User Manual

Wrist Oximeter

Quality Certificate

Name: _____

Model: _____

Date: _____

QA: _____

The Product has been Inspected in accordance
with the standards specified in User's Manual
Shenzhen Creative Industry Co.,Ltd.

Instructions to User

PC-68B Wrist Oximeter is a precision measuring device, please read the manual very carefully before using this device. Failure to follow these instructions may cause measuring abnormality or damage to the oximeter.

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Version of This Manual: Ver 1.1

Revised date: February 9th , 2015

Product service life: 5 years (no warranty)

Manufacturing date: See Label

3502-2290068

Notes

● The contents contained in this manual are subject to change without prior notice.

Information furnished by Creative is believed to be accurate and reliable. However, no responsibility is assumed by us for its use, or any infringements of patents or other rights of third parties that may result from its use.

● Instructions for Safe Operations

● Check the device to make sure that there is no visible damage that may affect user's safety and measurement performance. When there is obvious damage, stop using the device.

● Necessary servicing **must be performed by qualified** service engineers **ONLY**. Users are not permitted to maintain 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

- ☀ For individual patients, there should be a more prudent inspecting in the placing process. The device can not be clipped on the edema and tender tissue.

- ☀ The light (the infrared light is invisible) emitted from the sensor is harmful to the eyes, so the user or even the service engineer should not stare at the light emitting components.

- ☀ To dispose the device, the local law should be followed.

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 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.

Declaration of Conformity:

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

IEC 60601-1

ISO 9919

and follows the provisions of the council directive MDD93/42/EEC.

Contents

1 Overview

1.1 Appearance

Figure 1 Front View

1. LCD screen

2. Set Key "■" : shift display modes, confirm the operation etc.

3. Scroll Key"▲": Short Press to move display cursor, modify parameter values etc.

   Long Press to choose display always on or not which will be effective during measurement.
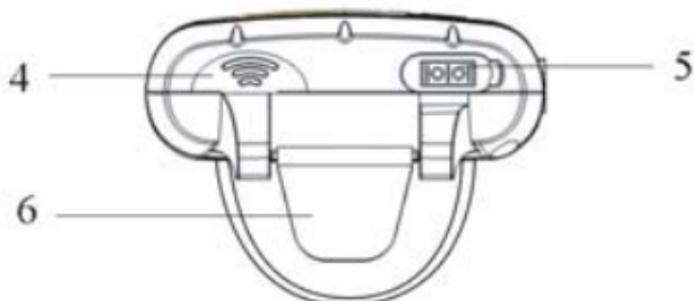
Figure 2 Frontal Side View

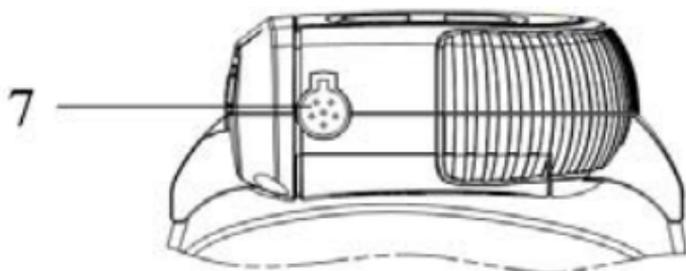**4. Buzzer**

5. Data interface

6. Wristband Underlay

Figure 3 Right Side View

7. SpO₂ probe receptacle

1.2 Name and Model

Name: Wrist Oximeter
Model: PC-68B

1.3 Conformation

It comprises the main unit and SpO_2 probe.

1.4 Features

Wrist Oximeter can be used to measure and record the functional oxygen saturation (SpO_2) and pulse rate accurately. Simply put your finger into sensor, SpO_2 value and pulse rate value will be displayed on screen and stored in the device.

- It is light weight, small in size and easy to carry;
- Color OLED display;
- Perfusion index (PI) display is available;
- Automatic starts to measure SpO_2 and Pulse Rate (PR);
- Real-time clock display and setting;
- Over-limit alert by audible beep, visible display and vibration of the oximeter, the over limits can be adjustable;
- It is convenient for you to measure SpO_2 and pulse rate in long-term while sleeping or at other daily activity.

