

iHealth®

Wireless Pulse Oximeter
Model PO3



OPERATION MANUAL



iHealth

MODEL PO3

Wireless Pulse Oximeter









OPERATION MANUAL

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SYMBOLS

The symbols below are associated with your PO3

| Symbols | Definition of Symbol |
|---|---|
|  | THE OPERATION MANUAL MUST BE READ |
|  | WARNING |
|  | TYPE BF APPLIED PARTS (Silica gel pad) |
|  | No alarm for SpO ₂ |
|  | ENVIRONMENT PROTECTION-Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local Authority or retailer for recycling advice |
|  | Manufacturer |
|  | Country of manufacture and Date of manufacture |
|  | SERIAL NUMBER |
| IP22 | IP code of the device: this device's grade of against ingress of solid foreign objects – ≥ 12.5 mm diameter (and the against access to hazardous parts with finger); the grade of waterproof is dripping (15° tilted). |
| CE 0197 | COMPLIES WITH MDD93/42/EEC REQUIREMENTS |

INTENDED USE

The PO3 Wireless Pulse Oximeter is a non-invasive device intended for spot-checking of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate.

The Wireless Pulse Oximeter is intended to measure blood oxygen saturation and pulse rate of people above 16 years old in home environments.

The Wireless Pulse Oximeter is not intended for continuous monitoring.

Compatibility

The Wireless Pulse Oximeter PO3 works with both iOS and Android devices.

For a complete list of compatible devices, visit our support page on www.ihealthlabs.com

PACKAGE CONTENTS

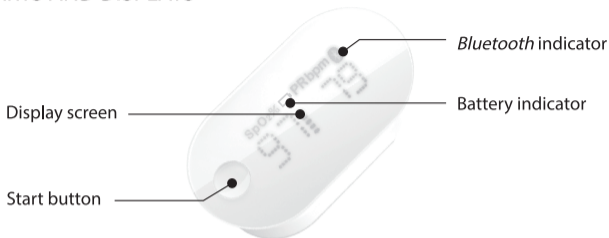
One (1) Wireless Pulse Oximeter PO3

One (1) Operation Manual

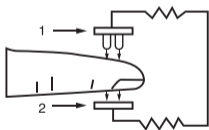
One (1) Quick Start Guide

One (1) Charging Cable

PARTS AND DISPLAYS



DEVICE DESCRIPTION



The PO3 pulse oximeter measures the amount of oxygen in your blood and the pulse rate. The oximeter works by shining two light beams into the finger's small blood vessels or capillaries; the measured signal is then obtained by a photosensitive element and processed by the microprocessor. The oxygen saturation (SpO2) is

measured as a percentage of full capacity.

Typically, an SpO2 reading between 94%-99% is considered normal. High altitudes and other factors may affect what is considered normal for a given individual.

Concerns about your readings should be shared with your physician or healthcare professional.

IEC 60601-1Edition 3.1 2012-08/EN 60601-1:2006/A1:2013 Medical electrical equipment-Part1: General requirements for basic safety and essential performance)
IEC 60601-1-2:2014/EN 60601-1-2:2015 (Medical electrical equipment-- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests)
IEC 60601-1-11:2015 (Medical electrical equipment-Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment)
ISO 80601-2-61:2011 (Medical electrical equipment-Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use).
Hence, [Andon Health CO., LTD], declares that this [PO3] complies with the essential requirements and other relevant provisions of Directive 2014/53/EU.
Directive 2014/53/EU declaration of conformity can be downloaded on the following link : <https://www.ihealthlabs.eu/support/certifications>

CONTRAINDICATIONS

The PO3 Wireless Pulse Oximeter cannot be used on infant babies.

WARNINGS

- 1.This device is for use on people above 16 years old only.
- 2.Do not use the device in a magnetic resonance (M.R.) environment.

NOTICE

1. Do not use the device as the only basis for making medical decisions.
2. The device might misinterpret excessive movement as good pulse strength. Limit finger movement as much as possible when using the device.
3. The device has no alarms for blood oxygen saturation and pulse rate. If the measurement of SpO₂ and pulse rate is not in the normal range, please contact your health care professional.
4. Do not place the device in liquid or clean it with agents containing ammonium chloride or products not listed in this Operation Manual.
5. Any of the following conditions may reduce the performance of the device:
 - a) Flickering or very bright light;
 - b) Excessive Movement;
 - c) Weak pulse quality (low perfusion);
 - d) Low hemoglobin;
 - e) Nail polish, long fingernails, and artificial nails;
 - f) Any tests recently performed on you that required an injection of intravascular dyes.
6. The device may not work if you have poor circulation. Rub your finger to increase circulation, or place the device on another finger.
7. The device measures the percentage of hemoglobin molecules carrying oxygen. High levels of dysfunctional hemoglobin (caused by sickle cell anemia, carbon monoxide, etc.) could affect the accuracy of the measurements.

