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PROFESSIONAL MEDICAL PRODUCTS

PULSOXIMETRO VETERINARIO OXY-100
OXY-100 VET PULSE OXIMETER

Manuale d'uso - User manual

ATTENZIONE: *Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.*
ATTENTION: *The operators must carefully read and completely understand the present manual before using the product.*

REF 34343

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Made in China

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CE 0123

M34343-M-Rev.2-11.19

Instructions for Safe Operations

- Check the device to make sure that there is no visible damage that may affect user's safety and measurement performance. When there is obvious damage, stop using the device.
- Necessary service must be performed only by qualified technicians. Users are not permitted to repair it by themselves.
- The oximeter cannot be used together with the devices not specified in User Manual.

Cautions

- 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 testee is under MRI or CT scanning.

Warnings

- An uncomfortable or painful feeling may appear if using the sensor of this device continuously on the same place for a long time, especially for the testee with poor microcirculation. It is recommended that the sensor should not be applied to the same location for longer than 2 hours. If any abnormal condition is found, please change the position of sensor.
- For the individual testee, there should be a more prudent inspecting in the placing process. The sensor can not be clipped on the edema and tender tissue.
- The local law should be followed when disposing of the expired device or its accessories.

Attentions

- Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- If the oximeter gets wet, please stop operating it. When it is carried from a cold environment to a warm and humid environment, please do not use it immediately.
- DO NOT operate the button on the front panel with sharp materials.
- High temperature or high pressure steam disinfection to the oximeter or sensors is not permitted. Refer to related chapter for instructions of cleaning and disinfection.
- The intended use of this device is not for therapy purpose.
- Caution: U.S. federal law restricts this device to sale or use by or on the order of a physician.

1 Overview

1.1 Appearance

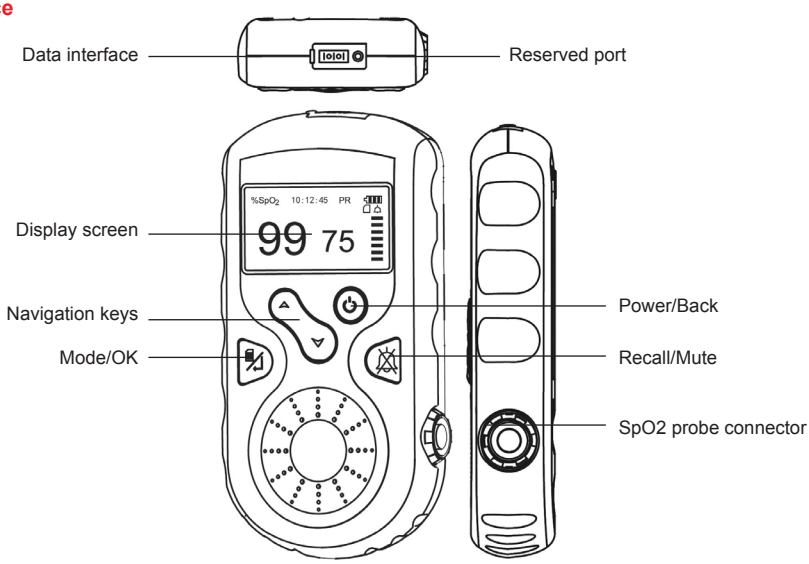


Figure 1

1. Display screen: display SpO2 plethysmogram and parameter values.
2. Navigation key:

: Up/Left/Increase
Press this key, the default screen can be shifted to display pulse rate (PR) or perfusion index (PI). If on the system setup screen, press it to move the cursor upwards or to the left and adjust parameter values.

: Down/Right/Decrease

Its function is similar with the key "▲: Up/Left/Increase".

3. (Mode/OK): press this key, the screen can be shifted between default screen and other screen layout; longtime press it, the menu screen will be displayed; when you finish parameter setting, press this key to confirm.
4. (Data interface): used for uploading data (Optional function).
5. (Reserved port): for future use.

6. (Power/Back): Power on/off the device by longtime pressing; short time press it to back to upper level operation.

