

# CMS60D User Manual Pulse Oximeter



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### User Notice

Dear users, thank you very much for purchasing the Pulse Oximeter (hereinafter referred to as device). This Manual is written and compiled in accordance with the council directive MDD93/42/EEC for medical devices and harmonized standards. In case of modifications and software upgrades, the information contained in this document is subject to change without notice.

It is a medical device, which can be used repeatedly.

The Manual describes, in accordance with the device's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the user and device. Refer to the respective chapters for details.

Please read the User Manual carefully before using this device. The User Manual which describes the operating procedures should be followed strictly. Failure to follow the User Manual may cause measuring abnormality, device damage and human injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, human injury and device damage due to users' negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

Owing to the forthcoming renovation, the specific products you received may not be totally in accordance with the description of this User Manual. We would sincerely regret for that.

Our company has the final interpretation to this manual. The content of this manual is subject to change without prior notice.

### Warnings

**Remind that it may cause serious consequences to tester, user or environment.**

- ⚠ Explosive hazard—DO NOT use the device in environment with inflammable gas such as anesthetic.
- ⚠ DO NOT use the device while examining by MRI or CT, as the induced current may cause burn.
- ⚠ Do not take the information displayed on the device as the sole basis for clinical diagnosis. The device is only used as an auxiliary means in diagnosis. And it must be used in conjunction with doctor's advice, clinical manifestations and symptoms.
- ⚠ The maintenance to the device can only be performed by qualified service personnel specified by manufacturer. Users are not permitted to maintain or refit the device by themselves.
- ⚠ Uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the microcirculation disturbance users. It is not recommended that the sensor is used on the same finger for more than 2 hours.
- ⚠ For some special users who need a more careful inspection on the test site, please don't place the device on the edema or tender tissue.
- ⚠ Please do not stare at the red and infrared light emitter (the infrared light is invisible) after turning on the device, including the maintenance staff, as it may be harmful to the eyes.
- ⚠ Each part of the device is firmly fixed, if accidental falling leads to the small parts such as a button to fall off, avoid swallowing of these parts, it may cause suffocation.
- ⚠ The device contains silicone, PVC, TPU, TPE and ABS materials, whose biocompatibility has been tested in accordance with the requirements in ISO 10993-1, and it has passed the recommended biocompatibility test. The person who is allergic to silicone, PVC, TPU, TPE or ABS can not use this device.
- ⚠ The disposal of scrap device, its accessories and packaging should follow the local laws and regulations, to avoid polluting to the local environment. And the packaging materials must be placed in the region where the children are out of reaching.
- ⚠ The device can not be used with the equipment not specified in the Manual. Only the accessories appointed or recommended by the manufacturer can be used, otherwise it may cause injury to the tester and operator or damage to the device.
- ⚠ The SpO<sub>2</sub> probe accompanied is only suitable for using with the device. The device can only use the SpO<sub>2</sub> probe described in the Manual, so the operator has the responsibility to check the compatibility between the device and the SpO<sub>2</sub> probe before using, incompatible accessories may cause device performance degradation, device damage or patient injury.
- ⚠ Do not reprocess the accompanying SpO<sub>2</sub> probe.
- ⚠ Check the device before use to make sure that there is no visible damage that may affect user's safety and device performance. When there is obvious damage, please replace the damaged parts before use.
- ⚠ When the message "Sensor Off" or "Sensor Fault" appears on the screen, it indicates that the SpO<sub>2</sub> probe is disconnected or line fault occurs. Check the connection of the SpO<sub>2</sub> probe and whether there is damage for the probe; if necessary, please replace the probe to avoid risks. The probe fault will not result in a safety hazard.
- ⚠ Functional testers can not be used to assess the accuracy of the SpO<sub>2</sub> probe and Pulse Oximeter.
- ⚠ Some functional testers or patient simulators can be used to verify whether the device works normally, for example, INDEX-2LFE Simulator (software version: 3.00), please refer to the Manual for the detailed operation steps.
- ⚠ Some functional testers or patient simulators can measure the accuracy of the device copied calibration curve, but they can not be used to evaluate the device accuracy.
- ⚠ When using the device, please keep it away from the equipment which can generate strong electric field or strong magnetic field. Using the device in an inappropriate environment may cause interference to the surrounding radio equipment or affect its working.
- ⚠ When storing the device, keep it away from children, pets and insects to avoid affecting its performance.
- ⚠ Do not place the device in places exposed to direct sunlight, high temperature, humidity, dust, cotton wool or easy to splash water, to avoid affecting its performance.
- ⚠ The measured accuracy will be affected by the interference of electrosurgical equipment.
- ⚠ When several products are used on the same patient simultaneously, danger may occur which is arisen from the overlap of leakage current.
- ⚠ CO poisoning will appear excessive estimation, so it is not recommended to use the device.
- ⚠ This device is not intended for treatment.
- ⚠ The intended operator of the device may be a patient.
- ⚠ Avoid maintaining the device during using.
- ⚠ Users should read the product manual carefully before use and operate according to the requirements.

