

Fingertip Pulse Oximeter

User Manual



Revision: V1.1
Effective: 2022.6
ENSM60A1202309269YWW/25111415.010/13.14.001.0109

- moving status.
- 4.Read relevant datum from display screen.
- 5.Press the measure button , if we want change display direction;
- 6.The instrument has the function of automatic standby, no signal 8seconds will enter standby state
- 7.Please charge the device in time when TFT indicates the batteries are in low power.

⚠ Attention ⚠

Do not use the device while it is being charged.

Lanyard installation

- Put the lanyard thin end through the hole.
- Put the lanyard coarser end through its already wearing thin end part and tighten.

Communication function

The user downloads the "YonkerCare" APP from the client, Open "YonkerCare" APP and enter the main interface; Click the "Test" item to enter the "Test" interface, click "Add Device", select the corresponding oximeter for binding. After binding successfully, click "Detect" to enter the blood oxygen detection interface. The interface displays real-time blood oxygen and pulse rate values and graphs.

⚠ Attention ⚠

- Using devices outdoors or under strong light, please adjust the screen brightness to a higher proper level for observation.
- It's better for user to choose a lower brightness to conserve battery power.

Declaration: Please use the medical alcohol to clean the rubber before each test and clean the tested finger with alcohol before and after the test. (The rubber inside of the Oximeter adopts medical rubber, which has no toxin, no harm, and brings no side effect such as allergy to the our skin).

Default Setup
PR sound: off
Prompt sound: on

General Description

Haemoglobin Saturation is the percentage between the capacity of Oxyhemoglobin (HbO₂) that compounded with oxygen and that of all combinativable haemoglobin (Hb) in blood. In other words, it is the saturation of Oxyhemoglobin in blood. It is a very important physiological parameter for Respiratory and Circulation Systems. Many respiratory diseases could reduce haemoglobin saturation in human blood. Moreover, factors such as Automatic Organic Regulation Malfunction caused by anaesthesia, trauma resulted from major operation and some medical examination can also cause problems in oxygen supply, which might reduce human haemoglobin saturation. As a result, such symptoms as megrim, vomiting and asthenia might appear to patients. Hence, it is very important to know hemoglobin saturation of patient timely in clinical medical aspects.

The fingertip pulse oximeter features in small volume, low power consumption, convenient operation and portability. It is only necessary for patient to put one finger into fingertip photoelectric sensor for diagnosis, and the display screen will directly show measured value of hemoglobin saturation. It has been proved in clinical experiments that it possesses rather high precision and repeatability.

Intended use

The fingertip pulse oximeter can be used to measure human haemoglobin saturation and pulse rate and Heart Rate Variability through finger , it can be used in hospitals, families, schools and medical centers.

User Group

-People who need blood oxygen measurement .

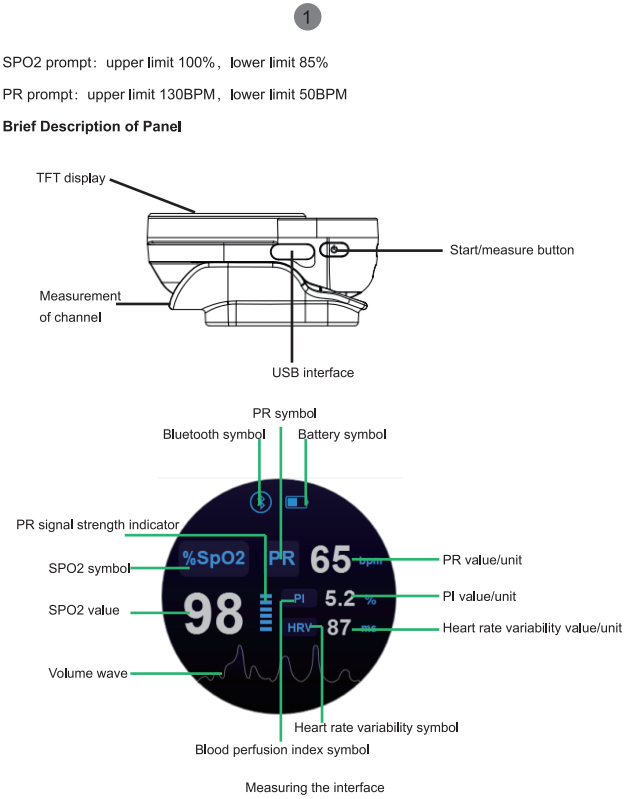
Contraindication: not found

Note:

- The image in the instruction may have slight differences with the actual instruments.
- Technical parameters and appearance change, without prior notice.

