Handheld Pulse Oximeter

USER MANUAL

Version of the Manual: Ver 1.0
Issued Date: November 3, 2022

Notes:

- **It's not a medical device.This device is for Sports and Aviation use only and not intended for medical use.**
- The contents contained in this manual are subject to change without prior notice.
- All the information is believed to be accurate and reliable. However, no responsibility is assumed for its use, or any infringements of patents or other rights of third parties that may result from its use.

3502-1290237

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 user 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 users 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 an Oxygen level probe with excessive pressure for prolonged periods can induce pressure injury.
- Place the oxygen level 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 users may still have anaphylaxis. Do not apply to those who have anaphylaxis.
- For the individual user, 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 strongelectro-magnetic interference exists, such as radiogram, television, radiophone, etc.
- Please pay attention to the oxygen level probe cable while using to avoid strangulating users.

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 fol lowing standards:
IEC 60601-1: 2005+A1:2012 -Part 1: General requirements for basic safe ty and essential performance;
ISO 80601-2-61:2017 - Part 2-61: Particular requirements for basic safet y and essential performance of pulse oximeter equipment.
And it also follows the provisions of the council directive MDD 93/42/EEC.

1 Overview

1.1 Appearance

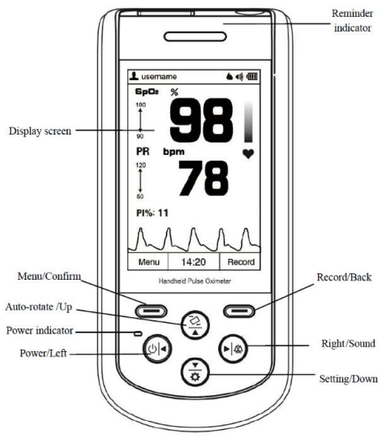

Figure 1.1 Front View

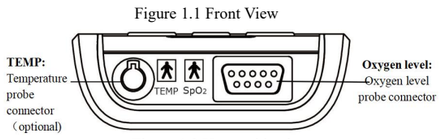

Figure 1.2 Upper-side view

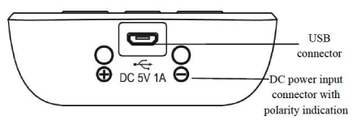

Figure 1.3 Bottom side view

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 reminder event occurs, then short time press it to reset (that's to say, to reminder will be muted). When the current reminder event ends or a new type of reminder event occurs, then former status of reminder will be ended (that's to say, the reminder will be generated again when an reminder 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 oxygen level record list screen, or to back to the previous level of menu.

8. **(Reminder indicator)**: If the probe is not well placed or disconnected, or the measured value exceeds the preset reminder limit value, then the reminder 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"( )**: Oxygen level Probe Connector.

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

12.(DC 5V 1A): DC power input connector 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 oxygen level probe.

1.4 Features

- It is lightweight, small in size and easy to carry
- Color LCD to display plethysmogram and parameters
- Measure oxygen level and heart rate simultaneously
- PI (Perfusion Index) display is available
- Up to 580 hours data storage for oxygen level and heart rate 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
- Reminder 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 heart rate and oxygen level of adult.

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, DC, 5V/1A

Output: Contact pins. DC, 5V/1A

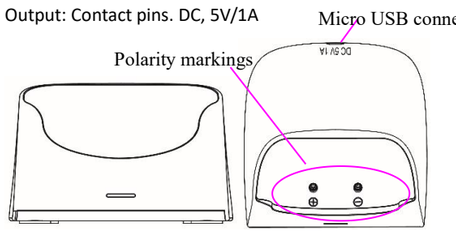

Figure 2.1A Base--front view Figure 2.1B Base--top view

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 DC 5V/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 DC 5V/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.

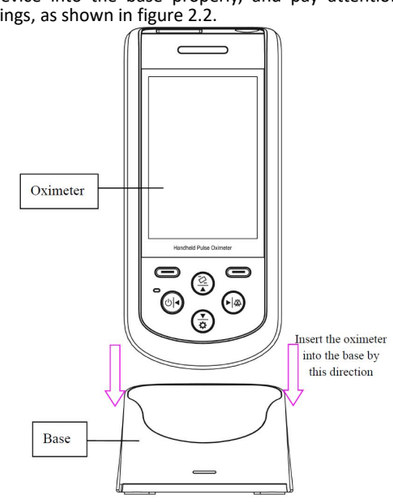

Figure 2.2 Connection between oximeter and base

3 Make Measurement

3.1 Oxygen Level Measurement

Operation procedures:

1. Connect the oxygen level 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 oxygen level 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 oxygen level probe

Safety instructions for oxygen level measurement

- Long term use of the oxygen level 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 oxygen level sensor, as using in high temperatures can cause burns.
- Do NOT place the oxygen level probe on a finger with edema or fragile tissue.
- Do NOT put the oxygen level probe and pressure cuff on the same limb, otherwise the blood pressure measurement may affect the oxygen level measurement.
- The device is calibrated to display functional oxygen saturation.
- Do NOT allow the sensor cable to twist or bend.
- Check the oxygen level sensor and cable before use. Do NOT use a damaged oxygen level sensor.
- When the temperature of the oxygen level 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 oxygen level sensor cannot be immersed into water, liquid or cleanser.
- The oxygen level sensor can be repeatedly used. Please clean and disinfect before reuse.

