GIMA
PROFESSIONAL MEDICAL PRODUCTS

SP-20 VET PULSE OXIMETER

REF SP-20 VET (GIMA 80805)

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IPX2

M80805-GB-Rev.0-11.23

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 1.2

Issued Date: November 17, 2023

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.

3502-1290166

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.
- Clip the SpO_2 probe on the measuring site 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.

Table of Contents

1 Overview

1.1 Appearance

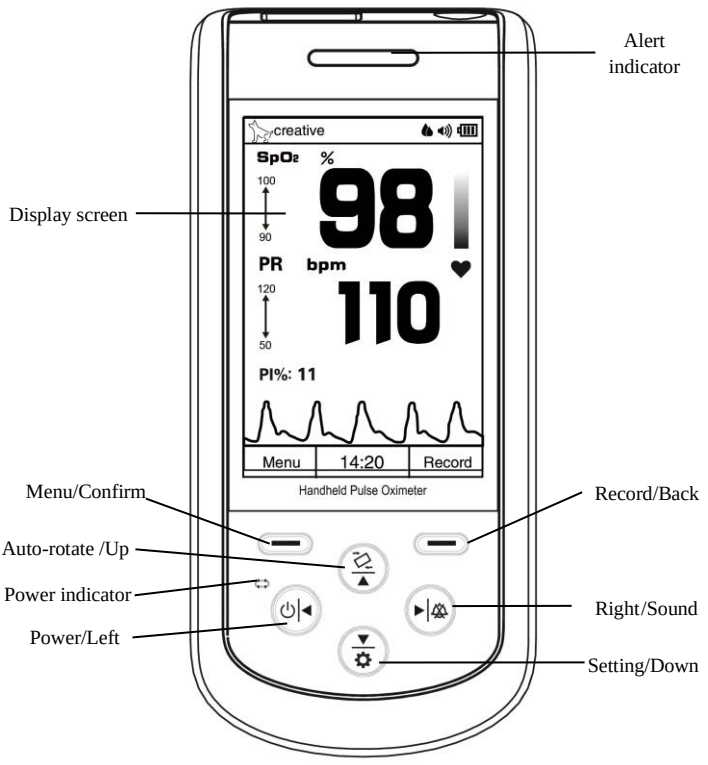


Figure 1.1 Front View

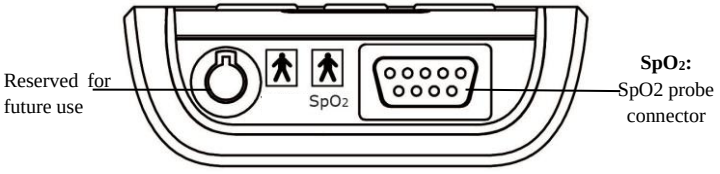


Figure 1.2 Upper-side view

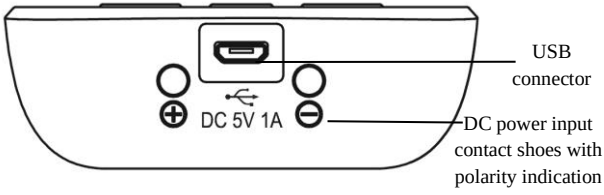


Figure 1.3 Bottom side view

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.  Reserved for future use.

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.

1.4 Features

- ✧ It is lightweight, small in size and easy to carry
- ✧ Color LCD to display plethysmogram and parameters
- ✧ Measure SpO_2 and Pulse Rate simultaneously
- ✧ PI (Perfusion Index) display is available
- ✧ Up to 500 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 and functional oxygen saturation (SpO_2).

It is to be used in but not restricted to veterinary institutions.