- Recording interval can be selected, up to 480 hours data memory;

- Applicable for longtime continuous measurement;

- PR trend curve and SpO_2 trend curve view;

- Data storage and transmission to PC for view and analysis (Optional);

1.5 Intended Use

This Wrist Oximeter is intended for measuring the pulse rate and functional oxygen saturation (SpO_2). It is applicable for long-term measurement of adult's SpO_2 and pulse rate in home and clinics.

1.6 Key of Symbols

| Symbol	Description
%SpO₂	Pulse Oxygen Saturation
PI%	Perfusion Index
PR	Pulse Rate
🛑	Wireless icon
⟻	USB interface
♥	Pulse rate icon
▭	Low battery voltage
●	icon for display always on
🗄	Full memory icon
SN	Serial number
ᴍᴵ	Date of manufacture
EC REP	Authorized 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

2 Battery Installation
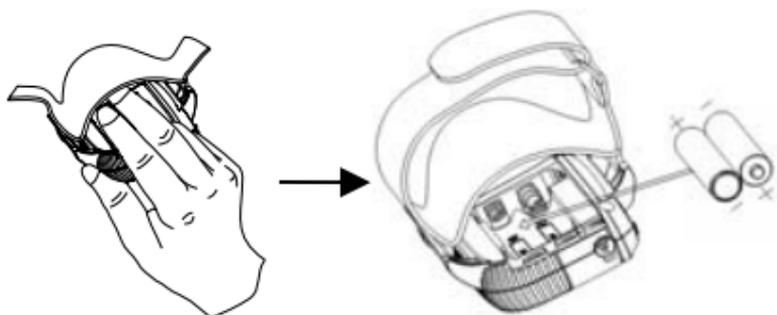
Figure 4 Battery Installation

1. Lift up the cloth covered on the battery cover. Then, use your index finger and middle finger to press against the battery cover. Meanwhile, slide it towards the side with SpO_2 probe (as shown in Figure 4).

2. Refer to Figure 4, insert two AAA size batteries into the battery compartment properly in the right direction.

3. Replace the cover.

Remark: After finishing battery installation, the oximeter will automatically power on and display software version number firstly.

⚠Please take care when you insert the batteries, as the improper insertion may make the device not work.

3 Operation

NOTE for key button operation:

Long pressing: press a key down more than 1 second.

Short pressing: press a key down then let it go immediately (less than 1 second).

The following methods can activate the device while it is in standby status:

1. Short press Set Key "■"to activate the screen display.

2. Insert finger into the probe to activate the measurement and screen display automatically.

3. When USB data cable is connected between the device and PC, it will enter data uploading mode.

NOTE : If the calendar clock time has not been set, the device will enter the Time Settings screen while it powers up.

The device will enter standby status automatically if there is no key-press and no measuring signal in 20 seconds. That is the only way to turn it off (i.e. at standby status).

3.1 Taking Measurement

1. Insert the SpO_2 probe connector into the SpO_2 probe receptacle on the device properly.
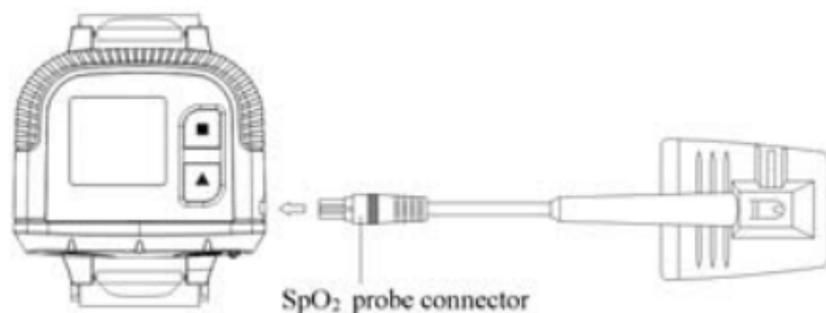
SpO₂ probe connector

