Closed-Loop Testing of Pulse Oximeters During Subject Motion

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Introduction: Recent changes to the international standard for oximeter safety and testing recommend the disclosure of measurements that indicate the degree of artifact created when evaluating performance during motion [1]. These recommendations have been incorporated into recently published FDA guidance [2]. We describe a new test methodology that provides a chain of evidence designed to illustrate protocol compliance (through pressure pad logging and video), the degree of induced signal artifact (through metric disclosure), and system performance (through results analysis). We further present the results when a popular pulse oximeter device (N600x, Covidien, Boulder, USA) is tested using this procedure.

Methods: Motions including tapping and rubbing were generated with amplitudes of 1-2 cm and random intermittency (frequencies of 1-4 Hz). Each subject was instructed to move their fingers such that a consistent area of effect was maintained on a calibrated pressure pad. The instructor had real-time feedback from the pad and video to aid coaching. The pad and video information was recorded and subsequently used to exclude subject data not consistent with protocol compliance. The finger movements were videoed next to a visible cue and displayed to the subjects to facilitate protocol compliance by closing the feedback loop identified by Shang et al. [3].

With IRB and informed consent, seventeen healthy, adult, volunteer, subjects were enrolled (age: 31.6 ± 6.5 years; 7 female / 10 male; Pigmentation: 2 dark, 2 olive and 13 light). An invasive blood hypoxia study during motion was conducted according to EN ISO 80601-2-61:2011 [1]. The reported SpO₂ and pulse rates were collected from the units under test: Nellcor N-60ox monitors (comprising the Nell-1 OEM board). These data were compared to reference-standard measurements of blood SaO₂ (by CO-Oximeter) and heart rate (by ECG) during motion conditions. Performance was evaluated using paired observations from the N-600x monitor and the reference over an SaO₂ range of 70% to 100%. System accuracies were calculated as Accuracy Root Mean Square (ARMSE) and the existence of a significant noise component was shown through percent modulation signal metrics, as recommended in [1].

Results: Fourteen subjects provided motion consistent within the protocol requirements and were included in the study analysis. Three were excluded, having too few points of contact with the pressure mat for more than 25% of the motion time of the study. Signal percent
modulation was statistically greater ($P<0.05$ Wilcoxon Rank sum) and 1.80 times larger during motion periods compared to quiescent periods. The $A_{RMS}$ for $\text{SpO}_2$ was 1.53% ($N = 1240$; range: 70 to 98.4%) and pulse rate was 1.64% ($N = 1300$; range: 47 to 102 beats per minute) during motion.

**Conclusion:** Novel monitoring equipment has been used to close a previously highlighted feedback loop [1]. It has further illustrated protocol compliance and ensured statistically significant artifact has been added during motion testing. Across the $\text{SaO}_2$ saturation range of 70 to 100%, these results indicate the N600x monitor provides accuracy better than 2% for both $\text{SpO}_2$ and pulse rate during the quantified motion conditions described.

**References**


![Sample video still (left) and pressure pad (right) data as used to ensure protocol compliance](image)
Figure 1: Correlation Plot for SpO₂ (left) and pulse rate (right) - All Data