OxSim Flex® SpO2 Simulator

Operator's Manual

Compliant products conforming to the relevant standards and directives required for CE have a CE Mark label, as shown below, affixed to the unit. CE Marked products also comply with the WEEE directive for category 9 Monitoring and Control Instrumentation products. Do not dispose of this product as unsorted waste. To dispose, contact Pronk Technologies at support@pronktech.com. A Return Material Authorization will be issued to return the unit for disposal.

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OxSim Flex Operation Instructions

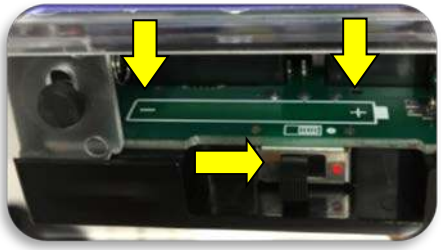
Introduction

The OxSim Flex SpO2 simulator is quick to set up, easy to use and ready to go where you need to be. Your OxSim Flex comes with a small 6VDC/1.8 amp power supply, carrying case, two AA batteries. OxSim Flex 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 Flex**. There are three ways to power up the unit: A single AA internal battery, AC/DC power supply or connecting to the Battery Boost Option in your SimCube carrying case.

   A. Install the AA battery in the correct orientation as labeled inside the battery compartment. See Figure below.



   B. The battery ON/OFF switch is ON with the slider towards the right side (Red Dot) of the OxSim Flex.

   Warning: Ensure the AC/DC power supply is labeled for use with the OxSim. The power supply should be a class II power supply with 6VDC output, 1.8amp, center positive, 2.1mm jack with limited power source.

   -VDC +VDC

   C. To replace the battery, use your finger or a flat edged tool to lift the battery out of the compartment starting from the (+) side of the battery.

   NOTE: *If, at any time the unit is left on, more than 10mins, with no key presses or probe attached, the OxSim Flex will go into "sleep" mode to save battery life. To power back on the unit, press any key. Note: Plugging in the AC/DC power supply or switching the slide switch off/on will not exit this "Sleep" mode.*

2. **Software Version Display.** The version number of the software installed in the OxSim Flex is displayed on boot up. There are three software components installed:

   C: Controller Software version

   S: Simulation Software version

   P: Probe Settings Software version

   Wait for the power-up sequence to complete. When complete, the color display will be illuminated and display saturation, heart rate default values as shown below. This will take two to three seconds.

3. **Preset Simulations.** The OxSim Flex comes programmed with (5) Preset simulations:

Preset	Saturation	BPM	Perfusion
1	85%	80	100%
2	95%	40	100%
3	98%	80	100%
4	98%	140	100%
5	99%	80	13%

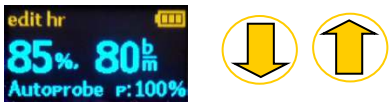
   A. The Preset simulations can be customized by the user and you can create up to (10) preset simulations. See section (10) for Creating/Editing Presets.

4. **Selecting Saturation value.** Press yellow button to access **Edit sat** screen. Use the Up and Down arrow keys to adjust saturation value. To exit

   this mode, press yellow button until you see Custom at top of screen, the press UP and Down arrow keys to select the next Preset.

   NOTE: *For saturation values below 85%, the specific manufacturer pulse oximetry under test can be selected for greater accuracy. See Section (7) for additional information.*

5. **Selecting Heart Rate value.** Press yellow button to access **Edit hr** screen. Use the Up and Down arrow keys to adjust rate value. To exit this mode, press yellow button until you see Custom at top of screen, the press UP and Down arrow keys to select the next Preset.



6. **Selecting Perfusion Index percentage.** Press yellow button to access the **Edit perf** screen. Use the Up and Down arrow keys to adjust perfusion value.

Decreasing Perfusion Index % reduces the size of the Plethysmograph (pleth) waveform. 100% Perfusion Index equals approximately 2.0 PI. To exit this mode, press yellow button until you see Custom at top of screen, the press UP and Down arrow keys to select the next Preset.

NOTE: *Some oximeters may not display results within OxSim Flex specifications at perfusion index values below 60%. Contact manufacturer of oximeter regarding expected performance at low perfusion before testing at lower perfusion levels.*

7. **Selecting manufacturer oximeter (Probe) type.** For most patient monitors/oximeters, accurate SpO2 simulations can be obtained using the Autoprobe type for saturation values from 85-100%. See Probe Type Selection Table page (8) for oximeters compatible in Autoprobe type.

