



**Selection of Independent and Objective Studies Comparing  
Masimo and Nellcor Technology**

# Table of Contents

Red indicates that the study is summarized herein.

- 1 New Pulse Oximetry Sensors with Low Saturation Accuracy Claims; A Clinical Evaluation.**  
Cox PN. 14th Annual World Congress of Anesthesiology, March 1-8, 2008; Capetown, South Africa. Available at <http://www.wca2008.com/images/abstractWCA/Monitoring.pdf>. Accessed 4/01/08.
- 2 Avoiding Hyperoxemia During Neonatal Resuscitation: Time to Response to Different SpO<sub>2</sub> Monitors.**  
Baquero H, Alviz R, Sola A. Presented at Pediatric Academic Societies Annual Meeting May 5-8, 2007. Available at <http://www.abstracts2view.com/pas/>. Accessed 4/30/07.
- 3 Clinical Practice and SpO<sub>2</sub> Technology in the Prevention of ROP in VLBW Infants.**  
Castillo AR, Deulofeut R, Sola A. Presented at Pediatric Academic Societies Annual Meeting May 5-8, 2007. Available at <http://www.abstracts2view.com/pas/>. Accessed 4/30/07.
- 4 A Comparison of Newer Generation Pulse Oximeters for Accuracy and Dropout Rate in Neonatal Intensive Care.**  
Lussky RC, Cifuentes RF, Kaestner K, Stanek G, Geppert J. Presented at Annenberg 25th Annual Conference Sleep Disorders in Infancy and Childhood. January 25-27, 2007. Ranch Mirage, CA. Available at: <http://www.5starmeded.org/sleepdisorders/abstracts.html>. Accessed 4/5/07.
- 5 New Pulse Oximetry Sensors with Low Saturation Accuracy Claims - A Clinical Evaluation.**  
Cox PN, M.D., F.R.C.P.C. *Anesthesiology*. 2007; 107: A1540.
- 6 New Generation and Old Generation Pulse Oxymeters in Children with Cyanotic Congenital Heart Disease.**  
Cannesson, M.D., Neidecker J., M.D., Bompard D., M.D., Védrinne C., M.D., Ph.D., Lehot J., M.D. *Anesthesiology* 2007; 107: A204.
- 7 A Comparison of Finger, Ear and Forehead SpO<sub>2</sub> on Detecting Oxygen Desaturation in Healthy Volunteers.**  
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Toda Y, Takeuchi M, Iwasaki T, Shimizu K, Morita K. *Anesthesiology* 2006; 105: A1704.
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- 10 Failure Rates & Recovery Times of New Generation POs during Motion and Low Perfusion in Volunteers.**  
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- 11 Impact of Motion and Low Perfusion on SpO<sub>2</sub> & Pulse Rate in Three New Generation POs in Volunteers.**  
Shah N, Estanol L. *Anesthesiology* 2006;105:A1433.
- 12 Comparison of Three New Generation Pulse Oximeters During Motion & Low Perfusion in Volunteers.**  
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- 13 An Evaluation of Three New Generation Pulse Oximeters During Motion and Low Perfusion in Volunteers.**  
Shah N, Patel V, Estanol L. *Anesth Analg* 2006;102:S-75.
- 14 Motion and Low Perfusion Induced Failures of New Generation Pulse Oximeters - Failure Rates and Recovery Times in Volunteers.**  
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- 15 Impact of Motion and Low Perfusion on the Performances of Three New Generation Pulse Oximeters for SpO<sub>2</sub> and Pulse Rate in Volunteers.**  
*Anesth Analg* 2006;102:S-148.
- 16 For the Capability of Pulse Oximetry with Moving Horizontal and Vertical Controlled by Accelerator.**  
Yamada A, Morioka N, Takada M, Inui T, Ozaki M. *Anesthesiology* 2006;105:A247.
- 17 Clinical Evaluation of Accuracy of Masimo LNOP Blue Sensor in Cyanotic Infants.**  
Tsutumi T, Nakashima M, Yasunaga H, Nakao F, Takamatsu J. *Crit Care Med* 2006; 34(12): A56.

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Ahrens TS, Ott K. *Crit Care Med* 2006; 34(12): A85.
- 20 Comparison of Two Types of Pulse Oximeters During Low Perfusion and Increased Motion Artifact in Pediatric Patients.**  
Downs B, Willis, R. *Crit Care Med* 2006; 34(12) A89.
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- 23 A Laboratory Comparison of the Newest Motion-Resistant Pulse Oximeters During Motion and Hypoxemia.**  
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- 32 Indication of False Unwarned Desaturations in the Neonatal Intensive Care Unit**  
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## Table of Contents Continued


*Red indicates that the study is summarized herein.*

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Brouillette RT, Lavergne J, Leimanis A, Nixon GM, Laden S, McGregor CD. *Anesthesia and Analgesia* 2002;94:S47-S53.
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## Table of Contents Continued

*Red indicates that the study is summarized herein.*

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Award winning Publication, Study or Presentation.

## Avoiding Hyperoxemia During Neonatal Resuscitation: Time to Response to Different SpO<sub>2</sub> Monitors.

Baquero H, Alviz R, Sola A. Presented at Pediatric Academic Societies Annual Meeting May 5-8, 2007. Available at <http://www.abstracts2view.com/pas/>. Accessed 4/30/07.

### Introduction

One to two percent of all births require aggressive therapeutic interventions such as neonatal resuscitation.<sup>1</sup> Neonatal resuscitation can lead to hyperoxemia and oxidative stress if excessive inspired oxygen (F<sub>i</sub>O<sub>2</sub>) is given however, so close monitoring of oxygen saturation values of these patients is necessary to avoid high SaO<sub>2</sub> values. Neonates are prone to exhibit motion and have low perfusion, both of which affect the accuracy and ability to obtain readings with most pulse oximeter technologies. In this study, the investigators tested the time it took for three different pulse oximeter technologies, the Masimo SET Radical, the Nellcor N-395 and the Ohmeda Biox 3700, to obtain stable oxygen saturation readings in newborn infants receiving resuscitation.

### Methods

Nineteen newborns from the delivery room and five from the NICU, who required resuscitation, were used for the study. During each resuscitation, two sensors for two different pulse oximeter technologies were applied to the feet or left palm or wrist of the patient. There were 24 resuscitation events during the study. The pulse oximeters used were the Masimo SET Radical with an LNOP Neonatal sensor (n = 24), the Nellcor N-395 with the Oximax-N sensor, (n = 9) and the Ohmeda Biox 3700 with disposable neonatal sensor, (n = 15). The time for each pulse oximeter to reach a stable reading was measured with a digital stop watch and recorded.

