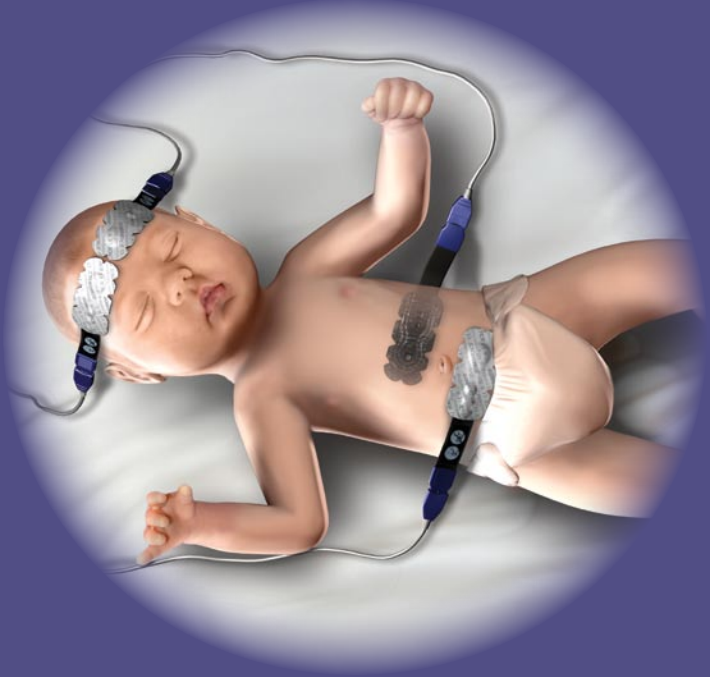
INVOS® Cerebral/Somatic Oximeter Quick Reference Guide for Pediatric Use



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CEREBRAL/SOMATIC

INVOS® OXIMETER

REFLECTING THE COLOR OF LIFE®

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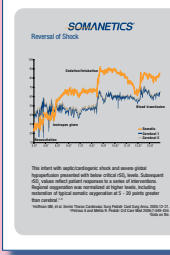
Key Code

Operating Basics

Science and Interventions



Case Examples

These guidelines are not designed to replace clinical judgment or individual patient needs. For complete instructions, indications for use, warnings and precautions, see the Operations Manual.

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Description of Symbols

OXIMETER ENCLOSURE

Blue LED – indicating AC Power Supply and charge ON

Caution; consult accompanying documents

Digital Output

Green LED – indicating power ON

HOME

ON/OFF

USB Port

VGA Port

DISPLAY

Alarm

Baseline

Battery

Signal Strength Indicator

Silence Alarm

OTHER LABELS

Consult operating instructions

Do not reuse

The noninvasive INVOS Cerebral / Somatic Oximeter is intended for use as an adjunct trend monitor of regional hemoglobin oxygen saturation of blood in the brain of an individual. It is also intended for use as an adjunct trend monitor of hemoglobin oxygen saturation of blood in a region of skeletal muscle tissue beneath the sensor in infants, children or adults at risk for reduced-flow or no-flow ischemic states. The prospective clinical value of data from the INVOS System has not been demonstrated in disease states. The INVOS System should not be used as the sole basis for diagnosis or therapy.

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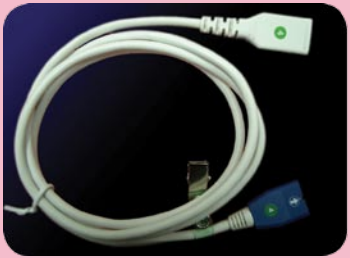
Initial Setup

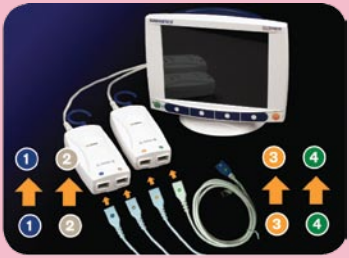
1. Plug in INVOS Monitor to power source.

THE BLUE LED ILLUMINATES TO INDICATE THE POWER IS CONNECTED AND THE BATTERY IS CHARGING. IF BLUE LIGHT IS NOT ON, TURN BACK PANEL MASTER (MAINS) POWER SWITCH ON.

2. Connect Preamplifier(s) to INVOS Monitor. Align red dot on the silver connector with red dot on side panel input connection. Insert cable connector into side panel connection while keeping the dots aligned. Be sure to fully insert the connector until it locks.

3. Connect the Reusable Sensor Cable Connectors to Preamplifier(s). Use color-coding.





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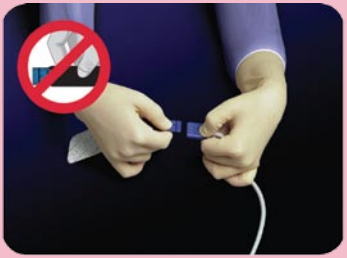
Initial Setup (continued)

4. Attach Sensors to Reusable Sensor Cables. Hold blue connectors. (Sensor cable can be connected to sensors before or after placement). Different INVOS System sensors (adult, pediatric and neonatal) cannot be used on the same monitor.
5. Connect any optional accessories, including the Somanetics USB Flash Drive.



FOR DATA COLLECTION, THE USB FLASH DRIVE MUST BE CONNECTED TO THE INVOS SYSTEM BEFORE TURNING ON THE MONITOR. OR, THE USB FLASH DRIVE CAN BE CONNECTED ANYTIME, PROVIDED THE INVOS MONITOR IS RE-BOOTED TO INITIALIZE THE USB FLASH DRIVE BY PRESSING THE **ON/OFF** KEY. IF REMOVED DURING A CASE, THE ORIGINAL SOMANETICS USB FLASH DRIVE CAN BE RE-INSERTED TO CONTINUE DATA COLLECTION OF THE SAME CASE BY RE-BOOTING THE MONITOR AND PRESSING THE "PREVIOUS PATIENT" MENU OPTION ON THE START SCREEN.

6. Turn power ON by selecting the green ⏻ **ON/OFF** key.
7. After displaying the Welcome Screen, the INVOS System performs a 10-second self-test, stopping at the Start Screen.
8. If necessary, set the **DATE/TIME** by following the options menus. The date and time may only be changed from the Start Screen.
9. Press **NEW PATIENT**. Monitoring begins.
10. If desired, set alarms, scales, data channel labels and other modifiable preferences via the User Configuration Menu Screen.

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Back Panel Connections and Elements

1. Digital Output Port
2. VGA Output Port
3. Potential Equalization (Grounding Post) Connector
4. Alarm Speaker and Cooling Fan
5. Fuse
6. AC Mains (Master) Power Switch
7. AC Input, Power Cord Connector
8. Serial Number

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Side Panel Connections and Elements

1. USB Connector
2. Preamplifier A, Channel 1 2 Connector
3. Preamplifier B, Channel 3 4 Connector

To connect Preamplifier(s) to INVOS Monitor, align red dot on the silver connector with red dot on side panel input connection. Insert cable connector into side panel connection while keeping the dots aligned. Be sure to fully insert the connector until it locks.

To disconnect the Preamplifier, unlock the connection by drawing back on the ridged, silver outer sleeve of the connector. Then pull the cable out of the Preamplifier connection.

