

INVOS™ Regional Saturation Patient Monitoring System

Model 5100C

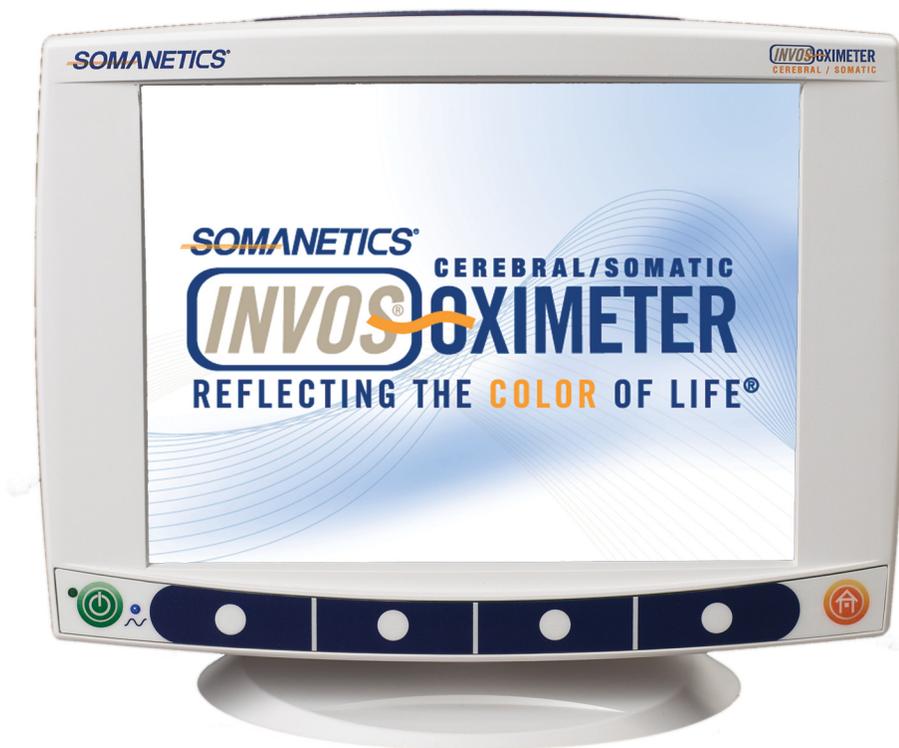


Table of Contents

1	Introduction	
1.1	Intended Audience	1-1
1.2	Key Terms	1-1
1.3	Labeling Symbols	1-1
1.3.1	Oximeter Enclosure	1-1
1.3.2	Monitor	1-3
1.3.3	Other Symbols	1-3
1.4	Warnings, Cautions, and Notes	1-5
1.4.1	Safety Symbols	1-5
1.4.2	General Warnings	1-5
1.4.3	General Cautions	1-7
1.4.4	General Notes	1-9
1.5	How to Use this Manual	1-9
1.6	Use of the Product	1-10
1.7	Customer Inquiries	1-10
1.7.1	Service and Repair	1-10
1.8	INVOS™ System Warranty	1-11
1.8.1	Key Points	1-11
1.8.2	Limited Warranty and Disclaimer	1-11
1.8.3	Warranty Labor	1-12
1.8.4	Disclaimer of Consequential Damages	1-12
1.8.5	Failure of Product	1-13
1.8.6	Purpose of Product	1-13
1.8.7	Warnings about Unauthorized Repair	1-13
1.8.8	Who to Contact for Authorized Repair	1-13
2	Product Overview	
2.1	Overview	2-1
2.2	Indications for Use	2-1
2.3	Contraindications	2-1
2.4	Brief Device Description	2-1
2.4.1	INVOS™ Adult Regional Saturation Sensor, Pediatric Regional Saturation Sensor, and OxyAlert NIRSensor	2-2
2.5	Principles of Operation	2-2
3	Installation	
3.1	Overview	3-1
3.2	Unpacking	3-1
3.3	Serial Numbers	3-2
3.4	Installation	3-2

3.5	Digital Output Port	3-3
3.6	VGA Output Port	3-4
3.7	Potential Equalization Connector	3-4
3.8	Alarm Speaker	3-4
3.9	Cooling Fan	3-4
3.10	AC Input and Fuse	3-4
3.11	USB Port	3-5
3.12	Accessories	3-5
3.13	Preamplifier	3-7
3.14	Reusable Sensor Cable	3-9
3.15	Adult and Pediatric Regional Saturation Sensor Application	3-9
3.15.1	Sensor Preuse Check	3-9
3.15.2	Sensor Lot Number	3-9
3.15.3	Sensor Cerebral Site Selection	3-9
3.15.4	Sensor Somatic Site Selection	3-10
3.15.5	Patient Prep	3-10
3.15.6	Sensor Placement	3-11
3.15.7	Care of and Removing the Sensor	3-12
3.16	Infant/Neonatal OxyAlert NIRSensor Sensor Application	3-12
3.16.1	OxyAlert NIRSensor Preuse Check	3-12
3.16.2	OxyAlert NIRSensor Lot Number	3-13
3.16.3	OxyAlert NIRSensor Cerebral Site Selection	3-13
3.16.4	OxyAlert NIRSensor Somatic Site Selection	3-13
3.16.5	Patient Prep	3-13
3.16.6	OxyAlert NIRSensor Placement	3-13
3.16.7	Monitoring with the OxyAlert NIRSensor	3-14
3.16.8	Care of and Removing the OxyAlert NIRSensor	3-15
3.17	When INVOS™ System is Part of a Medical Monitoring System	3-15
4	Quick Setup	
4.1	Overview	4-1
4.2	Initial Setup	4-1
5	Screens	
5.1	Overview	5-1
5.1.1	Welcome Screen	5-2
5.1.2	Start Screen, Navigation Bar, Key Panel and Software Version	5-2
5.1.3	Patient Identifier Screen	5-4
5.1.4	Main Screen	5-4
5.1.5	User Configuration Screen	5-7
5.1.6	Event Mark List Screen	5-8
5.1.7	Baseline Reset Screen	5-10
5.1.8	Channel Inactivity Screen	5-11

Table of Contents

5.1.9	RS-232 Digital Output Format Selection Screen	5-12
5.1.10	Tabular Trends Screen	5-13
5.1.11	Case Archive File List Screen	5-14
5.1.12	Review Screen	5-15
6	Operation	
6.1	Overview	6-1
6.2	INVOS™ System Preuse Check	6-1
6.3	Operational Modes	6-1
6.4	Date, Time, and Patient Identifier Settings	6-2
6.4.1	Date	6-2
6.4.2	Time	6-3
6.4.3	Patient Identifier	6-4
6.5	Run Function (Patient Monitoring) in Normal Mode	6-5
6.5.1	Baseline Set and Status	6-6
6.5.2	Event Mark	6-9
6.5.3	Alarm Limits	6-13
6.5.4	Alarm Volume	6-16
6.5.5	rSO ₂ Scale	6-18
6.5.6	Time Scale in User Configuration Menu	6-19
6.5.7	USB Storage Rate	6-20
6.5.8	Event Mark List	6-21
6.5.9	Data Channel Labels	6-22
6.5.10	Color-Coded Data Channel Labels	6-22
6.5.11	Two- or Four-Channel Monitoring	6-23
6.5.12	Restore Defaults	6-24
6.5.13	Alarms and Status Messages	6-25
6.5.14	Signal Strength Indicator (SSI)	6-32
6.5.15	Time Scale	6-33
6.5.16	Real-Time Review	6-33
6.6	Case Archive Function	6-35
6.6.1	Case Archive Function—Graphical Format	6-35
6.6.2	Case Archive Function—Tabular Trends Screen Format	6-36
7	Using the Monitor Ports	
7.1	Overview	7-1
7.2	Using the VGA Port	7-1
7.3	Using the USB Port	7-3
7.3.1	USB Port Output—Case Archive Function	7-3
7.3.2	USB Port Output—Run Function	7-6

7.4	Using the Digital Output Port	7-7
7.4.1	Using a Philips VueLink™* Open Interface (VOI) Module	7-8
7.4.2	Select Digital Output Port Data Format	7-10
7.4.3	Using HyperTerminal™* via Null Modem Cable to Capture and Store Data	7-11
7.5	Data Output Formats	7-15
7.5.1	Graph Data Files—rSO2 versus Time with Microsoft Excel	7-16
8	Database Operational Mode and Area Under the Curve	
8.1	Overview	8-1
8.1.1	INVOS™ System Database Application Software	8-1
8.2	Database Variable and Fields	8-2
8.2.1	Field Name: Preinduction Baseline Regional Oxygen Saturation—Left	8-2
8.2.2	Field Name: Preinduction Baseline Regional Oxygen Saturation—Right	8-2
8.2.3	Field Name: Cumulative Saturation Below Threshold—Left	8-2
8.2.4	Field Name: Cumulative Saturation Below Threshold—Right	8-2
8.2.5	Field Name: Cerebral Oximeter Provided the First Indication	8-3
8.2.6	Field Name: Skin Closure Regional Oxygen Saturation—Left	8-3
8.2.7	Field Name: Skin Closure Regional Oxygen Saturation—Right	8-3
8.3	Database Operational Mode Screens	8-3
8.3.1	Start Screen in Database Operational Mode	8-4
8.3.2	Main Screen in Database Operational Mode	8-6
8.3.3	Tabular Trends for Entering Induction Time Screen	8-7
8.3.4	Tabular Trends for Entering Skin Closure Time Screen	8-7
8.3.5	Database Summary Screen	8-8
8.4	Features	8-10
8.5	Operating in the Database Operational Mode	8-11
8.5.1	Baseline Set and Status Database Operational Mode	8-12
8.5.2	Patient Identifier in Database Operational Mode	8-13
8.6	Collecting Metrics in Database Operational Mode	8-14
8.6.1	Marking the Induction Time	8-15
8.6.2	Marking the Skin Closure Time	8-16
8.6.3	Capturing the First Alert Metric	8-17
8.6.4	Marking Metrics at the End of a Case	8-18
8.7	Reviewing the Case in Database Operational Mode	8-19
8.7.1	Real-Time Review of Database Information	8-19
8.7.2	Case Archive Function in Database Operational Mode	8-21
8.8	Outputting the Metrics in Database Operational Mode	8-22
8.8.1	Outputting Database Summary Screen to USB Flash Drive During a Case or Prior to Next Patient	8-22
8.8.2	Outputting Database Summary to USB Flash Drive in Case Archive Function	8-23

Table of Contents

9 Maintenance

9.1	Overview	9-1
9.2	Software Upgrades	9-1
9.3	Repair Policy	9-1
9.4	Cleaning the INVOS™ System	9-1
9.5	Battery Recharge	9-2
9.5.1	Check Battery Status	9-3
9.5.2	Recharge the Battery	9-3
9.6	Maintenance Schedule	9-4
9.7	Annual Inspection Procedure	9-4
9.7.1	Mechanical Inspection Points	9-4
9.7.2	Electrical Inspection Points	9-5
9.7.3	Functional Test with Optional Field Test Device	9-6
9.8	Troubleshooting Techniques	9-6
9.8.1	Who to Contact for Technical Service	9-7
9.8.2	Check Fuses	9-7
9.8.3	Troubleshooting Chart	9-8
9.8.4	Troubleshooting the Digital Output	9-9
9.8.5	Troubleshooting Signal Strength Indicator (SSI)	9-9

A Specifications

A.1	Overview	A-1
A.2	Specifications	A-1
A.2.1	Physical	A-1
A.2.2	Operational	A-1
A.2.3	Electrical	A-2
A.2.4	Environmental Requirements	A-2
A.2.5	Alarm Conditions	A-3
A.2.6	Alarm Tone Definitions	A-4
A.2.7	Default Settings	A-4
A.2.8	Additional	A-5
A.3	Guidance and Manufacturer's Declaration—Electromagnetic Compatibility (EMC)	A-6
A.3.1	Guidance and Manufacturer's Declaration—Electromagnetic Emissions	A-7
A.3.2	Guidance and Manufacturer's Declaration—Electromagnetic Immunity	A-7
A.3.3	Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the INVOS™ System	A-8
A.4	System Diagram	A-10

B	Clinical Studies	
B.1	Overview	B-1
B.2	Hypoxia Study	B-1
B.3	Pediatric Clinical Study	B-3
B.4	Interventional Studies	B-4
B.5	Validation Studies	B-5
C	Glossary	

List of Figures

Figure 2-1.	Disposable Sensors	2-2
Figure 2-2.	INVOS™ System (Model 5100C)	2-3
Figure 3-1.	Back Connections and Elements	3-3
Figure 3-2.	Side Connections	3-7
Figure 3-3.	Preamplifiers, Reusable Sensor Cables, and Sensor Connections	3-8
Figure 3-4.	Sensor Prep	3-10
Figure 3-5.	Sensor Placement	3-11
Figure 3-6.	OxyAlert NIRSensor Placements: Cerebral, Flank, and Abdominal Shown	3-14
Figure 4-1.	Connecting the Preamplifier to the Monitor	4-1
Figure 4-2.	Connecting the Sensor Cable Connectors to the Preamplifier	4-2
Figure 4-3.	Connecting the Sensors to the Sensor Cables	4-2
Figure 4-4.	Connecting Optional Accessories	4-3
Figure 5-1.	Welcome Screen	5-2
Figure 5-2.	Start Screen, Navigation Bar, Key Panel and Software Version	5-3
Figure 5-3.	Patient Identifier Screen	5-4
Figure 5-4.	Main Screen Elements (Two-Channel Monitoring)	5-5
Figure 5-5.	Main Screen (Four-Channel Monitoring)	5-6
Figure 5-6.	User Configuration Screen (Page 1)	5-7
Figure 5-7.	User Configuration Screen (Page 2)	5-7
Figure 5-8.	Event Mark List Screen (OR Event Mark List)	5-8
Figure 5-9.	Event Mark List Screen (ICU Event Mark List)	5-9
Figure 5-10.	Event Mark List Screen (Vascular Event Mark List)	5-9
Figure 5-11.	Event Mark List Screen (NICU Event Mark List)	5-10
Figure 5-12.	Baseline Reset Screen	5-11
Figure 5-13.	Channel Inactivity Screen	5-11
Figure 5-14.	RS-232 Digital Output Format Selection Screen (Two-Channel Monitoring)	5-12
Figure 5-15.	RS-232 Digital Output Format Selection Screen (Four-Channel Monitoring)	5-12
Figure 5-16.	Tabular Trends Screen—Run Function in Normal Mode	5-13
Figure 5-17.	Tabular Trends Screen—Case Archive Function in Normal Mode	5-13
Figure 5-18.	Tabular Trends Screen—Manual Set Baseline in Normal Mode	5-14
Figure 5-19.	Case Archive File List Screen	5-15
Figure 5-20.	Trend Graph Screen—Case Archive Function in Normal Mode	5-16
Figure 5-21.	Trend Graph Screen—Run Function in Normal Mode	5-16
Figure 6-1.	INVOS™ System in Normal Mode with Low Alarm	6-6
Figure 6-2.	rSO2 Alarm Indicated	6-26
Figure 6-3.	rSO2 Below Baseline	6-27
Figure 6-4.	Technical Alarm Indicated	6-28
Figure 7-1.	VGA Video Connector Pin-Out	7-2
Figure 7-2.	Digital Output Connector Pin-Out	7-8
Figure 7-3.	Null Modem Cable Diagram for Connection to Digital Output Port	7-12
Figure 8-1.	Two-Channel Start Screen in Database Operational Mode	8-4
Figure 8-2.	Four-Channel Start Screen in Database Operational Mode	8-5
Figure 8-3.	Main Screen (Four-Channel Monitoring) Database Operational Mode	8-6

Figure 8-4.	Tabular Trends for Entering Induction Time Screen.....	8-7
Figure 8-5.	Tabular Trends for Entering Skin Closure Time Screen.....	8-8
Figure 8-6.	Database Summary Screen—Auto Set Baseline.....	8-8
Figure 8-7.	Database Summary Screen—Real-Time Review Before Skin Closure.....	8-9
Figure 8-8.	Database Summary Screen—Real-Time Review After Skin Closure.....	8-9
Figure 8-9.	Database Summary Screen—Case Archive Review.....	8-10
Figure 8-10.	Events Marked on Main Screen During Database Operational Mode.....	8-16
Figure A-1.	Diagram of INVOS™ System (Model 5100C).....	A-10
Figure B-1.	rSO2 and fSO2, 20 Subjects.....	B-2
Figure B-2.	Trend Data, 22 Subjects, 90 Points.....	B-4

List of Tables

Table 1-1.	Safety Symbol Definitions	1-5
Table 5-1.	Tabular Trends Line of Data Format	5-14
Table 6-1.	Event Codes and Descriptions for Operating Room	6-10
Table 6-2.	Event Codes and Descriptions for Intensive Care Unit	6-11
Table 6-3.	Event Codes and Descriptions for Vascular Application	6-12
Table 6-4.	Event Codes and Descriptions for Neonatal Intensive Care Unit	6-13
Table 6-5.	Status Messages—rSO ₂ Value Displayed	6-30
Table 6-6.	Status Messages—rSO ₂ Value Not Displayed	6-31
Table 7-1.	VGA Video Connector Pin-Out Descriptions	7-2
Table 7-2.	Input COM Port Settings Using HyperTerminal™*	7-13
Table 9-1.	Maintenance Schedule	9-4
Table 9-2.	Electrical Inspection Points	9-5
Table 9-3.	INVOS™ System Troubleshooting Chart	9-8
Table 9-4.	Digital Output Troubleshooting Chart	9-9
Table 9-5.	Signal Strength Indicator Troubleshooting Chart	9-10
Table A-1.	Physical Specifications	A-1
Table A-2.	Operational Specifications	A-1
Table A-3.	Electrical Specifications	A-2
Table A-4.	Environmental Requirements	A-2
Table A-5.	Alarm Conditions	A-3
Table A-6.	Alarm Tone Definitions	A-4
Table A-7.	Default Settings	A-4
Table A-8.	Electromagnetic Emissions	A-7
Table A-9.	Electromagnetic Immunity	A-7
Table A-10.	Electromagnetic Immunity—Conducted and Radiated RF	A-9
Table A-11.	Recommended Separation Distances	A-9
Table B-1.	Bias, Error, and Correlation for rSO ₂ and fSO ₂	B-2

Page Left Intentionally Blank

1 Introduction

1.1 Intended Audience

This manual provides information to health-care professionals in a hospital setting for operation and maintenance of the INVOS™ regional saturation patient monitoring system. Refer to the institution for any additional training or skill requirements beyond those identified here for operation and maintenance of the INVOS™ system.

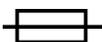
1.2 Key Terms

rSO ₂	Regional oxygen saturation
INVOS™	In vivo optical spectroscopy. Used in reference to the INVOS™ system.
Cerebral (application for INVOS™)	Brain area of measurement
Pediatric (application for INVOS™)	Disposable INVOS™ pediatric regional saturation sensor has been designed for use with pediatric patients weighing less than 40 kg
Infant/neonatal (application for INVOS™)	Disposable infant/neonatal INVOS™ OxyAlert NIRSensor sensor has a small adhesive pad and a gentle hydrocolloid adhesive for use with infant or neonatal patients. Suitable for patients weighing less than 5 kg.
Somatic (application for INVOS™)	Skeletal muscle tissue area of measurement
Sensor	Used in this manual to represent the INVOS™ patient-applied transducer.

1.3 Labeling Symbols

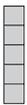
1.3.1 Oximeter Enclosure

	Alternating current
	Backup battery

	Blue LED—indicates AC power supply and battery charge ON
	Caution; consult accompanying documents
	Digital output
	Do not dispose in trash. Use special collection.
	Fuse
	Green LED—indicates power ON
	HOME
	Potential equalization
	Preamplifier
	Light source
	Serial number
	Stand-by (ON/OFF)
	Type BF equipment

	USB port
	VGA output port

1.3.2 Monitor

	Alarm
	Baseline
	Battery
 SSI	Signal strength indicator
	Silence alarm

1.3.3 Other Symbols

	Catalog number
	Follow instructions for use
	Consult instructions for use
	Authorized representative in the European community

	Do not reuse
	Manufacturer
	Type BF equipment
	Dangerous voltage
<p>Segurança</p>  	INMETRO certification
	CE – Conformité Européene authorization mark 0123 – TÜV SÜD Product Service GmbH (notified body)
	Prescription only US federal law restricts this device to sale by or on the order of a physician

1.4 Warnings, Cautions, and Notes

The INVOS™ system is easy to use; however, it is necessary to adhere to the warnings and cautions in this manual.

1.4.1 Safety Symbols

Table 1-1. Safety Symbol Definitions

Symbol	Definition
	WARNING Warnings alert users to potential serious outcomes (death, injury, or adverse events) to the patient, user, or environment.
	Caution Cautions alert users to exercise appropriate care for safe and effective use of the product.
	Note Notes provide additional guidelines or information.

1.4.2 General Warnings



WARNING:
Shock hazard:

- Ensure the INVOS™ system is properly grounded when operating on AC power.
- The backup battery is not user replaceable.
- Do not immerse the INVOS™ system in any liquids as they may cause electric shock hazard or damage the device.
- Only make external connections to the types of equipment specified in the interfacing chapter of this manual (see Chapter 7 *Using the Monitor Ports*). Connecting any other types of equipment may result in damage to the INVOS™ system or compromise its safety. When a personal computer (PC) or specified printer is used for data downloading and collection, the device should be in compliance with IEC 60601 “Medical Electrical Equipment” Standard or IEC: “Non-medical equipment in compliance with relevant IEC safety standards.” It is recommended that the PC be placed outside of the “Patient Environment.” If this condition cannot be met and the PC is also placed inside the “Patient Environment,” then additional protective earth or leakage current reduction measures, such as a power supply separation device shall be used (see IEC 60601-1-1, subclause 19.201 and table BBB. 201). Follow all warnings and precautions provided with device.



WARNING:

Shock and patient hazard: Users may not modify any components of the INVOS™ system or its software.



