INVOS™
Cerebral/Somatic Oximeter
Improving Patient Outcomes and Safety in Adult Surgery

Cerebral Perfusion Directly Revealed

Operating Room
Post-op Intensive Care
Specialty Support Units
A MONITOR WITH EVIDENCE-BASED OUTCOMES

The In-Vivo Optical Spectroscopy (INVOS™) System noninvasively monitors site-specific adequacy of perfusion in the brain or body tissue directly beneath its sensors. This arms you with real-time data on regional oxygen saturation (rSO₂), which can detect site-specific ischemic complications even when systemic parameters or lab tests are within normal limits.¹⁻⁴

A 2010 query of The STS Adult Cardiac Surgery Database showed a 23% incidence rate for cerebral oximetry data, such as that from the INVOS™ System, providing “the first indication of a technical problem or physiological change in the patient that could potentially lead to an adverse patient outcome.”⁵⁻⁶ This was based on cerebral oximetry data from 36,548 procedures – meaning a critical first alert in approximately 8,400 procedures. This data supports hundreds of other published study findings showing the INVOS™ System provides the care team with clinically-unique oxygen data for patient assessment and detection of complications, and enhances clinical decision making, rapid response, patient safety and outcomes.

In fact, the INVOS™ System is the only cerebral/somatic oximeter with a claim for improved outcomes after cardiac or major general surgery in patients >2.5 kg.¹⁻⁷ There was evidence – along with 600 peer-reviewed references and three randomized controlled trials – has made the INVOS™ System the clinical referenced standard in cerebral/somatic oximetry.

MICROVASCULATURE: A UNIQUE SITE OF MEASURE

INVOS™ System technology gives you a noninvasive “window” to the body’s microvasculature; a direct and dynamic site of gas exchange that transports about half the body’s blood volume. Measuring blood oxygenation in the microvasculature results in sensitive and site-specific insights on perfusion adequacy or – with multi-sensor monitoring – perfusion distribution across the brain and body.

Unlike parameters that measure only venous or arterial blood, INVOS™ technology includes contributions from both in a 3:1 ratio, yielding a venous-weighted percent saturation. This provides real-time data about the balance or imbalance of oxygen supply and demand, thus reflecting venous oxygen reserve - the oxygen remaining after extraction by tissues and vital organs. Decreases in venous oxygen reserve can be a warning of developing pathology and deteriorating patient condition. Published adult data has shown that an rSO₂ of 50 or a 20% decline from baseline are cause for concern and intervention, and an rSO₂ of 40 or a 25% decline from baseline are associated with neurologic dysfunction and other adverse outcomes.⁹⁻¹⁷

The INVOS™ System utilizes near-infrared light at wavelengths that are absorbed by hemoglobin (730 and 810 nm). Light travels from the sensor’s light emitting diode to either a proximal or distal detector, permitting separate data processing of shallow and deep optical signals. INVOS™ System’s ability to localize the area of measurement, called spatial resolution, has been empirically validated in human subjects.¹⁸ Data from the scalp and surface tissue are subtracted and suppressed, reflecting rSO₂ in deeper tissues. This same concept applies to somatic monitoring.

The result is continuous, real-time adequacy of perfusion data in up to four sites of your choice.

Cerebral oximetry provided a first alert in 23% of STS Adult Cardiac Surgery Database cases.⁵⁻⁶
Site-Specific Adequacy of Perfusion in Real Time

Available in two or four channels
Scalp and surface tissue are subtracted out
Intervention <50  Critical <40
BENEFITS HIGH- AND LOW-RISK PATIENTS

Due to the inherent complexity of surgery, complications often remain common even in instances where survival has improved (e.g., cardiac surgery\textsuperscript{19,20}). For example, a study of nearly 12,000 CABG patients showed 75% of postoperative strokes occurred among the 90% of patients classified as low to medium risk pre-operatively. This suggests that techniques to identify at-risk patients and protect them peri-operatively have room for improvement.\textsuperscript{21}

Additionally, a 2,279-patient study of all cardiac surgery procedures found that cerebral oximetry brought value to patients spanning New York Heart Association (NYHA) classes I-IV.\textsuperscript{22} Patients with INVOS™ System monitoring and interventions versus the control group had significant reductions in the incidence of stroke (0.97% vs. 2.5%; \( p < 0.044 \)), prolonged (>24 hours) postoperative mechanical ventilation time (6.8% vs. 10.6%; \( p < 0.0014 \)), and length of postoperative hospital stay (\( p < 0.046 \)). The most notable differences in these outcomes were found among NYHA Class I patients, the least acute. Conversely, these reduced complications were achieved in the INVOS™ System group despite this cohort having a higher acuity than the control (64.1% NYHA class III and IV vs. 30.7%).

<table>
<thead>
<tr>
<th>CARDIAC</th>
<th>VASCULAR</th>
<th>ORTHO</th>
<th>GENERAL ANESTHESIA</th>
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<tbody>
<tr>
<td>• Cardiac surgery</td>
<td>• Aorto bi-femoral bypass</td>
<td>• Sitting shoulder repair</td>
<td>• Cases with:</td>
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<tr>
<td>• Off pump/on pump procedures</td>
<td>• Fem pops</td>
<td>• Spine cases</td>
<td>– Deliberate hypotension</td>
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<tr>
<td>• Complex aortic surgery</td>
<td>• TAA</td>
<td>• Hip cases</td>
<td>– Prone positioning</td>
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<td>• DHCA procedures</td>
<td>• VAD cases</td>
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<td>– Hemodynamic challenges</td>
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<td>• Robotic/hybrid cases</td>
<td>• Robotic cases</td>
<td></td>
<td>• Major abdominal surgery</td>
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<tr>
<td>• Single lung vent cases</td>
<td>• Balloon cases</td>
<td></td>
<td>• Bariatric surgery</td>
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<tr>
<td>• AAA</td>
<td>• Endo Thoracic Aneurysm (TAG Stent)</td>
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INVOS™ System studies have shown that the brain serves as a surrogate organ to homeostasis; interventions to optimize cerebral perfusion have a similarly beneficial effect on systemic tissue perfusion and patient outcomes. But numerous physiologic, mechanical and procedural factors during surgery or intensive care can jeopardize adequate cerebral oxygenation – often developing unexpectedly or silently. Knowing when to intervene is key. Real-time rSO₂ data via the INVOS™ System helps you detect and manage ischemic complications whether catastrophic or silent in nature.