### Results: Time to Obtain a Stable SpO<sub>2</sub> Reading During Resuscitation

	Mean +/- std (sec)	Median (sec)	Range (sec)
<b>Masimo Radical</b> (n =24)	21.7 +/-7	21	18 - 32
<b>Nellcor N-395</b> (n = 9)	67.3 +/- 13	71	40 - 89
<b>Ohmeda 3700</b> (n = 15)	74.2 +/- 12	76	40 - 98

### Discussion and Authors' Conclusions:

A fast and accurate SpO<sub>2</sub> reading during newborn resuscitation is essential because even brief exposure to excessive oxygen may result in damage to the immature lung. This study shows that the Masimo SET Radical pulse oximeter was significantly faster at obtaining stable oxygen saturation readings during infant resuscitations compared to the other two other pulse oximetry technologies. The authors of this study conclude: "Adequate and clinically useful reading of SpO<sub>2</sub> is possible during newborn resuscitation. The time to stable and adequate reading is significantly different between SpO<sub>2</sub> monitors. The SpO<sub>2</sub> monitor with the fastest response time would allow for more rapid adjustments of F<sub>i</sub>O<sub>2</sub> during resuscitation and avoid unnecessary exposure to hyperoxia".

1. Leone TA, Finer NN. Neonatal Resuscitation: Beyond the Basics. Neo Reviews 2005; 6(4):e177-83.

## Clinical Practice and SpO<sub>2</sub> Technology in the Prevention of ROP in VLBW Infants.

Castillo AR, Deulofeut R, Sola A. Presented at Pediatric Academic Societies Annual Meeting May 5-8, 2007. Available at [http:// www.abstracts2view.com/pas/](http://www.abstracts2view.com/pas/) Accessed 4/30/07.

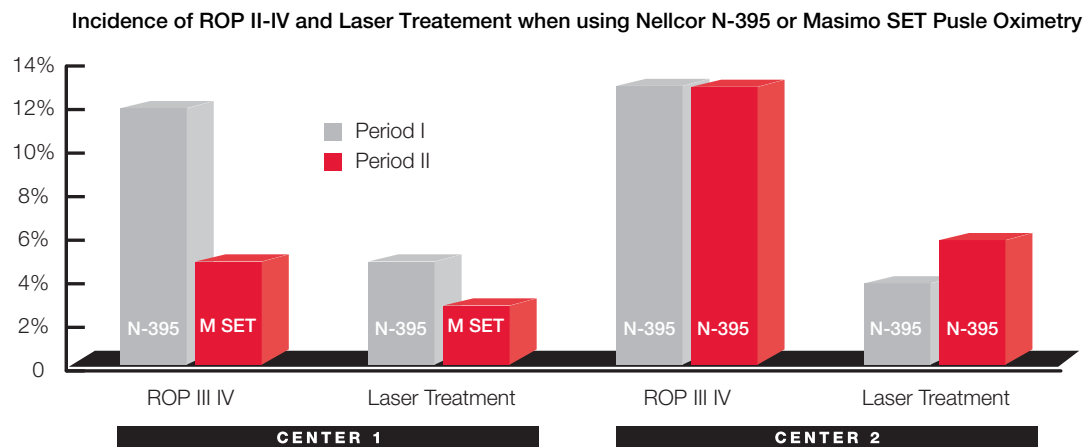
### Introduction

Strict management of O<sub>2</sub> delivery in very low birth weight (VLBW) infants has been associated with decreased rates of Retinopathy of Prematurity (ROP), a devastating disease that can result in lifetime blindness. Because the accurate monitoring of oxygen saturation in these patients is an essential part of the clinical practice change which is thought to decrease the incidence of ROP, these researchers tested whether the performance of the pulse oximeter used was associated with a reduction in the rate of ROP.

### Methods

To compare the incidence of severe ROP (ROP III-IV) and laser treatment at two centers using the same treatment protocol but different pulse oximetry technologies, the incidence of ROP was calculated for 449 VLBW infants (<1,250 gm) from two treatment centers during two time periods. Birth weight and gestational age of the patients from both centers were similar (895 +/- 190 gm; 27 +/- 2 days). During Period I (2000-2002) both treatment centers used Nellcor N-395 pulse oximeters to maintain O<sub>2</sub> saturation levels at >95%. During Period II (2003-2004) Center 1 changed to using Masimo SET Radical pulse oximeters and Center 2 continued to use the Nellcor devices (N-395) to maintain O<sub>2</sub> saturation levels at 88-93%. Eye exams for all patients were performed by the same ophthalmology department using the same criteria.

### Results



There was a relative risk reduction of 58% for the incidence of ROP III-IV and 40% for the incidence laser treatment following Period 2, with the use of Masimo SET pulse oximetry. There was no significant change in the incidence of these measures following Period 2 with the use of Nellcor pulse oximetry ( $p > 0.05$ ).

### Conclusion and Authors' comments

Changing to Masimo SET pulse oximetry as part of the overall clinical practice change was associated with a decreased incidence of severe ROP and the need for laser treatment during the period when SpO<sub>2</sub> levels were maintained at 88-93%, whereas no decrease in the incidence of ROP occurred during that period at the center that continued to use the Nellcor pulse oximeters. The authors concluded "Retinopathy of prematurity (ROP) can be a devastating disease. Efforts to lower ROP rates include... guidelines to decrease hyperoxemic periods and wide changes in oxygenation and the advances in SpO<sub>2</sub> technology... In a large group of examined inborn infants ... treated by the same neonatologists, MD's and NNP's, using the same clinical guidelines to decrease hyperoxemia and wide changes in oxygenation, the relative risk reduction of severe ROP and laser therapy are associated with SpO<sub>2</sub> technology utilized. This further supports the significance of adequate SpO<sub>2</sub> monitors in managing critically ill infants."

# New Pulse Oximetry Sensors with Low Saturation Accuracy Claims - A Clinical Evaluation.

Cox PN, M.D., F.R.C.P.C. *Anesthesiology*. 2007; 107: A1540.

## Introduction

Both Masimo and Nellcor claim to have pulse oximetry systems and sensors that are accurate for oxyhemoglobin saturations below 70%, and therefore appropriate for use on congenital cyanotic cardiac disease patients. This claim has previously been unmet by any commercial pulse oximetry technology. This study compares the accuracy of the Masimo Radical with LNOP Blue sensor and the Nellcor N-600 with Max-I LoSat sensor on congenital cyanotic cardiac lesion patients in the ICU.

## Methods

Twelve pediatric ICU patients with congenital cyanotic cardiac lesions were monitored with an LNOP digit sensor, an LNOP Blue sensor, each attached to a Masimo Radical, and a Nellcor Max-I sensor with LoSat attached to an N-600. A total of 60 arterial blood gases were obtained as clinically needed and compared to the pulse oximetry readings from the three sensors. A paired t-test was used to compare the  $A_{RMS}$  values from each of the three sensors to the blood gas readings. Laboratory CO-Oximetry readings ranged from 85 to 56.1% with a mean of 72.3%.

