GIMA

PROFESSIONAL MEDICAL PRODUCTS

PULSOXIMETRO OXY-200
OXY-200 PULSE OXIMETER
OXYMÈTRE DE POULS OXY-200
PULSIOXÍMETRO OXY-200

REF **CMS70A (GIMA 35213)**

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Instructions to User

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, patient 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 or replacement of the battery (non-detachable lithium battery) can only be performed by qualified service personnel specified by manufacturer, dangers (such as over-temperature, fire or explosion) may occur when replacing the battery by the personnel not fully trained. Patients are not permitted to maintain or refit the device by themselves.
- Please do not open the device enclosure to avoid possible electric shock.
- Uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the microcirculation disturbance patients. It is not recommended that the sensor is used on the same finger for more than 2 hours.
- For some special patients 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.
- 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_2 probe accompanied is only suitable for using with the device. The device can only use the SpO_2 probe described in the Manual, so the operator has the responsibility to check the compatibility between the device and the SpO_2 probe before using, incompatible accessories may cause device performance degradation, device damage or patient injury.
- Do not reprocess the accompanying SpO_2 probe.
- Check the device before use to make sure that there is no visible damage that may affect patient'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_2 probe is disconnected or line fault occurs. Check the connection of the SpO_2 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_2 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.
- Do not rely on the alarm system of the device solely, the alarm function must be verified regularly. The most reliable method of use is to closely monitor and correctly use it .
- 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.

CONTENTS

1 OVERVIEW

The oxygen saturation is the percentage of HbO_2 in the total Hb in the blood, so-called the O_2 concentration in the blood, it is an important physiological parameter for the respiratory and circulatory system. A number of diseases related to respiratory system may cause the decrease of SpO_2 in the blood, furthermore, some other causes such as the malfunction of human body's self-adjustment, damages during surgery, and the injuries caused by some medical checkup would also lead to the difficulty of oxygen supply in human body, and the corresponding symptoms would appear as a consequence, such as vertigo, impotence, vomit etc. Serious symptoms might bring danger to human's life. Therefore, prompt information of patients' SpO_2 is of great 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_2 value measured, it has a higher accuracy and repeatability.

1.1 Features

A. Operation is simple and convenient.
B. Product is handsome and fashion, and easy to observe
C. With two kinds of power supply mode (alternating current and internal electrical power source).

1.2 Indication for Use

The Pulse Oximeter can be used in measuring the pulse oxygen saturation and pulse rate through finger. The product is suitable for being used in family, hospital, oxygen bar, community healthcare, physical care in sports (It can be used before or after doing sports, and it is not recommended to use the device during the process of having sport) and etc.

1.3 Environment Requirements

Storage Transportation 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 User Manual in the relative chapter (6.1) for cleaning and disinfection. Please turn off the device and disconnect it from the power.
- The device is suitable for children and adult.
- The device may not be suitable for all patients, if you can't get a satisfactory result, please stop using it.
- Data averaging and signal processing generate delay on displayed and transmitted SpO_2 value and alarm signal generation. The data update period is shorter than 30 s, the time for obtaining dynamic average values will increase, which is arisen from signal degradation, low perfusion or other interference, it depends on the PR value.
- The device has 3-year service life, date of manufacture: see the label.
- To further detect the alarm of individual measurement parameter, measure and check oneself or with a simulator, adjust the alarm limit setting and check whether the correct alarm can be triggered.
- This device has the function of alarm, patients can check on this function according to chapter 5.3 as a reference.
- The device has the function of limits alarm, when the measured data is beyond the highest or lowest limit, the device would start alarm automatically on the premise of the alarm function is on.
- The device has the function of alarm, this function can either be paused, or closed for good. This function could be turned on through menu operation if you need. Please check the chapter 5.3 as a reference.
- The maximum temperature at the SpO_2 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 measure again.
- If some unknown error appears during measuring, press "RESET" button to reset it.
- 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 read is the 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_2 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 parameters 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.), so 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 color skin 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, so please 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 4), as improper installation or improper contact position for sensor will influence the measurement.
- The light between the photoelectric receiving tube and the light-emitting tube of the device must pass through the subject's 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), bilirubin lamp, fluorescent lamp, infrared heater and direct sunlight, etc. In order to prevent interference from ambient light, make sure 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_2 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 has not 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.
- The computer intended to be connected with this device,shall be approved and certificated according to IEC 60950.
- After the mains is interrupted, the device will automatically switch to battery for working, it will automatically switch to mains after it is restored.

