Operator's Manual

O3® Regional Oximeter

Masimo

For Sale in the USA.

These operating instructions intend to provide the necessary information for proper operation of the O3® Regional Oximeter System (O3® System) which consists of the O3® Module and O3® Sensor. There may be information provided in this manual that is not relevant for your system. General knowledge of pulse oximetry and an understanding of the features and functions of the O3® Regional Oximeter are prerequisites for proper use. Do not operate the O3® Regional Oximeter without completely reading and understanding these instructions.

Notice: Purchase or possession of this device does not carry any express or implied license to use with replacement parts which would, alone or in combination with this device, fall within the scope of one of the relating patents.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions, and adverse events.

This Operator's Manual describes how O3® Module information is displayed when used with O3® Sensor(s) and Root®, including display details as well as accessing and changing user-configurable settings. For additional information related to Root, refer to the Operator's Manual for Root. For additional information related to O3® Sensor, refer to the Directions for Use for O3® Sensor.

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About this Manual

This manual explains how to set up and use the O3® Regional Oximeter System (O3® System), which consists of the O3® Module and O3® Sensor. Important safety information relating to general use of the O3® System appears in this manual. Read and follow any warnings, cautions, and notes presented throughout this manual. The following are explanations of warnings, cautions, and notes.

A warning is given when actions may result in a serious outcome (for example, injury, serious adverse effect, death) to the patient and user. The following is an example of a warning:

WARNING: This is an example of a warning statement.

A caution is given when any special care is to be exercised by the patient and user to avoid injury to the patient and user, damage to this instrument or damage to other property. The following is an example of a caution:

CAUTION: This is an example of a caution statement

A *note* is given when additional general information is applicable. The following is an example of a note:

Note: This is an example of a note.

Product Description

The O3® Regional Oximeter System (O3® System), which consists of the O3® Module and O3® Sensor, is a patient-connected, noninvasive oximeter designed to continuously measure and monitor regional hemoglobin oxygen saturation in the tissue (rSO_2), including cerebral tissue. It can be used in any hospital and hospital-type facility where rSO_2 measurements might improve patient outcomes.

The O3® Regional Oximeter System (O3® System) should not be used as the sole basis for diagnosis or therapy.

Indications for Use

The non-invasive Masimo O3® Regional Oximeter System and accessories are indicated for use as an adjunct monitor of regional hemoglobin oxygen saturation of blood (rSO_2) in the cerebral region under the sensors in patients in healthcare environments. The O3® Regional Oximeter is only to be used with Masimo O3 sensors. The use of any other sensor is not supported or recommended by Masimo and could give erroneous results.

When used with the O3 Adult Sensor, the O3® Regional Oximeter is indicated for measuring absolute and trending regional hemoglobin oxygen saturation of blood (rSO_2) in adults ≥ 40 kg.

When used with the O3 Pediatric Sensor, the O3® Regional Oximeter is indicated for measuring absolute and trending regional hemoglobin oxygen saturation of blood (rSO_2) in pediatrics ≥ 5 kg and < 40 kg.

When used with the O3 Neonatal Sensor, the O3® Regional Oximeter is indicated for measuring only trending regional hemoglobin oxygen saturation of blood (rSO_2) in neonates < 10 kg.

Contraindication

There are no contraindications.

Safety Information, Warnings and Cautions

CAUTION: The O3® Regional Oximeter System is to be operated by, or under the supervision of, qualified personnel only. The manual, accessories, directions for use, all precautionary information, and specifications should be read before use. Refer to the Operator's Manual for Root for additional safety information, warnings and cautions.

Safety Warnings and Cautions

WARNING: Do not use the O3® Module if it appears or is suspected to be damaged.

WARNING: Only use O3® Module in conjunction with Root® and O3® Sensors. Do not use parts from other systems. Injury to personnel or equipment damage could occur.

WARNING: Do not adjust, repair, open, disassemble, or modify the O3® Module. Injury to personnel or equipment damage could occur.

WARNING: Do not start or operate the O3® Module unless the setup was verified to be correct.

WARNING: Do not use O3® Module during magnetic resonance imaging (MRI) or in an MRI environment.

WARNING: Explosion hazard: Do not use the O3® Module and O3® Sensor in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.

WARNING: To protect against injury, follow the directions below:

- Avoid placing the device on surfaces with visible liquid spills.
- Do not soak or immerse the device in liquids.
- Use cleaning solutions only as instructed in this Operator's Manual.
- Do not attempt to clean O3® Module while monitoring patient.

WARNING: As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

WARNING: Always verify the sensor description displayed correlates to the actual sensor application site on the patient.

Performance Warnings and Cautions

WARNING: The O3® Module may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.

WARNING: The O3® Module may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.

WARNING: The O3® Module may be used during defibrillation; however, the display may require up to 15 seconds to return to normal operation.

WARNING: The O3® Module is intended only as an adjunct device in patient assessment. It should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with clinical signs and symptoms.

WARNING: If the desired tissues cannot be palpated or visualized, it is recommended to use a secondary method of confirmation, such as ultrasound or X-ray.

WARNING: Optical measurements (rSO_2) can be affected by the following:

- Improper sensor application or use of incorrect sensor.
- Intravascular dyes such as indocyanine green or methylene blue or externally applied coloring (such as indelible ink).
- Venous congestion and pooled blood under the skin.
- Moisture, birthmarks, skin discoloration or foreign objects (e.g. metal plate) in the light path.
- Elevated level of total bilirubin.
- A physiological condition that may effect vasomotor tone or changes in vasomotor tone.
- Excessive ambient light, high intensity light, or direct sunlight.
- Adjacent placement of optical sensors that are not connected to the same O3® Module.
- Abnormal venous pulsations (e.g. tricuspid value regurgitation, Trendelenburg position).

WARNING: Inaccurate rSO_2 readings or no rSO_2 readings may be caused by:

- Anemia or low hemoglobin concentrations.
- Hemoglobinopathies (qualitative defects including sickle cell) and Hemoglobin synthesis disorders (Quantitative defects such as Thalassemias).
- Elevated COHb and/or MetHb levels.
- Non-normocapnic conditions or other conditions that affect blood volume.
- Hypotension, severe vasoconstriction, or hypothermia.
- Induction of extracranial hypoxia-ischemia.
- Cardiac arrest.
- Electrosurgical interference.
- Excessive induced motion.