8. Do not use the device in a combustible (oxygen-enriched) environment.
9. Do not use the device outside the specified operating temperature range, and do not store the device outside the specified storage temperature range.
10. The materials used in the device conform to biocompatibility and nontoxic regulations and present no hazard to the body.
11. Use in emergency vehicles with communication systems may affect the accuracy of the measurements.
12. The device's packaging is recyclable, and it must be collected and disposed of according to local regulations.
13. Any device material that may cause pollution must be collected and disposed of according to local rules and requirements.
14. Any single functional tester cannot be used to assess the accuracy of a pulse oximeter.
15. Do not stare at the lighting LED, as it may irritate your eyes.
16. The device is calibrated to display functional oxygen saturation.
17. Do not use the device continuously for more than 30 minutes.
18. The wavelength range of pulse oximeter can be especially useful to clinicians
19. Since the pulse oximeter measurements are statistically distributed, only about two-thirds of pulse oximeter measurements can be expected to fall within $\pm 2\sigma$ of the value measured by an oximeter.
20. Misapplication of a probe with excessive pressure for prolonged periods can induce pressure injury.

21. Please do not use the USB Cable other than supplied by the manufacturer, otherwise it may bring biocompatible hazard and might result in measurement error.
22. If some abnormal conditions appear on the screen during test process, pull out the finger and reinsert to restore normal use.
23. It is suggested that the wireless pulse oximeter be kept at least 30 cm away from other wireless devices, such as WLAN unit, microwave oven, etc.
24. The SpO₂ accuracy was tested by comparing it to a Co-oximeter and the pulse rate accuracy was tested by comparing it to a function tester.
25. The device shall not be installed close to or stacked with other devices. When it must be close to or stacked with other devices, please observe if the device can operate normally under such a setting first. For recommended measures for avoiding or reducing such interference, please refer to the section "ELECTROMAGNETIC COMPATIBILITY INFORMATION."
26. This device requires an AC adapter with an output of DC 5.0V that complies with IEC 60601-1/UL 60601-1 and IEC 60601-1-2/EN 60601-1-2 such as IEC 60950 approved computer could be used for charging the equipment.
ASP5-05010002JU(input: 100-240V,50/60Hz,200mA;output: DC 5V,1.0A).
Please note that the charging port size is USB Type-C. The USB port should be used for charging only.

⚠ This product might not meet its performance specifications if stored or used outside the specified temperature and humidity ranges.

⚠ The patient is an intended operator.

⚠ Keep the device out of the reach of children/pets to avoid inhalation or swallowing of small parts.

⚠ If you are allergic to plastic/rubber, please don't use this device. Be careful of strangulation due to cables and hoses, particularly due to excessive length.

⚠ Keep unit out of the reach of young children/pets.

⚠ Servicing/maintenance while the equipment is in use should be avoided.

USING YOUR PULSE OXIMETER



Before Using Pulse Oximeter

The wireless pulse oximeter may be used when the user is seated, standing or lying down. The user should not walk or run during measurements and should take care of not excessively moving the finger where the device is attached and the corresponding hand and arm.

It is recommended that the user should wash their hands before use. Nail polish, especially dark shades, may affect the accuracy of the measurement and it is suggested that any polish be removed before monitoring.

The index or middle finger is preferred when using the device.

Charge The Battery Before The First Use

Link the Wireless Pulse Oximeter to a USB port of an electrical power source, and press the “start” button. Then the battery indicator "  " will blink, which means the battery charging is started. When the battery indicator "  " turns off, it means the battery has been fully charged.

When charging/using, do not touch the charging USB port and the patient simultaneously.

Download App

Download the free “iHealth MyVitals” app from the Apple App Store or Google Play Store. Follow the on-screen instruction to register and set up your iHealth user account.

Access iHealth Cloud

Upon setting up your app user account, you can access a free, secure Health Cloud account using your email and password

Turn Bluetooth “On”

Your iHealth Wireless Pulse Oximeter uses *Bluetooth 5.0* Low Energy (BLE) technology. Enable *Bluetooth* on your mobile device and launch the app, add device “Air PO3/ PO3M”, press the Start button to activate Bluetooth. The *Bluetooth* icon will light up and flashing, it will stay on when a successful connection is established. The date and time of the Pulse Oximeter will be synced with your mobile device upon a successful connection.

