Wireless Fingertip Pulse Oximeter

USER MANUAL **OX200**

Ver2.0

ChoiceMMed

General Description

Oxygen Saturation is a percentage of Oxyhemoglobin (HbO_2) capacity, compounded with oxygen, by all combinative hemoglobin (Hb) capacity in blood. In other words, it is consistency of Oxyhemoglobin in blood. It is a very important parameter for the Respiratory Circulation System. Many respiratory diseases can result in oxygen saturation being lowered in human blood. Additionally, the following factors can reduce oxygen saturation: Automatic regulation of organ dysfunction caused by Anesthesia, Intensive Postoperative Trauma, injuries caused by some medical examinations. That situation might result in light-headedness, asthenia, and vomiting. Therefore, it is very important to know the oxygen saturation of a patient so that doctors can find problems in a timely manner.

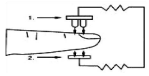
The fingertip pulse oximeter features low power consumption, convenient operation and portability. Place one fingertip into the photoelectric sensor for diagnosis and the pulse rate and oxygen saturation will appear on the display. It has been proven in clinical experiments that it also features high precision and repeatability.

Measurement Principle

Principle of the oximeter is as follows: A mathematical formula is established making use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin (RHb) and Oxyhemoglobin (HbO_2) in red and near-infrared zones. Operation principle of the instrument: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm red and 905nm near infrared light) can be focused onto a human nail tip through a clamping finger-type sensor. A measured signal obtained by a photosensitive element, will be shown on the oximeter's display through process in electronic circuits and microprocessor.

Diagram of Operation Principle

1. Red and Infrared-ray Emission Tube
2. Red and Infrared-ray Receipt Tube



Precautions For Use

1. Before use, carefully read the manual.
2. Operation of the fingertip pulse oximeter may be affected by the use of an electrosurgical unit (ESU).
3. The fingertip pulse oximeter must be able to measure the pulse properly to obtain an accurate SpO_2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO_2 measurement.
4. Do not use the fingertip pulse oximeter in an MRI or CT environment.
5. Do not use the fingertip pulse oximeter in situations where alarms are required. The device has no alarms. It is not for continuous monitoring.
6. Do not use the fingertip pulse oximeter in an explosive atmosphere.
7. The fingertip pulse oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
8. In order to ensure correct sensor alignment and skin integrity, the maximum application time at a single site for our device should be less than half an hour.
9. Do not sterilize the device using autoclaving, ethylene oxide sterilizing, or immersing the device in liquid. The device is not intended for sterilization.
10. Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
11. This equipment complies with IEC 60601-1-2:2007 for electromagnetic compatibility for medical electrical equipment and/or systems. However, because of the proliferation of radio-frequency 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.
12. Portable and mobile RF communications equipment can affect medical electrical equipment.
13. This equipment is not intended for use during patient transport outside the healthcare facility.
14. This equipment should not be used adjacent to or stacked with other equipment.
15. It may be unsafe to:
    —use accessories, detachable parts and 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.
16. These materials that contact with the patient's skin contain medical silicone and ABS plastic enclosure are all pass the ISO10993-5 Tests for invitro cytotoxicity and ISO10993-10 Tests for irritation and delayed-type hypersensitivity.
17. The patient is an intended operator. All functions of the device that the patient can safely use.
18. Keep the oximeter away from young children and pet.

Rx only: "Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner."

Contraindication

It is not for continuous monitoring.

Inaccurate measurements may be caused by

1. Significant levels of dysfunctional hemoglobin (such as carbonyl - hemoglobin or methemoglobin).
2. Intravascular dyes such as indocyanine green or methylene blue.
3. High ambient light. Shield the sensor area if necessary.
4. Excessive patient movement.
5. High-frequency electrosurgical interference and defibrillators.
6. Venous pulsations.
7. Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
8. The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
9. The patient is in cardiac arrest or is in shock.
10. Fingernail polish or false fingernails.
11. Weak pulse quality (low perfusion).
12. Low hemoglobin.

