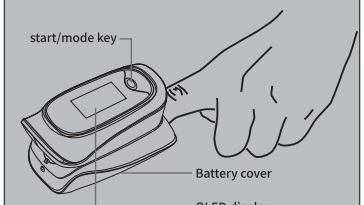
User Manual

Fingertip Pulse Oximeter



OLED

ENSM80-84202503073ZGZ/25111915.045/13.14.001.0017

1 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.

Version：Ver 1.4 Revision date：03-2023

This Fingertip Pulse Oximeter is a kind of innovated medical device with non-invasive features for artery SPO2 and PR detection. Being portable, it is able to measure SPO2 and PR values quickly and precisely.

2 Intended use

The fingertip pulse oximeter can be used to measure human haemoglobin saturation and pulse rate 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 ⚠

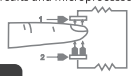
1.The image in the instruction may have slight differences with the actual instruments.
2.Technical parameters and appearance change, without prior notice.

Product include：main machine and SPO2 sensor。

3 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 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



1. Red-ray and Infrared-ray receiving diode
2. Red-ray and Infrared-ray transmitting diode

4 Precautions for use

1.Do not use the Fingertip Pulse Oximeter together with MRI or CT equipment.
2.Explosion hazard: Do not use the Fingertip Pulse Oximeter in an explosive atmosphere.
3.The Fingertip Pulse Oximeter is intended only as an adjunct in patient assessment. Doctors should make diagnosis in conjunction with clinical manifestation and symptoms.
4.Check the Fingertip Pulse Oximeter sensor application site frequently to make sure that the circulation and skin integrality of patient are under good condition.
5.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.
6.Please read the manual carefully before your operation.
7.The Fingertip Pulse Oximeter has no SpO2 alarm, it is not for continuous monitoring.
8.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.
9.Inaccurate measurements may be caused by autoclaving, ethylene oxide sterilizing, or immersing the sensors in liquid.
10.Significant levels of dysfunctional hemoglobins (such as carboxyl-he-moglobin or methemoglobin) may cause inaccurate reading.
11.Intravascular dyes such as indocyanine green or methylene blue may cause inaccurate reading.
12.SpO2 measurements may be adversely affected in the presence of high ambient light. Please shield the sensor area (with a surgical towel or direct sunlight, for example) if it is necessary.
13.Unexpected action may cause inaccurate reading.
14.Medical signal with high frequency or interference caused by defibrillator may lead to inaccurate reading.
15.Venous pulsations may cause inaccurate reading.
16.It may cause inaccurate reading when the positions of sensor and blood pressure cuff are on the same arterial catheter or intravascular line.
17.Hypotension, severe vasoconstriction, severe anemia, or hypothermia may cause inaccurate reading.
18.It may cause inaccurate reading by giving use of cardiotonic to patient after his cardiac arrest or when he is in quiver.
19.Bright nail or painted nail may cause inaccurate SpO2 reading.
20.Do not use this product if you are allergic to ABS, black silicone pad and other materials.
21.If the performance is inconsistent with the description or changes, stop using immediately and contact the manufacturer.
22.Measuring function should not be used to evaluate oximeter accuracy.
23.The effects of degraded sensors and electrodes, or loosened electrodes, that can degrade performance or cause other problems.
24.Please keep the oximeter out of reach of children, pets, etc.,so as to prevent falling, biting and affecting the product performance.
Do not use beyond the service life of the product, otherwise the accuracy of the instrument will be affected
26.No modification of this equipment is allowed.
27.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 oximeter could result.
28.Oximeter should be avoided in places with poor ventilation and high dust and lint content.
29.The products should be avoided direct sunlight and strong light sources.
30.Oximeter cannot be serviced and maintained during use.
31.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.
32.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.
33.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.

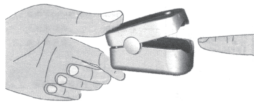
5 Features

◆ OLED display

1. Product adopts double color OLED display, can show the six different display mode.
【If the hand movements, under the effect of gravity induction, the interface can have four different kinds of display mode (suitable for matching gravity induction function instrument)】
2. Low-power consumption, continuously work for more than six hours with two AAA batteries
3. Low voltage indicator
4. In the absence of signals, the product will be in after 8 seconds to enter standby state.
5. Small in volume, light in weight, and convenient to carry
【Instrument has 5s automatic signal detection function, when you insert finger, timely will automatically start;Automatic startup function instrument (applicable to Automatic startup function instrument)】

6 Operation Instructions

1.Install two AAA batteries into battery cassette before covering its cover.
2.Plug one finger into rubber hole of the Oximeter (it is best to plug the finger thoroughly) before releasing the clamp with the nail upwards.
3.Press button on the front panel;
【Note: if equipped with automatic startup function refers to clamp oximeter, need not press the button, the instrument has 5 s automatic signal detection function, directly inserted into the finger, instrument is automatically switched on timely】
4.Don' t tremble your finger when the Oximeter is working. Your body is not recommended on moving status.
5.Press the button on the front panel, if we want change display direction;
【Note: if equipped with gravity sensing function of instrument then don't press the button, hand movements, the instrument with the gravity sensing has four corresponding interface switch】
6.Read relevant datum from display screen.
7.The instrument has the function of sleep, no signal 8seconds will enter standby state of sleep;
8.Please replace new batteries when OLED indicates the batteries are in low power.



