CREATIVE MEDICAL

Fingertip Oximeter

PC-60B1

User Manual

Shenzhen Creative Industry Co., Ltd.

Instructions to User

Dear Customers,

Thank you for purchasing this quality 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 14th, 2019

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Notes

- The contents contained in this manual are subject to change without notice.
- Information furnished by our company is believed to be accurate and reliable. However, no responsibility is assumed by us for its use, or any infringements of patients or other rights of third parties that may result from its use.

Instructions for Safe Operation

- 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 before each use. If there is obvious damage, stop using the device.
- Special attention should be paid while the oximeter is used constantly under the ambient temperature over 37°C, burning hurt may

occur because of over-heating of the sensor at this situation.

- Necessary maintenance must be performed only by qualified service technicians. Users are not permitted to service this device.
- The Oximeter must not be used with devices and accessories 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 patient is under MRI or CT scanning. This device is NOT MRI Compatible.

Warnings

- Discomfort or pain may appear if using the Oximeter continuously on the same location for a long time, especially for patient with poor microcirculation. 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.

- 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. Do not stare at the light.
- The oximeter is not a treatment device.
- Local laws and Regulations must be followed when disposing of the device.

Attentions

- Keep the Oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- The device should be kept out of the reach of children.

- If the Oximeter gets wet, please stop using it and do not resume operation until it is dry and checked for correct operation. When it is carried from a cold environment to a warm and humid environment, please do not use it immediately. Allow at least 15 minutes for Oximeter to reach ambient temperature.
- DO **NOT** operate the button on the front panel with sharp materials or sharp point.
- DO **NOT** use high temperature or high pressure steam disinfection on the Oximeter. Refer to Chapter 7 for instructions regarding cleaning and disinfection.
- The equipment is IP22 with protection against harmful solid foreign objects and ingress of liquid. So that means the equipment is protected against solid foreign objects of 12.5mm and greater, and protected against

vertically falling water drops when enclosure tilted up to 15°.

- Please pay attention to the effects of lint, dust, light (including sunlight), etc.

Declaration of Conformity

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

IEC 60601-1: 2005 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance;

BS/EN/ISO 9919:2009 or the equivalent ISO 80601-2-61:2011 - Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.

And it also 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.

