

NO OTHER REGIONAL OXIMETER HAS BEEN EVALUATED MORE.¹

When it comes to clinical evidence, the INVOS™ regional oximeter stands alone.¹

The INVOS™ regional oximeter has been shown to improve patient outcomes through rigorous, peer-reviewed clinical research. By detecting cerebral oxygen desaturation and facilitating timely interventions under normal practice conditions, the device may help prevent adverse outcomes and improve the patient experience. Accumulating evidence has demonstrated that INVOS™ regional oximetry values may be predictive of or potentially guide interventions to reduce postoperative adverse outcomes, including:

- Cognitive decline^{2,3}
- Major organ morbidity^{4,5}
- Delirium⁶
- Mortality⁴

Compared to other oximeters, the INVOS™ regional oximeter has a significantly greater body of evidence demonstrating its performance and positive impact on patient outcomes. Hundreds of studies have evaluated the unique characteristics of the INVOS™ system for monitoring real-time changes in regional oxygen saturation (rSO₂). These studies include a multitude of patient populations, settings, and interventions.¹ Because the INVOS™ system's algorithm reacts differently to acute alterations in hemodynamics, oxygen saturation, and oxygen metabolism — this evidence may not apply to other regional oximeters.⁷⁻¹¹ The American Society for Enhanced Recovery and Perioperative Quality Initiative Joint Consensus states that NIRS devices from different manufacturers have significantly different measurements and thus are not interchangeable.¹¹

Use this guide to review the evidence evaluating the uniqueness of the INVOS™ system's algorithm compared to other commercially available regional oximeters.

Significant differences in rSO₂ measurements suggest NIRS devices are not interchangeable

Evaluation of different near-infrared spectroscopy devices for assessing tissue oxygenation with a vascular occlusion test in healthy volunteers

CHUNG J, JI SH, JANG YE, ET AL. (South Korea)

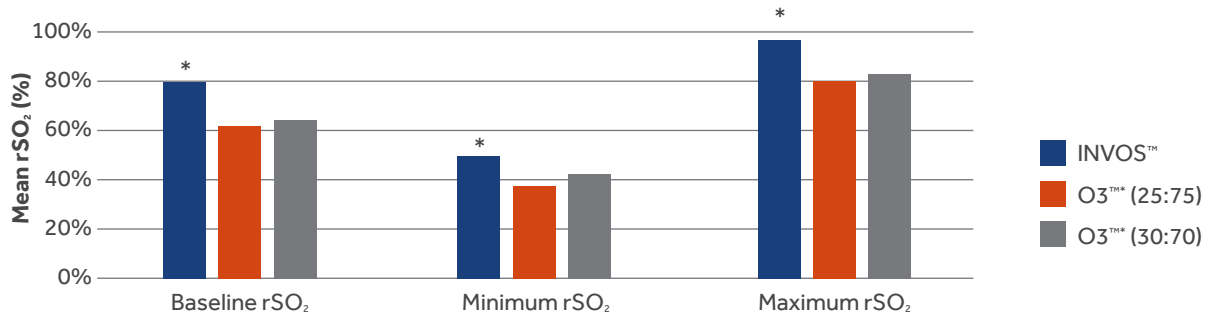


Figure: Comparison of INVOS™ system and Masimo O3™ system (25:75 and 30:70) in baseline rSO₂ measurement, minimum and maximum rSO₂ measurement during vascular occlusion test

*INVOS™ regional oximeter measurements were significantly different from both Masimo O3™ regional oximeter settings ($P < 0.05$). The two Masimo O3™ regional oximeter settings were not significantly different.

Compared to the Masimo O3™ regional oximeter, the INVOS™ regional oximeter had:

Significantly different
measurements of the
same clinical state



44%
faster reaction time
during cuff release

Study of 20 healthy volunteers evaluating the Masimo O3™ regional oximeter and INVOS™ regional oximeter in the measurement of tissue oxygenation during vascular occlusion

- The Masimo O3™ regional oximeter can measure arterial and venous blood at a 25:75 ratio or 30:70 ratio depending on the setting chosen. The INVOS™ regional oximeter measures arterial and venous blood at a 25:75 ratio.
- The objective of the study was to compare the tissue rSO₂ measurements recorded by the INVOS™ and the Masimo O3™ regional oximeters (at both ratio settings - 25:75 & 30:70) during states of perfusion and occlusion.
- Three sensors (INVOS™, O3™ - 25:75, O3™ - 30:70) were placed on the arm simultaneously. Measurements were taken at baseline, following blood pressure cuff inflation (occlusion), and following blood pressure cuff deflation (reperfusion).

