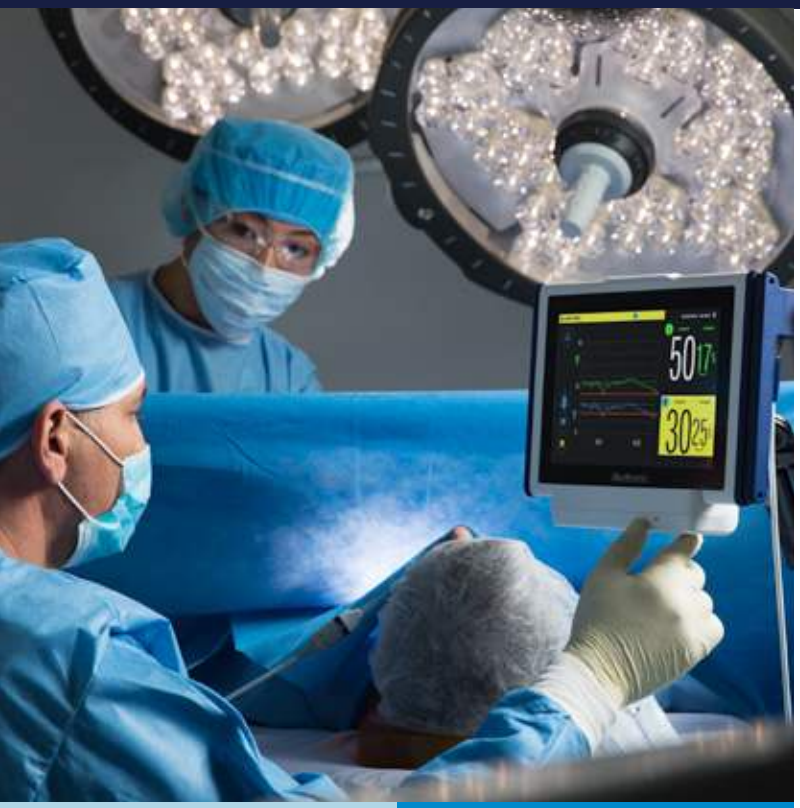
MAKE THE RIGHT CHOICE FOR REGIONAL OXIMETRY MONITORING.

A compelling case for the INVOS™ system



THE CEREBRAL DESATURATION CHALLENGE

The risks are real. Cerebral desaturation is common in cardiac surgery[1] and can lead to an array of adverse events.[2] In clinical trials, cerebral desaturation during cardiac surgery is associated with:

- Postoperative major organ morbidity and mortality (MOMM)[3]
- Neurologic injury[4,5]
- Increased time on mechanical ventilation[6]
- Prolonged hospital stay[3,4]

These risks underscore the need for regional oximetry systems that provide real-time monitoring of changes in regional oxygen saturation (rSO_2) of blood in the brain or other tissues beneath the sensor. These systems use near infrared spectroscopy (NIRS) to detect signs of hypoxia. The information generated by regional oximetry can help clinicians monitor oxygen levels in their patients and respond proactively to clinically significant changes in rSO_2. Regional oximetry systems need to be highly responsive to changes in cerebral blood oxygen saturation, so they can serve as a "first alert" for cerebral desaturations.

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Further, Together

The use of the INVOS™ technology as a "first alert" indicator of hemodynamic changes and deteriorating patient conditions is imperative in situations where timely intervention is critical.[2]

The INVOS™ system as a first alert

The INVOS™ system is designed to provide actionable trending values to support your clinical decision on when to intervene. These first alerts rely on speed of reaction and magnitude of response under clinically relevant scenarios.

In some cases, the INVOS™ system provides an indication of problems before other vital signs react.[2] Unlike pulse oximetry, which measures arterial oxygen, the INVOS™ system measures rSO_2, an indicator of cerebral oxygen saturation. Studies have demonstrated that intervening based upon a relative drop of rSO_2 from baseline, as indicated by the INVOS™ device, improved patient outcomes.[3,5,7]

SELECTING A REGIONAL OXIMETRY SYSTEM

Not all regional oximeters perform the same way. In side-by-side comparisons, devices from different manufacturers exhibit significant variations in responsiveness, sensitivity to hemodynamic changes, depth of response, and correlation to physiological changes.[8]

Those differences mean that comparing system specifications doesn't go far enough when evaluating regional oximetry systems. To select the right system, it's important to consider the entire platform. In particular, you should look for:

- A widely trusted solution
- Validated design features
- Peer-reviewed and published evidence
- Proven system performance

When these and other issues are considered, we believe the INVOS™ system clearly offers unique clinical and economic value for hospitals and other healthcare facilities. Using objective criteria based on what matters most for patient care, we have created this guide to identify key reasons why the INVOS™ system is the right choice for your regional oximetry monitoring needs.

LOOK FOR A WIDELY TRUSTED SOLUTION

Market leadership

The INVOS™ system is used in approximately 80 percent of monitored cases and has more than 1,200 installations around the world. That makes it the clear market leader — and the clinical reference standard — in regional oximetry monitoring.

