

Instructions to User

Dear Users,

Thank you very much for purchasing our product. Please read the manual very carefully before using this device. Please follow these instructions to operate.

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Notes:

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3502-2290040

Instructions for Safe Operations

- ☼ Check the device before using it to make sure that there is no visible damage that may affect user's safety and its performance. When there is obvious damage, stop using the device.
- ☼ Necessary service must be performed by qualified service engineers ONLY. Users are not permitted to repair it by themselves.
- ☼ The oximeter cannot be used together with the devices not specified in User Manual.

Cautions

- ☼ Explosive hazard—DO NOT use the oximeter in environment with inflammable gas such as some ignitable anesthetic agents.
- ☼ DO NOT use the oximeter while the testee is under MRI or CT scanning.

Warnings

- ☼ The uncomfortable or painful feeling may appear if using the sensor of this device continuously on the same place for a long time, especially for the patients with poor microcirculation. It is recommended that the sensor should not be applied to the same location for over 2 hours. If any abnormal condition is found, please change the position of sensor.
- ☼ For the individual patients, there should be a more prudent inspecting in the placing process. The sensor can not be clipped on the edema and tender tissue.

- ☛ To dispose the device or its accessories, the local law should be followed.

Attentions

- 🔔 Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- 🔔 If the oximeter gets wet, please stop operating it. When it is carried from cold environment to warm and humid environment, please do not use it immediately.
- 🔔 **DO NOT** operate the button on front panel with sharp materials.
- 🔔 High temperature or high pressure steam disinfection to the oximeter is not permitted. Refer to related chapter for instructions of cleaning and disinfection.
- 🔔 The intended use of this device is not for therapy purpose.

Caution: U.S. federal law restricts this device to sale or use by or on the order of a physician.

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1 Overview

1.1 Appearance

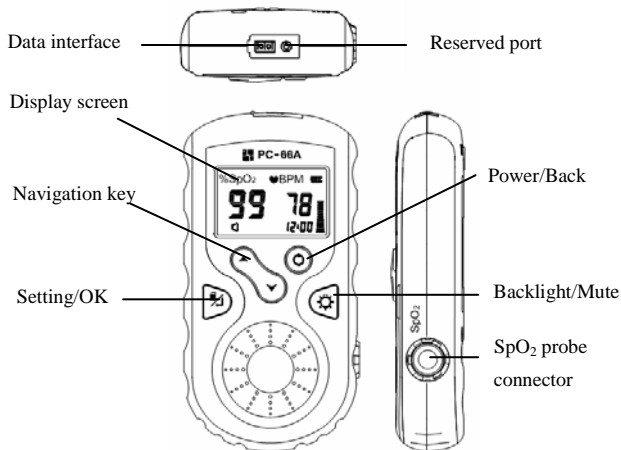


Figure 1

1. Display screen: display SpO₂ and PR values etc. data.


2. ▲ / ▼ (Navigation key):


When on the system setup screen, press it to choose the setting item or adjust parameter values.

3.  (Setting/OK):

Longtime press: enter setting mode;

Short time press: press to confirm;

4.  (**Data interface**): used for uploading data.

5.  (**Reserved port**): reserved for future use.

6.  (**Power/Back**):

Longtime press: turn the power on/off;

Short time press: exit the setting mode or back to previous setting item.

7.  (**Backlight/Mute**):

Longtime press: make the device stay in mute mode or turn the sounds on; this function is only effective during measuring;

Short time press: turn the backlight on/off;

8. **Icon: “SpO₂”**: SpO₂ Probe Connector.

Key definitions:

Longtime press: press for 2 seconds or longer;

Mute mode: except the key-press sound, other sounds (i.e. beat sound and alarm sound) shall be off.

1.2 Name and Model

Name: Handheld Pulse Oximeter

Model: PC-66A

1.3 Structure

It consists of the main unit and SpO₂ probe.

1.4 Features

- ✧ It is light, small in size and easy to carry;
- ✧ Segment LCD display, with LED backlight;
- ✧ Monitor SpO₂ and PR parameters simultaneously, and display pulse intensity bar graph as well;
- ✧ SpO₂ and PR etc. data storage and transmission to PC for viewing and analysis;
- ✧ Audible & Visual alarm function;
- ✧ Alkaline batteries or rechargeable batteries can be used and with power management function;
- ✧ Time setup and display function;

1.5 Intended Use

This Handheld Pulse Oximeter is intended for measuring and recording the pulse rate and functional oxygen saturation (SpO₂). It is applicable for monitoring SpO₂ and pulse rate of adult and pediatric patients in clinical institutions and homes.