TESTING INSTRUCTIONS

1. Open the clamp of the Pulse Oximeter, then place your index or middle finger into the rubber opening of the oximeter with the nail side down and display side up, as pictured.



2. Press the "Start" button on the front panel once to turn the oximeter on.
3. Keep your hand still for the reading.
4. After a few seconds, your SpO2 reading will appear on the oximeter display screen and the app if the app is turned on.
5. If the signal strength is too low, switch to another finger and repeat the test.

USING WITHOUT A SMART DEVICE


After it has been used for the first time, the date and time of the Pulse Oximeter PO3 will be synchronized with your device. It can also be used without being connected to a smart device. In this case, the measurement data is stored in the memory and can be uploaded to the app when the connection is re-established. The Pulse Oximeter PO3 can store 100 measurements. When the memory is full, any new measurement overwrites the oldest ones.

CARE AND MAINTENANCE

1. Clean the device once per week or more frequently if handled by multiple users.
2. Wipe the device with a soft cloth dampened with rubbing alcohol to prevent the spread of germs. Do not pour alcohol directly on or into the device.
Dry with a soft cloth, or allow to air dry.
3. Avoid dropping this device on a hard surface.
4. Do not immerse the device in water or other liquid, as this will damage the device.
5. If this device is stored below 0°C (32°F), please acclimate the device to room temperature before use.
6. Do not try to disassemble this device.
7. The PO3 is a precision electronic instrument and must be repaired/serviced by an accredited iHealth service center.
8. Incorrect battery replacement by inadequately trained personnel could result in an unacceptable risk (e.g., excessive temperatures, fire or explosion). The battery can maintain the performance characteristics for at least 300 charge cycles. If the battery cannot be charged or the Pulse Oximeter does not function normally, please contact iHealth customer service.
9. User can maintain no component in the device. The circuit diagrams, part lists, descriptions, calibration instructions, or other information which will assist the user's appropriately qualified technical personnel in repairing those parts of equipment which are designated repairable can be supplied.

10. The pulse oximeter tester and simulator "Index 2", made by the Fluke company, can be used to verify the operation of the oximeter.
11. The expected service life of the PO3 is about 5 years.

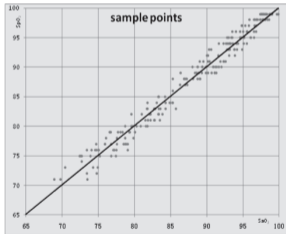
SPECIFICATIONS

1. Model: PO3
2. Classification: Internally powered, type BF (applied part: silica gel pad)
3. Enclosure degree of ingress protection: IP 22
4. Display System: LED
5. Power Source: battery 3.7V  Lithium-ion 390 mAh
6. Peak wavelength: 660nm/880nm;
7. Maximum optical output power: 1 mW;
8. SpO2 Measuring Range: 70-99%
9. Average Root Mean Square (ARMS) of SpO2 Accuracy: 80% ~ 99%: $\pm 2\%$,
70% ~ 79%: $\pm 3\%$, <70%: no definition.

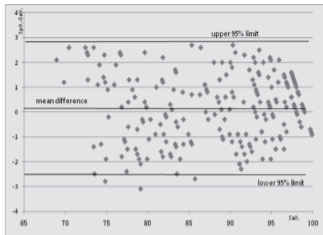
10.

| Range | Arms |
|----------|--------|
| 90%~100% | 1.2215 |
| 80%~89% | 1.3282 |
| 70%~79% | 1.7277 |

The figure below shows the graphical plot of all SaO₂ versus SpO₂ with linear regression fit for all the sample data in the clinical protocol.



Scatter plot of SaO₂ versus SpO₂ with linear regression fit




Scatter plot of the difference between methods against the SaO2

The figure above shows the graphical plot of SaO2 versus error ($SpO_2 - SaO_2$) with upper 5% and lower 95% limits of agreement:

11. Pulse Rate Measuring Range: 30/min-250/min
12. Pulse Rate Accuracy: 30/min ~ 99/min: ± 2 , 100/min ~ 250/min: $\pm 2\%$.
13. Data update period: 15s
14. Automatic Shut-off: After 8 seconds of no indication on the sensors
15. Operation Environment: 41°F-104°F (5°C-40°C); Humidity <80%RH;
Atmospheric pressure: 700hPa-1060hPa
16. Storage and Transport Environment: -4°F-131°F (-20°C-55°C);
Humidity <95%RH; Atmospheric pressure: 700hPa-1060hPa

