OPERATOR'S MANUAL

112PO

1. General Description

Thank you for purchasing the 112PO Fingertip Pulse Oximeter. This oximeter can be used to measure your blood oxygen saturation (in % SpO_2) and your pulse rate. This device is not to be used for continuous monitoring.

Indications for Use:

The 112PO Fingertip Pulse Oximeter is for spot checking oxygen saturation of arterial hemoglobin (SpO_2) and Pulse Rate in adults. Designed to be used for sports and aviation, it is ideal for use during sporting activities, mountain climbing, and piloting airplanes. It is not intended to diagnose any medical condition, or to be used in medical applications.

2. Package Contents

1. Fingertip Pulse Oximeter
2. Lanyard
3. User Manual
4. Carrying Case
5. 2 X AAA Batteries

3. Precautions for Use

1. Read the manual carefully before use.
2. Pulse oximeters are sensitive to motion. Keep still while taking a reading.
3. Pulse oximeters require sufficient blood flow to obtain proper readings.
4. Poor blood circulation can result in inaccurate readings. If your hands are cold, or you have poor circulation, warm your hands by rubbing them together or use another warming method before attempting a reading. Tourniquets, blood pressure cuffs, or other blood flow hindrances may also result in inaccurate readings.
5. Fingernail polish or acrylic nails can obstruct light transmission, and may result in inaccurate readings. If wearing fingernail polish and/or artificial nails, turn finger on its side to obtain an accurate reading.
6. Fingers must be clean to obtain an accurate reading.
7. The pulse oximeter must be clean to obtain an accurate reading.
8. If a reading is difficult to obtain, switch to another finger, or to the other hand.
9. There are a number of other conditions, which may lead to an inaccurate reading. These include but are not limited to: recent medical tests that included an injection of dyes, use of arterial catheters, a weak pulse, low levels of hemoglobin in the blood, low perfusion (the quality of your pulse), elevated levels of dysfunctional hemoglobin, the strength and type of light that you are in while using the pulse oximeter, and the existence of cell phones, radios, or fixed transmitters within certain ranges of the pulse oximeter during use.
10. The pulse oximeter will not alert you if your readings are out of normal range.
11. Explosion hazard: Do not use this pulse oximeter in an explosive atmosphere.
12. The pulse oximeter has no SpO_2 alarms; it is not for continuous monitoring, as indicated by the symbol.
13. Keep the pulse oximeter away from young children. Small parts such as battery or battery door may be hazardous if swallowed.
14. The lanyard may cause strangulation if it were to twist around the neck.
15. Operation of the fingertip pulse oximeter may be affected by the use of an electrosurgical unit (ESU).
16. The fingertip pulse oximeter must be able to measure pulse properly to obtain an accurate SpO_2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO_2 results.
17. Do not use the fingertip pulse oximeter in an MRI or CT environment.
18. Do not use the fingertip pulse oximeter in situations where alarms are required. The device has no alarms. It is not for continuous monitoring.
19. Do not sterilize the device using autoclaving, ethylene oxide sterilizing, or immersing the device in liquid.
20. This equipment complies with IEC 60601-1-2:2014 for electromagnetic compatibility for medical electrical equipment and/or systems. However, because of the proliferation of radio-frequency (RF) transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device.
21. Portable and mobile RF communications equipment can affect this device. The portable and mobile RF communications equipment should be used no closer than 30cm (12 inches) to any part of the device, including cables specified by the manufacturer.
22. This device should not be used adjacent to, or stacked with other equipment.
23. All functions of this device can be safely used by the intended operator.
24. Materials that contact the user's skin all pass the ISO10993-5 Tests for invitro cytotoxicity and ISO10993-10 Tests for irritation and delayed-type hypersensitivity.
25. The applied part of the device = the rubber hole of the device.
26. The presence of ambient light may affect the accuracy of the pulse oximeter's sensor.
27. When the signal is not stable, the reading may be inaccurate. Please do not reference.
28. This device is not intended for use in an oxygen rich environment.
29. This device is not intended for clinical use.
30. This device is calibrated to display functional oxygen saturation.
31. The waveform provided is normalized.
32. The essential performance of the device: can display the SpO_2 and PR value accurately. If the Essential Performance is lost or degraded due to EM disturbances, the reading may be inaccurate. Please do not refer to it.

Warning!

It may be unsafe to:

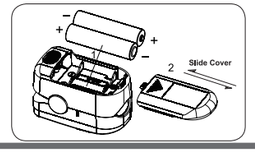
- use accessories, detachable parts, or materials not described in the instructions for use.
- interconnect this equipment with other equipment not described in the instructions for use.
- disassemble, repair or modify the equipment.
- use the monitor for more than 30 minutes. The maximum single site application time for the device should be less than half an hour. Using a probe with excessive pressure for a long time can cause pressure damage.