WARNING: For patients experiencing complete bilateral External Carotid Artery (ECA) occlusion, rSO_2 measurements may be lower than expected.

CAUTION: To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time the O3® Module is used.

CAUTION: Do not place the O3® Module on electrical equipment that may affect the device, preventing it from working properly.

CAUTION: To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to the O3® Module.

CAUTION: Reset Baseline for each new patient monitored, if applicable.

CAUTION: rSO_2 readings represent a small volume of tissue beneath the O3® Sensor site and may not reflect oxygenation elsewhere.

CAUTION: High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of the sensor.

CAUTION: Replace the sensor when a *Replace Sensor* message is consistently displayed while monitoring consecutive patients after completing the Replace Sensor troubleshooting steps listed in the troubleshooting section.

CAUTION: Check the sensor site periodically for circulatory status. Each patient's sensitivity to the O3® sensors may vary depending on their medical status or condition of their skin.

Note: The value of rSO_2 data from the system has not been demonstrated in specific disease states, under conditions of hemoglobinopathies or clinical conditions that may affect blood volume, or under hypocapnic and hypercapnic conditions.

Note: The O3® system is intended for the monitoring of rSO_2 in the cerebral region under the sensors. Other Body Sensor Sites selections are for reference only and are not intended for patient monitoring.

Note: The O3® Sensor duration of use is dependent on the condition of the sensor site and patient's skin integrity and sensor adhesion quality. The O3® Sensor has been biocompatibility tested for the intended continuous use up to 72 hours.

Note: Cables and sensors are provided with X-Cal® technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Cable or Sensor DFU for the specified duration of patient monitoring time.

Cleaning and Service Warnings and Cautions

WARNING: Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the O3® Module. These substances affect the device's materials and device failure can result.

WARNING: A functional tester cannot be used to assess the accuracy of the O3® Module.

CAUTION: Do not submerge the O3® Module in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the O3® Module.

CAUTION: An operator may only perform maintenance procedures specifically described in the manual. Refer servicing to qualified service personnel trained in the repair of this equipment.

Compliance Warnings and Cautions

WARNING: Changes or modifications not expressly approved by Masimo shall void the warranty for this equipment.

CAUTION: Disposal of product - Comply with local laws in the disposal of the device and/or its accessories.

CAUTION: For FCC compliance information, refer to the Operator's Manual for Root.

Note: Use the O3® Module in accordance with the *Environmental Specifications* section in the Operator's Manual.

Chapter 1: Technology

The principle of operation for the O3® Module System (O3® System) is as follows:

Overview

The O3® Regional Oximeter System (O3® System) operating principle is based on multi-distance diffuse reflectance spectroscopy. The O3® System uses light to examine a cross-section tissue microvasculature (a mixed bed of arterioles, capillaries, and venules) and analyzes the light returned after having passed through the tissues.

Principles of Beer-Lambert Law and Regional Oximetry

The Beer-Lambert Law describes the attenuation of light through a medium as a function of the path length (or distance) and the absorption coefficient of the medium. The Beer-Lambert Law may be written as:

$$I = I_0 e^{-\mu_a \Delta}$$

In the above equation, I_0 is light intensity at the source, and I is light intensity after having traveled a distance of Δ in a medium with an absorption coefficient of μa.

The human body is opaque to most visible light frequencies, yet it is more transparent to red and infrared light. Moreover, light absorptions of oxygen-related chromophores, such as oxygenated and deoxygenated hemoglobin, vary as a function of wavelength in the near infrared spectrum, as shown in Figure 1. Therefore, if the level of oxygenation in the tissue changes, optical characteristics of the tissue also change according to the concentrations of oxygenated and deoxygenated hemoglobin. This absorption of light by the chromophore concentrations forms the basis of measurement of oxygen saturation, defined as the ratio of oxygenated hemoglobin to total hemoglobin.

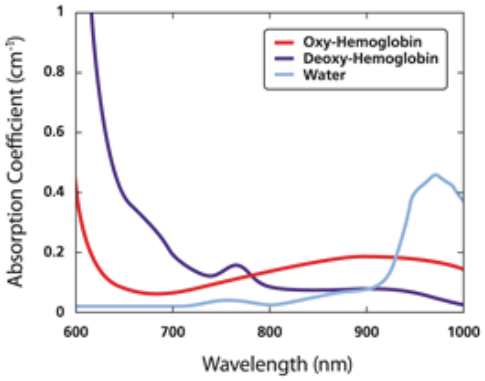


*Figure 1: Absorption coefficients of tissue chromophores in the NIR spectrum**

Masimo's O3® Regional Oximeter consists of a light emitter and multiple detectors. By emitting multiple wavelengths of light (LEDs), which pass through the region of interest, and measuring them (using photo-detectors) after they have traveled through the tissue, the system calculates attenuation experienced by each wavelength. These optical attenuations are then mapped to rSO_2.

* Beard P. Biomedical photoacoustic imaging. Interface Focus 2011; 1:602-631.

Components of the Regional Oximetry System

The Masimo O3® Regional Oximetry System uses a common emitter and at least two (2) detectors that are spaced apart from each other and are at different distances relative to the emitter. In the case of a two-detector system, as in Figure 2, the detectors may be known as:

- *Shallow detector*: This detector is closer to the emitter (LEDs) and receives the optical signal traveled through relatively superficial (shallow) section of tissue.
- *Deep detector*: This detector is farther from the emitter and receives optical signal traveled deeper into the tissue, in addition to passing through superficial layers.

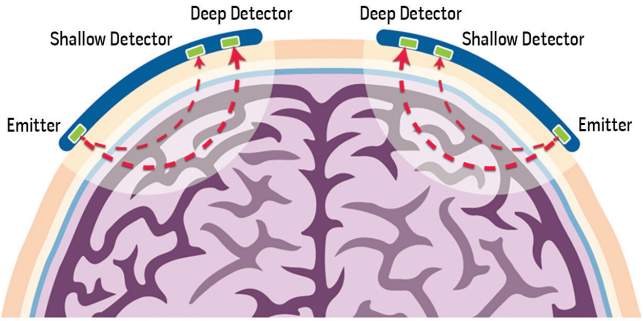


Figure 2: Schematic of an example of a regional oximeter sensor measuring deep tissue oxygenation.

This geometry leads to the following relationships that allow the calculation of rSO_2 in the deep tissue.