The findings

- There were significant differences in the tissue rSO₂ measurements between the devices during the same physiologic change (perfusion- occlusion- reperfusion), suggesting that these devices are not interchangeable.
 - The INVOS™ regional oximeter’s baseline rSO₂ was higher than the Masimo O3™ regional oximeter
 - The INVOS™ regional oximeter’s measurement decreased more rapidly during occlusion than the other device
 - The lowest measurement of rSO₂ by the INVOS™ regional oximeter was significantly higher than the lowest measurement of rSO₂ by the Masimo O3™ regional oximeter
 - The peak measurement of rSO₂ by the INVOS™ regional oximeter was significantly higher than the peak measurement of rSO₂ by the Masimo O3™ regional oximeter
 - The INVOS™ regional oximeter’s measurement increased more rapidly during cuff release (reperfusion) getting to its peak value faster than the comparison device
- There were no significant differences between the Masimo O3™ regional oximeter’s settings (25:75 & 30:70). This indicates that different ratios of arterial and venous blood do not seem to be contributing to the difference in measurements from varying NIRS devices.

NIRS devices from different manufacturers demonstrate unique responses to changes in cerebral desaturation during hypoxia

Detection of critical cerebral desaturation thresholds by three regional oximeters during hypoxia: a pilot study in healthy volunteers.

TOMLIN KL, NEITENBACH AM, BORG U. (US)

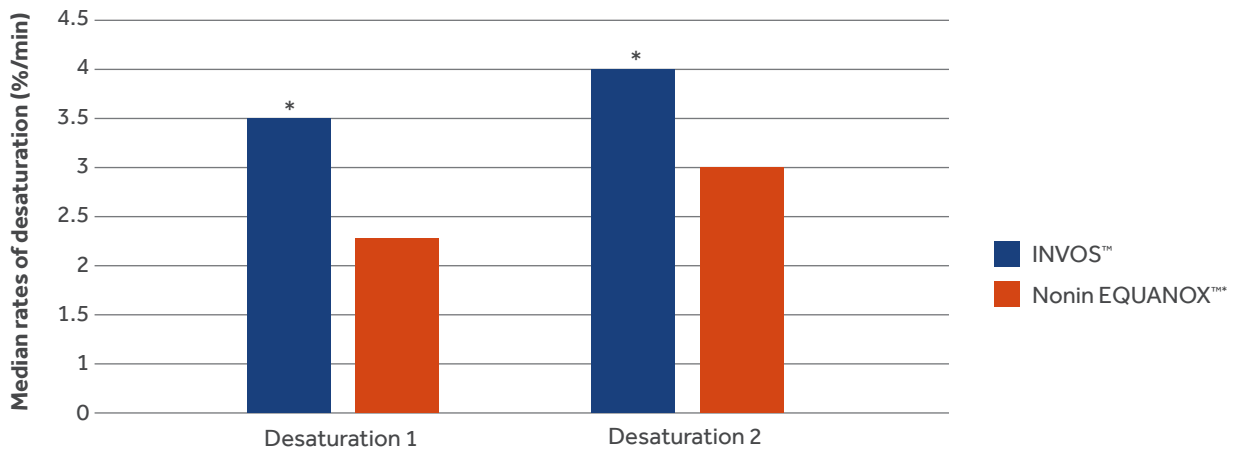


Figure: Median rates of absolute oxygen saturation change during desaturation

* $P < 0.05$; significant differences between device measurements

The INVOS™ regional oximeter detected a 10% relative change

28–43s

earlier than the Nonin EQUANOX™* and Edwards Fore-Sight™** regional oximeters

Only the INVOS™

regional oximeter detected a 20% relative decrease in rSO₂ in all subjects

Pilot study of 10 healthy volunteers comparing cerebral rSO₂ measurements from the INVOS™ regional oximeter to both the Nonin EQUANOX™* and the Edwards ForeSight™ regional oximeters during periods of hypoxia.**

