This Manual is written and compiled in accordance with the council directive MDD 93/42/EEC for medical devices and corresponding standards. The Manual written is in accordance with the Fingertip Pulse Oximeter. In case of modifications and software upgrades, you will be advised in due time with a Modification Notice.

The Manual includes the Fingertip 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.

This manual is used for the experienced personnel who is familiar with the measure and the use of the instrument. This manual is compiled by our company, and the copyright is possessed by our company.

Instructions to User

Dear Users, thank you very much for purchasing Fingertip Pulse Oximeter. Please read the following two pages very carefully before using this equipment.

Please read these instructions carefully before using this equipment. These instructions describing the operating procedures should 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.
This product is medical device, and can be used repeatedly. Its using life is 3 years.

WARNING:

- **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 special 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 should not stare at the light.**
- **Testee can not use enamel or other makeup.**
- **Testee's fingernail can not be too long.**
- **Please refer to the correlative literature about the clinical restrictions and caution.**
- **This device is not intended for treatment.**

Table of Contents

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. It is recommended that the device should be inspected once a week at least. Please stop using the monitor when there is obvious damage.
- 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. Please use the devices recommend by Manufacturer.

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 is under measurement of MRI and CT.
- Be cautious of the hanging rope, please do not break the hanging rope during usage to avoid device damage. Please don't use hanging rope if allergic to hanging rope.
- Please don't use this product if allergic to rubber cushion.
- Please dispose the device, accessory and packing (including plastic bag, foam and carton) according to local law.

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 using.
- 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's Manual for instructions of cleaning and disinfection.
- Do not have the oximeter immerged 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 less than 60℃.

2. Overview

The pulse oxygen saturation is the percentage of HbO_2 in the total Hb in the blood, so-called the O_2

concentration in the blood. It is an important bio-parameter for the respiration. Many of the respiration disease will cause hypoxemia, even damage the patient's life. As a result, monitoring the SpO_2 is indispensable in the clinical rescuing. The traditional method to measure SpO_2 is to analyze the sample of the patient's blood to get the partial pressure of oxygen and calculate the SpO_2 by use the blood-gas analyzer. This method is inconvenient and discontinuous. For the purpose of measuring the SpO_2 more easily and accurately, our company developed the Fingertip Pulse Oximeter. The device can measure the pulse rate simultaneously.

The Fingertip Pulse Oximeter is tiny, and with low power consumption, convenient to use and carry. You just need to put the fingertip into the sensor of the device, the SpO_2 value will appear on the screen immediately. In the clinical practice, the tolerance is smaller than ±2% in the range from 70% to 100%.

2.1. Features

A. The device can accurately measure SpO_2.

B. The device will power off automatically if no signal is detected within 5 seconds.

C. Two AAA size batteries are required for operating, and the continuous working time is 30 hours.

D. When Low-Voltage Warning is shown on screen, the device maybe not operate normally.

E. Light and portable, total weight with batteries is about 50g.

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

2.2. Anticipative application

The Fingertip Pulse Oximeter can detect SpO_2 and pulse rate through patient's finger, and indicate the pulse intensity by the bar-display. This device is applicable for use in home, hospitals (ordinary sickroom), oxygen bar, the community medical treatment, physical care in sports (you can use the device before or after the sport, but it is not recommended to use it during the sport) and so on.

⚠ This device is not appropriate for the ceaseless monitoring of the patients.

2.3. Environment requirements

Transport and storage

a）Temperature: -20°C~55°C

b）Humidity: ≤95%

c）Pressure: 500hPa~1060hPa

Operating

a）Temperature: 10°C ~40°C

b) Humidity: 35%~75%
c) Pressure: 700hPa~1060hPa

3. Principle and Caution

3.1. Principle of measurement

The measurement of pulse oximeter is that it uses a multi-functional oxyhemoglobinometer to transmit some narrow spectrum light bands through blood samples, and to measure attenuation of spectrum with different wavelengths according to the characteristic that RHb, O_2Hb, Met Hb and COHb absorb the light of different wavelength, thereby determining O_2Hb saturation of different fractions. O_2Hb saturation is called “fractional” O_2Hb saturation.

