INVOS™
System Inservice Guide for Neonatal Use

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Key Terms

rSO_2: Regional oxygen saturation

INVOS™: In Vivo Optical Spectroscopy

Cerebral Application: Brain area measurement

Somatic Application: Tissue area of measurement

Regional Oximetry vs. Other Oximetry

Regional (Capillary) Oximetry (rSO_2) Clinical Characteristics

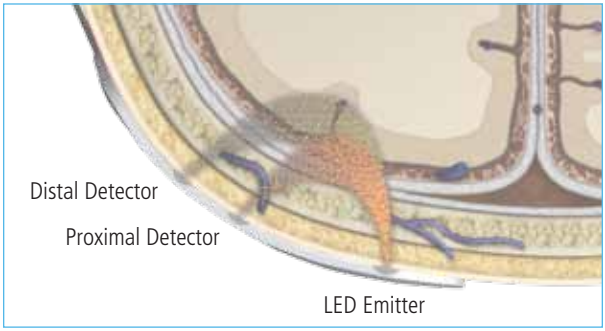
- Noninvasive
- Capillary (venous and arterial) sample
- Measures the balance between O_2 supply and demand beneath the sensor
- End-organ oxygenation and perfusion
- Requires neither pulsatility nor blood flow

Pulse (Arterial) Oximetry (SpO_2) Clinical Characteristics

- Noninvasive
- Arterial sample
- Measures O_2 supply in the periphery
- Systemic oxygenation
- Requires pulsatility and blood flow

Central (Venous) Oximetry (SvO_2) Clinical Characteristics

- Invasive
- Venous sample
- Measures O_2 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]

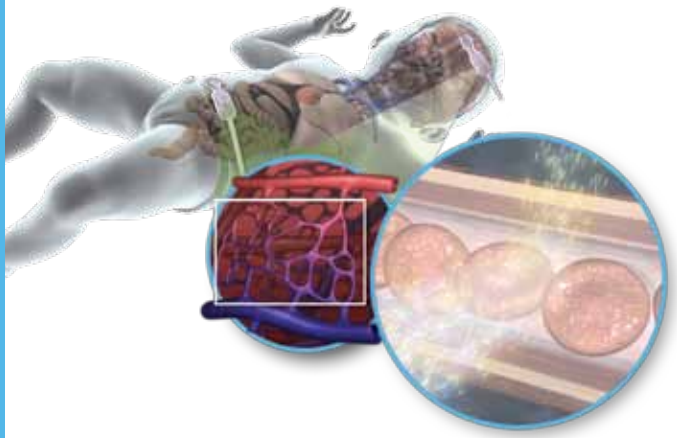
The INVOS™ System provides perfusion data from vascular beds that represent opposite poles of regional circulation and have different extraction ratios.

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 O_2 extraction
- Flow is highly influenced by autonomic (sympathetic) tone
- Somatic desaturations may be an *early* indicator of shock (i.e., peripheral circulation is shutting down to preserve the brain)



In neonates, infants and children, cerebral and somatic rSO_2 provide noninvasive indications of oxygen changes in the cerebral and peripheral circulatory systems and may provide an early indication of oxygen deficits associated with impending shock states and anaerobiosis.[4]

rSO_2 Reflects Oxygen Balance

rSO_2 = 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

Decreased by:

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

Interpreting the Numbers

Premature or medically challenged neonates face a variety of physiologic conditions that can threaten adequate cerebral and tissue perfusion. rSO_2 values reflect these patient-specific comorbidities as well as other variables such as circulating blood volume, cardiac function, peripheral vascular resistance, muscular activity, circulating hormones and venous pressure.

As such, there is no "one number" to act on. Instead each patient serves as his/her own control based upon an rSO_2 baseline set at the outset of monitoring. The monitor displays rSO_2 in two ways: a real-time rSO_2 number and as a percent change from baseline. Clinicians may use either number to enhance their patient assessment, decision making and interventions.

Following are the most recognized rSO_2 values published on pediatric patients – most often congenital heart neonates that have been sent for surgery and then recovery in the pediatric ICU. Patients with other diagnoses and comorbidities may differ from this.

Cerebral — High blood flow, high O_2 extraction

- Typical rSO_2 range: 60-80; assuming SpO_2 is >90
- Common intervention trigger: rSO_2 <50 or 20% change from rSO_2 baseline
- Critical threshold: rSO_2 <45 or 25% change from rSO_2 baseline

Somatic — Variable blood flow, lower O_2 extraction

- Variances in the cerebral-somatic relationship may be indicative of 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_2 monitoring can help guide caregivers in balancing cardiac performance and peripheral perfusion to avoid no- and low-flow states associated with shock and other complications.