The findings

- 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 Edwards ForeSight™** regional oximeter. However, the study was underpowered to detect a significant difference.
- In subjects (n = 6) with both the INVOS™ and Nonin Equanox™* regional oximeter sensors, the INVOS™ regional oximeter detected a 20 percent relative decrease from baseline in all subjects and a decrease to the absolute threshold of 50 percent in four subjects, while the Nonin Equanox™* regional oximeter only detected the 20 percent decrease in one subject.
- In subjects (n = 4) with both the INVOS™ and the Edwards ForeSight™** regional oximeter sensors, the INVOS™ regional oximeter detected a 20 percent relative decrease from baseline in all subjects and a decrease to an absolute threshold of 50 percent in three subjects while the Edwards ForeSight™** regional oximeter only detected the 20 percent decrease in two subjects.

Peripheral rSO₂ measurements by the INVOS™ regional oximeter and Nonin Equanox™ regional oximeter vary significantly in absolute change and rate of change during vascular occlusion tests

Dynamic evaluation of near-infrared peripheral oximetry in healthy volunteers: a comparison between INVOS and Equanox

FELLAHI JL, BUTIN G, FISCHER MO, ET AL. (France)

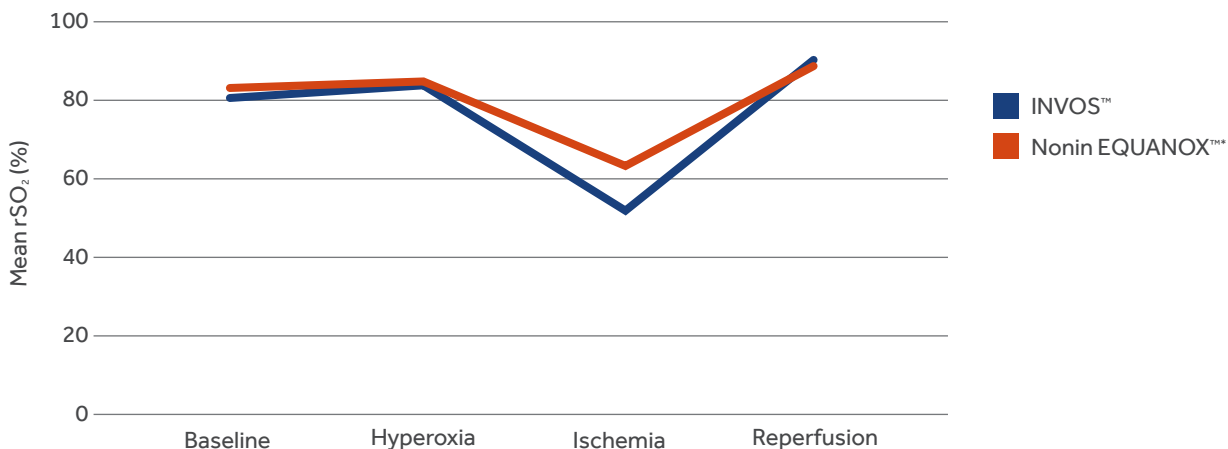


Figure: Mean measurements of peripheral left leg rSO₂ with both INVOS™ and Nonin EQUANOX™ regional oximeters following hyperoxia, ischemia, and reperfusion

The INVOS™ regional oximeter had a **significantly quicker** desaturation and resaturation rate compared to the Nonin EQUANOX™ regional oximeter



No significant correlation between measurements by the two devices

Study of 20 healthy volunteers undergoing vascular occlusion testing in their left leg comparing measurements of rSO₂ from the INVOS™ regional oximeter and Nonin EQUANOX™ regional oximeter.

The findings

- 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 percent and the Nonin EQUANOX™ regional oximeter decreased 21 percent from baseline during the occlusive vascular test.
- The rate of desaturation (3.65 percent vs. 2.36 percent, $P = 0.027$) and resaturation (30.42 percent vs. 16.28 percent $P = 0.004$) per minute was significantly greater in the INVOS™ regional oximeter compared to the Nonin EQUANOX™ regional oximeter.

