

NEONATAL MONITORING IN-SERVICE GUIDE

 $\mathsf{INVOS}^{\scriptscriptstyle{\mathsf{TM}}}$ cerebral/somatic oximetry system



Key terms

- rSO₂: regional oxygen saturation
- INVOS™ system: In vivo optical spectroscopy
- Cerebral application: brain area measurement
- Somatic application: tissue area of measurement

Regional oximetry versus other oximetry

Regional (capillary) oximetry (rSO₂):

- Is noninvasive
- Provides a capillary (venous and arterial) sample
- Measures the balance between O₂ supply and demand beneath the sensor
- Alerts to changes in end-organ oxygenation and perfusion
- Requires neither pulsatility nor blood flow

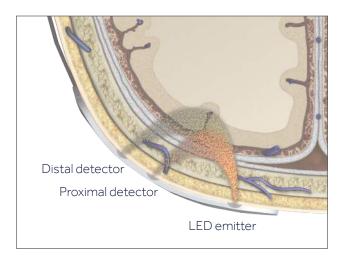


Pulse (arterial) oximetry (SpO₂):

- Is noninvasive
- Uses an arterial sample
- Measures O₂ supply in the periphery
- Measures systemic oxygenation
- Requires pulsatility and blood flow

Central (venous) oximetry (SvO₂):

- Is invasive
- Uses a venous sample
- Measures O₂ surplus in central circulation
- Systemic oxygen reserve
- Requires blood flow



The INVOS™ system uses two depths of light penetration to subtract out surface data, resulting in a regional oxygenation value for deeper tissues.

The cerebral-somatic relationship 1-3

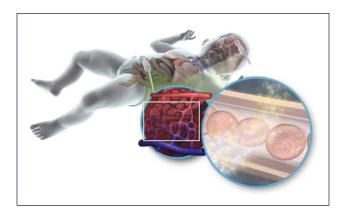
The INVOS™ system provides perfusion data from vascular beds that represent opposite poles of regional circulation and have different extraction ratios.

Cerebral:

- · High-flow, high-extraction organ
- Compensatory mechanisms
 - Autoregulation
 - Flow-metabolism coupling
- Cerebral desaturations are a late indicator of shock if cerebral autoregulation is intact

Somatic:

- Variable flow, lower O₂ extraction
- Flow highly influenced by autonomic (sympathetic) tone
- Somatic desaturations as possible early indicator of shock (i.e., peripheral circulation is shutting down to preserve the brain)



In neonates, infants, and children, cerebral and somatic rSO₂ values provide noninvasive indications of oxygen changes in the cerebral and peripheral circulatory systems. These values may provide an early indication of oxygen deficits associated with impending shock states and anaerobiosis.4

rSO₂ reflects oxygen balance

rSO₂ = regional oxygen saturation:

- Increases with rise in delivery or fall in demand
- Decreases when delivery falls or if there is an uncompensated rise in demand

Oxygen delivery/supply influenced by:

- Oxygen content
 - Hemoglobin concentration
 - Hemoglobin saturation
- Cardiac output
 - Optimize heart rate
 - Idealize preload
 - Improve contractility
 - Manipulate afterload

Oxygen demand/consumption increased by:

- Fever, shivering
- Malignancy, severe infection
- Cold stress
- Seizures, status epilepticus
- Wounds and burns
- Pain

Oxygen demand/consumption decreased by:

- Hypothermia, without shivering
- Sedation and paralysis
- Shunting or decreased extraction

Interpreting the numbers

rSO₂ values reflect a variety of patient-specific comorbidities as well as other variables. These include:

- Circulating blood volume
- Cardiac function
- Peripheral vascular resistance
- Muscular activity
- Circulating hormones
- Venous pressure

The rSO₂ value is expressed both as a real-time numerical value and a percent change from baseline. With the patient serving as his/her own control, you can use either to customize patient assessment, decision making, and interventions.

The most recognized rSO₂ values published on pediatric patients follow below. These patients are most often congenital heart neonates undergoing surgery and recovery in the pediatric ICU. Values for patients with other diagnoses and comorbidities may differ from this.

Cerebral — high blood flow, high O₂ extraction:

- Typical rSO₂ range is 60 to 80, assuming SpO₂ is >90.
- Common intervention trigger is rSO₂ <50 or 20% change from rSO₂ baseline.
- Critical threshold is rSO₂ < 45 or 25% change from rSO₂ baseline.

Somatic — variable blood flow, lower O₂ extraction:

- Variances in the cerebral-somatic relationship may indicate pathology.
- Watch for drops of 20% below patient baseline.

The balance of perfusion distribution in premature neonates depends on gestational age, day of life, and comorbidities. Simultaneous cerebral/somatic rSO, monitoring can help you balance cardiac performance and peripheral perfusion to avoid no- and low-flow states associated with shock and other complications.

