Listing of Full Articles, Abstracts that Strongly Support
Masimo SET Pulse Oximetry
[Excluding all company produced or company sponsored studies]

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

1. Trang H, Leske V, Boureghda S, Gaultier C. Masimo SET pulse oximetry improves detection of sleep apnea-related hypoxemia. *American Journal of Respiratory and Critical Care Medicine* 2001;163(5):A298

2. Barker SJ. The performance of six "motion-resistant' pulse oximeters during motion, hypoxemia and low perfusion in volunteers. *Anesthesiology*, 2001; 95:A587.

3. Clack SL, Shah N, Hoang TD, Gupta B. A comparison of four major brands of pulse oximeters (PO) with Masimo SET PO during motion and low perfusion under normoxic and hypoxic conditions in human volunteers. *Anesthesiology* 2001;95:A586. (http://www.asa-abstracts.com)

4. Shah N, Clack SL, Hoang TD. Is there a difference in the recovery time for the accurate display of oxygen saturation (SpO_2) 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)

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 (SpO_2) and pulse rate (PR) in human volunteers. *Anesthesiology* 2001;95:A553 (http://www.asa-abstracts.com)

6. Barker SJ. The effects of motion and hypoxemia upon the accuracy of 20 pulse oximeters in human volunteers. *Sleep* 2001;24:A406-7

7. Ogino MT. The advantages of a new technology pulse oximeter in neonatal care. *Neonatal Intensive Care* 2002;15(1):24-27.

8. Barker SJ. Standardization of the testing of pulse oximeter performance. *Anesthesia and Analgesia* 2002;94:S17-S20.

9. Brouillette RT, Lavergne J, Leimanis A, Nixon GM, Laden S, McGregor CD. Differences in pulse oximetry technology can affect detection of sleep disorders in children. *Anesthesia and Analgesia* 2002;94:S47-S53.

10. Goldstein MR, Furman GI, Pernia ML, Lawas-Alejo P, Yang LL, Sindel BD, Ochikubo CG, Martin GI. Performance of motion-resistant pulse oximeters in tracking neonatal heart rate variability. *Anesthesia and Analgesia* 2002;94:S102(A5).

11. Torres A, Skender K, Wohrley J, Aldag J, Raff G, Geiss D. Assessment of 2 New Generation Pulse oximeters During Low Perfusion in Children. *Critical Care Medicine* 2002;29(12):A117.

12. 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).

13. Barker S. Motion resistant pulse oximetry: Comparison of new and old models. *Anesthesiology*; 2002. (In press).

14. Robertson F, Hoffman G. Effects of signal integrity and saturation on accuracy of Masimo SET and Nellcor N395 Pulse Oximeters. *Anesthesiology*; 2002.

15. Robertson F, Hoffman G. Effects of signal integrity and saturation on data availability in Masimo SET and Nellcor N395 pulse oximeters. *Anesthesiology*; 2002.

16. Robertson F, Hoffman G. Clinical evaluation of Masimo SET and Nellcor N395 oximeters during optimal signal conditions in difficult-to-monitor neonates. *Anesthesiology*; 2002.

17. Goldstein M, Kemp S, Martin G, Sindel B, Pernia L, Ochikubo C, Yang L, Lawas-Alejo P. The anatomy of a product evaluation: Nellcor N-595 and Masimo SET Radical pulse oximeters. *Respiratory Care*; 2002. (In press).

18. Whitman R, Garrison M, Oestreich T. Comparison between two oximeter technologies in the detection of desaturation during polysomnography. *Respiratory Care*; 2002. (In press).

19. Lichtenthal P, Barker S. An Evaluation of Pulse Oximetry-Pre, during, and Post-Cardiopulmonary Bypass. *Anesthesiology*; 2002.

20. Kawagishi M, Kanaya N, Nakayama M, Namiki A. A Comparison of the Performance of Pulse Oximeters during Blood Pressure Cuff-Induced Hypoperfusion in Volunteers. *Anesthesiology*; 2002.

21. Wischniewski E, Erler T, Avenarius S. Multicenter trial of neonatal pulse oximeter sensor usage: a difference between manufacturers. *Anesthesia and Analgesia* 2002;94:S110(A21).

