Physio logic DigiPulse Digital Pulse Oximeter User Guide

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Thank you for purchasing the DigiPulse Oximeter.
By selecting this product, you have chosen a high quality, innovative device. Before using the DigiPulse Oximeter for the first time, please read through these instructions carefully. If you still have any questions regarding its use, visit the A.M.G. Medical website or contact our Customer Service team at 1-800-363-2381. The DigiPulse™ Oximeter is an accurate and easy to use device with One-Touch Operation. This compact oximeter is light weight making it convenient to carry anywhere. Additional state of the art features include: OLED screen with six different

display modes – Low power consumption, new batteries can last over six hours – Auto shut-off. The DigiPulse™ oximeter is intended for single measurement home-use for adults and children over the age of 4. This device is indicated for use in measuring functional oxygen saturation (%SpO2) and pulse rate. This device is not designed for continuous monitoring, nor meant for life-supporting activities.

Precautions

- Before first time use, read the Pulse Oximeter instructions thoroughly. Save the user guide for future reference.
- This device is not meant for treatment and does not replace examination by a physician.
- The operation of the DigiPulse Oximeter may be affected by the use of an electrosurgical unit (ESU).
- The pulse oximeter must be able to measure the pulse properly to obtain an accurate SpO2 measurement. Verify that nothing is hindering the pulse measurement before relying on it.
- Explosive hazard-DO NOT use the oximeter in environments with flammable gas such as ignitable anesthetic agents.
- Do not use the pulse oximeter in an MRI or CT environment.
- Do not sterilize the device using autoclaving, ethylene oxide, or by immersing the device in liquid. Refer to the cleaning section for more information.
- This equipment complies with IEC 60601-1-11 for electromagnetic compatibility for medical electrical equipment and/or systems. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device.
- Portable and mobile RF communications equipment can affect medical electrical equipment.
- This device is not intended for use during patient transport outside a healthcare facility.
- This unit should not be used adjacent to or stacked with other equipment.
- Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- When the device is carried from a cold environment to warm or humid environments, please do not use the DigiPulse Oximeter immediately.
- If the oximeter gets wet, please stop operating it.
- Do not operate button on front panel with sharp objects.
- If fingers are too thin or too cold, it could affect SpO2 and pulse rate readings. Please insert the largest finger such as thumb or middle finger deeply into the probe.
- Nail polish (shellac) may produce variable results.
- It may be unsafe to:
  - use accessories, detachable parts and materials not described in these instructions.
  - interconnect this equipment with other equipment not described in these instructions.
  - disassemble, repair or modify the equipment.
- To avoid any possibility of accidental strangulation, keep lanyard away from children and do not wear lanyard around the neck. If a sensitivity or rash develops from wearing the lanyard, please stop using it.
- This oximeter has a visible low-battery indicator. Please change batteries when it is low.
- Remove the batteries if the unit will not be used for an extended period of time. Always replace all the batteries with new ones at the same time.
- Keep the oximeter out of reach of children. Some parts are small and may represent a choking hazard.
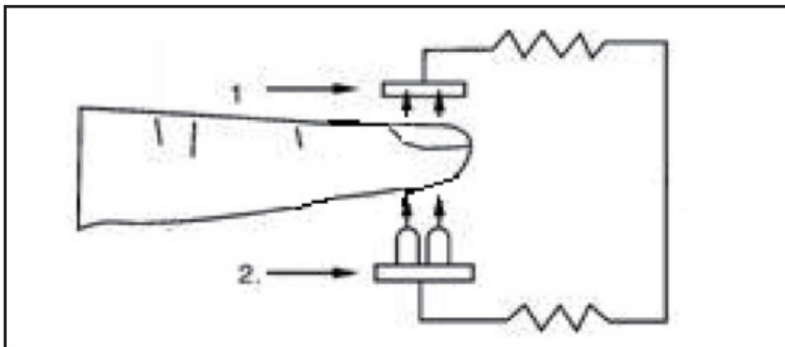- Do not use this device on infants. This product is suitable for children over 4 years old

