

Instructions to User

Dear Users, thank you very much for purchasing our product.

This Manual is written and compiled in accordance with the council directive 93/42/EEC for medical devices and harmonized standards. The Manual is written for the current Pulse Oximeter. In case of modifications and software upgrades, the information contained in this document is subject to change without notice.

The Manual describes, in accordance with the Pulse Oximeter's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details.

Please read the Manual very carefully before using this equipment. These instructions describe the operating procedures to be followed strictly, Failure to follow these instructions can cause measuring abnormality, equipment damage and personal injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, personal injury and equipment damage due to user's negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

WARNING:

- ☼ **The uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the microcirculation barrier patients. It is recommended that the sensor should not be applied to the same finger for over 2 hours.**
- ☼ **For the individual patients, there should be a more prudent inspecting in the placing process. The device can not be clipped on the edema and tender tissue.**
- ☼ **The light (the infrared is invisible) emitted from the device is harmful to the eyes, so the user and the maintenance man, can not stare at the light.**
- ☼ **Testee can not use enamel or other makeup.**
- ☼ **Testee's fingernail can not be too long.**
- ☼ **Please peruse the relative content about the clinical restrictions and caution.**
- ☼ **This device is not intended for treatment.**

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1 Safety

1.1 Instructions for safe operations

- Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect patient's safety and monitoring performance about cables and

transducers. It is recommended that the device should be inspected once a week at least. When there is obvious damage, stop using the monitor.

- Necessary maintenance must be performed by qualified service engineers ONLY. Users are not permitted to maintain it by themselves.
- The oximeter cannot be used together with devices not specified in User's Manual.

1.2 Warnings

- Explosive hazard—DO NOT use the oximeter in environment with inflammable gas such as some ignitable anesthetic agents.
- DO NOT use the oximeter while the testee measured by MRI and CT .
- The disposal of scrap instrument and its accessories(including battery) should follow the local laws and regulations.

1.3 Attentions

- 🔔 Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- 🔔 If the oximeter gets wet, please stop operating it.
- 🔔 When it is carried from cold environment to warm and humid environment, please not use it immediately.
- 🔔 DO NOT operate keys on front panel with sharp materials.
- 🔔 High temperature or high pressure steam disinfection of the oximeter is not permitted. Refer to User Manual for instructions of cleaning and disinfection.
- 🔔 Do not have the oximeter immersed in liquid. When it needs cleaning, please wipe its surface with disinfect solution by soft material. Do not spray any liquid on the device directly.
- 🔔 When cleaning the device with water, the temperature should be lower than 60°C.
- 🔔 For patient's finger too thin or too cold, it may effect the normal measure, using the instrument to clip the thick finger(thumb or middle finger), and insert the finger deeply enough.
- 🔔 The product is suitable for children above four years old and adults (Weight should be between 15kg to 110kg) .
- 🔔 If some abnormal conditions appear on the screen during test process, pull out the finger and reinsert to restore normal use.
- 🔔 The instrument has normal useful life for five years since the first electrified use.
- 🔔 The hanging rope attached the product is made from Non- allergy material, if particular group are sensitive to the hanging rope, stop using it. In addition, pay attention to the use of the hanging rope , do not wear it around the neck avoiding cause harm to the patient.
- 🔔 The instrument dose not have low-voltage alarm function, it only shows the battery energy, please change the battery when the battery energy is used out.
- 🔔 When the parameter is particularly, The instrument dose not have alarm function

2 overview

The pulse oxygen saturation is the percentage of HbO₂ in the total Hb in the blood, so-called the O₂ concentration in the blood. It is an important bio-parameter for the respiration. For the purpose of measuring the SpO₂ more easily and accurately, our company developed the Pulse Oximeter. At the

same time, the device can measure the pulse rate simultaneously.

The 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 fingertip photoelectric sensor for diagnosis, and a display screen will directly show measured value of Hemoglobin Saturation.


2.1 Classification: Class II a, (MDD93/42/EEC IX Rule 10)

2.2 Features

- Operation of the product is simple and convenient.
- The product is small in volume, light in weight (total weight is about 75g including batteries) and convenient in carrying.
- Power consumption of the product is low and the two originally equipped two AAA batteries can be operated continuously for 30 hours.
- Voltage indication will be displayed when power on.
- The product will automatically be powered off when no signal is in the product for longer than 8 seconds.