## Results

	Masimo SET Radical with Blue Sensor	Nellcor N-600 and Max-I sensor with LoSat	LNOP Sensor
Mean $\pm$ SD	70.5 (7.5)	75.9 (5.6)	75.2 (6.4)
Range %	87 - 52	89 - 61	91 - 57
Bias	-1.91	3.81	1.86
Precision	3.50	5.26	6.24
$A_{RMS}$	3.97*	6.49	6.51
$R^2$ value	.886	.698	.60

Table 1- The bias, precision,  $A_{RMS}$  and regression analysis for the new sensors with low saturation accuracy claims, and the LNOP sensor in 12 children with congenital cyanotic cardiac lesions. Paired t-test of the  $A_{RMS}$  shows a significant difference between the Masimo LNOP Blue and the other sensors,  $p < 0.001$ .

## Conclusion and Author's Comment:

Although the N-600 and Max-I sensor with LoSat claims accuracy of 3.0  $A_{RMS}$  in patients with saturations from 60 - 80%, that accuracy claim was not met and the accuracy was not significantly different from the Masimo LNOP sensor on these patients. The Masimo Radical with Blue sensor, on the other hand, claims accuracy of 4.0  $A_{RMS}$  on saturation levels between 60 - 80% and had an accuracy of 3.97. The author concludes, "Despite advances in technology, only the Masimo Blue sensor demonstrates acceptable accuracy as demonstrated by a smaller bias and precision and  $A_{RMS}$ ."



# A Comparison of Finger, Ear and Forehead SpO<sub>2</sub> on Detecting Oxygen Desaturation in Healthy Volunteers.

Tokuda K., M.D., Hayamizu K., M.D., Ogawa K., M.D., Hirai T., M.D., Irita K, M.D., Ph.D. *Anesthesiology* 2007; 107: A1544.

## Introduction

Forehead reflectance oximetry has been marketed as having a faster response to changing oxygen saturations compared to standard digit pulse oximetry. In this study, Tokuda and coworkers compare the response times to changing SaO<sub>2</sub> of a Masimo LNOP digit sensor, a Nellcor MaxFast forehead sensor and a Masimo TC-1 ear sensor in healthy subjects during breath-holding while in three body positions; head-down, supine and head-up.

## Methods

Eight healthy volunteers each wore a Nellcor MaxFast forehead sensor with headband, a Masimo TC-1 ear sensor and a Masimo LNOP digit sensor, connected to the appropriate pulse oximeters and a computer to record data every second. To test the response time to desaturation and resaturation of each pulse oximeter and sensor pair, subjects were instructed to take a deep breath then hold it for as long as possible while in head-up, head-down and supine positions. Recorded data was then analyzed with a Kruskal-Wallis or Wilcoxon Signed Ranks test, as appropriate.

## Results

Observed SpO <sub>2</sub> and time for desaturation and resaturation in three positions			
Position	SpO <sub>2</sub> Site	Time for desaturation (sec)	Time for start of resaturation (sec)
Head-down	Finger	122.4 ± 42.6	17.2 ± 6.2
	Forehead	111.9 ± 43.4 †	9.6 ± 3.2 ‡
	Ear	112.6 ± 41.1 ‡	10.5 ± 2.2 ‡
Supine	Finger	137.9 ± 51.3	18.8 ± 4.2
	Forehead	134.7 ± 49.2	10.3 ± 2.5 ‡
	Ear	131.0 ± 51.3 †	10.5 ± 2.1 ‡
Head-up	Finger	142.6 ± 46.2	19.5 ± 5.0
	Forehead	136.4 ± 44.9	10.6 ± 3.3 ‡
	Ear	133.8 ± 47.2 †	9.7 ± 3.3 ‡

Data are expressed as mean ± SD. \* P < 0.05 compared with each other. † P < 0.05 and ‡ P < 0.01, compared with the finger SpO<sub>2</sub> at each position. Time for desaturation is the interval from the beginning of breath-holding to SpO<sub>2</sub> declining below 90%. Time for resaturation is the interval from the end of breath holding to SpO<sub>2</sub> exceeding minimum value.

While in the head-down position, the ear and forehead sensors detected desaturations significantly faster than the digit sensor. In the supine and head-up position, the ear sensor but not the forehead sensor was significantly faster than the finger sensor. For detecting the time until recovery, both the ear and forehead sensor were significantly faster than the digit sensor.

## Conclusions

Forehead reflectance oximetry has been marketed as being faster to changes in oxygen saturation and not prone to the effects of low peripheral perfusion compared to digit transmission pulse oximetry, but its accuracy can be significantly impaired by venous pooling in supine patients. The ear lobe is a central site where transmission oximetry can be used, thus avoiding low perfusion problems that can affect oximetry from the finger or toe and the accuracy problems that plague forehead reflectance oximetry. This study shows that the Masimo ear sensor is as fast or faster than the Nellcor forehead sensor in detecting desaturations and resaturations in healthy subjects.

# Comparison of Three New Generation Pulse Oximeters during Motion & Low Perfusion in Volunteers

Shah N, Estanol L. *Anesthesiology* 2006;105:A929.

## Introduction

Many pulse oximeter (PO) technologies claim to give accurate readings during conditions of patient motion and low perfusion. Accurate and reliable pulse oximetry monitoring is an increasingly essential clinical tool throughout the hospital with the trend of moving patients earlier from the ICU onto the general care floor. In order to determine which of three new generation pulse oximetry technologies provide the most reliable and accurate readings during difficult patient conditions, these researchers compared the specificity (ability to reject false alarms) and sensitivity (ability to detect true alarms) of the Masimo Radical, the Nellcor N-600 and the Datex Ohmeda TruSat on healthy volunteers during periods of normoxia and hypoxia during motion and induced low perfusion.

## Methods

To test the performance of three pulse oximetry technologies; the Masimo Radical (V5.0), the Nellcor N-600 (V1.1.2.0) and the Datex Ohmeda TruSat optically shielded sensors were randomly placed on index, middle, and ring fingers of left hand (test), and right hand (control) of 10 healthy volunteers. Low peripheral perfusion was induced by lowering the room temperature to 16-18°C. The motions were random self generated (SG) and machine generated (MG) with the test hand attached to a motion table. A rebreathing circuit with a CO<sub>2</sub> absorber was used to induce desaturation to approximately 75%. The subject was then given 100% O<sub>2</sub> until the control pulse oximeters reached a SpO<sub>2</sub> of 100%. The sensors were rotated laterally and tested on all three fingers during the room air events. A computer recorded SpO<sub>2</sub> and pulse rate (PR) data. A missed event was defined as the inability of the PO to detect desaturation and/or recover from a desaturation by the time the control reached 100%. A false alarm was recorded during the normoxic phase, and defined as a SpO<sub>2</sub> ≤ 90% during motion. ANOVA, with a Fischer's post hoc test, and Chi-square analysis, as appropriate, were used to compare the sensitivity and specificity for the three oximeters. A p < 0.05 was considered statistically significant.

## Results

One hundred and sixty (160) motion tests were performed; 120 on room air and 40 during desaturation. Missed events (sensitivity) were counted for the desaturation episodes (20 with MG and 20 with SG). False alarms were counted for the 120 room air motions (60 with MG and 60 with SG). The results are shown in the table below.

