

Nonin EQUANOX Advance™ 8004CA Cerebral Oximeter Sensor Provides Valid Assessment of True Tissue Oxygen Saturation

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INTRODUCTION

Since its introduction 30 years ago, the use of pulse oximetry to continuously monitor the saturation of arterial blood led to dramatic improvements in patient safety.^{1,2} Like pulse oximetry, cerebral oximeters use the principles of light transmission and absorption to noninvasively measure the concentration of oxygenated and deoxygenated hemoglobin within brain tissue, thus providing a continuous measure of cerebral oxygenation. Cerebral tissue oxygenation is of particular interest, as cerebral hypoxia rapidly leads to irreversible injury. Circumstances occur, however, where tissue hypoxia can exist in the presence of appropriate arterial oxygenation.

Most oximeters consist of the same basic components: light source to deliver light of a known wavelength to the tissue; a light detector to measure the intensity of light exiting the tissue, and a process to translate changes in light intensity to a cerebral oxygen saturation value.³ Although all cerebral oximeters use these same components, each commercially available cerebral oximeter employs a unique set of wavelengths and algorithms to derive saturation values. These characteristics can impact the stability, the reliability and the accuracy of the oximeter. Despite these differences between devices, continuous, noninvasive monitoring of cerebral oxygenation is beginning to reach its long anticipated potential.

Over the last decade, numerous case reports and case series in cardiac surgery have verified the ability of cerebral oximeters to rapidly detect changes in cerebral oxygenation due to mechanical or physiological induced decreases in cerebral blood flow.^{4,6} These changes in cerebral oxygenation can occur even when systemic parameters (blood pressure and heart rate) are unchanged.^{7,8} During cardiac surgery, cerebral oxygen desaturation predicts cognitive impairment postoperatively,⁹ and the use of cerebral oximetry for intraoperative management has been shown to reduce morbidity and mortality.¹⁰

Prior research has validated the accuracy of the Nonin EQUANOX™ Regional Oximeter System with the three-wavelength EQUANOX Classic™ 8000CA sensor as a reliable trend monitor. The objective of this study was to validate the EQUANOX Advance™ 8004CA four-wavelength sensor.

STUDY DEVICE

The study device, EQUANOX 7600 with EQUANOX Advance™ 8004CA sensor, was developed by Nonin Medical, Inc. and measures regional blood oxygen saturation utilizing a patented technology with a dual emitter and dual detector sensor topology. Most NIRS cerebral oximeters use a single emitter and two detectors for the optical measurements. The optical measurements from the shorter path (representing extracranial blood oxygen) is subtracted from the longer path (representing intracranial and ex-

tracranial blood oxygen) to give measurements for intracranial blood oxygen.¹¹ Any surface and shallow tissue variation between the two detector sites introduces error into the measurement. The EQUANOX System's dual emitter and dual receiver sensor cancels out surface and shallow tissue variations allowing for a more targeted tissue reading. EQUANOX has been shown to provide improved isolation of targeted tissue compared to single emitter systems¹² and excellent repeatability when measuring regional tissue oxygenation.¹³ The system is completely noninvasive. The emitters are light emitting diodes (LEDs) with the following four wavelengths: 730nm, 760nm, 810nm, 880nm. Each wavelength allows for isolating a single chromophores that may vary from subject to subject. Thus, the additional wavelength in the 8004CA sensor is expected to further remove intersubject variability and provide greater accuracy in assessing cerebral oxygenation status.

