The Performance of Three Pulse Oximeters during Low Perfusion in Volunteers.

Introduction
In a recent study, we compared the performance of three current pulse oximeters during controlled hand motion in volunteers. The study found that both accuracy and reliability are compromised by the selected motions. The performance of the Masimo SET prototype was superior to both the Nellcor N-200 and the Nellcor N-3000 in terms of bias, precision, dropout rate and alarm specificity. The present study performs a similar comparison of the same instruments during low perfusion states induced by cold and arm elevation.

Methods
Six healthy volunteers participated with informed consent in this Human Subjects Committee-approved study. Each was instrumented with six pulse oximeter sensors: Masimo SET, Nellcor N-200 and N-3000 on both the test hand and the control hand. The test arm was wrapped with a cooling blanket set at 5 degrees C and then gradually elevated to 75 degree inclination above horizontal. Blood samples were periodically obtained from a radial artery cannula in the control hand and analyzed by a Radiometer OSM-3 Co-Oximeter for SaO2 values. Test hand SpO2 values were compared with control hand SpO2 and CO-Oximeter Sao2 during normoxemia and hypoxemia to saturations near 80%. Hypoxemia was achieved by controlling FiO2 using an anesthesia machine blending nitrogen and oxygen. Differences between SpO2 and CO-Oximetry SaO2 values were analyzed using bias (mean error), and precision (standard deviation of error). Test SpO2 values were compared with control SpO2 values by calculating percentage of time for which error was greater than 7% (E7), dropout rate (DR) or percentage of time no SpO2 value was displayed, and total error: TE = E7 + DR.

Results
A total of 94 blood samples and 341 minutes of data were analyzed. Table 1 shows values of bias/ precision (N= number of samples), E7, DR, and TE for the test pulse oximeters. The total error TE or percentage of time with either no display or greater than 7% error, was Masimo: 2.3%, N-200: 19.7%, N-3000:10.6%. Both N-200 and N-3000 failed to detect two of six hypoxemic events; Masimo detected all six. The control oximeters exhibited no dropouts and somewhat lower precision values (i.e. less scatter) than their test hand counterparts.

Conclusions
In terms of dropout rate (DR) and total error (TE), the Masimo oximeter performed significantly better than the N-3000, which in turn performed better than the N-200. The N-3000 exhibited the lowest value of E7, but had a much higher dropout rate (DR) than Masimo (9.9% vs. 0.8%). These results for cold-induced low perfusion are consistent with our previous results for controlled hand motion.