The INVOS™ Cerebral/Somatic Oximeter

The full physiologic perspective, when it absolutely matters

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positive results for life™

Everything in Perspective

The Clinical Standard

When it comes to clinical evidence, the INVOS™ cerebral/somatic oximeter stands alone. Clinicians around the world have come to rely on the INVOS™ system to guide their decisions in critical situations. Trust has been earned through both clinical performance and by extensive published research. For those reasons, the **INVOS system is the clinical standard in regional oximetry.**

The INVOS System – A Clear Choice Supported by Clinical Data

- The only cerebral oximeter on the market to be tested and validated under varying levels of CO_2 to ensure measurement sensitivity during changing levels of blood volume under the sensor.[1]
  Refer to figure 1
- Provides reliable, real-time data (what some manufacturers call "absolute") in patients > 2.5 kg.
- The only cerebral/somatic oximeter with rigorous, peer-reviewed clinical investigations demonstrating ability to improve patient outcomes.[3,4]
  Refer to figure 2
  - More than 1,000 clinical studies (more than 600 which are peer-reviewed) show the INVOS system as the clinical standard.
  - Three published, randomized, controlled trials have established the clinical value of the INVOS system to aid clinicians in improving patient outcomes.
- The only device with a claim for improved outcomes after surgery.[3,4,6]

Figure 1: The INVOS system's validation is extensive

	Validation: FiO_2 normoxia and hypoxia	Validation: CO_2 normocarbia and hypercarbia	Validation: Published emitter sensor spacing	Validation: Published sensitivity to changes in oxygenation
INVOS™ 5100C Monitor	Yes[1]	Yes[1]	Yes[2]	Yes[1]

Figure 2: Documented clinical performance[5]

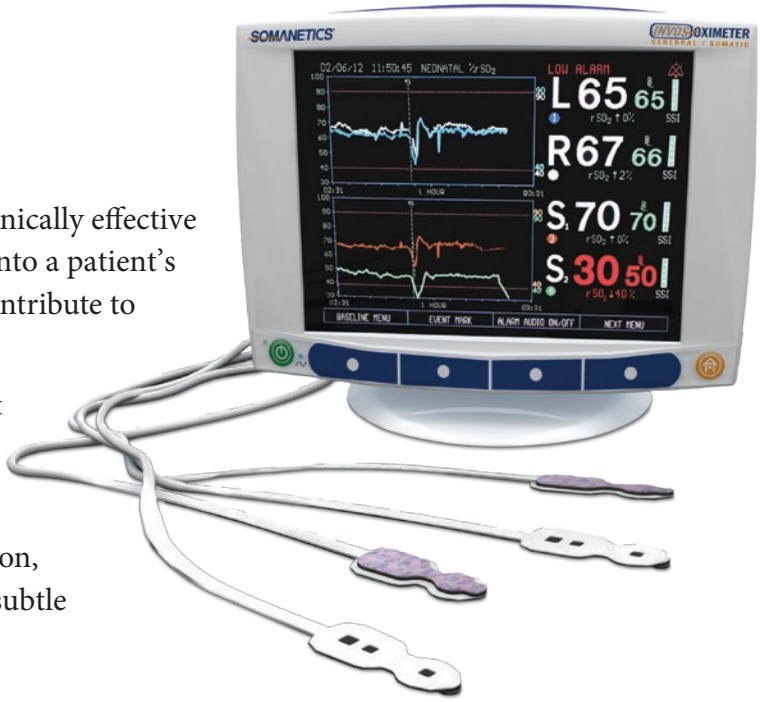
	All articles, abstracts, and posters	Published and peer-reviewed articles	Outcome correlation (peer-reviewed)	Outcome improvement (peer-reviewed)
INVOS™ System	1,000+	600+	30+	3

June 2013

The INVOS™ System Difference

Before you decide which NIRS technology to use, consider this: All NIRS technology is not the same. Clinical evidence for one technology does not necessarily apply to another. Each cerebral oximeter uses unique methodologies, algorithms and sensor design to analyze the oxy-hemoglobin saturation in tissue. The clinical evidence supporting the INVOS system is specific to INVOS™ technology and does not reflect the performance of competitive products.

The INVOS System Offers a Measure of rSO_2 Not Available With Other Oximeters



Only the INVOS system has been proven to be clinically effective in providing clinicians with physiologic insights into a patient's status to make care management decisions that contribute to improving patient outcomes.

- It is the ONLY cerebral oximeter on the market that is validated via a published hypoxia study under different levels of $PaCO_2$.[1]
- Using an optimized emitter spacing configuration, the INVOS system demonstrates sensitivity to subtle changes in saturation and cerebral blood flow.