7. "" (Recall/Alarm mute): Longtime press it to enter SpO2 recall screen; when the device is alarming, short time pressing will mute the alarm sound, the mute state will persist for about 90s. If the alarm event still exist after this mute period (90s), then the alarm sound will resume.
8. Icon: "SpO2": SpO2 Probe Connector.

1.2 Product Name and Model
Name: Handheld Pulse Oximeter
Model: PC-66V

1.3 Structure
It consists of the main unit and veterinary SpO2 probes.

1.4 Features
- It is lightweight, small in size and easy to carry;
- 2.2" high resolution color LCD to display plethysmogram and measured data;
- Data storage for SpO2 and Pulse Rate value with trend review, up to 384 hours of data memory (with 1/2/4/8 seconds recording interval);
- Two options for measurement on thin tissue (such as tongue or ear) and thick tissue (such as leg or tail);
- PI (Perfusion Index) display is available;
- Data transmission to PC for view and analysis(optional);
- 3 AA alkaline or rechargeable batteries or AC adapter (optional) can be used.

1.5 Intended Use
This Handheld Pulse Oximeter is intended for measuring and recording the pulse rate and functional oxygen saturation (SpO2) by placing the sensor on the certain part of the animal, such as tongue, ear, leg, or tail. It also provides plethysmogram, bar-graph and perfusion index display for signal adequacy indication. Three types of sensor adapters are equipped for different size of animal or animal's body part.

1.6 Working Environment
Operating temperature: 5~40°C
Operating humidity: 30~80%
Atmospheric pressure: 70kPa~106kPa

2 Installation of Battery and Holder

1) Open the rear panel with coin or an ordinary flat screwdriver, as shown in Figure 2.

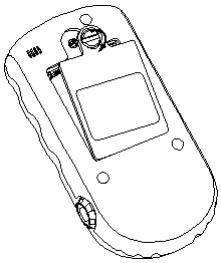


Figure 2

2) According to the polarity mark, insert three AA batteries into battery house, as shown in Figure 3.

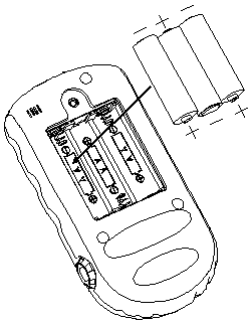


Figure 3

3) Close the battery cover and lock it.

4) Fixing Holder

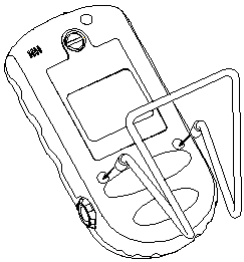


Figure 4 Fixing Holder

3 SpO2 Sensor Connection

3.1 Choose SpO2 Sensor Adapter

The device is equipped with universal Y-type sensors including different adapters for various measuring sites. Three types of sensor adapters (big clip, small clip and rubber wrapper) are provided for the Y-type SpO2 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 SpO2 Sensor

Follow the installing methods below to install the sensor adapter onto the sensor, and then connect the SpO2 sensor cable to the connector labeled "SpO2" at the right side of the device.
After starting the oximeter, clip or wrap the sensor on to the measuring site.

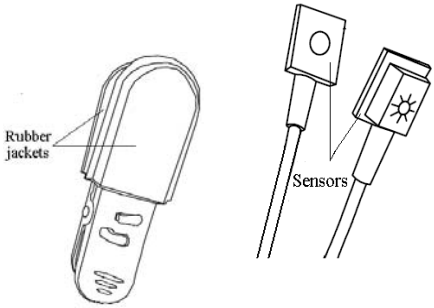


Figure 5 Clip type sensor adapter

Installation of Big Clip

1. Slip off the two rubber jackets from the clip;
2. Fix the sensor cable to the clip (Figure 6A);
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 6B), and then fix the other branch;
4. Install the two rubber jackets onto the clip (Figure 6C).

