ModeL:FL-100

FaceLake®

Pulse Oximeter

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 user 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 user 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 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
3. 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 user 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 user.

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 user'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 cause inaccurate 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 user movement may cause inaccurate readings.

15 Venous pulsations may cause inaccurate readings.

16 High-frequency electrosurgical interference may cause inaccurate readings.

17 Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.

18 The user has hypotension, severe vasoconstriction, severe anemia, or hypothermia.

19 The user 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 24 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 16 seconds.

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 user at home, and hospital (including clinical use in internist/surgery, Anesthesia, intensive care etc). It is not for continuously monitoring.

Operation Instructions

1 Install two AAA batteries into battery compartment correctly.

2 Place clamp over finger nail as the following diagram.

3 Insert one finger into rubber hole of the Oximeter fully.

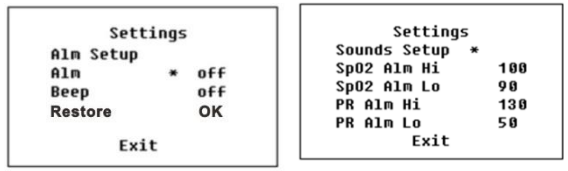
4 Press the switch once on the front panel.

5 Finger and body should not tremble during measuring.

6 Read correct data from display screen.

After turn on the oximeter, each time you press the function button, the oximeter will switch to another display mode, there are 4 display modes totally.

Long press the function button to enter the settings screen.



Short press to switch among the settings, long press to change the current settings of sounds and alarm limits.

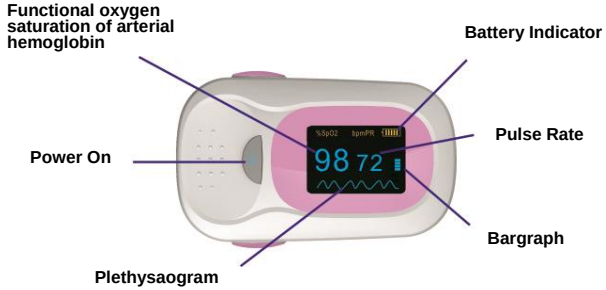
Notes:

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

✧ The results may be wrong if you did not plug the finger thoroughly in the Oximeter.

✧ Please use 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).

Brief Description of Front Panel



The Pulse bar graph displays correrndng with the user's pulse beat. The height of the bar graph shows the user's pulse strength.

Product Accessories

1. Lanyard
2. Two batteries
3. One user manual

Battery Installation

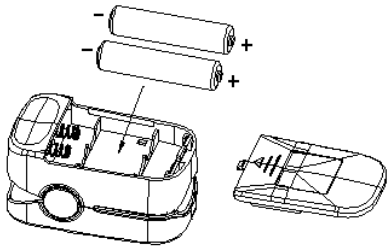
1. Put the two AAA batteries into battery compartment in correct polarities.
2. Push the battery cover horizontally along the arrow shown as below:

Notes:

✧ Battery polarities should be correctly installed. Otherwise, damage may be caused to the device.

✧ Please put in or remove batteries in right order, or may cause damage to the device bracket.

✧ 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.

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 users.
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℃～50℃and relative humidity is 10%-95%.
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. Avoid exposure or direct sunlight.
7. Avoid excessive radioactive infrared rays or ultraviolet rays.
8. Please follow the law of the local government to deal with used battery.

Technical Specification

1. Display Type:
Color OLED display, 4 display directions

2. SPO2:
Measurement range: 0%-100%
Resolution: 1%
Accuracy: 70%-100%, ±2%; 0%-69% no definition.

3. Pulse Rate:
Measure range：25BPM -250 BPM
Resolution: 1bpm,
Accuracy： 2bpm
Pulse Intensity: Bargraph Indicator

4. Power Requirements:
Two AAA alkaline Batteries
Power consumption: 30mA(Normal)
Low power indication:
Battery Life: Two AAA 1.5V, 600mAh alkaline batteries could be continuously operated as long as 24 hours.
5. Dimension:
Length: 64mm
Width: 35mm
Height: 34mm
Weight: 57g (including two AAA batteries)

6. Environment Requirements:
Operation Temperature: 5℃～40℃
Storage Temperature: -10℃～50℃
Ambient Humidity: 15%-80%, no condensation in operation.
10%-93%, no condensation in storage

7. Measurement Performance in Low Perfusion Condition:0.3%.

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

Guidance and manufacturer'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 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 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 inserted correctly 2. User's Oxyhemoglobin value is too low to be measured	1..Retry by inserting the finger 2. Try some more times, If you can make sure no problem is existing in the product. Please go to a hospital timely for exact diagnosis.
SPO_2 or PR is shown unstably	1. Finger might not be inserted deep enough. 2. Finger is trembling or user'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
The screen 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

There are no user-serviceable parts inside the oximeter. The cover should only be removed by qualified service personnel.

If you are uncertain about the accuracy of any measurement, check the user's vital signs by alternate means; then make sure the oximeter is functioning correctly.

Do not spray, pour, or spill any liquid on the oximeter, its accessories, connectors, switches, or openings in the enclosure as this may damage the oximeter.

Symbol Definitions

Symbol	Definition
CE 0482	CE Mark: The Product system conforms to essential requirements of the Medical Device Directive 93/42/EEC.
	Type BF equipment (Refer to IEC 60601-1:1995)
	Attention, consult accompanying documents.
%SPO_2	Oxygen saturation
/Min	Pulse rate
	Symbol for the marking of electrical and electronics devices according to Directive 200296/EC. The device, accessories and the packaging have to be disposed of waste correctly at the end of the usage. Please follow Local Ordinances or Regulations for disposal. Note: The Oximeter is applied to this regulation.

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

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