WARNING:

Explosion hazard: Do not use the INVOS™ system in the presence of flammable anesthetics or in other flammable environments.



WARNING:

Cross-contamination hazard: The INVOS™ adult regional saturation sensor, pediatric regional saturation sensor, and OxyAlert NIRSensor are designed for single use only and may not be reused. Reuse may cause inaccurate readings, erratic readings, or no readings at all. Also, reuse may cause an increased risk of cross-contamination among patients.



WARNING:

Patient hazard: The INVOS™ adult regional saturation sensor, pediatric regional saturation sensor, and OxyAlert NIRSensor are designed for external use only as described in the instructions. Do not use the sensors internally for any reason.



WARNING:

Fire hazard: Do not block airflow to the back of the INVOS™ monitor.



WARNING:

The clinical value of trend data has not been demonstrated in disease states. The INVOS™ system should not be used as the sole basis for diagnosis or therapy. It is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.



WARNING:

Do not set alarm limits to extreme values that can render the INVOS™ system ineffective. Ensure alarm limits are appropriate for each patient.



WARNING:

Do not silence, pause, or decrease the volume of audible alarms if patient safety could be compromised.



WARNING:

A hazard can exist if different alarm presets are used for the same equipment in a single area, such as an operating theater or intensive care unit. Verify alarm limits with each patient.



WARNING:

While the INVOS™ system is connected to a remote display, the remote display will not generate alarm signals if communication between that display and the INVOS™ system is interrupted.

During this period of no communication, the INVOS™ system will continue to monitor the patient and generate alarm signals. The operator of the remote display should not rely upon the remote display's alarm system to generate alarm signals.



WARNING:

The use of accessories, sensors, and cables other than those specified may result in poor performance of the INVOS™ system and increased electromagnetic emissions or decreased electromagnetic immunity of the INVOS™ system.



WARNING:

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the INVOS™ system, including cables. Otherwise, degradation of INVOS™ system performance may result.



WARNING:

Choking hazard — The reusable sensor cables (RSCs) include a strain-relief clip that, if detached, may pose a choking hazard.



WARNING:

As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.



WARNING:

Always disconnect and remove the INVOS™ system and sensors during magnetic resonance imaging (MRI) scanning. Attempting to use the INVOS™ system during an MRI procedure could cause burns or adversely affect the MRI image or the INVOS™ system's performance.

1.4.3 General Cautions



Caution:

INVOS™ system readings represent a small volume of tissue beneath the sensor and may not reflect oxygenation disturbances that occur elsewhere.



Caution:

Make sure all connectors are fully engaged and free from moisture. Moisture intrusion may cause inaccurate readings, erratic readings or no readings at all.



Caution:

Use care when placing or removing sensor. Do not place on broken or undeveloped skin.



Caution:

For cerebral site selection, 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.



Caution:

For somatic site selection, 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 somatic tissue or no readings at all.



Caution:

Use only Covidien recommended or provided accessories. Use of the INVOS™ system with any other sensor will compromise accuracy.



Caution:

If present, the following may cause inaccurate readings:

- Cardiogreen, Indigo Carmine, Methylene Blue, or other intravascular dyes
- Carboxyhemoglobin or other dyshemoglobins
- Hemoglobinopathies
- Conjugated hyperbilirubinemia (direct)
- Myoglobin (Mb) in muscle tissues



Caution:

Do not place the sensor on regions with severe tissue edema to reduce the possibility of skin lesions.



Caution:

Use of an electrosurgical/electrocautery instrument in the vicinity of the INVOS™ system may interfere with the signal and result in no readings and the status message "INTERFERENCE DETECTED."



Caution:

Environments with excessive ambient light such as bright sunlight or strong operating room lighting may require loosely covering the area of the sensor with an opaque drape.



Caution:

In order to maintain full backup battery charge, the INVOS™ system must be plugged into AC mains power with the back panel AC mains power switch turned on. The blue  LED on the key panel illuminates to indicate the power is connected and the battery is charging. Periodically

disconnect the INVOS™ monitor from the AC power source and briefly operate the monitor to check the charge condition of the backup battery.



Caution:

Adult, pediatric and infant/neonatal sensors cannot be mixed/used simultaneously on the same monitor or a "REPLACE SENSOR" status message will appear. Cerebral sensors can be used with somatic sensors on the same monitor.



Caution:

To avoid pressure sores do not apply external pressure (for example, headbands, wraps, tape) to sensor.



Caution:

Sensors do not need to be removed for x-ray or CT scan. However, sensors will appear on image. Sensors must be removed for MRI.



Caution:

Do not attempt to perform any service or tamper with the warranty seal unless you have been authorized in writing by Covidien. Repairs made by anyone not authorized by Covidien during the warranty period will void the product warranty.

1.4.4 General Notes



Note:

U.S. federal regulations restrict the sale of this device to, or on the order of, licensed medical practitioners.

1.5 How to Use this Manual

Please comply with the warnings listed in this chapter, and consult this manual for operation and maintenance instructions. Read the manual completely before using the INVOS™ system to ensure proper, safe operation. Do not attempt to repair the INVOS™ system during the warranty period. Only Covidien or its authorized repair representative should make repairs during the warranty period.

Whenever the symbol  is seen on the device, this manual should be consulted for a complete explanation. Please read this manual completely before attempting to operate the device.

1.6 Use of the Product

Do not use this product if it is found defective in any way; contact the Covidien customer service department for repair or replacement. If the INVOS™ system is not operated, maintained, and repaired in compliance with this manual (including product inserts and warnings), it will not function as described. The user is responsible for operating and maintaining the INVOS™ system according to instructions outlined in this manual. The manufacturer (Covidien) is not responsible for injury or losses if the INVOS™ system is not used in compliance with instructions.

1.7 Customer Inquiries

For any questions regarding INVOS™ system safety and effectiveness or any other information, please contact the Covidien customer service department.

Covidien llc
15 Hampshire Street
Mansfield, MA 02048 USA
Phone: 800 635 5267
Web: www.covidien.com
Email: Customer.Service-RMS@Covidien.com

1.7.1 Service and Repair

If the INVOS™ system fails to operate as stated, it should be taken out of service immediately (see section [9.8 Troubleshooting Techniques](#)).



Caution:

Do not attempt to perform any service or tamper with the warranty seal unless you have been authorized in writing by Covidien. Repairs made by anyone not authorized by Covidien during the warranty period will void the product warranty.

For troubleshooting assistance, contact Covidien's customer service department at 800 635 5267, Customer.Service-RMS@Covidien.com, www.covidien.com, or via an authorized repair representative.

If the problem cannot be solved via phone or online, perform the following steps to return the unit for service:

1. Obtain a return material authorization (RMA) number by contacting a Covidien customer service representative (see section [1.7 Customer Inquiries](#)).
2. When returning an INVOS™ system, ship it prepaid, in the original container as received. It is important to use the original container and packing material to prevent damage to the INVOS™ system in shipping.

Covidien will not assume responsibility for damage caused in shipment if the customer does not use original shipping materials. Shipping materials can be obtained by contacting the Covidien customer service department. Also include the following items:

- Detailed description of the problem or need
- RMA number and serial number of the INVOS™ system monitor
- Name and phone number of the person to contact within your facility
- Information regarding where and to whom to return the INVOS™ system
- All accessories that came with the product (preamplifier, reusable sensor cable, AC line cord, and any other optional attachments)

1.8 INVOS™ System Warranty

1.8.1 Key Points

- The INVOS™ system is warranted free of defects for 1 year from date of delivery to the customer.
- Warranty repairs can be obtained by calling Covidien's customer service department.
- All returned merchandise shipments must be prepaid and have a return materials authorization (RMA) number.
- Certain software or hardware upgrades may be provided free of charge during the warranty period when units are returned to Covidien.
- Unauthorized repairs, misuse, or abuse of the device will void the warranty.

**Note:**

Save the box and packing material for any future transport.

**Caution:**

Do not attempt to perform any service or tamper with the warranty seal unless you have been authorized in writing by Covidien. Repairs made by anyone not authorized by Covidien during the warranty period will void the product warranty.

1.8.2 Limited Warranty and Disclaimer

Covidien warrants the products to be free of defects in material or workmanship resulting in the products failing to meet Covidien's published specifications at the time of delivery. Claims may be made under this warranty only in the event of failure due to such defect within 1 year of delivery. Covidien sole and exclusive obligation (customer's sole and exclusive remedy) with respect to this warranty shall be to repair or, at Covidien sole discretion, replace products that prove to be defec-

tive in material and workmanship resulting in the products failing to meet Covidien published specifications during the 1 year warranty period from delivery to the customer, provided they are returned to Covidien, prepaid.

CUSTOMER'S SOLE AND EXCLUSIVE REMEDY FOR COVIDIEN LIABILITY OF ANY KIND, INCLUDING, WITHOUT LIMITATION, NEGLIGENCE, WITH RESPECT TO ANY ITEM FURNISHED UNDER THIS AGREEMENT, SHALL BE LIMITED TO THE REMEDY PROVIDED IN THE PRECEDING SENTENCE. NO OTHER WARRANTY OR REMEDY IS EXPRESSED OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, ANY WARRANTY IMPLIED BY CUSTOM OF TRADE OR COURSE OF DEALING, OR ANY WARRANTY AGAINST HIDDEN DEFECTS. NO REPRESENTATIONS CONCERNING THE PRODUCTS ARE OR WERE MADE OR RELIED UPON WITH RESPECT TO THE QUALITY OR FITNESS OF THE PRODUCTS. DISTRIBUTOR AND ITS ULTIMATE CUSTOMERS WAIVE THE RIGHT TO ANY CLAIMS BASED ON AN ALLEGED BREACH OF WARRANTY BY COVIDIEN EXCEPT AS OTHERWISE PROVIDED IN THIS AGREEMENT.

The customer shall immediately notify Covidien of any claims under any of the foregoing warranties. All of the products are warranted to the distributor and its ultimate customers, as set forth herein, and to no other persons. Covidien and designees, may alter, modify or deviate from this warranty with respect to any products sold to the customer after the customer receives written notice of the revised warranty. This limited warranty specifically excludes disposable sensors, accessory items and fuses.

1.8.3 Warranty Labor

If Covidien determines that the product is defective and that the claim was made within the warranty period, Covidien shall satisfy its obligations under this warranty by repairing or replacing the product and returning it to the customer, within the parameters established above, at Covidien's expense. If Covidien determines that the product is not defective or that the claim was not made within the warranty period, Covidien will return the product to the customer and charge the customer for shipping, handling, and diagnostic fees specified in the Covidien terms and conditions of sale.

1.8.4 Disclaimer of Consequential Damages

Covidien's liability of any losses, damages, or expenses of any kind that arise out of, or which are in connection with, the products covered by the warranty set forth herein or their design, manufacture, or sale, whether the claim is in contract, tort, or otherwise, including, without limitation, liability for breach of the warranty provided herein, is limited, unless otherwise prohibited by law, to an amount not exceeding the cost of performing the obligations contained in the warranty according to its terms, and in no event shall Covidien's liability exceed the value of the product giving rise to such liability. UNDER NO CIRCUMSTANCES SHALL COVIDIEN BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING, WITHOUT LIMITATION, LOSS, DAMAGE, OR EXPENSE ATTRIBUTABLE TO A LOSS OF USE OF THE PRODUCT, A LOSS OR DAMAGE TO PROPERTY OTHER THAN THE PRODUCT, A LOSS OF EXPECTED INCOME, LOSS FROM BUSINESS DISRUPTION, OR OTHER COMMERCIAL LOSS, DUE TO ANY CAUSE, EVEN IF COVIDIEN HAS BEEN ADVISED

OF THE POSSIBILITY OF SUCH DAMAGES, IN CONNECTION WITH THIS AGREEMENT, THE PRODUCTS, OR ANY USE OF THE PRODUCTS (EXCEPT FOR LIABILITY FOR CONSEQUENTIAL DAMAGES THAT BY LAW MAY NOT BE DISCLAIMED).

1.8.5 Failure of Product

Covidien shall not be responsible for failure of products, and the warranty provided herein will not apply if such failure is attributable to accident (including, without limitation, damage during shipment), neglect, misuse, abuse or exposure of the products to conditions beyond the environmental and operating constraints specified by Covidien.

1.8.6 Purpose of Product

This limited warranty is given on the basis that Covidien's INVOS™ system is designed and intended solely for the purpose of providing patients and physicians with information concerning regional oxygen changes in the brain and somatic tissue. Accordingly, Covidien makes no claim or warranty, express or implied, related to the use of Covidien's INVOS™ system as a test for a patient's overall condition or any specific disease.

1.8.7 Warnings about Unauthorized Repair

Performing unauthorized service or repairs not described in this manual on any Covidien's INVOS™ system will void the product's warranty.



Note:

If the unit in question is under warranty, do not attempt to repair the unit. Instead, return it to Covidien for repair (see section [1.8.8 Who to Contact for Authorized Repair](#)). Repairs made by anyone not authorized by Covidien during the warranty period will void the product warranty.

1.8.8 Who to Contact for Authorized Repair

For authorized repair of a Covidien INVOS™ system, contact a Covidien customer service representative (see section [1.7 Customer Inquiries](#)).

Page Left Intentionally Blank

2 Product Overview

2.1 Overview

This chapter provides information that the operator should know before attempting to operate the INVOS™ regional saturation patient monitoring system.

2.2 Indications for Use

The noninvasive INVOS™ 5100C is intended for use as an adjunct monitor of regional hemoglobin oxygen saturation of blood in the brain or in other tissue beneath the sensor. It is intended for use in individuals greater than 2.5 kg at risk for reduced-flow or no-flow ischemic states. It is also intended for use as an adjunct trend monitor of regional hemoglobin oxygen saturation of blood in the brain or in other tissue beneath the sensor in any individual.

2.3 Contraindications

None.

2.4 Brief Device Description

The INVOS™ system provides noninvasive and continuous information of changes in regional oxygen saturation of blood. The measurement takes place in real time, providing an immediate indication of a change in the critical balance of regional oxygen delivery and oxygen consumption.

The INVOS™ system consists of the following items:

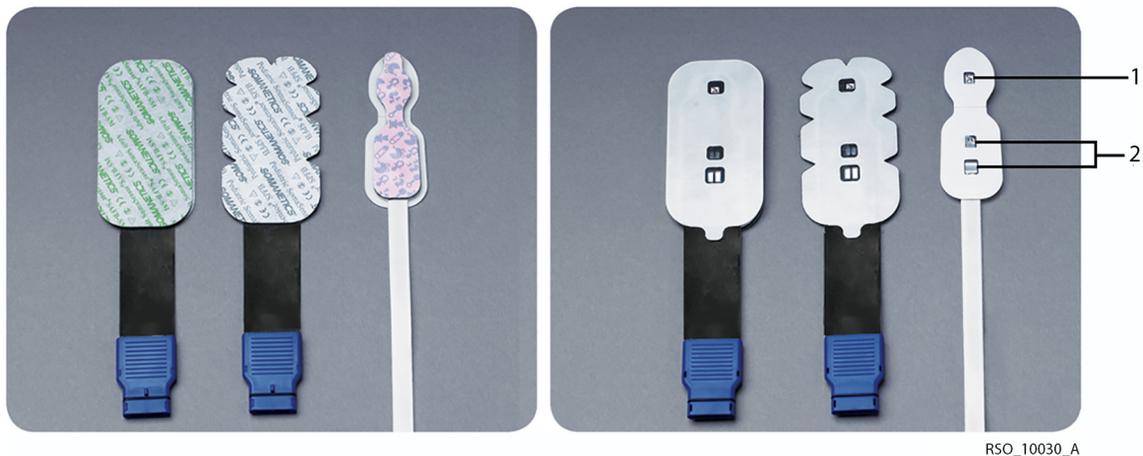
- Monitor and power cord
- One or two preamplifiers with cables and hooks
- Reusable sensor cables for use with sensor models SAFB-SM (adult) and SPFB (pediatric)
- Disposable sensors (one through four)
- Accessories (see section [3.12 Accessories](#))

2.4.1 INVOS™ Adult Regional Saturation Sensor, Pediatric Regional Saturation Sensor, and OxyAlert NIRSensor

The INVOS™ adult regional saturation sensor, pediatric regional saturation sensor, and OxyAlert NIRSensor are disposable transducers capable of producing and detecting optical data from the patient, converting that data to electrical signals, and sending them to the INVOS™ system. They are applied to the forehead or somatic region via self-contained, medical-grade patient adhesive. Electrical signals from the detectors are sent through the shielded cable to the INVOS™ system for processing.

The sensors are designed for single-use only and may not be reused. Reuse of the sensors may cause inaccurate readings, erratic readings, or no readings at all. Reuse will also cause an increased risk of cross-contamination (see section 3.15 *Adult and Pediatric Regional Saturation Sensor Application*, section 3.16 *Infant/Neonatal OxyAlert NIRSensor Sensor Application*, and instructions for use inside carton).

Figure 2-1. Disposable Sensors

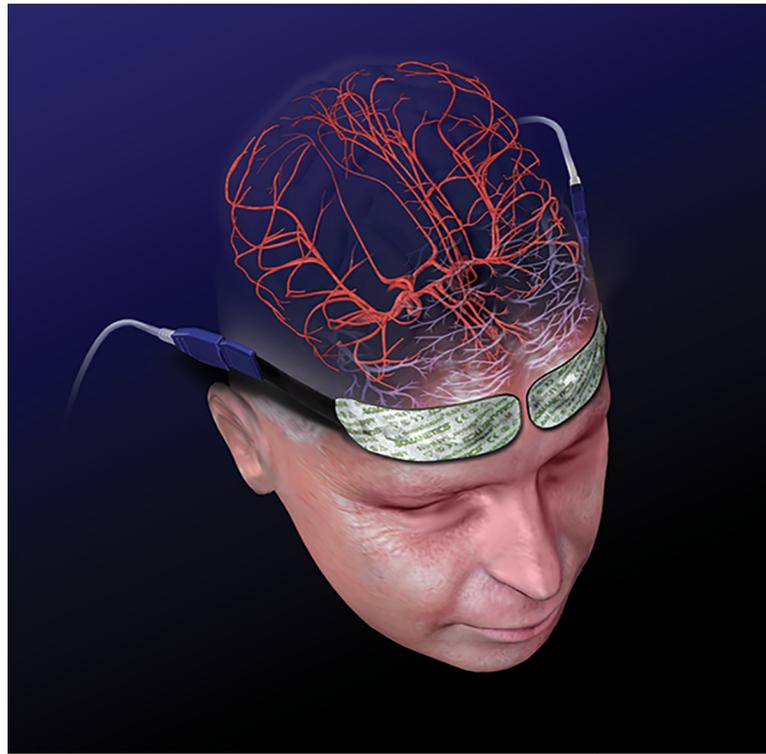


RSO_10030_A

1 Light emitting diode (LED) 2 Detectors

2.5 Principles of Operation

The INVOS™ system “reflects the color of life.®” The harmless, near-infrared wavelengths generated by the system’s light-emitting diodes (LEDs) easily pass through scalp and bone tissue beneath the sensor. Once in vivo they are either absorbed or scattered back up to the sensor’s shallow and deep detectors.

Figure 2-2. INVOS™ System (Model 5100C)

RSO_10035_A

Red-colored hemoglobin molecules within red blood cells have the highest light absorption of the wavelengths used. The exact shade of red of each hemoglobin molecule indicates the amount of oxygen it is carrying.

The type and quantity of absorption data returned to the detectors reflects relative amounts of deoxyhemoglobin and total hemoglobin, from which a regional oxygen saturation (rSO_2) value unique to the specific area under the sensor is calculated. Values are measured continuously, with screen updates provided to clinicians every 5 seconds.

Since brain cells and organ tissues die within minutes without proper oxygenation, measurement of this color provides potentially life-saving or life-changing information. When rSO_2 values show an oxygen deficit or change, the care team can intervene to potentially lessen or prevent adverse events.

Page Left Intentionally Blank

3 Installation

3.1 Overview

This chapter provides information for unpacking and installing the INVOS™ regional saturation patient monitoring system, as well as connections and elements.

3.2 Unpacking



Note:

Verify all the environmental requirements are met before unpacking the INVOS™ system (see section [A.2 Specifications](#)).

Inspect the shipping container visually for signs of damage or abuse during transit.

Carefully unpack the INVOS™ system and all accessories. Verify the following pieces are present:

- INVOS™ system monitor
- Preamplifier A, channel 1 and 2
- Reusable sensor cable, channel 1
- Reusable sensor cable, channel 2
- Power cord
- USB flash drive
- Operator's manual
- Any other ordered accessories



Note:

The INVOS™ system components listed are for two-channel monitoring. The four-channel system will also include preamplifier B and reusable sensor cables for channels 3 and 4.



Note:

Save the box and packing material for any future transport.

Remove all tape and packing materials from the INVOS™ system and accessories.

Visually inspect the INVOS™ system and accessories for signs of shipping damage. If there is damage, report it to the shipping carrier (UPS, FedEx, or other) immediately.



Note:

Upon initial unpacking, the battery may be partially discharged. Before attempting battery operation, the battery must be charged by connecting the INVOS™ system oximeter to AC power in either operational or nonoperational mode. A charge time of 24 hours is required to recharge a fully depleted battery. When the system is on, the blue  LED on the key panel illuminates to indicate the power is connected and the battery is charging.

3.3 Serial Numbers SN

The INVOS™ system serial number appears on the back of the INVOS™ system monitor. For the Monitor, the serial number format is YY-1XXXX (where the YY 2-digits stands for year). The preamplifier serial number appears on the back of the preamplifier. For preamplifier A, the serial number format is YY-2XXXX. For preamplifier B, the serial number format is YY-3XXXX.

Record the serial numbers in the following table:

INVOS™ system monitor serial number	
Preamplifier A, channel 1 and 2, serial number	
Preamplifier B, channel 3 and 4, serial number	

3.4 Installation

Place the monitor on a sturdy, flat surface or attach it to the optional mounting system (see Roll Stand and Mounting System Instructions ).

