User Manual

Ver.1.0

Fingertip Pulse Oximeter

This Fingertip Pulse Oximeter is a kind of innovated medical device with non-invasive and continuous features for artery SPO2 and PR detection. Being portable, it is able to measure SPO2 and PR values quickly and precisely.

General Description

Haemoglobin Saturation is the percentage between the capacity of Oxyhemoglobin (HbO2) that compounded with oxygen and that of all combinativable haemoglobin (Hb) obin (HbO2) in blood. In other words, it is the saturation of Oxyhemoglobin in blood. It is a very important physiological parameter for Respiratory and Circulation Systems. Many respiratory diseases could reduce haemoglobin saturation in human blood. Moreover, factors such as Automatic Organic Regulation Malfunction caused by anaesthesia, trauma resulted from major operation and some medical examination can also cause problems in oxygen supply, which might reduce human haemoglobin saturation. As a result, such symptoms as megrim, vomiting and asthenia might appear to patients. Hence, it is very important to know hemoglobin saturation of patient timely in clinical medical aspects.

The fingertip pulse oximeter features in small volume, low power consumption, convenient operation and portability. It is only necessary for patient to put one finger into fingertip photoelectric sensor for diagnosis, and the display screen will directly show measured value of hemoglobin saturation. It has been proved in clinical experiments that it possesses rather high precision and repeatability.

Measurement principle

The principle of the oximeter is as follows: An experience formula of data process is established by exerting Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin(R Hb) and oxyhemoglobin (O2 Hb) in glow and near-infrared zones. Operation principle of the instrument is to combine Photoelectric Oxyhemoglobin Inspection Technology with Capacity Pulse Scanning and Recording Technology, so that two lights with different wavelength (660nm glow and 940nm near infrared light) can be focused onto human nail 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
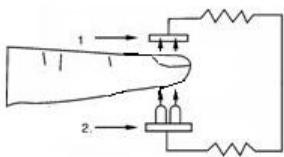
1. Infrared-ray receiving tube
2. Infrared-ray transmitting tube

Precautions for use

1. Do not use the pulse oximeter together with MRI or CT equipment.
2. Explosion hazard: Do not use the pulse oximeter in an explosive atmosphere.
3. The pulse oximeter is intended only as an adjunct in patient assessment. Doctors should make diagnosis in conjunction with clinical manifestation and symptoms.
4. Check the pulse oximeter sensor application site frequently to make sure that the circulation and skin integrality of patient are under good condition.
5. Do not stretch the adhesive tape while applying the pulse oximeter sensor. This may cause inaccurate reading or skin blisters.
6. Please read the manual carefully before your operation.
7. The pulse oximeter has no SpO2 prompt, it is not for continuous monitoring.
8. Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrality, circulatory status, and correct alignment at least every 2 hours.

9. Inaccurate measurements may be caused by autoclaving, ethylene oxide sterilizing, or immersing the sensors in liquid.
10. Significant levels of dysfunctional hemoglobins (such as carboxyl- hemoglobin or methemoglobin) may cause inaccurate reading.
11. Intravascular dyes such as indocyanine green or methylene blue may cause inaccurate reading.
12. SpO2 measurements may be adversely affected in the presence of high ambient light. Please shield the sensor area (with a surgical towel or direct sunlight, for example) if it is necessary.
13. Unexpected action may cause inaccurate reading.
14. Medical signal with high frequency or interference caused by defibrillator may lead to inaccurate reading.
15. Venous pulsations may cause inaccurate reading.
16. It may cause inaccurate reading when the positions of sensor and blood pressure cuff are on the same arterial catheter or intravascular line.
17. Hypotension, severe vasoconstriction, severe anemia, or hypothermia may cause inaccurate reading.
18. It may cause inaccurate reading by giving use of cardiotonic to patient after his cardiac arrest or when he is in quiver.
19. Bright nail or painted nail may cause inaccurate SpO2 reading.

Follow local ordinances and recycling instructions regarding to disposal or recycling of the device and device components, including batteries.

Features

◆ OLED display

➢ Product adopts double color OLED display，can show the six different display mode
➢ Low-power consumption, continuously work for 6 hours
➢ Low voltage indicator
➢ In the absence of signals, the product will be in after 8 seconds to enter standby state
➢ Small in volume, light in weight, and convenient to carry

Product Operation Scope

The fingertip Oximeter can be used to measure human haemoglobin saturation and heart rate through finger. The product applies to using in family, hospital (including clinical use in internist/surgery, anaesthesia, paediatrics, intensive care, 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). It is also applicable to enthusiasts on mountaineering, patients (convalescents at home or those need first aid treatment), elders over 60, those work more than 12 hours, sporters and those work in the hermetic circumstance, etc. The product is not suitable to monitor patient continuously.

Operation Instructions

1. Install two AAA batteries into battery cassette before covering its cover.
2. Plug one finger into rubber hole of the Oximeter (it is best to plug the finger thoroughly) before releasing the clamp with the nail upwards.
3. Press button on the front panel;
4. Don't tremble your finger when the Oximeter is working. Your body is not recommended on moving status.
5. Press the button on the front panel, if we want change display direction;
6. Read relevant datum from display screen.
7. The instrument has the function of sleep, no signal will enter standby state of sleep;
8. Please replace new batteries when OLED indicates the batteries are in low power.
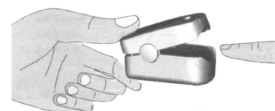
When plugging your finger into the Oximeter, your nail surface must be upward.

