Assessing the Accuracy of Pulse Oximetry in True Clinical Settings

Introduction

Pulse oximeter accuracy, along with clinical reliability are the two most important parameters to consider when choosing a technology for the critical task of monitoring the oxygenation of patients. To establish their accuracy claims for market clearance by the FDA, pulse oximetry manufacturers provide data from studies done in their laboratory on healthy volunteers. In order for accuracy claims made by a manufacturer to be clinically meaningful they must be validated by independent, clinical research. It is not until the technology is tested by independent investigators on patients in clinical settings or on volunteers during challenging physiological conditions where the SpO_2 readings are compared against arterial blood analysis, that the "working accuracy" of the pulse oximetry technology is truly revealed. Here we discuss how accuracy claims are established, how accuracy is measured in clinical studies and how motion, low perfusion and specific patient conditions like cyanosis can affect accuracy. We then discuss the independent, clinical studies that evaluate the "working accuracy" of current technologies and compare the results to the accuracy claims made by the manufacturers. Lastly we discuss how sensor choice and proper application can assure that the maximum accuracy in pulse oximetry readings is achieved by the caregiver.

Establishment of Accuracy Claims

Pulse oximeters are empirically calibrated on normal, healthy volunteers during desaturation studies. When a manufacturer has validated the accuracy of their new instrument and/or sensor they will submit data to the FDA for clearance to market their product. All manufacturers either perform these accuracy validation studies internally or hire an outside lab to perform them. The study methodology for validating accuracy is outlined in the pulse oximetry International Standard, ISO 9919. During these validation studies, warm, healthy, young adult volunteers are slowly desaturated to as low as 60% SaO_2. Arterial samples are drawn during stable plateaus to decrease any physiologic delays that might occur from sampling site to monitored site. Since this data is performed on healthy volunteers in a controlled environment, the accuracy established in these trials is the best that can be achieved by the pulse oximeter system. For examples of how manufacturers' published accuracy claims for specific sensor types compare the accuracy measured on actual patients, see Appendix 1, Tables 1 and 2.

Numerous factors can influence the accuracy of pulse oximeters in the clinical environment however. During the empirical calibration of pulse oximeter systems, great care is taken to only use volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb) because values above 2 to 3% COHb and 1 to 1.5% MetHb seen clinically, will affect the accuracy of the SpO_2 measurements. Additionally, body temperature can cause as much as a 3% difference in the SpO_2 measurements. Digits that are warm (> 30 °C) may read 96 to 97% SpO_2 while cold digits (< 20 °C) may read 99 to 100% SpO_2 in the subject at the same PaO_2. This phenomenon is thought to be due to arterial to venous (A-V) shunting in the digits. A-V shunts may be open in warm hands causing "venous pulsations" which result in a lower SpO_2 compared to cold hands with no A-V shunting.[1] That is why the empirical calibration is always done on normothermic volunteers. There are conflicting studies regarding the effect on skin pigment and painted fingernails on the accuracy of pulse oximeters.[2,3] Thus numerous factors can cause the pulse oximeter system to exceed its specified accuracy in actual patients. In addition, pulse oximetry has been notoriously inaccurate in cyanotic congenital heart disease infants.[4,5]

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Because all manufacturers submit similar data from normal healthy volunteers to the FDA for market clearance, one can expect pulse oximeters from various manufacturers to perform similarly on healthy subjects or patients who are not physiologically compromised. However, factors such as motion and low perfusion in patients that are compromised can significantly affect the accuracy of SpO_2 measurements. Thus, when evaluating the accuracy of a device it is important to review published clinical studies that test the performance of the device on compromised patients. A device that is marketed to have accuracy of $\pm$ 2% in the 70% to 100% range may not achieve those results on a poorly perfused patient, or even worse, a poorly perfused, moving patient. Likewise, a device that has an accuracy claim of $\pm$ 3% from 60% to 80% (for healthy adult volunteers) may not accurately display data on a cyanotic congenital heart disease infant whose SaO_2 is chronically below 80%. For this reason, pulse oximeters need to be tested in all these clinical populations.

Definition of Accuracy

Oxygen concentration in blood can be measured as functional saturation (SO_2) or fractional saturation (HbO_2). Commercial pulse oximeters display functional saturation (SO_2) which takes into account two species of hemoglobin, oxyhemoglobin (SO_2) and deoxyhemoglobin, also called reduced hemoglobin (RHb). Simply put, functional saturation is the amount of oxygenated blood compared to deoxygenated blood. A laboratory CO-Oximeter, which utilizes four or more wavelengths of light instead of two, is capable of measuring both functional saturation and fractional saturation, a more specific and accurate measurement of blood oxygenation. Fractional saturation takes into account all common species of hemoglobin: HbO_2, RHb, methemoglobin (MetHb) and carboxyhemoglobin (COHb). In most clinical situations, when it can be assumed that MetHb and COHb levels are normal, functional saturation is adequate for determining a patient's respiratory status and pulse oximetry can be used to monitor the patient. However when MetHb or COHb levels of the patient are outside the normal ranges they can interfere with the accurate reading of oxygenated hemoglobin by pulse oximetry. In these cases, CO-Oximetry is needed to monitor the patient's true respiratory status.

