

PulseOx 6100™ -Hand Held User Guide

Blood Oxygen Saturation & Heart Rate Spot-Monitor

Dear User,

Thank you for purchasing the SPO Medical PulseOx 6100™ Hand-Held Oximeter ("PulseOx"). By purchasing this pulse oximeter, you have chosen a high quality device. SPO is convinced that you will be fully satisfied with your new pulse oximeter. Please take a few moments to review the following instructions before using the PulseOx for the first time. If you still have questions, please contact your local dealer for assistance or SPO Medical at support@spomedical.com

⚠ Attention: See Instructions for Use

Statement of Use: Spot-check pulse oximetry

Safety:

- ❑ Please follow your physician's instructions. Self-diagnosis of measured results and self-treatment are dangerous.
- ❑ Diseases that cause peripheral circulatory disturbance may cause incorrect readings (including, but not limited to, diabetes, hyperlipidemia, hypertension and arterial sclerosis). Carboxyhemoglobin and/or dyes may also cause erroneous readings.
- ❑ The PulseOx is not intended for use as an apnea monitor.
- ❑ Do not use cellular phones near the PulseOx as it may cause interference.
- ❑ The PulseOx is a precision electro-optical device that, with the exception of replacing the battery, has no user serviceable or adjustable components inside.
- ❑ The PulseOx must be serviced by trained SPO Medical personnel only.
- ❑ If the PulseOx is mechanically damaged or the LCD presentation is blurred, the device must not be used.
- ❑ If the elastic thimble changes color (gray or white) or loses elasticity (enough to fall off the finger) the sensor must be replaced.
- ❑ Replacement sensors are available from our local dealer or SPO Medical and sold separately.
- ❑ The PulseOx is **not** water-proof. Water penetration invalidates the warranty.
- ❑ Please note that the PulseOx includes batteries that should be disposed of in accordance with local environmental regulations.
- ❑ The pulse rate indicator is not suitable for monitoring cardiac pacemaker frequency.
- ❑ The PulseOx should only be used on intact skin.
- ❑ The use of the PulseOx by special need patients should be supervised by his/her caregiver.

System Parts:

1. PulseOx 6100™ measuring unit (see figures 1, 2, 3)
2. Sensor (see figure 4)
3. Storage pouch sold separately
4. User instructions
5. Manufacturer's warranty

Measuring Unit Components: (Figure 1)

