Instructions to User

Dear Users,

Thank you very much for purchasing our product. Please read the manual very carefully before using this device. Failure to follow these instructions can cause measuring abnormality or damage to the oximeter.

The manual is published in English and we have the ultimate right to explain the Manual. No part of this manual may be photocopied, reproduced or translated into another language without the prior written consent. We reserve the right to improve and amend it at any time without prior notice.

Version of the Manual: Ver 1.1

Revised date: July 19, 2012

3502-2290049

Warnings

- Check the device to make sure that there is no visible damage that may affect user's safety or measurement performance with regard to sensors and clips. It is recommended that the device should be inspected minimally once a week. When there is obvious damage, stop using the device.
- Special attention should be paid while the oximeter is used continuously under the ambient temperature exceeds 37°, burning hurt may occur because of over-heating on the sensor.
- An uncomfortable or painful feeling may appear if using the oximeter continuously on the same place for a long time, especially for poor microcirculation patients.
- It is recommended that the oximeter should not be applied to the same location for longer than 2 hours. If any abnormal condition is found, please change the position of oximeter.
- Avoid placing the device on the same limb which is wrapped with a cuff for blood pressure measurement or during venous infusion.

- DO NOT clip this device on edema or tender tissue.
- The light (the infrared light is invisible) emitted from the device is harmful to the eyes, so service technician or testee should not stare at the light.
- The oximeter is not a treatment device.
- When disposing of the monitor and its accessories, the local law should be followed.

Instructions for Operation

- The finger should be put in properly and correctly.
- Do not shake the finger. Keep at ease during measurement.
- Do not put wet finger directly into sensor.
- Avoid placing the device on the same limb which is wrapped with a cuff for blood pressure measurement or during venous infusion.
- Do not let anything block the emitting light from device.
- Vigorous exercise and electrosurgical device interference may affect the measuring accuracy.
- Using enamel or other makeup on the nail may affect the accuracy of measurement, too long fingernail may cause failure of measurement or

inaccuracy measurement result.

- Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- Existence of high intensive light sources, such as fluorescence light, ruby lamb, infrared heater or strong sunshine, etc. may cause inaccuracy of measurement result. Please put an opaque cover on the sensor or change the measuring site.
- 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.

Declaration of Conformity:

The manufacturer hereby declares that this device complies with the following standards:

IEC 60601-1

IEC 60601-1-2

ISO 9919

and follows the provisions of the council directive

MDD 93/42 EEC

Caution:

