OxSim SpO_2 Simulator

Operator's Manual

Pronk Technologies

www.pronktech.com

OxSim is excluded from ROHS standards. To dispose this product, contact Pronk Technologies at support@pronktech.com. We will issue a RMA and pay for return shipment.

Table of Contents

Contact Us

Sales:	800/609-9802
Technical Support	800/541-9802
FAX:	323/258-5817
Email:	Sales@pronktech.com
Web site:	www.pronktech.com

OxSim Ox-1 Operation Instructions

Introduction

The OxSim pulse Oximeter Simulator is quick to set up, easy to use and ready to go where you need to be. Your OxSim may come with a small 6VDC/1.8 amp power supply, a carrying case and a set of AA batteries, depending on configuration. OxSim Simulations are intended to produce simulated values within the specified tolerance of the Oximeter sensors. Most durable oximeter sensors have a tolerance of +/- 2%, and most disposable oximeter sensors have a tolerance of +/- 3% or +/-2%.

Getting Started

1. **Power up the OxSim.** There are three ways to power your OxSim: A single AA internal battery, using the OxSim AC/DC power supply, or connecting the OxSim to the battery boost option in your SimCube's carrying case. The internal battery ON/OFF switch is ON with the slider towards the right side of the OxSim. ***Warning:*** Ensure the power supply is labeled for use with the OxSim. The OxSim power supply is 6VDC, 1.8amp, center positive, 2.1mm jack.

2. **Wait for the power-up sequence to complete.** When complete, a simulation **"MODE"** and sensor "**TYPE"** LED will be lit. This will take one or two seconds.
3. **Select the desired mode by pressing the yellow MODE button.** Each time the mode button is pressed the mode will be changed and the LED indicating the new mode will be lit. The SpO_2 Value, Heart Rate, and Perfusion level corresponding to each mode are printed on the front panel next to the LED horizontally. For more detailed information on each mode, refer to the 'Detailed Mode Information' section in this manual.
4. **Select the desired sensor type by pressing the yellow TYPE button**. A detailed list of which monitor and sensor types will work best with which

mode is found later in this document, but the majority of the most common monitors and sensors work best with the Nellcor/Masimo sensor type setting.

5. **Install the SpO_2 sensor onto the finger portion of the OxSim** with the sensor's LEDs shining onto the top side of the OxSim.

Important Operation Notes

1. **Sensor- LED Indicators.** The OxSim has two LEDs near the bottom of its display labeled 'IR' and 'Red'. The LED labeled 'IR' illuminates when a significant amount of IR light is detected on the input side of the finger and the LED labeled 'Red' illuminates when a significant amount of Red light is detected on the input side of the finger. When a properly working oximeter and sensor are connected to the OxSim, both LEDs should be solidly illuminated (not flashing). Sensor failures can often be detected by just checking these LEDs.

2. **Power Save Mode.** When no sensor is connected to the OxSim for ten minutes, it shuts itself off to save power. To turn it back on you can either power cycle it, or press either of the Mode or Type buttons. The OxSim will not remember your prior Mode or Type settings, so when you turn it back on be sure to reconfigure them.

3. **Battery Level Indicator.** The OxSim will perform active SpO2 simulation for approximately 8 to 12 hours on a single AA battery, depending primarily on the brightness of the light emitted by the oximeter it is testing. When the battery condition is good (loaded battery voltage in the range of 1.6V to about 1.1V…about 80% of the total run time) the battery indicator will be green. When the battery condition is marginal (loaded battery voltage in the range of 1.1V to 1V…about 15% of the total run time) the battery indicator will be orange. When the battery is depleted the battery indicator will be red. When the battery indicator is red, the OxSim may boot and appear to operate correctly, but may reset when a SpO2 sensor is installed.

4. **Software Version Display.** The version number of the software installed in the OxSim is shown at bootup. During the bootup process the number of flashes of the 'IR' led indicates the major digit of the

software version, and the number of flashes of the ‘Red’ led indicates the minor digit of the software version.

Detailed Mode Information

Generally, durable SpO_2 sensors have a tolerance specification of +/- 2%, disposable SpO2 sensors have a tolerance specification of +/- 2% or +/- 3%, and most oximeters have an additional tolerance specification of +/- 1%. This points towards a theoretical error total of up to 4%, but in most cases it should be possible to achieve oximeter readings within 2% of the values labeled on the OxSim.

The 85%, and 98% modes are designed to let you check the basic functionality of your Oximeter, while the other modes have features which allow you to challenge your Oximeter's performance.

- **85%**

  Simulates a patient with saturation of 85%, heart rate of 80 bpm, and perfusion index of approximately 2.0.

