Instructions to User

Dear Customer,

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

Version of the Manual: Ver 1.7

Issued Date: July 4, 2022

Notes:

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

3502-2290079

Instructions for Safe Operation

Check the device to make sure that there is no visible damage that may affect user's safety and measurement performance. It is recommended that the device should be inspected minimally before each use. If there is obvious damage, stop using the device.

Necessary service must be performed only by qualified technicians. Users are not permitted to service this device.

The oximeter must not be used with the devices and accessories not specified in User Manual.

Warnings

- Explosive hazard—DO NOT use the oximeter in environment with inflammable gas such as some ignitable anesthetic agents.
- **DO NOT** use the oximeter while the Patient is under MRI or CT scanning. This device is NOT MRI Compatible.

Cautions

- Discomfort or pain may occur if using the sensor of this device continuously on the same location for a long time, especially for the patients with poor microcirculation. It is recommended that the Oximeter should not be applied to the same location for longer than 2 hours or less if any abnormal condition is found. Frequently check and re-position the Oximeter sensor.
- Misapplication of a SpO_2 probe with excessive pressure for prolonged periods can induce pressure injury.
- Place the SpO_2 probe on the finger tightly will cause venous pulse and effect blood circulation, and lead to interstitial edema, hypoxia and inaccurate measurement.

- Biocompatibility tests have been performed on all the applied parts, some exceptional allergic patients may still have anaphylaxis. Do not apply to those who have anaphylaxis.
- For the individual patients, there should be a more prudent inspecting in the placing process. The sensor can not be placed on the edema and tender tissue.
- The local law should be followed when disposing of the expired device or its accessories.
- DO NOT operate in the environment where strong electro-magnetic interference exists, such as radiogram, television, radiophone, etc.
- Please pay attention to the SpO_2 probe cable while using to avoid strangulating patient.

Notes

- Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- If the Oximeter gets wet, please stop operating it and do not resume operation until it is dry and checked for correct operation. When it is carried from a cold environment to a warm and humid environment, please do not use it immediately. Allow at least 15 minutes for the Oximeter to reach ambient temperature.
- **DO NOT** operate the button on the front panel with sharp materials or sharp point.
- DO NOT use high temperature or high pressure steam disinfection on the oximeter and probes. Refer to related chapter for instructions regarding cleaning and disinfection.
- The intended use of this device is not for therapy purpose.

☞ The equipment is IP22 with protection against harmful solid foreign objects and ingress of liquid. So that means the equipment is protected against solid foreign objects of 12.5mm and greater, and protected against vertically falling water drops when enclosure tilted up to 15°.

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

Declaration of Conformity

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

IEC 60601-1: 2005+A1: 2012 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance;

ISO 80601-2-61: 2017 - Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse Oximeter equipment.

And it also follows the provisions of the council directive MDD 93/42/EEC.

Table of Contents

1 Overview

1.1 Appearance

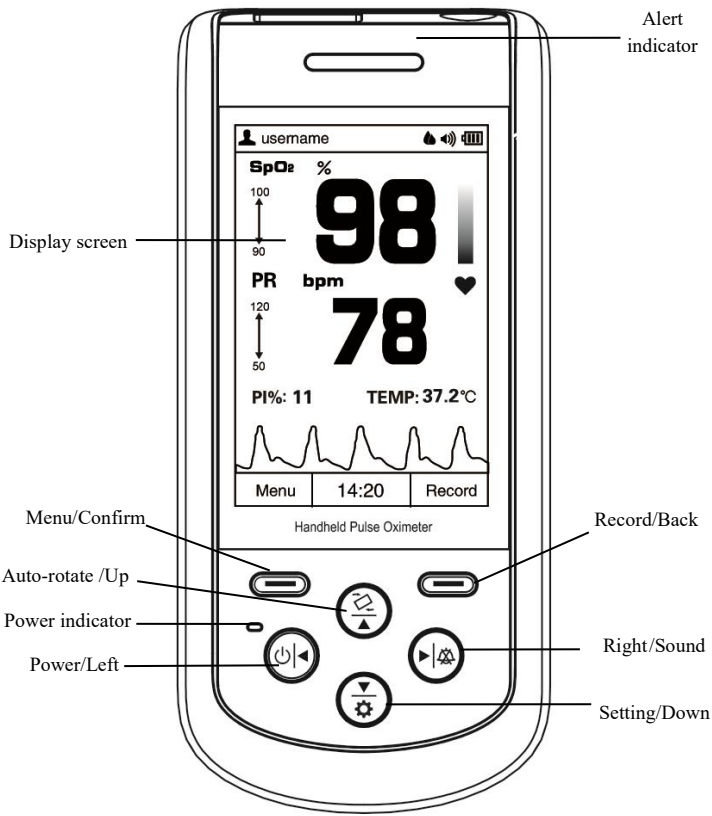


Figure 1.1 Front View

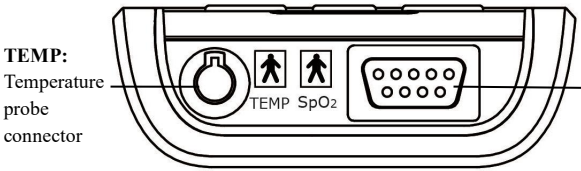


Figure 1.2 Upper-side view

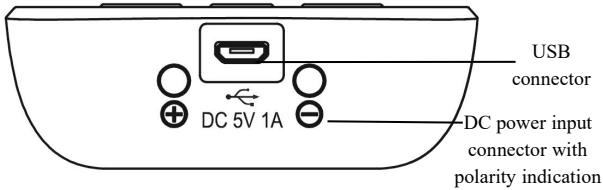


Figure 1.3 Bottom side view

1. **Display screen:** Display measurement result, trends and menus.

2. **(Power/Left):** Power on/off the device by longtime pressing; On menu or sub-menu screen, short time press it to move the cursor left or adjust the parameter values.

3. (**Right/Sound**): On data recall screen, longtime press this key, then the delete dialog pops up; On measuring screen, longtime press it to disable or enable the global sound.

On measuring screen, if the global sound is enabled, and alert event occurs, then short time press it to perform audible alert reset (that's to say, to alert sound will be mute). When the current alert event ends or a new type of alert event occurs, then status of audible alert reset will be ended (that's to say, the alert sound will be generated again when an alert event occurs). On menu or sub-menu screen, short time press it to move the cursor right or adjust the parameter values.

4. **(Auto-rotate/Up):** On measuring screen, longtime pressing to enable or disable the automatic screen orientation (on horizontal or vertical direction); On menu or sub-menu screen, short time press it to move the cursor upwards or adjust the parameter value.

5. **(Setting/Down):** On measuring screen, longtime pressing to enter into setting screen; On menu or sub-menu screen, short time press it to move the cursor downwards or adjust the parameter value.

6. **(Menu/Confirm):** Short time press it to enter into menu screen, or to confirm the selection.

7. **(Record/Back):** Short time press it to enter into SpO_2 record list screen, or to back to the previous level of menu.

8. **(Alert indicator)**: If the probe is not well placed or disconnected, or the measured value exceeds the preset alert limit value, then the alert indicator will flash with orange color.

9. **(Power saving mode indicator)**: If the device is set as power saving mode, then the indicator lights up. And on measuring screen, the indicator flashes with the pulse beep.

10. **Icon: "SpO_2"(** **)**: SpO_2 Probe Connector.

11. **Icon: "TEMP"(** **)**: Temperature Probe Connector.

12.( ): USB connector. Used for data uploading or charging.

13.(DC 5V 1A): DC power input contact shoes with polarity indication. Used for connecting external DC power input for charging the built-in rechargeable battery via the base.

1.2 Product Name and Model

Name: Handheld Pulse Oximeter

Model: SP-20

1.3 Structure

It consists of the main unit and SpO_2 probe.

(Note: with optional temperature prob, this Oximeter can make temperature measurement.)

