A Comparison of Four Major Brand of Pulse Oximeters (PO) with Masimo SET PO during Motion and Low Perfusion under Normoxic and Hypoxic Conditions in Human Volunteers.
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Introduction
Despite significant improvements in PO technology the problem of being able to accurately obtain a PO reading during patient movement in presence of low perfusion still persists. Many PO manufacturers claim better performance of their PO in those conditions. We, therefore, after approval from the Institutional Review Board for human subjects undertook the following study to compare four major brand of POs to the Masimo SET PO during motion and low perfusion under normoxic and hypoxic conditions.

Methods
Seven competent, healthy, adult volunteers (5-females & 2-males) between 18 and 40 years of age (mean 27 +/- 3 SD), with a physical status ASA I, after written informed consent, were enrolled in the study. Masimo Radical version v3 (Masimo I) was compared with Agilent Viridia 24C version Rev B and Novametrix MARS Model 2001 version TBD, and Masimo Radical version v3 (Masimo II) was compared with Nellcor N-395 version v1620 and HP CMS version Rev B. The left hand was used as the test hand and sensors were placed on index, middle & ring fingers. Similar fingers of the right hand had sensors for the same PO to serve as their control. Ear sensor of Ohmeda PO was used as a control for hypoxia. The room was cooled down to a temperature of 16-18 degree C to reduce peripheral perfusion. The motion (performed by a motor-driven motion table) during normoxia (breathing room air) consisted of tapping at 3 Hz, tapping at 3 Hz with disconnect and reconnect of sensors during motion, and random rubbing. The initial selection of fingers for the sensor of the PO was randomized. The sensors were than rotated in a lateral fashion allowing for sensor placement on each finger and the motion was repeated after each sensor change. The study was repeated for a second time with two other POs along with Masimo which was used in both sets of experiments.

The motion during hypoxia (induced employing a disposable re-breathing circuit with a CO2 absorber to a SpO2 of 76 +/- 0.48) consisted of random tapping with disconnect and reconnect of sensors during motion, 3 Hz tapping with disconnect and reconnect during motion, random rubbing, and 3 Hz rubbing. Once the SpO2 reached 75% as measured by ear sensor, the subjects were given 100% oxygen to breathe until his/her SpO2 on the control monitor reached 100%.

A missed event was defined as the inability of the monitor during desaturation to recover before the control monitor reached 100%. A false alarm was considered to be a reading of less than 90% during motion while breathing room air.

Results
False alarms were counted out of 63 occasions during motion on room air, while missed events were counted out of 28 occasions during desaturation episodes for each PO. Sensitivity, specificity, and false alarm rates were calculated for each PO. Our results are summarized in the table. Statistical analysis was performed on the data using chi square analysis, P <.05 was considered statistically significant. * = P<.05 vs Masimo I, # = P<.05 vs HP Viridia 24C, @ = P<.05 vs Masimo II.

Conclusion
While no PO withstood 100% of this vigorous test schedule, Masimo SET PO performed the best and has the highest sensitivity, specificity with fewest false alarm rate. HP CMS, Nellcor N-395, HP Viridia 24C, and Novametrix MARS performed in decreasing order based on the sensitivity, specificity, and false alarm rate.

PO	Missed Events	False Alarms	False Alarms Rate	Sensitivity	Specificity
Masimo I	6/28	5/63	7.9%	78.6%	92.1%
HP Viridia 24C	15/28*	27/63*	42.9%	46.4%	57.1%
Novametrix-MARS	23/28*£	45/63*£	71.4%	17.9%	28.6%
Masimo II	1/28	8/63	12.7%	96.4%	87.3%
N-395	13/28@	21/63@	33.3%	53.6%	66.7%
HP CMS Rev B	8/28@	15/63	23.8%	71.4%	76.2%