☞ Connector with the label "SpO_2" can only be connected with oxygen level probe.

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).

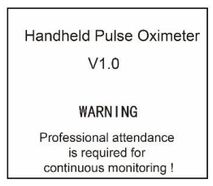

Figure 4.1

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.

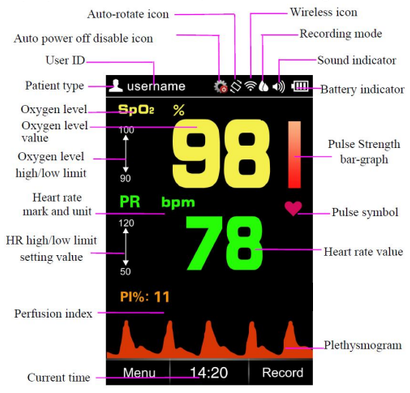

Figure 4.2A Default Display Screen---in vertical

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 the device beeps simultaneously. The reminder sustains 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.

➢ If the global sound is enabled by longtime pressing " " key, then during the measurement, over-limit reminder event or probe off event can activate the reminder. Refer to Section 6.2 for more details.

➢ If the memory is full, the corresponding memory full icon appears on the screen, " " means oxygen level spot-check record memory is full, " " means oxygen level 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 (see Figure 4.3).

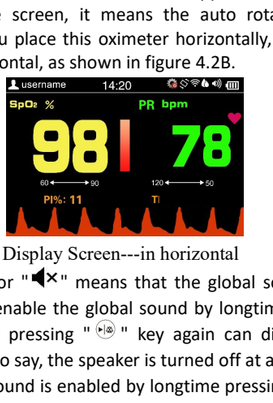

Figure 4.3 Main menu

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 user type, "Adult" and "Neonate" for option.

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

➢ Recording mode: Select the data recording mode, "Spot-check Record" and "Trend Record" for option.

➢ Oxygen level 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.

➢ 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.

➢ reminders: Set the low reminder limit for oxygen level and the high/low reminder limit for heart rate, see Section 4.3.8 for details.

➢ Help: To view the tips information of oxygen level 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.

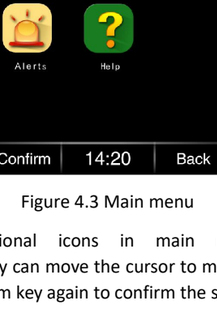

Figure 4.4A User ID setup screen

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.

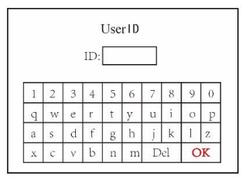

Figure 4.4B User ID edit screen

4.3.2 User

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

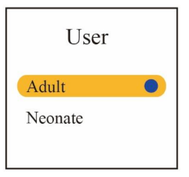

Figure 4.5 User type setup screen

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.

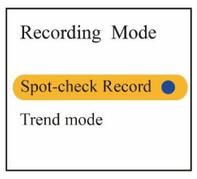

Figure 4.6 Recording mode setup screen

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 Oxygen level Record

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

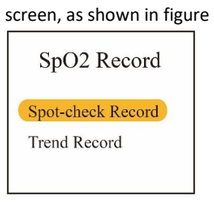

Figure 4.7 Oxygen level record review method selecting screen

Refer to Section 4.4 for details.

4.3.5 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.

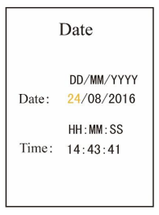

Figure 4.9 Date setup screen

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.

4.3.6 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.

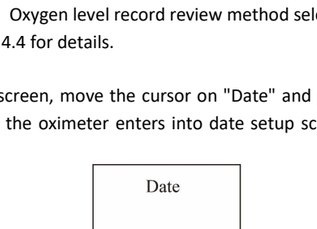

Figure 4.10 System setting screen

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 reminder, 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 oxygen level 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.

➢ Version: For viewing version number of the software, as shown in figure 4.10I.

➢ Factory Default: Enter into the factory default setting, as shown in figure 4.10J.

➢ Demo: Enter into the Demonstration mode, as shown in figure 4.10K.