1.6 Working Environment

Operating temperature:	5~40 °C
Operating humidity:	30~80%

Atmospheric pressure: 70kPa~106kPa

2 Installation of Battery and Holder

- 1) Open the rear panel with coin or an ordinary flat screwdriver, as shown in Figure 2.

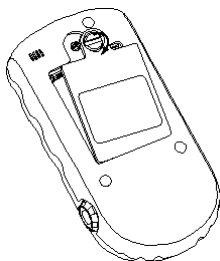


Figure 2

- 2) According to the polarity mark, insert three AA batteries into battery house, as shown in Figure 3.

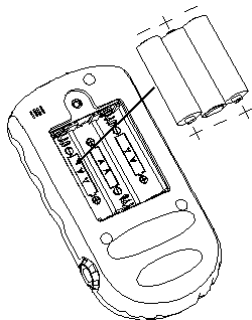


Figure 3

- 3) Close the battery cover and fasten it.
- 4) Fixing Holder

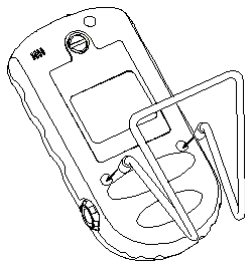


Figure 4 Fixing Holder

3 SpO₂ Probe Connection

Connect the SpO₂ probe to the right panel's connector labeled "SpO₂". After starting the monitor insert one finger into the probe (index finger, middle finger or ring finger with proper nail length) according to demonstration, as shown in the following figure.

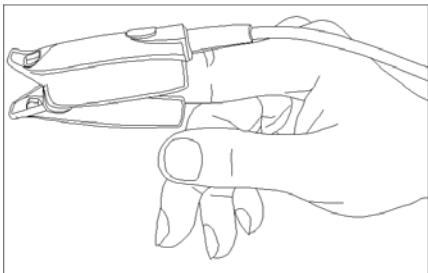



Figure 5 Demonstration for using SpO₂ probe (finger clip)

Instructions of Operation

1. The finger should be put properly and correctly.
2. Do not shake the finger and keep at ease during using.
3. Do not put wet finger directly into sensor.
4. Avoid placing the sensor on the same limb which is wrapped with a cuff for blood pressure measurement or during venous infusion.
5. Do not let anything block the emitting light from the sensor.
6. Vigorous exercise and electrosurgical device interference may affect the measuring accuracy.
7. Using enamel or other makeup on the nail may affect the measuring accuracy.
8. If the first reading appears with poor waveform (irregular or not smooth), then the reading is unlikely true, the more stable value is expected by waiting for a while, or a restart is needed when necessary.

4 Operation

4.1 Default Screen

Longtime press “” key to start the Oximeter, then insert finger into rubber cushions of the probe, the screen will display the default screen, as shown in Figure 6.

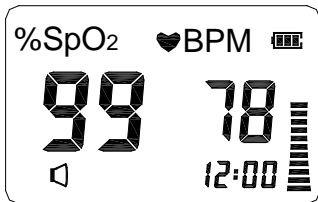






Figure 6 Default Screen

Screen Description:

- ✧ “%SpO₂” “99”: SpO₂ value; “99” is a percentage value;
- ✧ “BPM 78”: Pulse rate value: 78bpm.
- ✧ “”: Battery indication; when low battery power is detected by the oximeter during measurement, this icon will change to be “” and blinks for reminding user to replace batteries as soon as possible.
- ✧ “12:00”: Current time;
- ✧ “”: pulse strength bar-graph;

- ◇ “🔊”: Sound indication; When the icon becomes “🔇”, the oximeter stays in mute mode.

Prompt for Data Storage

If the memory is full or the total number of the records reaches 256 pieces during measuring, the earliest records will be overwritten and the icon “📁” will display on the screen for prompt, as shown in the figure below.