Measurement principle

The principle of the oximeter is as follows: An experience formula of data process is established by exerting Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin and oxyhemoglobin (HbO₂) in red light and infrared light zones. Operation principle of the instrument is to combine Photoelectric Oxyhemoglobin Inspection Technology with Capacity Pulse Scanning and Recording Technology, so that two lights with different wavelength (660nm red light and 940nm infrared light) can be focused onto human nail through



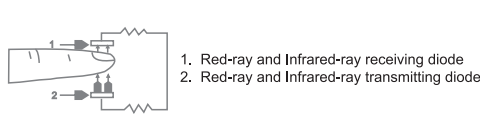
Parameter Setup

1.Main menu interface

- Long press the measurement button for about 3 seconds, the oximeter will sound "BI" and enter the main menu interface; If no operation is performed within 15

perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on two groups of diodes through process in electronic circuits and microprocessor.

Diagram of Operation Principle

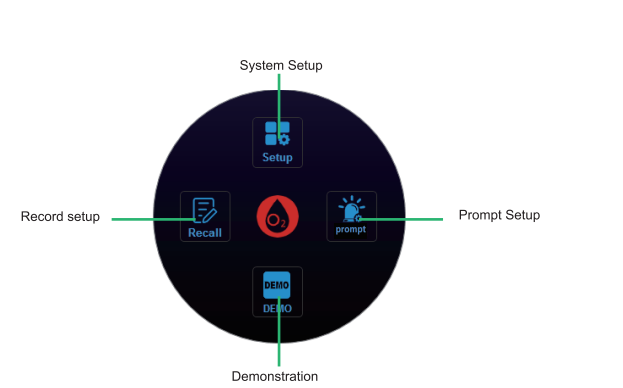


Precautions for use

- Do not use the Fingertip Pulse Oximeter together with MRI or CT equipment.
- Explosion hazard: Do not use the Fingertip Pulse Oximeter in an explosive atmosphere.
- The Fingertip Pulse Oximeter is intended only as an adjunct in patient assessment. Doctors should make diagnosis in conjunction with clinical manifestation and symptoms.
- Check the Fingertip Pulse Oximeter sensor application site frequently to make sure that the circulation and skin integrity of patient are under good condition.
- The sensor of the oximeter is not suitable for contacting the adhesive tape, which may lead to the error of measurement data or mistaking that there are blisters on the tested skin.
- Please read the manual carefully before your operation.
- The Fingertip Pulse Oximeter has no SpO₂ alarm, it is not for continuous monitoring.
- When used for a long time, it will produce discomfort or tenderness, especially for patients with microcirculation disorders. Please change the test sites periodically according to different situations of patients. The test site must be changed and the skin integrity and circulation condition of the patient must be checked at least every 2 hours, and the correct adjustment must be made.
- Inaccurate measurements may be caused by autoclaving, ethylene oxide sterilizing, or immersing the sensors in liquid.
- Significant levels of dysfunctional hemoglobins (such as carboxyl-hemoglobin or methemoglobin) may cause inaccurate reading.
- Intravascular dyes such as indocyanine green or methylene blue may cause inaccurate reading.
- SpO₂ measurements may be adversely affected in the presence of high ambient light.

seconds, the measurement interface is displayed.

- On the main menu interface, press the measurement button to select System Setup, Sounds Setup, demonstration and record setup. As figure 1.



2.System Setup

- On the main menu interface, the cursor is displayed at "Setup", long press the measurement button to enter the system setup interface. Short press the measurement button can select items in turn, and long press the measurement button can set the pulse sound and prompt sound on/off, restore factory Settings and adjust backlight brightness in turn. As shown in figure 2.

- Select "Exit" and long press the measurement button to exit the system setup and enter the measurement interface.

Please shield the sensor area (with a surgical towel or direct sunlight, for example) if it is necessary.

