

New Study Investigates the Performance of Masimo SpHb®



<u>Masimo</u> announced today the findings of a recently published study in which researchers at Cairo University in Egypt evaluated the accuracy and trending of Masimo noninvasive and continuous hemoglobin (SpHb®), referenced to an invasive laboratory hemoglobin (Lab-Hb) measurement, during acute bleeding and after fluid resuscitation.

In the study, Dr. Adel and colleagues sought to investigate the performance of SpHb in different volume statuses and perfusion states. They utilized intraoperative data from 70 patients scheduled for major orthopedic procedures with anticipated major blood loss. SpHb, as well as Masimo PVi® and Pi, were measured using a Masimo Radical-7® Pulse CO-Oximeter®. Lab-Hb was measured using a Beckman Coulter LH 750 analyzer. SpHb and Lab-Hb were recorded at three times – a baseline reading five minutes after endotracheal intubation, after major bleeding, and after fluid resuscitation – resulting in 210 time-matched readings, which were divided into fluid responsive and fluid non-responsive samples and low and high perfusion index samples.

Using Bland-Altman analysis, the researchers found "excellent correlation" between Lab-Hb and SpHb (r=0.938). In addition, they reported "excellent accuracy with moderate levels of agreement," as noted below, for various sample sets:

Sample set	Mean bias	Limits of agreement
All	0.01	-1.33 to 1.34 g/dL
Fluid non-responsive	-0.08	-1.27 to 1.11 g/dL
Fluid responsive	0.09	-1.36 to 1.54 g/dL
High Pi	0.01	-1.34 to 1.31 g/dL
Low Pi	0.04	-1.31 to 1.39 g/dL

The researchers also noted that polar plot analysis (angular bias of -4°) showed "good trending ability for SpHb as a follow-up monitor."

The investigators concluded that, "SpHb showed excellent correlation with Lab-Hb in fluid responders, fluid non-responders, low-Pi, and high-Pi states. Despite a favorable mean bias of 0.01 g/dL for SpHb, the relatively wide levels of agreement (-1.3 to 1.3 g/dL) might limit its accuracy. SpHb showed good performance as a trend monitor."

SpHb is not intended to replace laboratory blood testing. 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.

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