GIMA

PROFESSIONAL MEDICAL PRODUCTS

PULSOXIMETRO OXY 9 - wireless
OXY 9 OXIMETER - wireless
OXYMÈTRE OXY 9 - sans fil
OXY 9 OXÍMETRO - inalámbrico
OXY 9 OXYMETER - kabellos
OXY 9 OXÍMETRO - sem fio

REF **CMS50D-BT (35078)**

CE 0123

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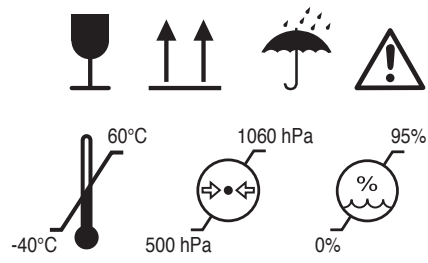

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Instructions to User

Dear users, thank you very much for purchasing the Pulse Oximeter.

In case of modifications and software upgrades, the information contained in this document is subject to change without notice.

The Manual describes, in accordance with the Pulse Oximeter's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details.

Please read the User Manual carefully before using this product. The User Manual which describes the operating procedures should be followed strictly. Failure to follow the User Manual may cause measuring abnormality, equipment damage and human injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, human injury and equipment damage due to users' negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

Owing to the forthcoming renovation, the specific products you received may not be totally in accordance with the description of this User Manual. We would sincerely regret for that.

This product is medical device, which can be used repeatedly.

WARNING:

- Uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the microcirculation barrier patients. It is recommended that the sensor should not be applied to the same finger for over 2 hours.
- For the special patients, there should be a more prudent inspecting in the placing process. The device can not be clipped on the edema and tender tissue.

- The light (the infrared is invisible) emitted from the device is harmful to the eyes, so the user and the maintenance man should not stare at the light.
- Testee can not use enamel or other makeup.
- Testee's fingernail can not be too long.
- Please refer to the correlative literature about the clinical restrictions and caution.
- This device is not intended for treatment.

1 SAFETY

1.1 Instructions for Safe Operations

Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect patient's safety and monitoring performance about cables and transducers. It is recommended that the device should be inspected once a week at least. When there is obvious damage, stop using the device. In addition ,the overall check of monitor, including the safety check such as the leakage current, should be performed only by qualified personnel once every 12 months.

- Necessary maintenance must be performed by qualified service engineers ONLY. There are no user serviceable parts and users are not permitted to maintain it by themselves.
- The oximeter cannot be used together with devices not specified in User's Manual. Only the accessory that appointed or recommendatory by manufacture can be used with this device.
- This product is calibrated before leaving factory.

1.2 Warning

- Explosive hazard—DO NOT use the oximeter in environment with inflammable gas such as some ignitable anesthetic agents.
- Ensure that the environment in which the device is op-

erated is not subject to any sources of strong electromagnetic interference, such as radio transmitters, mobile telephones, etc. Keep them far away High level electromagnetic radiation emitted from such devices may greatly affect the monitor performance.

- DO NOT use the oximeter while the testee measured by MRI and CT.
- Be careful with the use of the lanyard cord. Improper use of the lanyard cord will cause device damage not covered under the manufacturer's warranty. Swinging the device by the lanyard cord will void the warranty. Please do not use lanyard cord if allergic to lanyard cord.
- The person who is allergic to rubber can not use this device.
- The disposal of scrap instrument and its accessories and packings(including battery, plastic bags, foams and paper boxes) should follow the local laws and regulations.
- Please check the packing before use to make sure the device and accessories are totally in accordance with the packing list, or else the device may have the possibility of working abnormally.
- Please choose the accessories and probe which are approved or manufactured by the manufacturer, or else it may damage the device.
- Please don't measure this device with functional tester for the device's related information.
- When uploading, do keep the patient form touching the USB port. The computer used when uploading must be in accordance with EN60950. In addition, when the data line connected to a computer, the medical electrical systems should be in accordance with IEC60601-1-1.

1.3 Attention

- 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 cold environment to warm or hu-

mid environment, please do not use it immediately.

