



# PULSE OXIMETER

## GENERAL DESCRIPTION

The measurement of oxygen saturation of arterial blood (also known as pulse oxygen saturation, usually shortened as SpO<sub>2</sub>) 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.

$$\text{SpO}_2\% = \frac{\text{oxygenated hemoglobin}}{\text{oxyhemoglobin} + \text{deoxyhemoglobin}} \times 100\%$$

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

The oximeter is standalone, reusable, and not reprocessed. The sensor of the oximeter is built-in.

## CAUTION

- Federal Law Restricts this device to sale by or on the order of a physician.
- Please read the user manual carefully prior to operating.

## 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 as high voltage cables, X-ray machine, ultrasound equipment and electricizer 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 the batteries have sufficient capacity; otherwise there might be such phenomena as hstarting-up abnormalities or inaccurate measurement data, etc.
- Please do not use such pointed objects as pen point or nails for pressing operation, otherwise it might cause permanent damage to the surface of the keyboard.
- Do not make any clinical judgments based solely 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<sub>2</sub> measurement on the finger smeared with nail polish, otherwise this will lead to unreliable measurement results.
- Please do not open the enclosure. The enclosure shall only be opened by the authorized person.
- In order to have more accurate measurements of SpO<sub>2</sub> 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.
- The expected service life of the device is three years.

## INTENDED USE

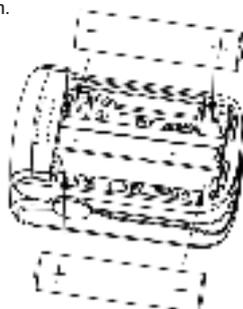
The Fingertip Pulse Oximeter is intended to measure functional arterial oxygen saturation (SpO<sub>2</sub>) and pulse rate of adult, pediatric and adolescent patients in hospital, hospital type facilities, and in the home care environment. The oximeter is not suitable to monitor patients continuously for long term.

## BATTERY INSTALLATIONS

1. Press the button down on the back panel of the oximeter.
2. Push the battery cover horizontally along the arrow shown on the back panel of the oximeter.
3. Install two AAA batteries into the battery cabin.
4. Close the battery cover.

**NOTES: Be sure to install batteries as directed by the polarity indicators in the battery cabin. Batteries in this device are different than conventional battery installation.**

- Please put or remove batteries in right order, or it is likely to damage the device bracket.
- Battery polarities must be correctly installed. Otherwise, damage might be caused to the device.



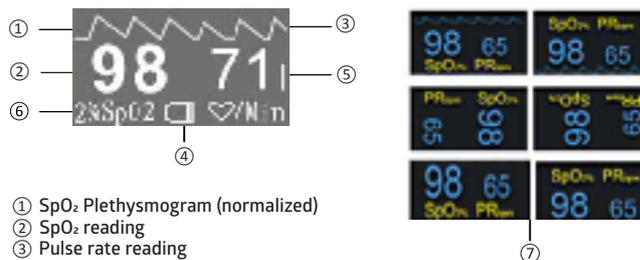
## LANYARD INSTALLATIONS

1. Attach the lanyard through the hole in the middle of the front face as the arrows show.
2. Complete.



## OPERATION INSTRUCTIONS

1. Install batteries as indicated by the battery installation instructions.
2. Open the oximeter. Insert one finger into the rubber hole of the oximeter before releasing. Your nail surface must be upward.
3. Press the function button once on the front panel.
4. Read corresponding data on the display screen.
5. After turning on the oximeter, each time you press the power switch, the display screen will change to another direction. If you hold down the power switch, you can adjust the brightness of the screen from 1 to 5.



