

Comparative Analysis of Measurement Accuracy of Three SpO₂ Monitors During Low Perfusion Conditions

John Beard, MD¹; Robert N. Bilkovski, MD²; Karen Giuliano, PhD, RN, MBA³; Sakari Lamminmaki, M.Sc. (Tech.)¹
 GE HealthCare¹, RNB Ventures Consulting Inc.², University of Massachusetts Amherst³

Background

- Pulse oximetry (SpO₂) is the standard of care for assessing oxygen saturation in the acute care setting¹
- Low-perfusion degrades pulse oximeter performance and represents a clinical challenge²
- Manufacturers have developed pulse oximetry technologies to minimize the impact of artifacts on sensor performance

Objectives

- A comparative study was conducted to evaluate SpO₂ accuracy during low-perfusion conditions among three currently available devices: GE HealthCare CARESCAPE, Masimo RADICAL-7 and Medtronic Nellcor PM1000N

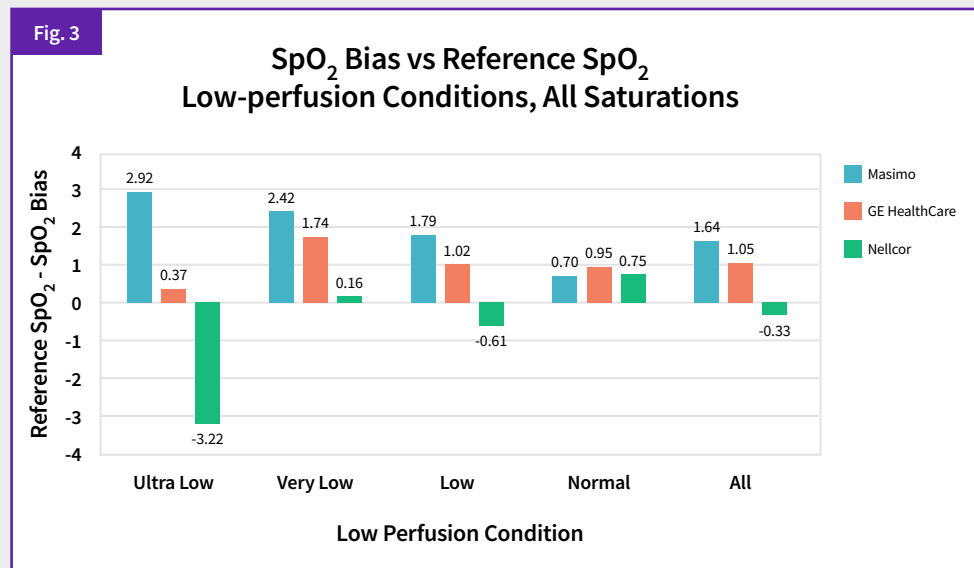
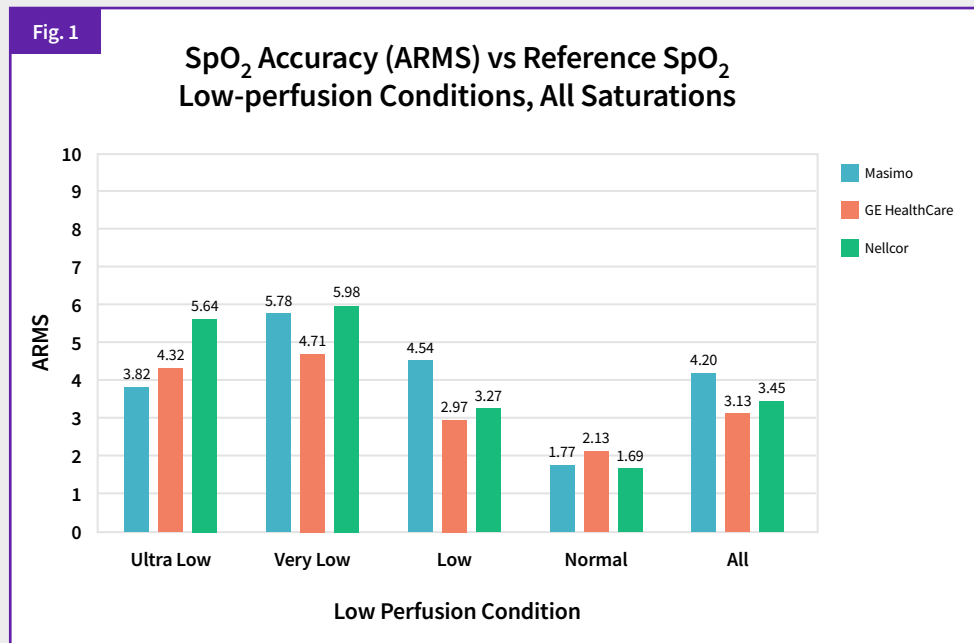
Methods