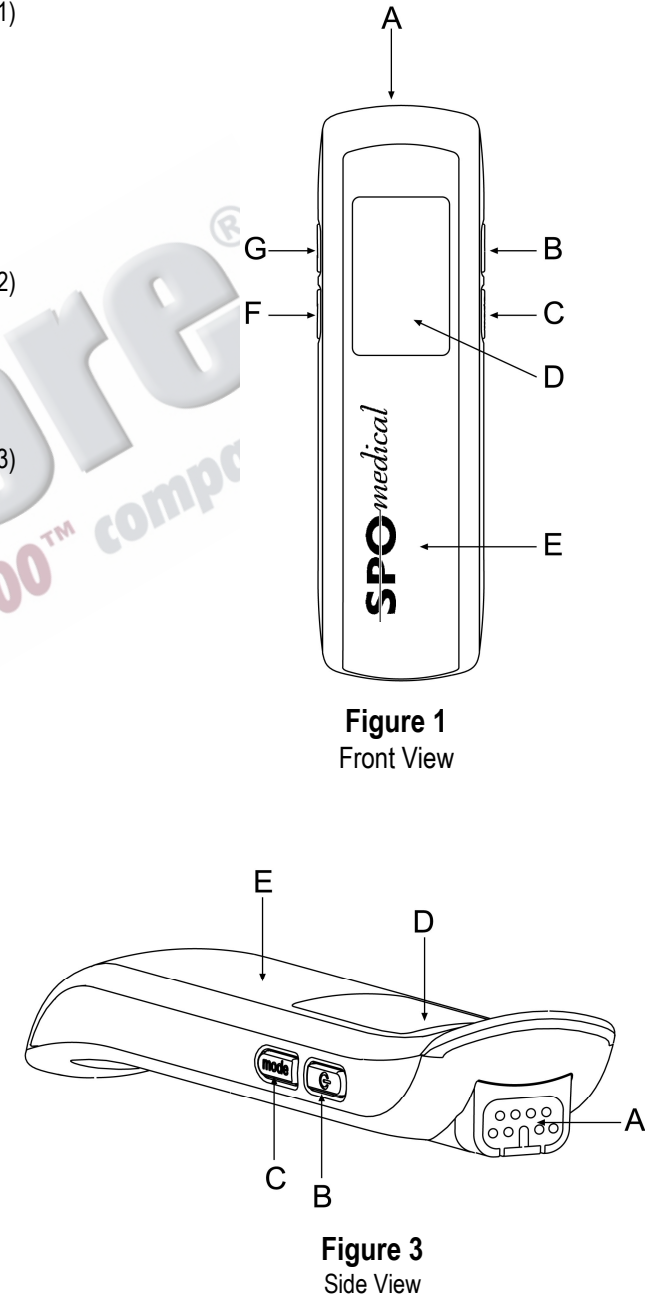
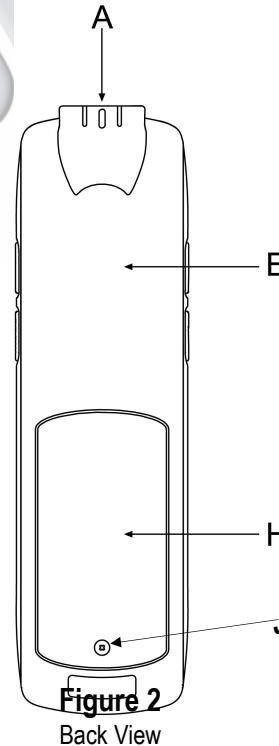
- A. Connector socket
- B. On/Off button
- C. Mode button
- D. Liquid crystal display (LCD)
- E. Plastic casing
- F. Down button
- G. Up button

Measuring Unit Components: (Figure 2)

- A. Connector socket
- E. Plastic casing
- H. Battery cover
- J. Battery cover screw

Measuring Unit Components: (Figure 3)

- A. Connector socket
- B. On/Off button
- C. Liquid crystal display (LCD)
- D. LCD window



Sensor Components: (Figure 4)

- I. Silicone Elastic Thimble
- II. Cable
- III. Connector Plug

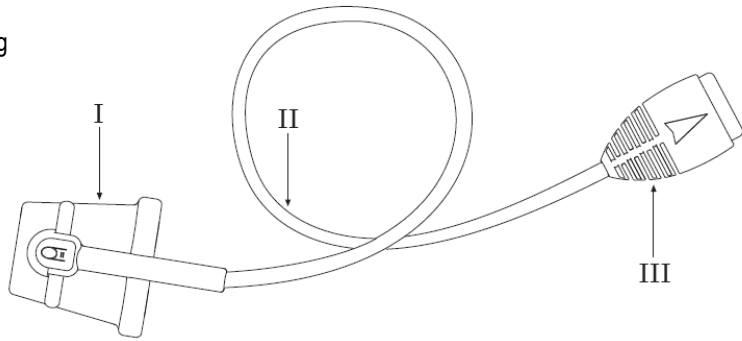


Figure 4

Liquid Crystal Display (LCD)

Indicators and Symbols: (Figure 5)

- 1. Pulsing heart indicator
- 2. SpO₂ legend
- 3. (M) Memory indicator
- 4. (Mode) Mode indicator
- 5. "Weak signal" indicator
- 6. Buzzer level indicator
- 7. "Battery status" indicator
- 8. Sensor "off" indicator
- 9. Saturation rate (%)
- 10. Heart rate (bpm)