2.3 Major applications and scope of application

The Pulse Oximeter can be used to measure human Hemoglobin Saturation and pulse beat through finger, and indicate the pulse intensity by the bar-display. The product is suitable for use in family, hospital (Ordinary sickroom), Oxygen Bar, social medical organizations and also the measure of saturation oxygen and pulse rate.

 The product is not suitable for use in continuous supervision for patients.

2.4 Environment requirements

Temperature:

Operating Temperature: 0~55°C;

Storage Temperature: -20°C~75°C;

Humidity:

Operating Humidity: 15~95%RH

Storage Humidity: 10~95%RH

3 Principle and Caution

3.1 Principle of measurement

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 Oxyhemoglobin (O₂ Hb) in glow & near-infrared zones. Operation principle of the instrument is: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning & 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 LCD through treatment in electronic circuits and microprocessor.

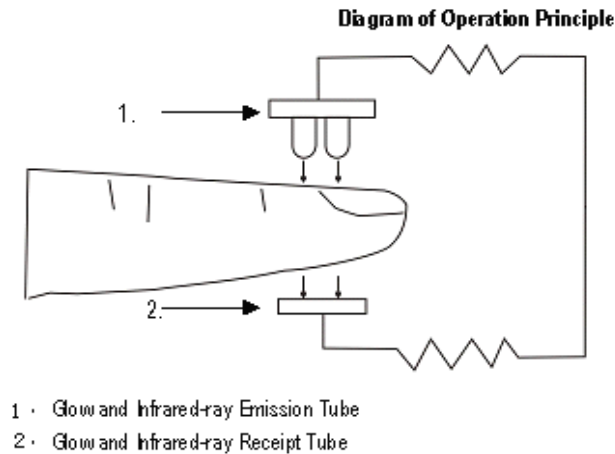


Figure 1. Operating Principle

3.2 Caution

1. The finger should be placed properly (see the attached illustration of this manual), or else it may cause inaccurate measurement.
2. The SpO₂ sensor and photoelectric receiving tube should be arranged in a way with the subject's arteriole in a position there between.
3. The SpO₂ sensor should not be used at a location or limb tied with arterial canal or blood pressure cuff or receiving intravenous injection.
4. Make sure the optical path is free from any optical obstacles like rubberized fabric.
5. Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight and etc.
6. Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.
7. Testee can not use enamel or other makeup.

3.3 Clinical restrictions

1. As the measure is taken on the basis of arteriole pulse, substantial pulsating blood flow of subject is required. For a subject with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO₂ waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.
2. For those with a substantial amount of staining dilution drug (such as methylene blue, indigo green and acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (Me+Hb) or thiosalicylic hemoglobin, and some with icterus problem, the SpO₂ determination by this monitor may be inaccurate.
3. The drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for serious error of SpO₂ measure.
4. As the SpO₂ value serves as a reference value for judgement of anemic anoxia and toxic anoxia, some patients with serious anemia may also report good SpO₂ measurement.

4 Technical specifications

4.1 Display Format: LCD Display;

SpO₂ Display Range: 0- 99%;

Pulse Ratio Display: 30 – 255bpm

Pulse Wave Display: columniation display and the waveform display

Battery Voltage Indication: three segments display

4.2 Power Requirements: 2 × 1.5V AAA alkaline battery (or using the rechargeable battery instead), , adaptable range: 2.2V~3.6V

4.3 Power Consumption: ≤ 30mA

4.4 Resolution: 1% for Hemoglobin Saturation and 1 BPM for Pulse Rate

4.5 Measurement Accuracy:

SpO₂ : 70 to 99% ±2 digits, Below 70% unspecified

Pulse rate: ±2 bpm or ±2% (select larger)

4.6 Measurement Performance in Weak Filling Condition:

Oxyhemoglobin and pulse value can be shown correctly when pulse-filling ratio is 0.4%.

4.7. Resistance to surrounding light:

The difference between the value measured in the condition of indoor natural light and that of darkroom is less than ±1%.

4.8. Resistance to interference of man-made light:

The difference between the value measured in the condition of man-made light and that of darkroom is less than ±1%.