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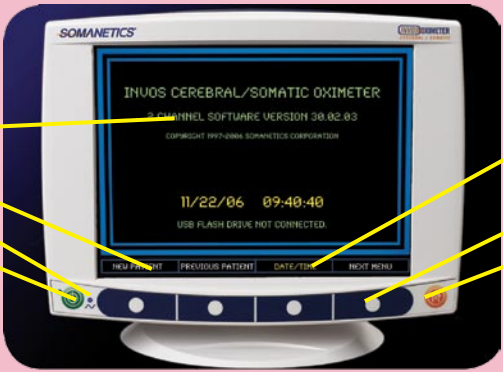
Start Screen: Date and Time Setting



1. Software Version
2. Navigation Bar (menu options)
3. Blue LED charge indicator
4. ON/OFF key
5. Date and Time on Navigation Bar
6. Menu keys
7. Home key

For changing the date or time, after the INVOS System is turned ON, follow these navigation menu options:

NEW PATIENT	PREVIOUS PATIENT	**DATE/TIME**	NEXT MENU
DATE	**TIME**		PREVIOUS MENU
DAY	**MONTH**	**YEAR**	PREVIOUS MENU
DAY = XX	**INCREASE**	**DECREASE**	**PREVIOUS MENU**

Select DAY, MONTH or YEAR followed by the INCREASE or DECREASE options to adjust the date as necessary. Select HOURS, MINUTES or SECONDS followed by the INCREASE or DECREASE options to adjust the time as necessary. Press PREVIOUS MENU again to return to the Start Screen.

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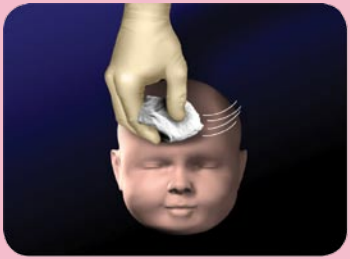
Cerebral Sensor Placement

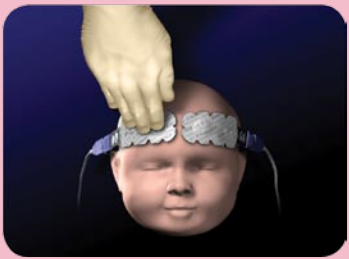
1. To ensure good contact, clean/degrease the skin using mild soap and water. Ensure patient's skin is completely dry with a gauze pad.
2. Select sensor site on right and/or left sides of forehead (site selection will determine which region of the brain is monitored). Placement of the sensor in other locations, or over hair, may cause inaccurate readings, erratic readings, or no readings at all. Do not place the sensor over 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.
3. Peel off backing label from sensor and apply to the forehead as illustrated.
4. Secure the cable to a fixed object to avoid strain on the sensor to skin interface. (Sensor cable can be connected to sensors before or after placement. Hold blue connectors, not the black flex circuit.)
5. Press NEW PATIENT.

FOR EXTENDED MONITORING, SOMANETICS RECOMMENDS USING A NEW SOMASENSOR EVERY 24 HOURS AND FOLLOWING YOUR INSTITUTION'S GUIDELINES FOR SKIN INTEGRITY.

CAUTION: TO AVOID PRESSURE SORES, DO NOT APPLY EXTERNAL PRESSURE (E.G. HEADBANDS, WRAPS, TAPE) TO SENSOR.

SENSORS MAY OVERLAP, PROVIDED THE THREE OPTICAL WINDOWS ON EACH PAD REMAIN UNOBSTRUCTED.





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Somatic Sensor Placement

Select sensor site over skeletal muscle tissue (site selection will determine which body region is monitored). Avoid placing the sensor over thick 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.

Typical monitoring locations include:

- Renal area: over the latissimus dorsi muscle, T10-L2, posterior flank, right or left of midline
- Abdomen/gut: over the external abdominal oblique muscle
- Chest: over the pectoralis major muscle
- Forearm: over the brachioradialis muscle
- Upper arm: over the biceps muscle
- Calf: over the gastrocnemius muscle
- Upper leg: over the quadriceps muscle

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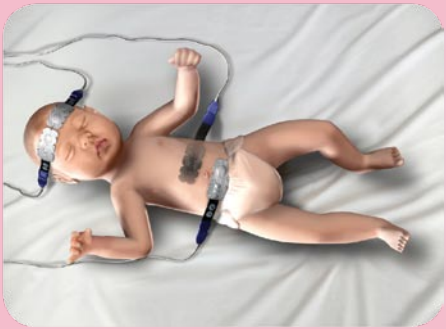
Somatic Sensor Placement (continued)

FOR EXTENDED MONITORING, SOMANETICS RECOMMENDS USING A NEW SOMASENSOR EVERY 24 HOURS AND FOLLOWING YOUR INSTITUTION'S GUIDELINES FOR SKIN INTEGRITY.

CAUTION: TO AVOID PRESSURE SORES, DO NOT APPLY EXTERNAL PRESSURE (E.G. WRAPS, TAPE) TO SOMASENSOR.

SENSORS MAY OVERLAP, PROVIDED THE THREE OPTICAL WINDOWS ON EACH PAD REMAIN UNOBSTRUCTED.

1. To ensure good contact, wash area with mild soap and water and dry thoroughly.
2. Peel off backing and place SomaSensors. (Sensor cable can be connected to sensors before or after placement. Hold blue connectors, not the black flex circuit.)
3. Press NEW PATIENT.



User Configuration Menu Settings

The User Configuration Menu can be used to adjust a variety of settings including 2 or 4 channel monitoring, Alarms, rSO_2 Scale, Time Scale, USB Storage Rate, Event Mark Lists, color coding and naming of Channel Labels.

Assuming you have connected INVOS System components, the Monitor is ON and in Run Mode, press the HOME ⌂ key to display the Main Screen and follow these navigation bar options:

BASELINE MENU	EVENT MARK	ALARM AUDIO ON/OFF	**NEXT MENU**
OUTPUT SELECT	**USER CONFIGURATION**	TIME SCALE	PREVIOUS MENU
NEXT	**PREVIOUS**	INCREASE	DECREASE

In the User Configuration Menu, select NEXT and PREVIOUS to scroll to the setting you wish to change. Adjust the setting.

When finished, press the HOME ⌂ key to return to the Main Screen. On the Main Screen, adjustments will appear.

User Configuration Menu Settings (continued)

Page Two

The User Configuration Menu default settings are:

	DEFAULT	RANGE
Upper Alarm Limit	OFF	20-95
Lower Alarm Limit	40	15-90
Alarm Volume	Medium	Low, Medium, High
Upper rSO_2 Scale Limit	100	60-100 in increments of 10; 5 above High Alarm Limit
Lower rSO_2 Scale Limit	30	0-30 in increments of 10; 5 below Low Alarm Limit
Trend (Time) Scale	1 hour	1, 2, 4, 8, 12, 24 hours
USB Storage Rate	5 seconds	5, 30, and 60 seconds
Event Mark List	OR	OR, ICU, VASCULAR, NICU
Channel Labels	L, R, S_1, S_2	A-Z, S_1-S_4
Color Coded Labels	NO	YES, NO

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User Configuration Menu (2- or 4-Channel Monitoring)

THE INVOS SYSTEM MUST BE RESTARTED FOR THIS CHANGE TO TAKE EFFECT.

To change the software version from two to four channel monitoring (assuming you have connected INVOS System components, the Monitor is ON and in Run Mode), press the HOME key to display the Main Screen and follow these navigation bar options:

BASELINE MENU	EVENT MARK	ALARM AUDIO ON/OFF	**NEXT MENU**
OUTPUT SELECT	**USER CONFIGURATION**	TIME SCALE	PREVIOUS MENU
NEXT	**PREVIOUS**	INCREASE	DECREASE
NEXT	PREVIOUS	INCREASE	DECREASE
NEXT	PREVIOUS	YES	NO
NEXT	PREVIOUS	**INCREASE**	**DECREASE**

In the User Configuration Menu, select NEXT to scroll to the 2 OR 4 CHANNELS setting. Select INCREASE and DECREASE to choose the number of channels monitored and displayed.

When finished, press the HOME key to return to the Main Screen. **Press the ON/OFF key twice to restart the system.** When the Monitor has returned to Run Mode, the number of channels selected should be displayed.

SEPARATE SETS OF USER CONFIGURATION PARAMETERS ARE STORED FOR 2- AND 4-CHANNEL MONITORING. PREVIOUS SETTINGS FOR 2-CHANNEL MONITORING WILL RESUME WHEN THIS CONFIGURATION IS SELECTED, AND VICE VERSA.

