Operator's Manual
Fingertip Pulse Oximeter

CE_{0123}

Version number of this manual: V1.1

General Description

The measurement of oxygen saturation of arterial blood (also known as pulse oxygen saturation, usually shortened as SpO_2) adopts the principles of light spectra and volume tracing. The LED emits lights with two specific wavelengths, which are selectively absorbed by oxygenated hemoglobin and deoxyhemoglobin. The optical receptor measures the changes in the light intensity after the light passes the capillary network and estimates the ratio of oxygenated hemoglobin and the total hemoglobin.

$$SpO_2 \% = \frac{oxygenated \quad hemoglobin}{oxyhemoglo \quad bin + deoxyhemog \quad lobin} \times 100 \%$$

The mechanical activity of the heart cause arterial pulse, by measuring the pulse we can get PR value .

Precautions For Use

- Explosion hazard. Do not use the oximeter in the presence of flammable anesthetics mixture with air, oxygen, or hydrogen.
- When the oximeter is in use, there should not be any great power appliances such as high voltage cables, X-ray machine, ultrasound equipment and electrizer in use nearby.
- Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- This oximeter does not have alarm function; please do not use this product in the environment where alarm is required.
- The oximeter should be handled with care so as to avoid shocks and falls.
- When the oximeter is in use, it must be ensured that the batteries have sufficient capacity; otherwise there might be such phenomena as starting-up abnormalities or inaccurate measurement data, etc.
- Please don't use pointed objects such as pen point or nails to press operation, otherwise it might cause permanent damage to the surface of the keyboard.
- Don't make any clinical judgments based only on the oximeter. The oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms, as well as doctor's diagnoses.
- To ensure accurate performance and prevent device failure, do not expose the oximeter to extreme moisture, such as direct exposure to rain. Such exposure may cause inaccurate performance or device failure.
- Do not conduct SpO_2 measurement on the finger smeared with nail polish, otherwise this will lead to unreliable measurement results.
- The enclosure shall only be opened by the authorized person.
- In order to have more accurate measurements of SpO_2 and PR, the oximeter should be used in quiet and comfortable environment.
- Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
- Prolonged continuous monitoring may increase the risk of unexpected changes in skin characteristics, such as irritation, reddening, blistering or burns. Inspect the sensor site every two hours and move the sensor if the skin quality changes.
- Pulse oximeter simulator can not be used to access the accuracy of the pulse oximeter.
- 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; (2) This device must accept any interference received, including interference that may cause undesired operation.

The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment

FCC STATEMENT:

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 against 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 correct 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.

Intended Use

The Fingertip Pulse Oximeter is intended to measure functional arterial oxygen saturation (SpO2) and pulse rate of adult and pediatric patients in hospital, hospital type facilities, as well as in the home care environment.

The oximeter is not suitable to monitor patient continuously for long term.

Battery Installations

1. Press the button down on the back panel of oximeter and push the battery cover horizontally along the arrow shown as below:
2. Install the batteries into battery cabin in correct polarities.
3. Close the battery cover.

Press the button down

Notes:

- **Put or remove batteries in right order, or it may damage the bracket.**
- **Battery polarities must be correctly installed. Otherwise, damage might be caused to device.**
- **Please remove the battery if the oximeter will not be used for long time.**

Software Download And Installation

1. Software download methods：
- Users who use the ISO system device can log in iphone App Store, enter "wearcare" and search for the of "SpO2 monitoring software" in the searching results.
- Users who use the Android system device can log in the wearcare official website: http://www.wearcare.cn for download.
2. Download SpO2 monitoring software, click installation button for free installation.

Operation Instructions

1. Install two AAA batteries into battery cassette before closing its cover.
2. Open the receiving device (such as mobile phone, tablet PC etc.), then turn on the Bluetooth.
3. Start the SpO2 monitoring software and connect automatically, the prompt message" Complete device connection". Till now, users can perform SpO2 monitoring.
4. Nip the oximeter, then insert one finger into the rubber hole of the oximeter before releasing the oximeter, and your nail must be upward.
5. Press the function button once on front panel.
6. Your finger and body do not tremble during measuring.
7. Read corresponding data on the display screen.
8. After turning on the oximeter, each time you press the power switch, the display screen will change to another direction. There are two display modes. If you long press the power switch, you can adjust the brightness of screen from 1 to 5.
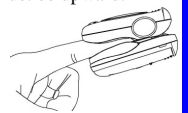
① SpO2 Plethysmogram（normalized）
② SpO2 reading
③ Pulse rate reading
④ Indication of battery capacity
⑤ Indication of pulse intensity
⑥ Indication of screen brightness
⑦ Display modes