- Unexpected action may cause inaccurate reading.

- Medical signal with high frequency or interference caused by defibrillator may lead to inaccurate reading.

- Venous pulsations may cause inaccurate reading.

- It may cause inaccurate reading when the positions of sensor and blood pressure cuff are on the same arterial catheter or intravascular line.

- Hypotension, severe vasoconstriction, severe anemia, or hypothermia may cause inaccurate reading.

- It may cause inaccurate reading by giving use of cardiotonic to patient after his cardiac arrest or when he is in quiver.

- Bright nail or painted nail may cause inaccurate SpO₂ reading.

- Do not use this product if you are allergic to ABS, black silicone pad and other materials.

- If the performance is inconsistent with the description or changes, stop using immediately and contact the manufacturer.

- Measuring function should not be used to evaluate oximeter accuracy.

- The effects of degraded sensors and electrodes, or loosened electrodes, that can degrade performance or cause other problems.

- Please place the oximeter in a place where children, pets, etc. can not be touched, so as to prevent falling, biting and affecting the product performance.

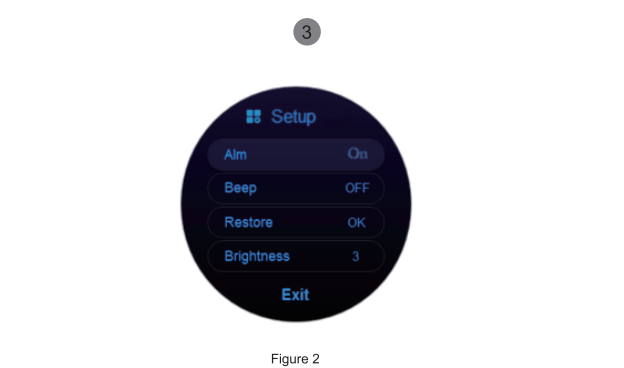
- The height of the oximeter should not exceed two meters.

- Do not use beyond the service life of the product, otherwise the accuracy of the instrument will be affected

- No modification of this equipment is allowed.

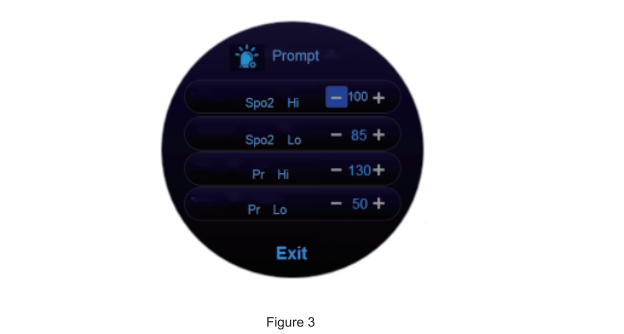
- Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the oximeter, including cables specified by the manufacturer. Otherwise, degradation of the performance of this Fingertip Pulse Oximeter could result. Otherwise, degradation of the performance of this oximeter could result.

- Oximeter should be avoided in places with poor ventilation and high dust and lint content.



3. Prompt Setup

- On the main menu interface, the cursor is displayed at "Prompt", long press the measurement button to enter the prompt setup interface. Short press the measurement button can select items in turn, and long press the measurement button can set the upper and lower values of blood oxygen and pulse rate in turn. When the measured value is out of range, there will be a continuous "BI" sound and the value will blink. As shown in figure 3.



- Avoid direct sunlight and strong light sources.
- Oximeter cannot be serviced and maintained during use.
- The internal structure of the Fingertip Pulse Oximeter adds magnetic rings, magnetic beads, and conductive cloth to spray conductive paint to avoid electromagnetic interference, so as to prevent adverse events to patients and operators due to electromagnetic interference.
- The Fingertip Pulse Oximeter can be maintained and calibrated once every two years, and the basic safety and basic performance of the Fingertip Pulse Oximeter have been guaranteed
- It is necessary to change the placement position of the oximeter regularly, check the placement position of the oximeter every 2 hours, check the impact of the oximeter on the skin, and move the oximeter to different positions.

⚠ Attention ⚠

- The PI and HRV of the device only show the status value, not for clinical reference.
- The mobile terminal software data of the product is stored locally and cannot be backed up or restored. Therefore, delete the local data with caution.