Machine and Self Generated Motion					
Device		Missed Event	Sensitivity	False Alarm	Specificity
MasimoSET™ Radical (v5.0)	MG	0/20	100	4/60	93
	SG	1/20	95	2/60	97
Nellcor N-600 (v1.1.2.0)	MG	7/20	65*	20/60	67*
	SG	10/20	50*	14/60	77*
Datex-Ohmeda TruSat	MG	16/20	20*	10/60	83*
	SG	17/20	15*	11/60	82*

p < 0.05 compared to Masimo

## Authors' Conclusions

“During hypoxic/normoxic and low perfusion states, Nellcor N-600 (v1.1.2.0) and Datex Ohmeda TruSat performed inferior to Masimo Radical (v5.0) with respect to maintaining accurate readings during both machine generated and self generated motions. It appears from this study that Masimo Radical may work better for patient safety, especially at critical times in OR, PACU, and ICU.”

# 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  $\text{SaO}_2$  of whole blood.

## Results

A total of 22  $\text{SaO}_2$  measurements were recorded. The mean  $\text{SaO}_2$  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 ( $\pm 1$  SD) between the sensors detected in patients with cyanotic congenital heart disease ( $p = 0.0001$ ). See the table below.

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

## Authors' Conclusions

“Masimo SET Blue Sensor technology offers improved accuracy in the monitoring of  $\text{SaO}_2$  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.”

# An Intraoperative Comparison of Ear Transmission and Forehead Reflectance Oximetry in Pediatric Surgical Patients

Redford D, Lichtenthal P, Barker S. *Anesthesiology* 2004;101: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 SpO<sub>2</sub> and pulse rate of the two digit sensors was calculated as the control value. SpO<sub>2</sub> 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 SpO<sub>2</sub> reading is outside 7% of the control value in stable conditions), and Performance Index (percentage of time during which the SpO<sub>2</sub> 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 <sup>™</sup> TC-I	0.3 ± 0.7	0.5 ± 0.5	0.6 ± 1.5	99.4%
Masimo SET <sup>™</sup> 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] SpO<sub>2</sub> reading was falsely low, it is unacceptable for work in the pediatric surgical patient."**

# Evaluation of 2 Forehead Reflectance Oximeters in Pediatric Intraoperative Surgical Patients

Redford DT, Lichtenthal PR, Barker SJ. *Anesth Analg* 2004;98 (2S):S-92.

## Introduction

The digit is the primary site for pulse oximetry sensors. Due to infrequent periods of low peripheral perfusion or movement, however, alternative sensor sites are sometimes useful. These researchers tested the nares and the ear as alternative sensor sites, using the Masimo TC-I ("Tip Clip") connected to a Masimo SET Radical pulse oximeter.

## Methods

Following IRB approval, 17 adult surgical patients undergoing general anesthesia were monitored with five pulse oximeter sensors. A Masimo SET TC-I sensor placed on the ear, a Masimo SET TC-I sensor placed on the nares, and a Nellcor MAX-FAST forehead sensor connected to a Nellcor N595 pulse oximeter served as test sensors. A Masimo SET LNOP Adt sensor placed on a digit and connected to a Masimo SET Radical pulse oximeter and a Nellcor D25 sensor placed on a digit and connected to a Nellcor N200 pulse oximeter served as controls. Data from all oximeters were continuously recorded. The bias (mean error) and precision (standard deviation of the error) of the control (digit) sensors were compared to the mean bias and precision of the forehead, ear and nares sensors. E7 (the amount of time during which the error was greater than 7% in stable conditions) was also analyzed. Error was defined as the difference between the ear or nares sensor and the control sensors.

## Results

	% Bias	% Precision	% E7
Control Value (pooled digit data)	-0.1 ± 0.9	0.5 ± 0.4	n/a
 MasimoSET™ TF-I	-0.5 ± 0.7	0.7 ± 0.4	1.0 ± 2.0
 MasimoSET™ TC-I	-0.2 ± 0.7	1.0 ± 1.0	0.7 ± 1.0
Nellcor MAX-FAST Forehead Sensor	-4.0 ± 7.0	3.0 ± 5.0	13 ± 26

## Authors Discussion and Conclusions

"Studies from 12 years ago reported that reflectance oximetry sensors performed poorly.<sup>1</sup> Despite advancements in technology, this study demonstrates similar poor performance of the forehead reflectance pulse oximeter. The MAX-FAST sensor attached to the N595 oximeter demonstrated an unacceptable bias and precision and was in error by more than 7% for more than 30% of the total operative time in 18% of patients."

1. *J Clin Monit.* 1991; 7:102-103

# Longevity of Masimo and Nellcor Pulse Oximeter Sensors in the Care of Infants

Erler J, Avenarius S, Wischniewski E, Katerina S, Klaber HG. *J. Perinatology* 2003, 23: 133-135.

## Introduction

Pulse oximetry is routine for monitoring oxygenation in neonates. If the pulse oximeter sensor is single-patient use and it is short-lived, the cost of monitoring can be high. Since pulse oximetry monitoring of sick newborns is often lengthy, the use of long-lived sensors would benefit the hospital management and lessen patient costs. These physicians (at two hospitals) compared the longevity of the Masimo LNOP Neo and LNOP Neo PT sensors to the Nellcor Oxisensor II N-25 sensors on infants in their Neonatal Intensive Care Units and step-down nurseries.

## Methods

121 sick newborns were enrolled in this multicenter study: 56 used Masimo LNOP Neo and LNOP Neo PT sensors and 65 used the Nellcor N-25 sensors. Infants were randomly chosen for monitoring with either the Masimo SET Radical or the Nellcor N-395 and Nellcor N-3000 pulse oximeters. They remained on this monitor/sensor combination throughout the study. The sensors were positioned in an identical fashion and in accordance with the manufacturers' user instructions. The time of sensor placement and replacement were noted along with the reason for changing the sensor. The standard care practices for pulse oximetry were followed, per each institution's use protocol.

## Results

A total of 835.5 patient days of monitoring were accumulated on 121 infants. The Masimo Neo sensors had over twice (2.33) the useful life of the Nellcor N-25 sensors ( $9.05 \pm 4.4$  versus  $3.9 \pm 2.3$  days, respectively,  $p < 0.05$ ). In addition, the magnitude of the useful life between the two institutions was not significantly different in the Masimo group (2.35 verses 2.22-fold).

	 Masimo LNOP Neo	Nellcor N-395 / N-3000 N-25
Sensor life in days (mean $\pm$ sd)	9.05 $\pm$ 4.4	3.9 $\pm$ 2.3

## Authors' Discussion and Conclusions

"We are aware that the pricing of the Masimo and Nellcor pulse oximeters is similar, as is the cost of the LNOP Neo and N-25 sensors. Given this, a two-fold increase in sensor life translates into dramatic savings in settings where long-term PO (pulse oximetry) monitoring is routine, such as neonate care."

# Is Pulse Search Technology a Predictor of Unreliable Saturation Monitoring?

Goldstein MR, Louie N, Yang LL, Ochikubo, Martin GI. *Anesthesiology* 2003;99:A555.