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

Content

1 Overview

1.1 Appearance

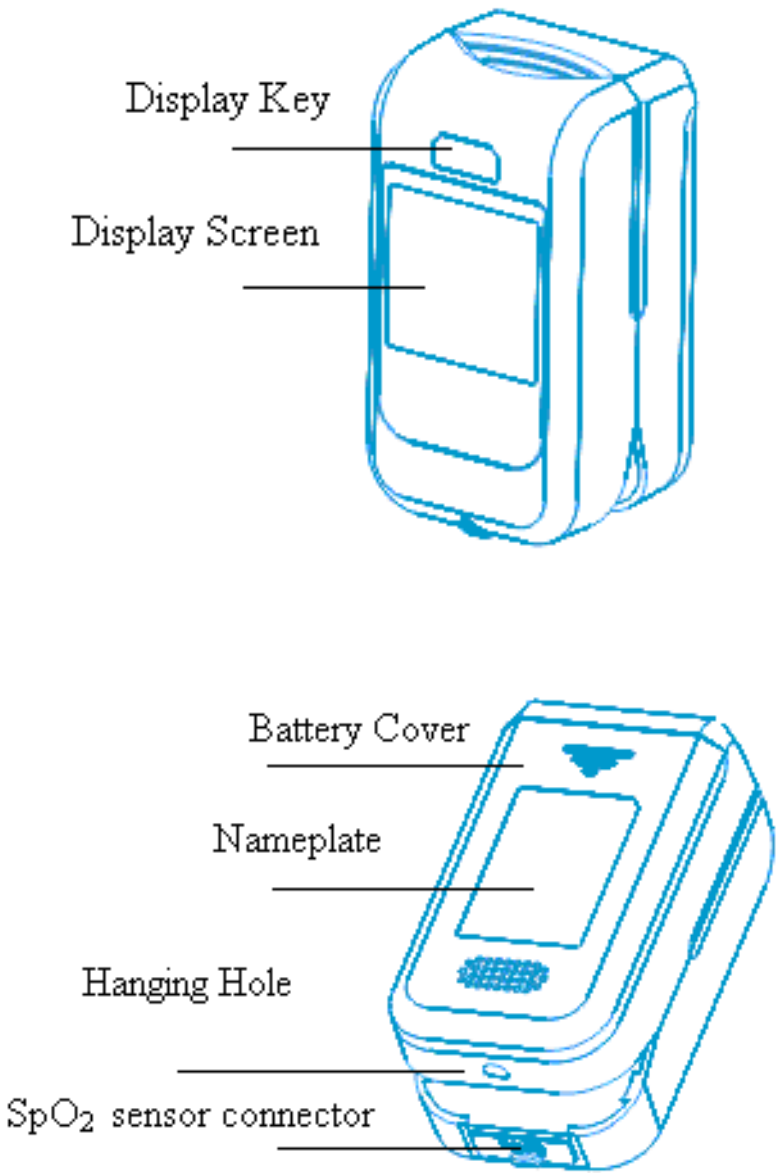

Figure 1 Front/Rear View

1.2 Name and Model

Name: Fingertip Oximeter

Model: PC-60N

1.3 Intended Use

This Fingertip Oximeter is intended for measuring the pulse rate and functional oxygen saturation (SpO_2) through patient's finger. It is applicable for spot-checking SpO_2 and pulse rate of adult and pediatric patients in homes and clinics.

1.4 Structure and Conformation

It consists of main unit and photoelectric sensor, and additional data upload connector.

1.5 Features

- External pediatric SpO_2 probe available
- Large true color OLED display of SpO_2, PR Pulse Bar, PI & Plethysmogram
- Innovative 4 directions display
- Automatic power on/off
- Audible & visible over-limit indication, high & low limits are adjustable

- Shift parameter display between PR and PI
- 2AAA alkaline batteries with low power consumption
- Low battery voltage indication

2 Battery Installation

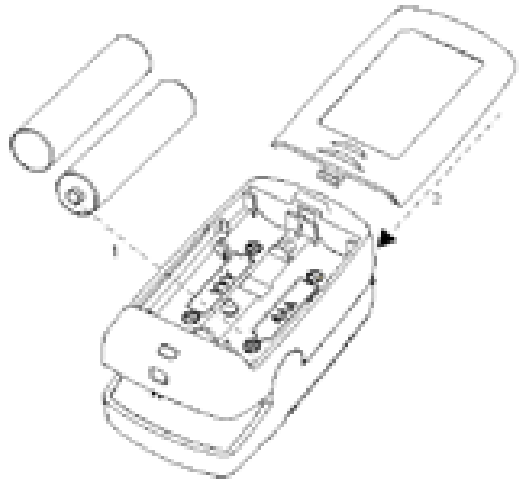

Figure 2 Battery Installation

1. Refer to Figure2, insert two AAA size batteries into the battery compartment properly.

2. Replace the cover.

Please make sure that the batteries are correctly installed, or incorrect installation may cause the device not to work.

3 Operation

3.1 Directly Measurement

1. Open the clip as shown in Figure 3.

Figure 3 Put finger into the Oximeter

2. Put finger into the rubber cushions of the clip (make sure the finger is in the correct position), and then clip the finger.
3. The device will power on automatically in 2 seconds, and start to display software version number.
4. Next enter into data display screen (as shown in Figure 4). User can read the values and view the waveform from display screen.