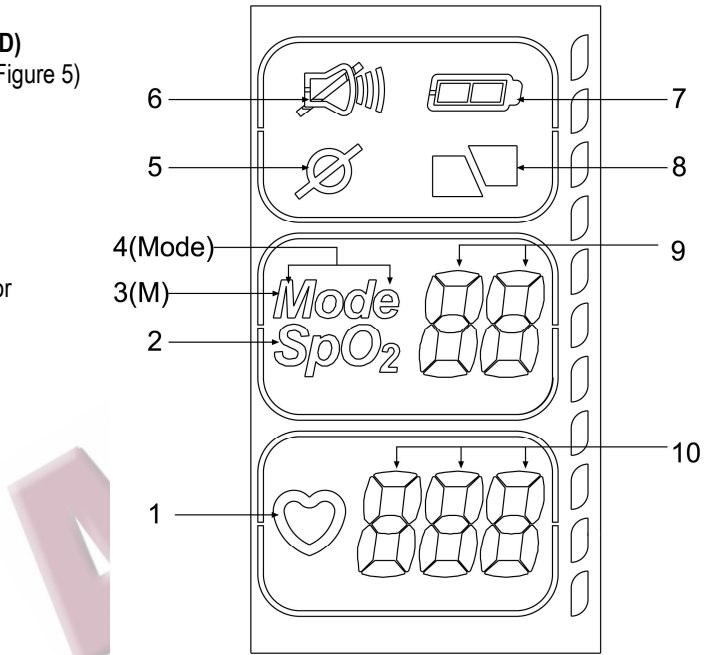


Figure 5

Please Note Before Use:

- ❑ All activity should cease prior to initiating measurements (e.g. eating, drinking, smoking, or exercising) since these, among other activities, may affect the readings.
- ❑ The hand should be relaxed (e.g. lying on a flat surface) and still during the measurement process.
- ❑ Inserting a finger into the elastic thimble should be easy and comfortable, IF INSERTION IS TOO TIGHT OR DIFFICULT, USE A SMALLER FINGER. **Damage caused by force will void the warranty.**

Using the PulseOx:

- ❑ Before use, the sensor must be connected to the measuring unit properly. Gently insert the connector plug (Figure 4-III) into the socket (Figure 3-A) ensuring that the pins are aligned correctly.
- ❑ Gently place a finger into the elastic thimble (Figure 6) so that the nailbed figure is facing in the upward direction. Slightly press on the thimble sides to ease the finger inside.
- ❑ Verify that the finger feels comfortable. Do not use force.
- ❑ Hold the hand relaxed and still.
- ❑ Press the on/off button (Figure 3-B)
- ❑ The SPO legend will appear (Figure 5-10), followed by a series of flashing dashes.
- ❑ The PulseOx will initiate readings within 6-8 Seconds. Data will automatically be stores in the memory (See memory section below). The device will continue to monitor SpO₂ (Figure 5-9) until the finger is removed from the thimble (Figure 4-I) or if the on/off button is pressed.
- ❑ Once the finger is removed from the elastic thimble, the PulseOx will automatically turn off within 15 seconds.
- ❑ The PulseOx has an option to be stored in a pouch; sold separately.

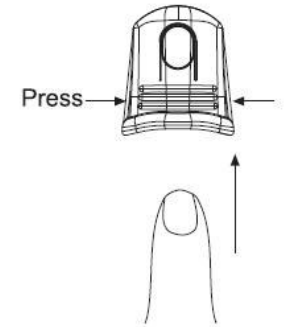


Figure 6

Set-Up Memory:

- ❑ The PulseOx is designed with an internal memory which retains the previously selected buzzer and volume and back illumination settings , even when the PulseOx is turned off.

Memory:

- ❑ The PulseOx has an internal memory for 10 heart rate and SpO₂ readings.
- ❑ Subsequent readings (e.g. 11th) delete the earliest reading and push the latest one in memory a space back.

Accessing the PulseOx Memory Readings:

- ❑ To access the memory reading, press the mode button (Figure 3-C) once. The LCD screen will show "Mode 1".
- ❑ Press the "arrow up" key (Figure 1-G) and M (Figure 5-3&10) will appear on the screen. After a few seconds the last heart rate and SpO₂ reading (Figure 6-1, 2, 3, 9&10) will appear on the screen.
- ❑ To access earlier readings, use the "up arrow" key (Figure 1-G). By using both arrow keys (Figure 1-F&G) you can toggle between memory entries. The last entry will appear as M1 and the earliest memory entries will appear after that in chronological order.

Deleting Memory:

- ❑ Press the mode button (Figure 3-C) four times. The LCD screen will show Mode 4 and "dEL".
If in fact you wish to delete the stored SpO₂ and heart rate reading from the memory, press both up and down arrow together (Figure 1- F&G). The "dEL" will flash and a double beep will sound. The memory has been deleted.