1.4 Features

- ✧ It is lightweight, small in size and easy to carry
- ✧ Color LCD to display plethysmogram and parameters
- ✧ Measure SpO_2, Pulse Rate and Temperature simultaneously
- ✧ PI (Perfusion Index) display is available
- ✧ Up to 580 hours data storage for SpO_2 and PR and can be recalled
- ✧ 16 user IDs for marking data and can be added
- ✧ A built-on holder for convenient standing on desktop and display viewing
- ✧ Real-time battery status display and low battery voltage indication
- ✧ Auto power off is available
- ✧ Audible and visual alert function is available
- ✧ Data uploading to PC for management (Optional)
- ✧ Power saving mode is available

1.5 Intended Use

This Handheld Pulse Oximeter is intended for measuring and recording the pulse rate, functional oxygen saturation (SpO_2) and temperature (optional). It is applicable for detecting SpO_2, pulse rate and temperature of adult and neonate patients in clinical institutions and homes.

1.6 Working Environment

Operating temperature:	5~40℃
Operating humidity:	15%~93% (non-condensing)
Atmospheric pressure:	70kPa~106kPa

2 Power Supply

1. Internal power supply with built-in battery:

Built-in battery specification: 2000mAh lithium battery.

2. External power from the AC power adapter:

Use the AC power adapter provided by the manufacturer. Make sure the mains power supply is 100-240VAC with 50/60Hz.

Note: it's recommended to use the AC power adapter provided by the manufacturer.

3. The Base:

Input: Micro USB connector, 5VDC/1A

Output: Contact pins. 5VDC/1A

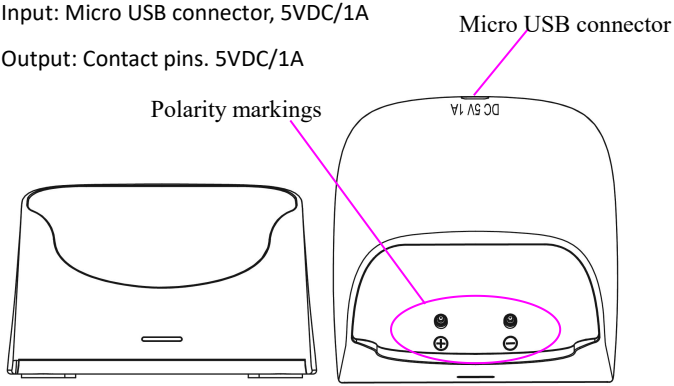


Figure 2.1A Base--front view Figure 2.1B Base--top view

Description:

The base is used to hold the oximeter, and also for charging the oximeter. You can charge the oximeter by the following methods:

1) When the oximeter is held by the base, you can connect one end of the USB cable to the USB connector on the back of the base marked with “DC 5V/1A”, and the other end to the USB power source with output capacity of 5V DC/1A;

2) If the oximeter is not held by the base, then you can just connect one end of the USB cable to the USB connector on the device marked with "⇆", and the other end to the USB power source with output capacity of 5V DC/1A.

Notes:

1) During charging, if the oximeter is held by the base, please do not tilt the base backwards too much, or the USB cable and the USB connector may be damaged.

2) Put the device into the base properly, and pay attention to the polarity markings, as shown in figure 2.2.

Cautions

- The external 5V DC output power supply device (computer or power adapter) connected to charging base or directly connected to the Oximeter must comply with standard IEC 60950 or IEC 60601-1. It’s strongly recommended to use the power adapter provided by manufacturer for your safety!
- Please unplug the SpO_2 probe and temperature probe while charging to prevent danger caused by children touching and playing by mistake.
- Do not measure temperature or SpO_2 while charging to avoid electric shock.

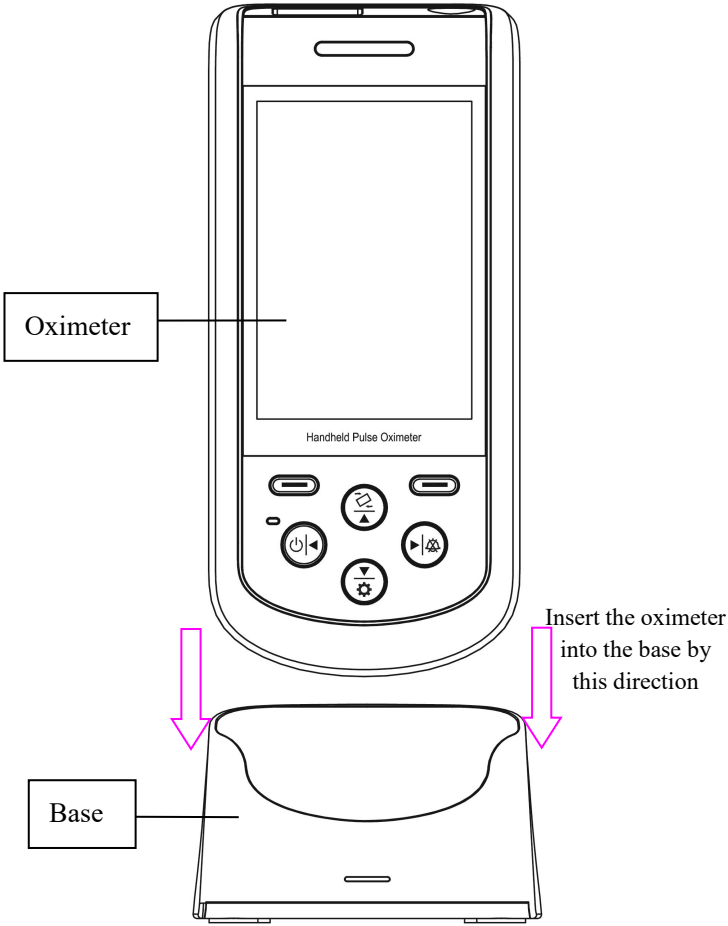


Figure 2.2 Connection between oximeter and base

3 Make Measurement

3.1 SpO_2 Measurement

Operation procedures:

1. Connect the SpO_2 probe to the connector on the upper-side of the device marked with "SpO_2". (Note: When disconnecting the connector, be sure to hold the head of the connector firmly and pull).

2. The red blinking light inside the clip of the SpO_2 probe indicates a successful connection.

3. Insert one finger (index finger is preferred, the nail should be not too long) into the clip of the probe according to the finger mark,as shown in figure 3.1.

4. The device will begin to take the measurement, and the measured result will be displayed on the screen, as shown in figure 4.2.

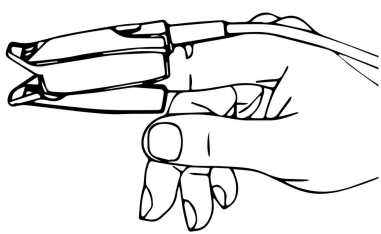


Figure 3.1 demonstration for SpO_2 probe

Safety instructions for SpO_2 measurement

- Long term use of the SpO_2 probe on the same place may result in discomfort or pain, especially for those with microcirculatory problems. It is recommended that the probe should NOT be applied to the same place for over two hours, change the measurement site periodically and when necessary.
- When the ambient temperature is over 35℃, please change the measuring site every two hours; when the ambient temperature is over 37℃, please do NOT use the SpO_2 sensor, as using in high temperatures can cause burns.
- Do NOT place the SpO_2 probe on a finger with edema or fragile tissue.
- Do NOT put the SpO_2 probe and pressure cuff on the same limb, otherwise the blood pressure measurement may affect the SpO_2 measurement.
- The device is calibrated to display functional oxygen saturation.
- Do NOT allow the sensor cable to twist or bend.
- Check the SpO_2 sensor and cable before use. Do NOT use a damaged SpO_2 sensor.
- When the temperature of the SpO_2 sensor is abnormal, do not use it further.
- Remove nail polish or other cosmetic products from the fingernail.

- The fingernail should be of normal length.
- The SpO_2 sensor cannot be immersed into water, liquid or cleanser.
- The SpO_2 sensor can be repeatedly used. Please clean and disinfect before reuse.