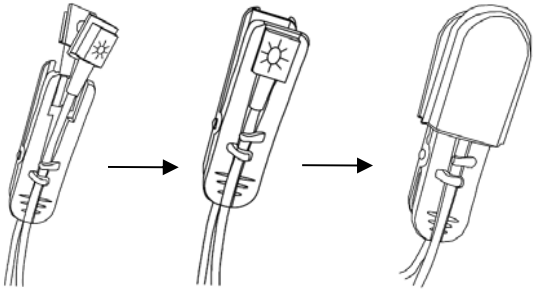


Figure 6A Figure 6B Figure 6C
Big Clip installation

Installation of Small Clip

Follow the step 1, step 3 and step 4 mentioned in Section Installation of Big Clip and refer to Figure 7A and Figure 7B.

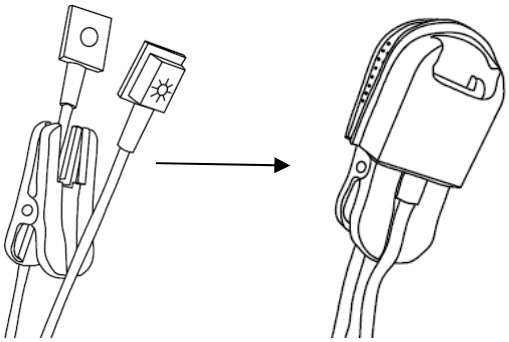


Figure 7A Figure 7B

Small Clip Installation

Installation of Rubber Wrapper

1. Spread the rubber wrapper, there are two fixing slots (Figure 8A);
2. Hold the rubber wrapper and press one branch of the Y-type sensor into one of the fixing slots (Figure 8B), then fix the other branch.

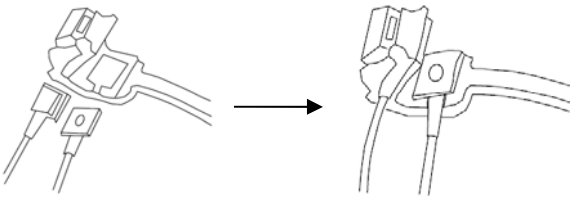


Figure 8A Figure 8B

Rubber Wrapper Installation

3.3 Placement of Veterinary SpO2 Sensor

As a general rule, measuring SpO2 and pulse rate for animal is performed when the animal is calm or under anaesthesia, and the first choice of measuring site is their ears, then the second choice is their tongues. Normally the animal's tongue will slip out after anaesthesia. At first, clip the sensor on its ear (Figure 9) or tongue (Figure 10). Then, according to perfusion index (PI) value (greater PI is better) you can find an appropriate site.

Besides the ear and tongue, you can wrap the SpO2 sensor onto other places such as leg (Figure 11) or tail (Figure 12). 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.

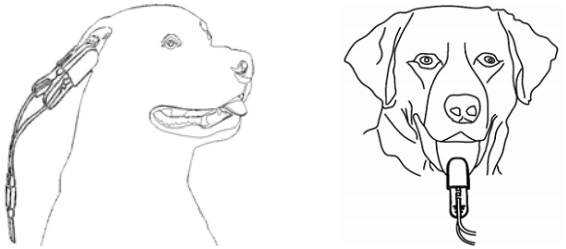


Figure 9 clip the sensor on tongue Figure 10 clip the sensor on tongue

Figure 11 wrap the sensor on leg

Figure 12 wrap the sensor on tail

Tips for SpO2 Monitoring

A. 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.

B. 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.

C. For thin tissue (without bone) such as tongue or ear, please make sure the measurement option "Thin Tissue" in the setup menu is selected as "YES"

4 Operation

4.1 Default Screen

Press " ⏻ " power key for 2 seconds to start the Oximeter, then insert finger into rubber cushions of the probe, the screen will display the default screen, as shown in Figure 13.

