

Instructions to User

Dear Users, thank you very much for purchasing our product. 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, as well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details.

Please read the Manual very carefully before using this device. These instructions describe the operating procedures to be followed strictly, failure to follow these instructions can cause measuring abnormality, equipment damage and personal injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, personal injury and equipment damage due to user's negligence of the operation instructions. The manufacturer's warranty service does not cover such faults. the specific products you received may not be exactly as described in this User Manual.

If you have any questions regarding to the use of this product, please call us at 888-970-2999 Monday-Friday from 8:00 AM to 5:00 PM Central Time.

Notice : Please read the Manual very carefully before using this device.

1 Safety

1.1 Instructions for safe operations

- 1) Inspect periodically, make sure that there is no visible damage that may affect user's safety and monitoring performance about cables and transducers. It is recommended that the device should be inspected at least once a week. Please stop using the device if there is obvious damage to the device
- 2) Necessary maintenance must be performed by qualified service engineers appointed by our company ONLY. Users are not permitted to maintain the device by themselves.
- 3) The oximeter cannot be used together with devices not specified in User's Manual. Only the accessory that is appointed or recommendatory by manufacture can be used with this device.
- 4) The device has been calibrated before leaving factory.

1.2 Precautions

- 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 the device is carried from cold environment to warm or humid environment, please do not use it immediately.
- DO NOT operate the button 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 (6.1) 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. Do not spray any liquid on the device directly.
- For fingers which are too thin or too cold improved readings can be achieved by placing on a thicker finger such as thumb or middle finger.
- Do not use the device on infant or neonatal patients.
- The product is suitable for pediatric and adults (Weight should be between 15kg/ 33lbs to 110kg/243lbs).
- The device may not work for all users. If you are unable to achieve stable readings, discontinue use.
- The data refresh is less than 5 seconds, If some abnormal conditions appear on the screen during test process, pull out the finger and reinsert to restore normal use.
- The device's typical life is for three years.
- The device does not have low-voltage alarm function, it shows the low-voltage indicator when the battery is low, requiring a battery replacement.
- The maximum temperature for the contact surface of the device with the body is less than 41°C/105F and the temperature is measured by a temperature measuring device.
- Batteries must be removed if the device is going to be stored for more than one month, or else batteries may leak.
- Do not twist or pull on the connection circuit.

1.3 Warnings

Warning :

- 1) Explosive hazard—DO NOT use the device in environment with flammable gas such as some ignitable anesthetic agents.
- 2) DO NOT use the device while the user is being scanned by MRI or CT.
- 3) .The person who is allergic to rubber can not use this device.
- 4) The disposal of scrap device and its accessories and packing (including battery, plastic bags, foams and paper boxes) should follow the local laws and regulations.
- 5) 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.
- 7) The uncomfortable or painful feeling may appear if using the device ceaselessly. It is recommended that the sensor should not be applied to the same finger for over 2 hours.
- 8) The SpO₂ probe can not be clipped on the edema and tender tissue.
- 9) The infrared is harmful to eyes, so the user and the maintenance man should not stare at the light part of the SpO₂ probe (the infrared is invisible).
- 10) User can not use **finger nail polish, fake nails** or other makeup.
- 11) The fingernails of the User should not be too long.

13)The device is not intended for treatment.

1.4 Attention for operation

- Please check the device before using, and confirm that it can work normally.
- The finger should be placed properly (see the attached illustration of this manual, Figure 1), or else it may cause inaccurate measurement.
- The SpO₂ sensor and photoelectric receiving tube should be arranged in a way with the subject's arteriole in a position there between.
- The SpO₂ sensor should not be used at a location or limb tied with arterial canal or blood pressure cuff or receiving intravenous injection.
- Make sure the optical path is free from any optical obstacles like rubberized fabric.
- Excessive ambient light may affect the measurement result. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight etc.
- Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.
- User can not use **finger nail polish, fake nails** or other makeup.
- Please clean and disinfect the device after operating according to the User Manual (6.1.1)
- The Pedometer should be worn on the waist, and fixed well.

1.5 Clinical restrictions

1. 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.
2. 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.
- 3. The drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for serious error of SpO₂ measure.
- 4. As the SpO₂ value serves as a reference value for judgement of anemic anoxia and toxic anoxia, some users with serious anemia may also report good SpO₂ measurement.

