Reorder No. 7090

Pediatric Finger Pulse Oximeter

USER MANUAL

General Description

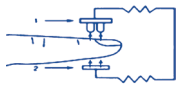
Oxygen Saturation is a percentage of Oxyhemoglobin (HbO2) capacity, compounded with oxygen, by all combinative hemoglobin (Hb) capacity in blood. In other words, it is consistency of Oxyhemoglobin in blood. It is a very important parameter for the Respiratory Circulation System. Many respiratory diseases can result in oxygen saturation being lowered in human blood. Additionally, the following factors can reduce oxygen saturation: Automatic regulation of organ dysfunction caused by Anesthesia, Intensive Postoperative Trauma, injuries caused by some medical examinations. That situation might result in light-headedness, asthenia, and vomiting. Therefore, it is very important to know the oxygen saturation of a patient so that doctors can find problems in a timely manner.

The fingertip pulse oximeter features low power consumption, convenient operation and portability. Place one fingertip into the photoelectric sensor for diagnosis and the pulse rate and oxygen saturation will appear on the display. It has been proven in clinical experiments that it also features high precision and repeatability.

Measurement Principle

Principle of the oximeter is as follows: A mathematical formula is established making use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin (RHb) and Oxyhemoglobin (HbO2) in glow and near-infrared zones. Operation principle of the instrument: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of light of different wavelengths (660nm glow and 940nm near infrared light) can be focused onto a human nail tip through a clamping finger-type sensor. A measured signal obtained by a photosensitive element will be shown on the oximeter's display through process in electronic circuits and microprocessor.

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 Pediatric Finger Pulse Oximeter may be affected by the use of an electrosurgical unit (ESU).
3. The Pediatric Finger 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 Pediatric Finger Pulse Oximeter in an MRI or CT environment.
5. Do not use the Pediatric Finger Pulse Oximeter in situations where alarms are required. The device has no alarms. It is not for continuous monitoring.
6. Do not use the Pediatric Finger Pulse Oximeter in an explosive atmosphere.
7. The Pediatric Finger 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 this device should be less than four hours.
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 60601-1-2:2007 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.

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. Operation of the product is simple and convenient.
2. The product is small in volume, light in weight and convenient to carry.
3. Power consumption of the product is low and the two AAA batteries can be operated continuously for 30 hours.
4. A low voltage warning will be indicated when battery voltage is low and normal operation of the oximeter might be influenced.
5. The product will automatically power off when there is no signal for longer than eight seconds.

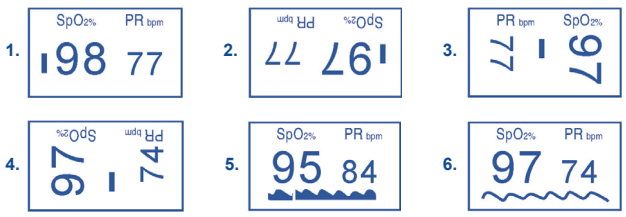
Intended Use

The Pediatric Finger Pulse Oximeter is a portable non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of pediatric patients at home and in hospital (including clinical use in internist/surgery, anesthesia, intensive care, etc). It is not for continuous monitoring.

Operation Instructions

1. Install two AAA batteries according to the Battery Installation instructions listed above in the right column.
2. Open the clamp as illustrated in the picture below.
3. Fully insert one fingertip into the silicone hole of the oximeter before releasing the clamp.
4. Press the switch button once on front panel.
5. Keep your finger still during measurement.
6. Read corresponding data from display screen.
7. Press the button again to toggle between six display modes.

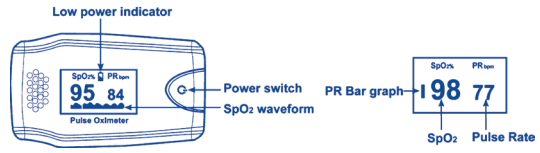
After turning on the oximeter, each time you press the power switch the oximeter will switch to another display mode. There are 6 display modes shown as follows:



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

Patient pulse quality signals are indicated by bar graph. The bar is graded as 10 levels, if the strength is level 2 to 3, the pulse signal is inadequate.

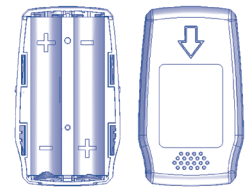


Product Accessories

1. One lanyard - Included
2. Two AAA batteries - Not included
3. One user manual - Included
4. One silicone case - Included

Battery Installation

1. 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.
2. Slide the battery door cover horizontally along the arrow shown as the picture.

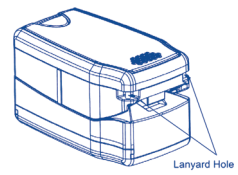


Notes:

- Install the batteries with the correct polarity. Incorrect placement may cause damage to the bracket.
- Please remove the batteries if the pulse oximeter will not be used for long periods of time.

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.

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 -20°C ~ +55°C and ≤93% humidity.
5. Keep in a dry place. Extreme moisture may affect oximeter lifetime and may cause damage.
6. Dispose of batteries properly; follow any applicable local battery disposal laws.

Cleaning the Pediatric Finger Pulse Oximeter

Please use medical alcohol to clean the silicone touching the finger inside of oximeter with a soft cloth dampened with 70% isopropyl alcohol. Also clean the finger being tested 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.

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.

The Pediatric Finger Pulse Oximeter requires no routine calibration or maintenance other than replacement of batteries.