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Main Screen (Two-Channel Monitoring)

1. Date and Time
2. Adult, Pediatric or Neonatal Indication
3. Upper and Lower Alarm Limits
4. Trend Data Graph (Channel 1)
5. Trend Data Graph (Channel 2)
6. rSO_2 Trend Scale (High & Low)
7. Time Scale; in hours
8. Menu Options (Navigation Bar)
9. Alarm Status Message
10. Alarm Symbol
11. Signal Strength Indicator
12. rSO_2 Baseline and Symbol
13. rSO_2 Relative (%) change from Baseline
14. Real-Time rSO_2 (index) Values
15. Data Channel Label (e.g. L; left cerebral, R; right cerebral, S; somatic)
16. Event Mark line and numerical code
17. Battery Power Status

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Main Screen (Four-Channel Monitoring)

1. Date and Time
2. Adult, Pediatric or Neonatal Indication
3. Upper and Lower Alarm Limits
4. Trend Data Graph (for Channels 1 & 2)
5. Trend Data Graph (for Channels 3 & 4)
6. rSO_2 Trend Scale (High & Low)
7. Time Scale; in hours
8. Menu Options (Navigation Bar)
9. Alarm Status Message
10. Alarm Symbol
11. Signal Strength Indicator
12. rSO_2 Baseline and Symbol
13. rSO_2 Relative (%) change from Baseline
14. Real-Time rSO_2 (index) Values
15. Data Channel Label (e.g. L; left cerebral, R; right cerebral, S; somatic)
16. Event Mark line and numerical code
17. Battery Power Status

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Setting rSO_2 Baselines

An rSO_2 Baseline should be set so subsequent rSO_2 changes from baseline can be measured. rSO_2 numbers will turn red if rSO_2 is above or below set alarm thresholds. Baseline status will turn red if rSO_2 is $\leq$ 20% below set baseline.

In the Baseline Menu, baseline(s) may be set for all channels in use at once, individually for selected channel(s) or manually to a previous rSO_2 value.

IF A BASELINE CANNOT BE SET PRE-INDUCTION FOR PEDIATRIC PATIENTS, IT IS RECOMMENDED THAT A VALUE OF 50 IS USED FOR THE DESATURATION THRESHOLD.

Setting an Awake rSO_2 Baseline for All Channels: Recommend Prior To Pre-op or O_2 Mask

As soon as rSO_2 trend data begins to be gathered and patient condition is stable, an awake baseline reading should be obtained (e.g. for surgical patients, prior to induction).

To set a baseline for all channels, press the HOME ⌂ key to display the Main Screen, then follow these navigation menu options:

BASELINE MENU	EVENT MARK	ALARM AUDIO ON/OFF	NEXT MENU
SET BASELINES	RESTORE BASELINES	SET CHANNEL	MANUAL SET

Set Individual Channels to Current rSO_2 Baseline

To set an individual channel baseline, press the HOME ⌂ key to display the Main Screen, then follow these navigation menu options:

BASELINE MENU	EVENT MARK	ALARM AUDIO ON/OFF	NEXT MENU
SET BASELINES	RESTORE BASELINES	**SET CHANNEL**	MANUAL SET
CHANNEL 1 SET	**CHANNEL 2 SET**	**CHANNEL 3 SET**	**CHANNEL 4 SET**

Select the channel(s) to set the baseline at the current rSO_2 value. This will display an event mark line and code on the display screen. When finished, press the HOME ⌂ key to exit the Baseline Menu and return to Main Screen.

Setting rSO_2 Baselines (continued)

WHEN USING THE MANUAL SET BASELINE FEATURE, THE NEW BASELINE VALUES WILL NOT BE REFLECTED IN ANY REAL-TIME DATA OUTPUT, INCLUDING TO THE USB FLASH DRIVE, OR WHEN REVIEWING CASES IN CASE ARCHIVE MODE. FOR ARCHIVING PURPOSES, THE CASE SHOULD BE DOWNLOADED IN CASE HISTORY, BEFORE TURNING OFF THE MONITOR, IMMEDIATELY AT THE COMPLETION OF THE CASE.

Manually Set Baselines to Previous rSO_2 Value

The manually set baseline feature is used when previous rSO_2 values are to be set as baselines (e.g., an awake baseline was forgotten to be set prior to induction). To select and manually set previous rSO_2 values, press the HOME ⌂ key to display the Main Screen, then follow these navigation menu options:

BASELINE MENU	EVENT MARK	ALARM AUDIO ON/OFF	NEXT MENU
SET BASELINES	RESTORE BASELINES	SET CHANNEL	**MANUAL SET**
NEXT PAGE	**PREVIOUS PAGE**	**LAST PAGE**	SCROLL MENU

Select NEXT PAGE, PREVIOUS PAGE or LAST PAGE to review pages of rSO_2 data and locate the desired time and value to set baselines to.

Once the time and data on the page being displayed has been located, follow these navigation bar menu options:

NEXT PAGE	PREVIOUS PAGE	LAST PAGE	**SCROLL MENU**
NEXT	**PREVIOUS**	**SELECT BASSELINES**	PREVIOUS MENU

Select NEXT or PREVIOUS to scroll to the desired line of rSO_2 data, then SELECT BASELINES to manually set the baseline.

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Setting rSO_2 Baselines (continued)

Restoring a Baseline/Replacing a Sensor

To restore a baseline or replace a sensor, press the HOME key to display the Main Screen. If necessary, select the ALARM AUDIO ON/OFF option to deactivate audible alarms.

CAUTION: SELECTING THE ALARM AUDIO ON/OFF OPTION WILL SILENCE THE AUDIBLE ALARMS PERMANENTLY UNTIL RE-ACTIVATED OR THE INVOS SYSTEM IS REBOOTED.

FOR CONTINUOUS MONITORING WHILE CHANGING MULTIPLE SENSORS, REMOVE ONE SENSOR FOLLOWED BY SENSOR PREP AND PLACEMENT INSTRUCTIONS BEFORE REPLACING OTHER SENSORS.

Prep the patient, apply sensors, then follow these navigation menu options:

BASELINE MENU	EVENT MARK	ALARM AUDIO ON/OFF	NEXT MENU
SET BASELINES	**RESTORE BASELINES**	SET CHANNEL	MANUAL SET

Select ALARM AUDIO ON/OFF to re-activate audible alarms, if necessary.

Event Marking

An Event Mark may be used to mark significant occurrences. It is displayed on the screen or stored in memory for later review. A vertical dashed line and event code will appear on the trend graph at the marked time. An event code will also appear at that time in the line of tabular trends screen or stored and outputted data.

To mark an event, press the HOME key to display the Main Screen, then follow these navigation menu options:

BASELINE MENU	**EVENT MARK**	ALARM AUDIO ON/OFF	NEXT MENU
NEXT EVENT	**PREVIOUS EVENT**	**SELECT EVENT**	PREVIOUS MENU

From the Event Mark List, select NEXT EVENT and PREVIOUS EVENT to highlight the desired event code or description. SELECT EVENT to choose the highlighted event code and return to the trend data graph. Press the HOME key to return to the trend data graph without storing an event code.

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OR EVENT MARK LIST

1 Miscellaneous
2 Set baseline
3 Intubated
4 Sternotomy
5 Cannulate
6 On CPB
7 Cross Clamp On
8 Cooling
9 Cardioplegia
10 Warming
11 Cross Clamp Off
12 Off CPB
13 Closing Sternum
14 Arrhythmia
15 Circulatory Arrest
16 Hypocapnia
17 Hypotension
18 One Lung Ventilation
19 Pump Flow Down
20 Reduced Venous Return
21 Afterload Reduction
22 Blood Transfusion
23 Cardioversion
24 Cell saver blood
25 Cerebral Perfusion On
26 ECLS On
27 FFP / Platelets
28 Fluid/Volume Expander
29 Hemoconcentrate / MUF
30 Inotrope
31 Increase Anesthetic
32 Increase CO2
33 Increase FiO2
34 Increase Pump Flow
35 Paced
36 Reposition Cannula
37 Reposition Clamp
38 Reposition Head
39 Reposition Heart
40 Vasopressor

Event List Key Code:

White events - reflect relatively routine occurrences during surgery. These are listed in the order they typically occur during a case.

