




OPERATOR'S MANUAL

VER 2.0C3B

Pulse Two

FingertipPulse Oximeter 

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.

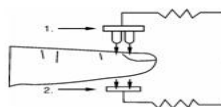
The fingertip pulse Oximeter features small size, low power consumption, convenient operation and portability. It is only necessary for a patient to put one of his fingers into the fingertip photoelectric sensor for diagnosis, and a display screen will show oxygen saturation. It has been proven in clinical 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 is Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (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 two groups of LEDs through process in electronic circuits and microprocessor shown on two groups of LEDs through electronic circuits and a microprocessor.

Diagram of Operation Principle

1. Red and Infrared-ray Emission Tube
2. Red and Infrared-ray Receipt Tube



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, circulation, and skin sensitivity.
- 5 Do not stretch the adhesive tape while applying the pulse Oximeter sensor. This may cause inaccurate readings or skin blisters.
- 6 Before use, carefully read the manual.
- 7 The pulse Oximeter has alarms, but it is not for continuous monitoring, as indicated by the symbol.
- 8 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.
- 9 Inaccurate measurements may be caused by autoclaving, ethylene oxide sterilizing, or immersing the sensors in liquid.
- 10 Significant levels of dysfunctional hemoglobins (such as carboxyhemoglobin or methemoglobin) may cause inaccurate readings.
- 11 Intravascular dyes such as indocyanine green or methylene blue may cause inaccurate readings.
- 12 SpO₂ measurements may be adversely affected in the presence of bright light. Shield the sensor area (with a towel, from direct sunlight, for example) if necessary.
- 13 Excessive patient movement may cause inaccurate readings.
- 14 High-frequency electrosurgical interference.
- 15 Venous pulsations may cause inaccurate readings.
- 16 Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line may cause inaccurate readings.
- 17 Hypotension, severe vasoconstriction, severe anemia, or hypothermia may cause inaccurate readings.
- 18 Cardiac arrest or shock may cause inaccurate readings.
- 19 Fingernail polish or false fingernails may cause inaccurate SpO₂ readings.

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

Product Properties

- 1 Operation of the product is simple and convenient.
- 2 The product is small in size, light in weight (total weight is about 50g including batteries).
- 3 Power consumption of the product is low and the ~~two~~ originally-equipped, two AAA batteries can be operated continuously for 30 hours.
- 4 A low voltage warning will be shown on the display when battery voltage is so low that the Oximeter might not operate normally.
- 5 The product will automatically be powered off when no signal is detected for longer than 8 seconds.

Product Operation Scope

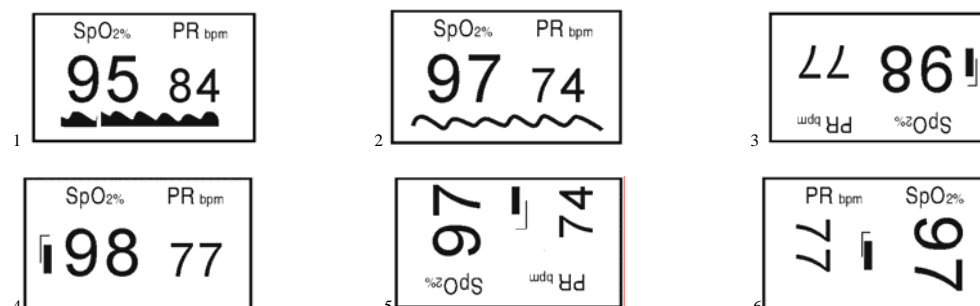
The fingertip Oximeter can be used to measure human Oxygen Saturation and heart rate through the finger. The product is suitable for use in families, hospitals (including clinical use in internist/surgery, anesthesia, pediatrics, intensive care etc.) Oxygen Clubs, social medical organizations, and in sports (It can be used before or after sports. Operation during sports is not recommended.).

The product is not suitable to monitor a patient continuously.

Operation Instructions

- 1 Install two AAA batteries into battery cassette before closing its cover.
Insert a finger into the rubber hole of the Oximeter, as shown in the diagram below. (It is best to insert the finger as far as possible before releasing the clamp.)
- 2 Press the switch button once on front panel.
- 3 While using the Oximeter, your finger should not tremble and you should not move around.
- 4 Read corresponding data on the display screen.
- 5 Six display modes

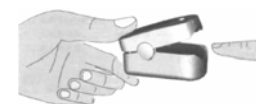
After turn on the Oximeter, each time you press the power switch, the Oximeter will switch to another display mode, there are 6 display modes shown as follows:



When you press the power switch for a long time (more than one second), the brightness of the Oximeter will be changed by degrees, there are 10 levels on brightness; the default level is level four.

Note: Please use medical alcohol to clean the rubber, inside the Oximeter, that touches the finger. Also, clean the test finger with alcohol before and after each test. (The rubber inside of the Oximeter is medical rubber, which has no toxins, and is not harmful to the skin).

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



- 6 OLED display
- 7 Adjustable brightness
- 8 Alarm:

Alarm range:

SpO₂: <90

Pulse rate: <60 or >100

Alarm mode: audio alarm and visual alarm

Visual alarm: The measuring value will be flashing when it is through over the alarm limitation.

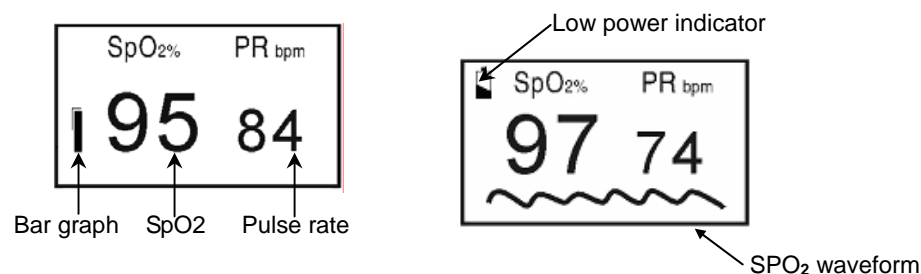
Audio alarm: The buzzer will beep shortly for two times when the value exceeds the alarm limitation.