Note: When plugging your finger into the Oximeter, your nail surface must be upward.

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).

Battery installation

1.According to the positive and negative identity right will be two AAA batteries into the battery compartments.
2.Push the battery cover horizontally in the direction of the arrow at the bottom.
Please note: pay attention to the battery positive and negative polarity, must be installed correctly, otherwise it may cause damage to instrument.

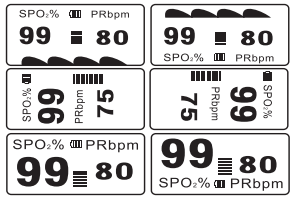
Lanyard installation

1. Put the lanyard thin end through the hole.
2.Put the lanyard coarser end through the thin end and tighten it.

7 Brief Description of Front Panel

◆ OLED display: start/mode key

◆ OLED display modes：



Keys function description: in standby mode, start the key instrument into the working state, push down this button under working state, can change the display mode.

⚠ Note

The instruments equipped with gravity sensing function , OLED display mode only1. 2.3.4, figure 5 and 6 are not shown

⚠ Note

The machine profile picture only for your reference use, specific in kind prevail

Parameter setup：

·Press start button（>3s）, into parameter setup .As menu ①:
·1. In menu ①, When the "*" signal is shown on the "Alm Setup" , press the button（>3s) and enter into the menu ②. Press the button (<1s) can select item, then press button（>3s) to set the on/off for prompt ,beep,demo and screen brightness adjustment (optional "1" ," 2 "," 3 "and" 4 "). When the "*" signal is shown on the "Restore" ,press the button（>3s) and all the settings are back to the factory settings.

⚠ 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.
2. In menu ②, When the "*" signal is shown on the "Sounds Setup" , press the button（>3s) and enter into the menu ②,Press the button (<1s) can select item ,then press the button（>3s) to setup data.choose "+" or "-" to plus or minus values.

Settings	
Alm Setup	*
Alm	off
Beep	off
Demo	off
Restore	OK
Brightness	3
Exit	

Menu 1

Settings	
Sounds Setup	*
Spo2 Alm Hi	99
Spo2 Alm Lo	85
PR Alm Hi	130
PR Alm Lo	50
+/-	+
Exit	

Menu 2

Note: If the matching refers to oximeter is basic, not equipped with parameter setting function

8 Detailed descriptions of product functions:

1.Display Type：OLED display
2.SpO2：Measurement range：70%～100%
Accuracy：80%～100%:±2% (Including 80%);
70%～79%: ±3% ;
Below 70% no requirement;
Resolution：1%
3.PR：Measurement range：30BPM～254BPM
Accuracy：≤100BPM ,±1BPM
>100BPM ,±2BPM
4.Parameters of LED probe

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

This parameter can be especially useful to clinicians.
5. PI index：measurement scope：0%~20% (optional)
6. Power：two AAA 1.5V batteries
7. Automatic standby：the product shuts off by itself when no finger is in the product about 8 seconds
8. Automatic start up: The device has the function of 5S automatic signal detection. When the finger is inserted, it will start up automatically;(optional)
9. Gravity sensing function: finger movement, the screen display will change with the gravity sensing changes (optional)
10. Dimension：about 58mm×36mm×33mm
11. Operation environment:
Temperature: 5 °C ~ 40 °C
Humidity: 15%RH ~ 80%RH,no condensing
Atmospheric pressure: 70kPa ~ 106kPa
Transport, storage environment:
Temperature: -10 °C ~ 40 °C
Humidity: 10%RH~ 95%RH,no condensing
Atmospheric pressure: 70kPa ~ 106kPa, non-corrosive gas and well-ventilated environment.
12.Declaration：EMC of this product comply with IEC60601-1-2 standard.
13.This equipment has no alarm function.
14.Data averaging and signal processing delay the display and transmission of SpO2 data.
The date update period :<12S
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
18.Service life:5 years

Expected medical instructions	The fingertip pulse oximeter can be used to measure human haemoglobin saturation and pulse rate through finger
Expected patient population	-People who need blood oxygen measurement .
Expected use or interaction with body parts tissue type	Finger
Expected user profile	People who need blood oxygen measurement , doctors, etc
Application environment	Avoid electromagnetic interference Extreme temperature Avoid pollution and dust Avoid direct sunlight, etc
Operating principle	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 glow and 940nm near infrared light) can be focused onto human nail through 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.