Yellow events - mark events clinicians may consider “cautionary” because they could cause ischemia. These are listed alphabetically.

Green events - mark interventions taken and are listed alphabetically.

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PEDIATRIC/ADULT ICU EVENT MARK LIST

41 Miscellaneous
42 Set Baseline
43 Enteral feeding
44 Extubated
45 Intubated
46 Reposition Patient
47 Sensor Change
48 Apnea
49 Arrhythmia
50 Bradycardia
51 Cardiac Arrest
52 ICP Changes
53 LOC Changes
54 Painful Procedure
55 Seizure Activity
56 Tamponade
57 Afterload Reduction
58 Anti-Arrhythmic
59 Anti-Epileptic
60 Anti-Pyretic
61 Blood Transfusion
62 Chest Closed
63 Dialysis / CRRT
64 Diuretic
65 ECLS On
66 ECLS Circuit Change
67 ECLS Off
68 ET Tube Suctioned
69 Fluid Bolus
70 FFP/Platelets
71 Hi Frequency Vent
72 Hypothermia
73 Inotrope
74 Nitric Oxide
75 Paralytic
76 PDA Ligated
77 Prostaglandin
78 Sedation
79 Vasopressor
80 Ventilator Change

Event List Key Code:

White events - reflect relatively routine occurrences. These are listed in the order they typically occur.

Yellow events - mark events clinicians may consider “cautionary” because they could cause ischemia. These are listed alphabetically.

Green events - mark interventions taken and are listed alphabetically.

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NICU EVENT MARK LIST

121 Miscellaneous
122 Set Baseline
123 Enteral Feeding
124 Extubated-Intubated
125 Bag Mask Ventilation
126 Conventional Vent
127 Hi Frequency Vent
128 Position Change
129 Sensor Change
130 Weigh Patient
131 Apnea
132 Arrhythmia
133 Cardiac Arrest/CPR
134 ICP Changes
135 LOC Changes
136 Seizure
137 Tamponade
138 Anti-Arrhythmic
139 Anti-Epileptic
140 Blood Trans/Platelets
141 Cooling Cap On-Off
142 Dialysis/CRRT
143 ECLS On
144 ECLS Circuit Change
145 ECLS Off
146 Fluid Bolus
147 Fem Art CutDwn Start
148 Fem Art CutDwn Stop
149 Hypothermia
150 Nitric Oxide On – Off
151 NG Tube In – Out
152 Paralytic
153 PDA Ligated
154 Prostaglandin
155 OR Procedure Bedside
156 Sedation
157 Suction ET Tube
158 Vasopressor
159 Ventilator Change/BMV
160 Whole Body Cooling

Event List Key Code:

White events - reflect relatively routine occurrences. These are listed in the order they typically occur.

Yellow events - mark events clinicians may consider “cautionary” because they could cause ischemia. These are listed alphabetically.

Green events - mark interventions taken and are listed alphabetically.

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Alarms and Status Messages with rSO_2 Values Displayed

During normal monitoring situations when rSO_2 values are being displayed, alarm and status messages may appear at the top of the Main Screen. Additional operating indications to assist the user will appear on the display screen at the right of the affected channel label (e.g. 2-digit rSO_2 values turn red when value is below baseline desaturation threshold.)

STATUS MESSAGE	COLOR, LOCATION	CAUSE	ACTION
ALARM HIGH *accompanied by alarm tone* *STATUS CODE: 5*	Red, top right	Upper Alarm Limit is exceeded.	Profile Patient
ALARM LOW *accompanied by alarm tone* *STATUS CODE: 6*	Red, top right	Lower Alarm Limit is exceeded.	Profile Patient
BATTERY LOW *accompanied by alarm tone* *STATUS CODE: 9*	Red, bottom right above navigation bar	Battery power is critical.	Plug in A/C Power and turn master (mains) switch on.
COM PORT UNAVAILABLE *STATUS CODE: 12*	Yellow, top right	Output device not connected.	Check connections with Com Port device (PC).
USB FULL *STATUS CODE: 20*	Yellow, top right	USB Flash Drive memory is full.	Insert a blank Flash Drive.
USB STORAGE ERROR *STATUS CODE: 14*	Yellow, top right	USB Flash Drive error.	Check USB Flash Drive connection. Insert a Flash Drive.
DATE AND TIME	Green, top left		
ADULT, PEDIATRIC or NEONATAL	Green, top left	Adult, Pediatric or Neonatal application dependent on sensor model used.	
SYSTEM SIGNAL OK *STATUS CODE: 4*	No text message displayed on screen	SSI at full strength	

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Alarms and Status Messages without rSO_2 Values Displayed

During situations when rSO_2 values cannot be calculated, status messages may appear in place of the rSO_2 values at the right of the corresponding affected channel label indicator.

STATUS MESSAGE	CAUSE	ACTION
SENSOR NOT CONNECTED *accompanied by alarm tone* *STATUS CODE: 1*	Disconnect at sensor (patient) or cable. No rSO_2 value will appear.	Check Sensor to Reusable Sensor Cable connection. Check Sensor Cable connection to the Preamplifier. Restore baseline values.
EXCESSIVE LIGHT *accompanied by alarm tone* *STATUS CODE: 2*	Sensor has lifted off the patient, or there is too much outside light. No rSO_2 will appear.	Check the connection to patient and replace sensor, if necessary. If the sensor is properly adhered to the patient, try loosely draping the sensor.
POOR SIGNAL QUALITY *accompanied by alarm tone* *STATUS CODE: 3*	INVOS System is operating, but rSO_2 values will not appear because they are unstable or may be corrupted by a noisy power source or a very weak signal.	Try another hospital grade electrical outlet. Relocate sensor, if possible.
PREAMP NOT CONNECTED *STATUS CODE: 11*	Preamplifier is not connected to the INVOS Monitor.	Make sure the Preamplifier connector is locked into the side of the monitor. Normal operation of the INVOS System will resume when the Preamplifier is reconnected.
REPLACE SENSOR *accompanied by alarm tone* *STATUS CODE: 17*	INVOS System cannot read calibration data from the sensor. Mixed adult, pediatric and neonatal sensor models, moisture intrusion, a defective sensor, or a defective Reusable Sensor Cable could cause this.	Check for correct sensor model type. Connect new SomaSensor. Replace Reusable Sensor Cable.
INTERFERENCE DETECTED *accompanied by alarm tone* *STATUS CODE: 19*	Noise corrupting rSO_2 data (e.g. electrocautery).	Move or turn off source of interference. Normal operation of the INVOS System will resume when the excessive noise stops.

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CEREBRAL / SOMATIC

Troubleshooting Signal Strength Indicator (SSI)

The Signal Strength Indicator (SSI) reflects the strength and stability of the signal that is used to make an rSO_2 measurement. The SSI depends on physiological factors (different from individual to individual) and possible disturbances from secondary sources/influences in the monitor's environment. An inherent benefit of the technology is the ability of the device to determine rSO_2 values from very small signals.

The chart below provides SSI ranges and a list of the possible causes and action to correct for each.

