



The INVOS[™] System Improving Patient Outcomes Through Cerebral/Somatic Oximetry





Backed by an improved patient outcomes claim and 600⁺ peer-reviewed references.

INVOS[™] System Advantages

- Not just "next-generation," it's SIXTH generation technology
- The only regional oximeter with clinical evidence to support a claim of improved patient outcomes after surgery in patients >2.5 kg
- The clinical referenced standard in cerebral/somatic oximetry with more than 800 clinical references; 600 of which are peer reviewed
- Because these are unique to INVOS[™] technology, applying these clinical findings to other cerebral oximeters may not be clinically or scientifically valid
- The only regional oximeter with peer-reviewed evidence validating its accuracy and clinical efficacy including three randomized controlled trials

- The only regional oximeter that enables simultaneous, 4-channel cerebral and somatic monitoring
- Intended for patients of any age or weight; with tailored sensors for adults, children, infants and neonates
- Cleared for real-time data accuracy in patients >2.5 kg (what some call "absolute")
- The only regional oximeter with a 14year proven history meeting the rigors of the clinical environment and continuous evolution of software and hardware for expanded applications
- Supported by a world-class customer clinical team for technology education and implementation

Not just "Next-Gen," it's SIXTH generation technology

With new cerebral oximeters entering the market, you may be wondering which is the best fit for your institution. In the INVOS[™] System, you will find the only cerebral/ somatic oximeter backed by an improved patient outcomes claim.¹⁻³ We attained this through a commitment to clinical research and independent investigations that have led to expanded clinical applications and foundations for patient care. It also resulted in 800+ clinical references unique to our product – of which 600 are peer reviewed – making the INVOS[™] System the referenced standard in clinical academia and the medical device industry. In addition, we continually invest in innovating INVOS[™] technology to further increase its clinical utility and ability to improve patient care. When partnering with us you'll have the confidence that comes from a technology proven to make a positive clinical impact and from the support of an expert sales and clinical education team.



The INVOS[™] System provides site-specific insights on perfusion adequacy and with multi-sensor monitoring – perfusion distribution across the brain and body. Its noninvasive sensors emit near infrared light into the microvasculature below, measuring oxy and deoxy hemoglobin in venous and arterial blood at a 75:25 ratio. This results in a sensitive, real-time measure of venous oxygen reserve; the blood oxygen remaining after extraction by tissues. Monitoring site-specific perfusion often provides an earlier warning of developing pathology and deteriorating patient condition than systemic measures or laboratory tests which can remain normal even when ischemia is occurring at the regional level.4-7

What about baselines?

The INVOS[™] System provides real-time measurement and display of regional oxygen saturation (rSO_2) in the microvasculature beneath the sensor. This data provides critical insight into site-specific hemodynamics and perfusion status. The INVOS[™] System features an optional baseline setting which adds additional dimension and value to the rSO₂ measurement. Continuous monitoring from a baseline provides an early warning of developing pathology and deteriorating patient condition.⁸⁻¹¹ And, since there are natural variations in patient "normals," a baseline can help show where your patient falls on this bell curve so you can customize care unique to the individual. Patient baselines also enable compliance with STS Adult Cardiac Surgery and Congenital Heart Database collection. These databases collect patient baseline data as well as cumulative saturation below threshold (an area-underthe-curve measure). With INVOS[™] System software, baseline settings can trigger the automatic collection and calculation of area under the curve.

In fact, a 2010 query of The STS Adult Cardiac Surgery Database showed a 23% incidence rate (8,406 of 36,548 procedures) for cerebral oximetry providing the first indication of a technical problem or physiological change in the patient that could potentially lead to an adverse patient outcome.¹²⁻¹³ Without baseline data, this clinical revelation may not have come to light. As with EEG, TCD and BP monitoring, utilizing baseline data is just good medicine.



The "absolute" misnomer

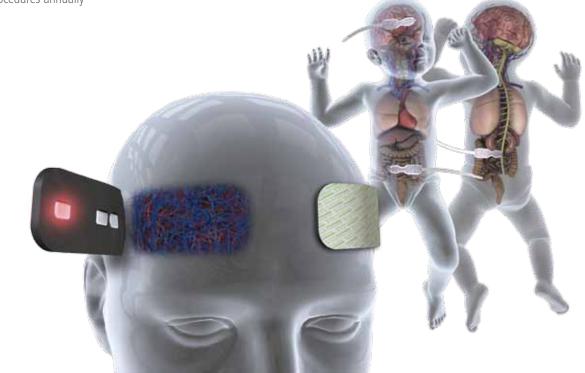
The INVOS[™] System is cleared for real-time data accuracy (what some companies call "absolute") in patients >2.5 kg. So why don't we call it "absolute?" The answer is simple and it is steeped in physiology. Oxygen saturation represents the relative proportion of two substances: oxy-hemoglobin to total hemoglobin. Because these substances are constantly changing within us, the term "absolute" seems incongruous. Patients don't have an absolute blood pressure or an absolute heart rate – nor should we expect them to have an absolute oxygen saturation. To us, "real-time data accuracy" is more suitable.

THE CLINICAL REFERENCED STANDARD

- 800+ clinical references (nearly 600 are peer reviewed)
- Three prospective, randomized controlled trials
- 800+ centers nationwide
 - Includes 90% and 80% of the top 10 adult and pediatric heart hospitals respectively (U.S. News & World Report, 2010)
- Approximately 6,000 units worldwide
- 250,000 procedures annually

LEADING THE WAY IN NIRS TECHNOLOGY

- First U.S. adult cerebral oximeter (1996)
- First pediatric cerebral oximeter (2000)
- First cerebral/somatic oximeter (2005)
- First cerebral/somatic oximeter backed by an improved patient outcomes claim after surgery in patients >2.5 kg (2009)



References

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11-PM-0256 MN21010

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