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 a subject with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO_2 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 sulfhaemoglobin (SuHb)), but the tester may appear hypoxia, it is recommended to perform further assessment according 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:
   a. The person who is allergic to silicone, PVC, TPU TPE or ABS can not use this device.
   b. The damaged skin tissue can't be measured.
   c. During cardiopulmonary resuscitation.
   d. When the patient is too hypovolemic.
   e. For assessing the adequacy of ventilatory support.
   f. For detecting worsening lung function in patients on a high concentration of oxygen.

2 PRINCIPLE

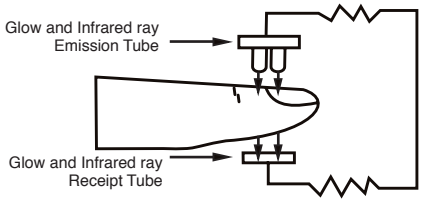

Figure 1. Operating principle

Principle of the Oximeter is as follows: An experience formula of data process is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO_2) in glow & near-infrared zones. Operation principle of the device is: Photo-electric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning & Recording Technology, so that two beams of different wavelength of lights can be focused onto human nail tip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on screen through treatment in electronic circuits and microprocessor.

3 FUNCTIONS

A. SpO_2 value display
B. Pulse rate value display, bar graph display
C. PI value display
D. Pulse waveform display
E. Battery power display
F. Low-power indication: low-power indication symbol appears before working abnormity which is due to low-power.
G. Review function
H. Screen brightness can be adjusted
I. Volume can be adjusted
J. Display mode can be adjusted
K. Pulse sound indication
L. With alarm function, the patient could set alarm limit.
M. With real-time data uploading function.
N. With clock function
O. With two kinds of power supply mode(alternating current and internal electrical power source)

4 INSTALLATION

4.1 Appearance

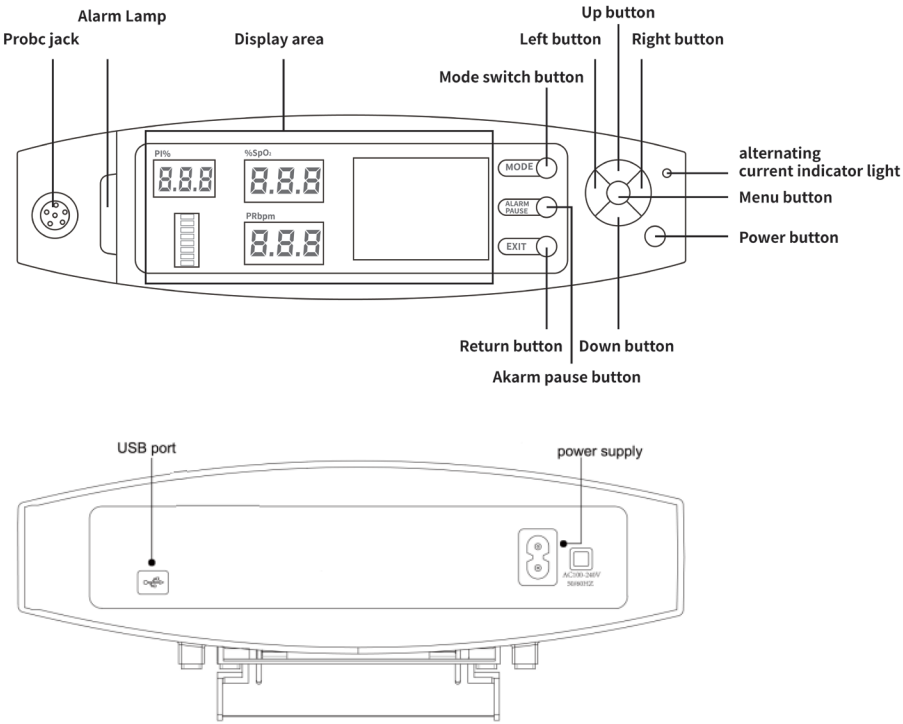

Figure 2. Appearance

Alternating current indicator lint: the light is green when powered on.
Probe jack: it is used to connect Oximeter probe to measure the oxygen saturation, pulse rate and PI.
Alarm lamp: When data's going beyond the limits, low-voltage, finger out, sensor off or sensor fault, the alarm light will be on.
Display area: display measure information.
Button Area:

1. Mode switch button: click it to switch mode (Measure interface 1 / Measure interface 2)
2. Alarm pause/confirm button: when alarm happens, short press it to make alarm sound pause. The pause time could be set by menu. Long press it to confirm the alarm, and there will be no alarm this time.
3. Return button: return to the previous menu.
4. Up button/down button/left button/right button: change the choice bar position left/ right button: set part function.
5. Menu button: in waveform measure interface, press the button to enter the menu setting; in menu interface, press the button to enter the corresponding submenu.
6. Power button: in power-off state, long press the button to turn on the device; in power-on state, long press the button to turn off the device.
   USB port: It is used to connect computer to transmit data by data line.
   Power supply jack: power supply line interface.