- **95%**

  Simulates a patient with saturation of 95%, heart rate of 40 bpm, and perfusion index of approximately 2.0. Note that this heart rate is right at the limit of the performance specification for many Oximeters and some may have trouble with it.

- **98%**

  Simulates a patient with saturation of 98%, heart rate of 80 bpm, and perfusion index of approximately 2.0.

- **140 BPM**

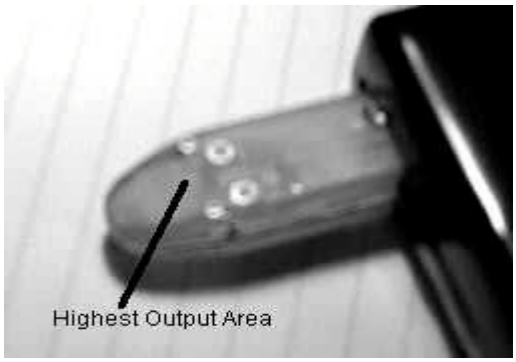
  Simulates a patient with saturation of 98%, heart rate of 140 bpm, and perfusion index of approximately 2.0.

- **Low Perfusion**

  Simulates a patient with saturation of 99%, heart rate of 80 bpm, and perfusion index of approximately 0.2. Note that this mode simulates a challengingly low perfusion level and will not work with all monitors and sensors.

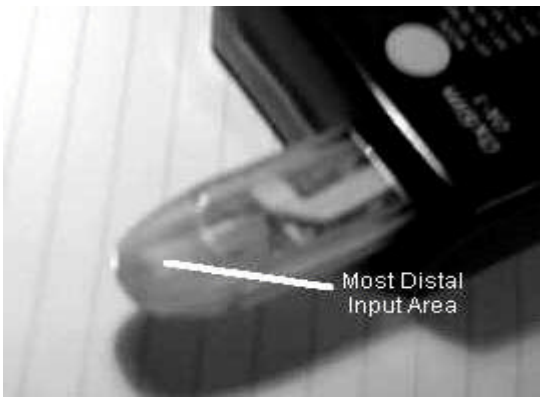
Optimal Durable Sensor Placement Directions

Most sensors will work best when fully inserted all the way onto the OxSim simulated finger, but some sensors may require slight adjustment to find the optimal location. In most cases, best results will be achieved by aligning the sensor's photo detector with the OxSim's Highest Output Area. The location of this area is shown in the figure below. It is about 0.1" in the direction of the tip from the torx head screws in the finger.

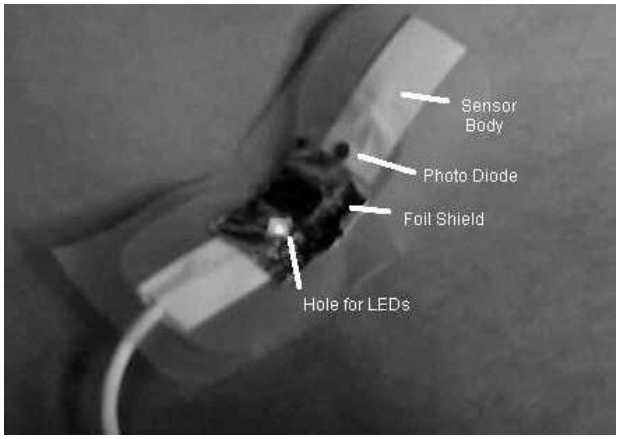


Optimal Disposable Sensor Placement Directions

Disposable sensors should be placed by first positioning the sensor's photo diode in the OxSim's Highest Output Area, as shown above, and then wrapping the rest of the sensor around the finger so that the sensor's LEDs are wrapped as far as possible onto the top side. The further onto the top side of the OxSim the LEDs are placed, the less leakage light there will be, but they should go at least to the point shown in the figure below, which is about 0.1" away from the tip. Both photo diode and LEDs should be well centered between the two sides of the OxSim's finger.



Some popular disposable sensors have little shielding around their LEDs and therefore radiate a great deal of leakage light. Also the body of the sensor, and the plastic packaging around the sensor, can act as a light pipe which conducts leakage light around the OxSim. Performance of this type of sensor can be improved by using a shield made from a small piece (approx 1" x 1") of metal foil with a hole punched in it for the sensor's LEDs to shine through.



It is worth noting that the leakage light issue is not specific to the OxSim, and any techniques you develop for minimizing leakage light might be useful in challenging clinical situations.

Sensor Placement Background

- **Why Sensor Placement Can Affect Your Readings**

For most applications you can get good simulation values from the OxSim by simply installing the sensor all the way into the OxSim's finger, but for a few applications a little more attention to placement may be helpful. This section explains why placement can affect your readings, and how to optimize it.

