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.

Version of the Manual: Ver 2.1

Revised date: October 18, 2012

Notes:

- The contents contained in this manual are subject to change without prior notice.
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3502-2490001

Instructions for Safe Operations

- Check the device before using it to make sure that there is no visible damage which may affect user's safety and measurement performance. When there is obvious damage, stop using the device.
- Necessary service must be performed only by qualified technicians. 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

- An 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 longer than 2 hours. If any abnormal condition is found, please change the position of sensor.
- For the individual patients, there should be a more prudent inspection in the placing process. The sensor can not be clipped on the edema and tender tissue.

- The local law should be followed when disposing of the expired device or its accessories.

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 a cold environment to a warm and humid environment, please do not use it immediately.
- **DO NOT** operate the button on the 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.

Table of Contents

1 Overview

1.1 Appearance

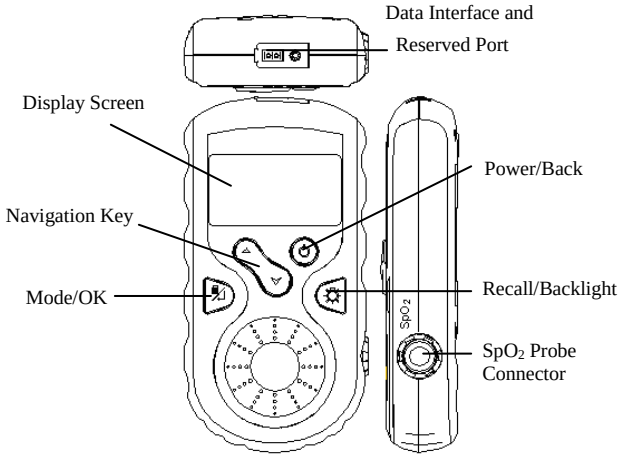


Figure 1

1. Display screen: display SpO_2 plethysmogram and parameter values.

2. Navigation key:

▲ : Up/Left/Increase

Press this key, the default screen can be shifted to display pulse rate (PR) or perfusion index (PI). When on the system setup screen, press it to move the cursor upwards or to the left and

adjust parameter values.

: Down/Right/Decrease

Its function is similar with the key "▲ : Up/Left/Increase".

3.  **(Mode/OK):** press this key, the screen can be shifted between default screen and other screen layout; longtime press this key, the menu screen will be displayed; when you finish parameter setting, press this key to confirm.

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

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

6.  **(Power/Back):** Power on/off the device by longtime pressing; short time press it to back to upper level operation.

7.  (**Recall/Backlight**): Longtime press it to enter SpO_2 recall screen; short time press it to turn on/off the backlight;

8. Icon: "SpO_2": SpO_2 Probe Connector.

1.2 Name and Model

Name: Handheld Pulse Oximeter

Model: PC-66B

1.3 Structure

It consists of the main unit and SpO_2 probe.

1.4 Features

- ✧ It is lightweight, small in size and easy to carry.
- ✧ High resolution LCD to display plethysmogram and measured data.
- ✧ Monitor SpO_2 and PR parameters simultaneously;
- ✧ PI (Perfusion Index) display is available;
- ✧ Real-time store and recall SpO_2 and Pulse Rate value.
- ✧ Data transmission to PC for view and analysis(Optional);
- ✧ Audible & Visual alarm function;
- ✧ Power management function;

1.5 Intended Use

This Handheld Pulse Oximeter is intended for measuring and recording the pulse rate and functional oxygen saturation (SpO_2). It is applicable for monitoring SpO_2 and pulse rate of adult and pediatric patients in clinical institutions and homes.

1.6 Working Environment

Operating temperature:	5~40 ℃
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.

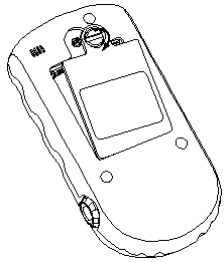


Figure 2

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

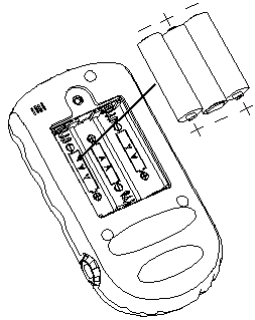


Figure 3

3）Close the battery cover and fasten it.