Product include: main machine · SPO₂ sensor and mobile terminal software (V1.2).

Product features

- When the battery voltage is too low that may affect normal use, there is a low voltage warning indication;
- In the absence of signals, the product will be in after 8 seconds to enter standby state.
- The device can transmit the measurement results to the client through Bluetooth.
- Small in volume, light in weight, and convenient to carry.

Operation Instructions

- Plug one finger into rubber hole of the Oximeter ((it is best to plug the finger thoroughly) Note: When plugging your finger into the Oximeter, your nail surface must be upward.
- Press the measurement button on the side panel to start the oximeter;
- Don't tremble your finger when the Oximeter is working. Your body is not recommended on

4.Demonstration

- On the main menu interface, the cursor is displayed at "DEMO", long press the measurement button to enter the "DEMO" interface. Long press the measurement button to exit the demonstration mode and enter the main menu interface. As shown in figure 4.

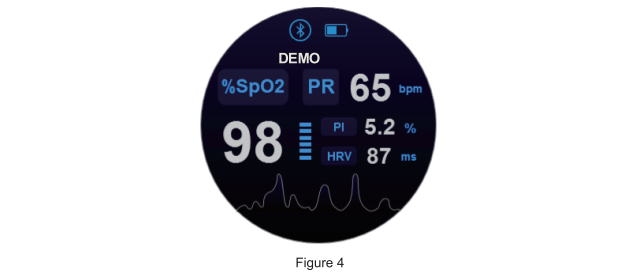


Figure 4

5.Record setup

- On the main menu interface, the cursor is displayed at "Recall", long press the measurement button to enter the "Recall" interface. Long press the measurement button to exit the "Recall" and enter the main menu interface. As shown in figure 5.

Note: During the measurement process, the device records the blood oxygen and pulse rate every 10s and can save five sets of data of the latest measurement.

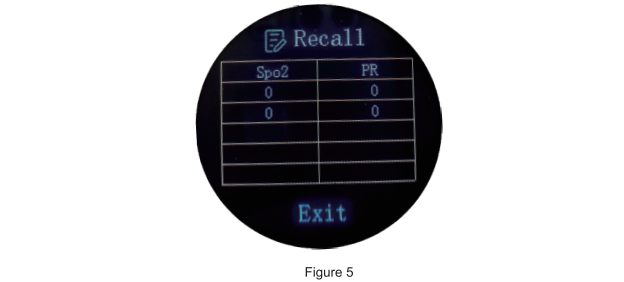


Figure 5

Battery

1.The oximeter is powered by an internal lithium battery, the status of which is indicated by an icon in the upper right corner of the screen.

2.When the battery is too low, you need to charge the battery, otherwise the oximeter will automatically turn off.

The first charge

●When using the oximeter for the first time, please charge it for about 2 hours, and then use it when fully charged.

Charging method

1.Connect one end of the USB cable to the charging port of the oximeter;

2.Connect the other end of the USB cable plug to the adapter jack;

3.Insert the adapter into the socket, in the charging process, the electric quantity display symbol flashes according to the electric quantity. When the battery is full, the battery icon stops flashing.

4.When charging is complete, remove the adapter from the socket.Remove the USB cable from the oximeter.

Attention

●Please use a power adapter that meets the safety certification standards.The oximeter is connected to an external DC 5.0V/1.0A adapter to charge the battery.

●The battery's power supply time depends on the device configuration and operation. If the use times are greatly reduced after the battery is fully charged, it is recommended to contact the manufacturer to replace the internal dedicated battery.

●When the adapter is connected to charge, the oximeter will automatically enter the charging state.

●When the oximeter is working, it cannot be charged.

Main technical parameters

1.Display Type: TFT display

2.SpO2: Measurement range: 70%~100%

Accuracy: 80%~100%;±2% (Including 80%);

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

Guidance and manufacturer´s declaration – electromagnetic immunity		
The Fingertip Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Fingertip Pulse Oximeter should assure that it is used in such an environment.		
Immunity test	EN 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15kV air
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lnes	± 2 kV for power supply lines
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	±1kV differential mode
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 sec	< 5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles (30 % dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 sec
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30A/m
NOTE UT is the a. c. mains voltage prior to application of the test level.		

