

Advanced Monitoring Technology for Perioperative Care

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



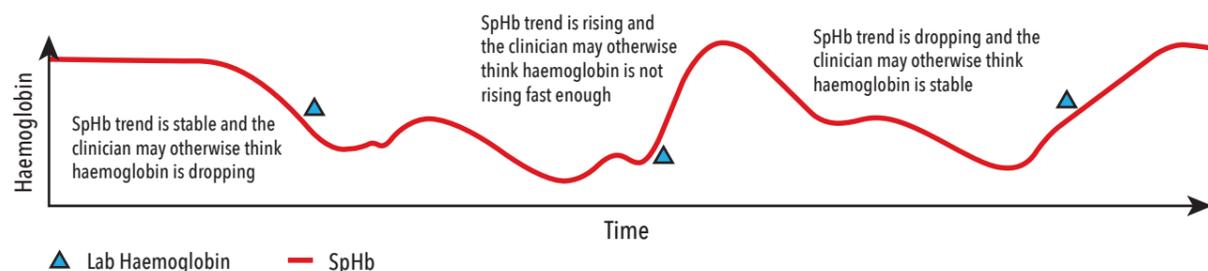
Root is a versatile and expandable platform that provides noninvasive and continuous:

- > Total Haemoglobin (SpHb®)
- > Pleth Variability Index (PVi®)
- > SedLine® Brain Function Monitoring
- > O3™ Regional Oximetry
- > Oxygen Reserve Index™ (ORi™)

Total Haemoglobin (SpHb)

Real-time Visibility to Changes, or Lack of Changes, in Haemoglobin Between Invasive Blood Samples

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



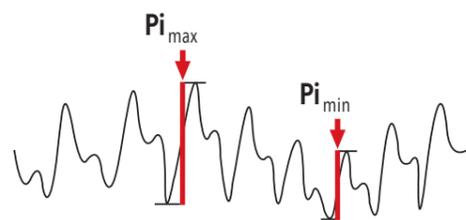
Clinical Application

- > In a randomised trial study of 327 patients undergoing elective orthopaedic 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 utilisation in high-blood-loss neurosurgery, while also facilitating earlier transfusions.^{2*}

Pleth Variability Index (PVi)

A Noninvasive Dynamic Parameter that May Help Assess Fluid Responsiveness

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



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

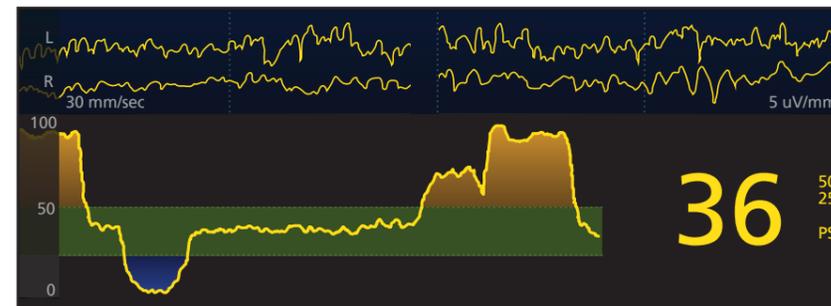
Clinical Application

- > In a study of 82 patients undergoing major abdominal surgery, researchers found that PVi-based goal-directed fluid management reduced the volume of intraoperative fluid infused and reduced intraoperative and postoperative lactate levels.³
- > In a study of 109 patients undergoing colorectal surgery, researchers found that implementation of an enhanced recovery protocol (that included PVi) led to improved patient satisfaction and substantial reductions in lengths of stay, complication rates, and costs for patients undergoing both open and laparoscopic colorectal surgery.⁴

Monitored simultaneously, SpHb and PVi can provide additional insight into haemodilution and haemoconcentration

SedLine Brain Function Monitoring

More Complete Data, Now With An Enhanced Patient State Index (PSi)



Next Generation SedLine Brain Function Monitoring reduces electromyography (EMG) susceptibility and improves PSi performance in cases of low power EEG.

