

# MCKESSON

## FINGERTIP PULSE OXIMETER

### INSTRUCTIONS FOR USE

**GENERAL DESCRIPTION:** Oxygen Saturation is a measure of how much oxygen the blood is carrying as a percentage of the maximum it could carry. Normal saturation is 95% - 100%. 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 and Intensive Postoperative Trauma, which are 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 is a compact device that features low-power consumption as well as convenient operation and portability. It is only necessary for a patient to put one finger into the fingertip photoelectric sensor and a display screen will show oxygen saturation and heart rate.

**CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.

### PRECAUTIONS

- Do not use the pulse oximeter in an MRI or CT environment.
- The pulse oximeter has no SpO2 alarms; it is not for continuous monitoring.
- 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.
- Assess the circulation and skin sensitivity of the patient prior to use to determine the positioning of the sensor on the application site.
- Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.
- Before use, carefully read the manual.
- Do not use near any flammable materials.
- Inaccurate measurements or readings may be caused by the following:
  - Autoclaving, sterilization using ethylene oxide, or immersing the sensors in liquid
  - Significant levels of dysfunctional hemoglobins (such as carboxyhemoglobin or methemoglobin)
  - Intravascular dyes such as indocyanine green or methylene blue
  - The presence of high ambient light (shield the sensor area if necessary)
  - Excessive patient movement
  - Venous pulsations
  - High-frequency electrosurgical interference
  - Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
  - The patient has hypertension, severe vasoconstriction, severe anemia or hypothermia
  - The patient is in cardiac arrest or is in shock
  - Fingernail polish or false fingernails

Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.

### PRODUCT PROPERTIES

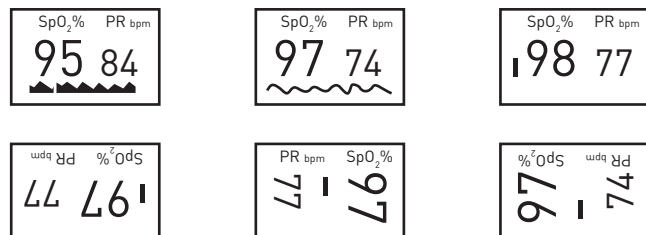
- Operation of the product is simple and convenient.
- The product is compact, lightweight and portable.
- Power consumption of the product is low; two AAA batteries can power the Fingertip Pulse Oximeter continuously for up to 16 hours.
- A low voltage warning will appear when the power is so low that normal operation of the oximeter might be influenced.
- The product will automatically be powered off when not in use for longer than 8 seconds.

**PRODUCT OPERATION SCOPE:** The Fingertip Pulse Oximeter is a portable non-invasive device used to determine the oxygen saturation of arterial hemoglobin [SpO2] and pulse rate of adult and pediatric patients. The device is intended for use by health care professionals. It can be used in a variety of health care settings including clinical use in internist/surgery, anesthesia, intensive care, etc. It is not to be used for continuous monitoring. The Fingertip Pulse Oximeter requires no routine calibration or maintenance other than the replacement of batteries.

### OPERATION INSTRUCTIONS

- Install two AAA batteries into the battery compartment.
- Place clamp over the fingernail.
- Fully insert one finger into rubber hole of the oximeter.
- Press the switch on the front panel.
- Finger and body should not tremble during measuring.
- Read correspondent data from display screen.

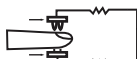
After turning on the oximeter, each time you press the power switch, the oximeter will switch to another display mode. There are 6 display modes shown as follows:



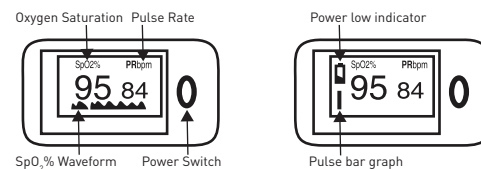
When you press and hold the power switch, the brightness of the oximeter will change. There are 10 levels of brightness, and the default is level four.

**NOTE:** Please use 70% isopropyl alcohol before and after each test to clean the oximeter's silicon rubber hole and the patient's test finger.

When your finger is inserted into the oximeter, your nail surface must be upward.



### BRIEF DESCRIPTION OF FRONT PANEL



The Pulse bar graph corresponds with the patient's heart rate. The height of the bar graph shows the patient's pulse strength.

### PRODUCT ACCESSORIES

- One lanyard
- Two AAA batteries
- One Instructions for Use

### BATTERY INSTALLATION

- Put the two AAA batteries into battery compartment in correct polarities.
- Push the battery cover horizontally along the arrow.
  - Battery polarities should be correctly installed. Otherwise, damage may be caused to the device.
  - Please put in or remove batteries in right order, or may cause damage to the device bracket.
  - Please remove the batteries if the oximeter will not be used for a long time to avoid corrosion.

### LANYARD INSTALLATION

- Thread the thin end of the lanyard through the loop.
- Thread the thick end of the lanyard through the threaded end and pull it tight.

### MAINTENANCE AND STORAGE

- Replace the batteries in a timely manner when low voltage lamp is lighted.
- Clean surface of the fingertip oximeter before it is used in diagnosis for patients.
- Remove the batteries if the oximeter is not operated for a long time.
- It is best to store the product in -20 ~ 55°C (-4 ~ 131°F) and <93% humidity.
- Keep in a dry place. Extreme moisture may affect oximeter lifetime and may cause damage.
- Dispose of battery properly; follow any applicable local battery disposal laws.