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70%~79%; ±3% ;

Below 70% no requirement;

Resolution: 1%

3.PR: Measurement range: 30BPM~250BPM

Accuracy: ≤100BPM ,±1BPM

>100BPM ,±2BPM

4.Parameters of LED probe

	wavelength	radiation power
RED	660nm	1.8mW
IR	940nm	2.0mW

This parameter can be especially useful to clinicians.

5.PI index: measurement scope: 0~20

6.HRV index: measurement scope: 0-999

7.Data averaging and signal processing delay the display and transmission of SpO2 data.

The date update period :< 12S

8.Data transmission: the measurement data can be transmitted to the terminal device in real time through Bluetooth.

9.Bluetooth communication protocol: Bluetooth 4.0 communication protocol.

10.Software introduction

Software Name: Health management software

Software model: Yonker care

Software release: V1.2

11.Lithium battery specifications: 3.7V, 190mAh

The AC adapter:Rated input AC100~240V, 50~60HZ; Output DC5V, 1A

12.Dimension: about 63mm×40mm×31mm

Weight : about 30g

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Guidance and manufacturer´s declaration – electromagnetic immunity – for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

Guidance and manufacturer´s declaration –electromagnetic immunity		
The Fingertip Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Fingertip Pulse Oximeter should assure that it is used in such an environment.		
Immunity	EN 60601 test level	Compliance level
Conducted RF IEC 61000-4-6	3 V 0, 15 MHz -80 MHz 6 V in ISM and amateur radio bands between 0, 15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0, 15 MHz -80 MHz 6 V in ISM and amateur radio bands between 0, 15 MHz and 80 MHz 80 % AM at 1 kHz 3 V 0, 15 MHz -80 MHz 6 V in ISM and amateur radio bands between 0, 15 MHz and 80 MHz 80 % AM at 1 kHz
Radiated RF EM fields IEC 61000-4-3	10 V/m 80 MHz -2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz -2,7 GHz 80 % AM at 1 kHz

13.Operation environment:

Temperature: 5 ℃ ~ 40 ℃

Humidity: 15%RH ~ 80%RH,no condensing

Atmospheric pressure: 70kPa ~ 106kPa

Transport, storage environment:

Temperature: -10 ℃ ~ 40 ℃

Humidity: 10%RH~ 95%RH,no condensing

Atmospheric pressure: 70kPa ~ 106kPa, non-corrosive gas and well-ventilated environment.

14.Declaration: EMC of this product comply with IEC60601-1-2 standard.

15.About 30min required for oximeter to warm from the minimum storage temperature between uses until it is ready for intended use.

16.About 30min required for oximeter to cool from the maximum storage temperature between uses until it is ready for intended use.

17.Applied parts specified: Probe and its circuit.

Classification

1.Management Class for Medical Devices: II equipment

2.Anti-electric Shock Type: Internally powered equipment

3.Anti-electric Shock Degree: Type BF equipment

Maintenance and Preservation

1.Charge the device in time when TFT indicates the batteries are in low power.

2.Clean the surface of fingertip pulse oximeter before use.

3.Remove the batteries when the oximeter is not likely to be used for some time when leakage from batteries would result in an unacceptable risk.

4.It would be better to preserve the product in -10~40 ℃ (14-104 ℉) and humidity is 10%-95%.

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Table 9 - Test specifications for enclosure port immunity to RF wireless communications equipment

Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	Immunity TEST LEVEL
385	380-390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0.3	27
450	430-470	GMRS 460, FRS 460	FMc) ± 5 kHz deviation	2	0.3	28
710	704-787	LTE Band 13,17	Pulse modulation b) 217 Hz	2	0.3	9
745	800 - 960	GSM 800/900, TETRA 800,iDEN 820,CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0.3	28
780	1700-1990	GSM 1800,CDMA 1900;GSM 1900; DECT;LTE Band 1, 3 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0.3	28
1720	2400-9570	Bluetooth,WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0.3	28
1845	5100-5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0.3	9
1970						
NOTE: If necessary to achieve the immunity test level, the distance between the transmitting antenna and the me equipment or me system may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3. a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.						

