

FINGER PULSE OXIMETER

USER'S MANUAL V1.0

Section 1 Safety

1.1 Instructions for Safe Operation and the Use of Pulse Oximeter

- Do not attempt to service the pulse oximeter. Only qualified service personnel should perform necessary 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. Cover the sensor area from direct sunlight (with a surgical towel, for example) if necessary.
- The following reasons will cause interference to the device.
 - High-frequency electrosurgical.
 - Placement of this oximeter on the same 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 fake 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 explosion.

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

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

CAUTION: Do not operate the unit if it is damp or wet because of condensation or spill. 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 location periodically. Change sensor location and check skin condition, circulatory status and correct alignment every hour.

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 fire and explosion.

CAUTION: Never use sharp 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 period of time.

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

CAUTION: The battery must be properly disposed according to local regulations and law.

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

The product is intended for noninvasive monitoring of the adult or child's SpO2 and PR.

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

Install two AAA batteries into battery compartment in correct polarities and put cover back on. (see Figure 3.1.1)

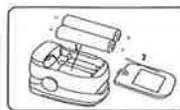


Figure 3.1.1

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

3.1.2 Turn the Pulse Oximeter on

Put one of your fingers into rubber hole of the oximeter (as much area as possible) with nail surface upward(as Figure 3.1.2), then release the clamp.

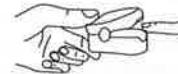


Figure 3.1.2

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

The oximeter will automatic fall into standby or sleep mode after 16 seconds without finger in it.

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

3.2 Description

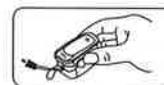


Figure 3.2.1 OLED display

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

3.3 Install Hanging Cable

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



3.3.1 Install Hanging Cable

3.4 Data analysis

There are two ways to operate the bar 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 Figure 3.4.2 and Figure 3.4.3).

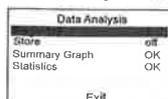


Figure 3.4.1

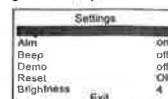


Figure 3.4.2



Figure 3.4.3

3.4.1 How to start a new analysis

Just before going to bed, select the item of "Store", change its 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 device is taken off.

When storing mode is working, the oximeter will display "Rec" 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 3.4.1. Now the status of "Store" is off and "Summary Graph" and "Statistics" is OK. Select "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 " " 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

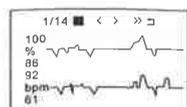


Figure 3.4.5

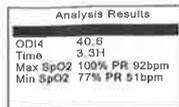


Figure 3.4.6

Note: If starting a new storage and the time is longer than ten minutes, the previous storage information will be replaced.

Note: "Summary graph" and "Statistics" cannot 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 "Alm" / "Beep" / "Demo", long press the button to turn on/off the item.

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

Select '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 permeating into the device.

4.2 Disinfection

Disinfect the machine after each use if multiple patients use the device in hospital. Use 75% density of medical alcohol to clean the surface that is in contact with patients.

CAUTION: Don't use strong solvent, such as acetone.

CAUTION: Never use abrasive cleaning supplies 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 liquid.

CAUTION: Avoid pouring liquid on the device while cleaning.

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

4.3 Warranty

The host product's design life is 2 years, with 1 years warranty. Under normal circumstances, the malfunctioning product during the warranty period (from the date of purchase) should be sent back to the company for repair, and our company is responsible for all repairing costs (users should cover the freight themselves). Outside the warranty period, our company may charge repair cost (users should also cover the freight themselves) if the product has broken down and is sent back for repair. Battery is not included in the scope of the warranty. If you have the purchase and sale contract, the cost of the repair shall be in accordance with the purchase and sale contract execution. Besides, it is recommended that users should use the device for no more than five years, as risk may increase due to the long term use.

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 compartment if the Oximeter will not be operated for a long period of time.
- It is better to store the product in a place where temperature is -20 - 55°C and humidity is 10%-95%.
- Regular inspection to make sure that no obvious damage to affect the safety and performance of the device.
- No flammable substance, extreme high or low temperature and humidity.

4.5 Troubleshooting

Table 4.5 Troubleshooting

Problems	Possible Reason	Resolutions
Oxyhemoglobin or pulse rate cannot be shown normally.	1. Finger is not plugged correctly. 2. Patient's perfusion is too low to be measured.	1. Retry by plugging in the finger properly. 2. Try several more times, if you are sure it is not the product issue, please go to a hospital immediately for correct diagnosis.
Oxyhemoglobin or pulse rate is shown unstably.	1. Finger might not be plugged the deep enough. 2. Finger is trembling or patient's body is in movement status.	1. Retry by plugging in the finger properly. 2. Try not to move, Let the patient keep still.

The oximeter cannot 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 a local customer service center.
The screen is suddenly off.	1. The product automatically goes to standby or sleep mode when no signal is detected longer than 16 seconds. 2. Battery power 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 it in accordance with your country's law because the equipment contains electrical and electronic parts.

Section 5 Specification

Device Dimensions: 64mm (L) x 38.8mm (W) x 35.5mm (D)

Device Weight -approx: 64.5g (including 2 x AAA battery)

Classification

Anti-electric Shock Type: Internally powered equipment

Anti-electric Shock Degree: Type BF equipment

EMC: Group 1 Class B

Mode of operation: Continuous Operation

Enclosure Degree of ingress protection: IP22

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

Power

Internal:	2 x AAA 1.5V alkaline battery
Power Consumption:	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: A_{rms} *	Hemoglobin Saturation	2% (80% - 100%) 3% (70% - 80%) Unspecified (<70%)
	Pulse Rate	2 bpm
	Perfusion Index	1% (0-20%) Unspecified (20%-30%)

* A_{rms} accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within +/- Arms of the reference measurements in a controlled study.

Applicable models

0010-20-00144