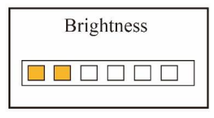

Figure 4.10A Brightness setup

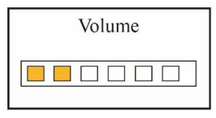

Figure 4.10B Volume setup

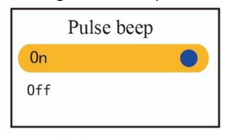

Figure 4.10C Pulse beep setup

Figure 4.10D Language setup

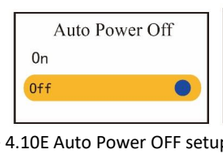

Figure 4.10E Auto Power OFF setup

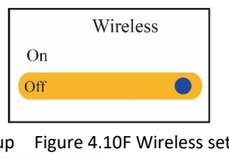

Figure 4.10F Wireless setup

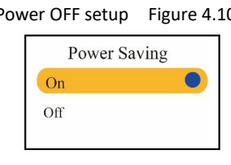

Figure 4.10G Power Saving setup

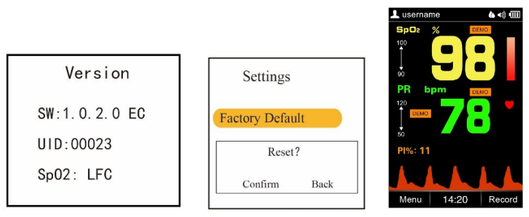

Figure 4.10I Version info Figure 4.10J Default setting Figure 4.10K Demo mode

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.

4.3.7 Reminders

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

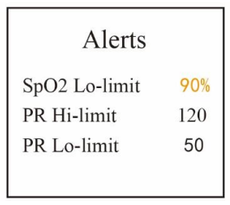

Figure 4.11 Reminders setting screen

- ➢ **Oxygen level Lo-Limit:** Oxygen level low limit setting; range: 50%~99%, the step is 1%. The factory default value for adult is 90% and 95% for Neonate.
- ➢ **Heart rate Hi-Limit:** High limit setting of heart 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.
- ➢ **Heart rate Lo-Limit:** Low limit setting of heart rate; range: 30~99bpm, and the step is 1bpm. The factory default value for adult is 50bpm and 60bpm for neonate.

Note: When the oxygen level reading is lower than or equal to the preset reminder setting or the heart rate reading is higher than or equal to the preset high limit or the heart rate reading is lower than or equal to the preset low limit, then the over-limit reminder event will be activated, that's, the device beeps and the corresponding reading(s) blinks. When measured on neonate, if the oxygen level reading is lower than or equal to the preset reminder setting for 10 seconds, then the reminder will be activated.

4.3.8 Help

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

Figure 4.12 Help information---oxygen level 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.

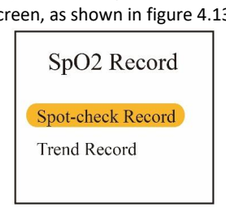

Figure 4.13 Oxygen level record

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

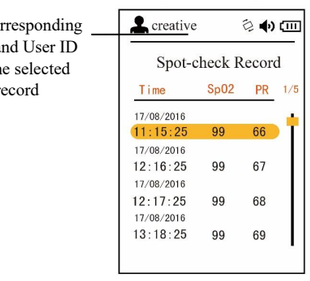

Figure 4.14 Spot-check Record list

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 minute), 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.

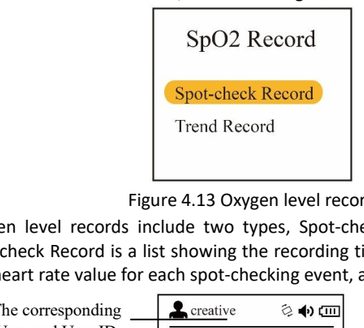

Figure 4.15 Trend record---List

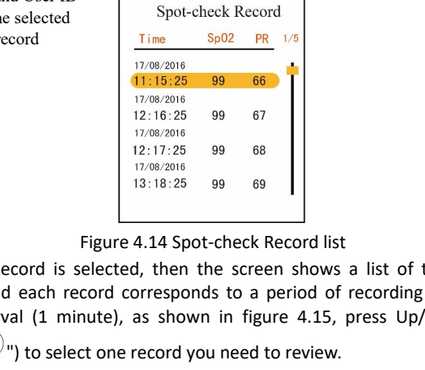

Figure 4.16 Trend record---Trend graph

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 heart rateessing Sound/Right key(" "), then an message "Are you sure to delete all?" prompts on the screen, as shown in figure 4.17.

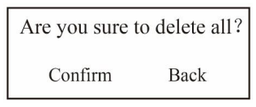

Figure 4.17 Delete records

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.

Note: The data will be permanently deleted. Please confirm carefully before deleting.

4.4.3 Data Upload

If you want to upload the stored data (oxygen level and heart rate 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.

