dynarex Resp-O2™

Reorder No. 36402

Fingertip Pulse Oximeter (Pediatric)

General Description

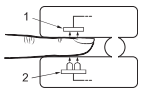
Oxygen binds to hemoglobin in red blood cells when moving through the lungs. It is transported throughout the body as arterial blood. A pulse oximeter uses two frequencies of light (red and infrared) to determine the percentage (%) of hemoglobin in the blood that is saturated with oxygen. The percentage is called blood oxygen saturation, or SpO_2. A pulse oximeter also measures and displays the pulse rate at the same time it measures the SpO_2 level.

Measurement Principle

Principle of the oximeter is as follows: The pulse oximeter works by applying a sensor to a fingertip. 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 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 SpO_2.

Diagram of Operation Principle

1. Red and Infrared-ray Detector
2. Red and Infrared-ray Light Source



Precautions For Use

1. Before use, carefully read the manual.
2. Operation of the pulse oximeter may be affected by the use of an electrosurgical unit (ESU).
3. The 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 pulse oximeter in an MRI or CT environment.
5. Do not use the pulse oximeter in situations where alarms are required. The device has no alarms. It is not for continuous monitoring.
6. Do not use the pulse oximeter in an explosive atmosphere.
7. The 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 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 medical electrical equipment.
The portable and mobile RF communications equipment should be used no closer than 30cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
13. This equipment is not intended for use during patient transport outside the healthcare facility.
14. The patient is an intended operator. All functions of the device can be safely used by the patient.
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. The material that contact with the patient's skin has passed the ISO10993-5 Tests for invitro cytotoxicity and ISO10993-10 Tests for irritation and delayed-type hypersensitivity.
17. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
18. The use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
19. When the signal is not stable, the reading may be inaccurate, please do not refer.
20. The material of the device has no nature latex.
21. The pulse oximeter equipment is calibrated to display functional oxygen saturation.
Rx only: "Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner."

Contraindication

Not yet found.

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 Properties

1. Simple to operate and convenient to carry.
2. Small volume, light weight and low power consumption.
3. OLED display SpO_2, PR, and Pulse bar.
4. Level 1-10 adjustable brightness.
5. 6 display modes.
6. 2pcs AAA-size alkaline batteries; battery-low indicator.
7. When no or low signal is detected, the pulse oximeter will power off automatically in 8 seconds.

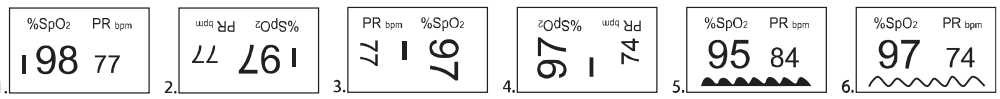
Intended Use

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

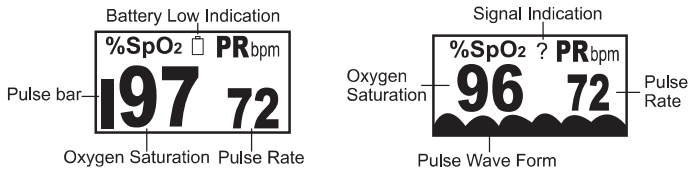
1. Install two AAA batteries according to the Battery Installation instructions.
2. Place one of your fingers into the rubber opening of the pulse oximeter.
3. Press the switch button one time on front panel to turn the pulse oximeter on.
4. Keep your hands still for the reading. Do not shake your finger 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. Press the button again to toggle between six display modes.

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:



Holding 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.

Front Panel



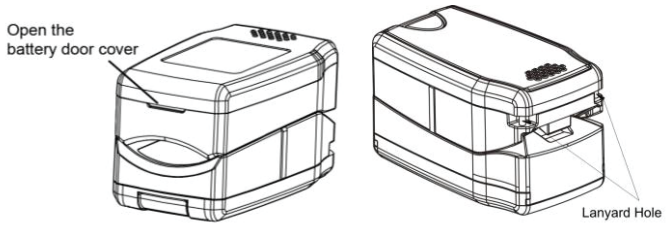
Notes:
1. The pulse bar less than 30% indicates signal inadequacy and the displayed SpO_2 and pulse rate value is potentially incorrect.
2. If the screen displays "?", it means the signal is unstable, please keep your hands still and retry.

Battery Installation

1. Open the battery door cover shown as the picture.
2. 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.
3. Close the battery door cover.

Note:

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



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.
3. Please notice that the lanyard which is tied to the oximeter may cause strangulation due to excessive length.

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 -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.

Clean and disinfect the device

- It is recommended to clean and disinfect the silicone touching the finger inside of device with a soft cloth dampened with recommended alcohol of 70% isopropyl or 70% ethanol before and after each use.
- Excessive disinfection may cause damage to the device and is therefore not recommended for this device unless otherwise indicated in your hospital's servicing schedule.
- Do not pour or spray liquids onto the device and do not allow any liquid to enter any openings in the device. Allow the device to dry thoroughly before reuse.

The Fingertip Pulse Oximeter requires no routine calibration or maintenance other than replacement of batteries.
Caution: Never use EtO (ethylene oxide) or formaldehyde for disinfection.

