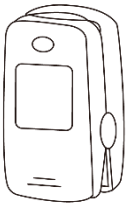
Wireless Digital Pulse Oximeter



Thank you for choosing the PeakLife360 Wireless Digital Pulse Oximeter. This product has been listed with the FDA and features lab-tested technology to deliver stable and accurate measurements each time you use. This product is designed to measure and monitor blood oxygen saturation level and pulse rate at home or within a clinical setting. It is not intended for use on children under three months of age.

Instructions for Safe Operation

- ✔ Check the device and ensure there is no visible damage that may affect the user's safety or measurement performance with regard to sensors and clips. The device should be inspected minimally before each use. If there is evident damage, stop using the device immediately.
- ✔ This device should not be used in a room or outdoor setting where temperatures exceed 98.6°F, as burning may occur due to sensor overheating.
- ✔ If a malfunction occurs, maintenance should be performed by a qualified service technician. Users should not service this device.
- ✔ This oximeter should not be used with devices or accessories not specified in this manual.

Cautions

- ✔ DO NOT, under any circumstances, use the oximeter in an environment with flammable or explosive materials or gas (including anesthetic agents).
- ✔ DO NOT use the oximeter while under an MRI or CT scanning. This device is NOT MRI Compatible.

Warnings

- ✔ It is advised to alternate finger use with each reading. Discomfort or pain may appear if the oximeter is used continuously on the same finger for extended periods of time, especially for users with poor microcirculation.
- ✔ Do not use the oximeter on same finger location for longer than two hours.
- ✔ If any abnormal condition is found, change the position of oximeter.
- ✔ DO NOT clip this device on a swollen or tender finger.
- ✔ DO NOT stare into the infrared sensor light. It can be harmful to the eyes.
- ✔ This oximeter is not a treatment device. It is solely to be used as a measurement device.
- ✔ Local laws and Regulations must be followed when disposing of the device.

Advisories

- ✔ Keep the oximeter away from dust, vibration, corrosive substances,

explosive materials, high temperature and moisture.

- ✔ The device should be kept out of the reach of children.
- ✔ If the oximeter gets wet, stop use and do not resume operation until it is dry and inspected for correct operation. When it is carried from a cold environment to a warm and humid environment, please do not use immediately. Allow at least 15 minutes for oximeter to reach ambient temperature.
- ✔ DO NOT use sharp objects to operate front panel button.
- ✔ DO NOT use in high temperatures. DO NOT use high-pressure steam to disinfect device. Refer to Section 7 for cleaning and disinfection guidelines.
- ✔ The device has an IP22 protection against gentle liquid sprays and water drops.
- ✔ Keep device free of lint, dust, and direct sunlight.

Product Overview

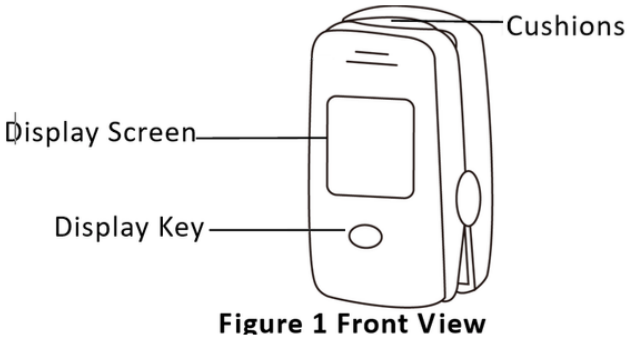


Figure 1 Front View

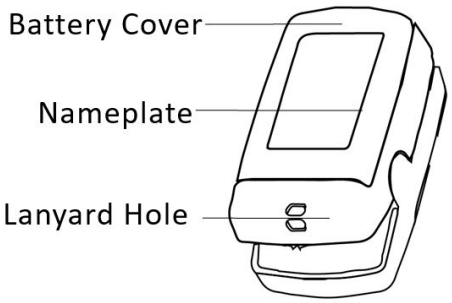


Figure 2 Rear View

Intended Use

This fingertip oximeter is intended for measuring the pulse rate and functional oxygen saturation (SpO2) through a user's finger. It is applicable for spot-checking SpO2 and pulse rate of adult and pediatric patients in homes and medical clinics.