Table of Contents

1 Overview

1.1 Appearance

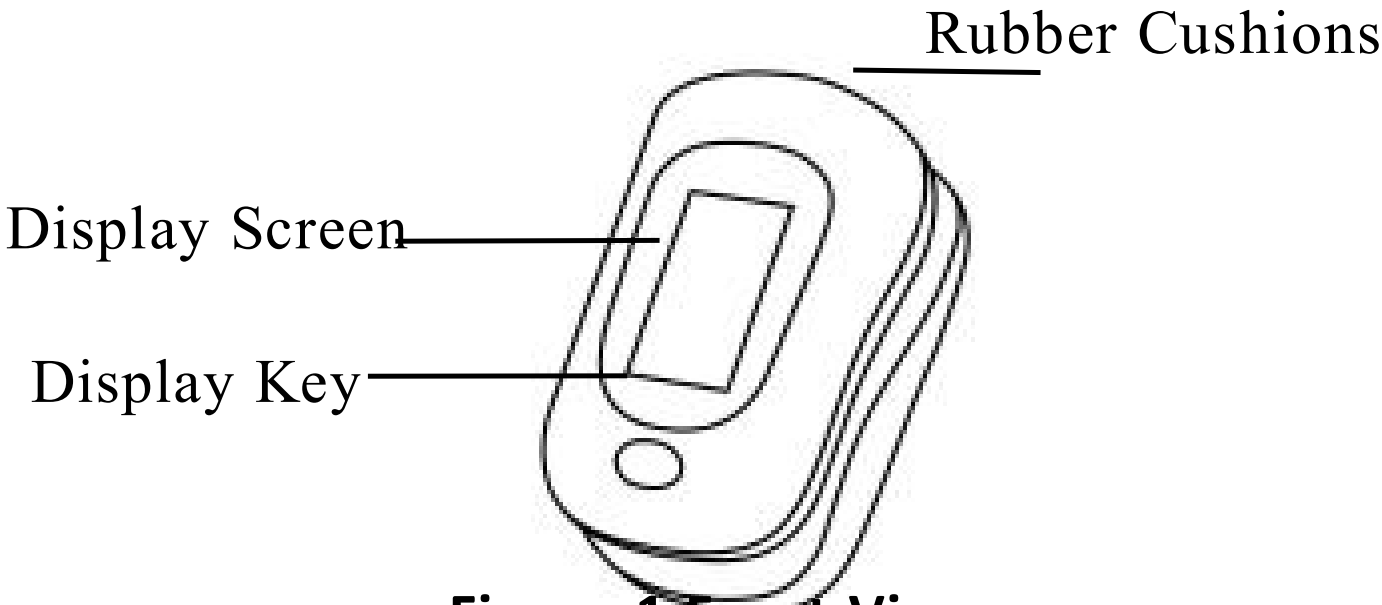

Figure 1 Front View

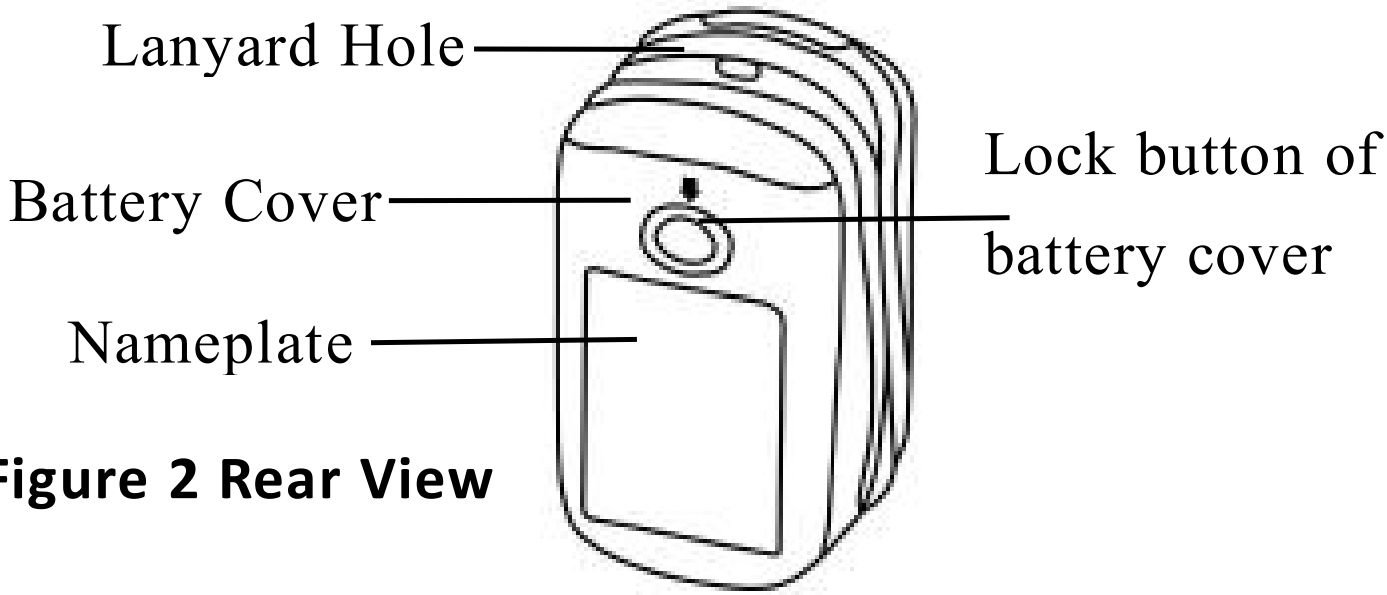

Figure 2 Rear View

Note: the appearance is for demonstration only, please refer to the oximeter you purchased.

1.2 Name and Model

Name: Fingertip Oximeter

Model: PC-60B1

1.3 Intended Use

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

1.4 Feature List

- ✧ Large true color OLED display of SpO_2, PR and pulse plethysmogram.
- ✧ PI display is available
- ✧ Innovative 4 directions display
- ✧ Automatic power on/off

- ✧ Audible & visible over0limit indication
- ✧ Setting menu is available
- ✧ Shift parameter display between PR and PI
- ✧ 2 AAA alkaline batteries with low power consumption
- ✧ Low battery voltage indication