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:

- Any of the problems in the *Possible Problems and solutions* cannot be solved.
- The oximeter cannot be powered on in any case and not the reasons of battery.
- 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. 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 80601-2-61, 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: 30bpm~250bpm
Measure range: 30bpm~250bpm
Accuracy: 30bpm~99bpm, ±2bpm; 100bpm~250bpm, ±2%
Resolution: 1bpm

4. Probe LED Specifications

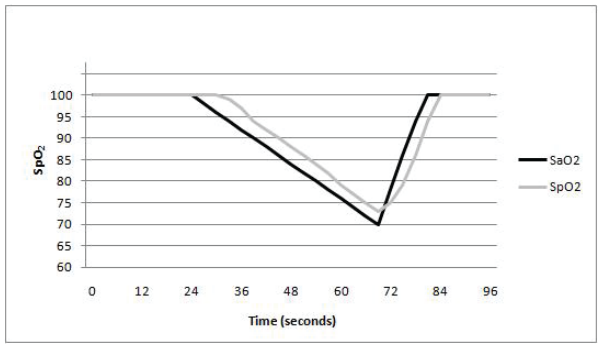
	Wavelength	Radiant Power
RED	660±3nm	3.2mW
IR	905±10nm	2.4mW

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

5. Power Requirements
Two AAA alkaline Batteries
Power consumption: Less than 40mA
Battery Life: Two AAA 1.5V, 1200mAh alkaline batteries could be continuously operated as long as 24 hours.

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.



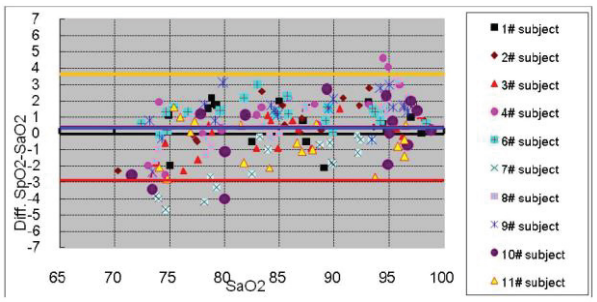
8. Classification
According to the type of protection against electric shock: INTERNALLY POWERED EQUIPMENT;
According to the degree of protection against electric shock: TYPE BF APPLIED PART, (applied part: the rubber hole of the device);
According to the degree of protection against ingress of water: 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 are shown as follows:

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

Electromagnetic Compatibility

The device conforms to IEC60601-1-2:2014 Electromagnetic Compatibility (EMC) standard.
Essential performance is defined as SpO_2 accuracy and pulse rate accuracy or an indication of abnormal operation. Accuracies may be affected as a result of exposure to electromagnetic disturbances that are outside of the environments listed in the intended use. If issues are experienced, move the device away from the source of electromagnetic disturbances.

Table 1: Electromagnetic Emissions Limits and Compliance

Emissions Test	Compliance
RF Emissions CISPR 11	Group 1, Class B
Note: Harmonic Emissions (IEC 61000-3-2), Voltage Flicker Emissions (IEC 61000-3-3) are not applicable.	

Table 2: Electromagnetic Immunity

Immunity Test	Compliance	
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	
Rated power Frequency Magnetic Fields IEC 61000-4-8	30 A/m 50Hz and 60 Hz	
Radiated RF IEC 61000-4-3	80 MHz – 2.7 GHz	10 V/m 80% AM 1kHz
	380 – 390 MHz	27 V/m Pulse mod. 18Hz
	430 – 470 MHz	28 V/m FM±5Hz deviation 1kHz sine
	704 – 787 MHz	9 V/m Pulse mod. 217Hz
	800 – 960 MHz	28 V/m Pulse mod. 18Hz
	1.7 – 1.99 GHz	28 V/m Pulse mod. 217Hz
	2.4 – 2.57 GHz	28 V/m Pulse mod. 217Hz
	5.1 – 5.8 GHz	9 V/m Pulse mod. 217Hz
Note: Electrical Fast Transients (IEC 61000-4-4), Surge (IEC 61000-4-5), Voltage dips (IEC 61000-4-11), Conducted Immunity (IEC 61000-4-6) are not applicable.		

Possible Problems and Solutions

Problems	Possible reason	Solution
SpO_2 or PR cannot 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. Try some more times. If you can make sure no problem exist in the product, please go to a hospital timely 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. Be calmness
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 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 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.	Check the emission LED and reception diode.

Symbol Definitions

Symbol	Definition	Symbol	Definition
	Type BF applied part.		Caution
	Follow instructions for use		Low power indication
SpO_2	No SpO_2 Alarm	% SpO_2	Oxygen saturation
IP22	Protected against dripping water.	SN	Serial No.
PR bpm	Pulse rate (BPM)	?	Indicate the signal is not stable
+158°F +70°C / -13°F -25°C	Temperature limit		Date of Manufacture
93% / 0%	Humidity limitation	DEHP	Does not contain Phthalates (DEHP)
	Non-ionizing electromagnetic radiation		Waste electrical and electronic equipment
Rx Only	Prescription use only		
LOT	Batch code		

Box Contents

1. Fingertip pulse oximeter
2. One lanyard
3. Two AAA batteries
4. One user manual
5. Silicon rubber boot

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.**

Manufactured for: Dynarex Corporation
10 Glenshaw Street • Orangeburg, NY 10962
USA • www.dynarex.com

Made in China R210909