Fingertip Pulse Oximeter

User Manual

Please read the user manual before use!

The contents of this manual and the specifications of this product are subject to change without notice!

Version	Date	Document Number
V1.0	2022-04-30	FPO_0002

I. Declaration

MC of this product complies with IEC60601-1-2 standard.

The materials which the user can come into contact with have no toxicity and no action on tissues comply with ISO10993-1, ISO10993-5 and ISO10993-10.

II. Overview

1. Features

Blood oxygen saturation is the percentage of the capacity of hemoglobin (oxyhemoglobin HbO2) combined with oxygen molecules in the blood to the total capacity of bindable hemoglobin (oxyhemoglobin HbO2 and reduced hemoglobin Hb). Blood oxygen saturation is used to evaluate the ability of human blood to carry and transport oxygen. It is a very important physiological parameter in the respiratory system and cardiovascular system. Knowing the blood oxygen saturation of the body in time will help users make correct judgments.

The fingertip pulse oximeter (hereinafter referred to as the oximeter) has the advantages of small size, low power consumption, simple operation and convenient carrying. During the measurement, as long as the finger is inserted into the device correctly, the blood oxygen and pulse rate information of the body can be quickly obtained. The device collects the human body signal through a photosensitive detector. After the signal is processed by the internal circuit, the measurement result will be displayed on the front panel display. The clinically proven oximeter has high accuracy and repeatability.

2. Main purpose and scope of application

The finger clip pulse oximeter is mainly used to measure the user's blood oxygen saturation and pulse rate. It is suitable for families, hospitals, oxygen bars, community medical places and other environments.

3. Environmental requirements

a) Working environment: temperature: 5℃～40℃, relative humidity: 15%～ 80%, atmospheric pressure: 86kPa～106kPa.

Transportation and storage environment: temperature: -10℃～40℃, relative humidity: 15%～95%, atmospheric pressure: 50kPa～106kPa.

4. Power supply : DC3V (two 1.5VAAA batteries).

5. Disposal of waste: Products should be disposed of as electronic waste or in accordance with local regulations after end of life.

6. Safety classification : This equipment is a type BF equipment powered by an internal power supply .

7. Mass: 33±3g (without battery).

8. Dimensions (unit: mm): Dimensions of Alpine20/ 20L series : 61×37×33; Dimensions of Alpine30/ 30L series : 61×34×32.

9. Continuous use for 24 hours with 2 AAA1.5 V alkaline batteries.

10. Emission light information

	wavelength	Maximum optical output power
RED	660 ±3 nm	1.2mW
IR	905 ±10 nm	1.2mW

11. The device has been calibrated when it is out of the field, and does not need to be calibrated by the user.

12. The data update cycle of the device is 15 seconds.

III. Safety Information

1. Be sure to read this manual carefully before use.

2. Using this device , make sure that the oximeter is in normal working condition and operating environment.

3. This device is suitable for children and adults over the age of 4 (should weigh between 15kg and 110kg).
This device contains small parts and should be used by children under adult supervision.

4. Function of this instrument when monitoring patients, which must be verified regularly. The most reliable monitoring method is the close monitoring and proper use of the oximeter by the medical staff.

5. When using the oximeter, please stay away from devices that generate strong electric and magnetic fields (such as MR equipment). Using it in an inappropriate environment may affect the work of the oximeter.

6. When several devices are used on the same patient at the same time, it may bring additional danger. It is recommended to consult the manufacturer for the correct use method to ensure that the leakage current is within the safe allowable range and will not cause harm to the patient, operator and surrounding environment.

7. Do not use this device in the presence of flammable gases, such as certain flammable anesthetics.

8. Keep the oximeter away from dust, corrosive substances, flammable and explosive materials, and away from high temperature and humid environments.

9. Do not use this device under strong light or high-frequency magnetic fields.

10. Do not use this device during MRI or CT.

11. If the user has severe hypotension, vasoconstriction, severe anemia or hypothermia, the measurement may be erroneous.

12. This device is not intended for users in a state of carbon monoxide poisoning or other abnormal hemoglobin conditions and will result in erroneous results.

13. The temperature should not exceed 40°C when in contact with the patient. The maximum time of use on the same part should not exceed 2 hours.

14. Do not repair the device by yourself, if necessary, please contact the after-sales personnel for repair.

15. If the device is to be stored for more than a month, remove the battery or the battery may leak.

16. Interference from medical high-frequency signals or defibrillators can cause erroneous degrees.

17. False readings can be caused by the patient after the heart has stopped beating or on inotropes or when the patient is shaking.

18. It is not recommended that users use this device while exercising.

19. The cleaning of this device should follow the instructions in this manual, and this device is prohibited for those who are allergic to medical silicone.

20. Do not use the information displayed by the oximeter as the sole basis for clinical diagnosis. The oximeter is only used as an aid in diagnosis. The clinical manifestations and symptoms must be combined with the doctor's diagnosis.