The most widely accepted method for determining the accuracy of pulse oximetry readings is a direct comparison with functional arterial saturation readings (SaO_2) from a laboratory CO-Oximeter. This comparison has routinely been reported in the literature in the terms of bias and precision. Bias is the mean difference between SaO_2 and SpO_2. Precision is defined as the standard deviation (SD) of the differences between SaO_2 and SpO_2. In the 1980s, pulse oximeter manufacturers stated their accuracy as 2% or 3% $\pm$ 1 SD), where $\pm$ 1 SD mathematically represents approximately two thirds of the population. (This number assumed that the bias was 0.) Therefore, a device and sensor combination with a 3% ($\pm$ 1 SD) accuracy, would have results that were within $\pm$ 3% (digits) 2/3 of the time. Thus if the actual SaO_2 is 94%, a device with $\pm$ 3% accuracy can be expected to read SpO_2 values between 91% to 97% approximately 2/3 of the time. Recently, the FDA has required manufacturers to report their accuracy based on an accuracy specification metric referred to as 'root mean square' which reports accuracy as a function of both bias and precision. The root mean square is calculated by taking the square root of the sum of the square of the bias plus the square of the precision.

$$A_{RMS} = \sqrt{[(bias)^2 + (precision)^2]}$$

Example:

A device with a bias of -2.0% and a precision of 2.0%:

$$A_{RMS} = \sqrt{[(bias)^2 + (precision)^2]}$$

$$= \sqrt{[(2)^2 + (2)^2]} \quad = \sqrt{4+4} \quad = \sqrt{8} \quad = 2.8$$

This device would be submitted to the FDA for an accuracy clearance of an A_{RMS} of 3. It is not accurate enough to submit for a FDA clearance of an A_{RMS} of 2.

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Laboratory Testing of Accuracy

Masimo has an in-house desaturation laboratory for testing and verification of pulse oximetry systems (instruments, cables, and sensors). Masimo tests its instruments for performance during motion and non-motion conditions and during normal and low temperature to simulate clinical conditions. For calibration and validation studies, the radial artery of healthy subjects are cannulated to facilitate numerous samples. All studies are performed under IRB approved protocols and a clinician is always in attendance for arterial line insertion and study observation. Figure 1 shows the SpO_2 data that was obtained with the R25-L adult/neonatal adhesive sensors during controlled desaturation from 100% to 60% on a population of healthy volunteers. Notice as SaO_2 drops below 80% there is a larger spread in the SpO_2 data. Because of this phenomenon, the FDA requires that the data be displayed in 20% segments when giving accuracy data below 70%. For example data points would be grouped and accuracy expressed for the SpO_2 ranges 50 to 70% or 60% to 80%. (See Tables 1 & 2)

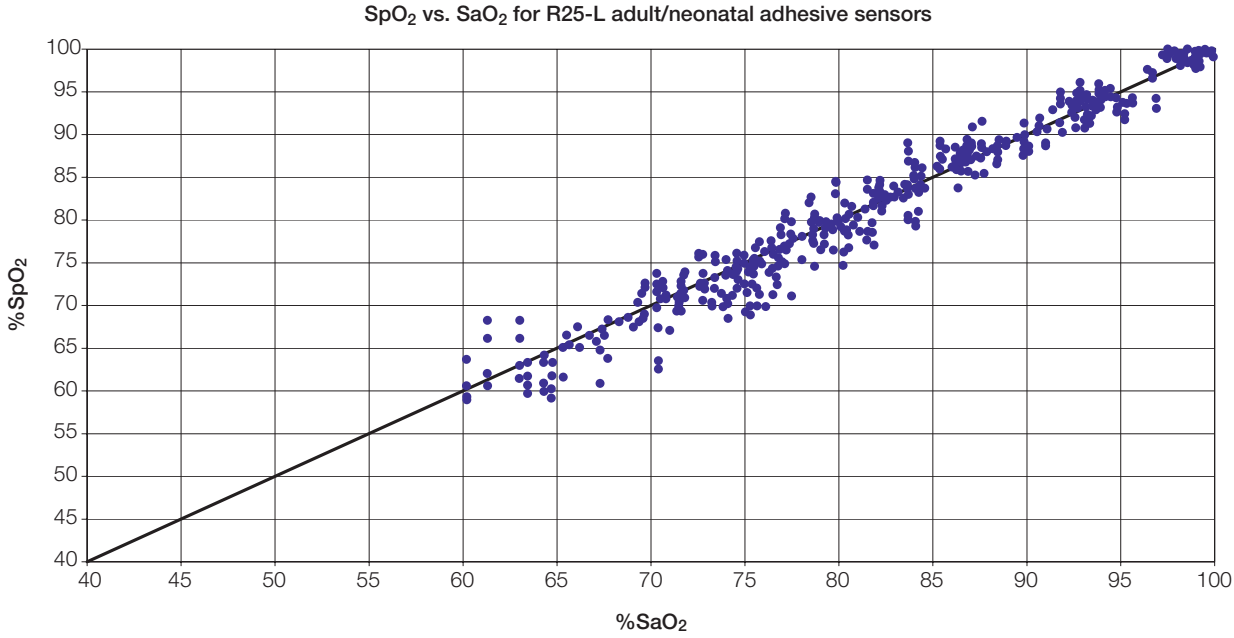

Figure 1. *Plot of 636 data pairs of SpO_2 vs. SaO_2 in 17 healthy volunteers in the 60% to 100% SaO_2 range during normothermic, no motion conditions.*