Product Features

1. Simple to operate and convenient to carry.
2. Small volume, light weight and low power consumption.
3. High brightness LED display SpO_2, PR, and Pulse bar.
4. Automatically power on/off.
5. 250mAH lithium battery; real-time battery status indication.
6. Wireless Bluetooth for data transmission.
7. Weak or unstable signal prompt provides more accurate measurements.
8. When no signal or low signal is detected, the pulse oximeter will power off automatically in 8 seconds.
9. Compatible with iChoicelife App.

Intended Use

Fingertip pulse oximeter is a portable non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult and pediatric patients in hospitals, hospital-type facilities and homecare

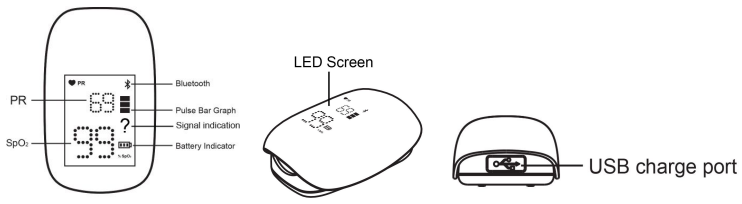
Operation Instructions

1. Download the APP from http:// www. Ichoicelife.com and connect the device following these steps: click tap to add devices --clickiChocie OX200(Wireless Fingertip Oximeter) --Add to My Devices -- add device successfully.
2. Place one of your fingers into the rubber opening of the Pulse Oximeter. The device will turn on automatically
3. Keep your hands still for the reading. Do not shake your finger during the test. It is recommended that you do not move your body while taking a reading.
4. When the Bluetooth icon stop flashing and the reading starts to flash, it means the data has been uploaded to the App successfully.
5. Read the data from the display screen or from the main page of the iChoice App on your Smartphone.
6. When you plug out your finger, the Pulse Oximeter will power off automatically in 8 seconds.

NOTE:

The measurement data cannot be stored in the device, if the Bluetooth connection is not available for any reasons, the measurement will be lost, or you can enter the measurement to the App manually.

Know your device



NOTE:

1. The pulse bar less than 30% indicates signal inadequacy SpO_2 or pulse rate value is potentially incorrect.
2. If the screen display "?", it means the signal is unstable, please keep your hands still and retry.

Battery Charge

1. The device adopts the lithium battery (250mAH), the battery can support 2h of continue measuring or more than 400 measurements.
2. Charging time is less than 2h.

NOTE:

1. The battery indicator symbol on the front panel display will flash when the battery voltage is too low for normal operation of the Pulse Oximeter. Please charge the battery when indicator symbol flash.
2. Use the USB charge cable or the adapter to charge the battery.
3. Make sure the adapter's output voltage is DC5V and the output current is ≤1000mA

Warnings!

1. Keep the oximeter away from young children. Small items such as the USB charge cable are choking hazards.
2. If the device is charging, please do not take measurement.

Maintenance and Storage

1. Charge the battery in a timely manner when low battery indicator symbol flash.
2. Clean surface of the fingertip oximeter before it is used in diagnosis for patients.
3. It is best to store the product in -25℃～+70℃ and ≤93% humidity.
4. Keep in a dry place. Extreme moisture may affect oximeter lifetime and may cause damage.
5. Dispose of battery properly; follow any applicable local battery disposal laws.

Cleaning the fingertip pulse oximeter

Please use medical alcohol to clean the silicone touching the finger inside of oximeter with a soft cloth dampened with 70% isopropyl alcohol. Also clean the being tested finger using alcohol before and after each test.

Do not pour or spray liquids onto the oximeter, and do not allow any liquid to enter any openings in the device. Allow the oximeter to dry thoroughly before reuse.

The Wireless fingertip pulse oximeter requires no routine calibration or maintenance other than replacement of batteries.