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5.It is recommended that the product should be kept dry anytime. A wet ambience might affect its lifetime and even damage the product.

Cleaning frequency

If the oximeter is dirty when used at home, it is recommended to clean the enclosure and silicone pad after each use.If the oximeter is not dirty, simply clean the black silicone pad before and after each use.

When used in a medical institutions, clean it after each use.

Cleaning method

When the oximeter is used at home, wipe and disinfect with 75% alcohol, then dry naturally or clean the product with dry cloth. Clean at least twice a week.

When using in medical institutions, clean the tested finger with 75% alcohol before use. After each measurement, wipe and disinfect the contact part between black silicone and enclosure with 75% alcohol.

8.The oximeter can display functional arterial oxygen saturation and pulse rate after calibration.

9.The name of the simulator is FLUKE Index2 simulator, and the version number is 3.00.

10.The Blood oxygen simulator is calibrated to display functional oxygen saturation.

11.The maximum temperature of the contact surface between the product and human body does not exceed 41 ℃ .

Waste disposal

1.Please follow local laws to dispose of waste scrap.

2. Follow local ordinances and recycling instructions regarding to disposal or recycling of the device and device components, including used batteries and packaging box.

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Possible Problems and Resolutions

Problem	Possible reason	Solution
SpO2 or PR can not be shown normally	1. Finger is not plugged correctly 2.Patient's Oxyhemoglobin value is too low to be measured	1. Retry by plugging the finger 2. Try more times. If you can make sure there is no problem in the product, please go to hospital timely for exact diagnosis
SpO2 or PR is shown unsteady	1. The finger might not be plugged deep enough 2. Finger is trembling or the patient is on movement status	1. Retry by plugging the finger 2. Please remain at rest
The Oximeter can not be turned on	1. Inadequate power or power off 2. The Oximeter might be damaged	1. Please charge the battery 2. Please contact with local customer service centre
During the measurement, the oximeter suddenly shut down	1. The product automatically shuts off when no signal is detected in 8 seconds 2. Inadequate power	1. Normal 2. Please charge the battery
App terminal blood oxygen or heart rate cannot be displayed normally	1.Fingers not properly placed 2.Bluetooth connection failed	1. Put your finger correctly and try again 2. Reconnect the device
App side software crashes during operation	There is a hardware problem with the mobile phone Not the latest version	1.Contact the mobile phone manufacturer 2.Go to the corresponding application mall and download the latest app version
The app end cannot be connected to the oximeter	1.The mobile phone version is not compatible with Android 6.0 or above; Or apple IOS 6.0 and above 2.Not the type of finger clip pulse oximeter specified	1.Update the mobile phone version to Android 6.0 and above compatible version; Or apple IOS 6.0 and above 2.Use finger pulse oximeter of the specified type
App cannot be opened normally or flash back	App is not the latest version	Go to the corresponding application mall and download the latest app version

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Product Accessories	
Inventory list	Quantity
The host	1 set
Lanyard	1 pcs
USB cable	1 pcs
User manual	1 pcs

Guidance and manufacturer´s declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS

1	Guidance and manufacturer´s declaration – electromagnetic emission	
2	The Fingertip Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of Fingertip Pulse Oximeter should assure that it is used in such an environment.	
3	Emissions test	Compliance
4	RF emissions CISPR 11	Group 1
5	RF emissions CISPR 11	Class B
6	Harmonic emissions IEC 61000-3-2	Class B
7	Voltage fluctuations / flicker emissions IEC 61000-3-3	Compliance

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Symbols and Definitions

	BF type application part		This device has no alarm function
	Up toward		Humidity range
	Reference manual		Keep dry
	Cautions		Lot number
	Serial number		Temperature range
	Date of manufacture		Avoid sunlight
	Manufacturer		
	To protect the environment, dispose of empty batteries at appropriate collection sites according to national or local regulations.		
IP22	First characteristic numeral 2: Against ingress of solid foreign objects:≥12.5mm diameter Second characteristic numeral 2 Against ingress of water with harmful effects:dripping(15° tilted)		
	signal inadequacy ①Indication of probe faults (open circuit condition or close circuit condition) ②Indication of Probe cable faults ③Indication of Probe cable extender faults		

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