

Instructions to User

Thank you 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:

- Discomfort or pain may occur if using the device for long periods of time, especially for microcirculation barrier patients. It is recommended that the sensor is not applied to the same finger for over 2 hours.
- The light (infrared is invisible) emitted from the device is harmful to the eyes, so the user and all maintenance should not stare at the light.
- Enamel or acrylic nail polish or other nail applications may distort and/or produce inaccurate readings.
- Please refer to the correlative literature about any clinical restrictions or cautions.
- This device is not intended for treatment.

1 Safety

1.1 Instructions for Safe Operation

- 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 is 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 the User Manual. Only accessories appointed or recommended by the manufacture can be used with this device.
- This product is calibrated before leaving factory.

1.2 Warnings

- Explosive hazard: DO NOT use the oximeter in an environment with inflammable gas such as ignitable anaesthetic agents.
- DO NOT use the oximeter if the user is being measured by an MRI or CT scan.
- DO NOT use the device if allergic to rubber.
- The disposal of scrap material, the device's accessories and packaging (including batteries, plastic, foam and paper) should follow the local laws and regulations.
- Please check the pack's contents before use to make sure the device and accessories are in accordance with the packing list, otherwise the device may work abnormally.

1.3 Attentions

- Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- If the oximeter gets wet, stop operation.
- If the device is moved from a cold environment to a 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 section 7 of the User Manual for instructions on cleaning and disinfection.
- Do not immerse the oximeter in liquid. To clean, wipe its surface with alcoholic wipes. Do not spray any liquid on the device directly.
- Do not use the device on small children and babies.
- The product is suitable for 4+ years old and for those who weigh between 15kg – 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 may change according to the individual's pulse rate.
- The device has a normal lifespan of five years since the first electrified use.
- The device shows low-voltage but does not have a low-voltage alarm function. Please change the battery when the battery dies.
- Batteries must be removed if the device is going to be stored for more than a month in case batteries leak.

1.4 Indication for use

The Finger Pulse Oximeter is a non-invasive device intended for the spot-check of oxygen saturation of arterial haemoglobin (SpO₂) and the pulse rate of adult and paediatric patients in home and hospital environments (including clinical use in internist/surgery, anaesthesia, intensive care etc.) This device is not intended for continuous monitoring.

2 Overview

The pulse oxygen saturation is the percentage of HbO₂ in the total Hb in the blood, also known as the O₂ concentration in the blood. It is an important bio-parameter for respiration. For the purpose of measuring the SpO₂ more easily and accurately, our company developed the Finger Pulse Oximeter. The device can also measure pulse rate simultaneously. The Pulse Oximeter features a convenient operation, low power consumption, small size and portability. The Pulse Oximeter features a convenient operation, low power consumption, small volume, low power consumption, convenient operation and portability. A patient needs to put just one finger onto the photoelectric sensor for diagnosis, and a display screen will directly show the measured value of Haemoglobin Saturation.

2.1 Classification:


Class II b (MDD 93/42/EEC IX Rule 10)

2.2 Features

- Simple and convenient operation
- Small size, lightweight and portable (total weight is 50g est. including batteries)
- Low power consumption
- The product will automatically turn off when out of use for over 16 seconds

2.3 Major Applications and Scope of Application

The Pulse Oximeter can be used to measure Haemoglobin Saturation and pulse rate through the finger, and indicate the pulse intensity by the bar-display. The product is suitable for use at home, in hospital, oxygen bar, social medical organisations and to measure oxygen saturation and pulse rate. The product is not suitable for continuous supervision of patients.

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

2.4 Environment Requirements

Operation Temperature: 5°C-40°C
 Storage Temperature: -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
 50kPa-106 kPa, in storage

3 Principle and Caution

3.1 Principle of Measurement

Principle of Oximeter: An experienced formula of data processing is established using Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive Haemoglobin (Hb) and Oxyhaemoglobin (HbO₂) in glow & near-infrared zones.