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

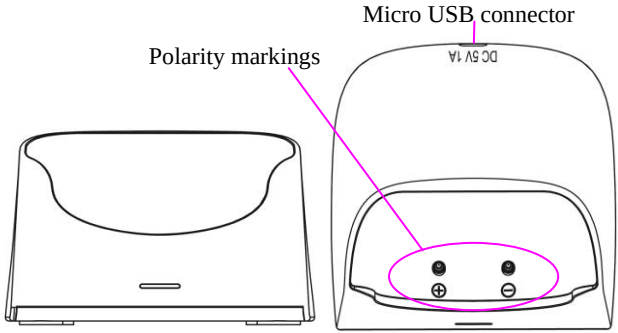


Figure 2.1A Base--front view Figure 2.1B Base--top view

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:

3) 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.

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

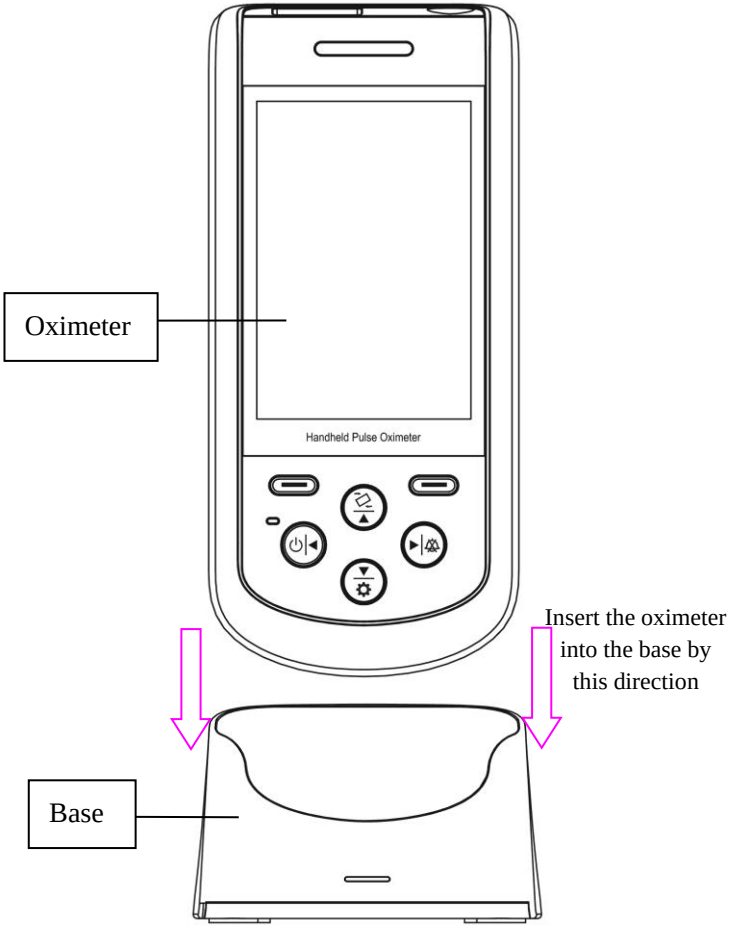


Figure 2.2 Connection between oximeter and base

3 SpO_2 Sensor Connection

3.1 Choose SpO_2 Sensor Adapter

The device is equipped with universal Y-type sensors including different adapters for various measuring sites.

Two types of sensor adapters (big clip and small clip) are provided for the Y-type SpO_2 sensor. They can be used to place on different measuring sites, such as ear, tongue, leg or tail. Please select the appropriate sensor and adapter according to its shape size and the measuring site.

3.2 Install Sensor Adapter onto SpO_2 Sensor

Follow the installing methods below to install the sensor adapter onto the sensor, and then connect the SpO_2 sensor cable to the connector labeled "SpO_2" at the upper side of the device. After starting the oximeter, clip the sensor on to the measuring site.