## Introduction


To increase clinical confidence in true alarm situations, such as desaturations, and to reduce the lack of confidence in good data during episodes of patient motion, manufacturers claiming motion tolerant pulse oximetry have attempted to provide easy and continuous assessments of the signal quality of the information used in SpO<sub>2</sub> and pulse rate measurement. The "Pulse Search" warning on the Nellcor N-395 and N-595 oximeters is such a measure. The product manual on the N-395 states, "If the acquired pulse is lost during monitoring, the N-395 enters Pulse Search. During pulse search, the monitor attempts to detect a pulse from which to take a measurement." The Masimo indicator of suspect data is the "Low Signal IQ" message display, which flashes on the screen of the Masimo Radical pulse oximeter when the received signal may be overly compromised. These researchers tested the reliability of the Masimo and Nellcor suspect data indicators.

## Methods

The subjects of the test were 19 at-risk neonates. Sensor placement was randomized to one of four extremities and all oximeters were connected to a data collection computer. When a false desaturation to < 85% was noted and confirmed by lack of central cyanosis and presence of normal readings on the other pulse oximeters, presence or absence of the warning indicator (PS or Low SIQ) was recorded. When false desaturation occurred without the presence of a warning indicator, the desaturation was classified as "Unwarned". Conversely, if the false desaturation occurred with the presence of a warning indicator it was classified as "Warned". The duration of the warning indicator was noted and compared to the duration of the associated false desaturation event. Data was compared for statistical significance by ANOVA and a p value of < 0.05 was considered significant.

## Results

6,811 minutes of oximetry data were studied. A significant difference in the reliability of the warning indicators to indicate false events occurred (see table).

Comparison of Pulse Search and Low Signal IQ to Warn of False Desaturation Events					
	"Warned" # events	Total Time (seconds)	Low SIQ / PS indicator (% total time)	"Unwarned" # events	Total Time (seconds)
 Masimo Radical	45	835	96.2	11	65
Nellcor N-595	15	1150	33.0	67	1036
Nellcor N-395	19	510	28.0	37	635

\*ANOVA analysis showed a statistically significant difference between the Pulse Search events and duration comparing N-395 / N-595 and the Masimo Radical Low Signal IQ measure for p<0.001.

## Authors' Conclusion

"Significant differences in total warned time, duration of warning indicator and unwarned time for detecting false desaturation events are evident between Masimo Radical and the N-395 and N-595 oximeters. The Masimo Radical Low Signal IQ measurement was more reliable in its ability to discern potentially confounding false desaturation."

# Evaluation of a New Reflectance Forehead Sensor in Detecting Oxygen Desaturation in Patients Undergoing Polysomnography

Whitman RA, Garrison ME, Oestreich TJ, Musumbi MS. *Anesthesiology* 2003;99:A553.

## Introduction


Pulse oximetry provides a critical parameter in the diagnosis and treatment of sleep apnea. This group of researchers has studied Masimo SET pulse oximetry in the past and found it to have better fidelity for Sleep-Disordered Breathing testing as compared to Nellcor pulse oximetry.<sup>1,2</sup> In this study, these researchers wanted to test whether the Nellcor MaxFast forehead sensor, used with the Nellcor OxiMax system improved the performance of the Nellcor system in this clinical environment as compared to the Masimo SET technology.

## Methods

Twenty (20) patients undergoing polysomnography were monitored with both MaxFast forehead and Masimo LNOP-Adult digit sensors which were applied according to manufacturer's instructions and connected to the Nellcor N-595 and Masimo Radical pulse oximeters, respectively. The pulse oximeters were turned on simultaneously at the start of the study and turned off simultaneously at the end of the study, and data from the pulse oximeters were downloaded into PROFOX oximetry analysis software. The mean SpO<sub>2</sub>, lowest SpO<sub>2</sub>, and time with SpO<sub>2</sub> less than 90% were extracted.

## Results

In eight (8) of the twenty (20) studies (40%) using the MAXFAST sensor, artifact was clearly identifiable in the graphic output of the saturation profile. This artifact caused erroneous data which was characterized by a sudden shift in saturation that was maintained for a substantial time period not characteristic of desaturation profiles associated with sleep-disordered breathing. No artifact was observed with the Masimo digit sensor. The data pairs were divided into two groups, one comparing the data from the two pulse oximeters for the 8 studies with the MaxFast sensor and having artifact, and the second group with the remaining 12 studies without artifact. (See tables)

Sensor	Mean SpO <sub>2</sub>	Lowest SpO <sub>2</sub>	Time < 90%
 MASIMO LNOP-Adt	96.2 ± 2.0 %	83 ± 8%	0.5 ± 1.3%
Nellcor MAX-FAST	94.0 ± 2.6%	73 ± 11%	14.9 ± 17.4%

Group 1. Data from 8 patients with artifact displayed by MaxFast sensor

Sensor	Mean SpO <sub>2</sub>	Lowest SpO <sub>2</sub>	Time < 90%
 MASIMO LNOP-Adt	94.6 ± 2.3 %	78 ± 14%	5.5 ± 12.3%
Nellcor MAX-FAST	94.2 ± 2.7%	82 ± 11%	7.1 ± 15.5%

Group 2. Data from 12 patients with no artifact displayed

## Authors' Conclusions

**"The Nellcor MAX-FAST reflectance forehead sensor failed to provide accurate SpO<sub>2</sub> data in 40% of the patients undergoing polysomnography. In these cases, the forehead sensor registered a significantly greater percent of time with saturation less than 90%. The use of this sensor during anesthesia could negatively impact the therapeutic approach in patients with sleep apnea during pre-anesthesia and during post-anesthesia recovery."**

- Whitman RA. Comparison of the new Masimo SET V3 technology with a conventional pulse oximeter during polysomnography. *Sleep* 2001;24:A412.
- Whitman RA, Garrison ME, Oestrich PJ. Influence of pulse oximeter technology on hypopnea diagnosis using the newly proposed definition of a respiratory hypopnea. *Sleep* 2002; 25: A509(727.R).

## "Motion-Resistant" Pulse Oximetry: A Comparison of New and Old Models

Barker, S.J. *Anesth Analg* 2002 ; 95 (4):967-72.

### Introduction

In previous studies, this researcher compared the performance of several pulse oximeters during mechanically controlled persistent motion and hypoxemia.<sup>1,2</sup> In this study, using the same test protocol, he studied all commercially available motion resistant pulse oximeters along with numerous conventional pulse oximeters during reduced perfusion and mechanically controlled motion (both periodic and random) on volunteers breathing room air and hypoxic gas mixtures.