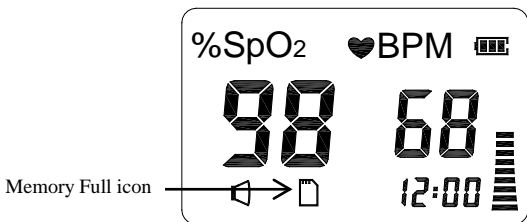



Figure 7

The record interval is 2seconds, that is the oximeter records a group of SpO₂ value and PR value every 2 seconds. The length of data record is limited to 30 seconds at least and truncated to 2 hours at most.

You can clear the memory (deleting all the records) via restoring default factory setting or by data manager software(optional).

Note: It is suggested that the data shall be uploaded to computer for saving, or the earliest records will be overwritten.

4.2 Indication for No Signal

If No Signal icon “” prompts on screen (as shown in Figure 8), please check whether the probe connects well and whether the finger is in appropriate position.

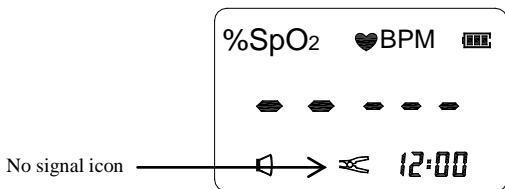



Figure 8 No Signal

4.3 Setting Mode

When the oximeter stays in measuring mode, longtime press “” key for entering into setting mode (as shown in Figure 9).

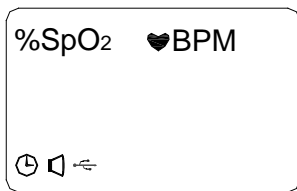






Figure 9 Setting Screen

There are 4 setting icons: “%SpO2♥BPM”, “”, “” or “”, and “” on setting screen. When entering into its corresponding setting screen, you may view the current settings,

or may modify them.

Screen Description:

- ✧ Icon “%SpO₂ ♥BPM” is for setting Low alarm limit of SpO₂ and High/Low alarms of PR;
- ✧ Icon “🕒” is for setting date and time;
- ✧ Icon “🔊” or “🔇” which indicates the current status of sound is for setting sound status;
- ✧ Icon “📶” indicates the data uploading mode;

Operation Instructions:

- 1) Press “▲/▼” Navigation key to choose the setting item (icon). The current selected setting icon starts to flash.
- 2) Press “📄/📌” key to confirm and enter into its corresponding setting screen or data uploading screen.

Note: The measurement will be terminated when entering into setting mode or data uploading mode.

4.3.1 SpO₂ /PR Alarm Settings

On the setting screen, select “%SpO₂ ♥BPM” and then press “📄/📌” key for entering into SpO₂ alarm setting screen and PR Hi/Low alarm limit setting screen. The setting screens are as shown in the following figures.

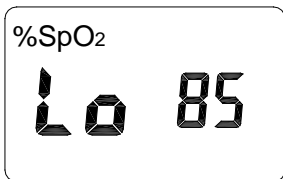


Figure 10A SpO₂ alarm setting

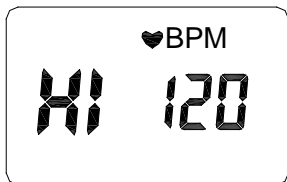
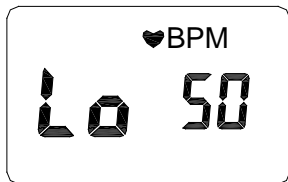



Figure 10B PR Low limit setting Figure 10C PR Hi limit setting screen







Operation Instructions:


1. “%SpO₂ Lo”: SpO₂ alarm setting; default value: “85%”;

Read the following for the detailed setting method:



- a. When the display screen is SpO₂ alarm setting screen, press “” key to active SpO₂ alarm setting option, the preset value starts to flash;
- b. Press “▲”/“▼” (Navigation key) to adjust numerical value.
 - “▲”: short time press it to increase the numerical value single time; longtime press it to increase the numerical value continuously;
 - “▼”: short time press it to reduce the numerical value single time; longtime press it to reduce the numerical value

continuously;

- c. Press “” key to confirm the modification.
 - d. Press “”/ “” (Navigation key) circularly, the display screen will be shift among SpO₂ alarm setting screen, PR Low limit setting screen and PR Hi limit setting screen. You can follow the setting steps mentioned above to adjust PR Low/Hi limit;
 - e. After completing the settings, short time press “” key to return to menu screen;
2. “ **BPM Lo**”: High alarm limit setting of pulse rate; default value: 120bpm;
 3. “ **BPM HI**”: Pulse rate: Low alarm limit setting of pulse rate; default value: 50 bpm.