Note: During data transmitting, please do not use this device.

4.2 Interface introduction

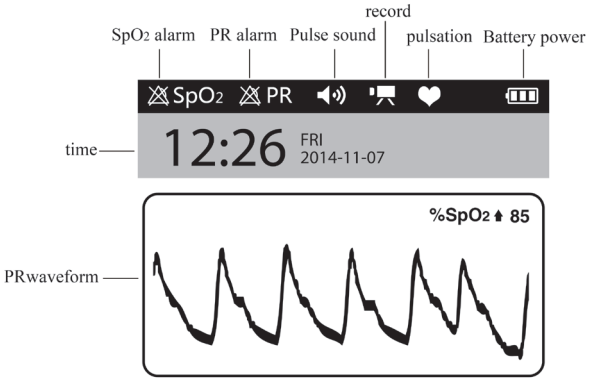

Figure 3. Measurement interface

4.3 SpO2 probe installation

Inserting the lemo probe into the lemo jack of the device (The probe is limited to the one that is provided by our company; and can't be replaced with the similar one by other manufacturers).

4.4 Connection of data line

Please connect the data line to device, the other end into computer.

4.5 Structure, accessories and software description

A. Structure: main unit, Oximeter probe, A power supply line and A data line.
B. Accessories: one User Manual, one power supply line, one data line, one Oximeter probe.
Optional: A Other Oximeter probe
C. Software description
Release version: 2.0

5 OPERATING

5.1 Measurement

Put the finger into the probe as Figure 4.

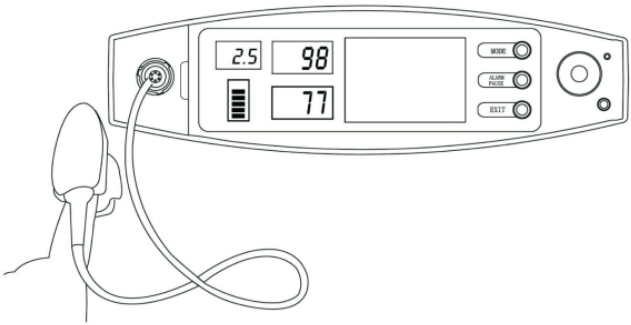

Figure 4. Sketch map for finger placement
(The appearance of actual probe may be different with the one shown as Figure 4, please refer to the actual probe.)

A. Short press power button to turn on the device. If use alternating current, make sure that the power supply line is connected accurately.
B. Do not shake the finger and keep the patient in a stable state during the process.
C. The data can be read directly from the screen in the measure interface.
Note: Fingernails and the luminescent tube should be at the same side.
Note: If the alarm function is on, the device will provide alarm signal when probe or finger is out.

5.2 Measurement interface

A. Alarm including the alarm of measure data's going beyond the limits, the alarm of low-voltage, the alarm of finger out, the alarm of sensor off, the alarm of sensor fault.
B. When alarm is on, short press the alarm pause button to make the alarm pause, it can renew alarm after period of time, alarm pause time can be set by menu. Long press it to confirm the alarm, and there will be no alarm this time.

5.3 Menu operation

Under the measurement interface, press the menu button to enter the main menu interface as shown in Figure 5, system, display, clock, alarm and record , etc. can be set, methods are as followings:

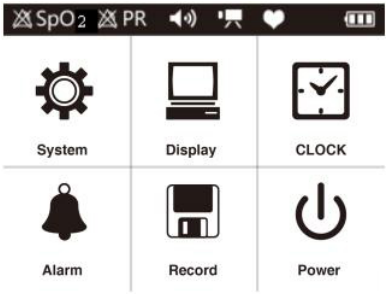

Figure 5. Main menu

5.3.1 System setting

In the main menu interface, choose "System" item, then press menu button to enter the System setting menu as figure 6:

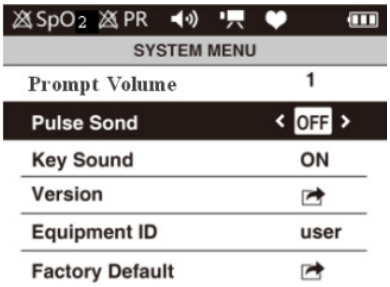

Figure 6. System setting menu

A. Prompt volume: move the choice bar to the "Volume" item, then press left/right button to set the volume (three levels).
B. Pulse sound: move the choice bar to the "Pulse sound" item, then press left/right button to set pulse sound.
C. key sound: move the choice bar to the "key sound" item, then press left/right button to set key sound.
D. Version: move the choice bar to the "Version" item, then press the menu button to see the edition information of hardware and software, and return to the system setting menu interface after 2 seconds.
E. Equipment ID: see the ID information of device. The ID of the device can be set by the PC software. Please refer to <Smart Device Assistant> for detail.

F. Factory Default: move the choice bar to the “Factory Default” item, enter the password in the pop-up interface(Please refer to chapter 5.3.4), then press the menu button to pop-up “Factory Default” window. Press up/down button to choose whether to resume Factory Default, and press menu button to affirm setting, then press return button to return the system setting menu interface.

5.3.2 Display setting

In the main menu interface, choose “Display” item, then press menu button to enter the display setting menu as Figure 7:

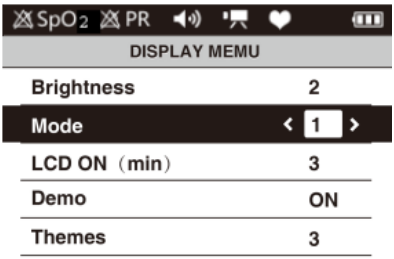

Figure 7. Display setting menu

A. **Brightness:** move the choice bar to the “Brightness” item, then press left/right button to set (three levels)
B. **Mode:** move the choice bar to the “Mode” item, then press left/right button to switch display mode (two kinds of display mode) as figure 8 and figure 9.

Note: in measure interface,the patient could press mode switch button to switch display mode too.

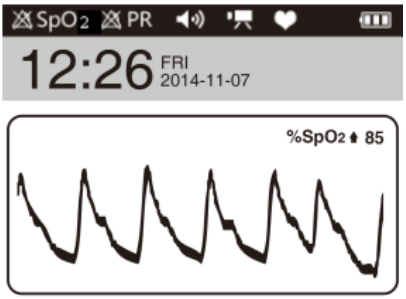

Figure 8. Interface 1

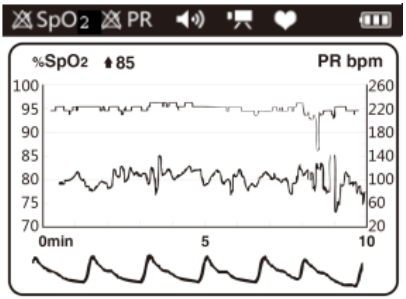

Figure 9. Interface 2

C. **LCD ON (min):** move the choice bar to the “LCD ON” item, then press left/right button to set display time (range:1~60min). INF means display at all times.
D. **Demo:** move the choice bar to the “Demo” item, then press left/right button to turn on/off demo function.
E. **Theme:** move the choice bar to “Theme” item, then press left/right button to set theme (Three kinds of theme are optional).

5.3.3 Clock setting

In the main menu interface, move the choice bar to “Clock” item, then press the menu button to enter the clock setting menu of Figure 10:

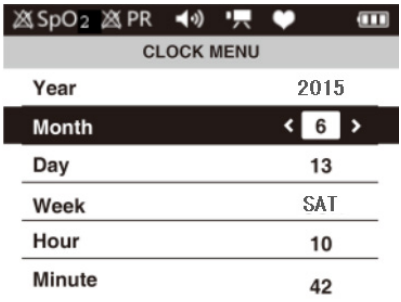

Figure 10. Clock setting menu

Move the choice bar to the menu item that you want to set, and press left/right button to begin to set. After resetting time, press return button to return to the main menu.

5.3.4 Alarm setting

When the device is turned on, the red and yellow alarm lamp flash alternately once, which indicates that the alarm system is working.

In the main menu interface, move the choice bar to “Alarm” item, then press menu button to enter the password interface of Figure 11.

