

PULSE OXIMETER - USER MANUAL

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

This manual contains information written in accordance with the council directive MDD93/42/EEC for medical devices and harmonized standards

Please note that this manual refers to the current model - any modifications and software updates may render this information subject to change

Thank you for purchasing this Pulse Oximeter device.

Please read the manual carefully before using. These instructions must be strictly followed. Failure to follow these instructions may result in inaccurate usage, equipment damage, and personal injury. The manufacturer cannot be held responsible for issues arising from negligence of these instructions.

This product is a medical grade device.

1. Overview

This device is designed to measure the oxygen levels in your blood. It is designed to also measure your pulse/heart rate simultaneously.

WHAT ARE BLOOD OXYGEN LEVELS?

The pulse oxygen saturation is the % of oxyhaemoglobin (HbO₂) present in the total haemoglobin (Hb) found within the blood. It is a bio-parameter for respiration. Our device is designed to measure oxygen saturation (SpO₂) levels easily and accurately.

Features

- Simple and convenient operation
- Portable, being small in volume and lightweight
- Low power consumption, with 2 x AAA batteries allowing 20hrs of continuous use
- Automatic power off without signal for 5 seconds
- Using life of 3 years.

2. Accessories

- 1 x hypoallergenic lanyard
- 2 x batteries (optional)
- 1 x user manual

3. Installation

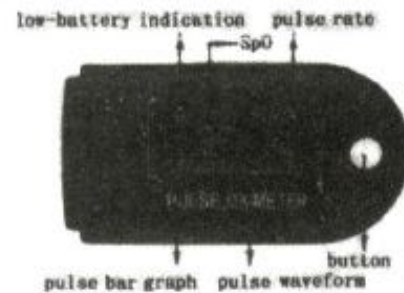


Figure 2 Front view

Battery

Remove the back cover and place in the batteries. Ensure the batteries are the correct way round before replacing the cover. Check the cover is secure before using.



Figure 3 Batteries installation

Lanyard

Pull the thin end through the hole at the tip of the device. Thread the other end through the inserted rope and pull to tighten.

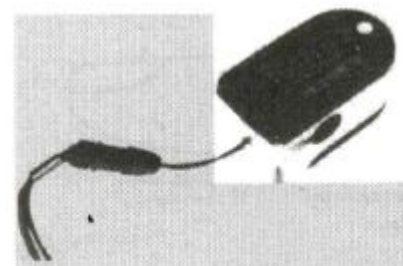


Figure 4 Mounting the hanging rope

4. Operating guide

1. Assemble device as instructed above
2. Open the clip as per fig. 5

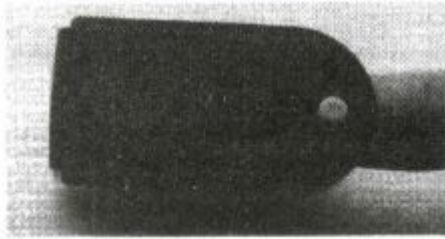


Figure 5 Put finger in position

3. Position finger into rubber cushions, then lower clip.
4. Press the switch button on the front panel once to turn on the device
5. Keep finger and body still throughout process.

The main button has 3 functions:

- When powered off the button will open it
- When powered on a short press changes screen direction
- When powered on a long press changes screen brightness

For accuracy:

- Use on the thumb or middle finger
- Carefully align the finger as shown in fig. 5
- Do not take measurements straight after engaging in a strenuous activity
- Do not take measurements while other medical procedures are happening
- Avoid using in the presence of ambient light such as fluorescent lamps, infrared heaters, etc.
- Use on peoples aged 4+ and weighing between 15kg to 110 kg
- Do not use if the individual is wearing nail varnish or has long fingernails
- Allow the device time to acclimatise if it changes environments
- Regularly calibrate the device

Discontinue use if readings are consistently unstable.