4.9. Automatic shutdown function:

The device will power off automatically in 4 seconds when there is no finger in the device.

5 Accessories

- One hanging rope;
- Two batteries;
- One User manual.

6 Installation

6.1 View of the front panel

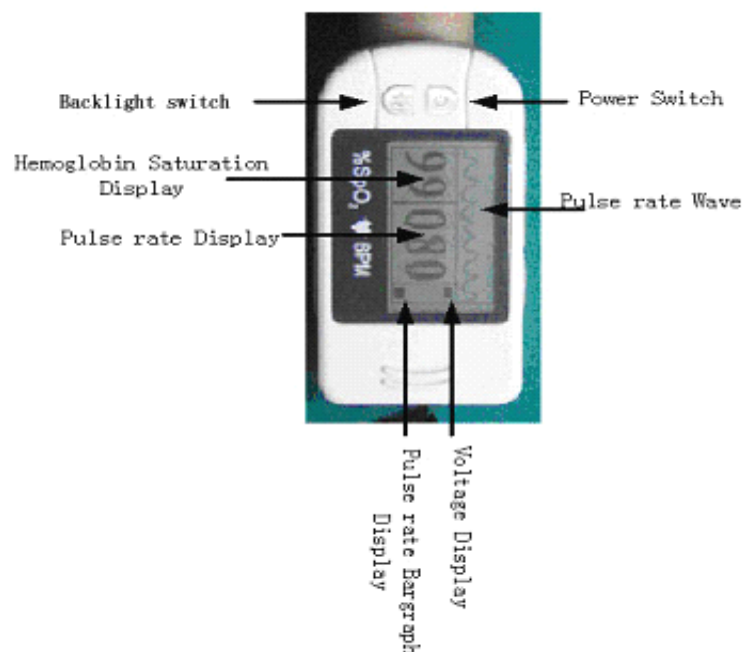


Figure 2. front view

6.2 Battery

Step 1. Refer to Figure 3. and insert the two AAA size batteries properly in the right direction.

Step 2. Replace the cover.

⚠ Please take care when you insert the batteries for the improper insertion may damage the device.

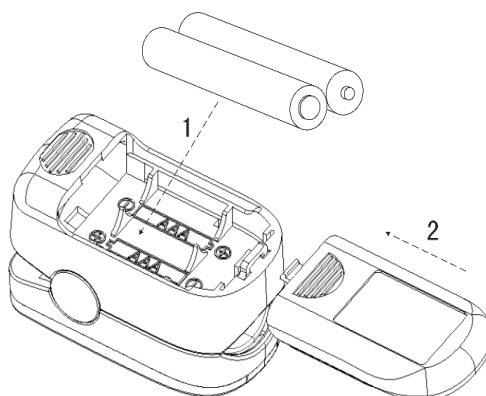


Figure 3. batteries installation

6.3 Mounting the hanging rope

Step 1. Put the end of the rope through the hole.

Step 2. Put another end of the rope through the first one and then tighten it.