Figure 5 SpO₂ Probe Connection

2. Fix the oximeter on your left wrist (Figure 6);

3. Then, hold the probe with its opening towards your index finger. The probe should be oriented in such a way that the sensor side with a finger tip icon is positioned on the top (Figure 6).
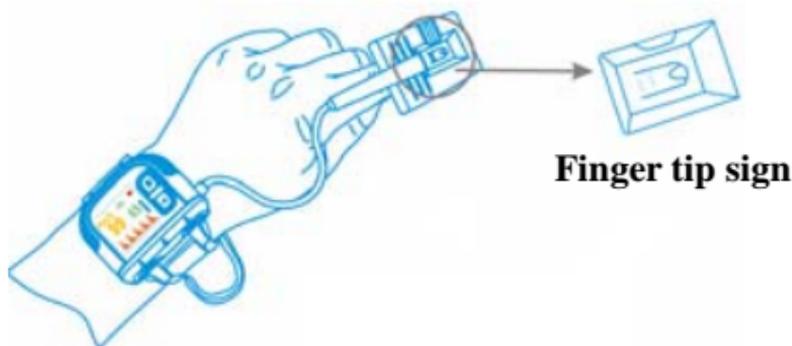

Finger tip sign

Figure 6 Placement Illustration

4. Next, insert your index finger into the probe until the fingernail tip rests against the stop at the end of the probe

(Figure 7). Adjust the finger to be placed evenly on the middle base of the sensor (make sure the finger is in the right position). If the index finger cannot be positioned correctly, or is not available, other finger can be used.

Figure 7

Wrong Placement of the Probe:

Finger out　　　　**Not deep enough**

Figure 8

5. The oximeter will automatically start measurement in 2 seconds. Then the default screen will be displayed (Figure 9A). User can read the values and view the waveform from the display screen.
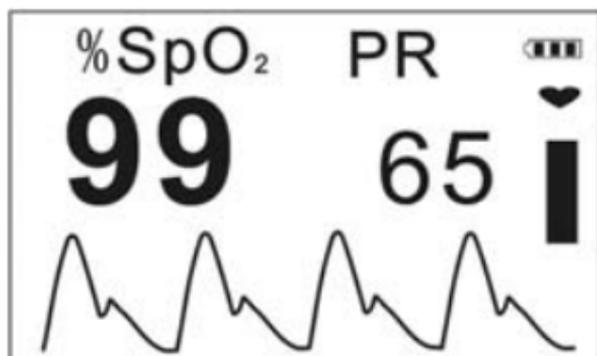
Figure 9 Default Screen Display

- ✧ **"%SpO$_2$":** SpO$_2$ label; **"99":** SpO$_2$ value;
- ✧ **"PR":** Pulse rate label; **"65":** Pulse rate value;
- ✧ **"❤":** Pulse beat icon;
- ✧ **"▥":** Battery indicator;
- ✧ **"▮":** Pulsation bar-graph;
- ✧ The displayed waveform is plethysmogram.

Key Operations:

- Short press " ■ " key to switch display modes circularly, display screen will be switched among the three measure screens displays as shown in Figure 9A, Figure 9C and Figure 9D.
- Long press " ▲ " key: choose display always on or not which will be effective during measurement. If you choose display always on, the icon (" ● ")for "display always on" will appear on the screen as

shown in Figure 9B.

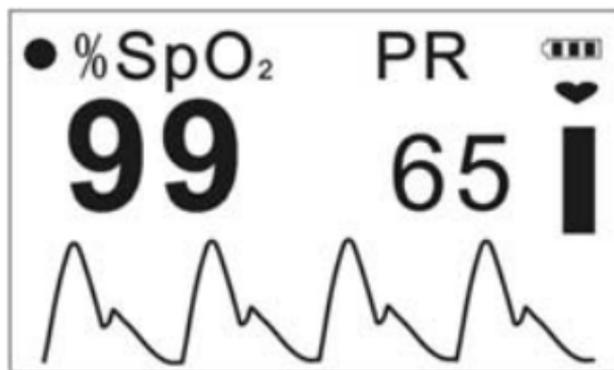- Short press "▲" key during measurement, the screen display direction can flip 180°.

