

Evaluation of Masimo SET Ear and Forehead Pulse Oximetry and Nellcor MAX-FAST Forehead Pulse Oximetry

Redford D, Lichtenthal P, Barker SJ. *Anesthesiology*. 2004; 101: A593 and A579

Introduction

Most clinical research has found that digit pulse oximetry is typically less subject to the kind of artifact that can compromise a pulse oximeter's ability to faithfully read changing physiology. However, in an effort to achieve faster pulse oximetry response times and access to more stable perfusion, researchers tested sensors designed by Masimo and Nellcor for use on alternative sensor sites - the forehead and the ear. Nellcor manufactures the MAX-FAST forehead sensor for use with the N-595 pulse oximeter. Masimo manufactures the TF-I forehead sensor and the TC-I ("tip-clip") multi-site sensor, for use primarily on the earlobe. Each Masimo sensor is intended for use with the Masimo SET Radical pulse oximeter.

Methods

Following IRB approval, 24 pediatric surgical patients undergoing general anesthesia were monitored with the Nellcor MAX-FAST forehead sensor, the Masimo SET TF-I Forehead Sensor, and the Masimo SET TC-I sensor connected to the earlobe. As controls, the Nellcor Max-P or Max-I connected to the N-595 Pulse Oximeter, and the Masimo LNOP Pdt or Inf-L connected to the Masimo SET Radical were attached to the digits of the test subjects. All pulse oximetry sensors were optically shielded from each other to prevent cross-talk. The mean SpO₂ and pulse rate of the two digit sensors was calculated as the control value. SpO₂ and pulse rate values were recorded from each of the three test sensors and then compared for statistical significance against the control value. Analysis focused on bias (mean error), precision (standard deviation of the E7), E7 (percentage of time during which the SpO₂ reading is outside 7% of the control value in stable conditions), and Performance Index (percentage of time during which the SpO₂ reading is within 7% of the control value).

Results

In 33% of the patients, the MAX-FAST forehead sensor was in error greater than 7% of the control for more than 20% of the surgical procedure. The Masimo sensors both displayed high reliability and accuracy.

	% Bias	% Precision	% E7	Performance Index
Masimo SET [™] TC-I	0.3 ± 0.7	0.5 ± 0.5	0.6 ± 1.5	99.4%
Masimo SET [™] TF-I	0.1 ± 0.5	0.5 ± 0.6	0.6 ± 1.7	99.4%
Nellcor MAX-FAST Forehead Sensor	-4.1 ± 6.0	2.7 ± 3.4	20.2 ± 30.7	79.8%
* p-value (TC-I vs. MAX-FAST)	0.005	0.006	0.004	
* p-value (TF-I vs. MAX-FAST)	0.002	0.006	0.004	

Authors' Discussion and Conclusions

A statistically significant difference was displayed between the Nellcor MAX-FAST forehead sensor and the Masimo SET TC-I and TF-I sensors, with Masimo SET sensors showing much higher accuracy and reliability than the Nellcor MAX-FAST. **The researchers stated, "Because the Nellcor MAX-FAST sensor had significantly longer periods of time [when] SpO₂ reading was falsely low, it is unacceptable for work in the pediatric surgical patient."**