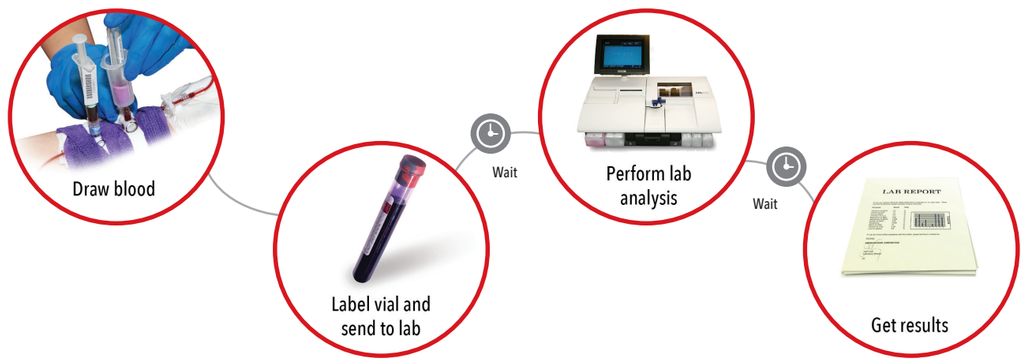
Noninvasive and Continuous Hemoglobin (SpHb®) Monitoring

Real-time visibility to changes, or lack of changes, in hemoglobin between invasive blood samples

Masimo

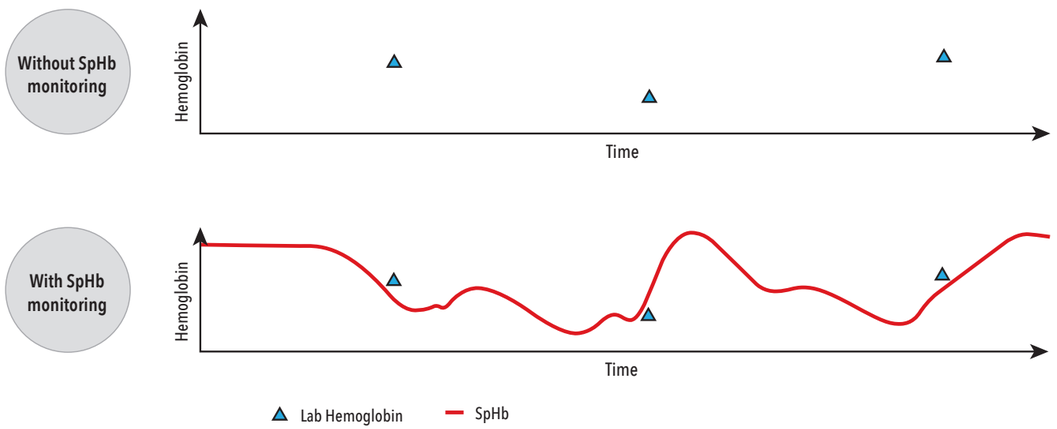
Traditional Methods

Without SpHb, clinicians are often limited to invasive blood samples, which provide intermittent and delayed laboratory hemoglobin results



Value of SpHb Monitoring

SpHb can be used in conjunction with traditional laboratory methods to obtain real-time visibility to changes, or lack of changes, in hemoglobin between invasive blood samples

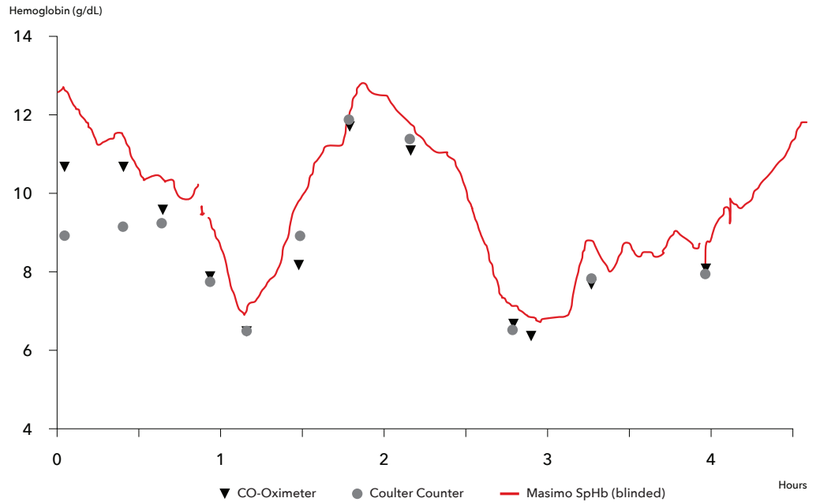


SpHb trend monitoring may provide additional insight between invasive blood samples when:

> The SpHb trend is stable and the clinician may otherwise think hemoglobin is dropping
> The SpHb trend is rising and the clinician may otherwise think hemoglobin is not rising fast enough
> The SpHb trend is dropping and the clinician may otherwise think hemoglobin is stable

Clinical Case

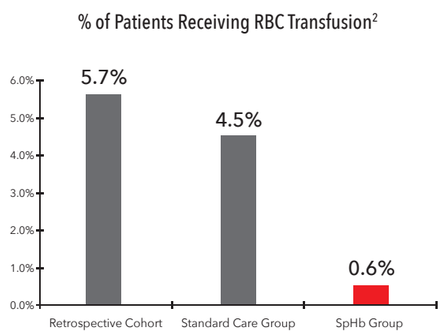
SpHb was retrospectively obtained for the surgical case shown below, in which clinicians could not assess the hemoglobin trend between invasive blood samples during the procedure[1]



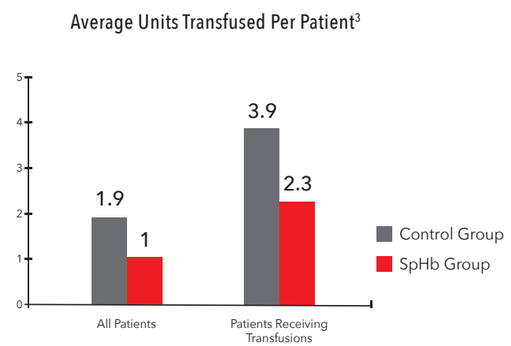
SpHb Utility

Studies have shown that SpHb may help clinicians reduce blood transfusions in both low and high blood loss surgeries[2, 3]

> A randomized trial of 327 patients undergoing elective orthopedic surgery, conducted at Massachusetts General Hospital (MGH), found that the use of continuous, noninvasive hemoglobin monitoring reduced the rate of transfusions when compared to standard care without continuous, noninvasive hemoglobin monitoring[2]



> A prospective cohort study of 106 neurosurgical patients found that adding SpHb monitoring to standard-of-care blood management resulted in decreased blood utilization in high-blood-loss neurosurgery, while also facilitating earlier transfusions[3]*



Clinical decisions regarding red blood cell transfusions should be based on the clinician's judgment considering among other factors: patient condition, continuous SpHb monitoring, and laboratory diagnostic tests using blood samples.

* **Study Protocol:** The transfusion threshold of 10g/dL was predetermined by the study protocol and may not be appropriate for all patients. The blood sampling technique was the same for patients in both the control and the test group. Arterial blood was drawn from a 20 gauge radial artery cannula into 2mL ethylenediaminetetraacetic acid collection tubes, thoroughly mixed then sent immediately to the central lab for analysis by a hematology analyzer. The reference laboratory device used for hemoglobin measurements in the study was a Coulter GEN-S Hematology Analyzer.

SpHb Monitoring Across the Continuum of Care

Monitoring hemoglobin continuously and noninvasively through different care areas

Upgradable rainbow SET™ Technology Platform

Masimo rainbow SET is a noninvasive monitoring platform featuring Masimo SET® Measure-through Motion and Low Perfusion™ pulse oximetry with the option to measure multiple additional parameters

- > Oxygen Saturation (SpO_2)
- > Pulse Rate (PR)
- > Perfusion Index (Pi)
- > Pleth Variability Index (PVi®)
- > Total Hemoglobin (SpHb)
- > Methemoglobin (SpMet®)
- > Oxygen Content (SpOC™)
- > Carboxyhemoglobin (SpCO®)
- > Acoustic Respiration Rate (RRa®)

Specifications

TOTAL HEMOGLOBIN (SpHb)	
Measurement Range	0 – 25 g/dL
Accuracy Range	8 – 17 g/dL
Accuracy (A_{RMS}[4]) (Adults/Infants/Pediatrics)	1 g/dL

[1] Peiris P. et al. Proceeding for the Society for the Advancement of Blood Medicine 2010 Annual Meeting. Abs 4091. [2] Ehrenfeld et al. *J Blood Disorders Transf*. 2014. 5:9. [3] Awada WN et al. *J Clin Monit Comput*. DOI 10.1007/s10877-015-9660-4. [4] A_{RMS} accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within ± A_{RMS} of the reference measurements in a controlled study.

SpHb monitoring is not intended to replace laboratory blood testing. Blood samples should be analyzed by laboratory instruments prior to clinical decision making.