Figure 11. password interface

After inputting password (The factory default is7762), move the choice bar to  , then press menu button to enter the alarm menu of Figure 12.

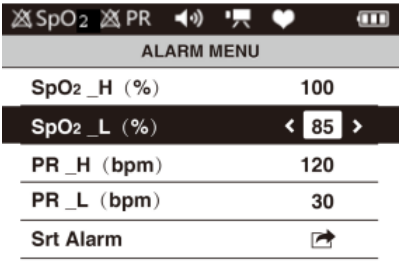

Figure 12. Alarm menu

A. Set the high/low limit of alarm
In alarm setting menu, you can set the high/low limit of alarm. Move the choice bar to the menu item that you want to set, and press left/right button to set value, then press menu button for affirming.

Note: If the alarm function is on, the device will provide alarm sound when the measure value is beyond the limit.

B. move the choice bar to “Set Alarm” item, then press menu button to enter the set alarm menu of Figure 13.

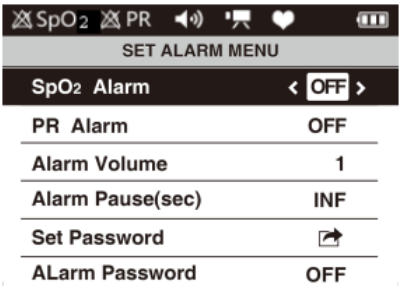

Figure 13. set alarm menu

a. **SpO2 Alarm:** move the choice bar to the “SpO_2 Alarm” item, then press left/ right button to set SpO_2 Alarm.
b. **PR Alarm:** move the choice bar to the “PR Alarm” item, then press left/ right button to set PR Alarm.
c. **Alarm Volume:** move the choice bar to the “Alarm Volume” item, then press left/ right button to set the volume (three levels).
d. **Alarm Pause(sec):** move the choice bar to the “Alarm Pause(sec)” item, then press left/right to set the alarm pause time. (60/120/600/INF, INF mean display at all times).
e. **Set Password:** move the choice bar to the “Set Password” item, then press menu button to enter the Password interface of Figure 14 to set a new password.

Figure 14. New Password interface

Note: Password can be 1~4 digits. The new password cannot be the same as the old password.

f. **Alarm Password:** move the choice bar to the “Alarm Password” item, then press left/right button to set Alarm Password.

Note: When on, you need a password to enter the alarm menu, but you don’t need a password to enter the set alarm menu. When off, you don’t need a password to enter the alarm menu, but you need a password to enter the set alarm menu.

5.3.5 Record setting

In the main menu interface, move the choice bar to “Record” item, then press menu button to enter record menu as Figure 15.

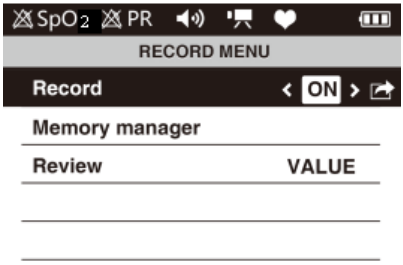

Figure 15. Record Menu

A Record setting

a. In the record menu interface, move the choice bar to “Record” item, then press left/ right button to choose on/ off. When displaying “on”, press menu button enter the input ID interface as Figure 16. When recording, choose “off”, and press menu button to stop recording.

Figure 16. Input ID interface

b. In “Input ID” interface, aglimmer cursor appears in the ID input box. The pink letter is the selected letter in dummy keyboard. Press direction key to choose the letter to input and press menu button to input. You can input 4 letters most. choose  then press menu button to delete letter.

After inputting, choose  , then press menu button to begin to record data and return to measure interface.

c. If the inputed ID has existed, the prompt dialog box as figure 17 will appear. Choose “Yes” and click menu button to replace the existed ID, at the same time begin to record and return to the measure interface; choose “No” to return the “Input ID” interface.

Figure 17. Replace the existed ID dialog box

d. Every patient ID could save 24-hour data, the device could save 16 patient ID.
e. When the memory is full, the system will stop recording automatically.
f. When the 16 groups of ID all have data, click “record” menu again, the device will appear “No Memory” dialog box. After deleting ID, the record can be continued.

Note: If the device is restarted in the process of recording, the device will lose the segment of recording data.
Note: In the process of recording, don’t allow deleting and reviewing recording information.

B Memory Manager setting
In the Record menu interface, move the choice bar to the “Memory Manager” item, then press menu button to enter ID Manager interface as figure 18.

