

Fingertip Pulse Oximeter Operation Manual

General Description

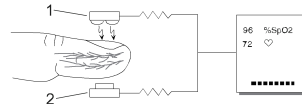
The Fingertip Pulse Oximeter iO2 is a low cost equipment for the non-invasive estimation of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR) for adults and children. The equipment is a battery powered. It may be used in the hospital, clinic, home healthcare environment. The oximeter will operate accurately over an ambient temperature range of 41 to 104°F (5 to 40°C).

NOTE: The product is not suitable to monitor patient continuously.

Measurement Principle

The pulse oximeter determines %SpO2 and pulse rate by passing two wavelengths of low intensity light, one red and one infrared, through body tissue to a photodetector. Information about wavelength range can be especially useful to clinicians. Wavelength information for this device can be found in the SpO2 Specifications section of this manual. Pulse identification is accomplished by using plethysmographic techniques, and oxygen saturation measurements are determined using spectrophotometric oximetry principles. During measurement, the signal strength resulting from each light source depends on the color and thickness of the body tissue, the sensor placement,

the intensity of the light sources, and the absorption of the arterial and venous blood (including the time varying effects of the pulse) in the body tissues.



Precautions for Use

1. Do not use the pulse oximeter in an MRI or CT environment.
2. Explosion hazard: Do not use the pulse oximeter in an explosive atmosphere.
3. 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.
4. Check the pulse oximeter sensor application site frequently to determine the positioning of the sensor and circulation and skin sensitivity of the patient.
5. Before use, carefully read the manual.
6. It is not for continuous monitoring, as indicated by the symbol.

7. 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.
8. Inaccurate measurements may be caused by autoclaving, ethylene oxide sterilizing, or immersing the sensors in liquid may cause inaccurate readings.
9. Intravascular dyes such as indocyanine green or methylene blue.
10. SpO2 measurements may be adversely affected in the presence of high ambient light. Shield the sensor area (with a surgical towel, or direct sunlight, for example) if necessary.
11. Excessive patient movement.
12. Venous pulsations.
13. Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
14. The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
15. The patient is in cardiac arrest or is in shock.
16. Fingernail polish or false fingernails may cause inaccurate SpO2 readings.

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

Product Properties

1. Easy to use.
2. Small dimension, light in weight (total weight is about 65g including batteries).
3. Lower power consumption; originally-equipped two AAA batteries can last to 15 hours.
4. Low voltage warning will be indicated in visual window when battery voltage is too low and normal application of the oximeter might be influenced.
5. The product will automatically be powered off when no signal is in the product for longer than 10 seconds.

Operation Instructions

1. Installing two AAA batteries into battery cassette before closing its cover.
2. Press the power button for 3 seconds on front panel.
3. Open the clamp, put one of your fingers into rubber hole of the oximeter (it is better to let your finger touch the bottom) before releasing the clamp shown as below:



4. Do not rock your fingertip when starting test. Do not move your body at the same time.
5. Reading data from display screen.
6. Six display modes.



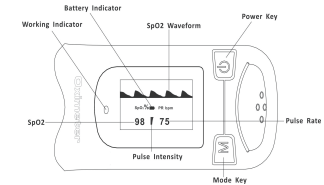
The following two modes can only be switched by pressing the M key.



7. Changing the high/low alarm limits of SpO2 and PR:

- 1) Press the Mode key for 3 seconds to enter the SpO2 [H/L], H is flashing. Each press will enter SpO2[L], PR [H/L].
- 2) To adjust the high limits of SpO2 or PR, press

press the Mode key for 3 seconds to adjust the low limits, then press the Mode key to increase the limit, and then press the Power key to decrease the limit, use the Mode key to exit.



NOTE! Please use the medical alcohol to clean the rubber touching the fingertip inside of oximeter, and clean the test sensor using alcohol before and after operation. (The rubber inside of the oximeter is medical rubber, which has no toxin, and no harmful to the skin of human being).

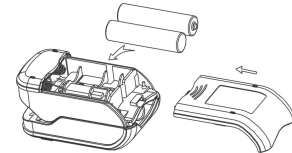
NOTE! When you put finger into the oximeter, your nail surface must be upward.

Brief Description of Front

Patient pulse quality signals are indicated as such by bar graph. The bar is graded as 8 levels, if the strength is two to three levels, the pulse signal is inadequate.

