol

Caution: Avoid liquid flowing into the instrument during cleaning.

Caution: Do not immerse any part of the instrument into any liquid.

Disinfection

Before measurement with the instrument, wipe the rubber finger pad using a piece of dry soft cloth dipped with 75% medical alcohol. Clean the finger to be measured using the medical alcohol for disinfection purposes before and after use.

⚠ Do not disinfect the instrument by means of high-temperature/high-pressure or gas disinfection.

Maintenance

- Remove the batteries from the battery slot and properly store them if you do not plan to use the Oximeter for a long period of time.
- Avoid using the Oximeter in an environment with inflammable gases or in an environment where the temperature or humidity is excessively high or low.
- Check the accuracy of the oxygen saturation and pulse rate readings by using an appropriate calibration apparatus.

Technical Specifications

1. Dimensions: 2.1 in (52.6 mm) L × 1.35 in (34.1 mm) W × 1.2 in (31.2 mm) H Weight: 2 Ounces (48.4 g) (including two AAA dry batteries)
2. Peak wavelength range of the light emitted from the probe: red light 663 nm ± 3; infrared light 900 nm ± 7.
3. Maximum optical output power of the probe: 60 mW for infrared light (905 nm).
4. Working power supply and maximum current: DC 3.0V; 45mA
5. Normal working condition

Working Temperature	5°C to 40°C (41°F to 104°F)
Relative Humidity	15% to 80%, non-condensing
Atmospheric Pressure	70 kPa to 106 kPa
Rated Voltage	DC 3.0 V

6. Default values and conditions of alert

Parameter	Value
Oxygen saturation	Upper limit: 99 Lower limit: 94

Pulse rate	Upper limit: 130 Lower limit: 50
Alert condition	When the alert switch is on and the actual measured value goes beyond the preset alert parameter range, the Oximeter gives an alert sound.

7. Technical parameters

Parameter		Value
Display range	Oxygen saturation	35% to 99%
	Pulse rate	35 bpm to 250 bpm
Resolution	Oxygen saturation	1%
	Pulse rate	1 bpm
Measurement precision	Oxygen saturation	±2% (70% to 99%) No requirement (≤ 69%)
	Pulse rate	±2 bpm
Alert range	Oxygen saturation	Upper limit: 50% to 100% Lower limit: 50% to 100%
	Pulse rate	Upper limit: 35 bpm to 250 bpm Lower limit: 35 bpm to 250 bpm
Alert error	Oxygen saturation	± 1% of the preset value
	Pulse rate	The greater of ±10% of the preset value and ±5 bpm
PI	Weak PI	Min. 0.3%

Safety Type

Anti-electric-shock type: internal power supply device

Anti-electric-shock degree: Type BF applied part

Running mode: continuous working

Waterproof grade: IP22

Storage and Transportation

Temperature : –10°C - 50°C(14℉-122℉)

Relative humidity : 10%-93% (no condensation)

Atmospheric pressure : 50kPa–106 kPa.

Product Accessories

1. One strap
2. Two AAA batteries
3. One user manual

ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES

Guidance and manufacturer's declaration - electromagnetic emissions

The device is intended for use in the electromagnetic environment specified below. The customer or the user assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Group 1	The device use 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 CISPR11	Class B	The device is suitable for use in all establishments other than domestic and those directly connected to the
Harmonic emissions lEC61000-3-2	Not applicable	public low-voltage power supply network that supplies buildings used for domestic purposes
Voltage fluctuations/ Fick + ++er emissions lEC61000-3-3	Not applicable	

Guidance and manufacturer's declaration — electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) lEC61000-4-2	±6kV contact ±8kV air	±6kV 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%
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ± 1 kV Input/ output line	not applicable	not applicable (For INTERNALLY POWERED ME EQUIPMENT)
Surge IEC 61000-4-5	± 1 kV Differential mode voltage ± 2 kV Common mode voltage	not applicable	not applicable (For INTERNALLY POWERED ME EQUIPMENT)
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	not applicable	not applicable (For INTERNALLY POWERED ME EQUIPMENT
Power frequency (50Hz/60Hz) 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.

NOTE UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacture's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Blood Pressure Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=1.2\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol:

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.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the unit is used exceeds the applicable RF compliance level above, the unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the unit.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [Vi] V/m.

Recommended separation distances between portable and mobile RF communications equipment and the device.

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

Maximum output power of transmitter (W)	Separation distance according to frequency of transmitter(m)		
	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=1.2\sqrt{P}$
0.01	/	0.12	0.23
0.1	/	0.38	0.73
1	/	1.2	2.3
10	/	3.8	7.3
100	/	12	23

For transmitters rated at a maximum output power not listed above, There commended separation distance d 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) accordable to the transmitter manufacturer.

NOTEI At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and refection from structures, objects and people.

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