Stop using and contact local service center if one of the following cases occurs:

- An error in the *Possible Problems and solutions* is displayed on screen.
- The oximeter cannot be powered on in any case and not the reasons of battery.
- There is a crack on the oximeter or damage on the display resulting readings cannot be identified; the spring is invalid; or the key is unresponsive or unavailable.

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 9919:2005, 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 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.

Specifications

1. Display Type

LED display

2. SpO_2

Display range: 35%~99%

Measurement range: 70%~99%

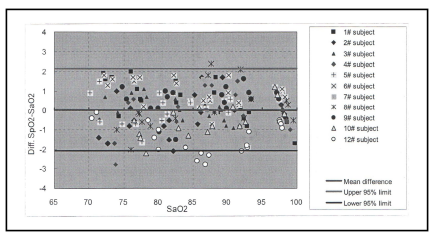
Accuracy: 70%~99%: ±2%; 0%~69% no definition

Resolution: 1%

A_{RMS} Value Analysis

Item	70--100	90--100	80--<90	70--<80
#pts	231	82	89	60
Bias	0.03	-0.06	0.07	0.12
A_{RMS}	1.07	0.92	1.13	1.18

Bland-Altman plot analysis of sampled data points on all subjects as below



3. Pulse Rate

Display range: 30bpm~250bpm

Measure range: 30bpm ~250bpm

Accuracy: 30bpm ~99bpm, ±2bpm; 100bpm ~250bpm, ±2%

Resolution: 1bpm

4. Probe LED Specifications

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

NOTE: The information about wavelength range can be especially useful to clinicians.

5. Power Requirements

Lithium battery (250mAH) for power supply

Battery Life: One250mAH, 3.7V Lithium battery could be continuously operated as long as 2 hours.

Input voltage：AC100V~240V

Input frequency：50Hz~60Hz

Output voltage：DC5V

Output current：1000mA（MAX）

6. Environment Requirements

Operation Temperature: 5℃～40℃

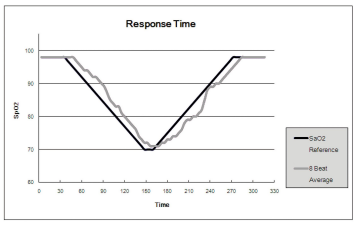
Storage/ Transport Temperature: -25℃～+70℃

Ambient Humidity: 15%～93% no condensation in operation; ≤93% no condensation in storage/transport

Atmosphere pressure: 70kPa～106kPa

7. Equipment data update period

As shown in the following figure. Data update period of slower average is 12.4s.



8. Classification

According to the type of protection against electric shock: INTERNALLY POWERED EQUIPMENT;
According to the degree of protection against electric shock: TYPE BF APPLIED PART, (applied part: the rubber hole of the device);
According to the degree of protection against ingress of water: IP22
According to the mode of operation: CONTINUOUS OPERATION

FCC Declaration

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.
Please take attention that changes or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
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 off 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.

Declaration

Guidance and Manufacturer's declaration – electromagnetic emissions-
For all EQUIPMENT and SYSTEMS

Guidance and Manufacturer's declaration - electromagnetic emission		
The Wireless fingertip Pulse Oximeter OX200 is intended for use in the electromagnetic environment specified below. The customer or the user of the Wireless fingertip Pulse Oximeter OX200 should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic Environment – guidance**
RF emissions CISPR 11	Group 1	The Wireless fingertip Pulse Oximeter OX200 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 Wireless fingertip Pulse Oximeter OX200 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.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and Manufacturer's declaration – electromagnetic immunity-
For all EQUIPMENT and SYSTEMS

Guidance and Manufacturer's declaration - electromagnetic immunity			
The Wireless fingertip Pulse Oximeter OX200 is intended for use in the electromagnetic environment specified below. The customer or the user of the Wireless fingertip Pulse Oximeter OX200 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic Environment – guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 6kV contact +/- 8kV air	+/- 6kV contact +/- 8kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.