Common applications for INVOS™ technology are shown below. While use spans many medical specialties and departments, there are commonalities across them. For example, since blood pressure can be an unreliable indicator of adequate cerebral perfusion, rSO₂ data can help guide deliberate hypotension and blood pressure management in both cardiac and non-cardiac cases such as sitting shoulder repairs. In addition, coherent patterns between rSO₂ and mean arterial pressure can help you identify a patient’s autoregulatory threshold, which may differ from the generally-accepted lower limit of 50 mmHg, as well as assist you in adjusting care accordingly.

In procedures requiring cannulation, rSO₂ data can augment your ability to assess flow abnormalities or proper reperfusion to the immediate area or extremities. Knowing this peri-operatively can avert delayed discovery of complications, such as compartment syndrome, in the ICU and the need for re-operation.

INVOS™ System readings function independent of pulse, pressure or temperature. This provides a reliable guide to perfusion adequacy during scenarios such as cardiopulmonary bypass, hypothermic circulatory arrest or other hypothermic therapies, treatment of shock and/or cardiovascular collapse, and ventilator or ECMO management.

Though the applications are many, INVOS™ System’s role is singular: providing site-specific rSO₂ data so you can optimize patient safety and positive outcomes.

<table>
<thead>
<tr>
<th>CEA/CAROTID</th>
<th>POST-OP ICU</th>
<th>NEURO</th>
<th>SPECIALTY UNITS</th>
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<tbody>
<tr>
<td>• Any carotid (awake or general) to better assess:</td>
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<tr>
<td>– Neck positioning</td>
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<tr>
<td>– Need for and efficacy of shunts</td>
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<tr>
<td>– Pressure management</td>
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<td></td>
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<tr>
<td>• Hemodynamic instability</td>
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<tr>
<td>• Compartment syndrome</td>
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<tr>
<td>• Efficacy of vents, ECMO and VADs</td>
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<td>• Vasospasm (neuro patients)</td>
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<td>• Hyperemia (carotid patients)</td>
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<td>• TBI</td>
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<td>• Aneurysm clipping</td>
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<td>• Spines</td>
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<tr>
<td>• Cardiac catheterization and EP labs</td>
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<td>• Interventional radiology</td>
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<td></td>
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<td>• Emergency room</td>
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Interventions to improve Cerebral rSO$_2$ in the Adult OR$^{7,9,14,27}$

When used as an indication of compromised cerebral oxygenation, interventions to return the patient’s rSO$_2$ to baseline using the INVOS$^TM$ System have been shown to improve outcomes after surgery.$^{1,7-8}$ Corrective interventions are routine, but without cerebral rSO$_2$ data the ability to detect and optimize otherwise silent and potentially adverse perturbations would remain limited.$^7$

**RULE OUT MECHANICAL CAUSE**
- Head position
- Cannula/clamp position

**INCREASE SUPPLY (OXYGEN DELIVERY)**
- Increase blood pressure
- Normalize CO$_2$ to physiologic level
- Increase FiO$_2$
- Increase cardiac output (pump flow)
- Vasodilate cerebral blood vessels
- Increase hematocrit

**DECREASE DEMAND (CEREBRAL METABOLISM)**
- Increase anesthetic
- Decrease temperature

Reduce complications. Improve outcomes.

The 600 peer-reviewed references and three randomized controlled trials examining INVOS$^TM$ System use have reported numerous patient benefits. These include, but are not limited to, those listed below.

**REDUCTIONS IN:**
- Major organ morbidity or mortality$^7$
- Stroke$^{22}$
- Post-op cognitive decline$^{28}$
- Respiratory failure/vent time$^{22}$
- Adverse surgical events$^{29}$
- Coma$^{30}$
- ICU length of stay$^7$
- Hospital length of stay$^1$

Clinically-Unique Data$^{27}$

Cerebral/somatic (capillary) oximetry (rSO$_2$) clinical characteristics
- Noninvasive
- Capillary (venous and arterial) sample
- Measures the balance of site-specific O$_2$ delivery and consumption
- End organ oxygenation and perfusion
- Requires neither pulsatility nor flow

_Typical values: 58%-82%

Pulse (arterial) oximetry (SpO$_2$) clinical characteristics
- Noninvasive
- Arterial sample
- Measures O$_2$ supply in the periphery
- Systemic oxygenation
- Requires pulsatility and flow

_Typical values: >90%

Central (venous) oximetry (SvO$_2$) clinical characteristics
- Invasive
- Venous sample
- Measures O$_2$ surplus in central circulation
- Systemic oxygen reserve
- Requires flow

_Typical values: 60%-80%
References


8. FDA 510(k) K082327.


10. Alexander HC, Kronenfeld MA, Dance GR. Reduced postoperative length of stay may result from using cerebral oximetry. J Cardiothorac Vasc Anesth. 2002;16(2):244-245.


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