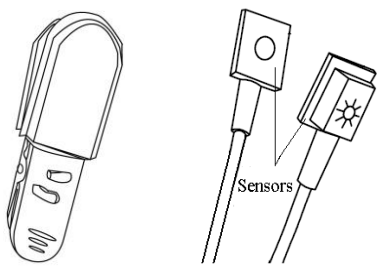
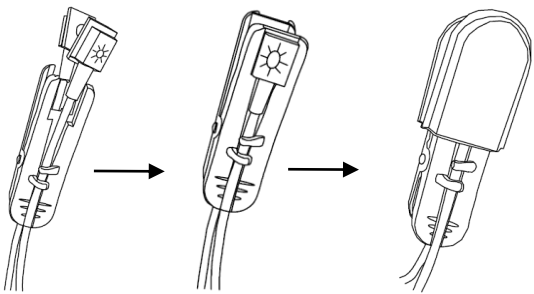


Figure 3.1 Clip type sensor adapter

Installation of Big Clip

1. Slip off the two rubber jackets from the clip;
2. Fix the sensor cable to the clip (Figure 3.2A);
3. Slide one branch of Y-type sensor (the side with coating inward) into the fixing slot from the clip opening to the stop at the end of the slot (Figure 3.2B), and then fix the other branch;
4. Install the two rubber jackets onto the clip (Figure 3.2C).



A B C

Figure 3.2 Big Clip installation

Installation of Small Clip

Follow the step 1, step 3 and step 4 mentioned in Section Installation of Big Clip and refer to Figure 3.3A and Figure 3.3B

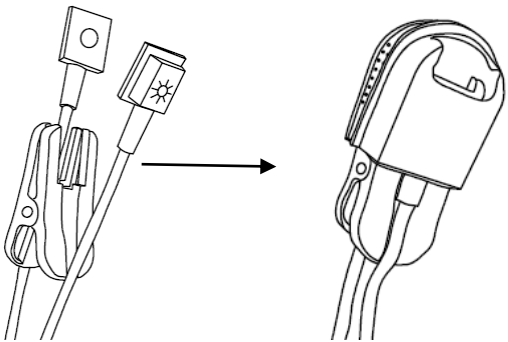


Figure 3.3 Small Clip Installation

3.3 Placement of Veterinary SpO_2 Sensor

As a general rule, measuring SpO_2 and pulse rate for animal is performed when the animal is under anaesthesia, and the optimal measuring site is its tongue. Normally the animal's tongue will slip out after anaesthesia. At first, clip the sensor on its tongue (Figure 3.4). Then, check SpO_2 reading and perfusion index (PI) value (greater PI is better) to confirm appropriate measurement.

Besides the tongue, if the hair is not dark and bristal, you can

wrap the SpO_2 sensor onto other places such as ear (Figure 3.5) or claw/leg (Figure 3.6). Since animal hair will decrease the sensitivity or even make the measurement failure, please always choose the place with less hair under the sensor. If necessary, shave off the hair on the measuring site.

Figure 3.4 Clip the sensor on tongue

Figure 3.5 Clip the sensor on ear

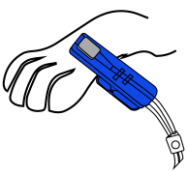


Figure 3.6 Clip the sensor on claw or leg

3.4 Tips for SpO_2 Monitoring

1. If there is strong ambient light interference, you can use opaque thing to cover the measuring site and the sensor. By dong so, measurement error may be decreased.
2. The light including surgery lamp, halogen lamp, fluorescent

lamp and infrared heating lamp can also cause measurement error. In such condition, you can use solid black thing to cover the measuring site and the sensor.

3. If the measured tissue is too thin to get stable readings, a layer of gauze can be wrapped on one or both side of the sensor.

3.5 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. Clip the SpO_2 probe on the measuring site.

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.

Safety instructions for SpO_2 measurement

- Long term use of the SpO_2 probe on the same place may result in discomfort or pain. 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 the measuring site 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.
- 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.

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).

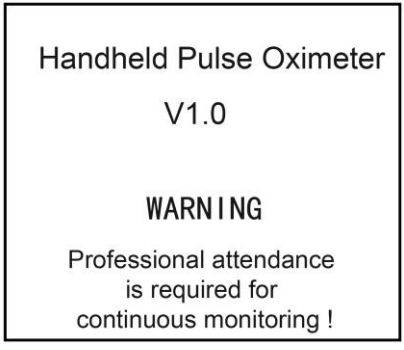


Figure 4.1

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.

