

# OPERATOR'S MANUAL

Ver. 3.2C  
Fingertip Pulse Oximeter

CE 0123

## General Description

Haemoglobin Saturation is percentage of HbO<sub>2</sub> (Oxyhemoglobin), compounded with oxygen, in haemoglobin (Hb). In other words, it indicates the saturation of HbO<sub>2</sub> in blood. It is a crucial physiological parameter for Respiration System. Many respiratory diseases can lead to decrease of SPO<sub>2</sub> saturation. Moreover, such factors as organic automatic adjustment malfunction derived from anesthesia, side effect of major operation and injures aroused from physical check can also cause problems about SPO<sub>2</sub> saturation variation, which contributed to such adverse symptoms such as faint, vomit and feel weakness and so on. What's more, if can not get the right remedy, it can lead to dangers to human's life. Hence, it is very feasible for doctors to analyze patients' SPO<sub>2</sub> saturation as reference to detect the root of the causes, which is more effective to relieve patients' pain and conduct suitable therapy plan as soon as possible.

The fingertip pulse oximeter with features of small dimension, low power consumption, easy-to-use and convenience for carry. As long as you put your figure in the device which read data through a light-sensitive probe, then the associated reading will be displayed on the indicator. It is proved by clinical trial Pulse Oximeter have outstanding precise and could repeat to measure the SPO<sub>2</sub> more accurately and stably.

## Measurement Principle

The fingertip pulse oximeter contains a dual light source and photodetector. Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO<sub>2</sub>.

The principle of the oximeter rely on the property of spectrum which collect data from

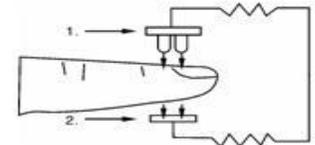
hemoglobin and oxyhemoglobin in glow area and area of approximate infrared source and apply the formular  $I = I_0 e^{-\mu c l}$  to establish the evaluating equation. In fact, the basic calculating technique is to combine electro-photo SPO<sub>2</sub> detecting technology with recording mock pulse rate technology to get the result, the process demonstrate as below:

Firstly, use glow with wavelength of 660nm and approximate infrared with wavelength of 940nm to put light on the finger tip ready to read analogue data.

Secondly, to process the data by electric circuit and microprocessor, then convey the data to LED display for reading.

## Diagram of Operation Principle

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



## Technical Specifications

1. Display mode: LED.  
Measuring range for SPO<sub>2</sub>: 35-99%  
Measuring range for PR: 30-235 BPM  
PR display mode: bargraph  
  
Low power indication: 
2. Battery standard: Two AAA 1.5V Alkaline Battery
3. Power consumption: Less than 40mA
4. Resolution: ±1% for SPO<sub>2</sub> and ±1BPM for Pulse Rate
5. Measurement accuracy:  
SpO<sub>2</sub>: 80%--99%, ±2%; 70%--80%, ±3%; <math>\leq 70\%</math>, no definition.  
PR: 30--235 BPM, ±2% or 2 BPM
6. Sensitive degree test: Under the condition of poor perfusion, when the amplitude of pulse waveform is 6% detected by BIO-TEK INDEX tester. Then it can be proved the sensitive degree is Ok.
7. Resistance capacity against ambient light: Device work normally when mixed noise produced by BIO-TEK INDEX Pulse Oximeter tester
8. Automatic power off: When no finger in the device for 8 seconds, it will power off

automatically.

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

**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 50g including batteries) and convenient for portable.
3. Lower power consumption; originally-equipped two AAA batteries can last to 30 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. No signal can be tested, device will power off automatically in 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.

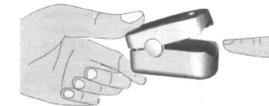
The pulse oximeter requires no routine calibration or maintenance other than replacement of batteries.

#### Operation Instructions

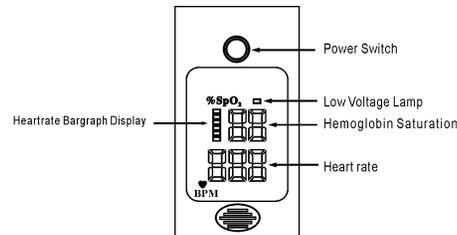
1. Installing two AAA batteries into battery cassette before closing its cover.
2. Open the clamp shown as in the picture below:
3. Put one of your fingers into rubber hole of the Oximeter (it is better to let your finger touch the bottom.) before releasing the clamp
4. Press the switch button for one time on front panel.
5. Do not rock your finger when starting test. Recommend you do not move your body at the same time.
6. Read correspondent data from display screen.

**Declaration:** Please use the medical alcohol to clean the rubber touching the finger 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).

When you put finger into the Oximeter, your nail surface must be upward.



## Brief Description of Front Panel



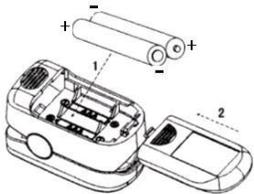
The length of the bargraph indicates the intensity of the pulse

## 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 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 end of the lace through the threaded end before pulling it tightly

## Maintenance and Storage

1. Replace the batteries timely when low voltage indicator is on.
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 better to preserve the product in a place where ambient temperatures range from . 10 to -40 (14-104 ) and humidity range from 10% to 80%.
5. It is recommended that the product be kept in a dry place. A damp ambient might affect its lifetime and even might damage the product.
6. Please follow the articles of the local government to deal with run-out-of battery

## Calibrating the 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.
- 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 are no toxicity and no action on tissues; comply with ISO10993-1,-5,-10.

## 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 <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
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 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. Lower power	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

### Symbol Definitions

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