Guidance and Manufacturer's declaration – electromagnetic immunity-
For all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and Manufacturer's declaration - electromagnetic immunity			
The Wireless fingertip Pulse Oximeter OX200 is intended for use in the electromagnetic environment specified below. The customer or the user of the Wireless fingertip Pulse Oximeter OX200 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic Environment – guidance**
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Wireless fingertip Pulse Oximeter OX200, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations, Electromagnetic propagation is affected by absorption and reflection structures, objects and people.			

a Field strengths from fixed transmitters, such as base station for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Wireless fingertip Pulse Oximeter OX200 should be observed to verify normal operation. If abnormal performance is observed, additional measurements may be necessary, such as reorienting of the relocating the Wireless fingertip Pulse Oximeter OX200.
b Over the frequency range 150 kHz to 80 MHz, fields strengths should be less than 3 V/m

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEMS - For all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and *Pulse Oximeter (OX200)*				
The Wireless fingertip Pulse Oximeter OX200 is intended for use in electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Wireless fingertip Pulse Oximeter OX200 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Wireless fingertip Pulse Oximeter OX200 as recommended below, according to the maximum output power of the communications equipment.				
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**			
	80 MHz to 800 MHz $d=1.2\sqrt{P}$		800 MHz to 2.5 GHz $d=2.3\sqrt{P}$	
0.01	0.1167		0.2334	
0.1	0.3689		0.7378	
1	1.1667		2.3334	
10	3.6893		7.3786	
100	11.6667		23.3334	
For transmitters rated at a maximum output power not listed above, the recommended separation distanced in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.				

Possible Problems and Solutions

Problems	Possible reason	Solution
SpO_2 or PR can not be shown normally	1. Finger is not inserted correctly 2. Patient's Oxyhemoglobin value is too low to be measured	1.Retry by inserting the finger 2. Try some more times. If you can make sure no problem exist in the product, please go to a hospital timely for exact diagnosis.
SpO_2 or PR is shown unstably	1. Finger might not be inserted deep enough. 2. Finger is trembling or patient's body is in movement status.	1. Retry by inserting the finger 2. Try not to move
The oximeter can not be powered on	1. Power of batteries might be inadequate or not be there at all. 2. The oximeter might be damaged.	1. Please charge battery 2. Please contact with local customer service centre
Indication lamps are suddenly off	1. The product is automatically powered off when no signal is detected longer than 8 seconds 2. Power quantity of the batteries is started being inadequate	1. Normal 2. Please charge battery
"Error3"	1. Low power 2. Receiving tube being shielded or damaged together with broken connector. 3. Mechanical Misplace for receive-emission tube. 4. Amp circuit malfunctions.	1. Please charge battery 2. Please contact local customer service center 3. Please contact local customer service center 4. Please contact local customer service center
"Error7" is displayed on screen	1. Low power 2. Emission tube damaged. 3. Current control circuit malfunctions.	1. Please charge battery 2. Please contact local customer service center 3. Please contact local customer service center

Symbol Definitions

Symbol	Definition
	Type BF applied part.
	Attention.
	Follow instruction for use
IP22	Degrees of protection provided by enclosure.
%SpO_2	Oxygen saturation
	Pulse rate (BPM)
	The battery icon flash means power low
SpO_2	No SpO_2 Alarm
SN	Serial No.
?	The signal inadequacy indicator
	Bluetooth indicator
	The waste electrical and electronic equipment
+70℃ max, -25℃ min, RH≤93% non-condensing	Storage temperature and relative humidity
	Manufacturer's information
	Date of Manufacture
CE 0123	European union approval

Box Contents

1. The wireless fingertip pulse oximeter OX200
2. USB charge cable
3. One user's manual

Applicable Models

OX200

Notes:
1. The illustrations used in this manual may differ slightly from the appearance of the actual product.
2. The specifications are subject to change without prior notice.
3. To obtain the more information about the App, please visit the http:// www. ichoicelife.com

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Revised Date: September 18，2016