Figure 9B "Display Always On" is enabled

✧ "●": Icon for display always on, it indicates that the screen display is always on during measurement. If the icon is disappeared, it indicates that the screen display will be off after a period of displaying time during measurement for power saving.
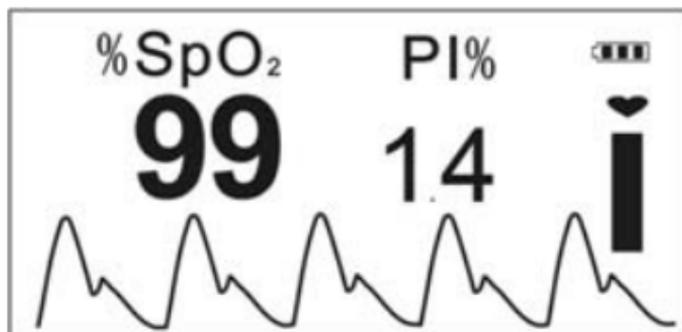
Figure 9C

✧ **"PI%":** Perfusion index label;

20:34
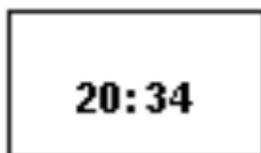
Figure 9D Real Time Clock

✦ **"20:30":** the current time;

Key Operations:

- Long press "■" key, menu screen will be displayed, refer to section 3.2 for details;

6. Prompt information

- During measurement, if you haven't inserted your finger into the probe or the probe is off, "Finger out " will be prompted on the screen.

- During measurement, if the probe is not connected to the oximeter, "No Signal!" will be prompted on the screen, as shown in Figure 10.

Figure 10 "No Signal" Indication

- During measurement, if the memory is full or the total number of the records reaches to 1024 pieces, the earliest record will be overwritten and the icon "⊟" will appear on the screen for prompt, as shown in Figure 11.

Figure 11 When Memory is Full

✧ "▼": Wireless icon; If the wireless (bluetooth communication) function is enabled, the icon will be

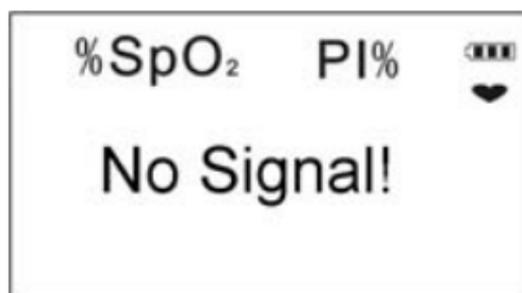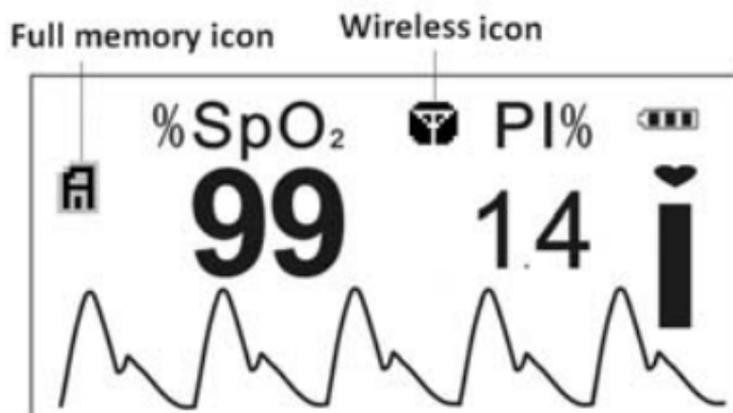displayed on screen. Please refer to chapter 3.2.5
Wireless Setting.

Note: It is suggested that the data shall be uploaded
to computer when memory is full, or the earliest
record will be overwritten.

