

Instructions for CMS-60C Pulse Oximeter

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

This Manual is written and compiled in accordance with the council directive MDD93/42/EEC for medical devices and harmonized standards. 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 cannot 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 cannot use enamel or other makeup.**
- **Testee's fingernail cannot be too long.**
- **Please refer to the correlative literature about the clinical restrictions and caution.**
- **This device is not intended for treatment.**

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APPENDIX 14

1 Safety

1.1 Instructions for safe operations

- ü 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.
- ü Necessary maintenance must be performed by qualified service engineers ONLY. Users are not permitted to maintain it by themselves.
- ü 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.
- ü 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.
- ⚠ DO NOT use the oximeter while the testee measured by MRI and CT.
- ⚠ The person who is allergic to rubber cannot use this device.
- ⚠ The disposal of scrap instrument and its accessories and packing's (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 choose the battery chargers which should be ensured compliance with the requirements of IEC 60601-1, or else it may damage the device.
- ⚠ The device can only be matched with the compatible probe.
- ⚠ Please don't measure this device with functional tester for the device's related information.

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 humid 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 immersed 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' SpO₂ and pulse rate, please clip the thick finger such as thumb and middle finger deeply enough into the probe.
- 🔔 The pulse oximeter can be used to adult or infant. Whether the device is used to adult or infant, it depends on the probe selected.
- 🔔 The update period of data is less than 5 seconds, which is changeable according to different individual pulse rate.
- 🔔 Please read the measured value when the waveform on screen is equably and steady-going, 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.
- 🔔 This device has the function of alarming, users can check on this function according to chapter 6.1 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 6.1 as a reference.
- 🔔 The device may not work for all patients. If you are unable to achieve stable readings, discontinue use.

2. Overview

The pulse oxygen saturation is the percentage of HbO₂ in the total Hb in the blood, so-called the O₂ 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 SpO₂ 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' SpO₂ 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 Features

- A.** Operation of the product is simple and convenient.
- B.** The product is small in volume, light in weight and convenient in carrying.

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C. Low power consumption

2.2 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.

2.3 Environment requirements

Storage Environment

- a) Temperature : $-40^{\circ}\text{C} \sim +60^{\circ}\text{C}$
- b) Relative humidity :5% ~ 95%
- c) Atmospheric pressure :500hPa ~ 1060hPa

Operating Environment

- a) Temperature: $10^{\circ}\text{C} \sim 40^{\circ}\text{C}$
- b) Relative Humidity :30% ~ 75%
- c) Atmospheric pressure:700hPa ~ 1060hPa

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 wavelength 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.

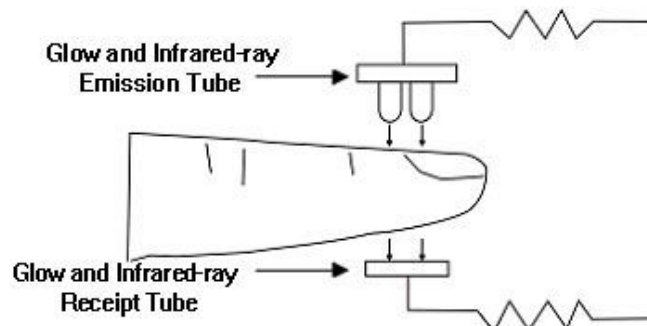


Figure 1.

4. Technical specifications

4.1 Main performance

- A. SpO₂ 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. The display mode can be changed
- F. Screen brightness can be changed
- G. A pulse sound indication
- H. With alarm function
- I. With SpO₂ value and pulse rate value of storage, the stored data can be uploaded to computers
- J. It can be connected with an external oximeter probe
- K. Real-time data can be transmitted to computers.

4.2 Main Parameters

A. Measurement of SpO₂

Measuring range: 0% ~ 100%

Accuracy:

When the SpO₂ measuring range is 70% ~ 100%, the permission of absolute error is $\pm 2\%$;
below 70% unspecified

B. Measurement of pulse rate

Measuring range: 30bpm ~ 250bpm

Accuracy: ± 2 bpm or $\pm 2\%$ (select larger)

C. Resolution

SpO₂ : 1%, Pulse rate: 1bpm.

D. Measurement Performance in Weak Filling Condition

SpO₂ and pulse rate can be shown correctly when pulse-filling ratio is 0.4%. SpO₂ error is $\pm 4\%$, pulse rate error is ± 2 bpm or $\pm 2\%$ (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 $\pm 1\%$.