2 Battery Installation

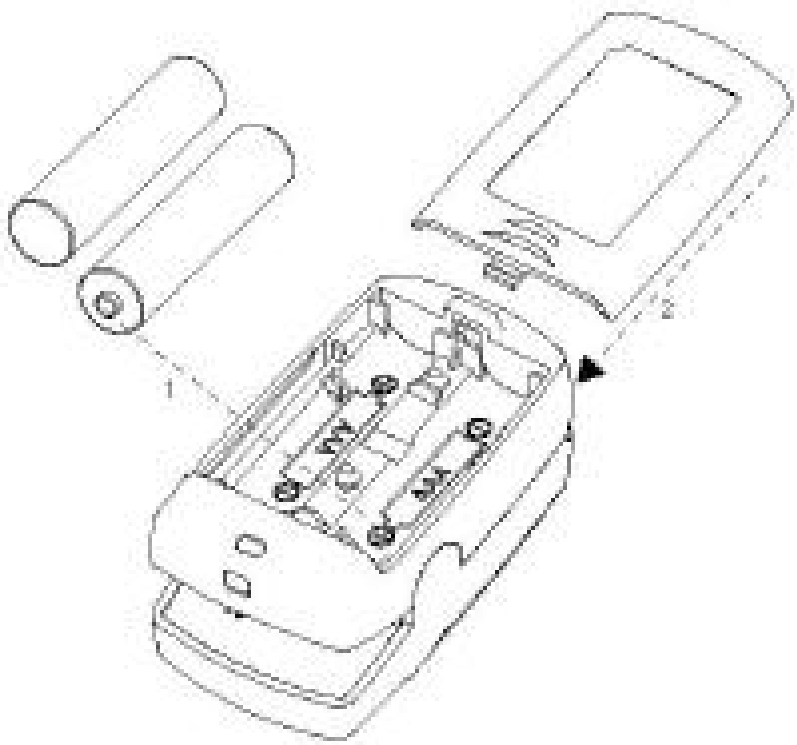

Figure 3 Battery Installation

1. Refer to Figure 3, insert two AAA size batteries into the battery compartment properly, and

note the polarity markings.

2. Replace the cover.

- Please make sure that the batteries are correctly installed. Incorrect installation may cause the device not to work.
- Please remove batteries if the device is not being used for more than 7 days to prevent and avoid potential damage from the battery leaking. Any such damage is not covered under the product warranty.

3 Operation

1. Open the clip as shown in figure 3.

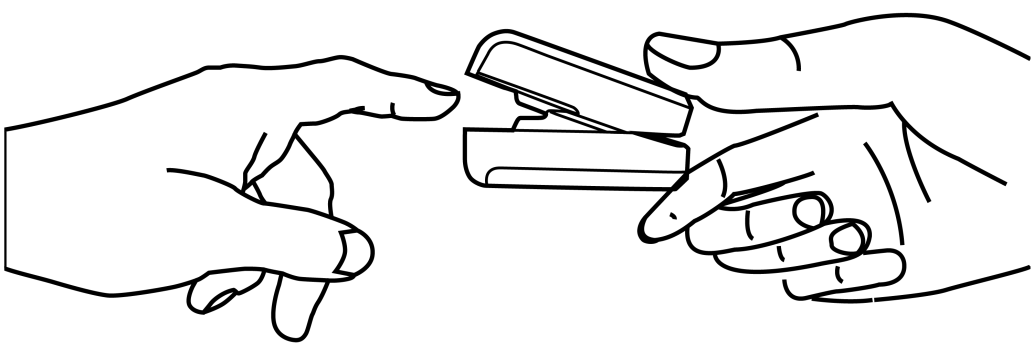

Figure 4 Put finger into the Oximeter

2. Put finger inside 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. Then the device enter into data display screen, as shown in figure 5. The user can read the values and view then waveform from display screen.