Shift parameter display between PR and PI during measurement:

Short time press Display Key, the display orientation will rotate 90 degree, at the same time, PR value is shifted to PI value automatically (as shown in 4B). When shown as 4B, the display will shift to 4C automatically after 20 seconds without operation. Press the key again, the screen

will change another direction (as shown in 4D). It obviously shows that shifting parameter between PR and PI is under the condition of the display orientation rotating to a side, as shown in 4B and 4E. After 20 seconds without operation, the PI will automatically shift back to PR, as shown in 4C and 4F.

Figure4A

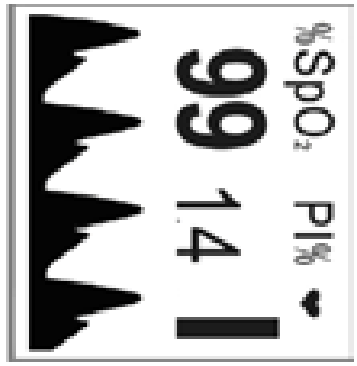

Figure4B

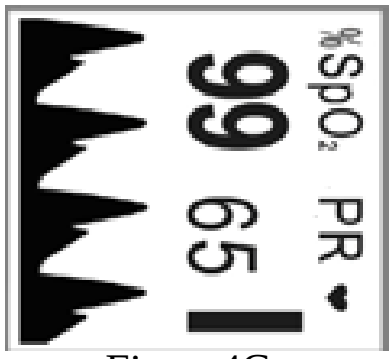

Figure4C

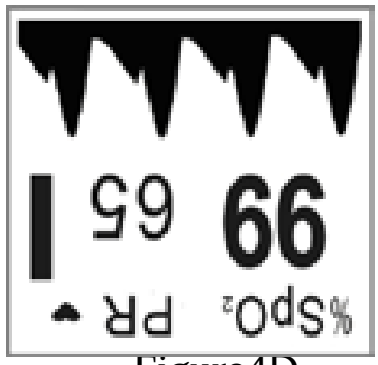

Figure4D

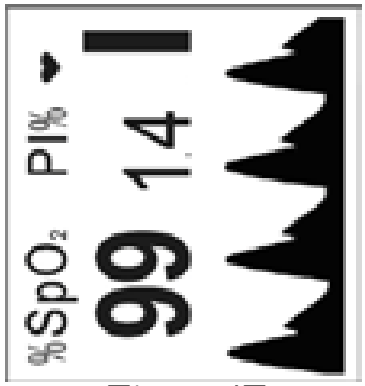

Figure4E

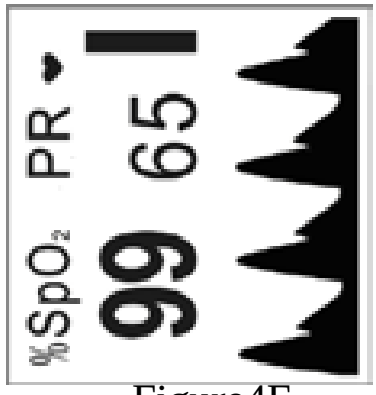

Figure4F

Screen Description:

- ✧ **"%SpO_2":** SpO_2 symbol; **"99":** SpO_2 value;
- ✧ **"PR":** Pulse Rate icon; **"65":** Pulse Rate value;
- ✧ **"❤":** Pulse beat symbol;
- ✧ **"▌":** Pulse intensity bar graph.
- ✧ **"PI%":** Perfusion index icon; **"1.4":** Perfusion Index value;

3.2 Over-limit indication and Beep Silence

When measuring, if SpO_2 value or pulse rate value exceeds the preset alarm limit, the device will beep automatically and the value which exceeds limit on the screen will flash. The detailed information refers to chapter 4.

When the beep sound is activated by over-limit, it will become silence at the following situations:

1. When SpO_2 and PR value return to normal range.

2. Press Display Key to mute. If this over-limit event continues, the oximeter will resume beeping automatically later in 2 minutes.