F. Power supply requirement : 3.6 V DC ~ 4.2V DC.

G. Optical Sensor

Red light (wavelength is 660nm , 6.65mW)

Infrared (wavelength is 880nm, 6.75mW)

H. Adjustable alarm range

SpO₂ : 0%~100%

Pulse Rate : 0bpm~254bpm

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5 Installation

5.1 View of the front panel

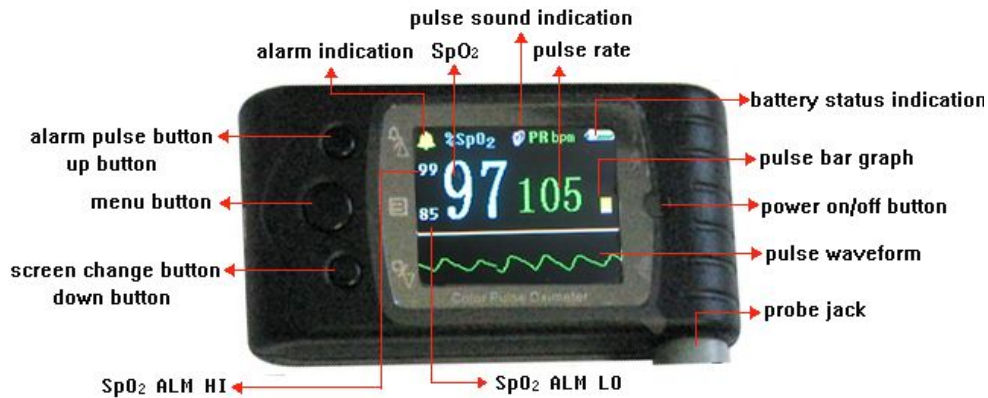


Figure 2. Front View

5.2 Underside View and Left View

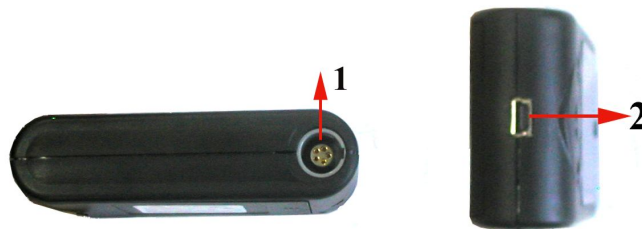


Figure 3. Underside View and Left View

1. Probe jack : It is used to connect a SpO₂ sensor to measure the oxygen saturation and pulse rate.
2. USB port :It is used to connect a personal computer to export the trend data(or real-time data) or charge the lithium battery via a data line.

5.3 RearView



Figure 4. RearView

(Refer to Figure 4 and insert the lithium battery properly in the right direction.)

5.4 Accessories

- A. A lithium battery
- B. A User Manual
- C. A power adapter
- D. A data line
- E. A disk (PC software)
- F. An adult-oximeter probe
An infant-oximeter probe (May purchase selectively)

6 Operating Guide

6.1 Application method

A.

- a) Open the lid of battery box and put the battery inside, then close.
- b) Put the suitable probe into the jack on the right side of the oximeter. (The probe is limited to be produced by our company; never replace it with the similar ones by other manufacturers).
- c) Put the finger into the probe.
- d) Press the "power on/off button" long about a few seconds, the power is on, and the device will start to self-inspect. The device displays the measuring interface after self-inspecting.
- e) Do not shake the finger and keep the patient in a stable state during the process.
- f) The data can be read directly from the screen on the measuring interface.

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

⚠ If the alarm function is on, the device will provide medium-priority alarm signal when probe or finger is out . Intermittent alarm will occur and the user interface presents "FINGER OUT".

Medium priority indicating that prompt operator response is required.



Figure 5

(Actual probe may be different with the probe as figure 5, please accept the actual probe with the device)

B. Change display direction:

On the measuring interface, press the "screen change button" can change the display direction.

C. Pause alarm:

- Alarm including the alarm of measure data's going beyond the limits, the alarm of low-voltage, the alarm of probe or finger's out of position.
- When alarm is on, press the "alarm pause button" can pause the alarm, it can renew alarm in about 60s, and if pressing the "alarm pause button" again within 60s, it can renew alarm.
- If you want to turn off the alarm for good, you should enter the menu for operation.