When the measuring value exceeds the preset value, the oximeter will alarm and backlight will be turned on automatically, the corresponding value displayed on screen will flash as well. At this time, press “” key to turn the backlight off.

4.3.2 Date and time Settings

On the setting screen, select “” and then press “” key for entering into date and time setting screen. The setting screens are as shown in the following figures.

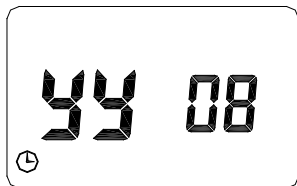


Figure 11A Year Setting



Figure 11B Month Setting

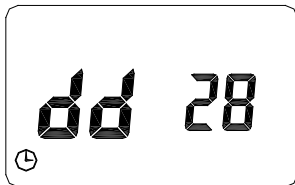


Figure 11C Day Setting

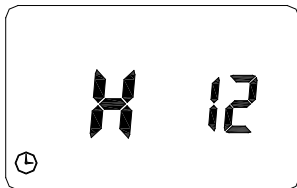


Figure 11D Hour Setting

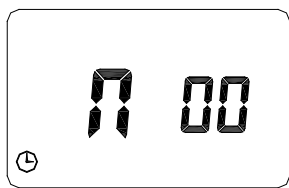



Figure 11E Minute Setting

Operation Instructions:

1. “99”: Year Setting.


Read the following for the detailed setting method:

- a. When the display screen is Year setting screen, press “”, key to active Year setting option, the preset value starts to flash;


b. Press “▲”/ “▼” (Navigation key) to adjust year.

“▲”: short time press it to increase the numerical value single time; longtime press it to increase the numerical value continuously;

“▼”: short time press it to reduce the numerical value single time; longtime press it to reduce the numerical value continuously;

c. Press “” key to confirm the setting.

d. Press “▲”/ “▼” (Navigation key) circularly, the display screen will be shift among Year setting screen, Month setting screen, Day setting screen, Hour setting screen and Minute setting screen. You can follow the setting steps mentioned above to adjust;

e. After completing the settings, short time press “” key to return to setting screen;




2. “”: Month setting;

3. “”: Day setting;

4. “”: Hour setting;

5. “”: Minute setting;

4.3.3 Sound Setting

On the setting screen, select “” or “” and then press “” key for entering into Sound setting screen, as shown in the figure below.

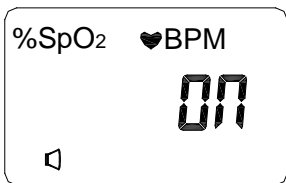


Figure 12A Sound On

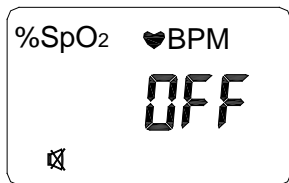


Figure 12B Mute Setting



Operation Instructions:

Press “▲”/ “▼” (Navigation key) to turn the sound on or make the oximeter stay in mute mode. Default setting is “ON”;

“ON”: the sound setting is ON,

“OFF”: the sound setting is OFF, the oximeter stays in mute mode.

4.3.4 Upload Data

On the setting screen, select “” and then press “” key for entering into data uploading screen (as shown in Figure 13). When you transmit data (SpO₂ and PR values) to your computer, please let the oximeter stay in connecting status.

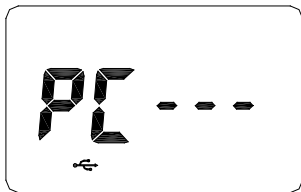


Figure 13 Data uploading Screen(Connecting Status)

4.4 Low Battery Prompt

When the battery is too low, if you power up the oximeter, it will display as the figure below to indicate low battery. Please replace the batteries, or the oximeter may not work.

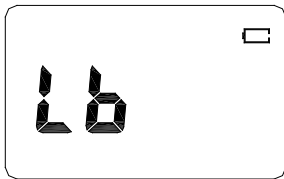





Figure 14

4.5 Resume Default Setting

When the oximeter is off, press the “” key, “” key and “” at the same time until the default setting display is shown on the screen, it indicates the operation has succeeded.

