Instruction Manual
(V2.0)

Product/project name：Wireless Pulse Oximeter

Model name：PO8BT .

Project number：30000072 .

Drafted by：_____ Date：_____.

Reviewed by：_____ Date：_____.

Approved by：_____ Date：_____.

Wireless Pulse Oximeter

MODEL PO8BT

Instruction Manual

TABLE OF CONTENTS

SYMBOL

The symbols below associate with your PO8BT

Symbols	Definition of Symbol
	Symbol for “THE INSTRUCTION MANUAL MUST BE READ.” (The sign’s background color is blue, and the sign's graphical symbol is white.)
	Symbol for “WARNING”
	Symbol for “CAUTION”
	Symbol for “TYPE BF APPLIED PARTS”(Silica gel pad)
	Symbol for “no alarm"
	Symbol for “ENVIRONMENT PROTECTION” Electrical products should not be disposed of as household waste. Please recycle where facilities exist. Check with your local authority or retailer for advice on recycling.
	Symbol for “MANUFACTURER”
CE 0197	Symbol for “COMPLIES WITH MDD93/42/EEC REQUIREMENTS”
	Symbol for “DATE OF MANUFACTURE”
EU REP	Symbol for “EUROPEAN REPRESENTATION”
SN	Symbol for “SERIAL NUMBER”
IP22	The first characteristic numeral symbol for “Degrees of protection against access to hazardous parts and against solid foreign objects”. The second characteristic numeral symbol for “Degrees of protection against ingress of water”
	MR Unsafe
MD	Medical device

INTENDED USE

The PO8BT 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 adults patients in home and hospital environments (including clinical use in internist/surgery, anesthesia, intensive care, etc).
The Wireless Pulse oximeter is not intended for continuous monitoring.

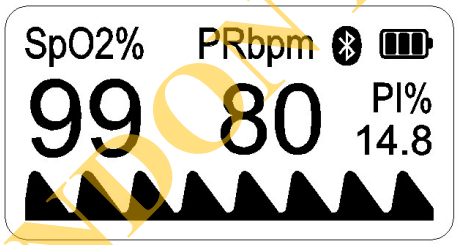
COMPATIBILITY

The Wireless Pulse Oximeter PO8BT is designed for use with the following devices:
iPhone 5+
iPad 3+
iPad Mini+
iPadAir+
iPod Touch (5th generation)
Select Android devices
Requires iOS version 7.0+ or Android version 4.4+

PACKAGE CONTENTS

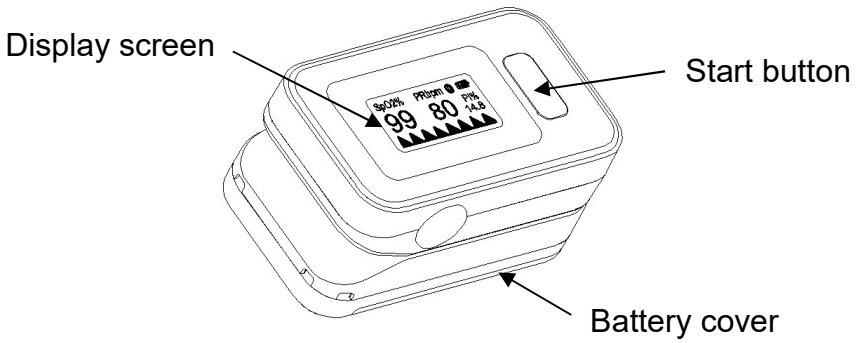
- 1 Wireless Pulse Oximeter
- 1 Lanyard
- 1 Instruction Manual

PARTS AND DISPLAYS

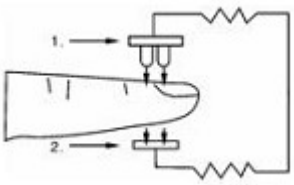


Bluetooth symbol

Battery symbol



DEVICE DESCRIPTION



Pulse oximeter measures the amount of oxygen in your blood and the pulse rate. The oximeter works by shining two light beams into the small blood vessels or capillaries of the finger, reflecting the amount of oxygen in the blood and displaying the measurement on the screen. The oxygen saturation (SpO2) is measured as a percentage of full capacity.

Typically, a 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 60601-1: 2005+AMD1: 2012+AMD2:2020/EN 60601-1:2006+AC:2010+A1:2013+A12:2014+AC:2016+A2:2021 (Medical electrical equipment-Part1: General requirements for basic safety and essential performance).

IEC 60601-1-2:2014/AMD1:2020/EN 60601-1-2:2015+A1:2021 (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 +A1:2020/EN 60601-1-11:2015 +A1:2021 (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 80601-2-61:2017/ EN ISO 80601-2-61:2019 (Medical electrical equipment-Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use).