Clinical studies

The INVOS™ system is not only the most widely used cerebral oximetry system, it's also the most studied. It has been discussed in more than 600 peer-reviewed publications, and it is the only cerebral/somatic oximetry system with FDA-cleared improved outcome claims.[3,7,10] Furthermore, the key outcomes studies assessed INVOS™ technology exclusively.[3,4]

Ongoing investments[11]

We are investing in the future of the INVOS™ system platform. And that investment includes working closely with customers who use the system daily in their healthcare environments. Considering your feedback is part of our commitment to bring meaningful innovation to our technologies.

LOOK FOR VALIDATED DESIGN FEATURES

A unique system design

The devices offered by Masimo, CASMED, and Nonin are all fundamentally different from the INVOS™ system in terms of sensor design, arterial/venous weighting, and algorithm tuning. Given these differences, these devices cannot be considered equivalent to the INVOS™ system.

Each factor of the INVOS™ system was developed with the intention of making it a viable first alert.[2,12]

We therefore caution applying the results and intervention thresholds that have been derived from studies using the INVOS™ system to other systems.[10]

A Research Finding

Significant differences exist between the various regional oximetry devices on the market today in how they respond to changes in oxygen saturation in healthy volunteers. We suggest caution when applying evidence generated with one manufacturer's device to all devices.[10]

Emitter/detector spacing

The emitter/detector spacing in the INVOS™ system has been clinically validated.[13] We are not aware of any published validation data on the sensor spacing of the systems from CASMED, Nonin, and Masimo.

	Emitter/detector spacing
INVOS™ system	3 cm and 4 cm
CASMED	1.5 cm and 5 cm
Nonin	2 cm and 4 cm
Masimo	3 cm and 4 cm

Arterial/venous weighting

The INVOS™ system's arterial/venous weighting ratio of 25:75 has been validated. The system's rSO_2 values were compared against the field saturation (25 percent arterial:75 percent venous).[14]

	Assumed weighting used in the algorithm
INVOS™ system	25:75
CASMED	30:70
Nonin	30:70
Masimo	30:70

CASMED, Nonin, Masimo ratios[15,16]

Algorithm tuning

Our goal is to ensure that the INVOS™ system gives you an accurate first alert to clinical change. With this in mind, the mathematical algorithm at the heart of the INVOS™ system was designed to balance both instantaneous and trending accuracy. It has also been tuned and calibrated based upon empirical data sets.

LOOK FOR PEER REVIEWED AND PUBLISHED EVIDENCE

Research findings: clinical outcomes

The INVOS™ system has been used in many peer-reviewed studies that evaluated and confirmed the clinical benefits associated with the use of regional oximetry systems. For example:

- Murkin et al. concluded: "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]
- Slater et al. concluded: "Intraoperative cerebral oxygen desaturation is significantly associated with an increased risk of cognitive decline and prolonged hospital stay after CABG [coronary artery bypass grafting]."[7]

Each system is different

These systems are all designed differently. That means that relying on data generated by the INVOS™ system to determine the intervention threshold of another device may not lead to the outcomes demonstrated by the many clinical studies of the INVOS™ system.

LOOK FOR PROVEN SYSTEM PERFORMANCE

A focus on relevant responses

We designed the INVOS™ system with clinically relevant responsiveness to help physicians quickly intervene during the most critical moments. This responsiveness to clinical change is part of what distinguishes the INVOS™ system from other systems.

The depth of the response of the INVOS™ system gives clinicians the information they need to intervene and improve patient outcomes.[3,12] Our data shows that other NIRS devices on the market do not react the same as the INVOS™ system during clinically challenging situations.[17,18,19]

In a head-to-head comparison, the INVOS™ system and the Masimo Root®* O3™* system exhibited notable differences in clinically relevant responsiveness.[14] Contact us for a copy of this study and its key findings.

Research findings: System performance

Here are a few examples of the research-based findings that evaluated the performance of regional oximetry systems in clinical studies:

- The INVOS™ system outperformed the systems from CASMED and Masimo in terms of responsiveness and depth of response.[8]
- During characterization studies in an animal model, the time it took Masimo's and CASMED's regional oximeters to reach 80 percent of baseline in their devices was significantly slower when compared to the INVOS™ system.[8]
- When compared to the devices from Masimo and CASMED, the depth of response at 10 minutes was significantly lower than the INVOS™ system.[8]
- When compared to the systems from Nonin, CASMED, and Masimo, the INVOS™ system's rSO_2 measurements most closely correlated with SpO_2 levels and the physiology of the subject, and previous data have shown the correlation between rSO_2 and mixed venous oxygen saturation.[18]
- The desaturation frequency, depth, slope, and duration of the INVOS™ system are highly sensitive. The system detects a decrease in cerebral oxygenation in an induced hypoxic state faster and more deeply than the Masimo and CASMED systems.[8]

KEY TAKEAWAYS

When selecting a regional oximetry system, it's important to look at the entire platform in terms of:

- Market acceptance
- Validated design features
- Peer-reviewed and published evidence
- Proven performance

The INVOS™ system sets the standard in each of those categories, making it the right choice for regional oximetry monitoring.

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IMPORTANT: Please refer to the package insert for complete instructions, contraindications, warnings and precautions.

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