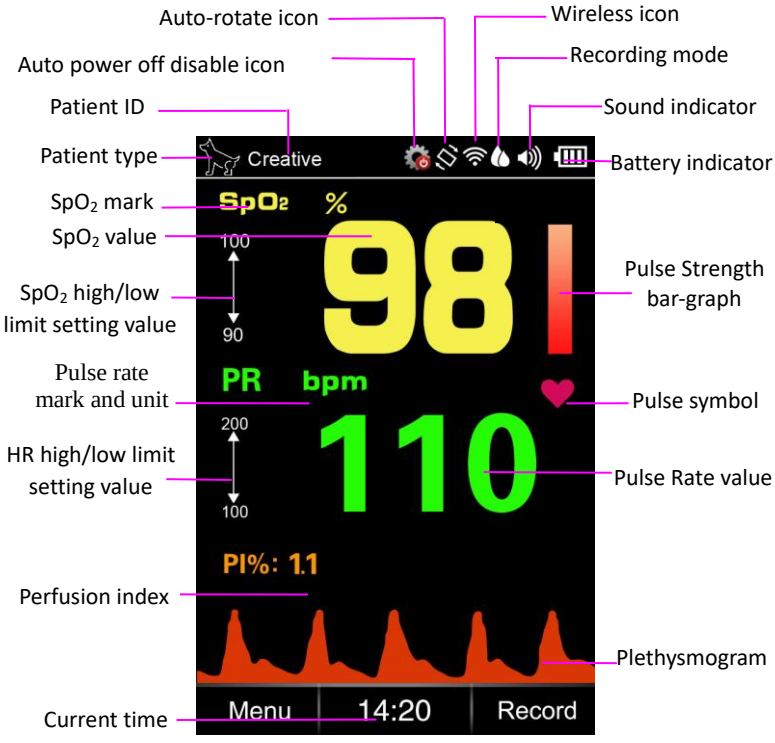


Figure 4.2A Default Display Screen---in vertical

Description:

- During measurement, if the probe is not placed properly, or

the probe is not connected or the probe is off from the measuring site, 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.

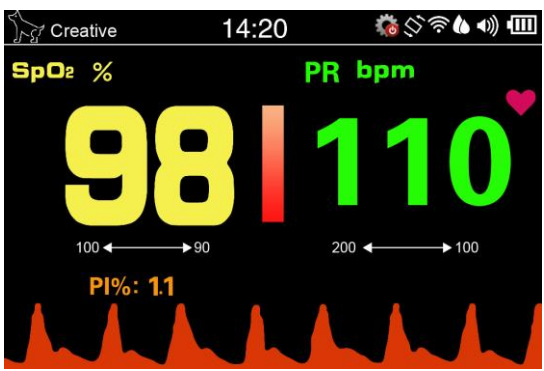


Figure 4.2B Default Display Screen---in horizontal

- 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 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).

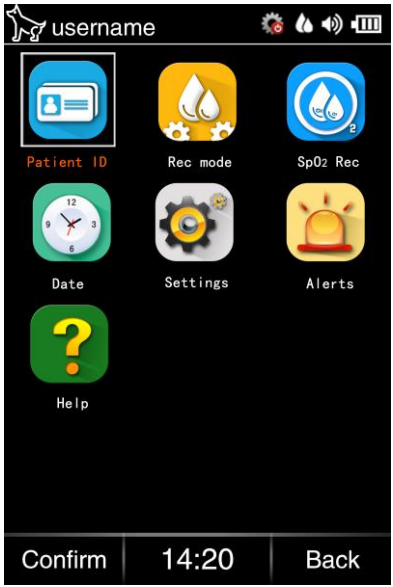


Figure 4.3 Main menu

There are 7 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.