Contents

General Information

Oxygen binds to hemoglobin in red blood cells when moving through the lungs. It is transported throughout the body as arterial blood. A pulse oximeter uses two frequencies of light (red and infrared) to determine the percentage (%) of hemoglobin in the blood that is saturated with oxygen. The percentage is called blood oxygen saturation, or SpO2. A pulse oximeter also measures and displays the pulse rate at the same time it measures the SpO2 level.
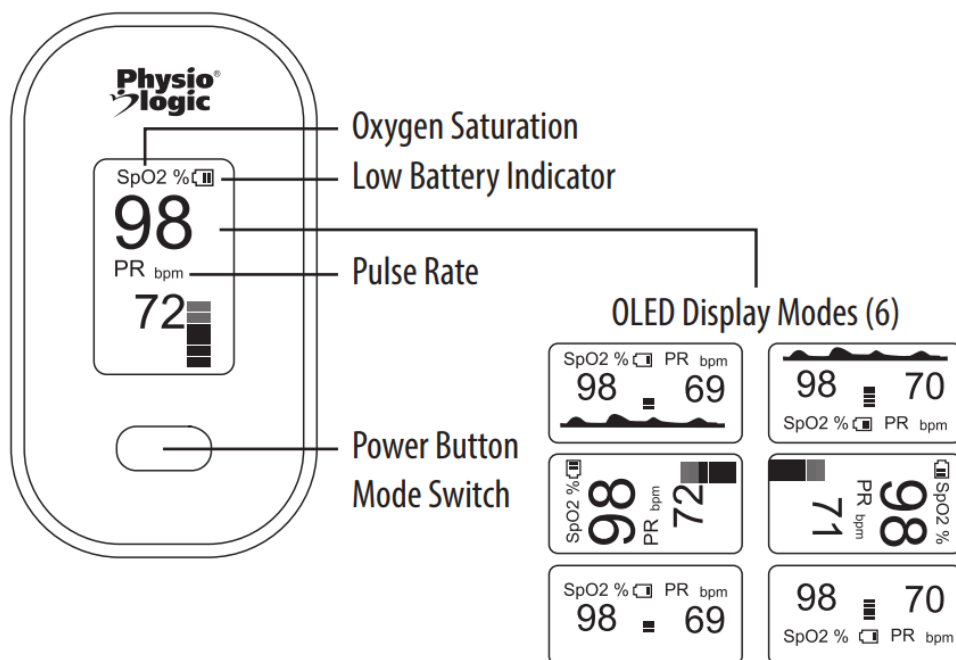
Diagram of Operation Principle

1. Red and Infrared-Ray Emission Tube
2. Red and Infrared-ray Receipt Tube

Your Oximeter
CONTENTS: 1 Oximeter, 1 Lanyard, 1 User Guide

Oxygen Saturation
Low Battery Indicator

Pulse Rate

OLED Display Modes (6)

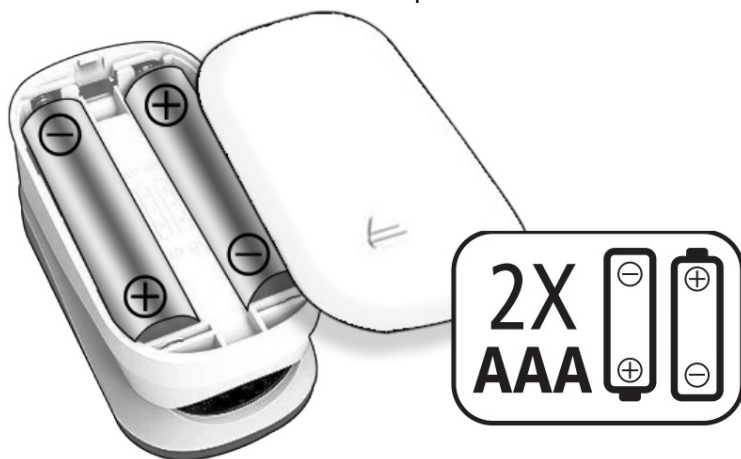**Power Button**
Mode Switch

Battery Installation

1. Slide off the battery cover.
2. Install two AAA batteries by matching the correct polarity, as shown. If the polarities are not matched, damage may be caused to the oximeter.
3. Close the cover.