21. When the ambient temperature is 20°C, take the device out of the environment with the highest or lowest storage temperature and wait for 20 minutes before it can be used normally.

22. Do not mix new and old batteries .

23. Do not look directly at the light-emitting tube to avoid damage to the eyes.

24. Functional testers cannot be used to identify or verify the true accuracy of a pulse oximeter.

25. This device shows where the pulse wave is normalized.

This device does not have an alarm function!
Do not use this device on infants or newborns!
This device is not suitable for continuous monitoring!
No modification of this equipment is allowed.

IV. Structural features and working principle

1. Product structure: This device is a single host device.

2. Measurement principle
The measurement principle of this equipment is based on the spectral characteristics of reduced hemoglobin (Hb) and oxyhemoglobin (HbO2) with different absorption rates of red light with a wavelength of 660 nm and infrared light with a wavelength of 905 nm. Law) established a data empirical formula to calculate blood oxygen saturation.

1. Red light infrared light emitting tube
2. Photoelectric receiving sensor

V. System settings

1. System default settings.

LED version default settings

a) Low blood oxygen saturation prompt threshold 94

b) Low pulse rate prompt threshold 50

c) High pulse rate prompt threshold 130

d) Default beep on

e) Default flashing character prompt

f) Default pulse tone off

2. manual setting

Long press the power button for 3 seconds to enter the setting interface. After entering the setting interface, long press the power button to execute the operation, short press the power button to select the operation , and long press the Exit or no operation for 40 seconds to automatically exit the setting interface.

Setting interface description:

1) Remind Setup : Remind Setup

2) Limit Setup : Threshold setting

3) SpO2 Hi: High blood oxygen prompt tone setting

4) SpO2 Lo: low blood oxygen tone setting

5) PR Hi: high pulse rate beep sound setting

6) PR Lo: low pulse rate beep setting

7) +/-: Addition and subtraction settings

8) Sound Reminder : Reminder sound switch

9) Beep: Pulse rate tone switch

10) Demo: demo mode switch

11) Restore: restore factory settings

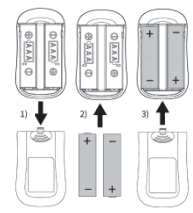
12) Brightness: Brightness setting

13) E xit : Exit the setting interface

VI. User guides

1. battery installation

1) Open the battery compartment door
2) Correctly insert the battery according to the positive and negative symbols in the battery compartment
3) Install the battery compartment door

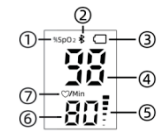


2. Measurement

Keep your fingers and the device clean. When the device is turned on, insert your finger in the direction shown in the picture (nails are facing the light-emitting direction) . Do not move during measurement. After the measurement is completed, the device will automatically shut down if no operation is performed for 10 seconds.

3. Display interpretation

1) oxygen saturation symbol
2) bluetooth symbol
3) battery level symbol
4) blood oxygen saturation
5) stick figure
6) pulse rate
7) pulse rate symbol



CAUTION!: If the measurement result shows that the blood oxygen saturation or pulse rate is abnormal, please ensure that the correct measurement method is used to measure again . If it is determined that the oximeter is normal, please go to the hospital for confirmation in time.

4. Accuracy Statement

project	Measuring range	Resolution	Accuracy
blood oxygen saturation	35-100%	1%	70-100%, ±2%; 69% and below undefined
pulse rate	25-250bpm	1bpm	±2bpm

VII. Cleaning and Maintenance

1. Equipment cleaning: Do not allow any liquid to enter the inside of the equipment. If you need to clean or sterilize the equipment, you can wipe the surface of the equipment with 75% alcohol at room temperature and soft materials with the battery removed, and let it dry before use.
2. Storage: If not in use for a long time, please remove the battery and store it in a cool and dry place.
3. Equipment maintenance: This equipment can only be repaired by professionals from the factory.
4. Long-term placement in a humid environment will shorten the service life of the device.

VIII. Troubleshooting

Fault	possible reason	solution
Blood oxygen or pulse rate not displayed	1. Finger not inserted properly 2. fingers too thin 3. Ambient light is too strong	1. Refer to the instruction manual to insert the finger correctly 2. Try several times, if you confirm that the machine is normal, please go to the hospital for diagnosis in time 3. Use thumb or middle finger to measure 4. Take measurements after leaving the strong light environment
unstable blood	1. fingers or body in motion	1. Keep your fingers and body relaxed

oxygen or pulse rate	2. Finger not inserted correctly	2. Refer to the instruction manual to insert the finger correctly
Can not boot	1. battery not installed correctly 2. battery is low 3. Equipment damage	1. Install the battery correctly according to the instruction manual 2. Replacement battery 3. Please contact the after-sales staff for processing
Screen suddenly turns off	1. The device automatically turns off without detecting a finger for a long time 2. battery is low 3. Equipment damage	1. The machine is normal 2. Replacement battery 3. Please contact the after-sales staff for processing

IX. Electromagnetic Compatibility

NOTICE:

- The finger clip pulse oximeter meets the relevant requirements of 9706.102-2021 and YY0784-2010 standards for electromagnetic compatibility.
- Users should install and use according to the electromagnetic compatibility information provided in this manual.
- Portable and mobile RF communication equipment may affect the performance of the finger clip pulse oximeter, avoid strong electromagnetic interference when using, such as near mobile phones, microwave ovens, etc.;
- Guidelines and manufacturer's declarations are detailed in the appendix.