### 1 Overview

The oxygen saturation is the percentage of HbO<sub>2</sub> in the total Hb in the blood, so-called the O<sub>2</sub> concentration in the blood, important physiological parameter for the respiratory and circulatory system. A number of diseases related to respiratory may cause the decrease of SpO<sub>2</sub> in the blood, furthermore, some other causes such as the malfunction of human self-adjustment, damages during surgery, and the injuries caused by some medical checkup would also lead to the diffi-

oxygen supply in human body, and the corresponding symptoms would appear as a consequence, such as vertigo, impo-

vomit etc. Serious symptoms might bring danger to human's life. Therefore, prompt information of patients' SpO<sub>2</sub> is help for the doctor to discover the potential danger, and is of great importance in the clinical medical field.

Insert the finger when measuring, the device will directly display the SpO<sub>2</sub> value measured, it has a higher accuracy and repeatability.

#### 1.1 Features

- A. Easy to use.
- B. Small in volume, light in weight, convenient to carry.
- C. Low power consumption.

#### 1.2 Intended purpose

The Pulse Oximeter is a non-invasive device intended for the spot-check or continuously monitor of oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>) and the pulse rate of adult, pediatric and neonate patients through finger in home and environments (including clinical use in internist/surgery, anesthesia, intensive care etc.). The device is not intended for use and out-of-hospital transport use.

#### 1.3 Environment requirements

##### Storage Environment

- a) Temperature: -40 °C ~ +60 °C
- b) Relative humidity: ≤ 95%
- c) Atmospheric pressure: 500 hPa ~ 1060 hPa

##### Operating Environment

- a) Temperature: +10 °C ~ +40 °C
- b) Relative Humidity: ≤ 75%
- c) Atmospheric pressure: 700 hPa ~ 1060 hPa

#### 1.4 Precautions

##### 1.4.1 Attention

Point out conditions or practices that may cause damage to the device or other properties.

- ⚠ Before using the device, make sure that it locates in normal working state and operating environment.
- ⚠ In order to get a more accurate measurement, it should be used in a quiet and comfortable environment.
- ⚠ When the device is carried from cold or hot environment to warm or humid environment, please do not use it immediately, wait four hours at least is recommended.
- ⚠ If the device is splashed or coagulated by water, please stop operating.
- ⚠ DO NOT operate the device with sharp things.
- ⚠ High temperature, high pressure, gas sterilizing or immersion disinfection for the device is not permitted. Refer to Manual in the relative chapter (6.1) for cleaning and disinfection. Please take out the internal battery before cleaning and disinfection.
- ⚠ The device is suitable for adult.
- ⚠ The device may not be suitable for all users, if you can't get a satisfactory result, please stop using it.
- ⚠ Data averaging and signal processing have a delay in the upgrade of SpO<sub>2</sub> data values. When the data update period is less than 30 seconds, the time for obtaining dynamic average values will increase, which is arisen from signal degradation or other interference, it depends on the PR value.
- ⚠ The device has 3-year service life, date of manufacture see the label.
- ⚠ The expected service life of the attached parts or accessories of the equipment is two year.
- ⚠ If the shelf life is less than the expected service life, the shelf life of the attached parts or accessories of the equipment is two year.
- ⚠ The device does not provide over-limit alarm function for SpO<sub>2</sub> and PR, so it is inapplicable for using in the place where need such function.
- ⚠ This device has the function of prompting, users can check on this function according to chapter 5.5.1 as a reference.
- ⚠ The device has the function of limits prompting, when the measured data is beyond the highest or lowest limit, the device would start prompting automatically on the premise of the prompting function is on.
- ⚠ The device has the function of prompting, this function can either be paused, or closed for good. This function can be turned on through menu operation if you need. Please check the chapter 5.5.1 as a reference.
- ⚠ The device hasn't low-voltage alarm function, it only shows the low-voltage, please change the battery when the voltage is used up.
- ⚠ The maximum temperature at the SpO<sub>2</sub> probe -tissue interface should be less than 41°C which is measured by the temperature tester.
- ⚠ During measuring, when abnormal conditions appear on the screen, please pull out your finger and reinsert it to the device again.
- ⚠ If some unknown error appears during measuring, remove the battery to terminate operating.
- ⚠ Do not contort or drag the wire of the device.
- ⚠ The plethysmographic waveform is not normalized, as a signal inadequacy indicator, when it is not smooth and stable, the accuracy of the measured value may degrade. When it tends to be smooth and stable, the measured value will be optimal and the waveform at this time is also the most standard.
- ⚠ If necessary, please visit our official website to get the information about SpO<sub>2</sub> probe that can be used with this device.
- ⚠ If the device or component is intended for single-use, then the repeated use of these parts will pose risks on the patient and technical parameters of the equipment known to the manufacturer.
- ⚠ If necessary, our company can provide some information (such as circuit diagrams, component lists, illustrations, etc.) that the qualified technical personnel of the user can repair the device components designated by our company.
- ⚠ The measured results will be influenced by the external colouring agent (such as nail polish, colouring agent or cosmetic care products, etc.), so don't use them on the test site.
- ⚠ As to the fingers which are too cold or too thin or whose fingernail is too long, it may affect the measured results, insert the thicker finger such as thumb or middle finger deeply enough into the probe when measuring.
- ⚠ The finger should be placed correctly (see Attached figure 6), as improper installation or improper contact position of the sensor will influence the measurement.
- ⚠ The light between the photoelectric receiving tube and the light-emitting tube of the device must pass through the arteriole. Make sure the optical path is free from any optical obstacles like rubberized fabric, to avoid inaccurate results.
- ⚠ Excessive ambient light may affect the measured results, such as surgical light (especially xenon light sources), lamp, fluorescent lamp, infrared heater and direct sunlight, etc. In order to prevent interference from ambient light, please to place the sensor properly and cover the sensor with opaque material.
- ⚠ Frequent movement (active or passive) of the subject or severe activity can affect the measured accuracy.
- ⚠ The SpO<sub>2</sub> probe should not be placed on a limb with the blood pressure cuff, arterial ductus or intraluminal tube.
- ⚠ The measured value may be inaccurate during defibrillation and in a short period after defibrillation, as it is not a defibrillation function.
- ⚠ The device has been calibrated before leaving factory.
- ⚠ The device is calibrated to display functional oxygen saturation.
- ⚠ The equipment connected with the Oximeter interface should comply with the requirements of IEC 60601-1.