Turning Off the Oximeter:

- ❑ To turn off the PulseOx, press the on/off button (Figure 3-B) or simply remove the finger from the elastic thimble (Figure 4-I) and wait 15 seconds for the unit to turn off.
- ❑ "Off" will appear on the screen just before the unit shuts down.

Buzzer:

Buzzer (Mode 2) can be adjusted at any time. To adjust the buzzer level, press the mode button (Figure 3-C) twice so that M2 appears on the screen. To adjust the buzzer levels press on the arrow keys (Figure 1-F&G) until the desired level is reached. The buzzer can be mute as well. Note: Set-up memory maintains buzzer levels even after the PulseOx has been turned off and restarted.

Back light:

Back light intensity can be adjusted at any time, to adjust the back light intensity, press the mode button (Figure 3-C) three times so that Mode3 appears on the screen. Then, use the arrow keys (Figure 1-F&G) to increase or decrease light intensity. There are 5 levels of back light intensity from full to off.

Note: Set-up memory maintains back light intensity levels even after the PulseOx has been turned off and restarted.

Battery Status:

- ❑ Battery display indicates the approximate power remaining in the battery.
- ❑ Display of a single battery bar indicates that the battery will soon require replacement
- ❑ Blinking of the battery icon indicates that the battery needs to be replaced.
- ❑ Battery requirements: 2 x 1.5V Alkaline AA batteries (1,200mAh).

Battery Replacement Method:

- ❑ Open the screw (Figure 2-J) on the battery compartment with a standard Phillips screwdriver and remove the old batteries.

- ❑ Discard the used batteries according to local environmental regulations.
- ❑ Insert 2 new AA batteries. Verify the battery polarization (+/-) is in accordance with the battery compartment symbols.
- ❑ Replace the battery cover (Figure 2-H) by gently sliding it into place.
- ❑ Tighten the screw (Figure 2-J) with a standard Phillips screwdriver.
- ❑ Note: Press the On/Off button - If the unit starts and shows dashes, the batteries have been place correctly.

PulseOx Cleaning Instructions:

- ❑ Wipe the exposed surfaces with a soft cloth or a moistened pad with a mild detergent solution or an isopropyl alcohol solution (70%).
- ❑ Clean the inside of the elastic thimble and the optical elements with a cotton swab moistened with a mild detergent solution or an isopropyl alcohol solution (70%).
- ❑ Clean your PulseOx whenever you see any kind of soil, dirt or obstruction in the unit.
- ❑ Ensure that no dirt or blood is on the optical components inside the elastic thimble.
- ❑ A transparent protective plastic sleeve, supplied by SPO, can be placed on the finger if the user sees fit.

Product Specifications:

| | |
|---|---|
| Effective Measuring Range | |
| Saturation | 40 to 99% |
| Heart Pulse Rate | 40 to 250 bpm |
| Resolution | 1 digit |
| Accuracy (incl. minor motion and low perfusion) | |
| Saturation (70%-99%) | ±2% or ±2 digits |
| Heart Rate | ±3% or ±3 digits |
| Display | |
| Saturation | 2 characters |
| Heart Rate | 3 characters |
| Signal Indications: | Sensor 'OFF' and 'Weak Signal' Flashing Heart Icon |
| Battery Indication | Full power, 1/3 and near empty |
| Power Requirements | 2 x 1.5V Alkaline Batteries (1,200mAh) |
| Mechanical | |
| Overall Dimensions | 6.3" x 1.73" x 1.06" (160 x 44 x 27mm) |
| Storage Temperature | -4° to 158F° (-20°C to 70°C) |
| Operating Temperature | 39° to 107F° (4°C to 42°C) |
| Humidity | Up to 95% non-condensing |
| Weight | 3oz (85g) not including battery and sensor |
| Sensor Weight | 1.37oz (39g) |

Manufactured by



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Spot
measurements
No alarms

Rx
only



Device Catalog Number: 90401000
Design and specifications are subject to change without notice.
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Manufacturer's End User Product Warranty - PulseOx 6100™

