

# Comparative Analysis of Signal Accuracy of Three SpO<sub>2</sub> Monitors During Motion and Non-Motion Conditions

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## Background

- Pulse oximetry (SpO<sub>2</sub>) is the standard of care for assessing oxygen saturation in the acute care setting<sup>1</sup>
- Motion artifact degrades pulse oximeter performance and represents a clinical challenge<sup>2</sup>
- Manufacturers have developed pulse oximetry technologies to minimize the impact of motion on sensor performance

## Objectives

- A comparative study was conducted to evaluate SpO<sub>2</sub> accuracy of three currently available devices: GE 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 SpO<sub>2</sub> finger placement to control for order bias
- The non-motion hand had an arterial catheter used for sampling reference co-oximetry oxyhemoglobin (SaO<sub>2</sub>) measurements
- SpO<sub>2</sub> readings from the 3 devices on the motion hand were compared to SpO<sub>2</sub> 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)

## Results

Fig. 1

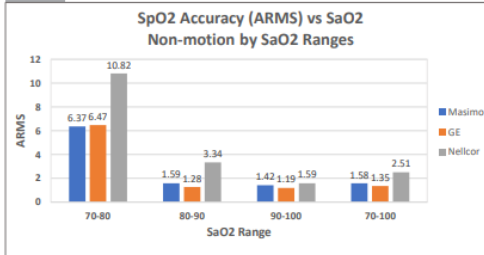


Fig. 2

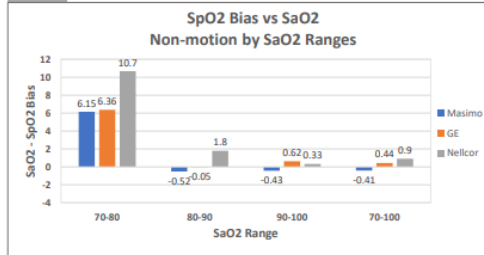


Fig. 3

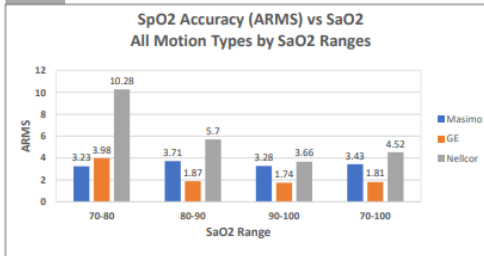
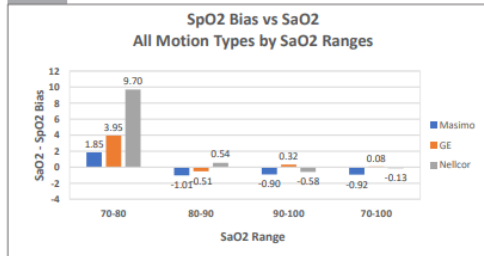


Fig. 4



## 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), 1.58 (Masimo) and 2.51 (Nellcor), with overall mean bias (Fig. 2) of -0.41 (Masimo), 0.44 (GE), and 0.90 (Nellcor)
- During motion conditions, mean ARMS (Fig. 3) were 1.81 (GE), 3.43 (Masimo) and 4.52 (Nellcor), with overall mean bias (Fig. 4) of -0.92 (Masimo), 0.08 (GE), and -0.13 (Nellcor)
- The AD5 for all saturation levels was 4.7% (GE), 7.9% (Masimo), and 16.3% (Nellcor). AD10 was 0.8% (GE), 3.0% (Masimo), and 5.8% (Nellcor).
- Under 3 simulated conditions for both motion and oxygenation, the Nellcor, GE, 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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- 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/ain.0000000000002002>

## DISCLOSURES

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