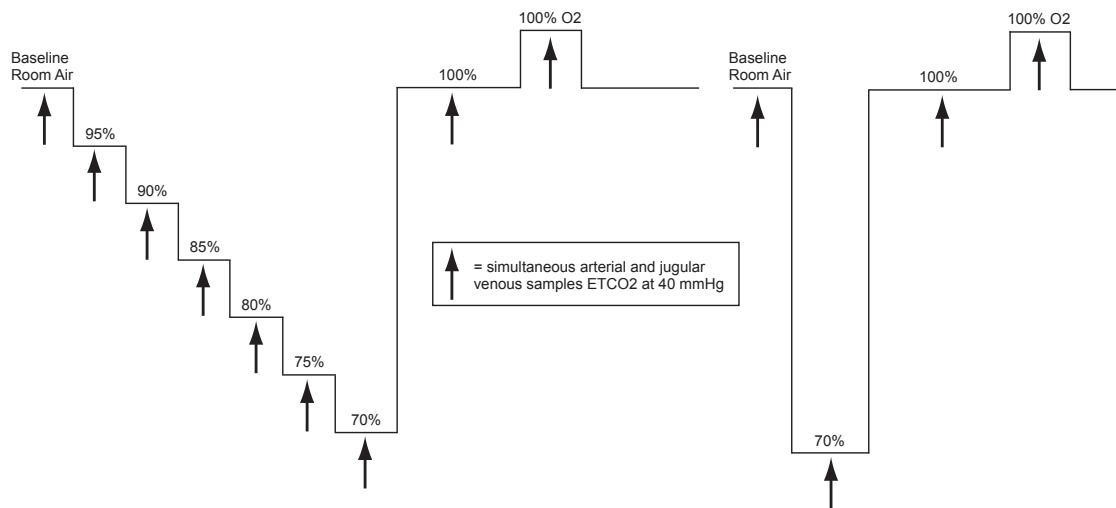
METHODS AND MATERIALS

Testing was conducted at Duke University Human Pharmacology Lab under the direction of the author, was approved by the Duke University Institutional Review Board, and enrolled healthy, non-smoking subjects between 21–34 years of age. All 12 subjects gave written, informed consent. One subject enrolled was excluded as an arterial line could not be placed. The remaining subjects had a jugular venous catheter and a radial artery catheter placed. The venous catheter position was confirmed with a lateral skull x-ray. The subjects were maintained in a semi-recumbent position, and a 8004CA sensor was placed on each side of the forehead. Hypoxia was induced and managed via a dedicated facemask and breathing apparatus (RespirAct) that can precisely control blood carbon dioxide as well as deliver precise oxygen fractions to achieve hypoxemia. Subjects underwent a standard, breathdown protocol to allow for a clinically relevant range of oxygenation values. (See Figure 1 on the following page.)

Each hypoxic plateau lasted approximately 6 minutes, with a jugular bulb blood sample drawn over a 2-minute period at the end of the plateau; arterial blood samples were drawn at the beginning and the end of the jugular blood draw. Laboratory analysis (co-oximetry) was performed to determine the venous saturation (SvO₂) and arterial saturation (SaO₂); the two arterial samples were averaged to provide a single value for each plateau. The arteriovenous saturation (SavO₂) was calculated as a 70:30 ratio: **SavO₂ = (0.7 x SvO₂) + (0.3 x SaO₂)**. SavO₂ is a measured approximation of the cerebral oxygen saturation and was used as the reference value against which the accuracy of the rSO₂ was assessed. Data collected during unstable plateaus, blood draw difficulties, co-oximeter errors or other similar circumstances were excluded.

Accuracy was determined using A_{RMS}, a common statistic for oximetry devices which estimates the agreement between a test

Figure 1. Summary of the step-down plateaus



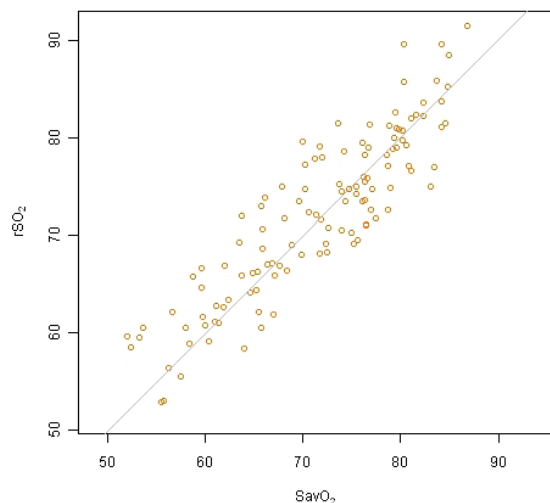
device and an accepted reference value. A_{RMS} consists of two components: mean bias and precision. Mean bias is the average difference between the test device value and the reference value across all observations. Precision is the scatter of possible test device values around the mean bias for a single reference value.

RESULTS

Readings were achieved in all subjects that were attempted and every subject who underwent the breathdown was included in the analysis. A total of 119 samples from 11 subjects were analyzed. Baseline $SavO_2$ readings breathing room air average 76.8 ± 4.8 with the 11 readings ranging from 68 to 84. The readings for rSO_2 were comparable at a baseline reading of 76.6 ± 4.9 with the 11 readings with an average of 68 to 84.

The absolute accuracy of rSO_2 compared to $SavO_2$ as measured by A_{RMS} is 4.1%. Mean bias was $0.8 \pm 4.0\%$. Figure 2 presents a graphical representation of the absolute accuracy. The observed rSO_2 values are plotted against the measured $SavO_2$ values. If the device had an A_{RMS} of 0, all data would lie on the line of identity, indicating perfect agreement.

Figure 2. Agreement between rSO_2 and $SavO_2$



CONCLUSION

The Nonin EQUANOX™ Regional Oximeter System and EQUANOX Advance™ 8004CA sensor provides accurate measures of both absolute cerebral oxygen saturation and relative change in cerebral oxygen saturation across a clinically relevant range of saturations.

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