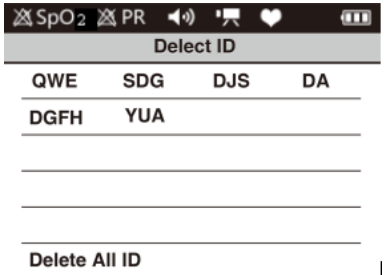

Figure18. ID Manager interface

In ID Manager interface, press direction button to choose ID or “Delete ID”, and press menu button to prompt deleting operation as figure 19. Choose “Yes” and press menu button to delete ID. Choose “No” to return to the memory manager interface.

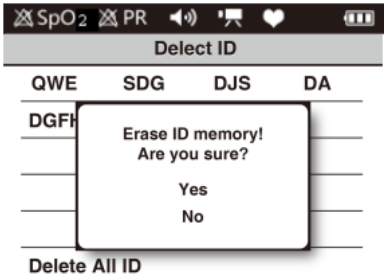

Figure 19. Delete ID dialog box

C Review function setting
In record menu interface, move the choice bar to the “Review” item, then choice frame will appear. Press the “left/right button” to choose “VALUE”/”TREND”, then press menu button to enter “select ID” interface as figure 20.

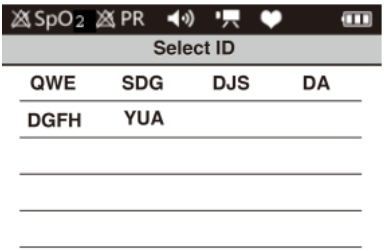

Figure 20. Select ID interface

Choose the review record and press menu button to enter the review interface. Choose “VALUE” to enter true value review interface as figure 21. Choose “TREND” to enter trend review interface as figure 22.

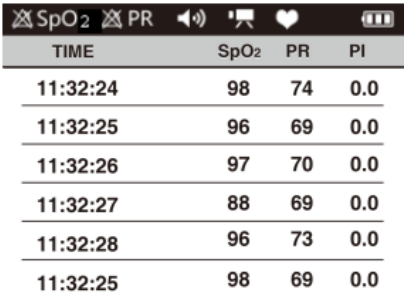

Figure 21. VALUE review interface

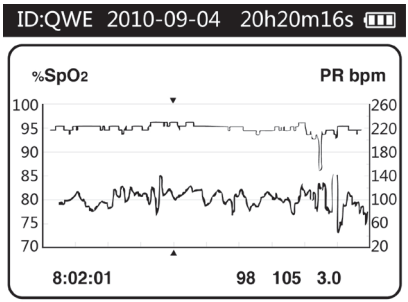

Figure 22. TREND review interface

In value review mode, press “left button” or “right button” to page up or page down, press “up button” or “down button” to page up or page down quickly. The displayed time on the right top is the total recording time.
In trend review mode, the pink number on the left bottom is current recording time point of the trend graph, the middle azury font is SpO_2 value, yellow font is pulse rate value, the green front on the right bottom is PI value. Press “up button” or “down button” to page up or page down; Press “left button” or “right button” to move the recording time which is denoted by pink triangle.

5.3.6 Close the device

A. In the main menu interface, move the choice bar to the “Power “ item, then press menu button to close the device. If the record function has been opened, the prompt interface of “Recording...” will appear when closing the device. It means that the device is in the record state, can’t be closed.
B. In the state of boot-strap, long press power button could close the device too.

5.4 Data upload

Please connect the device to the computer by data line, then double click “SpO_2 Assistant” icon to run the PC software. The functions such as uploading real time/ memory data and change device ID could be carried out by the software. Please refer to <Smart Device Assistant> for detail.
Note: If the patients choose to turn on the display function on computer, it would probably take several seconds for the data to appear on the computer screen. (If there is no data on the computer screen, unplug data line,then repeat step again.)

5.5. Charging
Connect the device to power supply with power line.
Note: When the device is closed and the battery is charging up, short press power button and the device will display dynamic charge icon, it means that the device is charging up. When the battery status is full, the charging has been finished. When the device is open and the battery is charging up, the battery status icon on the right top will display dynamically. It means that the device is charging up. When the battery status is full, the charging has been finished.

