
Study Objectives
The Masimo Radical-7 is a medical device recently approved by the Food and Drug Administration that performs noninvasive oximetry and estimated venous or arterial hemoglobin measurements. A portable, non-invasive device that rapidly measures hemoglobin concentration could be useful in both austere and modern hospital settings. The objective of this study is to determine the degree of variation between the device’s estimated hemoglobin measurement and the actual venous hemoglobin concentration in undifferentiated emergency department (ED) patients.

Methods
We conducted a prospective, observational, cross-sectional study of adult patients presenting to the ED. The subjects consisted of a convenience sample of adult ED patients who required a complete blood count (CBC) as part of their care in the ED. A simultaneous probe hemoglobin was obtained and recorded.

Results
There were 127 measurements recorded with corresponding laboratory hemoglobin determinations. Overall, the mean absolute difference between probe and laboratory measurement was 1.6 g/dL (95%CI 1.4-1.9). For laboratory hemoglobin concentrations of less than eight, 8-11.5, and greater than 11.5, the mean absolute difference was 1.6 (95%CI 1.0-2.2), 1.9 (95%CI 1.4-2.4), and 1.6 (95%CI 1.2-2.0) respectively. Statistical equivalence testing between the two methods for hemoglobin concentrations less than eight were considered not equivalent using a difference threshold of 1 g/dL (p =0.1) and were considered equivalent for hemoglobin concentrations of 8-11.5 (p = 0.004) and >11.5 (p = 0.0004).

Conclusion
For hemoglobin values in the normal range, variances of 1-2 g/dL are not likely to result in altered decision-making. For extremes in hemoglobin, modest variances could be more important. Occasionally large variances occurred. For the majority of hemoglobin determinations, the noninvasive device was accurate to within 1.6 g/dL.