☞ Connector with the label "SpO_2" can only be connected with SpO_2 probe, and connector with the label "TEMP" can only be connected with the temperature probe.

3.2 Temperature Measurement (optional)

The infrared temperature probe is a delicate transducer. To operate please follow these steps and procedures. Failure to accurately operate may cause damage to the probe.

The infrared temperature probe is as shown in figure 3.2.

Please place the infrared temperature probe in a stable ambient temperature for 30 minutes before taking a measurement.

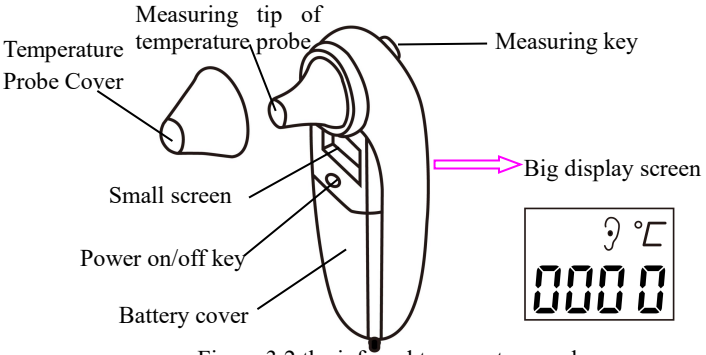


Figure 3.2 the infrared temperature probe

Operation procedure:

1. Connect the infrared temperature probe to the connector on the upper side of device marked with "TEMP".
2. When the screen shows as the big display screen in figure 3.2 and the temperature unit "℃" is blinking, the user can begin to take the measurement.
3. Insert the tip of the temperature probe into the earhole and press the measuring key to start the measurement. A short beep means the measurement has finished and the result will be displayed on the big display screen on temperature probe and the display screen of the Oximeter.

Note:

- If the temperature probe detects a hardware failure, the display screen on the infrared temperature probe will show "Err" and will not enter into measurement mode.

- The infrared temperature probe will switch to standby state automatically if there is no operation for 1 minute. If a further measurement is needed, press the measuring key and repeat step 2 and step 3.
- Normal body temperature varies depending on the position/area the measurement is taken from. The following table shows the varying temperature ranges of the different body positions.

Temperature varying range at different body positions:

Arm	34.7 ~ 37.3 ℃
Oral	35.5 ~ 37.5 ℃
Rectal	36.6 ~ 38.0 ℃
Ear	35.8 ~ 38.0 ℃

Safety Instruction for Temperature Measurement

- Do NOT take a measurement when the patient is moving.
- Patients with tympanitis or otitis problems should NOT use this device.
- When the infrared temperature probe is connected to the device, the probe will consequently be at power-on status, therefore pressing the power on/off key on the temperature probe will not cause any effect.

4 Operation

4.1 Power on/off the Oximeter

- Long pressing"  " Power/Left key for 1~2 seconds, then the oximeter will be powered on. The oximeter will do self-test and then the software version and warning

message "Professional attendance is required for continuous monitoring!" will be shown on the screen, as shown in figure 4.1 (refer to your oximeter for actual version).

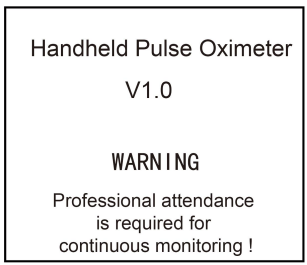


Figure 4.1

4.2 Default Display Screen

Press "⏻"power key for 2 seconds to start up the Oximeter, then the screen will display the default screen, as shown in Figure 4.2.

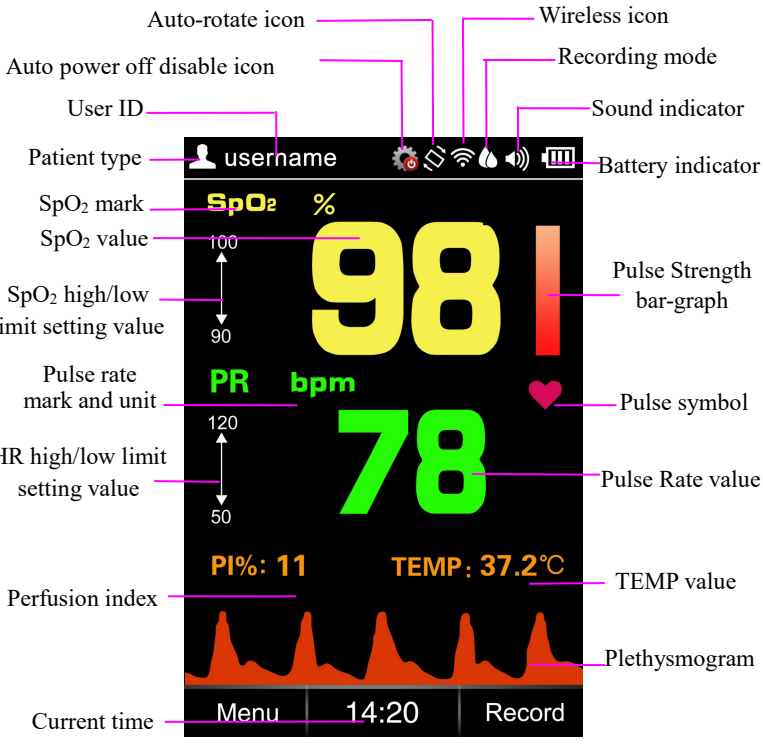


Figure 4.2A Default Display Screen---in vertical

Description:

- During measurement, if the finger is not inserted properly, or the probe is not connected or the probe is off from the finger, then "Check Probe" message prompts and keeps

blinking on the screen, and "bibibi..." alert sound appears simultaneously. Alert sound is sustaining for about 3 minutes, and if there is no any key operation in this period, then the device will power off automatically (if the auto power off function is enabled).

- During measurement, longtime pressing Auto-rotate/Up key "  ", then the Auto-rotate white icon "  " appears on the upper right corner of the screen, it means the auto rotation function is enabled, if you place this oximeter horizontally, then the display shows in horizontal, as shown in figure 4.2B.

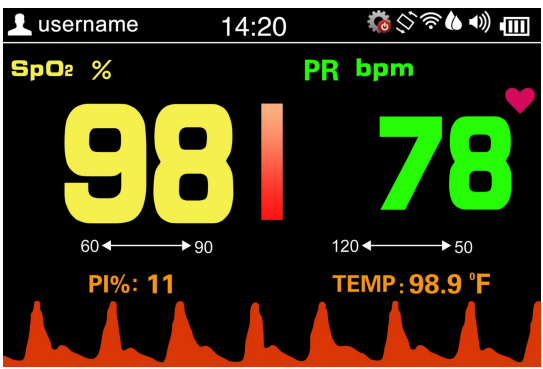


Figure 4.2B Default Display Screen---in horizontal

- Sound indicator "  " means that the global sound is disabled, the user can enable the global sound by longtime

pressing "  " key. Longtime pressing "  " key again can disable the global sound, that's to say, the speaker is turned off at all, therefore, no pulse beep sound, no audible alert and no key click sound.

- If the global sound is enabled by longtime pressing "  " key, then during the measurement, over-limit alert event or probe off event can activate the audible alert. Refer to Section 6.2 for detailed alert indication sound.
- If the memory is full, the corresponding memory full icon appears on the screen, "  " means temperature memory is full, "  " means SpO_2 spot-check record memory is full, "  " means SpO_2 trend record memory is full. No display of the icon means the current corresponding storing space is not full. If the memory is full, the data storing will continue in such way the new record will overwrite the oldest record, so that it's recommended to upload the stored data into the computer in time.

4.3 Menu

On the default measuring screen, short time press " ▬ " Menu/Confirm key for entering into main menu screen (as shown in Figure 4.3).