Notice

The product is not suitable for use in continuous supervision for the user. The problem of overrating would emerge when the user is suffering from toxicosis which caused by carbon monoxide, the device is not recommended to be used under this circumstance.

2 Principle

2.1 Operation principle for Pulse Oximeter

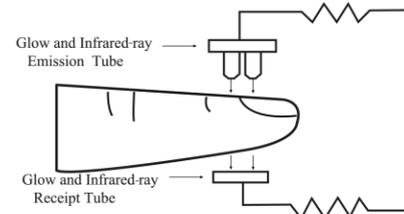


Figure 1 Operating principle

Principle of the Oximeter is as below: 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 (HbO₂) in glow & near-infrared zones. Operation principle of the instrument 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.

2.2 Operation principle for Pedometer

The Pedometer, basing on counting steps by acceleration sensor, adopts the recognition principle of pace waveform and its acceleration and deceleration process for recognizing the waveform produced by person walking, finally gets the number of steps. Detailed method: use the acceleration sensor to collect user's steps(more than three steps), via analyzing and calculating, obtain the peak value of step vibration waveform and the average value of acceleration difference value, and set it to the threshold value. Collect the user's actual step waveform data, if it is in the threshold range, then it is considered that user walks one step forward.

3 Technical specifications

3.1 Main performance

- 1) Display of SpO₂ value.
- 2) Display of pulse rate and bar graph.
- 3) Low-battery indication.
- 4) Storage function of SpO₂ and pulse rate value
- 5) Sync time function.
- 6) Display of steps, calorie and time.
- 7) The pedometer can store data
- 8) Display direction can be changed automatically.
- 9) Height, weight and target calorie can be set by the server.
- 10)Extra low-power consumption setting.
- 11)The device will automatically enter to blank screen state when there is no operation for one minute.
- 12)The data stored can be uploaded to APP by Bluetooth, APP will upload the data to CLOUD platform for analyzing.

3.2 Main Parameters

1. SpO₂ measurement range: 0%~100%
Accuracy: 70%~100%: ±2%
0%~69%: unspecified
2. PR measurement range: 30bpm~250bpm
Accuracy: ±2bpm or ±2%, whichever is greater.
3. Resolution:
SpO₂: 1%
PR: 1bpm
4. **Measurement Performance in Weak Filling Condition:** SpO₂ and pulse rate can be shown correctly when pulse-filling ratio is 0.4%. SpO₂ error is ±4%, pulse rate error is ±2 bpm or ±2%, whichever is greater.
5. **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%.
6. Pedometer measurement:
Measurement range: 0~65535 steps
Resolution: one step
7. **Memory function:** record 1000 groups of SpO₂ data, 224-day pedometer data.
8. Working voltage: DC 3V
9. **Optical Sensor:** red light (wavelength is 660nm,6.65mW) Infrared (wavelength is 880nm, 6.75mW)

3.3 Environment requirements

- Storage Environment
- a)Temperature: -40°C~ +60°C
 - b)Relative humidity: ≤95%
 - c)Atmospheric pressure: 500hPa~1060hPa
- Operating Environment
- a)Temperature: 10°C~ 40°C
 - b)Relative humidity: ≤75%
 - c)Atmospheric pressure: 700hPa~ 1060hPa