D. Menu operations:

On the measuring interface, press the "menu button" can enter the menu of figure 6. Users can adjust the setting through the main menu, such as alarm, pulse sound indication, backlight, data storage, ID function. The specific method is as follows:



Figure 6. Main Menu Interface

a) Alarm setting

On the main menu interface, press the "up button" or "down button", move the menu choice bar to "Alarm", then press the "menu button" to enter the alarm setting menu of figure 7:

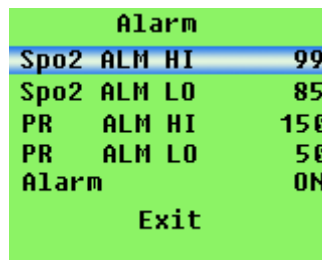


Figure 7. Alarm Setting Menu

a. The highest/lowest alarm limit setting

Press the "up button" or "down button" to choose the parameter to be adjusted, then press the "menu button" again to enter the similar dialog box shown as figure 8, then press the "up button" or "down button" to change data. Each press of the "up button" or "down button", the data will raise or descend for one time accordingly, until it gets to the required number, then press the "menu button" for another time to end the setting.

⚠ If the alarm function is on, the device will provide medium-priority alarm signal when the data of SpO₂ or pulse rate is beyond the limit. Intermittent alarm will occur and the measurement shows in yellow.

Medium priority indicating that prompt operator response is required.

When operating at the beginning, the operator inserts his finger, and setup the Spo2 ALM HI lower than the current measured value, then the machine will start alarm. The pulse rate alarm test is the same with the above.



Figure 8.

b. The alarm state setting

Press the "up button" or "down button", move the menu choice bar to "Alarm", then choose the alarm state (on/off) by pressing the "menu button", choose "on" to start the alarm function, and choose "off" to close it for good.

b) Pulse sound indication setting

On the main menu interface, press the "up button" or "down button", move the menu choice bar to "Pulse Sound", then choose the pulse sound indication state (on/off) by pressing the "menu button", press "on" to start the function, and press "off" to close it.

c) Backlight adjustment

On the main menu interface, press the "up button" or "down button", move the menu choice bar to "Brightness", then press the "menu button" to change the number in order to adjust the brightness of screen.

d) Data storage setting

This device has the function of 24 hours data storage, it has the capability of accurately storing pulse rate and SpO₂ data, then transmit the data to computer with the data line for replay and analysis.

a. On the main menu interface, press the "up button" or "down button", move the menu choice bar to "Record", then press the "menu button" again to enter the dialog box of figure 9: if it is in recording state, the "Stop" is displayed on menu; if it is not in recording state, the "Start" is displayed on menu.



Figure 9.

b. When the "Start" is displayed on the menu, if the memory still have the former data in storage, the CMS-60C

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" Do you really want to recover the memory" dialog box will be displayed when pressing the "menu button", then press the "up button" or "down button" to choose setting, then press the "menu button" to confirm setting, the dialog box will be displayed as figure 10: It needs to set the starting time for data storage by users, users can change the setting value by pressing the "up button" or "down button", and confirm the setting value by pressing the "menu button", the black cursor will move to next place after setting. When the black cursor move to "Yes" (store) or "No" (don't store), press the "up button" or "down button" to choose setting, then press the "menu button" to confirm setting.

c. When the "Stop" is displayed on menu, the " Do you really want to stop recording " dialog box will be displayed when pressing the "menu button". then press the "up button" or "down button" to choose setting, then press the "menu button" to confirm setting.



Figure 10.

d. If the data storage function is being turned on, when return to the measuring interface, a red "REC" sign and a flashing red dot would appear on screen, which means the device is in a state of storing.

e. In the state of storing, whatever interface the device is on (measuring interface, menu interface), the sign "Recording" would appear on the screen in 30 seconds, and then the screen will be automatically shut down. If pressing any button (power on/off excluded) at this moment, the sign "Recording" would appear on the screen, and then the screen will be automatically shut down again; if pressing the "power on/off button", the device would return to the former interface.

f. If turning on the data storage function, the former data storage will be automatically removed.

g. In the state of data storing, after the screen is automatically shut down, the pulse sound indication would be off for saving power.

h. When the storage space is full, it displays "Memory is full" on the screen, and then shut down in a few seconds. But it will still display "Memory is full" by the next time you turn on the device on the purpose of warning the user, if press any button (power on/off excluded) again, it will enter the measuring interface.

e) Device ID

The user could modify device ID by software "SpO₂ Assistant".

f) Exit the main menu

On the main menu interface, press the "up button" or "down button" in order to move the menu choice bar to "Exit", then press the "menu button" to exit the main menu.

E. PC software operation






Please connect the device with computer by the USB data line, then double click "SpO₂ Assistant" icon to run the PC software. The functions such as uploading data and change device ID could be carried out by the software. Please refer to <SpO₂ Assistant user manual> for detail.

⚠ If the users choose to turn on the synchronizing display function on computer, it would probably take several seconds for the data to appear on the computer screen.(If there is no data on the computer screen ,unplug USB data line , then repeat step "E" again .)

