OPERATOR'S MANUAL

Ver 2.2D
Fingertip Pulse Oximeter

CE 0123

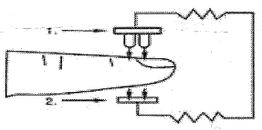
General Description

Haemoglobin Saturation is percentage of Oxyhemoglobin (HbO2) capacity, compounded with oxygen, by all combinativable haemoglobin (Hb) obin (HbO2) capacity in blood. In other words, it is consistence of Oxyhemoglobin in blood. It is a very important ecological parameter for Respiratory circulation System. Many respiratory diseases can result in haemoglobin Saturation being lowered in human blood. Moreover, the following factors can also lead to problems in oxygen supply, so that human haemoglobin saturation might be reduced: Automatic Organic Regulation Malfunction caused by Anesthesia, Intensive *Postoperative Trauma, hurts resulted in* by some medical examination and etc. In the situation, illnesses, such as light head, asthenia, vomitory and etc, might happen to patients and even endanger the patient's life. Therefore, it is very important to know Hemoglobin saturation of patient timely in clinical medical aspects. So that doctors can find problems in time.
The fingertip pulse oximeter features in small volume, low power consumption, convenient operation and being portable. It is only necessary for patient to put one of his fingers into a fingertip photoelectric sensor for diagnosis, and a display screen will directly show measured value of hemoglobin Saturation. It has been proved in clinical experiments that it features in rather high precise and repeatability.

Measurement principle

Principle of the oximeter is as follows: An experience formula of data process is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin(R Hb) and Oxyhemoglobin (O2 Hb) 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 human nail tip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on two groups of LEDs 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 Do not use the pulse oximeter in an MRI or CT environment
2 Do not use the pulse oximeter in situations where alarms are required. The device has no alarms.
3 Explosion hazard: Do not use the pulse oximeter in an explosive atmosphere.
4 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.
5 Check the pulse oximeter sensor application site *frequently* to determine the positioning of the sensor and circulation and skin sensitivity of the patient.
6 Do not stretch the adhesive tape while applying the pulse oximeter sensor. This may cause inaccurate readings or skin blisters.
7 Before use, carefully read the manual.
8 The pulse oximeter has no SpO2 alarms; it is not for continuous monitoring, as indicated by the symbol.
9 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.
10 Inaccurate measurements may be caused by autoclaving, ethylene oxide sterilizing, or immersing the sensors in liquid may cause inaccurate readings.
11 Significant levels of dysfunctional hemoglobins (such as carbonxy-hemoglobin or methemoglobin)
12 Intravascular dyes such as indocyanine green or methylene blue
13 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.
14 Excessive patient movement
15 Venous pulsations
16 Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
17 The patient has hypotension, severe vasoconstriction, severe anemia, or *hypothermia*
18 The patient is in cardiac arrest or is in shock
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 volume, light in weight (total weight is about 50g including batteries) and convenient in carrying
3 Power consumption of the product is low and the two originally-equipped two AAA batteries can be operated continuously for 30 hours.
4 Low voltage warning will be indicated in visual window when battery voltage is so low that normal operation of the oximeter might be influenced.
5 The product will automatically be powered off when no signal is in the product for longer than 8 seconds.

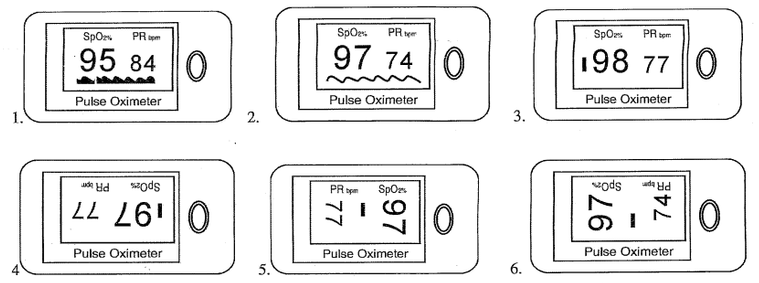
Product Operation Scope

The fingertip Oximeter can be used to measure human Haemoglobin Saturation and heart rate through finger. The product is suitable for use in family, hospital (including clinical use in internist/surgery, Anaesthesia, paediatrics, intensive care and etc.) Oxygen Club, social medical organizations, physical care in sports (It can be used before or after sports. Operation in sport procedure is not recommended) and etc.
The product is not suitable to monitor patient continuously.