##### 1.4.2 Clinical restriction

- A. As the measure is taken on the basis of arteriole pulse, substantial pulsating blood flow of subject is required. For

with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO<sub>2</sub> waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.

**B.** The measurement will be influenced by intravascular staining agents (such as indocyanine green or methylene blue), skin pigmentation.

**C.** The measured value may be normal seemingly for the tester who has anemia or dysfunctional hemoglobin (such as carboxyhaemoglobin (COHb), methaemoglobin (MetHb) and sulphaemoglobin (SuHb)), but the tester may appear hypoxia, it is recommended to perform further assessment according to the clinical situations and symptoms.

**D.** Pulse oxygen only has a reference meaning for anemia and toxic hypoxia, as some severe anemia patients still show better pulse oxygen measured valued.

**E.** Contraindication:

- The person who is allergic to silicone, PVC, TPU TPE or ABS.
- The damaged skin tissue.
- During cardiopulmonary resuscitation.
- When the patient is hypovolemic.
- For assessing the adequacy of ventilatory support.
- For detecting worsening lung function in patients on a high concentration of oxygen.

#### 1.5 Clinical indications

The Pulse Oximeter can be used in measuring the pulse oxygen saturation and pulse rate through finger.

## 2 Principle

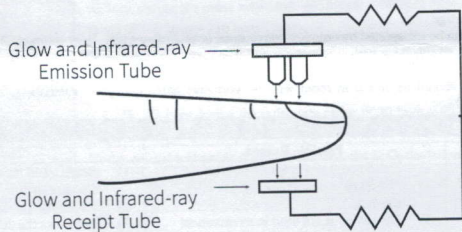


Figure 1. Operating principle

An experience formula of data processing is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO<sub>2</sub>) in red light & near-infrared light zones. On the basis of the principle of Photoelectric Oxyhemoglobin Inspection Technology and Photoplethysmography technology, it uses two light beams of different wavelengths to irradiate the human fingertip to obtain the measurement information from the photosensitive element, after processed by the electronic circuits and microprocessor, displays the measured results on the screen.

## 3 Functions

- SpO<sub>2</sub> value display
- PR value and bar graph display
- Pulse waveform display
- Low-battery indication: low-battery indication appears when the battery voltage is too low to work
- Adjustable screen brightness
- PR sound indication
- Voice prompt for over-limit, sensor off /finger-out and low battery
- With SpO<sub>2</sub> value and pulse rate value record function, the stored data can be uploaded to computer
- It can be connected with an external oximeter probe
- Real-time data can be transmitted to computer
- Review function
- Clock function

## 4 Installation

### 4.1 Appearance

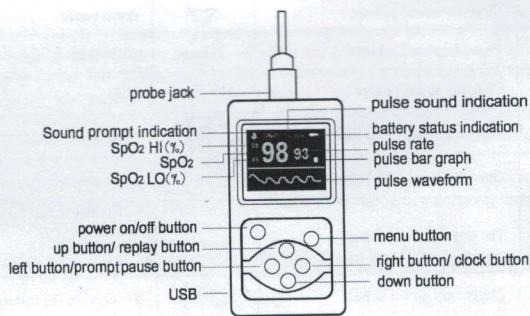


Figure 2. Front View

### 4.2 Battery installation

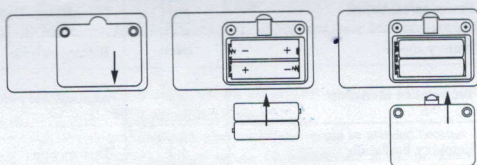


Figure 3. Batteries Installation

- Refer to Figure 3. Use a screwdriver to unscrew the two screws from the battery compartment on the back of the product and open the back cover of the battery compartment.
- Insert the two AA size batteries properly in the right direction.
- Close the battery back cover, screw on the screw.

- ⚠ Please take care when you insert the batteries, for the improper insertion may damage the device.
- ⚠ Please replace two new batteries of the same kind at the same time.

### 4.3 Probe installation

Inserting the SpO<sub>2</sub> probe of the pulse oximeter in the upper jack (see Figure 4). (The probe is limited to be produced by our company; never replace it with the similar one by other manufacturers).

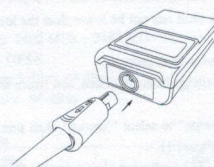


Figure 4. Probe Installation



Figure 5. USB Port

- ⚠ when inserting the probe, make the protruding part of the probe plug correspond to the groove of the probe socket. Pull out the probe directly and don't rotate the probe.