Working Mode

- The measurement will start automatically when the
  finger is inserted into the SpO₂ probe, so the data
  recording (SpO₂ and PR value) starts simultaneously
  as well. The display is as shown in Figure 9A.

- During measurement, if the icon **"●"** (for "display
  always on") is not shown on screen and no key
  button operation for 30 seconds, the screen display
  will be blank for power saving even when the
  measurement and data recording are still undergoing,
  but short pressing any key will activate the display
  for viewing the current measuring information again.

- If there is no signal and no key press to be detected
  (e.g. finger off) for 20 seconds, the device will be at
  standby status (i.e. blank screen and standby for
  measurement).

- When the device is at standby status, short pressing

any key will activate the screen to default display screen, or once the finger is inserted in the SpO$_2$ probe, the measurement will start and screen display will be activated as well.

Note: During measurement, there is a green-dot flashing on the screen for indicating the measurement and data recording are undergoing when the display screen is blank, and if SpO$_2$ or/and PR values exceed the preset limit, it will activate the display and the value exceeded limit will flash.

3.2 Menu Operation

On display screen, long press "■" key menu screen will be displayed on the screen, as shown in Figure 12.
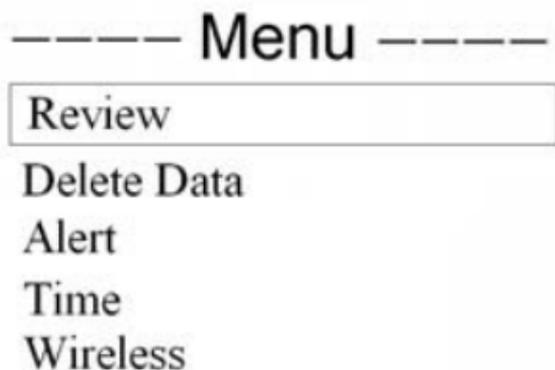
```
———— Menu ————

  Review
  Delete Data
  Alert
  Time
  Wireless

  Rec Interval
```

Figure 12 Menu Screen

- ✧ **Review:** view SpO_2 and pulse rate trend graph ;
- ✧ **Delete Data:** delete all the records.
- ✧ **Alert:** set SpO_2 low limit and pulse rate high/low limit;
- ✧ **Time:** set current date and time;
- ✧ **Wireless:** set or unset wireless function;
- ✧ **Rec Interval:** set the time interval to record SpO_2 and pulse rate data;

Operation Instructions:

- **Short press "▲" key:** shift cursor circularly;

- **Short press " ■ " key:** confirm the selection and enter into the corresponding screen;
- **long press " ■ " key:** go back to the default screen display;

3.2.1Trend Review

On menu screen, select "Review" and press " ■ " key to enter Trend Review screen, as shown in Figure 13.
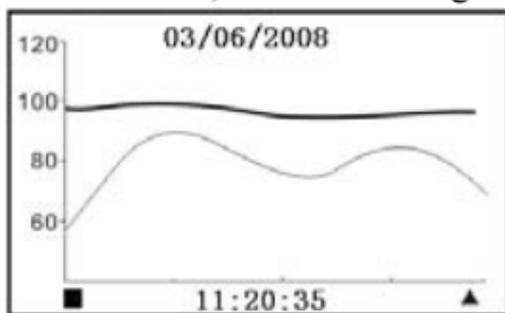
Figure 13 Trend Review Screen

- ✧ **"03/06/2008":** date of the measurement
- ✧ **"11:20:35":** start time of trend graph displayed on this screen;
- ✧ **"■ ▲":** Page scroll (backward/forward) button;
- ✧ **Curves in the middle area:**
  Green curve: indicate pulse rate trend curve;
  Orange curve: indicate SpO₂ trend curve;

Operation Instructions:

- **Short press "▲" key:** Page scroll forward;
- **Short press "■" key:** Page scroll backward;

- **Long press "■" key:** go back to the menu screen;

Note: when the display screen is menu screen or its submenu screen, the measurement will be interrupted.