- DO NOT operate keys on front panel with sharp materials.
- High temperature or high pressure steam disinfection of the oximeter is not permitted. Refer to User Manual in the relative chapter (7.1)for instructions of cleaning and disinfection.
- Do not have the oximeter immerged in liquid. When it needs cleaning, please wipe its surface with medical alcohol by soft material. Do not spray any liquid on the device directly.
- When cleaning the device with water, the temperature should be lower than 60°C.
- As to the fingers which are too thin or too cold, it would probably affect the normal measure of the patients' SpO_2 and pulse rate, please clip the thick finger such as thumb and middle finger deeply enough into the probe.
- The update period of data is less than 5 seconds, which is changeable according to different individual pulse rate.
- The waveform is normalized. Please read the measured value when the waveform on screen is equably and steady-going. Here this measured value is optimal value, and the waveform at the moment is the standard one.
- If some abnormal conditions appear on the screen during test process, pull out the finger and reinsert to restore normal use.
- The device has normal useful life for three years since the first electrified use.
- The hanging rope attached to the device is made from Non- allergy material, if particular group are sensitive to the hanging rope, stop using it. In addition, pay attention to the use of the hanging rope , do not wear it around the neck on the purpose of avoiding harm to the patient.
- This device has the function of alarming, users can check on this function according to chapter 6.2 as a reference.
- The device has the function of limits alarming, when the

measured data is beyond the highest or lowest limit, the device would start alarming automatically on the premise of the alarming function is on.

- The device has the function of alarming, this function can either be paused, or closed (default setting) for good. This function could be turned on through menu operation if you need. Please check the chapter 6.2 as a reference.
- The device may not work for all patients. If you are unable to achieve stable readings, discontinue use.
- A flexible circuit connects the two parts of the device. Do not twist or pull on the connection.

2 OVERVIEW

The pulse oxygen saturation is the percentage of HbO_2 in the total Hb in the blood, so-called the O_2 concentration in the blood. It is an important bio-parameter for the respiration. A number of diseases relating to respiratory system may cause the decrease of SpO_2 in the blood, furthermore, some other causes such as the malfunction of human body's self-adjustment, damages during surgery, and the injuries caused by some medical checkup would also lead to the difficulty of oxygen supply in human body, and the corresponding symptoms would appear as a consequence, such as vertigo, impotence, vomit etc. Serious symptoms might bring danger to human's life. Therefore, prompt information of patients' SpO_2 is of great help for the doctor to discover the potential danger, and is of great importance in the clinical medical field.

The Pulse Oximeter features in small volume, low power consumption, convenient operation and being portable. It is only necessary for patients to put one of his fingers into a probe for diagnosis, and a display screen will directly show the measured value of pulse oxygen saturation with the high veracity and repetition.

2.1 Classification:

Class II b(MDD93/42/EEC IX Rule 10)

2.2 Features

A. Operation of the product is simple and convenient.
B. The product is small in volume, light in weight and convenient in carrying.
C. Low power consumption

2.3 Major Applications and Scope of Application

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

⚠ **The problem of overrating would emerge when the patient is suffering from toxicosis which caused by carbon monoxide, the device is not recommended to be used under this circumstance.**

2.4 Environment Requirements

Storage Environment

a) Temperature : -40°C ~ +60°C
b) Relative humidity : ≤ 95%
c) Atmospheric pressure: 500 hPa ~ 1060 hPa

Operating Environment

a) Temperature: 10°C ~ 40°C
b) Relative Humidity: ≤ 75%
c) Atmospheric pressure: 700 hPa ~ 1060 hPa

3 PRINCIPLE

Principle of the Oximeter is as follows: An experience formula of data process is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO_2) in glow & near-infrared zones. Operation principle of the device is: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning & Recording Technology, so that two beams of different wave-

length of lights can be focused onto human nail tip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on screen through treatment in electronic circuits and microprocessor.

