User Manual

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Product name：Fingertip Pulse Oximeter

Model: C1-LED

This Fingertip Pulse Oximeter is a kind of innovated medical device with non-invasive and continuous features for arterial SpO_2 and PR detection. Being portable, it is able to measure SpO_2 and PR values quickly and precisely.

General Description

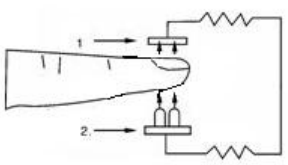
Hemoglobin Saturation is the percentage between the capacity of Oxyhemoglobin (HbO_2) that combines with oxygen and that of all combinative hemoglobin (Hb) in blood. In other words, it is the saturation of Oxyhemoglobin in blood. Hemoglobin Saturation is a very important physiological parameter for Respiratory and Circulation Systems. Many respiratory diseases could reduce hemoglobin saturation in human blood. Moreover, factors such as Automatic Organic Regulation Malfunction caused by anesthesia, trauma from a major operation and some medical examinations that can also cause problems in oxygen supply, which might reduce human hemoglobin saturation. As a result, such symptoms as megrim, vomiting and asthenia might appear to patients. Hence, it is very important to have a timely knowledge of the hemoglobin saturation of patients in clinical medical aspects.

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

Measurement principle

The principle of the oximeter is as follows: An experience formula of data process is established by exerting the Beer-Lambert Law according to Spectrum Absorption Characteristics of Reductive hemoglobin (RHb) and oxyhemoglobin (O_2Hb) in glow and near-infrared zones. The 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 wavelengths (660nm glow and 940nm near infrared light) can be focused onto human nail through a perspective clamp finger-type sensor. The measured signal can be obtained by a photosensitive element and the information acquired 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 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 a 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 integrality of patient are in good condition.
5. Do not stretch the adhesive tape while applying the pulse oximeter sensor. This may cause inaccurate readings and skin blisters.
6. Please read the manual carefully before your operation.
7. The pulse oximeter has no SPO_2 prompt; therefore, 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 hemoglobin (such as carboxyl- hemoglobin or methemoglobin) may cause an inaccurate reading.
11. Intravascular dyes such as indocyanine green or methylene blue may cause an inaccurate reading.
12. SpO_2 measurements may be adversely affected in the presence of high ambient light. Please shield the sensor area (with a surgical towel from direct sunlight, for example) if it is necessary.
13. Unexpected actions may cause inaccurate readings.
14. A medical signal with high frequency or interference caused by defibrillator may lead to an inaccurate reading.
15. Venous pulsations may cause inaccurate readings.
16. There could be an 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 readings.
18. An inaccurate reading may be caused by use of cardiotonic in a patient after his cardiac arrest or when he is in a quiver.
19. Bright nail or painted nail may cause inaccurate SpO_2 reading.

Follow local ordinances and recycling instructions regarding the disposal or the recycling of the device and device components.

Scope of application / intended use

The Fingertip pulse oximeter can be used in hospitals, families, schools and medical centers to detect blood oxygen saturation and pulse rate

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.

Features

- LED display
  - Product adopts LED display.
  - Low-power consumption, continuously work for more than six hours with Two AAA alkaline battery.
  - A battery life indicator.
  - In the absence of signals, the product would power-off automatically after 8 seconds.
  - Small in volume, light in weight, and convenient to carry.

Operation Instructions

1. Install a pair of AAA alkaline batteries into battery compartment.
2. Plug a finger into rubber hole of the Oximeter.
3. Press button on the front panel to start.
4. Do not shake your finger or move your body when the Oximeter is working.
5. Read relevant value from display screen.
6. The device will automatically power off in 8 seconds if there is no finger signal.

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 is a medical rubber which has no toxin, causes no harm, and brings no side effect such as allergy to the skin).