SPO Medical Equipment Ltd. (the "Company") warrants (except as otherwise noted below) that its products (the "Product") are free from defects in materials and workmanship for a period of one (1) year from the date of purchase by the end user. In the event that the Product qualifies for coverage under this warranty, the Company, at its option and at no charge, may either repair or replace the Product (not including, shipping, handling, delivery or installation) with an identical product or product having similar features and functionality, as determined by the Company. The warranty period for any repaired or replaced Product shall be the remainder of the original warranty term for the original product. Notwithstanding the above, the Company only warrants that the Company's sensor incorporated in its Product known as the PulseOx 6100 sensor will be free from defects in materials and workmanship for a period of 180 days from the date of purchase by the end user.

The Company does not warranty the installation, maintenance, or service of its Product. The Company is not responsible for ancillary equipment not supplied by the Company, which is attached to or used in connection with the Company's Product, or for the operation of the Product with any ancillary equipment, and all such equipment and operation of such equipment with the Product, is expressly excluded from this limited warranty. Furthermore, the Company shall not be responsible for any damage to the Product resulting from the use or operation of the ancillary equipment not furnished by the Company for use with the Product. Use of this product with any sensor not supplied by Company will render the warranty void.

The Company extends this limited warranty only to the original end-user. This limited warranty and the remedies hereunder are limited to Products properly used, maintained, stored, installed and used for their intended purpose and use only, in accordance with the Company instructions. This warranty shall not apply to Product installed, operated or maintained in or under abnormal conditions. This warranty is not applicable to any Product which is not operated and/or installed in accordance with the Company's specifications and or industry practices and standards. This warranty does not extend to any battery power supply included in / with the Product.

This warranty sets forth all of the Company's responsibilities for the Product.

THIS WARRANTY IS GIVEN IN LIEU OF ALL OTHER EXPRESS WARRANTIES. IMPLIED WARRANTIES, STATUTORY OR OTHERWISE, INCLUDING BUT NOT LIMITED TO ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, ARE LIMITED TO THE DURATION OF THIS LIMITED WARRANTY. IN NO EVENT, INCLUDING WITHOUT LIMITATION, IN CONTRACT, TORT, STRICT LIABILITY OR WARRANTY, SHALL THE COMPANY BE LIABLE TO THE PURCHASER OR TO ANY THIRD PARTY, FOR ANY DAMAGES OR FOR ANY LOSS OF USE, LOSS OF TIME, INCONVENIENCE, COMMERCIAL LOSS, LOST PROFITS OR SAVINGS OR INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES ARISING OUT OF THE USE OR INABILITY TO USE SUCH PRODUCT. TO THE FULL EXTENT THAT SUCH MAY BE DISCLAIMED BY LAW, COMPANY'S SOLE LIABILITY SHALL BE TO REPLACE OR REPAIR THE PRODUCT.

Some states within the United States do not allow the exclusion or limitation of consequential or incidental damages, or limitations on the duration of an implied warranty. Therefore, the limitations or exclusions of consequential or incidental damages and implied warranties set forth herein may not apply to you. This warranty gives you specific legal rights, and you may also have other rights, which vary from state to state.

If it appears that the Product does not meet the terms of the limited warranty set forth above, within the Warranty Period, the purchaser must notify the Company in writing of the warranty claim and after receiving proper authorization, return the Product to the nearest Company certified distributor for exchange or repair of Product.

FAQ's (Frequently Asked Questions) on the SPO PulseOx 6100™

- Q:** Which finger should be used to obtain best results?
A: Use any finger that easily fits into the thimble; do not force the finger into the thimble.
- Q:** After I start the Oximeter, only dashes appear.
A: This is normal for the first ten (10) seconds. If the reading takes longer than 10 seconds to appear, it may be indicating that the thimble is too tight on the finger, causing impairment or restriction of the circulation. Ensure that the finger is properly placed inside the elastic thimble as indicated in the user instructions. Pull the finger out a little and the Oximeter will restart. If the second try is unsuccessful, repeat the insert/start process on a smaller finger. If the user has very small fingers (e.g. children), try using the thumb.
- Q:** I get a "weak signal" icon, what does this mean?
A: Once the Oximeter is operational and getting a reading and the sensor does not receive a signal for more than approximately 5 seconds this icon will appear, even though the LCD continues to show the last update. The "weak signal" reading may indicate that the unit is too tight and the finger and is restricting or stopping circulation. Please refer to FAQ # 2.

