OPERATOR'S MANUAL

VER1.0C615

Fingertip Pulse 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.

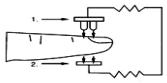
The fingertip pulse Oximeter features small size, low power consumption, convenient operation and portability. It is only necessary for a patient to put one of his fingers into the fingertip photoelectric sensor for diagnosis, and a display screen will show oxygen saturation. It has been proven in clinical 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: 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 the Oximeter's display through process in electronic circuits and microprocessor shown on the Oximeter's display through electronic circuits and a microprocessor.

Diagram of Operation Principle

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



Product Operation Scope

Fingertip Pulse Oximeter is a portable non-invasive, spot-check, oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult and pediatric patients at home, and hospital (including clinical use in internal medicine/surgery, anesthesia, intensive care and etc). The device is not intended for continuously monitoring.

The PULE OXIMETER requires no routine calibration or maintenance other than replacement of batteries.

Technical Specifications

1. Display: LED

2. SpO_2:
Measurement range：70～99%
Accuracy： 70%～99%, ±3%; <70% no definition

3. Pulse Rate:
Measure range：30~235 bpm
Accuracy：30~100bpm ±2bpm; 101~235bpm, ±2%
Pulse Intensity: Bar graph 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 be continuously operated as long as 30 hours.

5. Dimension:
Length: 58mm
Width: 32mm
Height: 37mm
Weight: 33g (without batteries)

6. Environment Requirements:
Operation Temperature: 5～40℃
Storage Temperature: -20～55℃
Ambient Humidity: ≤80%, no condensation in operation;
≤93%, no condensation in storage

7.Measurement Performance in Low Perfusion Condition: The pulse wave is available without failure when the simulation pulse wave amplitude is at 0.6% using the test equipment (BIO-TEK INDEX Pulse Oximeter Tester).

8.Interference Resistance Capacity against Ambient Light: Device works normally when mixed noise produced by BIO-TEK INDEX Pulse Oximeter Tester.

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_2 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_2 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 may cause accurate readings.

15 Venous pulsations may cause accurate readings.

16 Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line may cause accurate readings.

17 The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.

18 The patient is in cardiac arrest or in shock.

19 Fingernail polish or false fingernails may cause inaccurate SpO_2 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 in volume, light in weight.
3. Lower power consumption.
4. Low voltage warning will be indicated in visual window when battery voltage is low.
5. The product will automatically be powered off when no signal is in the product for longer than 8 seconds.

Operation Instructions

1. Install two AAA batteries into battery cassette, and then close its cover.
2. Open the clamp as shown in the picture below.
3. Insert one finger into the flexible fingertip of the Oximeter fully.
4. Press the power switch once on the front panel.
5. The patient's finger should remain still while the Oximeter is working.
6. Read corresponding data from display screen.

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

NOTE: 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 harm to the skin of human being).

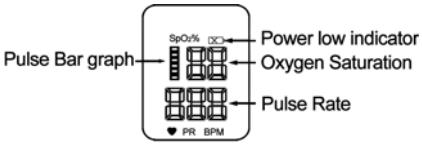
Product Accessories

1. One strap
2. Two batteries
3. One user's manual

Strap Installation

1. Thread thinner end of the strap through the loop.
2. Thread thicker end of the strap through the threaded end before pulling it tightly.

Brief Description of Front Panel



The Pulse Bar graph displays the strength of the pulse rate signal. The height of the bar graph shows the patient's pulse strength.

Battery Installation

1. Put the two AAA batteries into battery cassette in correct polarities.
2. Press the button down along the arrow and push the battery cover shown as below:

Notes:

- ✧ Battery polarities must be correctly installed to avoid damage to the device.
- ✧ Please insert or remove batteries in right order, or may cause damage to the device bracket.
- ✧ Please remove batteries if the Oximeter will not be used for a long time.

Maintenance and Storage

1. Replace batteries in time when low voltage lamp is lighted.
2. Clean surface of the fingertip Oximeter before it is used in diagnosis for patients.
3. Remove 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 temperature –20～55 ℃ and humidity is <93%, no condensation.
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 batteries.

Calibrating the Oximeter

1. The functional tester cannot be used to assess the accuracy of the oximeter.
2. The test method used to establish the SpO_2 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.
3. *Index 2* that made by Bioteck company is a function tester. Set Tech to 1, R curve to 2, and then users can use this particular calibration curve to measure the oximeter.

Declaration

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

The materials which the user can come into contact have no toxicity and no action on tissues, comply with ISO10993-1, ISO10993-5 and ISO10993-10.

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 or the user of the *Pulse Oximeter sh*ould 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
SpO_2 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.
SpO_2 or PR is shown unstably	1.Finger might not be plugged deeply 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" is displayed on screen.	1 Low power 2 Receiving tube being shielded or damaged together with broken connector. 3.Mechanical malfunction for receive-emission tube 4 Amp circuit malfunction.	1 Change new batteries. 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
	Type BF applied part
	Attention, consult accompanying documents.
SpO_2%	Oxygen saturation
BPM	Pulse rate (BPM)
	Low power indication
	NOT for continuous monitoring
SN	Serial No.

Applicable models

SM-210 SM-220

Note: The illustrations used in this manual may differ slightly from the appearance of the actual product.

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