IMPORTANT INFORMATION

The **Bluetooth**® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc and any use of such trademarks by ANDON HEALTH CO., LTD. is under license.

Other trademarks and trade names are those of their respective owners.

Hereby, [Andon Health CO.,LTD], declares that this [PO8BT] is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU.

CONTRAINDICATIONS

⚠The Wireless Pulse Oximeter PO8BT cannot be used on infant babies.

⚠WARNINGS

1. This device is for use on adults only.
2. Certain activities may pose a risk of injury, including strangulation, if the lanyard should become wrapped around your neck. Use the lanyard with caution.

⚠NOTICE

1. Do not use the device as the only basis for making medical decisions. It is intended only to be used as additional information that you can give to your licensed healthcare professional.
2. The device may misinterpret excessive movement as good pulse strength. Limit finger movement as much as possible when using the device.
3. The device has no alarms of blood oxygen saturation and pulse rate, and it will not sound if the amount of oxygen in your blood is too low or your pulse rate is abnormal. If the measurement of SpO2 and pulse rate is not in the normal range, please contact your healthcare professional.
4. Do not place the device in liquid or clean it with agents containing ammonium chloride or products that are not listed in this Operation Manual.
5. Any of the following conditions may reduce the performance of the device:
   1) Flickering or very bright light;
   2) Excessive Movement;
   3) Weak pulse quality (low perfusion);
   4) Low haemoglobin;
   5) Nail polish and/or artificial nails;
   6）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 oxygen saturation of functional haemoglobin. High levels of dysfunctional haemoglobin (caused by sickle cell anaemia, carbon monoxide, etc) could affect the accuracy of 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 ranges.
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 measurements.
12. The packaging of the device is recyclable and must be disposed according to your local regulation.
13. Any material of the device that may cause pollution must be disposed 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. Because the pulse oximeter measurements are statistically distributed, only about two-thirds of pulse oximeter measurements can be expected to fall within ±Arms of the value measured by a oximeter.

20. 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. Function tester cannot be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter monitor.
21. The device should not be kept close to or stacked with other devices. When it is necessary to be close to or stacked with other devices, please observe if the device can operate normally first. For recommended measures of avoiding or reducing such interference, please refer to the section "ELECTROMAGNETIC COMPATIBILITY INFORMATION". It is suggested that the pulse oximeter be kept at least 30 cm away from other wireless devices such as WLAN unit, microwave oven, etc. It cannot be used near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.
22. ⚠ This product may not meet its performance specifications if stored or used outside its specified temperature and humidity ranges.
23. ⚠The patient is an intended operator.
24. ⚠Keep the device out of the reach of children/pets to avoid inhalation or swallowing of batteries / small parts.
25. ⚠If you are allergic to plastic/rubber, please do not use this device.
26. ⚠No servicing/maintenance while the device is in use.
27. The device is not intended to exposed to the Electromagnetic Interference (EMI) environment . 

Please do not use the device within the following environments: Magnetic Resonance Imaging (MRI), computerised axial tomography (CT), diathermy, Radio Frequency Identification (RFID) , electromagnetic security systems such as metal detectors, and not intended for use in an oxygen-rich environment..
28. Misapplication of a probe with excessive pressure for prolonged periods can induce pressure injury.
29. If some abnormal conditions appear on the screen during test process, pull outthe finger and reinsert to restore normal use.

SETUP AND OPERATING PROCEDURES

1. BATTERY LOADING

a. Open battery cover at the back of the device.
b. Load two “AAA” size batteries. Make sure the batteries are inserted according to the positive and negative marks("+"and"-") printed in the battery housing.
c. Close the battery cover.

When LCD shows battery symbol , replace all batteries with new ones.
Rechargeable batteries are not suitable for this device.
Remove the batteries if the device will not be used for a month or more to avoid damage of battery leakage.

⚠Avoid getting battery fluids in your eyes; if this happens, immediately rinse with plenty of clean water and contact a physician.

⚠The negative terminal of the battery needs to be compressed into the battery compartment properly after horizontal compression of the negative electrode. The battery should be in contact with the spring.

⚠Make sure the battery cover is intact and not damaged before installing the battery.

The device and the batteries must be disposed of according to local regulations at the end of their usage.

2. BEFORE USING PULSE OXIMETER

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

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

c. The device is suitable for use on any finger excluding the thumb. It is preferable to use the index or middle finger.

3. TESTING INSTRUCTIONS

1) Open the clamp of the Pulse Oximeter, then place your middle, ring or index finger of your left hand into the rubber opening of the oximeter with nail side down and display side up, as pictured.
2) On the front panel, press the "Start" button 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 it is turned on.
5) If the signal strength is too low, switch to another finger and perform the test again.
6) The device could change display direction according to the handing direction.
7) During the measurement, you can quickly double-click the key to change the color of the LCD content.
8) If the finger is removed, the device will automatically shut down after 8s.