Fractional O_2Hb saturation = [O_2Hb / (RHb + O_2Hb + Met Hb + COHb) x 100

Oppositely, pulse oxygen oximeter measures functional O_2Hb saturation:

Functional O_2Hb saturation = [O_2Hb / (RHb + O_2Hb)] x 100

Present SpO_2 oximeter transmits light of two wavelengths only, red light (wavelength 660 nm) and infrared (wavelength 940nm), to differentiate HbO_2 from HbR. One side of the sensor contains two LEDs, and the other side contains a photoelectric detector. SpO_2 oximeter measures HbO_2 saturation in the blood by the light plethysmograph when the pulse beats. The result is quite precise when HbO_2 saturation is over 70 % ~ 100%.

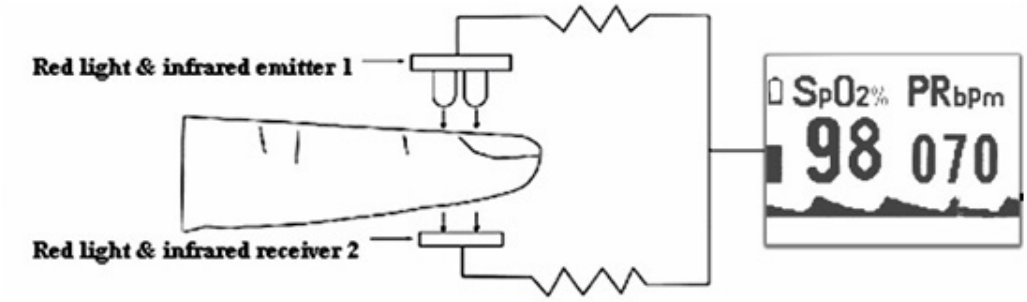

Figure1. Operating Principle

3.2. The attention of Operation

A. The equipment should be fully tested to see if it can be used normally before using.

B. The finger should be placed properly (see the attached illustration of this manual), or else it may cause inaccurate measurement.

C. The SpO_2 sensor and photoelectric receiving tube should be arranged in a way with the testee’ s arteriole in a position in between .

D. The SpO_2 sensor should not be used at a location or limb tied with arterial canal or blood pressure cuff or receiving intravenous injection.

E. Make sure the optical path is free from any optical obstacles like rubberized fabric, otherwise it may result in venous pulsation and inaccurate measure of SpO_2.

F. Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight and etc.

G. Strenuous action of the testee or extreme electrosurgical interference may also affect the accuracy.

H. Testee can not use enamel or other makeup.

I. Please clean and disinfect the device after operating according to the user manual.

3.3. Clinical restrictions

A. As the measure is taken on the basis of arteriole pulse, substantial pulsating blood flow of the testee is required. For a testee with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO_2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.

B. 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 SpO_2 determination by this monitor may be inaccurate.

C. The drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for serious error of SpO_2 measure.

D. The SpO_2 value serves only as a reference value for judgement of anemic anoxia and toxic anoxia, some patients with serious anemia may also report good SpO_2 measurement.

4. Technical specifications

A. Display mode： double Color OLED display

SpO_2 measuring range: 35%~100%

Pulse rate measuring range: 30bpm ~ 240bpm

Pulse waveform display: bar graph display

Battery indication: OLED Signal

B. Power supply requirement:

1.5V (AAA size) alkaline batteries × 2

Adaptable range: 2.6V~3.6V

C. Operating current: ≤30mA

D. Resolution: SpO_2 : 1%

Pulse Rate : 1bpm

E. Accuracy: SpO_2 ：70% to 100%±2 digits, below 70% unspecified

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

F. Measurement at low perfusion:

The values of SpO_2 and pulse rate can be displayed properly when pulse saturation is at 0.4%.

Accuracy of SpO_2：±4%

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

G. Resistance to surrounding light:

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

H. Automatic shutdown function:

The device will power off automatically within 5 seconds when there is no finger in the device.