### CLEANING THE FINGERTIP PULSE OXIMETER

Gently wipe screen and all surface areas using a cloth dampened with 70% isopropyl alcohol.

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 SpO2 accuracy. The measured arterial hemoglobin saturation value [SpO2] of the sensors is compared to arterial hemoglobin oxygen [SaO2] 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 SpO2 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 fingertip pulse oximeter requires no routine calibration or maintenance other than replacement of batteries.

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:

- An error in the Possible Problems and Solutions is displayed on screen
- The oximeter cannot be powered on in any case not due to battery problems
- There is a crack in the oximeter or damage to the display resulting in readings that cannot be identified; the spring is broken; or the key is unresponsive

### DETAILED DESCRIPTIONS OF PRODUCT FUNCTIONS

#### 1. Display Type: OLED

#### 2. SpO<sub>2</sub>:

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

#### 3. Pulse Rate:

- Display range: 0 ~ 250 BPM
- Measure range: 30 BPM - 250 BPM
- Accuracy: 30 BPM ~ 99 BPM, ± 2 BPM; 100 BPM ~ 250 BPM, ± 2%
- Resolution: 1 BPM

#### 4. Probe LED Specifications:

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

#### 5. Power Requirements:

- Two AAA alkaline Batteries
- Power consumption: Less than 30mA
- Low power indication:
- Battery Life: Two AAA 1.5V, 800mAh alkaline batteries could be continuously operated as long as 16 hours. It is equipped with a function switch, through which the oximeter can be powered off in case no finger is in the oximeter longer than 8 seconds.

#### 6. Outline Dimension:

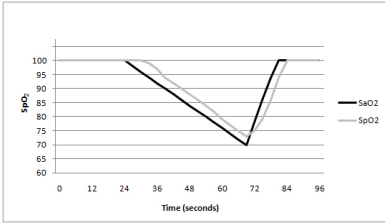
- Length: 56 mm
- Width: 32 mm
- Height: 34 mm
- Weight: 50 g (including two AAA batteries)

#### 7. Environment Requirements:

- Operation Temperature: 5°C ~ 40°C (41°F ~ 104°F)
- Storage Temperature: -20°C ~ 55°C (-4°F ~ 131°F)
- Ambient Humidity: ≤ 80%, no condensation in operation  
≤ 93%, no condensation in storage

**8. Equipment response time:**

As shown in the following figure. The slower average response time is 8s.



**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 mode of operation: CONTINUOUS OPERATION

**DECLARATION**

The Fingertip Pulse Oximeter is intended for use in the electromagnetic environment specified in this manual. The customer or the user of the pulse oximeter should assure that it is used in such an environment.


**Guidance and Manufacturer's Declaration - Electromagnetic Emissions**

Emission Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The 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 emission CISPR 11	Class B	The Pulse Oximeter is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
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**

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	The 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.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	The Pulse Oximeter is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

**Guidance and Manufacturer's Declaration - Electromagnetic Immunity - For all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING**

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	+/- 6kV contact +/- 8kV air	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Fingertip Pulse Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p>80 MHz to 800 MHz <math>d=1.2\sqrt{P}</math></p> <p>800 MHz to 2.5 GHz <math>d=2.3\sqrt{P}</math></p> <p>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).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with following symbol:</p> 

- 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 structures, objects and people.

- a. Field strengths from fixed transmitters, such as base station for radio (cellular/cordless) telephones and land mobile radios, 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 Fingertip Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measurements may be necessary, such as reorienting of the relocating the Fingertip Pulse Oximeter.
- b. Over the frequency range 150 kHz to 80 MHz, fields strengths should be less than 3 V/m.

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

**Recommended separation distances between portable and mobile RF communications equipment and the Fingertip Pulse Oximeter**









Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)	
	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.1167	0.2334
0.1	0.3689	0.7378
1	1.1667	2.334
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.

**SYMBOL DEFINITIONS**

Symbol	Definition	Symbol	Definition
	Type BF applied part.		Pulse Rate (BPM)
	Oxygen saturation		Low Power Indication
	No SpO2 Alarm		Validity
	Batch No.		
	Attention, consult accompanying document.		

**POSSIBLE PROBLEMS AND RESOLUTIONS**

- SpO<sub>2</sub> or PR can not be shown normally:**
  - If the finger is not inserted correctly, retry by reinserting the finger
  - If the patient's oxyhemoglobin value is too low to be measured, please go to a hospital for exact diagnosis
- SPO<sub>2</sub> or PR is shown unstably:**
  - If the finger is not inserted deep enough, retry by reinserting the finger
  - If the finger is trembling or the patient is moving, stabilize the patient
- The oximeter can not be powered on:**
  - If the battery power has depleted, replace the batteries
  - If the batteries are installed incorrectly, reinstall the batteries
  - If the oximeter is damaged, contact the Product Support Team at 1-800-777-4908
- Indication lamps are suddenly off:**
  - If the product is automatically powered off when not in use for longer than 8 seconds, this is normal
  - If the battery power has depleted, replace the batteries
- "Error3" or "Error4" is displayed on screen:**
  - Contact the Product Support Team at 1-800-777-4908
- "Error7" is displayed on screen:**
  - If the battery power is low, replace the batteries
  - If the emission tube is damaged, or the current control circuit malfunctions, contact the Product Support Team at 1-800-777-4908

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