Interventions

You have an opportunity to intervene when rSO, rises and falls from the patient's baseline. Follow your hospital's intervention protocols for restoring adequate perfusion. Methods to improve cerebral and somatic perfusion may include:

Improve cerebral perfusion by:

- Increasing cerebral perfusion pressure
- Increasing arterial oxygen content
- Reducing cerebral metabolic rate

Improve somatic perfusion by:

- Increasing total cardiac output
- Reducing sympathetic outflow
- Increasing hematocrit
- Maintaining normal temperature
- Considering regional vasodilation in shock

Setup and baselines

- Plug the sensor cable(s) into the preamplifier(s) connector (Figure 1). When two somatic site sensors are placed, they must be connected into the same preamplifier. Secure the sensor cable to a fixed object to avoid strain on the sensor-to-skin interface using strain-relief clips. Ensure the cable is properly inserted into the preamplifier. Sensor cable can be connected before or after placement. Different INVOS™ system sensors (adult, pediatric, and infant/neonatal) cannot be used on the same monitor (Figure 2).
- Press NEW PATIENT. Monitoring begins displaying the patient's rSO₂ values in white.
- When the patient's rSO₂ values have been displayed for approximately 1 minute, set a baseline. For all channels, press BASELINE MENU, then press SET BASELINE.

Status messages on the INVOS™ system display will appear if monitoring conditions are compromised. Periodically check skin integrity according to your institution's patient care protocol or at least every 24 hours.

For extended monitoring, if adhesive is inadequate to seal the sensor to the skin, apply a new sensor.

When removing sensors, start at the distal tab and slowly and carefully peel back while placing fingers on the exposed skin. Based on your institution's guidelines, warm water, petrolatum, or commercial adhesive removal solutions may be helpful.



For complete instructions, warnings, and precautions, see the operations manual and instructions for use inside the sensor carton.



Figure 1 - INVOS™ 5100C system connections

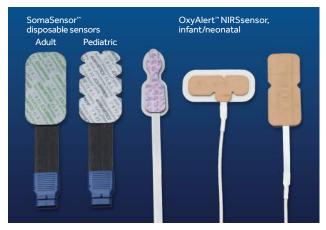


Figure 2 - INVOS™ system sensors

Patient preparation

For optimum adhesion, clean and dry the patient's skin with a gauze pad. Warm the sensor in your hands or an incubator to ease placement.

Sensor placement

With the white liner facing up, gently bend the center of the sensor upward until the ends of the liner lift away from the sensor's surface. Peel off each side, being careful not to touch the adhesive surface. Apply to the skin. Continue applying the sensor by smoothing it to the skin from the center outward. Ensure the edges of the sensor are sealed.

Site selection

To help preserve skin integrity, do not place on undeveloped skin and do not apply pressure (e.g., headbands, wraps, tape) to the sensor.

Cerebral

Select the sensor site on the right or left side of the forehead. Placing the sensor in other cerebral locations, or over hair, may cause inaccurate readings, erratic readings, or no readings at all. Do not place the sensor over nevi, sinus cavities, the superior sagittal sinus, subdural or epidural hematomas or other anomalies such as arteriovenous malformations, as this may cause readings that do not reflect brain tissue or no readings at all.

Somatic

Select the sensor site over the tissue area of interest (site selection will determine which body region is monitored). Avoid placing the sensor over fatty deposits, hair, or bony protuberances. Do not place the sensor over nevi, hematomas, or broken skin, as this may cause readings that do not reflect tissue or no readings at all. Locate the sensor at your discretion, following the criteria in the Instructions for Use. Placements may include but are not limited to:

- Posterior flank (T10-L2, right or left of midline)
- Abdomen
- Forearm

- Calf
- Upper arm
- Chest
- Upper lea

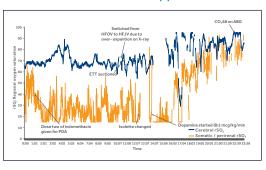
Case graphs

The following case graphs demonstrate the clinical utility of the INVOS™ system. These sample cases reflect use of the device as indicated; other patient populations and applications exist.

Reversal of shock⁵



Alterations in ventilation support in RDS⁶



References

- Clavijo-Alvarez JA, Sims CA, Pinsky MR, Puyana JC. Monitoring skeletal muscle and subcutaneous tissue acid-base status and oxygenation during hemorrhagic shock and resuscitation. Shock. 2005;24(3):270-275.
- Fries M, Weil MH, Sun S, et al. Increases in tissue Pco2 during circulatory shock reflect selective decreases in capillary blood flow. Crit Care Med. 2006;34(2):446-452.
- Hoffman GM, Ghanayem NS, Tweddell JS. Noninvasive assessment of cardiac output. Semin Thorac Cardiovasc Surg Pediatr Card Surg Annu. 2005:12-21.
- 4. FDA 510(k) #K082327
- 5. Underlying data and case notes on file ISC-10001.
- 6. Underlying data and case notes on file ISC-10023.

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