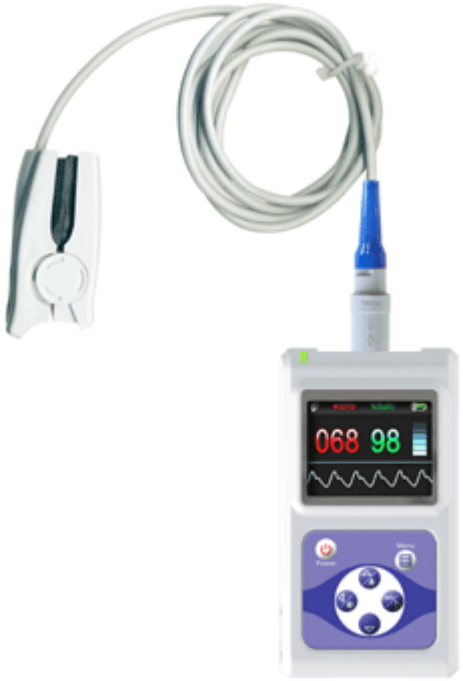
Pulse Oximeter

User Manual



CMS-60D

SOUTHEASTERN MEDICAL SUPPLY, INC

Instructions to User

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 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.**

Contents

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.

✧ Necessary maintenance must be performed by qualified service engineers ONLY. 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.

DO NOT use the oximeter while the testee measured by MRI and CT.

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.

The device can only be matched with the compatible probe.

Please don't measure this device with function test paper 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 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□.

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 enought into the probe.

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 for good, 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 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, 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.

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□ ~ +60□

b) Relative humidity :5% ~ 95%

c) Atmospheric pressure :500hPa ~ 1060hPa

Operating Environment

a) Temperature:0□ ~ 50□

b) Relative Humidity :15% ~ 95%

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.

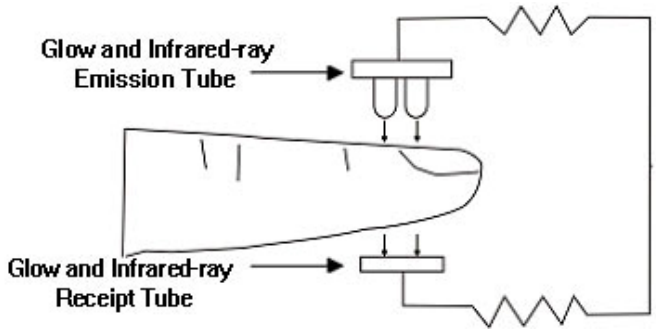


Figure 1.

4. Technical specifications

4.1. Main performance

A. 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. Screen brightness can be changed
F. A pulse sound indication
G. With alarm function

H. With SpO_2 value and pulse rate value of storage, the stored data can be uploaded to computers

I. It can be connected with an external oximeter probe

J. Real-time data can be transmitted to computers

K. Review function

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:25bpm～250bpm

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: : 2.2 V DC ~ 3.6V DC.

G. Optical Sensor

Red light (wavelength is 660nm，6.65mW)

Infrared (wavelength is 880nm, 6.75mW)

5. Installation

5.1. View of the front panel

Figure 2. Front View

5.2. Battery and probe installation

A. Refer to Figure 3. and insert the two AA size batteries properly in the right direction.

Figure 3.batteries installation

B. Replace the cover.

C. Inserting the SpO_2 probe of the pulse oximeter in the upper jack.(The probe is limited to be produced by our company; never replace it with the similar ones by other manufacturers).

⚠ **Please take care when you insert the batteries for the improper insertion may damage the device.**

⚠ **If the alarm function is on,the device will provide high-priority alarm signal when the battery is in low power status and intermittent alarm will occur.**

5.3. Accessories

A. Dry battery(2AA)
B. A User Manual
C. A data line
D. A disk (PC software)
E. An oximeter probe

6. Operating Guide

6.1. Application method

A.

a) Put the finger into the probe. Refer to Figure 4.

b) Press the "power on/off button" long , until the device turns on..

c) Do not shake the finger and keep the patient in a stable state during the process.

d) 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 midium-priority alarm signal when**

probe or finger is out and intermittent alarm will occur.

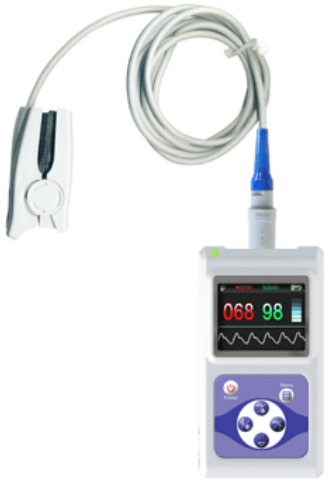


Figure4.