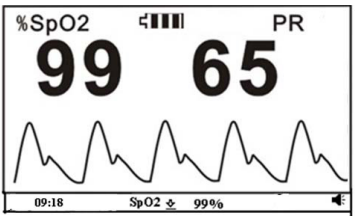


Figure 13 Default Screen

Screen Description:

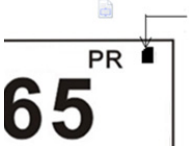
"%SpO2" "99": SpO2 value; "99" is a percentage value;

"19:18": Current time;

"PR 65": Pulse rate value: 65bpm;

"▭▮▮▮": Battery voltage indication;

"▯": Data memory icon; when the data on screen becomes stable, the device will start to store data automatically. No icon means the current data will not be stored. If the memory is full or the total number of the records reaches 256 pieces, the earliest record will be overwritten and the icon " ■ " will appear on the screen for prompt, as shown in the figure below.



***Note:** It is suggested that the data shall be uploaded to computer for saving, or the earliest record will be overwritten.*

“ ”: Alarm mute icon, when the icon becomes “ ”, it means that the oximeter's alarm sound is disabled.

“ ”: Pulse strength bar-graph.
Lower part displays plethysmogram.

4.2 Display Screen with PI Value

On the default screen, press “ / ” Navigation key to shift screens between default screen and display screen with PI value.
The display screen with PI value is shown below.

Figure 14 Display Screen with PI Value

4.3 Indication for No Signal

If “check probe” prompts on screen (as shown in Figure 15), please check whether the probe cable connects well and whether the sensor is in appropriate position.

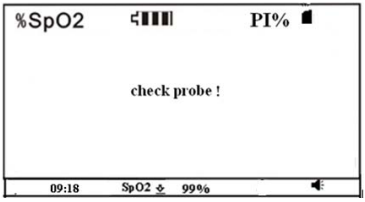


Figure 15 Check Probe Screen

4.4 Menu Setup

On the above mentioned screens, longtime press “ ” key for entering into menu screen (as shown in Figure 16).

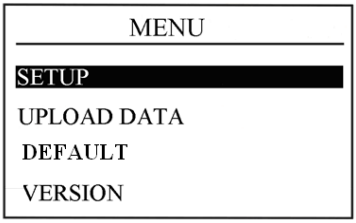


Figure 16 Menu Screen

Screen Description
“**SETUP**”: set parameter values, refer to Chapter 4.4.1 for details.
“**UPLOAD DATA**”: enter into uploading status, refer to Chapter 4.4.2 for details.
"DEFAULT": enter into the factory default setting, refer to Chapter 4.4.3 for details.
“**VERSION**”: for viewing version number of the software, refer to Chapter 4.4.4 for details.

4.4.1 Setup

On the menu screen, select "**SETUP**" and then press " " key for entering into system setup screen. The setup screen is as shown in the following figures.

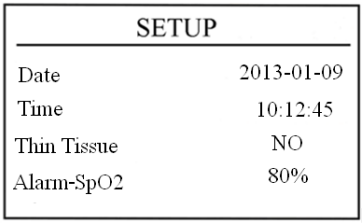


Figure 17 System Setup Screen (A)

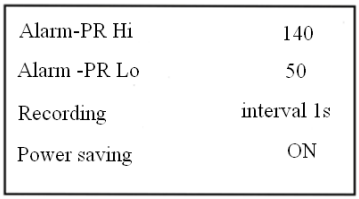


Figure 17 System Setup Screen (B)

Operation Instructions:

1. **DATE**: Date setting

1) When cursor stays on the Year of the date, press " " (Mode/OK) key to active Year option, the cursor flashes on the Year of the date;

2) Press / (Navigation key) to adjust year.

3) Press " " (Power/back) key or " " (Mode/OK) key to confirm and exit from date setting.

4) The procedures of adjusting Month value and Day value are the same with Year adjustment.
Date Format: yy-mm-dd

Note: The setting operations of other parameters (such as TIME, RECORDING INTERVAL, POWER SAVING etc.) are the same with date setting.

