Accuracy of Methemoglobin Detection by Pulse CO-Oximetry during Hypoxia.

Introduction
Methemoglobin in the blood cannot be detected by conventional pulse oximetry, although it can bias the oximeter's estimate (Spo2) of the true arterial functional oxygen saturation (Sao2). A recently introduced "Pulse CO-Oximeter" (Masimo Rainbow SET Radical-7 Pulse CO-Oximeter, Masimo Corp., Irvine, CA) is intended to additionally monitor noninvasively the fractional carboxyhemoglobin and methemoglobin content in blood. The purpose of our study was to determine whether hypoxia affects the new device's estimated methemoglobin reading accuracy, and whether the presence of methemoglobin impairs the ability of the Radical-7 and a conventional pulse oximeter (Nonin 9700, Nonin Medical Inc., Plymouth, MN) to detect decreases in Sao2.

Methods
Eight and 6 healthy adults were included in 2 study groups, respectively, each fitted with multiple sensors and a radial arterial catheter for blood sampling. In the first group, IV administration of approximately 300 mg sodium nitrite increased subjects' methemoglobin level to a 7% to 8% target and hypoxia was induced to different levels of Sao2 (70%-100%) by varying fractional inspired oxygen. In the second group, 15% methemoglobin at room air and 80% Sao2 were targeted. Pulse CO-oximeter readings were compared with arterial blood values measured using a Radiometer multi-wavelength hemoximeter. Pulse CO-oximeter methemoglobin reading performance was analyzed by observing the incidence of meaningful reading errors at the various hypoxia levels. This was used to determine the impact on predictive values for detecting methemoglobinemia. Spo2 reading bias, precision, and root mean square error were evaluated during conditions of elevated methemoglobin.

Results
Observations spanned 66.2% to 99% Sao2 and 0.6% to 14.4% methemoglobin over the 2 groups (170 blood draws). Masimo methemoglobin reading bias and precision over the full Sao2 span was 7.7% +/- 13.0%. Best accuracy was found in the 95% to 100% Sao2 range (1.9% +/- 2.5%), progressing to its worst in the 70% to 80% range (24.8% +/- 15.6%). Occurrence of methemoglobin readings in error >5% increased over each 5-point decrease in Sao2 (P < 0.05). Masimo Spo2 readings were biased -6.3% +/- 3.0% in the 95% to 100% Sao2 range with 4% to 8.3% methemoglobin. Both the Radical-7 and Nonin 9700 pulse oximeters accurately detected decreases in Sao2 <90% with 4% to 15% methemoglobin, despite displaying low Spo2 readings when Sao2 was >95%.

Conclusions
The Radical-7's methemoglobin readings become progressively more inaccurate as Sao2 decreases <95%, at times overestimating true values by 10% to 40%. Elevated methemoglobin causes the Spo2 readings to underestimate Sao2 similar to conventional 2-wavelength pulse oximeters at high saturation. Spo2 readings from both types of instruments continue to trend downward during the development of hypoxemia (Sao2 <90%) with methemoglobin levels up to 15%.