Pulse Oximeter Model: 500-LTE
Date of Issue: 2024.03, Version: V1.0

Precautions

- Only qualified professionals should perform maintenance on the oximeter.
- Periodically change the position of the oximeter probe on your finger before each measurement. Ensure your skin is intact, check your finger's blood circulation, and adjust the probe's position as needed.
- This product is not suitable for newborns or babies.
- Seek medical attention quickly if your readings are out of range or otherwise abnormal.
- Do not look directly at the oximeter's light-emitting components to avoid damage to your eye.
- Keep the device away from lint, dust, sunlight, pets, pests, and children.
- This pulse oximeter is not intended to diagnose or treat any medical condition. Consult your physician before using this or any pulse oximeter device if you need SpO2 and pulse rate measurements for medical reasons. Do not self-diagnose or treat based on measurement results; always consult a doctor.
- Consult relevant medical literature for details about clinical limitations and contraindications.
- Allow the device to warm or cool for at least 30 minutes to room temperature before use if it has been stored at extreme temperatures.
- Be aware that degraded sensors can affect performance or cause problems.
- The patient is an intended operator.
- Contact the manufacturer for assistance with setup, use, maintenance, or to report unexpected issues.

Factors that may affect accuracy include:

- ◆ High-frequency devices nearby (e.g., electric knives, CT scanners)
- ◆ Probe placement on the same limb as a blood pressure cuff or intravenous line
- ◆ Conditions such as hypotension, severe vascular atrophy, severe anemia, or low oxygen
- ◆ Sudden cardiac arrest or shock state.
- ◆ Nail polish or fake nails

- Do not mix old and new batteries or different brands of batteries.
- Avoid using the device continuously on the same finger for more than 2 hours, especially if you have a microcirculation condition, to prevent discomfort or pain.
- Do not use this device if you are allergic to silicone rubber.

Warnings

Warning: Do not use the oximeter in environments with flammable gases, anesthetics, or other flammable substances.
Warning: Do not attempt to charge dry batteries. This can cause leakage, fire, or explosion. Dispose of used batteries according to environmental regulations.
Warning: Do not use the oximeter in MRI or CT environments.
Warning: Do not operate the oximeter if it is damp or has water condensation. Avoid moving it from a cold environment to a warm, moist one.to a high-temperature moist environment.
Warning: No modification of this equipment is allowed for safety reasons.
Warning: Only use accessories and parts specified or authorized by the manufacturer to avoid damage or danger.
Warning: Keep the unit and lanyard away from children. The lanyard may present an entanglement or choking hazard. Always supervise children around the unit and lanyard.
Warning: Do not throw batteries or this device into fire to avoid explosions.
Warning: Close the battery cover when the instrument is in use.

Symbol Conventions

Symbol	Description
	Type BF applied part
	Caution: Please see this manual.
%SpO2	Symbol of oxygen saturation
bpmPR	Symbol of pulse rate
	No SPO2 alarms.
	Consult the instructions for use.
	Temperature limitation
IP22	The degree of protection against harmful ingress of water and particulate matter
	User must recycle this product when ready for disposal
	Date of Manufacture
	Information of manufacturer
MD	Medical device
10% 93%	Humidity
50kPa 106kPa	Atmospheric Pressure

Overview

Oxygen saturation is the percentage of oxyhemoglobin (HbO2) in the blood compared to the total hemoglobin (Hb) that can bind with oxygen. This is a crucial physiological parameter for assessing respiration and circulation. In a healthy person, arterial blood oxygen saturation is about 98%. Typically, oxygen saturation should not fall below 94%. Values below 94% indicate an insufficient oxygen supply.

The pulse rate is the number of heartbeats per minute and is usually consistent with the heart rate. A normal pulse rate ranges from 60 to 90 beats per minute.

The Perfusion Index (PI) reflects the limb's blood flow and the instrument's detection accuracy. The PI indicates that the examination can be performed even under low or weak perfusion conditions. A normal PI is 3% or higher.

Intended Use

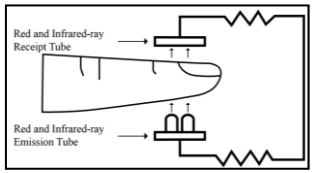
The Fingertip Pulse Oximeter is a non-invasive device for spot-checking arterial hemoglobin oxygen saturation (SpO2) and pulse rate. It is indicated for adults and adolescents in home and hospital settings. The device can be used by both professionals and laypersons.

Scope of Application

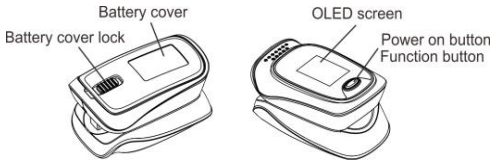
The oximeter is suitable for use in various settings, including homes, hospitals, social medical care institutions, and for sports and health purposes. Use this device for measurements before or after sports activities, but not during. It is not intended for continuous monitoring of patients.