Interventions

Rises and falls in rSO_2 from the patient's baseline are an opportunity to intervene. The care team should follow its hospital's intervention protocols for restoring adequate perfusion. These may include efforts to improve cerebral and somatic perfusion through a variety of methods such as:

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*).
- Turn power ON by selecting the green ON/OFF key. The INVOS™ System performs a 10-second self-test, stopping at the Start Screen.
- Press NEW PATIENT. Monitoring begins with display of the patient's rSO_2 values in white.
- When the patient's rSO_2 values have been displayed for approximately 1 minute, set a baseline. For all channels, press the BASELINE MENU button followed by pressing 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 sensor carton.

Figure 1 - INVOS™ 5100C System Connections

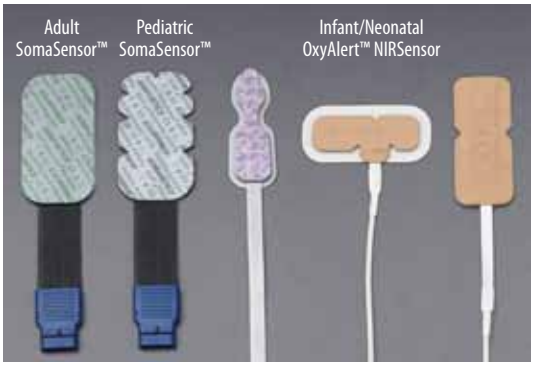


Figure 2 - Sensors

Patient Preparation

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

Sensor Placement

With white liner facing up, gently bend center of sensor upward until ends of 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 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 sensor.

Cerebral

Select sensor site on the right or left side of forehead. Placement of 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 are not reflective of brain tissue or no readings at all.

Somatic

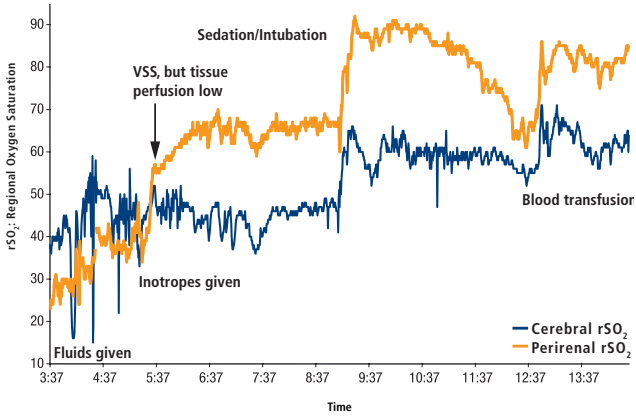
Select sensor site over tissue area of interest (site selection will determine which body region is monitored). Avoid placing the sensor over fatty deposits, hair or bony protuberances. Do not place the sensor over nevi, hematomas or broken skin, as this may cause readings that are not reflective of tissue or no readings at all. Sensor location is at the clinician's discretion, provided it adheres to the criteria noted on this Instruction For Use. Placements may include:

- Posterior flank (T10-L2, right or left of midline)
- Abdomen
- Forearm
- Calf
- Upper arm
- Chest
- Upper leg

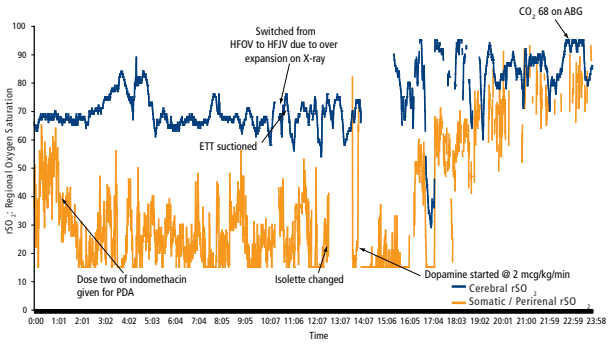
Case Graphs

Following are case graphs to help demonstrate the clinical utility of the INVOS™ System. The sample cases shown here reflect use of the device as indicated; more patient populations and applications exist.

Reversal of Shock[5]



Alterations in Ventilation Support in RDS[6]



References
1. 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.
2. 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.
3. 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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6135 Gunbarrel Avenue
Boulder, CO
80301

800-635-5267

www.covidien.com
www.somanetics.com