Saturation Analysis: R25-L Adult/Neonatal Adhesive Sensor on Digit under No Motion: 70-100% SpO_2			
	Bias	**Precision**	**A_{RMS} (Accuracy)**
SpO_2 compared to SaO_2	-0.10	1.79	1.79

Table 1. *Accuracy data for 17 healthy adult volunteers in 70% to 100% (516 data points)*

Saturation Analysis: R25-L Adult/Neonatal Adhesive Sensor on Digit under No Motion: 60-80% SpO_2			
	Bias	**Precision**	**A_{RMS} (Accuracy)**
SpO_2 compared to SaO_2	-0.64	2.53	2.61

Table 2. *Accuracy data for 15 healthy adult volunteers in 60% to 80% (120 data points)*

As can be seen from Figure 1 and Tables 1 and 2, the Masimo SET R25-L adult/neonatal sensors are accurate to +/- 2% in the range of 70% to 100% and +/- 3% in the 60% to 80% range when used on healthy volunteers. This accuracy may vary in different clinical situations.

Clinical Studies on Pulse Oximetry Accuracy

The accuracy of pulse oximeter systems has been tested by independent researchers with many different protocols, in laboratories with healthy subjects and in numerous clinical situations on critically ill patients of all ages. In addition to A_{RMS} values, studies on pulse oximetry performance have referred to accuracy in terms of sensitivity and specificity,[6] performance index[7,8] and recovery time and failure rates[9] among other measures.

Clinical Studies on Stable Patients

Most pulse oximetry technologies have similar accuracy when used on healthy volunteers or stable, well perfused patients. Ahrens and Ott[10] and Branson et al.[11] are examples of studies where similar A_{RMS} values were reported when different pulse oximetry technologies were tested on stable, well saturated patients. Ahrens and Ott found the Masimo Radical, the Nellcor N-600 and the Philips FAST SpO_2 all had similar accuracies (2.0, 2.3 and 2.6 respectively) when tested on 100 stable ICU patients. In another study done on 50 stable, well perfused patients, Branson et al. found similar results with Masimo Radical having an A_{RMS} of 2.6, Nellcor N-600, 2.4 and Philips FAST SpO_2, 3.1.

Performance During Motion and Low Perfusion During Desaturation:

For studies conducted on challenging patients or subjects, an A_{RMS} calculation alone may not provide a functionally appropriate measure of a pulse oximeter's performance. Bias and precision data does not take into consideration false alarms, data drop outs and 'freezing,' all of which can present significant problems for the clinician when pulse oximetry is used in physiologically unstable patients. For this reason, some researchers have used performance measures other than, or in addition to A_{RMS} to determine differences in accuracy and reliability among pulse oximetry technologies during rigorous testing protocols. Shah and coworkers for example, used measures of failure rate, false alarms, performance index, and sensitivity and specificity to test pulse oximetry accuracy during desaturation combined with subject motion and low perfusion in a series of laboratory studies presented at the 2006 American Society of Anesthesiologists Annual Meeting. [9,12,13]

For each of these studies, 10 healthy volunteers, with temperature induced low peripheral perfusion, wore pulse oximetry finger sensors from three manufacturers while performing random hand movements and undergoing a desaturation protocol. The studies compared the performance of the Masimo Radical, the Nellcor N-600 and the GE/Datex Ohmeda TruSat pulse oximeters during the combined challenges of low perfusion, motion and desaturation. A summary of the results of three studies is depicted in Figure 2A and B, which show various positive (2A) and negative (2B) performance measures for the pulse oximeters when tested during conditions of motion and low perfusion. Positive performance measures included performance index, defined as the percentage of the time that the pulse oximeter gave SpO_2 and pulse rate readings within 7% and 10% respectively of the control SpO_2 and pulse rate readings. Sensitivity is defined as the percentage of time that the pulse oximeter is able to detect true desaturations. Specificity is defined as the proportion of time that the non-alarm condition is correctly detected by the pulse oximeter i.e., lack of false alarms. Negative performance measures included missed events, false alarms and failure rates. As illustrated in Figures 2A and 2B, there were significant differences in the performance of the three oximeters tested in all performance categories. The differences in sensitivity (missed events) are potentially of most interest clinically.