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, and precautions.

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7905/PLM-10283B-0217

Root® with SedLine® Brain Function Monitoring

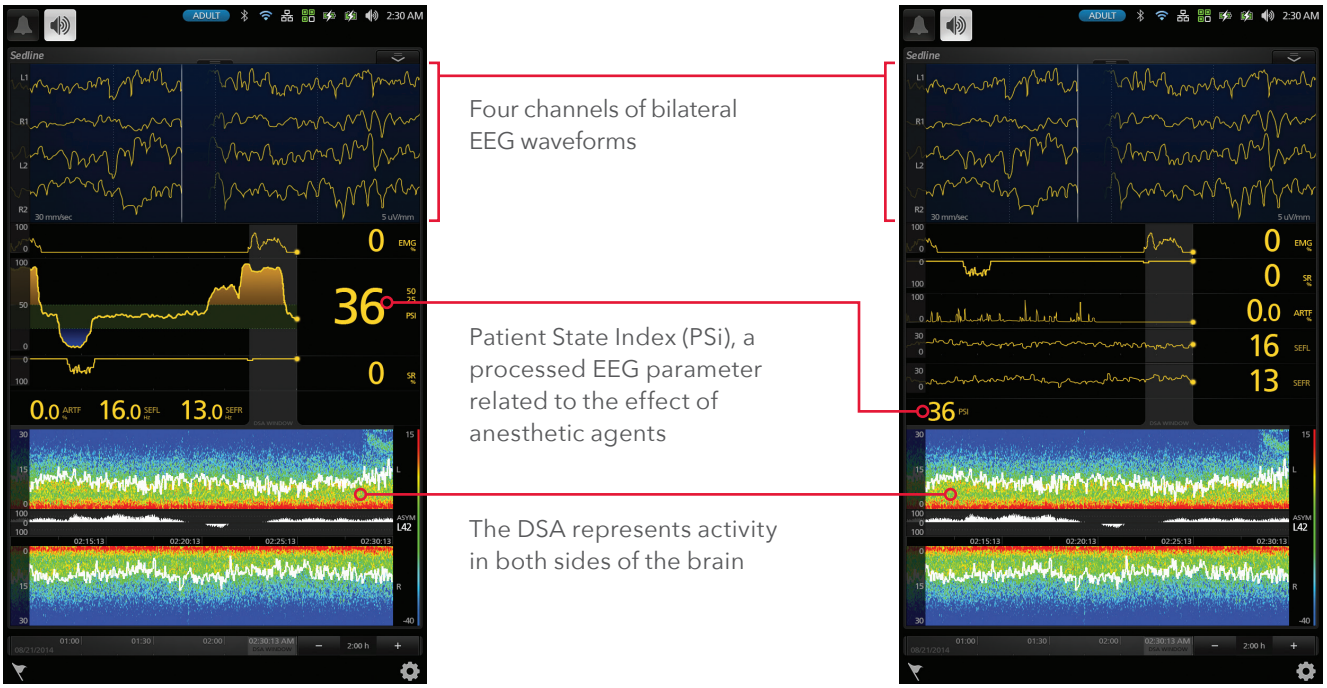
A More Complete Picture Starts With More Complete Data

Root with SedLine Brain Function Monitoring helps clinicians monitor the state of the brain under anesthesia with bilateral data acquisition and processing of Electroencephalogram (EEG) signals

- Four simultaneous channels of frontal EEG waveforms
- Patient State Index (PSi) is a processed EEG parameter that is related to the effect of anesthetic agents
- A Density Spectral Array (DSA) display, which contains left and right spectrograms representing the power of the EEG on both sides of the brain
- Multiple screen views, which expand information while enabling customization in the operating room and intensive care unit

Masimo

Monitor Display



The SedLine EEG Sensor

- Four active leads collect data from the frontal lobe
- Allows simultaneous application of SedLine and O3® Regional Oximetry sensors
- Soft foam pads improve patient comfort

The SedLine module plugs into the Root patient monitoring platform via Masimo Open Connect™ (MOC-9™) ports

SedLine Specifications

PHYSICAL CHARACTERISTICS	
Module Physical Dimensions	
Width	1 3/10 in (33mm)
Length	4 in (102mm)
Thickness	3/4 in (19mm)

ENVIRONMENTAL	
Module Operating Conditions	
Temperature at Ambient Humidity	5–40° C
Module Storage and Shipping Conditions	
Temperature at Ambient Humidity	-40–70° C
Storage Humidity	15–95%, non-condensing
Exposure to Pressure	500–1060 mbar