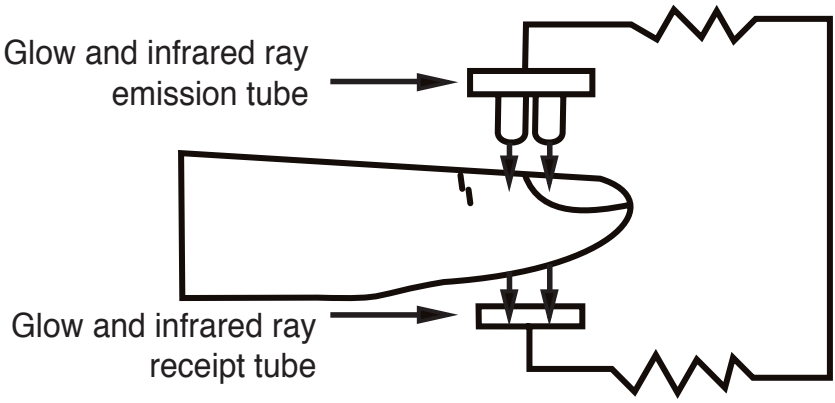


Figure 1.

4 TECHNICAL SPECIFICATIONS

4.1 Main Performance

A. SpO_2 value display
B. Pulse rate value display, bar graph display
C. Pulse waveform display
D. Low-voltage indication: low-voltage indicator appears before working abnormally which is due to low-voltage
E. Display direction can be changed automatically.
F. Enter standby mode automatically.
G. PR sound indication; sound prompt for over-limit, finger-out and low battery
H. Memory function.
I. The data can be uploaded to the terminal equipment by wired mode(Wire or Bluetooth wired equipment)
J. The data can be uploaded to the terminal equipment by wireless mode (Bluetooth or Bluetooth wired equipment)
K. Time display(Wire or Bluetooth wired equipment)

4.2 Main Parameters

A. Measurement of SpO_2
Measuring range: 0% ~ 100%

Accuracy: When the SpO_2 measuring range is 70%~ 100%, the permission of absolute error is ±2%; below 70% unspecified

B. Measurement of pulse rate

Measuring range: 30 bpm ~ 250 bpm
Accuracy: ±2 bpm or ±2% (select larger)

C. Resolution

SpO_2: 1%, Pulse rate: 1bpm.

D. Measurement Performance in Weak Filling Condition

SpO_2 and pulse rate can be shown correctly when pulse-filling ratio is 0.4%. SpO_2 error is ±4%, pulse rate error is ±2 bpm or ±2% (select larger).

E. Resistance to surrounding light

The deviation between the value measured in the condition of man-made light or indoor natural light and that of darkroom is less than ±1%.

F. Power supply requirement:

2.6 V DC ~ 3.6V DC.

G. Optical Sensor

Red light (wavelength is 660 nm, 6.65 mW)
Infrared (wavelength is 905 nm, 6.75 mW)

H. Adjustable prompt range:

SpO_2 : 0% ~ 100%
Pulse Rate: 0 bpm ~ 254 bpm

I. Bluetooth specifications

Bluetooth protocol: Bluetooth Low Energy
USB protocol: None
Operating frequency: 2.4 GHz ISM band
Modulation: GFSK (Gaussian Frequency Shift Keying)
Transmitting power: 0 dBm, -6 dBm, -23 dBm
Sensitivity: ≤-84 dBm @ 0.1% BER
Transfer rate: 1 Mbps
Safety features: Authentication and encryption
Support Services: Bluetooth Data Transfer