5.6 Reset
Long press the power key to reset.

6 MAINTAIN, TRANSPORT AND STORAGE
6.1 Cleaning and disinfection
Please turn off the device and disconnect it from the power,do not immerse it into liquid.
Use 75% alcohol to wipe the device enclosure, and use liquid soap or isopropanol to wipe the watch-band for disinfection, nature dry or clean it with clean and soft cloth. Do not spray any 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 peopls safety and monitoring performance. It is recommended that the device should be inspected weekly at least. When there is obvious damage, stop using it.
B. Please clean and disinfect the device before/after using it according to the User Manual (6.1).
C. Recharge the battery soon after the over-discharge. The device should be recharged every six months when it is not regular used. It can extend the battery life following this guidance.
D. The device need not to be calibrated during maintenance.
E. Please recharge the battery when the screen shows low power alarm information.
F. Patients are advised to calibrate the device termly (or according to the calibrating program of hospital). It also can be performed at the state-appointed agent or just contact us for calibration.
G. Check the backup power of the device regularly, when it can not support 1-hour continuous operation, please contact after-sales to replace the battery.

6.3 Transport and Storage
A. The packed device can be transported by ordinary conveyance or according to transport contract. During transportation, avoid 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°C ~ +60°C; Relative humidity: ≤95%.

7 TROUBLESHOOTING

Trouble	Possible Reason	Solution
The values can not be displayed normally or stably.	1) 1.The finger is not properly inserted. 2) The finger is shaking or the patient is moving. 3) The device is not used in environment required by the manual. 4) The device works abnormally.	1) Please insert the finger properly and measure again. 2) Let the patient keep calm. 3) Please use the device in normal environment. 4) Please contact the after-sales.
The device can not be turned on	1) 1. Low battery or the battery is drained away. 2) The device works abnormally.	1) Please charge the battery. 2) Please contact the after-sales
The display disappears suddenly.	1) 1. Low battery. 2) The device works abnormally.	1) 1. Please charge the battery. 2) Please contact the after-sales
The device can not be used for full time after charge	1) 1. The battery is not charged fully. 2) The device works abnormally.	1) Please charge the battery. 2) Please contact the after-sales
The battery can not be full charged even after 10 hours charging time.	The device works abnormally	Please contact the after-sales
The data can not be stored.	1) The device is not operated according to the manual. 2) The device works abnormally.	1) Please operate the device according to the manual. 2) Please contact the after-sales

8 KEY OF SYMBOLS

Symbols	Meaning	Symbols	Meaning
	Follow instructions for use		Pulse rate (bpm)
	Perfusion Index (%)		Pulse oxygen saturation (%)
	The battery power is full		Two grid of the battery
	One grid of the battery		Low battery
	Pulse oxygen saturation Alarm		Pulse rate Alarm
	Pulse sound indication: cyan- on; white-off		Kinescope indication: when Kinescope-red; else circs-white
	PR indication: when there is pulse jumpiness, it glitters and flop		Finger out (no finger)
	Alarm off		Alarm pause
	Alarm on		Type BF applied part
	Power on/off button	**Finger Out**	Probe error Signal indication is not enough.
	USB	**SENSOR FAULT**	Sensor fault(probe fault)
SN	Serial number		Class II applied

SENSOR OFF	The sensor is off (probe-off)		Manufacturer
	Alternating current indicator light		Temperature limit
IP21	Covering Protection rate		Atmospheric pressure limit
	Date of manufacture		Fragile, handle with care
	Humidity limit		Recovery
	This side up	LOT	Lot number
	Keep in a cool, dry place	EC REP	Authorized representative in the European community
P/N	Material code		WEEE disposal
CE	Medical Device complies with Directive 93/42/EEC	REF	Product code
Note: Your device may not contain all the following symbols.			

9 SPECIFICATION

SpO2 [see note 1]	
Display range	0% ~ 100%
Measured range	0% ~ 100%
Accuracy [see note 2]	70% ~ 100%: ±2%; 0% ~ 69%: unspecified.
Resolution	1%
PR	
Display range	30 bpm ~ 250 bpm
Measured range	30 bpm ~ 250 bpm
Accuracy [see note 3]	±2 bpm or ±2%, whichever is greater.
Resolution	1 bpm
PI	
Display range	0% ~ 20%
Measured range	0% ~ 20%
Accuracy	1% ~ 20%: ±1% 0% ~ 0,9%: ±0,2%
Resolution	0,1%
Accuracy under low perfusion [see note 4]	Low perfusion 0.4%: SpO2: ±4%; PR: ±2 bpm or ±2%, whichever is greater
Light interference	Under normal and ambient light conditions, the SpO2 deviation ≤ 1%
Pulse intensity	Continuous bar graph display, the higher display indicates the stronger pulse.
Upper and lower limit of alarm values	
SpO2	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	Every patient ID could save 24-hour data, the device could save 16 patient ID.
Safety class	II genus, Interior Battery, BF Type
International Protection	IP21
Alternating current supply	100 ~ 240V CA, 50/60 Hz
Internal electrical power source	3,6V CC ~ 4,2V CC
Power supply	A rechargeable lithium battery (3.7 V) (The red wire on the battery denotes anode, the black wire on the battery denotes cathode.)
Battery life	Charge and discharge: no less than 500 times.
Dimension and Weight	
Dimension	269(L) × 222(W) × 79(H) mm
Weight	About 1 kg (with a lithium battery)