TROUBLESHOOTING

| Problem | Possible Cause | Solution |
|---|---|--|
| SpO2 or pulse rate shows no value, or the number fluctuates. | 1.Finger may not be inserted correctly. 2.Finger or hand may be moving. 3.The device may be damaged | 1.Remove finger and re-insert, as directed. 2.Try to keep perfectly still and test again. 3.Please contact the iHealth Customer Service. |
| The device does not turn on. | 1.The battery may be low. 2.The device might be damaged. | 1.Charge the battery and try again. 2.Please contact the iHealth Customer Service. |
| “E1” is displayed on the screen | The sensor is damaged | Please contact the iHealth Customer Service. |
| The Battery Indicator  is blinking. | The battery is low. | Charge the battery and try again. |
| The app cannot find the Wireless Pulse Oximeter PO3. | The <i>Bluetooth</i> does not work or <i>Bluetooth</i> settings are incorrect on the smartphone/tablet. | Re-establish the <i>Bluetooth</i> connection.If still not successful, restart your smart device. |

IMPORTANT INFORMATION REQUIRED BY THE FCC

This device complies with Part 15 of the FCC Rules. Its 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 product 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 product 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 product does cause harmful interference to radio or television reception, which can be determined by turning the equipment of and on, the user 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.

MANUFACTURER INFORMATION



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CE 0197

ELECTROMAGNETIC COMPATIBILITY INFORMATION

This product applies to the equipment and system requirements to receive radio frequency energy for the purpose of the work, Bluetooth receive bandwidth 2M. This product can also be used to include RF transmitter equipment and system requirements and emission frequency of 2.4GHz ISM band, Bluetooth modulation types: GFSK, effective radiated power: < 20dBm

Table 1 - Emission

| | | |
|--------------|------------------------------|-----------------------------|
| Phenomenon | Compliance | Electromagnetic environment |
| RF emissions | CISPR 11 Group 1, Class B | Home healthcare environment |

Table 2 - Enclosure Port

| Phenomenon | Basic EMC standard | Immunity test levels |
|--|--------------------|--|
| | | Home healthcare environment |
| Electrostatic Discharge | IEC 61000-4-2 | ±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air |
| Radiated RF EM field | IEC 61000-4-3 | 10V/m 80MHz-2.7GHz 80% AM at 1kHz |
| Proximity fields from RF wireless communications equipment | IEC 61000-4-3 | Refer to Table 3 |
| Rated power frequency magnetic fields | IEC 61000-4-8 | 30A/m 50Hz or 60Hz |

Table 3 – Proximity fields from RF wireless communications equipment

| Test frequency (MHz) | Band (MHz) | Immunity test levels |
|----------------------|------------|--|
| | | Professional healthcare facility environment |
| 385 | 380-390 | Pulse modulation 18Hz, 27V/m |
| 450 | 430-470 | FM, ± 5 kHz deviation, 1kHz sine, 28V/m |
| 710 | 704-787 | Pulse modulation 217Hz, 9V/m |
| 745 | | |
| 780 | | |
| 810 | 800-960 | Pulse modulation 18Hz, 28V/m |
| 870 | | |
| 930 | | |
| 1720 | 1700-1990 | Pulse modulation 217Hz, 28V/m |
| 1845 | | |
| 1970 | | |
| 2450 | 2400-2570 | Pulse modulation 217Hz, 28V/m |
| 5240 | 5100-5800 | Pulse modulation 217Hz, 9V/m |
| 5500 | | |
| 5785 | | |

Table 4 – Input AC Power Port

| Phenomenon | Basic EMC standard | Immunity test levels |
|---|--------------------|--|
| | | Home Healthcare Environment |
| Electrical fast transients/burst | IEC 61000-4-4 | ± 2 kV 100 kHz repetition frequency |
| Surges Line-to-line | IEC 61000-4-5 | ± 0.5 kV, ± 1 kV |
| Surges Line-to-ground | IEC 61000-4-5 | ± 0.5 kV, ± 1 kV, ± 2 kV |
| Conducted disturbances induced by RF fields | IEC 61000-4-6 | 3 V, 0.15 MHz to 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz |
| Voltage dips | IEC 61000-4-11 | 0% U_T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° |
| | | 0% U_T ; 1 cycle and 70% U_T ; 25/30 cycles Single phase: at 0° |
| Voltage interruptions | IEC 61000-4-11 | 0% U_T ; 250/300 cycles |

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