SpO_2 works by using the fact that hemoglobin with oxygen attached to it has a red color, and hemoglobin with no oxygen has a blue color, so the task of determining the O_2 saturation becomes the task of determining how red the blood is. This task is complicated by the fact that different people have different color flesh and skin and that the output of the light sources

might not be consistent, and that the output of receiving photo diode in the sensor will generally not be consistent at different wavelengths.

These complications can be managed by sending two colors of light through the finger (Red and Infrared) and normalizing the output in two ways. The first normalization is done by breaking the transmitted light for each wavelength into a small AC component, generated by the patient's pulse, and a larger DC component which represents the optical properties of the flesh overall, and then taking the ratio of the two. This calculation is basically the percentage of the light at each wavelength that is pulsing. The second normalization is done by taking the ratio of these two percentages:

$$R= (Red_{AC}/Red_{DC})/(IR_{AC}/IR_{DC})$$

SpO_2 is then calculated according to an equation which is a polynomial in R, and which depends on the exact wavelengths used. For most applications this equation ends up being pretty much a straight line, between 100% saturation having a R value of around 0.6 (the blood is very red so it stops about two times as much Red light as IR light) and 81% saturation having a R value of 1.0 (the blood is less red so it stops about the same amount of Red and IR light).

The OxSim is designed to intercept the light flashes from the oximeter, block them, and, using electronic, optical, and mechanical techniques, produce new optical flashes that represent the optical signals that would be seen coming through a patient's finger in the different simulation scenarios.

The reason why sensor placement can be an issue is that, depending on sensor placement, some of the light from the sensor's LEDs is not blocked by the OxSim, but rather leaks around it and finds its way directly the sensor's receiving photo diode.

To understand this better we can rewrite our equation for R as:

$$R= (Red_{AC}/ IR_{AC}) * (IR_{DC}/ Red_{DC})$$

So, R can also be viewed as the AC ratio times the DC ratio. Both IR AC and Red AC signals come entirely from the OxSim, so sensor placement is

not an issue with them, but the DC signals are the sum of the DC signals produced by the OxSim and the DC signals that leak around it.

Even with substantial leakage we can get a good R value as long as the relative Red and IR sensitivity of the OxSim's input circuitry matches that of the sensor and the same percentage of Red and IR light leak around the OxSim. Unfortunately, different models of sensors have different relative sensitivity and while the OxSim's relative sensitivity is designed to mimic the most common sensors, it cannot match them all perfectly. Also, IR light can quite easily go through many things which block Red light, so generally we would not expect to always see consistent leakage at the two wavelengths.

So, in some cases, too much leakage light can throw off the ratio of DC light that the sensor's photo diode sees and affect the reading.

Optimizing placement consists of making sure that the DC light ratio seen by the sensor's photo diode is strongly dominated by the OxSim's output signal rather than leakage light by:

1. Positioning the sensor's LEDs such that the maximum amount of their light is blocked by the OxSim's finger.
2. Positioning the sensor's photo detector such that it is as protected as possible from leakage light.
3. Positioning the sensor's photo detector such that it gets the maximum possible light from the OxSim, by placing it near the brightest part of the OxSim's output area, its Highest Output Area.

Correct Sensor Type Selections

Sensor Type Setting	Monitor
#1 Nell/Mas	All Nellcor Masimo Datascope Protocol Spacelabs HP/Philips (blue extension cable) HP/Philips (tan soft sensor) Nihon Kohden Colin GE/Marquette Welch Allyn Datex Ohmeda (SpO2 SW ver dated 1990-2001)
#2 HP/Ohm	HP/Philips (cocoa brown soft sensor) Novametrix Ohmeda (GE/Datex/Ohmeda SpO2 SW ver dated 2006+)
#3	Datex Ohmeda (SpO2 SW ver Dated 2001-2005)

Note: Some popular monitoring companies have used a variety of OEM technology in their monitors and so, for example, one Marquette Tram monitor may use Ohmeda technology while another may use Nellcor technology. Also note that the correct 'Type' setting to use depends on the sensor rather than the monitor. For example: some HP/Philips monitors can use either the cocoa brown HP sensor or a Nellcor sensor. In this case you would need to use the HP/Ohm setting when using the HP sensor, but the Nell/Mas setting when using a Nellcor sensor on the same monitor.

