

# Root<sup>®</sup> with O3<sup>®</sup> Regional Oximetry

Available for Adult, Pediatric, Infant, and Neonatal Applications  
for Cerebral and Somatic Monitoring Sites



# O3 Regional Oximetry

O3 Regional Oximetry helps clinicians monitor cerebral oxygenation in situations in which peripheral pulse oximetry alone may not be fully indicative of the oxygen in the brain.<sup>1</sup>

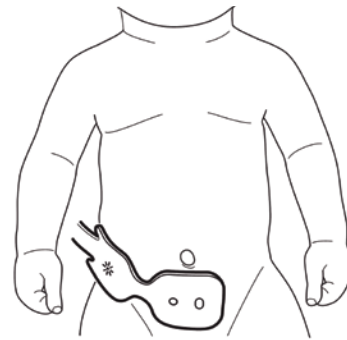
O3 Regional Oximetry monitors the regional hemoglobin oxygen saturation of blood (rSO<sub>2</sub>) in the region of interest for infant, neonatal, pediatric, and adult patients.<sup>2-5</sup>

With their flexible design, O3 sensors easily conform to and allow for ergonomic application.



## Infant and Neonatal Application

- > 3% ARMS trending accuracy specification
- > Patients less than 10kg



## Pediatric Application

- > 5% ARMS absolute and 3% ARMS trending accuracy specifications
- > Patients between 5kg and 40kg



## Adult Application

- > 4% ARMS absolute and 3% ARMS trending accuracy specifications
- > Patients greater than 40kg

# Expansion with Root

The expandable, versatile, and customizable Root patient monitoring and connectivity platform allows O3 Regional Oximetry to be combined with other monitoring modalities and automatically charts patient data in electronic medical records (EMRs).

## Expanded Visibility of the Brain

*Root with O3 Regional Oximetry and Next Generation SedLine® Brain Function Monitoring provides a more complete picture of the brain*

Root with **Next Generation SedLine brain function monitoring** helps clinicians monitor the state of the brain under anesthesia with bilateral data acquisition and processing of four leads of electroencephalogram (EEG) signals, enabling continuous assessment of both sides of the brain.



When used together on Root, SedLine and O3 provide a more complete picture of the brain on an instantly interpretable, integrated display.

Patient State Index, **PSi**, a processed EEG parameter related to the effect of anesthetic agents

Density Spectral Array (DSA) display contains left and right spectrograms representing the power of the EEG on both sides of the brain

rSO<sub>2</sub> provides tissue oxygen saturation



### Expanded Visibility of Oxygenation Status

Root with O3 Regional Oximetry and Masimo SET® Pulse Oximetry (SpO<sub>2</sub>)

O3 is displayed with Masimo SET® pulse oximetry on Root, providing clinicians with expanded visibility of a patient's oxygenation status.<sup>7</sup>



### Expanded Visibility of Patient Data

Iris Gateway® for Advanced Connectivity and Interoperability

Integrate data from Root and third-party devices using Iris® ports for automated charting in EMRs.



Data from Root and connected third-party devices

Device data and alarms are automatically charted in EMRs

## Expanded Visibility Through Supplemental Display

UniView™ aggregates data and alarms from multiple Masimo and third-party devices – such as patient monitors, ventilators, anesthesia machines, IV pumps and others connected through Masimo systems – on a supplemental display.

- > Integrated real-time data visualization reduces cognitive overload and promotes data sharing among multiple clinicians, helping them to spot trends and coordinate care
- > Visual alarm indicators, relayed from connected devices, help care teams recognize patient distress and target areas for clinical focus
- > Tailored use-case-specific screen layouts optimize the presentation of advanced and integrated parameters, trend data, and waveforms in critical care areas
- > Adaptable layout automatically reconfigures based on connected devices



Kite® expands visibility by providing a supplemental display of patient data from Root, with the ability to customize the layout differently from Root.

By allowing customization of what can be displayed, Kite allows clinicians to focus on the most pertinent data for each stage of a patient's journey, empowering them to make more informed decisions.

With Kite, all clinicians in the OR can view brain monitoring information instantly, simultaneously.