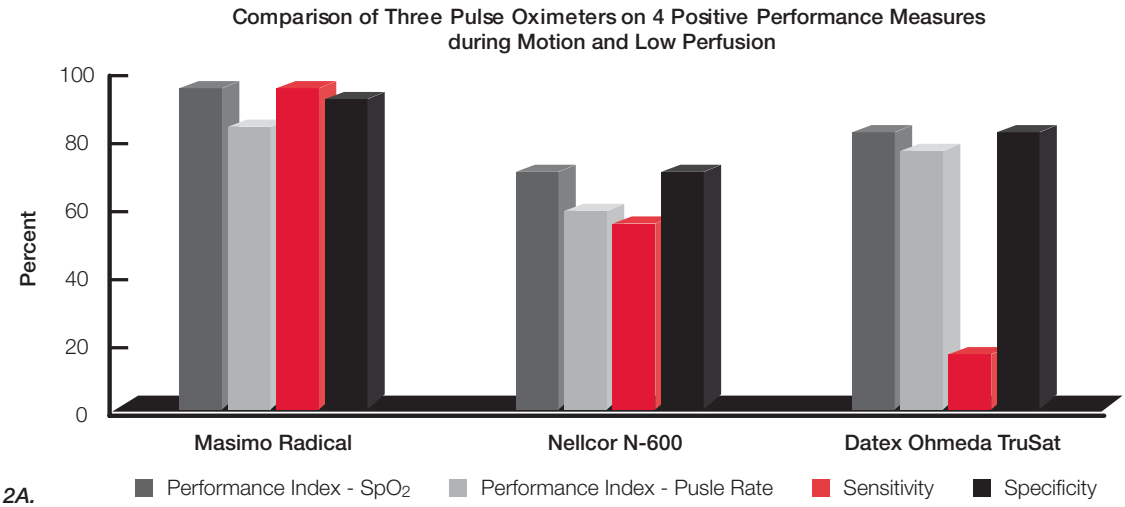

Figure 2A.

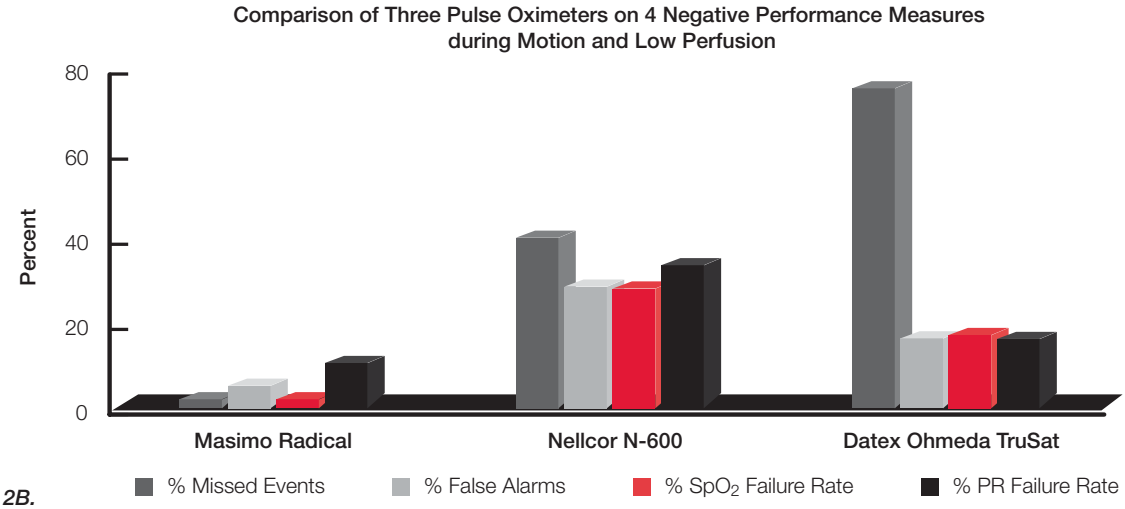

Figure 2B.

Clinical Studies on Patients with Low Saturations

The accuracy of pulse oximeter technologies can vary widely when tested on chronically hypoxic patients. SpO_2 measurements on cyanotic congenital heart infants for example, have always been a challenge for pulse oximeters. These infants are poorly perfused and the SaO_2 levels are often consistently below 80%. Numerous studies have shown that most pulse oximetry technologies perform outside the stated accuracy specifications in this population. It is commonly concluded that because the margin of safety is small in this patient population, pulse oximetry alone is not a reliable means of determining respiratory status of these patients. Clinicians caring for children with cyanotic heart disease often resort to frequent arterial blood gas draws to accurately assess the oxygen saturation of their patients. This invasive method of assessment is far from ideal, particularly for small infants with low blood volume. Prior to the development of the Masimo SET Blue sensor, Olivier and co-workers from the Mayo Clinic tested the accuracy of Masimo SET and two other pulse oximetry technologies when used on three groups of patients with SaO_2 readings above 90%, from 80-90% and those with SaO_2 readings of less than 80%.[14] The results of the study, shown in Figure 3, demonstrate that while the accuracies of all technologies deteriorate when used in patients with lower oxygen saturations, (as shown by the higher A_{RMS} values) the accuracies of specific technologies differ widely when measuring lower saturations.