2. **TIME**: Time setting
3. **Thin Tissue**: Setting measurement option for thin tissue (without bone) such as ear pr tongue; two options:"YES" and "NO". The factory default setting is "NO", which is for thick tissue option such as leg or tail.
4. **Alarm-SpO2**: SpO2 alarm setting; the factory default value is 80%.
5. **Alarm-PR Hi**: Pulse Rate High limit setting, the factory default value is 140.
6. **Alarm-PR Lo**: Pulse Rate Low limit setting, the factory default value is 50.
7. **RECORDING INTERVAL**: Record interval setting; five options: "1s, 2s, 4s, 8s" and "OFF"; When the option is "OFF", the device will not record real-time measurement data.

Note: The length of data record is limited to 30 seconds at least, and the maximal length for one record is also limited to one hour (for one second interval) , 2hours (for 2 seconds interval) 4 hours (for 4 seconds interval) or 8 hours (for 8 seconds interval).

8. **POWER SAVING**: power saving setting; two options: "on" and "off". The factory default setting is "on".

4.4.2 Upload Data

On the menu screen, select “UPLOAD DATA” and then press “ ” key for entering into connecting status (as shown in Figure 18). When you transmit data (SpO2 and PR values) to your computer, please let the oximeter stay in connecting status.
Do the following operation by the instruction in “Oximeter Data Manager User Manual”. The data uploading will be activated.

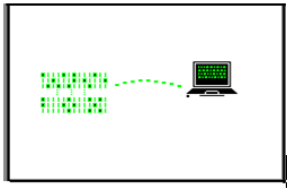


Figure 18 Connecting Status Screen

4.4.3 Default

On the menu screen, select "Default " and then press “ ” key for entering into default setting screen (as shown in Figure 19)

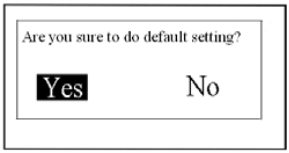


Figure 19 Default Setting Screen

4.4.4 Version

On the menu screen, select “VERSION” and then press “ ” key for entering into version screen (as shown in Figure 20).

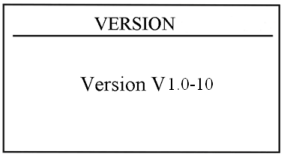


Figure 20

4.5 Data Recall

On the default display screen, longtime press “ ” (Recall/alarm mute) key to enter into recall list screen.

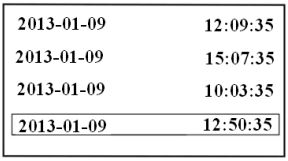


Figure 21 Recall List

4.5.1 Data Recall

Choose one record in the recall list, then press " " key, the display screen will display trend graph, as shown in Figure 22A.

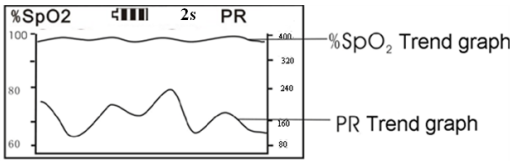


Figure 22A Trend Graph Recall Screen

Screen description:
"%SpO2": The left ordinate value is %SpO2 value;
"12:50:35": Measuring time
"2s": Record interval is 2 seconds.
"PR": The right ordinate value is pulse rate value

Operation Instructions:
Press " " key to shift trend recall screens (as shown in Figure 22A , Figure 22B and Figure 22C)

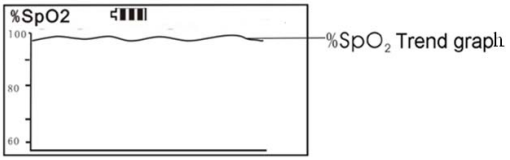


Figure 22B Trend Graph Recall Screen

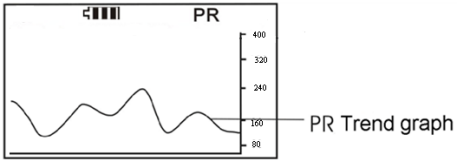


Figure 22C Trend Graph Recall Screen

Press " / " key to view trend graph. Press " " key to return to recall list screen.

4.5.2 Data Deletion

On the menu screen, longtime press " " key and the records list will appear. When the cursor stays on the record needed to be deleted, longtime pressing " " key again, an message "Are you sure to delete all?" prompts on the screen, as shown in Figure 23.