OxSim Troubleshooting Tips

TROUBLESHOOTING TIPS	
SYMPTOM	**SOLUTION**
OxSim resets when sensor is attached	Low battery: replace battery or run off external power supply
Oximeter does not show waveform or numerics, IR and RED LEDs are not illuminated on OxSim	Make sure the LEDs of the sensor is placed on the top side of the OxSim. Bear in mind that the sensor itself may be defective.
Incorrect waveform	Possible initialization error. The OxSim uses optical feedback to initialize itself, and has advanced algorithms to allow it to do this correctly in the presence of optical interference from Oximeters, fluorescent lights, and slowly changing ambient light. However, it is difficult to anticipate every possible optical interference pattern that might occur in the field. Try rebooting the OxSim with the sensor removed. If this does not solve the problem try placing the OxSim in a reduced light configuration, while booting it. In direct sunlight, for example, you can simply shade the (bottom side of the) OxSim finger with your hand during bootup.
Bottom half of finger is internally illuminated, but mode and Type and Mode LEDs do not illuminate	The OxSim is having trouble initializing. See above.
Saturation values are significantly off	Make sure correct sensor “Type” is selected.
Saturation values are significantly off	The OxSim adapts its gain according to the amount of input light from the sensor when it is first placed on the OxSim. If the ambient light level is too high the OxSim may not detect that the sensor has been removed and therefore may not readjust its gain when OxSim is moved from monitor to monitor. If neither the ‘IR’ or “Red’ indicator LEDs turn off when the sensor is removed this may be happening. You can resolve this by either shading the OxSim until one of the indicator LEDs turns off when you are changing between

	monitors, or tapping the Type button twice to force the OxSim to readapt.
SYMPTOM	**SOLUTION**
Saturation values are slightly off	Sensor position can affect reading. Try adjusting sensor position. The primary parameter is the amount of light that leaks from the sensor's LEDs around the OxSim to the sensor's detector. Generally, values will be best with the minimum leakage light.
Display LEDs are off and OxSim does not respond	The OxSim may be in power save mode. To recover from this mode press either the Mode or Type button or power cycle the OxSim. When power cycling it may be necessary to leave the OxSim in the off position for around 2 seconds. The ON/OFF switch is ON when the slider is to the right. Of course, the battery may need to be replaced.
Difficulty getting reading in Low Perfusion mode	This mode is intentionally designed to be challenging to oximeters and some will not perform well. Marginal oximeters will perform better with better quality sensors.
Difficulty getting a stable HR at 40bpm	This heart rate is the lower limit of many manufacture's oximeter HR specification, and some will have difficulty with it.
Incorrect reading on unusual sensors	You may encounter a few devices in the field which do not match either of the standard probe types. For example, Dynamap Plus monitors with a small round 7 pin connector use SensorMedics technology and typically read 5% low on the higher saturation values. If you have a particular need to support a device such as this contact Pronk Technologies to find out about having a third 'custom' probe type added to your OxSim.
Unable to resolve problem	Contact Pronk Technologies Technical Support at: **(800) 541-9802**

Services (Prices subject to change without notice)

SERVICE ITEM NUMBER	DESCRIPTION	PRICE (USD$)
Annual OxSim P.M. Service	Full checkout and adjustment	100.00

OxSim Limited Warranty

The OxSim SpO2 simulator is warranted against defects in materials and workmanship for a period of twelve (12) months from the date of shipment to the original purchaser. Warranty is valid only to the original buyer. Defective equipment should be returned freight prepaid to Pronk Technologies. Equipment returned with defective parts and assemblies shall be either repaired or replaced at the manufacturer's sole discretion. This warranty is not applicable if the unit has been opened, if repair has been attempted, if the unit has been damaged due to operation outside the environmental and power specifications for the product, or due to improper handling or use.

If any fault develops, notify Pronk Technologies (*see Returns and Repairs, below*) giving full details of the difficulty, and include the model and serial number of the device. Upon receipt of shipping instructions, forward the device prepaid and repairs will be made at the factory.

The foregoing warranty is in lieu of all other warranties expressed or implied, including but not limited to any implied warranty or merchantability, fitness or adequacy for any particular purpose or use. Pronk Technologies shall be liable only for repair or replacement of the OxSim SpO2 Simulator and optional features. Pronk Technologies shall not be liable for any incidental or consequential damages.

Order Cancellation and Refund Policy

You may return your item within 14 days of delivery for a full refund. We are unable to exchange items (however, if you received a defective or incorrect item, we will be happy to make an exchange). Item(s) returned for refund must be in its original condition, undamaged and with no missing parts, packed in its original packaging, and include both the original receipt and an RMA number.

We will notify you via e-mail or fax of your refund once we have received and processed the returned item. You can expect a refund in the same form of payment originally used for purchase within 7 to 14 business days of our receiving your return.

Returns and Repairs

Please call Pronk Technologies' Service Department at 800-541-9802 to obtain a Return Merchandise Authorization (RMA) number and the shipping address. Returns should be packaged securely in the original packaging materials. The RMA number should be clearly marked on the packaging. If the return is for a new item and is a

result of our error, we will make arrangements for payment of return shipping. Otherwise, items should be returned freight prepaid to Pronk Technologies.