

Masimo's Analysis of Nellcor Published Bibliography of Clinical Studies and Related Publications

Nellcor has disseminated their listing of clinical studies and related publications, which is attached hereto. The document includes a total of 40 references that are broken into three categories:

1. Abstracts – 24 Each
2. White Papers (unpublished technical marketing documents) – 7 Each
3. Invited Papers and Original Manuscripts – 9 Each (3 papers, 6 manuscripts)

Of the 40 documents referenced in Nellcor's bibliography, they state that 34 (85%) were company sponsored.

The 4 studies they claim to be independent can be broken down as follows:

- C3: Accuracy of Two Pulse Oximetry Devices with Motion Artifact Reduction Technology on Very Small Birth Weight Infants in an Intensive Care Nursery, Slogic.** (*Abstract*) 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.
- H1: A Characterization of Motion Affecting Pulse Oximetry in 350 patients, Tobin, et al.** This study was funded by Datex-Ohmeda and did not compare oximeters, but rather was an observational study investigating the nature of patient motion.
- H2: False Alarm Rates of Three Third-Generation Pulse Oximeters in PACU, ICU and IABP Patients, Lutter, et al.** This study compared older Nellcor technology (N3000) to older Masimo SET technology (V2) and the Philips Viridia. This study did not have any reference (e.g. ABG) for SpO₂ verification. In addition, the authors did not conclude that Nellcor was superior to Masimo SET.
- H3: Comparison of Two Pulse Oximeters during Sub-Maximal Exercise in Healthy Volunteers: Effects of Motion, Kist, et al.** 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 study was published online (Internet) and therefore is not referable by Index Medicus.

Summary: Of the papers listed in Nellcor's published bibliography there are only three studies (C3, H2, H3) that appear to be independent. However, as explained above, the studies are not scientifically objective.