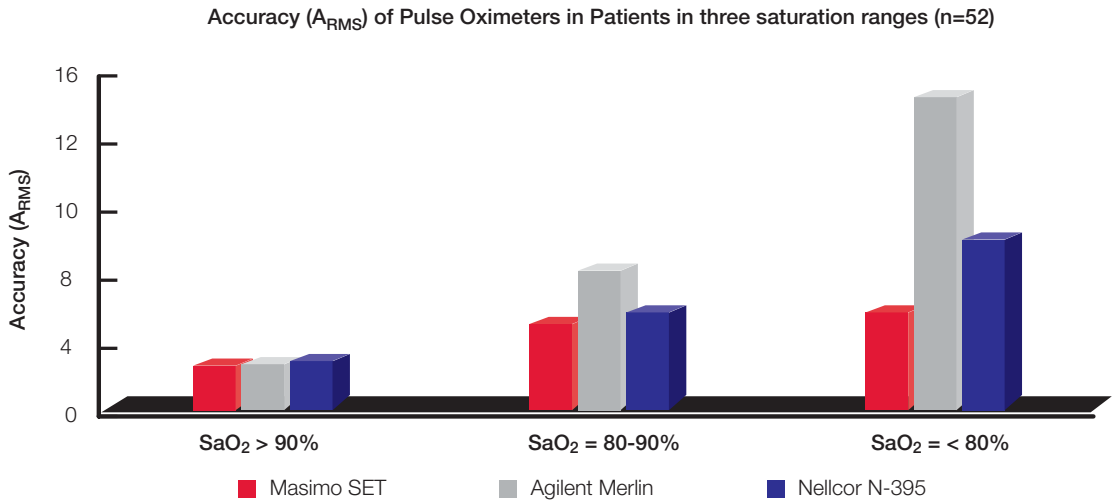

Figure 3. Adapted from Olivier et al., *Anesthesia and Analgesia.* 2003; 96: SCA-135.

To deliver accuracy for this population, Masimo's Clinical Research team collected data on cyanotic infants at three major international hospitals for sensor and algorithm development. This included documenting the distribution of saturation ranges found among these patient populations of cyanotic infants. The data showed that a majority of these patients had saturation values in the 60-80% SaO_2 range (mean $\pm$ 1 SD) (see Table 3). Through this process the Masimo Research and Development group designed a unique sensor and a specific algorithm for this population. Additional data was collected for verification of the system's accuracy and this data was submitted to the FDA for clearance. Masimo received clearance in June 2005 and to date, the Masimo Blue Sensor is the only oximetry sensing solution available that is specifically designed, calibrated and verified for this population.

Saturation Range	# of Samples	Bias	Precision	A_{RMS} (Accuracy)
60%-80%	324	0.91	3.67	3.78%
80%-100%	71	0.00	2.63	2.63%
70%-100%	287	0.67	3.19	3.26%

Table 3

Since the development of the Masimo Blue Sensor, several independent researchers have published clinical evaluations on the accuracy and reliability of the sensor. The first study, conducted by Cox and Fernandes at The Hospital for Sick Children in Toronto, compared the accuracy of the Blue Sensor to the standard infant sensor (the Masimo LNOP) and a laboratory CO-Oximeter in 21 children with congenital cyanotic cardiac disease.[15] In this patient population, with mean SaO_2 readings of approximately 72%, the Masimo Blue sensor had an A_{RMS} of 3.8, whereas the standard sensor had an A_{RMS} of 7.0. Dr. Peter Cox has since published two studies comparing the accuracy of the Masimo Blue sensor to Nellcor's LoSat pulse oximetry product marketed for use on patients with low saturations.[16] The first study, conducted on 8 cyanotic infants with an average SaO_2 of 72% showed the Masimo Blue sensor to have an A_{RMS} of 3.83, consistent with the previous study, whereas the Nellcor N-600 with Lo-Sat Max-I sensor had an A_{RMS} of 5.71. A larger study conducted on 12 infant patients with congenital cyanotic cardiac lesions, showed the Masimo Blue sensor to have an accuracy value of 3.97 whereas the Nellcor N-600 with LoSat had an accuracy of 6.49 when compared to laboratory blood analysis, findings consistent with the previously published studies.[17]

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Cannesson and co-workers from the Hospital Louis Pradel in Lyon, France also compared the accuracy of the Masimo Blue sensor to the Nellcor sensor.[18] That study showed the Nellcor accuracy in 10 pediatric cyanotic congenital heart disease patients to be 6.9, whereas the Masimo Blue sensor was shown to have an accuracy of 3.6. Two other studies, conducted on cyanotic pediatric or neonatal patients, showed that Masimo Blue sensor had a significantly smaller bias and precision when compared to the Nellcor N-595 with OxiMax Max-I sensor, or the Nellcor 550 Plus.[19, 20] These studies indicate that the Masimo SET Blue sensor has superior accuracy in patients with low saturations compared to Masimo's standard infant sensors or Nellcor's sensors. Figure 4 summarizes these results in relation to each technology's currently published accuracy specifications for patients with saturations between 60-80%.

