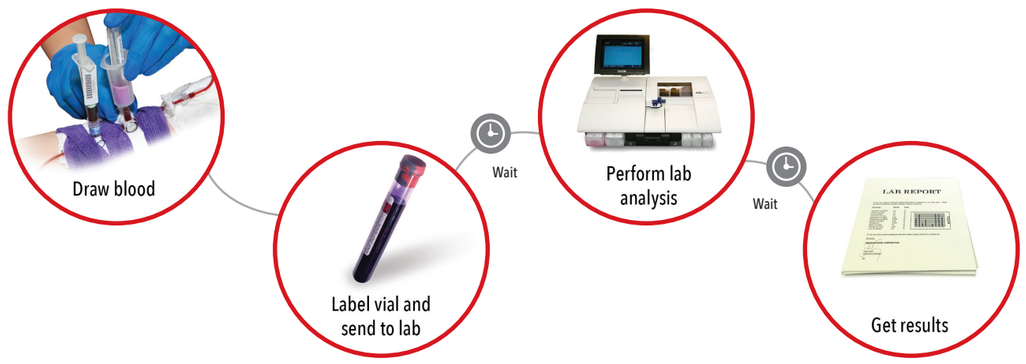
Noninvasive and Continuous Hemoglobin (SpHb®) Monitoring

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

Masimo

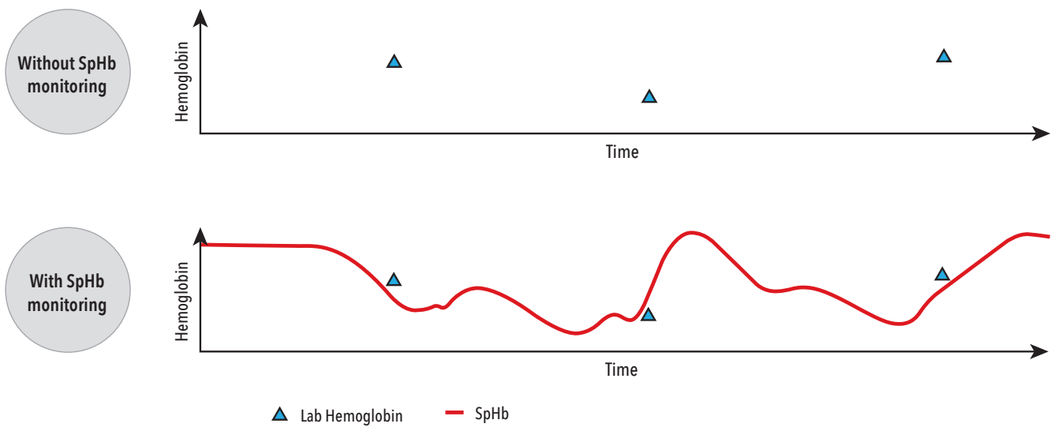
Traditional Methods

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

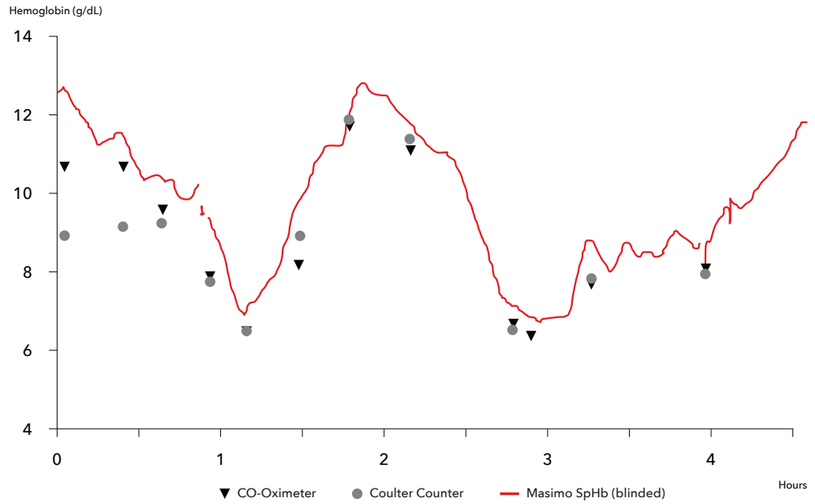


SpHb trend monitoring may provide additional insight between invasive blood samples when:

> 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

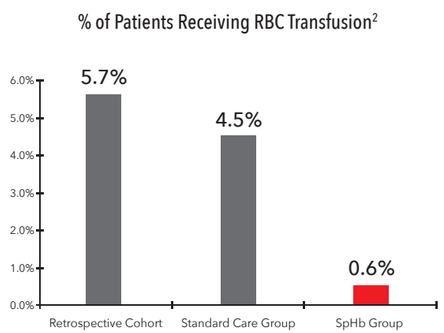
SpHb was retrospectively obtained for the surgical case shown below, in which clinicians could not assess the hemoglobin trend between invasive blood samples during the procedure[1]



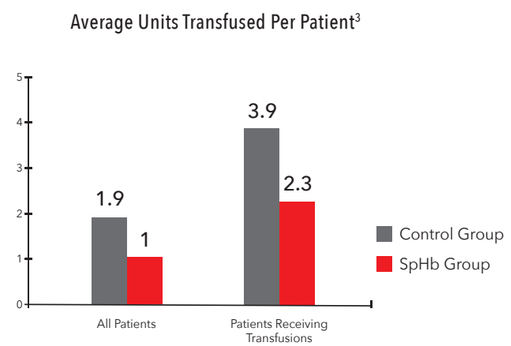
SpHb Utility

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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