### 4.4 USB port

It is used to connect a personal computer to export the trend data (see Figure 5).

### 4.5. Structure, accessories and software description

- Structure: main unit, SpO<sub>2</sub> probe, USB cable, Bluetooth adapter (optional).
- Accessories: one SpO<sub>2</sub> probe, two AA size batteries (optional), one USB cable, one CD disk (including PC software, optional), one User Manual, Bluetooth adapter (optional). Please check the device and accessories according to the list to avoid that the device can not work normally.
- Software description  
Release version: V2

## 5 Operating

### 5.1 Application method

- Insert the finger into the probe as shown in Figure 6.

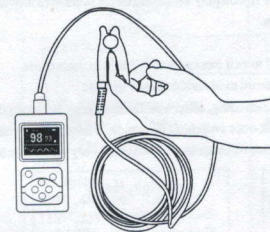


Figure 6. Sketch map for finger placement

(The appearance of actual probe may be different with the one shown as Figure 6, please refer to the actual probe.)

- ⚠ when inserting the finger, the light emitting from the sensor must be directly irradiated to the side of the fingernail.
- ⚠ In the process of using the tested finger had better not shake, the human body also had better not be in motion state.

- Long press the "power on/off" button, until the device turns on.
  - Do not shake the finger and keep the user in a stable state during the measurement process.
  - Wait a few seconds, the data can be read directly from the screen in the measure interface.
- 5.2 Pause sound prompt**
- Sound prompt, including: over-limit, low-battery, finger out, sensor off and sensor fault.
  - Under the measurement interface, turn on the sound prompt, when the sound prompt occurs, short press the button to pause the sound prompt, and it will resume automatically after about 60s.
  - If you want to turn off the sound prompt permanently, please set it in menu.

### 5.3 Review Interface

- In the measure interface, press "up button" to enter the Review Interface 1 directly, as shown in Figure 7:

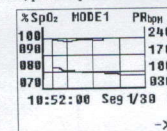


Figure 7-1. Review Interface 1

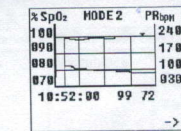


Figure 7-2. Review Interface 2

- In review interface, press "menu button" to switch between Review Interface 1 and Review Interface 2.
- In Review Interface 1, the user can observe the trend waveform composed by storage data. Each screen can show storage data for 105 seconds. The yellow line shows the SpO<sub>2</sub> trend waveform, and the red line shows the PR trend waveform. The time underside shows the starting time of displaying the date in the screen, press the "left button" or "right button" to view the information on the previous or next page of the stored data trend chart.
- The Review Interface 2 shown based in Review Interface 1, the stored SpO<sub>2</sub> value and PR value in each second can be observed here, the underside date from left to right marks time, SpO<sub>2</sub> value, PR value. Press "left button" or "right button" to display the blood oxygen and pulse of the previous or next second; Long press the "left button" or "right button", and the pulse and blood oxygen will be display with a data interval of 10 seconds.
- Press "up button" to exit the review Interface, return to the measure interface.

### 5.4 Clock interface

- In the measure interface, press the "right button" can enter the clock interface of Figure 8. Press the "right button" again can return to the measure interface.

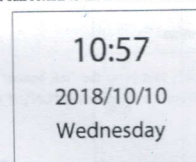


Figure 8. Clock interface

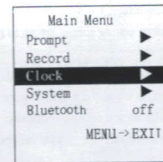


Figure 9. Main Menu

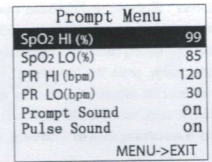


Figure 10. Setting for sound prompt

### 5.5 Menu operations

In the measure interface, press the "menu button" can enter the menu of Figure 9. Users can adjust the setting through the main menu, such as the sound prompt, record, clock, system, etc. can be set, methods are as follows:

#### 5.5.1 Sound prompt setting

Under main menu, press the "up button" or "down button" to select "Prompt", then press the "left button" or "right button" to enter its setting interface shown in Figure 10.

Press the "up button" or "down button" to select the option to be adjusted, then press the "left button" or "right button" to change the value.

"SpO<sub>2</sub> HI(%)": upper limit prompt for SpO<sub>2</sub> over-limit

"SpO<sub>2</sub> LO(%)": lower limit prompt for SpO<sub>2</sub> over-limit

"PR HI(bpm)": upper limit prompt for PR over-limit

"PR LO(bpm)": lower limit prompt for PR over-limit

"Prompt Sound": prompt for over-limit, low-battery, finger out, sensor off and sensor fault, "off": close, "on": open.

"Pulse Sound": PR sound, "off": close, "on": open.

Lower limit can not exceed the upper limit, and the upper limit can not be lower than the lower limit when adjusting the values. SpO<sub>2</sub> range: 0% ~ 100%, PR range: 0 ~ 254 bpm

The values displayed in Figure 10 are the initial values of over-limit prompt.

After setting, press the "menu button" to exit the Prompt Settings Menu interface, and return to "Main Menu" interface.

### 5.5.2 Data storage

Under the main menu, press the "up button" or "down button" to select "Record", then press the "left button" or "right button" to enter the "Record Menu" interface as shown in Figure 11.

