# Root with O3 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>

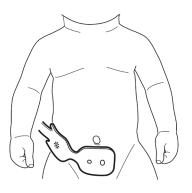
O3 Regional Oximetry monitors the regional hemoglobin oxygen saturation of blood (rSO2) in the region of interest for infant, neonatal, pediatric, and adult patients.<sup>2-5</sup>

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



#### Infant and Neonatal Application

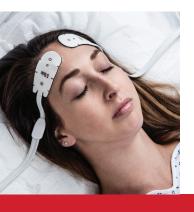
- > When placed on forehead or body:
  - 3% A<sub>RMS</sub> trending accuracy specification
- > Patients less than 10kg





#### Pediatric Application

- > When placed on forehead:
  - 5% ARMS absolute accuracy specification
  - 3% A<sub>RMS</sub> trending accuracy specification
- > When placed on body:
  - 3% A<sub>RMS</sub> trending accuracy specification
- > Patients between 5kg and 40kg



#### Adult Application

- > When placed on forehead:
  - 4% ARMS absolute accuracy specification
  - 3% ARMS trending accuracy specification
- > When placed on body:
  - 5% ARMS absolute accuracy specification
  - 3% ARMS trending accuracy specification
- > Patients greater than 40kg

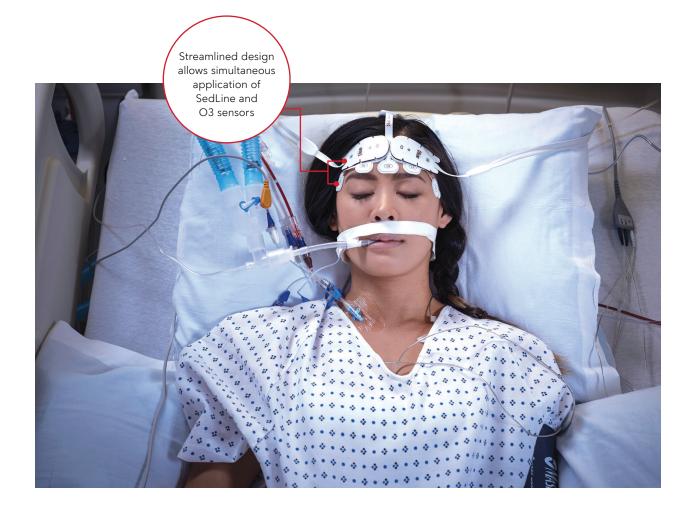
## Expansion with Root

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

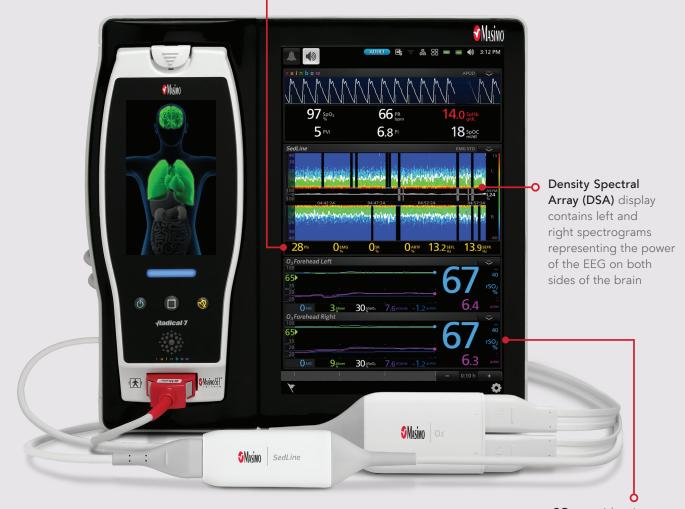
Root with O3 Regional Oximetry and Next Generation SedLine® Brain Function Monitoring provides a more complete picture of the brain

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



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

#### **Expanded Visibility of Oxygenation Status**

Root with O3 Regional Oximetry and Masimo SET® Pulse Oximetry (SpO2)

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.



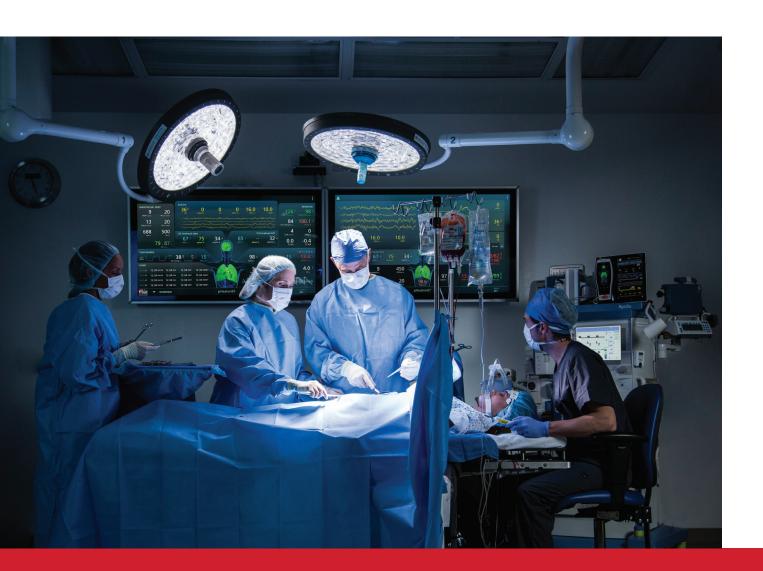
Data from Root and connected third-party devices

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	)

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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	
Adult rSO2 Sensor Accuracy (ARMS)6	≥40 kg
Cerebral Absolute Regional Oxygen Saturation (rSO2)	4%
Cerebral Trending Regional Oxygen Saturation (rSO2)	
Somatic Absolute Regional Oxygen Saturation (rSO2)	5%
Somatic Trending Regional Oxygen Saturation (rSO2)	
Pediatric rSO <sub>2</sub> Sensor Accuracy (A <sub>RMS</sub> ) <sup>6</sup>	. ≥5 kg and <40 kg
C	
Cerebral Absolute Regional Oxygen Saturation (rSO2)	5%
Cerebral Absolute Regional Oxygen Saturation (rSO2)	
Cerebral Trending Regional Oxygen Saturation (rSO2)	3% 3%
Cerebral Trending Regional Oxygen Saturation (rSO2)	3% 3% <10 kg

#### 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	6 to 140°F (30 to 60°C)

#### SedLine Module Specifications

PHYSICAL CHARACTERISTICS
Todule Physical Dimensions Width
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)

## **SedLine Sensor Specifications**

Application Site	
Active Channels	
Active ElectrodesL1, L2, R1, and R2	

Ground Electrode	CB
Reference Electrode	
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, Time-Delay, Metric, (5x20mm), 250V
Battery Type
ENVIRONMENTAL         32°F to 122°F (0°C to 50°C)           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	5 in x 5.5 in (27.94 cm x 26.67 cm x 13.97 cm)
Туре	Backlit Active Matrix TFT LCD
Resolution	
Color	24 bit RGB
Size Touchscreen	
Туре	Multi-Touch P-Cap
CONNECTIONS	
Connector Nurse Call	Type (Number of Ports)1/4-in Round Female (1)

CONNECTIONS	
Connector Nurse Call	Type (Number of Ports)
MOC-9	Masimo Connector (3)
USB	USB 2.0 (2)

<sup>&</sup>lt;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-36374 - This study demonstrates the trending accuracy for neonate sensors with reference to adult sensors. <sup>5</sup> ARMs accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements and reference measurements and reference 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

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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<sup>\*</sup> In countries with regulatory approval and Root devices with the correct software version.