

## **Validation of a New Noninvasive Hemoglobin Algorithm in Patients Undergoing Liver Transplantation.**

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### **Introduction**

Measurement of total hemoglobin concentration (tHb) is one of the most frequently ordered laboratory tests. Serial measurements are often made to assess disease progression, blood loss, or effectiveness of transfusion. Technology for laboratory tHb measurement has rapidly advanced and today there are many techniques for measuring it. Recently, a new device was released to the market (Rainbow Pulse CO-Oximeter®, Masimo Corporation, Irvine, CA, USA) that measures total hemoglobin (SpHb) continuously and noninvasively. The purpose of this study was to validate the latest commercially available algorithm (v 7.4.0.9) and compare the values to laboratory measurements of tHb.

### **Methods**

After IRB approval, a total of 55 blood samples were obtained from 5 consecutive patients undergoing liver transplantation. After a 10 ml waste, a 2 ml sample of arterial blood was taken for tHb measurement using a CO-Oximeter (Nova Biomedical pHox Plus). The device was maintained and calibrated at the start of each case according to the manufacturer's recommendations. The Masimo pulse co-oximeter acquired raw waveform data continuously, using “Responsible” sensors (R225 ADT, commercial release March 23, 2009). The new algorithm (V. 7.4.0.9), which was developed using a different dataset, was retrospectively applied to those raw waveform data for validation of the SpHb. Accuracy was determined by calculating bias, precision and root mean square of the differences (ARMS) between SpHb and CO-Oximeter tHb values. Statistical differences were assessed by t-test after confirming normality of the data.

### **Results**

The 5 liver transplant patients (3 males and 2 females) had a mean age of  $54 \pm 5$  years (range 50 to 62 years). There was an average of 11 blood samples taken per patient during the surgical procedure. The mean surgery time was  $2.58 \pm 0.9$  hours per case with a range of 0 to 16 packed red blood cell transfusions (mean =  $6 \pm 12$ ). Figure 1 shows the Bland-Altman plot highlighting the differences between SpHb minus tHb versus tHb by CO-Oximeter.

### **Conclusions**

By applying a new algorithm to an existing data set, accuracy of the noninvasive SpHb measurements obtained by the pulse co-oximeter “Responsible” sensors was high, compared to the laboratory CO-Oximeter pHox Plus in 5 liver transplant cases. When considering the clinical utility of hemoglobin measurements, continuous Hb accuracy must be considered within the context of the inherent device and physiologic variation that exists with all conventional tHb measurements. A prospective study to determine the accuracy of this device using the current sensors and algorithm is needed.

Figure 1

### SpHb Accuracy Compared to CO-Oximeter Hb