   A. When saturation simulations below 85% are needed, select the manufacturer of the SpO2 technology Probe Type as listed in the Probe Type Selection Table on page 8.

   NOTE 1: *Remove oximeter sensor from OxSim Flex before changing Probe Type to ensure it auto calibrates properly to the new selection.*

B. To change the Probe Type, press and hold the yellow button for two seconds. You will see **set probe (p.1/3)** screen.

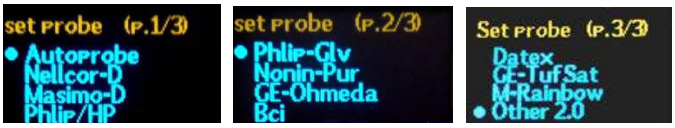
Click the down arrow key to scroll through selections and to access pages 2 & 3.

1) Move cursor to desired probe, and then press the yellow button to accept.
2) When the (•) appears next to the Probe Type desired, press the Yellow Button to select.

8. **Change Default Probe Type.** You can customize the manufacturer probe you wish the OxSim Flex to default to on power up.

   A. With the unit running on battery power <u>only</u>, move power switch to the OFF position, then press and hold the UP arrow key while moving power switch to ON position until you see the Settings screen as shown below.

   B. Use the DOWN arrow key to highlight SET. DEF. PROBE then Press the yellow button.
   C. Scroll using the UP/DOWN arrow keys to select desired probe from menu.



   D. Press and hold the yellow button to save.
   E. Press the yellow button to OK changes made.
   F. When back at the “Settings” menu, press and hold the Yellow Button to exit to simulation mode or power cycle the unit.

9. **Connect to oximeter.** Install the SpO2 sensor from the oximeter onto the finger portion of the OxSim Flex with the sensor’s LEDs emitting onto the front side of the unit. See page 11 for more information on aligning sensors.

Probe Type Selection Table

Probe Type	Manufacturer	Range	Accuracy
Autoprobe[1]	Nellcor, Masimo, Datascope, Welch Allyn, Spacelabs[2], Philips (blue cable), Nihon- Kohden, Philips (tan/soft), Colin, Nonin- 8500/9500, GE/Marquette, CASMED Draeger/Siemens, Mindray, , Mediaid, Midmark, Protocol, Datex Ohmeda (SW 1990-2001)**	Sat. 85%-100% Sat. 75%-84% BPM 30-240	± 2% Sat. ± 3% Sat. ± 2 BPM
Nellcor-D	All monitors using Nellcor™ reusable Sensor	Sat. 70%-100% BPM: 30-240	± 2% Sat. ± 3 BPM
Masimo-D	All monitors using Masimo reusable Sensor ***(*Testing with LNOP blue sensors Sat. accuracy is ± 4% between 60%-80%)***	Sat. 70%-100% BPM 30-240	± 2% Sat.***** ± 3 BPM
Phlip-Glv	Philips Healthcare monitors using Glove Sensor	Sat. 70%-100% BPM 30-240	± 2% Sat. ± 3 BPM
Nonin-Pur	Nonin oximeters utilizing PureSAT® technology Onyx® series	Sat. 70%-100% BPM 25-240	± 2% Sat. ± 3 BPM
GE-Ohmeda	Ohmeda oximeters, GE TruSat	Sat. 80%-100% Sat. 70%-79% BPM 30-240	± 2% Sat. ± 3% Sat. ± 2 BPM
Datex	Datex-Ohmeda oximeters, S/5 monitors (Ohmeda SpO2 option) ***(**SpO2 software 1990--2001 ± 5% accuracy)***	Sat. 80%-100% BPM 25-240 Sat. 70%-79% BPM 30-240	± 2% Sat. ± 3 BPM ± 3% Sat.** ± 5 BPM
BCI	BCI and Smith Medical oximeter	Sat. 80%-100% Sat. 70%-79% BPM 30-240	± 2% Sat. ± 3% Sat. ± 2 BPM
M-Rainbow	Compatible with Masimo rainbow® Test Sensor ***NOTE:*** *Test Sensor must be purchased from Masimo* ***(*** At 100% Perfusion Level only)***	Sat. 70%-100% BPM 25-240	± 2% Sat.*** ± 3 BPM
Phlip/HP	HP and Viridia brand monitors	Sat. 80%-100% Sat. 70%-79% BPM 30-240	± 2% Sat. ± 3% Sat. ± 3 BPM
GE-TufSat	GE TuffSat oximeters	Sat. 80%-100% Sat. 70%-79% BPM 40-240	± 2% Sat. ± 3% Sat. ± 3 BPM
Other 2.0	Creative Medical, Pulxy, Datex Ohmeda (SpO2 SW ver. Dated 2001-2005), Novametrix and low signal intensity oximeters	Sat. 80%-100% BPM 30-240	± 2% Sat. ± 3 BPM

