Fingertip Pulse Oximeter

MEDSOURCE

USER MANUAL

MD

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 SpO_2. A pulse oximeter also measures and displays the pulse rate at the same time it measures SpO_2 level.

Measurement Principle

Principle of the oximeter is as follows: 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 varible amounts of light during systole and diastole, as blood volume increases and decreases. The ration of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO_2.

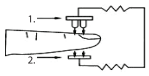


Diagram of Operation Principle

1. Red and Infrared-ray Emission Tube
2. Red and Infrared-ray Receipt 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 properly to obtain an accurate SpO_2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO_2 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 an alarm is 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. 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.
9. Do not sterilize the device using autoclaving, 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 60601-1-2:2014 for electromagnetic compatibility for medical electrical equipment and/or systems. However, because of the frequent use of radio-frequency transmitting equipment and other sources of electrical noise healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of æource might disrupt the performance of this device.
12. Portable and mobile RF communications equipment can affect medical electrical equipment
13. This equipment is not intended for use during patient transport outside the healthcare facility.
14. This equipment should not be used adjacent to or stacked with other equipment.
15. 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

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

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

Contraindication

This device is not for continuous monitoring.

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 patient 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 intravascular line.
8. The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
9. The patient is in cardiac arrest or is in shock.
10. Fingernail polish or false fingernails.
11. Weak pulse quality (low perfusion).
12. Low hemoglobin.

Product Features

1. This device is simple to operate and convenient to carry.
2. This device is compact, light weight and uses low power consumption.
3. Dual color OLED displays SpO_2, PR, Pulse bar, and waveform.
4. Level 1-10 adjustable brightness.
5. 6 display modes.
6. Two AAA-size alkaline batteries; battery-low indicator.
7. When it shows Finger out the pulse oximeter will power off automatically in 8 seconds.

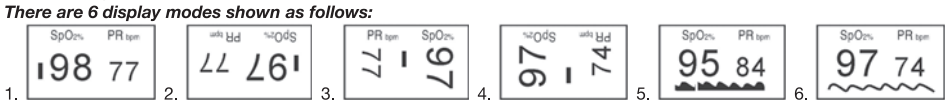
Intended Use

The Fingertip Pulse Oximeter is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO_2) and Pulse Rate of adult, adolescent and child patients in hospitals, hospital-type facilities and homecare.

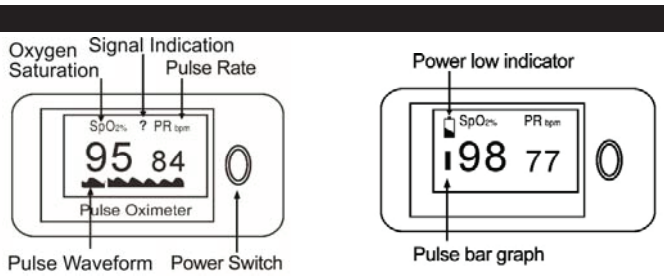
Operation Instructions

1. Install two AAA batteries according to the Battery Installation instructions.
2. Place one of your fingers into the rubber opening of the pulse oximeter.
3. Press the switch button one time on front panel to turn the pulse oximeter on.
4. 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.
5. Read the data from the display screen.
6. Pressing the power switch for longer than one second, will adjust the brightness of the oximeter. There are 10 levels of brightness. The default is level four.

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



Note:

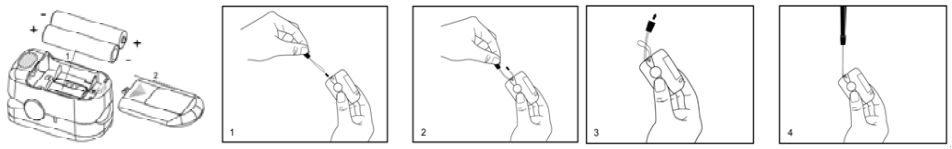
1. If the screen displays "?" it means the signal is unstable. Please keep your hands still and retry.
2. If the pulse bar is less than 30% this indicates signal inadequacy, and the displayed SpO_2 and pulse rate value are potentially incorrect.

Battery Installation

1. Install two AAA batteries into the battery compartment, being sure to match the plus (+) and minus (-) signs in the compartment. Not matching the polarities may damage the oximeter.
2. Slide the battery door cover horizontally along the arrow shown as the picture.