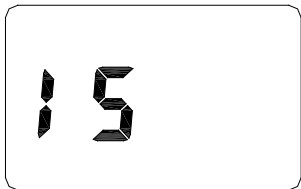


Figure 15 default setting screen

After restoring default setting, all the record stored in oximeter will be cleared, but the time will not be changed.

5 Technical Specifications

A. Display mode: Segment LCD Display

B. Power supply requirement:

3 ×LR6 (AA) alkaline battery or Ni-MH rechargeable batteries;

Supply voltage: 4.5V

Operating current: <50mA

C. SpO₂ Parameter Specifications

Transducer: dual-wavelength LED sensor

Measurement wavelength:

Red light: 660 nm, Infrared light: 905 nm.

Maximal optical output power:

Less than 2mW maximum average

Measuring range: 35~99%

Measuring accuracy:

not greater than 3% for SpO₂ range from 70% to 100%

Note: Accuracy is defined as root-mean-square value of deviation according to ISO 9919.

SpO₂ low alarm limit setting range: 85%~99% (default 85%)

D. Pulse Rate Parameter Specifications

Measuring range: 30bpm~240bpm

Accuracy: ±2bpm or ±2% (whichever is greater)

Alarm limit setting range: 30bpm~240bpm

Default alarm limits: High: 120bpm Low: 50bpm

E. Perfusion Index (PI) Display

Range: 0~20%

F. Data Record

The record interval is 2 seconds, that is the oximeter records a group of SpO₂ value and PR value every 2 seconds. The length of a record is limited to 30 seconds at least and truncated 2 hours at most. Up to 12-hour data can be recorded.

G. Resistance to interference of surrounding light:

The difference between the value measured in the condition of indoor natural light and that of darkroom is less than $\pm 1\%$.

H. The performance under low perfusion condition

The accuracy of SpO₂ and PR measurement still meet the precision described above when the modulation amplitude is as low as 0.5%.

I. Resistance to 50Hz/60Hz interference

SpO₂ and PR are precise which have been tested by BIO-TEK pulse oximeter simulator.

J. Dimensions: 145 mm (L) × 74 mm (W) × 29 mm (H)

Net Weight: 140g (not including batteries and accessories)

K. Classification

The type of protection against electric shock:

Internally powered equipment

The degree of protection against electric shock:

Type BF applied parts.

The degree of protection against harmful ingress of

liquids: Ordinary equipment without protection against ingress of water.

Electro-Magnetic Compatibility: Group I, Class B

6 Accessories

1. A probe
2. A holder
3. Battery (AA) × 3
4. A User Manual
5. A Quality Certificate
6. A data cable (optional)
7. Oximeter Data Manager software (optional)

Note: The accessories are subject to change. See the Packing List for detailed items and quantity.

7 Repair and Maintenance

7.1 Maintenance

The life of this device is 5 years. In order to ensure its long service life, please pay attention to the maintenance.

- A. Please change the batteries when the low-voltage indicator appears.
- B. Please take out the batteries if the oximeter will not be used for a long time.
- C. The recommended storage environment of the device:
Ambient temperature: $-20^{\circ}\text{C} \sim 60^{\circ}\text{C}$
Relative humidity 10%~95%
Atmospheric pressure: 50kPa~107.4kPa
- D. The oximeter is calibrated in the factory before sale, there is no need to calibrate it during its life cycle. However, if it is necessary to verify its accuracy routinely, the user can do the verification by means of SpO_2 simulator, or it can be done by the local third party test house.

7.2 Cleaning and Disinfecting Instruction

- A. Surface-clean sensor with a soft cloth by wetting with a solution such as 75% isopropyl alcohol, if low-level disinfection is required, use a 1:10 bleach solution.
- B. Then surface-clean by a dampened cloth and let it air dry or wipe it with a cloth.

⚠ High-pressure sterilization cannot be used on the device.
















⚠ Do not immerse the device in liquid.

