REF MD1940
Model: JPD-500F
Version: V1.1

LIFESENSE® BLUETOOTH PULSE OXIMETER

The **Medicare Lifesense® Bluetooth Pulse Oximeter** is an easy to use, non-invasive and completely painless test which gives quick and accurate results within 10 seconds.

Overview

Oxygen saturation is the percentage of oxyhemoglobin (HbO2) that is combined with oxygen against all combinable hemoglobin (Hb). It is an important physiological parameter involved in respiration and circulation. The oxygen saturation of arterial blood in a normal human body is 98%. Oxygen saturation is an important indicator of the oxygen condition in the human body. In general, the normal values of oxygen saturation shall not be lower than 94%. If the measured value of oxygen saturation is lower than 94%, an insufficient supply of oxygen is considered.

The pulse rate is the number of pulse beats per minute. Normally, the pulse rate is consistent with the heart rate. In general, the pulse rate of every people is 60 to 90 beats per minute.

The Perfusion Index (PI) usually reflects the limb perfusion status of an examined patient, and shows the detection precision of the instrument as well; that is, examination can still be performed even in the low or weak perfusion condition.The PI of a normal human body is 3% or greater.

FCC Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions :

(1) this device may not cause harmful interference.

(2) this device must accept any interference received,including interference that may cause undesired operation.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the ser is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Warning: Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Symbol Conventions

Symbol	Description
	Type BF applied part.
	Caution: Please see this manual.
%SpO2	Symbol of oxygen saturation.
bpmPR	Symbol of pulse rate.
	No SpO_2 alarms.
	Bluetooth symbol.
	Consult the instructions for use.
	When end users adandon this product, they must send the product to the collection place for recycling.

Precautions

- Do not attempt to maintain the Oximeter unless you are professional engineers. Only professionals with maintenance qualification are allowed to perform interior maintenance as necessary.
- Periodically change the contact position between the Oximeter probe and the finger for a measurement that lasts a long time. Adjust the position of the probe before the measurement lasts two hours, and check the integrity of skin, the blood circulation condition of the finger as well as the position of the finger.
- This product is not applicable to the examination of newborn babies.
- Seek for medical care in time if the measured value goes beyond the normal range while you are sure that the instrument does not malfunction.
- Do not directly expose your eyes to light-emitting components of the Oximeter, as that could cause harm to your eyes.
- For details about clinical limitations and contraindications, please carefully consult relevant medical literatures.

The following factors may cause disturbance to or affect the accuracy of examination:

- This product is used in an environment involving high-frequency devices, such as high-frequency electric knives and CT apparatuses.
- The probe of the Oximeter is placed on the same body part or limb as with blood pressure cuff arterial duct or intravenous injection.
- The user suffers from hypotension, severe vascular atrophy, severe anemia, or low oxygen.
- The user is in sudden cardiac arrest or shock state.
- The finger with nail polish or a fake fingernail may cause wrong readings of pulse oxygen saturation.

Warnings

Warning: Do not use the Oximeter in an environment with any inflammable gases, inflammable anesthetic, or other inflammable substances.

Warning: Do not attempt to charge any common dry battery, as that could cause leakage, fire disaster, or even explosion. Dispose of exhausted batteries in accordance with environment protection regulations.

Warning: Do not use the Oximeter in an MRI or CT environment.

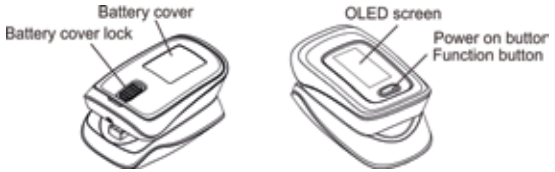
Warning: Do not operate the Oximeter when it is damp with overflow or water vapor condensation. Avoid moving the Oximeter from an excessively-cold environment to a high-temperature moist environment.

Working Principles, Expected Usage, and Applicable Scope

Based on full digital technology, the Finger Pulse Oximeter non-invasively measures the actual content (oxygen saturation) of oxyhemoglobin (HbO2) in arterial blood using the optical transmittance method.