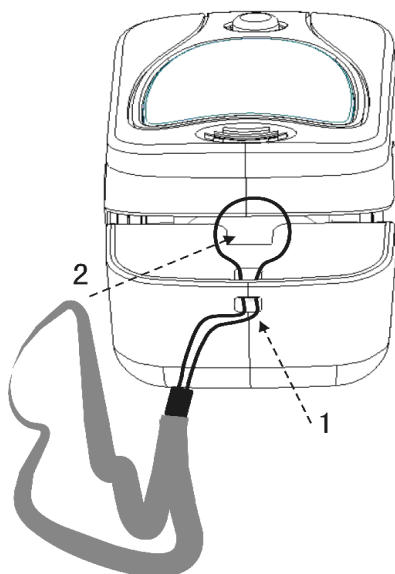


Figure 4. mounting the hanging rope

7 Operating Guide

7.1 Insert the two batteries properly to the direction, and then replace the cover.

7.2 Open the clip as shown in Figure 5.

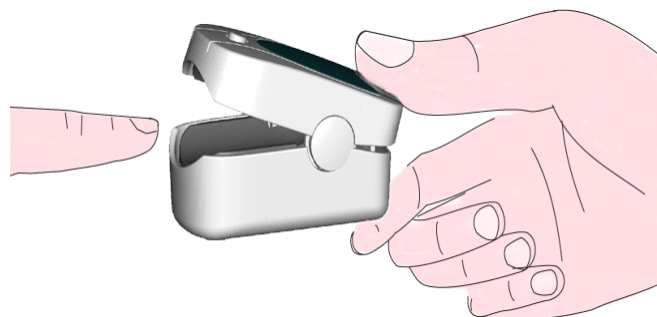


Figure 5. put finger in position

7.3 Let the patient's finger put into the rubber cushions of the clip (make sure the finger is in the right position), and then clip the finger.

7.4 Press the switch button once on front panel.

7.5 Do not shake the finger and keep the patient at ease during the process. Meanwhile, human body is not recommended in movement status.

7.6 Get the information directly from screen display.

⚠ When your finger is plugged into the Oximeter, your nail surface must be upward.

8 Repairing and Maintenance

- Please change the batteries when the low-voltage displayed on the screen(the battery energy displays whole blank).
- Please clean the surface of the device before using. Wipe the device with alcohol first, and then let it dry in air or clean it by dry clean fabric.
- Using the medical alcohol to disinfect the product after use, prevent from cross infection for next time use.
- Please take out the batteries if the oximeter is not in use for a long time.
- The best storage environment of the device is - 20°C to 75°C ambient temperature and not higher than 95% relative humidity.

The device needs to be calibrated once a year (or according to the calibrating program of hospital). It also can be performed at the state-appointed agent or just contact us for calibration.

⚠ High-pressure sterilization cannot be used on the device.

⚠ Do not immerse the device in liquid.












⚠ It is recommended that the device should be kept in a dry environment. Humidity may reduce the useful life of the device, or even damage it.

9 Troubleshooting

Trouble	Possible Reason	Solution
The SpO ₂ and Pulse Rate can not be displayed normally	1. The finger is not properly positioned. 2. The patient's SpO ₂ is too low to be detected.	1. Place the finger properly and try again. 2. Try again; Go to a hospital for a diagnosis if you are sure the device works all right.
The SpO ₂ and Pulse Rate display instable	1. The finger is not placed inside enough.	1. Place the finger properly and try again.

	2. The finger is shaking or the patient is moving.	2. Let the patient keep calm
The device can not turn on	1. The batteries are drained or almost drained. 2. The batteries are not inserted properly. 3. The device's malfunction	1. Change batteries. 2. Reinstall batteries. 3. Please contact the local service center.
The indicator light is off suddenly	1. The device will power off automatically when it gets no signal for 8 seconds. 2. The batteries are almost drained.	1. Normal. 2. Change batteries.

10 Key of Symbols

Symbol	Description
	Type BF
	Warning – See User Manual
%SpO₂	The pulse oxygen saturation
 BPM	Pulse rate (per minute)
	The battery voltage indication is adequate
	The battery voltage indication is deficient in (change the battery in time avoiding the exact measure)
	the finger clip falls off (no finger inserted)
	battery positive electrode
	battery cathode
	Power switch
	Backlight switch
SN	Serial number
	This item is compliant with Medical Device Directive 93/42/EEC of June 14, 1993, a directive of the European Economic Community.

11 Function Specification

Display Information	Display Mode
The Pulse Oxygen Saturation (SpO ₂)	LCD
Pulse Rate (bpm)	LCD
Pulse Intensity (bar-graph)	LCD bar-graph display
Pulse wave	LCD

SpO₂ Parameter Specification	
Measuring range	0%~99%, (the resolution is 1%).
Accuracy	±2% during 70%~99%, Below 70% unspecified.
Optical Sensor	Red light (wavelength is 660nm) Infrared (wavelength is 940nm)
Pulse Parameter Specification	
Measuring range	30bpm~255bpm (the resolution is 1 bpm)
Accuracy	±2bpm or ± 2% (select larger)
Pulse Intensity	
Range	15-segment amplitude display
Battery Requirement	
1.5V (AAA size) alkaline batteries × 2 or rechargeable battery	
Dimensions and Weight	
Dimensions	65(L) × 35(W) × 40 (H) mm
Weight	About 75g (with the batteries)