PMD Pulse Oximeter

User Manual

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Part Number: 10000225 Rev A

Instructions for Use

This User Manual is written and compiled in accordance with standards IEC 60601-1, IEC 60601-1-11 and ISO 80601-2-61. In the case of revisions, modifications, and/or software upgrades, the information contained in this document is subject to change without notice.

This User Manual describes 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. Please reference the applicable sections for further instructions.

Please read this User Manual carefully before using the Pulse Oximeter as it describes the operating procedures that are to be followed for the proper use, care and handling of the device. Failure to not follow the User Manual may cause measuring abnormality, equipment damage and injury. The distributor and manufacturer are NOT responsible for the safety, reliability and performance issues, any monitoring abnormality, injury and equipment damage due to User's negligence in following the provided operating and care instructions. The distributor and manufacturer's warranty does not cover such defects.

The PMD Pulse Oximeter is a reusable medical device.

WARNINGS:

- **Pain or discomfort may appear if the device is used continuously, especially in microcirculation barrier Users. It is recommended that the sensor should not be applied to the same finger for periods that exceed 2 hours.**
- **For special Users, caution must be taken when inspecting for device placement. The device can not be clipped on an edema and/or tender tissue.**
- **Do not stare at the Pulse Oximeter light that is emitted as it is harmful to the eyes. Please note that the infrared light is invisible.**
- **The Pulse Oximeter is not designed to be used over nail polish or other makeup that may be on the finger. Please remove polish/make up before use.**
- **Please ensure that the User's nails are not so long as the device does not fit as shown in Figure 1.**
- **Please reference section 5.3 for Clinical Restrictions.**
- **This device is not intended for diagnosis/treatment.**

1 Overview

The Pulse Oxygen Saturation is the percentage of HbO2 in the total Hb in the blood, commonly referred to as the O2 concentration in the blood. It is an important bio-parameter for respiration. A number of diseases relating to the respiratory system may cause a decrease of SpO2 in the blood, additionally, other causes such as the malfunction of the human body's self-adjustment, damages during surgery, and the injuries caused by some medical conditions would also lead to the difficulty of oxygen supply in the human body, and the corresponding symptoms would appear as a consequence, such as vertigo, impotence, vomiting etc. Serious symptoms may be hazardous, contact your doctor, go to an emergency room or call 911. Prompt relaying of the User's SpO2 measurements to their Doctor is of assistance for the Doctor to discover potential danger and is useful in the clinical medical field.

It is only necessary to place one finger into the device for measurement. The display screen will show repeating, accurate measured values of pulse oxygen saturation.

1.1 Features:

A. Operation of this Pulse Oximeter is easy and convenient.

B. The device is small in size, light in weight and convenient for carrying.

C. Low power consumption.

1.2 Scope of application:

This Pulse Oximeter can be used for measuring the pulse oxygen saturation and pulse rate through a finger. The device is suitable for being used in home, hospital, oxygen bar, community healthcare settings as well as for physical care in sports. It can be used before or after, but it is not recommended to be used during the sports activity.

⚠ High measurements can occur when the User is suffering from toxicosis which is caused by carbon monoxide. This device is not recommended for use under this circumstance.

1.3 Environment Requirements:

Storage Environment

a) Temperature: -40ºC~ +60ºC

b) Relative humidity: ≤95%

c) Atmospheric pressure: 500hPa~1060hPa

Operating Environment

a) Temperature: 10ºC~ 40ºC

b) Relative humidity: ≤75%

c) Atmospheric pressure: 700hPa~ 1060hPa

1.4 Safety:

1.4.1 Instructions for Safe Operations:

- Inspect the device and accessories periodically to ensure there is no visible damage that may affect the User's safety and monitoring. It is recommended that the device be inspected at least once per week. Stop using the Pulse Oximeter if there is obvious damage to the device or accessories.
- Necessary repairs must be performed by qualified service provider appointed by our company ONLY. Users are not permitted to repair the device.
- This Pulse Oximeter cannot be used with devices that are not specified in this User Manual. Only the accessories appointed or recommended by the distributor can be used with this device.
- This device has been calibrated before leaving the manufacturing factory.