Declaration: Please use the medical alcohol to clean the rubber before each test and clean the

tested finger with alcohol before and after the test. (The rubber inside of the Oximeter adopts medical rubber, which has no toxin, no harm, and brings no side effect such as allergy to the our skin).
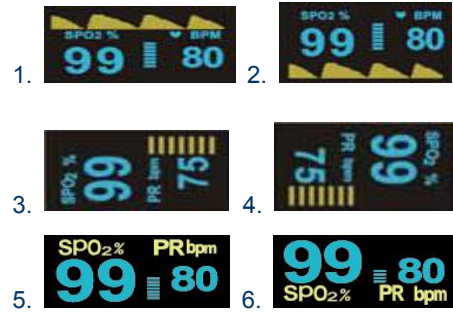
Brief Description of Front Panel

◆ OLED display:

start/mode key

◆ OLED display modes：

Keys function description: in standby mode, start the key instrument into the working state, push down this button under working state, can change the display mode.

Parameter Setup：

1. Press the menu button (> 3 seconds), the pulse oximeter will enter the parameter settings interface just like figure 1:

In the menu 1, press the button (< 1 second) can choose the options in turn, and press the button (> 3 seconds) can set up the sound and alarm on/off.

When the signal "*" is in the column " Alm Setup", press the button (> 3 seconds) can enter the menu 2.

In the menu 2, press the button (< 1 second) can choose the options in turn, and press the button (> 3 seconds) can set up the data as you need. Select "+" or "-" to increase or decrease the value.

```
        Settings
   Alm Setup     *

   Alm           off
   Deep          off
   Restore       OK

        Exit
```
figure 1

```
        Settings
   Sounds Setup    *

   SpO2 Alm Hi    100
   Spo2 Alm Lo    100
   PR Alm Hi      100
   PR Alm Lo      100
   +/-              +
        Exit
```
figure 2

Detailed descriptions of product functions:

1. Display Type：OLED display
2. SpO2：Measurement range：70%～99%
   Accuracy：±2% on the stage of 70%～99%，Unspecified(≤70%) for SPO2
   Resolution：±1%
3. PR：Measurement range：30BPM～240BPM
   Accuracy：±1BPM or ±1%（the larger one）
4. Power： two AAA 1.5V alkaline batteries
5. Power consumption：below 30mA
6. Automatic power-off：the product shuts off by itself when no finger is in the product in 8 seconds
7. Dimension：58mm×36mm×33mm
8. Operation Environment：Operation Temperature：5℃～40℃
   Storage Temperature：-10℃～40℃
   Ambient Humidity：15%～80% on operation
   10%～80% in storage
   Air Pressure： 70kPa～106kPa
9. Declaration：EMC of this product comply with IEC60601-1-2 standard.
10. Measurement Performance in Low Perfusion Condition ： required test equipment (BIO-TEK INDEX Pulse Oximeter tester) could measure the available pulse wave with the amplitude of 6% of the simulation pulse wave amplitude.
11. 11. Interference Resistance Capacity against Ambient Light:：Device works normally when

BIO-TEK INDEX Pulse Oximeter tester exerts interfering signal test.

Classification

1. Management Class for Medical Devices: Ⅱ equipment
2. Anti-electric Shock Type: Internally powered equipment
3. Anti-electric Shock Degree: Type BF equipment

Maintenance and Preservation

1. Replace the batteries timely when low voltage lamp is on.
2. Clean the surface of fingertip oximeter before it is used to diagnose patients.
3. Remove the batteries inside if you will not operate the Oximeter for a long time.
4. It would be better to preserve the product in -10~40 ℃ （14-104 ℉) and humidity is 10%-80%.
5. It is recommended that the product should be kept dry anytime. A wet ambience might affect its lifetime and even damage the product.
6. Please follow the law of the local government to deal with used batteries.

Product Accessories

1. One hang lace
2. Two batteries
3. One user manual

Guidance and manufacture's declaration-electromagnetic radiation-for other EQUIPMENTS and SYSTEMS

The Pulse Oximeter is designed to be used in specified electromagnetic environment . Users of the Pulse Oximeter must use it in the following environments.

Radiation Test	Compliance	Electromagnetic environment-guidance
RF interference CISPR 11	Group 1	RF signal of Pulse Oximeter is simply created by its internal function. Therefore, its RF interference is very low and is not likely to cause any interference to nearby electronic equipment.
RF interference CISPR 11	Class B	The Pulse Oximeter applies to 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

Problem	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 more times. If you can make sure there is no problem in the product, please go to hospital timely for exact diagnosis
SpO2 or PR is shown unsteady	1. The finger might not be plugged deep enough 2. Finger is trembling or the patient is on movement status	1. Retry by plugging the finger 2. Please remain at rest
The Oximeter can not be turned on	1. Inadequate power or power off 2. Batteries might be installed incorrectly 3. The Oximeter might be damaged	1. Please replace the batteries 2. Please reinstall the batteries 3. Please contact with local customer service centre
Indication lamps are suddenly off	1. The product automatically shuts off when no signal is detected in 8 seconds 2. Inadequate power	1. Normal 2. Replace the batteries

Symbols and Definitions

Symbol	Definition
⬚	The equipment type is BF
⚠	Refer to user manual before application
%SpO2	Hemoglobin Saturation
PR BPM	Heart Rate(BPM)

🔋	Low power indication
SN	Serial No.

Reserves the right to technical change appearance, our products are subject to change without prior notice, please forgive me!