In addition to items described in the Precautions for Use, inaccurate measurements may be caused by FACTORS including but not limited to:

1. Autoclaving, ethylene oxide sterilizing or immersing the sensors in liquid.
2. Significant levels of dysfunctional hemoglobin (such as carbonxy-hemoglobin or methemoglobin).
3. Intravascular dyes such as indocyanine green or methylene blue.
4. SpO_2 measurements may be adversely affected in the presence of high ambient light such as direct sunlight. In bright light conditions, cover the sensor area if necessary.
5. Excessive user movement.
6. High-frequency electrosurgical interference and defibrillators.
7. Venous pulsations
8. Hypotension, severe vasoconstriction, severe anemia or hypothermia.
9. Fingernail polish or false fingernails may cause inaccurate SpO_2 readings. If wearing fingernail polish and/or artificial nails, turn finger on its side to obtain an accurate reading.

4. Battery Installation

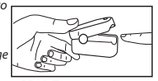
1. Install two AAA batteries into the battery compartment. Match the polarity signs in the compartment. If they are not matched, damage may be caused to the oximeter.
2. Slide the battery door cover horizontally along the arrows shown in the picture.
3. The battery indicator symbol on the front panel display will flash when voltage is too low for normal operation.
4. Replace the batteries when indicator symbol flashes.



NOTE: Install the batteries following the correct polarity. Incorrect placement may cause damage to the bracket.
NOTE: Remove the batteries if the pulse oximeter is not intended to be used for long periods of time.

5. Using the Oximeter

1. Open the clamp as shown in the picture.
2. Place one of your fingers into the rubber opening of the pulse oximeter (your finger should touch the bottom portion) before releasing the clamp.
3. Press the switch button once on the front panel to turn the pulse oximeter on.
4. Keep your hand still for the reading. Do not shake your finger during the test. It is recommended that you stay as still as possible while taking a reading.
5. Read the data from the display screen.
6. There are six display modes. After turning on the pulse oximeter, each time you press the power switch, the pulse oximeter will switch to another display mode.

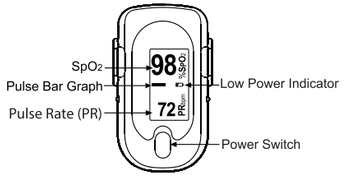


7. When you hold the power switch for more than one second, the brightness of the pulse oximeter will change by degrees. The default level is set to 4. There are 10 levels of brightness that are shown as BR1, BR2, BR3, up to BR10. The setting is shown on the display as the numbers cycle through all levels while the power button is held.
8. The device automatically powers off after 8 seconds on non-use, when "finger out" is displayed.

6. Maintenance

1. Clean the pulse oximeter and sensor with a soft cloth dampened with isopropyl alcohol. Do not pour or spray any liquids onto the pulse oximeter. Do not allow any liquid to enter any openings in the device. Allow the pulse oximeter to dry thoroughly before reusing. (The rubber inside of the pulse oximeter is composed of medical grade rubber. It is non-toxic and is not harmful to the skin.)
2. The pulse oximeter requires no routine calibration or maintenance other than replacement of the batteries.

7. Brief Description of Front Panel



The height of the Pulse Bar graph indicates the intensity of the pulse and signal strength. The bar should be greater than 30% for a proper reading.

8. Technical Specifications

***1. Display**: OLED display*
***PR display mode**: Bar graph*
***Low power indication**:*

***2. Battery Standard:** Two AAA 1.5V Alkaline Batteries*

***3. Power Consumption:** Less than 40mA*

***4. Battery Life:** Two AAA 1.5V, 1200mAh alkaline batteries can be continuously operated for as long as 24 hours.*

***5. Resolution:** 1% for SpO_2 ; 1 BPM for Pulse Rate*

***6. Measuring range:** SpO_2 : 70%-100%; PR: 30bpm-250bpm*

***7. Display range:** SpO_2 : 0%-100%; PR: 30bpm-255bpm*

Note: A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor. Clinical testing is used to establish the SpO_2 accuracy. The measured arterial hemoglobin saturation value (SpO_2) of the sensors is compared to arterial hemoglobin oxygen (SaO_2) value, determined from blood samples with a laboratory CO-oximeter. The accuracy of the sensors in comparison to the CO-oximeter samples measured over the SpO_2 range of 70%-100%. Accuracy data is calculated using the root-mean-squared (Arms value) for all subjects, per ISO 80601-2-61, Medical Electrical Equipment–Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.
A functional tester is used to measure how accurately the Fingertip Pulse Oximeter is reproducing the specified calibration curve and the PR accuracy.

