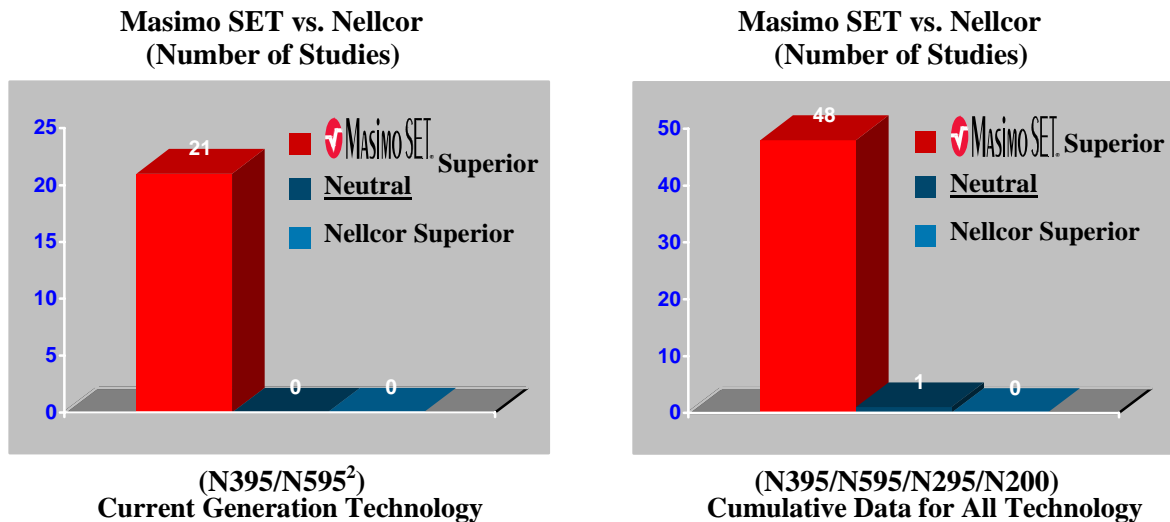


Literature Summary of Published Studies Comparing Masimo to Nellcor

While clinical literature often reflects an even distribution of opinion on debatable medical issues and technologies, a review of the independent literature on pulse oximetry overwhelmingly demonstrates the superior performance of Masimo SET pulse oximetry. The below graphic demonstrates the distribution of opinion when Masimo SET is compared with Nellcor pulse oximetry head-to-head. Note that in 49 independent and objective comparative studies, the researchers concluded Masimo SET was superior to Nellcor (N200, N295 & N395/595) in 48. One study reported neutral results¹. Of the 21 studies comparing current generation technology, all concluded that Masimo SET was superior:



Studies listed are independent and objective as defined below:

Objective: Defined as studies conducted under established scientific protocols, which introduce no bias toward one technology over another.

Independent: Studies not conducted by a manufacturer or funded by a manufacturer.

There were only two independent studies that favored Nellcor, however the two studies did not satisfy the criteria for an objective study:

Kist W, et al, Comparison of Two Pulse Oximeters during Sub-Maximal Exercise in Healthy Volunteers: Effects on Motion, *Journal of Exercise Physiology online* 5(1): 42-48, 2002.

This study compared the Nellcor N395 to the Allegiance Oxi-Reader 2000 (Masimo SET) 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 unscientific approach drew conclusions based on the performance the researchers expected to see, and had no controls or references in place to validate their conclusions. This study was published online (Internet) and doesn't therefore not referable by Index Medicus.

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 & Analgesia* 2002;94 (S1):S108, A16.

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 biases. Also, 50% of the 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.

¹ Testing was conducted patients on intra-aortic balloon pumps, thus introducing artificial 'pulses.' Both pulse oximeters did not match the ECG heart rate.

² Nellcor's literature indicates that both the N-395 and N-595 utilize Oxismart XL pulse oximetry algorithms. Additionally, Nellcor's 510K submission describes the N-595 as "substantially equivalent to the N-395."