

FINGERTIP Pulse Oximeter



USER'S MANUAL

Section 2 Introduction

2.1 Brief Device Description

The Pulse Oximeter, based on all digital technology, is intended for noninvasive spot-check measurement of functional oxygen saturation of arterial hemoglobin (SpO₂). Advanced DSP algorithm can minimize the influence of motion artifact and improve measurement accuracy of low perfusion. The Oximeter can be used to measure human Hemoglobin Saturation and heart rate through finger. The product is suitable for family, hospital (including clinical use in internist/surgery, pediatrics, etc), Oxygen Bar, social medical organizations, physical care in sports and etc.

2.2 Intended use

This product is suitable for the hospital (including surgery, paediatrics, and clinical use), oxygen bar, sports health (using them before or after sports, do not advise using them during the movement), and community health care, etc.

2.3 Product Features

Lightweight for carrying and Easy-To-Use. Manually adjust the direction of interface. LED display, simultaneous display for testing value and bargraph. Low Battery voltage indicator. Automatically standby or sleep.

Section 1 Safety

1.1 Instructions for the Safe Operation and Use of the Finger Pulse Oximeter

- Do not attempt to service the pulse oximeter. Only qualified service personnel should attempt any needed internal servicing.
- Do not use the oximeter in situations where alarms are required.
- 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 2 hours.
- SpO₂ 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.
- The following reasons will cause interference:
 - High-frequency electrosurgical
 - Placement of a sensor on an extremity with a blood pressure cuff arterial catheter, or intravascular line
 - The patient has hypotension severe vasoconstriction severe anemia or hypothermia
 - The patient is in cardiac arrest or is in shoe

1.2 Warnings

WARNING: EXPLOSION HAZARD--Do not use the oximeter in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.

WARNING: Do not throw batteries in fire as this may cause them to explode.

WARNING: Do not attempt to recharge normal dry-cell batteries, they may leak. And may cause a fire or even explode.

WARNING: Do not use the pulse oximeter in an MRI or CT environment.

CAUTION: Keep the operating environment free of dust, vibrations, corrosive, or flammable materials, and extremes of temperature and humidity.

CAUTION: The battery must be taken out from the battery compartment if the device will not be used for a long time.

CAUTION: Do not operate the unit if it is damp or wet because of condensation or spills. Avoid using the equipment immediately after moving it from a cold environment to a warm, humid location.

CAUTION: Never use sharp or pointed objects to operate the front-panel key.

CAUTION: The device shall only be used if the battery cover is closed.

CAUTION: The battery must be properly disposed according to local regulation after their use.

1.3 Definitions and Symbols

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).

Section 3 Installation, Setup, and Operation

3.1 Description of the Front Panel (as figure 3.1.1)

Figure 3.1.1 Parts of front/back panel

Table 3.1.1 Part Definition and Description

Item	Name	Description
1	Power button	Turn on the machine, direction change and Parameter setting
2	OLED Panel	Display the SpO ₂ /PR data and Plethysmogram

3.2 Display

After switch on, the OLED display of the Oximeter is as follow

3.3 Parameter setting:

Press the power button (> 0.5s), the oximeter will enter into parameter setting.

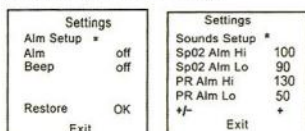


Figure 3.3.1

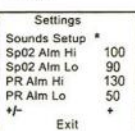


Figure 3.3.2

3.4 Operation

3.4.1 Install battery

Installing two AAA batteries into battery cassette in correct polarities and cover it.

WARNING: Do not attempt to recharge normal alkaline batteries, they may leak and may cause a fire or even explode.

3.4.2 Turn the Pulse Oximeter on/off

Put one of fingers into rubber hole of the Oximeter (It is best to put the finger thoroughly) with nail surface upward, then releasing the clamp.

Press power button to turn the Pulse Oximeter on. The oximeter will automatically be powered off when no finger in the device for longer than 16 seconds.

3.4.3. Read correspondent data from display screen.

3.4.4 Display Description of OLED

The display interface of "OLED" can rotate four directions with six different display modes after pressing the power button for less than 0.5s. It is shown as below:



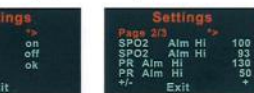
3.5 Date Analysis

3.5.1 How to find the "date analysis".

Long-press on the power button, the oximeter will display pages 1 as shown figure 3.5.1 ~ 3.5.3, long-press page1/3 and page2/3 make the screen display the next page.



3.5.1



3.5.2



3.5.3

3.5.2 How to start a new analysis

Select the item of "record" page 3/3 and long-press its status from "off" to "on"; select "ok" when the display is shown as

figure 3.5.4. then return to page 3/3 choose "exit"; put the finger into oximeter rubber hole to start measurement as figure 3.4.3. The sign of "battery power" and "Rec" appear in turn during measuring, the maximum of recording time is 8 hours and the minimum time is 2 minutes.



3.5.4



3.5.5

3.5.3 How to see the analysis result

1. Take out your finger, wait for 8 seconds then the oximeter turn off. turn on the oximeter again. long-press to enter "data analysis": page3/3, now the status of "records" is off and "summary graph" and "statistics" is ok, long

-press "summary graph" shown in figure 3.5.8 2. Select "statistics" and long press to open the statistics page as shown figure 3.5.91. the meaning of "time" is the measuring time. it will show the date of max and Min about the spO₂ and Bmp.

Note: summary graph and statistics can not be opened when the storage is empty



3.5.6



3.5.7



3.5.8

3.5.4 Setting in Figure 3.5.2

Select the SpO₂ or PR Alarm limits, long-press will change the limits. Select "+/-" long-press will set the direction of changing the limits. "+" is increasing the number, "-" is decreasing the number.

Features

OLED display

- Two color OLED display, more display modes.
- Low-power consumption, continuously four direction adjustable
- Low voltage indicator
- Automatically power off in 8 seconds when there is no signal
- Small in volume, light in weight, and convenient to carry

Section 4 Product classification, maintenance and solution

4.1 Classification

Management Class for Medical Devices: Equipment
Anti-electric Shock Type: Internally powered equipment
Anti-electric Shock Degree: Type BF equipment

4.2 Maintenance and Preservation

- Replace the batteries timely when low voltage lamp is on.
- Clean the surface of fingertip oximeter before it is used to diagnose patients.
- Remove the batteries inside if you will not

operate the Oximeter for a long time.

- "It would be better to preserve the product in 10-40 °C (14-104 °F) and humidity is 10%-80%."
- It is recommended that the product should be kept dry anytime. A wet ambience might affect its lifetime and even damage the product.
- Please follow the law of the local government to deal with used batteries.

4.3 Product declaration

Guidance and manufacturer'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	Electromagnetic environment--guidance
RF interference CISPR 11	Class B 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 environments, including domestic environments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

4.4 Possible problems and effective solutions

Problem	Possible reason	Solution
SpO ₂ or PR can not be shown normally	1. Finger is not plugged correctly 2. Patient's Oxygenhemoglobin 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
SpO ₂ 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