Equanox Technology with Dual Emitter-Dual Detector Cancels Surface and Shallow Tissue Variation When Measuring Cerebral Oxygenation

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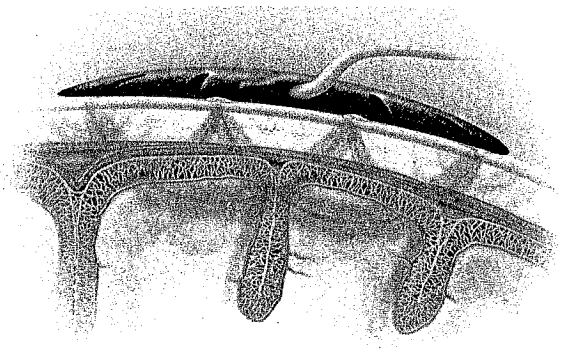
INTRODUCTION

Near-infrared spectroscopy (NIRS) is gaining adoption as a trending tool to measure regional oxygen (rSO_2) saturation in the cerebral cortex. Under this monitoring regime, a baseline must be set and subsequent measurements are compared to that benchmark. Throughout the course of treatment, a patient may be physically moved between clinical departments and be subject to monitoring for periods within which the instructions for use (IFU) require a sensor change. The ability to reliably obtain a consistent reading when a sensor is moved or replaced can remove the requirement of establishing a new baseline measurement, reducing workload while improving consistency in measurement accuracy.

Conventional NIRS cerebral oximeters use a single emitter and two detectors for the optical measurements. The optical measurement from the shorter path (representing extracranial blood oxygen) is subtracted from the longer path (representing intracranial and extracranial blood oxygen) to isolate measurements for intracranial blood oxygen.[1] Any surface and shallow tissue variation between the two detector sites introduces error into the measurement.

The Nonin® Model 7600 regional oximeter with 8000CA sensor utilizes Equanox™, a patented technology with a dual emitter and dual detector sensor topology. This system has been proven to provide an accurate measure of trends in cerebral oxygen saturation.[2] Equanox is designed to provide improved accuracy and repeatability by removing the error due to skin coupling or surface and shallow tissue variations. The Model 7600 system is completely noninvasive. The 8000CA sensor incorporates light emitting diodes (LEDs) with three wavelengths in the 700 to 900 nanometer range.

The present study was designed to assess the ability of Equanox to eliminate the effects of surface and shallow tissue variation by determining the intra-sensor repeatability and inter-sensor repeatability.



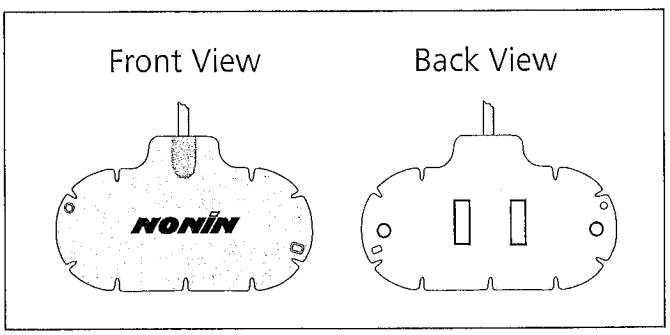
EQUANOX Technology Used in Cerebral Applications

Unique to the EQUANOX technology, dual emitters alternately create pairs of reflected light paths through surface tissue to the shallow receiver and through the cerebral cortex to the far receiver. The system algorithm first uses the dual emitter architecture to remove surface effects that modulate light amplitude and then uses the shallow path to remove the surface tissue components from the deep path signals — resulting in a cerebral cortex measurement that is unaffected by intervening tissue or surface effects.

METHODS

The study was reviewed and approved by an independent institutional review board (IRB). After providing informed consent, subjects were seated in a private location and asked to perform a consistent task (watching a movie) throughout the study. Two Equanox cerebral sensors were placed bilaterally on the subject's forehead in compliance with the instructions for use (IFU).

Equanox Cerebral Sensor



The subjects then underwent two sequences of testing to allow for assessment of intra-sensor and inter-sensor repeatability. The subjects were randomly assigned to have either the left sensor or the right sensor remain on without removal throughout the study to provide a reference (control sensor).

- *Sequence 1:* Intra-sensor repeatability (variation due to sensor location): the sensor from one side was removed and the same sensor reapplied. A total of 10 repetitions were performed with each subject.
- *Sequence 2:* Inter-sensor repeatability (variation due to sensor): one sensor was removed and a different sensor applied to the same location. A total of 10 repetitions were performed with each subject, with five of each sensor alternating between the two.

Throughout both sequences, the number of seconds from sensor placement to a reading being displayed on the device was measured to assess signal acquisition time.

Repeatability was defined in accordance with the industry standard definition of precision from ISO 5725-1:1994(E)[3], where independent test results were obtained with the same method on identical subjects within a short interval of time either using the same piece of equipment (intra-sensor) or using a different piece of equipment (inter-sensor). In this case, the "piece of equipment" of interest is a sensor. Repeatability was determined for the control side (no sensor removal) and the test side (sensor removal and replacement). The repeatability of the control side represents the inherent variation in the cerebral tissue oxygenation due to slight fluctuations in the physiological state underneath the sensor.

RESULTS

A total of 814 recorded plateaus from 42 healthy, non-smoking adult subjects are included in this analysis. There were 29 males (69%) and 40 Caucasians (95%) with an average age of 43 years (range: 23 to 58).

The repeatability of the control side was 1% throughout the testing period. The intra-sensor repeatability and inter-sensor variability were both 2%. Thus, removing and repositioning the same sensor or exchanging a new sensor resulted in a 1% increase in measurement variation from the fluctuation that would occur due to physiologic variations alone.

Signal acquisition time was consistent across subjects. Readings were provided by the Model 7600 regional oximeter with 8000CA cerebral sensor within 2 seconds of placement of the sensors throughout testing.

DISCUSSION

By repeatedly placing the same sensor on subjects and repeatedly placing different sensors on subjects during a controlled steady state, this study was designed to assess the ability of Equanox to eliminate surface and shallow tissue variation. The patented sensor configuration of two emitters and two detectors allows for the signal from the two short paths to be subtracted from the two long paths. Thus, any variation in the coupling of light into the skin due to surface anomalies or the application of the sensor is eliminated. Likewise, any variations in the skin/skull layers due to their non-homogeneous nature are also cancelled.

Removing and repositioning the same sensor resulted in clinically irrelevant increases in the variation from the inherently occurring physiologic variations. And thus the possible error introduced by surface and shallow tissue variations is successfully reduced by the use of this technology. These findings confirm that the two emitter/two detector sensor architecture cancels out the surface and shallow tissue variations providing a robust technology. The precise location of the sensor on the frontal bone has little impact on cerebral oxygenation measure. There is minimal variation in the cerebral oxygenation due to the sensor replacement. Thus, the need to establish a new baseline is eliminated, resulting in decreased workload and enhanced measurement consistency.

CONCLUSIONS

The Nonin Model 7600 regional oximeter and 8000CA sensor with dual emitter and dual detector Equanox technology cancels out the surface and shallow tissue variations resulting in a robust, stable clinical measure of cerebral oxygenation, eliminating the need to establish a new baseline when sensors are moved or changed.

REFERENCES

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3. ISO 5725-1:1994(E) Accuracy (trueness and precision) of measurement methods and results – Part 1: General Principles and Definitions. 1998.