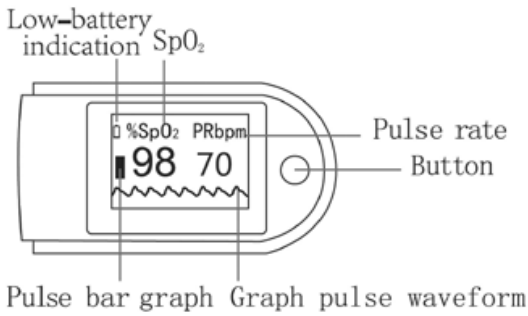
J. FCC ID:2ABOGCMS50D-BT

5 INSTALLATION

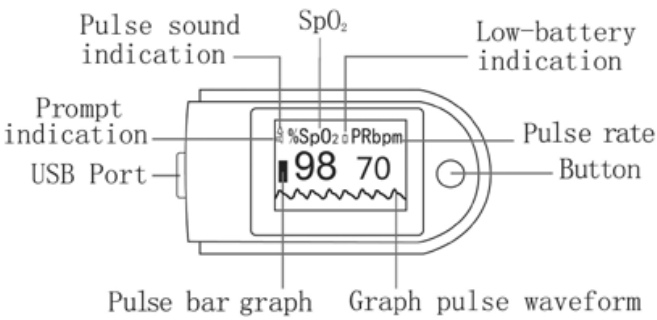
5.1 View of the Front Panel

Figure 2

Front view - Bluetooth equipment



Front view - Wire or Bluetooth wired equipment



USB interface: connect with USB cable (Wire or Bluetooth wired equipment)

Button: exit standby; pause sound prompt, enter menu, menu operation (Wire or Bluetooth wired equipment).

5.2 Battery Installation

A. Refer to Figure 3 open the battery compartment cover on the back of the device,and insert the two AAA size batteries properly in the right direction.

B. Replace the cover.

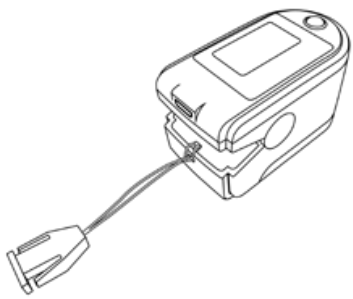
⚠ Please take care when you insert the batteries for

the improper insertion may damage the device.

⚠ When you don't use the device for more than 2 hours, please take out the dry batteries.

Figure 3

Figure 4



5 3 Accessories

A. Put the thinner side of the rope through the hole (see Figure4).

B. Put the wider side of the rope through the thinner side which has been put through the hole, then tighten it.

5.4 USB port (Wire or Bluetooth wired equipment)

USB port :It is used to connect a personal computer to export the trend data (see Figure 4).

5.5 Accessories

A. Structure: main unit, USB cable. (Wire or Bluetooth wired equipment)

B. Accessories: one hanging, one USB cable, one CD disk (including PC software, optional) .

⚠ Please check the device and accessories according to the list to avoid that the device can not work normally.

6 OPERATING GUIDE

6.1.1 Application Method

A.

a) Insert the two batteries properly to the direction, and then replace the cover.
b) Open the clip as shown in Figure 5.
c) Let the user's finger put into the rubber cushions of the clip (make sure the finger is in the right position), and then clip the finger.
d) Do not shake the finger and keep the user in a stable state during the process.
e) Press "Button" to exit from the standby mode. The data can be read directly from the screen on the measuring interface.

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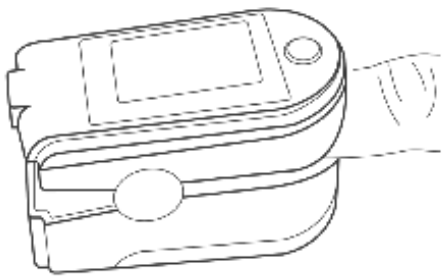

Figure 5 Put finger in position

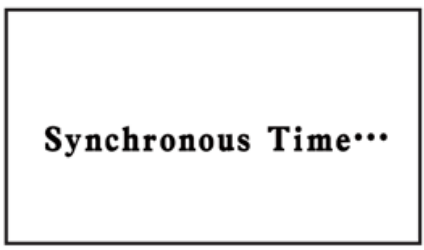

Figure 6-1 Synchronous time interface

Figure 6-2 Time interface

1) Enter to "Synchronous Time..." interface(as Figure 6-1). (Bluetooth equipment)
2) Three methods to exit from "Synchronous Time..." interface.(Bluetooth equipment)

The first method:
Don't perform sync time, press the button, then the device will enter to measurement interface from "Synchronous Time..." interface.
The second method:
Don't perform sync time, wait for several minutes, then the device will enter to measurement interface from "Synchronous Time..." interface.
The third method:
Perform sync time, connect to power, then the device will turn on automatically, when it enters to "Synchronous Time..." interface, connect it with App, then it will automatically adjust time.