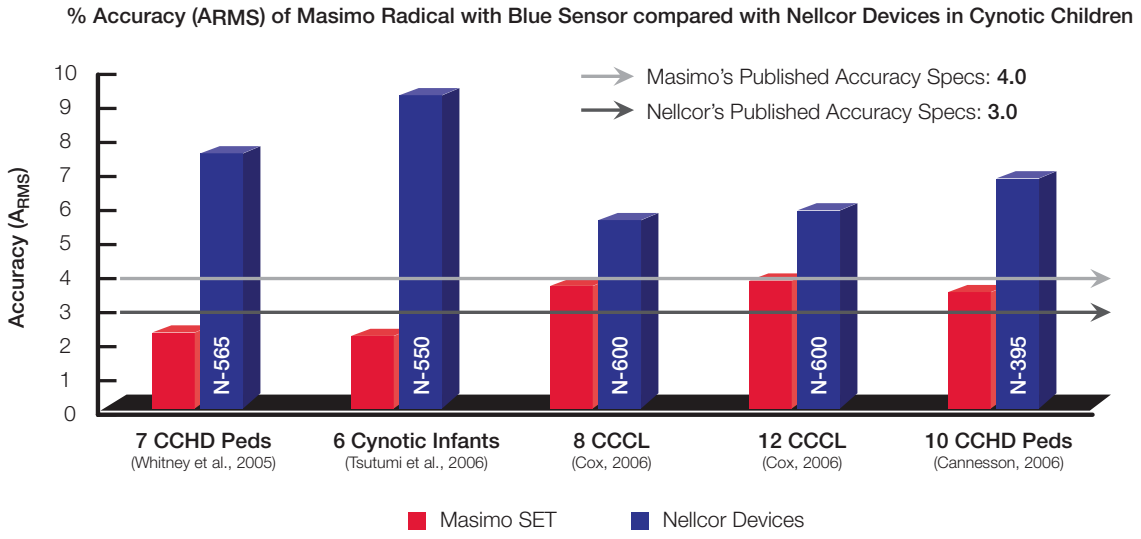

Figure 4.

Reflectance Oximetry Accuracy Studies:

Since patient motion and low perfusion can have deleterious effects on the accuracy of pulse oximetry and these conditions usually affect digit sensors more than sensors placed on the head, several manufacturers, have marketed a reflectance forehead sensor as a solution to reduce false alarms and achieve improved SpO_2 accuracy. While sensor placement in a central location like the forehead may prevent errors due to some kinds of patient motion, reflectance oximetry has had a poor record for accuracy and reliability. Specifically, the accuracy of reflectance oximetry has been shown to be negatively affected by venous pooling in the head which occurs in supine patients. In the supine patient, venous blood in the head will pulsate at the same frequency as arterial blood. The reflectance sensor on the head, therefore will receive a signal derived from a mix of arterial and venous pulsating blood resulting in an SpO_2 reading lower than the actual SaO_2. The degree to which this handicap affects the accuracy of the pulse oximetry readings from the forehead sensor however, will depend in part on the underlying pulse oximetry signal processing technology. To determine the accuracies of three types of sensors from a central site, Redford, Lichtenthal and Barker from the University of Arizona in Tucson, performed several studies on the Nellcor reflectance forehead sensor, the Masimo ear sensor and the Masimo reflectance forehead sensor on surgery patients.[21-25] A compilation of the accuracy values determined for the Nellcor reflectance pulse oximetry sensor and the two types of Masimo sensors from these studies, as well as the manufacturer's accuracy specification claims for the specific sensor types is shown in Figure 5. In all the studies, the A_{RMS} value calculated for the Nellcor reflectance sensor did not meet the manufacturers accuracy specifications and was determined by the authors of the study to be unacceptably high when used in surgery patients. Since the publication of these studies, Nellcor has introduced the use of a headband which applies external pressure to the sensor to overcome venous pulsations.[26] The headband however, may introduce other complications such as pressure induced tissue injury, problems with patient tolerance and infection control issues.[27]

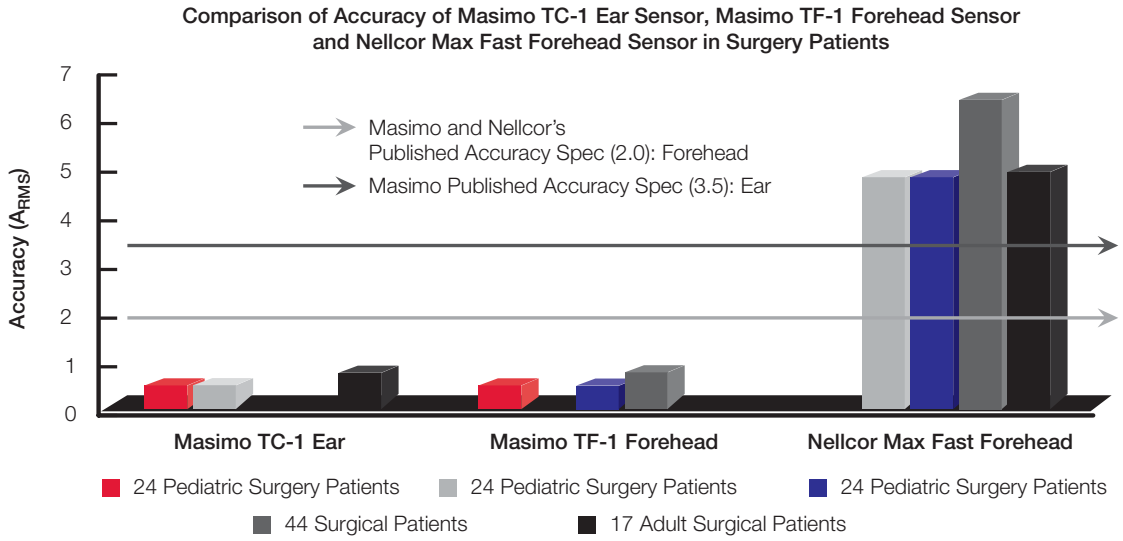

Figure 5.