4 Device introduction

4.1 Appearance introduction

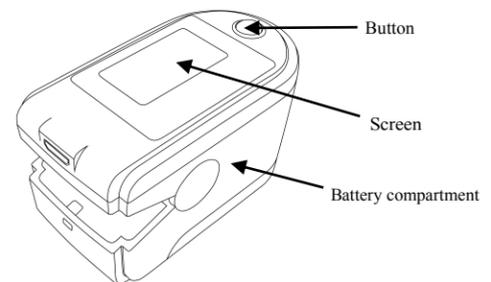


Figure 2 Sketch map for Pulse Oximeter

4.2 Interface introduction



Figure 3 SpO₂ interface

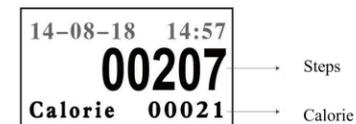


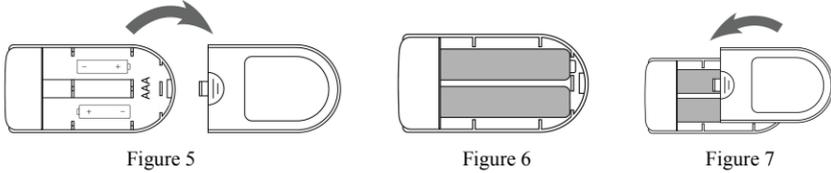
Figure 4 Step interface

4.3 Parameter introduction

Parameter	Description	Unit
%SpO ₂	Oxygen saturation	%
PRbpm	Pulse rate	bpm
Calorie	Calorie	Calorie
Steps	Step	Step

5 Operation guide

5.1 Installation of batteries



- 1) Open the battery compartment cover on the back of the device, shown as Figure 5.
- 2) Install the two “AAA” Alkali batteries, pay attention to the direction, shown as Figure 6 also see diagram in bottom of unit.
- 3) Install the battery compartment cover, shown as Figure 7 by sliding the cover back onto the unit. Follow the tabs on the inside of the cover.

△Notice△

- ◆ Please make sure the batteries polarities are installed properly, to avoid any damage to the device.
- ◆ Please take out the batteries if the device is not used for a long time.
- ◆ Please replace the batteries in time when low-battery appears on the screen.
- ◆ Please replace two new batteries with same type at the same time.
- ◆ After replacing batteries, perform sync time with App again.

△Notice△

Disposal of scrap batteries should follow local regulations about environment.

5.2 Data measurement

- 1) Install the two “AAA” batteries properly, then the device will turn on automatically and enter to “Synchronous Time...” interface.

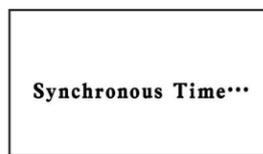


Figure 8 Synchronous time interface

△Notice△

In “Synchronous Time...” interface, Bluetooth will be turned on automatically.

- 2) Three methods for “Synchronous Time...” interface.

△Notice△

Before each measurement, make sure the device has performed a sync time, to insure the accurate time is stored for the data. It indicates that the device needs to perform sync time when it displays “Synchronous Time...” when you first turn the unit on, otherwise if it not synced it will not store measurement results.

The first method:

If you do not want to perform sync time, simply press the button, then the device will enter to “Steps” interface from “Synchronous Time...” interface.

The second method:

If you do not want to perform sync time, wait for several minutes, then the device will enter to “Steps” interface from “Synchronous Time...” interface.

The third method:

To sync the time, push the power button, and the device will turn on automatically. When it enters to “Synchronous Time...” interface, connect it to the App and then it will automatically adjust time.

- 3) In the “Steps” interface, fully insert the finger into the probe and the device will automatically enter to “SpO₂” interface from “Steps” interface, shown as Figure 3.

△Notice△

- ◆ If the time is wrong, the device will not store data.
 - ◆ Fingernails and the luminescent tube should be on the same side.
 - ◆ During use the user’s finger should stay still, and limit movement.
- 4) Read SpO₂ and pulse rate value directly from the screen after inserting the finger for about 4~20s, shown as Figure 3. Pull out the finger after your reading appears on the screen. Only one result is stored each time your finger is inserted.
 - 5) In SpO₂ state, screen direction can be changed automatically by changing the direction of your hand.
 - 6) The interface between “Steps” and “SpO₂” interface can be switched by inserting the finger.
 - a. In “Steps” interface, insert the finger to enter to “SpO₂” interface.
 - b. In “SpO₂” interface, pull out the finger to enter to “Steps” interface, shown as Figure 4

△Notice△

In “Steps” interface, mode Bluetooth will be in “ON” state all the time.

- 7) In “Steps” interface for 1 minute, it will automatically enter standby mode.

△Notice△

In standby mode, the screen does not display any contents, but the pedometer can work normally.

In standby mode, Bluetooth is in “OFF” state.

- 8) In standby mode, press Button to turn on screen display and enter to “Steps” interface shown as Figure 4.

△Notice△

Before uploading steps data, please do sports for 5 minutes at least.

The Pedometer can only upload stored data for the past 24 hours.

5.3 Data upload

- 1) The device can transmit SpO₂, pulse rate, steps and calorie to your iOS or Android phone or tablet using your Wi-Fi connection.
- 2) In your IOS or Android App Store search for the free PHMS App by Contec Medical systems.