⚠ **Fingernails and the luminescent tube should be on the same side.**

⚠ **If the prompt function is on, the device will provide medium-priority prompt signal when finger is out. Intermittent prompt will occur and the user interface presents "FINGER OUT".**
Medium priority indicating that prompt operator response is required.

⚠ **Please synchronize the time with the master device when using it for the first time or after replacing batteries, refer to chapter 6.1.1.e or 6.1.3.c for relative operations.**

B. The device could change display direction according to the handing direction.
C. Under measurement interface and non-prompt state, short press the button to enter the clock interface (as Figure 6-2). (Wire or Bluetooth wired equipment)
D. Under non-measurement state, it will enter standby mode automatically when there is no operation within 5s. (Wire or Bluetooth wired equipment)

6.1.2 Pause sound prompt

(Wire or Bluetooth wired equipment)

A. Sound prompt, including: over-limit, low-battery and finger out.

B. Under the measurement interface, turn on the sound prompt, when the sound prompt occurs, short press the button to pause the sound prompt, and it will resume automatically after about 60s.

C. If you want to turn off the sound prompt permanently, please set it in menu.

6.1.3 Menu operation

(Wire or Bluetooth wired equipment)

Under the measurement interface, long press the button to enter the main menu interface as shown in Figure 7, prompt, record,system, clock etc. can be set, methods are as followings:

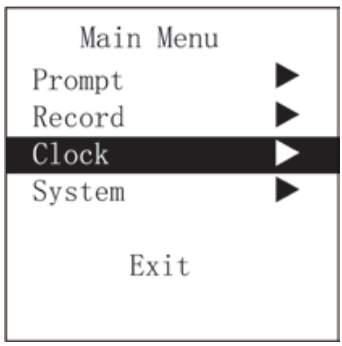

Figure 7 Main menu

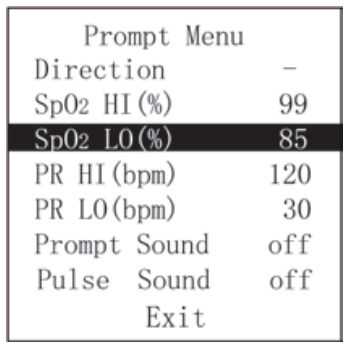

Figure 8 Setting interface for sound prompt

Figure 9 Record menu

A. Prompt setting

Under main menu, short press the button to select “Prompt”, then long press the button to enter its setting interface shown in Figure 8.

Short press the button to select the option to be adjusted, then long press the button to change the value.

“Direction”: direction, “+”: increase the value, “-”: decrease the value

“SpO2 HI (%)”: upper limit prompt for SpO2 over-limit

“SpO2 LO (%)”: lower limit prompt for SpO2 over-limit

“PR HI (bpm)”: upper limit prompt for PR over-limit

“PR LO (bpm)”: lower limit prompt for PR over-limit

“Prompt Sound”: prompt for over-limit, “off”: close, “on”: open.

“Pulse Sound”: PR sound, “off”: close, “on”: open.

Lower limit can not exceed the upper limit, and the upper limit can not be lower than the lower limit when adjusting the values. SpO2 range: 0% ~ 100%, PR range: 0 ~ 254 bpm

The values displayed in Figure 8 are the initial values of over-limit prompt.

After setting, short press the button to select “Exit”, then long press the button to exit sound setting interface, and return to “Main Menu” interface.

B. Data storage

Under the main menu, short press the button to select “Record”, then long press the button to enter the “Record Menu” interface as shown in Figure 9. It indicates that the device is storing when the red dot “●” in measurement interface flickers.

Short press the button to select the option to be adjusted, then long press the button to change the value.

“Mode”: record mode selection, including: “Auto” and “Manual” mode. Under “Manual” mode, select to turn on / off memory by “Record”.