Plug in the monitor to an AC mains power source by attaching the AC line power cord to AC input (see [Figure 3-1](#)).



Note:

Only use hospital-grade AC mains outlets.

The blue  LED on the key panel illuminates to indicate the power is connected and the battery is charging. If the blue light is not on, turn the master (mains) power switch ON (see [Figure 3-1](#)).

Connect any optional accessories to the monitor (see [Figure 3-1](#) . and [Figure 3-2](#)).

**WARNING:**

All equipment used within two meters of the patient (patient environment) must be IEC 60601-1 approved. All equipment used outside the patient environment must be approved to the appropriate IEC or ISO standards (for example, IEC 950 for office equipment).

Figure 3-1. Back Connections and Elements



- | | | | |
|---|---|---|--|
| 1 | Digital output port IOIOI | 5 | Fuse  |
| 2 | VGA output port | 6 | AC mains (master) power switch |
| 3 | Potential equalization (grounding post) connector  | 7 | AC input, power cord connector |
| 4 | Alarm speaker and cooling fan | 8 | Serial number SN |

3.5 Digital Output Port **IOIOI**

This port provides real time (every 5–6 seconds) and stored (every 30 seconds) digital data communications with other devices such as a PC. Consult Covidien for compatibility with other commercial devices (see section [7.4 Using the Digital Output Port](#)).

3.6 VGA Output Port

This port provides standard video signals for an external monitor (see section [7.2 Using the VGA Port](#)).

3.7 Potential Equalization Connector

The potential equalization connector (grounding post) provides a redundant external connection to earth ground if necessary.

3.8 Alarm Speaker

The alarm speaker provides an audio output signal to alert the operator to problems and alarms that may occur while monitoring (see sections [6.5.3 Alarm Limits](#), [6.5.4 Alarm Volume](#), and [6.5.13 Alarms and Status Messages](#)).

3.9 Cooling Fan

The cooling fan provides air circulation through the monitor. Cooling air enters through the vents in the back of the monitor and exhausts through the fan. The fan does not require maintenance.



WARNING:

Fire hazard: Do not block airflow to the back of the INVOS™ monitor.

3.10 AC Input and Fuse

The AC input provides a connection for AC power. The INVOS™ system will operate on 100-240 V AC/50 or 60Hz. The AC input has a master (mains) power switch that turns AC power to the monitor ON and OFF. If this switch is in the OFF position, the monitor can only be turned on from the internal backup battery.



Caution:

When the INVOS™ system is not in use, the master (mains) power switch must be turned on with AC power connected in order to keep the battery charged. The battery has a nominal capacity of 1.2 Ah (ampere-hours). The charging time is 24 hours at 20°C for a fully discharged battery.

3.11 USB Port

The USB port allows data from the INVOS™ system to be transferred via a USB 2.0 flash memory drive to other devices, such as a PC or other devices that have a USB port. A USB 2.0 flash memory drive is supplied at the time of purchase. The USB flash drive allows the operator to download INVOS™ system data in real-time (every 5–6 seconds) and stored (every 30 seconds) case history. The USB port also allows for software upgrades (see section [7.3 Using the USB Port](#)).



Note:

USB flash drives not supplied by Covidien may not meet system requirements. Additional drives may be ordered from Covidien (see section [3.12 Accessories](#)).

3.12 Accessories



WARNING:

Accessories not supplied by Covidien may not meet IEC 60601-1 standards. Contact the Covidien Customer Service Department for compatible products that meet these requirements.

REF number	Description
RSC-1	Reusable sensor cable channel 1 (blue), INVOS™ 5100C
RSC-2	Reusable sensor cable channel 2 (taupe), INVOS™ 5100C
RSC-3	Reusable sensor cable channel 3 (orange), INVOS™ 5100C
RSC-4	Reusable sensor cable channel 4 (green), INVOS™ 5100C
SAFB-SM	INVOS™ adult regional saturation sensor (>40 kg)
PMAC71RSC-L-CH1	Reusable sensor cable for 5100C, channel 1 ¹
PMAC71RSC-L-CH2	Reusable sensor cable for 5100C, channel 2 ¹
PMAC71RSC-L-CH3	Reusable sensor cable for 5100C, channel 3 ¹
PMAC71RSC-L-CH4	Reusable sensor cable for 5100C, channel 4 ¹
SPFB	INVOS™ pediatric regional saturation sensor (<40 kg)
CNN	Disposable OxyAlert NIRSensor, neonatal—cerebral (<5 kg) with sensor cable
SNN	Disposable OxyAlert NIRSensor, neonatal—somatic (<5 kg) with sensor cable
CNN/SNN	Disposable OxyAlert NIRSensor, neonatal—cerebral/somatic (<5 kg) with sensor cable
PMSENS71-A	Adult rSO ₂ sensor ²
5100C-PA	Preamplifier A with cable, channel 1 and 2, INVOS™ 5100C

REF number	Description
5100C-PB	Preamplifier B with cable, channel 3 and 4, INVOS™ 5100C
5100C-M-USA	Additional operator's manual, INVOS™ system (model 5100C)
4100-FTD	Field test device, INVOS™ system
5100C-RS	Roll stand, INVOS™ 5100C
5100C-SA	Swivel arm, INVOS™ 5100C
5100C-GCX	Mounting plate, INVOS™ 5100C
5100C-TC	Travel case, INVOS™ 5100C
5100C-USB	USB 2.0 flash drive, hi speed, INVOS™ 5100C
312170	Null modem cable (for digital output), INVOS™ system
VLI	VueLink™™ adapter cable (for connecting to Philips VueLink™™ Interface module), INVOS™ system

1. This reusable sensor cable enables use of the PMSENS71-A sensor with the INVOS™ 5100C. Check with your sales representative on availability in your region.
2. Must be used with the PMAC71RSC-L-CHn reusable sensor cables. Check with your sales representative on availability in your region.

Accessories can be ordered by contacting the Covidien customer service department at 800 635 5267, Customer.Service-RMS@covidien.com, or via the internet at www.covidien.com.

Figure 3-2. Side Connections



- 1 USB connector 
- 2 Preamplifier A, channel 1 and 2 connector   
- 3 Preamplifier B, channel 3 and 4 connector   

3.13 Preamplifier

The preamplifier provides an electrically isolated connection for the sensor.

Connect the 15 foot preamplifier cable to the side panel connection on the monitor. To do this, hold the connector at the end of the preamplifier cable with the red dot facing up. Align the red dot on the silver connector with the red dot on the side panel connection. Insert the cable connector into the side panel connection while keeping the dots aligned. Be sure to fully insert the connector until it locks. When using two preamplifiers, repeat this operation for the second preamplifier.



Caution:

Do not twist or bend the connector while inserting. The connector should be pushed straight in without need for excessive force.

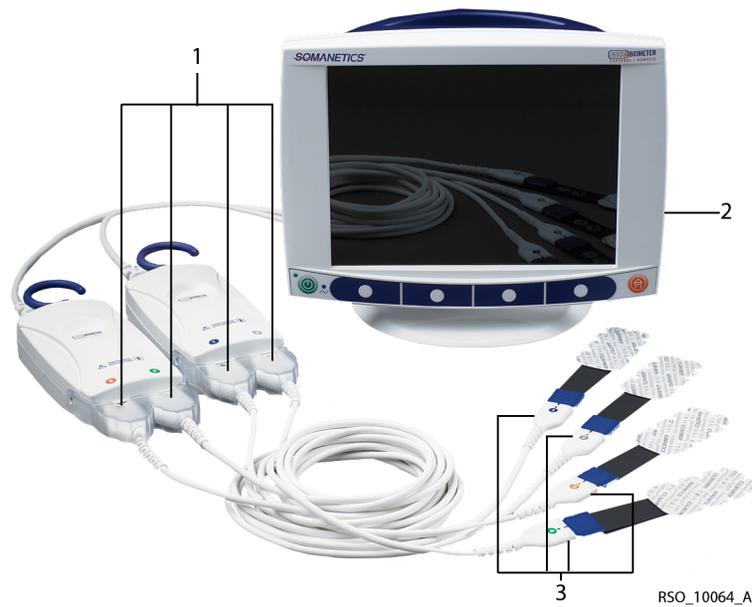
If the connector will not fully enter the side panel connection, remove it and examine for any defects in both components. If both components show no signs of damage, realign the dots and try again.

Caution:
Make sure all connectors are fully engaged and free from moisture. Moisture intrusion may cause inaccurate readings, erratic readings or no readings at all.

Caution:
Make sure that preamplifier A, channel 1 and 2, is connected to the upper input and preamplifier B, channel 3 and 4, is connected to the lower input.

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.

Figure 3-3. Preamplifiers, Reusable Sensor Cables, and Sensor Connections



- 1 Preamplifier to reusable sensor cable connection
- 2 Preamplifier cable to monitor connection
- 3 Sensors to reusable sensor cable connection

3.14 Reusable Sensor Cable

The reusable sensor cables are intended for multiple use and should not be discarded.

Connect the reusable sensor cables to the preamplifier (see [Figure 3-3](#)).



Caution:

Make certain to connect the sensor cables as follows: Cable 1 to the preamplifier connector marked 1, cable 2 to the preamplifier connector marked 2, cable 3 to the preamplifier connector marked 3, and cable 4 to the preamplifier connector marked 4.

To remove the reusable sensor cable, grip the connector while pulling straight out. Do not pull or twist the cable.

3.15 Adult and Pediatric Regional Saturation Sensor Application



(See section [3.16](#) for infant/neonatal OxyAlert NIRSensor application.)



Caution:

Sensors do not need to be removed for x-ray or CT scan. However, sensors will appear on image. Sensors must be removed for MRI.

3.15.1 Sensor Preuse Check



WARNING:

The disposable INVOS™ adult regional saturation sensor and pediatric regional saturation sensor are designed for use with the INVOS™ system. Use of these sensors with any other device may compromise patient safety.

Remove the sensor from the package and examine for visual signs of damage. If any signs of damage are observed, select another sensor.

3.15.2 Sensor Lot Number

The sensor lot number appears on the individual sensor packaging.

3.15.3 Sensor Cerebral Site Selection

Select the sensor site on the right and left 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.

3.15.4 Sensor Somatic Site Selection

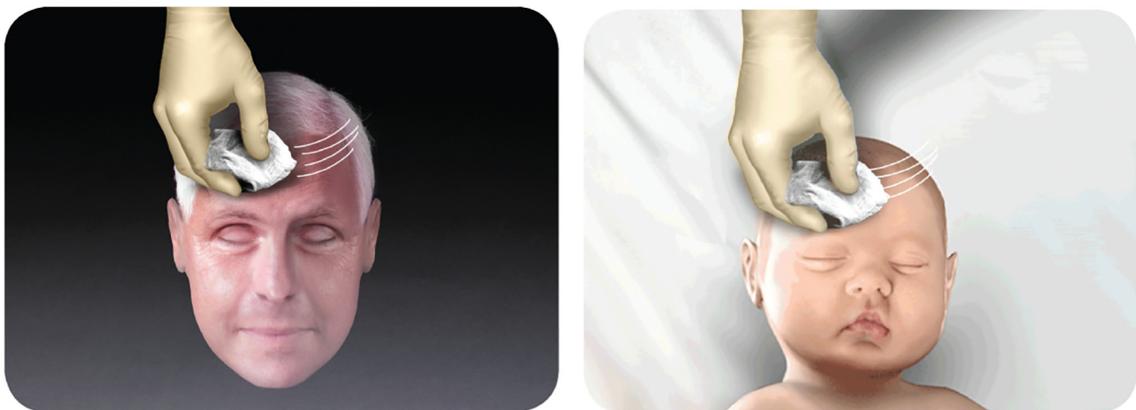
Select the sensor site over the tissue area of interest (site selection will determine which body region is monitored). Avoid placing the sensor over thick fatty deposits, hair, or bony protuberances. Do not place the sensor over nevi, hematomas, or broken skin, as this may cause readings that are not reflective of tissue or no readings at all. When two somatic site sensors are placed, they must be connected into the preamplifier. Sensor location is at the clinician's discretion, provided it adheres to the criteria noted on the instructions for use  inside carton. Placements may include the following locations:

- Over the spine (upper and lower)
- On the lateral or posterior calf
- The upper arm or leg
- On the forearm
- On the chest
- Posterior flank (T10-L2, right or left of midline)
- Abdomen

3.15.5 Patient Prep

Remove any moisture or perspiration from the patient's skin with a dry gauze pad. Then, degrease the skin. Ensure the patient's skin is completely dry and remove degreaser residue, if any, with a dry gauze pad.

Figure 3-4. Sensor Prep



RSO_10103_A

3.15.6 Sensor Placement

Remove the protective backing label from the adhesive side of the sensor and 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 to prevent light from entering (see [Figure 3-5](#) and sensor instructions for use  inside carton).

Secure the sensor cable to a fixed object to avoid strain on the sensor-to-skin interface using strain-relief clips.

Figure 3-5. Sensor Placement



RSO_10104_A



Caution:

To avoid pressure sores, do not apply external pressure (for example, headbands, wraps, tape) to the sensor.



Note:

EEG and level of consciousness monitoring can be used simultaneously with INVOS™ adult regional saturation or pediatric regional saturation sensors (overlapping sensor pads if necessary), provided they do not block the three optical windows on the sensor.



Note:

If space is limited, sensors may overlap, provided the three optical windows on each sensor pad remain unobstructed.



Note:

For extended monitoring, Covidien recommends using a new sensor every 24 hours.

3.15.7 Care of and Removing the Sensor

Although the sensor is a nonsterile, disposable item, it should be treated with proper care to prevent damage or data corruption.

To remove any sensor from the sensor cable, grip the blue sensor and cable connectors while pulling out. Do not pull on any cables. Avoid straining or twisting the reusable sensor cable.



Caution:

Use care when removing the sensor from the patient. If difficult to remove, follow your institution's patient care protocol to prevent damage to the patient's skin.

Commercially available adhesive solvents include the following items:

- Uni-solve, Smith and Nephew, Hull, United Kingdom, telephone: 01482 673204 or wound.smithnephew.com/uk/
- Detachol, Ferndale Laboratories, Inc., Ferndale, Michigan, U.S.A., telephone: 248 548 0900 or www.ferndalelabs.com
- 3M Remover Lotion, 3M Health Care, telephone: +31 071 5450450 in the Netherlands, +01 30 31 82 82 in France, 02 9498 9333 in Australia, 08705 360036 in the United Kingdom, or www.3M.com/healthcare

3.16 Infant/Neonatal OxyAlert NIRSensor Sensor Application

(See section 3.15 for adult and pediatric sensor application)



Caution:

Sensors do not need to be removed for x-ray or CT scan. However, sensors will appear on image. Sensors must be removed for MRI.

3.16.1 OxyAlert NIRSensor Preuse Check



WARNING:

The disposable OxyAlert NIRSensor has a small adhesive pad and a gentle hydrocolloid adhesive. It is designed for use with pediatric/neonatal patients monitored with the INVOS™ system. Use of the OxyAlert NIRSensor with any other device may compromise patient safety.



Caution:

Use care when placing or removing sensor. Do not place on broken or undeveloped skin.

Remove the sensor from the package and examine for visual signs of damage. If any signs of damage are observed, select another OxyAlert NIRSensor.

3.16.2 OxyAlert NIRSensor Lot Number

The OxyAlert NIRSensor lot number appears on the individual sensor packaging.

3.16.3 OxyAlert NIRSensor Cerebral Site Selection

Select the 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.

3.16.4 OxyAlert NIRSensor Somatic Site Selection

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 are not reflective of tissue or no readings at all. When two somatic site sensors are placed, they must be connected into the preamplifier. Sensor location is at the clinician's discretion, provided it adheres to the criteria noted on the instructions for use  inside carton. Placements may include the following locations:

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

3.16.5 Patient Prep

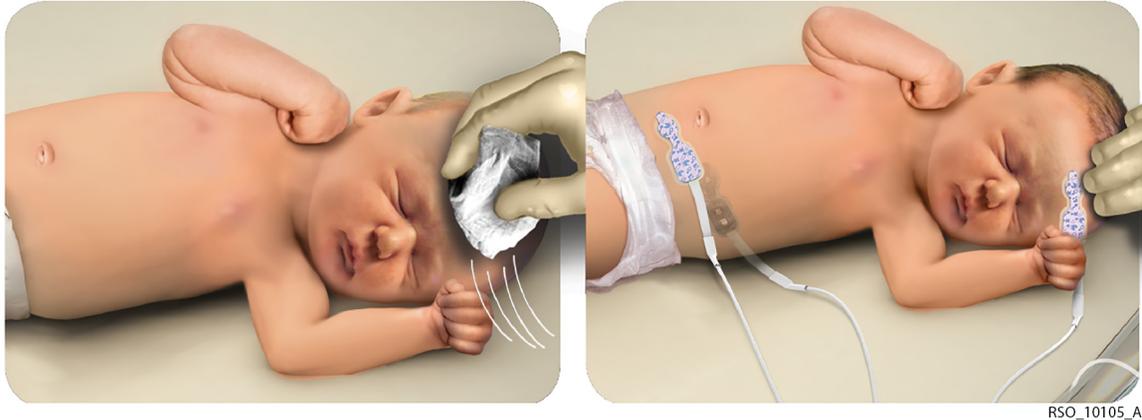
To achieve optimum adhesion, the patient's skin must be clean and dry.

3.16.6 OxyAlert NIRSensor Placement

Holding the cable, peel back the white liner from the thin, clear adhesive beginning at the point where the cable meets the sensor pad. 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 (see [Figure 3-6](#). and sensor instructions for use  inside carton).

Figure 3-6. OxyAlert NIRSensor Placements: Cerebral, Flank, and Abdominal Shown



Caution:

To avoid pressure sores, do not apply external pressure (for example, headbands, wraps, tape) to the sensor.



Note:

Periodically check skin integrity according to your institution's patient care policy. After the sensors are removed or peeled back to check skin, be sure sensor is properly resealed to skin to avoid light entering. For extended monitoring, Covidien recommends using a new sensor every 24 hours or if the adhesive is inadequate to seal the sensor to the skin.

3.16.7 Monitoring with the OxyAlert NIRSensor



Note:

The OxyAlert NIRSensor is a disposable sensor with sensor cable that connects directly to the preamplifier. There are no reusable sensor cables in this configuration.

Plug the sensor cable into the preamplifier 9-pin connector. Make sure that the wide side of the 9-pin connector on the sensor's cable is positioned toward the wide side of the 9-pin female connector of the 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. Calibration is automatic and monitoring will begin in seconds.

Status messages on the INVOS™ system screen will appear if monitoring conditions are compromised.

3.16.8 Care of and Removing the OxyAlert NIRSensor

Although the OxyAlert NIRSensor is a disposable item, it should be treated with proper care to prevent damage or data corruption.

To remove the sensor from the preamplifier, grip the sensor cable connectors while pulling out. Do not pull on any cables. Avoid straining or twisting the sensor cable.



Caution:

Use care when removing the sensor from the patient. If difficult to remove, follow your institution's patient care protocol to prevent damage to the patient's skin.

3.17 When INVOS™ System is Part of a Medical Monitoring System

When the INVOS™ system is connected to other equipment, such as a PC, external VGA monitor, or other medical monitoring system, the whole system shall provide the following items:

- Within the patient environment, the level of safety equivalent to a medical system in compliance with IEC 60601-1-1
- Outside the patient environment, the level of safety equivalent to equipment complying with their respective IEC or ISO safety standards

Within the patient environment, it is essential to reduce the enclosure leakage currents of the whole system. The reduction measures may include the following items:

- Additional protective earthed parts
- A separation transformer in compliance with IEC 61558:1997 sub clause 5.12

Do not use a multiple portable socket outlet without a separation transformer. If used, the interruption of its protective earthing may result in enclosure leakage current equal to the sum of the individual leakage current.

The system integrator is responsible for complying with IEC 60601-1-1 "General Requirements for Safety"—Collateral Standard "Safety Requirements for Medical Electrical Systems" (see clause 19.201 and table BBB 201).



Note:

The USB port cannot be used for connecting to external equipment.

Page Left Intentionally Blank

4 Quick Setup

4.1 Overview

This chapter briefly describes the setup of the INVOS™ regional saturation patient monitoring system (see also Chapter 1 *Introduction*, Chapter 3 *Installation*, and Chapter 6 *Operation* for complete instructions).

4.2 Initial Setup

1. Plug in the INVOS™ system monitor to a power source.



Note:

The blue  LED illuminates to indicate the power is connected and the battery is charging. If the blue light is not on, turn the back panel master (mains) power switch on.

2. Connect the preamplifier or preamplifiers to the monitor. Align the red dot on the preamplifier cable silver connector with the red dot on side panel input connection. Insert the cable connector into the side panel connection while keeping the dots aligned. Be sure to fully insert the connector until it locks.

Figure 4-1. Connecting the Preamplifier to the Monitor



3. Connect the reusable sensor cable connectors to the preamplifier or preamplifiers. Use the color coding.

Figure 4-2. Connecting the Sensor Cable Connectors to the Pre-amplifier



Note:

OxyAlert NIRSensor sensors connect directly to the preamplifier and do not use the reusable sensor cable (applies to steps 3 and 4).