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

- 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.
- Date: Set the time and date, see Section 4.3.4 for details.
- Settings: Set the system parameter, including brightness, sound volume, display language, power saving mode etc., see Section 4.3.5 for details.
- Alerts: Set the low alert limit for SpO_2 and the high/low alert limit for PR, see Section 4.3.6 for details.
- Help: To view the tips information of SpO_2 measurement, see Section 4.3.7 for details.

4.3.1 Patient ID

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

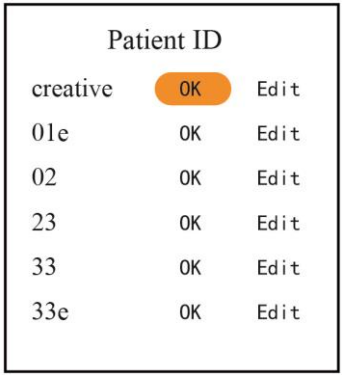


Figure 4.4A Patient ID setup screen

Move the cursor on "Edit" and press Confirm key "[ ]", when the cursor turns to blue, then the user can edit the patient ID, and move the cursor on "OK" to confirm the edit, the edit screen is as shown in figure 4.5.

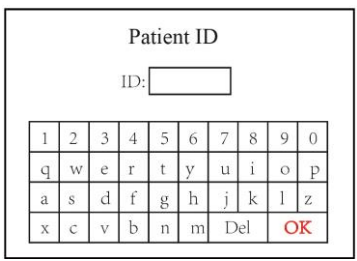


Figure 4.5 Patient ID edit screen

4.3.2 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.

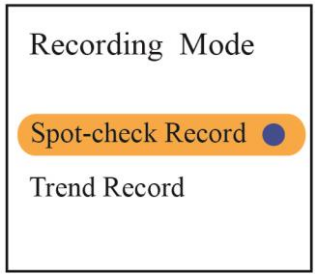


Figure 4.6 Recording mode setup screen

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.

4.3.3 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.

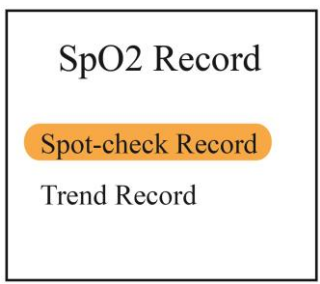


Figure 4.7 SpO_2 record review method selecting screen

Refer to Section 4.4 for details.

4.3.4 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 4.8.

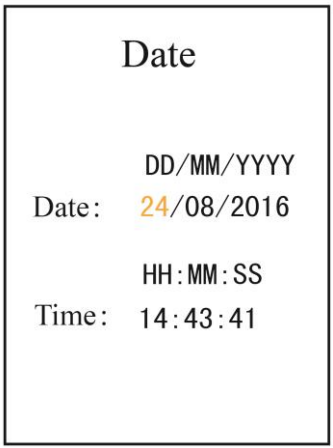


Figure 4.8 Date setup screen

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.

4.3.5 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 4.9.

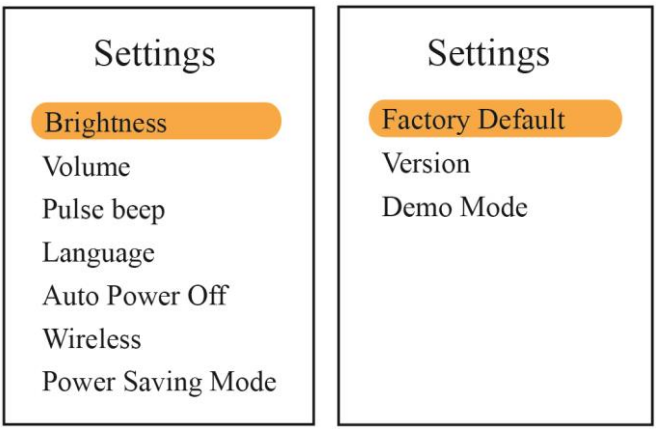


Figure 4.9 System setting screen

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 three languages: Simplified Chinese, English and Spanish, 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.
- Factory Default: Enter into the factory default setting, as shown in figure 4.10H.
- Version: For viewing version number of the software, as shown in figure 4.10I.
- Demo: Enter into the Demonstration mode, as shown in figure 4.10J.