1- Autoprobe is not compatible with Nonin PurSat, GE-TuffSat, Masimo rainbow, BCI. When testing those devices, select manufacturer probe type for best performance.
2- Spacelabs monitors should be tested at minimum 50% Perfusion Level.

IMPORTANT: *Some oximeters may not display results within OxSim Flex specifications at perfusion index values below 60%. Contact manufacturer of oximeter regarding expected performance at low perfusion before testing at lower perfusion levels.*

Note: *Probe setting to select depends on sensor rather than the monitor. Example: some Philips/HP monitors can use either the cocoa brown sensor or a Nellcor sensor. In this case, you would need to use the Phlip/HP setting using the cocoa sensor, but the Autoprobe setting when using a Nellcor sensor.*

10. **Creating/Editing Preset Simulations.** OxSim Flex can be programmed to store user defined preset simulations for saturation, heart rate and perfusion index. Up to (10) preset simulations can be stored on the unit.

With the unit running on battery power only, move power switch to the OFF position, then press and hold the UP ⇧ arrow key while moving power switch to ON position until you see the Settings screen as shown below.

EDIT EXISTING PRESET

1) Select EDIT PRESETS and then press the yellow button.
2) The OxSim Flex will display “Hold yellow button to save all presets”. Press yellow button to confirm message.
3) For editing existing Preset, select preset you want to edit using the
4) UP/DOWN arrow keys, and then select the parameter to edit by pressing the yellow button.
5) Press and hold the yellow key to save changes.
6) Press yellow button to OK changes made.
7) If you want to change other presets, repeat step 1 – 6 above.
8) When you have made all the changes you would like, press and hold the yellow button the exit back to simulation mode or power cycle the unit.

ADD PRESET

1) Using ⇩ Key and scroll until you see a preset where the saturation value=0%
2) Press the yellow button to select the parameter to edit then use UP/DOWN arrow keys to change to desired value.
3) Press and hold the yellow button to save new preset.

4) Press yellow button to OK changes made.
5) Repeat steps 1-4 to add additional presets. Up to (10) Presets.
6) Press and hold the yellow button to return to simulation mode or power cycle the unit.

DELETE PRESET

1) Using the UP/DOWN arrow keys, locate the Preset you wish to delete.
2) Press the yellow button to Edit sat., and then change value to 0%.
3) Press and hold the yellow button to save changes.
4) Press yellow button to OK changes made.
5) Repeat steps 1-4 to delete additional presets.
6) Press and hold the yellow button to return to simulation mode or power cycle the unit.

11. **Testing Masimo rainbow® SET -** The OxSim Flex can be utilized in combination with the Masimo Test Sensor to verify operation of oximeters configured with Masimo rainbow SET for SpO2, Total Hemoglobin, Oxygen Content, Pleth Variability Index, Methemoglobin and Carboxyhemoglobin. The Masimo Test Sensor is a sensor utilized to simulate the above mentioned rainbow SET parameters and can be purchased from Masimo Corporation.
    A. Connect Masimo rainbow test sensor to Masimo oximeter configured for rainbow SET.
    B. Power up the OxSim Flex and configure probe type to M-Rainbow as described in Section 8.
    C. Connect Masimo Test Sensor to OxSim Flex. Select desired SpO2 saturation and pulse rate. The Test Sensor will simulate the rainbow Set parameters as specified on the Test Sensor Data Sheet.

    NOTE: *Perfusion Index must be set to 100% for proper operation of simulation when using Masimo Test Sensor.*

Battery Operation and Power Save Mode

1. **Battery Level Indicator.** The unit will perform active SpO2 simulations for approximately 10 to 12 hours on a single AA battery, depending primarily on the brightness of the light emitted by the oximeter under test. There are four battery level indicators:

When the battery is depleted, the battery indicator will have zero bars.
NOTE: *When the battery indicator is zero bars, the unit may appear to operate*

correctly, but may reset and/or provide invalid simulations when a SpO2 sensor is attached.