### Methods

Seventy (70) healthy volunteers participated in this study, with IRB approval and informed consent. Each subject was monitored with 6 oximeter sensors: three on digits 2,3, and 4 of the moving "test" hand and 3 of the same make and model on the digits of the non-moving "control" hand. The room temperature was reduced to 16° - 18° C to decrease peripheral perfusion. The test hand motions were achieved in a standardized, repeatable fashion by a computer-driven motion table. Tapping and rubbing motions at both fixed and randomly varied frequencies were studied. Data were recorded during various motions while subjects breathed room air, and during rapid arterial desaturation to SpO<sub>2</sub> ~ 75%. During the room air studies, 2 minutes of data were recorded for 2 motions: 1) fingers tapping at 3 Hz or at a frequency that varied randomly between 1 and 3 Hz and 2) fingers rubbing at these same frequencies. Once the two motions were completed and all SpO<sub>2</sub> values returned to baseline, the sensors were moved to different test fingers and the series was repeated twice, so that all 3 test digits were monitored with each test pulse oximeter. The protocol during hypoxemia included the addition feature of disconnecting and reconnecting (DC/RC) all test sensors after the motion had begun. The hypoxemia series was as follows: 1) non-motion hypoxemia to assess differences in instrument, limb, and finger response times; 2) random tapping motion with DC/RC at start of hypoxemia; 3) 3 Hz tapping motion with DC/RC at start of hypoxemia; 4) 3 Hz tapping during hypoxemia; and 5) random rubbing without DC/RC during hypoxemia. This series was performed once with each subject. Test and control SpO<sub>2</sub> values were compared in terms of sensitivity and specificity. Sensitivity measured a pulse oximeter's ability to detect a true desaturation, and specificity measured the pulse oximeter's likelihood of not generating false alarms during motion. An SpO<sub>2</sub> of 90% was chosen as the low alarm threshold. An SpO<sub>2</sub> performance index (PI) and pulse rate performance index along with drop out rate were calculated for each pulse oximeter. The SpO<sub>2</sub> PI measured the percentage of total time the displayed SpO<sub>2</sub> was within 7% of the control, and the PR PI measured the percentage of total time the pulse rate was within 10% of the control. The drop out % measured the total time the SpO<sub>2</sub> displayed was either zero or dashes.

### Author's Discussion and Conclusion

"In summary, our volunteer data provide strong evidence that newer-generation pulse oximeters exhibit improved performance during patient motion. In particular, the Masimo SET appears to provide superior performance during patient motion, with substantially higher values of PI, sensitivity, and specificity." "The clinical implications of this performance improvement are significant. Because awake, hypoxic patients tend to be agitated and moving, pulse oximeters are more likely to be affected by motion artifact when the patient is in distress. Motion-resistant or read-through-motion oximeters, particularly the Masimo, will be more capable of displaying accurate SpO<sub>2</sub> values in this setting, which will improve our ability to detect life-threatening hypoxemia."

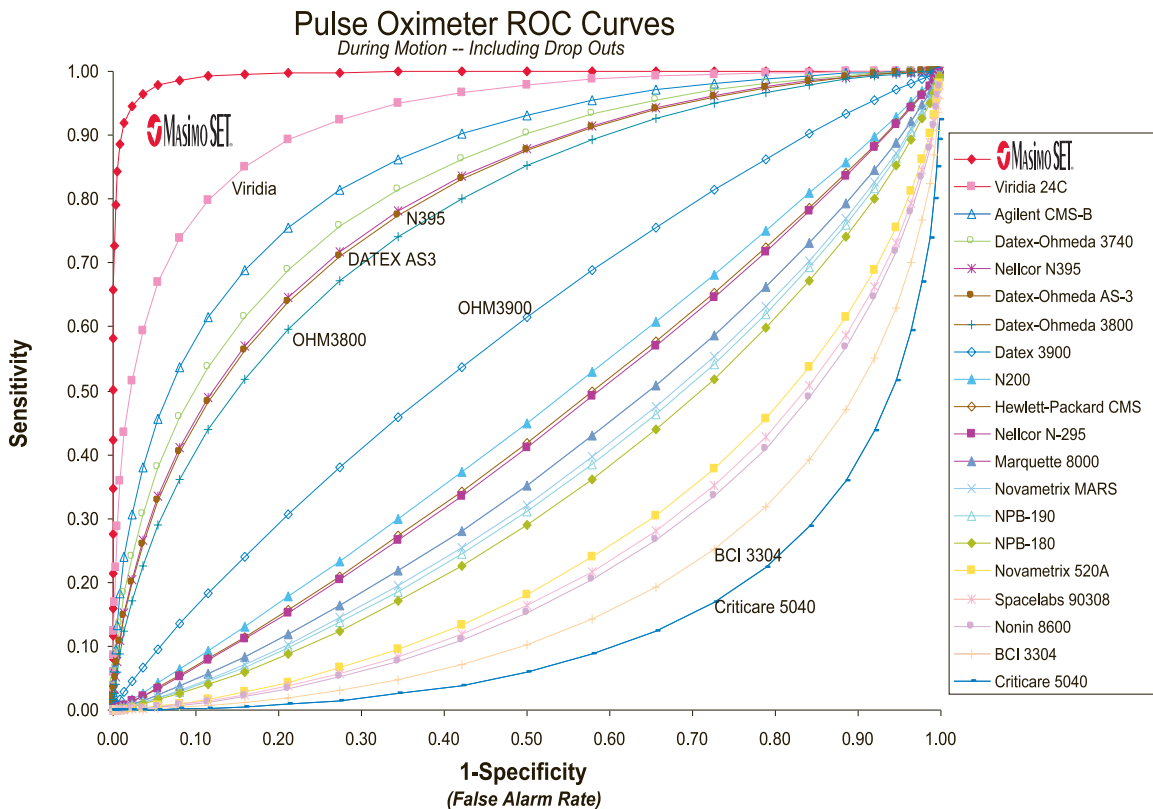
1. Barker SJ, Shah NK. The effects of motion on the performance of pulse oximeters in volunteers. *Anesthesiology* 1997;86(1):101-108
2. Barker SJ. The performance of six "motion-resistant" pulse oximeters during motion, hypoxemia, and low perfusion in volunteers. *Anesthesiology* 2001;95:A587

## Results

Pulse oximeter	SpO <sub>2</sub> Performance Index	Pulse Rate Performance Index	SpO <sub>2</sub> sensitivity	SpO <sub>2</sub> specificity	Dropout rate [%]	Bias (%)	Precision (%)
Masimo SET (v2)*	94	85	98	93	0.2	-0.41	2.98
Philips Viridia 24 C (Rev B.0)*	84	75	78	90	1.6	-1.52	4.51
Philips CMS (Rev B.0)*	80	73	70	83	3.7	-1.87	5.96
Datex-Ohmeda 3740	80	11	68	80	0.0	-2.33	4.20
Datex-Ohmeda 3800	79	12	63	77	0.7	-2.24	4.17
Datex-Ohmeda AS/3	77	67	90	45	0.2	-3.73	5.30
Nellcor N-395 (v 1620)*	71	47	66	78	4.1	-3.17	5.44
Datex-Ohmeda 3900	68	12	60	52	1.0	-3.20	4.22
Novamatrix MARS (2000-10)*	58	27	40	42	2.4	-4.42	5.39
Hewlett-Packard CMS	57	20	63	30	0.5	-8.52	7.11
Nellcor N-180	57	15	35	43	3.1	-5.90	5.95
Marquette 8000	55	27	40	45	0.2	-6.22	6.68
Nellcor NPB-295	55	16	39	53	8.0	-5.79	6.21
Novamatrix 520A	54	11	35	30	0.7	-5.03	5.07
Nellcor N-200	53	19	53	43	0.8	-7.18	5.97
BCI 3304	53	10	28	25	1.2	-7.38	5.74
Nonin 8600	48	13	45	18	1.4	-6.19	5.67
SpaceLabs 90308	46	40	40	23	0.8	-9.50	6.89
Nellcor NPB-190	43	16	48	33	11.1	-9.41	6.07
Criticare 5040	27	5	30	15	5.4	-12.64	6.44

\* indicates pulse oximeters, which claim "motion resistance"

Table 1. Pulse oximeters are listed in descending order of SpO<sub>2</sub> performance index, which is the percentage of time the pulse oximeter displays an SpO<sub>2</sub> within 7% of control.