(Actual probe may be different with the probe as figure 4,please accept the actual probe with the device)

B. Pause alarm:

a) 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.

b) 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 with in 60s,it can renew alarm .

c) If you want to turn off the alarm for good, you should enter the menu for operation.

C.Review Interface

a) On the measuring interface, press "up button" to enter the **Review Interface 1** directly, as shown in figure5:

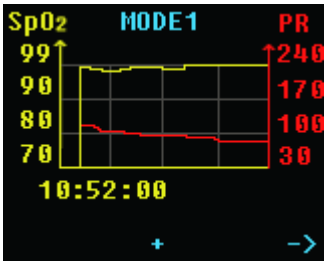


Figure5. **Review Interface 1**

b) In review interface, press "menu button" to switch between **Review Interface 1** and **Review Interface 2**; press "Down button" to enter the review interface for next hour or last hour; In **Review Interface 1**, press "left button" or "right button" can move the trend graph for storage data, When the trend graph cannot be moved any more, the sign——"<-"or"->" shown under the LCD screen will disappear; in **Review Interface 2**, press "left button" or "right button" can move the arrow; Press "up

button" to exit the review Interface.

c) In **Review Interface 1**, can observe the trend waveform composed by storage data, each screen can show storage data for 114 seconds, the yellow line shows the SpO_2 trend waveform, the red line shows the PR trend waveform, the time underside shows the starting time of dispalying the date in the screen, the middle "+" and "-" underside the screen means the operation direction of the "Down button". Press "right button", it will show "+" in the position, then press "Down button" to enter next hour; Press "left button", it will show "-" in the position, then press "Down button" to enter last hour.

d) The **Review Interface 2** shown based on **Review Interface 1**, the stored SpO_2 value and PR value in each second can be observed here, the underside date from left to right marks time, SpO_2 value, PR value. when the stored data exceeds the upper and lower limit setted by user, the relevant value will turn green.

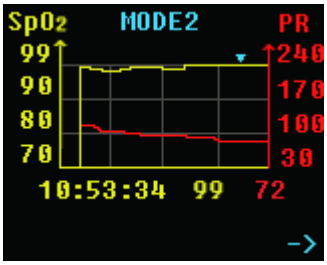


Figure6. **Review Interface 2**

D. Menu operations:

On the measuring interface, press the"menu button"can enter the menu of figure 7.Users can adjust the settings through the main menu, such as alarm, pulse sound indication,backlight, data storage, data transmission (with the use of data line), the specific method is as follows:

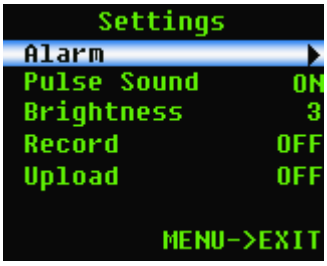


Figure 7. Main Menu Interface

a) Alarm setting

On the main menu interface, press the"up button"or"down button" to select "Alarm" , then press the"left button" or “right button”to enter the alarm setting menu of figure 8:

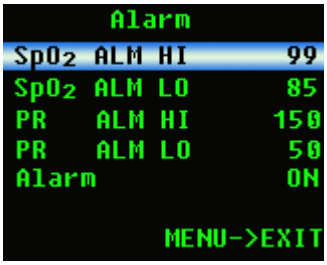


Figure 8. Alarm Setting Menu

a. The highest/lowest alarm limit setting

Press the"up button"or"down button"to choose the parameter to be adjusted, then press the"left button" or "right button" to change data. Each press of the"left button"or"right button", the data will raise or descend for one time accordingly.

⚠If the alarm function is on,the device will provide midium-priority alarm signal when the data of SpO_2 or pulse rate is beyond the limit and intermittent alarm will occur.

b. The alarm state setting

Press the"up button"or"down button" to select"Alarm",then choose the alarm state (on/off) by pressing the"left button"or"right button", choose "on"to turn on the alarms, and choose "off" to turn off the alarms for good.

c. Exit the Alarm settings

Press the "menu button" to exit the Alarm Settings Menu.

b) Pulse sound indication setting

On the main menu interface,press the"up button"or"down button" to select "Pulse Sound", then Press the "left button" Or "right button" to choose to have the Pulse Sound (heart beat)"on" or "off ".

c) Backlight adjustment

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

d) Data storage setting

This device has the ability to store 24 hours worth of data .It can store the measured pulse rate and SpO_2 value accurately, transfer the data to the computer, display the data and print reports (with the included SpO_2 Software - Green Heart)

a. On the main menu interface,press the"up button"or"down button" to select "Record",then press the"left button"or"right button"again to enter the dialog box of figure 9 or finger 10:if it is not in recording state, will come into figure 9; if it is in recording state, will come intofigure 10.

