

FINGER PULSE OXIMETER

USER'S MANUAL V1.0

Section 1 Safety

1.1 Instructions for the Safe Operation and Use of the 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.
- 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 shock.
 - Fingernail polish or false fingernails may cause inaccurate SpO2 readings.

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 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: 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.

WARNING: During prolonged periods of use, if you feel discomfort or pain in finger, please take off the oximeter immediately to prevent the finger injuries.

WARNING: Prolonged use or the patient's physical condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status and correct alignment at most every 4 hours.

WARNING: The oximeter is not intended to use in ICU, because the device's alarm does not meet requirements of EN 60601-1-8

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

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

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

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

Symbol	Description	Symbol	Description
	Type BF Equipment		Information of manufacture, including name and address
	Refer to the instruction manual /booklet		When the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling
	Serial NO*		The important information you should know
	The information you should know to protect the equipment from possible damage		The information you should know to protect patients and medical staff from possible injury

Section 2 Introduction

2.1 Brief Device Description

The Oximeter can be used to measure human Hemoglobin Saturation and pulse 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, anesthesiology, 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 Contraindication

It is not for intensive care or person whose finger is injured.

2.4 Product Features

- Lightweight for carrying and Easy-To-Use.
- Manually adjust the direction of interface.
- OLED display, simultaneous display for testing value and plethysmogram.
- Real-time spot-checks.
- Low Battery voltage indicator.
- Automatically standby or sleep.
- Sleep monitoring function.
- Data storing and data analysis function.

Section 3 Installation, Setup, and Operation

3.1 Operation

3.1.1 Install battery

Installing two AAA batteries into battery cassette in correct polarities and cover it (as Figure 3.1.1)

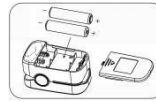


Figure 3.1.1

3.1.2 Turn the Pulse Oximeter on

Put one of fingers into rubber hole of the oximeter (it is best to put the finger thoroughly) with nail surface upward (as Figure 3.1.2), then releasing the clamp.

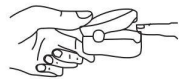


Figure 3.1.2

Press the button, oximeter will go into the working state.

The oximeter will automatic standby or go asleep after 8 seconds without finger in.

3.1.3 Read correspondent data from display screen (see Figure 3.2.1).

3.2 Description

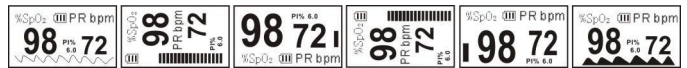
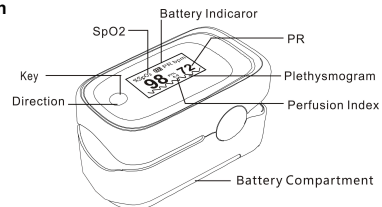
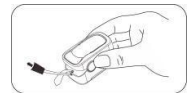


Figure 3.2.1 OLED display

Note: When battery power is at lowest level, the battery capacity indicates symbol of " " in OLED, remind users of replacement of battery.

3.3 Install Hanging Rope

Let the thin end of the rope go through the rope hole, next let the big point of rope go through the hole, then tighten the rope.



3.3.1 Install Hanging Rope

3.4 Data analysis

There are two ways to operate the button according to the pressing time, long-press is longer than 0.5 second and short press is shorter than 0.5 second. Short-press is used to select a item by moving a light bar to the line of this item, long-press is used to change the item's value, status or open a new page.

Long-press on the power button, the oximeter will display Data Analysis page as shown in Figure 3.4.1. When the bar is on the second row, long-press make the screen display the next page as shown in Figure 3.4.2~3.4.3.

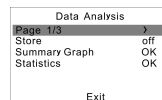


Figure 3.4.1

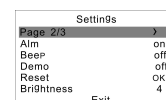


Figure 3.4.2

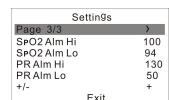


Figure 3.4.3

3.4.1 How to start a new analysis

Just before going to bed, select the item of "Store", change it's status to "on", select "OK" when the display is shown as Figure 3.4.1. Then put the finger into rubber hole of the oximeter to start a new continuous measurement. Take off the oximeter 2 hours later or after getting up, the oximeter will shut down automatically after the finger is taken off. When storing mode working, the oximeter will display "Sto" and battery volume alternately in the same position of screen. The maximum of recording time is 8 hours.

3.4.2 How to see the analysis results

Turn on the oximeter again, long press to enter "Data analysis" page as shown in Figure 3.4.4. Now the status of "Store" is off and "Summary Graph" and "Statistics" is OK. Select the item "Summary Graph", long press to open the graph page as shown in Figure 3.4.5. Each full page display 15 minutes' data. Select "<" or ">" and long press to see the previous or next page, select "<<" or ">>" and long press to see the

first or last page. Select \square to return Figure 3.4.1.

Select "Statistics" and long press to open the Statistics page as shown Figure 3.4.6. ODI4 indicates the severity of hypoxia during sleep, if this number is greater than 5, please go to the hospital for further examination.

"ODI4" (Oxygen desaturation Index of 4%) means Events of Desaturation which is not less than 4% per hour during the total recording time.

"Time" means the total recording time of last storage.

Max SpO2/PR is the maximum SpO2/PR value of the entire storage.

Min SpO2/PR is the minimum SpO2/PR value of the entire storage.