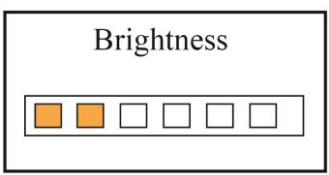


Figure 4.10A Brightness setup

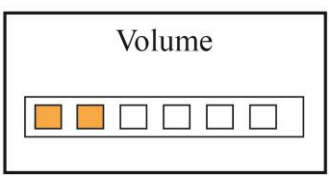


Figure 4.10B Volume setup

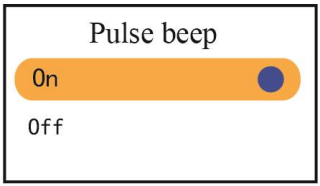


Figure 4.10C Pulse beep setup

Figure 4.10D Language setup

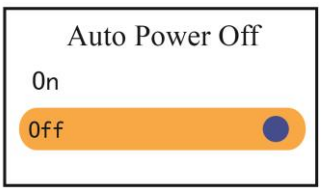


Figure 4.10E Auto Power OFF setup

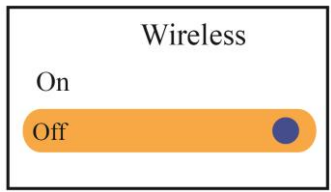


Figure 4.10F Wireless setup

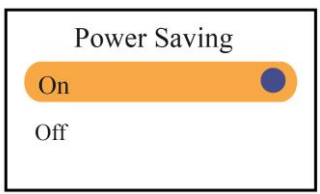


Figure 4.10G Power Saving setup

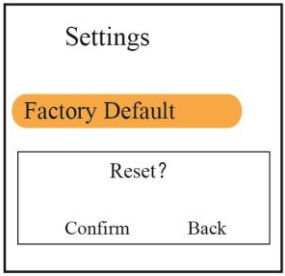


Figure 4.10H Default setting

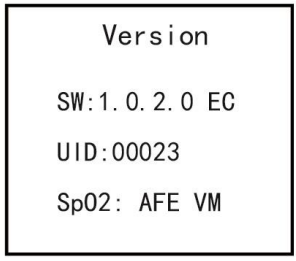


Figure 4.10I Version info

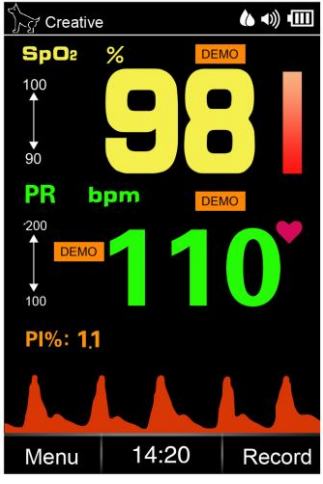


Figure 4.10J Demo mode

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.

4.3.6 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.

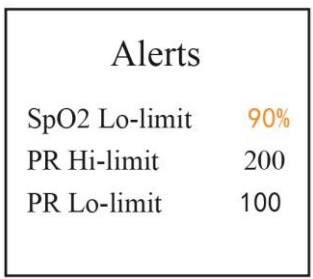


Figure 4.11 Alerts setting screen

- **SpO_2 Lo-Limit:** SpO_2 low limit setting; range: 0%~99%, the step is 1%. The factory default value is 90%.
- **PR Hi-Limit:** High limit setting of pulse rate; range: 120~400bpm. From 120 to 150, the step is 1bpm, and from 150 to 400, the step is 5bpm. The factory default value is 200bpm.
- **PR Lo-Limit:** Low limit setting of pulse rate; range: 30~119bpm, and the step is 1bpm. The factory default value is 100bpm.