1.4.2 Warning:

- Explosive hazard—DO NOT use the device in an environment with flammable gas such as some anesthetic agents.
- DO NOT use the Pulse Oximeter during MRI or CT scanning.
- Use caution when using the lanyard. Improper use of the lanyard cord will cause device damage that is not covered under the warranty. Swinging the Pulse Oximeter by the lanyard will void the warranty. DO NOT use the lanyard if you are allergic to the lanyard cord material.
- DO NOT wrap the lanyard cord around the neck.
- DO NOT use this device if you are allergic to rubber.
- Follow your local laws and regulations when disposing of this device, accessories and packing. This includes the battery, plastic bags, foams and paper boxes.
- Please review the packing list to ensure the device and all accessories noted in Section 4.3 are included with your Pulse Oximeter.
- Only use the accessories which are approved by the distributor to avoid device damage.
- Please don't measure this device with a functional tester for the device's related information.

1.4.3 Attention:

- Keep the device away from dust, vibration, corrosive substances, explosive materials, high temperature and humidity.
- DO NOT continue to use the device if it gets wet.
- DO NOT immediately use the device when going from a cold to warm or humid environment.
- DO NOT use sharp instruments to operate the front panel of the device.
- High temperature or high-pressure steam disinfection of the Pulse Oximeter is not permitted, please reference Section 6.1 for cleaning and disinfection instructions.
- DO NOT submerge the device in liquids. When using alcohol to wipe the surface of the device, do not pour directly onto the device. Use a soft cloth for cleaning.
- When using water to clean, water temperature is to be below 60°C.
- Fingers that are too thin or cold may affect the accuracy of the measurements. If this happens use a thicker finger or thumb and ensure that they are inserted far enough into the device as shown in Figure 1.
- The refresh time for data is less than 5 seconds and is dependent on the individual's pulse rate.
- The Pulse Rate Waveform is regular when it becomes smooth and stable. The read value is the optimal value, and the Waveform at the moment is the most standard one.
- If abnormal values appear on the screen during the measurement, remove the finger from the device then reinsert in order to restart the measurement.
- The life of the device is three years.
- The device has alarm functions, reference 5.1.3 and 5.1.4 for additional information.
- The device has an alarm limit function for when the measured data is above the highest limit or below the lowest limit and will automatically alarm if this feature is on.
- This device may not work for all people, if you are unable to achieve stable readings, discontinue use.
- A flexible connection attaches the two parts of the device. Do not pull, twist or force the connection.
- The maximum temperature for the contact surface of the device with the body is less than 42°C, as measured with a thermometer.

2 Principle

Principle of the Pulse Oximeter is as follows: A formula of data processing is established taking use of the Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO2) in glow & near-infrared zones. Operating principle of the Pulse Oximeter: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning & Recording Technology, so that two beams of different wavelengths of lights can be focused into the human finger through a perspective clamp finger-type sensor as illustrated in Figure 1. The measured signal is obtained by a photosensitive element and calculated electronically with the results showing on the device screen.