Product Accessories

1. One hanging strap



2. Two AAA batteries
3. One operation manual

Battery Installations

1. The two AAA batteries into battery cassette in correct polarities.
2. Push the battery cover horizontally along the arrow shown as below:

NOTE! Battery polarities must be correctly installed. Otherwise, damage might be caused to device.

WARNING! Please put or remove batteries in right order, or is likely to damage the device bracket.

CAUTION! Please remove the battery if the Oximeter will not be used for long time.

Hang Lace Installations

- 1. Thread thinner end of the hang lace through the hanging hole.
- 2. Thread thicker and of the lace through the threaded end before pulling it tightly.

Maintenance and Storage

- 1. Replace the batteries timely when the battery icon is empty.
- 2. Clean surface of the fingertip oximeter before it is used in diagnosis for patients.
- 3. Remove the batteries inside the battery cassette if the Oximeter will not be operated for a long time.
- 4. Environment Requirements:
Operation temperature: 5-40 °C
Operation Humidity:15%~90%RH(No condensation)
Storage temperature: -25 to 70 °C
Storage Humidity: 0%~100%RH
Atmospheric pressure: 700hPa~1060hPa

- 5. It is recommended that the product should be kept in a dry environment. Wet ambient might affect its lifetime and even might damage the product.
- 6. Clean inside of oximeter with a soft cloth dampened with 70% isopropyl alcohol. Clean the test fingertip using alcohol before and after each test.
- 7. Do not pour or spray and liquids onto the Oximeter. Do not allow any liquid to enter any openings in the device. Allow the Oximeter to dry thoroughly before reusing.

NOTE! It is recommended that the product be kept in a dry environment. Wet environment may affect its life and even damage the product.

NOTE! Please keep it out of reach of children and pets.

Detailed Description of Product Function

- 1. Display type: OLED display
- 2. SpO2:
Measurement range: 70-100%
Accuracy: ±2%at 70-100%
SpO2 alarm limit: high: 100%, Low: 90%
- 3. Pulse rate:
Measurement range: 30-250 bpm
Accuracy: ± 2 bpm or ± 2% of the measured value (whichever is the largest)
Pulse Intensity: Bargraph Indicator Pulse rate alarm limit: high: 120 bpm, low: 60 bpm
- 4. Power Requirement
Two AAA alkaline batteries
Power consumption: Average working current is less than 30mA
Low power indication
Battery life: At least 15 hours
- 5. Dimension:
71.99(L) *36.84(W)*35.8(H) mm
Weight: 42g (without battery)

Possible Problems and Solutions

Problems	Possible reason	Solution
SpO2% or pulse rate can not be shown normally.	1. Finger is not plugged correctly. 2. Patient's SpO2 value is too low to be measured. 3. Low battery.	1. Retry by plugging the finger. 2. a) There is excessive illumin-ation. b) Measuring more times, If you can make sure about no problem existing in the product. Please go to a hospital timely for exact diagnosis. 3.Please replace the battery.
SpO2% or pulse rate is shown unstably	1.Finger might not be plugged deep enough 2.Excessive patient movement	1. Retry by plugging the finger 2. Be calmness.
The Monitor can not be powered on	1.No battery or low power of battery 2.Battery might be installed incorrectly 3.The Monitor might be damaged	1. Please replace battery 2. Please reinstall the battery 3. Please contact with local customer service centre
Indication is suddenly off	1.The oximeter is automatically powered off when no signal is detected longer than 10 seconds 2.The batteries power is too low to work	1.Normal 2.Please replace the battery

Declaration

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

Guidance and Manufacture's declaration - electromagnetic emission		
Guidance and Manufacture's declaration – electromagnetic environment specified below. The customer of the user of the Pulse Oximeter (18705) should assure that it is used in such and environment.		
Emission test	Compliance	Electromagnetic Environment – guidance
RF emissions CISPR 11	Group 1	The pulse Oximeter (18711) uses RF energy only for very low and is not likely to cause interference in nearby electronic equipment. The pulse Oximeter (18711) 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.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC	Not Applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-2	Not Applicable	

Symbol Definitions

SYMBOLS	DEFINITION
	Attention, see in instructions for use
	Type BF Defibrillation
	Standby Key
	Mode Key
	Date of Manufacturing
IP22	Drip Proof (monitor only)
	Indicates separate collection for electrical and electronic equipment.