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.

4.3.7 Help

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

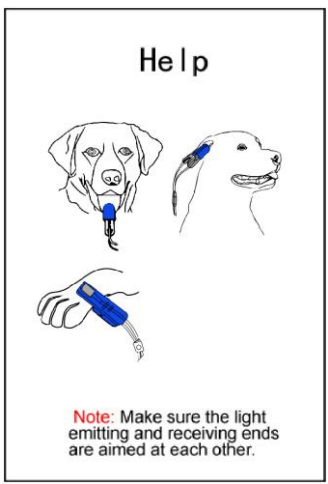


Figure 4.12 Help information---SpO_2 measurement

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.

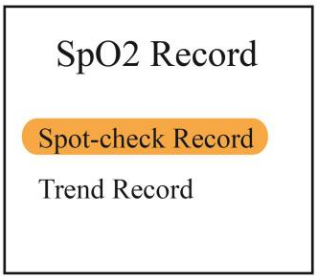


Figure 4.13 SpO_2 record

SpO_2 records include two types, Spot-check Record 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.

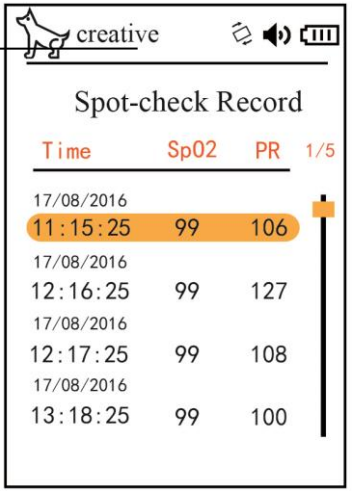


Figure 4.14 Spot-check Record list

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.