4）Fixing Holder

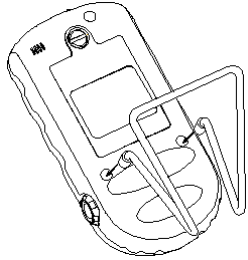


Figure 4 Fixing Holder

3 SpO_2 Probe Connection

Connect the SpO_2 probe to the right panel's connector labeled "SpO_2". 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.

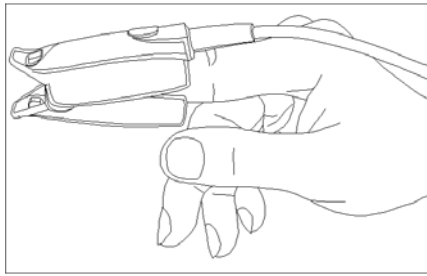


Figure 5 Demonstration for using SpO_2 probe (finger clip)

Instructions of Operation

1. The finger should be put in properly and correctly.
2. Do not shake the finger and keep at ease during measurement.
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

Press "⏻" power key for 2 seconds 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.

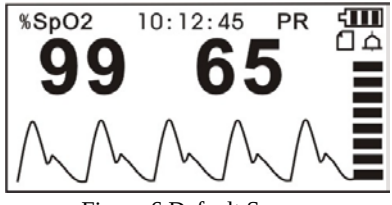


Figure 6 Default Screen

Screen Description:

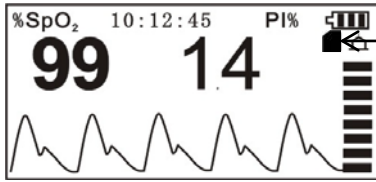
"%SpO_2" "99": SpO_2 value; "99" is a percentage value;

"10:12:45": Current time;

"PR 65": Pulse rate value: 65bpm.

"▭": Battery indication;

"🗋": Data memory icon; when the data on screen becomes stable, the device will start to store data automatically. No icon means the current data will not be stored. If the memory is full or the total number of the records is 256 pieces, the earliest records will be overwritten and the icon "🗋" will appear on the screen for prompt, as shown in the figure below.



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

"": Alarm Icon

"": Pulse strength bar-graph

Lower part displays plethysmogram.

Note: If the leadwire falls off during the measurement process, screen will appear "No Signal". Oximeter gives off the sound alarm like "beep" (intervals of 5 seconds) and continues for about 1 minute. if the leadwire is still off at this time, oximeter will automatically shut down.

4.2 Display Screen with PI Value

On the default screen, press "▲/▼" Navigation key to shift screens between default screen and display screen with PI value. The display screen with PI value is shown below.

Figure 7 Display Screen with PI Value

4.3 Other Screen Layouts

On default screen, press "  " Mode/OK key to enter into other screen layouts (as shown in Figure 8A).

Operation：

- ▲/▼**(Navigation key):** shift screens between PR observation screen (Figure 8A) and PI observation screen (Figure 8B).
-  **(Mode/OK key):** shift screens among four screens (as shown in Figure 6, Figure 7, Figure 8A and Figure 8B.)

Figure 8A PR Observation Screen

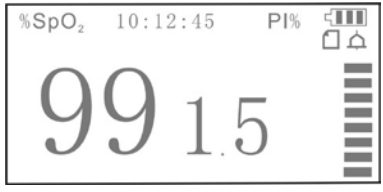


Figure 8B PI Observation Screen

4.4 Indication for No Signal

If “No Signal” prompts on screen (as shown in Figure 9), please check whether the probe connects well and whether the finger is in appropriate position. If the state of “No Signal” lasts for more than 1 minute, oximeter will automatically shut down.

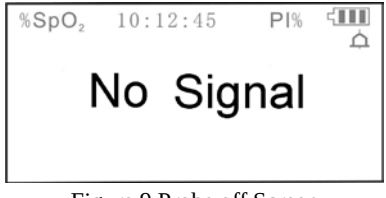


Figure 9 Probe off Screen

4.5 Menu Setup

On the above mentioned screens, longtime press "" key for entering into menu screen (as shown in Figure 10).