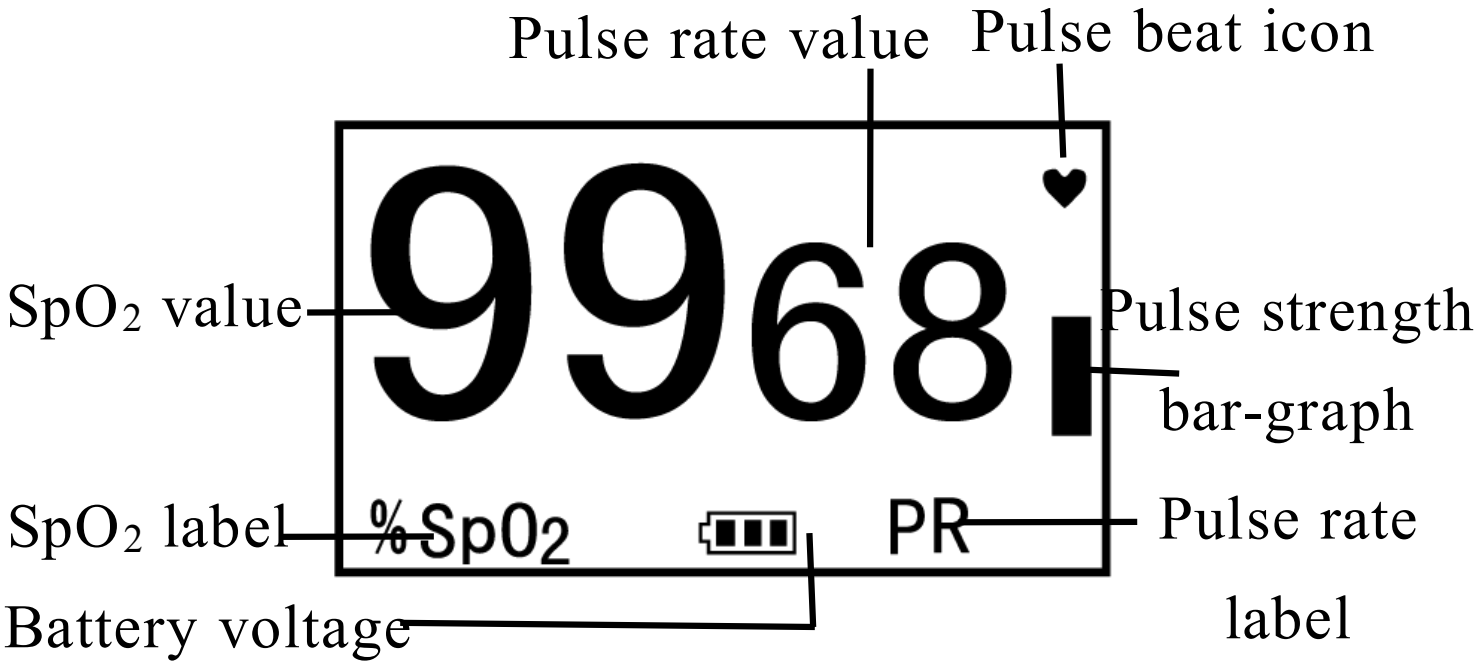

Figure 5 Default measuring screen

➢ For PC-60B1, when short time press Display Key to change display direction, PI value will automatically display on the device instead of PR value, PR value will restore after 20 seconds. Please refer to figure 6~9 for the oximeter with 4 display directions and PI display.