The INVOS™ regional oximeter and the Edwards ForeSight™* regional oximeter demonstrated significant differences in absolute values and degree of responsiveness to hemodynamic changes

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

MOERMAN A, VANDENPLAS G, BOVE T, ET AL. (Belgium)

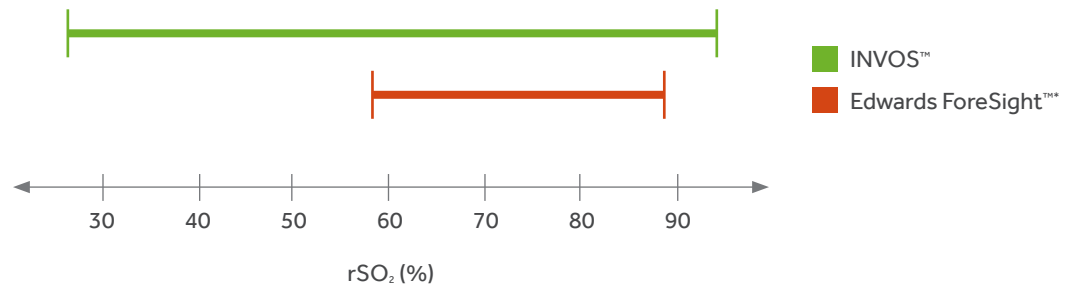


Figure: Distribution of the regional cerebral oxygen saturation (rSO₂) data measured with the Edwards ForeSight™* regional oximeter and INVOS™ regional oximeter

The INVOS™ regional oximeter measurements had a **significantly more positive correlation** with MAP and SvO₂ than the Edwards ForeSight™* regional oximeter measurements



Study of 42 patients undergoing off-pump coronary artery bypass graft surgery comparing measurements of cerebral rSO₂ by the INVOS™ regional oximeter and Edwards ForeSight™* regional oximeter with mixed venous oxygen saturation (SvO₂).

The findings

- Changes in the INVOS™ regional oximeter measurements in response to hemodynamic changes resulting from placement of deep pericardial stitches were significantly greater than those by the Edwards ForeSight™* regional oximeter ($P < 0.001$).
- When both sensors were running simultaneously, the Edwards ForeSight™* regional oximeter experienced interference from the INVOS™ regional oximeter sensor causing more variability in its measurements.
- For each percent change in SvO₂, there was a significantly greater percentage change in the INVOS™ regional oximeter measurements compared to the Edwards ForeSight™* regional oximeter
- There was a significantly more positive slope of rSO₂ versus MAP for the INVOS™ regional oximeter measurements compared with the Edwards ForeSight™* regional oximeter ($P = 0.001$).
- The ratio of changes in rSO₂ to changes in MAP was significantly greater for the INVOS™ regional oximeter (21 versus 11, $P < 0.001$).

Evidence generated with one NIRS device may not be applied to other manufacturer's devices due to measurement variation

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 system and ForeSight Elite cerebral oximeters

SCHMIDT C, HERINGLAKE M, KELLNER P, ET AL. (Germany)