Battery Installation

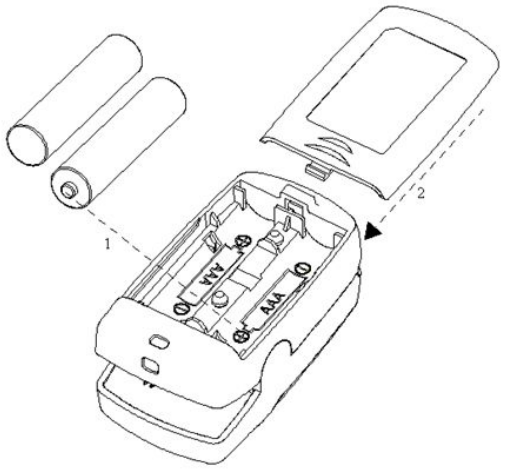
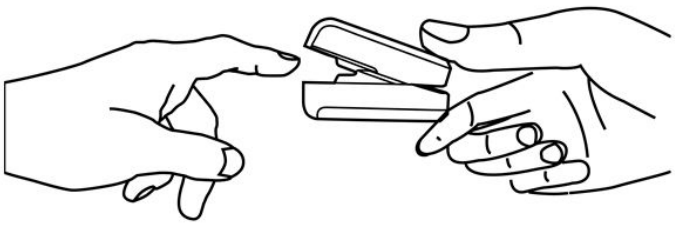


Figure 3 Battery Installation

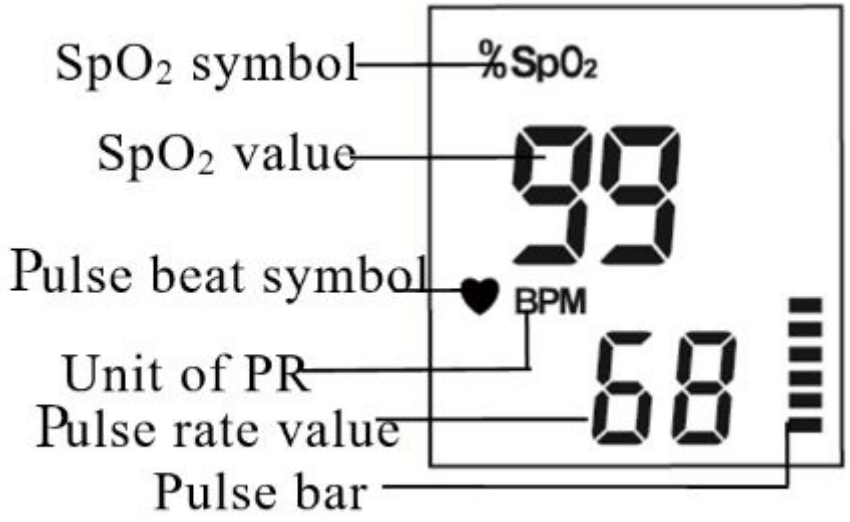
- ✔ Refer to Figure 3; insert two AAA size batteries into the battery compartment properly, noting the polarity markings.
- ✔ Replace the cover.
- ✔ Ensure batteries are correctly installed. Incorrect installation of batteries will cause device to not function.
- ✔ Remove batteries if the device is not being used for more than seven days to prevent damage from battery leaking. Any battery related damage will not be covered under the product warranty.

Operation

Open the clip and insert finger inside the cushions of the clip. Make sure finger is fully inserted and in correct position, as shown below.