CARE AND MAINTENANCE

1. Clean the device once a week, or more frequently if handled by multiple users.
2. Wipe the device with a soft cloth dampened with rubbing alcohol to avoid cross infection. Do not pour the alcohol directly on or into the device. Dry with a soft cloth or allow to air dry.
3. Avoid dropping this device on a sharp and strong subject.

4. Do not immerse the device in water or other liquid as this will damage it.
5. If this device is stored below 0℃, please acclimatise the device to room temperature before use.
6. Do not try to disassemble this device.
7. The device is a precision electronic instrument and must be only repaired by us; please contact the service center.
8. We can provide product circuit diagrams and repairable component information to qualified maintenance service personnel if necessary.
9. The pulse oximeter tester and simulator "Index 2", made by the Fluke company,can be used to verify the operation of the oximeter.
10. The expected service life of the PO8BT is about 5 years.
11. Please wait when moving the device between extreme temperatures (e.g., storage, during transport) to a normal operating environment. The device takes approximately two hours to warm up or cool down before use.
12. ⚠ Avoid high temperature and solarisation.

SPECIFICATIONS

1. Model: PO8BT
2. Classification: Internally powered, type BF, IP22
3. Machine size: Approx. 58.4mm×37.3mm×30.5mm (2 5/16″x 1 15/32″x 1 3/16″)
4. Weight: Approx. 27g (15/16 oz.) (excluding batteries)
5. Display System: TFT LCD
6. Power Source: battery 2 ×1.5V ⎓ SIZE AAA
7. Peak wavelength: 660nm/880nm;
8. Maximum optical output power: 1mW;
9. SpO2 Measuring Range: 70-99%;
10. Average Root Mean Square (ARMS) of SpO2 Accuracy: 80%~99%:±2%, 70%~79%: ±3%,<70%: no definition. SpO2 and pulse rate can be shown correctly when pulse-filling ratio is greater than 0.4%.11. Pulse Rate Measuring Range: 30/min-250/min
12. Pulse Rate Accuracy: 30/min - 99/min：±2 , 100/min - 250/min:±2%.
13. Automatic Shut-off: After 8 seconds of no indication on the sensors
14. Operation Environment: 5℃-40℃ (41℉～104℉); Humidity <80%RH; Atmospheric pressure: 700hPa-1060hPa
15. Storage and transport Environment: -20℃-55℃ (-4℉～131℉); Humidity <95%RH; Atmospheric pressure:700hPa-1060hPa
16. Bluetooth:
    Operation frequency: 2402MHZ-2480MHZ
    Max power: -0.1dBm

TROUBLESHOOTING

PROBLEM	POSSIBLE CAUSE	SOLUTION
SpO2 or pulse	1. Finger may not be inserted correctly.	1. Remove finger and

rate shows no value, or the number fluctuates.	2. Finger or hand may be moving. 3. The device may be damaged.	reinsert, as directed. 2. Try to keep perfectly still and test again. 3. Please contact your supplier.
The device does not turn on.	1. The battery may be low. 2. The device may be damaged.	1. Charge the battery and try again. 2. Please contact your supplier.
Low Battery indicator is displayed.	The battery is low.	Change the batteries and try again.
The app cannot find the Pulse Oximeter PO8BT.	The Bluetooth does not work	Reestablish the Bluetooth connection. If still not successful, restart your wireless device.

IMPORTANT INFORMATION REQUIRED BY THE FCC

1. 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.

2. Attention that changes or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

3. 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 supplier or an experienced radio/TV technician for help.

MANUFACTURE INFORMATION

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Tel: 86-22-87611660

EU REP iHealthLabs Europe SAS
36 rue de Ponthieu, 75008, Paris, France

ELECTROMAGNETIC COMPATIBILITY INFORMATION

This product is applicable to the equipment and system requirements for the purpose of receiving 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.

- The essential performance: 1.Average Root Mean Square (ARMS) of SpO2 Accuracy:80%~99%:±2%, 70%~79%: ±3%,<70%: no definition;
  2. Pulse Rate Accuracy: 30/min - 99/min：±2, 100/min - 250/min:±2%.
- When electromagnetic interference affects the above performance, please stop using the device.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. “

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	IEC 61000-4-3	Refer to table 3

from RF wireless communications equipment		
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz
Proximity magnetic fields	IEC 61000-4-39	Refer to table 4

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, ±5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
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-Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz	CW	8
134,2 kHz	Pulse modulation 2,1 kHz	65
13,56 MHz	Pulse modulation 50 kHz	7.5

Date of issue: Mar. 31, 2025