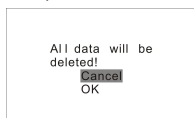


Figure 3.4.4

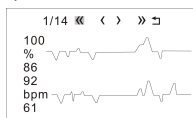


Figure 3.4.5

Analysis Results	
Return	
ODI4	40.6
Time	3.3H
Max SpO2	100% PR 92bpm
Min SpO2	77% PR 51bpm

Figure 3.4.6 Note: If

start a new storage and the time is longer than ten minutes, the previous storage will be replaced.

Note: "Summary graph" and "Statistics" can not be opened when the storage is empty.

Note: The analysis results of ODI may be inaccurate when total sleep time is less than 2 hours.

3.5 Settings of the oximeter

3.5.1 Settings in Figure 3.4.2

Select the item of "Alm"/ "Beep" / "Demo", long press the button to turn on/off the item.

Select the item of "Reset", long press the button will reset all settings.

Select the item of 'Brightness', long press the button to change the brightness of screen.

3.5.2 Settings in Figure 3.4.3

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.

Section 4 Maintenance

4.1 Cleaning

Switch off the power and take out the batteries before cleaning. Cleaning exterior surface (screen included) of the unit with a dry and soft cloth. Use 75% density of medical alcohol to clean the surface and use dry fabric with little alcohol to avoid alcohol permeates into the device.

4.2 Disinfection

Disinfect the machine after using by the patient if multiple patient use the machine in the hospital. Use 75% density of medical alcohol to clean the surface that contacting with the patient.

CAUTION: Don't use strong solvent. For example, acetone.

CAUTION: Never use an abrasive such as steel wool or metal polish.

CAUTION: Do not allow any liquid into the product, and do not immerse any parts of the device into any liquids.

CAUTION: Avoid pouring liquids on the device while cleaning.

CAUTION: Don't remain any cleaning solution on the surface of the device.

4.3 Warranty

The host product' design life is 2 years, and 1 years warranty. Under normal circumstances, the malfunction of the product during the warranty period (from the date of purchase) should be sent back to the company for maintenance, and our company is responsible for all maintenance costs (users should cover the freight themselves). Outside the warranty period, our company shall charge some maintenance fee (users should cover the freight themselves) if the product has broken down and is sent back for maintenance. The battery is beyond the scope of the warranty. If you have the purchase and sale contract, the costs of the maintenance shall be in accordance with the purchase and sale contract execution. Our company can provide the designated qualified technical personnel with files listed GB9706.1 6.8.3 C. Besides, it is recommended that users should use them no more than five years. And over the using life, the using risks may increase due to the equipment' aging.

4.4 Maintenance

- Replace the batteries timely when battery indication is low. Clean surface of the Pulse Oximeter before it is used in diagnosis for patients.
- Remove the batteries inside the battery cassette if the Oximeter will not be operated for a long time.
- It is better to preserve the product in a place where ambient temperature is -20 - 55°C and humidity is 10%-95%.
- Regular inspection to make sure that no obvious damage existed to affect the safety and performance of device.
- No flammable substance, overtop or lower temperature and humidity existed in operation conditions.

4.5 Troubleshooting

Table 4.5 Troubleshooting

Problems	Possible Reason	Resolutions
Oxyhemoglobin or pulse rate can not be shown normally	1. Finger is not plugged correctly. 2. Patient's perfusion is too low to be measured.	1. Retry by plugging the finger. 2. Try some more times, if you can make sure about no problem existing in the product, Please go to a hospital timely for exact diagnosis.
Oxyhemoglobin or pulse rate is shown unstably	1. Finger might not be plugged deep enough. 2. Finger is trembling or patient's body is in movement status.	1. Retry by plugging the finger. 2. Try not to move, Let the patient keep calm.
The oximeter can't go into the working state	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 center
The screen are suddenly off	1. The product is automatically standby or sleep when no signal is detected longer than 8 seconds. 2. Power quantity of the batteries is exhausted.	1. Normal. 2. Replace the batteries.

4.6 Disposal

To avoid contaminating or infecting personnel, the environment or other equipment, make sure you disinfect or decontaminate the device appropriately before disposing of it in accordance with your country's law for equipment containing electrical and electronic parts.

Section 5 Specification

Physical Characteristics

Machine Dimensions: 64mm (L) * 38.8mm (W) * 35.5mm (D)

Machine Weight -approx: 64.5g (including 2 * AAA battery)

Classification

Anti-electric Shock Type: Internally powered equipment

Anti-electric Shock Degree: Type BF equipment EMC:

Type B class I

Mode of operation: Continuous Operation

Enclosure Degree of ingress protection: IP22

※IP22 means shell of this product can withstand the water dropping to the surface when the shell deviate 15 degree from horizontal surface.

Power

Internal:	2*AAA 1.5v alkaline battery
Power Consumption:	Smaller than 30mA(Normal)

Environmental

Operating Temperature:	5°C to 40°C
Storage Temperature:	- 20°C to 55°C
Relative Humidity:	15% to 85% non-condensing

Electronics Parameters

Parameter	Value	
Hemoglobin saturation Display	35-100%	
Pulse rate Display	25-250 BPM	
Perfusion Index Display	0-30%	
Resolution	Hemoglobin Saturation	1%
	Pulse rate	1 BPM
	Perfusion Index	0.1%
Measurement Accuracy	Hemoglobin Saturation	2% (80% - 100%) 3% (70% - 80%) Unspecified (\leq 70%)
	Pulse rate	2 BPM
	Perfusion Index	1% (0-20%) Unspecified (20%-30%)

Applicable models