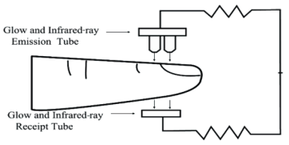

Figure 1: Principle

3 Technical Specifications

3.1 Main performance:

A. SpO2 value display.

B. Pulse rate value display, bar graph display.

C. Pulse waveform display.

D. Low Power indication: Low Power Indicator will appear before the device works abnormally due to low power.

E. Auto power off: NOTE: Device will power off within 1 minute of inactivity.

F. The display mode can be changed.

G. Screen brightness can be changed.

H. Pulse rate sound indication.

I. Alarm functions.

J. SpO2 and pulse rate value auto storage function.

K. Wireless Bluetooth transmission function.

3.2 Main Parameters:

A. Measurement of SpO2:
Measurement Range: 0%~100%
Accuracy: 70~100%: ±2%;
Below 70%: unspecified

B. Measurement of pulse rate:
Measurement Range: 30bpm~ 250bpm
Accuracy: ±2bpm or ±2% (select the larger)

C. Resolution: SpO2:1%, Pulse rate: 1bpm

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

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

F. Optical Sensor: Red light (wavelength is 660nm,6.65mW) Infrared (wavelength is 880nm, 6.75mW)

4 Installation

4.1 View of the Front Panel:

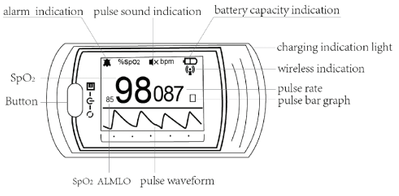

Figure 2: Front View

4.2 Attaching the Lanyard:

A. Insert the thinner end of the lanyard through the hole in the end of the device.

B. Insert the wider side of the lanyard through the thinner side which had been put through the hole in the device and pull to tighten.

4.3 Accessories included with the Pulse Oximeter:

A. Lanyard

B. User Manual

C. AC adapter

D. USB Cable

5 Operating Guide

5.1 Application Method:

5.1.1 Measurement:

a) Squeeze to open the device, insert User's finger into the rubber opening and allow to close.

b) Press the button on the panel to turn on the device.

c) Do not shake the finger when in use and remain still while the device is measuring.

d) The measurement will display on the screen once the measurement is complete.

⚠ **The Pulse Oximeter display and the User's fingernail are to be on the same side.**

⚠ **If the alarm function is on, the device will sound a medium-priority alarm when finger is removed and an intermittent alarm will occur.**

Figure 3: Finger Placement

5.1.2 Change the Display Direction:

In the measuring screen, you can change the display direction by pressing the button.

5.1.3 Pause Alarm:

a) The Pulse Oximeter includes alarms for when the measurement goes beyond the limits, for low power and for when the finger is out of the device.

b) On the measuring screen, if the alarm function is on it can be suspended by pressing the button. NOTE: The alarm function will restart in approx. 60 seconds.

c) To permanently turn the alarm off, reference the Setting the Alarm Section in this document.

5.1.4 Menu Operations:

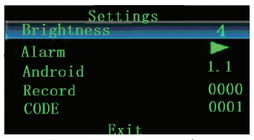

Figure 4: Main Menu Interface

To go to the measuring screen, press and hold the button in until the screen in Figure 4 is shown. NOTE: When the display mode is portrait, you cannot enter the main menu screen. Press and release the button again to switch the orientation to landscape in order to enter the main menu screen. Once in this screen you can set the backlight brightness and alarms by following the steps below:

a. Backlight Adjustment:

In the main menu screen, press the button to select "Brightness". Press and hold the button to adjust the brightness of the screen. NOTE: The brightness of screen is divided into four levels, level 4 is the brightest and level 1 is the darkest.

b. Alarm Setting:

In the main menu screen, press the button to select "Alarm". Press and hold the button to enter the alarm setting screen as shown in Figure 5:

Figure 5: Alarm Setting Menu

a) Setting the high and low alarm limits for measurement:

Press and release the button to toggle the position of menu selection bar to "Dir". Press and hold the button to select the desired value adjusting direction: up or down. If you want raise the high and low limit value of SpO2 and pulse rate, adjust "Dir" to "up", then press the button to select the parameter which you wish to raise: SpO2 high limit (SpO2 ALM HI), SpO2 low limit (SpO2 ALM LO), Pulse rate high limit (PR ALM HI), Pulse rate low limit (PR ALM LO). Once selected, press and hold the button to adjust the value. The alarm low limit can't be higher than the alarm high limit. In the same way, if you want to reduce the high and low limit value of SpO2 and pulse rate, adjust "Dir" to "down", click button to select the parameter you want to reduce, then press and hold the button to adjust the value. NOTE: The SpO2 alarm range is 0%~100%, the pulse rate alarm range is 0bpm~254bpm.