The 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:

- An error in the ***Possible Problems and Solutions*** is displayed on screen.
- The oximeter cannot be powered on in any case and the battery is not the cause.
- 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: 0～99%
   Measurement range: 70～99%
   Accuracy: 70%～99%: ±3%; 0%～69% no definition
   Resolution: 1%
3. **Pulse Rate**
   Display range: 0～254bpm
   Measure range: 30～235bpm
   Accuracy: 30～99bpm, ±2bpm; 100～235bpm, ±2%
   Resolution: 1bpm
4. **Probe LED Specifications**

	Wavelength	Radiant Power
RED	660 ±2nm	1.8mW
IR	940 ±10nm	2.0mW

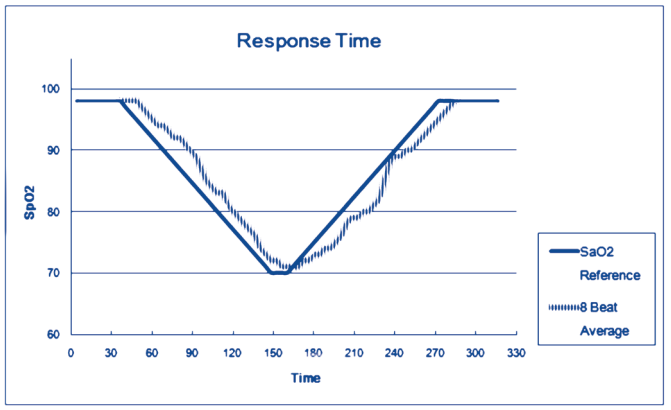
5. **Power Requirements**
   Two AAA alkaline batteries
   Power consumption: Less than 30mA
   Battery Life: Two AAA 1.5V, 600mAh alkaline batteries could be continuously operated as long as 30 hours.

   It is equipped with a function switch, through which the oximeter can be powered off if no finger is present in the oximeter for longer than eight seconds.

6. **Outline Dimensions**
   Length: 49~51mm
   Width: 28~30mm
   Height: 28~30mm
   Weight: 30~50g (including two AAA batteries)

7. **Environment Requirements**
   Operation Temperature: 5 ~ 40°C
   Storage Temperature: -20 ~ +55°C
   Ambient Humidity: ≤80% no condensation in operation
   ≤93% no condensation in storage

8. **Equipment Response Time**
   As shown in the following figure.
   Response time of slower average is 12.4s.



9. **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
   According to the degree of protection against ingress of water: IPX1
   According to the mode of operation: CONTINUOUS OPERATION

Declaration

Guidance and Manufacturer's declaration – electromagnetic emissions – For all EQUIPMENT and SYSTEMS

Guidance and Manufacturer's declaration – electromagnetic emission		
The Pediatric Finger Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic Environment – guidance**
RF emissions CISPR 11	Group 1	The Pediatric Finger Pulse Oximeter uses 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 CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and Manufacturer's declaration – electromagnetic immunity – For all EQUIPMENT and SYSTEMS

Guidance and Manufacturer's declaration – electromagnetic immunity			
The Pediatric Finger Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic Environment – guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 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%.
Power frequency (50/60 Hz) 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.

Guidance and Manufacturer's declaration – electromagnetic immunity
For all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and Manufacturer's declaration - electromagnetic immunity

The Pediatric Finger Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user 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 Pediatric Finger Pulse Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 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 meters (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 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.

Guidance and Manufacturer's declaration – electromagnetic immunity
For all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING – CONTINUED

a Field strengths from fixed transmitters, such as base station for radio (cellular/cordless) telephones and land mobile radio 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 Pediatric Finger Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measurements may be necessary, such as reorienting or relocating the Pediatric Finger Pulse Oximeter.

b Over the frequency range 150 kHz to 80 MHz, fields strengths should be less than 3 V/m

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEMS – For all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and Pediatric Finger Pulse Oximeter

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)	
	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz	$d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz
0.01	0.1167	0.2334
0.1	0.3689	0.7378
1	1.1667	2.3334
10	3.6893	7.3786
100	11.6667	23.3334

For transmitters rated at a maximum output power not listed above, the recommended separation distance 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) according to the transmitter manufacturer.

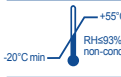
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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. Try some more times. If you can make sure no problem is existing in the product, please go to a hospital in a timely manner for exact diagnosis.
SpO_2 or PR is unstable	1. Finger might not be inserted deep enough. 2. Excessive patient movement.	1. Retry by inserting the finger. 2. Be calm.
The oximeter cannot be powered on	1. No battery or low battery power. 2. Batteries might be installed incorrectly. 3. The oximeter might be damaged.	1. Please replace the batteries. 2. Please reinstall the batteries. 3. Please contact your local customer service center.
Indication lamps are suddenly off	1. The product is automatically powered off when no signal is detected for longer than eight seconds. 2. The battery power is too low to work.	1. This is normal. 2. Please replace the batteries.
"Error 3" or "Error 4" is displayed on screen	1. "Error 3" means the red emission LED is damaged. 2. "Error 4" means the infra-red emission LED is damaged.	1. Check the red emission LED. 2. Check the infra-red emission LED.
"Error 6" is displayed on screen	"Error 6" means the screen has failed.	Change the screen.
"Error 7 " is displayed on screen	"Error 7" means the emission LED or reception dioxide is damaged.	Check the emission LED and reception dioxide.

Symbol Definitions

Symbol	Definition	Symbol	Definition
	Type BF applied part		No SpO_2 Alarm
	Consult accompanying documents		Storage temperature and relative humidity
	Protected against dripping water	SN	Serial No.
%SpO₂	Oxygen saturation		Manufacturer's information
PR bpm	Pulse rate (BPM)		Date of Manufacture
	Low power indication		

Please complete the attached warranty card and return for our record. Refer to the Dynarex website for complete warranty details.

Note: The illustrations used in this manual may differ slightly from the appearance of the actual product.

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