Clinical Application

- > EMG, a consequence of spontaneous muscle movement, can interfere with the EEG signals used in brain function monitoring. In a study of 20 patients treated in a general ICU, researchers found that 38% of the EEG data points (37 out of 97) were associated with excessive muscle movement.⁵
- > Low power can provide a challenge for conventional brain function monitors. In a study of 155 patients undergoing general anesthesia, researchers found that power across all EEG frequency bands decreased with age, and was significantly lower in elderly patients.⁶

O3 Regional Oximetry

Noninvasive Monitoring of Tissue Oxygen Saturation (rSO₂) in the Brain



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.

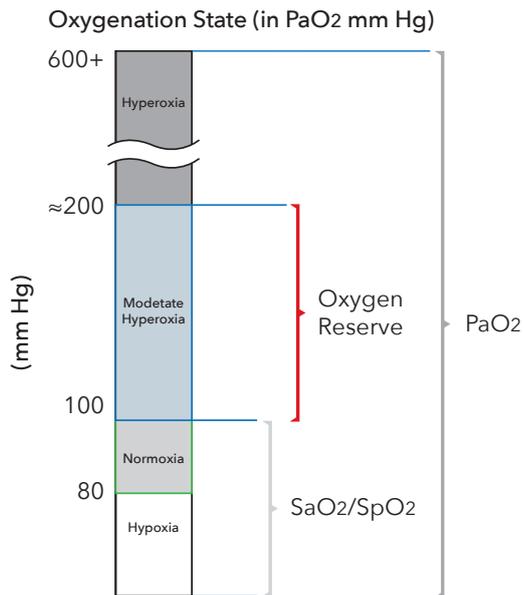
Clinical Application

- > 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.⁷

Combining O3 Regional Oximetry and SedLine Brain Function Monitoring provides a more complete brain monitoring solution

Oxygen Reserve Index (ORi)

Insight into the Oxygen Reserve of Patients Receiving Supplemental Oxygen



ORi is a noninvasive and continuous parameter intended to provide insight into a patient's oxygen status in the moderate hyperoxic range (PaO₂ between 100 and ≈200 mm Hg). ORi is an index with a unit-less scale between 0 and 1.

Clinical Application

- > In a study of 25 paediatric patients undergoing general anaesthesia with orotracheal intubation, researchers found that ORi detected impending desaturation in a median of 31.5 seconds before noticeable changes in SpO₂ occurred.⁸
- > In a study of 106 patients undergoing scheduled surgery in which arterial catheterization and intraoperative arterial blood gas analyses were planned, researchers found that decreases in ORi to near 0.24 may provide advance indication of falling PaO₂ approaching 100 mm Hg when SpO₂ is >98% and above the PaO₂ level at which SaO₂ declines rapidly.⁹

Performance and Specifications

TOTAL HAEMOGLOBIN (SpHb)

Measurement Range	0-25 g/dL
Accuracy Range	8-17 g/dL
Accuracy (ARMS ¹⁰) (Adults/Infants/Paediatrics)	1 g/dL

O3 REGIONAL OXYGEN SATURATION (rSO₂)

Paediatric Sensor	
Trend Accuracy (ARMS ¹⁰)	3%
Adult Sensor	
Trend Accuracy (ARMS ¹⁰)	3%
Absolute Accuracy (ARMS ¹⁰)	4%

¹ Ehrenfeld et al. *J Blood Disorders Transf.* 2014. ² Awada et al. *J Clin Monit Comput.* 2015. ³ Forget et al. *Anesth Analg.* 2010. ⁴ Thiele et al. *Journal of the American College of Surgeons.* 2015. ⁵ Narasway et al. *Critical Care Med.* 2002. ⁶ Purdon P et al. *British Journal of Anaesthesia.* ⁷ Redford et al. *Anesth Analg.* 2014. ⁸ Szmuk P et al. *Anesthesiology.* 2016. ⁹ Applegate et al. *Anesth Analg.* 2016. ¹⁰ 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.

SpHb monitoring is not intended to replace laboratory blood testing. Blood samples should be analysed 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 haematology analyser. The reference laboratory device used for haemoglobin measurements in the study was a Coulter GEN-S Hematology Analyzer.

Next Generation SedLine has obtained CE Marking and is not available in the U.S.

O3 Paediatric Sensor and ORi Parameter have obtained CE Marking and are not available in the U.S. or Canada.

For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, and precautions.

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