Notes:

- Please remove the batteries if the pulse oximeter will not be used for long periods of time.
- Please replace the battery when the power indicator starts flickering.



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!**

- Keep the oximeter away from young children. Small items such as the battery door, battery, and lanyard are choking hazards.
- Do not hang the lanyard from the device's electrical wire.
- Please note that attaching the lanyard to the oximeter will add a strangulation risk.

Maintenance and Storage

1. Replace the batteries in a timely manner when power indicator starts flickering
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 -25° ~+70° and ≤ 93% 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.

Cleaning the fingertip pulse oximeter

Please use medical alcohol to clean the silicone. Wipe the finger inside of oximeter with a soft cloth dampened with 70% isopropyl alcohol. Also clean the tested finger using alcohol before and after each test.
Do not pour or spray liquids onto the oximeter, and do not allow any liquid to enter any openings in the device. Allow the oximeter to dry thoroughly before reuse.
The fingertip pulse oximeter requires no routine calibration or maintenance other than replacement of batteries.

The device should last 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:

- An error in the Possible Problems and solutions is displayed on screen.
- The oximeter cannot be powered on and battery is not dead.
- 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.

Disinfecting

The applied parts touching the patients' body are required to be disinfected once after each use. The recommended disinfectants include: ethanol 70%, isopropanol 70%, glutaraldehyde-type 2% liquid disinfectants.
Disinfection may cause damage to the equipment and is therefore not recommended for this pulse oximeter unless otherwise indicated in your hospital's servicing schedule. Clean the pulse oximeter before disinfecting it.
CAUTION: Never use EtO or formaldehyde for disinfection.

Specifications

1. Display Type
OLED display

2. SpO_2
Display range: 0%~100%
Measurement range: 70%~100%
Accuracy: 70%~100%±2%; 0%~69% no definition
Resolution: 1%

Note：A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor. Clinical testing is used to establish the SpO_2 accuracy. The measured arterial hemoglobin saturation value (**SpO_2**) of the sensors is compared to arterial hemoglobin oxygen (**SaO_2**) value, determined from blood samples with a laboratory CO-oximeter. The accuracy of the sensors in comparison to the CO-oximeter samples measured over the **SpO_2** range of 70%~100%. Accuracy data is calculated using the root-mean-squared (Arms value) for all subjects, per ISO 9919:2005, Medical Electrical Equipment– Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.
A functional tester is used to measure how accurately Fingertip Pulse Oximeter is reproducing the specified calibration curve and the PR accuracy.
The model of functional tester is Index2 FLUKE simulator and the version is 2.1.3.

3. Pulse Rate
Display range: 0bpm~250bpm
Measure range: 30bpm~250bpm
Accuracy: 30bpm~99bpm, ±2bpm; 100bpm~250bpm, ±2%
Resolution: 1bpm

4. Probe LED Specifications

	Wavelength	Radiant Power
RED	660 ± 3nm	3.2mw
IR	905 ± 10nm	2.4mw

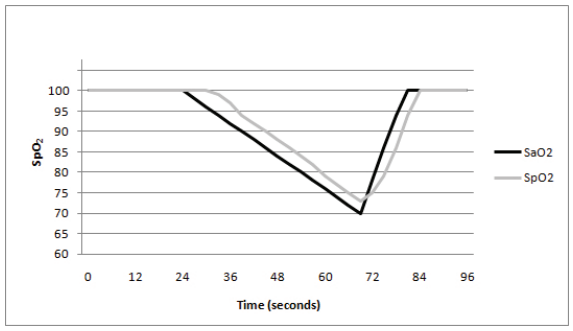
NOTE: The information about wavelength range can be especially useful to clinicians.

5. Power Requirements
Two AAA alkaline Batteries
Power consumption: Less than 40mA

6. Environment Requirements
Operation Temperature: 5° ~40°
Storage Temperature: -25° ~+70°
Ambient Humidity: 15%～93% no condensation in operation; ≤93% no condensation in storage/transport
Atmosphere pressure: 70kPa~106kPa

7. Equipment data update period

As shown in the following figure. Data update period of slower average is 8s.