1. Optical signals received at the same detector have traveled the same path. However, due to their different wavelengths, their attenuations are different, as light absorption depends on the wavelength. (In the Beer-Lambert Law, it leads to *different* μa and *same* Δ.)
2. Optical signals of the same wavelength received at different detectors see the same tissue absorption coefficient, but experience different attenuation due to the different paths they have traveled. (In the Beer-Lambert Law, it leads to *same* μa and *different* Δ.)

Deep tissue oxygenation can therefore be calculated by subtracting the effects of shallow tissue from deep tissue via manipulating signals received at the deep and shallow detectors.

Chapter 2: System Description

The O3® Regional Oximeter System (O3® System) is comprised of three (3) components:

- Root®
- O3® Module
- O3® Sensor(s)

Up to two (2) O3® Sensors can be connected to a single O3® Module.

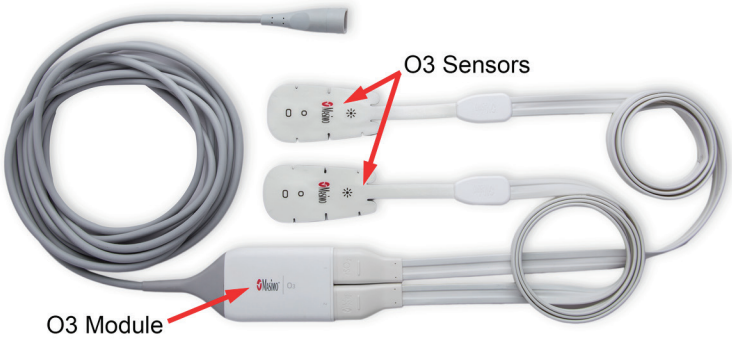
Up to two (2) O3® Modules can be connected to Root®.

Root

Root® displays parameters and trends that relate to regional oxygen saturation (rSO_2).

For more information about Root®, see Operator's Manual for Root®.

O3® Module and O3® Sensor



The O3® System consists of the O3® Module and O3® Sensors.

The O3® Sensors comprise of LED components that collect physiological signals. The O3® Module includes Masimo technology for processing the signals which result in rSO_2 measurements. In turn, these measurements are displayed on the Host/Backboard device.

The O3® Sensors are a single-patient use adhesive sensor, which comprises of a single emitter and two detectors. For more information about the O3® Sensor series, see Directions for Use for the O3® Sensor series.

Chapter 3: Setting Up the O3® System

For initial use of the O3® System, the following setup instructions must be followed.

Unpacking and Inspecting the System

1. Remove the components from the shipping carton and examine them for signs of shipping damage.
2. Check all materials against the packing list. Save all packing materials, invoice and bill of lading. These may be required to process a claim with the carrier.
3. If anything is missing or damaged, contact the Masimo Technical Service Department.

Preparation for Use

Prior to using the O3® System for monitoring

1. Confirm that you have all system components:
   - Root®
   - O3® Module
   - O3® Sensor(s)
2. Confirm that Root® holds adequate battery power.

Connecting the O3® Module to Root®

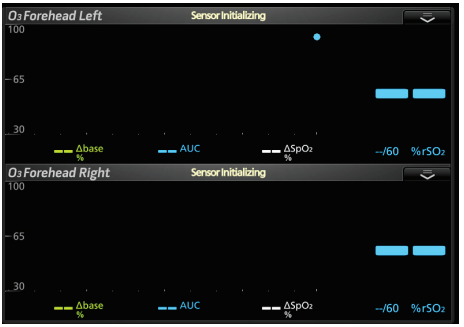
Up to two (2) O3® Modules can be connected to Root®.

To connect a Module to Root®:

1. Identify the Masimo Open Connect (MOC-9®) connector on the O3® Module, as illustrated in the image below.

2. Insert the MOC-9® connector securely into a MOC-9® Port on Root®, as illustrated in the image below.

3. The module is now activated. This is verified when the O3® Module window displays on Root® with all parameters and measurements dashed out because no O3® Sensor has been connected to the module.



For more information on the O3® Module window, see ***The O3® Module Window*** on page 22.

Repeat the steps above for the second module if more than two (2) O3® Sensors are intended to be used.

Connecting the O3® Sensor(s) to the O3® Module

Up to two (2) O3® Sensors can be connected to each O3® Module. The two (2) connections are symmetrical in orientation and clearly marked "1" and "2" on the module.

To connect an O3® Sensor to an activated O3® Module:

1. Apply sensor on the patient. For more instructions on applying the sensor on the patient, see the *Directions for Use* for the O3® Sensor series.
2. Once the sensor(s) has been properly applied on the patient, identify the connector end on the sensor, illustrated in the image below.

3. Align the connector with the appropriate sensor connection on the module, as illustrated in the image below. Note the markings of "1" and "2" above the connections.

1 - Left Forehead

2 - Right Forehead

4. Insert the connector securely into the sensor connection. Note that "1" is defaulted to the left forehead and "2" is defaulted to the right forehead. The sensor site selection can be modified by accessing the Site Selection menu. For information on how to access the Site Selection menu, see ***The O3® Module Window*** on page 22.
5. Press the *Home* button on the touchscreen to return to the main display.

Chapter 4: Operation

The following sections describe how O3® Module information is displayed when used with Root®, including display details and user-configurable settings. For additional information on Root®, see Operator's Manual for Root®.

Regional Oxygenation Information

Regional Oxygenation (rSO2)

rSO_2, measured in percentage (0 to 99%), is the regional tissue oxygenation level in the deep tissue local to the sensor site.

AUC Index (Area under the Curve)

AUC, measured in % · minutes, is displayed as an index which quantifies the duration and depth of patient's stay below the user-defined rSO_2 low alarm limit (LAL). Duration (minutes) refers to the amount of time the patient stays below the rSO_2 LAL. Depth (%) refers to the gap between the patient's rSO_2 level and the rSO_2 LAL. AUC increases only when rSO_2 level drops below the selected LAL.

Baseline

This feature is displayed when Set Baseline has been enabled. To enable this option see ***Baseline View*** on page 25.

Baseline rSO_2 displays the user-defined baseline value for rSO_2. Baseline is also shown as a triangular pointer on the y-axis of the trend display for rSO_2.

Note: When the sensor is on the patient, the baseline rSO_2 value defaults to the current rSO_2 value. When the sensor is not on the patient, the Baseline rSO_2 value defaults to a minimum value of 10%.

