BodyMed® Fingertip Pulse Oximeter

SECTION 1 - Safety

1.1 Instructions for the Safe Operation and Use of the Pulse Oximeter

- Do not attempt to service the pulse oximeter. Only qualified service personnel should attempt any needed internal servicing.
- Do not use the oximeter in situations where alarms are required.
- Prolonged use or the user's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 2 hours.
- SpO_2 measurements may be adversely affected by the presence of high ambient light. Shield the sensor area as needed (with a surgical towel or similar item).

The following factors will cause interference:

- High-frequency electrosurgical.
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
- The user has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
- The user is in cardiac arrest or is in shock.
- Fingernail polish or false fingernails may cause inaccurate SpO_2 readings.

1.2 Warnings

WARNING: EXPLOSION HAZARD — Do not use the pulse oximeter in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.

WARNING: Do not throw batteries in a fire; they may explode.

WARNING: Do not use the pulse oximeter in an MRI or CT environment.

CAUTION: Keep the operating environment free of dust, vibrations, corrosive or flammable materials, and extremes of temperature and humidity.

CAUTION: Do not operate the unit if it is damp or wet from condensation or spills. Avoid using the equipment immediately after moving it from a cold environment to a warm, humid location.

WARNING: Do not attempt to recharge normal dry-cell batteries; they may leak, cause a fire, or even explode.

CAUTION: Never use sharp or pointed objects to operate the front-panel switches.

CAUTION: The battery must be removed from the battery compartment if the device will not be used for a long time.

CAUTION: The device should only be used with the battery cover closed.

CAUTION: When no longer usable, the battery should be disposed of properly according to local regulation.

1.3 Definitions and Symbols

Symbol	Description
	Type BF Equipment
	Refer to the instruction manual/booklet
SN	Serial Number
SpO_2	No SpO_2 Alarm
	When the end-user wishes to discard this product, it cannot be placed in the regular trash. It must be sent to a collection facility for appropriate recovery or recycling.
Warning:	Crucial information for protecting users and medical staff from possible injury.
Caution:	Information for protecting the equipment from possible damage.
Note:	The important information you should know.

SECTION 2 - Intended Use and Introduction

2.1 Intended Use

This product is solely for use with sporting and aviation activities. It is not intended for medical use.

2.2 Brief Device Description

SpO_2 (Functional oxygen saturation) is the amount of oxy-hemoglobin expressed as a percentage of the Functioning Hemoglobin. Functioning Hemoglobin is capable of carrying oxygen and includes oxygenated hemoglobin (HbO_2) and deoxygenated hemoglobin (Hb).

PR (Pulse Rate), measured in beats per minute (bpm), is the frequency of heart beats.

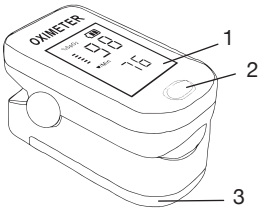
The Pulse Oximeter, based on all digital technology, is intended for noninvasive spot-check measurement of functional oxygen saturation of arterial hemoglobin (SpO_2). Advanced DSP algorithm can reduce the influence of motion artifact and improve measurement accuracy of low perfusion.

2.3 Contraindication

It is not for intensive care and person whose finger is injured.

SECTION 3 - Installation, Setup, and Operation

3.1 Description of the Front Panel (as FIG.1)



1. LED Panel displays the SpO_2/PR data and bar graph
2. Pressing this key initiates the working state.
3. Battery Compartment Holds two AAA 1.5V alkaline batteries

FIG.1 Parts Of Front & Back Panel

3.2 Display

After switch-on, the LED display shows:

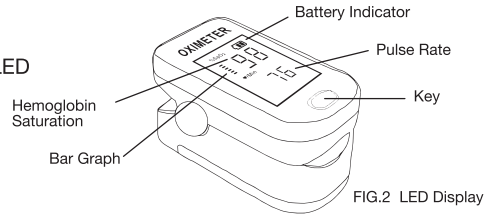


FIG.2 LED Display

3.3 Operation

3.3.1 Install the batteries.

Install two AAA batteries in the correct direction in the battery compartment and put the cover back on. (FIG.3)

Warning: Do not attempt to recharge normal alkaline batteries; they may leak and may cause a fire or even explode.

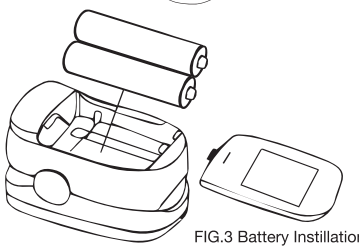


FIG.3 Battery Instillation

3.3.2 Turn the Pulse Oximeter on

Put one of finger into the rubber hole of the pulse oximeter (as much area as possible) with nail facing upward (as FIG.4), then releasing the clamp.

FIG.4

Press the key, pulse oximeter will go into the working state.

Keep the tested hand still during measurement.