The model of functional tester is Index2 FLUKE simulator and the version is 2.1.3.

8. Measurement Accuracy:
SpO_2: 70%-100%, ±2 digits; 0%-69%, no definition
PR: 30bpm-99bpm, ±2bpm; 100bpm-250bpm, ±2%

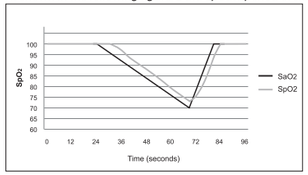
9. Probe LED Specifications

	Wavelength	*Radiant Power*
RED	*660±3nm*	*3.2mw*
IR	*905±10nm*	*2.4mw*

10. Environment Requirement:
Operation Temperature: 5°C-40°C (41°F-104°F)
Storage Temperature: -25°C-70°C (-13°F-158°F)
Ambient Humidity: 15%-93%, no condensation in operation;
≤93%, no condensation in storage

Atmosphere Pressure: 70kPa-106kPa

11. Equipment data update period
As shown in the following figure. Data update period of slower average is 8s.



***12. Automatic Power Off:** The device will automatically power off after no operation for 8 seconds when "finger out" is displayed.*

***13.** It is recommended that the product be kept in a dry place. A damp environment may affect its lifetime and could damage the product.*

***14. Mode of Operation:** Continuous*

***15. Declaration**: EMC of this product complies with IEC60601-1-2 standard.*
The materials which users can come into contact with are non-toxic and comply with ISO10993-5 and ISO10993-10.

9. Troubleshooting

Problems	*Possible Reason*	*Solution*
SpO_2 or PR is not shown normally.	*1. Finger is not inserted correctly.* *2. User's oxyhemoglobin value is too low to be measured.*	*1. Re-insert finger.* *2. There is excessive illumination* *3. If issue persists, and you are certain there is no problem with the device, please go to your nearest hospital for diagnosis.*
SpO_2 or PR is shown unstably.	*1. Finger might not be inserted deep enough.* *2. Finger is trembling or user's body is in movement.*	*1. Re-insert finger.* *2. Try not to move.*
The pulse oximeter cannot be powered on.	*1. The batteries might be installed incorrectly.* *2. The batteries' power might be inadequate.* *3. The pulse oximeter might be damaged.*	*1. Re-install the batteries according to the polarity marked inside the battery compartment.* *2. Replace the batteries.* *3. Contact customer service.*
Indication lamps are suddenly off	*1. The product is automatically powered off when no signal is detected for longer than 8 seconds* *2. The battery power is too low to work.*	*1. Normal.* *2. Replace the batteries.*
"Err7" displayed on screen.	*1. Emission LED or reception diode is damaged.*	*1. Contact customer service.*

10. Declaration

Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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

Guidance and manufacturer's declaration – electromagnetic emission		
The pulse oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the pulse oximeter should ensure that it is used in such an environment.		
Emission test	***Compliance***	***Electromagnetic Environment – Guidance***
RF emissions	*GROUP 1*	*The pulse oximeter 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 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.*

11. Symbol Definitions

Symbol	***Definition***	***Symbol***	***Definition***
% SpO_2	*Oxygen Saturation*		*Low Power Indication*
PR bpm	*Pulse Rate (bpm)*		*Full Power Indication*
LOT	*LOT Number*	*?*	*Indicate the signal is not stable*
	Follow instruction for use		*Type BF applied part*
	Date of Manufacture	SpO2	*No SpO_2 Alarm*
	Conformity to WEEE Directive	-25°C min, +70°C max, RH≤93% non-condensing	*Storage temperature and relative humidity*
IP22	*The degree of protection against ingress of dust and water: The first number 2: Protected against solid foreign objects of 12.5 mm Φ and greater; The second number 2: Protection against vertically falling water drops when ENCLOSURE tilted up to 15° on either side of the vertical.*		

12. Contraindication

Not found yet.

13. Notes:

1. *Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.*
2. *The illustrations used in this manual may differ slightly from the appearance of the actual product.*
3. *The use life of the device is five years when it is used for 15 measurements every day (10 minutes per measurement).*

In compliance with the European Directive on Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC, do not dispose of this product as unsorted municipal waste. This device contains WEEE materials; please contact your distributor regarding take-back or recycling of the device. Please dispose of all components in accordance with your local, state or national regulations regarding waste management.

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