8. Classification

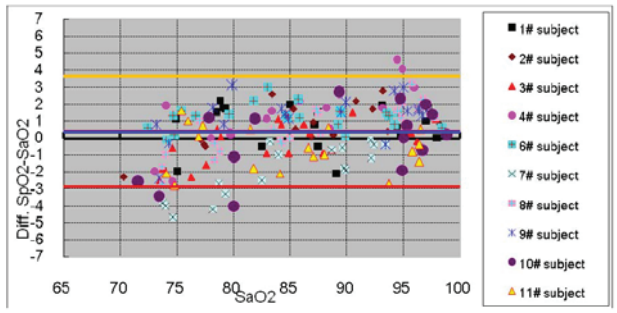
According to the type of protection against electric shock: INTERNALLY POWERED EQUIPMENT;
According to the degree of protection against electric shock: TYPE BF APPLIED PART, (applied part: the rubber hole of the device);
According to the degree of protection against ingress of water: IP22
According to the mode of operation: CONTINUOUS OPERATION

Clinical Study Summary

The following details are provided to disclose actual performance observed in the clinical validation study of healthy adult volunteers. The ARMS value analysis statement and Bland-Altman plot of data is shown as following:

ARMS Value Analysis Statement

Item	90--100	80--<90	70--<80
#pts	78	66	63
Bias	1.02	0.40	-0.48
ARMS	1.66	1.46	1.93



Bland-Altman Plot Graphic

Declaration

Requirement-Test	Result/Comments	Verdict
Clause 7 - Emissions		
Classification	–	—
Class A or B.....:	Class B	—
Group 1 or 2.....:	Group 1	—
CISPR 11, 14-1, 32 or ISO 7137.....:	CISPR 11	—
Conducted RF Emissions.....:	N/A	N/A
Radiated RF Emissions.....:	–	P
Disturbance Power (if applicable).....:	N/A	N/A
Harmonic Distortion per IEC61000-3-2 (Class A, B, C, D)...:	N/A	N/A
Voltage Fluctuations and Flicker per IEC61000-3-3.....:	N/A	N/A
Clause 8 - Immunity		
Electrostatic Discharges.....:	IEC 61000-4-2	P
Radiated RF EM Fields and Proximity Wireless fields.....:	IEC 61000-4-3	P
Electrical Fast Transients and bursts.....:	IEC 61000-4-4	N/A
Surges.....:	IEC 61000-4-5	N/A
Conducted Disturbances, Induced by RF fields.....:	IEC 61000-4-6	N/A
Voltage Dips and Interruptions.....:	IEC 61000-4-11	N/A
Rated Power-frequency Magnetic Field.....:	IEC 61000-4-8	P

Possible Problems and Solutions

Problems	Possible reason	Solution
SpO_2 or PR can not be shown normally	1. Finger is not inserted correctly 2. Patient's SpO_2 value is too low to be measured	1. Retry by inserting the finger 2. There is excessive illumination 3. Retry. If product demontrates no problems please go to hospital for exact diagnosis
SpO_2 or PR is shown unstably	1. Finger might not be inserted deep enough. 2. Excessive patient movement	1. Retry by inserting the finger 2. Calm patient
The oximeter cannot be powered on	1. No battery or low power of battery 2. Batteries might be installed incorrectly 3. The oximeter might be damaged	1. Please replace batteries 2. Please reinstall the batteries 3. Please contact customer service
Indication lamps are suddenly off	1. The product is automatically powered off when no signal is detected longer than 8 seconds 2. The battery power is too low to work	1. Normal 2. Replace the batteries
"Err7" is displayed on screen	Err 7 means all the emission LED or reception diode is damaged.	Please contact local customer service center.

Symbol Definitions

Symbol	Definition	Symbol	Definition
	Type BF applied part.		Attention
IP22	Protected against dripping water.	SpO_2	Oxygen saturation
PR bpm	Pulse rate (BPM)		Low power indication
SpO_2	No SpO_2 Alarm	SN	Serial No.
+ 158°F / 70°C max; -13°F / -25°C min; RH≤93% non-condensing	Storage temperature and relative humidity		Follow instruction for use
	Date of Manufacture	EC REP	Authorized representative in the European community
CE 0123	European union approval		Manufacturer's information
	Conformity to WEEE Directive	?	Indicate the signal is not stable
	Importer	MD	Medical device
UDI	Unique device identifier		

Box Contents

1. Fingertip pulse oximeter
2. One lanyard
3. Two AAA batteries
4. One instruction manual

Applicable Models

MS-74002

Notes:

1. **The illustrations used in this manual may differ slightly from the appearance of the actual product.**
2. **The specifications are subject to change without prior notice.**

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