

## Instructions to User

Dear users, thank you very much for purchasing the Pulse Oximeter. This Manual is written and compiled in accordance with the council directive MDD 93/42/EEC for medical devices and harmonized standards. In case of modifications and software upgrades, the information contained in this document is subject to change without notice. Please read the User Manual carefully before using this product.

### WARNING:

- Uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the microcirculation barrier patient. It is recommended that the sensor should not be applied to the same finger for over 2 hours.
- 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.
- Enamel or Acrylic fingernail polish or other fingernail applications may distort and/or produce inaccurate readings.
- Please refer to the correlative literature about the clinical restrictions and caution.
- This device is not intended for treatment.

## 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 about cable and transducers. It is recommended that the device should be inspected once a week at least. When there is obvious damage, stop using the monitor.
- 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 Manual. Only accessories recommended by the manufacturer should be used with this device.
- This product is calibrated before leaving factory.

### 1.2 Warning

- 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 user is measured by MRI and CT.
- The person who is allergic to rubber cannot use this device.
- The disposal of scrap instrument and its accessories and packing (including battery, plastic bags, foams and paper boxes) should follow the local laws and regulations.
- Please check the packing before use to make sure the device and accessories are totally in accordance with the packing list, or else the device may have the possibility of working abnormally.

### 1.3 Attention

- Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- If the oximeter gets wet, please stop operating it.
- When it is carried from cold environment to warm or humid environment, please do not use it immediately.
- High temperature or high pressure steam disinfection of the oximeter is not permitted. Refer to User Manual in the relative chapter for instructions of cleaning and disinfection.
- Do not have the oximeter immersed in liquid. When it needs cleaning, please wipe its surface with medical alcohol by soft material. Do not spray any liquid on the device directly.
- Do not use the device on infant or neonatal patients.
- The product is suitable for children above four years old and adults (Weight should be between 33 lbs (15kg) to 242 lbs (110kg)).

- The device may not work for all patients. If you are unable to achieve stable readings, discontinue use.
- The update period of data is less than 5 seconds, which is changeable according to different individual pulse rate.
- The device has normal useful life for five years since the first electrified use.
- The instrument does not have low-voltage alarm function, it only shows the battery symbol, please change the battery when the battery energy is used out.
- The instrument does not have alarm function. Do not use the device in situations where alarm are required.
- Batteries must be removed if the device is going to be stored for more than one month, or else batteries may leak.

### 1.4 Indication for use

The Fingertip Pulse Oximeter is a non-invasive device intended for the spot-check of oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>) and the pulse rate of adult and pediatric patients in home and hospital environments (including clinical use in internist/surgery, anesthesia, intensive care etc.). This device is not intended for continuous monitoring.

## 2 Overview

The pulse oxygen saturation is the percentage of HbO<sub>2</sub> in the total Hb in the blood, so-called the O<sub>2</sub> concentration in the blood. It is an important bio-parameter for the respiration. For the purpose of measuring the SpO<sub>2</sub> more easily and accurately, our company developed the Pulse Oximeter. At the same time, the device can measure the pulse rate simultaneously. The Pulse Oximeter features in small volume, low power consumption, convenient operation and being portable. It is only necessary for patient to put one finger into the sensor for diagnosis, and a display screen will directly show measured valued of Hemoglobin Saturation.

### 2.1 Classification:


Class II b (MDD 93/42/EEC IX Rule 10)  
Class II (U.S.FDA)

### 2.2 Feature

- Operation of the product is simple and convenient.
- The product is small in volume, light in weight (total weight is about 50g including batteries) and convenient in carrying.
- Power consumption of the product is low.
- The product will automatically be powered off when no signal is in the product within 16 seconds.

### 2.3 Major Applications and Scope of Application

The Pulse Oximeter can be used to measure human Hemoglobin Saturation and pulse rate through finger, and indicate the pulse intensity by the bar-display. The product is suitable for use in family, hospital (Ordinary sickroom), Oxygen Bar, social medical organizations and also the measure of saturation oxygen and pulse rate.

 The product is not suitable for use in continuous supervision for patients.

### 2.4 Environment Requirements

Operation Temperature: 40°F – 104°F (5°C-40°C)  
Storage Temperature: 14°F – 122°F (-10°C-50°C)  
Ambient Humidity: 15%-80% RH, no condensation in operation  
10%-93% RH, no condensation in storage  
Atmospheric Pressure: 70 kPa to 106 kPa, in operation (10 – 15 PSI)  
50kPa – 106 kPa, in storage

## 3 Principle and Caution

### 3.1 Principle of Measurement

Principle of the Oximeter is as follow: An experience formula of data process is

established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO<sub>2</sub>) in glow & near-infrared zones. Operation principle of the instrument is : Photoelectric Oxyhemoglobin inspection Technology is adopted in accordance with Capacity Pulse Scanning & Recording Technology, so that two beams of different wavelength of lights can be focused onto human fingertip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be show on screen through treatment in electronic circuits and microprocessor.

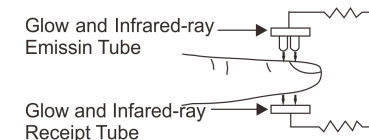


Figure 1 Operating principle

### 3.2 Caution

- The finger should be placed properly (see the attached illustration of this manual, Figure 5), or else it may cause inaccurate measurement.
- The SpO<sub>2</sub> sensor and photoelectric receiving tube should be arranged in a way with the subject's arteriole in a position there between.
- Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight and etc.
- Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.

## 4 Accessories

- One hanging rope;
- Two batteries (included);
- One User Manual.

