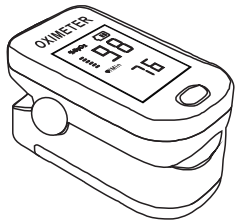
Fingertip Pulse Oximeter

Operator's Manual



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2.3 Product Features

- Lightweight for carrying and Easy-To-Use.
- LED display, simultaneous display for testing value.
- Low Battery voltage indicator.
- Automatically switch off.
- One button and ease to operation
- Auto turn off after 8 ~16seconds when there is no signal.
- Two direction display the Data.

CAUTION: The device can't used to measure the child below 4 years as the testament result is not guarantee to accurate.

CAUTION: The fingertip pulse oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms

Section 3

Installation, Setup, and Operation

3.1 Description of the Front Panel (as figure 3.1.1)

Section 1

Safety

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

- Do not attempt to service the Fingertip Pulse Oximeter. Only qualified service personnel should attempt any needed internal servicing.
- 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 reason will cause interference to the testing accuracy of the pulse oximeter.
  - High-frequency electrosurgical equipment.
  - 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.

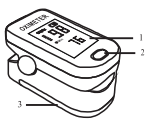


Figure 3.1.1 Parts of front & back panel

Table 3.1.1 Part Definition and Description

Item	Name	Description
1	Power button	Turn on /off the machine
2	LED Panel	Display the SPO2/PR data
3	Battery Compartment	

3.2. Display

After switch on, the LED display of Fingertip is as follows:

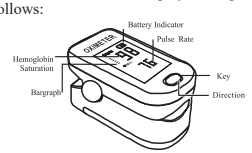


Figure 3.2.1 LED display

1.2 Warnings

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

WARNING: Do not throw batteries in fire as this may causes 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.

WARNING: Do not modify this equipment without authorization of the manufacturer.

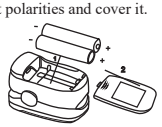
WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.

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

3.3 Operation

3.3.1 Install battery

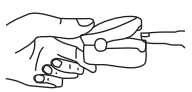
Installing two AAA batteries into battery cassette in correct polarities and cover it.



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

3.3.2 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, 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.

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 switches.

CAUTION: The batteries 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 batteries must be proper disposed according to local regulation after their use.

CAUTION: The device should keep away from the children, pets and pests to avoid swallowing.

3.3.3 Read correspondent data from display screen.

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

Section 4

Cleaning and Disinfection

4.1 Cleaning

Clean the machine once every day. Switch off the power and take out the batteries before cleaning, cleaning exterior surface (LED display 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.

1.3 Definitions and Symbols

Symbol	Description
	Type BF Equipment
	The device has no Alarm System
	Date of manufacture *
SN	Serial NO *
	Information of manufacture, including name and address
	Temperature limitation
	When the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling
	Follow instruction for use
IP22	Anti-dust& Anti-water class
Warning	The information you should know to protect patients and medical staff from possible injury
Caution	The information you should know to protect the equipment from possible damage
Note	The important information you should know

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.

Section 5

Troubleshooting and Maintenance

5.1 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 -10-50C and humidity is 15%-80%.
- 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.

* Date of manufacturer and Serial No are printed on the label on the battery cover.

Section 2

Introduction

2.1 Principle

The principle of pulse oximeter is based on the red and infrared light absorption characteristics of oxygenated and deoxygenated hemoglobin. Oxygenated hemoglobin absorbs more infrared light and allows more red light to pass through. Deoxygenated (or reduced) hemoglobin absorbs more red light and allows more infrared light to pass through.Red light is in the 600-750 nm wavelength light band. Infrared light is in the 850-1000 nm wavelength light band.

Pulse oximeter sensors have red and infrared low voltage light emitting diodes (LEDs) which serve as light sources. The emitted light is transmitted through the tissue, then detected by the photodetector and sent to the microprocessor of the pulse oximeter. All constituents of the human body, venous and arterial blood, and tissue absorb light . Since HbO2 and Hb absorb light to varying degrees, this varying absorption is translated into plethysmographic waveforms at both red and infrared wavelengths. The relationship of red and infrared plethysmographic signal amplitude can be directly related to arterial oxygen saturation.

5.2 Troubleshooting

Table 5.2.1 troubleshooting

Problems	Possible Reason	Resolutions
Oxy hemoglobin or heart 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
Oxy hemoglobin or heart 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.