Working Principles

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 arteriolar bed normally pulsates and absorbs variable amounts of light during systole land diastole, as blood volume increases and decreases.

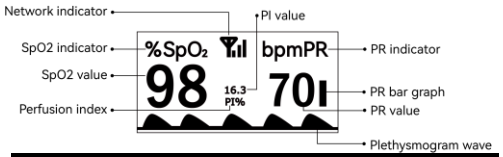


Device Structure



Screen Display

The following figure shows the pulse oximeter display during normal measurement operation:



Power Button and Other Functions

- Press and release the button to turn the oximeter on.
- Press and hold the button for about one second to access the parameter setting interface.
- Use the button for different operations:
  - Press (less than 0.5 seconds) to switch options.
  - Hold (more than 0.5 seconds) to set an item.

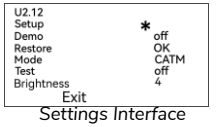
Settings

●**Brightness setting**：Within the Settings interface, press the function button to select the Brightness option. Hold the function button to set the brightness to a value from 1 to 5. Higher values increase the screen brightness.

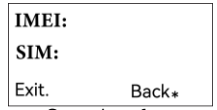
●**Mode selecting**：Within the Settings interface, press the function button to select the Mode option. Hold the function button to set the network (CATM/NB/JB). After switching networks, a reboot is required. Note: The default network is set to CATM.

Note：The matching network has already been set up by default（CATM）.

● **Device information**：Hold the function button when the "*" is next to 'Setup' to enter the Setup Interface screen to view the IMEI and SIM information.

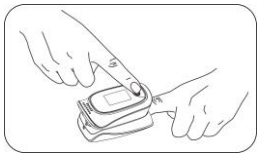


Settings Interface



Setup Interface

Operation Guide



1. Insert one finger fully into the measuring part of the oximeter, with the fingernail facing upward, and release the clip.
2. Press the power button to turn on the oximeter.
3. Ensure your finger is completely inserted into the chamber for accurate measurement results.
4. Keep your finger still and avoid moving your body during measurement.
5. Once the readings stabilize, read the oxygen saturation and pulse rate values on the screen.

Note: The oximeter will automatically shut down 10 seconds after your finger is removed.

Data Communication Feature

1. Once the data has been displayed on the screen, the cellular data transfer will begin automatically. Uploading will appear on the screen.（as shown in **Figure 1 and 2**）
2. The SPO2 reading, and the PR will be uploaded in the patient record associated with the device serial number. Once the data has been transferred the screen will display a message " SUCCESS".（as shown in **Figure 3**）
3. The device will automatically be powered off after about 10 seconds.
4. When the received signal is inadequacy, " FAILED " will be display on the screen (as shown in **Figure 4).**

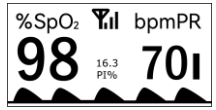


Figure 1

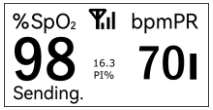


Figure 2

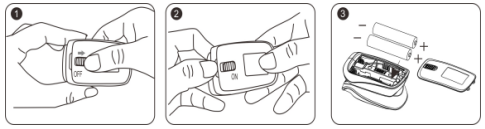
Figure 3

Figure 4

Replacing the Batteries

Replace the batteries when the low power icon （▭） flickers on the screen.

1. Open the battery cover with your fingers.
2. Replace the batteries, ensuring they are inserted with the correct polarity.



Cleaning

1. Power off the instrument and remove the batteries before cleaning.
2. Ensure the instrument is neat, dust-free, and dirt-free.
3. Clean the outer surface, including the OLED screen, with 75% medical alcohol and a dry, soft cloth before using it on a new patient.

Caution: Avoid liquid flowing into the instrument during cleaning.
Caution: Do not immerse any part of the instrument in any liquid.

Disinfection

1. Wipe the silicon rubber finger pad with a dry, soft cloth dipped in 75% medical alcohol.
2. Clean the finger to be measured with medical alcohol for disinfection before and after use.purposes before and after use.

⚠ Do not disinfect the instrument using high-temperature, high-pressure, or gas disinfection methods.

Maintenance

- Remove the batteries and store them properly if you do not plan to use the oximeter for an extended period.
- Avoid using the oximeter in environments with flammable gases or where the temperature or humidity is excessively high or low.
- Check the accuracy of oxygen saturation and pulse rate readings with an appropriate calibration device once a year.
- Ensure the transmitting and receiving windows are free of obstructions before and after use.
- Do not perform service or maintenance while the equipment is in use.

Troubleshooting

Problem	Possible Cause	Solution
The unit fails to power on.	Low battery	Change the batteries.
	Polarities of the batteries are reversed.	Make sure the batteries are installed correctly.
	The unit is damaged.	Contact the manufacturer.
The unit doesn't display any information.	The emitting light doesn't power on.	Contact the manufacturer.

Product Accessories

1.One hanging rope;2.Storage bag;3.Two AAA batteries;4.One user manual;5.Quick guide.