Classification

1.Management Class for Medical Devices: Class IIa
2.Anti-electric Shock Type: Internally powered equipment
3.Anti-electric Shock Degree: Type BF equipment
4.Overvoltage category classification:Class I
5.Pollution degree:
Pollution degree2:Micro-environment with non-conductive pollution,expect occasional conductivity caused by condensation

Maintenance and Preservation

1.Replace the batteries timely when the low battery indicator flashes
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°C (14-104°F) and humidity is 10%-95%.
5.It is recommended that the product should be kept dry anytime. A wet ambience might affect its lifetime and even damage the product.
6.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.
7.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 °C.

Waste disposa

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

Components

Components	Quantity
The host	1 set
Lanyard	1 pcs
User manual	1 pcs
AAA battery (optional)	2pcs

Manufacturer' s Declaration of the EUT

Statement:
1.The Fingertip Pulse Oximeter or user should use the product in the electromagnetic environment specified in the following table, otherwise it may cause abnormal operation of the product.
2. Fingertip Pulse Oximeter is a table-top equipment, it suitable for medical unit and home use.
3. 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 theoximeter ,including cables specified by the manufacturer.Otherwise, degradation of the performance of this Fingertip Pulse Oximeter could result
4. Warning: Use of this Fingertip Pulse Oximeter adjacent to or stacked with other equipment should be avoided because it could result in improper observed to verify that they are operating normally.
5 .Warning: 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.

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	N/A
7	Voltage fluctuations /flicker emissions IEC 61000-3-3	N/A

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	N/A
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	N/A
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	N/A
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30A/m

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 Vrms 150 kHz to 80 MHz	N/A

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]	1,8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM[c] ± 5 kHz deviation	2	0.3	28
710 745 780	704 - 787	LTE Band 13,17	Pulse modulation [b] 217 Hz	2	0.3	9
810 870 930	800 - 960	GSM 800/900.TETRA 800, iDEN 820,CDMA 850,LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
1 720 1 845 1 970	1 700-1 990	GSM 1800;CDMA 1900; GSM 1900;DECT;LTE Band 1, 3 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
2 450	2 400-2 570	Bluetooth,WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5 240 5 500 5 785	5 100-5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0.3	9

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.

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. Batteries might be installed incorrectly 3. The Oximeter might be damaged	1. Please replace the batteries 2. Please reinstall the batteries 3. Please contact with local customer service centre
Indication lamps are suddenly off	1. The product automatically shuts off when no signal is detected in 8 seconds 2. Inadequate power	1. Normal 2. Replace the batteries

Symbols and Definitions

	Type BF applied part		This device has no alarm function		separate collection for electrical and electronic equipment
	This way up		Humidity limitation		Not made with natural rubber latex / Consult instructions for use
	Refer to instruction manual		Keep dry	IP22	First characteristic numeral 2: Against ingress of solid foreign objects:≥12.5mm diameter Second characteristic numeral 2 Against ingree of water with harmful effects:dripping(15° tilted)
	Caution	MD	Medical device		
SN	Serial number	LOT	Batch code	#	Model number
	Date of manufacture		Temperature limit	UDI	Unique Device Identifier
	Manufacturer		Keep away from sunlight	——	signal inadequacy ①Indication of probe faults (open circuit condition or close circuit condition) ②Indication of Probe cable faults ③Indication of Probe cable extender faults
	Stand-by		Use-by date		

Reserves the right to technical change appearance, our products are subject to change without prior notice, please forgive me!

Statement:
1, If you need maintenance, please contact the manufacturer
2, The company can be in the form of email or other electronic files provide users with random files.
3, The instrument is not used for evaluation of blood oxygen probe pulse and pulse blood oxygen monitor accuracy.

After-sales service
Ensure that users

● Please read user manual before using the instrument;
● According to the requirement of the instruction manual for the operation and daily maintenance, and make sure the machine power supply, and environmental requirements

Maintenance regulations

●To conform to the regulations, free maintenance within the scope of products, with warranty card for free maintenance.All that is beyond the scope of free maintenance product, provide paid services.
● With warranty card and shopping invoice,main machine for a year, accessories for three months are under free maintenance services from the date of purchase.
● Following does not belong to the scope of free maintenance
☞ The fault caused by human factors, the damage;
☞ Due to the use to be inconsistent with the provisions of our company work environment to cause damage;
☞ Due to the product in the our company authorized personnel disassembling or repairing damaged;
☞ Products beyond the warranty period.