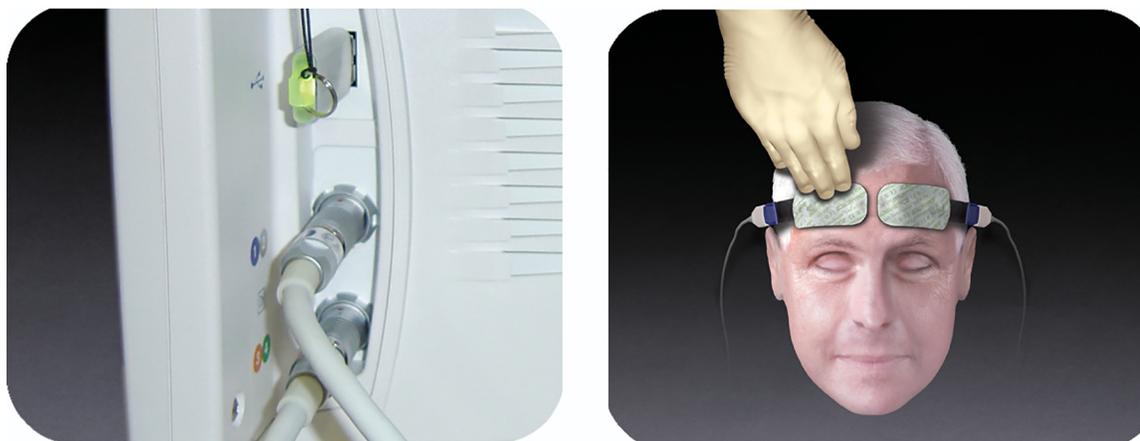
4. Attach the sensors to the reusable sensor cables. Hold the connectors. (The sensor cable can be connected to sensors before or after placement). Different INVOS™ system sensors (adult, pediatric, and infant/neonatal) cannot be used on the same monitor. (See sensor instructions for use ⓘ inside carton.)

Figure 4-3. Connecting the Sensors to the Sensor Cables



5. Connect any optional accessories, including the Covidien USB flash drive.

Figure 4-4. Connecting Optional Accessories



RSO_10034_A

**Note:**

The USB flash drive should be inserted when the case begins to capture real-time data to the USB. Keep the USB flash drive inserted for the full duration of the case. If removed, there will be gaps in the case data collected. Regardless of USB flash drive usage, the INVOS™ system will monitor and store data to its internal memory, so entire cases can be downloaded in the “case history” format (see section 7.3 *Using the USB Port*).

As a reminder to insert the USB, the blinking message “USB flash drive not connected” will appear on the Start screen when the system is turned on. USB flash drives not supplied by Covidien may not meet system requirements. Additional drives may be ordered from Covidien (see section 3.12 *Accessories*).

6. Check the location of all cables connected to the INVOS™ system. Make sure that the patient is not lying on any cables or connectors. To prevent entanglement and prolonged contact with patient skin, you can secure the reusable sensor cables with the strain-relief clips attached to the cables. Do not place the reusable sensor cables, preamplifiers, or cables connecting the preamplifiers to the monitor in contact with the patient.
7. Turn the power on by selecting the green ON/OFF  key.
8. After displaying the Welcome screen, the INVOS™ system performs a 10-second self-test, stopping at the Start screen, and shows the software version, date and time.
9. If necessary, set the DATE/TIME by following the options menus. The date and time may only be changed from the Start screen.
10. Press NEW PATIENT. Monitoring begins.

**Note:**

Avoid contact with the digital output port while operating the INVOS™ system. For the location of the digital output port, see *Figure 3-1*.

Page Left Intentionally Blank

5 Screens

5.1 Overview

The INVOS™ regional saturation patient monitoring system shows the following different screens, which the operator can access using the navigation bar:

- Welcome
- Start
- Patient identifier
- Main
- User configuration
- Event mark list
- Baseline reset warning
- Channel inactivity warning
- RS-232 digital output format selection
- Tabular trends
- Case archive file list
- Review

For more information about additional AUC and Database operational mode (to collect cerebral oximetry metrics for submission to the STS adult cardiac surgery database) database screens, see Chapter 8 *Database Operational Mode and Area Under the Curve*.

5.1.1 Welcome Screen

The Welcome screen is displayed, followed by a 10-second self-test after pressing the ON/OFF  key.

Figure 5-1. Welcome Screen



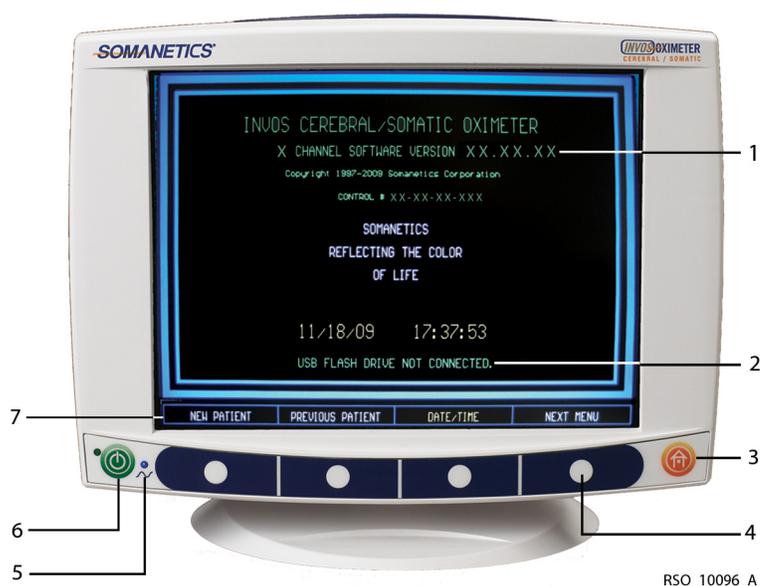
5.1.2 Start Screen, Navigation Bar, Key Panel and Software Version

The Start screen displays the software version, date, time, and operator-selectable navigation bar. For each screen, the navigation bar is displayed at the bottom of the screen and above the corresponding menu key. The operator selects the desired menu option by pressing the white menu keys or the HOME key on the key panel.

The INVOS™ system software version appears where XX.XX.XX is shown in [Figure 5-2](#).

The message "USB FLASH DRIVE NOT CONNECTED" will blink on the Start screen if the USB flash drive is not inserted or fully engaged. The operation of the INVOS™ system will occur with or without the USB flash drive connected. However, for real-time data collection to the USB flash drive, it must be connected prior to beginning a case.

Figure 5-2. Start Screen, Navigation Bar, Key Panel and Software Version



- | | | | |
|---|--|---|--|
| 1 | Software version | 5 | Blue  LED, AC power, and charge indicator |
| 2 | Reminder to connect the USB flash drive | 6 | ON/OFF (stand-by)  key |
| 3 | HOME  key | 7 | Navigation bar (menu options) |
| 4 | Menu keys | | |

New Patient/Previous Patient

Select NEW PATIENT to begin monitoring a new case. New patient data files are created.

Select PREVIOUS PATIENT to continue monitoring. When pressing PREVIOUS PATIENT within 24 hours of the last power down, all patient data is restored and monitoring of the same patient continues.



Note:

The informational message “RESTORING PATIENT DATA” appears when selecting PREVIOUS PATIENT and there is a large amount of data to recall.



Note:

After any power interruption, the monitor restores the previously set user configuration values and retains the trend data for the current patient.

5.1.3 Patient Identifier Screen

The Patient identifier screen allows for storing in memory the individual patient medical record number or name. The identifier allows the operator to locate the stored files when using the Case archive function or AUC and Database operational mode.

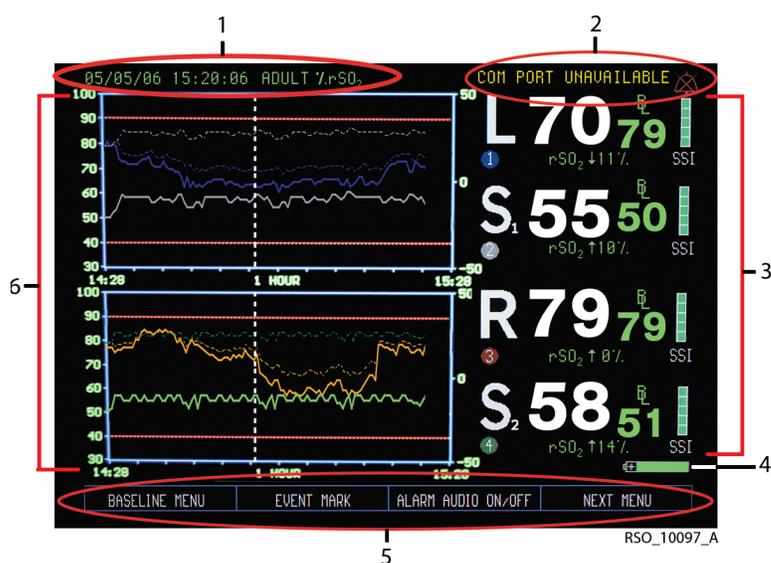
Figure 5-3. Patient Identifier Screen



5.1.4 Main Screen

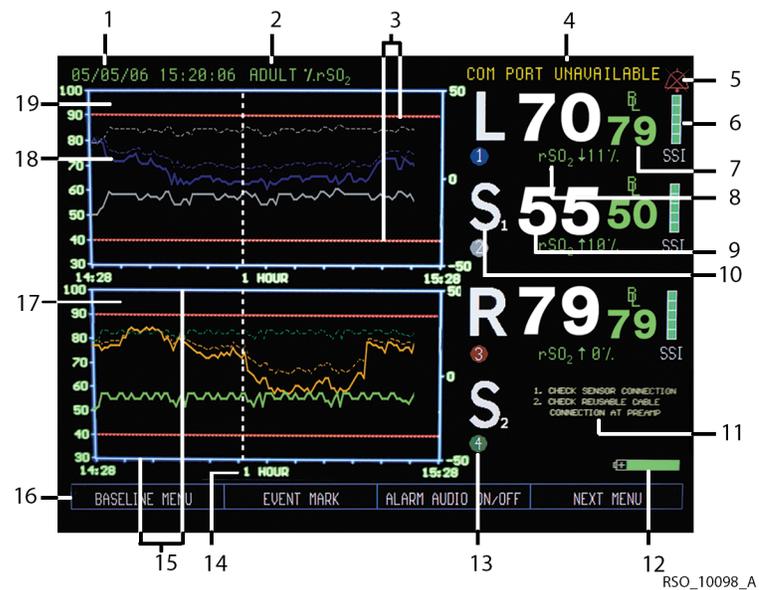
The Main screen is composed of several elements. These include real-time rSO₂ values, trend data, system status, alarm limits and messages, rSO₂ limits, the date, and time. It also displays navigation bar options for the baseline parameter, event marking, audible alarms, and other default parameters.

Figure 5-4. Main Screen Elements (Two-Channel Monitoring)



- | | | | |
|---|---|---|-------------------------------|
| 1 | Date/time and operating status messages area | 4 | Battery symbol |
| 2 | Alarm messages and symbol area | 5 | Navigation bar (menu options) |
| 3 | Data channel area (data channel label, rSO ₂ values, baseline, SSI, status messages) | 6 | Trend data graph area |

Figure 5-5. Main Screen (Four-Channel Monitoring)



1	Date and time	11	Monitoring status messages
2	Adult, pediatric, or neonatal indication for sensor model	12	Battery power status
3	Upper and lower alarm limits	13	Channel indicator 
4	Alarm status message	14	Time scale, in hours; selectable up to 24 hours
5	Alarm symbol	15	rSO ₂ trend (high and low) scale
6	Signal strength indicator	16	Menu options (navigation bar)
7	rSO ₂ baseline and symbol	17	Trend data graph (for data channels 3 and 4)
8	rSO ₂ relative (%) change from baseline, updated continuously while monitoring	18	Event mark line and numerical code
9	Real-time rSO ₂ values, updated continuously while monitoring	19	Trend data graph (for data channels 1 and 2)
10	Data channel label (for example, L: left cerebral, R: right cerebral, S: somatic)		

**Note:**

The data in the data channel area is updated every 5–6 seconds. The data in the graph area is updated every 30 seconds.

5.1.5 User Configuration Screen

The User configuration screen consists of two pages, displaying settings for parameters that the operator can change, such as alarms and scales (see section 6.5 *Run Function (Patient Monitoring) in Normal Mode*). Alarm messages, channel identification, and rSO₂ area elements will continue to be displayed.

Figure 5-6. User Configuration Screen (Page 1)



Figure 5-7. User Configuration Screen (Page 2)



5.1.6 Event Mark List Screen

An event mark may be stored in memory and displayed on the screen to mark significant events. A vertical dashed line and event code will appear on the Main screen at the event time, and an event code will appear in the event mark column of the Tabular trends screen, digital output, or USB flash drive output data (see section 6.5.2 *Event Mark*).

There are four event mark lists to choose from: OR, ICU, vascular, and NICU. White events reflect relatively routine occurrences. 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.

Only one list is “in use” at a time. The list may be changed in the User configuration menu (see section 6.5.8 *Event Mark List*).

Figure 5-8. Event Mark List Screen (OR Event Mark List)

```
OR EVENT MARK LIST
 1 Miscellaneous          21 Afterload Reduction
 2 Set Baseline           22 Blood Transfusion
 3 Induction              23 Cardioversion
 4 Sternotomy             24 Cell Saver Blood
 5 Cannulate              25 Cerebral Perfusion On
 6 On CPB                 26 ECLS On
 7 Cross Clamp On        27 FFP / Platelets
 8 Cooling                28 Fluid/Volume Expander
 9 Cardioplegia          29 Hemoconcentrate / MUF
10 Warming                30 Inotrope
11 Cross Clamp Off       31 Increase Anesthetic
12 Off CPB                32 Increase CO2
13 Skin Closure          33 Increase FIO2
14 Arrhythmia            34 Increase Pump Flow
15 Circulatory Arrest    35 Paced
16 Hypocapnia            36 Reposition Cannula
17 Hypotension           37 Reposition Clamp
18 One Lung Ventilation  38 Reposition Head
19 Pump Flow Down        39 Reposition Heart
20 Reduced Venous Return 40 Vasopressor

NOTE: THE EVENT MARK CODE WILL APPEAR IN THE EVENT
      COLUMN OF THE USB FLASH DRIVE AND DIGITAL OUTPUTS.
```

RSO_10047_A

Figure 5-9. Event Mark List Screen (ICU Event Mark List)

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

NOTE: THE EVENT MARK CODE WILL APPEAR IN THE EVENT COLUMN OF THE USB FLASH DRIVE AND DIGITAL OUTPUTS.

RSO_10048_A

Figure 5-10. Event Mark List Screen (Vascular Event Mark List)

VASCULAR EVENT MARK LIST	
81 Miscellaneous	101 Balloon Inflated
82 Set Baseline	102 Balloon Deflated
83 Intubated	103 Blood Transfusion
84 Incision	104 EPD Deployed
85 Heparin Given	105 Fogarty Catheter In
86 Cannulate	106 FFP / Platelets
87 Clamp On Vessel	107 Hemostasis Device In
88 Suturing Vessel/Graft	108 IAB Catheter In/On
89 Clamp Off Vessel	109 IAB Catheter Out/Off
90 Decannulate	110 Increase Anesthetic
91 Extubated	111 Increase etCO2
92 Arrhythmia	112 Increase FiO2
93 Blood Loss	113 Shunt Flushed
94 Contrast Dye Injected	114 Shunt Open
95 Dissection	115 Shunt Repositioned
96 EEG Change	116 Stent Deployed
97 Hypotension	117 Thrombus Removed
98 Hypocapnia	118 Vasopressor
99 Shunt Clamped	119 Vasodilator
100 Thrombus Suspected	120 Vessel Repaired

NOTE: THE EVENT MARK CODE WILL APPEAR IN THE EVENT COLUMN OF THE USB FLASH DRIVE AND DIGITAL OUTPUTS.

RSO_10049_A

Figure 5-11. Event Mark List Screen (NICU Event Mark List)



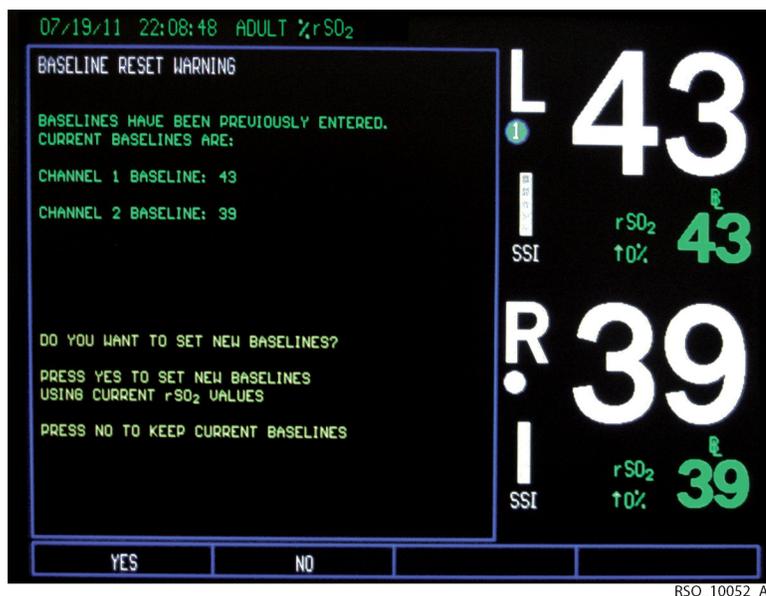
```
NICU EVENT MARK LIST
121 Miscellaneous
122 Set Baseline
123 Physical Assessment
124 Reposition Patient
125 Heel Stick/Lab Draw
126 Suction ET Tube
127 Weigh Patient
128 Enteral Feeding
129 Extubated-Intubated
130 Vent Change
131 Conventional Vent
132 Hi Frequency Vent
133 Bag Mask Vent
134 Hand Bag Vent
135 Sensor Change
136 Apnea/Bradycardia
137 Arrhythmia
138 Cardiac Arrest/CPR
139 ICP Changes
140 LOC Changes
141 Seizure
142 Anti-Arrhythmic
143 Anti-Epileptic
144 Blood Trans/Platelets
145 Cooling Cap On-Off
146 Dialysis/CRRT
147 ECLS On
148 ECLS Circuit Change
149 ECLS Off
150 Fluid Bolus
151 Fem Art CutDown
152 Hypothermia
153 Nitric Oxide On-Off
154 NG Tube In-Out
155 Paralytic
156 Prostaglandin
157 OR Procedure Bedside
158 Sedation
159 Vasopressor
160 Whole Body Cooling
NOTE: THE EVENT MARK CODE WILL APPEAR IN THE EVENT
COLUMN OF THE USB FLASH DRIVE AND DIGITAL OUTPUTS.
```

RSO_10050_A

5.1.7 Baseline Reset Screen

The Baseline reset screen is displayed when the operator attempts to reset a baseline after the baseline has been previously set either manually or automatically (see section [6.5.1 Baseline Set and Status](#)).

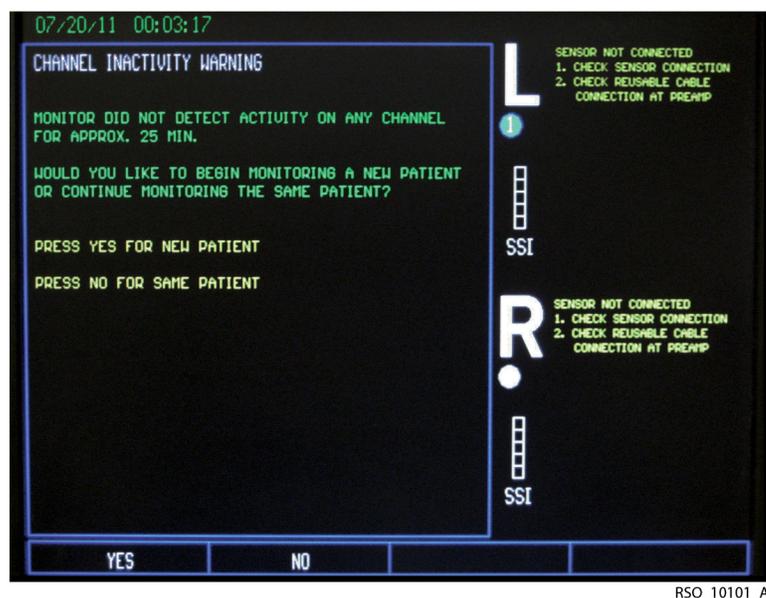
Figure 5-12. Baseline Reset Screen



5.1.8 Channel Inactivity Screen

The Channel inactivity screen is displayed if all channels are inactive for 25 minutes.

Figure 5-13. Channel Inactivity Screen



5.1.9 RS-232 Digital Output Format Selection Screen

The RS-232 digital output format selection screen is displayed to select the real-time and case history data output formats. The operator should select Output Formats 1–3 based on the personal computer, multi-parameter monitor or data collection system interface software (see section 7.5 *Data Output Formats*).