Delta Baseline (Δbase)

This feature is displayed when Set Baseline has been enabled. To enable this option see ***Baseline View*** on page 25.

Δbase, measured in percentage, is the relative decrease in rSO_2 with respect to baseline rSO_2.

Delta SpO2 (ΔSpO2)

About

An informational read-only screen appears with the following definition for ΔSpO_2 Settings:

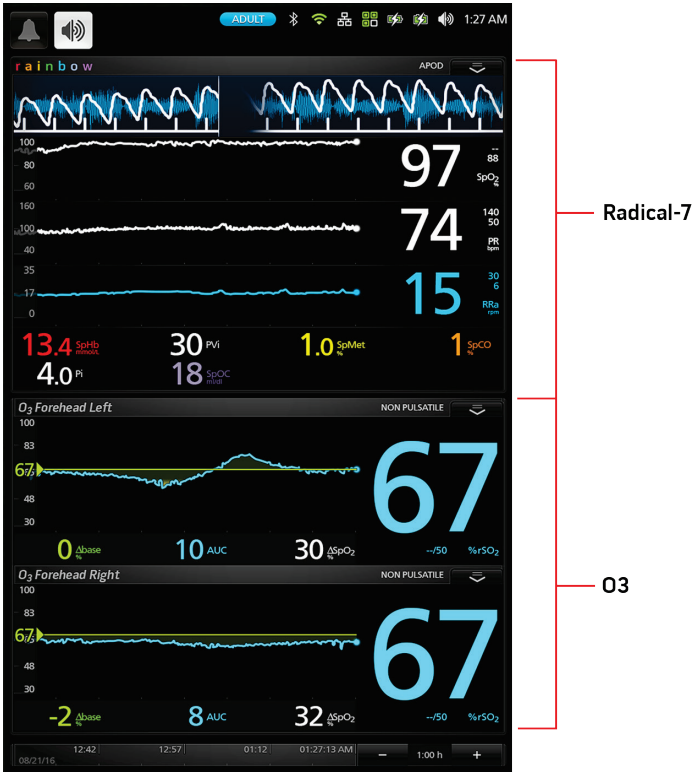
Delta SpO_2 (ΔSpO_2), displayed as a percentage, is the calculated difference between rSO_2 and SpO_2. Source of SpO_2 is the peripheral SpO_2 (using a pulse oximeter, if available), depending on user selection.

The O3® Module Window

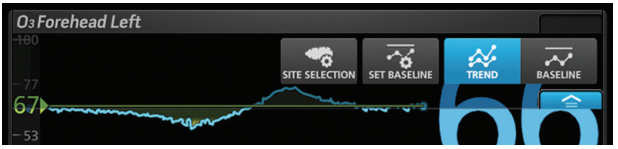
When an O3® Module is connected to Root, O3® Module parameters and measurements display in the O3® Module window as numeric values with graphical representations. Each O3® Sensor connected will generate a separate O3® Module window, with the Sensor Label displayed in the name of the window.

When multiple technologies are connected to Root®, each technology's parameters are displayed in an individual window. The relative size of each window can be configured using the *Layout* feature, which is accessible by pressing the "Layout" icon in the Main Menu. For more information, see Operator's Manual for Root®.

In the image below, Masimo Radical-7 Pulse CO-Oximeter parameters and measurements are displayed in the rainbow window; and O3® Module parameters and measurements are displayed in a separate O3® Module window.



At the top-right corner of each O3® Module window, there is an action menu which allows you to display options and access the site selection and set baseline menus for each O3® Sensor.



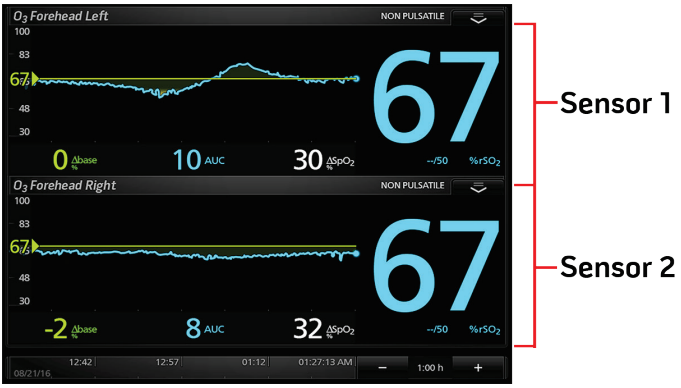
Display Options

There are two (2) display options available:

1. Trend View
2. Baseline View

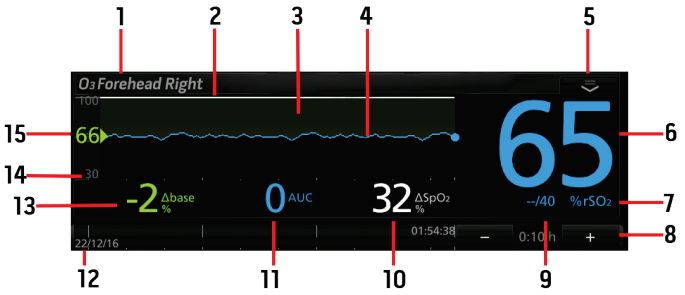
Trend View

Trend View is the default viewing option for an O3® window. The trend view displays rSO_2 trends. This view offers two (2) sensor displays for the two (2) O3® Sensors that can connect to the module, as illustrated in the image below. Note that each sensor display is distinguished by the Sensor Label on the top left corner of each window.



To enable/disable Trend View, tap the action menu on the top right corner of the O3® Module window. Press the *Trend* button to enable or disable Trend View.

Each sensor display shows a multitude of information about O3® Module parameters and measurements and also allows the user to customize how the information is displayed. The various portions of a sensor display are outlined in the illustration and each portion is explained in more detail in the table below.