Press the "up button" or "down button" to select the option to be adjusted, then press the "left button" or "right button" to change the value.

It indicates that the device is storing when the red dot "REC•" in measurement interface flickers

"Mode": record mode selection, including: "Auto" and "Manual" mode. Under "Manual" mode, select to turn on / off memory by "Record".

Auto record: start recording after stable data appear, pull out the finger to finish recording a group of data (99 group of data at most), the total duration does not exceed 72 hours.

Manual record: after manual storage is started, the storage state needs to be terminated manually to complete a group of store, store up to 24-hour data.

When the memory is full, it will display "Memory is full!", then it will enter the standby mode after several seconds. When exiting the standby mode next time, it will display "Memory is full!" to prompt user that the memory has been full, then it will enter the measure interface.

△ Under manual mode, when "Record" is "ON", the device will prompt to clear the data stored last time.

It will display "Recording..." when there is no operation under record state for 15s, then it will enter energy saving mode after several seconds, pressing the "power on/off button", the device would return to the former interface; pressing any button(power on/off excluded), it will display "Recording..."

△ Under data recording state, after the display screen turns off automatically, in order to save power, pulse sound indication will turn off automatically.

"Seg": data segment.

After setting, press the "menu button" to exit storage menu, return to main menu.

"Delete All": delete all records (auto record mode is shown as Figure 11).

△ Please upload data in time after recording, otherwise the data may be covered when the storage space is full.

△ The historical data will be deleted once switching the mode. Under record state, the record mode can not be switched; under manual mode, the record mode can be switched only when turning off recording firstly.

| Record Menu |      |
|-------------|------|
| Mode        | Auto |
| Seg         | 12   |
| Delete All  |      |

Figure 11. Record menu

| Clock Menu |      |
|------------|------|
| Set Time   | no   |
| Set Year   | 2019 |
| Set Month  | 01   |
| Set Day    | 01   |
| Set Hour   | 03   |
| Set Minute | 00   |
| MENU→EXIT  |      |

Figure 12. Clock menu

| System Menu  |       |
|--------------|-------|
| Hard. Ver.   | 2.0.0 |
| Soft. Ver.   | 2.0.2 |
| ID           | user  |
| Demo         | off   |
| Sound Volume | 3     |
| Brightness   | 1     |
| MENU→EXIT    |       |

Figure 13. System menu

### 5.5.3 Clock setting

a. Connect the master device to synchronize device time

Under the PC software interface, after search for the device (refer to relative chapter (5.6) for the connection method), then can synchronize the device time.

b. Set device time manually

Under main menu, press the "up button" or "down button" to select "Clock", then press the "left button" or "right button" to enter its setting interface shown in Figure 12.

Press the "up button" or "down button" to select the option to be adjusted, then press the "left button" or "right button" to change the value.

"Set Time": set the time, "yes": allow, "no": prohibit

"Set Year": set the year

"Set Month": set the month

"Set Day": set the day

"Set Hour": set the hour

"Set Minute": set the minute

Adjustable range for year: 2015 ~ 2045, month: 1 ~ 12, day: 1 ~ 30 (when there are 31 days in a month, it is 1 ~ 31), hour: 1 ~ 23, minute: 1 ~ 59.

After setting, press the "menu button" to exit clock menu, return to main menu.

### 5.5.4 System setting and other options introduction

Under main menu, press the "up button" or "down button" to select "System", then press the "left button" or "right button" to enter the interface as shown in Figure 13.

Press the "up button" or "down button" to select the option to be adjusted, then press the "left button" or "right button" to change the value.

"Hard. Ver.": hardware version

"Soft. Ver.": software version

"ID": user name

"Demo": set the Demo mode, "on": turn on the Demo mode, "off": turn off the Demo mode.

"Sound Volume": set the sound volume, adjustable range: 1 ~ 3

"Brightness": set the screen brightness, adjustable range: 1 ~ 4

After setting, press the "menu button" to exit system setting menu, return to main menu.

### 5.5.5 Bluetooth setting (Bluetooth equipment)

Under main menu, press the "up button" or "down button" to select "Bluetooth", then press the "left button" or "right button" to enter its selection interface as shown in Figure 14 and Figure 15 When the Bluetooth is "ON", if no data is transmitted for some time, then the Bluetooth will be turned off automatically.

△ Under transmitting data by Bluetooth, the Bluetooth can not be turned off.

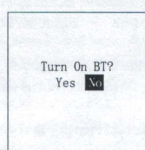


Figure 14. Bluetooth "ON" interface

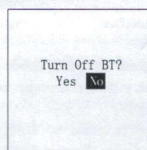


Figure 15. Bluetooth "OFF" interface

### 5.5.6 Exit main menu

Under main menu, press the "menu button" to exit the main menu and return to the measurement interface.

### 5.6 Data upload

#### A. Wired transmission

Connect the device to the computer by the USB cable, upload the data after connecting the PC software properly, refer to the operating instruction" for details.

△ The PC software can be downloaded from our official website.

#### B. Bluetooth transmission (Bluetooth equipment)

Turn on the device Bluetooth and the PC software to upload data, refer to "Software operating instruction" for details.

### 5.7 Power off

Long press the "power on/off" button, until the device turns off.

△ when the device is in storing, it can't be turned off.

