

Fingertip Pulse Oximeter

English

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 arterial 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

- Red and Infrared-ray Emission Tube
- Red and Infrared-ray Receipt Tube

Precautions For Use

- Before use, carefully read the manual.
- Operation of the fingertip pulse oximeter may be affected by the use of an electro-surgical unit (ESU).
- 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.
- Do not use the fingertip pulse oximeter in an MRI or CT environment.
- Do not use the fingertip pulse oximeter in situations where alarms are required. The device has no alarms. It is not for continuous monitoring.
- Do not use the fingertip pulse oximeter in an explosive atmosphere.
- 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.
- 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.
- Do not sterilize the device using autoclaving, ethylene oxide sterilizing, or immersing the device in liquid. The device is not intended for sterilization.
- Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
- This equipment complies with IEC 60601-1-2:2014 for electromagnetic compatibility for medical electrical equipment and/or 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.
- Portable and mobile RF communications equipment can affect medical electrical equipment.
- This equipment is not intended for use during patient transport outside the healthcare facility.
- This equipment should not be used adjacent to or stacked with other equipment.
- 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

- These materials that contact with the patient's skin contain medical silicone and ABS plastic enclosure are all pass the ISO10993-5 Tests for invitro cytotoxicity and ISO10993-10 Tests for irritation and delayed-type hypersensitivity.
- When the signal is not stable, the reading may inaccurate. Please do not reference.

Rx only: **"Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner."**

Contraindication

It is not for continuous monitoring.

Inaccurate measurements may be caused by

- Significant levels of dysfunctional hemoglobin (such as carbonyl - hemoglobin or methemoglobin).
- Intravascular dyes such as indocyanine green or methylene blue.
- High ambient light. Shield the sensor area if necessary.
- Excessive patient movement.
- High-frequency electro-surgical interference and defibrillators.
- Venous pulsations.
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
- The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
- The patient is in cardiac arrest or is in shock.
- Fingernail polish or false fingernails.
- Weak pulse quality (low perfusion).
- Low hemoglobin.

Product Features

- Simple to operate and convenient to carry.
- Small volume, light weight and low power consumption.
- Dual color OLED displays SpO₂, PR, PI (Perfusion Index), Pulse bar, and waveform.
- 7 display modes.
- Level 1-10 adjustable brightness.
- 2pcs AAA-size alkaline batteries; real-time battery status indication.
- Weak or unstable signal prompt provides more accurate measurements.
- The device automatically shuts off after no operation in 8 seconds when "finger out" displays.
- Multiple-patient reusability.

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 homecare.

Operation Instructions

- Install two AAA batteries according to the Battery Installation instructions.
- Place one of your fingers into the rubber opening of the Pulse Oximeter.
- Press the switch button one time on front panel to turn the pulse oximeter on.
- 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.
- Read the data from the display screen.
- The display modes are as follows.