Ref.	Feature	Description
1	Sensor Label	Label identifies the sensor site that corresponds to the application site of the O3® Sensor.
2	SpO_2 Trend Line	Displays SpO_2 level from the peripheral SpO_2 sensor site over time[1].
3	ΔSpO_2 Region	Displays the difference between levels of SpO_2 (peripheral SpO_2 sensor site) and rSO_2 of the O3® Sensor site over time.
4	rSO_2 Trend Line	Displays rSO_2 level of the O3® Sensor site over time.
5	Action Menu	Allows user to change display options and access the site selection and set baseline menus for each O3® Sensor.
6	rSO_2 Value	Indicates the current rSO_2 level of the O3® Sensor site. Press the value to access the rSO_2 menu.
7	%rSO_2	Indicates the unit of measurement for rSO_2 .
8	Time Frame Configurator	Displays the current time frame of trending shown. Press "-" to shorten and "+" to lengthen the time frame of the trending displayed.
9	rSO_2 Alarm Limits	Indicates the selected high and low limit values which triggers an rSO_2 alarm. Press the value to access the rSO_2 menu.
10	ΔSpO_2%	Displays the difference between levels of SpO_2 (peripheral SpO_2 sensor site) and rSO_2 of the O3® Sensor site.

Ref.	Feature	Description
11	AUC	Displays the Area Under the Curve cumulative index.
12	Timeline	Displays timestamps and corresponding date.
13	Δbase%	Displays the current difference between levels of rSO_2 and selected baseline rSO_2. Also displays the unit of measurement (%). Press the value to access the Delta Baseline menu.
14	Y-axis	Shows the current view range for rSO_2. Press the axis to customize the viewing range for rSO_2.
15	Baseline Indicator	Indicates the baseline rSO_2 value selected by the user.

[1] From the pulse oximetry sensor connected to the Radical-7® in the Root device.

Baseline View

In the Baseline view, the baseline rSO_2 is seen as a horizontal green line across the entire trend display. To enable/disable Baseline View, tap the action menu on the top right corner of the O3® Module window. Press the *Baseline View* button to enable or disable Baseline View.

Ref.	Feature	Description
1	Baseline Indicator	Indicates the baseline rSO_2 value selected by the user.
2	Baseline	Displays Baseline across the Trend area.

The Baseline View is displayed only when Set Baseline has been enabled. The Baseline can be enabled in two (2) ways:

1. Tap the action menu on the top right corner of the O3® Module window. Press the *Set Baseline* button to enable the baseline for the sensors.

   Or

2. Press the "Gear" icon on the lower right corner of the main window of Root® to access the Main Menu, then press the "O3" icon to access the O3® Module Menu and select the Set Baseline menu. In the Set Baseline menu, select Enable. Press Ok to confirm and press the *Home* button to return to the Main Window.

CAUTION: Reset Baseline for each new patient monitored, if applicable.

Note: Configuration for this option does not hold through power cycle.

Site Selection Menu

Note: The O3® system is intended for the monitoring of rSO_2 in the cerebral region under the sensors. Other Body Sensor Site selections are for reference only and are not intended for patient monitoring.

When the connector end on the O3® Sensor is first inserted into the O3® Module, "1" is defaulted to the left forehead and "2" is defaulted to the right forehead. The sensor site selection can be modified by accessing the Site Selection menu.

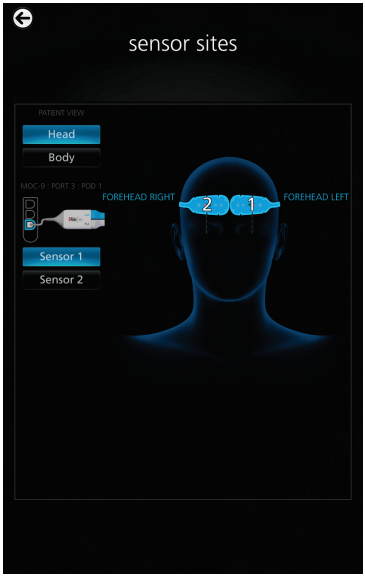
There are two (2) ways to access this menu:

1. To access this menu tap the action menu on the top right corner of the O3® Module window. Then press on the *Site Selection* button.

   Or

2. Press the "Gear" icon on the lower right corner of the main window of Root® to access the Main Menu, then press the "O3" icon to access the O3® Module Menu and select the *Site Selection* Menu.

When the Site Selection menu is accessed, the sensor site screen displays on Root®, as illustrated below:

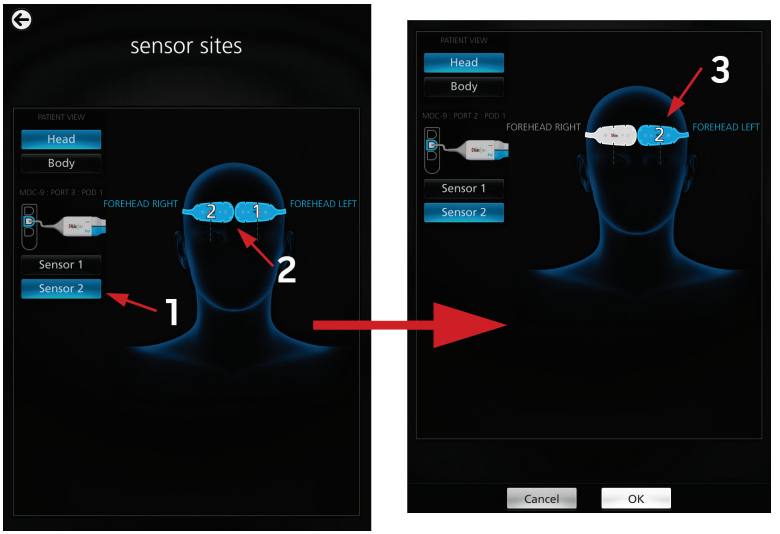


Select the *Head* or *Body* buttons at the upper left corner of the screen to switch between Head and Body Patient View site selection menus.

Note: Sensor icons appear white when not selected and blue (with the corresponding sensor number) when selected.

Head Patient View

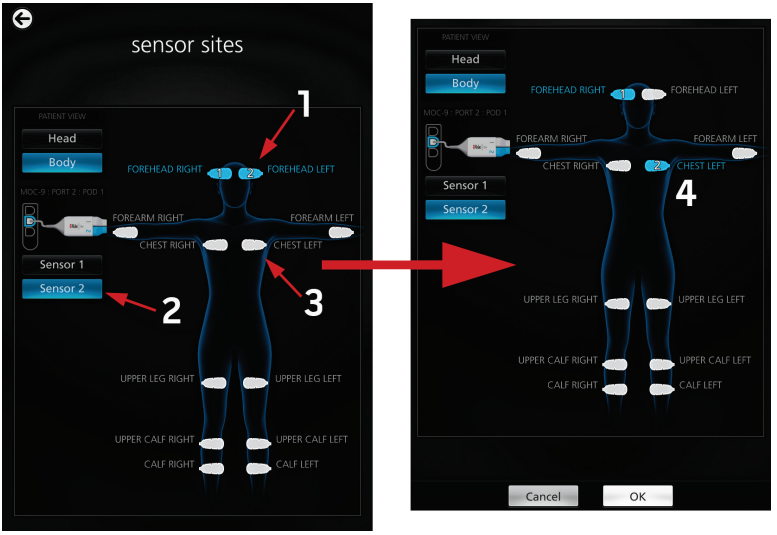
Head is the default view when Site Selection is displayed.