Sensor Specifications

Patient Weight	> 30 kg
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

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6563/PLM-10020B-0717

Root® with O3® Regional Oximetry

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

Masimo

O3 Regional Oximetry

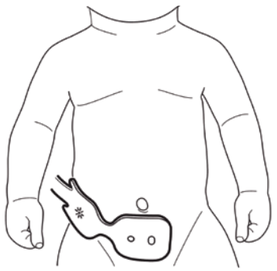
O3 Regional Oximetry helps clinicians monitor cerebral oxygenation in situations in which peripheral pulse oximetry alone may not be fully indicative of the oxygen in the brain.[1]

O3 Regional Oximetry monitors the regional hemoglobin oxygen saturation of blood (rSO_2) in the region of interest for infant, neonatal, pediatric, and adult patients.[2-5]

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

Infant and Neonatal Application

- 3% A_{RMS} trending accuracy specification
- Patients less than 10kg



Pediatric Application

- 5% A_{RMS} absolute and 3% A_{RMS} trending accuracy specifications
- Patients between 5kg and 40kg

Adult Application

- 4% A_{RMS} absolute and 3% A_{RMS} 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).

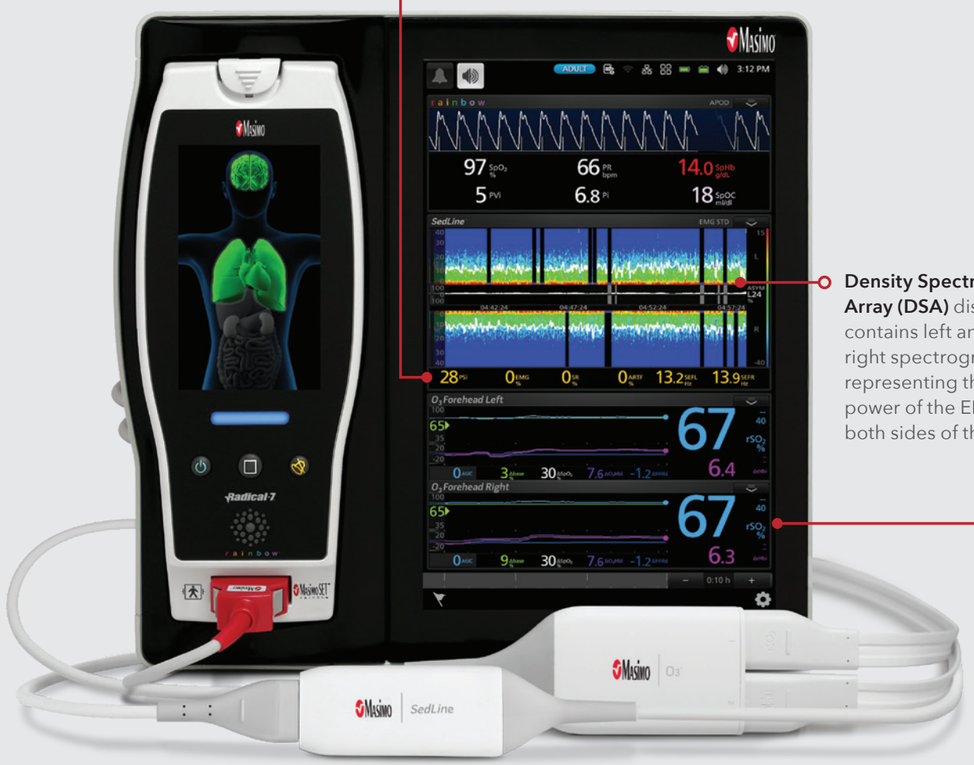
Expanded Visibility of the Brain

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

rSO2 provides tissue oxygen saturation

Expanded Visibility of Oxygenation Status

Root with O3 Regional Oximetry and Masimo SET® Pulse Oximetry (SpO_2)

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

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
Adult rSO_2 Sensor Accuracy (A_{RMS})[6]	≥40 kg
Cerebral Absolute Regional Oxygen Saturation (rSO_2)	4%
Cerebral Trending Regional Oxygen Saturation (rSO_2)	3%
Somatic Trending Regional Oxygen Saturation (rSO_2)	3%
Pediatric rSO_2 Sensor Accuracy (A_{RMS})[6]	≥5 kg and <40 kg
Cerebral Absolute Regional Oxygen Saturation (rSO_2)	5%
Cerebral Trending Regional Oxygen Saturation (rSO_2)	3%
Somatic Trending Regional Oxygen Saturation (rSO_2)	3%
Neonatal rSO_2 Sensor Accuracy (A_{RMS})[6]	<10 kg
Cerebral and Somatic Trending Regional Oxygen Saturation (rSO_2)	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[8]
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)