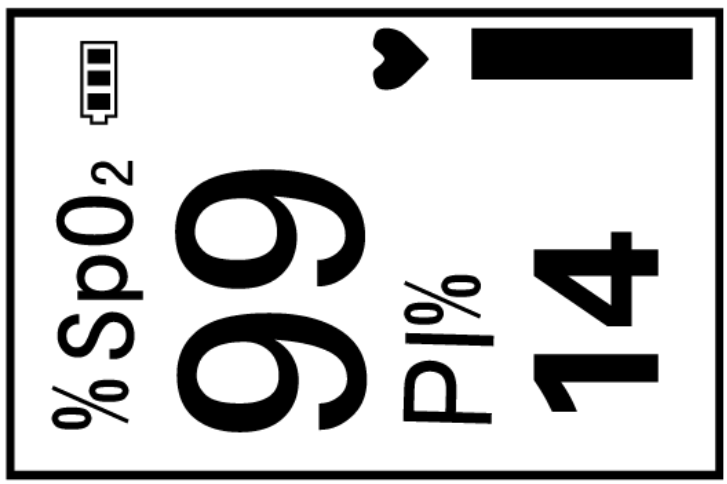

Figure 6

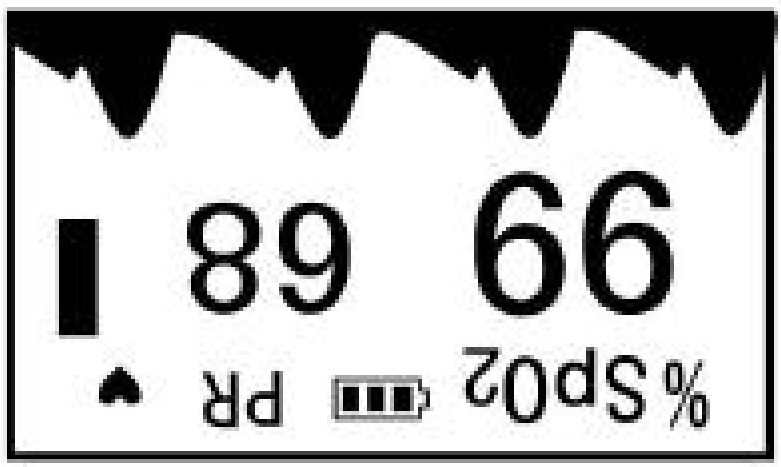

Figure 7

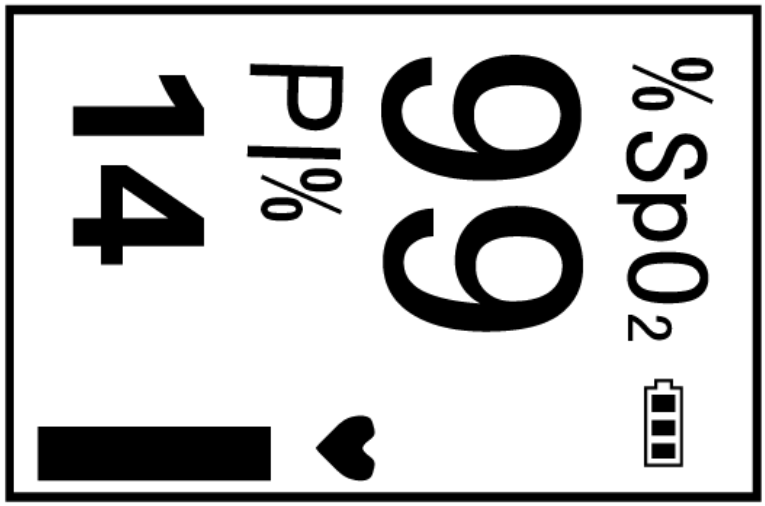

Figure 8

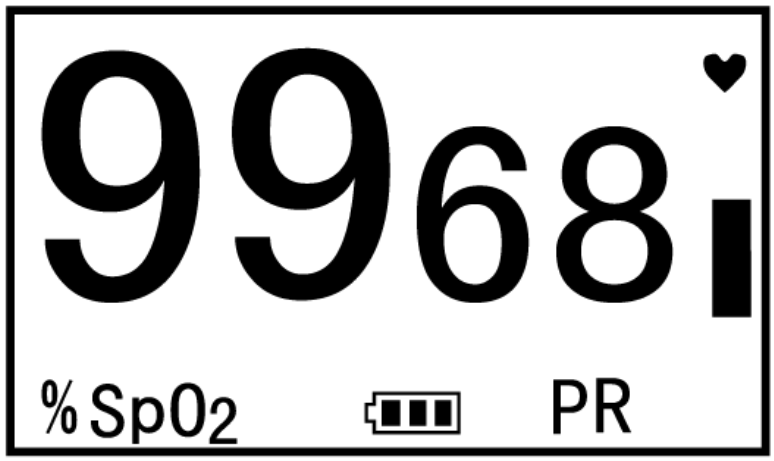

Figure 9

5. Long time press Display key to enter into the Setup Menu screen, as shown in figure 10.

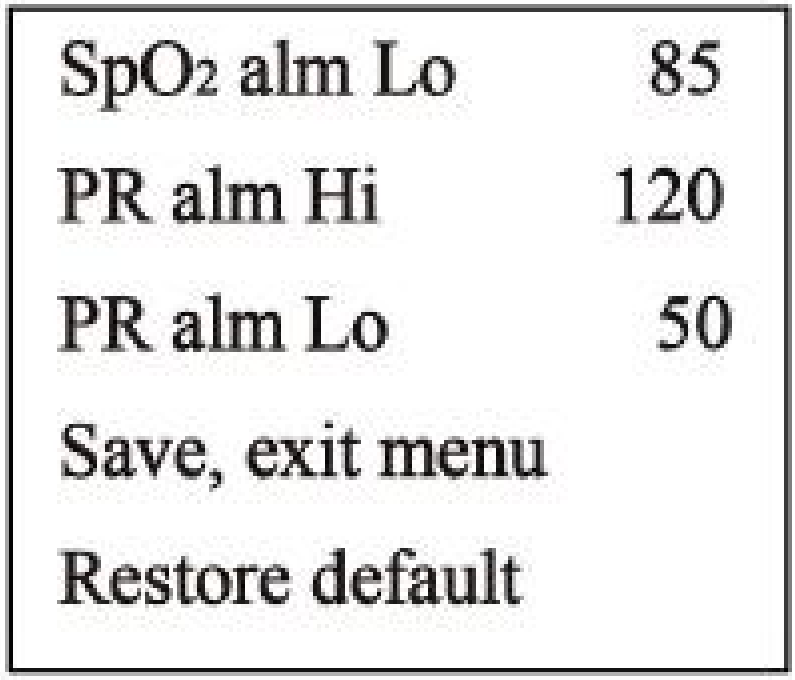

Figure 10

- **SpO_2 alm Lo:** SpO_2 low limit setting; range: 85%~99%, the step is 1%. The factory default value 85%.
- **PR alm Hi:** High limit setting of pulse rate; range: 100~240bpm, the step is 5bpm. The factory default value is 120bpm.
- **PR alm Lo:** Low limit setting of pulse rate; range: 30~60bpm, and the step is 1bpm. The factory default value for is 50bpm.

- **Save, exit menu:** Move the setting item to “Save, exit menu”, and long time pressing Display Key to store the modification and exit from the setup menu.
- **Restore default:** Move the setting item to “Restore default”, and long time pressing Display Key to restore to default setting.

Menu setup:

Short time press Display Key to choose the setting item; Longtime press Display Key to active the setting item, then short time press it to modify the setting parameter; Next, longtime press Display Key to confirm the modification and exit from this setting item. 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.

Attention to the operation

- The finger should be put into the sensor

correctly.

- Do not shake the finger and relax 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, i.e. do not use finger nail polish/paints.
- Vigorous exercise and electrosurgical device interference may affect the measuring accuracy.
- The orientation-sensor works on the basis of the gravity. A small movable metal ball is built in the orientation-sensor for detecting the orientation of the oximeter. When you want to change the oximeter’s display

direction, if you move the Oximeter too slowly, the movable metal ball will also move slowly because of not enough acceleration. Consequently the response of orientation detection would be delayed. Acceleration needs to be provided to the orientation-sensor for quick sensing the orientation change.

- Nail polish may affect the measuring accuracy, and too long fingernail may cause failure of measurement or inaccurate result.
- 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 necessary.
- 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 Technical Specifications

A. SpO_2 Measurement

Transducer: dual-wavelength LED sensor with wavelength:

Red light: 663 nm, Infrared light: 890 nm.

Maximal average optical output power: ≤2mW

SpO_2 display range: 35%~100%

SpO_2 measuring accuracy:

≤ 3% for SpO_2 range from 70% to 100%

B. Pulse Rate measurement