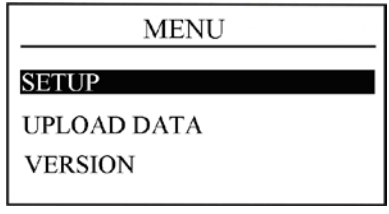


Figure 10 Menu Screen

Screen Description

"SETUP": set parameter values, refer to Chapter 4.5.1 for details.

"UPLOAD DATA": enter into uploading status, refer to Chapter 4.5.2 for details.

"VERSION": for viewing version number of the software, refer to Chapter 4.5.3 for details.

4.5.1 Setup

On the menu screen, select "SETUP" and then press "" key for entering into system setup screen. The setup screen is as shown in the following figures.

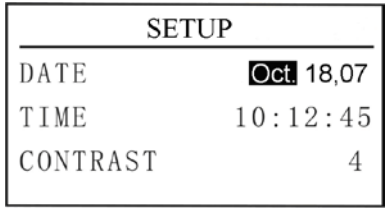


Figure 11 System Setup Screen (A)

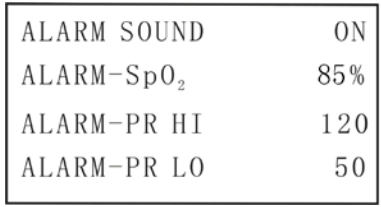


Figure 11 System Setup Screen (B)

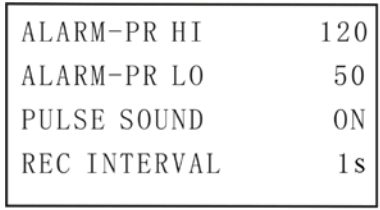


Figure 11 System Setup Screen (C)

Operation Instructions:

1. **DATE:** Date setting

1）When cursor stays on the Month of the date, press "  " (Mode/OK) key to active Month option, the cursor flashes on the Month of the date;

2）Press ▲/▼ (Navigation key) to adjust month.

3）Press "  " (Power/back) key or "  " (Mode/OK) key to confirm and exit from date setting.

4）The procedures of adjusting Day value and year value are the same with Month adjustment.

Date Format: MM. dd, yy.

Note: The setting operations of other parameters (such as TIME, CONTRAST, ALARM SOUND etc.) are the same as date setting.

2. **TIME:** Time setting

3. **CONTRAST:** LCD contrast setting

4. **ALARM SOUND:** The factory default value is "ON".

When the set is "ON", the device stays in alarm status and the alarm icon displays on the upper right display screen.

5. **ALARM SpO_2:** SpO_2 alarm setting; the factory default value: 85%.

6. **ALARM PR HI/LO:** Pulse rate: High/Low limit setting; the factory default value: High limit: 120, Low limit: 50.

7. **PULSE SOUND:** Pulse beep sound switch.

8. **REC INTERVAL:** Record interval setting; five options: “1s, 2s, 4s, 8s” and “OFF”; When the option is “OFF”, the device will not record real-time measurement data.

> **Note:** The length of data record is limited to 30 seconds at least, and the maximal length for one record is also limited to one hour (for one second interval) , 2hours(for 2 seconds interval) 4 hours (for 4 seconds interval) or 8 hours (for 8 seconds interval).

4.5.2 Upload Data

On the menu screen, select “UPLOAD DATA” and then press “” key for entering into connecting status (as shown in Figure 12). When you transmit data (SpO_2 and PR values) to your computer, please let the oximeter stay in connecting status. Do the following operation by the instruction in “Oximeter Data Manager User Manual”. The data uploading will be activated.

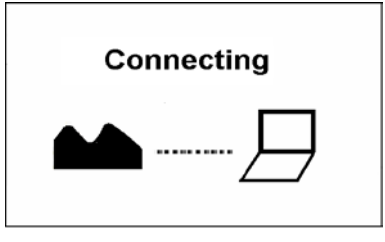


Figure 12 Connecting Status Screen

4.5.3 Version

On the menu screen, select “VERSION” and then press “” key for entering into version screen (as shown in Figure 13).

