The INVOS™ regional oximeter has been demonstrated through rigorous, peer-reviewed clinical research to improve patient outcomes by detecting cerebral oxygen desaturation and facilitating timely interventions under normal practice conditions. Accumulating evidence has demonstrated that INVOS™ cerebral oximetry values may be predictive of or potentially guide interventions to reduce postoperative adverse outcomes, including cognitive decline, major organ morbidity, delirium, and mortality.

Compared to other oximeters, the INVOS™ regional oximeter has a significantly greater body of evidence demonstrating its performance and positive impact on patient outcome. Hundreds of studies have evaluated the unique characteristics of the INVOS™ system for monitoring real-time changes in regional oxygen saturation (rSO₂) in a multitude of patient populations, settings, and interventions. Because the INVOS™ system’s algorithm reacts differently to acute alterations in hemodynamics, oxygen saturation, or oxygen metabolism, applying this evidence to other cerebral oximeters may not be clinically or scientifically valid.

Use this guide to review the evidence evaluating the uniqueness of the INVOS™ system’s algorithm compared to other commercially available regional oximeters.
## Objective
Determine how different regional oximeters respond differently to changes in oxygen saturation in volunteers undergoing induced hypoxia.

## Arms
- Arm 1 (n=6): INVOS™ 5100 sensor applied to left forehead and the Nonin Equanox™ 7600 sensor applied to right forehead.
- Arm 2 (n=4): INVOS™ 5100 sensor applied to left forehead and the CASMED Fore-Sight™ sensor applied to right forehead.

## Population
Healthy volunteers (N=10)

## Methods
Hypoxia was induced and reversed two times in each patient by altering FiO₂. Endpoints included the magnitude and rate of rSO₂ change.

## Results
- During both desaturation and resaturation, the INVOS™ regional oximeter had a significantly greater median rate of absolute rSO₂ change, compared to the Nonin Equanox™ regional oximeter.
- There was a trend towards greater median rate of absolute rSO₂ change in the INVOS™ regional oximeter compared to the CASMED Fore-Sight™ regional oximeter. However, the study was underpowered to detect a significant difference.
- In subjects (n=6) with both the INVOS™ and Nonin Equanox™ sensors, the INVOS™ regional oximeter detected a 20% absolute decrease from baseline in five subjects and detected a 50% absolute decrease from baseline in four subjects without a concurrent decrease in the Nonin Equanox™ regional oximeter.
- In subjects (n=4) with both the INVOS™ and CASMED Fore-Sight™ sensors, the INVOS™ regional oximeter detected a 20% absolute decrease from baseline in two subjects and detected a 50% absolute decrease from baseline in three subjects without a concurrent decrease in the CASMED Fore-Sight™ regional oximeter.

## Conclusion
Regional oximeters from different manufacturers demonstrate unique responses to changes in cerebral oxygen desaturation in volunteers undergoing hypoxia.
**Objective**
Evaluate the relative responsiveness of the INVOS™ and Nonin Equanox™ regional oximeters to changes in peripheral regional tissue oxygen saturation in the calf muscles of healthy volunteers undergoing vascular occlusion test via application of a pneumatic cuff.

**Population**
20 healthy volunteers

**Methods**
Two INVOS™ sensors and two Nonin Equanox™ sensors were applied to both the left and right calves of 20 volunteers. An pneumatic cuff was applied to left leg in order to induce hyperoxia, ischemia, and reperfusion (occlusion test). Endpoints included range of rSO₂ values, rSO₂ values at during occlusion test (hyperoxia, ischemia, and reperfusion), maximum change from initial baseline values, rate of desaturation (%/min), and rate of resaturation (%/min).

**Results**
- Inducement of ischemia resulted in a significant reduction from baseline in both monitors.
- Subsequent reperfusion resulted in significant increase above baseline in both monitors.
- The INVOS™ regional oximeter decreased 33% and the Nonin Equanox™ regional oximeter decreased 21% from baseline during the occlusive vascular test.
- The rate of desaturation (3.65% vs. 2.36, P=0.027) and resaturation (30.42% vs. 16.28%, P=0.004) per minute was significantly greater in the INVOS™ regional oximeter compared to the Nonin Equanox™ regional oximeter.

**Conclusion**
The INVOS™ system and Nonin Equanox™ system measures of peripheral regional tissue oxygen saturation are not interchangeable in terms of absolute change or rate of change during induced hyperoxia, ischemia, and reperfusion.
Relation between mixed venous oxygen saturation and cerebral oxygen saturation measured by absolute and relative near-infrared spectroscopy during off-pump coronary artery bypass grafting.

