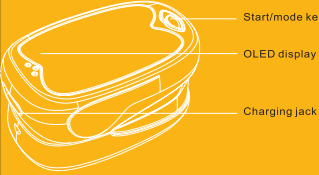


Fingertip Pulse Oximeter

User Manual
Ver. 2.3 revision date: 03-2023
ENSMKM12025030712GZ
13.14.001.0011(25061015.045

Product name: Fingertip Pulse Oximeter
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.



Fingertip Pulse Oximeter

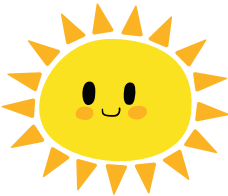


After-sales service

- 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 time
Monday to Friday 9 to 17:30pm, except for the national legal holiday

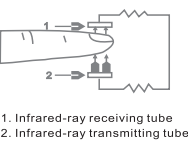
- Maintenance regulations**
- To conform to the regulations, free maintenance within the scope of products, with warranty card for free maintenance.All that is beyond the scope of free maintenance product, provide paid services.
 - With warranty card and shopping invoice,main machine for a year, accessories 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.
 - If any problem, please call us in 9:00 am to 5:30 pm from Monday to Friday(except national holiday)



General Description

Haemoglobin Saturation is the percentage between the capacity of Oxyhemoglobin (HbO2) that compounded with oxygen and that of all combinative haemoglobin (Hb) 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

Diagram of Operation Principle

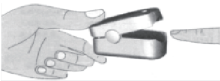


Features

- OLED display
- Product adopts double color OLED display , can show the six different display mode
- Low-power consumption, continuously work for more than six hours with one rechargeable lithium battery
- Battery power indicator
- In the absence of signals, the product will be in after 8 seconds to power-off automatically
- Small in volume, light in weight, and convenient to carry

Operation Instructions

1. Plug one finger into rubber hole of the Oximeter (it is best to plug the finger thoroughly) .
2. Press button on the front panel;
3. Don't tremble your finger when the Oximeter is working. Your body is not recommended on moving status.
4. Press the button on the front panel, if we want change display direction;
5. Read relevant datum from display screen.
6. Please charge batteries in time when OLED indicates the batteries are in low power.



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).

Hang rope installation

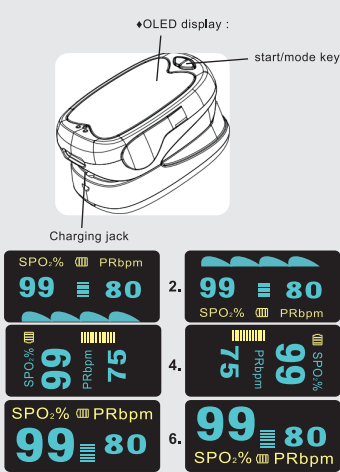
1. Put the rope thin end through the hole.
2. Put the rope coarser end through the thin end and tighten it.

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.

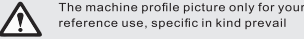
Measurement principle

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 glow and near-infrared 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 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 LEDs through process in electronic circuits and microprocessor.

Brief Description of Front Panel



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.



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 alarm , 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 1. Press the button (<1s) can select item, then press the button (>3s) to setup data,choose "+>or-" to plus or minus values.

Settings	Settings
Alm Setup	Sounds Setup
Alm	SpO2 Alm Hi 100
Beep	SpO2 Alm Lo 85
Demo	PR Alm Hi 130
Restore	PR Alm Lo 50
Brightness 3	+/-
Exit	Exit
menu 1	menu 2

Precautions for use

- 1.Do not use the pulse oximeter together with MRI or CT equipment.
 - 2.Explosion hazard: Do not use the pulse oximeter in an explosive atmosphere.
 - 3.The 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 pulse oximeter sensor application site frequently to make sure that the circulation and skin integrity 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 pulse oximeter has no SpO2 alarm, it is not for continuous monitoring.
 - 8.Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 2 hours.
 - 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- hemoglobin 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 cardiotoxic to patient after his cardiac arrest or when he is in quiver.
 - 19.Bright nail or painted nail may cause inaccurate SpO2 reading.
 - 20.Follow local ordinances and recycling instructions regarding to disposal or recycling of the device and device components.
- Scope of application / Intended use**
The fingertip pulse oximeter can be used to measure human haemoglobin saturation and heart rate through finger , it can be used in hospitals, families, schools and medical centers.
contraindication: not found

- !** 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.