Technical Specifications

1. Dimensions: 62.2 mm (W) × 37.0 mm (D) × 33.1 mm (H)
Weight: 42.5 g (including two AAA dry batteries)
2. Peak wavelength range of the light emitted from the probe: red light 660 nm ± 3; infrared light 905 nm ± 5.
3. Maximum optical output power of the probe: 1.2 mW for infrared light (905 nm).
4. Manufacturing date: see the label
5. Expected service life of the device including parts and accessories: 5 years.

6. Normal working conditions:

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

7. Technical parameters: (Software version: V2.12)

Parameter		Value
Display range	Oxygen saturation	35% to 100%
	Pulse rate	25 bpm to 250 bpm
Resolution	Oxygen saturation	1%
	Pulse rate	1 bpm
Measurement precision	Oxygen saturation	±2% (70% to 100%) No requirement (≤ 69%)
	Pulse rate	±2 bpm
Alert error	Oxygen saturation	± 1% of the preset value
	Pulse rate	The greater of ±10% of the preset value and ±5 bpm
Battery	times	High-performance dry battery can be used for about 685 times at normal temperature

8. Technical statement
- The device does not have an alarm system for SpO2 or pulse rate physiological conditions.
- If the signal detected by the pulse oximeter is inadequate or weak, the SpO2 and pulse rate readings will display as "--" and "---".
- A functional tester cannot assess the accuracy of a pulse oximeter probe or monitor.
- The pulse oximeter has a specific calibration curve accurate for the combination of the pulse oximeter and its probe. If a functional tester measures an error from the main part of the pulse oximeter, the accuracy replicating this calibration curve can be verified.
- The manufacturer will provide circuit diagrams, component part lists, descriptions, calibration instructions, or other information to assist designated service personnel with repairs upon request.
- The pulse rate waveform is normalized. Optimal measurement values are achieved when the waveform is smooth and stable. Data updates every 30 seconds, with data averaging every 8 data points.

Note：Pulse oximeter measurements are statistically distributed, with about two-thirds of measurements expected to fall within ±Arms of the value measured by a co-oximeter.

Note：The statistical conclusion of a controlled desaturation study, guided by ISO 80601-2-61, Annex EE, shows the accuracy distribution within the range of 70%-100%.

Safety Type

Anti-electric-shock type: Internal power supply device
Anti-electric-shock degree: Type BF applied part
Running mode: Continuous operation
Waterproof grade: IP22

Storage and Transportation

Packaged products should be stored in well-ventilated rooms without corrosive gases. The storage conditions should be:
Ambient temperature: –10°C to +50°C
Relative humidity: 10% to 93% (without condensation)
Atmospheric pressure: 50 to 106 kPa

Statement

Lay responsible organizations must contact local authorities to determine the proper disposal method for potentially biohazardous parts and accessories, as applicable.

Any serious incident related to the device should be reported to the manufacturer without delay.

Support and Service

For after-sale service and support, please contact:
Pylo Health
3250 N Post Road, STE 180
Indianapolis, IN 46226
info@pylo.com
(818) 253-8867

EMC Guidance and Manufacturers Declaration

WARNING: Avoid using this equipment adjacent to or stacked with other equipment, as it could result in improper operation. If necessary, ensure both this equipment and the other equipment are operating normally.

WARNING: Using accessories, transducers, and cables other than those specified or provided by the manufacturer may increase electromagnetic emissions or decrease electromagnetic immunity, leading to improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the medical equipment, including cables specified by the manufacturer. Otherwise, performance degradation of this equipment may occur.

Table 1

Declaration - electromagnetic emission	
Emissions test	Compliance
RF emissions (CISPR 11)	Group 1
RF emissions (CISPR 11)	Class B
Harmonic emissions (IEC 61000-3-2)	Not applicable
Voltage fluctuations/flicker emissions (IEC 61000-3-3)	Not applicable

Table 2

Declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) (IEC 61000-4-2)	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles	Not applicable
IEC 61000-4-11	Single phase: at 0° 0 % UT; 250/300 cycles	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
NOTE: UT is the a.c. mains voltage prior to application of the test level.		

Table 3

declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz	Not applicable
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m

Table 4

declaration - IMMUNITY to proximity fields from RF wireless communications equipment

Immunity test	IEC60601 test level				Compliance level
	Test frequency	Modulation	Max power	Immunity level	
Radiated RF IEC 61000-4-3	385 MHz	**Pulse Modulation : 18Hz	1.8W	27 V/m	27 V/m
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation : 217Hz	0.2 W	9 V/m	9 V/m
	810 MHz 870 MHz 930 MHz	**Pulse Modulation : 18Hz	2 W	28 V/m	28 V/m
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation : 217Hz	2 W	28 V/m	28 V/m
	2450 MHz	**Pulse Modulation : 217Hz	2 W	28 V/m	28 V/m
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation : 217Hz	0.2 W	9 V/m	9 V/m

Note* - As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.
Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.

Distributed by:

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