3. Remove the finger from the oximeter or SpO_2 probe.

3.3 Setup Menu Screen

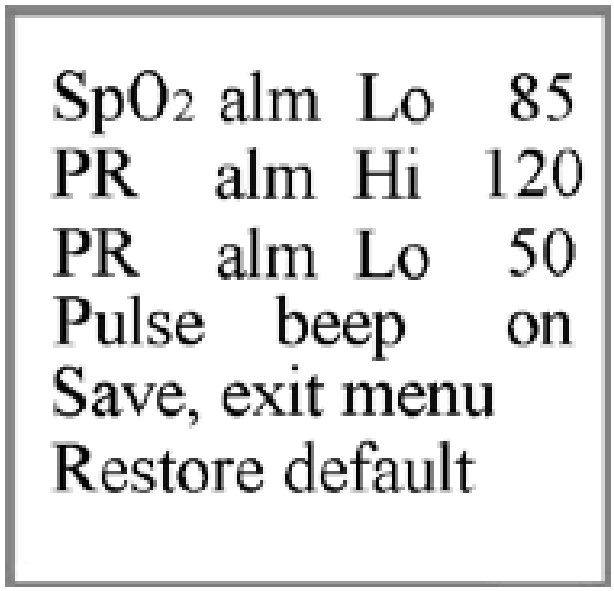

Figure 5 Menu Screen

Long time pressing display key could enter the setup menu screen.

Setup Menu Screen Description：

“SpO_2 alm Lo”: SpO_2 lower limit. The user can modify the value within 85~99, the step is “1”, the default is 90.

“PR alm Hi”: Pulse Rate high limit. The user can modify the value within 100~240, the step is “5”, the default is 120.

“PR alm Lo”：Pulse Rate low limit. The user can modify the value within 30~60, the step is “1”, the default is 50.

“Pulse beep”：Pulse beep option. If it is set to on, every pulse beat makes a beep, and the pitch tone of this beep changes according to SpO_2 value (within 90~99%).

“Save, exit menu”：Long time pressing this item

to store settings and exit from the setup menu to the normal display screen.

“Restore default”：Restore default setting. Refer to Figure 5 for each default value.

On setup menu screen:

1. Short time press Display Key to choose the setting item;
2. Longtime press Display Key to active the setting item, then short time press it to modify the setting parameter;
3. Next, longtime press Display Key to confirm the modification and exit from this setting item.
4. At last, move the setting item to “Save, exit menu”, and long time pressing Display Key to store the modification and exit from the setup menu.

3.4 External SpO_2 Probe Connection

1. Connect the external SpO_2 probe to SpO_2 sensor connector in the following way. Make sure the side with “Arrow” faces upwards.

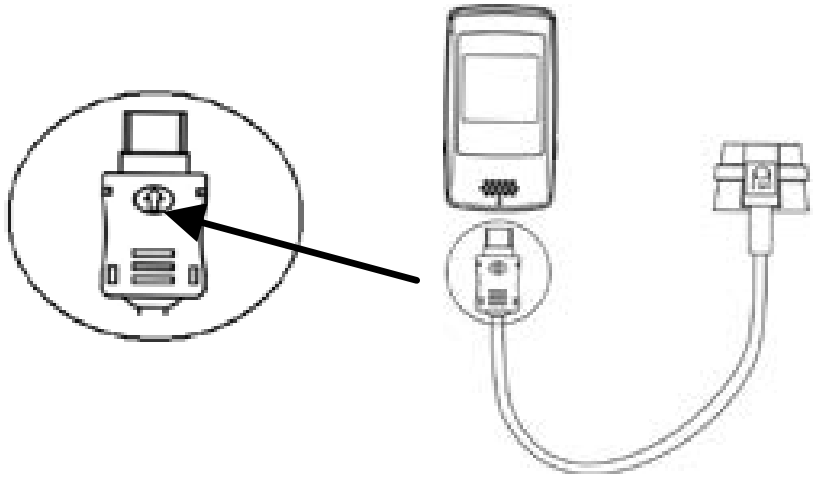

Figure 6 Probe Connection

Note: when the external SpO_2 probe is connected well, the built-in finger clip sensor will be disabled. The measurement is detected from the external SpO_2 probe.