⚠ **If the alarm function is on, the device will provide a medium-priority intermittent alarm when the measurement is above or below the set limits.**

b) Setting the Alarm:

Press and release the button to select the "Alarm". Press and hold the button to turn the alarm on/off. Select "on" to turn the alarm on and select "off" to turn the alarm off.

c) Setting the Pulse Sound:

Press and release the button to select "Pulse Sound". Press and hold the button to turn the pulse sound on/off. Select "on" to turn on the pulse sound and "off" to turn off the pulse sound.

d) Exiting the settings:

Press and release the button to select "EXIT". Press and hold the button to exit the alarm setting menu and return to the main menu.

c. Other Menu options:

Android: The device version.

Record: Storage data segment number.

CODE: Device number.

d. Exiting the Main Menu:

In the main menu screen, press and release the button to select "EXIT", then press and hold the button to exit the main menu.

5.1.5 Data Storage:

a) Turn on the device and keep the finger inserted until the readings become stable.

b) The storage data will be automatically deleted after successfully being uploaded. If the upload failed and there is no available storage space on the device, the new data will override the previously stored data.

⚠ **Device requires calibration when a red "X" is displayed on the screen. Data cannot be stored when calibration is required.**

⚠ **The storage space on the site is factory set and cannot be changed.**

⚠ **The Bluetooth is on by default and cannot be changed.**

5.1.6 Data Upload Function:

After the Pulse Oximeter has finished reading, the data is automatically uploaded.

5.1.7 Charging the Device:

There are two methods to charge the device:

a) Connect the device to a computer via the USB cord.

b) Plug the AC Adapter into a power socket and connect to the device via the USB cord.

⚠ **The charging indicator light will be on during charging and will go off once charging is complete.**

⚠ **If the alarm function is on, an intermittent high-priority alarm will sound when the battery is low.**

5.2 Operating Instructions:

A. Please check the device before use to ensure it is properly working.

B. The finger should be in inserted as illustrated in Figure 3 in order to obtain accurate measurements.

C. The ray between the luminescent tube and photoelectric receiving tube must get across subject's arteriole.

D The oximeter should not be used at a location or a limb using an arterial canal, blood pressure cuff or an IV.

E. Ensure there is no tape or other barrier that would block the light path, or else it may result in inaccurate measurement of SpO2, and pulse rate.

F. Excessive ambient light, including fluorescent lamp, dual ruby light, infrared heater, direct sunlight, etc., may affect the measurement accuracy.

G Intense activity of the User or extreme electrosurgical interference may also affect accuracy.

H. User cannot use nail polish or other makeup where device is used.

I. Please clean and disinfect the device after use according to the Section 6.1.

5.3 Clinical Restrictions:

A. As the measurement is taken based on the arteriole pulse; substantial pulsating blood flow of the User is necessary. For a subject with a weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO2 waveform (PLETH) will be decreased. In this case, the measurement will be more sensitive to interference.

B. For those with a substantial amount of a staining dilution drug (such as Methylene Blue, Indigo Green and Acid Indigo Blue), Carbon Monoxide Hemoglobin (COHb), Methionine (Me+Hb), Thiosalicylic Hemoglobin, and some with Jaundice, the SpO2 determination by this device may be inaccurate.

C. Drugs like Dopamine, Procaine, Prilocaine, Lidocaine and Butacaine may also be a major factor which could result in serious error of the SpO2 measurement.

D. The SpO2 value serves as a reference value for judgment of anemic anoxia and toxic anoxia. Some Users with serious anemia may also report good SpO2 measurement.

6 Cleaning, Maintenance, Transportation and Storage

6.1 Cleaning and Disinfecting:

To disinfect, wipe the device with alcohol. Allow to air dry or wipe with a clean, soft cloth.