Note 1: the claims of SpO_2 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_2, compare the SpO_2 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.(It is applicable for the probes equipped.)
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 ±Arms 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_2 and PR values are different due to low signal conditions, compare them with the known SpO_2 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.

10 FACTORY DEFAULT

	default	unit
Brightness	3	
Measure interface display mode	1	
LCD Brightness time	INF (mean display at all times)	
Demo mode	off	
Themes	3	
SpO_2 alarm sound indication	on	
Pulse rate alarm sound indication	on	
Alarm pause time	120	sec
SpO_2 alarm high limit	100	%
SpO_2 alarm low limit	85	%
Pulse rate alarm high limit	120	bpm
Pulse rate alarm low limit	30	bpm
Prompt volume	3	
Password	7762	
Alarm volume	3	
Alarm password	on	
Pulse sound	on	
Key sound	on	

APPENDIX

Alarm state	Alarm state delay	Alarm signal generation delay
Low battery alarm	60 s	5 ms
Over-limit alarm for SpO_2	1 s	5 ms
Over-limit alarm for pulse rate	1 s	5 ms
“Sensor Off” alarm	16 ms	5 ms

EMC

Table 1

Guidance and manufacturer’s declaration –electromagnetic emission	
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The purchaser or the user of the device should assure that it is used in such environment.	
Emission test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies

Table 2

Guidance and manufacturer’s declaration-electromagnetic immunity		
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The purchaser or the user of the Pulse Oximeter should assure that it is used in such environment.		
Immunity test	**IEC60601 test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±15 kV air	±8kV contact ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1 kV for input/output line	±2kV for power supply lines Not Applicable
Surge IEC 61000-4-5	±1 kV lines to lines ±2 kV lines to earth	±1 kV lines to lines Not Applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5%UT(>95%dip in UT) for 0.5 cycle 40% UT(60%dip in UT) for 5 cycle 70%UT(30%dip in UT) for 25 cycle <5%UT(>95%dip in UT) for 5 sec	<5%UT(>95%dip in UT) for 0.5 cycle 40% UT(60%dip in UT) for 5 cycle 70%UT(30%dip in UT) for 25 cycle <5%UT(>95%dip in UT) for 5 sec
Power frequency (50 / 60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity		
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer the user of the Pulse Oximeter should assure that it is used in such environment.		
Immunity test	**IEC 60601 test level**	**Compliance level**
Conducted RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz
Conducted RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz
Radiated RF IEC61000-4-3	10 V/m 80 MHz - 2,7 GHz	10 V/m80 MHz - 2,7 GHz
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Pulse Oximeter is used exceeds the applicable RF compliance level above, the Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Pulse Oximeter.		

Table 4

Guidance and manufacturer's declaration - electromagnetic Immunity							
The [Code SI] is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment							
	Test Frequency (MHz)	**Band a) (MHz)**	**Service a)**	**Modulation b)**	**Modulation b) (W)**	**Distance (m)**	**IMMUNITY TEST LEVEL (V/m)**
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380 -390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27
	450	380 -390	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0,3	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9
	745						
	780						
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	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	2	0,3	28
	1845						
	1970						
	2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28
	5240	5 100 – 5 800	WLAN 802,11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9
	5500						
	5785						
NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.							
a)) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.							
The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: $E = \frac{6}{d}\sqrt{P}$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.							

⚠ **Warning**

1) 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.
2) 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.
3) 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.
4) 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 device including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
5) Active medical devices are subject to special EMC precautions and they must be installed and used in accordance with these guidelines.

⚠ **Note:**

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

Disposal: *The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.*

CONDIZIONI DI GARANZIA GIMA

Si applica la garanzia B2B standard Gima di 12 mesi.