

# Instruction Manual

## OxiSmarter I Finger type Pulse Oximeter

No. AE-XX

### 1. General Description

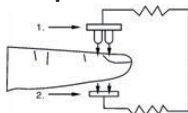
Haemoglobin Saturation is percentage of Oxyhaemoglobin (HbO<sub>2</sub>) capacity, compounded with oxygen, by all combinative haemoglobin (Hb) (HbO<sub>2</sub>) capacity in blood. In other words, it is consistence of Oxyhaemoglobin in blood. It is a very important ecological parameter for Respiratory 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 Finger type 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 finger type 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.

### 2. 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 Oxyhaemoglobin (O<sub>2</sub> Hb) in glow and near-infrared zones. Operation principle of the instrument is Photoelectric Oxyhaemoglobin 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
2. Red and Infrared-ray Receipt



### 3. 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 read the manual.

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. High-frequency electrosurgical interference and defibrillators
  16. Venous pulsations
  17. Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
  18. The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia
  19. The patient is in cardiac arrest or is in shock
  20. Fingernail polish of false finernails 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.

### 4. 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 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.

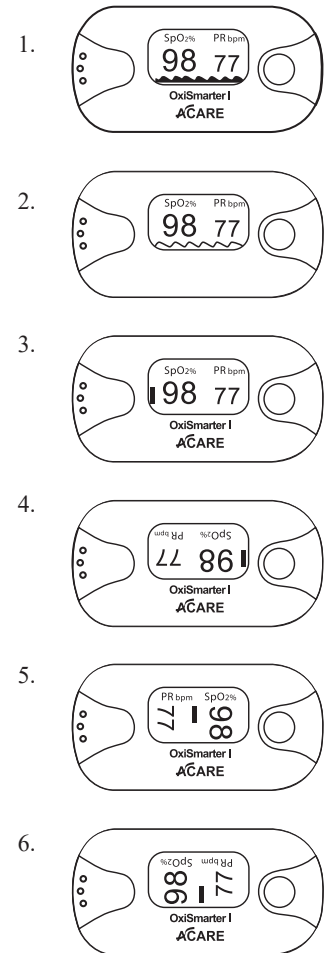
### 5. Product Operation Scope

The finger type 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, pediatrics, 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.

### 6. 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

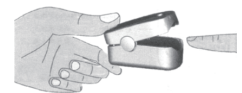
After turn on the oximeter, each time you press the power switch, the oximeter will switch to another display mode, there are 6 display modes shown as follows:



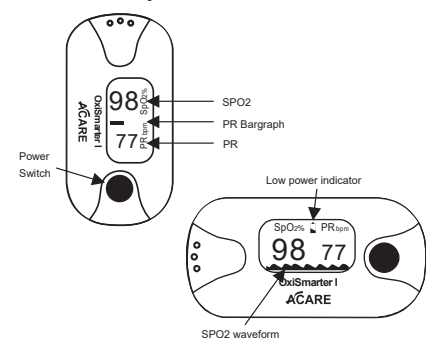
When you press the power switch for a long time (more than on second), the brightness of the oximeter will be changed by degrees, there are 10 levels on brightness; the default level is level four.

**Declaration:** Please use the medical alcohol to clean the rubber touching the finger inside of Oximeter, and clean the test finger using alcohol before an after each test. (The rubber inside os 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.



### 7. Brief Description of Front Panel



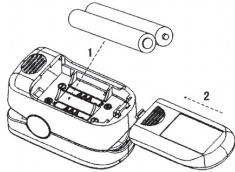
It is apparent the heart rate bargraph display corresponds with pulse rate.

## 8. Product Accessories

- 1 One hang lace
- 2 Two batteries
- 3 One User manual
- 4 One drawing bag

## 9. Battery Installations

- 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

## 10. Hang Lace Installations

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

## 11. Maintenance and Storage

1. Replace the batteries timely when low voltage lamp is lighted.
2. Clean surface of the finger type 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 range from -20°C to 55°C and ≤ 93% humidity.
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.

## 12. Calibrating the pulse oximeter


1. The functional tester cannot be used to assess accuracy of the oximeter.
2. Index 2 that made by Biotech 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 SpO<sub>2</sub> 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.

## 13. Declaration

EMC of this product comply with IEC60601-1-1-2 standards.  
The materials which user can come into contact is no toxicity and no action on tissues, comply with ISO10993-1 -5, -10.

## 14. Detailed descriptions of product functions

1. Display Type: OLED display
2. SpO<sub>2</sub> :  
Measurement range: 70%~100%  
Accuracy: ±2% on the stage of 70%~100%  
0%~69% no definition
3. Pulse Rate:  
Measure range: 30~235 BPM  
Accuracy: 30~99BPM, ±2 BPM ;  
100~235BPM, ±2 %

4. Power Requirements: Two AAA 1.5V 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: 61mm  
Width: 32mm  
Height: 37mm  
Weight: 50g(including two AAA batteries)
6. Environment Requirements:  
Operation Temperature: 5 ~ 40°C  
Storage Temperature: -20 ~ 55°C  
Ambient Humidity: ≤80% no condensation in operation  
≤93% no condensation in storage
7. Declaration: EMC of this product comply with IEC60601-1-1-2 standard.
8. Measurement Performance in Weak Filling 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.

## 15. Possible Problems and Resolutions

Problems	Possible reason	Solution
SpO <sub>2</sub> or PR can not be showed 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
SpO <sub>2</sub> or PR is showed 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

"Error6"	Err6 means the screen is failure.	Please contact 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





## 16. Guidance and manufacture's declaration - electromagnetic emissions - for all Equipmnet 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 an 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 use for domestic purposes.

## 17. Symbol Definitions

Symbol	Definition
	The equipment type is BF
	Refer to user manual before application
	No SpO <sub>2</sub> alarm
<b>SpO<sub>2</sub>%</b>	Hemoglobin saturation
<b>PRbpm</b>	Heart rate (BPM)
	Low power indication
<b>SN</b>	Serial No. (Attached inside of the unit )

**Notes:** Please remove the battery when product will not be in used for period of time.

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