- ① SpO<sub>2</sub>: Plethysmogram (normalized)
- ② SpO<sub>2</sub>: reading
- ③ Pulse rate reading
- ④ Indication of battery capacity
- ⑤ Indication of pulse intensity
- ⑥ Indication of screen brightness (Default value of brightness is 3)
- ⑦ Display modes

## MAINTENANCE

1. Use a soft cloth dampened with either a commercial, nonabrasive cleaner, or a solution of 70% alcohol in water, lightly wipe the surfaces of the oximeter.
2. Avoid using alcohol-based, amido or acetone-based detergents.
3. 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, do not spill the liquid onto the instrument. Ensure no liquid is allowed to enter the inside of the oximeter.
4. It is forbidden to use such grinding materials as wire brush or metal polishing agent, because these materials may cause damage to the panels of the oximeter.
5. Please do not soak the oximeter in liquid.
6. 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

SpO <sub>2</sub>	
Measuring Range	0-100%
Resolution	1%
Accuracy	At 70-100%, ±2%; At 0-69%, unspecified
Data updated period	<13 s
Accuracy in the discrete SpO <sub>2</sub> ranges	At 70%-80%, ±2%; At 80%-90%, ±2%; At 90%-100%, ±2%
PR	
Measuring Range	25-250 bpm
Resolution	1 bpm
Accuracy	±1% or ± 1 bpm, whichever is greater
Data updated 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°C ~ +40°C
Atmospheric Pressure	700hPa ~ 1060hPa
Relative Humidity	≤85%

Transport and Storage

Temperature	+20°C ~ +55°C
Atmospheric Pressure	500hPa ~ 1060hPa
Relative Humidity	≤93%

◆ Physical specifications

Weight	about 21g (exclude battery) about 54g (include battery)
Dimensions	60mm(length) x 35mm(width) x 35mm(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. <b>Note:</b> Sensor LED light emissions fall within Class 1 level, according to IEC 60825-1. No special safety precautions are required.
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**POSSIBLE PROBLEMS AND RESOLUTIONS**

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 missing, 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.

**SYMBOLS DEFINITIONS**

Symbol	Definition
	Type BF equipment (Refer to IEC 60601-1)
	Attention! Please refer to this manual.
%SpO <sub>2</sub>	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
	Refer to this user's manual.
	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. <b>Note:</b> The Oximeter is applied to this regulation.
	Date of Manufacture
	Manufacturer's information

**Guidance and manufacture's declaration-electromagnetic emissions-for all EQUIPMENT and SYSTEMS**

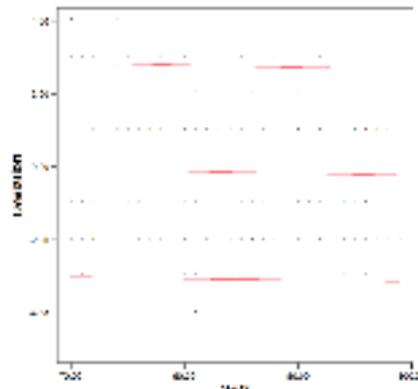
Guidance and manufacture's declaration - electromagnetic emission		
The Fingertip Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Fingertip Pulse Oximeter should assure that it is used in such an environment.		
Emission test	Compliance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

Declaration: After the electromagnetic compatibility test, the essential performance of SpO<sub>2</sub> and PR meet the requirements as follow:

- a) SpO<sub>2</sub>: Accuracy at 70%-100% is ±2%, at 0-69% is unspecified. Measuring range is 0-100%.
- b) PR: Accuracy is ±1% or ± 1 bpm, whichever is greater. Measuring range is 25 bpm-250bpm.

**CLINICAL TRIAL RESULTS**

SpO <sub>2</sub> range %	70-100	70-79	80-89	90-100
The number of samples	325	83	87	155
Mean Bias	-0.1692	-0.0843	-0.2874	-0.1484
Standard Deviation	1.4779	1.9140	1.6347	1.0678
Standard Error	0.0819	0.2100	0.1753	-0.086
95% CI	Lower Bound	-0.3305	-0.5023	-0.6358
	Upper Bound	-0.0080	0.3336	0.0610
Minimum SpO <sub>2</sub> %	70.00	70	80	90
Maximum SpO <sub>2</sub> %	99.00	79	89	99
Arms	1.4853	1.9043	1.6900	1.0746



**APPLICABLE MODELS**

HCSM70C
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**PACKING LIST**

No.	Item	Quantity	
1	Oximeter	1	<input type="checkbox"/>
2	AAA battery	2	<input type="checkbox"/>
3	Cord	1	<input type="checkbox"/>
4	User's manual	1	<input type="checkbox"/>

**Warranty**

One year
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