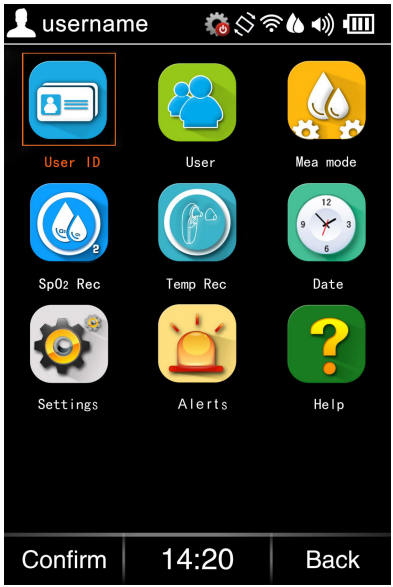


Figure 4.3 Main menu

There are 9 functional icons in main menu screen, press Up/Down/Left/Right key can move the cursor to make selection and press " ▬ " Menu/Confirm key again to confirm the selection.

- User ID: Add new or edit the current User ID.

- User: Select patient type, "Adult" and "Neonate" for option.

Note: when the device is set to the neonate patient type, then the User icon "  " turns to grey "  ", and the patient type on upper left corner turns to pink "  ".

- Recording mode: Select the data recording mode, "Spot-check Record" and "Trend Record" for option.
- SpO_2 record: Recall and review the records stored on the oximeter, two types of record for option: "Spot-check Record" and "Trend Record", see Section 4.4 for details.
- TEMP Record: Review the temperature record list.
- Date: Set the time and date, see Section 4.3.6 for details.
- Settings: Set the system parameter, including brightness, sound volume, display language, power saving mode etc., see Section 4.3.7 for details.
- Alerts: Set the low alert limit for SpO_2 and the high/low alert limit for PR, see Section 4.3.8 for details.
- Help: To view the tips information of SpO_2 measurement and temperature measurement, see Section 4.3.9 for details.

4.3.1 User ID

On main menu screen, move the cursor on "User ID" and press Confirm key "  ", then the oximeter enters into User ID Setup screen, as shown in figure 4.4.

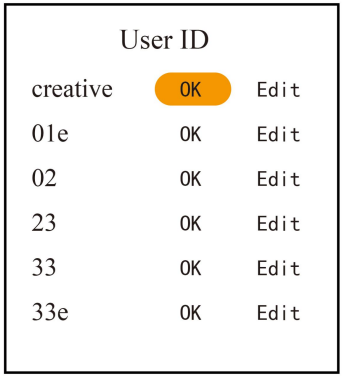


Figure 4.4A User ID setup screen

Move the cursor on "Edit" and press Confirm key "▬", when the cursor turns to blue, then the user can edit the User ID, and move the cursor on "OK" to confirm the edit, the edit screen is as shown in figure 4.4B.

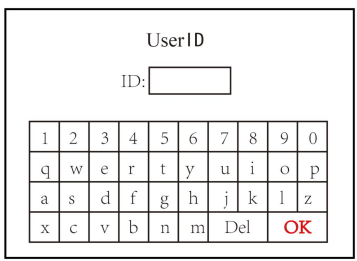


Figure 4.4B User ID edit screen

4.3.2 User

On main menu screen, move the cursor on "User" and press Confirm key "▬", then the oximeter enters into Patient type Setup screen, as shown in figure 4.5.

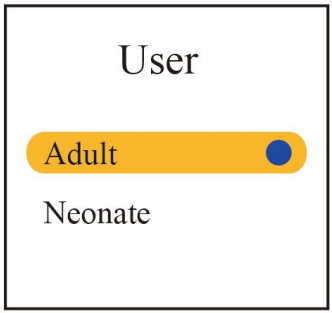


Figure 4.5 Patient type setup screen

4.3.3 Recording Mode

On main menu screen, move the cursor on "Recording Mode" and press Confirm key " ", then the oximeter enters into Recording Mode Setup screen, as shown in figure 4.6.

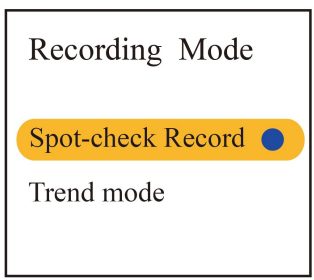


Figure 4.6 Recording mode setup screen

Note: When selecting “Spot-check Record” for data recording, the measuring time should last over 10 seconds to get one spot-check reading, or no reading value will not be recorded in Spot-check data record; When selecting “Trend Record”, the measuring time

should exceed 30 seconds, or no one record will be recorded in Trend data record list.

4.3.4 SpO_2 Record

On main menu screen, move the cursor on "SpO_2 Record" and press Confirm key " ", then the oximeter enters into SpO_2 record review method selecting screen, as shown in figure 4.7.

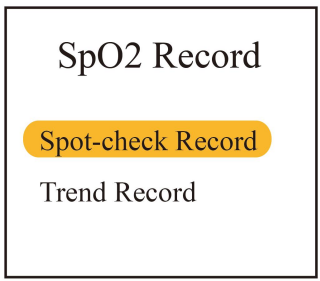


Figure 4.7 SpO_2 record review method selecting screen

Refer to Section 4.4 for details.

4.3.5 TEMP Record

On main menu screen, move the cursor on "TEMP Record" and press Confirm key " ", then the oximeter enters into temperature record list screen, as shown in figure 4.8.

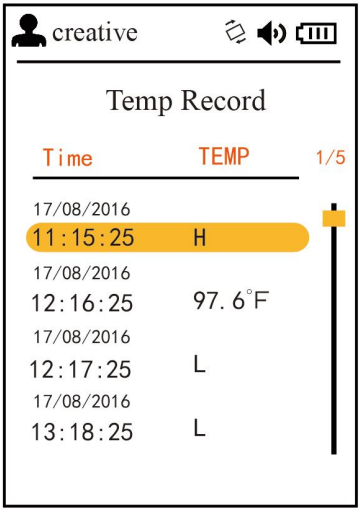


Figure 4.8 TEMP record list screen

4.3.6 Date

On main menu screen, move the cursor on "Date" and press Confirm key "  ", then the oximeter enters into date setup screen, as shown in figure 4.9.

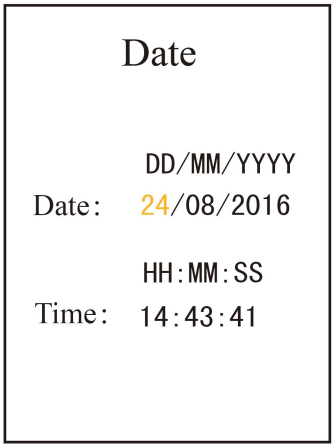


Figure 4.9 Date setup screen

Date setting procedure:

1) Move the cursor stays on the Year of the date, press Confirm key "▬" to active Year option, the cursor flashes on the Year of the date;

2) Press Up/Down key to adjust Year;

3) Press "▬" (Confirm) key to confirm and exit from date setting;

4) The procedures of adjusting Month, Day, Hour, Minute and Second value are the same with Year adjustment.

Date Format: DD-YY-MM; Time Format: HH:MM:SS

Note: The setting operations of other parameters (such as User ID, User, Auto Power Off, Power Saving etc.) are the same with date setting.

4.3.7 Settings

On main menu screen, move the cursor on "Settings" and press Confirm key "▬", then the oximeter enters into system

setting screen, as shown in figure 4.10.