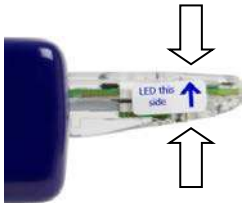
2. **Power Save Mode.** When no sensor is connected and no key presses, to the OxSim Flex for ten minutes, it shuts itself off to save power. To turn it back on, you can press any key.

   ***NOTE:** The OxSim Flex will reset back to the default when reinitialized after a power save.*

Optimal Durable Sensor Placement Directions

Most sensors will work best when fully inserted all the way onto the OxSim Flex 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 LED (light source) with the arrow on the finger label, as shown below.

MOST DISTAL INPUT AREA



HIGHEST OUTPUT AREA

Optimal Disposable Sensor Placement Directions

Disposable sensors should be placed by first positioning the sensor's LED (light source) in alignment with the arrow on the finger label, as shown above. Wrap the rest of the sensor around the finger so that the sensor's detector is opposite the LED, as shown in the figure above labeled "Highest Output Area." The further onto the bottom side of the OxSim Flex the detector is placed, the less leakage light there will be. Both photo detector and LED should be well centered between the two sides of the unit'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 unit. 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 Flex, 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 Flex by simply installing the sensor all the way into the unit'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.

SpO2 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 O2 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 that the output of the light sources might not be consistent and the output of the 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= (RedAC/RedDC)/(IRAC/IRDC)

SpO2 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 unit 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.
Sensor placement can be an issue because depending on sensor placement, some of the light from the sensor's LEDs is not blocked by the OxSim Flex, but rather leaks around it and finds its way directly to the sensor's receiving photo diode. To understand this better we can rewrite our equation for R as:

R= (RedAC/ IRAC) * (IRDC/ RedDC)

R can also be viewed as the AC ratio times the DC ratio. Both IR AC and Red AC signals come entirely from the unit, so sensor placement is not an issue with them, but the DC signals are the sum of the DC signals produced by the OxSim Flex 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 Flex's input circuitry matches that of the sensor and the same percentage of Red and IR light leak around the unit. Unfortunately, different models of sensors have different relative sensitivity and while the OxSim Flex 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 unit'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 unit'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 Flex by placing it near the brightest part of the unit's output area, its' Highest Output Area.

Troubleshooting Tips

Symptom	Solution
Unit resets when sensor is attached	Low battery: replace battery or connect to external DC power adaptor.
Oximeter does not display waveform or numerical values.	1. Make sure the LED of the sensor is placed on the front side of the OxSim Flex. 2. Sensor may be defective. Test with another sensor. 3. Ensure sunlight is not interfering with operation.
Saturation values inaccurate	1. Verify proper Probe Type selected. See page 7. 2. Verify proper placement of sensor . See page 9. 3. Verify excessive ambient light is not causing interference. 4. If Probe Type Changed, remove sensor from OxSim Flex, wait 10 seconds and reattach. 5. If using 3rd party sensor, test oximeter with OEM sensor to verify.
Unit will not turn on to Home Screen	1. Verify not in Power Save Mode. Press any key to “wake up” OxSim Flex. 2. Reset the OxSim via the power switch. 3. Verify using a fresh battery.
Calibration Required Message Displayed	Contact Technical Support 800-541-9802.
Difficulty obtaining reading with Perfusion % below 100%	1. This mode is designed to simulate weak signals. Some oximeters may not be designed to operate at those perfusion levels. 2. Verify using original manufacturer’s sensor. 3. Verify sensor is not defective. 4. Test oximeter at Perfusion levels above 50%.
Unstable HR Heart Rates	1. Verify simulated heart rate is within Oximeter specifications. 2. Verify Perfusion index within Oximeter specifications. Try changing PI to 100% to verify.
Unable to resolve problem	Contact Pronk Technologies Technical Support. **800-541-9802**

OxSim Flex Limited Warranty

The OxSim Flex OX-2 SpO2 simulator is warranted against defects in materials and workmanship for a period of forty eight (48) 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 Flex 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.

Calibration

Pronk Technologies recommends annual calibration of the OxSim Flex. Please call for pricing.