Ref	Description
1	Choose either sensor "1" or sensor "2" to change sensor site location. Only the selected sensor location can be changed. Note that "1" is defaulted to Forehead Left and "2" is defaulted to Forehead Right.
2	Touch the new desired sensor site location in the image. The sensor site can be on the left, or right side of the body.
3	The new sensor site location will be displayed. Select OK to confirm the change. Repeat this process for the corresponding sensor as necessary. Press the *Home* button to return to the Main Screen.

Body Sensor Sites

Select Body in the upper left corner of the screen to switch to the Body Sensor Site locations display.



Ref	Description
1	Current location of sensor "1" and sensor "2" (Head).
2	Choose either the *Sensor 1* or *Sensor 2* button to select the sensor and change sensor site location. Only the selected sensor can be changed.
3	Touch the new desired sensor site location in the image. The sensor site can be on the left, or right side of the body.
4	The new sensor site location will be displayed. Select OK to confirm the change. Repeat this process for the corresponding sensor as necessary. Press the *Home* button to return to the Main Screen.

Display and Alarm Settings

There are two (2) ways to configure all parameter display and alarm settings:

1. Press the parameter icon in the O3® Module window of the specific sensor. This will take you directly to the settings options for the parameter. Select the appropriate setting and press Ok to confirm. Press the *Home* button to return to the main screen.

   Or

2. Press the "Gear" icon on the lower right corner of the main window to access the Main Menu. Then press the "O3" icon to access the O3® Module menu. In the O3® Module menu select the "POD" icon to access the sensor menu. Press the appropriate O3® Sensor for which to configure specific parameter display and alarm settings.

Below are the various setting options for each parameter.

Note: All setting options will hold through power cycle, unless otherwise stated.

rSO2 Settings

The following are the various setting options for rSO_2:

About

An informational read-only screen appears with the following definition for rSO_2:

rSO_2, displayed as a percentage (0 to 99%), is the measure of regional tissue oxygenation (at the deep tissue level) local to the sensor site.

Alarms

Option	Description	Factory Default	Configuration Options	Resolution
High Limit	Upper threshold of rSO_2 level that triggers an alarm.	Off	2% to 99% Off	1%
Low Limit	Lower threshold of rSO_2 level that triggers an alarm.	40%	1% to 98%	1%
Silence Duration	Duration of the temporary suspension of audible alarm for rSO_2 when the "Alarm Silence" icon is pressed on Root.	2m	30s, 1m, 2m, 5m	N/A

Trend

Option	Description	Factory Default	Configuration Options
Y-Axis Max	Maximum rSO_2 level displayed in Trends area.	100%	5% to 100%
Y-Axis Min	Minimum rSO_2 level displayed in Trends area.	30%	0 to 95%

Additional Settings

Option	Description	Factory Default	Configuration Options
Averaging Time	Length of time over which the system calculates the average of all data points.	8s	8s, 16s, 24s

AUC Settings

The following are the various setting options for AUC:

About

An informational read-only screen appears with the following definition for AUC Settings:

Area Under the Curve (AUC) (% · minutes), displayed as an index, quantifies the duration and depth of patient's stay below the user-defined rSO_2 low alarm limit (LAL). Duration (minutes) refers to the amount of time the patient stays below the rSO_2 LAL. Depth (%) refers to the gap between the patient's rSO_2 level and the rSO_2 LAL. AUC increases only when rSO_2 level drops below the selected LAL.

Additional Settings

Option	Description	Factory Default	Configuration Options
Reset AUC	Resets the AUC Index	N/A	Press Reset AUC to reset the value

Delta Baseline (Δbase) Settings

The following are the various setting options for Delta Baseline:

About

An informational read-only screen appears with the following definition for Delta Baseline Settings:

Relative deficit below baseline displayed as a percentage of the baseline rSO_2 level, is the difference between the user defined baseline rSO_2 level and current rSO_2 level.

Alarms

Option	Description	Factory Default	Configuration Options	Resolution
Delta Limit	Threshold of Δbase that triggers an alarm.	Off	Off -1% to -99%	1%
Silence Duration	Duration of the temporary suspension of audible alarm for Δbase when the "Alarm Silence" icon is pressed on Root®.	2m	30s, 1m, 2m	N/A

Delta SpO2 (ΔSpO2) Settings

About

An informational read-only screen appears with the following definition for ΔSpO_2 Settings:

Delta SpO_2 (ΔSpO_2), displayed as a percentage, is the calculated difference between rSO_2 and SpO_2. Source of SpO_2 is the peripheral SpO_2 (using a pulse oximeter, if available), depending on user selection.

Chapter 5: Errors and Alarms

Exception Messages

The table below lists the types of messages that can appear on Root® when using O3® Module and O3® Sensor.

Exception Message	Indication
Check Sensor Connection	The O3® Sensor may not be properly connected to the O3® Module.
Incompatible Sensor	The O3® Sensor connected to the O3® Module cannot be used with the O3® Module.
Interference Detected	Signal interference to the O3® Module has been detected.
Low Perfusion Index	The signal detected is too weak.
No Sensor Connected	The O3® Sensor is not connected, not fully inserted into the O3® Module.
Pulse Search	The O3® Module is searching for pulse.
Regional Oximeter Disconnected	The O3® Module has been disconnected from Root®.
Replace Sensor	The O3® Sensor is defective or sensor life has expired.
Sensor Initializing	The O3® Module is checking the connected O3® Sensor for proper functioning and performance.
Sensor Off Patient	The O3® Sensor is not applied on the patient, the sensor is not properly applied on the patient, or the sensor is damaged.

Alarms Messages

The table below lists the types of alarms that can appear on Root® when using O3® Module.