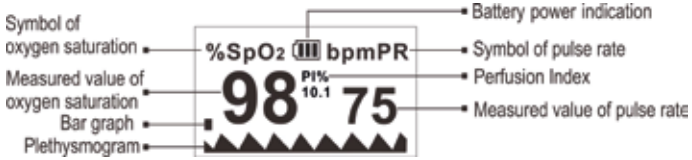
The Finger Pulse Oximeter measures the blood oxygen saturation and pulse rate of a human body via finger artery. It is applicable to a wide range of fields, such as families, hospitals (including operation rooms of the departments of internal medicine and surgery, the department of anesthesiology, the department of paediatrics, and intensive care rooms), oxygen bars, social medical care institutions, and sports & health. Use this instrument for measurement before or after sports. You are not advised to use this instrument during sports activities. Do not use it for continuous care for patients.

Appearance of the structure



Screen Display

The following figure shows the information display on the OLED screen of the Oximeter in normal detection state:



Note: Battery power indication and bluetooth symbol will alternately displayed.

Power-On button/Functional button Operations

Press and release the button to turn on, hold the button for about one second. The Oximeter shows a parameter setting interface. Press or hold the button to perform corresponding operations. Hold it to set an item, or press it to switch an option or switch the display mode. Press means no more than 0.5 seconds, while Hold means more than 0.5 seconds.

Alert Sound Setting

Hold the functional button while the Oximeter is in powered-on state. Parameter setting interface 1 is displayed, as shown in the following figure. Move "*" to the corresponding option, and hold the functional button to set **Alm** to **on** and set **Beep** to **off**. When **Alm** is set to **on** and the measured values of the blood oxygen saturation and pulse rate go beyond the upper limit or lower limit, the Oximeter

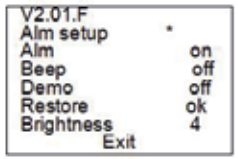
gives off an alert sound. When **Alm** is set to **off** and the measured values go beyond the limit, the Oximeter will not give any alert sound. When **Beep** is set to **on**, a tick will be heard along with pulse beats during pulse rate measurement. When **Beep** is set to **off**, no sound will be output along with pulse beats during pulse rate measurement. While the "*" symbol stays on the **Restore** option, hold the functional button to restore factory settings.

Brightness Setting

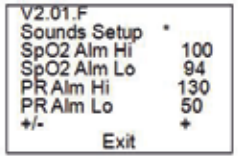
On parameter interface 1, press the functional button to select the **Brightness** option and then hold the functional button to set the brightness to a value ranging from 1 to 5. The greater the value, the greater the brightness of the screen.

Alert Range Setting

On parameter interface 2, press the functional button to switch between options. On this interface, you can set the upper limit and lower limit of **SpO2 Alm** and **PR Alm**. While the "*" symbol stays on the **+/-** option, hold the functional button to set the option to **+** or **-**. In **+** mode, select the corresponding option and hold the functional button to increment the upper or lower limit; in **-** mode, hold the functional button to decrement the upper or lower limit. Move "*" to the **Exit** option, and hold the functional button to return to the monitoring interface.



Interface 1



Interface 2

Operation Guide

Stick one finger completely into the measuring parts of the Oximeter, keep the fingernail surface upward, and release the clip. Then press the power button to power on the Oximeter.

⚠ If you do not yet completely insert your finger into the cavity, the measurement result may be inaccurate.

⚠ Do not vibrate your finger during measurement. Preferably, ensure that your body does not move. After the readings become stable, read the measured values of oxygen saturation and the pulse rate on the screen.

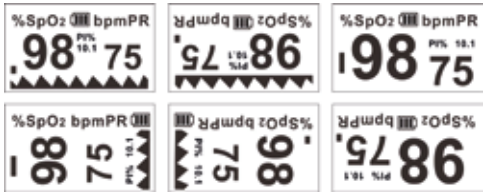
NOTE: The Oximeter will automatically shut down 10 seconds later after your finger leaves away.

Connecting the Instrument to a Mobile Phone via Bluetooth

Note: For details on specific operations, see the APP operation instructions.