Sensor Alignment Can Affect Accuracy

The typical pulse oximeter sensor is shaped so that when properly applied to the patient, the two light emitting diodes (LEDs), which project wavelengths of light through the patient's tissue (such as a finger or toe of an adult and the hand or foot in the neonate), are directly opposite a photo detector which detects the transmitted light as it emerges from the tissue. If the sensor is positioned on the patient so that the emitters and detector are not aligned, the light may pass through the patient's tissue but not be fully captured by the detector. This generally results in the loss of signal so that no SpO_2 value will be displayed. A potentially more dangerous situation can occur when the sensor is positioned on the patient so that the detector and emitters are not properly aligned and some of the light reaches the detector without first passing through the patient's tissue. Rather than a loss of signal, this can result in erroneous SpO_2 readings without affecting the pulse rate reading, a parameter which is commonly used to confirm a pulse oximeter's SpO_2 accuracy. The pleth waveform may also appear normal because one wavelength (infrared) is predominately depicted in the photoplethysmographic waveform. Referred to as optical shunting or the penumbra effect, this can result in artificially low SpO_2 readings in normoxic patients and have unpredictable effects on readings in hypoxic patients. Barker and co-workers investigated the effects of optical shunting on pulse oximetry accuracy by incorrectly positioning single use and reusable sensors from three different manufacturers on desaturating subjects.[28] This study showed that all of the devices tested displayed large errors in the saturation readings compared to CO-Oximeter SaO_2 values. In a more recent study from Tyco Healthcare, Campbell and co-workers found that when a reusable Nellcor DS-100A sensor was positioned sideways on a subject's finger, the pulse oximeter's accuracy (A_{RMS}) deteriorated from 2.1 to 5.3.[29] Similar decreases in accuracy were found for the two other types of reusable sensors tested. Correct sensor position appears to be even more critical for the accuracy of reflectance forehead sensors. Because forehead oximetry is prone to errors caused by venous pooling, it is usually recommended that the sensor be placed just above the brow and lateral to the iris in order to avoid placement over any of the larger vessels.

Sensor Placement is Important for all Non-Invasive Transmittance Monitoring

Proper placement of the sensor on the patient is not only essential for accurate pulse oximetry readings but is important for all noninvasive, transmittance technology measurements (e.g., Pulse CO-Oximetry). Although the effect of incorrect sensor placement on the accuracy of SpCO and SpMet readings from the Pulse CO-Oximeter has not been formally studied, like pulse oximetry, the technology depends on the transmittance and detection of light waves through tissue and therefore is subject to some of the same limitations. For example, Masimo's Clinical Research team has documented decreases in the accuracy of readings from the Rad-57 Pulse CO-Oximeter when a reusable sensor is positioned so that the emitter portion is over the distal joint of the patient's finger instead of the middle of the nail bed, as shown in the Directions for Use, (DFU).

Optimizing Performance with Proper Sensor Placement

In order to optimize the accuracy and reliability of a pulse oximetry system, the sensor should be appropriate for the patient's weight, activity level and the anticipated duration of monitoring. Choosing the appropriate size and style of sensor for the specific monitoring needs of the patient will help the clinician avoid accuracy problems due to incorrect sensor placement. Following the sensor application guidelines provided by the manufacturer's DFU assures that the highest accuracy will be achieved.

Summary

Pulse oximetry is an easy, robust and accurate means of determining a patient's oxygenation status when used appropriately. A manufacturer's published accuracy specifications provide a measurement of a system's accuracy, as determined by the manufacturer's laboratory testing on healthy volunteers. A manufacturer's accuracy specifications therefore will likely be considerably better than the accuracy obtained on actual patients. To obtain a realistic assessment of pulse oximetry performance it is necessary to consider the independent clinical research that evaluates the accuracy and reliability of SpO_2 readings on a variety of patients in the clinical setting. Numerous factors can influence the accuracy of pulse oximeters in the clinical environment, including patient motion, perfusion and saturation levels, the algorithms used for signal processing, the sensor design, the appropriate choice of sensor for the patient's size, health concern and activity level and the proper application of the sensor on the patient. Independent clinical and laboratory studies performed on patients or subjects during challenging conditions show that there are significant differences in accuracy and other performance measures between different pulse oximetry technologies. Most clinical and laboratory studies show that Masimo SET pulse oximetry has the highest accuracy and best performance when compared against other pulse oximetry technologies during challenging conditions.

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Appendix I

Documented Accuracy in Independent Clinical Studies Comparing Masimo SET to Nellcor OxiMax Technology

Performance Claim	Based on Independent Studies % Accuracy (A_{RMS})* Nellcor Pulse Oximeters	Meets Nellcor's Published Specs	Based on Independent Studies % Accuracy (A_{RMS})* Masimo Radical Pulse Oximeter	Meets Masimo's Published Specs	Study Population	Nellcor Device	Masimo & Nellcor Footnote
SpO_2 Accuracy (70-100%)							
Adult/Pediatric (digit)	2.26	**Yes**	2.00	**Yes**	100 ICU patients	N-600 n/a	1
Neonate (hand/foot)	3.70	**No**	3.13	**Yes**	17 newborns	N-600 n/a	2
Forehead Sensor	4.91	**No**	0.51	**Yes**	24 Pediatric Surgery Patients	N-595 0.006	3
Forehead Sensor	6.42	**No**	0.85	**Yes**	44 Adult Surgical Patients	N-595 0.00003	4
Fragile Skin	No studies	n/a	2.50	**Yes**	56 term & preterm infants	n/a	5
SpO_2 Accuracy (60-80%)							
Adult/Pediatric (digit)	7.69	**No**	2.52	**Yes**	7 CCHD Peds	N-595 0.0001	6
Infant (toe/thumb)	6.49	**No**	3.97	**Yes**	12 CCCL Infants	N-600 0.001	7
Infant (toe/thumb)	9.26	**No**	2.31	**Yes**	6 Cyanotic Infants	N-550 n/a	8
Neonate	5.71	**No**	3.83	**Yes**	8 CCCL Infants	N-600 0.001	9