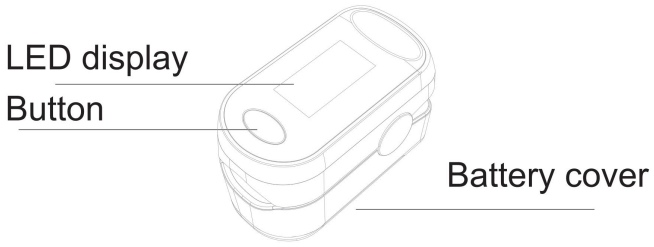
Hang rope installation

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

◆ LED display:



⚠Note⚠：The machine profile picture is only for reference use, specificity in kind prevails.

Detailed descriptions of product functions:

1. Display Type：LED display.
2. SpO2：Measurement range：70%～99%.
   Accuracy：±2% on the stage of 80%～99%
   ±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)
4. Power：Two AAA 1.5V alkaline batteries
5. Power consumption：Below 30mA
6. Automatic power-off：The product power off by itself when no finger is in the product ≥8 seconds.
7. Dimension：58mm×36mm×33mm
8. Operation Environment：Operation Temperature：5 ºC～40 ºC
   Storage Temperature：-10 ºC～40 ºC
   Ambient Humidity：15%～80% on operation
   10%～80% in storage
   Air Pressure： 86kPa～106kPa
9. Declaration：The EMC of this product complies with the IEC60601-1-2 standard.

Classification

1. Management Class for Medical Devices: Class II equipment
2. Anti-electric Shock Type: Internally powered equipment
3. Anti-electric Shock Degree: Type BF equipment

Maintenance and Preservation

1. Clean the surface of fingertip oximeter before it is used to assess patients.
2. It is best to preserve the product at a temperature -10~40ºC (14-104 ºF) and humidity of 10%-80%.
3. It is recommended that the product should be kept dry all times. A wet ambience might affect its lifetime and even damage the product.
4. Remove the batteries inside if you will not operate the Oximeter for a long time

Product Accessories

1. A hang lace.
2. A user manual.

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

The Pulse Oximeter is designed to be used in specified electromagnetic environments. The Pulse Oximeter must be used 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 domestic buildings.

Possible Problems and Resolutions

Problem	Possible reason	Solution
SPO_2 or PR cannot 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 again. 2. Try more times. If you can make sure there is no problem with the product, please go to hospital timely for an exact diagnosis.
SPO_2 or PR is shown unsteady.	1. The finger might not be plugged deep enough. 2. Finger is trembling or the patient is moving.	1. Retry by plugging the finger again. 2. Please remain at rest.
The Oximeter cannot be turned on.	1. Inadequate power or power off. 2.The Oximeter might be damaged.	1. Please replace the batteries timely 2. Please contact with local customer service center.
Indication lamps suddenly went off.	1. The product automatically shuts off when no signal is detected in 8 seconds. 2. Inadequate power.	1. Normal. 2. Please replace the batteries

Symbols and Definitions

	BF type application part	SN	Serial number
	Separate collection		Date of manufacture
	See the Instruction		Manufacturer
	Cautions		Warning of no SpO_2
IP22	IP degree		Temperature range
	Humidity range		Avoid sunlight
	Keep dry		Up toward

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

Statement:

1. Maintenance with data such as circuit diagram, components list, figure and detailed rules of correction and injection are available only to the repair factory qualified personnel and units.
2. The company can communicate in the form of email or other electronic files to provide users with random files.
3. The instrument is not to be used for evaluation of blood oxygen probe pulse and pulse blood oxygen.

After-sales service

Users are to ensure that:

● They carefully read the user manual before using the instrument.

● According to the instruction manual for the operation and daily maintenance, they make sure they meet the machine power supply and environmental requirements.

Maintenance time

Monday to Friday; 9:00 to 17:30, except for the national legal holidays.

Maintenance regulations

● Conformation to the regulations within the scope of the product, there will be warranty cards for free maintenance. All that is beyond the scope of the product will attract paid services.

● With a warranty card and shopping invoice, the instrument and its accessories are under free maintenance services from the date of purchase till one-year and three months for the instrument and its accessories respectively.

● The following does not belong to the scope of free maintenance:

☞ Damage caused by human factors.

☞ Damage resulting from use that is inconsistent with the provisions of our company.

☞ Damage to the product by unauthorized personnel in the process of disassembling or repairing.

☞ Products beyond the warranty period.

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