Operation Instructions

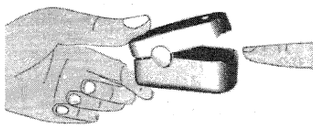
1 Installing two AAA batteries into battery cassette before covering its cover.
2 Nip the clamp as diagram
3 Plug one of fingers into rubber hole of the Oximeter (it is best to plug the finger thoroughly) before releasing the clamp
4 Press the switch button once on front panel.
5 Your finger do not tremble during the Oximeter is working. Your body is not recommended in moving status
6 Read correspondent datum from display screen.
7 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:

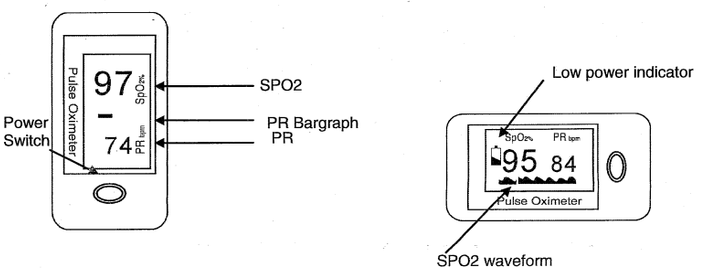


When you press the power switch for a long time (more than one second), the brightness of the oximeter will be changed by degrees, there are 10 levels on brightness; the default level is level four.
Declaration: Please use the medical alcohol to clean the rubber touching the finger inside of Oximeter, and clean the test finger using alcohol before and after each test. (The rubber inside of the Oximeter belongs medical rubber, which has no toxin, and no harmful to the skin of human being).

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



Brief Description of Front Panel



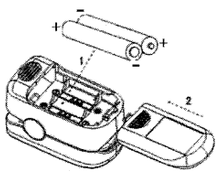
It is apparent the heart rate bargraph display corresponds with pulse rate.

Product Accessories

1. One hang lace
2. Two batteries
3. One user manual

Battery Installation

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



Notes: Battery polarities must be correctly installed. Otherwise, damage might be caused to device.
Please put or remove batteries in right order, or is likely to damage the device bracket.
Please remove the battery if the Oximeter will not be used for long time

Hang Lace Installation

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 low voltage lamp is lighted
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. It is best to preserve the product in a place where ambient temperatures –10-40℃(14-104℉) and humidity is 10%-80%
5. It is recommended that the product should be kept in a dry environment anytime. A wet ambient might affect its lifetime and even might damage the product.
6. Please follow the law of the local government to deal with used battery

Calibrating the pulse oximeter

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 haemoglobin 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, 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：30-235 BPM
   Accuracy：±2 BPM or ±2%（larger）
   Pulse Intensity: Bargraph Indicator
4. **Power Requirements:**
   Two AAA alkaline Batteries
   Power consumption: Less than 40mA

   Low power indication:
   Battery Life:
   Two AAA 1.5V, 600mAh alkaline batteries could be continuously operated as long as 30 hours.
5. **Dimension:**
   Length: 58mm
   Width: 32mm
   Height: 34mm
   Weight: 50g (including two AAA batteries)
6. **Environment Requirements:**
   Operation Temperature: 5-40℃
   Storage Temperature: -10-40℃
   Ambient Temperature: 15%-80% in operation
   10%-80% in storage
7. **Declaration:** EMC of this product comply 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 6%.**
9. **Interference Resistance Capacity against Ambient Light: Device work normally when mixed noise produced by BIO-TEK INDEX Pulse Oximeter tester**

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

Guidance and manufacture's declaration – electromagnetic emission

The *Pulse Oximeter* is intended for use in the electromagnetic environment specified below. The customer of the user of the *Pulse Oximeter* 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* 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.

Possible Problems and resolutions

Problems	Possible reason	Solution
SpO2 or PR can not be shown normally	1. Finger is not plugged correctly 2. Patient's Oxyhemoglobin value is too low to be measured	1. Retry by plugging the finger 2. Try some more times. If you can make sure about no problem existing in the product. Please go to a hospital timely for exact diagnosis
SpO2 or PR is shown unstably	1. Finger might not be plugged deep enough 2. Finger is trembling or patient's body is in movement status	1. Retry by plugging the finger 2. Try not to move
The Oximeter can not be powered on	1. Power of batteries might be inadequate or not be there at all 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. Power quantity of the batteries is started being inadequate	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. Change new battery 2. Please contact with local customer service center 3. Please contact with local customer service center 4 Please contact with local customer service center
"Error7" displayed on screen	1. Low power 2. Emission tube damaged. 3. Current control circuit malfunction.	1 Please change battery 2 Please contact with local customer service center 3 Please contact with local customer service center

Symbol Definitions

Symbol	Definition
	The equipment type is BF
	Refer to user manual before application
%SpO2	Hemoglobin saturation
BPM	Heart rate (BPM)
	Low power indication
SN	Serial No