

PulseOx 6000™ Technical Report

Goal

To assess accuracy of the SPO Medical PulseOx 6000™ finger oximeter unit compared with an existing professional oximeter in low perfusion patient population.

Study population



Six individuals with a diagnosis of Chronic Obstructive Pulmonary Disease (COPD) of varying degrees of severity were studied at a Pulmonary Clinic of a large Medical Center. This allowed for measurements over a wide range of clinically relevant oxygen saturation levels; 74-94%. Simultaneous upper extremity digital measurements were obtained from the PulseOx 6000™ and the Masimo Radical™ pulse oximeters. Measurements were obtained from adjoining digits of the same hand. Thirty simultaneous measurements were obtained from each study patient resulting in 180 data points for analysis.

Results

Figure 1 graphically displays the correlation between the SPO PulseOx 6000™ oximeter unit and the Masimo Radical™ oximeter. A regression coefficient (R²) of 0.9719 was obtained when utilizing the Masimo Radical™ as the reference unit. Table A depicts the correlation coefficient of the measurements of the two oximeter units and notes a correlation of 0.988901.

Conclusion

The SPO Medical PulseOx 6000™ is clinically accurate ($\pm 2\%$) with results comparable in the low perfusion patient population to the Masimo Radical™ unit which is currently used as the standard oximeter in many hospitals and medical centers worldwide.

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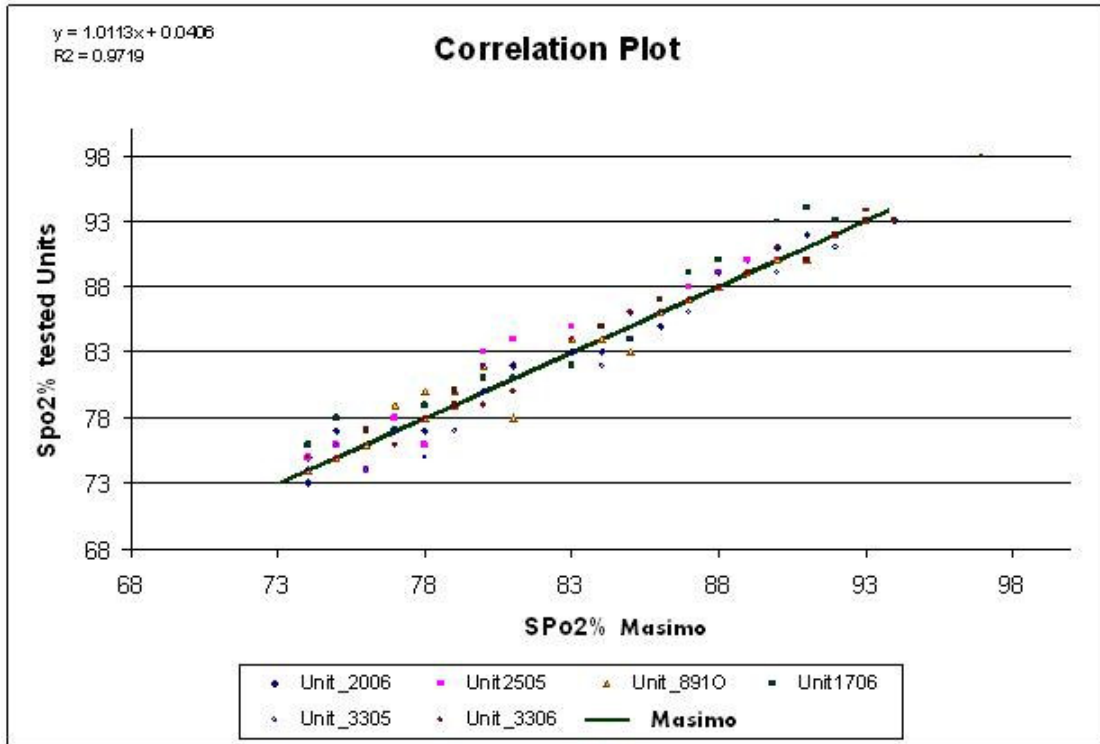


Figure 1

Correlation test		
	Masimo – SpO ₂ %	PulseOx 6000™ – SpO ₂ %
Masimo – SpO ₂ %	1	
PulseOx 6000™ – SpO ₂ %	0.988901	1

Table A