## 6 Maintain, Transport and Storage

### 6.1 Cleaning and disinfection

The device must be turned off before cleaning, and it should not be immersed into liquid.

Please take out the internal battery before cleaning, do not immerse it into liquid.

Use 75% alcohol to wipe the device enclosure and the nail pad, nature dry or clean it with clean and soft cloth. Do not liquid on the device directly, and avoid liquid penetrating into the device.

### 6.2 Maintenance

A. Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect safety and monitoring performance. It is recommended that the device should be inspected weekly at least. When obvious damage, stop using it.

B. Please clean and disinfect the device before/after using it according to the User Manual (6.1).

C. Please replace the batteries in time when low-battery appears.

D. Please take out the batteries if the device is not used for a long time.

E. The device need not to be calibrated during maintenance.

### 6.3 Transport and Storage

A. The packed device can be transported by ordinary conveyance or according to transport contract. During transportation, strong shock, vibration and splashing with rain or snow, and it can not be transported mixed with toxic, harmful, corrosive material.

B. The packed device should be stored in room with no corrosive gases and good ventilation. Temperature: -40°

Relative humidity: ≤95%.

## 7 Troubleshooting

| Trouble                                             | Possible Reason                                                  | Solution                                                |
|-----------------------------------------------------|------------------------------------------------------------------|---------------------------------------------------------|
| The values can not be displayed normally or stably. | 1) The finger is not properly inserted.                          | 1) Please insert the finger properly and measure again. |
|                                                     | 2) The finger is shaking or the patient is moving.               | 2) Let the patient keep calm.                           |
|                                                     | 3) The device is not used in environment required by the manual. | 3) Please use the device in normal environment.         |
|                                                     | 4) The device works abnormally.                                  | 4) Please contact the after-sales.                      |
| The device can not be turned on                     | 1) The battery is drained away or almost drained away.           | 1) Please change batteries.                             |
|                                                     | 2) The battery is installed incorrectly.                         | 2) Please Install the battery again.                    |
|                                                     | 3) The device's malfunction.                                     | 3) Please contact the local service center.             |
| The display disappears suddenly.                    | 1) The device enters into the energy saving mode.                | 1) Normal.                                              |
|                                                     | 2) Low battery.                                                  | 2) Please change batteries.                             |
|                                                     | 3) The device works abnormally.                                  | 3) Please contact the after-sales.                      |
| The data can not be stored.                         | 1) The device is not operated according to the manual.           | 1) Please operate the device according to the manual.   |
|                                                     | 2) The device works abnormally.                                  | 2) Please contact the after-sales.                      |

## 8 symbols

| Symbols    | Meaning                                                                                                | Symbols      | Meaning                                                                                               |
|------------|--------------------------------------------------------------------------------------------------------|--------------|-------------------------------------------------------------------------------------------------------|
|            | Caution, consult accompanying documents                                                                |              | Left button/prompt pause button                                                                       |
|            | Pulse oxygen saturation (%)                                                                            |              | Menu button                                                                                           |
|            | Pulse rate (bpm)                                                                                       |              | Right button/clock button                                                                             |
|            | Close the sound prompt                                                                                 |              | down button                                                                                           |
|            | Pause the sound prompt                                                                                 |              | Up button/replay button                                                                               |
|            | Open the sound prompt                                                                                  |              | USB                                                                                                   |
|            | Close the pulse sound indication                                                                       |              | Type BF applied part                                                                                  |
|            | Open the pulse sound indication                                                                        |              | Serial number                                                                                         |
| Finger Out | The finger is not inserted.                                                                            | ---          | 1. The finger clip falls off (no finger inserted)<br>2. Probe error<br>3. Signal inadequacy indicator |
|            | The battery power is full                                                                              |              | Two grid of the battery                                                                               |
|            | One grid of the battery                                                                                |              | The lack of battery power. (Please change batteries in time for exact measuring)                      |
|            | Alarm inhibit                                                                                          |              | Manufacturer                                                                                          |
|            | Power on/off button                                                                                    |              | Manufacture Date                                                                                      |
|            | Battery anode                                                                                          |              | Battery cathode                                                                                       |
|            | Temperature limitation                                                                                 |              | Atmospheric pressure limitation                                                                       |
|            | Humidity limitation                                                                                    |              | This way up                                                                                           |
|            | Fragile, handle with care                                                                              |              | Keep away from rain                                                                                   |
| IP22       | It means this pulse oximeter is protected against harmful effects of dripping water when tilted at 15° |              | Recyclable                                                                                            |
|            | Bluetooth: ON (Bluetooth equipment)                                                                    |              | Recycling garbage WEEE (2012/19/EU)                                                                   |
| REC•       | Recording                                                                                              |              | Use-by date                                                                                           |
| Sensor Off | The probe is disconnected.                                                                             | Sensor Fault | Probe failure                                                                                         |

| P/N    | Material code           | LOT     | Batch No.                                                                                                                                                                |
|--------|-------------------------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| EC REP | European Representative | CE 0123 | This item is compliant with Directive 93/42/EEC of 14 June 1993 concerning medical devices, including, at 21 March 2010, the amendments by Council Directive 2007/47/EC. |

Note: Your device may not contain all the following symbols.