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

22. Barker SJ, Shah NK. The effects of motion on the performance of pulse oximeters in volunteers. *Anesthesiology* 1997;86(1):101-108.

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24. Witucki PJ, Bell SJ. Comparison of three new technology pulse oximeters during recovery from extreme exercise in adult males. *Critical Care Medicine* 1999;27(12):A224.

25. Liberman R, Holmes M, Taschuk R, Snelling L. Accuracy of pulse oximeters during neonatal motion. *Respiratory Care* 1999;44(12);1499.

26. Bohnhorst B, Peter CS, Poets CF. Pulse oximeters' reliability in detecting hypoxemia and bradycardia: Comparison between a conventional and two new generation oximeters. *Critical Care Medicine* 2000;28(5):1565-1568.

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

28. Poets CF, Urschitz MS, Bohnhorst B. Pulse oximetry in the neonatal intensive care unit (NICU): detection of hyperoxemia and false alarm rates. *Anesthesia and Analgesia* 2002;94:S37-S40.

Masimo SET versus Conventional Pulse Oximetry

29. Dumas C, Wahr J, Tremper KK. Clinical evaluation of a prototype motion artifact resistant pulse oximeter in the recovery room. *Anesthesia & Analgesia* 1996;83(2):269-272.

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32. Goldstein MR, Martin GI, Sindel BD, Cunningham MD. Novel pulse oximeter technology resistant to noise artifact and low perfusion. *American Journal of Respiratory and Critical Care Medicine* 1997;155(4):A712.

33. Goldstein MR, Barnum PT, Vogt J, Gangitano ES, Stephenson CG, Liberman RL. Conventional pulse oximetry can give spurious data in a neonatal population at risk for retinopathy of prematurity (ROP). *Pediatric Research* 1998; 43(4):216A.

34. Goldstein MR, Liberman RL, Taschuk RD, Thomas A, Vogt JF. Pulse oximetry in transport of poorly perfused babies. *Pediatrics* 1998;102(3):818.

35. Goldstein MR. Left heart hypoplasia: a life saved with the use of a new pulse oximeter technology. *Neonatal Intensive Care* 1998;12(1):14-17.

36. Holmes M, Thomas A, Vogt J, Gangitano E, Stephenson C, Liberman R. CO-oximetry validation of a new pulse oximeter in sick newborns. *Respiratory Care* 1998;43(10):860.

37. Thomas a, Holmes M, Vogt J, Gangitano E, Stephenson C, Liberman R. Useful life of pulse oximeter sensors in a NICU. Respiratory Care 1998; 43(10): 860.

38. Gangitano ES, Taschuk RD, Liberman RL. Near continuous pulse oximetry during newborn ECLS *ASAIO Journal* 1999;45(2):125.

39. Harrington S, Henderson D, Burton GG. Reliable pulse oximetry during exercise testing. *Respiratory Care* 1999;44(10):1226.

40. Malviya S, Reynolds PI, Voepel-Lewis T, Siewert M, Watson D, Tait AR, Tremper KK. False alarms and sensitivity of conventional pulse oximetry versus the Masimo SET technology in the pediatric postanesthesia care unit. *Anesthesia and Analgesia* 2000;90(6):1336-1340.

41. Hay WW, Rodden DJ, Collins SM, Melara DL, Hale KA, Fashaw LM. Pulse oximetry in the NICU: conventional vs. Masimo SET. *Pediatric Research* 1999;45(4):304A.

42. Patel DS, Rezkalla R. Weaning protocol possible with pulse oximetry technology. *Advance for Respiratory Care Managers* 2000; 9(9):86.
43. Sahni R, Gupta A, Rosen TS. Motion-resistant pulse oximetry during circumcision in neonates. *Pediatric Research* 2000;47(4):430A(2544).

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45. Durbin CG, Rostow SK. Improved pulse oximeter technology changes caregiver practice patterns: Masimo SET vs. conventional pulse oximetry. *Respiratory Care* 2000;45(8):986.

46. Whitman RA, Garrison ME. Comparison of the new Masimo SET V3 technology with a conventional pulse oximeter during polysomnography. *Sleep* 2001;24:A412.

