

## **In-Vivo Calibration Improves Accuracy of Non-Invasive Hemoglobin Measurements**

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### **Introduction**

Noninvasive hemoglobin measurements (SpHb) using pulse oximetry has been developed by Masimo, (Irvine, CA, USA) in 2008. Since then refinements in algorithm and sensors have increased the accuracy of SpHb measurements. Possible causes for differences between SpHb measurements and invasive hemoglobin (Hgb) blood tests using laboratory (lab) instruments may include: 1) The hospital reference instrument might be different from the reference instrument to which the non-invasive device was calibrated to. We have found a bias of 1 g/dl and precision of 0.6 g/dl between 2 different lab instruments. Others reported differences in Hgb values of up to 0.77 g/dl using the same model of instrument and point of care devices have shown variation up to 1.4 +/- 0.4 g/dl. The lab director can adjust some instruments mathematically to bring their values closer to the reference instrument of the institution. 2) Misapplication of the sensor or ambient light interference may be another potential error of SpHb measurements. This could be analogous to a pre-analytical error using the traditional lab, which is thought to account for most of the lab instrument variation, when a repeat sample returns a value that differs greatly from a previous value. Masimo has recently developed the ability to adjust the Hgb value of the Radical 7® device to a lab reference value. This should have the ability to mitigate some of the potential measurement variations and bring the SpHb value closer to a lab instrument, used to make clinical decisions. The aim of this study was to assess the impact on accuracy on subsequent SpHb measurements when a one-time adjustment to the Radical 7® is made.

### **Methods**

After IRB approval, a data set of 55 sensors, with 261 paired SpHb (Rev F sensors) and lab Hgb measurements, obtained in the operating room (OR), underwent a one-time adjustment of the SpHb difference compared to the first lab Hgb value. Per our study protocol, all blood samples were measured using a hematology analyzer (AcT diff 2®, Beckman Coulter, Miami, FL, USA or XE5000®, Sysmex, Wundelein, IL, USA) as well as a blood gas analyzer (pHOx® or CCX®, Nova Biomedical, Waltham, MA, USA). The precision, bias and accuracy root mean square (ARMS) was calculated using the Bland Altman method.

### **Results**

After excluding the first measurement that was used to “calibrate” the Radical 7®, 206 measurements were available for analysis. The one time mathematical adjustment improved the bias from 0.78 to 0.07 g/dl and the precision from 0.95 to 0.78 g/dl (ARMS 1.23 to 0.79) when using Co-oximeter values for calibration. Using the hematology analyzer from the same blood draw, the calibration improved the bias from 1.49 to -0.37 g/dl and the precision from 1.14 to 0.83 g/dl (ARMS 1.88 to 0.9).

### **Discussion**

We have shown that a one time mathematical adjustment can improve accuracy and reduce bias, improving the ability of the Radical 7® instrument to trend changes in Hgb in the OR. Even though this is a retrospective application of a data set to a new algorithm, this in-vivo calibration feature does not alter the way of measuring SpHb, but just adds or subtracts a constant to the reported values, based on a lab instrument. Therefore this should be applicable to prospectively generated data points. Other medical devices are commonly calibrated to different instruments, for example: 1) SVO2 calibrations to a co-oximeter in oximetric pulmonary artery catheters 2) Cardiac output calibrations to a pulmonary artery catheter in the new non-invasive estimated continuous cardiac output monitor from Nihon Kohden® 3) Blood gas analyzers to other lab reference instruments.

### **Conclusion**

A onetime calibration is a useful tool to use a non-invasive Hgb monitor to trend the Hgb values during surgery and may reduce the number of blood draws needed to check for Hgb using a lab instrument. The impact of the in-vivo calibration to future prospective data is currently underway.