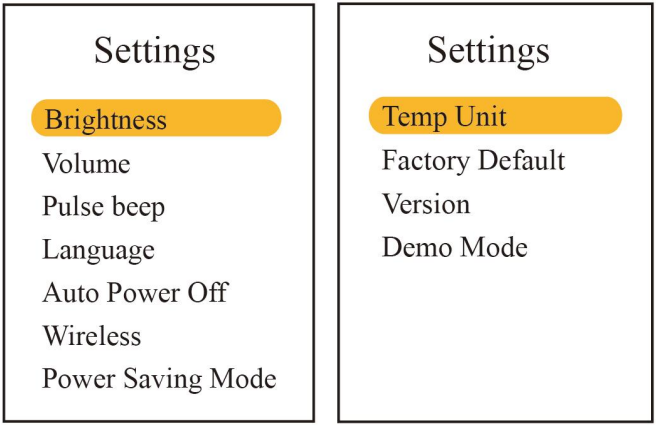


Figure 4.10 System setting screen

Description:

- Brightness: To set the brightness of backlight, 6 levels for optional, the factory default is level 3, as shown in figure 4.10A.
- Volume: To set the sound volume (including alert sound, pulse beep sound and key click sound), 6 levels sound volume for optional, the factory default is level 3, as shown in figure 4.10B.
- Pulse beep: To turn on/off pulse beep, the factory default is "On", as shown in figure 4.10C. If the global sound is enables by longtime pressing "  "key, and the pulse beep is set to "On" option, and when there is no over-limit event, then pulse beep sound can be heard during SpO_2 measurement.
- Language: This oximeter provides the display with two languages: English and Simplified Chinese, the factory

default is "English", as shown in figure 4.10D.

- Auto power off: To turn on/off the Auto Power Off mode, the factory default is "On", as shown in figure 4.10E.
- Wireless: To turn on/off the wireless connection function, the factory default is "On", as shown in figure 4.10F.
- Power saving mode: To turn on/off the Power Saving mode, the factory default is "On", as shown in figure 4.10G.
- TEMP unit: To set the temperature unit, "℃(Celsius)" and "℉(Fahrenheit)" for option, the factory default is "℉", as shown in figure 4.10H.
- Factory Default: Enter into the factory default setting, as shown in figure 4.10I.
- Version: For viewing version number of the software, as shown in figure 4.10J.
- Demo: Enter into the Demonstration mode, as shown in figure 4.10K.

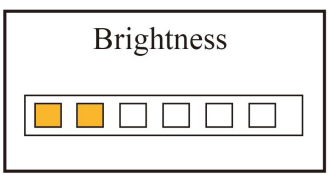


Figure 4.10A Brightness setup

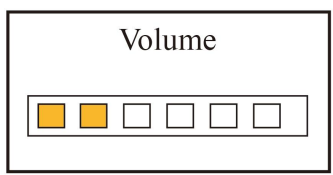


Figure 4.10B Volume setup

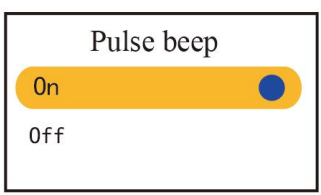
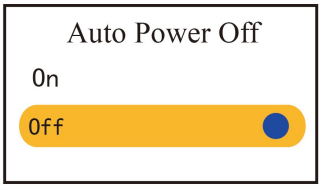


Figure 4.10C Pulse beep setup

Figure 4.10D Language setup



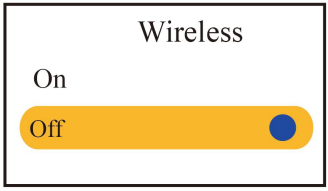
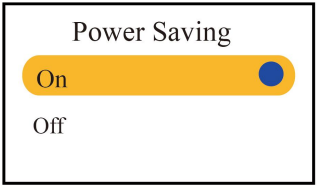


Figure 4.10E Auto Power OFF setup

Figure 4.10F Wireless setup



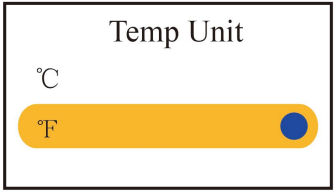
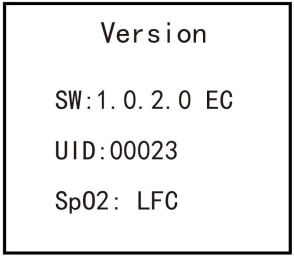


Figure 4.10G Power Saving setup

Figure 4.10I TEMP unit setup



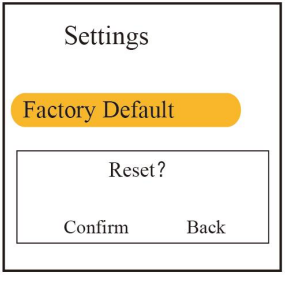


Figure 4.10H Version info

Figure 4.10J Default setting

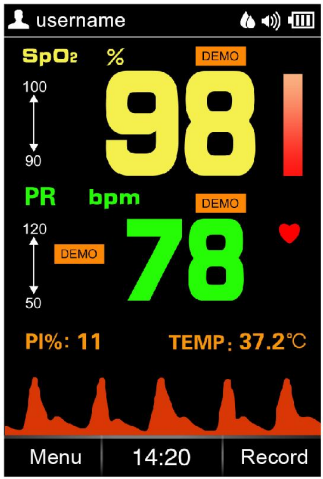


Figure 4.10K Demo mode

Notes:

- ✧ When the Auto Power Off is set to "On" option, if there is no key operation for 3 minutes, then the oximeter will power off automatically.
- ✧ When the Power Saving Mode is set to "On" option, during the measurement, if there is no key operation for 1 minute, the screen display will be dim for power saving. The display brightness will resume to normal condition by pressing any key.

4.3.8 Alerts

On main menu screen, move the cursor on "Alerts" and press Confirm key "▬", then the oximeter enters into alerts setting screen, as shown in figure 4.11.

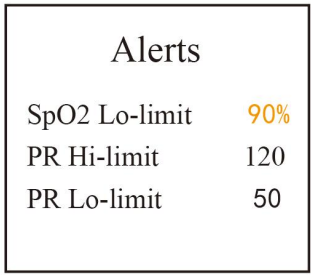


Figure 4.11 Alerts setting screen

- **SpO_2 Lo-Limit:** SpO_2 low limit setting; range: 50%~99%, the step is 1%. The factory default value for adult is 90% and 95% for Neonate.
- **PR Hi-Limit:** High limit setting of pulse rate; range: 100~240bpm. From 100 to 150, the step is 1bpm, and from 150 to 240, the step is 5bpm. The factory default value for adult is 120bpm and 160bpm for neonate.
- **PR Lo-Limit:** Low limit setting of pulse rate; range: 30~99bpm, and the step is 1bpm. The factory default value for adult is 50bpm and 60bpm for neonate.

Note: When the SpO_2 reading is lower than or equal to the preset alert setting or the PR reading is higher than or equal to the preset high limit or the PR reading is lower than or equal to the preset low limit, then the over-limit alert event will be activated, that's, the alert sound "bibibibi..." occurs, and the corresponding reading(s) blinks. When measured on neonate, if the SpO_2 reading is lower than or equal to the preset alert setting for 10 seconds, then the alert sound and blinking display will be activated.

4.3.9 Help

On main menu screen, move the cursor on "Help" and press Confirm key "  ", then the oximeter help information screen, which shows SpO_2 and temperature measurement tips, as shown in figure 4.12.

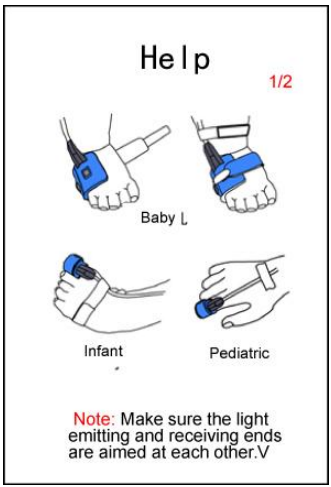


Figure 4.12 Help information---SpO_2 measurement

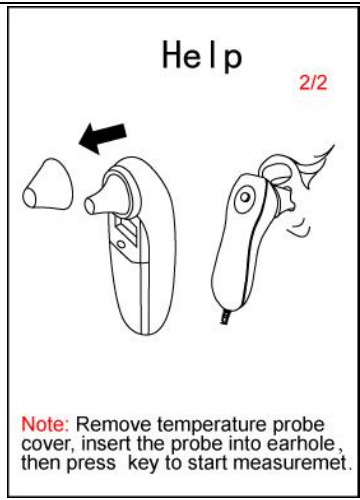


Figure 4.12 Help information---TEMP measurement

4.4 Record

4.4.1 Data Recall

On main default screen, short time press Record/Back key "▬" to enter into data recall screen, as shown in figure 4.13.