PR display range: 30bpm~240bpm

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

C. Perfusion Index(PI) Display range

0%~20%

D. Over-limit indication settings:

SpO_2:

low limit setting range: 85%~95%

Default setting: 85%

Pulse Rate:

Low limit setting range: 30~60bpm;

High limit setting range: 100~240bpm;

Default setting: high: 120bpm; low: 50bpm

E. Audible & visual alert function

When measuring, if SpO_2 value or pulse rate value exceeds the preset limit, the device will alert with beep automatically and the value which exceeds limit will flash on the screen.

H. Power supply requirement:

2 x LR03 (AAA) alkaline batteries

Supply voltage: 3.0VDC

Operating current: ≤40mA

I. Environmental Conditions:

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

J. Low Perfusion Performance:

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

K. Ambient Light Interference:

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

L. **Dimensions:** 66 mm (L) × 36 mm (W) × 33 mm (H)

Net Weight: approx. 60g

M. 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 solid foreign objects and ingress of liquid: The equipment is IP22 with protection against harmful solid foreign objects and ingress of liquid.

Electro-Magnetic Compatibility: Group I, Class B

5 Repair and Maintenance

5.1 Maintenance

The expected service life (not a warranty) 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 lightens.
- Please clean the surface of the device before using, with 75% alcohol wipes, then let it air dry or wipe it dry. Do not allow liquid to enter the device.
- Please take out the batteries if the oximeter will not be used any more than 7 days.
- 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, so there is no need to calibrate it during its life cycle. Any SpO_2 simulators should not be used to validate the accuracy of the oximeter, they can only be used as functional testers to verify its precision. The SpO_2 accuracy claimed in this manual is supported by the clinical study conducted by inducing hypoxia on healthy, non-smoking, light-to-dark skinned subjects in an independent research laboratory.
- If it is necessary to verify the precision of the oximeter 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. Please note that the specific calibration curve (so called R-curve) should be selected when use of SpO_2 simulator, e.g. for Index 2 series SpO_2 simulator from Fluke Biomedical Corporation, please set "Make" to "DownLoadMake: KRK", then the user can use this particular R-curve to test the oximeter. If the SpO_2 simulator does not contain "KRK"

R-curve, please ask the manufacturer for helping to download the given R-curve into the SpO_2 simulator.