Figure 5-14. RS-232 Digital Output Format Selection Screen (Two-Channel Monitoring)

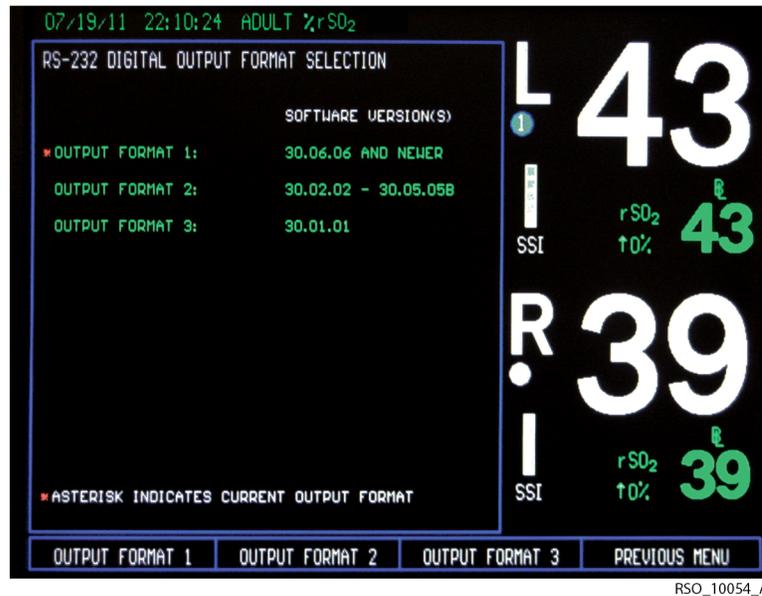


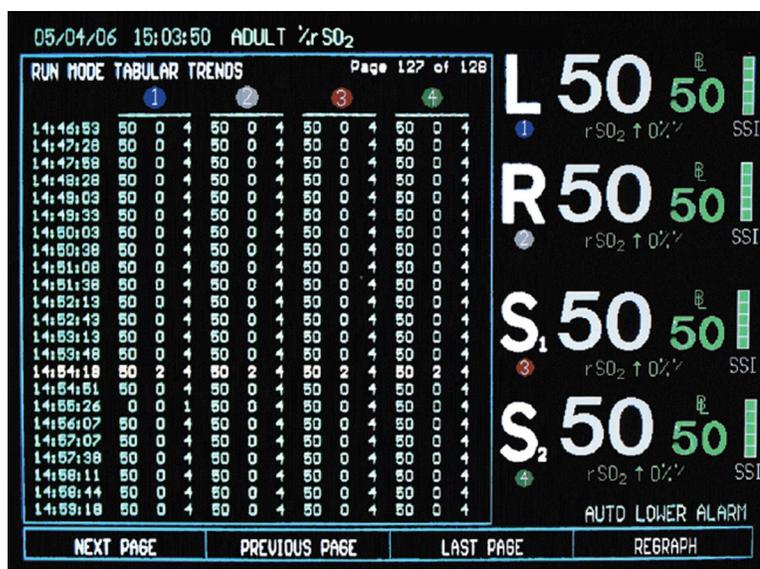
Figure 5-15. RS-232 Digital Output Format Selection Screen (Four-Channel Monitoring)



5.1.10 Tabular Trends Screen

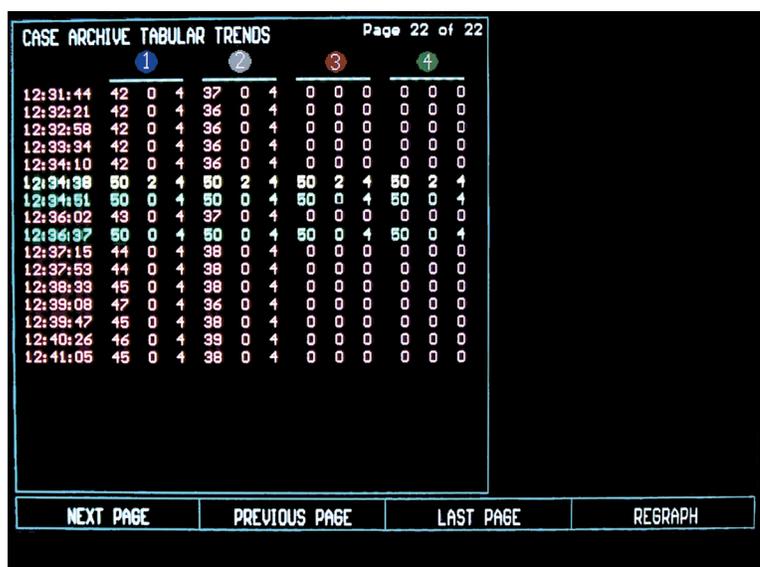
The Tabular trends screen displays stored data in a numerical, tabular format (see sections [6.5 Run Function \(Patient Monitoring\) in Normal Mode](#) and [6.6 Case Archive Function](#)). Alarm messages, channel identification, and rSO₂ area elements will continue to be displayed when operating in Run function.

Figure 5-16. Tabular Trends Screen—Run Function in Normal Mode



RSO_10056_A

Figure 5-17. Tabular Trends Screen—Case Archive Function in Normal Mode



RSO_10057_A

Figure 5-18. Tabular Trends Screen—Manual Set Baseline in Normal Mode

When displaying the Tabular trends screen, lines of data are color coded to increase visibility of marked events and baseline status. Yellow indicates an event mark. Red indicates a baseline status desaturation $\geq 20\%$ or ≤ 40 rSO₂ value. Tabular trends are displayed in multiple pages of 23 lines of data each (see [Table 5-1](#)).

Table 5-1. Tabular Trends Line of Data Format

	1			2			3			4		
Time	rSO ₂	Event code	Status code	rSO ₂	Event code	Status Code	rSO ₂	Event code	Status code	rSO ₂	Event code	Status code

5.1.11 Case Archive File List Screen

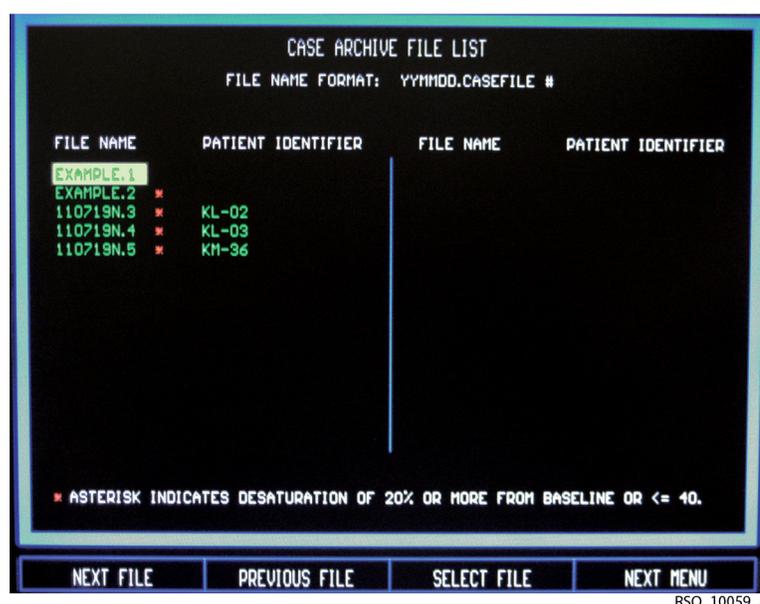
The Case archive file list screen allows the operator to select stored case history data files to review. The Case archive file list screen is displayed in Case archive function (see section [6.6 Case Archive Function](#)).



Note:

The Case archive list screen will display only the cases with four-channel monitoring when the configuration is for four channels, respectively, it will display only the cases with two-channel monitoring when the configuration is two channel.

Figure 5-19. Case Archive File List Screen



Data File Name Format

Stored 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 function, C = control, I = intervention) and a file extension consisting of a sequence number. For example, a CASE HISTORY file recorded on September 13, 2009 in Normal run function would have a filename of 090913N.1. An asterisk (*) indicates a desaturation of $\geq 20\%$ from baseline or ≤ 40 rSO₂ values occurred during the case.

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.

Stored case data files can be viewed on screen or downloaded (see sections [6.5.16 Real-Time Review](#), [6.6 Case Archive Function](#), [7.3 Using the USB Port](#), and [7.4 Using the Digital Output Port](#)).

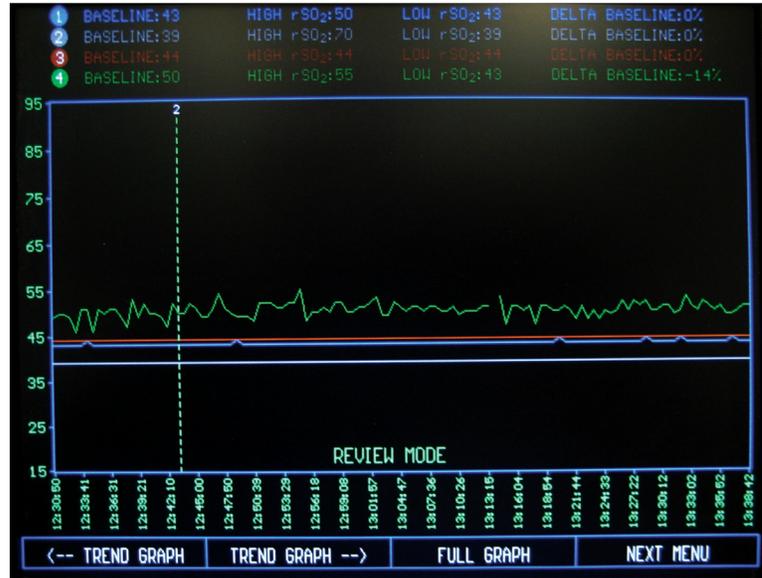
5.1.12 Review Screen

The Review screens display stored real-time (Run function) and case history (Case archive function) data in trend graph and tabular trend formats (see sections [6.5 Run Function \(Patient Monitoring\) in Normal Mode](#) and [6.6 Case Archive Function](#)).

When reviewing in trend graph format, the "REVIEW MODE" message will appear at the center of the graph indicating that the reviewed trend data is not displayed in real-time. No data channel area elements will be displayed when in Case archive function (as it is in the Main screen, for real-time format). The trend graph will be displayed as a full screen.

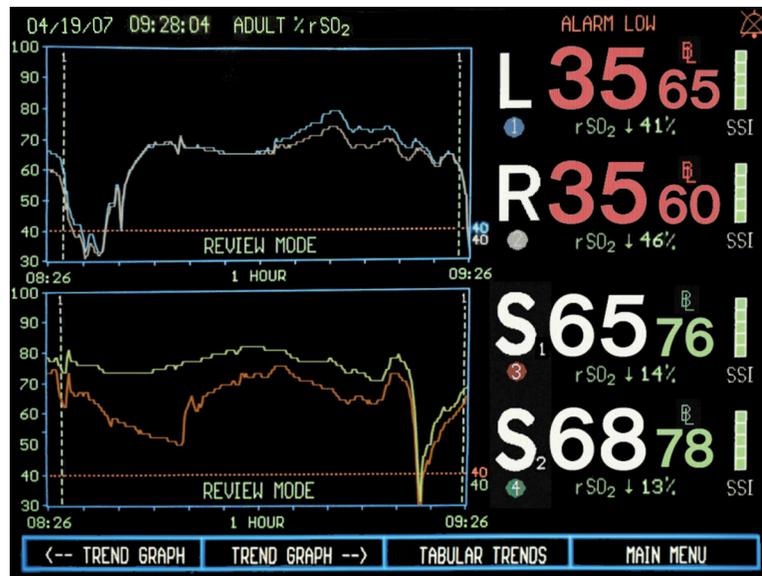
In Real-time review—tabular trends approximately 28 hours of data will be temporarily stored until the unit is turned off. When the case memory is full, the oldest line of data will be deleted to make room for newer line of data.

Figure 5-20. Trend Graph Screen—Case Archive Function in Normal Mode



RSO_10060_A

Figure 5-21. Trend Graph Screen—Run Function in Normal Mode



RSO_10102_A

6 Operation

6.1 Overview

This chapter provides instructions on how to change settings and operate the INVOS™ regional saturation patient monitoring system. Read this chapter completely before attempting to operate the system.

Prior to initial installation in a clinical setting, have a qualified service technician verify the performance of the INVOS™ system, including the alarms, per the service manual.

6.2 INVOS™ System Preuse Check

A visual inspection of the INVOS™ system and sensors must be performed prior to use. Visually inspect the parts, confirming the following conditions are met:

- The monitor enclosure and monitor should be clean and show no signs of damage.
- The power cord and preamplifier cable should show no signs of damage.
- The preamplifier should be clean and show no signs of damage.
- The pins of the reusable sensor cable connector should not be bent.
- The sensor should show no signs of damage.
- Check the location of all cables connected to the INVOS™ system. Make sure that the patient is not lying on any cables or connectors. To prevent entanglement and prolonged contact with patient skin, you can secure the reusable sensor cables with the strain-relief clips attached to the cables. Do not place the reusable sensor cables, preamplifiers, or cables connecting the preamplifiers to the monitor in contact with the patient.

6.3 Operational Modes

The INVOS™ system operates in four modes. This manual primarily addresses normal and AUC and database modes.

Normal mode:

The Normal mode is for patient monitoring and reviewing cases stored in the INVOS™ system (see section [6.5 Run Function \(Patient Monitoring\) in Normal Mode](#) and [6.6 Case Archive Function](#)).

- Clinical study mode: The Clinical study mode (also known as Control mode) is for investigational use only. Contact Covidien customer service for additional information regarding Clinical study mode.
- AUC and database mode: The AUC and database mode is for patient monitoring, and collecting and downloading cerebral oximetry metrics for submission to the STS adult cardiac surgery database (see Chapter 8 *Database Operational Mode and Area Under the Curve*).
- Diagnostic mode: The Diagnostic mode is for technical service. Contact Covidien customer service for more information regarding this mode.



Note:

STS database users, see Chapter 8 *Database Operational Mode and Area Under the Curve*.

6.4 Date, Time, and Patient Identifier Settings

This section provides instructions for changing the date and time settings, and adding a patient identifier.



Note:

The date and time may only be changed from the Start screen prior to entering Run function.



Note:

A type-matic (repeat) function is active for navigation key menus that are repetitive (for example, Next). It allows the operator to navigate faster through the options by pressing and holding the Menu key.

6.4.1 Date

After the INVOS™ system is turned ON , perform the following menu options to change the **DATE**:

Day

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

Use the **INCREASE** or **DECREASE** options to adjust and change the day as necessary. Press **PREVIOUS MENU** again to return to the Start screen.

Month

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

Use the **INCREASE** or **DECREASE** options to adjust and change the month as necessary. Press **PREVIOUS MENU** again to return to the Start screen.

Year

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

Use the **INCREASE** or **DECREASE** options to adjust and change the year as necessary. Press **PREVIOUS MENU** again to return to the Start screen.

6.4.2 Time

After the INVOS™ system is turned ON , perform the following menu options to change the **TIME**:

Hours

NEW PATIENT	PREVIOUS PATIENT	DATE/TIME	NEXT MENU
DATE	TIME		PREVIOUS MENU
HOURS	MINUTES	SECONDS	PREVIOUS MENU
HOURS = XX	INCREASE	DECREASE	PREVIOUS MENU

Use the **INCREASE** or **DECREASE** options to adjust and change the hour as necessary. Press **PREVIOUS MENU** again to return to the Start screen.

Minutes

NEW PATIENT	PREVIOUS PATIENT	DATE/TIME	NEXT MENU
DATE	TIME		PREVIOUS MENU
HOURS	MINUTES	SECONDS	PREVIOUS MENU
MINUTES = XX	INCREASE	DECREASE	PREVIOUS MENU

Use the **INCREASE** or **DECREASE** options to adjust and change the minutes as necessary. Press **PREVIOUS MENU** again to return to the Start screen.

Seconds

NEW PATIENT	PREVIOUS PATIENT	DATE/TIME	NEXT MENU
DATE	TIME		PREVIOUS MENU
HOURS	MINUTES	SECONDS	PREVIOUS MENU
SECONDS = XX	INCREASE	DECREASE	PREVIOUS MENU

Use the **INCREASE** or **DECREASE** options to adjust and change the seconds as necessary. Press **PREVIOUS MENU** again to return to the Start screen.

6.4.3 Patient Identifier



Note:

The patient identifier can be stored or edited by inputting after the Start screen or at anytime during the run function.

A patient identifier allows the operator to locate stored data files with a unique alphanumeric identification when using the Case archive function or AUC and Database operational mode.

Entering Patient Identifier after Start Screen

After the INVOS™ system is turned ON , perform the following menu options to enter the unique patient identifier:

NEW PATIENT	PREVIOUS PATIENT	DATE/TIME	NEXT MENU
<-	->	NEXT ROW	SELECT
<-	->	NEXT ROW	SELECT

Select <-, ->, and **NEXT ROW** to scroll through the characters and **SELECT** to enter highlighted character. When entry is complete, select **DONE** in the Patient identifier entry screen to save the unique alphanumeric identification and display the Main screen.

Up to 24 alphanumeric characters may be entered.

Entering or Editing Patient Identifier in Run Function

To enter or edit a patient identifier, press the **HOME**  key to display the Main screen, then perform the following navigation bar options:

BASILINE MENU	EVENT MARK	ALARM AUDIO ON/OFF	NEXT MENU
OUTPUT SELECT	USER CONFIGURATION	TIME SCALE	NEXT MENU
REVIEW	PATIENT ID	PREVIOUS MENU	MAIN MENU
<-	->	NEXT ROW	SELECT
<-	->	NEXT ROW	SELECT

Select <-, ->, and **NEXT ROW** to scroll through the characters and **SELECT** to enter highlighted character. When entry is complete, select **DONE** in the Patient identifier entry screen to save the unique alphanumeric identification and display the Main screen.

Up to 24 alphanumeric characters may be entered.

6.5 Run Function (Patient Monitoring) in Normal Mode

The Run function is for real-time rSO₂ trend monitoring.

Once INVOS™ system components are connected and the system is on, select **NEW PATIENT** or **PREVIOUS PATIENT**. The monitor displays the Patient identifier screen followed by the Main screen and Run function (rSO₂ trending) begins (see sections [3.4 Installation](#), [3.15 Adult and Pediatric Regional Saturation Sensor Application](#), and [3.16 Infant/Neonatal OxyAlert NIRSensor Sensor Application](#)).



Note:

The informational message “RESTORING PREVIOUS PATIENT DATA” appears when selecting **PREVIOUS PATIENT** and there is a large volume of data to recall.

In Run function, the operator can set baseline status, mark an event, and adjust User configuration menu settings (see sections [6.5.3 Alarm Limits](#), [6.5.4 Alarm Volume](#), [6.5.5 rSO₂ Scale](#), [6.5.6 Time Scale in User Configuration Menu](#), [6.5.7 USB Storage Rate](#), [6.5.8 Event Mark List](#), [6.5.9 Data Channel Labels](#), [6.5.10 Color-Coded Data Channel Labels](#), [6.5.11 Two- or Four-Channel Monitoring](#), and [6.5.12 Restore Defaults](#)).

Both decreases and increases from baseline may signify dysfunction and developing pathology. Changes in rSO₂ values of ≥20% from baseline are considered clinically significant and cause for concern and possible interventions (see Appendix *B Clinical Studies*).



Note:

At start up, when selecting new patient or previous patient, the alarms for each channel become active only after a sensor has been connected. This is to prevent alarm conditions on an inactive channel or channels.



Note:

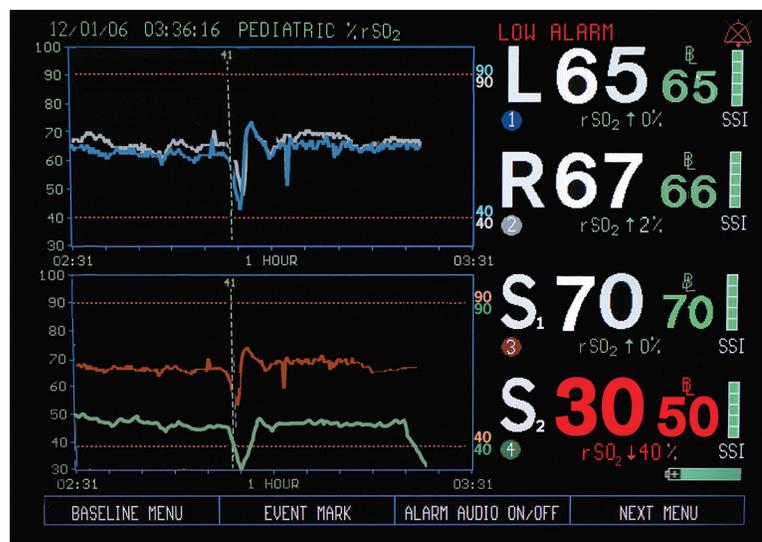
Separate sets of user configuration parameters are stored for two- and four-channel monitoring. Previous settings for two-channel monitoring will resume when this configuration is selected, and vice versa.



Note:

A type-matic (repeat) function is active for navigation key menus that are repetitive (for example, Next). It allows the operator to navigate faster through the options by pressing and holding the Menu key.

Figure 6-1. INVOS™ System in Normal Mode with Low Alarm



RSO_10106_A

6.5.1 Baseline Set and Status

An rSO₂ baseline should be set so subsequent rSO₂ changes from baseline can be measured. rSO₂ numbers will turn red if rSO₂ is above or below set alarm thresholds. Baseline status will turn red indicating a baseline status desaturation ≥20% or ≤40 rSO₂ value (see *Figure 6-1.*).

As soon as rSO₂ trend data begins to be gathered and patient condition is stable, an awake baseline reading should be obtained (for example, for surgical patients, prior to induction). A baseline

or baselines may be set for all channels in use at once, individually for a selected channel or channels and manually to a previous rSO₂.

Set Current rSO₂ as Baseline for All Channels

To set a baseline, press the HOME  key to display the Main screen, then perform the following navigation bar options:

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

The baseline value or values will be set at the current rSO₂ value or values and the menu will return to the Main screen. This will display an event mark line and code on the screen in the graph of each channel. The baseline value or values will not be saved if the INVOS™ system is turned off.



Note:

If a baseline cannot be set preinduction, it is recommended that a desaturation threshold be set using the manual baseline feature.

Set Individual Channels to Current rSO₂ Baseline

Set Individual Channels to Current rSO₂ Baseline—Two-Channel Monitoring

To set an individual channel baseline, press the HOME  key to display the Main screen, then perform the following navigation bar options:

BASELINE MENU	EVENT MARK	ALARM AUDIO ON/OFF	NEXT MENU
SET BASELINES	SET CHANNEL	MANUAL SET	PREVIOUS MENU
CHANNEL 1 SET	CHANNEL 2 SET	PREVIOUS MENU	MAIN MENU

Select the channel or channels to set the baseline at the current rSO₂ value. This will display an event mark line and code on the screen in the graph area for the individual channel only.

When finished, press the HOME  key to exit the Baseline menu and return to the Main screen.

Set Individual Channels to Current rSO₂ Baseline—Four-Channel Monitoring

To set an individual channel baseline, press the HOME  key to display the Main screen, then perform the following navigation bar options:

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

Select the channel or channels to set the baseline at the current rSO₂ value. This will display an event mark line and code on the screen in the graph area for the individual channel only.

When finished, press the HOME  key to exit the Baseline menu and return to the Main screen.

Manually Set to Previous rSO₂ Value Baselines



WARNING:

When using the manual set baseline feature, the baseline values will be reflected on the screen and in the case history file. To capture the new baseline on the USB drive or digital output, the case should be downloaded in case history, before turning off the monitor, immediately at the completion of the case (see section [Case History Data to USB Flash Drive for Downloading Case Data at the End of a Case](#)). If the case runs overnight and the manual set baseline is set to a time corresponding to the previous day, the manual set baseline is not displayed in the case history of the previous day.

