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**LBT07**

October 17, 2011

3:00:00 PM - 4:30:00 PM

Room Hyatt Regency 10CD

**Performance of 5 Cerebral Oximeters During Hypoxia in Healthy Volunteers**

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**Introduction:** Cerebral Oximetry is a non-invasive, optically-based technology that integrates frontal cortex blood hemoglobin-oxygen saturation. The performance of commercially available cerebral oximeters (CerOx) has not been independently evaluated and there are currently no FDA standards for accuracy as with pulse oximeters.

**Methods:** We evaluated the accuracy performance of the four commercially available CerOx's in routine, worldwide use: the EQUANOX 7600 in 3- and 4-wavelength versions (Nonin Medical, Plymouth, MN, USA), FORE-SIGHT (Casmed, Branford, CT, USA), INVOS 5100C (Covidien, Boulder, CO, USA), and the Niro-200NX (Hamamatsu Photonics, Hamamatsu City, Japan). With IRB approval and informed consent, 23 healthy adult volunteers of mixed gender and ethnicity were monitored with CerOx sensors randomly placed on each side of the forehead. To acquire a broad range of oxygenation data, the fraction of inspired oxygen ( $FiO_2$ ) was stepwise changed to produce oxygen saturation ( $SaO_2$ ) levels of 70-100%, while the end-tidal  $CO_2$  was maintained constant. A series of targeted steady-state oxygenation plateaus were created and blood samples from the jugular bulb and radial artery were collected and analyzed with a multi-wavelength oximeter to determine oxygen saturation (OSM-3, Radiometer). The CerOx's stated arterial/venous ratios were applied ("reference saturation": INVOS 25/75 and all others 30/70) to determine accuracy by calculating the mean bias (CerOx reading ( $ScO_2$ )-reference saturation), precision (SD of the bias) and the  $A_{rms}$  statistic, established for regulatory claims of  $SpO_2$  accuracy performance.<sup>1</sup>

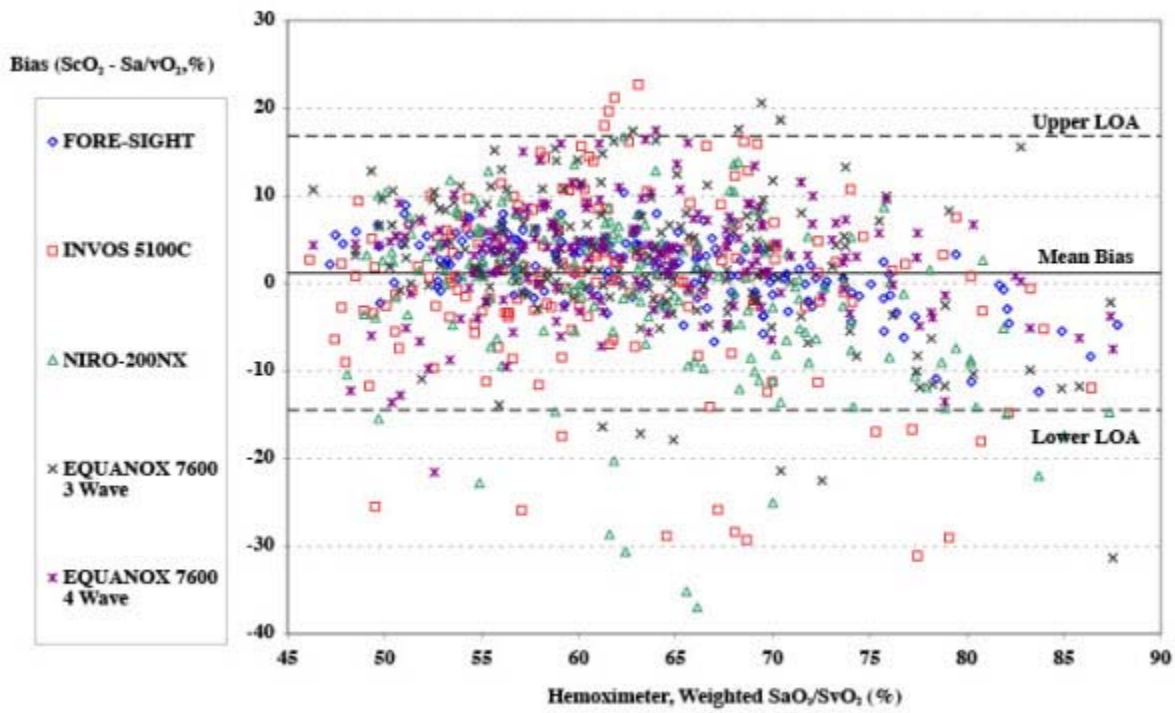
**Results:** 542 comparisons between paired blood samples and oximeter readings were analyzed in the 23 subjects. The pooled RMS error was 9.1%, a value substantially high than that for pulse oximeters (typically 2-3%) (Fig.1). The mean bias  $\pm$  SD (precision) and  $A_{rms}$  errors were: FORE-SIGHT  $1.73 \pm 3.90$  and 4.26; INVOS  $0.05 \pm 9.72$  and 9.69; Niro-200NX  $-1.23 \pm 9.64$  and 9.68; Equanox-3  $\lambda$   $2.48 \pm 8.12$  and 8.47; EquanoxX-4  $\lambda$   $2.84 \pm 6.27$  and 6.86. In addition, the FORE-SIGHT, Niro-200NX, and EQUANOX-3  $\lambda$  had significantly greater bias at lower  $SaO_2$ .

**Discussion:** Currently, there are no requirements to disclose accuracy performance data for CerOx monitors. If CerOx performance in patients is similar to healthy volunteers, users should be aware that readings may systematically, and significantly differ from that based on weighted averages of cerebral mixed venous and arterial blood. The assumption of fixed weighted averages of venous and arterial blood at all levels of oxygenation may not be physiologically correct, and may explain the greater bias at low saturation in the Casmed, Hamamatsu, Nonin 3  $\lambda$  and Somanetics instruments.

1. ISO 9919:2005; Medical electrical equipment -- Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use

Fig 1. Bias (cerebral oximeter saturation [ $ScO_2$ ]-"reference saturation") of 5 cerebral oximeters. The "reference saturation" is the hemoximeter values weighted according to manufacturer specifications for the mixture of cerebral venous and arterial blood "seen" by the sensors (25/75 arterial/venous for INVOS and others 30/70). Mean bias, upper and lower limits of agreement (LOA) are show with solid and dashed horizontal lines respectively.

**Figure 1**



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