**A Survey of Indicators of Pulse Oximetry Validity.**

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## Background

Despite substantive improvements in technology, pulse oximetry is not able to read a pulse signal in all clinical circumstances. Certain types of motion, low perfusion, and other artifact interfere with the ability of the oximeter to generate a valid reading. This effect is most clearly evident in the neonatal population. To better enable the clinician to discern situations that might indicate the presence of interference affecting the reliability of the pulse oximeter signal, manufacturers have included indicators designed to signal problems with the integrity of the data collection: the Motion Indicator on the Nellcor N-395 and N-595 and the Low Signal IQ on the Masimo Radical. We tested the hypothesis that no difference exists between the number or frequency of indicator events during monitoring of neonates for the 3 oximeters tested.

## Methods

Three next generation pulse oximeters were studied: the Nellcor N-595, the Nellcor N-395, and the Masimo Radical. The oximeters were randomized to one of four extremities. Rotation of the oximeters after randomization was by protocol such that excessive motion of one extremity would not bias the results. Data from the 3 oximeters was recorded continuously to a data collection computer. ANOVA was used to test for statistical significance, with $p < 0.05$ considered significant.

## Results

A total of 19 patients were studied for an average of 361 ± 2.9 minutes. Results for duration of motion light events (N-395 and N-595) and low signal IQ (Masimo Radical) are presented in the table. Analysis of the waveforms indicated no change in the perceived motion state, reported saturation, or heart rate variability in >>90% of the sample during alleged motion events. As such, there was no indication as to whether motion indicator light adequately reflected motion, was influenced by some other aberrancy in measurement, or was too overly sensitive to be of clinical utility. Frequent false signaling of suspect data greater than 100 times an hour ( in both N-395 and N-595) can inure the clinician to real clinical issues. In contrast, the Masimo Radical indicated low signal IQ less than 4 times an hour

"Questionable" Data Comparisons

| **N-395** | | **N-595** | | **Masimo Radical** | |
|---|---|---|---|---|---|
| Motion Light Events | Motion Light Duration/Percent total time | Motion Light Events | Motion Light Duration/percent total time | Low Signal IQ Events | Low Signal IQ Event Duration/percent total time |
| 812±199 | 63.5±31.1 minutes | 748±276 | 50.5±24.2 minutes | 19.4±14.0 * | 6.5±5.6 minutes * |
| | 17.5±8.4% | | 14.1±6.8% | | 1.8±1.6% |

* ANOVA analysis showed a statistically significant difference between the motion light events and duration comparing N-395/N-595 and the Masimo Radical low Signal IQ measure for $p < 0.0001$

## Conclusion

Although the reference technologies are different, motion tolerance is a de facto standard of the newer generation pulse oximeters. The presence of motion alone may not cause a clinician to question the validity of the oximeter reading, but the presence of the motion indicator where motion is clearly not clinically relevant is of dubious value. In sum, indicators of pulse oximeter validity must have a high specificity and reasonable sensitivity to be of clinical utility.