Auto record: start recording after stable data appear, pull out the finger to finish recording a group of data (99 group of data at most), the total duration does not exceed 72 hours.

Manual record: store up to 24-hour data.
When the memory is full, it will display “Memory is full!”, then it will enter the standby mode after several seconds. When exiting the standby mode next time, it will display “Memory is full!” to prompt user that the memory has been full, press the button again to enter the measurement interface.

⚠ **Under manual mode, when “Record” is “ON”, the device will prompt to clear the data stored last time.**
It will display “Recording...” when there is no operation under record state for 15s, then it will enter energy saving mode after several seconds, long press the button to exit this mode; short press the button, it will display “Recording”.

⚠ **Under data recording state, after the display screen turns off automatically, in order to save power, pulse sound indication will turn off automatically.**

“Seg”: data segment.
After setting, short press the button to select “Exit”, long press the button to exit record menu and return to main menu.

“Delete All”: delete all records (auto record mode is shown as Figure 9).

⚠ **Please upload data in time after recording, otherwise the data may be covered when the storage space is full.**

⚠ **The historical data will be deleted once switching the mode. Under record state, the record mode can not be switched; under manual mode, the record mode can be switched only when turning off recording firstly.**

Figure 10 Time menu

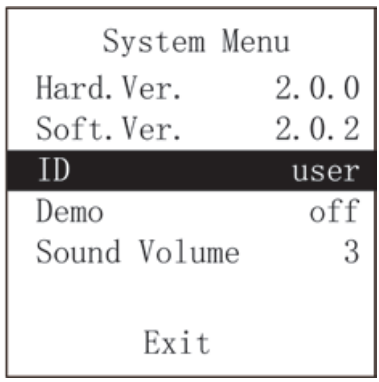

Figure 11 System menu

C. Time setting

a. Connect the master device to synchronize device time

Under the PC software interface, after search for the device (refer to relative chapter (6.1.4) for the connection method), then can synchronize the device time.

b. Set device time manually

Under main menu, short press the button to select “Clock”, long press the button to enter its sub-menu as shown in Figure 10.

Short press the button to select the option to be adjusted, then long press the button to change the value.

“Set Time”: set the time, “yes”: allow, “no”: prohibit
“Set Year”: set the year
“Set Month”: set the month
“Set Day”: set the day
“Set Hour”: set the hour
“Set Minute”: set the minute

Adjustable range for year: 2015 ~ 2045, month: 1 ~ 12, day: 1 ~ 30 (when there are 31 days in a month, it is 1 ~ 31), hour: 1 ~ 23, minute: 1 ~ 59.

After setting, short press the button to select “Exit”, then long press the button to exit time setting interface and return to main menu.

D. System setting and other options introduction

Under main menu, short press the button to select “System”,

then long press the button to enter the interface as shown in Figure 11.
Short press the button to select the option to be adjusted, then long press the button to change the value.

"Hard.Ver.": hardware version
"Soft.Ver.": software version
"ID": user name
"Demo": set the Demo mode, "on": turn on the Demo mode, "off": turn off the Demo mode.
"Sound Volume": set the sound volume, adjustable range: 1 ~ 3

After setting, short press the button to select "Exit", then long press the button to exit the system menu and return to main menu.

E. Exit main menu

Under main menu, short press the button to select "Exit", then long press the button to exit the main menu and return to the measurement interface.

6.1.4 Data upload

A. Wired transmission (Wire or Bluetooth wired equipment)
Connect the device to the computer by the USB cable,upload the data after connecting the PC software properly, refer to "Software operating instruction" for details.

⚠ The PC software can be downloaded from our official website.

B. Bluetooth transmission (Bluetooth or Bluetooth wired equipment)
Turn on the device Bluetooth and the PC software to upload data, refer to "Software operating instruction" for details.

