

Clinical Evaluation of the Accuracy of Masimo SET and Nellcor N-595 Oximeters in Children with Cyanotic Congenital Heart Disease

Whitney GM, Tucker LR, Hall SR, Chang AC. *Anesthesiology* 2005;103:A1344.

Introduction

Masimo has developed a unique pulse oximetry sensor – the Masimo SET LNOP Blue Sensor - specifically for children with cyanotic congenital heart disease. This patient population, due to their chronically poor peripheral perfusion and low oxygen saturation, has long suffered from pulse oximetry inaccuracy. These researchers tested the new Blue sensor, used with the Masimo SET Radical pulse oximeter, by running side-by-side performance tests against the Nellcor Oximax Max-I sensor, Nellcor's standard sensor for children 3 – 20 kg.

Methods

Seven cyanotic congenital heart disease patients with $\text{SaO}_2 < 90\%$ were enrolled and continuously monitored with the Nellcor Oximax Max-I sensor connected to the Nellcor N-595 pulse oximeter and the Masimo SET LNOP Blue Sensor connected to the Masimo SET Radical pulse oximeter. The sensors were used on sites recommended by the manufacturers. Pulse oximetry measurements were analyzed and compared to periodic measurements of SaO_2 of whole blood.

Results

A total of 22 SaO_2 measurements were recorded. The mean SaO_2 was $75.8\% \pm 9.3\%$ (60.9% - 91.0%). There was a significant difference in bias ($\text{SaO}_2 - \text{SpO}_2$) and precision (± 1 SD) between the sensors detected in patients with cyanotic congenital heart disease ($p = 0.0001$). See the table below.

Bias and Precision of Masimo SET Radical with LNOP Blue Sensor vs. Nellcor N-595 with Max-I sensor		
	Bias ($\text{SaO}_2 - \text{SpO}_2$)	Precision (± 1 SD)
Radical with Blue sensor	0.17	2.51
Nellcor N-595 with Max-I sensor	5.63	5.24

Authors' Conclusions

“Masimo SET Blue Sensor technology offers improved accuracy in the monitoring of SaO_2 when compared to the Nellcor N-595 pulse oximeter in patients with cyanotic congenital heart disease. This represents a significant advance in the care of this complicated group of patients.”