WARNING:

- The finger clip pulse oximeter should not be used close to or stacked with other equipment. If it must be used close to or stacked, it should be observed and verified that it can operate normally in the configuration it is used in;
- finger-clip pulse oximeter below the minimum amplitude or minimum values above may result in inaccuracy;
- The finger clip pulse oximeter uses Bluetooth technology, the sending and receiving frequency is 2400-2483.5MHz, the modulation type is: GFSK, and the effective radiation power is -2.4dBm;
- Even if other devices meet the emission requirements of the corresponding national standards, the finger clip pulse oximeter may still be interfered by other devices.

Guidance and manufacturer's declaration-Electromagnetic emission

Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Model AOJ-70B should assure that it is used in such an environment.

Emissions	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	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.
Harmonic emissions IEC61000-3-2	N.A.	N.A.
VoltageFluctuations /flicker emissions IEC61000-3-3	N.A.	

Guidance and manufacturer's declaration- Electromagnetic immunity

The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of Pulse Oximeter 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	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC 61000-4-4	Not applicable	Not applicable	
Surge IEC 61000-4-5	Not applicable	Not applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable	
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz	Power frequency magneticfields should be at levels characteristic of a typicallocation in a typicalcommercial or hospital environment.
Conducted RF IEC61000-4-6	Not applicable	Not applicable	
Radiated RF IEC61000-4-3	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	

NOTE: UT is the a.c. mains voltage prior to application of the test level

Guidance and manufacturer's declaration - electromagnetic immunity

The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of Pulse Oximeter should assure that it is used in such an environment.

	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	IEC 60601-1-2 Test Level (V/m)	Compliance level (V/m)
Radiated RF IEC 61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380 –390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27	27
	450	430 –470	GMRS 460, FRS 460	FM ± 5kHz deviation 1 kHz sine	2	0.3	28	28
	710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0.3	9	9
	810 870 930	800 –960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28	28
	1720 1845 1970	1700–1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28	28
	2450	2400 –2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28	28
	5240 5500 5785	5100 –5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0.3	9	9

X. Symbol Description

	Type BF applied part		Read the manual before use
	Garbage sorting	IP22	Anti-dust&Anti-water class
	Alarm inhibit		warn
	power switch		afraid of rain
	Non-ionizing electromagnetic radialion		Fragile
	Low battery alert		This way up
	Manufacturer	EC REP	European representative
CE 0344	CE mark	RoHS	RoHS mark
MD	Medical device	SN	Serial Number

IP22 : IP22 means shcll of this product can withstand the water dropping to the surface when the shelldeviate 15 degree from horizontal surface

XI. Warranty Regulations

This product has quality problems that are not caused by human factors within one week from the date of sale, and the company is responsible for the return, replacement and repair. The company will provide free maintenance; if the product has quality problems one year after the date of leaving the factory, the user can go to the company's after-sales service department, office or dealer according to the invoice and warranty card. The company provides spare parts for maintenance, and only charges The cost of fees.

The following situations are not covered by the warranty:

1. The failure caused by the user's disassembly, repair and modification of the product;
2. Failure caused by accidental falling during use, handling, etc.;
3. Damage caused by improper use by the user;
4. Failure caused by the user not operating in the correct way in accordance with the instruction manual;
5. Damage caused by unforeseen natural disasters (such as fire, earthquake, flood, etc.).

Boxing List		
serial number	project	quantity
1	Finger clip pulse oximeter host	1
2	1.5V AAA battery	2
3	Manual, Warranty Card, Certificate of Conformity , Packing List	1
4	certificate	1

Warranty Card	
Product number	
Serial number	
dealer (stamp)	
Invoice number	
username	
contact number	

Maintenance records		
date		Maintenance staff

XII. Corporate Information

Shenzhen Small Signal Technology Co., Ltd.

Room 901-7, Building 1, No. 9, Jinxiu Middle Road, Laokeng Community, Longtian Street, Pingshan District, Shenzhen

Email:service@smallsignal.cn

Website:https://www.smallsignal.cn

Tel : +86-0755-23010489

CE 0344 RoHS MD

EC REP Share Info GmbH

Address: Heerdter Lohweg 83, 40549 Düsseldorf, Germany

FCC Warning

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, and

this device must accept any interference received, including interference that may cause u ndesired operation.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This equipment 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 a gainst harmful interference in a residential installation. This equipment 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 equipment 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 co rrect 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.

FCC Radiation Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment .

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.