The manually set baseline feature is used when previous rSO₂ values are to be set as baselines (for example, an awake baseline was forgotten to be set prior to induction). The Manual baseline set screen will appear as tabular rSO₂ data. To select and manually set previous rSO₂ values, press the HOME  key to display the Main screen, then perform the following navigation bar options:

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

Select **NEXT PAGE**, **PREVIOUS PAGE**, or **LAST PAGE** to review pages of rSO₂ 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, perform the following navigation bar options:

NEXT PAGE	PREVIOUS PAGE	LAST PAGE	SCROLL MENU
NEXT	PREVIOUS	SELECT BASELINES	PREVIOUS MENU

Select **NEXT** or **PREVIOUS** to scroll to the desired line of rSO₂ data, then **SELECT BASELINES** to manually set the baseline.

On the Main screen, the manually set baselines will be displayed in the graph area for each channel.

Baseline Reset

If baselines have already been entered and an operator selects **SET BASELINE**, a Baseline reset menu will be displayed:

YES	NO		
-----	----	--	--

Select **YES** to set a new baseline or baselines using current rSO₂ values or select **NO** to restore to the previously set baseline setting or settings (see section [5.1.7 Baseline Reset Screen](#)).

When changing the sensors or if the sensors were disconnected and reconnected, the baselines previously set will automatically be restored.

6.5.2 Event Mark

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 appear at that time in the line of tabular trends screen or stored and outputted data.

There are four event mark lists to choose from: OR, ICU, vascular, and NICU. White events reflect relatively routine occurrences during surgery or ICU recovery. 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.

To mark an event, press the HOME  key to display the Main screen, then perform the following navigation bar options:

BASELINE MENU	EVENT MARK	ALARM AUDIO ON/OFF	NEXT MENU
<--- --->	NEXT EVENT	PREVIOUS EVENT	SELECT EVENT

From the event mark list, select **NEXT EVENT** and **PREVIOUS EVENT** to highlight the desired event code or description. <---|---> can be used to toggle between the two columns of events. Select **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 (see [Table 6-1](#), [Table 6-2](#), [Table 6-3](#), and [Table 6-4](#)).

Table 6-1. Event Codes and Descriptions for Operating Room

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

RSO_10067_A

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.

Table 6-2. Event Codes and Descriptions for Intensive Care Unit

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

RSO_10066_A

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.

Table 6-3. Event Codes and Descriptions for Vascular Application

VASCULAR EVENT MARK LIST	
81 Miscellaneous	101 Balloon Inflated
82 Set Baseline	102 Balloon Deflated
83 Intubated	103 Blood Transfusion
84 Incision	104 EPD Deployed
85 Heparin Given	105 Fogarty Catheter In
86 Cannulate	106 FFP / Platelets
87 Clamp On Vessel	107 Hemostasis Device In
88 Suturing Vessel/Graft	108 IAB Catheter In/On
89 Clamp Off Vessel	109 IAB Catheter Out/Off
90 Decannulate	110 Increase Anesthetic
91 Extubated	111 Increase etCO2
92 Arrhythmia	112 Increase FiO2
93 Blood Loss	113 Shunt Flushed
94 Contrast Dye Injected	114 Shunt Open
95 Dissection	115 Shunt Repositioned
96 EEG Change	116 Stent Deployed
97 Hypotension	117 Thrombus Removed
98 Hypocapnia	118 Vasopressor
99 Shunt Clamped	119 Vasodilator
100 Thrombus Suspected	120 Vessel Repaired

RSO_10068_A

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.

Table 6-4. Event Codes and Descriptions for Neonatal Intensive Care Unit

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

RSO_10069_A

White events reflect relatively routine occurrences in the environment. 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.

6.5.3 Alarm Limits



WARNING:

Do not set alarm limits to extreme values that can render the INVOS™ system ineffective. Ensure alarm limits are appropriate for each patient.

Alarm limits can be set and adjusted in the User configuration menu.



Note:

Alarm limits are stored in the INVOS™ system nonvolatile memory. They will reappear as the operator set them when the INVOS™ system is rebooted.



Note:

The upper and lower alarm limits for each channel are not allowed to cross. When being increased, the lower alarm limit is allowed to bump the upper alarm limit higher until it reaches 5 units below the upper

rSO₂ scale limit. When being decreased, the upper alarm limit is allowed to bump the lower alarm limit until it reaches 5 units above the lower rSO₂ scale limit.

Upper Alarm Limits

To manually change the upper alarm limit settings, press the HOME  key to display the Main screen, then perform the following navigation bar options:

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

In the User configuration menu, under UPPER ALARM LIMITS, select **ON** then **NEXT** to scroll to the channel or channels to be changed. Select the **INCREASE** and **DECREASE** options to adjust the upper alarm value or values.

When finished, press the HOME  key to exit the User configuration menu and return to the Main screen. On the Main screen, the new alarm limit is displayed (numerical and graphical).

The upper alarm limits may be turned on or off according to operator preference:

- The default setting is **OFF**.
- To disable the visual and audible **UPPER ALARM LIMITS**, select **OFF**.
- To enable the visual and audible **UPPER ALARM LIMITS**, select **ON**.

Auto Lower Alarm Limits

The lower alarm limits may be set automatically. Each lower alarm limit will be independently set to the percentage below baseline (variance) at the time of setting a baseline.



Note:

When the Auto lower alarm is activated, the “Auto Lower Alarm” message appears in the lower right corner of the screen. If the system is operating on battery backup, the “Auto Lower Alarm” message will not appear on the screen.

To automatically set lower alarm limits, press the HOME  key to display the Main screen, then perform the following navigation bar options:

BASILINE MENU	EVENT MARK	ALARM AUDIO ON/OFF	NEXT MENU
OUTPUT SELECT	USER CONFIGURATION	TIME SCALE	NEXT MENU
NEXT	PREVIOUS	OFF	ON
NEXT	PREVIOUS	MANUAL	AUTO

In the User configuration menu, select **NEXT** to scroll to **LOWER ALARM LIMITS** and select **AUTO**. Select **NEXT** to scroll to the channel or channels to be changed, and **INCREASE** and **DECREASE** options to adjust the variance value or values. The options for percentage below baseline are 5% to 30%.

When finished, press the HOME  key to exit the User configuration menu and return to the Main screen. On the Main screen, the new alarm limit is displayed (numerical and graphical).



Note:

The INVOS™ system will remain in Auto lower alarm mode with the selection of a new patient. However, the lower alarm limits when selecting a new patient are set to default=40 prior to baseline capture.



Note:

If the variance value or values are changed for a channel subsequent to setting the baseline, the lower alarm limit for the corresponding channel will be automatically changed to reflect the change in the variance value.

Manual Lower Alarm Limits

To manually change the lower alarm limits, press the HOME  key to display the Main screen, then perform the following navigation bar options:

BASILINE MENU	EVENT MARK	ALARM AUDIO ON/OFF	NEXT MENU
OUTPUT SELECT	USER CONFIGURATION	TIME SCALE	NEXT MENU
NEXT	PREVIOUS	OFF	ON
NEXT	PREVIOUS	MANUAL	AUTO
NEXT	PREVIOUS	INCREASE	DECREASE

In the User configuration menu, select **NEXT** to scroll to **LOWER ALARM LIMITS** and select **MANUAL**. Use the **INCREASE** and **DECREASE** options to adjust the alarm limit. The lower alarm limit range is 15–90.

When finished, press the HOME  key to exit the User configuration menu and return to the Main screen. On the Main screen, the new alarm limit is displayed (numerical and graphical).

6.5.4 Alarm Volume

To change the alarm volume, press the HOME  key to display the Main screen, then perform the following navigation bar options:

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

In the User configuration menu, select **NEXT** to scroll to **ALARM VOLUME**. Use **INCREASE** and **DECREASE** options to adjust the volume.

When finished, press the HOME  key to exit the User configuration menu and return to the Main screen.

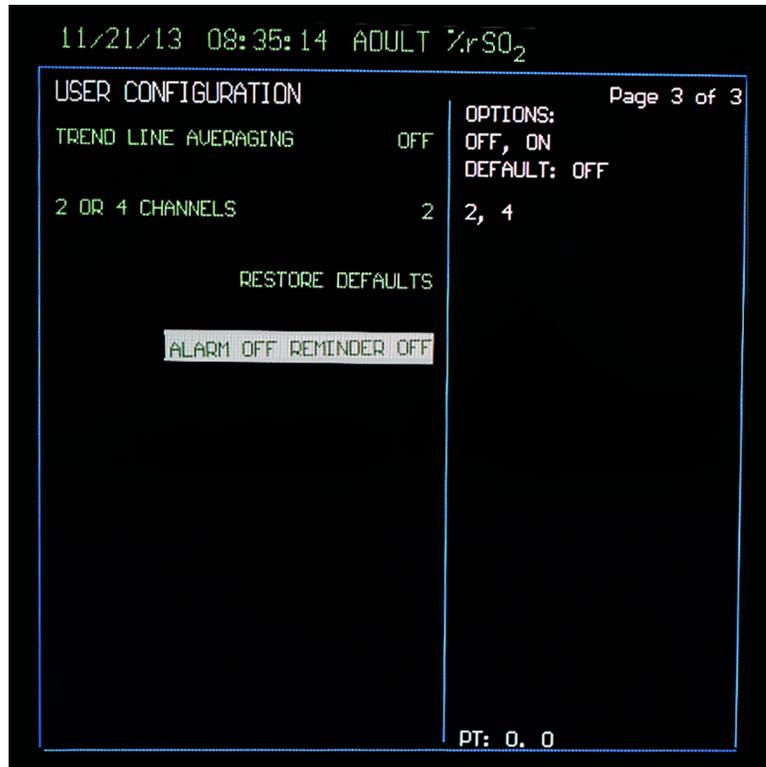
Alarm Audio Off Reminder

When this feature is enabled, the monitor emits a beep (longer than the low priority alarm tone) every 3 minutes while alarms are muted. When the monitor turns on, the feature is disabled.

By default, the Alarm audio off reminder is set to OFF.

To turn the Alarm audio off reminder on:

1. Navigate to page 3 of the User configuration screen.
2. Continue pressing **NEXT** until **ALARM OFF REMINDER OFF** is highlighted.



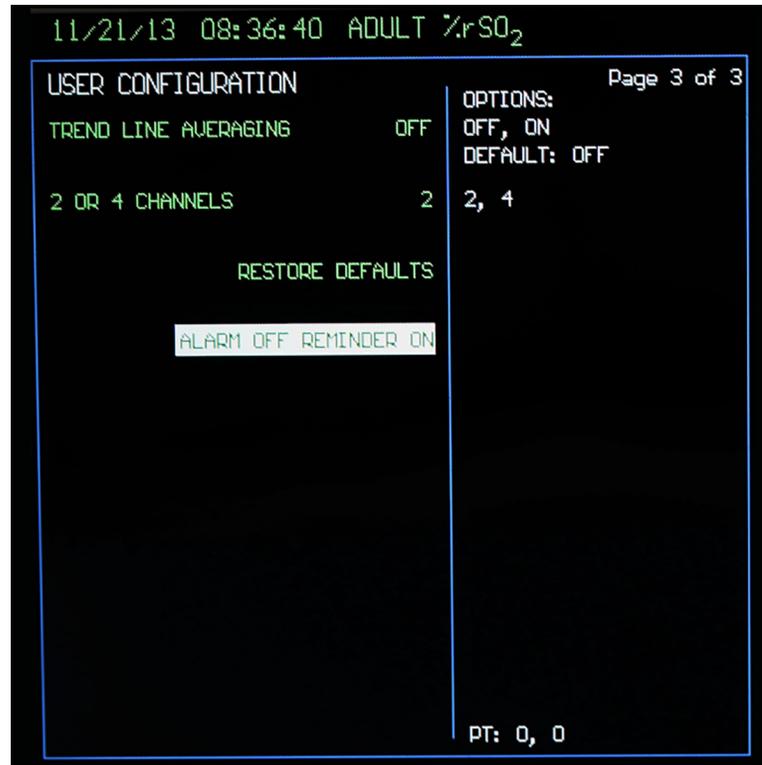
RSO_10024_A

3. Press key #3 five times.



RSO_10025_A

The indication changes to ALARM OFF REMINDER ON.



RSO_10026_A

4. Press the HOME  key to save changes.

To turn the Alarm audio off reminder off:

1. Navigate to page 3 of the User configuration screen.
2. Continue pressing **NEXT** until **ALARM OFF REMINDER ON** is highlighted.
3. Press key #3 six times. The indication changes to **ALARM OFF REMINDER OFF**.
4. Press the HOME  key to save changes.

Absent further changes, the setting is retained until the monitor is turned off.

6.5.5 rSO₂ Scale

To change the rSO₂ value axis (y-scale) on the trend data graph, adjust the rSO₂ scale.



Note:

If the Upper alarm limit setting is on, the maximum upper rSO₂ scale is 5 rSO₂ points above the upper alarm limit setting. If the Upper alarm limit setting is off, the upper rSO₂ scale range is 60 to 100.

Upper rSO₂ Scale

To change the upper rSO₂ scale limit, press the HOME  key to display the Main screen, then perform the following navigation bar options:

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

In the User configuration menu, select **NEXT** to scroll to **UPPER rSO₂ SCALE**. Select the **INCREASE** and **DECREASE** options to adjust the scale.

When finished, press the HOME  key to exit the User configuration menu and return to the Main screen. On the Main screen, the upper rSO₂ scale limit is numerically displayed.

Lower rSO₂ Scale

To change the lower rSO₂ scale limit, press the HOME  key to display the Main screen, then perform the following navigation bar options:

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

In the User configuration menu, select **NEXT** to scroll to **LOWER rSO₂ SCALE**. Select the **INCREASE** and **DECREASE** options to adjust the scale.

When finished, press the HOME  key to exit the User configuration menu and return to the Main screen. On the Main screen, the lower rSO₂ scale limit is numerically displayed.

6.5.6 Time Scale in User Configuration Menu



Note:

For quicker access to parameters on page 2 of the User configuration menu, select **PREVIOUS** to wrap around from the top to bottom of page 1, then select **NEXT**  to access page 2.

The time scale may be adjusted in the Time scale menu or the User configuration menu. To change the hours viewed (x-scale) of rSO₂ values plotted on the trend data graph, adjust the time scale.

To adjust the time scale in the User configuration menu, press the HOME  key to display the Main screen, then perform the following navigation bar options:

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

In the User configuration menu, select **NEXT** to scroll to **TIME SCALE**. Select the **INCREASE** and **DECREASE** options to adjust the time scale. The time scale range options are: 1, 2, 4, 8, 12, and 24 hours. The default time scale is 1 hour.

When finished, press the HOME  key to exit the User configuration menu and return to the Main screen. On the Main screen, the time scale limit is numerically displayed.

6.5.7 USB Storage Rate



Note:

The USB flash drive should be inserted when the case begins to capture real-time data to the USB. Keep the USB flash drive inserted for the full duration of the case. If removed, there will be gaps in the case data collected. Regardless of USB flash drive usage, the INVOS™ system will monitor and store data to its internal memory, so entire cases can be downloaded in the case history format (see section 7.3 *Using the USB Port*).

USB flash drives not supplied by Covidien may not meet system requirements. Additional drives may be ordered from Covidien (see section 3.12 *Accessories*).



Note:

For quicker access to parameters on page 2 of the User configuration menu, select **PREVIOUS** to wrap around from the top to bottom of page 1, then select **NEXT** to access page 2.

To adjust the USB storage rate, press the HOME  key to display the Main screen, then perform the following navigation bar options:

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

In the User configuration menu, select **NEXT** to scroll to **USB STORAGE**. Select the **INCREASE** and **DECREASE** options to adjust the storage rate. The time scale range options are: 5, 30, and 60 seconds. The default rate is 5 seconds (see section [7.3 Using the USB Port](#)).

When finished, press the HOME  key to exit the User configuration menu and return to the Main screen.

6.5.8 Event Mark List



Note:

For quicker access to parameters on page 2 of the User configuration menu, select **PREVIOUS** to wrap around from the top to bottom of page 1, then select **NEXT** to access page 2.

An OR event mark list, ICU event mark list, vascular event mark list or NICU event mark list may be set for the user to mark events during the case. To determine which event mark list appears in Run function, press the HOME  key to display the Main screen, then perform the following navigation bar options:

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

In the User configuration menu, select **NEXT** to scroll to **EVENT MARK LIST**. Select the **INCREASE** and **DECREASE** options to choose the appropriate list.

When finished, press the HOME  key to exit the User configuration menu and return to the Main screen. When accessing the event mark option from the Main screen, the set list should appear.

6.5.9 Data Channel Labels



Note:

For quicker access to parameters on page 2 of the User configuration menu, select **PREVIOUS** to wrap around from the top to bottom of page 1, then select **NEXT** to access page 2.

To assist in identifying sensor site locations, data channel labels are displayed in Run function.

To change a data channel label, press the HOME  key to display the Main screen, then perform the following navigation bar options:

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

In the User configuration menu, select **NEXT** to scroll to **CHANNEL LABELS**. Select the **INCREASE** and **DECREASE** options to choose characters (for example, A-Z, S1, S2, S3, S4).

When finished, press the HOME  key to exit the User configuration menu and return to the Main screen. On the Main screen, characters appear to the left of the real-time rSO₂ value.

6.5.10 Color-Coded Data Channel Labels



Note:

For quicker access to parameters on page 2 of the User configuration menu, select **PREVIOUS** to wrap around from the top to bottom of page 1, then select **NEXT** to access page 2.

The option to change the data channel colors on the Main screen (to match channel indicators or the preamplifiers and sensor cables) can be selected in the User configuration menu. To change the color-coded labels, press the HOME  key to display the Main screen, then perform the following navigation bar options:

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

In the User configuration menu, select **NEXT** to scroll to **COLOR CODED LABELS**. Select **YES** or **NO**.

When finished, press the HOME  key to exit the User configuration menu and return to the Main screen.

6.5.11 Two- or Four-Channel Monitoring

When using just one preamplifier, specify two-channel monitoring. When the system is set to two-channel monitoring, only channels 1 and 2 appear on the screen, and only the top preamplifier port (1 and 2) is active. To use two preamplifiers, you must specify four-channel monitoring to enable all channels to appear on the screen.



Note:

The INVOS™ system must be restarted for this change to take place.



Note:

Separate sets of user configuration parameters are stored for two- and four-channel monitoring. Previous settings for two-channel monitoring will resume when this configuration is selected, and vice versa.



Note:

For quicker access to parameters on page 2 of the User configuration menu, select **PREVIOUS** to wrap around from the top to bottom of page 1, then select **NEXT** to access page 2.

To change the software version from two- to four-channel monitoring, press the HOME  key to display the Main screen, then perform the following navigation bar options:

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

In the User configuration menu, select **NEXT** to scroll to **2 OR 4 CHANNELS**. Select the **INCREASE** and **DECREASE** options to choose the number of channels monitored and displayed. Press the ON/OFF  key twice to restart the system. When the monitor has returned to Run function, the number of channels selected should be displayed.

6.5.12 Restore Defaults

The Restore defaults function sets many user configuration settings to their factory default values.

To access the Restore defaults function:

1. Navigate to page 3 of the User configuration screen.
2. Continue pressing **NEXT** until **RESTORE DEFAULTS** is highlighted.
3. Press the RESTORE key.
4. Press the HOME  key to save settings.



Note:

For quicker access to parameters on page 2 of the User configuration menu, select **PREVIOUS** to wrap around from the top to bottom of page 1, then select **NEXT** to access page 2.

Restore defaults affects the following settings:

- rSO₂ alarm limit and alarm volume settings
 - Upper alarm limits are set to OFF
 - Lower alarm limits are set to MANUAL at 40
 - Alarm volume is set to MEDIUM
- rSO₂ and time scales
 - Upper RSO₂ scale is set to 100
 - Lower rSO₂ scale is set to 30
 - Time scale is set to 1 HOUR
- USB storage rate (set to every 5 seconds)
- Event mark list (set to OR)
- Channel labels and color coding
 - Channel 1 is set to L
 - Channel 2 is set to R
 - Color-coded labels is set to NO
- AUC settings (normal mode AUC is set to OFF)
- Trend line averaging (set to OFF)

Restore defaults does not affect the following settings:

- Date
- Time
- Language
- Number of channels (two or four)
- Control mode
- Intervention mode
- Database features
- Digital output enable
- Digital output format
- Alarm audio ON/OFF
- Alarm audio off reminder
- Settings for the channel count that is not currently selected



Note:

Changing the number of channels and restarting the monitor brings up the last saved user configuration settings for the new number of channels. To restore defaults for both two-channel and four-channel operation, change the number of channels, restart the monitor, and repeat the Restore defaults procedure.

6.5.13 Alarms and Status Messages

Alarms are visual and audible. Alarm messages and tones alert the INVOS™ system operator of a condition in the patient or the INVOS™ system requiring attention. Upon alarm, the operator should check the patient's condition first to determine the cause of alarm. Sensor attachment to the patient, upper and lower alarm limits, battery capacity, and other messages that may appear on the screen should be verified to validate the alarm condition.

Visual communication of parameter values and alarms is visible by an operator with 20/20 vision (corrected as necessary) from a distance of 1 meter when the monitor is placed in an environment with ambient light in the range of 100 to 1500 lux and the operator's position is anywhere on or within the base of a cone subtended by an angle of 30° normal to the center of the plane of display of the monitor. Visual communication of parameter alarm priority is visible under the same conditions from 4 meters.

**Note:**

Physiological alarms and technical alarms related to the sensor (POOR SIGNAL QUALITY, EXCESSIVE LIGHT, INTERFERENCE DETECTED, SENSOR NOT CONNECTED, REPLACE SENSOR, SENSOR UNUSABLE) may be delayed by up to 5 seconds. PREAMP NOT CONNECTED, USB STORAGE FULL, USB STORAGE ERROR, COM PORT UNAVAILABLE, and PRINTER UNAVAILABLE have no inherent delay. AUTO BASELINE SET occurs after 5 minutes of monitoring without a baseline; there is no additional delay to generate the alarm. BATTERY LOW is based on a measurement of battery voltage, which depends on the age and condition of the battery; there is no additional delay once the condition is detected.