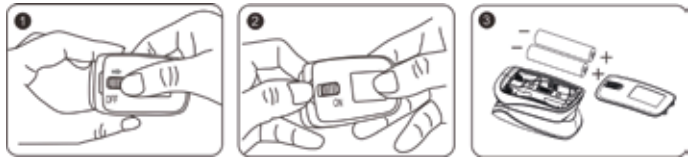
About the Display

Continuously press the functional button in the monitoring process. The monitored data and the display mode will be cyclically displayed on the OLED screen in two different ways (large fonts and plethysmogram) and four directions, as shown in the following figure.



⚠ Replace the batteries when the battery capacity is insufficient and the symbol (▭) flickers on the screen.

Open the battery cover with your fingers, you can replace the batteries according to the correct battery polarity.



Cleaning

Power off the instrument and remove the batteries before cleaning. Ensure that the appearance of the instrument is neat, dust-free, and dirt-free. Clean the outer surface of the instrument (including the OLED screen) using 75% medical alcohol and a piece of dry soft cloth.

Caution: Avoid liquid flowing into the instrument during cleaning.

Caution: Do not immerse any part of the instrument into any liquid.

Disinfection

Before measurement with the instrument, wipe the rubber finger pad using a piece of dry soft cloth dipped with 75% medical alcohol. Clean the finger to be measured using the medical alcohol for disinfection purposes before and after use.

Maintenance

- Remove the batteries from the battery slot and properly store them if you do not plan to use the Oximeter for a long period of time.
- Avoid using the Oximeter in an environment with inflammable gases or using it in an environment where the temperature or humidity is excessively high or low.
- Check the accuracy of the oxygen saturation and pulse rate readings by using an appropriate calibration apparatus.

Technical Specifications

1. Dimensions: 62.0 mm (Width) × 37.0 mm (Depth) × 32.0 mm (Height)
   Weight: 42.5 g (including the height of the two AAA dry batteries)
2. Peak wavelength range of the light emitted from the probe: red light 660 nm ± 3; infrared light 905 nm ± 5.
3. Maximum optical output power of the probe: 1.2 mW for infrared light (905 nm).
4. Bluetooth module: 4.0
5. Normal working condition

Working Temperature	5°C to 40°C (41°F to 104°F)
Relative Humidity	15% to 80%, non-condensing
Atmospheric Pressure	70 kPa to 106 kPa
Rated Voltage	DC 3.0 V

6. Default values and conditions of alert

Parameter	Value
Oxygen saturation	Upper limit: 100 Lower limit: 94
Pulse rate	Upper limit: 130 Lower limit: 50
Alert condition	When the alert switch is on and the actual measured value goes beyond the preset alert parameter range, the Oximeter gives an alert sound.

7. Technical parameters

Parameter		Value
Display range	Oxygen saturation	35% to 100%
	Pulse rate	25 bpm to 250 bpm
Resolution	Oxygen saturation	1%
	Pulse rate	1 bpm
Measurement precision	Oxygen saturation	±2% (70% to 100%) No requirement (≤ 69%)
	Pulse rate	±2 bpm
Alert range	Oxygen saturation	Upper limit: 50% to 100% Lower limit: 50% to 100%
	Pulse rate	Upper limit: 25 bpm to 250 bpm Lower limit: 25 bpm to 250 bpm
Alert error	Oxygen saturation	± 1% of the preset value
	Pulse rate	The greater of ±10% of the preset value and ±5 bpm
PI	Weak PI	Min. 0.2%

Safety Type

Anti-electric-shock type: internal power supply device
Anti-electric-shock degree: Type BF applied part
Running mode: continuous working
Waterproof grade: IP22

Storage and Transportation

Temperature : –10°C - 50°C(14℉-122℉)
Relative humidity : 10%-93% (no condensation)
Atmospheric pressure : 50kPa–106 kPa.

Shenzhen Jumper Medical Equipment Co. Ltd.
D Building, No. 71, Xintin Road, Fuyong Street,
Baoan, Shenzhen, Guangdong, China

EC REP **MedPath GmbH**
Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

Distributed by: FLEMING MEDICAL LTD
Limerick, V94 K6W4, Ireland
1800 307777 (IRE) 0800 7314315 (UK)
WWW.FLEMINGMEDICAL.IE

CE 0482

Rev.:24112020