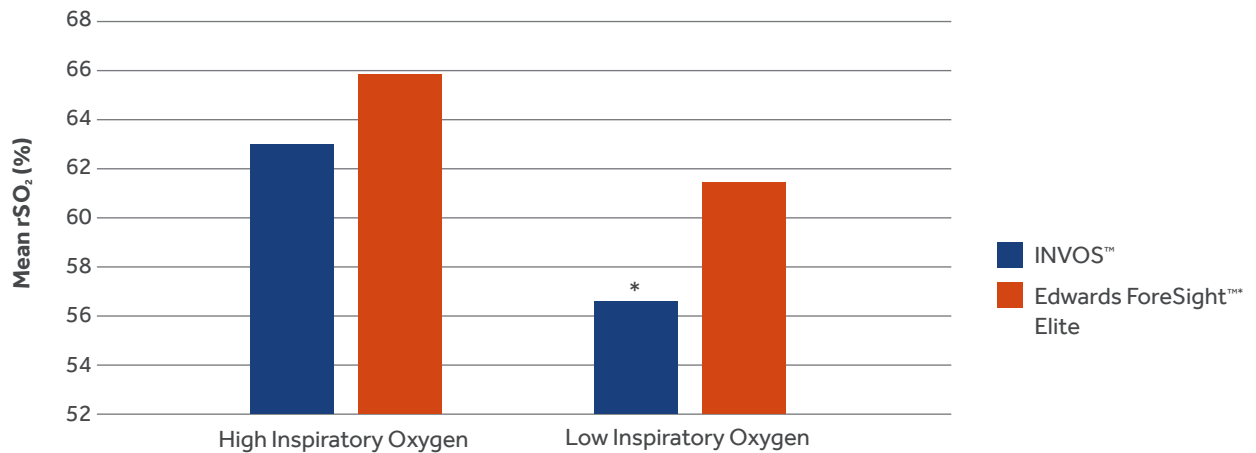


Figure: Mean minimum measurement of rSO₂ during high and low inspiratory oxygen

* $P < 0.01$; rSO₂ measurements significantly different during low inspiratory oxygen



During low oxygen levels,
the INVOS™ regional oximeter had
significantly lower
readings of rSO₂ compared to the
Edwards ForeSight™ Elite regional oximeter

Study of 48 extubated postcardiac surgery patients exposed to high and low oxygen delivery comparing rSO₂ measurements by the INVOS™ regional oximeter and the Edwards ForeSight™ Elite regional oximeter to mixed venous oxygen saturation (SvO₂).

The findings

- The INVOS™ regional oximeter reported significantly lower median and mean minimum rSO₂ during low oxygen delivery data collection only.
- During individual measurement periods, rSO₂ measured by the INVOS™ regional oximeter during low and high oxygen delivery showed significant correlations with SvO₂. No significant correlation was seen between the Edwards ForeSight™ Elite regional oximeter measurements and SvO₂.
- 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™ regional oximeter: $r = 0.59$ ($P = 0.001$)
 - Edwards ForeSight™ Elite regional 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 percent: INVOS™ regional oximeter = 0.83 ($P = 0.005$); Edwards ForeSight™ Elite regional oximeter = 0.51 ($P = 0.12$)
 - SvO₂ < 60 percent: INVOS™ regional oximeter = 0.76 ($P < 0.001$); Edwards ForeSight™ Elite regional oximeter = 0.61 ($P = 0.92$)

Device-specific thresholds determined by interventional trials are required to guide interventions

Direct comparison between cerebral oximetry by INVOS™ and Equanox™ during cardiac surgery: a pilot study

PISANO A, GALDIERI N, LOVINO TP, ET AL. (Italy)

Table: Type of surgery and number of desaturations ≥20 percent from baseline (displayed by one or both of the two devices)

Patient	Type of Surgery	# of Desaturations ≥20% from Baseline		
		INVOS™	Nonin EQUANOX™	Both
1	AVR	0	0	0
2	CABG	5	3	3
3	OPCAB	5	0	0
4	MVR	6	0	0
5	CABG	0	0	0
6	AVR	0	0	0
7	MVR	0	0	0
8	OPCAB	0	0	0
9	OPCAB	4	0	0
10	MVR	0	0	0

AVR = aortic valve replacement; CABG = coronary artery bypass graft; OPCAB = off-pump coronary artery bypass; MVR = mitral valve replacement

Cerebral desaturation events (CDE) are defined as **≥ 20%** decrease in rSO₂ from baseline



The INVOS™ regional oximeter detected almost **7x** more CDEs than the Nonin EQUANOX™ regional oximeter

Study of 10 patients undergoing cardiac surgery on and off pump comparing simultaneous measurements of rSO₂ by INVOS™ and Nonin EQUANOX™ regional oximeters.

The findings

- The INVOS™ regional oximeter captured 20 instances in four patients where oxygen saturation reduction was greater than or equal to 20 percent from the baseline value.
- The Nonin EQUANOX™ regional oximeter captured three instances in one patient where oxygen saturation reduction was greater than or equal to 20 percent from the baseline value.
- The mean bias between the INVOS™ and Nonin EQUANOX™ regional oximeters was -5.10 percent.
- The limits of agreement between the INVOS™ regional oximeter and Nonin EQUANOX™ regional oximeter were ±16.37 percent.

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The INVOS™ monitoring system should not be used as the sole basis for diagnosis or therapy and is intended only as an adjunct in patient assessment. Reliance on the INVOS™ system alone for detecting cerebral desaturation events is not recommended

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6135 Gunbarrel Avenue
Boulder, CO 80301 800.635.5267 [medtronic.com/covidien](https://www.medtronic.com/covidien)

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