Figure 1



Figure 2



Figure 3

- ① Download the free App to your phone or tablet.
- ② Now you can enter your account number. You will use your 10 digit wireless number. As seen in figure 1
- ③ Your password will be the last 6 numbers of your wireless number. You can check the Auto Login box for the device to automatically log you in each time you open the App.
- ④ Once you have logged into the PHMS App you will want to touch the circle in the middle of the screen that says “NewDevice” Figure 2 to add the device to your App.
- ⑤ The App will now search for your device, once the App has been located your device a pop up will appear on your screen as seen in Figure 3. Choose sure and you will now see your Bluetooth Oximeter in the Data section of the App.
- ⑥ To upload your most recent readings tap on the small grey box located in the left corner under the image of your Oximeter. It will turn orange as it is connecting to the device and green once it has successfully added the reading to the Data section in the App.

5.4 Set up My info

- 1) In the “My Info” Tab you can change your password and set up your BMI information.

5.5 Accessories

- A. A lanyard, carrying case and protective boot cover
- B. Two batteries
- C. A User Manual

6 Maintenance

6.1 Routine maintenance

6.1.1 Cleaning and disinfecting

Turn off the device before cleaning. Use medical Alcohol to clean and disinfect the device, let air-dry or clean it with a dry clean cloth. Avoid any liquid entering to the device.

6.1.2 Maintenance

- 1) Keep the device away from dust, high temperature and humidity, and avoid strong shaking and hitting.
- 2) When the device needs to clean, please wipe its surface with neutral detergent, avoid using strong corrosive liquid, like alcohol and gasoline, etc.
- 3) Please clean and disinfect the device before using according to the User Manual (6.1.1).
- 4) Please replace the batteries in time when low-battery appears.
- 5) Please take out the batteries if the device is not used for a long time.
- 6) The device needs to be calibrated periodically. It also can be performed at the state-appointed agent or just contact us for calibration.

6.2 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; Relative Humidity: ≤95%; Atmospheric pressure: 500hPa~1060hPa

7 Troubleshooting

Trouble	Analysis of cause	Solution
The SpO ₂ or Pulse Rate can not be displayed normally	1) The finger is not properly inserted. 2) The SpO ₂ value of patient is too low to be detected.	1) Insert the finger properly and try again. 2) Please try several times more; Go to a hospital for a diagnosis if you are sure the device works all right.
The SpO ₂ or Pulse Rate are not displayed stably	1) The finger is not inserted inside deep enough. 2) The finger is shaking or the user is moving.	1) Insert the finger properly and try again. 2) Please do not move.
The device can not be turned on	1) The batteries are drained or almost drained. 2) The batteries are installed improperly. 3) The device’s malfunction.	1) Please replace the batteries. 2) Please install the batteries again. 3) Please contact the local service center.
The display disappears suddenly	1) Low voltage 2) The device enters to standby mode automatically if there is no operation for 1 minute.	1) Please change the batteries. 2) Normal.
Data can not be stored.	1) False time. 2) Measurement time is too short.	1) Sync time. 2) Normal.

8 Meaning of Symbol

Symbol	Meaning
	Warning – refer to User Manual
	Refer to instruction manual/booklet
%SpO ₂	The pulse oxygen saturation(%)
PRbpm	Pulse rate(bpm)
Calorie	Calorie
	Low-voltage
	Battery anode
	Battery cathode
IP22	Ingress of liquids rank
	Type BF applied part

9 Specification

Display 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
Calorie	5-digit digital OLED display
Steps	5-digit digital OLED display
Time	Year-month-day hour-minute OLED display
SpO₂ parameter	
Measurement range	0%~99% (resolution: 1%)
Pulse parameter	
Measurement range	30bpm~250bpm (resolution: 1bpm)
Pedometer	
Measurement range	0~65535 steps (resolution: one step)
Safety classification	
Internally powered equipment, type BF applied part	
Pulse Intensity	
Range	Continuous bar-graph display, the higher display indicates the stronger pulse.
Power supply	
Two “AAA” batteries	
Dimension and weight	
Dimension	58mm(L) x 32mm(W) x 34mm(H)
Weight	About 52g (including batteries)

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