** A_{RMS} is what is accepted by the FDA and ISO standards for pulse oximetry (ISO 9019) when manufacturers provide accuracy data for market clearance of a device. $A_{RMS} = \sqrt{[(bias)^2 + (precision)^2]}$ where bias = mean difference between SaO_2 and SpO_2 and precision = standard deviation of the differences.*

1) Comparison of Three New Generation Pulse Oximeters in a Medical Intensive Care Unit. Ahrens TS, Ott K. *Crit Care Med* 2006; 34(12): A85.

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2) 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.
3) Evaluation of 2 Forehead Reflectance Oximeters in Pediatric Intraoperative Surgical Patients. Redford D, Lichtenthal P, Barker S. *Anesthesiology.* 2004; 101:A593.
4) Evaluation of Two Forehead Reflectance Oximeters in Intraoperative Surgical Patients. Redford DT, Barker SJ, Lichtenthal PR. Society for Technology in Anesthesia, January 16-18, 2004. A19. Available at http://www.anestech.org/publications_abtracts.htm. Accessed 7/11/07.
5) 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.
6) 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.
7) New Pulse Oximetry Sensors with Low Saturation Accuracy Claims – A Clinical Evaluation Cox P. *Anesthesiology.* 2007; 107: A1540. Available at http://www.asa-abstracts.com/. Accessed 7/12/07.
8) 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.
9) New Pulse Oximetry Sensors with Low Saturation Accuracy Claims; A Clinical Evaluation. Cox PN. *Respir Care.* 2006; 51 (11) 1332. Abstract 158.

Performance Comparison
Nellcor® N600™ Pulse Oximeter / Masimo® Radical® Pulse Oximeter / Masimo® Radical-7™ Pulse CO-Oximeter

Performance Claim	Nellcor®-N600™ Pulse Oximeter	Masimo® Radical® Pulse Oximeter	Masimo® Radical-7™ Pulse CO-Oximeter
SpO_2 Accuracy (70%-100%)			
Adult/Pediatric (No Motion)	±2 digits	±2 digits	±2 digits
Motion	Not Currently Claimed	±3 digits	±3 digits
Neonate (No Motion)	±2 digits	±3 digits	±2 digits
Motion	Not Currently Claimed	±3 digits	±3 digits
Perfusion Range	0.03%-20%	0.02%-20%	0.02%-20%
Accuracy in Low Perfusion	±2 digits	Adult ±2/Neo ±3 digits	Adult, Pediatric ±2 digits Neo ±3 digits
Forehead Sensor	MAX-FAST ±2 digits	TF-I ±2 digits	TF-I ±2 digits
Fragile skin non-adhesive (No Motion)	SoftCare ±2 digits	SoftTouch ±3 digits	SoftTouch ±3 digits
Motion	Not Currently Claimed	SoftTouch ±3 digits	SoftTouch ±3 digits
SpO_2 Accuracy (60%-80%)			
Adult/Pediatric (No Motion)	±3 digits	60% - 80% ±4 digits* 70% - 100% ±3 digits* 80% - 100% ±3 digits*	±3 digits
Infant (No Motion)	±3 digits		±3 digits
Neonate (No Motion)	±4 digits		60% - 80% ±4 digits* 70% - 100% ±3 digits* 80% - 100% ±3 digits*
Congenital Cyanotic Cardiac Lesions (No Motion)	Not Currently Claimed		
Forehead	±3 digits	Not Currently Claimed	Not Currently Claimed
Pulse Rate Accuracy (70%-100%)			
Pulse Rate (No Motion)	20 - 250 bpm ±3 digits	25 - 240 bpm ±3 digits	25-240 bpm ±3 digits
Motion	Not Currently Claimed	25 - 240 bpm ±5 digits	25-240 bpm ±5 digits
Pulse Rate-Low Perfusion	20 - 250 bpm ±3 digits	25 - 240 bpm ±3 digits	25-240 bpm ±3 digits
Carboxyhemoglobin Saturation (%SpCO) Accuracy (No Motion)	Not Currently Claimed	Not Currently Claimed	**1% - 40%** ±3 digits
Methemoglobin Saturation (%SpMet) Accuracy (No Motion)	Not Currently Claimed	Not Currently Claimed	**1% - 15%** ±1 digit

* Validated with LNOP Blue

Instruments containing Masimo Rainbow SET technology are identified with the Masimo Rainbow SET logo. Look for the Masimo designation on both the sensors and monitors to ensure accurate monitoring when needed most.

Masimo Corporation 40 Parker Irvine, California 92618 Tel 949-297-7000 Fax 949-297-7001 www.masimo.com

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