Note: Remove the batteries if the pulse oximeter will not be used for long periods of time.
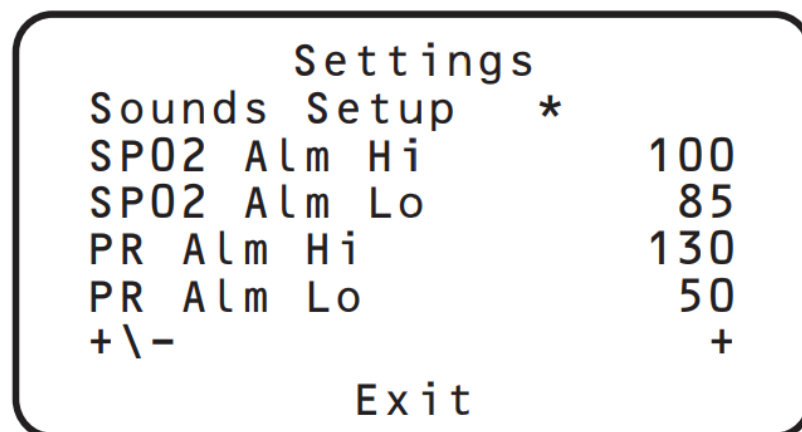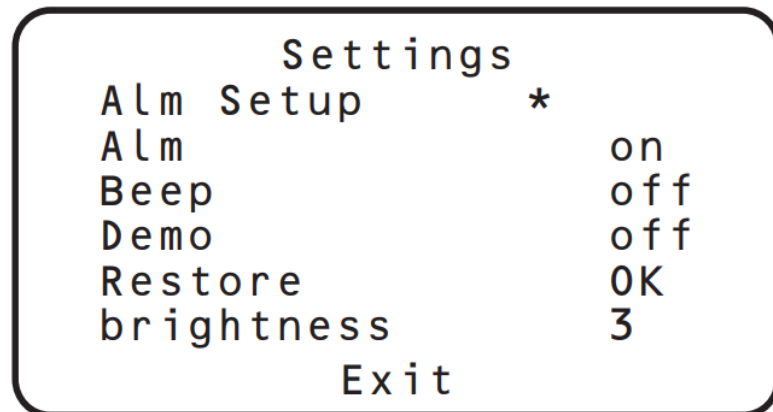

Getting Started

Setting the Alarm, Sound, and Screen Brightness.

1. With power off, press the "Power" button for 3 seconds to activate the set up mode.
2. Press the "Power" button to toggle between the alarm, sound, and brightness options.
3. By clicking the alarm feature and holding the "Power" button for 1 second, select "ON" or "OFF".
4. Repeat step 3 to select the sound "ON' or "OFF" and brightness level.
5. Click and hold for 3 seconds on "RESTORE" to return to the original factory settings.

Alarm Setting

1. Once alarm setting is activated, hold the "Power" button for 3 seconds to adjust the high and low limits for the SPO2 and Pulse alarms.
2. Choose "+" or "-" to increase or decrease values.
3. For each parameter, continue to press the "POWER" button until desired high and low limits are reached, then release the button.
4. The alarm will beep when a reading is out of range including: an SPO2 ≥ 99 or < 85 and PR bpm ≥ 130 or < 50.

```
        Settings
 Alm Setup        *
 Alm                 on
 Beep               off
 Demo               off
 Restore            OK
 brightness          3
           Exit
```

```
         Settings
 Sounds Setup    *
 SPO2 Alm Hi        100
 SPO2 Alm Lo         85
 PR Alm Hi          130
 PR Alm Lo           50
 +\-                  +
           Exit
```

Operation Instructions

- Install two AAA batteries following the battery installation instructions.
- Place one of your fingers into the rubber opening of the pulse oximeter.
- When placing your finger into the oximeter, your nail surface must be upward.
- Press button on the front panel to turn the pulse oximeter on.
- Keep your hand still. Do not move your finger or body when taking a reading.
- Press the power button if you want to change display mode.
- Read the relevant data from the display screen.
- The device will automatically power off in 8 seconds if there is no finger signal

Important Note: The rubber inside the device along with the finger being used for testing should be cleaned with medical alcohol before and after each test. (The rubber inside of the oximeter is medical grade and should not cause any skin irritations).