Detailed descriptions of product functions

- 1.Display Type : OLED display
- 2.SpO2: Measurement range: 70% ~ 100%
Accuracy: ±2% on the stage of 80% ~ 100%;
±3% on the stage of 70% ~ 79%;
Below 70% no requirement

Resolution: 1%
3.PR: Measurement range: 30BPM ~ 240BPM
Accuracy: ±1BPM or ±1% (the larger one)

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

- This parameter can be especially useful to clinicians.
- 5 Power: rechargeable lithium battery
 - 6 Automatic standby : the product shuts off by itself when no finger is in the product about 8 seconds
 - 7.Dimension: 44mm×28.3mm×26.5mm
 8. Operation Environment: Operation Temperature: 5℃ ~ 40℃
Storage Temperature: -10℃ ~ 40℃
Ambient Humidity: 15%RH ~ 80%RH on operation
10%RH ~ 80%RH in storage
 - Air Pressure: 86kPa ~ 106kPa
 - 9 Declaration: EMC of this product comply with IEC60601-1-2 standard.
 - 10.Service life:5 years

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

Maintenance and Preservation

- 1.Charge batteries timely when the battery power is too low.
- 2.Clean the surface of fingertip oximeter before it is used to diagnose patients.
- 3.It would be better to preserve the product in -10~40℃ (14-104 ℉) and humidity is 10%-80%.
- 4.It is recommended that the product should be kept dry anytime. A wet ambience might affect its lifetime and even damage the product.

Components

- 1.One Fingertip Pulse Oximeter
- 2.One hang lace
- 3.One user manual
- 4.One charging line
- 5.One adapter (optional)

Guidance and manufacture's declaration-electromagnetic radiation-for other EQUIPMENTS and SYSTEMS

The Pulse Oximeter is designed to be used in specified electromagnetic environment . Users of the Pulse Oximeter must use it in the following environments.		
Radiation Test	Compliance	Electromagnetic environment-guidance
RF interference CISPR 11	Group 1	RF signal of Pulse Oximeter is simply created by its internal function. Therefore, its RF interference is very low and is not likely to cause any interference to nearby electronic equipment.
RF interference CISPR 11	Class B	The Pulse Oximeter applies to all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Possible Problems and Resolutions

Problem	Possible reason	Solution
SpO2 or PR can not be shown normally	•Finger is not plugged correctly •Patient's Oxyhemoglobin value is too low to be measured	•Retry by plugging the finger •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	•The finger might not be plugged deep enough •Finger is trembling or the patient is on movement status	•Retry by plugging the finger •Please remain at rest
The Oximeter can not be turned on	•Inadequate power or power off •The Oximeter might be damaged	•Please charge the batteries timely •Please contact with local customer service centre
Indication lamps are suddenly off	•The product automatically shuts off when no signal is detected in 8 seconds •Inadequate power	•Normal •Please charge the batteries timely

Symbols and Definitions

	Type BF applied part		This device has no alarm function
	This way up		Humidity limitation
	Refer to instruction manual		Keep dry
	Caution		Use-by date
	Serial number		Batch code
	Date of manufacture		Temperature limit
	Manufacturer		Keep away from sunlight
	Stand-by		Unique Device Identifier
	Not made with natural rubber latex		Consult instructions for use
	Model number		Medical device
	separate collection for electrical and electronic equipment		
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)		
---	signal inadequacy ①Indication of probe faults (open circuit condition or close circuit condition) ②Indication of Probe cable faults ③Indication of Probe cable extender faults		

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

Statement:

1. maintenance with data such as circuit diagram, components list, figure and the detailed rules of correction, injection, available only to the repair factory training qualified personnel and units.
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.