3.2.2 Delete Data

On menu screen, select "Delete Data" and press "■" key to enter into Deletion Confirmation screen. Then, select "Yes" with "▲" key(short time press), after short pressing "■" key, all the records will be deleted.

```
———— Delete ————


      Yes      No
```
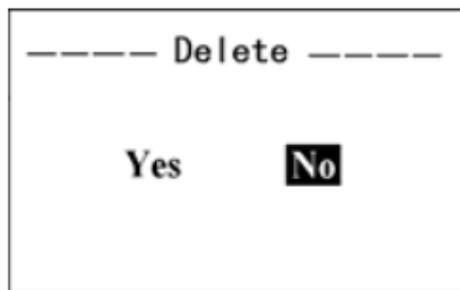
Figure 14 Delete Records

3.2.3 Over-limit indication Settings

On menu screen, select "Alert" and press "■" key to enter Alert Limit Settings screen, as shown in Figure 15.

```
-----Alert-----
SpO₂ Lo        85
PR  Hi         120
PR  Lo         50
Alert          On
```

Figure 15 Over-limit indication Settings

❖ **SpO₂ Lo:** set SpO₂ low limit; Setting range:85%~95%, default setting: 85%;

❖ **PR Lo:** set pulse rate low limit; Setting range:25bpm~99bpm, default setting: 50bpm;

❖ **PR Hi:** set pulse rate high limit; Setting range: 100bpm~250bpm, default setting: 120bpm;

❖ **Alert:** enable/disable the function of over-limit alert by audible beeping, visual display and vibration of the oximeter.

If select "ON", when SpO₂ value or/and PR value exceeds its/their preset limits during measurement, the oximeter will beep and vibrate, and the numerical value exceeded limit will flash.

Operation Instructions:

- **Short press "▲" key:** shift cursor circularly;

- **Short press "■" key:** active the option;

- **Short press "▲" key:** increase numerical value one time;
- **long press " ▲ " key:** increase numerical values continuously;
- **Short press "■" key:** confirm the selection;
- **long press "■" key:** go back to the menu screen;

3.2.4 Time Settings

On menu screen, select "Time" and press "■" key to enter Time Settings screen, as shown in Figure 16.

```
---- Time ----
MM / DD / YYYY
10/28/2007
12 : 30 : 10
```
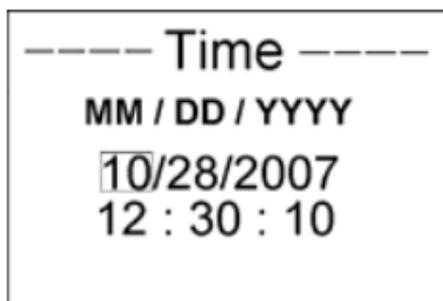
Figure 16 Date and Time Settings

✧ **Date format:** MM/DD/YYYY;

✧ **Time format:** hh:mm:ss;

Operation Instructions:

- **Short press "▲" key:** shift cursor circularly;
- **Short press "■" key:** active the option;
- **Short press "▲" key:** increase numerical value one

time;

- **long press " ▲ " key:** increase numerical value continuously;
- **Short press "■" key:** confirm the modification;
- **long press "■" key:** go back to the menu screen;

3.2.5 Wireless Setting(Optional)

On menu screen, select "Wireless" and press "■" key to enter Wireless Setting screen, as shown in Figure 17.

Figure 17 Wireless Setting Screen

select "ON" or "OFF" with " ▲ " key(short press), then short press "■" key to confirm the selection.

If you select "ON", bluetooth communication will be enabled and the wireless icon displays on the screen. Meanwhile the oximeter can communicate with the bluetooth enabled host device such as a smart phone which is running specific application software(APP) to receive

the measured data (SpO_2 ,PR values and plethysmogram etc.).Please refer to the user manual of relative application software.

NOTE: Only the bluetooth protocol version 4.0 or later is supported.

