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.