Importance of Using Professional Pulse Oximetry for Clinical SpO₂ Measurement

Numerous studies have evaluated and compared the accuracy of different pulse oximeters over a wide range of clinical conditions. Most manufacturers claim that their instruments are accurate to within ±2% the SaO₂ range between 70% and 100% and ±3% for saturations between 50% and 69%. While most may be accurate in standard circumstances, some pulse oximeters have limitations that should be taken into account when making a purchase decision.

Clinical and technical situations may interfere with the proper acquisition of reliable data or the interpretation of pulse oximeter readings. Patients may present with common clinical issues that impede the ability of many pulse oximeters to properly acquire and interpret signal data. Most commonly, these patient conditions include low peripheral vascular perfusion, dark skin pigmentation, and motion artifact.

Low peripheral vascular perfusion is often present in older patients and people with hypotension, vasoconstriction, or hypothermia. These conditions may produce a signal too small to be measured reliably by a pulse oximeter.

Dark skin pigmentation has historically challenged pulse oximeters because it may cause an overestimation of arterial oxyhemoglobin saturation at low SaO₂ levels. Measurement of arterial oxyhemoglobin levels is based on the illumination of infrared light through a finger, ear, or other tissue. Dark skin pigmentation can interfere with this transmission, producing artificially high oxygen saturation readings.

A study conducted by Feiner, Severinghaus, and Bickler compares Masimo Radical®, Nellcor N-595, and Nonin 9700 finger probe sensors across 36 subjects having a range of skin tones. The results of the multivariate analysis indicated that the SaO₂ level, sensor type, skin color, and gender were predictive of errors in the SpO₂ estimates at low SaO₂ levels. The data suggest that clinically important bias should be considered when monitoring patients with dark skin pigmentation.

| Table 1: NONIN PureSAT® Reusable Sensors Have Less Error/Bias in Most Challenging Patient Population: Dark Skin Pigmentation (Lower Values Indicate Superior Performance) |
| Nonin | Nellcor | Masimo |
| Bias (Mean) | Precision (SD) | Accuracy (Aₑ) | Bias (Mean) | Precision (SD) | Accuracy (Aₑ) | Bias (Mean) | Precision (SD) | Accuracy (Aₑ) |
| >90% | -0.5 | 1.0 | 1.1 | 1.3 | 1.4 | 1.9 | 1.4 | 1.7 | 2.2 |
| 80% – 90% | -1.1 | 0.8 | 1.4 | 2.4 | 1.7 | 3.7 | 2.5 | 2.6 | 3.6 |
| 70% – 80% | -0.6 | 1.4 | 1.6 | 2.6 | 2.6 | 3.7 | 2.6 | 3.0 | 3.9 |
| 60% – 70% | 0.5 | 1.8 | 1.8 | 1.5 | 2.8 | 3.2 | 2.6 | 3.5 | 4.4 |
| All Saturation Levels | -0.6 | 1.2 | 1.3 | 2.0 | 2.1 | 2.9 | 2.1 | 2.9 | 3.4 |

Bias (Mean) = Mean Differences Between Oximeter Readings and Co-Oximeter

Bias is the mean of the differences between oximeter readings and the functional SpO₂ values as measured by a co-oximeter from an arterial sample. Positive bias means the test oximeter overestimates saturation. Negative bias means the oximeter underestimates the saturation. Units are in % saturation.

Precision (SD) = Standard Deviation of Differences from Co-Oximeter Measurements

Precision is the standard deviation of the difference between oximeter readings and the functional SpO₂ pt values as measured by a co-oximeter from an arterial sample. Units are in % saturation.

Accuracy (Aₑ) = Combination of Both the Bias and the Precision

The Aₑ, or accuracy, is a standard method for reporting pulse oximeter accuracy which combines both the Bias and the Precision into a single term for reporting the accuracy of the pulse oximeter. Accuracy in terms of Aₑ is equivalent to the Square Root of the (Bias² + Precision²).
Motion artifact is often present in the non-invasive measurement of pulse oximetry. Solutions with tolerance to motion are strongly recommended because any transient motion of the sensor relative to the skin can cause a significant artifact in the optical measurement. If these transient artifacts mimic a heartbeat, the instrument may be unable to differentiate between the pulsations that are due to the motion artifacts and the normal arterial pulsations, thereby causing erroneous readings.

Motion artifact can reduce the perceived clinical significance of pulse oximetry alarms by causing false alarms and data drop outs when the signal processing is overwhelmed by the motion noise. Several research studies document the effects of motion on accuracy and false alarms:

• Dr. Lawless found that of 957 pulse oximetry alarms that occurred in a 3-day trial period, 71% were false and only 7% were clinically significant.
• Wiklund L, HBk B, Stahl K, and Jordeby-Jönsson studied 123 patients recovering from general anesthesia and found that of 1,516 pulse oximeter alarms during 207 hours of observation, only 23% were true.

The ability of pulse oximeters to provide accurate SpO₂ and pulse rate readings in the presence of motion artifact is often studied on infants due to their challenging physiology. Fletcher, Page, and Jeffrey quantified the presence of motion artifact on this population to determine the proportion of pulse oximeter readings affected by movement artifact. They found that in a group of term and preterm infants, motion artifact was present in all infants studied, comprising 19% of monitored time during quiet sleep, 49% of the time during active sleep, 49% of the time during indeterminate sleep, and 91% of the time during wakefulness.

Summary

Many environmental and physiological factors affect the accuracy of pulse oximeters. Professional pulse oximeters such as Masimo, Nonin, and Nellcor are optimized for clinical use as they have the capability to account for one or more of the factors that can lead to inaccurate measurements: low perfusion, dark skin pigmentation, and motion artifacts. The manufacturers of professional pulse oximeters are able to provide documented clinical evidence of performance in the presence of these conditions.

References

4Fletcher J, Page M, Jeffrey HE. Sleep states and neonatal pulse oximetry. Sleep. 1998; 21: 305-10