3.2.6 Record Interval Settings

On menu screen, select "Rec Interval" and press "■" key to enter Record Interval Setting screen, as shown in Figure 18.

```
---Interval---

  Interval   1s
```
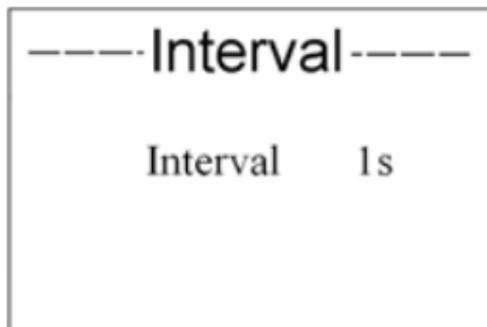
Figure 18 Record Interval Setting

Operation Instructions:

- **Short press "■" key:** active the option;
- **Short press "▲" key:** select record interval; three options: "1s", "4s" and "8s;
- **Short press "■" key:** confirm the selection;

- **long press "■" key:** go back to the menu screen;

Note: The length of data record is constrained to at least 30 seconds, and the maximal length for one record is also limited to 60 hours (for 1 second interval) , 240 hours (for 4 second interval) or 480 hours (for 8 second interval) respectively.

3.3 Upload Data

Before uploading the data to PC, please quit from the menu screen if you are doing the setup or trend view operation.

Before uploading, connect the USB data cable between the oximeter and PC.

- Do the following operations by the instruction in "Oximeter Data Manager User Manual", then the data uploading will be activated.
- Copy the data from the oximeter to PC (or other host device) as the oximeter will be mapped as a removable disk when it is connected to PC by USB data cable.

3.4 Low Battery Indication

If " ▭ " appears on the screen, it indicates that battery power is not enough, please change batteries. If you keep on using it, after a while the batteries are exhausted and the oximeter will be off.

4 Additional Advice for Operation

- The finger should be put properly and correctly.

- Avoid shaking finger as possible as you can 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.

- Electrosurgical device interference may affect the measuring accuracy.

- Using enamel or other makeup on the nail may affect the measuring accuracy.

- 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.

5 Technical Specifications

A. Display mode： Color OLED Display

B. Power supply requirement:

2 x LR03 (AAA) alkaline batteries

or Ni-MH rechargeable batteries
Supply voltage: 3.0VDC

Continues working time (display is off): 70hours

C. Operating current: ≤40mA

D. SpO₂ Parameter Specifications

Transducer: dual-wavelength LED
Measurement wavelength:

Red light: 663 nm, Infrared light: 890 nm.
Maximal optical output power: less than 1.5mW
maximum average
Measuring range: 35~100%
Measuring accuracy:
Not greater than 3% for SpO₂ range from 70% to 100%
NOTE: A_{rms} is defined as root-mean-square value of deviation according to ISO 9919.

E. Pulse Rate Parameter Specifications

Measuring range: 30bpm~240bpm
Accuracy: ±2bpm or ±2% (whichever is greater)

F. Preset limits:

SpO$_2$ Low limit setting: 85%

Pulse Rate limit setting range:

Upper limit: 120bpm

Lower limit: 50bpm

G. Update rate:

6 seconds moving average for SpO$_2$ and 8 beats average for Pulse Rate readings.

H. Perfusion Index Display

Range: 0.2%~20%

I. 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. Resistance to 50Hz /60Hz interference:

SpO$_2$ and PR are precise which have been tested by Fluke Biomedical Index 2 series SpO$_2$ simulator.

L. Dimensions: W 59mm×D 49mm×H 22mm

Net Weight: about 60g (not including batteries)

M. Classification

The type of protection against electric shock: Internally powered equipment.

The degree of protection against electric shock: Type BF applied part.

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

- A data cable (optional)
- Oximeter Data Manager software (optional)
- A Wristband
- A SpO$_2$ Probe
- Two batteries (AAA)
- A User Manual

Note: The accessories are subject to change. See the items and quantity in your hand for detailed .

7 Repair and Maintenance

7.1 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 maintenance.

- Please change the batteries when the low-voltage indicator lightens.
- Please clean the surface of the device before using. Use cloth with alcohol to wipe the device 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 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.