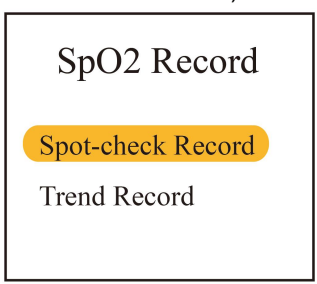


Figure 4.13 SpO_2 record

SpO_2 records include two types, Spot-check and Trend Record, Spot-check Record is a list showing the recording time, SpO_2 value and pulse rate value for each spot-checking event, as shown in figure 4.14.

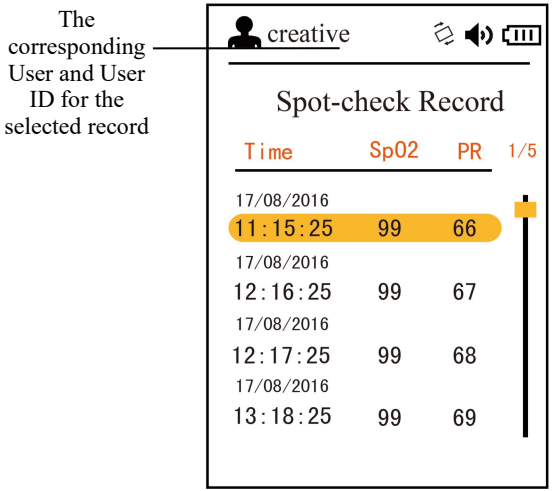


Figure 4.14 Spot-check Record list

If Trend Record is selected, then the screen shows a list of trend data record, and each record corresponds to a period of recording at a fixed time interval (1 second), as shown in figure 4.15, press Up/Down key (" / ") to select one record you need to review.

Select one record you need to review, and press Confirm key "", then the screen shows the corresponding User, User ID, and trend graph, as shown in figure 4.16.

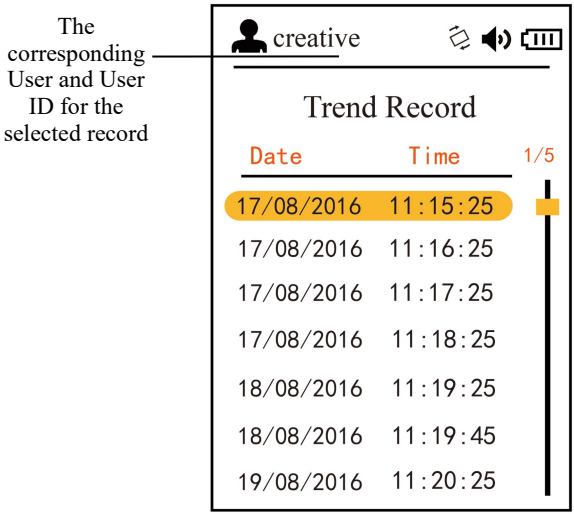


Figure 4.15 Trend record---List

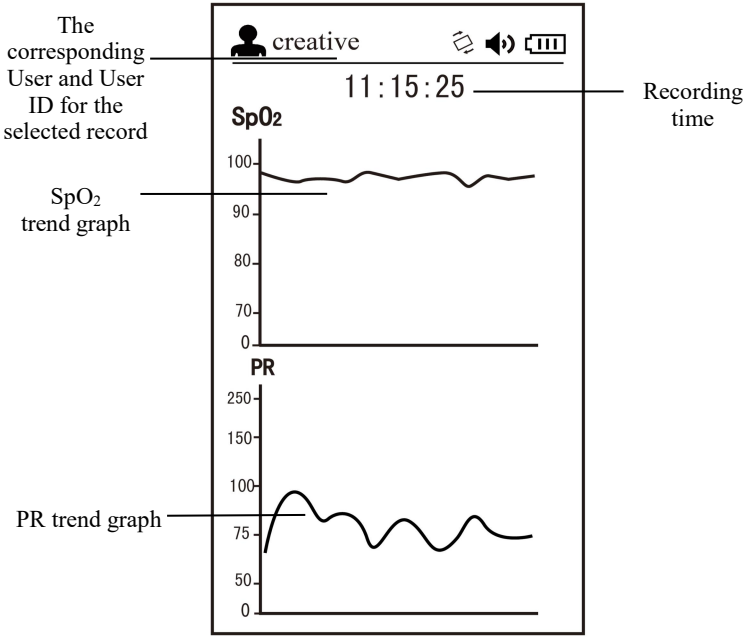


Figure 4.16 Trend record---Trend graph

4.4.2 Data Deletion

On the record list screen shown in figure 4.14 or 4.15, move the cursor on the record you want to delete, and longtime pressing Sound/Right key(" "), then an message "Are you sure to delete all?" prompts on the screen, as shown in figure 4.17.

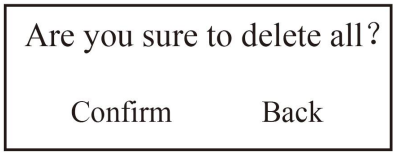


Figure 4.17 Delete records

At this time, short time press Menu/Confirm ("▬") key to confirm and delete the records. Or short time press Record/Back ("▬") key to return to record list screen.

4.4.3 Data Upload

If you want to upload the stored data (SpO_2, PR and TEMP values) to the computer, then Make sure the provided USB data cable is well connected between the device and PC before uploading data, as shown in figure 4.18. Refer to the instruction in "Oximeter Data Manager User Manual"for detailed operation.

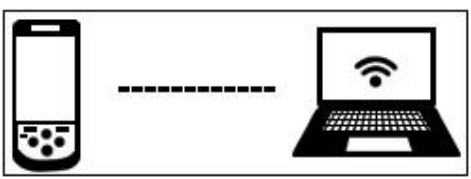


Figure 4.18 Data uploading screen

- **During data uploading, the user can not do any operation on the oximeter.**

When the wireless transmission function is on, the Handheld Pulse Oximeter can communicate with a host (such as computer or mobile) for viewing and management.

a. Open the host's wireless function and procedure and start to

scan the SP-20 Oximeter.

b. The host will pair with the SP-20 Oximeter at a moment.

c. After connecting, the host can display and manage the measurement data of SP-20 by wireless.

The pairing and transmitting distance of wireless function is 8 meters in the normal. If the host can't pair with the SP-20, you will try to narrow the distance between the host and SP-20.

The SP-20 can pair and transmit with the host under the wireless coexistence environment, but other wireless device may still interface with pairing and transmission between the host and the SP-20 device under uncertain environment. If the host and the SP-20 display inconsistent, you may need to change the environment.

4.4.4 Data Management

The user can go to our website to download the corresponding PC Software "Oximeter Data Manager" for this oximeter with the link: http://www.creative-sz.com/downloads

With the computer installed this PC software, you can upload the data stored in the oximeter to your PC via wireless or data cable . It's convenient for user to review the data records and statistical result, aa well as archive patients' data.

5 Technical Specifications

A. Display Panel: 3.5 inch color TFT LCD;

B. Power Supply:

Internal power supply: 2000mAh lithium battery

AC power adapter: 5VDC/1A,

Working current: ≤180mA

Input power for AC power adapter: <15VA

The typical continuous operation time of the battery: 18 hours (when screen display is automatically off and wireless function is disabled).

The typical service life of the battery: 5 years.

C. SpO_2 Measurement

Transducer: dual-wavelength LED sensor with wavelength:

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

Maximal average optical output power: ≤ 2mW

Display range: 0~100%

Measuring accuracy: A_{RMS} value (defined in ISO 80601-2-61) is not greater than 2% for SpO_2 range from 70% to 100%.