Physiological Alarms

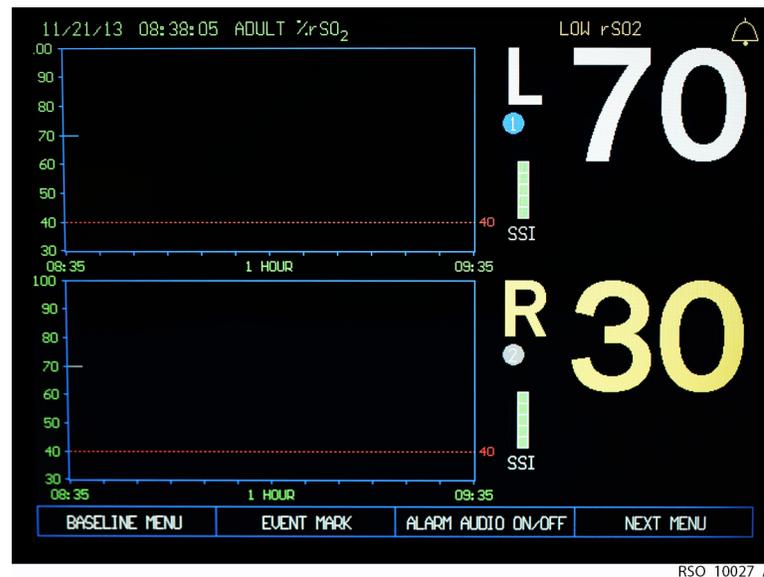
Physiological alarm conditions arise from a change in the patient's condition. Upon an alarm, the patient should be profiled immediately.

The following alarm conditions are physiological (medium priority):

- High rSO₂: the rSO₂ value in any channel is at or above the upper limit
- Low rSO₂: the rSO₂ value in any channel is at or below the lower limit

When the rSO₂ exceeds the upper or lower alarm limits, the INVOS™ system alerts the operator to this condition. Physiological alarms are presented by flashing the channel label, displaying a bell symbol in the upper right corner, and indicating the alarming rSO₂ value in yellow, as shown in [Figure 6-2](#).

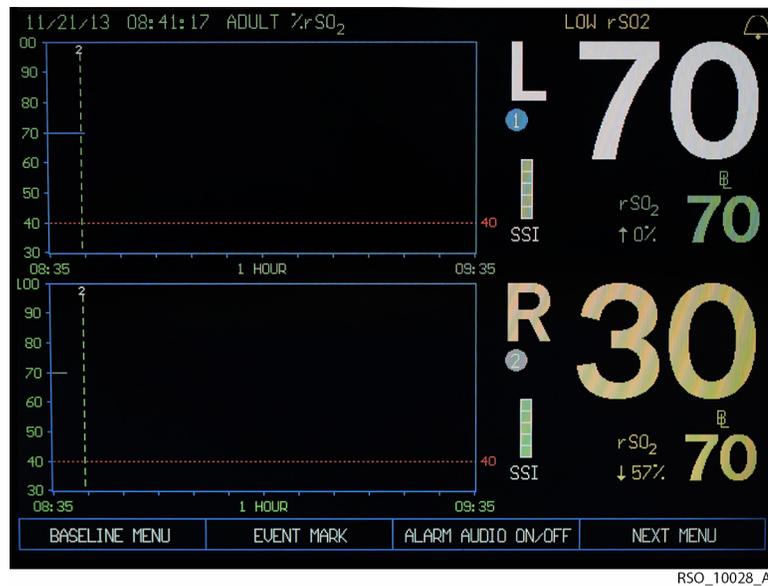
Figure 6-2. rSO₂ Alarm Indicated



RSO_10027_A

If the rSO_2 should drop below the baseline threshold, the baseline and percentage change are shown in yellow, as in [Figure 6-3](#).

Figure 6-3. rSO_2 Below Baseline



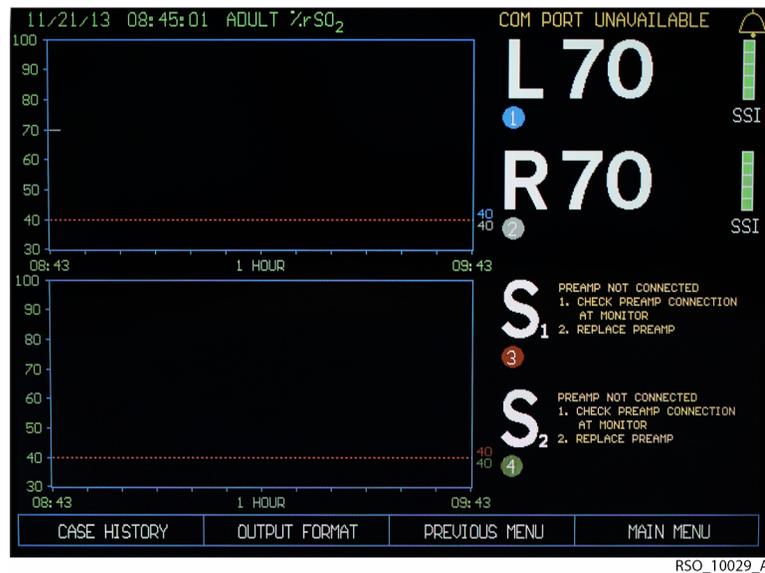
In addition to the visual indicator, a repeated series of tones is generated (see section [A.2.6 Alarm Tone Definitions](#)). The alarm is nonlatching; that is, if the condition passes the alarm will automatically reset (see section [6.5.4 Alarm Volume](#)).

During a physiological alarm condition, trend data continues to be gathered.

Technical Alarms

Technical alarm conditions arise from conditions related to the equipment. Technical alarms are presented with a message in yellow, either in place of the rSO_2 value or as a message in the upper right corner of the screen, as shown in [Figure 6-4](#).

Figure 6-4. Technical Alarm Indicated



The following conditions are medium-priority technical alarms:

- Preamp not connected: one or both preamplifiers are disconnected
- Sensor not connected: one or more sensors are disconnected, or a reusable cable is disconnected
- Poor signal: signal quality is too low for a reliable measurement; check sensor placement
- Excessive light: an ambient light source is affecting the quality of the measurement; check sensor placement, cover sensor if needed
- Interference detected: an electromagnetic interference source such as an electrosurgical unit is affecting the quality of the measurement; remove the interference or move the sensor
- Replace sensor: both adult and infant/neonatal sensors are connected, or sensor is damaged or defective; make sure that only sensors appropriate for the patient are in use
- Sensor unusable: the sensor has reached the end of its useful life (seen only on older monitors with older preamplifiers; new monitors do not present this condition)

The following conditions are low-priority technical alarms:

- Battery low: battery voltage is critically low, switch immediately to AC mains power to avoid an interruption in monitoring
- USB storage error: there is no compatible USB storage device connected
- Com port unavailable: the serial port device or its serial cable is disconnected
- Printer unavailable: the printer or its serial cable is disconnected
- Auto baseline set: 5 minutes of monitoring have elapsed without setting a baseline

There may be a delay of up to 5 seconds between the detection of an alarm condition and its presentation.

Battery Capacity Alarm Notification

Battery operation symbol/gauge —Appears in the lower right corner above the navigation bar when the INVOS™ system is operating on battery power. When using A/C power, no battery symbol appears. The symbol fill indicates approximate battery capacity. The “BATTERY LOW” message and alarm tone accompanies the depleted battery/symbol gauge if the battery power is critical. Plug into A/C power or turn on the master (mains) switch on the monitor back. The battery has an approximate 20 minute operation capacity. Recharge time from 50% discharge to full charge is approximately 20 hours and from 100% discharge to full charge is approximately 24 hours.

Alarm Tones

Medium-Priority Alarms

If audio alarms are not muted, when a medium-priority alarm condition is present, the monitor issues a medium-priority alarm tone. The alarm tone is a burst of three short beeps on the same pitch, repeated at 9 second intervals until the alarm condition is resolved. Medium-priority alarm conditions are listed in [Physiological Alarms](#) and [Technical Alarms](#).

Low-Priority Alarms

If audio alarms are not muted and no medium-priority alarm condition is present, when a low-priority alarm condition is present, the monitor issues a low-priority alarm tone. The alarm tone is a single beep, repeated at 16 second intervals while the corresponding visual alarm is presented. Low-priority conditions are listed in [Technical Alarms](#).

Silencing Audible Alarms

To silence audible alarms, press the HOME  key to display the Main screen, then select the **ALARM AUDIO ON/OFF** option.



Caution:

Selecting the ALARM AUDIO ON/OFF option will silence the audible alarms permanently until reactivated or until the INVOS™ system is rebooted.

A bell  appears in the upper right corner of the screen. To activate alarms again when channels are silenced, select the **ALARM AUDIO ON/OFF** option from the Main screen.

Status Codes

Status codes are numbers associated with specific conditions that are displayed in the Tabular trends screen as lines of data in Run function and Case archive function (see section [5.1.10 Tabular Trends Screen, Table 5-1.](#) , [Table 6-5.](#) and [Table 6-6.](#)). The status codes help the user to identify alarm and status message conditions and troubleshoot the system setup.

Alarms and Status Messages with rSO₂ Values Displayed

During normal monitoring situations when rSO₂ values are being displayed, alarm and status messages may appear at the top of the Main screen. Actions in [Table 6-5.](#) are listed to assist the operator to try to correct a problem, if necessary. Additional operating indications to assist the user will appear on the screen at the right of the corresponding affected channel label indicator (for example, two-digit rSO₂ values turn yellow when below baseline desaturation threshold).

Table 6-5. Status Messages—rSO₂ Value Displayed

Status message	Status code	Color, location	Cause	Action
ALARM HIGH accompanied by alarm tone	5	Red, top right; corresponding rSO ₂ value is red	Upper alarm limit is exceeded.	Profile patient.
ALARM LOW accompanied by alarm tone	6	Red, top right; corresponding rSO ₂ value is red	Lower alarm limit is exceeded.	Profile patient.
BATTERY LOW accompanied by alarm tone	9	Yellow, top right	Battery power is critical.	Plug in A/C power and turn master (mains) switch on.
COM PORT UNAVAILABLE	12	Yellow, top right	Output device not connected.	Check connections with Com port device (PC).
PRINTER UNAVAILABLE	13	Yellow, top right	Printer not connected.	Check connections with Com port device (PC), power connection, and online status.
USB FULL	20	Yellow, top right	USB flash drive memory is full.	Insert a blank flash drive.
USB STORAGE ERROR	14	Yellow, top right	USB flash drive error.	Check USB flash drive connection. Insert a flash drive.
DATE AND TIME	N/A	Green, top left	N/A	N/A
ADULT, PEDIATRIC OR NEONATAL	N/A	Green, top center	Adult, pediatric, or infant/neonatal application dependent on sensor model used.	N/A

Table 6-5. Status Messages—rSO₂ Value Displayed (Continued)

Status message	Status code	Color, location	Cause	Action
SYSTEM SIGNAL OK	4	No text message displayed on screen	SSI at full strength	See section 9.8.5 Troubleshooting Signal Strength Indicator (SSI) for SSI unstable and less than full strength.

Alarms and Messages without rSO₂ Values Displayed

During situations when rSO₂ values cannot be calculated, status messages may appear in place of the rSO₂ values at the right of the corresponding affected channel label indicator. Actions in [Table 6-6](#) are listed to assist the operator to try to correct a problem.

Table 6-6. Status Messages—rSO₂ Value Not Displayed

Status message	Status code	Cause	Action
SENSOR NOT CONNECTED accompanied by alarm tone	1	Disconnect at preamplifier or sensor (patient). No rSO ₂ value will appear.	Check sensor to reusable sensor cable connection. Check sensor cable connection to the preamplifier.
EXCESSIVE LIGHT accompanied by alarm tone	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	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	11	Preamplifier is not connected to the INVOS™ system 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	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. Sensor has reached the end of its useful life.	Check that all sensor models in use match. Connect new sensor. Replace reusable sensor cable.

Table 6-6. Status Messages—rSO₂ Value Not Displayed (Continued)

Status message	Status code	Cause	Action
INTERFERENCE DETECTED accompanied by alarm tone	19	Noise corrupting rSO ₂ data (for example, electrocautery).	Move or turn off source of interference. Normal operation of the INVOS™ system will resume when the excessive noise stops.
SENSOR UNUSABLE	22	Sensor has reached the end of its useful life.	Connect new sensor.



Caution:

Make sure all connectors are fully engaged and free from moisture. Moisture intrusion may cause inaccurate readings, erratic readings or no readings at all.

Channel Inactivity

When no rSO₂ values are displayed for 25 minutes, the Channel inactivity will alert. Situations causing this would be all channels showing a “SENSOR NOT CONNECTED” or “PREAMP NOT CONNECTED” status message.

If the Channel inactivity warning “**WOULD YOU LIKE TO BEGIN MONITORING A NEW PATIENT OR CONTINUE MONITORING THE SAME PATIENT?**” is displayed, perform the following navigation bar options:

YES	NO		
-----	----	--	--

Select **YES** to begin a new patient (previous patient case data will be stored) or select **NO** to continue monitoring the patient.

6.5.14 Signal Strength Indicator (SSI)



The signal strength indicator (SSI) reflects the strength and stability of the signal that is used to make an rSO₂ measurement. The SSI depends on physiological factors (different from individual to individual) and possible disturbances from secondary sources/influences in the monitor’s environment.

The SSI scale ranges from one to five bars, with five bars being the highest. Generally, the SSI symbol will read five bars. However, rSO₂ values displayed on-screen with one through four stable SSI bars are also reliable. It just means the rSO₂ values are being generated from a signal intensity that is lower than normal (see section [9.8.5 Troubleshooting Signal Strength Indicator \(SSI\)](#)).

SSI at full strength (five bars) is displayed in tabular trends lines of data (Run function and Case archive function) as the status code 4 (see sections [9.8.5 Troubleshooting Signal Strength Indicator \(SSI\)](#), [5.1.10 Tabular Trends Screen](#) and [Table 5-1](#)).

The SSI bar shows as empty for a disconnected sensor.

6.5.15 Time Scale

The trend graph time scale may be adjusted in the Time scale menu or the User configuration menu. To change the hours viewed (x-scale) of rSO₂ values plotted on the trend data graph, adjust the time scale.

To adjust the time scale without having to use the User configuration menu, press the HOME  key to display the Main screen, then perform the following navigation bar options:

BASELINE MENU	EVENT MARK	ALARM AUDIO ON/OFF	NEXT MENU
OUTPUT SELECT	USER CONFIGURATION	TIME SCALE	NEXT MENU
SCALE HOURS = XX	INCREASE	DECREASE	MAIN MENU

Select the **INCREASE** and **DECREASE** options to adjust the time scale. The time scale range options are: 1, 2, 4, 8, 12 and 24 hours. The default time scale is 1 hour.

When finished, select **MAIN MENU** or press the HOME  key and return to the Main screen. On the Main screen, the time scale limit is numerically displayed.

6.5.16 Real-Time Review

Real-time review allows the operator to review the most recent 24 hours of stored data trends and event marks on the monitor. The data may be displayed in graphical (trend data graph) or tabular trend screen format. The stored trending rate is two per minute.

In Real-time review—tabular trends, approximately 28 hours of data will be temporarily stored until the unit is turned off. When the case memory is full, the oldest line of data will be deleted to make room for newer line of data.

Real-Time Review—Graphical Format



Note:

More than 1 hour of data must be stored to activate trend graph review. Data can only be reviewed in 1 hour increments.



Note:

Alarm messages, channel identification, and rSO₂ area elements will continue to be displayed while in Real-time review.

To use Real-time review in graphical format, press the HOME  key to display the Main screen, then perform the following navigation bar options:

BASILINE MENU	EVENT MARK	ALARM AUDIO ON/OFF	NEXT MENU
OUTPUT SELECT	USER CONFIGURATION	TIME SCALE	NEXT MENU
REVIEW	PATIENT I.D.	PREVIOUS MENU	MAIN MENU
<- TREND GRAPH	TREND GRAPH ->	TABULAR TRENDS	MAIN MENU

Select the **<- TREND GRAPH** or **TREND GRAPH ->** options to scroll across the trend lines on the screen.

When reviewing is completed, press the HOME  key or **MAIN MENU** to exit Real-time review and return to the Main screen.

When reviewing in graphical format during a case, a message in yellow may be displayed in the upper area of the graphs to alert for the following causes: "USB STORAGE ERROR", "USB STORAGE FULL", and "COM PORT UNAVAILABLE." This message will appear until the error is corrected and the screen is refreshed.

Run Function—Tabular Trends Screen Format



Note:

Alarm messages, channel identification, and rSO₂ area elements will continue to be displayed while in real-time review.

To use Real-time review in tabular trends screen format, press the HOME  key to display the Main screen, then perform the following navigation bar options:

BASILINE MENU	EVENT MARK	ALARM AUDIO ON/OFF	NEXT MENU
OUTPUT SELECT	USER CONFIGURATION	TIME SCALE	NEXT MENU
REVIEW	PATIENT I.D.	PREVIOUS MENU	MAIN MENU
<- TREND GRAPH	TREND GRAPH ->	TABULAR TRENDS	MAIN MENU
NEXT PAGE	PREVIOUS PAGE	LAST PAGE	REGRAPH

Select **NEXT PAGE**, **PREVIOUS PAGE**, and **LAST PAGE** to scroll through the data (see [Table 5-1](#)).

When reviewing is completed, select **REGRAPH** to exit Tabular trends and return to the Real-time review trend graph.

NEXT PAGE	PREVIOUS PAGE	LAST PAGE	REGRAPH
-----------	---------------	-----------	----------------

Press the HOME  key to exit Real-time review and return to the Main screen.

6.6 Case Archive Function

Case archive function allows review of up to 28 separate cases of 24-hour duration and two case examples. When run-on data storage exceeds 24-hours, it will be stored as a separate case. Case history data files are selected for review in the Case archive file list. The data may be viewed in graphical or tabular format (see sections [5.1.10 Tabular Trends Screen](#), [5.1.11 Case Archive File List Screen](#), and [5.1.12 Review Screen](#)).

The first two cases are EXAMPLE.1 and EXAMPLE.2, which permanently reside in the Case archive file list. EXAMPLE.1 is an uneventful CABG patient with a hospital length of stay of 5 days. EXAMPLE.2 is a CABG patient who had rSO₂ desaturations of >20% and a hospital length of stay of 18 days. Files with an asterisk (*) next to them indicate rSO₂ desaturations of ≥20% or values ≤40 (see section [Data File Name Format](#)).

6.6.1 Case Archive Function—Graphical Format



Note:

More than 1 hour of data must be stored to scroll in Case archive function.

To access Case archive function in graphical format, press the ON/OFF  key to display the Start screen and then perform the following navigation bar options:

NEW PATIENT	PREVIOUS PATIENT	DATE/TIME	NEXT MENU
CASE ARCHIVE	PREVIOUS MENU		
NEXT FILE	PREVIOUS FILE	SELECT FILE	NEXT MENU
<- 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 1 hour increments. Select **FULL GRAPH** to display the entire case.

When reviewing is completed, perform the following navigation bar options to return to the Start screen:

<- TREND GRAPH	TREND GRAPH ->	FULL GRAPH	NEXT MENU
TABULAR TRENDS	DOWNLOAD	PREVIOUS MENU	NEXT MENU
CASE ARCHIVE	START SCREEN		PREVIOUS MENU



Note:

The Case archive list will display only the cases with four-channel monitoring when the configuration is for four channels, respectively, it will display only the cases with two-channel monitoring when the configuration is two channel.

When reviewing in graphical format during Case archive function, a message in yellow may be displayed in the upper area of the graphs to alert for the following cases: "USB STORAGE ERROR", "USB STORAGE FULL", and "COM PORT UNAVAILABLE." This message will appear until the error is corrected and the screen is refreshed.

6.6.2 Case Archive Function—Tabular Trends Screen Format

To access Case archive function in Tabular trends screen format, press the ON/OFF  key to display the Start screen, then perform the following navigation bar options:

NEW PATIENT	PREVIOUS PATIENT	DATE/TIME	NEXT MENU
CASE ARCHIVE	PREVIOUS MENU		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
NEXT PAGE	PREVIOUS PAGE	LAST PAGE	REGRAPH

Select **NEXT PAGE**, **PREVIOUS PAGE**, and **LAST PAGE** to scroll through the data. Case archive tabular data is displayed in pages of 23 lines of data (see [Table 5-1](#). and sections [7.3 Using the USB Port](#) and [7.4 Using the Digital Output Port](#)).

When reviewing is completed, to return to the Start screen:

NEXT PAGE	PREVIOUS PAGE	LAST PAGE	REGRAPH
<- TREND GRAPH	TREND GRAPH ->	FULL GRAPH	NEXT MENU
TABULAR TRENDS	DOWNLOAD	PREVIOUS MENU	NEXT MENU
CASE ARCHIVE	START SCREEN		PREVIOUS MENU

7 Using the Monitor Ports

7.1 Overview

This chapter addresses how to accomplish the following items:

- Display INVOS™ regional saturation patient monitoring system screens to an external VGA monitor connected to the video out port
- Use the USB port
- Use the serial (digital) out port to perform digital data outputting (download) functions



WARNING:

Accessories not supplied by Covidien may not meet IEC 60601-1 standards. Contact the Covidien customer service department for compatible products that meet these requirements.