SSI INDICATION	DESCRIPTION/CAUSE	ACTION
5 bars *STATUS CODE: 4*	Full strength signal.	No action required.
1 through 4 bars - stable	Signal is weaker, but is strong and stable enough to generate an accurate rSO_2 value.	No action required.
1through 4 bars - fluctuating and unstable	Signal is weak and unstable.	
	Signal Interference.	Identify any possible sources of interference, such as electro-cautery or similar electrical equipment interferences, intense light or radiation sources, moving artifacts or perturbations on the mains.
	Sensor application over nevi, sinus cavities, the superior sagittal sinus, subdural or epidural hematomas or other anomalies such as arteriovenous malformations, broken skin, thick fatty deposits, hair or bony protuberances, or area contaminated with residue.	Clean the area, re-apply SomaSensor to patient in an adjacent area; follow the sensor application instructions and make sure no hair, anomalies or residues are under the sensor.
	Defective Sensor.	Apply new Sensor to patient.
	Moisture in sensor connection.	Dry the cable and sensor connectors. Make sure the connection is not exposed to moisture.
0 bar	See Error Messages in data channel area on display screen (See Status Messages – without rSO_2 Values Displayed)	Follow on screen instructions.

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Reviewing Previous Cases on the Monitor

The INVOS System offers several different options to store, output and review data collected. One option is Case Archive Mode, allowing review of up to 28 cases of 24-hour duration. When data storage exceeds 24-hours or midnight is reached, a new case will be started. Case History data files are selected for review in the Case Archive File List.

Data files created by the INVOS System are automatically named by the software using the date (YYMMDD) followed by a letter indicating the type of recording (N = Normal Run Mode, C = Control, I = Intervention) and a file extension consisting of a letter (H = History, or R = Real-time) and a sequence number. For example, a CASE HISTORY file recorded on November 13, 2007 in Normal Run Mode would have a filename of 071113N.H1. An asterisk (*) indicates a desaturation of 20% or more from baseline or $\leq$ 40 rSO_2 values occurred during the case.

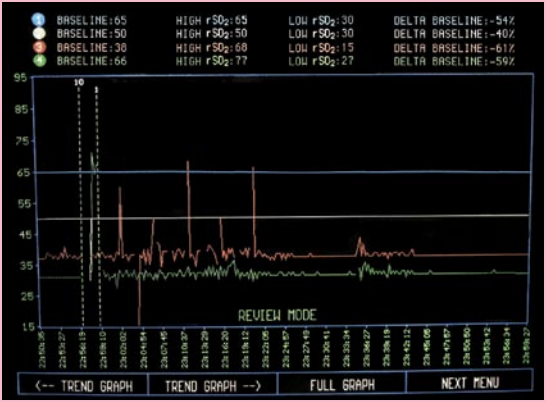
Reviewing Previous Cases on the Monitor (continued)

MORE THAN ONE (1) HOUR OF DATA MUST BE STORED TO SCROLL IN CASE ARCHIVE MODE.

To access Case Archive Mode in graphical format, press the ON/OFF ⏻ key to display the Start Screen and follow these navigation menu options:

NEW PATIENT	PREVIOUS PATIENT	DATE/TIME	**NEXT MENU**
CASE ARCHIVE	PREVIOUS MENU		
NEXT FILE	**PREVIOUS FILE**	**SELECT FILE**	START SCREEN
←TREND GRAPH	**TREND GRAPH→**	**FULL GRAPH**	NEXT MENU

Select NEXT FILE or PREVIOUS FILE to scroll through the Case Archive File List. SELECT FILE will load and display the entire patient file graphically. Select ← TREND GRAPH and TREND GRAPH → to scroll in one-hour increments. Select FULL GRAPH to display the entire case.



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Downloading Cases Via USB Flash Drive

The USB Flash Drive allows data from the INVOS System to be collected and transfered to other devices such as a PC. Data may be collected in REAL-TIME or CASE HISTORY formats.

Once the INVOS System and USB Flash Drive are connected and in Run Mode, the Monitor will begin data outputting to the USB Flash Drive automatically.

Up to 24 hours of data may be stored per case file. When data storage exceeds 24 hours or midnight is reached, a new case file will be started.

FOR DATA COLLECTION, THE USB FLASH DRIVE MUST BE CONNECTED TO THE INVOS SYSTEM BEFORE TURNING ON THE MONITOR. OR, THE USB FLASH DRIVE CAN BE CONNECTED ANYTIME, PROVIDED THE INVOS MONITOR IS RE-BOOTED TO INITIALIZE THE USB FLASH DRIVE BY PRESSING THE ON/OFF ⏻ KEY.

The stored data can be accessed and graphed on a personal computer using a common spreadsheet program like Microsoft Excel. The file will be stored as an ASCII text file. See the Operations Manual for the data format.

Downloading an Individual Case from Archive List

Access Case Archive Mode to download a desired file in the Case Archive File list. Assuming you have connected INVOS System components and connected the USB Flash Drive, press the ON/OFF ⏻ key to display the Start Screen and follow these navigation menu options:

NEW PATIENT	PREVIOUS PATIENT	DATE/TIME	**NEXT MENU**
CASE ARCHIVE	START SCREEN		PREVIOUS MENU
NEXT FILE	**PREVIOUS FILE**	**SELECT FILE**	NEXT MENU
← TREND GRAPH	TREND GRAPH →	FULL GRAPH	**NEXT MENU**
TABULAR TRENDS	**DOWNLOAD**	PREVIOUS MENU	NEXT MENU
USB STORAGE	DIGITAL OUTPUT		PREVIOUS MENU

Downloading Cases Via USB Flash Drive (continued)

Downloading All Stored Cases from Archive List

Access Case Archive Mode to download all files in the Case Archive File list. Assuming you have connected INVOS System components and connected the USB Flash Drive, press the ON/OFF ⏻ key to display the Start Screen and follow these navigation menu options:

NEW PATIENT	PREVIOUS PATIENT	DATE/TIME	**NEXT MENU**
CASE ARCHIVE	START SCREEN		PREVIOUS MENU
NEXT FILE	PREVIOUS FILE	SELECT FILE	**NEXT MENU**
DOWNLOAD FILES	DELETE FILES	START SCREEN	PREVIOUS MENU
DOWNLOAD ALL FILES	CASE ARCHIVE MENU	PREVIOUS MENU	

All files except EXAMPLE.1 and EXAMPLE.2 will be transferred to the USB Flash Drive in a maximum of four minutes (28 cases of 24-hour duration). As the files are downloading, the file currently being transferred appears above the Case Archive File List.

Downloading Case Data at the End of a Case

Assuming you have connected INVOS System components and connected the USB Flash Drive, press the HOME ⌂ key to display the Start Screen and follow these navigation menu options:

BASELINE MENU	EVENT MARK	ALARM AUDIO ON/OFF	**NEXT MENU**
OUTPUT SELECT	USER CONFIGURATION		PREVIOUS MENU
USB	DIGITAL OUTPUT	REVIEW	PREVIOUS MENU
CASE HISTORY		PREVIOUS MENU	MAIN MENU

The Case History data will output until complete.

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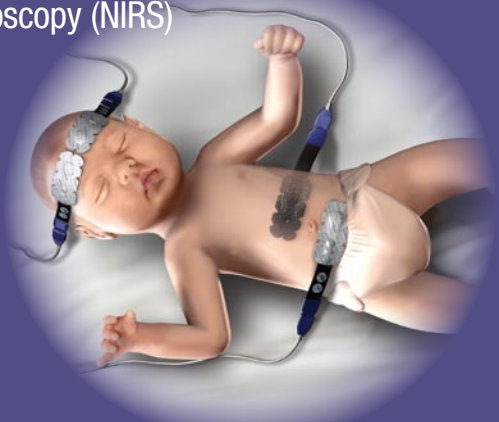
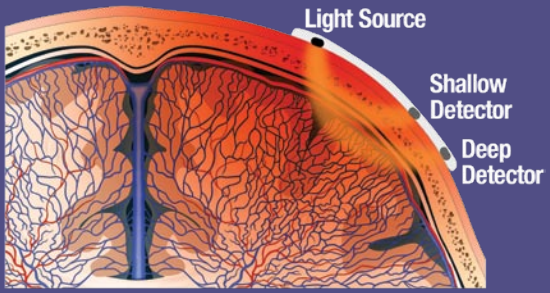
Site-Specific Saturation Data With Near-infrared Spectroscopy (NIRS)



Four data channels enable simultaneous monitoring of cerebral and somatic regional oxygen saturation (rSO_2)



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

INVOS OXIMETER
CEREBRAL / SOMATIC

Regional Oximetry Vs. Other Oximetry

Regional (Capillary) Oximetry (rSO_2) Clinical Characteristics

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

Pulse (Arterial) Oximetry (SpO_2) Clinical Characteristics

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

Central (Venous) Oximetry (SvO_2) Clinical Characteristics

- Invasive
- Venous sample
- Measures O_2 surplus in central circulation
- Systemic oxygen reserve
- Requires flow

Kim MB, et al. J Clin Monitor 2000;16:191-199.
Hoffman GM, et al. Semin Thorac Cardiovasc Surg Pediatr Card Surg Annu. 2005:12-21.