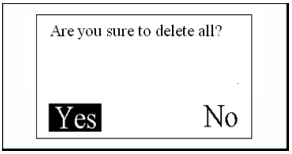


Figure 23

At this time select “Yes” and press “OK” key to delete all the selected records.

5 Technical Specifications

A. Display panel: color LCD;
B. Power supply:
3x LR6 (AA) alkaline batteries or Ni-MH rechargeable batteries
Supply voltage: 3.2~5.0VDC
Operating current: <150mA
Continuous working time: >30 hours
C. SpO2 Specifications
Transducer: dual-wavelength LED sensor
Measurement wavelength:
Red light: 660 nm, Infrared light: 905 nm.
Maximal optical output power: less than 2mW maximum average
Measuring range: 35~100%
Measuring accuracy: Not greater than 3% for SpO2 range from 70% to 100%
*NOTE: Accuracy defined as root-mean-square value of deviation according to ISO 9919.
Low alert setting range: 50%~99% (Default setting: 80%).
D. Pulse Rate Specifications
Range: 30bpm~400bpm
Accuracy: ±2bpm or ±2% (whichever is greater)
Alert setting range: 25bpm~400bpm
Default alert setting: High: 140bpm Low: 50bpm
E. Perfusion Index Display
Range: 0~20%
F. Update rate
8 beats moving average for both SpO2 and pulse rate readings
G. Data Recording
Store data every 1/2/4/8 seconds, up to 384–hour data record.
H. Low perfusion performance
The accuracy of SpO2 and PR measurement still meet the precision described above when the modulation amplitude is as low as 0.5%.
I. Dimensions: 145 mm (L) × 74 mm (W) × 29 mm (H)
Net Weight: 210g (including batteries)
J. Classification
The type of protection against electric shock: Internally powered equipment
The degree of protection against electric shock: Type BF applied parts.
The degree of protection against harmful ingress of liquids: Ordinary equipment without protection against ingress of water.
Electro-Magnetic Compatibility: Group I, Class B

6 Accessories

1. A set of veterinary probe
2. A holder
3. Battery (AA) × 3
4. A User Manual
5. A Quality Certificate
6. A data cable (optional)
7. Oximeter Data Manager software (optional)

Note: The accessories are subject to change. See the Packing List for detailed items and quantity.

7 Repair and Maintenance

7.1 Maintenance

The life of this device is 5 years. In order to ensure its long service life, please pay attention to the maintenance.

- Please change the batteries when the low-voltage indicator appears.
- Please take out the batteries if the oximeter will not be used for a long time.
- The recommended storage environment of the device:
  Ambient temperature: -20ºC ~60ºC
  Relative humidity 10%~95%
  Atmospheric pressure: 50kPa~107.4kPa
- 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 SpO2 simulator, or it can be done by the local third party test house.

7.2 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.

High-pressure sterilization cannot be used on the device.
Do not immerse the device in liquid.

8 Troubleshooting

Trouble	Possible Reason	Solution
The SpO2 and Pulse Rate display instable	1. The probe is not clipped correctly on the ear or tongue. 2. The tail or leg is shaking or the animal is moving.	1. Clip the probe on ear or tongue correctly and try again. 2. Let the animal keep calm.
Can not turn on the device	1. The batteries are drained or almost drained. 2. The batteries are not inserted properly. 3. The device is malfunctioning.	1. Change batteries. 2. Reinstall batteries. 3. 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 batteries are almost drained.	1. Normal. 2. Change batteries.

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: **$SpO_2 = HbO_2 / (HbO_2 + Hb) \times 100\%$**
HbO_2 are the oxyhemoglobins (oxygenized hemoglobin), Hb are those hemoglobins which release oxygen.