5. Maintenance of Device

- Change batteries when the screen indicates low-voltage
- Clean the device's surface before use, and always disinfect product after use
- Clean using medical alcohol. Do not apply directly, but with a clean, soft cloth
- Do not clean with water hotter than 60C
- Stop use if device is wet or has been submerged










Environmental requirements

	STORAGE	OPERATION
Temperature	-40C - +60C	10C – 40C
Relative Humidity		
Atmospheric Pressure	500hPa – 1060hPa	700hPa – 1060hPa

6. Troubleshooting

Trouble	Possible Reason	Solution
The SpO₂ and Pulse Rate cannot be displayed normally	<ol style="list-style-type: none"> 1. The finger is not properly positioned. 2. The patient's SpO₂ is too low to be detected. 	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 1. The finger is not placed inside deep enough. 2. The finger is shaking or the patient is moving. 	<ol style="list-style-type: none"> 1. Place the finger properly and try again. 2. Let the patient keep calm
The device cannot be turned on	<ol style="list-style-type: none"> 1. The batteries are drained or almost drained. 2. The batteries are not inserted properly. 3. The malfunction of the device. 	<ol style="list-style-type: none"> 1. Change batteries. 2. Reinstall batteries. 3. Please contact the local service centre.
The display is off suddenly	<ol style="list-style-type: none"> 1. The device will power off automatically when it gets no signal within 5 seconds. 2. The batteries are almost drained. 	<ol style="list-style-type: none"> 1. Normal 2. Change batteries.

7. Key of Symbols

Symbol	Description
	Type BF
	Warning – See User Manual
%SpO ₂	The pulse oxygen saturation (%)
PRbpm	Pulse rate (bpm)
	The battery voltage indication is deficient (change the battery in time avoiding the inexact measure)
	1. No finger inserted 2. An indicator of signal inadequacy
	Battery positive electrode
	Battery cathode
	1. Power switch 2. Change direction of the screen 3. Change brightness of the screen
SN	Serial number
	Alarm inhibit
	WEEE (2002/96/EC)
IP22	International Protection

8. Function Specification

Display Information	Display Mode
The Pulse Oxygen Saturation (SpO ₂)	TFT
Pulse Rate (PR)	TFT
Pulse Intensity (bar-graph)	TFT bar-graph display
Pulse wave	TFT
SpO₂ Parameter Specification	
Measuring range	0%- 100%, (the resolution is 1%)
Accuracy	70%- 100% ±2%, Below 70% unspecified
Optical Sensor	Red light (wavelength is 660nm) Infrared (wavelength is 880nm)
Pulse Parameter Specification	
Measuring range	30bpm ~250bpm (the resolution is 1 bpm)
Accuracy	±2bpm or ±2% select larger
Pulse Intensity	
Range	Continuous bar-graph display, the higher display indicates the stronger pulse.
Battery Requirement	
1.5V (AAA size) alkaline batteries x 2 or rechargeable battery	
Battery Useful Life	
Two batteries can work continually for 20 hours	
Dimensions and Weight	
Dimensions	58(L)x32(W)x34(H)mm
Weight	About 50g (with the batteries)

9. Safety Warnings – follow at all times

- Regularly check device to make sure there is **no visible damage** to any parts
- **Do not** leave this device on the same finger for over 2 hours
- Necessary maintenance must **only** be performed by qualified service engineers
- The infrared light emitted is harmful to the eye- **do not** stare at it for extended periods
- **Do not** use during an MRI or CT scan.
- **Do not** use on patients with a rubber allergy
- Keep oximeter away from dust, vibration, corrosive substances, explosive materials, high temperatures, and moisture
- Remove batteries for storage exceeding 1 month to avoid battery leakage
- **Do not** twist or pull the flexible circuit connection within this device
- **Explosive hazard** – do not use in an environment with flammable agents
- Dispose of individual components in accordance with local laws and regulations

10. Technical Specifications

Display Format	TFT Display
SpO ₂ Measuring Range	0% - 100%
Pulse Rate Measuring Range	30 bpm – 250 bpm
Pulse Wave Display	columnisation display and waveform display
Power Requirements	2 x 1.5V AAA alkaline battery, adaptable range 2.6V-3.6V
Power Consumption	smaller than 30mA
Resolution	1% for SpO ₂ and 1bpm for pulse rate
Measurement Accuracy	+2% for 20-100% SpO ₂ , meaningless in stage smaller than 70% +-2bpm or +-2% for pulse rate
Measurement Performance in Weak Filling Condition	SpO ₂ and pulse rate shown correctly when pulse-filling ratio is 0.4% SpO ₂ error is +-4%, pulse rate error is +-2bpm or +-2%
Resistance to Surrounding Light	deviation between manmade/indoor natural/darkroom light is less than +-1%
Optical Sensor	Red light (wavelength 660nm, 6.65mW) Infrared (wavelength 880nm, 6.75mW)