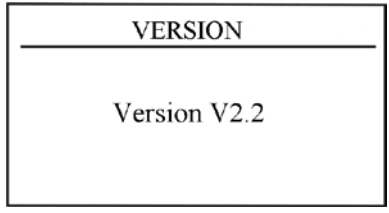


Figure 13

4.6 Data Recall

On the default display screen, longtime press “” (Recall/backlight) key to enter into recall list screen.

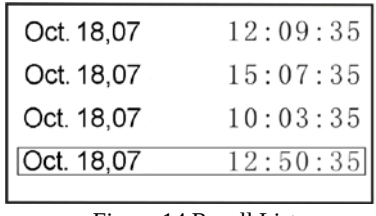


Figure 14 Recall List

4.6.1 Data Recall

Choose one record in the recall list, then press "" key, the display screen will display trend graph, as shown in Figure 15A.

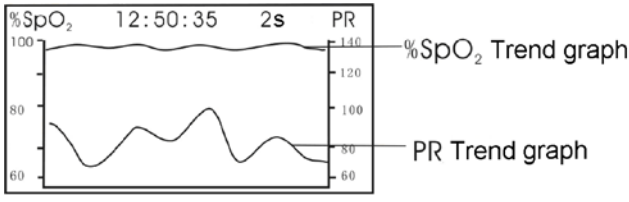


Figure 15A Trend Graph Recall Screen

Screen description:

"%SpO_2": The left ordinate value is %SpO_2 value;

"12:50:35": Measuring time

"2s": Record interval is 2 seconds.

"PR": The right ordinate value is pulse rate value

Operation Instructions:

- press "" key to shift trend recall screens (as shown in Figure 15A ， Figure 15B and Figure 15C)

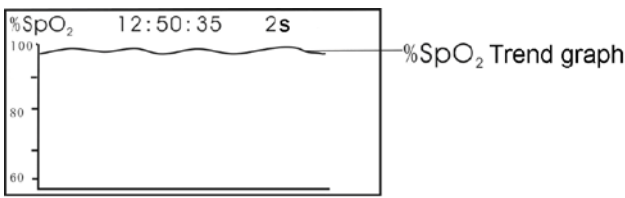


Figure 15B Trend Graph Recall Screen

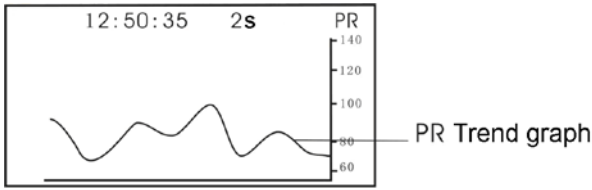


Figure 15C Trend Graph Recall Screen

- Press "▲/▼" key to view trend graph.
- Press "⏻" key to return to recall list screen.

4.6.2 Data Deletion

Choose one record in the recall list, then longtime press "☼" key, an icon "🗑" will be displayed in the back of this record, as shown in Figure 16.

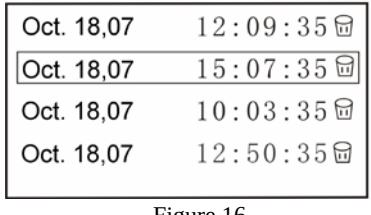


Figure 16

When finishing the selection of the records needed to be deleted, press "⏻" key, then the screen will prompt that "Delete all the marked records?" as shown in Figure 17, at this time select "Yes" and press "OK" key to delete all the selected records.

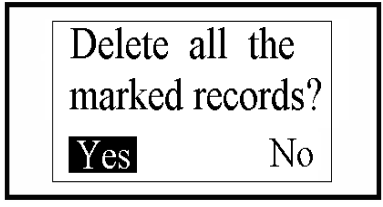


Figure 17

5 Technical Specifications

A. Display mode: dot-matrix monochrome LCD;

B. Power supply requirement:

3 x LR6 (AA) alkaline batteries

or Ni-MH rechargeable batteries

Supply voltage: 4.5V

Operating current: <50mA

Continuous working time: >30 hours

C. SpO_2 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: 35~100%

Measuring accuracy:

Not greater than 3% for SpO_2 range from 70% to 100%

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

Default alarm limit: 85%

SpO_2 alarm limit range: Low limit setting range: 85%~99%

D. Pulse Rate Parameter Specifications

Measuring range: 30bpm~240bpm

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

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

Pulse Rate alarm limit range：30bpm~240bpm

E. Perfusion Index Display

Range: 0~20%

F. Update rate:

8 beats moving average for both SpO_2 and pulse rate readings

G. Data Record

Record data once every 1/2/4/8seconds, up to 70–hour records.

