English

This manual is written in accordance with the council directive MDD93/42/EEC for medical device and harmonized standards.

User Manual

Ver 1.0

Fingertip Pulse Oximeter

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

General Description

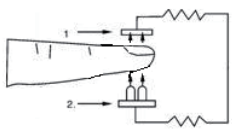
Haemoglobin Saturation is the percentage between the capacity of Oxyhemoglobin (HbO2) that compounded with oxygen and that of all combinativable haemoglobin (Hb) obin (HbO2) in blood. In other words, it is the saturation of Oxyhemoglobin in blood. It is a very important physiological parameter for Respiratory 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.

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(R Hb) and oxyhemoglobin (O2 Hb) 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.

Diagram of Operation Principle



1. Infrared-ray receiving tube
2. Infrared-ray transmitting tube

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.Do not stretch the adhesive tape while applying the Fingertip Pulse Oximeter sensor. This may cause inaccurate reading or skin blisters.
6.Please read the manual carefully before your operation.
7.The Fingertip Pulse Oximeter has no SpO2 prompt, 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 integrality, 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 cardiotonic to patient after his cardiac arrest or when he is in quiver.
19.Bright nail or painted nail may cause inaccurate SpO2 reading.

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

Scope of application / 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.

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。

Features

- OLED display
- Product adopts double color OLED display, can show the six different display mode

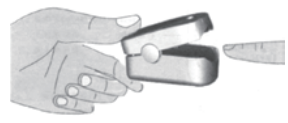
★If the hand movements, under the effect of accelerometer, the interface can have four different kinds of display mode (suitable for matching accelerometer function instrument)

- Low-power consumption, continuously work for more than six hours with two AAA batteries
- Low voltage indicator
- In the absence of signals, the product will be in after 8 seconds to enter standby state
- 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)

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 accelerometer function of instrument then don't press the button, hand movements, the instrument with the accelerometer has four corresponding interface switch)
6.Read relevant datum from display screen.
7. The instrument has the function of sleep, no signal will enter standby state of sleep;
8.Please replace new batteries 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).

Battery installation

1, According to the positive and negative identity right will be two AAA batteries into the battery

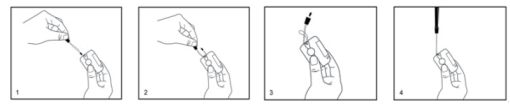
2, In the direction of the arrow at the bottom of the level of battery back cover.

Please note: pay attention to the battery positive and negative polarity, must be installed correctly, otherwise it may cause damage to instrument.

Hang rope installation

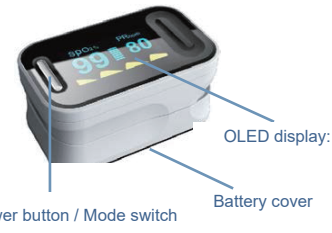
1, Put the rope thin end through the hole.

2, Put the rope coarser end through its already wearing thin end part and tighten。

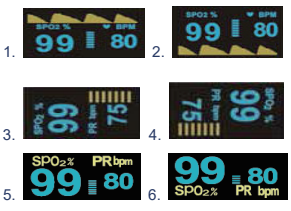


Brief Description of Front Panel

- OLED display:



- 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：instruments equipped with accelerometer function , OLED display mode only1. 2.3.4, no large font interface according to 5.6

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 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 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	100
Spo2 Alm Lo	85
PR Alm Hi	130
PR Alm Lo	50
+/-	+
Exit	

Menu 2

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

Detailed descriptions of product functions:

1.Display Type：OLED display

2.SpO2：Measurement range：70%～99%

Accuracy：80%～99%:±2% (Including 80%);

70%～79%: ±3% ; Below 70% no requirement;

Resolution：1%

3.PR：Measurement range：30BPM～240BPM

Accuracy：±1BPM or ±1%（the larger one）

4.Parameters of LED probe

	wavelength	radiation power
RED	660±2nm	1.8mW
IR	905±10nm	2.0mW

This parameter can be especially useful to clinicians.

5. PI index：measurement scope：0~20 （optional）

6. Power： two AAA 1.5V alkaline batteries

7. Automatic standby：the product shuts off by itself when no finger is in the product about 8 seconds

8. Automatic startup: every 5 s instrument will automatically detect the signal, after the hole with my finger, timely automatically boot;(optional)

9. Accelerometer function: finger movement, the screen display will change with the accelerometer changes (optional)

10. Dimension：58mm×36mm×33mm

11. Operation environment:

temperature: 5 ℃ ~ 40 ℃

Humidity: 15% ~ 80%

Atmospheric pressure: 86kPa ~ 106kPa

Transport, storage environment:

Temperature: -10 ℃ ~ 55 ℃

Humidity: ≤95%

Atmospheric pressure: 50kPa ~ 106kPa, non-corrosive gas and well-ventilated environment.

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

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.Replace the batteries timely when low voltage lamp is on.

2.Clean the surface of fingertip pulse oximeter before it is used to diagnose patients.

3.Remove the batteries inside if you will not operate the Oximeter for a long time.

4.It would be better to preserve the product in -10~40℃ (14-104℉) and humidity is 10%-80%.

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.Please follow the law of the local government to deal with used batteries.

Product Accessories

1.One hang lace

2.One user manual

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

The Fingertip Pulse Oximeter is designed to be used in specified electromagnetic environment . Users of the Fingertip Pulse Oximeter must use it in the following environments.

Radiation Test	Compliance	Electromagnetic environment-guidance
RF interference CISPR 11	Group 1	RF signal of Fingertip 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 Fingertip 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	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

	BF type application part	IP22	IP degree
	Separate collection		Humidity range
	Reference manual		Keep dry
	Cautions	CE 0123	Product certification
	Standby		Temperature range
	Up toward		Date of manufacture
SN	Serial number		Manufacturer
	Avoid sunlight	EC REP	European union representative

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.

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),call us：400-828-6667

Model: YK-80B

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