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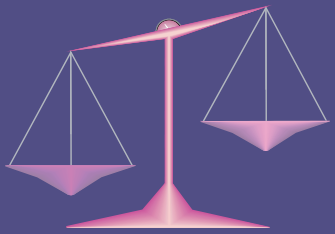
Factors That Can Affect Cerebral Oxygenation

Tailoring Oxygen Delivery

- Mean Arterial Pressure - rSO_2 values help to tailor individual treatment.
- CO_2 - Higher CO_2 causes cerebral vasodilation to allow greater blood flow to the brain.
- Cardiac Index and Pump Flow - Insufficient CI and pump flow cause rSO_2 declines.
- Blood Products - Hemodilution has a negative effect on oxygen carrying capacity; the addition of red blood cells increases rSO_2.
- Mechanical Issues - Cannula misplacement, neck position and other issues can cause rapid and dramatic rSO_2 changes.

Tailoring Oxygen Consumption

- Anesthetic Agent and Depth - Anesthesia decreases O_2 consumption by the brain; light anesthesia may require more O_2 delivery.
- Temperature - Temperature changes can cause rapid rSO_2 changes. Cooling usually increases rSO_2, while warming usually lowers it.



INVOS OXIMETER
CEREBRAL / SOMATIC

rSO_2 Reflects Oxygen Balance

rSO_2

- 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 (neonates)
- Seizures, status epilepticus
- Wounds and burns
- Pain

Decreased by:

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

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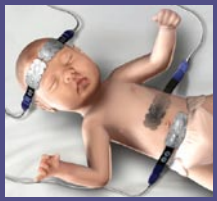
The Cerebral - Somatic Relationship

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)

Clavijo-Alvarez JA, et al. Shock. 2005 Sep;24(3):270-5.
Fries M, et al. Crit Care Med. 2006 Feb;34(2):446-52.
Hoffman GM, et al. Semin Thorac Cardiovasc Surg Pediatr Card Surg Annu. 2005:12-21.

INVOS OXIMETER
CEREBRAL / SOMATIC

rSO_2 Targets and Thresholds

Targets and thresholds are expressed in rSO_2 numerical values and % changes from baseline. This enables customized management based on each patient's unique physiology and clinical anomalies. As such, each patient serves as his/her own control rather than being relegated to a fixed protocol.

Cerebral

- High flow, high extraction organ
- Typical range: 60-80
- $\leq$ 50 rSO_2 or 20% Δ from rSO_2 baseline is common intervention trigger
- $\leq$ 45 rSO_2 or 25% Δ from rSO_2 baseline is critical threshold

Somatic

- Variable flow, lower O_2 extraction
- 5-20 points higher than cerebral rSO_2; changes in this cerebral - somatic variance may be indicative of pathology.

Hoffman GM, et al. Semin Thorac Cardiovasc Surg Pediatr Card Surg Annu. 2005:12-21.
Petrova A and Mehta R. Pediatr Crit Care Med 2006;7:449-454.
Dent CL, et al. J Thorac Cardiovasc Surg. 2006 Jan;131(1):190-7.
Data on file.

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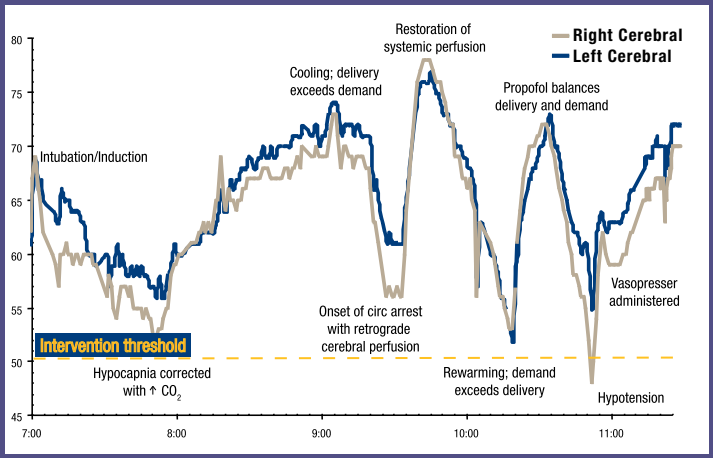
rSO_2 Reactions to Common Intra-Op Events



This aortic arch reconstruction with deep hypothermic circulatory arrest demonstrates common times when cerebral perfusion can be impacted both positively and negatively. Adequate rSO_2 levels can provide confidence that the brain is well perfused, while dips in rSO_2 near or past the patient's desaturation threshold indicate opportunities for therapeutic interventions.

Edmonds HL Jr, et al. Semin Cardiothorac Vasc Anesth 2004;8:147-66.

INVOS OXIMETER
CEREBRAL / SOMATIC

Operating Room Interventions to Improve rSO_2

While each hospital will have its own care protocols, the following interventions have been shown to improve rSO_2.

Perfusion imbalance

- Blood pressure
- Mechanical obstruction (cannula position)
- Increase cardiac output (pump flow)
- Plasma volume expansion
- CO_2 to physiologic level

Limited ischemia tolerance

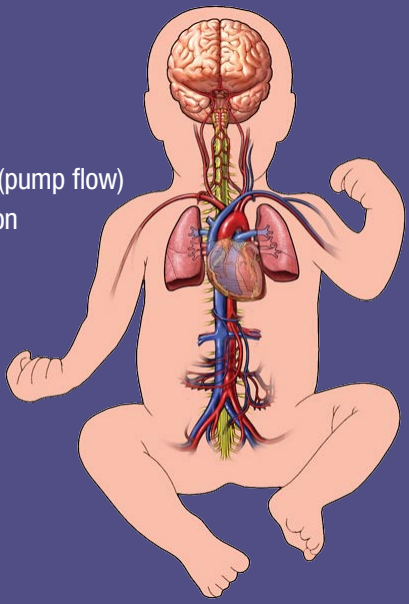
- Neuroprotective Agent
- Additional cooling

Dysoxygenation

- Increase FiO_2
- Whole blood
- Reintubate

Insufficient Anesthetic Depth

- Increase anesthetic delivery



Austin EH, et al. J Thorac Cardiovasc Surg 1997;114:707-17.

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PICU Interventions to Improve rSO_2 - Cerebral

While each hospital will have its own care protocols, the following interventions have been shown to improve rSO_2.