Operation of Oximeter: Photoelectric Oxyhaemoglobin 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 the fingertip through a perspective clamp finger-type sensor. The measured signal can be obtained by a photosensitive element, information acquired through which will be shown on screen through treatment in electronic circuits and a microprocessor.

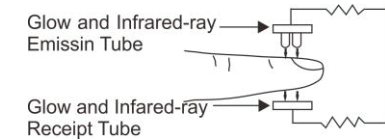


Figure 1 Operating principle

3.2 Caution

1. Place the finger properly (see Figure 5) to avoid inaccurate measurement.
2. The SpO₂ sensor and photoelectric receiving tube should be arranged with the subject's arteriole in between.
3. Excessive ambient light may affect the measuring result. This includes fluorescent lamps, dual ruby lights, infrared heaters direct sunlight and etc.
4. Strenuous action or extreme electrosurgical interference may also affect the accuracy.

4 Accessories

- 1 x Lanyard
- 2 x AAA Batteries
- 1 x User Manual.

5 Installation

5.1 View of the Front panel

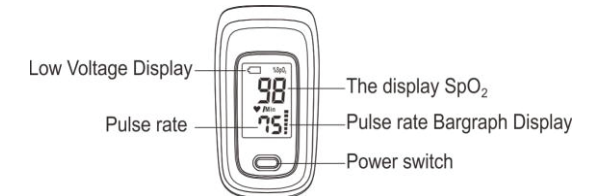



Figure 2. Front View

5.2 Battery

- Step 1. Refer to Figure 3. and insert the two AAA in the correct direction.
- Step 2. Replace the cover.

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

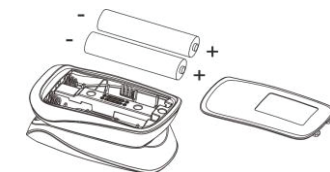


Figure 3. Batteries Installation

5.3 Attaching the Lanyard

- Step 1. Put one end of the lanyard through the hole.
- Step 2. Put the other end of the lanyard through the first one and tighten.



Figure 4. Attaching 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 Place finger into the clip with the fingertip over the sensor, and then clip the finger.
6.4 Press the button once on the front panel.
6.5 Do not shake the finger and remain still during the process.
6.6 Read the information on the screen display.
6.7 In boot-strap state press the button and the device will reset.

Fingernails and the luminescent tube should be on the same side.

7 Repairing and Maintenance & cleaning and disinfection

- Change the batteries when the low-voltage displays on the screen.
 - Clean the surface of the device with a medical alcoholic wipe before using. Allow it to air dry in air or dry with a clean fabric first.
 - Use a medical alcoholic wipe to disinfect the product after use to prevent cross infection in future use.
 - Please take out the batteries if the oximeter is not in 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 device's lifespan, or even damage it.

8 Troubleshooting

| Trouble | Possible Reason | Solution |
|---|---|---|
| The SpO ₂ and Pulse Rate can not be displayed normally | 1. The finger is not properly positioned. 2. The patient's SpO ₂ 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 ₂ and Pulse Rate are not displayed stably | 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 |
| 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 ₂ | 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 |
| | 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 ₂) | Digital |
| Pulse Rate (PR) | Digital |
| Pulse Intensity (bar-graph) | Digital bar-graph display |
| SpO ₂ 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. |
| Alert conditions | |
| SpO ₂ | Less than 94% |
| PR | Less than 50bpm or more than 130bpm |
| 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 switch off if there is no activity for 16 seconds. | |

| Optical Sensor | |
|---|--------------------------------|
| Red light (wavelength is 660nm) Infrared (wavelength is 905nm) | |
| Dimensions and Weight | |
| Dimensions | 62 (L)X37 (W)X32(H) mm |
| Weight | About 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 <i>JPD-500E</i> is intended for use in the electromagnetic environment specified below. The customer of the user of the <i>JPD-500E</i> should assure that it is used in such and environment. | | |
| Emission test | Compliance | Electromagnetic environment – guidance |
| RF emissions CISPR 11 | Group 1 | The <i>JPD-500E</i> 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 | The <i>JPD-500E</i> 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 there is the option to 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 the warranty, please contact the local distributor.



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