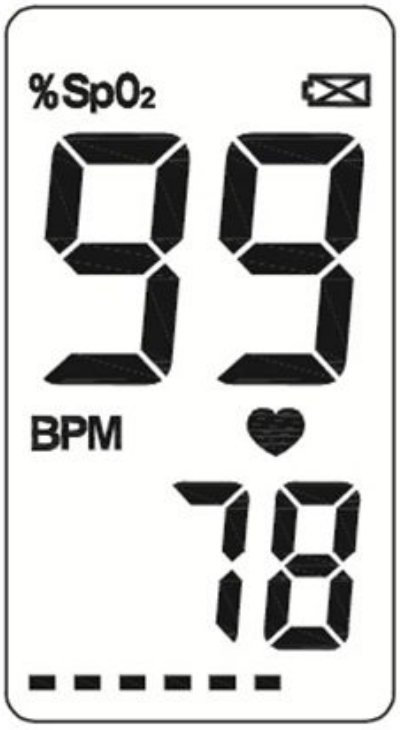


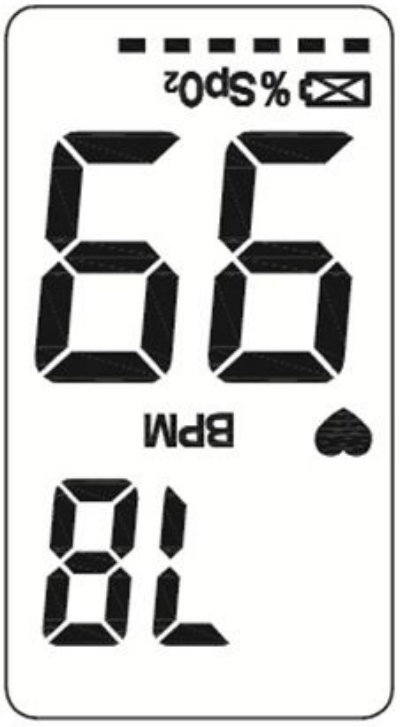
Display Reading Symbol Map



Directional Display

The oximeter can be read on two display directions, toward the user and away. To change the direction of display, press and hold the key button for 1 second.





PI (Perfusion Index) Measurements

Perfusion Index or PI is an indication of pulse strength. In addition to measuring oxygen saturation (SpO2) levels and pulse rate, users can use this oximeter to measure their perfusion index by inserting finger and holding key button for 4

seconds. A “PI” will appear on the display along with a number on the bottom right of display.

Technical Specifications

A. **SpO2 Measurement**

Transducer: dual-wavelength LED sensor with wavelength
Red light: 663 nm, Infrared light: 890 nm
Maximal average optical output power: ≤2mW
SpO2 display range: 35% - 100%
SpO2 measuring accuracy: ≤ 2% for SpO2 range from 70% to 100%

B. **Pulse Rate Measurement**

PR display range: 30bpm - 240bpm
PR measuring accuracy: ±2bpm or ±2% (whichever is greater)

C. P**erfusion Index (PI) Display range**

0% - 20%

D. **Preset over-limits**

SpO2 low limit: 90%
Pulse Rate: high limit: 120bpm
low limit: 50bpm

E. **Over-limit indication settings for PC-60C1,N,NW:**

SpO2: low limit setting range: 85% - 95%
Default setting: 85%
Pulse Rate:
Low limit setting range: 30 - 60bpm;
High limit setting range: 100 - 240bpm;
Default setting: high: 120bpm; low: 50bpm

F. **Over-limit settings SpO2:**

low limit setting range: 85% - 99%, step: 1%
Default setting: 90%
Pulse Rate:
Low limit setting range: 30~60bpm, step: 1bpm;
High limit setting range: 100~240bpm, step: 5bpm;
Default setting: high: 120bpm; low: 50bpm

G. **Visual alert function**

When measuring, if SpO2 value or pulse rate value exceeds the preset limit, the device will alert with a flash on the screen.

H. **Power supply requirement:**

2 x LR03 (AAA) alkaline batteries
Supply voltage: 3.0VDC
Operating current: ≤40mA

I. **Environmental Conditions:**

Operating Temperature: 41°F - 104°F
Operating Humidity: 30% - 80%
Atmospheric pressure: 70kPa - 106kPa

J. **Low Perfusion Performance:**

The accuracy of SpO2 and PR measurement meets the precision described above when the modulation amplitude is as low as 0.6%.

K. **Ambient Light Interference:**

The difference between the SpO2 value measured in the condition of indoor natural light and that of darkroom is less than ±1%.

L. **Classification**

The type of protection against electric shock: Internally powered equipment.
The degree of protection against electric shock: Type BF applied parts.
The degree of protection against harmful solid foreign objects and ingress of liquid:
The equipment is IP22 with protection against harmful solid foreign objects and ingress of liquid.
Electro-Magnetic Compatibility: Group I, Class B

Declaration of Conformity

The manufacturer hereby declares that this device complies with the following standards:
IEC 60601-1: 2005 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance; BS/EN/ISO 9919:2009 or the equivalent ISO 80601-2-61:2011 - Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment. It also follows the provisions of the council directive MDD 93/42/EEC.

Caution

U.S. federal law restricts this device to sale or use by or on the order of a physician.

FCC Rules are specifically for this oximeter

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Warranty

Limited one-year manufacturer's warranty to replace defective device. The following situations are exempt from warranty:
•problem caused by self-dismantling
•problem caused by power fluctuation during use or delivery
•problem caused by incorrect maintenance
•problem caused by incorrect use/operation of the device
•problem caused by repair from service providers that have not been authorized by the manufacturer.
•A proof of purchase will be required when requesting a claim for warranty

For user assistance information, visit: www.peaklife360.com

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Disclaimer: This device is intended for at-home measurement and can be safely used for athletes and aviators. This is not a medical device. If you have medical concerns, please consult with your doctor.