Another manufacturer's disclaimer – accurate when patients are "normal"

Another manufacturer states that their device is designed to determine regional hemoglobin oxygen saturation of blood underneath the sensor.[7] They also state that the performance and accuracy of the device can be degraded or impacted if the patient's CO_2 levels are non-normocapnic (non-normal) or if there are other conditions that affect blood volume.[7] Do your patients always have "normal" CO_2 levels?

The Whole Picture

Other companies promote the "absolute intervention threshold" or what is sometimes called "absolute accuracy" capability of their oximeters. There's more to the picture.

- Exactly what does "absolute intervention threshold" or "absolute accuracy" mean? At this time, there are no regulations or standards that define the parameters for these marketing terms.
- Current cerebral oximeter technology does not allow for "absolute" measurements. The only real way to measure "absolute" cerebral oxygenation levels is to sample blood from a patient's brain, which oximeters don't do.
- "Absolute intervention thresholds" or "absolute accuracy" alone are not definitive of a patient's full physiologic condition. Each patient is unique and there is a wide range of "normal" values for cerebral venous oxygenation, which is contrary to an absolute measurement threshold for intervention.[8]

> The INVOS™ system provides clinicians with vital physiological data, based on each patient's "normal", to allow the clinician to customize care for that individual.

Baselines Matter – Customize Care for Each Patient's "Normal"

What is "normal"? When it comes to an individual patient's measurement, "normal" can cover a wide range. That's why establishing an individualized baseline is so critical. It shows you where each patient's physiologic "normal" range begins and ends so that you can customize care for that individual. The INVOS™ cerebral/somatic oximeter features a baseline setting that provides additional dimension and value to the rSO_2 measurement. Combine this baseline with continuous monitoring and the result is critical, early warnings of developing pathology and deteriorating patient condition.[8,9,10,11] This is the kind of timely information you need – and can rely on – during surgery.

Unlike pulse oximetry, which measures arterial oxygen, the INVOS system measures rSO_2, a reflection of cerebral venous saturation. This is an important distinction, because cerebral saturation has a much wider range of normal values (45% to 75%) than arterial saturation, which has a very narrow range. With this wider range of cerebral saturation, clinicians will make more informed decisions about intervention during surgery, based on the most individualized "normal" for each patient. The end result? Studies have demonstrated that intervening based upon a relative drop of rSO_2 from baseline improved patient outcomes.[3,4]

There's No Better Choice for Better Patient Outcomes

The INVOS™ system is the only regional oximeter with improved patient outcomes labeling. It stands alone as the best (and tested) choice to improve patient outcomes after cardiac surgery. And for patients, that's big news.

Reduce Complications, Improve Outcomes

Reduced major organ morbidity or mortality (MOMM)[3]

A randomized, controlled clinical study demonstrated that monitoring cerebral rSO_2 in coronary artery bypass patients avoids profound cerebral desaturation and is associated with significantly fewer incidences of major organ dysfunction.[3]

- Only 3% of the INVOS system group experienced MOMM compared to 11% in the control group and compared to 13.4% from the Society of Thoracic Surgeons database.

Reduced length of ICU stay[3]

Also clinically demonstrated, ICU length of stay for the INVOS system group was significantly shorter.[3]

- Mean 0.62 day reduction in length of stay, $p<0.029$.

Reduced stroke and need for prolonged ventilation[6]

INVOS system use on cardiac surgery patients reduced permanent stroke and reduced total time needed for mechanical ventilation.[6]

- Incidence of permanent stroke <1% in the INVOS system group compared with 2% in the control group, $p <0.044$.[6]

  - The study group had greater comorbidities than those in the control group

  - Rated using New York Heart Association (NYHA) classifications

- Median ventilator time of four hours vs. five hours in the control group, $p<0.0016$. A significantly greater proportion of the patients in the control group required prolonged ventilation, 10.6% vs. 6.8%, $p<0.0014$.[6]

Everything in Perspective, When it Absolutely Matters

The INVOS™ system is the clinical standard in regional oximetry monitoring. It's also the most widely used regional oximeter in the world[12] – for a reason. The INVOS system has been proven by extensive clinical investigations to improve patient outcomes.[3-4] Unique INVOS™ technology enables clinicians to detect subtle, physiologic changes in saturation and cerebral perfusion in order to make timely, critical lifesaving decisions for improved patient outcomes.

Clinical Benchmark, Market Leader

The Covidien INVOS™ system has long been the clinical benchmark and market leader[12] in NIRS technology. It's no coincidence. Getting essential physiologic data about the patient's well-being, with actionable insights and trends, into your hands at the right moment helps you make lifesaving decisions.

INVOS system benefits:

- Continuous rSO_2 monitoring in multiple patient types[4,13,14,15,16,17]
- Timely rSO_2 data to trigger interventions[3,15,18,19]
- Improved patient outcomes[3,6,20]
- Reduced hospital resource requirements[3,6]

For more information about the INVOS system contact your local representative or visit covidien.com/rms/products/cerebral-somatic-oximetry.

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