47. Irita K, Kai Y, Takahashi S. Performance evaluation of Masimo SET pulse oximeter during mild hypothermic cardiopulmonary bypass. *Anesthesiology* 2001;95:A551. (http://www.asa-abstracts.com)

48. Bogy AT, Martinez D. Changing to Masimo SET improves patient outcome and staff satisfaction. *Respiratory Care* 2001;46(10):1140,OF-01-254.

49. Noblet T. Cost reduction following conversion to Masimo SET pulse oximetry-experience in the NICU. *Respiratory Care* 2001;46(10):1130,OF-01-223.

50. Noblet T. Patient safety and staff satisfaction following conversion to Masimo SET pulse oximetry-experience in the NICU. *Respiratory Care* 2001;46(10):1140,OF-01-224.

51. Rostow SK, Durbin CG. Clinicians quickly learn to utilize improved accuracy and reliability of the new generation of pulse oximeters. *Respiratory Care* 2001;46(10):1104,OF-01-147.

52. Rostow SK, Durbin CG. Improved accuracy of the Masimo SET™ oximeter (MSO) increases caregiver confidence in saturation values. *Respiratory Care* 2001;46(10):1104,OF-01-148.

53. Durbin CG, Rostow SK. Advantages of new technology pulse oximetry with adults in extremis. *Anesthesia and Analgesia* 2002;94:S81-S83.

54. Urschitz MS, Von Einem V, Seyfang A, Poets CF. Use of pulse oximetry in automated O_2 delivery to ventilated infants. *Anesthesia and Analgesia* 2002;94:S37-S40.

55. Sahni R, Ohira-Kist K, Polin RA. Pulse Oximetry during hypothermia in neonates: conventional versus Signal Extraction Technology. Presented at the 2002 Pediatric Academic Societies' Meeting.

56. Miyasaka K. Pulse oximetry in the management of children in the PICU. *Anesthesia and Analgesia* 2002;94:S44-S46.

57. Sahni S, Gupta A, Ohira-Kist K, Rosen T. Motion-resistant pulse oximetry in neonates. *Archives of Diseases in Childhood*: 2002 (In press).

58. Durbin CG, Rostow SK. More reliable oximetry reduces the frequency of Arterial Blood Gas Analysis and hastens oxygen weaning following cardiac surgery: A prospective randomized trial of the clinical impact of a new technology. *Critical Care Med*. 2002 . (In press).

59. Lekites K, Jackvony R. Conversion to Masimo SET pulse oximetry- Analysis of staff satisfaction and patient safety following conversion. *Respiratory Care*; 2002. (In press).

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

60. Peruzzi WT, Shapiro BA, Eds Respiratory Care Clinics of North America: 1995, 77-105.

61. Tobin MJ, Ed. Principles and Practices of Intensive Care Monitoring. 1998: 273.

Other

62. ECRI, Ed. Health Devices Evaluation – Next generation pulse oximetry – Focusing on Masimo SET. 2000: 29: (10)
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.

M1. Hay WW, Rodden DJ, Collins SM, Melara DL, Hale KA, Fashaw LM. Reliability of conventional and new oximetry in neonatal patients. *Journal of Perinatology.* 2002; 22:360-366.

Listing of Nellcor Internal Studies That Favor Masimo SET

1. Yamaya Y, Bogaard HJ, Wagner PD, Niizeki K, Hopkins SR. Validity of pulse oximetry during maximal exercise in normoxia, hypoxia, and hyperoxia. *Journal of Applied Physiology* 2002;92:162-168[1].
2. Jopling MW, Mannheimer PD, Bebout DE. Issues in the laboratory evaluation of pulse oximeter performance. *Anesthesia and Analgesia* 2002;94(S1):S62-68. (Mannheimer & Bebout are Nellcor Employees)

[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)

N1. Kist W, Hogan R, Weber-Hardy L, Dobey T, Moss K, Wernsman M, Minor M, Prewitt M. Comparison of two pulse oximeters during sub-maximal exercise in healthy volunteers: Effect of motion. *Journal of Exercise Physiology online* 2002; 5: 42-48.

N2. Slogic S. Accuracy of Two Pulse Oximetry Devices with Motion Artifact Reduction Technology on Very Small Birth Weight Infants in an Intensive Care Nursery
Anesthesia and Analgesia 94(1S): S108, 2002.

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].

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 (√) of the sum of the bias squared and the precision squared. $RMS = \sqrt{[(bias)^2 + (precision)^2]}$

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