Alarm Message	Indication
Low rSO_2	rSO_2 level is below low limit.
High rSO_2	rSO_2 level is above high limit.
Low Δbase	rSO_2 level is less than the Delta Baseline low limit.
Low ΔSpO_2	SpO_2 level is less than the Delta SpO_2 low limit.

Chapter 6: Troubleshooting

To troubleshoot issues with Root®, see the Operator's Manual for Root®. To troubleshoot issues with O3® Sensor, see the *Directions for Use* for the O3® Sensor. If a problem persists, contact an Authorized Masimo Representative.

Troubleshooting O3® Module

Message Displayed	Possible Cause	Action
Regional Oximeter Disconnected	O3® Module disconnected from Root.	Plug in O3® Module to Root again.
No Sensor Connected	O3® Sensor is not be properly inserted into O3® Module.	Confirm that O3® Sensor is securely inserted into O3® Module. For more information about connecting O3® Sensor to O3® Module, see ***Chapter 3: Setting Up the O3® System*** on page 17 of the Operator's Manual.
	O3® Sensor may be defective.	Replace O3® Sensor.
	O3® Module may be defective.	Replace O3® Module.
Incompatible Sensor	O3® Sensor is not properly inserted into O3® Module.	Confirm that O3® Sensor is securely inserted into O3® Module. For more information about connecting O3® Sensor to O3® Module, see ***Chapter 3: Setting Up the O3® System*** on page 17 of the Operator's Manual.
	O3® Sensor may have expired.	Confirm the expiration date of the O3® Sensor has not passed.
	O3® Sensor may be defective.	Replace O3® Sensor.
	O3® Module may be defective.	Replace O3® Module.
Replace Sensor	O3® Sensor may be defective or sensor lifetime has been depleted.	Replace O3® Sensor.
Sensor Off Patient	O3® Sensor is not properly applied on the patient.	Confirm that O3® Sensor is properly applied on the patient. For more information, see *Directions for Use* for the O3® Sensor.

Message Displayed	Possible Cause	Action
	O3® Sensor may be defective.	Replace O3® Sensor.
	O3® Module may be defective.	Replace O3® Module.

Chapter 7: Specifications

Display Ranges and Resolution

Parameter	Range	Resolution
rSO_2	0 to 99%	1%
ΔSpO2	0 to 99%	1%
Δbase	-100 to 890%	1%
AUC	0 to 9999	1 minute-%

Accuracy (ARMS)*

Regional Hemoglobin Oxygen Saturation of Blood (rSO_2)		
rSO_2 (trending) (from 45% to 85% $SavO_2$)	Adult [1], Pediatric [2], Neonate	3%
rSO_2 (absolute) (from 45% to 85% $SavO_2$)	Adult [1]	4%
	Pediatric [2]	5%

* ARMS accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell between +/- ARMS of the reference measurements in a controlled study.

Note: ARMS is indicative of use with the adult O3 Sensor >40kg only for adult patients, the pediatric O3 Sensor ≥5 kg to <40 kg only for pediatric patients and with the infant and neonatal O3 Sensor <10kg only for infant and neonatal patients.

Environment

O3® Module Operating Conditions

Item	Description
Operating Temperature	32˚F to 104˚F (0˚C to 40˚C)
Operational Humidity	10% to 95%, non-condensing

O3® Module Storage

Item	Description
Storage Temperature	-40˚F to 158˚F (-40˚C to 70˚C)
Storage Humidity	10% to 95%, non-condensing
Atmospheric pressure	range of 500 to 1060 mBar at ambient temperature and humidity

Physical Characteristics of the Module

Item	Description
Width	2 inches max. (5.1 centimeters)
Length	13 feet max. Cable and Pod (4 meters)
Thickness	1 inch max. (2.5 centimeters)
Weight	7 oz. max. (200 grams)

Symbols

The following symbols may appear on the product or product labeling:

Symbol	Description	Symbol	Description
	Follow instructions for use		Consult instructions for use
CE 0123	Mark of conformity to European medical device directive 93/42/EEC	IPX1	Protection against vertically falling water drops
	Type BF applied part		Non-Sterile

Symbol	Description	Symbol	Description
	Separate collection for electrical and electronic equipment (WEEE)		Recyclable
Rx ONLY	**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.	EC REP	Authorized representative in the European community
	Federal Communications Commission (FCC) Licensing	FCC ID:	Identifies unit has been registered as a radio device
	Non-ionizing electromagnetic radiation	IC Model:	Industry Canada Identification
	Warning, electricity		Biohazardous Waste
	Electrostatic	 SpO_2	Not for continuous monitoring (No alarm for SpO_2)
	No parameter alarms		Product contains no PVC (polyvinyl chloride) material
	Caution		Not made with natural rubber latex
	Manufacturer	REF	Catalog number (model number)
	Date of manufacture YYYY-MM-DD	####	Masimo reference number
	Storage temperature range	SN	Serial number

Symbol	Description	Symbol	Description
	Keep dry		Fragile, handle with care
	Storage humidity limitation		Do not use if package is damaged
	Atmospheric pressure limitation		Equipotential Ground Terminal
	AC current		Nurse Call Interface
	Fuse		SatShare Interface
	Stand-By		Wireless Symbol level
	RS-232 Interface		Wireless features can be used in member states with the restriction of indoor use in France -Class 2 wireless device
	Analog Out Interface		Iris Connection
	USB port		Ethernet
	Less than		Greater than
	China Restriction of Hazardous Substances		The names and content of the toxic and hazardous substances or elements shall be provided in the product instruction manual.

Symbol	Description	Symbol	Description
	Instructions/Directions for Use/Manuals are available in electronic format @ http:www.Masimo.com/TechDocs **Note:** eIFU is not available in all countries.		

Guidance and Manufacturer's Declarations

Safety Classifications

1. **Type of Protection against Electric Shock of the O3® Module**

   Class II: Electrical equipment in which protection against electric shock does not rely on BASIC INSULATION only, but in which additional safety precautions such as DOUBLE INSULATION or REINFORCED INSULATION are provided, there being no provision for protective earthing or reliance upon installation conditions.

2. **Degree of Protection against Electric Shock of the O3® Module with O3® Sensor**

   An F-type applied part is isolated from all other parts of the equipment to such a degree that the patient leakage current allowable in single fault condition is not exceeded when a voltage equal to 1.1 times the highest rated AC supply voltage is applied between the applied part and earth.
   Root® incorporates circuitry, creepage and clearance distances from the mains in accordance with EN 60601-1. Root® and the sensor provide patient isolation.