H. The performance under low perfusion condition

The accuracy of SpO_2 and PR measurement still meet the precision described above when the modulation amplitude is as low as 0.5%.

I. Resistance to interference of surrounding light:

The difference between the SpO_2 value measured in the condition of indoor natural light and that of darkroom is less than ±1%.

J. The resistance to 50Hz /60Hz interference

SpO_2 and PR are precise which have been tested by BIO-TEK pulse oximeter simulator.

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

Net Weight: 210g (including batteries)

L. 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 service life (not a warrantly) of this device is 5 years. In order to ensure its long service life, please pay attention to the maintenance.

- Please change the batteries when the low-voltage indicator appears.
- Please take out the batteries if the oximeter will not be used for a long time.
- The recommended storage environment of the device:

  Ambient temperature: -20ºC ~60ºC

  Relative humidity 10%~95%

  Atmospheric pressure: 50kPa~107.4kPa

- 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 SpO2 simulator, or it can be done by the local third party test house.

7.2 Cleaning and Disinfecting Instruction

- 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.
- 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 SpO_2 and Pulse Rate display instable	1. The finger is not placed far enough inside. 2. The finger is shaking or the patient is moving.	1. Place the finger correctly inside and try again. 2. Let the patient keep calm.
Can not turn on the device	1. The batteries are drained or almost drained. 2. The batteries are not inserted properly. 3. The device is malfunctioning.	1. Change batteries. 2. Reinstall batteries. 3. Please contact the local service center.
No Display	1. The device will power off automatically when there is no signal and no operation for 1 minute. 2. The batteries are almost drained.	1. Normal. 2. Change batteries.

Appendix

Key of Symbols

Symbol		Description
Symbols on the screen	**%SpO_2**	The pulse oxygen saturation
	PI	Perfusion Index
	bpm	Pulse rate (Unit: beats per minute)
		Low battery voltage
		Alarm Icon
		Memory Icon
		Memory full

Symbol		Description
Symbols on the panels	**SpO_2**	SpO_2 probe connector
		Power/Back Key
		Mode/OK Key
		Recall/Backlight Key
		Navigation Key
		Data Interface
		CE mark
		Serial number
		Date of manufacture
		Authorised representative in the European community
		Manufacturer (including address)
		With Type BF applied part
		Warning ─ See User Manual
		Disposal of this device according to WEEE regulations

Common Knowledge

1 Meaning of SpO_2

SpO_2 is the saturation percentage of oxygen in the blood, so called O_2 concentration in the blood; it is defined by the percentage of oxyhemoglobin (HbO_2) in the total hemoglobin of the arterial blood. SpO_2 is an important physiological parameter to reflect the respiration function; it is calculated by the following method:

$$\mathbf{SpO_2 = HbO_2 / (HbO_2 + Hb) \times 100\%}$$

HbO_2 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 (HbO_2) and deoxygenated hemoglobin (Hb) have different absorption character in the spectrum range from red to infrared light (600nm~1000nm wavelength), by using these characteristics, SpO_2 can be determined. SpO_2 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 metahemoglobin.

Clinical application of pulse oximeters: SpO_2 is an important physiological parameter to reflect the respiration and ventilation function, so SpO_2 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 SpO_2 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 SpO_2 Range and Default Low Alarm Limit

In Campagna area, healthy people's SpO_2 value is greater than 94%, so the values below 94% are determined as hypoxia. SpO_2<90% is considered as the default threshold for determining anoxia by most researchers, so SpO_2 low alarm limit of the oximeter is set as 90% generally.

4 Factors affecting SpO_2 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 an arterial occlusion proximal to the sensor
- ✧ Blood vessel contraction caused by peripheral vessel hyperkinesias or body temperature decreasing

5 Factors causing low SpO_2 Measuring value (pathology reason)

- ✧ Hypoxemia disease, functional lack of HbO_2
- ✧ 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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