Maintenance

1. Use a soft cloth dampened with either a commercial, nonabrasive cleaner, or a solution of 70% alcohol in water, softly wipe the surfaces of the oximeter.
2. The most commonly used hospital cleaning agent and non-corrosive detergents can be used for cleaning the oximeter, but please be careful that many types of detergents must be diluted before use; Please use them according to the directions of the manufacturers of the detergents.
3. Avoid using alcohol-based, amido or acetone-based detergents .
4. The casing of the oximeter should be kept from the contamination of filth and dirt, and it can be wiped with non-velvet soft cloth. When cleaning, don't spill the liquid onto the instrument. Ensure no liquid is allowed to enter the inside of the oximeter.
5. It's forbidden to use such grinding materials as wire brush or metal polishing agent, for these materials may cause damage to the panels of the oximeter.
6. Please do not soak the oximeter in liquid.

7. Under normal circumstances, it is unnecessary for the oximeter to have special maintenance, and cautions must be exercised on the following points during the use of the oximeter:
- Please use the oximeter in the environment according to the requirements of the performance criteria.
- Avoid exposure or direct sunlight.
- Avoid excessive radioactive infrared rays or ultraviolet rays.
- Avoid contacts with organic solutions, dusts or corrosive gases.

Product Specifications

◆ **Measurement specifications**

SpO₂	
Measuring Range	0~100%
Resolution	1%
Accuracy	At 70%~100%, ±2%；At 0~69%, unspecified
Data update period	<13 s

PR	
Measuring Range	25bpm~250 bpm
Resolution	1 bpm
Accuracy	±1% or ± 1 bpm, whichever is greater
Data update period	< 13 s

◆ **Battery specifications**

Type	Voltage
two AAA alkaline battery	1.5 Volts DC (per battery)

The oximeter uses two 1.5 V AAA type batteries and a set of new batteries can be used for more than 18 hours, depending on concrete battery types.

◆ **Environmental specifications**

Operation

Temperature	+5℃～+40℃
Atmospheric Pressure	700hPa～1060hPa
Relative Humidity	≤85%

Transport and Storage

Temperature	-20℃～+55℃
Atmospheric Pressure	500hPa～1060hPa
Relative Humidity	≤93%

◆ **Physical specifications**

Weight	about 21g/54g (exclude / include battery)
Dimensions	57mm(length) × 33mm(width) ×30mm(height)

◆ **Sensors specifications**

Wavelength	Pulse oximetry sensors contain LEDs that emit red light at a wavelength of approximately 660 nm and infrared light at a wavelength of approximately 905 nm.The total optical output power of the sensor LEDs is less than 15 mW. This information may be useful to clinicians, such as those performing photodynamic therapy. **Note:** Sensor LED light emissions fall within Class 1 level, according to IEC 60825-1:2001. No special safety precautions are required.

Symbols Definitions

Symbol	Definition
🏃	Type BF equipment (Refer to IEC 60601-1:2012)
%SpO₂	Oxygen saturation of arterial blood
♡/Min	Pulse rate
⊠	Non-Alarm indication (The device does not have alarm function)
IPX1	Enclosure degree of ingress protection.
SN	Serial number
⊠	Symbol for the marking of electrical and electronics devices according to Directive 2002/96/EC. The device, accessories and the packaging have to be disposed of waste correctly at the end of the usage. Please follow Local Ordinances or Regulations for disposal. **Note:** The Oximeter is applied to this regulation.
📖	Refer to this user's manual.

Possible Problems And Solutions

Problems	Possible causes	Solution
There is no response to the function button	The button can not be pressed to its position	Ensure that the button is fully depressed.
	Battery capacities are low	The batteries may be lost, discharged, or oriented incorrectly. Replaced them with new ones.
The Pulse search time is too long	Perfusion may be too low	Check the patient. Change the measuring site. Try another oximeter.
	Patient movement	Interference due to patient activity may be preventing the oximeter from tracking the pulse. Keep the patient still, if possible.
	Electromagnetic interference may be preventing the oximeter from tracking the pulse.	Remove the source of interference.
	There may be interference due to ambient light, or the oximeter may be on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.	Reposition oximeter, as necessary.
Display is dark-or-bright	Battery capacities are low.	Replace the batteries.

Guidance and manufacture's declaration – electromagnetic emission		
The Fingertip Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer of the user of the Fingertip Pulse Oximeter should assure that it is used in such and environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Fingertip Pulse Oximeter uses RF energy only for its internal function. Thus, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The Fingertip 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.

Applicable Models

M70C

Packing List

NO.	Item	Quantity	
1	Oximeter	1	☐
2	AAA battery	2	☐
3	Cord	1	☐
4	User's manual	1	☐

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