6.2 Maintenance:

A. Before using, clean and disinfect according to section 6.1.

B. Recharge the battery when this icon is on the screen: 

C. When not in regular use, the device should be charged every six months. Following these steps can extend the battery life.

D. Users are advised to calibrate the device annually, when the device indicates calibration is required, or according to the calibrating program of hospital. The calibration can be performed by a certified calibration facility or contact PMD Healthcare for assistance.

6.3 Transportation and Storage:

A. The packed device can be transported without restriction. The device cannot be transported with toxic, harmful or corrosive material/gases.

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

7 Troubleshooting

Trouble	Analysis of cause	Solution
The SpO2 or Pulse Rate cannot be displayed normally	1. The finger is not properly positioned in the device. 2. The SpO2 of User is too low to be detected.	1. Remove the User's finger, reinsert and try again. 2. Attempt several times to obtain a reading. If stable reading cannot be obtained, contact your health care professional for assistance.
The SpO2 or Pulse Rate are not displayed in a stable manner.	1. The finger is not inserted deep enough in the device. 2. The finger is shaking or the User is moving.	1. Remove the User's finger, reinsert and try again. 2. Please remain still during the measurement process.
The device will not turn on.	1. The battery is empty or almost empty. 2. The device malfunctioned.	1. Please charge the battery. 2. Please contact the distributor.
The display suddenly disappears.	1. The device is set to automatically power off within 60 seconds of no use. 2. The battery is empty or almost empty.	1. This is normal. 2. Please charge the battery.
Usage time after charging is short	1. The battery was not charged enough. 2.The battery is broken.	1. Please charge the battery to full power. 2. Please contact the distributor.
The battery cannot be fully charged even after 10 hours charging time	The battery is broken.	Please contact the distributor.

8 Meaning of Symbol

Symbol	Meaning
	Warning – Reference User Manual
	Reference the Instructions in User Manual
%SpO2	Pulse Oxygen Saturation (%)
bpm	Pulse Rate (bpm)
	Full Battery Indicator
	Low Battery Indicator
	Silenced Alarm
	Paused Alarm
	Alarm On
	Silenced Pulse Sound
	Pulse Sound On
	Bluetooth Indicator
	Menu button/power button/function button
	Type BF Patient Applied Part
SN	Serial Number
– – –	Device is Not on The Finger / The Finger is Not Inserted
IP22	Liquids Protection Rating
	Reference Local Regulations for Disposal: WEEE (2002/96/EC)
	Distributor: PMD Healthcare, 1555 Bustard Road, Suite 200, Lansdale PA 19446 Customer Service: Phone: 888-PMD4YOU eMail: Customercare@mypmd.com

9 Specifications

Display Information:	**Display Mode:**
The Pulse Oxygen Saturation (SpO2)	2-digit digital OLED display
Pulse Rate (PR)	3-digit digital OLED display
Pulse Intensity (bar-graph)	bar-graph OLED display
SpO2 Parameter:	
Measuring range	0%~100% (the resolution is 1%)
Accuracy	70%~100%: ±2%, Below 70% not defined
Pulse Parameter:	
Measuring range	30bpm~250bpm (the resolution is 1bpm)
Accuracy	±2bpm or ±2% (select the larger)
Safety Type	Interior Battery, BF Type
Pulse Intensity:	
Range	Continuous bar-graph display, a higher display indicates a stronger pulse.
Battery Requirement:	
One 3.7V rechargeable Lithium battery. To install, the red wire on the battery is the positive charge and the black wire is the negative charge.	
Battery life:	
Charge and discharge no less than 500 times.	
Adapter: Output voltage: DC 5V, Output current: 1000mA	
Dimensions and Weight:	
Dimensions	57(L) x 32(W) x 32(H) mm
Weight	About 50g (including lithium battery)

Appendix 1

Alarm State	Delay of alarm state	Delay of alarm signal generation
Low Voltage Alarm	60s	5ms
SpO2 Alarm	1s	5ms
Pulse Rate Alarm	1s	5ms
Probe Error Alarm	16ms	5ms