Alarm silence function:

When the audio alarm occurs, the alarm sound can stop for 30 seconds by pressing Power button and there is only the visual alarm. By pressing the power button again, the audio alarms will resume.

NOTE: This function is only valuable for audio alarms, but not for pulse rate sound.

Brief Description of Front Panel



Product Accessories

1. One hang lace
2. Two batteries
3. One operator's manual

Battery Installation

1. Put two AAA batteries into the battery cassette observing correct polarities.
2. Install the battery cover by sliding it horizontally in the direction of the arrow as shown below:



Notes: Batteries must be correctly installed. Otherwise, damage might be caused to the device.

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

Please remove the batteries if the Oximeter will not be used for a long time.

Hang Lace Installation

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

Maintenance and Storage

1. Replace the batteries 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 from the battery cassette if the Oximeter will not be operated for a long time
4. It is best to store the product in a place where ambient temperatures are -20~55°C (-4~131°F) and humidity is 10%-93%.
5. It is recommended that the product should be kept in a dry environment. High humidity might affect its lifetime or even damage the product.
6. Please follow local ordinances regarding the disposal of used batteries.

Calibrating


1. The functional tester cannot be used to assess the accuracy of the Oximeter.
2. Index 2 that made by Bioteck company is a function tester. Set Tech to 1, R curve to 2, then user can use this particular calibration curve to measure the Oximeter.
3. The test methods used to establish the SpO₂ accuracy is clinical testing. The Oximeter used to measure the arterial hemoglobin oxygen saturation levels and these levels are to be compared to the levels determined from arterial blood sampling with a CO-Oximeter.

Declaration:

EMC of this product comply with IEC60601-1-2 standard.

The materials which user can come into contact is no toxicity and no action on tissues, (I don't know what this means) comply with ISO10993-1,-5,-10.

Detailed descriptions of product functions:

1. **Display Type:** OLED display
2. **SpO₂:**
Measurement range: 70-99%
Accuracy: ±2% on the stage of 80%-99%; ±3% on the stage of 70%-80%;
3. **Pulse Rate:**
Measure range: 30-235bpm
Accuracy: 30-99bpm ±2bpm; 100-235bpm ±2%
Pulse Intensity: Bargraph Indicator
4. **Power Requirements:**
Two AAA alkaline Batteries
Power consumption: Less than 30mA
Low power indication: 
Battery Life:
Two AAA 1.5V, 800mAh alkaline batteries could continuously operate the Oximeter for 30 hours.
5. **Dimension:**
Length: 60mm
Width: 34mm
Height: 30mm
Weight: 50g (including two AAA batteries)
6. **Environment Requirements:**
Operation Temperature: 5~40°C
Storage Temperature: -10~40°C
Ambient Temperature: 15%-80% in operation; 10%-80% in storage
7. **Declaration:** EMC of this product complies with IEC60601-1-2 standard.
8. **Measurement Performance in Low Perfusion Condition:** required the test equipment (BIO-TEK INDEX Pulse Oximeter tester) the pulse wave is available without failure when the simulation pulse wave amplitude is at 0.6%.
9. **Interference Resistance Capacity against Ambient Light:** Device work normally when mixed noise produced by BIO-TEK INDEX Pulse Oximeter tester.

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

Guidance and Manufacturer's declaration – electromagnetic emission







The *Pulse Oximeter* is intended for use in the electromagnetic environment specified below. The customer of or the user of the *Pulse Oximeter* should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The <i>Pulse Oximeter</i> 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 <i>Pulse Oximeter</i> 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.

Possible Problems and resolutions

Problems	Possible reason	Solution
SpO ₂ or PR can not be shown normally	1. Finger is not inserted correctly 2. Patient's oxygen saturation value is too low to be measured.	1..Retry by reinserting the finger 2. Try some more times. If you can make sure no problems exist with the product, please go to a hospital in a timely manner for exact diagnosis.
SpO ₂ or PR is erratic	1. Finger might not be inserted deep enough. 2. Finger is trembling or patient's body is moving around.	1. Retry by reinserting the finger. 2. Try not to move around.
The Oximeter can not be powered on	1. Batteries might be low or missing. 2. Batteries might be installed incorrectly 3. The Oximeter might be damaged	1. Replace the batteries 2. Please reinstall the batteries. 3. Please contact a customer service center.
Indication lamps are suddenly off	1. The product is automatically powered off when no signal is detected for longer than 8 seconds 2. Batteries might be low.	1. Normal 2. Replace the batteries
"Error3" or "Error4" Displayed on screen	1. Low power 2. Receiving tube being shielded or damaged together with broken connector. 3. Mechanical Misplace for receive-emission tube. 4. Amp circuit malfunction.	1. Replace the batteries 2. Please contact a customer service center 3. Please contact a customer service center 4. Please contact a customer service center
"Error7" displayed on screen	1. Low power 2. Emission tube damaged. 3. Current control circuit malfunction.	1 Replace the batteries 2 Please contact a customer service center 3 Please contact a customer service center

Symbol Definitions

Symbol	Definition	Symbol	Definition
	The equipment type is BF		Heart rate (BPM)
	Refer to user manual before application		Low power indication
SpO ₂ %	Hemoglobin saturation	SN	Serial No
	Not for continuous monitoring		Date of manufacture

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