Cerebral Perfusion Directly Revealed

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

Operating Room
Post-Op Intensive Care
Specialty Support Units
Improving outcomes with site-specific adequacy of perfusion data

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 provides 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 Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database showed a 23 percent 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, which means that INVOS technology provided 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 weighing more than 2.5 kg.1,7-8 This 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™ technology provides a noninvasive window into the body’s microvasculature; the 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, 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 percent decline from baseline are cause for concern and intervention, and an rSO2 of 40 or a 25 percent decline from baseline are associated with neurologic dysfunction and other adverse outcomes.9-17

The INVOS system uses 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, enabling separate data processing of shallow and deep optical signals. The 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.
Distal detector
Proximal detector
LED emitter

Available in two or four channels
Scalp and surface tissue are subtracted out
Intervention <50  Critical <40

Site-specific adequacy of perfusion in real time
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 coronary artery bypass graft (CABG) patients showed 75 percent of postoperative strokes occurred among the 90 percent of patients classified as low to medium risk preoperatively. This suggests that techniques for identifying at-risk patients and protect them perioperatively 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>Aortobifemoral bypass</td>
<td>Sitting shoulder repair</td>
<td>Cases with:</td>
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<tr>
<td>Off-pump/on-pump procedures</td>
<td>Femoropopliteal bypass (fem pop)</td>
<td>Spine</td>
<td>Deliberate hypotension</td>
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<tr>
<td>Complex aortic surgery</td>
<td>Thoracic aortic aneurysm (TAA)</td>
<td>Hip</td>
<td>Prone positioning</td>
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<tr>
<td>Deep hypothermic circulatory arrest (DHCA)</td>
<td>Ventricular assist device (VAD)</td>
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<td>Hemodynamic challenges</td>
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<tr>
<td>Robotic/hybrid</td>
<td>Robotic</td>
<td></td>
<td>Major abdominal surgery</td>
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<tr>
<td>Single lung vent</td>
<td>Balloon</td>
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<td>Bariatric surgery</td>
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<tr>
<td>Abdominal aortic aneurysm (AAA)</td>
<td>Endothoracic aneurysm (TAG\textsuperscript{®} stent)</td>
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Added insights for multiple medical specialties

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. 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 identify a patient’s autoregulatory threshold, which may differ from the generally-accepted lower limit of 50 mm Hg, as well as assist you in adjusting care accordingly.

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

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 cardiovascular collapse, and ventilator or ECMO management.

Though the applications are many, INVOS system’s role is singular: providing site-specific rSO₂ data so to 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>
</tr>
</thead>
<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 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, extracorporeal membrane oxygenation (ECMO) and ventricular assist device (VAD)</td>
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<tr>
<td>• Vasospasm (neuro patients)</td>
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<td>• Hyperemia (carotid patients)</td>
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<td>• Traumatic brain injury (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 electrophysiology (EP) labs</td>
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<td>• Interventional radiology</td>
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<td>• Emergency room</td>
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Interventions to improve cerebral rSO₂ in the adult OR⁷,⁹,¹⁴,²⁷

When used as an indication of compromised cerebral oxygenation, interventions to return the patient’s rSO₂ to baseline using the INVOS system have been shown to improve outcomes after surgery.¹,⁷-⁸ Corrective interventions are routine, but without cerebral rSO₂ 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 CO₂ to physiologic level
• Increase FiO₂
• 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™ system use have reported numerous patient benefits. These include, but are not limited to, those listed below.

REDUCTIONS IN:
• Major organ morbidity or mortality⁷
• Stroke²²
• Post-op cognitive decline²⁸
• Respiratory failure/vent time²²
• Adverse surgical events²⁹
• Coma³⁰
• ICU length of stay⁷
• Hospital length of stay¹

Clinically-Unique Data²⁷

Cerebral/somatic (capillary) oximetry (rSO₂) clinical characteristics
• Noninvasive
• Capillary (venous and arterial) sample
• Measures the balance of site-specific O₂ delivery and consumption
• End-organ oxygenation and perfusion
• Requires neither pulsatility nor flow

Typical values: 58%-82%

Pulse (arterial) oximetry (SpO₂) clinical characteristics
• Noninvasive
• Arterial sample
• Measures O₂ supply in the periphery
• Systemic oxygenation
• Requires pulsatility and flow

Typical values: >90%

Central (venous) oximetry (SvO₂) clinical characteristics
• Invasive
• Venous sample
• Measures O₂ surplus in central circulation
• Systemic oxygen reserve
• Requires flow

Typical values: 60%-80%
References


6. Avery EG. NVDS cerebellar oximetry white paper series. 2010;5M51415(1).


8. FDA 510k K082327.