8 Troubleshooting

Trouble	Possible Reason	Solution
The SpO₂ and Pulse Rate display instable	<ol style="list-style-type: none"> 1. The finger is not placed inside enough. 2. The finger is shaking or the patient is moving. 	<ol style="list-style-type: none"> 1. Place the finger properly and try again. 2. Let the patient keep calm.
Can not turn on the device	<ol style="list-style-type: none"> 1. The batteries are drained or almost drained. 2. The batteries are not inserted properly. 3. The device's malfunction. 	<ol style="list-style-type: none"> 1. Change batteries. 2. Reinstall batteries. 3. Please contact the local service center.
No Display	<ol style="list-style-type: none"> 1. The device will power off automatically when there is no signal and no operation for 1 minute. 2. The batteries are almost drained. 	<ol style="list-style-type: none"> 1. Normal. 2. Change batteries.

Appendix

Key of Symbols

Symbol		Description
Symbols on the screen	%SpO₂	Pulse oxygen saturation
	♥ bpm	Pulse rate (Unit: beats per minute)
		Low battery voltage
		Memory full
		No signal
		Pulse strength bar-graph
		Date and time setup
		Connecting to PC
		Sound icon
		Mute icon
Symbols on the panels		With Type BF applied part
	SpO₂	SpO ₂ probe connector
		Power/Back Key
		Setting/OK Key
		Backlight/Mute Key
		Navigation Key
		Data Interface
	SN	Serial Number
		Separate collection for this device.

Common Knowledge for SpO₂ Measurement

1 Meaning of SpO₂

SpO₂ is the saturation percentage of oxygen in the blood, so called O₂ concentration in the blood; it is defined by the percentage of oxyhemoglobin (HbO₂) in the total hemoglobin of the arterial blood. SpO₂ is an important physiological parameter to reflect the respiration function; it is calculated by the following method:

$$\text{SpO}_2 = \text{HbO}_2 / (\text{HbO}_2 + \text{Hb}) \times 100\%$$

HbO₂ are the oxyhemoglobins (oxygenized hemoglobin), Hb are those hemoglobins which release oxygen.

2 Principle of Measurement

Based on Lamber-Beer law, the light absorbance of a given substance is directly proportional with its density or concentration. When the light with certain wavelength emits on human tissue, the measured intensity of light after absorption, reflecting and attenuation in tissue can reflect the structure character of the tissue by which the light passes. Due to that oxygenated hemoglobin (HbO₂) and deoxygenated hemoglobin (Hb) have different absorption character in the spectrum range from red to infrared light (600nm~1000nm wavelength), by using these characteristics, SpO₂ can be determined. SpO₂ measured by this oximeter is the functional oxygen saturation -- a percentage of the hemoglobin that can transport oxygen. In

contrast, hemoximeters report fractional oxygen saturation – a percentage of all measured hemoglobin, including dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin.

Clinical application of pulse oximeters: SpO₂ is an important physiological parameter to reflect the respiration and ventilation function, so SpO₂ monitoring used in clinical becomes more popularly, such as monitoring the patient with serious respiratory disease, the patient under anesthesia during operation, premature and neonate. The status of SpO₂ can be determined in time by measurement and find the hypoxemia patient earlier, thereby preventing or reducing accidental death caused by hypoxia effectively.

3 Normal SpO₂ Range and Default Low Alarm Limit

In Campagna area, healthy people's SpO₂ value is greater than 94%, so the values below 94% are determined as hypoxia. SpO₂<90% is considered as the default threshold for determining anoxia by most researchers, so SpO₂ low alarm limit of the oximeter is set as 90% generally.

4 Factors affect SpO₂ measuring accuracy (interference reason)

- ✧ Intravascular dyes such as indocyanine green or methylene blue
- ✧ Exposure to excessive illumination, such as surgical lamps, bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight.

- ✧ Vascular dyes or external used color-up product such as nail enamel or color skin care
- ✧ Excessive patient movement
- ✧ Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- ✧ Exposure to the chamber with High pressure oxygen
- ✧ There is arterial occlusion proximal to the sensor
- ✧ Blood vessel contraction caused by peripheral vessel hyperkinesias or body temperature decreasing

5 Factors caused low SpO₂ Measuring value (pathology reason)

- ✧ Hypoxemia disease, functional lack of HbO₂
- ✧ Pigmentation or abnormal oxyhemoglobin level
- ✧ Abnormal oxyhemoglobin variation
- ✧ Methemoglobin disease
- ✧ Sulfhemoglobinemia or arterial occlusion exists near sensor
- ✧ Obvious venous pulsations
- ✧ Peripheral arterial pulsation becomes weak
- ✧ Peripheral blood supply is not enough



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