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

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

7.2 Cleaning and Disinfecting Instruction

- Surface-clean sensor with a soft gauze 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 with a damp cloth and dry with a piece of cloth.

- Clean the wristband with soapy water. Please detach the wristband from the oximeter firstly.(Refer to Appendix for detailed disassembly method)

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

Do not use the sensor if it is damaged.

8 Troubleshooting

Trouble	Possible Reason	Solution
The SpO$_2$ and Pulse Rate display instable	1. The finger is not placed far enough inside.	1. Place the finger correctly inside and try again.
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.
Fragmental trend curve of SpO$_2$ and PR	1. Your finger is out of proper location in the probe. 2. Blood flow in the finger blocked. 3. Extreme movement	1. Adjust your finger location properly. 2. Make sure there is no object may occlude the blood flow. 3. Extreme movement may cause invalid measuring result.

Trouble	Possible Reason	Solution
Always display "No Signal"	1. The probe is not connected to the oximeter properly. 2. The finger is not placed well. 3. The probe connector or the probe sensor is broken.	1. Connect the probe to the oximeter properly and try again.; 2. Place the finger properly and try again. 3. Please contact the local service center.

9 Appendix

A Common Knowledge for SpO$_2$ Measurement

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:

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

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 measurement 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 Factors affecting 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 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)

- $\diamond$ Hypoxemia disease, functional lack of HbO$_2$
- $\diamond$ Pigmentation or abnormal oxyhemoglobin level
- $\diamond$ Abnormal oxyhemoglobin variation
- $\diamond$ Methemoglobin disease
- $\diamond$ Sulfhemoglobinemia or arterial occlusion exists near sensor
- $\diamond$ Obvious venous pulsations
- $\diamond$ Peripheral arterial pulsation becomes weak
- $\diamond$ Peripheral blood supply is not enough

B Wristband Installation and Disassembly

Step 1: Fix the wristband on your left wrist(Fig.A).

Fig. B
Wristband underlay

Wristband

Fig. A
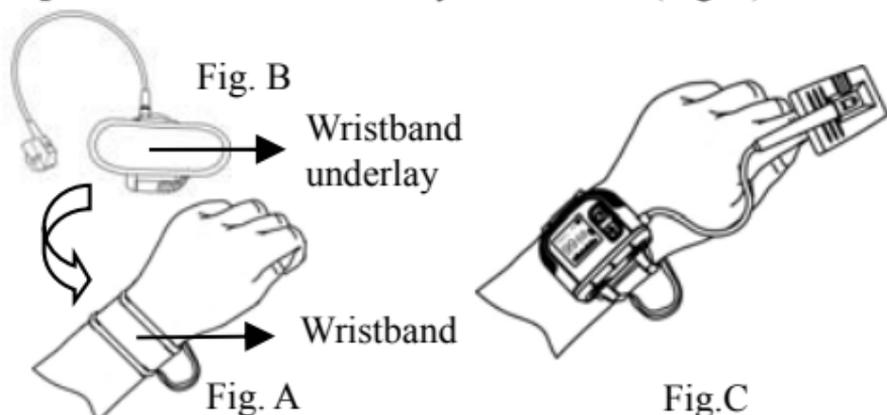
Fig.C

Step 2: Put the oximeter on the proper site of the wristband. Then press the oximeter to make the wristband underlay(Fig.B) stick to the wristband firmly. Next, follow the Fig.C to fix the oximeter well.

Step 3: The process of wristband disassembly is similar to the installation method, but with reverse procedure.

⚠ **Note: Please detach the wristband from the oximeter before cleaning the wristband.**

$C\ \epsilon_{0123}$

Shenzhen Creative Industry Co.,Ltd.

2/F, Block 3, Nanyou Tian'an Industry Town,

Shenzhen, GD 518054, P.R. China

Tel: +86-755-2643 3514

Fax: +86-755-2643 0930

E-mail: info@creative-sz.com

Website: www.creactive-sz.com