**Figure 1.** Receiver operating characteristic (ROC) curves calculated for 20 pulse oximeters in this study. The best-performance ROC curves lie in the upper left corner. Diagnosis of hypoxemia by a coin toss would produce an ROC curve along the line of identity,  $x=y$ .

# Detection of Hyperoxaemia in Neonates: Data from Three New Pulse Oximeters

Bohnhorst B, Peter CS, Poets CF. *Arch Dis Child Neonatal Ed.* 2002; 87: F217-F219.

## Introduction


The researchers objective was to investigate the ability of new generation pulse oximeters to detect hyperoxemia by maintaining a high degree of sensitivity [ability to detect hyperoxemia (too much oxygen in the blood)] while maintaining an acceptable level of specificity (ability to not falsely indicate hyperoxemia) while monitoring neonates. Reliable detection of hyperoxemia in neonates is important in minimizing the risks of acute and chronic oxygen toxicity, such as Retinopathy of Prematurity (infant eye disease or blindness).

## Methods

Fifty-six (56) term and preterm infants were enrolled in the study. The median age at time of study was six (6) days (range 1 - 149) and the median study weight was 2680 g (range 430 to 5800). Pulse oximeters used in the study were the Masimo SET, Philips (Agilent) Viridia, and Nellcor Oxismart. The sensors used were the Masimo LNOP Neo PT and the Nellcor N-25 for the Philips and Oxismart pulse oximeters. In addition to standard monitoring equipment, 46 infants had one and 10 infants had two additional sensors attached to a hand and/or foot; the clinical characteristics of the infants in these subgroups were similar. Whenever an arterial blood sample was taken for clinical reasons, the SpO<sub>2</sub> readings on the pulse oximeters were recorded (the SpO<sub>2</sub> had to be stable for 20 seconds prior to blood draw). PaO<sub>2</sub> was measured on a Radiometer ABL 505 blood gas analyzer and functional SaO<sub>2</sub> was measured with a Radiometer OSM-3 CO-Oximeter.

## Results

A total of 280 SpO<sub>2</sub>/SaO<sub>2</sub>/PaO<sub>2</sub> determinations were performed for the Philips (Agilent) Viridia, and 291 each for the Masimo SET and Oxismart pulse oximeters, with 105 (112 for Philips) in 27 (24) patients showing a PaO<sub>2</sub> > 80 mm Hg. Bias and precision (SaO<sub>2</sub> - SpO<sub>2</sub>) calculations were: Masimo SET -0.06 ± 2.5%, Philips Viridia -0.25 ± 2.5, Nellcor Oxismart -0.91 ± 2.6%. The table below shows sensitivity and specificity at an upper alarm limit of 95%. The specificity for the Masimo SET pulse oximeter was 73% greater than the Nellcor Oxismart, and 50% greater than the Philips/Agilent Viridia technologies. NOTE: at this upper limit for SpO<sub>2</sub> the Masimo SET pulse oximeter had comparable specificity as the laboratory CO-Oximeter (OSM-3).

Upper Alarm Limit of 95%	Radiometer OSM- 3	 Masimo SET®	Philips Viridia	Nellcor Oxismart
Sensitivity	99	94	93	95
Specificity	46	45	30	26

## Authors' Discussions and Conclusions

The authors stated, "Sensitivity can be increased by decreasing the upper alarm limit, but the specificity, which is already low, will then decrease even further. This carries the risk of keeping infants hypoxic if priority is given to the avoidance of hyperoxemia." They concluded, "With regard to specificity, the MaS [Masimo SET oximeter] seemed to perform better than the other two instruments, which may be related to differences in measurement bias. Although these differences were small (< 1%), they may still be relevant, as small changes in SaO<sub>2</sub> may be associated with large changes in PaO<sub>2</sub> in the hyperoxic range."

## Differences in Pulse Oximetry Technology Can Affect Detection of Sleep Disorders in Children

Brouillette RT, Lavergne J, Leimanis A, Nixon GM, Laden S, McGregor CD. *Anesthesia and Analgesia* 2002;94:S47-S53.

### Introduction



In spite of the frequency of motion-induced false desaturations, the Nellcor N-200, in its fastest averaging time, had been the preferred pulse oximeter in these researchers' sleep laboratory (The Montreal Children's Hospital). Ultimately, they desired to find a pulse oximeter that would more accurately diagnose sleep-disordered breathing in children.

### Methods

The study consisted of a series of three tests, involving 24 patients and compared the Nellcor N-200 and N-395 with the Masimo SET v2 (Q-400™) and Masimo SET v3 (Radical) pulse oximeters. Up to 30 pulse oximetry desaturation events were randomly selected per subject. These desaturations were delineated as true, false or missed by use of the computerized polysomnograph or apnea parameters, which included a transcutaneous oxygen probe as a referee for true hypoxemia "events".

### Results

The Masimo SET pulse oximeters captured 90% (v2) and 99% (v3) of the true desaturations, while the Nellcor devices captured 76% (N-200) and 45% (N-395). Notably, the Nellcor N-395 was 2.4 times more likely than the Masimo SET oximeter to report false desaturations during patient movement. The researchers offered a clinical caution. "On such abbreviated tests, clusters of movement-related artifactual desaturations could lead the physician to the mistaken impression of sleep-related desaturation events with the potential for unnecessary diagnostic testing or even inappropriate surgery."

	True Hypoxemia Detection
 Masimo SET <sup>®</sup> v3	99%
 Masimo SET <sup>®</sup> v2	90%
Nellcor N-200	76%
Nellcor N-395	45%

### Authors' Discussion and Conclusions

The researchers completed their quest to find a replacement for the N-200 with the affirmation, "In a pediatric sleep laboratory, use of a Masimo oximeter with very short averaging time could significantly reduce workload and improve reliability of desaturation detection." More pointedly, they warned that, "The sensitivity and motion artifact rejection characteristics of the Nellcor N-395 are not adequate for a pediatric sleep laboratory setting."

# Influence of Pulse Oximeter Technology on Hypopnea Diagnosis Using the Newly Proposed Definition of a Respiratory Hypopnea.

