



FORE-SIGHT[®] Absolute Cerebral Oximeter

FREQUENTLY ASKED QUESTIONS

WHY DO I NEED TO MONITOR BRAIN TISSUE OXYGEN SATURATION?

Brain tissue oxygen saturation values are important to clinicians because cerebral hypoxia (lack of oxygen supply to the brain) is a leading cause of neurological injuries,^{1,2} and occurs in many surgical and clinical situations.^{18,19} If left unchecked, cerebral hypoxia may lead to adverse clinical outcomes such as short or long term brain damage, paralysis, disabilities or death.^{1,19,20}

In cardiac surgery, use of cerebral oximetry has been shown to significantly reduce adverse clinical outcomes, including permanent stroke, and to improve economic outcomes via decreased ventilation time, decrease ICU stays and decreased hospital stays.^{3,4,5}

The CAS Medical FORE-SIGHT[™] Cerebral Oximeter was developed to provide information to guide the timely initiation of interventions and therapies to protect the brain from lack of oxygen.

HOW DOES THE FORE-SIGHT[™] CEREBRAL OXIMETER WORK?

The FORE-SIGHT[™] Cerebral Oximeter is a non-invasive device that incorporates CAS Medical System's exclusive LASER-SIGHT[™] technology to project harmless near infrared light through the scalp and skull and into the brain via a disposable sensor on the patient's forehead.

The FORE-SIGHT[™] Cerebral Oximeter operates based on the principle that blood contains hemoglobin in two primary forms, oxygenated hemoglobin (HbO₂) and de-oxygenated hemoglobin (Hb). These two forms of hemoglobin absorb light in different, measurable ways. Cerebral tissue oxygen saturation (SctO₂) levels are found by determining the ratio of oxygenated hemoglobin to total hemoglobin at the microvascular level (arterioles, venules and capillaries) in the region of the brain that is interrogated.

The FORE-SIGHT[™] Cerebral Oximeter continuously monitors cerebral tissue oxygen saturation SctO₂ which is a mixed oxygen saturation parameter and reflects a proportional mix of arterial (~30%) and venous (~70%) blood in the outlying regions of the brain. This 70/30 determination is based on results from PET scan studies on the brain.⁸

Laser light is projected into the brain in four precise (< 1nm) wavelengths to capture information needed for an absolute indication of cerebral tissue oxygen saturation levels. Four precise wavelengths are needed to maximize the measurement accuracy of oxy and de-oxy hemoglobin in determining cerebral tissue oxygen saturation (SctO₂), to compensate for wavelength dependent scattering losses, and to account for interference from other background light absorbers⁶ (such as fluid, tissue and skin pigmentation).

Reflected light is captured by detectors positioned on the sensor for optimal signal collection, and subtraction of interference from tissues outside the brain.⁷

After analyzing the reflected light, the FORE-SIGHT[™] Cerebral Oximeter displays the cerebral tissue oxygen saturation level on the monitor as an absolute number and provides a graphical representation of historical values.

HOW ACCURATE IS THE FORE-SIGHT[™] CEREBRAL OXIMETER?

FORE-SIGHT[™] Cerebral Oximeter readings have been confirmed in both animal and human studies. In a recent human validation study conducted at Duke University looking at 253 samples, the FORE-SIGHT[™] Cerebral Oximeter determined absolute cerebral tissue oxygen saturation values (SctO₂) showed a strong correlation with the reference SctO₂ over a wide range of pulse oxygen saturation values (SpO₂). The bias and precision (1 standard

deviation) for the FORE-SIGHT™ Cerebral Oximeter SctO₂, compared to reference SctO₂, (derived from co-oximetry of arterial and jugular bulb blood samples) was 0.07 ± 3.699 (The absolute root mean are accurate to within 3.69 points).

The high level of accuracy obtained by the FORE-SIGHT™ Cerebral Oximeter is achieved by compensating for the influence of background light absorbing and scattering elements in the blood and tissue not associated with hemoglobin. This is accomplished by a three-pronged technological approach: interrogation via a laser light source with four discrete wavelengths; a patented algorithm; and a novel sensor design.

IS THE ACCURACY OF THE UNIT AFFECTED BY THE PATIENT'S TEMPERATURE?

Temperatures changes have been shown to have little or no effect on the absorption intensity of oxy and deoxy hemoglobin.^{10,11} The validity of the saturation values should, therefore, not be affected by changes in patient temperature.

HOW OFTEN IS THE DATA UPDATED ON THE SCREEN?

The FORE-SIGHT™ Cerebral Oximeter absolute values are updated every 2 seconds.

HOW SAFE IS LASER-SIGHT™ TECHNOLOGY?