4. **Q:** The Sensor "OFF" icon is lit, what does this mean?
A: This means that the sensor is having a problem reading the signal from the finger. Ensure that the finger is properly placed inside the elastic thimble as indicated in the user instructions. The sensor will shut down if no signal is detected over a 15 second period. It may also indicate that the unit is placed too tight on the finger and is restricting or stopping circulation. Please refer to FAQ #2.
5. **Q:** How do I access memory reading saved in the PulseOx?
A: To access the memory reading, press the mode button (Figure 3-C) once. Press the "up arrow" key (Figure 1-G) and M1 (Figure 5-3) will appear on the screen. After a few seconds the last heart rate and SpO₂ reading (Figure 5-1, 2, 3, 9&10) will appear on the screen. To access earlier readings, use the "up arrow" key (Figure 1-G). By using both arrow keys (Figure 1-F&G) you can toggle between memory entries. The last entry will appear as M1 and the earliest memory entries will appear after that in chronological order.
6. **Q:** How do I delete the memory from the PulseOx?
A: Press the mode button (Figure 3-C) four times. The LCD screen will show Mode 4 and "dEL". If in fact you wish to delete the stored SpO₂ and heart rate reading from the memory, press both up and own arrow together (Figure 1- F&G). The "dEL" will flash and double beep will sound once. The memory has been deleted.
7. **Q:** How do I choose the volume of the buzzer?
A: To adjust the level of the buzzer, press the mode button (Figure 3-C) twice so that the message Mode 2 appears on the screen. There are 4 levels. To adjust the buzzer press on the up arrow to increase or down arrow to decrease the buzzer intensity (Figure 1 F&G) desired. The buzzer can be muted as well. Note: It is only necessary to set the volume level once, as the set-up memory maintains the buzzer levels even after the PulseOx has been turned off and restarted.
8. **Q:** How do I turn the buzzer off completely?
A: The buzzer off level is number one of the four buzzer level modes. See FAQ #7 above for adjustment of the buzzer volume.
9. **Q:** How do I choose the intensity of the backlight?
A: To adjust the screen illumination, press the mode button (Figure 3-C) three times so that the message Mode 3 appears on the screen. Then press on the up arrow to increase or down arrow to decrease (Figure 1 F&G) for the back light intensity desired. There are 5 levels of light intensity from full to off. Note: It is only necessary to set the light intensity once as the set-up memory maintains the light intensity level even after the PulseOx has been turned off and restarted.

10. **Q:** How do I change the battery?
A: Using a standard Phillips screwdriver, carefully remove the screw (Figure 2-J) that affixes the battery cover (Figure 2-H). Then slide off the cover. Carefully remove the old batteries. Discard the used batteries according to local environmentally regulations. Insert 2 new AA batteries into the battery compartment. Ensure that the battery polarization (+/-) is in accordance with the symbols within the battery compartment. Slide the battery cover back into its place and return the screw to the hole and affix in place. Press the On/Off button A working PulseOx indicates correct battery placement.
11. **Q:** Where can I purchase a new battery?
A: AA batteries are readily available in most stores. It is recommended to purchase high quality and long lasting batteries (1,200mAh) to ensure the proper function of the PulseOx.
12. **Q:** Where can I purchase a replacement sensor for the PulseOx?
A: Contact your local dealer or send an e-mail to support@spomedical.com and your query will be directed accordingly.
13. **Q:** What is the normal range for each display (SpO₂ and heart rate)?
A: Individual normal ranges should be defined by you physician.
14. **Q:** Can I put the PulseOx on a wet (or bloody) finger?
A: No. This model is not water resistant and, therefore, exposure to excessive moisture will damage the PulseOx and void the warranty. Wipe all moisture from the finger before inserting it into the thimble. If finger is injured or bleeding, use a different finger.
15. **Q:** The PulseOx dropped into water. What can I do?
A: Turn the unit immediately off and remove the batteries. Discard the unit at your local electronics recycling center.