If no finger is inserted, the pulse oximeter will automatically go into standby mode or go to sleep after 8 seconds.

3.3.3 Read the data from the display screen.

The LED display interface is shown below:

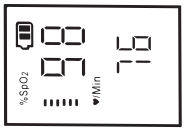


FIG.5

Note: When battery power is at the lowest level, the battery capacity indicates the symbol of ⊠ on the display to remind users to replace the batteries.

3.4 Turn Off the Pulse Oximeter

The pulse oximeter will turn off automatically after 16 seconds after removing the finger out of the device.

SECTION 4 - Maintenance

4.1 Cleaning

Switch “off” the power and take out the batteries before cleaning, Clean exterior surface (screen included) of the unit with a dry and soft cloth. Use isopropyl alcohol 75% to clean the surface. Use a small amount of alcohol on a dry fabric to avoid alcohol from permeating into the device.

4.2 Disinfecting

Disinfect the machine after using if multiple users are using the machine. Use isopropyl alcohol 75% to clean the surface in contact with the user.

CAUTION: Don’t use strong solvent such as acetone.

CAUTION: Never use an abrasive such as steel wool or metal polish.

CAUTION: Do not allow any liquid into the product, and do not immerse any parts of the device into any liquids.

CAUTION: Avoid pouring liquids on the device while cleaning.

CAUTION: Don’t allow any cleaning solution to remain on the surface of the device.

4.3 Maintenance

- Replace the batteries promptly when battery indicator shows they are low.
- Clean the surface of the pulse oximeter before it is used.
- Remove the batteries inside the battery cassette if the pulse oximeter will not be used for a period of time.
- It is best to store the unit in a place where the ambient temperature remains between -4°F and 131°F.
- Regularly inspect the unit to make sure no obvious damage has occurred that would affect the safety and performance of the device.
- Do not use the unit near any flammable substance, in extreme temperatures, or in places with excessive humidity.

4.4 Troubleshooting

Problems	Possible Reason	Resolutions
Oxyhemoglobin or heart rate cannot be shown normally.	1. Finger is not inserted deeply enough into the unit. 2. User perfusion is too low to be measured.	1. Try reinserting the finger. 2. If no result is achieved after several tries, and you can find no issue with the product, go to a hospital for an exact diagnosis.
Oxyhemoglobin or heart rate reading is unstable.	1. Finger is not inserted deeply enough into the unit. 2. Finger is trembling or user is moving too much.	1. Try reinserting the finger. 2. Remain calm and move as little as possible.
The pulse oximeter doesn’t turn on and start working.	1. Batteries may be missing or too low in power. 2. Batteries may be installed incorrectly. 3. The pulse oximeter may be damaged.	1. Replace the batteries. 2. Reinstall the batteries. 3. Contact the local customer service center.
The screen suddenly turns off.	1.The product automatically goes into standby or sleep when no signal is detected longer than 8 seconds. 2. The batteries may be too low in power.	1. This is normal. 2. Replace the batteries.

4.5 Disposal

To avoid contaminating or infecting users, the environment or, other equipment, make sure you disinfect or decontaminate the device appropriately before disposing of it in accordance with your country’s law for equipment containing electrical and electronic parts.

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Section 5 - Specification

5.1 Physical Characteristics

Dimensions: 2.25” (L) x 1.2” (W) x 1.2” (D)

Weight: approx: 2 oz. (including two AAA batteries)

5.2 Classification

Anti-Electric Shock Type: Internally powered equipment

Anti-Electric Shock Degree Type: BF equipment

EMC Type: B class I

Mode of Operation: Continuous operation

Enclosure Degree of Ingress Protection: IP22

*IP22 means the shell of this product can withstand the water dropping to the surface when the shell is angled 15 degrees from the horizontal surface.

5.3 Power

Internal	Two AAA 1.5v alkaline batteries
Power Consumption	Smaller than 30mA (normal)

5.4 Environmental

Operating Temperature	40°F to 100°F
Storage Temperature	-4°F to 131°F
Relative Humidity	15% to 85% non-condensing

Electronics Parameters

Parameter	Value	
Hemoglobin saturation Display	35%-100%	
Pulse Rate Display	25 BPM-250 BPM	
Resolution	Hemoglobin Saturation	1%
	Pulse Rate	1 BPM
Measure Accuracy	Hemoglobin Saturation	2% (80%-100%) 3% (70%-80%) Unspecified (※70%)
	Pulse rate	2 BPM

Section 6 - Warranty

Your BodyMed® Fingertip Pulse Oximeter is warranted to be free from defects in materials and workmanship occurring within one (1) year from date of purchase, when used in strict accordance with the instructions provided with the monitor. The sole remedy for a breach of this warranty is replacement of defective materials or components. This warranty extends only to the original purchase. The purchase receipt or other proof of date of original purchase is required before full replacement will be provided.

Please contact BodyMed® at:
1-866-528-2152

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