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

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

⚠ **It is recommended that the device should be kept in a dry environment. Humidity may reduce the life of the device, or even damage it.**

5.2 Cleaning and Disinfecting Instruction

- Surface-clean sensor with a soft cloth damped with a solution such as 75% isopropyl alcohol, if low-level disinfection is required, use a mild bleach solution.
- Then surface-clean with a cloth damped ONLY with clean water and dry with a clean, soft cloth.

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

Do not use the Oximeter if it is damaged.

6 Troubleshooting

Problem:

1. The SpO_2 and Pulse Rate display instable
2. Can not turn on the device
3. No display
4. Display direction doesn't change or changes insensitively.
5. No display of the wireless icon "  "

Solution

1. Place the finger correctly inside and try again.
2. Changing batteries.
3. Let the patient keep calm.
4. Please shake the oximeter with a certain force to make the movable metal ball move freely. If the problem still exists, maybe the orientation-sensor is not working properly.
5. Hardware failure of wireless transmission function.
6. If the above problem still exists please contact the local service center.

7 Packing List

1) Fingertip Oximeter
2) User Manual
3) Batteries

Note: the items and its quantity are subject to change, please refer to your subject in hand.

8 Key of Symbols

Symbol	Description
%SpO_2	Pulse oxygen saturation
♥BPM/PR	Pulse rate (beats per minute)
PI%	Perfusion Index (%)
	Pulse Strength Bar Graph
	Low battery voltage
	CE mark
SN	Serial number

	Date of manufacture
	Authorised representative in the European community
	Manufacturer (including address)
	BF type applied part
	Attention – refer to User Manual
	Follow WEEE regulations for disposal

9 Frequently Asked Questions

1. Q: What's SpO_2?

A: SpO_2 means the saturation percentage of oxygen in the blood.

2. Q: What's the normal range of SpO_2 value for healthy people?

A: The normal range varies by individual, but usually over 95%, otherwise, please consult your physician.

3. Q: What's the normal range of PR value for healthy people?

A: Usually, the normal range is 60bpm~100bpm.

4. Q: Why do the display value of SpO_2 and PR vary with time?

A: The measured SpO_2 and PR value changes in correspondence with the change of patient's

physiological conditions.

5. Q: What to do if there is no SpO_2 and PR reading?

A: Do not shake the finger, and keep calm during the measurement. Please also avoid the oximeter and the cuff on the same limb for blood pressure and oxygen saturation measurement simultaneously.

6. Q: How to confirm that the SpO_2 reading is true or accurate?

A: Hold breath for a while (50 seconds or more), if the SpO_2 value significantly decreases, it means that the SpO_2 reading truly reflects the physiological condition change.

7. Q: When to replace the batteries?

A: The icon of low battery will appear on the

screen when the battery voltages are low. By then, batteries need to be replaced.

8. Q: What to do if the oximeter is moistened or sprayed by water?

A: Remove the batteries immediately and dry the oximeter completely with a hair dryer.

9. Q: What factors will affect the SpO_2 accuracy?

A:a) Intravascular dyes such as indocyanine green or methylene blue;

b) Exposure to excessive illumination, such as surgical lamps, bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight;

c) Vascular dyes or external used color-up product such as nail enamel or color skin care;

d) Excessive patient movement;

e) Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line;

f) Exposure to the chamber with High pressure oxygen;

g) There is an arterial occlusion proximal to the sensor;

h) Blood vessel contraction caused by peripheral vessel hyperkinesias or body temperature decreasing;

i) Low perfusion condition (Perfusion Index is small).

Please contact the local distributor or manufacturer if necessary.

Quality Certificate

Name: Fingertip Oximeter

Model: _____

Date: _____

QA: _____

This prosuct has been inspected in accordance with the standards specified in the User Manual.

Shenzhen Creative Industry Co., Ltd

CE 0123

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