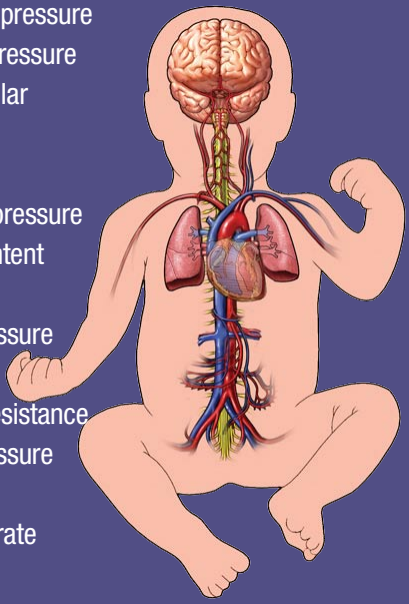
Cerebral

Increase cerebral perfusion pressure
- Increase arterial blood pressure
- Increase systemic vascular resistance
- Increase cardiac output
- Reduce central venous pressure

Increase arterial oxygen content
- Transfuse red cells
- Raise arterial partial pressure of oxygen

Reduce cerebral vascular resistance
- Raise arterial partial pressure of carbon dioxide

Reduce cerebral metabolic rate
- Control hyperthermia
- Sedation



Hoffman GM, Cardiol Young 2005;15(Suppl. 1):149-153.
Mott AR, et al. Pediatr Crit Care Med 2006;7:346-350.

INVOS OXIMETER
CEREBRAL / SOMATIC

PICU Interventions to Improve rSO_2 - Somatic

While each hospital will have its own care protocols, the following interventions have been shown to improve rSO_2.

Somatic

Increase total cardiac output

- optimize: preload, afterload, rate, rhythm and contractility

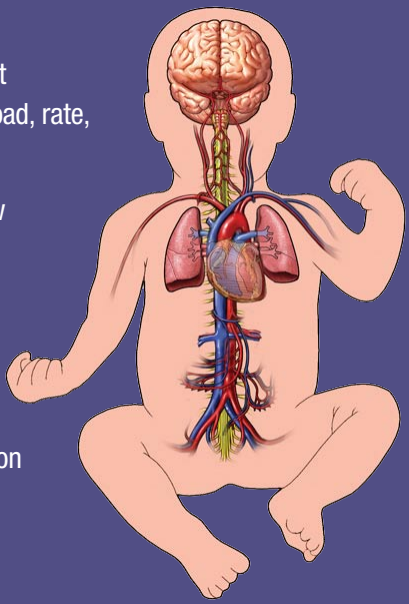
Reduce sympathetic outflow

- increase inotropes
- decrease Nitroprusside

Increase hematocrit

Maintain temperature WNL

Consider regional vasodilation



Han SH, et al. Acta Anaesthesiol Scand. 2004 May;48(5):648-52.
Hoffman GM, et al. Semin Thorac Cardiovasc Surg Pediatr Card Surg Annu. 2005:12-21.
Jonassen AE and Young WL. Anesthesiology 1994;81:A61.

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Patient Care

The care team should follow its institution's own protocols for patient monitoring and skin integrity. Some examples pertaining to INVOS System use include:

- Change sensors routinely
  - Recommended every 24 hours
  - Assess skin integrity
    - Skin under and around the sensor
    - Consider allowing the skin to "breathe"
  - Change one sensor at a time to ensure continuous monitoring
  - Place new sensor in the same location for continuity of measurements

Charting

The care team should follow its institution's own protocols for patient charting. Some examples pertaining to INVOS System use include:

- Report and record rSO_2 desaturations below 50, or below a 20% drop from the patient's baseline
- Report and record interventions taken, and your evaluation of interventions
- Share current and past rSO_2 trend data at shift changes, physician rounds, etc.
- Collaborate on appropriate treatment options

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CEREBRAL / SOMATIC

Interfering Factors

rSO_2 values can be affected by:

- Jaundice (hyper-bilirubinemia)
- Severe tissue edema
- Major sinus problems (cerebral)

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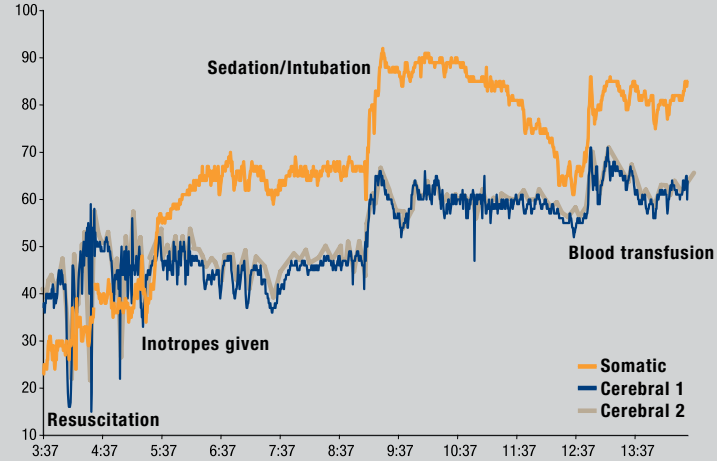
Reversal of Shock

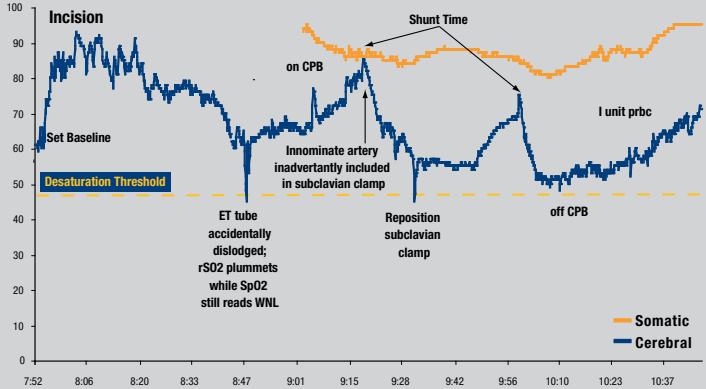


This infant with septic/cardiogenic shock and severe global hypoperfusion presented with below critical rSO_2 levels. Subsequent rSO_2 values reflect patient responses to a series of interventions. Regional oxygenation was normalized at higher levels, including restoration of typical somatic oxygenation at 5 - 20 points greater than cerebral.[1-3]

[1] Hoffman GM, et al. Semin Thorac Cardiovasc Surg Pediatr Card Surg Annu. 2005:12-21.
[2] Petrova A and Mehta R. Pediatr Crit Care Med 2006;7:449-454.
[3] Data on file.

INVOS OXIMETER
CEREBRAL / SOMATIC

Detection of Mechanical Obstructions - 5 kg Infant



During this BT shunt case, initial intubation was difficult and the ET tube later became dislodged. This mechanical obstruction caused an immediate ~20 point drop in cerebral rSO_2 to a critical level of 45. SpO_2 values remained normal until about 1 minute later.

Similarly, after cross clamping the right subclavian artery, cerebral rSO_2 fell ~40 points over a period of 12 minutes, again dipping below critical. The perfusionist changed flow and pressure with no improvement. The surgeon then checked the cross clamp which had inadvertently included the innominate artery occluding some flow to the brain. Upon clamp repositioning, cerebral rSO_2 immediately improved. There were no other hemodynamic indicators that the innominate artery was partially occluded. Without cerebral rSO_2 values, the brain would have had inadequate oxygenation for ~25 minutes.

Data on file.