## O3 Module Specifications

### PHYSICAL CHARACTERISTICS

Length (including cable)	12.1 ft (3.7 m)
Width	1.8 in (4.6 cm)
Thickness	0.6 in (1.5 cm)
Weight	7.1 oz max (200 g max)

### ENVIRONMENTAL

Operational Temperature	32 to 104° F (0 to 40° C)
Storage Temperature	-40 to 158° F (-40 to 70° C)
Operating and Storage Humidity	10 to 95%, non-condensing
Altitude	Up to 12,000 ft (3700 m)

## O3 Sensor Specifications

Application Site	Forehead and Body
Wavelengths	4
<b>Adult rSO<sub>2</sub> Sensor Accuracy (ARMS)<sup>6</sup></b>	≥40 kg
Cerebral Absolute Regional Oxygen Saturation (rSO <sub>2</sub> )	4%
Cerebral Trending Regional Oxygen Saturation (rSO <sub>2</sub> )	3%
Somatic Trending Regional Oxygen Saturation (rSO <sub>2</sub> )	3%
<b>Pediatric rSO<sub>2</sub> Sensor Accuracy (ARMS)<sup>6</sup></b>	≥5 kg and <40 kg
Cerebral Absolute Regional Oxygen Saturation (rSO <sub>2</sub> )	5%
Cerebral Trending Regional Oxygen Saturation (rSO <sub>2</sub> )	3%
Somatic Trending Regional Oxygen Saturation (rSO <sub>2</sub> )	3%
<b>Neonatal rSO<sub>2</sub> Sensor Accuracy (ARMS)<sup>6</sup></b>	<10 kg
Cerebral and Somatic Trending Regional Oxygen Saturation (rSO <sub>2</sub> )	3%

### ENVIRONMENTAL

Operating Temperature at Ambient Humidity	41 to 104° F (5 to 40° C)
Storage Temperature at Ambient Humidity	-40 to 140° F (-40 to 60° C)
Storage Humidity	15% to 90%, 86 to 140° F (30 to 60° C)

## SedLine Module Specifications

### PHYSICAL CHARACTERISTICS

#### Module Physical Dimensions

Width	1.3 in (3.3 cm)
Length	4.0 in (10.2 cm)
Thickness	0.8 in (2.0 cm)

### ENVIRONMENTAL

#### Module Operating Conditions

Operating Temperature	41-104°F (5-40°C)
Operational Humidity	15-95%, non-condensing

#### Module Storage Conditions

Storage Temperature	-40-158°F (-40-70°C)
Storage Humidity	15-95%, non-condensing
Exposure to Pressure	500-1060 mbar

## SedLine Sensor Specifications

Application Site	Forehead
Active Channels	4
Active Electrodes	L1, L2, R1, and R2

Ground Electrode	CB
Reference Electrode	CT
Duration of Use	Maximum of 24 hours
Latex Content	Does not contain natural rubber latex
Adult SedLine EEG Sensor	>18 years

## Root Specifications

### ELECTRICAL

#### Root

AC Power Requirements	100-240 VAC, 47-63 Hz
Power Consumption	.65W (Max)
Fuses Each With	2 Amp, Fast Acting, Metric, (5x20mm), 250V

#### Battery

Type	10.8V Lithium Ion (Nominal)
Capacity	4 Hours <sup>8</sup>
Maximum Charging Time	4 Hours

### ENVIRONMENTAL

Operating Temperature	32°F to 122°F (0°C to 50°C)
Transport/Storage Temperature	-40°F to 158°F (-40°C to 70°C)
Operating Humidity	10% to 95%, Non-Condensing
Storage Humidity	10% to 95%, Non-Condensing
Operating Altitude	500 mbar to 1060 mbar -1,000 ft to 18,000 ft (-304 m to 5,486 m)

### PHYSICAL CHARACTERISTICS

Weight	<8 lbs (3.63 kg)
Dimension	11 in x 10.5 in x 5.5 in (27.94 cm x 26.67 cm x 13.97 cm)
Display	
Type	Backlit Active Matrix TFT LCD
Resolution	1280 x 800 Pixels
Color	24 bit RGB
Size	10.1 in (25.65 cm) Diagonal
Touchscreen	
Type	Multi-Touch P-Cap

### CONNECTIONS

Connector	Type (Number of Ports)
Nurse Call	1/4-in Round Female (1)
MOC-9	Masimo Connector (3)
USB	USB 2.0 (2)

<sup>1</sup> Denault A et al. Chapter 7 - Near-Infrared Spectroscopy, Editor(s): Hemanshu Prabhakar, *Neuromonitoring Techniques*, Academic Press, 2018, 179-233. <sup>2</sup> TR-28465- This study demonstrates the absolute and trending accuracy for adult sensors. <sup>3</sup> TR-30742- This study demonstrates the trending accuracy for pediatric sensors with reference to adult sensors. <sup>4</sup> TR-36359- This study demonstrates the trending accuracy for neonate sensors with reference to adult sensors. <sup>5</sup> TR-36374- This study demonstrates the trending accuracy for neonate sensors with reference to blood reference to adult sensors. <sup>6</sup> ARMS accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within ± ARMS of the reference measurements in a controlled study. <sup>7</sup> TR-25818- This study demonstrates front end integration of O3 Regional Oximeter with Root. <sup>8</sup> This represents approximate run time at the lowest indicator brightness, using a fully charged battery.

\* In countries with regulatory approval and Root devices with the correct software version.

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

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