Using the Lanyard

- Put the thinner end of the lanyard through the loop.
- Then put the thicker end of the lanyard through the threaded end and tighten.

Cleaning Instructions
Before and after each use, wipe finger and device with medical alcohol and a soft cloth. Do not spray any liquid directly onto the device.

Maintenance
Do not attempt any repairs to the device or any of its accessories. Contact us at 1-800-363-2381 for repair information.

- The manufacturer will not be held responsible for the results of maintenance or repairs by unauthorized persons.
- Check the device before each use for signs of wear and/or damage. Replace worn items as required.

Disposal

- Please dispose of the device in accordance with local regulations (Waste Electrical and Electronic Equipment).
- Discard used batteries according to local environmental regulations.
- Contact your local distributor for information regarding disposal of the unit and accessories.

Troubleshooting		
Problem	**Possible Reason**	**Solution**
SpO2 or PR do not display normally	1. Finger is not inserted correctly2. The user's SpO2, is too low to be detected	1. Retry by reinserting finger2. Retry by reinserting finger. If device is functioning properly and SpO2 is not detected, please seek medical attention
SpO2 or PR can not display stably	1. Finger might not be inserted deep enough2. Finger or body is moving	1. Retry by reinserting the finger2. Stay still until reading is completed
The oximeter can not be powered on	1. Power of batteries might be inadequate or not be there at all2. Batteries are not inserted properly	1. Replace batteries2. Reinstall the batteries
The display screen suddenly turns off	1. The device will shut-off automatically when no signal is detected over 8 seconds2. Batteries are almost drained	1. Restart the oximeter2. Replace batteries

Technical Specifications	
Display Type	OLED Display
Sp02 Measurement Range	70%- 100%
Accuracy	± 2% in stage of 80% – 100% SpO_2± 3% in stage of 70% – 79% SpO_2Below 70 % no requirement resolution: ± 1 %
Pulse Rate	Measurement Range: 30 BPM – 240 BPM
Accuracy	±1BPM or ±1% (the larger one)
Power	2 AAA 1.5V alkaline batteries
Power Consumption	Below 30mA
Automatic Power-Off	The product powers off by itself when no signal is detected over 8 seconds
Operation Environment	Temperature: 5 °C – 40 °C \ Humidity: 15% – 80% \ Atmospheric Pressure: 70kPa – 106kPa
TransportStorage Environment	Temperature: -1 °C – 55 °C – Humidity: ≤ 95%Atmospheric Pressure: 50kPa – 10 6kPa, non-corrosive gas and well-ventilated environment

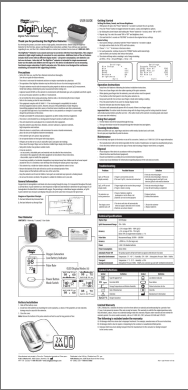| Symbol Definitions			
Symbol	**Definition**	**Symbol**	**Definition**
	Type BF Applied Part		Low Battery Indicator
PR bpm	Pulse Rate (BPM)		Power Button
	Storage Temperature and Relative Humidity		Follow Instructions for Use
	Date of Manufacture	SN	Serial No.
	Attention		Manufacturer's Information
SpO2	Oxygen Saturation		

Limited Warranty

A.M.G. Medical Inc. warrants the device to be free from defects in material and workmanship for a period of one (1) year, to be proven by means of the sales receipt or invoice. This warranty is valid for the original purchaser only. Any alterations, abuse, misuse or accidental damage voids this warranty. Repairs under warranty do not extend the warranty period. For service under warranty, call us at:1-800-363-2381, between 8:30 AM and 5 PM

EST.

The following is excluded under the warranty:

A) All damage which has arisen due to improper treatment. For example, nonobservance of the user instructions.
B) All damage which is due to repairs or tampering by the customer or unauthorized third parties.
C) Damage which has arisen during transport from the manufacturer to the consumer or during transport to the service centre.

Documents / Resources

Physio logic DigiPulse Digital Pulse Oximeter [pdf] User Guide
107-100, DigiPulse Digital Pulse Oximeter, Digital Pulse Oximeter, Pulse Oximeter

References

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