- After University of California San Francisco IRB approval, healthy adult (≥18 years) volunteer non-smokers with normal Hgb levels were recruited for this prospective, open-labeled study
- Testing was conducted using a minimum of 10 subjects, including ≥2 subjects with darkened skin pigment (FDA Pulse Oximetry Guidance (2013) & ISO 80601-2-61:2017)
- Skin pigmentation was categorized by the Fitzpatrick scale
- Low perfusion was simulated using ice-bath immersion with the left arm, while the right arm served as the control
- All 3 pulse oximeters were placed on both hands, using a randomized, counter-balanced approach for SpO₂ finger placement to control for order bias
- SpO₂ readings were compared between the normal perfusion and low perfusion hands to measure accuracy during low perfusion
- The Perfusion Index (PI), calculated as the ratio of pulsatile component to non-pulsatile component of the infrared plethysmographic signal, served as the measurement standard for flow: <0.1=ultra-low; ≥0.1 to <0.3=very low; ≥0.3 to <1=low; and ≥1=normal
- Induced hypoxia was used to provide a range of oxygen saturation levels (normal: >90% and low: 75-85%) by having subjects breathe mixtures of nitrogen, room air, and carbon dioxide
- Descriptive data for comparison included the Accuracy Root Mean Square (ARMS), bias, and absolute delta (AD)

DISCLOSURES

JB and SL are employees of GE HealthCare.
 RB and KG have received consulting fees from GE HealthCare.

Results



Discussion and conclusions

- The final sample (N=14) included 9 female and 5 male subjects, with a mean age of 28.7 years (SD=7.8) and a range of 20-48
- Skin tones varied by the Fitzpatrick scale as Type II (N=4), Type III (N=5), Type IV (N=3), Type V (N=1), and Type VI (N=1). Ethnicity varied as Asian (N=4), Caucasian (N=6), African American (N=1), and Multiethnic (N=3)
- Across all saturation levels, the overall ARMS (Figure 1) for each of the 3 devices were 3.13 (GE HealthCare), 3.45 (Nellcor), and 4.2 (Masimo). ARMS for low PI were 2.97 (GE HealthCare), 3.27 (Nellcor), 4.54 (Masimo) and during very low PI, the ARMS were 4.71 (GE HealthCare), 5.78 (Masimo) and 5.98 (Nellcor)
- The overall bias measurements (Figure 2) were 1.05 (GE HealthCare), -0.33 (Nellcor), and 1.64 (Masimo). Bias measurements at low PI were -0.61 (Nellcor), 1.02 (GE HealthCare), 1.79 (Masimo) and during very low PI the bias measurements were of 0.16 (Nellcor), 1.74 (GE HealthCare) and 2.42 (Masimo)
- The AD5 for all saturation levels and across all PI categories was 11.0% (Masimo), 11.6% (GE HealthCare) and 6.9% (Nellcor)
- Overall failure to measure an SpO₂ was lowest for GE HealthCare (1.9%), followed by Nellcor (7.9%) and Masimo (10.1%)
- The SpO₂ accuracy when tested under low and very low perfusion thresholds showed overall comparable performance across all three pulse oximeters
- While there were differences in some aspects of measurement performance, the clinical relevance of these results requires further study during clinical use

Directions for further study

- Evaluation of the technologies during clinical care under various measurement conditions
- Subgroup analysis based on skin pigmentation levels
- Analysis for statistically significant differences between technologies

References

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2. Louie, A, Feiner, J. R., Bickler, P. E., Rhodes, L., Bernstein, M., & Lucero, J. (2018) Four Types of Pulse Oximeters Accurately Detect Hypoxia during Low Perfusion and Motion. *Anesthesiology*, 128(3), 520-530. <https://doi.org/10.1097/aln.0000000000002002>