## 5 Installation

### 5.1 View of the Front panel

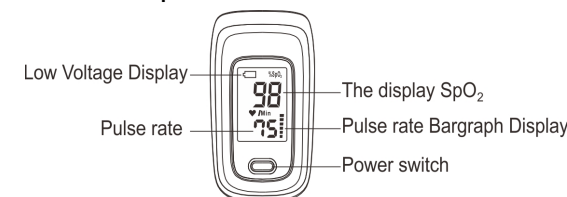



Figure 2. Front View

### 5.2 Battery

- Refer to Figure 3. and insert the two AAA size batteries properly in the right direction.
- Replace the cover.

 Please take care when you insert the batteries for the improper insertion may damage the device.

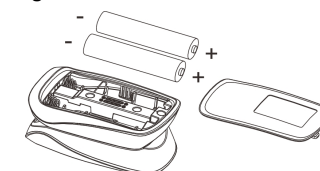


Figure 3. Batteries Installation

### 5.3 Mounting the Lanyard

Step 1. Put the end of the rope through the hole.

Step 2. Put another end of the rope through the first one and then tighten it.

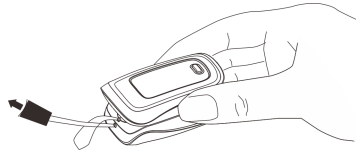


Figure 4. Mounting the Lanyard

### 6 Operating Guide

6.1 Insert the two batteries properly to the direction, and then replace the cover.

6.2 Open the clip as shown in Figure 5.



Figure 5. Put finger in position

6.3 Put patient's finger into the rubber cushions of the clip (make sure the finger is in the right position), and then clip the finger.

6.4 Press the switch button once on front panel.

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

6.6 Get the information directly from screen display.

6.7 In boot-strap state, press button, and the device is reset.

**⚠️ Fingernails and the luminescent tube should be the same side.**

### 7 Repairing and Maintenance & cleaning and disinfection

- Please change the batteries when the battery symbol is displayed on the screen.

- Please clean the surface of the device before using. Wipe the device with medical alcohol first, and then let it air dry or wipe with clean cloth.

- Using the medical alcohol to disinfect the product after use, prevent from cross infection for next time use.

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

**Warning:** High-pressure sterilization cannot be used on the device.

**Warning:** Do not immerse the device in liquid.

**Warning:** It is recommended that the device should be kept in a dry environment. Humidity may reduce the useful life of the device, or even damage it.

### 8 Troubleshooting

Trouble	Possible Reason	Solution
The SpO <sub>2</sub> and Pulse Rate cannot be displayed normally	1. The finger is not properly positioned. 2. The patient's SpO <sub>2</sub> 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 <sub>2</sub> and Pulse Rate are not displayed	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

stably		
The device can not be turned on	1. Low battery or no battery. 2. The batteries are not inserted properly. 3. The malfunction of the device.	1. Change batteries. 2. Reinstall batteries. 3. Please contact the local service center.
The display is off suddenly	1. The device will power off automatically when there is no signal within 16 seconds. 2. The batteries are almost drained.	1. Normal. 2. Change batteries.

### 9 Key of Symbols

Symbol	Description
	Type BF applied part
	Warning, see User manual.
%SpO <sub>2</sub>	The pulse oxygen saturation (%)
♥ /Min	Pulse rate (bpm)
	The battery voltage indication is deficient (change the battery in time avoiding the inexact measure)
---	1. No finger inserted 2. An indicator of signal inadequacy
	Alarm inhibit.
	When end users abandon this product, they must send the product to the collection place for recycling.
IP22	Ingress of liquids rank

### 10 Technical Specification

Display Information	Display Mode
Display Format	LED display
The Pulse Oxygen Saturation (SpO <sub>2</sub> )	Digital
Pulse Rate (PR)	Digital
Pulse Intensity (bar-graph)	Digital bar-graph display
SpO <sub>2</sub> Parameter Specification	
Measuring range	35%-100% (the resolution is 1%).
Accuracy	70%-100%;±2%, Below 70% unspecified.
Pulse Parameter Specification	
Measuring range	25bpm-250bpm (the resolution is 1 bpm)
Accuracy	±2bpm
Pulse Intensity	
Range	Continuous bar-graph display, the higher display indicates the stronger pulse.
Battery Requirement	
2 X 1.5V (AAA size) alkaline battery	
Power Consumption	
Smaller than 35 mA.	
Battery Useful Life	

Two batteries can work continually for 24 hours	
Power off	
The Oximeter will power off in case no finger is the Oximeter within 16 seconds.	
Optical Sensor	
Red light (wavelength is 660nm) Infrared (wavelength is 905nm)	
Dimensions and Weight	
Dimensions	2.4in(62mm)(L)X1.5in(37mm)(W)X1.25in(32mm)(H)
Weight	About 1.8 Oz (50g) (with the batteries)

### 11 Appendix: Electromagnetism Compatibility Guidance and manufacture's declaration – electromagnetic emissions-for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission		
The 50-100-004-L is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	This unit uses 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.
RF emission CISPR 11	Class B	This unit 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.

### Warranty

Your product is warranted to be free of defects in materials and workmanship for one year from the original purchase date.

The device was built to exacting standards and carefully inspected prior to shipment. In the event of a defect covered by this warranty, we will repair or replace the device.

This warranty does not cover device failure due to owner misuse or negligence, or normal wear and tear. If you have questions about your device, or this warranty, please contact us at the email address or phone number below.



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Manufactured By:  
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