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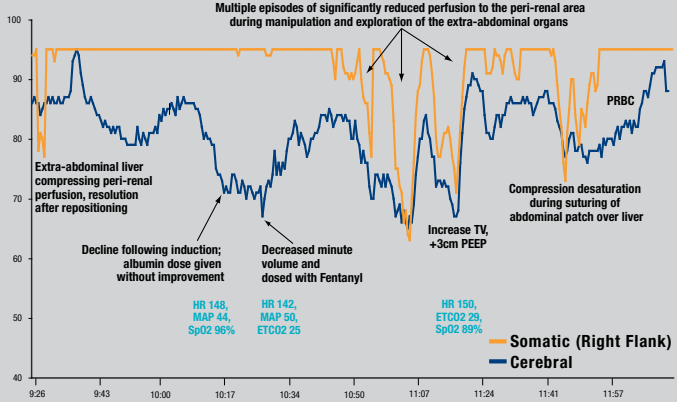
Effect of Organ Compression / Manipulation - Two-day-old Infant

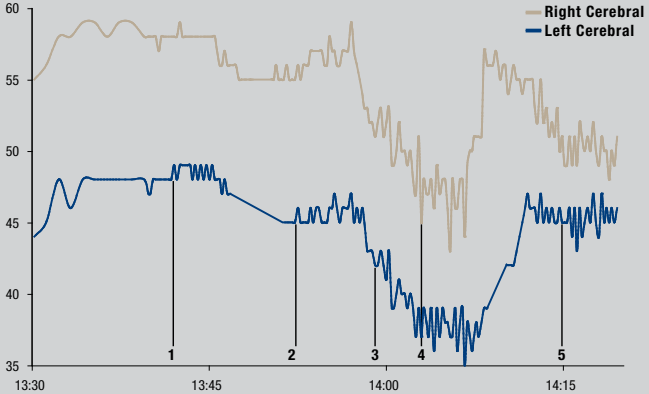


This giant omphalocele repair case emphasizes the potentially negative effects of organ compression and manipulation on regional oxygen saturation. Somatic monitoring enabled clinicians to visualize compromise to peri-renal perfusion in real-time and adjust their surgical approach to provide immediate relief of abdominal compression. Interventions included repositioning the omphalocele, spacing their manipulations to allow for perfusion recovery in between, vent changes and PRBCs to replace losses. Without placement of the peri-renal sensor, prolonged desaturation of the kidney area may have continued without notice for a significant period of time, increasing the risk of post-op renal dysfunction. This same desaturation threat can occur in similar compression-prone scenarios such as lifting/manipulating the heart and closure of the chest.

Data on file.

INVOS OXIMETER
CEREBRAL / SOMATIC

Oscillations and Desaturation Associated with Seizures



1-5. Episodes of Seizure; data recorded every 10 seconds for best resolution

An EEG monitoring study detected seizure activity in 26% of circulatory arrest infants during and after surgery, which can result in serious developmental consequences.[1] This cerebral oximetry trend graph is marked at the times of EEG documented seizures.[2] Note the transition from a smooth line to one with oscillations and a desaturation. The INVOS System can help identify potential seizure activity--even silent seizures and hemisphere of origin.[3-4]

[1] Newburger JW, et al. New Engl J Med 1993;329:1057-1064.
[2] Courtesy of HL Edmonds, Jr, PhD
[3] Diaz GA, et al. Eur J Paediatr Neurol. 2006;10(1):19-21. Epub 2006 Mar 10.
[4] Shuhaiber H, et al. J Child Neurol. 2004 Jul;19(7):539-40.

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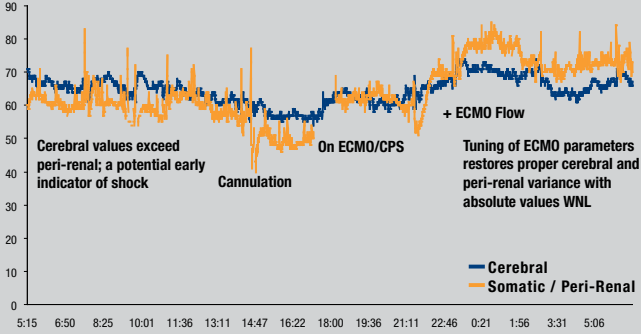
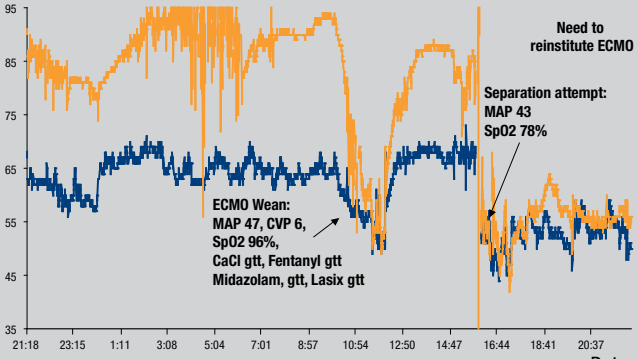
ECMO Management

rSO_2 values are useful in determining the need to initiate ECMO therapy as well as in providing immediate patient response to separation from ECMO.

Initiating ECMO



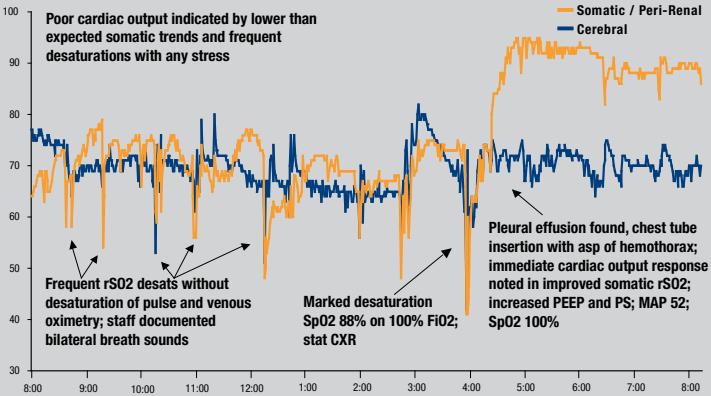
Separation from ECMO



Data on file

INVOS OXIMETER
CEREBRAL / SOMATIC

Sole Early Indicator of Low Cardiac Output Syndrome - 10 kg Child



Roughly 24 hours after ASD/ VSD repair, somatic and cerebral rSO_2 values frequently dipped to sub-optimal levels, while venous and pulse oximetry remained stable. Nursing and respiratory staff documented bilateral breath sounds throughout the night. By early morning, a critical desaturation of both SpO_2 and rSO_2 occurred with recovery of SpO_2 to only 88% despite increasing FiO_2 to 100%. A stat CXR was obtained revealing significant pleural effusion that was tapped and drained. This enabled the heart to pump sufficiently to perfuse the somatic/peri-renal area, as evidenced by the dramatic rise in somatic rSO_2. This case demonstrates the unique value of site-specific oxygenation data to aid in the detection of low cardiac output syndromes and limited regional perfusion.

Data on file.

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Ordering Information

Description	*Model Number*
Disposable Adult SomaSensor	SAFB-SM
Disposable Pediatric SomaSensor	SPFB
INVOS 5100C Cerebral/Somatic Oximeter	5100C-USA
Preamplifier with Cable, Channel 1 & 2 (Preamp)	5100C-PA
Preamplifier with Cable, Channel 3 & 4 (Preamp)	5100C-PB
Reusable Sensor Cable, Channel 1 (Blue)	RS-1
Reusable Sensor Cable, Channel 2 (Taupe)	RS-2
Reusable Sensor Cable, Channel 3 (Orange)	RS-3
Reusable Sensor Cable, Channel 4 (Green)	RS-4
Power Cord	5100-PCNAM
USB Flash Drive	5100C-USB
VueLink Adapter Cable (for connecting to a Philips VueLink Interface Module)	VLI
Null Modem Cable (for digital output)	312170
Portable Roll Stand (for 5100C)	5100C-RS
Swivel Arm (for 5100C)	5100C-SA
Operations Manual	5100C-M-USA
Quick Reference Guide for Adults	5100C-RFA
Quick Reference Guide for Pediatrics	5100C-RFP

Accessories can be ordered by contacting Somanetics' Customer Service at 800.359.7662 in the U.S. or 248.689.3050, ext. 255 outside the United States or via the Internet at www.somanetics.com.

Warning: Accessories not supplied by Somanetics may not meet EN60601-1-2 (IEC 601-1-2) standards. Contact Somanetics' Customer Service Department for compatible products that may meet these requirements.

Rx ONLY

PN 313380, rev. A

Somanetics Corporation • 1653 East Maple Road, Troy, MI, U.S.A. 48083
Phone: 800.359.7662• 248.689.3050, ext. 255 • www.somanetics.com