Dr. Morepen®

OPERATOR'S MANUAL
FINGER PULSE OXIMETER
V1.0

CE 0123

General Description

Oxygen Saturation is a percentage of Oxyhemoglobin (HbO$_2$) 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 (HbO$_2$) 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 oflights (660nm glow and 905nm 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 patient at home, and hospital (including clinical use in internist/surgery, Anesthesia, intensive care etc). It is not for continuously monitoring.

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.
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.
11. Significant levels of dysfunctional hemoglobins (such as carbonxy- hemoglobin or methemoglobin) may affect the readings.
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 inaccurate readings.
15. High-frequency electrosurgical interference may cause inaccurate readings.
16. Venous pulsations may cause inaccurate readings.
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, may cause inaccurate readings.
19. The patient is in cardiac arrest or is in shock.
20. 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. Operation of the product is simple and convenient.
2. The product is small in volume, light in weight and convenient in carrying.
3. Power consumption of the product is low and the two AAA batteries can be operated continuously for 20 hours.
4. A 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.
6. No need to maintance except change batteries.

Operation Instructions

Oxygen Saturation — 98 72 — Pulse Rate

SpO2% Waveform
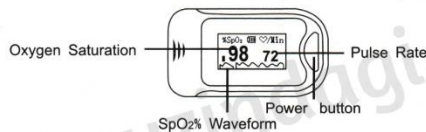
Power button

Parameter setting:

Press the power button (>0. 5s), the oximeter will enter into parameter setting. There are two submenu for choice:

When the '*' signal is shown on the 'Sounds setup', press the button (>0. 5s) and enter into the sounds setting menu , you can press the button in turn to select the item, and press the button to change the data you need. Select '+' or '-' to increase or decrease the numbet of settings.

When the '*' signal is shown on the 'Alm Setup', press the button (>0. 5s) and enter into the alarm setting menu . Press the button to set the on/off for the alarm and beep.

When the '*'signal is shown on the 'Restore', press the button (>0. 5s) and all the settings are back to the factory settings.

Settings	
Alm Setup *	
Alm	off
Beep	off
Restore	OK
Exit	

Settings	
Sounds Setup *	
SpO$_2$ Alm Hi	100
SpO$_2$ Alm Lo	90
PR Alm Hi	130
PR Alm Lo	50
+/-	+
Exit	

Battery Installation

1. Put the two AAA batteries into battery compartment in correct polarities.
2. Push the battery cover horizontally along the arrow shown as below:
   Notes:
   (1). Battery polarities should be correctly installed.
   (2). Otherwise, damage may be caused to the Device.
   (3). Please put in or remove batteries in right order, or may cause damage to the device bracket.
   (4). Please remove the batteries if the Oximeter will not be used for a long time.

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.

Operation Instructions

1. Install two AAA batteries into battery cassette before closing its cover.
2. Insert one finger into the Oximeter as following picture, the nail surface must be upward.

3. Insert one finger into rubber hole of the Oximeter fully.
4. press the Power button on the front case.
5. Finger and body should not tremble during measuring.
6. Read corresponding data on the display screen directly.
7. Finger leave the rubber hole for 8 seconds, it can auto off.

Note: Please use medical alcohol to clean the rubber, Oximeter inside. 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).

Detailed descriptions of product functions

1. Display Type: OLED

2. SpO₂:
Measurement range: 35%~100%
Accuracy:70%~99%, ±3%; ≤69%, no definition.

3. Pulse Rate:
Measure range: 30~250BPM
Accuracy:30~250BPM, ±2%。
Pulse rate display model: Bargraph Indicator

4. Power Requirements:
Two AAA alkaline Batteries
Power consumption: Less than 30mA
Low power indication: The low voltage lamp is lighted when the voltage less than 2.6V (error±0.2V)
Battery Life: Two AAA I.5V, 600mAh alkaline batteries could be continuously operated as long as 20 hours.

5. Dimension:
L×W×H: 57mm×31.5mm×30.5mm

6. Environment Requirements:
Operation Temperature: 5~40℃
Storage Temperature:-20~70℃
Ambient Humidity:
Work：15%~90%
Storage：15%~93%

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

8. Measurement Performance in Low Perfusion Condition: required the test equipment (FLUKE-INDEX 2XL) the pulse wave is available without failure when the simulation pulse wave amplitude is at 0.4%.

9. Interference Resistance Capacity against Ambient Light: Device works normally.
when mixed noise produced by FLUKE-INDEX 2XL.

Product Accessories

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

Maintenance and Storage

1. Replace the 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 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 is -10˚C~40˚C (14~104˚F) and relative humidity is during 15%~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 batteries.

Calibrating the pulse oximeter

1. Can not be used to assess the functional test equipment oximeter accuracy.
2. Produced using FLUKE oxygen analog meter, set the standard curve BCI oximeter calibration curve.

Note：The functional tester cannot be used to assess the accuracy of 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.

Possible Problems and resolutions

Problems	Possible reason	Solution
SpO₂ or PR can not be shown normally	Finger is not inserted correctly	Retry by inserting the finger
SpO₂ or PR is shown	1. Finger might not be inserted deep enough. 2. Finger is trembling or patient's body is in movement status.	1. Retry by inserting 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. Norma 2. Replace the batteries

Symbol Definitions

Symbol	Definition
👤	Type B applied part.
⚠	Attention, refer to the manual before using.
%SpO₂	Oxygen saturation
PRbpm	Heart rate (BPM)
▭	Low power indication
SpO₂	No SpO₂ Alarm
SN	Serial Number