6.2 Attention for Operation

A. Please check the device before using, and confirm that it can work normally.

B. The finger should be in a proper position (see
C. the attached illustration of Figure 4 for reference), or else it may result in inaccurate measure.
D. The SpO_2 sensor and photoelectric receiving tube should be arranged in a way with the subject's arteriole in a position there between.
E. The SpO_2 sensor should not be used at a location or limb tied with arterial canal or blood pressure cuff or receiving intravenous injection.
F. Do not fix the SpO_2 sensor with adhesive or else it may result in venous pulsation and inaccurate measure of SpO_2 and pulse rate.
G. Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight and etc.
H. Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.
I. Testee can not use enamel or other makeup.
J. Please clean and disinfect the device after operating according to the User Manual(7.1).

6.3 Clinical Restrictions

A. As the measure is taken on the basis of arteriole pulse, substantial pulsating blood flow of subject is required. For a subject with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO_2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.
B. For those with a substantial amount of staining dilution drug (such as methylene blue, indigo green and acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (Me+Hb) or thiosalicylic hemoglobin, and some with icterus problem, the SpO_2 determination by this monitor may be inaccurate.
C. The drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for se-

rious error of SpO_2 measure.

D. As the SpO_2 value serves as a reference value for judgement of anemic anoxia and toxic anoxia, some patients with serious anemia may also report good SpO_2 measurement.

7 MAINTAIN, TRANSPORTATION AND STORAGE

7.1 Cleaning and Disinfecting

Using medical alcohol to disinfect the device, nature dry or clean it with clean soft cloth.

7.2 Maintain

A. Please clean and disinfect the device before using according to the User Manual (7.1).

B. Please change the battery when the screen shows  .

C. Take out the battery if leave the equipment unused for long time.

D. Users are advised to calibrate the device termly (or according to the calibrating program of hospital). It also can be performed at the state-appointed agent or just contact us for calibration.

7.3 Transportation and Storage

A. The packed device can be transported by ordinary conveyance or according to transport contract. The device can not be transported mixed with toxic, harmful, corrosive material .

B. The packed device should be stored in room with no corrosive gases and good ventilation. Temperature: -40°C ~ 60°C; Humidity: ≤ 95%

8 TROUBLESHOOTING

Trouble	Possible Reason	Solution
The SpO_2 and Pulse Rate can not be displayed normally	1. The finger is not properly positioned. 2. The patient's SpO_2 is too low to be detected.	1. Place the finger properly and try again. 2. Try again, Go to a hospital for a diagnosis if you are sure the device works all right.
The SpO_2 and Pulse Rate are not displayed stably	1. The finger is not placed inside deep enough. 2. The finger is shaking or the patient is moving.	1. Place the finger properly and try again. 2. Let the patient keep calm.
The device can not be turned on	1. The battery is drained away or almost drained away. 2. The battery is installed incorrectly. 3. The device's malfunction.	1. Please change batteries. 2. Please Install the battery again. 3. Please contact the local service center.
The display is off suddenly	1. The product will enter standby mode when no signal is in the product within 5 seconds 2. The battery is drained away or almost drained away.	1. Normal 2. Please change batteries.

9 KEY OF SYMBOLS

Signal	Description
	Follow instructions for use
% SpO_2	The pulse oxygen saturation (%)
PR bpm	Pulse rate (bpm)
	Open the prompt sound indication (Wired or Bluetooth wired equipment)
	Open the pulse sound indication (Wired or Bluetooth wired equipment)

	Menu button (Wired or Bluetooth wired equipment)/ Exit standby mode.
	Type BF applied part
SN	Serial number
	1. The finger clip falls off (no finger inserted) 2. Signal inadequacy indicator
+	Battery positive electrode
—	Battery cathode
	USB (Wired or Bluetooth wired equipment)
• Recording..	Record state (Wired or Bluetooth wired equipment)
CE	Medical Device complies with Directive 93/42/EEC
Synchronous Time···	Synchronous time interface (Bluetooth equipment)
IP22	Covering Protection rate
	WEEE disposal
	The battery power is full(Wired or Bluetooth wired equipment)
	Low-voltage
	Manufacturer
	Date of manufacture
	Temperature limit
	Humidity limit
	Atmospheric pressure limit
	This side up
	Fragile, handle with care