3. **Degree of Protection against the Ingress of Liquid**

   Both Root® and the O3® Module have an ingress of liquid rating of IPX1 (drip proof).

4. **Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide**

   Equipment not suitable for use in the presence of a flammable anesthetic mixture with air, or with oxygen or nitrous oxide.

5. **Mode of Operation of the O3® Module**

   Continuous: The O3® Module may be operated under normal load for an unlimited period, without the specified limits of temperature being exceeded.

Safety Compliance

Safety Compliance
ANSI/AAMI ES 60601-1
EN/IEC 60601-1, 3rd Ed.
EN/ISO 80601-2-61

EMC Compliance

EMC Compliance
See Operator's Manual for Root®.

Citations

[1] Absolute and trending rSO_2 (ARMS) accuracy were determined by testing on healthy adult volunteers with light to dark pigmentation in the range of 45% to 85% $SavO_2$ against 30% arterial and 70% jugular venous blood oxygen saturations, measured with a laboratory CO-Oximeter.

[2] Absolute rSO_2 accuracy (ARMS) was determined by testing on pediatric patients ≥5 kg, <40 kg with varying skin pigmentation in the range of 45% to 85% $SavO_2$ against 30% arterial and 70% jugular venous blood oxygen saturations, measured with a laboratory CO-Oximeter.

Chapter 8: Service and Maintenance

Cleaning Procedure

The O3® Module should be cleaned at regular intervals or in accordance with hospital, local, and/or governmental regulations.

See ***Safety Information, Warnings and Cautions*** on page 9.

The O3® Module is a reusable instrument which is supplied non-sterile.

To clean the O3® Module:

- The outer surface of the instrument can be cleaned with a soft cloth dampened with a mild detergent and warm water solution.
- Do not allow liquids to enter the interior of the instrument.
- The outer surface of the instrument can also be wiped down using any of the following solvents:
    - Cidex Plus (3.4% glutaraldehyde)
    - 10% bleach solution
    - 70% isopropyl alcohol solution

General Maintenance for O3® Module

Safety tests and internal adjustments should be done by qualified personnel only. Safety checks should be performed at regular intervals or in accordance with hospital, as well as local and governmental regulations.

The following is a checklist for the general maintenance of the O3® Module:

- Visually inspect equipment for functional or structural damage, including poor seals, cracks, damaged springs, etc.
- Visually inspect cables, connectors, and connector pins for signs of damage or wear.
- Visually inspect product identification labels to ensure they are clear and legible.

Service Instructions

O3® Module has no customer serviceable parts. Attempting to service O3® Module will void the warranty. Safety tests and internal adjustments should be done by qualified personnel only. See ***Sales & End-User License Agreement*** on page 45.

To contact Masimo, see ***Contacting Masimo*** on page 44.

Repair Policy

Masimo or an authorized Service Department must perform warranty repair and service. Do not use malfunctioning equipment. Have the instrument repaired.

Please clean contaminated and/or dirty equipment before returning, following the cleaning procedure described in ***Cleaning Procedure*** on page 43. Make sure the equipment is fully dry before packing.

To return the O3® Module for service, please follow the ***Return Procedure*** on page 44.

Return Procedure

Clean contaminated/dirty equipment before returning, following instructions in Cleaning Procedure section. Make sure the equipment is fully dry before packing. Call Masimo at 800-326-4890 and ask for Technical Support. Ask for an RMA number. Package the equipment securely, in the original shipping container if possible, and enclose or include the following information and items:

- A letter describing in detail any difficulties experienced with the O3® Module. Include the RMA number in the letter.
- Warranty information, a copy of the invoice or other applicable documentation must be included.
- Purchase order number to cover repair if the O3® Module is not under warranty, or for tracking purposes if it is.
- Ship-to and bill-to information.
- Person (name, telephone/Telex/fax number, and country) to contact for any questions about the repairs.
- A certificate stating the O3® Module has been decontaminated for bloodborne pathogens.
- Return the O3® Module to the shipping address listed in the Contacting Masimo section below.

Contacting Masimo

To contact Masimo, refer to the following:

USA, Canada, and Asia Pacific	**Europe**	**All Other Locations**
Masimo Corporation 52 Discovery Irvine, California 92618 USA Tel:+1 949 297 7000 Fax:+1 949 297 7001	Masimo International Sàrl Puits-Godet 10 2000 Neuchatel- Switzerland Tel:+41 32 720 1111 Fax: +41 32 724 1448	Contact your local Masimo Representative

Sales & End-User License Agreement

This document is a legal agreement between you ("purchaser") and Masimo Corporation ("Masimo") for the purchase of this Product ("Product") and a license in the included or embedded Software ("Software") except as otherwise expressly agreed in a separate contract for the acquisition of this Product, the following terms are the entire agreement between the parties regarding your purchase of this Product. If you do not agree to the terms of this agreement, promptly return the entire Product, including all accessories, in their original packages, with your sales receipt to Masimo for a full refund.

Warranty

Masimo warrants to the initial Purchaser for a period of one (1) year from the date of purchase that: each new Product and the Software media as delivered are free from defects in workmanship or materials. Masimo's sole obligation under this warranty is to replace any product that it deems to be covered under warranty with a replacement O3® Module.

Exclusions

The warranty does not extend to, and Masimo is not responsible for, repair, replacement, or maintenance needed because of: a) modification of the Product or Software without Masimo's written authorization; b) supplies, instruments or electrical work external to the Product or not manufactured by Masimo; c) disassembly or reassembly of the Product by anyone other than an authorized Masimo agent; d) use of the Product with sensors or other accessories other than those manufactured and distributed by Masimo; e) use of the Product and Software in ways or in environments for which they are not labeled; and f) neglect, misuse, improper operation, accident, fire, water, vandalism, weather, war, or any act of God. This warranty does not extend to any product that has been used in violation of the operating instructions supplied with the product. This warranty does not extend to any Product that has been reprocessed, reconditioned or recycled.

This warranty also does not apply to any Products provided to Purchaser for testing or demonstration purposes, any temporary Products Modules or any Products for which Seller does not otherwise receive a usage or purchase fee; all such Products are provided AS-IS without warranty.

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