F. Charge

There are two kinds of charging methods:

- a) Connect the device with computer by data line, then the device should be under charging state.
- b) Connect the device with power supply by power adaptor, then the device should be under charging state.
- c) The five status of battery power are shown as follows:

	Power supply by battery only, and battery status is full
	Battery status is not full
	
	Battery status is draining away
	Low power alarm indication (Please charge the battery)
the four status above shows dynamically in turn	Battery is under charging

d) When charging the battery in the state of power off, the sign of battery status still exists on the screen, but it will disappear in about 60 seconds for saving power. However, the sign will appear again if you press any button(power on/off excluded) at this moment.

⚠ If the alarm function is on, the device will provide high-priority alarm signal when the battery is in low power status .Intermittent alarm will occur and the battery icon turns red in the state of flashing.

High priority indicating that immediate operator response is required.

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 the attached illustration of figure 3 for reference), or else it may result in inaccurate measure.
- C. The SpO₂ sensor and photoelectric receiving tube should be arranged in a way with the subject' s arteriole in a position there between.
- D. The SpO₂ sensor should not be used at a location or limb tied with arterial canal or blood pressure cuff or receiving intravenous injection.
- E. Do not fix the SpO₂ sensor with adhesive or else it may result in venous pulsation and inaccurate measure of SpO₂ and pulse rate.
- F. Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight and etc.

G. Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.

H. Testee cannot use enamel or other makeup.

I. 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 SpO₂ 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 SpO₂ 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 serious error of SpO₂ measure.

D. As the SpO₂ value serves as a reference value for judgment of anemic anoxia and toxic anoxia, some patients with serious anemia may also report good SpO₂ 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 recharge the battery when the screen shows .

C. Recharge the battery soon after the over-discharge. The device should be recharged every six months when it is no regular used. It can extend the battery life following this guidance.

D. Please take out the batteries if the oximeter is not in use for a long time.

E. The device needs to be calibrated once a year (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 cannot 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
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The SpO₂ and Pulse Rate cannot 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 SpO₂ 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 cannot be turned on	1. The battery is drained away or almost drained away. 2. The battery is installed incorrectly. 3. The malfunction of the device.	1. Please recharge the battery 2. Please Install the battery again. 3. Please contact the local service center.
The display is off suddenly	The battery is drained away or almost drained away .	Please recharge the battery
The device cannot be used for full time after charge	1.The battery is not full charged. 2. The battery is broken	1. Please recharge the battery 2. Please contact the local service center.
The battery cannot be full charged even after 10 hours charging time.	The battery is broken	Please contact the local service center.

9 Key of Symbols

Signal	Description
	Warning – See User Manual
%SpO₂	The pulse oxygen saturation(%)
PRbpm	Pulse rate (bpm)
	Close the alarm sound indication forever
	Pause the alarm sound indication
	Open the alarm sound indication
	Close the pulse sound indication

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	Open the pulse sound indication
	Power on/off button
	Alarm pause button/up button
	Menu button
	Screen change button/down button
	BType application part
SN	Serial number
	1. the finger clip falls off (no finger inserted)] 2. Probe error 3. Signal inadequacy indicator
IPX1	Ingress of liquids rank
	WEEE (2002/96/EC)
	This item is compliant with Medical Device Directive 93/42/EEC of June 14, 1993, a directive of the European Economic Community.

10 Function Specification

Information	Display Mode
The Pulse Oxygen Saturation (SpO ₂)	2-digit digital TFT display
Pulse Rate (PR)	3-digit digital TFT display
Pulse Intensity (bar-graph)	bar-graph TFT display
SpO₂ 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%.

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Pulse Parameter Specification	
Measuring range	30bpm ~ 250bpm, (the resolution is 1bpm)
Accuracy	±2bpm 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 application part
Pulse Intensity	
Range	Continuous bar-graph display, the higher display indicate the stronger pulse.
Battery Requirement	
Voltage 3.7 rechargeable lithium battery × 1	
Battery working life	
Charge and discharge no less than 500 times.	
Power Adapter	
Input Voltage	100 to 240 VAC, 50/60 Hz
Output voltage	5 VDC
Output current	250mA
Output power	1.25 W
Oximeter Probe	
Wavelength:660nm 880nm	
Dimensions and Weight	
Dimensions	87(L) × 45(W) × 22(H) mm
Weight	About 175 g (with the lithium battery*1)

Appendix

State	Alarm condition delay	Alarm signal generation delay
Low voltage alarm	1s	20ms

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Spo ₂ alarm	330ms	20ms
Pulse rate alarm	330ms	20ms
Probe error alarm	16ms	20ms