SpO_2 low alert limit setting range: 50%~99%

The device is calibrated to display functional oxygen saturation.

The functional tester cannot be used to assess the accuracy of the SpO_2 probe or the device.

D. Pulse Rate Measurement

Display and measuring range: 30bpm~250bpm

Accuracy: ±2bpm or ±2% (whichever is greater)

E. Perfusion Index Display

Range: 0.2%~20%

F. Temperature Measurement

Measuring range: 32.0℃~43.0℃

Measuring accuracy: ±0.2℃ for temperature range from 35.0℃ to 42.0℃, and ±0.3℃ for the rest.

Response time: ≤5s

Patient Group: Adult and Neonate

Measuring site: earhole

Deviation: ≤0.1℃

G. Operating Environment

Operating Temperature: 5°C ~40°C

Operating Humidity: 15%~93%

Atmospheric pressure: 70kPa~106kPa

Note: portable and mobile RF communications equipment may affect the performance of the Oximeter.

H. Low Perfusion Performance

The accuracy of SpO_2 and PR measurement still meet the precision described above when the modulation amplitude is as low as 0.4%.

I. Resistance to interference of surrounding light:

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

J. Wireless (bluetooth) function

Frequency band: 2.4GHz

Working profile: BLE V4.0

K. Dimensions: 158 mm (L) × 73 mm (W) × 25 mm (H)

Net Weight: about 230g (including battery)

L. Classification

Type of protection against electric shock:

Internally powered equipment and Class II.

Degree of protection:

Type BF applied parts.

Degree of protection against harmful ingress of liquids: The equipment is IP22 with protection against harmful solid

foreign objects and ingress of liquid.

Mode of operation: Continuous operation.

Electro-Magnetic Compatibility: Group I, Class B

M. Data update period

The update time for determining SpO_2 and PR value is 8 seconds, and the displaying update time is 1 second.

Remark: The oximeter calculates the SpO_2 and PR value, every second by use of recently acquired data segment, then yields the displaying value by moving average of the latest calculated parameters. The reading value of SpO_2 and PR on the oximeter is updated every second, and the displayed plethysmogram is a normalized waveform. If the signal is no integral (such as with too much noise, or poor signal to noise ratio or signal is lost), then the SpO_2 and PR will be identified as an invalid value, that's to say, the numeric reading will disappear and be displayed as "--" instead.

Note: The oximeter is calibrated in the factory before sale, and there is no need for user to calibrate again.

6 Over-limit Indication

6.1 Limit settings

- SpO_2 low limit setting range: 50% ~ 99%.
- Pulse Rate limits setting range:

High: 100bpm--240bpm Low: 30bpm--99bpm

During the measurement, if the measured value exceeds the preset value, the alert beeping sound will be activated, the value that is over-limit will blink at the same time.

6.2 Over-limit indication sound mute setting

- During the measurement, if the global sound is enables, then short time press"  " key to perform audible alert reset (that's to say, the alert sound will be mute, and icon "  " appears on the upper right corner of the screen), but the over-limited value still keeps blinking. when the current alert event ends or a new type of alert event occurs, then the status of audible alert reset will be ended (that's to say, the alert sound can be generated when an alert event occurs, and icon "  " appears on the upper right corner of the screen).
- When the global sound is enables, then the longtime pressing "  " key cam disable the global sound, and the sound icon becomes "". Longtime pressing "  " key again can enable the global sound. Note: "  " means the speaker volume is set as 1 or 2 grid(s); "  " means the speaker volume is set as 3 or 4 grids; "  " means the speaker volume is set as 5 or 6 grids.
- During the measurement, if the probe is off or disconnected, the message "Check Probe" shows and keeps blinking on

the display screen. The alert sound starts (interval is 5 seconds). If the probe is still off and lasts for about 3 minutes, then the Oximeter will power off automatically.

7 Packing List

1. An Oximeter
2. A SpO_2 probe
3. User Manual
4. A oximeter rubber cover
5. A charging base
6. A temperature probe (optional)
7. Charging cable (optional)
8. A USB data cable (optional)

Notes:

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

2. All the parts of the device should NOT be replaced at will. If necessary, please use the components provided by the manufacture or those that are of the same model and standards as the accessories along with the device which are provided by the same factory. Otherwise, negative effects concerning safety and biocompatibility etc. may be caused.

3. This device can only connect with the manufacture nominated device.

8 Repair and Maintenance

8.1 Maintenance

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

maintenance;

- If the battery is damaged, please contact your local sales representative or the manufacture.
- Please store the device carefully to avoid being damaged by pets, pests or children.
- The recommended storage environment of the device:

  Ambient temperature: -20ºC ~60ºC

  Relative humidity: 10%~95%

  Atmospheric pressure: 50kPa~107.4kPa

  Storage and Transportation between uses:

  – 25℃ without relative humidity control;

  and + 70℃ at a relative humidity up to 93% (non-condensing).
- The oximeter is calibrated in the factory before sale, there is no need to calibrate it during its life cycle. However, if it is necessary to verify its accuracy routinely, the user can do the verification by means of SpO_2 simulator, or it can be done by the local third party test house.

8.2 Cleaning and Disinfecting Instruction

- Surface-clean sensor with a soft cloth by wetting with a solution such as 75% isopropyl alcohol, if low-level disinfection is required, use a 1:10 bleach solution.
- Then surface-clean by a dampened cloth and let it air dry or wipe it with a cloth.
- Please clean and disinfect the device after using to avoid cross infection.

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

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

9 Troubleshooting

Trouble	Possible Reason	Solution
Unstable SpO_2 and Pulse Rate display	1. The finger is not placed far enough inside. 2. The finger is shaking or the patient is moving.	1. Place the finger correctly inside and try again. 2. Reduce patient movement.
Unable to measure Temperature	1. Temperature probe is not connected properly	1. Reinsert the probe into the device
Device will not switch on	1. The batteries are drained or almost drained. 2. The device is malfunctioning.	1. Recharge battery. 2. Please contact the local service center.
No Display	1. The device will power off automatically when there is no signal and no operation for 1 minute. 2. The battery voltage is low.	1. Normal. 2. Recharge battery.
No Signal	1. Probe off or incorrect connection 2. Incorrect finger insert 3. Probe is damaged	1. Reconnect the probe 2. Reinsert the finger 3. Replace a new probe

10 Frequently Asked Questions

1. Q: What's SpO_2?

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

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

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

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

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

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

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

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

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

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

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

7. Q: When to charge the batteries?

A: The icon of low battery will appear on the screen when the battery voltages are low. By then, device need to be charged.

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

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

b) Exposure to excessive illumination, such as surgical lamps,

bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight;

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

d) Excessive patient movement;

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

f) Exposure to the chamber with High pressure oxygen;

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

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

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

Please contact the local distributor or manufacturer if necessary.

Appendix

I Key of Symbols

Symbol		Description
Symbols on the screen	%SpO_2	The oxygen saturation
	PI%	Perfusion Index
		Pulse rate (Unit: beats per minute)
		Pulse bar graph
		Low battery voltage
		Battery is full
		Alert reset icon
		Speaker mute icon
		Speaker volume icon
		SpO_2 spot-check record memory full
		SpO_2 trend record memory full
		Temperature memory full
		Wireless transmission icon
		(Neonate/Adult) Patient type

Symbol		Description
Symbols on the panels	**SpO_2**	SpO_2 probe connector
	TEMP	Temperature probe connector
		Power/Left Key
		Right/ Sound Key
		Auto-rotate/Up Key
		Setting/Down Key
		Menu/Confirm key or Record/Back key
	SN	Serial number
		CE mark
		Authorized representative in the European Community
		UK Responsible Person
		Date of manufacture
		Manufacturer (including address)
		With Type BF applied part
		See User Manual
		Disposal of this device according to WEEE regulations
		No alarm

		Do not litter at will

II Common Knowledge

1 Meaning of SpO_2

SpO_2 is the saturation percentage of oxygen in the blood, so called O_2 concentration in the blood; it is defined by the percentage of oxyhemoglobin (HbO_2) in the total hemoglobin of the arterial blood. SpO_2 is an important physiological parameter to reflect the respiration function; it is calculated by the following method:

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

HbO_2 are the oxyhemoglobins (oxygenized hemoglobin), Hb are those hemoglobins which release oxygen.