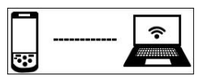

Figure 4.18 Data uploading screen

- ➢ **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: https://getwellue.com/pages/pc-software

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, as well as archive users' 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. Oxygen Level Measurement
Transducer: dual-wavelength LED sensor with wavelength:
Red light: 663 nm, Infrared light: 890 nm.
Maximal average optical output power: ≤ 2mW
Display range: 35~99%
Measuring accuracy: A_{RMS} value (defined in ISO 80601-2-61) is not greater than 2% for oxygen level range from 70% to 100%.
Oxygen level low reminder 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 oxygen level probe or the device.

D. Heart Rate Measurement
Display and measuring range: 30bpm~250bpm
Accuracy: ±2bpm or ±2% (whichever is greater)

E. Perfusion Index Display
Range: 0.2%~20%

F. 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.

G. Low Perfusion Performance
The accuracy of oxygen level and heart rate measurement still meet the precision described above when the modulation amplitude is as low as 0.4%.

H. Resistance to interference of surrounding light:
The difference between the oxygen level value measured in the condition of indoor natural light and that of darkroom is less than ±1%.

I. Wireless (bluetooth) function
Frequency band: 2.4GHz
Working profile: BLE V4.0

J. Dimensions: 158 mm (L) × 73 mm (W) × 25 mm (H)
Net Weight: about 230g (including battery)

K. 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

L. Data update period
The update time for determining oxygen level and heart rate value is 8 seconds, and the displaying update time is 1 second.
Remark: The oximeter calculates the oxygen level and heart rate 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 oxygen level and heart rate 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 oxygen level and heart rate 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

- ➢ Oxygen level low limit setting range: 50% ~ 99%.
- ➢ Heart rate limits setting range:
High: 100bpm--240bpm Low: 30bpm--99bpm

During the measurement, if the measured value exceeds the preset value, the reminder will be activated, the value that is over-limit will blink.

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 reminder reset (that's to say, the reminder 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 reminder event ends or a new type of reminder event occurs, then the status of audible reminder reset will be ended (that's to say, the reminder sound can be generated when an reminder 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 reminder 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. An oxygen level probe
3. User Manual
4. A oximeter rubber cover
5. A charging base
6. Charging cable (optional)
7. 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 oxygen level 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 oxygen level and heart rate display	1. The finger is not placed far enough inside. 2. The finger is shaking or the user is moving.	1. Place the finger correctly inside and try again. 2. Reduce user movement.
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 oxygen level?
A: Oxygen level means the percentage of oxygen in the blood.
2. Q: What's the normal range of oxygen level 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 heart rate value for healthy people?
A: Usually, the normal range is 60bpm~100bpm.
5. Q: Why do the display value of oxygen level and heart rate vary with time?
A: The measured oxygen level and heart rate value changes in correspondence with the change of user's physiological conditions.
5. Q: What to do if there is no oxygen level and heart rate 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 oxygen level reading is true or accurate?
A: Hold breath for a while (50 seconds or more), if the oxygen level value significantly decreases, it means that the oxygen level 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 oxygen level 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 user 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.

11 FCC Statement

FCC Warning:
FCC ID: A49SP-20
Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.
Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
-Reorient or relocate the receiving antenna.
-Increase the separation between the equipment and receiver.
-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
-Consult the dealer or an experienced radio/TV technician for help.
The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

Appendix

I Key of Symbols

Symbol		Description
Symbols on the screen	%SpO_2	Oxygen level
	PI%	Perfusion Index
	♥bpm	Heart rate (Unit: beats per minute)
		Pulse bar graph
		Low battery voltage
		Battery is full
		Reminder reset icon
		Speaker mute icon
		Speaker volume icon
		Oxygen level spot-check record memory full
		Oxygen level trend record memory full
		Wireless transmission icon
		(Neonate/Adult) User type

Symbol		Description
Symbols on the panels	SpO_2	Oxygen level 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
		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
	FC	This product complies with the rules and regulations of the Federal Communication Commission.
		Non-ionizing radiation
		This product complies with verpackG.

II Common Knowledge

1 Meaning of Oxygen Level

Oxygen level 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. Oxygen level is an important physiological parameter to reflect the respiration function; it is calculated by the following method:

Oxygen level = HbO_2/ (HbO_2 +Hb)×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, oxygen level can be determined. Oxygen level 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: Oxygen level is an important physiological parameter to reflect the respiration and ventilation function, so oxygen level tracking used in clinical becomes more popularly, such as tracking the user with serious respiratory disease, the user under anesthesia during operation, premature and neonate. The status of oxygen level can be determined in time by measurement and find the hypoxemia user earlier, thereby preventing or reducing accidental death caused by hypoxia effectively.

3 Normal Oxygen Level Range and Default Low Limit

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

4 Factors affecting Oxygen level 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 user 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 Oxygen level 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

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