

Advanced Monitoring Technology for Perioperative Care

Taking Noninvasive Monitoring to New Sites and Applications™ with Root®



Root is a versatile and expandable platform that provides noninvasive and continuous:

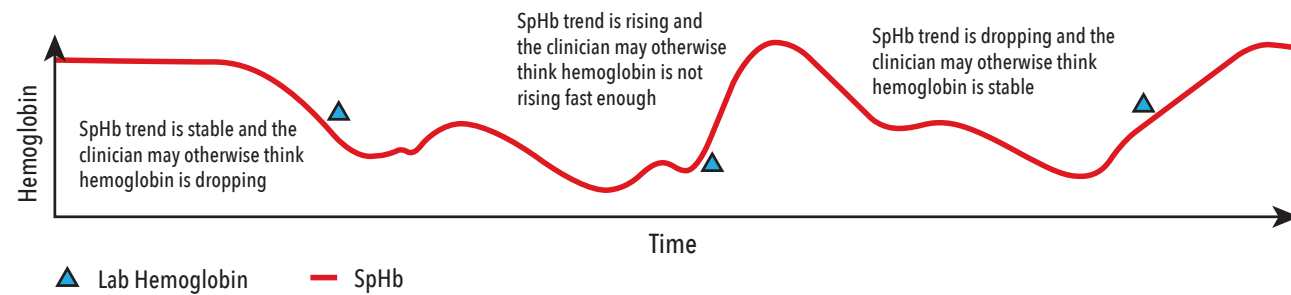
- > Total Hemoglobin (SpHb®)
- > Pleth Variability Index (PVi®)
- > SedLine® Brain Function Monitoring
- > O3™ Regional Oximetry



Total Hemoglobin (SpHb)

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:

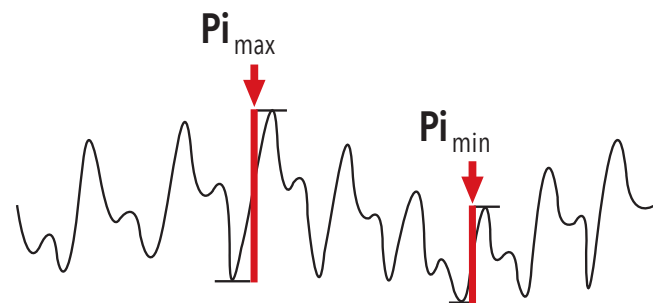


Clinical Application

- > In a randomized trial study of 327 patients undergoing elective orthopedic surgery, researchers found that the use of SpHb monitoring reduced the rate of transfusions when compared to standard care without SpHb monitoring.¹
- > In a prospective cohort study of 106 patients undergoing neurosurgical procedures, researchers 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.^{2*}

Pleth Variability Index (PVi)

An automatic measurement of the dynamic changes in Perfusion Index (Pi) that occur during one or more respiratory cycles



$$PVi = \frac{Pi_{max} - Pi_{min}}{Pi_{max}} \times 100$$

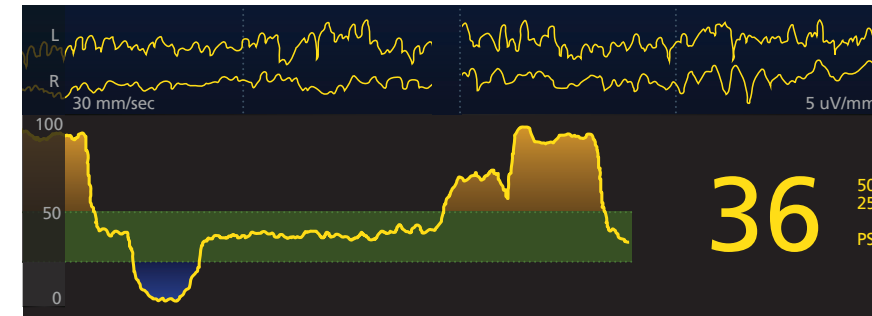
Clinical Application

- > PVi may show changes that reflect physiologic factors such as vascular tone, circulating blood volume, and intrathoracic pressure excursions.

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 with bilateral data acquisition and processing of Electroencephalogram (EEG) signals



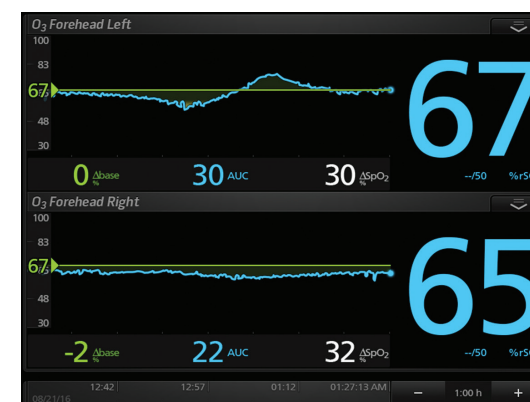
The Patient State Index (PSi) is a processed EEG parameter that is related to the effect of anesthetic agents.

Clinical Application

- > In a prospective, double-blinded, randomized, controlled comparative study of 60 post-operative, mechanically-ventilated liver transplant recipients, researchers found that sedation guided with PSi preserved better hemodynamics, enhanced recovery, and rapid ventilation weaning at a lower cost compared to the use of sedation scale monitoring.³

O3 Regional Oximetry

O3 Regional Oximetry uses near-infrared spectroscopy (NIRS) to enable monitoring of cerebral tissue oxygen saturation (rSO₂)



O3 Regional Oximetry may help clinicians monitor cerebral oxygenation in situations in which pulse oximetry alone may not be fully indicative of the oxygen in the brain.

Clinical Application

- > In a study of 27 healthy adult volunteers, researchers found that O3 regional oximetry provided absolute root-mean-squared error of 4% and relative root-mean-squared error of 2.1% in healthy volunteers undergoing controlled hypoxia.⁴

Advanced Clinical Monitoring in the Operating Room



Performance and Specifications

TOTAL HEMOGLOBIN (SpHb)

Measurement Range	0-25 g/dL
Accuracy Range	8-17 g/dL
Accuracy (ARMS ⁵) (Adults/Infants/Pediatrics)	1 g/dL

O3 REGIONAL OXYGEN SATURATION (rSO₂)

Adult Sensor	
Trend Accuracy (ARMS ⁵)	3%
Absolute Accuracy (ARMS ⁵)	4%

¹ Ehrenfeld et al. *J Blood Disorders Transf.* 2014. ² Awada et al. *J Clin Monit Comput.* 2015. ³ Sayed et al. *J Anesth Clin Res.* 2015. ⁴ Redford et al. *Anesth Analg.* 2014. ⁵ ARMS accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within \pm ARMS 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. Clinical decisions regarding red blood cell transfusions should be based on the clinician's judgement 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.

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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