LASER-SIGHT technology, used in the FORE-SIGHT™ Cerebral Oximeter, incorporates a laser system that is designated as a Class 1 laser product by the FDA. Class 1 lasers are considered by the FDA to be "non-significant risk" devices. The Food and Drug Administration (FDA) §1040.10 states that "Class I levels of laser radiation are not considered to be hazardous" ¹²

HOW DOES THIS TECHNOLOGY DIFFER FROM PULSE OXIMETRY?

Cerebral tissue oxygen saturation values are comprised of a mix of arterial (~30%) and venous (~70%) blood. Pulse oximeters monitor only arterial blood saturation values from peripheral tissue (oxygen supply).¹⁴ The FORE-SIGHT™ Cerebral Oximeter measures the balance of cerebral tissue oxygen supply to cerebral tissue oxygen demand in the brain, giving the clinician a better indication of the patient's actual cerebral tissue oxygen saturation status.

The FORE-SIGHT™ Cerebral Oximeter can also monitor cerebral tissue oxygen saturation values during low perfusion situations, and in cases in which there is no pulsatile flow - such as deep hypothermic circulatory arrest. Pulse oximetry requires pulsatile flow to operate.

AT WHAT DEPTH INTO THE BRAIN IS CEREBRAL OXYGEN SATURATION MEASURED?

Near-infrared light from the FORE-SIGHT™ Cerebral Oximeter penetrates the brain to measure mostly gray matter in the cerebral cortex.^{13,14}

The depth of penetration has been confirmed by comparing signals from cerebral oximetry to other established brain imagery modalities such as positron emission tomography (PET)¹⁵ and magnetic resonance imaging (MRI).¹⁶ Furthermore, it is confirmed by brain function activation studies.¹⁷

REFERENCES:

1. Arrowsmith., et al. Central nervous system complications of cardiac surgery. *Br J Anaesth* 2000;84: 378-93.
2. Van Dijk., et al. Neurocognitive Dysfunction After Coronary Artery Bypass Surgery: A Systemic Review. *J Thorac Cardiovasc Surg* 2000; 120: 632-9.
3. Goldman., et al. Optimizing intraoperative cerebral oxygen delivery using noninvasive cerebral oximetry decreases the incidence of stroke for cardiac surgical patients. Presented during the Cardiothoracic Techniques and Technologies Annual Meeting, March 10-13, 2004, Miami Beach, Florida.
4. Murkin., et al. Monitoring cerebral oxygen saturation significantly decreases stroke rate in CABG patients: A randomized blinded study. Presented at the Outcomes 2004: The Key West Meeting, Florida, May 19-24, 2004.

5. Murkin., et al. Monitoring cerebral oxygen saturation significantly decreases postoperative length of stay: A prospective randomized study. Presented at Outcomes 2003: The Key West Meeting, Florida. Heart Surgery Forum 2003;6:204
6. Strangman., et al. Non-Invasive Neuroimaging Using Near-Infrared Light. Soc of Biol Psych 2002;52:679-93.
7. Germon., et al. Cerebral near infrared spectroscopy: emitter-detector separation must be increased. Brit Journ of Anaesth 82 (6): 831-7(1999).
8. Ito., et al. Ann Nucl Med. 2005 Apr; 19(2):65-74
9. MacLeod., et al. IARS conference March 2006 Anesth Analg; 102; S-162.
10. Sfareni., et al. Near infrared absorption spectra of human deoxy-and oxyhaemoglobin the temperature range 20-40 degrees C. Biochim Biophys Acta. 1997 Jul 18; 1340(2): 165-9.
11. Kurth., et al. A multiwavelength frequency-domain near-infrared cerebral oximeter. Phys Med Biol 44 (1999) 727-740.
12. United States Food and Drug Administration: Regulatory Requirements for Laser Product Manufacturers, Laser Institute of America, Orlando, FL, 1985.
13. Owen-Reece H., et al. Near infrared spectroscopy. Br J Anaesth. 1999 Mar;82(3):418-26.
14. Webster JG, Design of Pulse Oximeters, IOP Publishing Ltd 1997.
15. Ohmae E., et al. Cerebral hemodynamics evaluation by near-infrared time-resolved spectroscopy: correlation with simultaneous positron emission tomography measurements. Neuroimage. 2006 Feb 1;29(3):697-705.
16. Strangman G., et al. A quantitative comparison of simultaneous BOLD fMRI and NIRS recordings during functional brain activation. Neuroimage. 2002 Oct;17(2):719-31.
17. Gratton E., et al. Measurement of brain activity by near-infrared light. J Biomed Opt. 2005 Jan-Feb;10(1):11008.
18. Mark., et al. Protecting the Brain in coronary Artery Bypass Graft Surgery. JAMA 2002 March Vol 287 No 11.
19. Werner Monitoring and Neuronal Protection European Society of Anaesthesiologists. Cerebral EAARC1 June 5 2004
20. McKhann., et al. Stroke and Encephalopathy After Cardiac Surgery, An Update. Stroke 2006; 37:562-571