	Keep in a cool, dry place
	Recyclable
REF	Product code
LOT	Lot number
	Caution: read instructions (warnings) carefully
EC REP	Authorized representative in the European community
	Expiration date

10 SPECIFICHE DI FUNZIONAMENTO

Information	**Display Mode**
The Pulse Oxygen Saturation(SpO_2)	2-digit digital LCD display
Pulse Rate(PR)	3-digit digital LCD display
Pulse Intensity (bar-graph)	Bar-graph LCD display
SpO_2 Parameter Specification	
Measuring range	0% ~ 100%, (the resolution is 1%).
Accuracy	70% ~ 100%: ±2% ,Below 70% unspecified.
Average value	Calculate the Average value in every 4 measure value. The deviation between average value and true value does not exceed 1%.
Pulse Parameter Specification	
Measuring range	30 bpm ~ 250 bpm, (the resolution is 1 bpm)
Accuracy	±2 bpm or ±2% (select larger)
Average pulse rate	Moving calculate the Average pulse rate every 4 cardio-beat,s cycle. The deviation between average value and true value does not exceed 1%

Safety Type	
Interior Battery, BF Type	
Pulse Intensity	
Range	Continuous bar-graph display, the higher display indicate the stronger pulse.
Battery Requirement	
1.5 V (AAA size) alkaline batteries × 2	
Battery working life	
Two1.5 V (AAA size) 600 mAh alkaline batteries can work continually for 24 hours	
Dimensions and Weight	
Dimensions	58(L) × 32(W) × 34 (H) mm
Weight	About 52 g (with the batteries)

Note 1: the claims of SpO_2 accuracy shall be supported by clinical study measurements taken over the full range. By artificial inducing, get the stable oxygen level to the range of 70% to 100% SaO2, compare the SpO_2 values collected by the secondary standard pulse oximeter equipment and the tested equipment at the same time, to form paired data, which are used for the accuracy analysis.
There are 12 healthy volunteers (male: 6. female: 6; age: 18~45; skin color: black: 2, light: 8, white: 2) data in the clinical report.
Note 2: because pulse oximeter equipment measurements are statistically distributed, only about two-thirds of pulse oximeter equipment measurements can be expected to fall within ±Arms of the value measured by a CO-OXIMETER.
Note 3: patient simulator has been used to verify the accuracy under conditions of low perfusion. SpO_2 and PR values are different due to low signal conditions, compare them with the known SpO_2 and PR values of input signal.
Note 4: optical sensors as the light-emitting components, will affect other medical devices applied the wavelength range. The information may be useful for the clinicians who carry out the optical treatment.

APPENDIX 1

Guidance and manufacturer's declaration – electromagnetic emissions- for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emission		
The CMS50D-BT is intended for use in the electromagnetic environment specified below. The customer of the user of the CMS50D-BT should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The CMS50D-BT uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The CMS50D-BT is suitable for use in all establishments other than domestic and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity			
The CMS50D-BT is intended for use in the electromagnetic environment specified below. The customer or the user of CMS50D-BT should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.

Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Mains power quality should be that of a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
The CMS50D-BT is intended for use in the electromagnetic environment specified below. The customer or the user of CMS50D-BT should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the CMS50D-BT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=\left[\frac{3.5}{V^1}\right]\sqrt{P}$ $d=\left[\frac{3.5}{E^1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d=\left[\frac{7}{E^1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz

			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CMS50D-BT is used exceeds the applicable RF compliance level above, the CMS50D-BT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CMS50D-BT. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the CMS50D-BT

The CMS50D-BT is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CMS50D-BT can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CMS50D-BT as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**	
	80 MHz to 800 MHz $d = \left[\frac{3.5}{E^1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E^1}\right]\sqrt{P}$
0,01	0,12	0,23
0,1	0,37	0,74
1	1,17	2,33
10	3,69	7,38
100	11,67	23,33

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

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

APPENDIX 2

State	Alarm condition delay	Alarm signal generation delay
Low voltage alarm	1s	20ms
SpO_2 alarm	330ms	20ms
Pulse rate alarm	330ms	20ms
Probe error alarm	16ms	20ms

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.*

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.