Masimo SET versus Nellcor Oxismart XL/OxiMax (N-395/N-595)


4. Shah N, Clack SL, Hoang TD. Is there a difference in the recovery time for the accurate display of oxygen saturation (SpO2) and pulse rate (PR) after motion induced failure of pulse oximeters (PO) during low perfusion and normoxemia or hypoxemia in human volunteers? *Anesthesiology* 2001;95:A552. ([http://www.asa-abstracts.com](http://www.asa-abstracts.com))

5. Shah N, Hoang TD, Clack SL, Anderson CT. The impact of motion and low perfusion on the performance of Masimo SET pulse oximeter (PO) and four other POs for measurement of oxygen saturation (SpO2) and pulse rate (PR) in human volunteers. *Anesthesiology* 2001;95:A553. ([http://www.asa-abstracts.com](http://www.asa-abstracts.com))


**Masimo SET versus Nellcor Oxismart Technology (N-295/N3000)**


27. Villareal D, Kukreja S. Masimo SET has major advantages for testing of infant apnea. *Respiratory Care* 2000;45(8):1009.

Masimo SET versus Conventional Pulse Oximetry


42. Patel DS, Rezkalla R. Weaning protocol possible with pulse oximetry technology. Advance for Respiratory Care Managers 2000; 9(9):86.


Medical Text Referencing Masimo as The Next Step in Evolution of Pulse Oximetry


Other


63. Awards

Premier Hospital Clinical Testimony:  Pulse Oximetry Technology Assessment at Palmetto Richland Memorial Hospital, a Premier member May, 2001

Sponsored by National Institute of Health & Masimo Corporation.

Listing of Nellcor Internal Studies That Favor Masimo SET


1. This study investigated the validity of pulse oximetry during maximal exercise under normoxia, hypoxia and hyperoxia on nine subjects (6 athletes and 4 patients with chronic disease). The study used a Nellcor RS-10 forehead reflectance sensor with N-395 pulse oximeter, a Nellcor D-25 digit sensor with N-395, and a Masimo LNOP Adt digit sensor with Ivy 2000 pulse oximeter (utilizing Masimo SET V2). The study demonstrates the correlation of all three sensors as follows:
   a. Nellcor N395/RS-10 Reflectance: $R^2 = 0.90$
   b. Ivy 2000 (Masimo SET V2)/Masimo LNOP Adt digit sensor: $R^2 = 0.78$
   c. Nellcor N395/D25 digit sensor: $R^2 = 0.52$

   When like sensors were compared (e.g. Masimo’s digit to Nellcor’s digit), Masimo’s correlation was 50% better than Nellcor’s. Unfortunately, the study did not consider an “apples to apples” comparison of the RS-10 to a like sensor from Masimo, namely the Masimo LNOP Ear sensor. Sensors affixed to the head (Ear/Forehead) provide different response profiles due to their proximity to the core arterial supply, and therefore cannot meaningfully be compared to digit sensors to assess correlation with the co-oximeter reading. Even more important, the movement of a bicyclist’s hands (gripping the handle bar) would be dramatically different than the movement at the sensor site of a sensor affixed to the head (whether forehead or ear). Obviously the head does not grip anything, so the two sites would present significantly different physiologic inputs to sensor, and could therefore not adequately be compared.

2. This study was conducted on Nellcor employees, and investigated the performance of different pulse oximeters under varying motion protocols. The study incorrectly hypothesizes that Masimo SET incorporates only saturation-based filtering when in fact Masimo SET has five parallel processing algorithms, including frequency domain filtering. Note in Figure 1 of the study that Masimo’s older version software, Masimo SET (V2), outperforms Nellcor in terms of number of false positives (x-axis) when true positives (y-axis) are over 80%. Using a straight edge and intersecting the line representing 80% true positives to the ROC curve for each company’s oximeter, then dropping down to the False Positive Probability x-axis, one can see that Nellcor’s false alarm rate is 4 times higher than Masimo’s for this performance level of 80% true positive.
Listing of Full Articles and Abstracts that compare
Nellcor to Masimo SET, which favor Nellcor.
(Excluding company produced or company-sponsored studies)

Comparison of two pulse oximeters during sub-maximal exercise in healthy volunteers: Effect of

N2. Slogic S. Accuracy of Two Pulse Oximetry Devices with Motion Artifact Reduction Technology on

The two studies that support Nellcor technology can not be considered objective however for the
following reasons:

**N1 (Kist et al.):**
This study compared the Nellcor N395 to the Allegiance Oxi-Reader 2000 (Masimo SET V2) on healthy
volunteers during exercise. This study was not objective, as the two oximeters were compared to one
another with no reference oximeter, no Arterial Blood Gas (ABG) sampling and no reference ECG
for pulse rate verification. This study was published online (Internet) and is not referable by Index
Medicus.

**N2 (Slogic):**
This study compared the Nellcor N395 to the Masimo SET pulse oximeter in a study investigating bias
and precision. The study was not scientific because the sensor sites were not switched in the middle
of each case, while neonates are known to have limb-to-limb arterial oxygen saturation biases of 2%
to 5%. Also, 50% of the blood samples (ABGs) drawn for comparison were conducted on 2 (22%)
of the 9 infants studied. Coincidentally, those 2 infants demonstrated the highest bias, thus skewing
the results.

**Nellcor Internal Studies Which Appear to Show N-595 Out of Specification.**

1. Cook CM, CC-Wun, Manheimer PD, Bebout DE, Tyco Healthcare, Pleasanton, CA, Pulse Oximetry
Accuracy and Performance During Combined Motion and Low Perfusion. *American Journal of
Critical Care* 2002;11(3).

1. The interesting fact in this Nellcor internal study is the N-595 does not meet the accuracy specification
of the FDA for motion claims, nor does it match the specification in their own product data sheet (for
the N-595). The N-595 FDA clearance for motion states that the RMS (root-mean-square) should be
equal or less than 3 (e.g. accuracy during motion spec is +/- 3, but according to this internal study by
Nellcor, the N-595’s accuracy is +/- 7, which is more than double the allowed value. The RMS figure
is arrived at using the following calculations:

- The RMS is calculated by taking the square root (\(\sqrt{}\)) of the sum of the bias squared and the
  precision squared. \( \text{RMS} = \sqrt{((\text{bias})^2 + (\text{precision})^2)} \)

- From the Nellcor abstract, their bias is 5 and the precision is 5, which would equate to the
  following RMS for the N595: \( \text{RMS} = \sqrt{(5)^2 + (5)^2} = \sqrt{(25) + (25)} = \sqrt{50} = 7.1 \)