## 9 Specification

|                                           |                                                                                                                                                                       |
|-------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| SpO <sub>2</sub> [see note 1]             |                                                                                                                                                                       |
| Display range                             | 0% ~ 100%                                                                                                                                                             |
| Measured range                            | 0% ~ 100%                                                                                                                                                             |
| Accuracy [see note 2]                     | 70%~100%: ±2%;<br>0%~69%: unspecified.                                                                                                                                |
| Resolution                                | 1%                                                                                                                                                                    |
| PR                                        |                                                                                                                                                                       |
| Display range                             | 30 bpm ~ 250 bpm                                                                                                                                                      |
| Measured range                            | 30 bpm ~ 250 bpm                                                                                                                                                      |
| Accuracy [see note 3]                     | ±2 bpm during the pulse rate range of 30 bpm ~ 99 bpm and ±2% during the pulse rate range of 100 bpm ~ 250 bpm                                                        |
| Resolution                                | 1 bpm                                                                                                                                                                 |
| Accuracy under low perfusion [see note 4] | Low perfusion 0.4%:<br>SpO <sub>2</sub> : ±4%;<br>PR: ±2 bpm during the pulse rate range of 30 bpm ~ 99 bpm and ±2% during the pulse rate range of 100 bpm ~ 250 bpm. |
| Light interference                        | Under normal and ambient light conditions, the SpO <sub>2</sub> deviation ≤ 1%                                                                                        |
| Pulse intensity                           | Continuous bar graph display, the higher display indicates the stronger pulse.                                                                                        |
| Upper and lower limit of measured values  |                                                                                                                                                                       |
| SpO <sub>2</sub>                          | 0% ~ 100%                                                                                                                                                             |
| PR                                        | 0 bpm ~ 254 bpm                                                                                                                                                       |
| Optical sensor [see note 5]               |                                                                                                                                                                       |
| Red light                                 | Wavelength: about 660 nm, optical output power: < 6.65 mW                                                                                                             |
| Infrared light                            | Wavelength: about 905 nm, optical output power: < 6.75 mW                                                                                                             |
| Memory                                    | Up to 99 group of data under auto mode, total duration does not exceed 72 hours.<br>Up to 24-hour data under manual mode.                                             |
| Safety class                              | Internally powered equipment, type BF applied part                                                                                                                    |
| International Protection                  | IP22                                                                                                                                                                  |
| Working voltage                           | DC 2.6 V - 3.6V                                                                                                                                                       |
| Working current                           | ≤ 100 mA                                                                                                                                                              |
| Power supply                              | Dry battery (2AA)                                                                                                                                                     |
| Operation time                            | The device can continuously work for 20 hours when it was powered by two new batteries within the warranty period.                                                    |
| Dimension and Weight                      |                                                                                                                                                                       |
| Dimensions                                | 110(L) × 60(W) × 24(H) mm                                                                                                                                             |
| Weight                                    | About 120g (with Dry battery(2AA))                                                                                                                                    |

Note 1: the claims of SpO<sub>2</sub> accuracy shall be supported by clinical study measurements taken over the full range. By artificial inducing, get the stable oxygen level to the range of 70 % to 100 % SpO<sub>2</sub>, compare the SpO<sub>2</sub> values collected by the secondary standard pulse oximeter equipment and the tested equipment at the same time, to form paired data, which are used for the accuracy analysis.

There are 12 healthy volunteers (male: 6, female: 6; age: 18~50; skin color: black; 2, light: 8, white: 2) data in the clinical report.

Note 2: because pulse oximeter equipment measurements are statistically distributed, only about two-thirds of pulse oximeter equipment measurements can be expected to fall within ±1σ of the value measured by a CO-OXIMETER.

Note 3: Patient simulator has been used to verify the pulse rate accuracy, it is stated as the root-mean-square difference between the PR measurement value and the value set by simulator.

Note 4: percentage modulation of infrared signal as the indication of pulsating signal strength, patient simulator has been used to verify its accuracy under conditions of low perfusion. SpO<sub>2</sub> and PR values are different due to low signal conditions, compare them with the known SpO<sub>2</sub> and PR values of input signal.

Note 5: optical sensors as the light-emitting components, will affect other medical devices applied the wavelength range. The information may be useful for the clinicians who carry out the optical treatment. For example, photodynamic therapy operated by clinician.

## Appendix

| State                   | Prompt condition delay | Prompt signal generation delay |
|-------------------------|------------------------|--------------------------------|
| Low voltage prompt      | 1s                     | 20ms                           |
| SpO <sub>2</sub> prompt | 330ms                  | 20ms                           |
| Pulse rate prompt       | 330ms                  | 20ms                           |
| Probe error prompt      | 16ms                   | 20ms                           |

## EMC

This equipment is suitable for professional healthcare facility environments and home healthcare environments.

### Warning:

- Don't near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the this equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

### Note:

- this equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- The basic performance: SpO<sub>2</sub> measured range: 70% ~ 100%, absolute error: ±2%; PR measured range: 30 bpm ~ 250 bpm, accuracy: ±2 bpm during the pulse rate range of 30 bpm ~ 99 bpm and ±2% during the pulse rate range of 100 bpm ~ 250 bpm.

When the device is disturbed, the data measured may fluctuate, please measure repeatedly or in another environment to ensure its accuracy.

Other devices may affect this device even though they meet the requirements of CISPR.