2**.** The finger should be put in SpO_2 probe properly and correctly.

3. The oximeter will power on automatically 2 seconds later, then display software version number.

4. Other operation is similar to chapter 3.1 directly measurement.

4. Technical Specifications

A. Technique: dual-wavelength LED sensor,

LED sensor wavelength:

Red light: 663 nanometers,

Infrared light: 890 nanometers.

Maximal optical output power:

less than 1.5mW maximum average.

B. SpO_2 measurement

Measuring range: 70%~100%

Measuring accuracy:

A_{rms} is not greater than 3% for SpO_2 range from 70% to 100%

Note: A_{rms} is defined as root-mean-square value of deviation according to ISO 9919.

SpO_2 low limit setting range:

85%~99% (default 90%)

C. Pulse Rate measurement

Measuring range: 30bpm~240bpm

Measuring accuracy: ±2bpm or ±2% (whichever is greater)

Pulse Rate limit setting range:

high limit: 100~240bpm (default 120bpm)

low limit: 30~60bpm (default 50bpm)

D. Perfusion Index(PI) Display

Range: 0.2%~20%

E. Audible &visual over-limit indication

When measuring, if SpO_2 value or pulse rate value exceeds the preset limit, the device will beep automatically and the value which exceeds limit on the screen will flash. The oximeter will shut down automatically in 8 seconds with no signal.

F. Display mode: Color OLED Display

G. Power supply requirement:

2 x LR03 (AAA) alkaline batteries

Supply voltage: 3.0VDC

Operating current: ≤40mA

H. Environment requirement

Operating Temperature: 5 ~40°C
Operating Humidity: 30~80%
Atmospheric pressure: 70~106kPa

I. The performance under low perfusion condition

The accuracy of SpO_2 and PR measurement still meets the specification described above when the modulation amplitude is as low as 0.6%.

J. 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%.

K. Dimensions: 60 mm (L) × 33 mm (W) × 30 mm (H)

Net Weight: 35g (including battery)

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

5. Accessories

A. A lanyard
B. Two batteries
C. A pouch
D. An External SpO_2 Probe (optional)
E. A User Manual
F. Quality Certificate

Note: The accessories are subject to change. Detailed items and quantity see the Packing List.

6. Repair and Maintenance

6.1 Oximeter Maintenance

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

- Please change the batteries when the low-voltage indicator lightens.
- Please clean the surface of the oximeter before use. Use soft cloth with alcohol to wipe the oximeter first, and then let it dry in air or wipe it dry.
- 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 precision 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.

- Necessary servicing must be performed by qualified service engineers ONLY. Users are not permitted to maintain it by themselves.

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

⚠ **Do not immerse the device in liquid.**

6.2 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 soft cloth wet with clean water and let air dry or wipe it dry.

Caution: Do not sterilize by irradiation steam, or ethylene oxide.

Do not use the sensor if it is damaged.

7. 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 it gets no signal for 8 seconds. 2. The batteries are almost drained.	1. Normal. 2. Change batteries.

Appendix

A Key of Symbols

Symbol	Description
	With Type BF applied part
	Warning — See User Manual
%SpO_2	The pulse oxygen saturation
PR	Pulse rate (beats per minute)
	Pulse rate icon
	Low battery voltage
SN	Serial number

B SpO_2 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 treatment has become more popular. (For example, such as monitoring patients with serious respiratory disease, patients under anesthesia during operation and premature and neonatal infants) The status of SpO_2 can be determined in timely manner by measurement and will allow finding the hypoxemia patient earlier, thereby preventing or reducing accidental death caused by hypoxia effectively.

3.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

4. 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