

Comparative Analysis of Signal Accuracy of Three SpO₂ Monitors During Motion and Non-Motion Conditions

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Background

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

Objectives

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

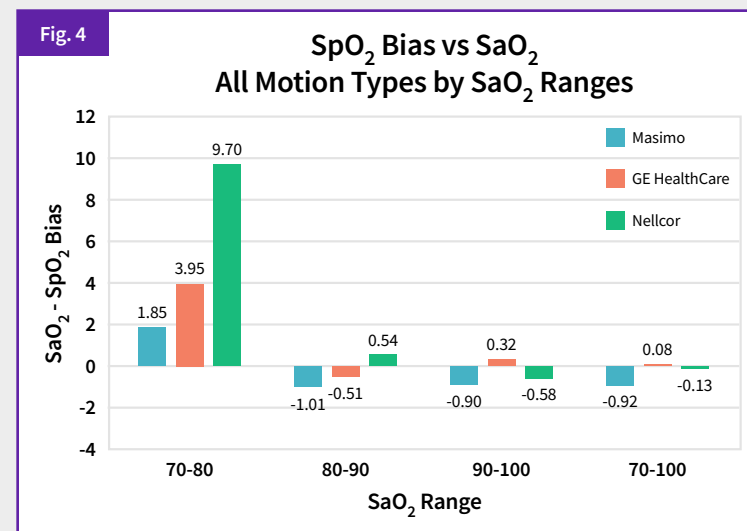
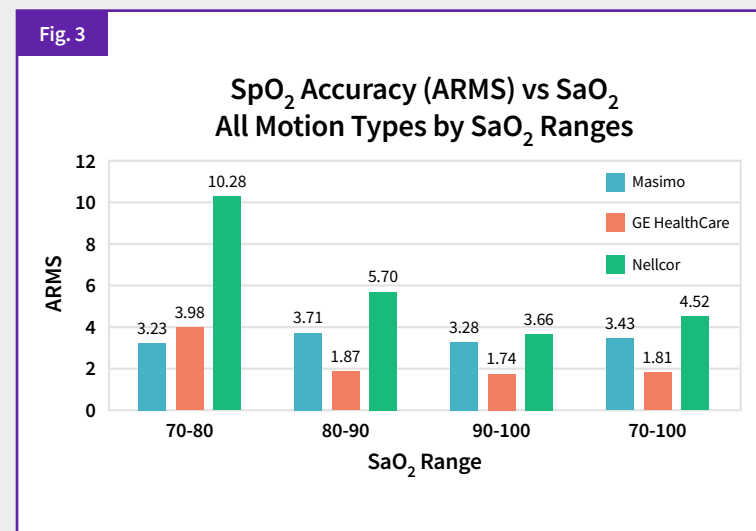
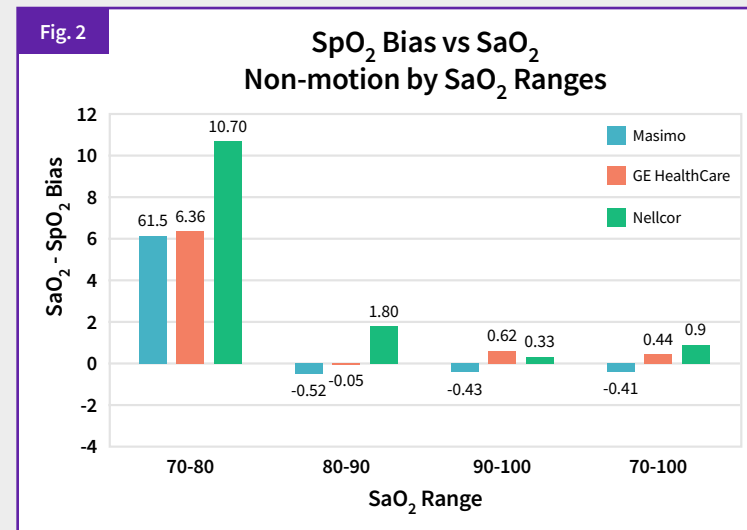
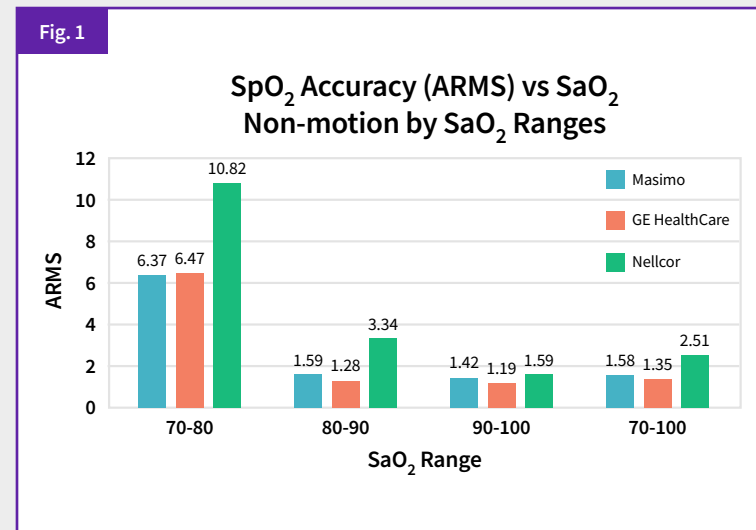
Methods

- 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
- All 3 pulse oximeters were placed on both hands (one hand was motion and one hand was non-motion), using a randomized, counter-balanced approach for SpO₂ finger placement to control for order bias
- The non-motion hand had an arterial catheter used for sampling reference co-oximetry oxyhemoglobin (SaO₂) measurements
- SpO₂ readings from the 3 devices on the motion hand were compared to SpO₂ readings from the corresponding devices on the non-motion hand
- Data were collected using three motion conditions (tapping, rubbing, clenching) and under 3 oxygenation conditions (room air, oxygen desaturation to <90%, and re-saturation phase)
- 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 study sample (N=14) included 9 male and 5 female subjects, with a mean age of 28.1 years (SD=5.3) and a range of 24-43
- Skin tones varied by the Fitzpatrick scale as Type II (N=1), Type III (N=6), Type IV (N=5), Type V (N=1), and Type VI (N=1). Ethnicity was Asian (N=5), Caucasian (N=5), Hispanic (N=2), Black (N=1), and Multiethnic (N=1)
- In non-motion conditions, mean ARMS (Fig. 1) for the 3 devices across all saturation phases, were 1.35 (GE HealthCare), 1.58 (Masimo) and 2.51 (Nellcor), with overall mean bias (Fig. 2) of -0.41 (Masimo), 0.44 (GE HealthCare), and 0.90 (Nellcor)
- During motion conditions, mean ARMS (Fig 3.) were 1.81 (GE HealthCare), 3.43 (Masimo) and 4.52 (Nellcor), with overall mean bias (Fig. 4) of -0.92 (Masimo), 0.08 (GE HealthCare), and -0.13 (Nellcor)
- The AD5 for all saturation levels was 4.7% (GE HealthCare), 7.9% (Masimo), and 16.3% (Nellcor). AD10 was 0.8% (GE HealthCare), 3.0% (Masimo), and 5.8% (Nellcor).
- Under 3 simulated conditions for both motion and oxygenation, the Nellcor, GE HealthCare, and Masimo pulse oximetry technologies demonstrated comparable performance, with no single device having the best measurements under all conditions
- The clinical relevance of these results requires further study during actual 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>