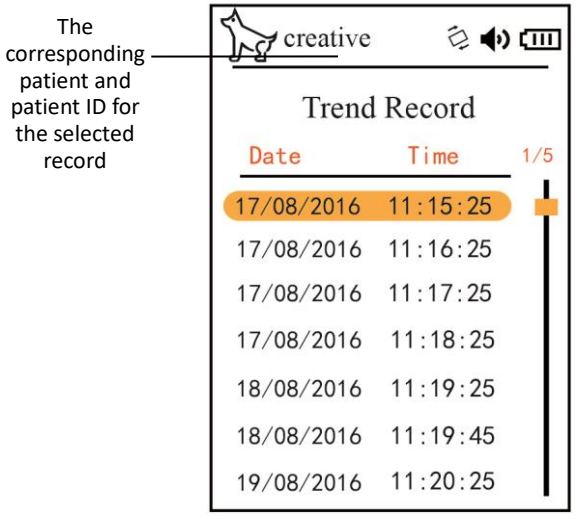


Figure 4.15 Trend record---List

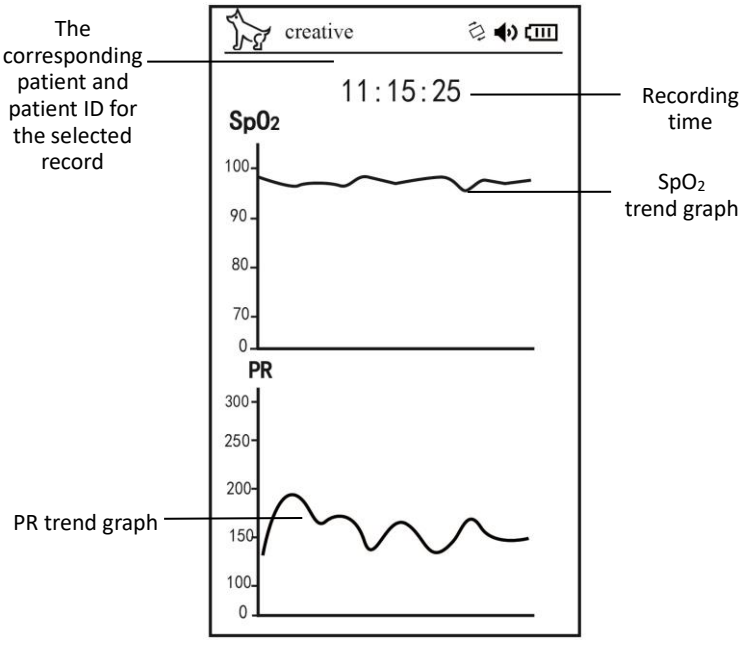


Figure 4.16 Trend record---Trend graph

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 4.16.

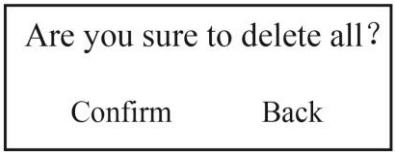


Figure 4.16 Delete records

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 4.17. Refer to the instruction in "Oximeter Data Manager User Manual"for detailed operation.

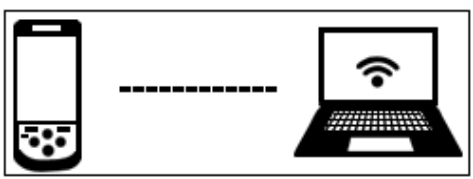


Figure 4.17 Data uploading screen

- **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, as 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: 660 nm, Infrared light: 905 nm.

Maximal average optical output power: ≤ 2mW

Display range: 0~100%

Measuring accuracy: This algorithm is based upon the human algorithm that meets accuracy requirements of ISO 80601-2-61(A_{RMS} value is not greater than 3% for SpO_2 range from 70% to 100%).

SpO_2 low alert limit setting range: 0%~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~400bpm

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. Performance under Low Perfusion condition

The accuracy of SpO_2 and PR measurement still meet the precision described above when the modulation amplitude is as low as 0.3%.

H. Resistance to ambient light interference:

The accuracy of SpO_2 and PR measurement still meet the precision described above when the device is tested by SpO_2 simulator (Fluke Biomedical Index 2 series) while setting the emulating interference of sun light and 50/60Hz fluorescent light.

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 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: 0% ~ 99%.
- Pulse Rate limits setting range:

  High: 120bpm--400bpm Low: 30bpm--119bpm

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. 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 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 clip is not well placed on the measuring site. 2. The patient is moving.	1. Place the clip on the measuring site correctly and try again. 2. Reduce patient 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 sensor placement 3.Probe is damaged	1. Reconnect the probe 2. Replace the sensor on the measuring site 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 animal?

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 animal?

A: Usually, the normal range is 100bpm~200bpm.

4. 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: Keep the animal 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) Presence of certain dyes, such as methylene and indigo carmine;

d) Animal hair color and skin color;

e) Excessive patient movement;

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

g) Exposure to the chamber with High pressure oxygen;

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

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

j) 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
	♥bpm	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
		Wireless transmission icon
		Patient type

Symbol	Description

Symbols on the panels	**SpO_2**	SpO_2 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	CE mark
	EC REP	Authorized representative in the European Community
		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 animal's SpO_2 value is greater than 90%, so the values below 90% 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)

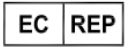
- ✧ Intravascular dyes such as indocyanine green or methylene blue
- ✧ Exposure to excessive illumination, such as surgical lamps, bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight
- ✧ Presence of certain dyes, such as methylene and indigo carmine
- ✧ Animal hair color and skin color
- ✧ 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

Quality Inspection Certificate

	Manufacturer
	Date of manufacture
	Lot number
	Follow instructions for use
	Keep in a cool, dry place
	Imported by
	Product code
	Authorized representative in the European community
	WEEE disposal
	Product complies with European Directive
	Caution: read instructions (warnings) carefully

	Keep away from sunlight
IPX2	Covering Protection rate
	Humidity limit
	Atmospheric pressure limit
	Temperature limit

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.

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