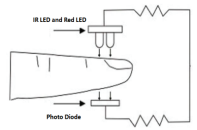


Figure 2.1.1 Oximeter's schematic illustration

2.2 Intended Use

The Fingertip Pulse Oximeter is a reusable non-invasive device intended for the spot checking of oxygen saturation of arterial hemoglobin (SpO2) and the pulse rate of adult patients in hospital and other healthcare environments. And it is not intended to be used under motion or low perfusion scenarios.

This pulse oximeter is intended for use in hospital, clinical institution, health-care community.

CAUTION: The pulse oximeter is NOT design for newborn and infant.
The product is suitable for adults(Weight should be between 25kg to 110kg).

Problems	Possible Reason	Resolutions
Oxyhemoglobin or heart rate is abnormal and cause alarm	1. Finger is not plugged correctly. 2. Patient's SPO2&PR is abnormal.	1. Retry by plugging the finger 2. go to the hospital for further examination.
The oximeter can not be powered on	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 powered off when no signal is detected longer than 8 seconds 2.Power quantity of the batteries is exhausted.	1.Normal 2.Replace the batteries

Section 6

Specification

Fingertip Pulse Oximeter Specifications:

Physical Characteristics

Machine:

Dimensions

-57.5 mm (L) x 32.5mm (W) x 32mm (D)

Weight -approx:

49 g（including 2 x AAA battery）

Classification：

Anti-electric Shock Type：Internally powered equipment

Anti-electric Shock Degree：Type BF equipment

EMC：Type A class II

Mode of operation: Spot Checking

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 Requirements

Alkaline batteries	Number	2
	Specification	1.5 V, AAA
	Operating current	30-60mA
	Run time	About 600 spot checks on two full power batteries at ambient temperature 25℃.

Environmental

Operating conditions	Temperature (℃)	15 to 40
	Humidity (non-condensing)	15% to 95%
	Atmospheric pressure (kPa)	70 to 106
Storage/ transportation conditions	Temperature (℃)	-20 to 60
	Humidity (non-condensing)	10% to 95%
	Atmospheric pressure (kPa)	50 to 107.4

Measurement Specifications

SpO2	Measurement range	0 to 100%
	Resolution	1%
	Accuracy*	80 to 100%: ±2% 70 to 80%: ±3% 0% to 69%: unspecified.
PR	Measurement range	25 to 254 bpm
	Resolution	1 bpm
	Accuracy*	±3 bpm

Probe LED Specification

	Wave Length	Radiant Power
RED	660±2 nm	1.8mW
Infra RED	905±2 nm	2.0mW

Manufacturer's Declaration of the EMC

Guidance and manufacturer´s declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS

1	Guidance and manufacturer´s declaration – electromagnetic emission		
2	The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.		
3	Emissions test	Compliance	Electromagnetic environment - guidance
4	RF emissions CISPR 11	Group 1	The Pulse Oximeteruses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
5	RF emissions CISPR 11	Class B	The Pulse Oximeter is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
6	Harmonic emissions IEC 61000-3-2	N/A	
7	Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration – electromagnetic immunity –for all EQUIPMENT and SYSTEMS

Guidance and manufacturer´s declaration – electromagnetic immunity
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximetershould assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete orceramic tile. If floors are covered withsynthetic material, the relative humidityshould be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ outputlines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles at 0° 0 % UT; 250/300 cyclee	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Pulse Oximeter requires continued operation during power mains interruptions, it is recommended that the Pulse Oximeter be powered from an uninterruptible power supply or a battery.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer´s declaration – electromagnetic immunity –for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

Guidance and manufacturer´s declaration – electromagnetic immunity			
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the Pulse Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=[\frac{3.5}{V_1}]\sqrt{P}$ $d=[\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d=[\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.5 GHz where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	6Vrms in ISM banda between 150 kHz to 80 MHz 80 MHz to 2.7 GHz	10 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Pulse Oximeter is used exceeds the applicable RF compliance level above, the Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Pulse Oximeter.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM -for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORT-ING

Recommended separation distances between portable and mobile RF communications equipment and the Pulse Oximeter
The Pulse Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pulse Oximeter as recommended below, according to the maximum output power of the communications equipment

Rated maximum output of transmitter W	Separation distance according to frequency of transmitter / m		
	150 kHz to 80 MHz $d=[\frac{3.5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d=[\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d=[\frac{7}{E_1}]\sqrt{P}$
0.01	/	0.12	0.23
0.1	/	0.38	0.73
1	/	1.2	2.3
10	/	3.8	7.3
100	/	12	23

For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.