<table>
<thead>
<tr>
<th>Objective</th>
<th>Evaluate the agreement between mixed venous oxygen saturation and two regional oximeters, the INVOS™ oximeter and CASMED Fore-Sight™ oximeter.</th>
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</thead>
<tbody>
<tr>
<td>Population</td>
<td>42 patients undergoing off-pump coronary artery bypass (OPCAB) surgery for at least three-vessel coronary artery disease</td>
</tr>
<tr>
<td>Methods</td>
<td>Four sensors, left and right sensors for both monitors, were placed on the forehead of each patient. Patients were randomized to determine placement of the INVOS™ or Fore-Sight™ electrodes on the lower or top half of the forehead. The INVOS™ regional oximeter, Fore-Sight™ regional oximeter, MAP, and SmVO₂ values were recorded before, during, and after each retraction of the heart associated with the placement of deep pericardial stitches.</td>
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</tbody>
</table>
| Results | • Changes in the INVOS™ monitoring technology were significantly greater than in the Fore-Sight™ system (p<0.001) in response to hemodynamic changes resulting from placement of deep pericardial stitches.  
• For each percent change in SmVO₂, there was a significantly greater percentage change in the INVOS™ monitoring technology compared to the Fore-Sight™ system (0.62% versus 0.22%, p<0.001)  
• Linear regression analysis demonstrated a significantly more positive slope of rScO₂ vs MAP for INVOS™ compared with the Fore-Sight™ system (p = 0.001).  
• The ratio of changes in rSO₂ to changes in MAP was significantly greater for the INVOS™ monitoring technology (21 versus 11, p<0.001) |
| Conclusion | Cerebral oximeter may be capable of more rapidly detecting instances of regional oxygen desaturation. The INVOS™ and Fore-Sight™ sensors demonstrated significant differences in terms of absolute values and degree of responsiveness to hemodynamic changes resulting from placement of deep pericardial stitches. |
The effects of systemic oxygenation on cerebral oxygen saturation and its relationship to mixed venous oxygen saturation: a prospective observational study comparison of the INVOS™ and ForeSight™ Elite cerebral oximeters.


<table>
<thead>
<tr>
<th>Objective</th>
<th>Evaluate the agreement between mixed venous oxygen saturation (SvO₂) and the ability to predict low SvO₂ for two regional oximeters, the INVOS™ oximeter and CASMED Fore-Sight™ oximeter, in the postoperative period.</th>
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<tr>
<td>Population</td>
<td>48 extubated, stable postoperative cardiac patients with a pulmonary artery catheter (PAC) still in place</td>
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<tr>
<td>Methods</td>
<td>Patients were monitored bilaterally with the INVOS™ oximeter intraoperatively. If the cerebral INVOS™ sensors were still in place on arrival in the ICU, then they were used as the first device studied in that patient. If not, two cerebral Fore-Sight™ sensors were placed. First phase: Each patient was subjected to high FiO₂ (10 L/min) and kept stable for 15 minutes (“high” data). The rSO₂, SvO₂, and hemodynamic variables were monitored for another 15 minutes. Then the sensors were switched to the other device and the process for collecting “high” data was repeated. Second phase: The above protocol was repeated to collect “low” data using room air (or FiO₂ of 1 to 2 L/min if the patient’s arterial oxygen saturation was &lt;90%).</td>
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</table>
| Results                                       | • The INVOS™ oximeter reported significantly lower median and mean minimum rSO₂ during low data collection only  
  • When the high and low data were combined for each device, the correlation coefficients (based on minimum rSO₂ measured versus minimum SvO₂ measured) were significantly different (p = 0.008)  
  – INVOS™ oximeter: r = 0.59 (p = 0.001)  
  – Fore-Sight™ oximeter: r = 0.28 (p = 0.006)  
  • The area under the receiver-operating curve for detecting low SvO₂ with the minimum rSO₂ value was also different between the two devices:  
  – SvO₂ <50%: INVOS™ rSO₂ value = 0.83 (p = 0.005); Fore-Sight™ rSO₂ value = 0.51 (p = 0.12)  
  – SvO₂ <60%: INVOS™ rSO₂ value = 0.76 (p<0.001); Fore-Sight™ rSO₂ value = 0.61 (p = 0.92) |
| Conclusion                                    | The two regional oximeters do not react comparably in clinical situations. Specific cut-off values for cerebral desaturation and interventions may need to be developed for each manufacturer’s oximeter. It is unclear whether evidence generated with one device can be applied to other manufacturer’s devices. |
Direct comparison between cerebral oximetry by INVOS™ and Equanox™ during cardiac surgery: a pilot study.

Pisano A, Galdieri N, Lovino TP, et al.
Heart Lung Vessel. 2014;6(3):197-203.

<table>
<thead>
<tr>
<th>Objective</th>
<th>Evaluate the agreement between the INVOS™ and Equanox™ monitors in patients undergoing cardiac surgical procedures.</th>
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<tr>
<td>Population</td>
<td>10 cardiac surgery patients undergoing procedures with or without cardiopulmonary bypass (CPB)</td>
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<tr>
<td>Methods</td>
<td>Both left and right INVOS™ and Equanox™ sensors were placed on the foreheads of all patients. The INVOS™ and Equanox™ sensor values were collected at baseline, after intubation, after CPB onset, at aortic cross-clamping and unclamping, at CPB offset, at the end of surgery, and in circumstances where oxygen saturation reduction was greater than or equal to 20% of the baseline value.</td>
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</table>
| Results         | • The INVOS™ sensors captured 20 instances in four patients where oxygen saturation reduction was greater than or equal to 20% of the baseline value  
• The Equanox™ sensors captured 4 instances in one patient where oxygen saturation reduction was greater than or equal to 20% of the baseline value  
• The mean bias between the INVOS™ and Equanox™ sensors was -5.10%  
• The limits of agreement between the INVOS™ and Equanox™ sensors were ±16.37% |
| Conclusion      | The INVOS™ and Equanox™ sensors cannot be used interchangeably during cardiac surgery. Device-specific thresholds determined by interventional trials are required in order to guide interventions. |

References


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