5. Accessories

A. A hanging rope

B. Two batteries

C. A User Manual

6. Installation

6.1. View of the front panel

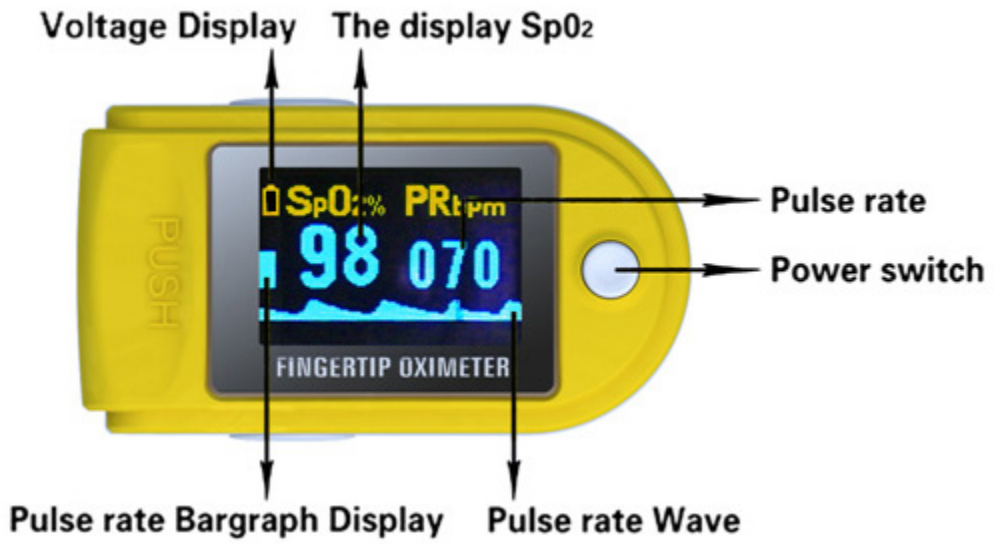

Figure2. front view

6.2. Mounting Of The Battery

1. Refer to Figure 3. And insert the two AAA size batteries properly in the right direction , according to the “ + “and “ - ”symbol.

2. Replace the cover.

⚠ Please be cautious when you insert the batteries for improper insertion may damage the device.

Figure 3.batteries installation

6.3. Mounting of the hanging rope

Refer to Figure 4:

Step1. Put the end of the rope through the hole.

Step2. Put another end of the rope through the first one and then tighten it.

Figure4. Mount the hanging rope

7. Operating Guide

A. Insert the two batteries properly to the direction, and then place the cover.

B. Open the clip as shown in Figure 5.

Figure5. Put finger in position

C. 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.

a) Press the Power Button on the front panel.

b) Using first finger, middle finger or ring finger when doing test. Low finger temperature, fat finger, thin finger may cause inaccurate measurement.

c) Do not shake the finger and keep the patient at ease during the process.

D. Get the information directly from screen display.

E. When working, the display direction can be changed by pressing the button shortly. There are six modes of direction.

F. In working item，long press can change the lighteness of the screen .

⚠ When finger put into the rubber cushions of the clip, make sure nail is upturned.

8. Cleaning and Disinfecting

Using alcohol to disinfect the device, nature dry or clean it with clean soft cloth.

9. Repairing and Maintenance

1. Please change the batteries when the low-voltage indicator lightens.

2. 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.

3. Please take out the batteries if the oximeter is not in use for a long time.

4. The best storage environment of the device is - 20ºC to 55ºC ambient temperature and not higher than 95% relative humidity.

Please maintain properly for ensuring the device can be used normally.

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 using life of the device, or even damage it.**

10 .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 deep enough. 2. The finger is shaking or the patient is moving.	1. Place the finger properly and try again. 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. Reinstall batteries. 2. Please contact the local service center.
The display is off suddenly	1. The device will power off automatically if no signal is detected within 5 seconds. 2. The batteries are almost drained.	1. Normal. 2. Change batteries.

11. Function Specification

Display Information	**Display Mode**
The Pulse Oxygen Saturation（SpO_2）	2-digit digital OLED display
Pulse Rate（bpm）	3-digit digital OLED display
Pulse Intensity (bar-graph)	bar-graph OLED display
SpO_2 Parameter Specification	
Measuring range	35% ~ 100%, (the resolution is 1%).
Accuracy	±2% during 70% ~ 100%.Below 70% unspecified.
Optical Sensor	Red light (wavelength is 660nm) Infrared (wavelength is 940nm) photosensor

Pulse Parameter Specification	
Measuring range	30bpm ~ 240bpm, (the resolution is 1bpm)
Accuracy	±2bpm or±2% (select larger)

Pulse Intensity	
Range	Continuous bar-graph display, the higher display indicate the stronger pulse.
Battery Requirement	
1.5V (AAA size) alkaline batteries × 2	
Battery useful life	
The two batteries can work continually 30 hours.	

Dimensions and Weight	
Dimensions	57(L) × 31(W) × 32(H) mm
Weight	About 50g (with the batteries)

12. Key of Symbols

Symbol	Description
	Type BF
	Warning – See User Manual
%Spo$_2$	The pulse oxygen saturation(%)
♥ bpm	Pulse rate (bpm)
	Low-voltage
SN	Serial number
	Battery anode
	Battery cathode

	Alarm inhibit