### Bluetooth Specification

Working frequency: 2402 MHz ~ 2480 MHz

Modulation mode: GFSK

Transmitting power: 0 dBm, +4 dBm

Receiving sensitivity: -93 dBm

### Product configuration:

| Serial number | name                   | Cable length |
|---------------|------------------------|--------------|
| 1             | SpO <sub>2</sub> probe | 1.5m         |
| 2             | USB cable              | 1m           |

Table 1

| Guidance and Declaration - Electromagnetic Emissions |                |
|------------------------------------------------------|----------------|
| Emissions test                                       | Compliance     |
| Radiated RF EMISSIONS<br>CISPR 11                    | Group 1        |
| Radiated RF EMISSIONS<br>CISPR 11                    | Class B        |
| Harmonic distortion<br>IEC 61000-3-2                 | Not applicable |
| Voltage fluctuations and flicker<br>IEC 61000-3-3    | Not applicable |

Table 2

| Guidance and Declaration - Electromagnetic Immunity          |                                                                                                                                                                                                                               |                                         |
|--------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|
| Immunity Test                                                | IEC 60601<br>Test level                                                                                                                                                                                                       | Compliance level                        |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2               | ±8 kV contact<br>±15 kV air                                                                                                                                                                                                   | ±8 kV contact<br>±15 kV air             |
| Electrical fast transient/burst<br>IEC 61000-4-4             | ±2 kV for power supply lines<br>±1 kV for input/output lines                                                                                                                                                                  | Not applicable                          |
| Surge<br>IEC 61000-4-5                                       | ±1 kV line(s) to line(s)<br>±2 kV line(s) to earth                                                                                                                                                                            | Not applicable                          |
| Voltage dips and<br>Voltage interruptions<br>IEC 61000-4-11  | 0 % U <sub>T</sub> ;<br>0.5 cycle.<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°:<br>0 % U <sub>T</sub> ; 1 cycle and 70 % U <sub>T</sub> ;<br>25/30 cycles; Single phase: at 0°:<br>0 % U <sub>T</sub> ; 250/300 cycle | Not applicable                          |
| Power frequency (50/60Hz)<br>magnetic field<br>IEC 61000-4-8 | 30 A/m<br>50Hz/60Hz                                                                                                                                                                                                           | 30 A/m<br>50Hz/60Hz                     |
| Conducted RF<br>IEC 61000-4-6                                | 3 V<br>0.15MHz - 80 MHz<br>6 V in ISM and amateur radio bands between 0.15MHz to 80 MHz<br>80%AM at 1kHz                                                                                                                      | Not applicable                          |
| Radiated RF<br>IEC 61000-4-3                                 | 10V/m<br>80 MHz-2.7GHz<br>80%AM at 1kHz                                                                                                                                                                                       | 10V/m<br>80 MHz-2.7GHz<br>80%AM at 1kHz |

NOTE U<sub>T</sub> is the a.c.mains voltage prior to application of the test level

Table 3

| Guidance and manufacturer's declaration - electromagnetic Immunity                                                       |                      |             |                                                                 |                                   |                               |                        |
|--------------------------------------------------------------------------------------------------------------------------|----------------------|-------------|-----------------------------------------------------------------|-----------------------------------|-------------------------------|------------------------|
| Radiated RF<br>IEC61000-4-3<br>(Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment) | Test Frequency (MHz) | Band (MHz)  | Service                                                         | Modulation                        | IEC60601-1-2 Test level (V/m) | Compliance level (V/m) |
|                                                                                                                          | 385                  | 380 - 390   | TETRA 400                                                       | Pulse modulation b) 18 Hz         | 27                            | 27                     |
|                                                                                                                          | 450                  | 430 - 470   | GMRS 460, FRS 460                                               | FM c) ±5 kHz deviation 1 kHz sine | 28                            | 28                     |
|                                                                                                                          | 710                  | 704 - 787   | LTE Band 13,17                                                  | Pulse modulation b) 217 Hz        | 9                             | 9                      |
|                                                                                                                          | 745                  |             |                                                                 |                                   |                               |                        |
|                                                                                                                          | 780                  |             |                                                                 |                                   |                               |                        |
|                                                                                                                          | 810                  | 800 - 960   | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5          | Pulse modulation b) 18 Hz         | 28                            | 28                     |
|                                                                                                                          | 870                  |             |                                                                 |                                   |                               |                        |
|                                                                                                                          | 930                  |             |                                                                 |                                   |                               |                        |
|                                                                                                                          | 1720                 | 1700 - 1990 | GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS | Pulse modulation b) 217 Hz        | 28                            | 28                     |
|                                                                                                                          | 1845                 |             |                                                                 |                                   |                               |                        |
|                                                                                                                          | 1970                 |             |                                                                 |                                   |                               |                        |
|                                                                                                                          | 2450                 | 2400 - 2570 | Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7            | Pulse modulation b) 217 Hz        | 28                            | 28                     |
|                                                                                                                          | 5240                 | 5100 - 5800 | WLAN 802.11 a/n                                                 | Pulse modulation b) 217 Hz        | 9                             | 9                      |
|                                                                                                                          | 5500                 |             |                                                                 |                                   |                               |                        |
|                                                                                                                          | 5785                 |             |                                                                 |                                   |                               |                        |