[1] Denault A et al. Chapter 7 - Near-Infrared Spectroscopy, Editor(s): Hemanshu Prabhakar, *Neuromonitoring Techniques*, Academic Press, 2018, 179-233. [2] TR-28465- This study demonstrates the absolute and trending accuracy for adult sensors. [3] TR-30742- This study demonstrates the trending accuracy for pediatric sensors with reference to adult sensors. [4] TR-36359- This study demonstrates the trending accuracy for neonate sensors with reference to adult sensors. [5] TR-36374- This study demonstrates the trending accuracy for neonate sensors with reference to blood reference to adult sensors. [6] A_{RMS} 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. [7] TR-25818- This study demonstrates front end integration of O3 Regional Oximeter with Root. [8] 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.

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61246/PLM-12599A-0820

Masimo softFlow™

Nasal High Flow Therapy for Spontaneously Breathing Adult Patients in Hospital and Long-Term Care Facilities

- Respiratory support delivered through a soft nasal cannula interface
- Wide flow range from 10-60 L/min* in 0.5 L/min steps to permit flow rate to be tailored to the specific needs of the patient
- Ability to supplement oxygen with 0-60 L/min flow and up to 100% FiO_2 from wall supply, oxygen cylinder, or concentrator
- Integrated flow driver provides flow without the need for wall air supply
- Warmed humidification of respiratory gas all the way to the patient's nose to enhance therapy comfort and aid in mucous clearance[1,2]
- Condensate-free delivery of a consistent, high-velocity flow during inspiration and exhalation to enhance therapy benefits
- Auto-identification of type of nasal cannula and breathing circuit to improve and simplify workflow through automated configuration
- Bacterial/viral filter between device and patient, rather than between device and room air, to reduce risk of cross-contamination

MASIMO

softFlow Accessories

softFlow Nasal Applicator

Available in Small, Standard, Standard-Plus, and Large sizes

Heater Wire in the Nasal Applicator

Unique one-piece design permits heater wire all the way to the nares to reduce condensation

softFlow Product Stand

Performance Data

- Adjustable flow rate: 10-60 L/min ± 2%, adjustable in 0.5 L/min steps to tailor flow to patient needs
- Oxygen Flow Rate support: 0-60 L/min and up to 100% FiO_2, with FiO_2% indicator integrated into the display
- Adjustable humidity/dew point settings from 30-37°C, adjustable in 1°C steps to tailor to patient needs
- Integrated micro-particle filter
- Nasal applicators include several sizes of soft, flexible nasal prongs to suit a wide range of patients
- Disposable bacterial/viral filter (bacterial efficiency >99.999%; viral efficiency >99.99%) between device and patient reduce risk of cross-contamination and transition time between patients
- Autofilling humidification water chamber eliminates need to manually refill humidity chamber between uses
- Entire respiratory circuit is disposable to minimize risk of cross-contamination and reduce time to clean and disinfect the device between patients

Product Specifications

PERFORMANCE DATA	
Intended Population	Adult patients
Flow Settings	10-60 L/min
Supplemental Oxygen	0-60 L/min
Humidity Dew Point	30-37 °C DP (adjustable in 1°C DP steps)
Event Memory	12 therapy months

ELECTRICAL	
AC Power Requirements	100-240 VAC, 50-60Hz
Power Consumption	300 VA (Max)

ENVIRONMENTAL	
Operating Temperature	64-78°F (18-26°C)
Transport/Storage Temperature	-13-158°F (-25-70°C)
Operating Humidity	15-93 % RH
Storage Humidity	< 93 % RH

PHYSICAL CHARACTERISTICS	
Dimension	12.6 in x 8.2 in x 12.6 in (32 cm x 210cm x 32cm)
Weight	>13lbs (5.6kg)

TECHNICAL DATA	
Medical Device (93/42/EEC)	IIa
Safety class, electrically	II
Safety level "applied part"	BF
Ingress Protection	IP21
Electromagnetic compatibility	EN 60601-1-2, Class B
Electrical safety	according to EN 60601-1 CSA C22.2/No 60601-1

[1] Hasani A et al. *Chron Respir Dis* 5, no. 2 (2008): 81-86. [2] Roca O et al. *Respir Care* 55, no. 4 (2010): 408-413.

* The softFlow is FDA cleared for flow rates up to 50 L/min and in hospital and long-term care facilities. The 60 L/min version and the home use version are being made available in the US under the FDA Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the COVID-19 Public Health Emergency.

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