2 Principle of Measurement

Based on Lamber-Beer law, the light absorbance of a given substance is directly proportional with its density or concentration. When the light with certain wavelength emits on human tissue, the measured intensity of light after absorption, reflecting and attenuation in tissue can reflect the structure character of the tissue by which the light passes. Due to that oxygenated hemoglobin (HbO_2) and deoxygenated hemoglobin (Hb) have different absorption character in the spectrum range from red to infrared light (600nm~1000nm wavelength), by using these characteristics, SpO_2 can be determined. SpO_2 measured by this oximeter is the functional oxygen saturation -- a percentage of the hemoglobin that can transport oxygen. In contrast,

hemoximeters report fractional oxygen saturation – a percentage of all measured hemoglobin, including dysfunctional hemoglobin, such as carboxyhemoglobin or metahemoglobin.

Clinical application of pulse oximeters: SpO_2 is an important physiological parameter to reflect the respiration and ventilation function, so SpO_2 monitoring used in clinical becomes more popularly, such as monitoring the patient with serious respiratory disease, the patient under anesthesia during operation, premature and neonate. The status of SpO_2 can be determined in time by measurement and find the hypoxemia patient earlier, thereby preventing or reducing accidental death caused by hypoxia effectively.

3 Normal SpO_2 Range and Default Low Limit

In campagna area, healthy people's SpO_2 value is greater than 94%, so the values below 94% are determined as hypoxia. SpO_2<90% is considered as the default threshold for determining anoxia by most researchers, so SpO_2 low limit of the oximeter is set as 90% generally.

4 Factors affecting SpO_2 accuracy (interference reason)

- ✧ Intravascular dyes such as indocyanine green or methylene blue
- ✧ Exposure to excessive illumination, such as surgical lamps, bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight.
- ✧ Vascular dyes or external used color-up product such as nail enamel or color skin care
- ✧ Excessive patient movement

- ✧ Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- ✧ Exposure to the chamber with High pressure oxygen
- ✧ There is an arterial occlusion proximal to the sensor
- ✧ Blood vessel contraction caused by peripheral vessel hyperkinesias or body temperature decreasing

5 Factors causing low SpO_2 value (pathology reason)

- ✧ Hypoxemia disease, functional lack of HbO_2
- ✧ Pigmentation or abnormal oxyhemoglobin level
- ✧ Abnormal oxyhemoglobin variation
- ✧ Methemoglobin disease
- ✧ Sulfhemoglobinemia or arterial occlusion exists near sensor
- ✧ Obvious venous pulsations
- ✧ Peripheral arterial pulsation becomes weak
- ✧ Peripheral blood supply is not enough

III EMC Compliance

Note:

Warnings:

● The instrument conforms to the requirements of IEC60601- 1 - 2 , EN 60601-1-2 and ISO 80601-2-61standards for electromagnetic compatibility.

● The user shall install and use the EMC information provided in the random file.

● Portable and mobile RF communication equipment may affect the performance
of the instrument, avoid strong electromagnetic interference when using, such
as close to the mobile phone, microwave oven, etc .

● The guidance and manufacturer's declaration are detailed in the table below .

● The instrument should not be close to or stacked with other equipment. If it must
to be close to or stacked, it should be observed and verified to be able to operate
normally under its configuration.

● In addition to the cables sold by the instrument manufacturer as spare parts for internal components, the use of other accessories and cables may result in increased emission or reduced immunity.

Table 1

Guidance and manufacturer's declaration-electromagnetic emission		
The Handheld Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Handheld Pulse Oximeter should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
Conducted emissions CISPR 11	Group 1 Class B	The Handheld Pulse Oximeter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radiated emissions CISPR 11		The Handheld Pulse Oximeter suitable for use in all establishments, including domestic establishments and
Harmonic emissions IEC61000-3-2	Class A	

Voltage fluctuations/flicker emissions IEC61000-3-3	Complies	those directly network that supplies buildings used for domestic purposes.

Table 2

Guidance and manufacturer's declaration-electromagnetic emission			
The Handheld Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Handheld Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge(ESD) IEC61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ± 15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. if floors are covered with synthetic material, the relative humidity should be at least 30%

Electrical fast transient/ burst IEC61000-4-4	±2kV for power Supply lines ±1kV for Input a.c. Power Ports	±2kV for power Supply lines ±1kV for Input a.c. Power Ports	N/A
Surge IEC 61000-4-5	±0.5 kV, 1kV line (s) to line(s) ±0.5 kV, ± 1 kV, ±2kV line(s) to earth	±0.5 kV, 1kV line (s) to line(s) ±0.5 kV, ± 1 kV, ±2kV line(s) to earth	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle <40% UT (60% dip in UT) for 5 cycles <70% UT	<5% UT (>95% dip in UT) for 0.5 cycle <40% UT (60% dip in UT) for 5 cycles <70% UT	N/A

	(30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	(30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	
Power frequency(50Hz/60Hz) magnetic field IEC61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity
The Handheld Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of The Handheld Pulse Oximeter should assure that it is

used in such an electromagnetic environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment -guidance
Conducted RF IEC61000-4-6	0,15MHz–80MHz 3 V RMS outside the ISM band, 6 V RMS in the ISM	0,15MHz–80MHz 3 V RMS outside the ISM band, 6 V RMS in the ISM	Portable and mobile RF communications equipment should be used no closer to any part of The Handheld Pulse Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC61000-4-3	80 MHz to 2.7 GHz 3V/m	80 MHz to 2.7 GHz 3V/m	

			Recommended separation distance d=1.2 $\sqrt{P}$ d=1.2 $\sqrt{P}$ 80MHz to 800MHz d=2.3 $\sqrt{P}$ 800MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). b Field strengths from fixed RF

			transmitters, as determined by an electromagnetic site survey ,a should be less than the compliance level in each frequency range .b Interference may occur in the vicinity of equipme  nt marked with the following symbol.

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, and electromagnetic site survey should be considered. If the measured field strength in the location in which The Handheld Pulse Oximeter is used exceeds the applicable RF compliance level above, The Handheld Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating The Handheld Pulse Oximeter.

b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Table 4

Frequency Range and Level: RF wireless communication equipment			
Test Frequency (MHz)	Modulation	Minimum immunity Level (V/m)	immunity Level Applied (V/m)
385	**Pulse Modulation: 18 Hz	27	27

450	☒ *FM + 5 Hz deviation: 1 kHz sine ☐ **Pulse Modulation: 18 Hz	28	28
710 745 780	**Pulse Modulation: 217 Hz	9	9
810 870 930	**Pulse Modulation: 18 Hz	28	28
1720 1845 1970	**Pulse Modulation: 217 Hz	28	28
2450	**Pulse Modulation: 217 Hz	28	28
5240 5500 5785	**Pulse Modulation: 217 Hz	9	9

ATTENTION: 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.

Table 5

Recommended separation distances between portable and mobile RF communication the equipment
The Handheld Pulse Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of The Handheld Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Handheld Pulse Oximeter as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W(Watts)	Separation distance according to frequency of transmitter M(Meters)		
	150kHz to 80MHz $d=1.2\sqrt{P}$	80MHz to 800MHz $d=1.2\sqrt{P}$	80MHz to 2,5GHz $d=2.3\sqrt{P}$
0,01	N/A	0.12	0.23
0,1	N/A	0.38	0.73
1	N/A	1.2	2.3
10	N/A	3.8	7.3
100	N/A	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 : At 80 MHz and 800 MHz, the separation distance for 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.

Quality Inspection Certificate