Whitman RA, Garrison ME, Oestrich PJ. *Sleep* 2002;25:A509(727.R).

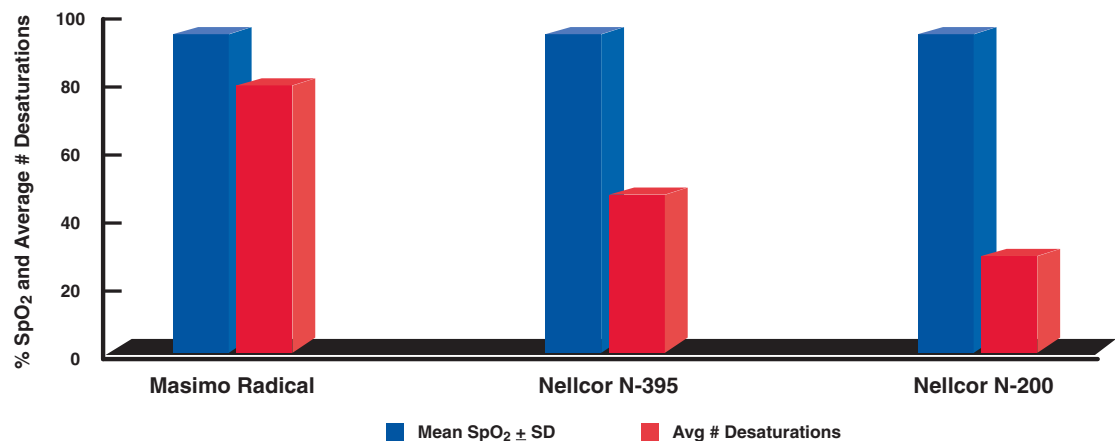
## Introduction

Accurate tracking of transient desaturations is an important part of diagnosing obstructive sleep apnea (OSA) and for establishing Medicare coverage of continuous positive airway pressure (CPAP) therapy. The currently accepted definition for OSA, developed by the American Academy of Sleep Medicine Task Force in 1999<sup>1</sup> is an apnea-hypopnea index of at least 15 events/hour with hypopnea being a 4% or greater drop in oxygen saturation and a 30% reduction in airflow. In this study, Whitman and co-workers compared three pulse oximeters, the Masimo Radical, the Nellcor N-395 and the Nellcor N-200 to determine if the pulse oximeter technology could influence the scoring of desaturations in patients with possible sleep-disordered breathing.

## Methods

Twenty-nine sleep lab patients with suspected sleep-disordered breathing were simultaneously monitored with three pulse oximeters, the Masimo Radical, the Nellcor N-395 and the Nellcor N-200, each set for the shortest averaging time. Trend data collected from the pulse oximeters was then downloaded onto a laptop computer for analysis with ProFox Oximetry Analysis software. Mean saturation and the number of desaturations greater to or equal to 4% SpO<sub>2</sub> were calculated and compared.

## Results



Average SpO<sub>2</sub> and Average Number of Desaturations by Pulse Oximetry Technology in Sleep Lab Patients (n=29)

There was no difference in the mean SpO<sub>2</sub> readings between the three pulse oximeters. There was a large difference however, in the number of desaturations detected by the different technologies. The Masimo Radical detected 69% more desaturations than the Nellcor N-395 and 161% more desaturations than the Nellcor N-200.

## Authors' Conclusions

There are serious health consequences to allowing OSA to go undiagnosed and untreated. Chronic or intermittent hypoxia, as occurs in patients with OSA and sleep disordered breathing, has been associated with numerous negative health consequences such as increased risk of heart failure, atrial fibrillation, stroke, high blood pressure, accidents and an overall decrease in quality of life.<sup>2</sup> The accurate diagnosis of OSA allows for more patients to receive CPAP treatment with coverage by Medicare. This study shows that, even when averaging times are similar, Masimo SET pulse oximetry is significantly better at tracking desaturations and therefore better for the diagnosis of OSA than other commonly used pulse oximetry technologies.

1. Sleep-related breathing disorders in adults; recommendations for syndrome definition and measurement techniques in clinical research. The report of an American Academy of Sleep Medicine Task Force. *Sleep*. 1999 Aug 1; 22(5):667-89.
2. Verneuil A, Marks JW. *Sleep Apnea*. MedicineNet.com 2005; Available at <http://www.medicinenet.com>. Accessed 5/3/07.

## Pulse Oximetry in Transport of Poorly-Perfused Babies

Goldstein MR, Liberman RL, Taschuk RD, Thomas A, Vogt JF. *Pediatrics* 1998; 102 (3): 818.

### Introduction

Poor perfusion and monitoring site motion can adversely affect pulse oximetry readings. This short coming worsens during patient transport in that the motion component is both innate and imposed. The degree of monitoring error can be so great as to render the output meaningless on the most acutely ill (a zero, dashed lines or a spurious % SpO<sub>2</sub> value is displayed). The paradox of conventional pulse oximetry has been that in those patients where continuous monitoring of oxygenation status would be most beneficial, their condition (physiology and environmental) can foil the measurement. Persistent Pulmonary Hypertension of the Newborn (PPHN) is a condition where venous blood mixes with systemic. If the peripheral pulsations are great enough and not confounded by artifact, the shunt can be detected by differential pulse oximetry (right arm versus any other extremity). Masimo has developed a unique sensor design and software algorithms designed to identify the % SpO<sub>2</sub> and pulse rate regardless of patient or environmental challenges. In particular, helicopter transport of acutely ill subjects has been associated with reports of pulse oximeter failures with various models from multiple manufacturers of conventional pulse oximeters.

### Methods

Five infants, all with documented cardiac shunting due to PPHN and transported via helicopter, comprised the study population. All infants were acutely ill and referred for extracorporeal membrane oxygenation (ECMO) or inhaled nitric oxide (INO) therapy. The effect of motion and low peripheral perfusion (variable cardiac shunt) on the reliability of two pulse oximeters (a conventional-type, the Nellcor N-200, and a new Masimo-based unit) were evaluated.

### Results

The pulse oximeters were functional on every infant prior to transport. However, both imposed motion and low perfusion were responsible for failures to read by the pulse oximeters. % SpO<sub>2</sub> readings were evaluated in terms of failure rate (number of failures/number of total data points). Failures were defined as a pulse oximeter display of zero or any SpO<sub>2</sub> value where the oximeter pulse rate and ECG heart rate were not within 5 beats/minute. A large and significant difference in failure rate was found between the two manufacturers.

	Masimo SET <sup>®</sup>	Nellcor N-200
Failure Rate due to Helicopter Takeoffs/Landings	0%	100%
Failure Rate due to Low Perfusion	5%	74%

### Authors' Discussion and Conclusions

“Access to the continuous output of post-ductal oximetry was extremely valuable to the clinical management of PPHN during transport. **Pulse oximetry with Masimo SET has dramatically fewer failures than conventional pulse oximetry during interhospital transport of poorly perfused infants.**”



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