2 Principle of Measurement

Based on Lamber-Beer law, the light absorbance of a given substance is directly proportional with its density or concentration. When the light with certain wavelength emits on human tissue, the measured intensity of light after absorption, reflecting and attenuation in tissue can reflect the structure character of the tissue by which the light passes. Due to that oxygenated hemoglobin (HbO_2) and deoxygenated hemoglobin (Hb) have different absorption character in the spectrum range from red to infrared light

(600nm~1000nm wavelength), by using these characteristics, SpO_2 can be determined. SpO_2 measured by this oximeter is the functional oxygen saturation -- a percentage of the hemoglobin that can transport oxygen. In contrast, hemoximeters report fractional oxygen saturation – a percentage of all measured hemoglobin, including dysfunctional hemoglobin, such as carboxyhemoglobin or metahemoglobin.
Clinical application of pulse oximeters: SpO_2 is an important physiological parameter to reflect the respiration and ventilation function, so SpO_2 monitoring used in clinical becomes more popularly, such as monitoring the patient with serious respiratory disease, the patient under anesthesia during operation, premature and neonate. The status of SpO_2 can be determined in time by measurement and find the hypoxemia patient earlier, thereby preventing or reducing accidental death caused by hypoxia effectively.

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

4 Factors affecting SpO_2 accuracy (interference reason)
- Intravascular dyes such as indocyanine green or methylene blue
- Exposure to excessive illumination, such as surgical lamps, bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight.
- Vascular dyes or external used color-up product such as nail enamel or color skin care
- Excessive patient movement
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- Exposure to the chamber with High pressure oxygen
- There is an arterial occlusion proximal to the sensor
- Blood vessel contraction caused by peripheral vessel hyperkinesias or body temperature decreasing

5 Factors causing low SpO_2 value (pathology reason)
- Hypoxemia disease, functional lack of HbO_2
- Pigmentation or abnormal oxyhemoglobin level
- Abnormal oxyhemoglobin variation
- Methemoglobin disease
- Sulfhemoglobinemia or arterial occlusion exists near sensor
- Obvious venous pulsations
- Peripheral arterial pulsation becomes weak
- Peripheral blood supply is not enough

Appendix
Key of Symbols

Symbol		Description
Symbols on the screen	**%SpO2**	The pulse oxygen saturation
	PI	Perfusion Index
	PR	Pulse rate (Unit: beats per minute)
		Low battery voltage
		Alarm Icon
		Memory Icon
		Memory full

Symbol		Description
Symbols on the panels	SpO2	SpO2 probe connector
		Power/Back Key
		Mode/OK Key
		Recall/Alarm mute
		Navigation Key
		Data Interface
	CE	Medical Device complies with Directive 93/42/EEC
	SN	Serial number
		Date of manufacture
	EC REP	Authorised representative in the European community

Symbol		Description
Symbols on the panels		Manufacturer (including address)
		Type BF applied part
		Caution: read instructions (warnings) carefully
		WEEE disposal
		Keep away from sunlight
		Keep in a cool, dry place
		Follow instructions for use
	REF	Product code
	LOT	Lot number

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.*
For further information on recycling points contact the local authorities, the local recycling center or the shop where the product was purchased. If the equipment is not disposed of correctly, fines or penalties may be applied in accordance with the national legislation and regulations.

GIMA WARRANTY CONDITIONS

Congratulations for purchasing a GIMA product.
This product meets high qualitative standards both as regards the material and the production. The warranty is valid for 12 months from the date of supply of GIMA.
During the period of validity of the warranty, GIMA will repair and/or replace free of charge all the defected parts due to production reasons. Labor costs and personnel traveling expenses and packaging not included. All components subject to wear are not included in the warranty.
The repair or replacement performed during the warranty period shall not extend the warranty.
The warranty is void in the following cases: repairs performed by unauthorized personnel or with non-original spare parts, defects caused by negligence or incorrect use.
GIMA cannot be held responsible for malfunctioning on electronic devices or software due to outside agents such as: voltage changes, electro-magnetic fields, radio interferences, etc.
The warranty is void if the above regulations are not observed and if the serial code (if available) has been removed, cancelled or changed.
The defected products must be returned only to the dealer the product was purchased from. Products sent to GIMA will be rejected.