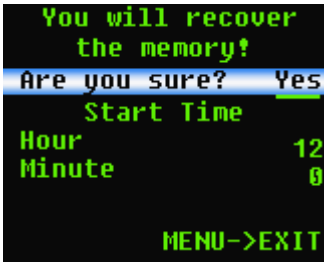


Figure 9.

b. In the status shown in Figure 9, press "up button" or "down button" can change the position of selection bar, choose the item to be setted, press "left button" or "right button" can change the setting of the item, then press "menu button" to exit the status in Figure 9, and perform setting. Notice:when choose NO(not recording), press "up button" or "down button", the selection bar cannot be moved,

when choose YES(recording), the selection bar can be moved, and set the starting time of record. After finish setting, press "menu button" to exit the status in Figure 9, or the equipment cannot perform the recording function.

c. In the status shown in Figure10, press "left button" or "right button" can change the setting, press "menu button" will exit the Figure10, and perform setting. YES for stopping recording, NO for continue recording.

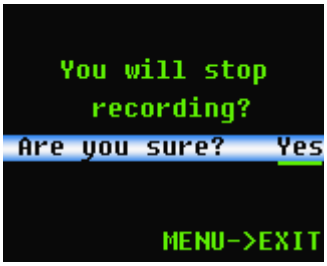


Figure 10.

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 ） Stored data transmission setting

Firstly, please install the affiliated software into the computer, and then two icons would appear on the desktop after installation. The icon of SpO2 is a program for receiving real-time data which is shown as figure 11; the icon of SpO2 Review is a program for receiving stored data which is shown as figure 12.

Figure 11.SpO2 program

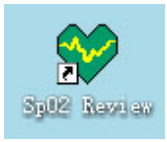


Figure 12. SpO2 Review program

a. Please connect the device with computer by the data line which is affiliated with the device,then double click"SpO_2 Review"icon to open"SpO_2 Review"program,click the 'New Session' Icon in the software, enter the patient data and then click 'ok'. The Software will then display "device connected, waiting for data".

b. On the main menu interface, press the"up button"or"down button" to select "Upload". Press the "left button" or "right button"to select "on" then the data will be transferred to your computer.

c. In the state of storing, it is not applicable for the users to upload the stored date to computer.

d. When the stored data is being uploaded,"ON" will be shown behind the upload item.

e. When the upload of stored data is finished, "OFF" will be shown behind the upload item.

f) Exit the main menu

On the main menu interface, press the"menu button" to exit the main menu.

E. Real-time data transmission

a) Please connect the device with computer by the data line which is equipped with the device, then double click "SpO2"icon to open"SpO2"program.

b) The data can be displayed on computer screen in a few seconds.

c) When you unplug the data line from computer, there is a dialog box "Save data at view" appearing on the desktop, in which you can input some patient's basic information.

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 4 for reference), or else it may result in inaccurate measure.

C. The SpO_2 sensor and photoelectric receiving tube should be arranged in a way with the subject's arteriole in a position there between.

D. 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.

E. 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.

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 can not 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 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 serious 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.

C. 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 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 malfunction of the device.	1. Please change batteries. 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 change batteries.

9. Key of Symbols

Signal	Description
	Warning – See User Manual
%Spo$_2$	The pulse oxygen saturation(%)
PR	Pulse rate (bpm)
	Close the alarm sound indication
	Open the alarm sound indication
	Close the pulse sound indication
	Open the pulse sound indication
	Power on/off button
	left button/Alarm pause button
	Menu button
	Right button
	down button

	Up button
	Type BF
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)

10. Function Specification

Information	Display Mode
The Pulse Oxygen Saturation（SpO_2）	2-digit digital OLED display
Pulse Rate（PR）	3-digit digital OLED display
Pulse Intensity (bar-graph)	bar-graph OLED display
SpO_2 Parameter Specification	
Measuring range	0%～100%, (the resolution is 1%).
Accuracy	70%～100%：±2% ,Below 70% unspecified.
Pulse Parameter Specification	
Measuring range	25bpm～250bpm, (the resolution is 1bpm)
Accuracy	±2bpm or±2% (select larger)
Safety Type	Interior Battery，ＢＦType
Pulse Intensity	
Range	Continuous bar-graph display, the higher display indicate the stronger pulse.

Battery Requirement	
Dry battery(2AA)	
Dimensions and Weight	
Dimensions	110(L) × 60(W) × 23(H) mm
Weight	About 180g (with Dry battery(2AA))

CONTEC

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