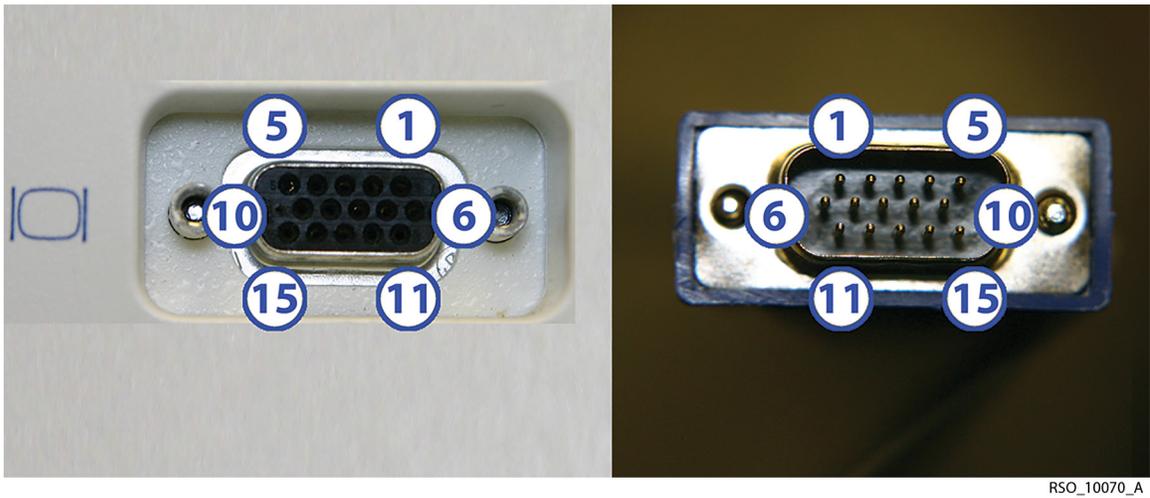
Note:

Make sure the appropriate output device is connected and ready to accept data before selecting an output. See Chapter 3 for setup and installation procedures.

7.2 Using the VGA Port

The VGA port allows the INVOS™ system screens to be displayed with a VGA monitor (see [Figure 7-1.](#) and [Table 7-1.](#)).

Figure 7-1. VGA Video Connector Pin-Out



Digital output female connector at monitor pin-out (left) Monitor cable male connector pin-out (right)

Table 7-1. VGA Video Connector Pin-Out Descriptions

Pin #	Signal name	Pin #	Signal name
1	Red	9	No connect
2	Green	10	Ground
3	Blue	11	No connect
4	No connect	12	DDC DAT
5	Ground	13	Horizontal synchronization
6	Ground	14	Vertical synchronization
7	Ground	15	DDC clock
8	Ground		

7.3 Using the USB Port

The USB port allows data from the INVOS™ system to be transferred to a USB flash drive. The communication protocol is designed to support a Covidien USB flash drive provided at the time of purchase. Additional USB flash drives are available from Covidien. A special USB flash drive may also be used to provide software upgrades for the INVOS™ system.

The USB flash drive supplements the storage function available in the INVOS™ system and offers the additional benefits of greater capacity and selectable storage rates on a nonvolatile medium. The USB flash drive allows cases containing rSO₂ data to be stored for future review, graphing, and archiving. It supports the following features and functions:

- Minimum 256 MB
- Hi-speed USB 2.0 certified and backwards compatible with all USB 1.1 ports
- Compatible with Windows™ ME, 2000, XP, macOS™ 9.1.x+, macOS™ X v10.1.2+ operating systems.



Note:

The USB flash drive should be inserted when the case begins to capture real-time data to the USB. Keep the USB flash drive inserted for the full duration of the case. If removed, there will be gaps in the case data collected. Regardless of USB flash drive usage, the INVOS™ system monitors and stores data to its internal memory, so entire cases can be downloaded in the case history format (see sections [7.3.1 USB Port Output—Case Archive Function](#) and [Case History Data to USB Flash Drive for Downloading Case Data at the End of a Case](#)).

As a reminder to insert the USB, the blinking message “USB FLASH DRIVE NOT CONNECTED” will appear on the Start screen when the system is turned on. USB flash drives not supplied by Covidien may not meet system requirements. Additional drives may be ordered from Covidien (see section [3.12 Accessories](#)).

7.3.1 USB Port Output—Case Archive Function

When the INVOS™ system is operating in Case archive function, stored cases may be downloaded to the USB flash drive in case history formats (see sections [5.1.11 Case Archive File List Screen](#) and [6.6 Case Archive Function](#)). Up to 28 separate cases will be stored for downloading in the Case archive file list.

Downloading an Individual Case Archive

To access Case archive function and download an individual case from the Case archive file list, press the ON/OFF  key to display the Start screen, then perform the following navigation bar 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

Select **USB STORAGE** to download the case history data.

When downloading is complete, select another case or return to the Start screen by performing the following navigation bar options:

USB STORAGE	DIGITAL OUTPUT		PREVIOUS MENU
TABULAR TRENDS	DOWNLOAD	PREVIOUS MENU	NEXT MENU
CASE ARCHIVE	START SCREEN		PREVIOUS MENU

When downloading a case, a message in yellow may be displayed in the upper area to alert for "USB STORAGE ERROR" and "USB STORAGE FULL." This message will appear until the error is corrected and the screen is refreshed.

Downloading All Case Archive Files

To access Case archive function and download all files in the Case archive file list, press the ON/OFF  key to display the Start screen, then perform the following navigation bar options:

NEW PATIENT	PREVIOUS PATIENT	DATE/TIME	NEXT MENU
CASE ARCHIVE	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 4 minutes (28 cases of 24 hour duration). As the files are downloading, the file currently being transferred appears above the Case archive file list.

When downloading a case, a message in yellow may be displayed in the upper area to alert for “USB STORAGE ERROR” and “USB STORAGE FULL.” This message will appear until the error is corrected and the screen is refreshed.

When downloading is complete, perform the following navigation bar options to return to the Start screen:

DOWNLOAD ALL FILES	CASE ARCHIVE MENU	PREVIOUS MENU	
DOWNLOAD FILES	DELETE FILES	START SCREEN	PREVIOUS MENU

Delete All Case Archive Files from Monitor

To access Case archive function and delete all files in the Case archive file list, press the ON/OFF  key to display the Start screen, then perform the following navigation bar options:

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

All files except EXAMPLE.1 and EXAMPLE.2 will be deleted and removed from the Case archive file list.

When deleting is complete, perform the following navigation bar options to return to the Start screen:

DELETE ALL FILES	DELETE ALL USB	CASE ARCHIVE MENU	PREVIOUS MENU
DOWNLOAD FILES	DELETE FILES	START SCREEN	PREVIOUS MENU

Delete All Case Archive Files from USB Flash Drive

To access Case archive function and delete all files on the USB flash drive, press the ON/OFF  key to display the Start screen, then perform the following navigation bar options:

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

All files will be deleted from the USB flash drive.

When deleting is complete, perform the following navigation bar options to return to the Start screen:

DELETE ALL FILES	DELETE ALL USB	CASE ARCHIVE MENU	PREVIOUS MENU
DOWNLOAD FILES	DELETE FILES	START SCREEN	PREVIOUS MENU

7.3.2 USB Port Output—Run Function

When the INVOS™ system is operating in Run function (normal patient monitoring), stored data may be downloaded to the USB flash drive in real-time or case history formats (see sections [6.5 Run Function \(Patient Monitoring\) in Normal Mode](#) and [7.5 Data Output Formats](#)).



WARNING:

Use only specified USB flash drives.

Real-Time Data to USB Flash Drive for Continuous Data Storage During a Case

Once the INVOS™ system components and the USB flash drive are connected, the monitor is on and in Run function, the monitor will begin data outputting to the USB flash drive automatically at the user-selected USB storage rate (see section [6.5.7 USB Storage Rate](#)).

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.

Case History Data to USB Flash Drive for Downloading Case Data at the End of a Case

Once the INVOS™ system components and the USB flash drive are connected, the monitor is on and in Run function, press the HOME  key to display the Main screen and perform the following navigation bar options:

BASILINE MENU	EVENT MARK	ALARM AUDIO ON/OFF	NEXT MENU
OUTPUT SELECT	USER CONFIGURATION	TIME SCALE	NEXT MENU
USB	DIGITAL OUTPUT		PREVIOUS MENU
CASE HISTORY		PREVIOUS MENU	MAIN MENU

The case history data will output until complete. Up to 24 hours of data may be stored per case history file.

7.4 Using the Digital Output Port



WARNING:

It is recommended that all equipment used together with the monitor for real-time data collection be placed outside of the “patient environment.” If this condition cannot be met, the monitor and the equipment shall be powered by using a separation device (please see IEC 60601-1-1, Table BBB.201). All equipment used outside the patient environment must be approved to the appropriate IEC or ISO standards (for example, IEC950 for office equipment).

This port provides digital data communications with other devices such as a Philips VueLink™* interfacing module or personal computer (PC). The data that can be transmitted through this port is either real-time, case history, or Database summary menu data. Digital output port interfacing is described in this section using a VueLink™* Open Interface module and the HyperTerminal™* program. Contact Covidien’s customer service department for compatibility with other commercial devices or to order a null modem cable (see sections [7.4.1 Using a Philips VueLink™* Open Interface \(VOI\) Module](#), [7.4.3 Using HyperTerminal™* via Null Modem Cable to Capture and Store Data](#), and [3.17 When INVOS™ System is Part of a Medical Monitoring System](#)).



Note:

Avoid contact with the digital output port while operating the INVOS™ system. For the location of the digital output port, see [Figure 3-1](#).

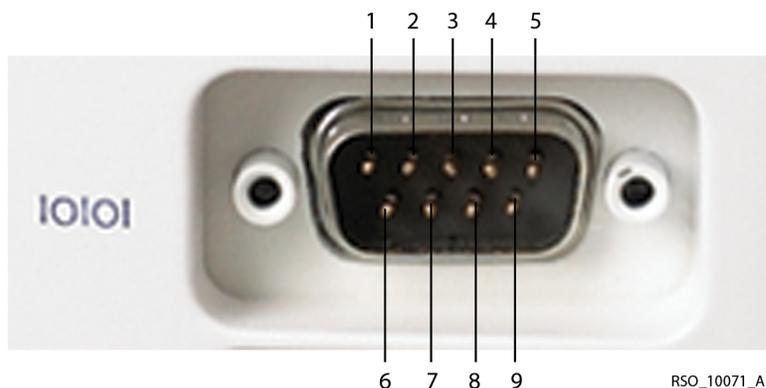
The digital communications output uses the following protocol:

- 9600 baud
- No parity
- 8 data bits
- 1 stop bit
- Flow control: None

(See [Figure 7-2](#).)

The digital output port should be set for the desired function (PC Link and VueLink™*).

Figure 7-2. Digital Output Connector Pin-Out



Pin #	Signal name	Pin #	Signal name
1	Data carrier detect	6	Data set ready
2	Receive data	7	Request to send
3	Transmit data	8	Clear to send
4	Data terminal ready	9	Ring indicator
5	Ground		

7.4.1 Using a Philips VueLink™* Open Interface (VOI) Module



Note:

The INVOS™ system will also interface with Hewlett Packard and Agilent multi-parameter systems that accept the VOI B module specified in this section.



WARNING:

The VueLink™* monitor will not generate an alarm or error message if remote communication between the VueLink™* monitor and the INVOS™ system has been broken. During this period of no remote communication, the INVOS™ system will continue to monitor, alarm, and display status messages. The VueLink™* monitor operator should not rely upon the distributed alarm system for generating alarms.

In Run function, the digital output port may be set to output real-time data to communicate with a Philips VueLink™* Open Interface (VOI) module for display on a Philips VueLink™* multi-parameter system. The data sent to the multi-parameter includes the rSO₂ values, alarms, and status messages (see section 6.5 Run Function (Patient Monitoring) in Normal Mode). The multi-parameter displays only error or alarm status messages.

The following hardware is needed for Philips VueLink™* communication:

- Philips VOI B module (Philips VueLink™* P/N M1032A #A05, driver code TU1AA)

- Philips VOI/RS-232 interface cable (Philips VueLink™* P/N M1032 #K6B)
- VueLink™* adapter cable, DB25F to DB9F (Covidien P/N VLI)

The following hardware is needed for Philips IntelliBridge™* communication:

- Philips IntelliBridge™* EC10 module (Philips P/N 865115, driver code IB-ED101-A.3)
- Philips ethernet cable or alternative (CAT-5 or better, straight-wired, not longer than 10 m)
- Philips IntelliBridge™* EC5 Open Interface module (Philips P/N 865114 #104)
- INVOS™ system (model 5100C) serial port extension

**Note:**

Philips IntelliBridge™* and VueLink™* Open Interface (IVOI) is a product of Philips Medical Systems, a part of Royal Philips Electronics (www.Medical.Philips.com).

If the VueLink™* Open Interface (VOI B) module is used, install the VOI B module and connect to the INVOS™ system by performing the following steps.

1. Insert the VOI B module into any of the open slots on the remote monitor, making sure the VOI B locks into place.
2. Connect the VOI/RS-232 interface cable to the VOI B module.
3. Connect the DB-25 plug of the VueLink™* adapter cable to the VOI/RS-232 interface cable.
4. Connect the DB-9 plug of the VueLink™* adapter cable to the digital output port on the INVOS™ system.
5. Tighten all screw locks at each connector junction.

If the IntelliBridge™* EC10 module is used, install the EC10 module and connect to the INVOS™ system by performing the following steps.

1. Insert the IntelliBridge™* EC10 module into any of the open slots on the remote monitor, making sure the EC10 module locks into place.
2. Connect the ethernet cable to the IntelliBridge™* EC10 module.
3. Connect the ethernet cable to the RJ-11 plug of the IntelliBridge™* EC5 Open Interface module.
4. Connect the INVOS™ system (model 5100C) serial port extension to the digital output port of the INVOS™ system and tighten the screws.
5. Connect the IntelliBridge™* EC5 Open Interface module to the INVOS™ system (model 5100C) serial port extension.
6. Tighten all the screw locks at each connector junction.

Once the INVOS™ system components and the Philips components are connected, the monitor is on and in Run function. To enable transmission from the INVOS™ system, press the HOME  key to display the Main screen and perform the following navigation bar options:

BASILINE MENU	EVENT MARK	ALARM AUDIO ON/OFF	NEXT MENU
OUTPUT SELECT	USER CONFIGURATION	TIME SCALE	NEXT MENU
USB	DIGITAL OUTPUT		PREVIOUS MENU
PCLINK	PHILIPS	PREVIOUS MENU	MAIN MENU

Restart the INVOS™ system to ensure proper connection. This setting will be retained until changed by selecting a different output format.



Note:

If INVOS™ system messages do not appear on the remote monitor's screen within a short period of time after restarting the INVOS™ system, it may be necessary to change the configuration of the remote monitor to accept device alarms. Consult with hospital staff to determine who has the password needed to do this.

While details will vary among particular monitor models, the general steps to configure the remote monitor include the following:

1. Press the **MONITOR SETUP** key on the front panel.
2. Press the **OPERATING MODES** soft key.
3. After entering the correct password, press the **CHANGE OPMODES** soft key.
4. Change **DEVICE ALARMS** to **ACCEPTED**.
5. Press **STORE** and **CONFIRM**.
6. Change back to **MONITORING** mode.
7. Press the **MAIN SCREEN** key to resume monitoring.

When the remote monitor setup is completed, press the HOME  key on the INVOS™ system monitor to display the Main screen.

7.4.2 Select Digital Output Port Data Format

When the INVOS™ system is part of a medical monitoring system, the INVOS™ system output format can be set to communicate with the external device's interface software (see section [7.5 Data Output Formats](#) to determine appropriate format). This setting will be retained until changed by selecting a different output format.

Selecting Digital Output Port Data Format—Four-Channel Monitoring

Once the INVOS™ system components and the external device are connected, the INVOS™ system monitor is on and in Run function, press the HOME  key to display the Main screen and perform the following navigation bar options to begin interfacing:

BASELINE MENU	EVENT MARK	ALARM AUDIO ON/OFF	NEXT MENU
OUTPUT SELECT	USER CONFIGURATION	TIME SCALE	PREVIOUS MENU
USB	DIGITAL OUTPUT		PREVIOUS MENU
PC LINK	VUELINK	PREVIOUS MENU	MAIN MENU
CASE HISTORY	OUTPUT FORMAT	PREVIOUS MENU	MAIN MENU
OUTPUT FORMAT 1	OUTPUT FORMAT 2		PREVIOUS MENU

Select **OUTPUT FORMAT 1** or **OUTPUT FORMAT 2**.

Selecting Digital Output Port Data Format—Two-Channel Monitoring

Once the INVOS™ system components and the external device are connected, the INVOS™ system monitor is on and in Run function, press the HOME  key to display the Main screen and perform the following navigation bar options to begin interfacing:

BASELINE MENU	EVENT MARK	ALARM AUDIO ON/OFF	NEXT MENU
OUTPUT SELECT	USER CONFIGURATION	TIME SCALE	PREVIOUS MENU
USB	DIGITAL OUTPUT		PREVIOUS MENU
PC LINK	VUELINK	PREVIOUS MENU	MAIN MENU
CASE HISTORY	OUTPUT FORMAT	PREVIOUS MENU	MAIN MENU
OUTPUT FORMAT 1	OUTPUT FORMAT 2	OUTPUT FORMAT 3	PREVIOUS MENU

Select **OUTPUT FORMAT 1**, **OUTPUT FORMAT 2**, or **OUTPUT FORMAT 3**.

7.4.3 Using HyperTerminal™* via Null Modem Cable to Capture and Store Data

Data can be outputted from the digital output port to a personal computer (PC) with a terminal emulator program via a 9-pin to 9-pin null modem cable. One such terminal emulator program is HyperTerminal™* (available in some Window operating systems). This section describes using HyperTerminal™* to output data from the INVOS™ system in Run and Case archive Functions via a null modem cable. Data can be downloaded in real-time and case history formats (see section [7.5 Data Output Formats](#) to determine appropriate format). This setting will be retained until changed by selecting a different output format.

Null Modem Cable

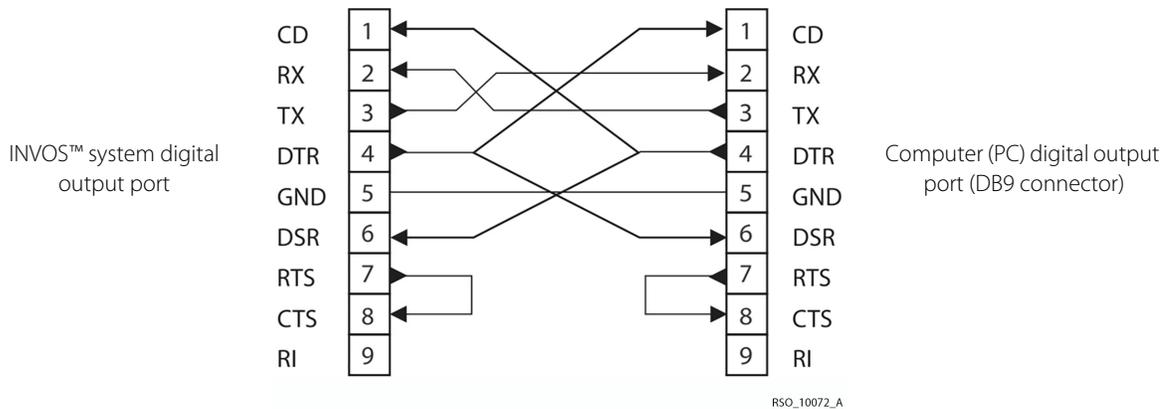
1. Connect Covidien’s null modem cable to the digital output port (see *Figure 7-3*, if not using Covidien’s null modem cable).
2. Connect the null modem to a COM port on the PC.



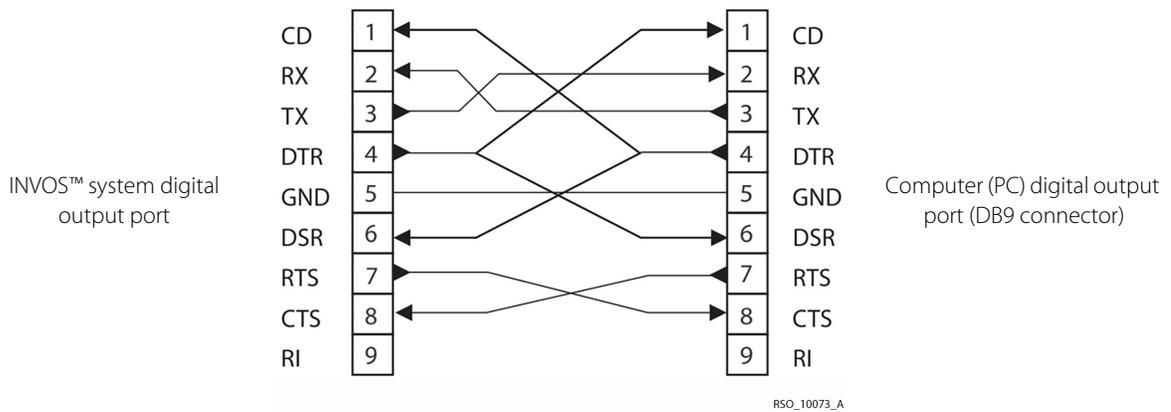
Note:

Both configurations shown in *Figure 7-3*, are acceptable.

Figure 7-3. Null Modem Cable Diagram for Connection to Digital Output Port



OR



HyperTerminal™* Settings

1. Open HyperTerminal™*. To locate the HyperTerminal™* program on the PC, select Start>All Programs>Accessories>Communications>HyperTerminal.
2. Create an INVOS™ system terminal icon.

3. Set the inputs for the COM port (see [Table 7-2](#)).

Table 7-2. Input COM Port Settings Using HyperTerminal™*

Input	Setting
Bits per second	9600 baud
Data bits	8
Parity	None
Stop bits	1
Flow control	None

For additional information about using HyperTerminal™*, select the Help menu in HyperTerminal™*.

Capturing Data Output Using HyperTerminal™*

Data can be captured and stored on the PC using HyperTerminal™*. When the INVOS™ system is operating in Run function, data can be output in real-time or case history formats. When the INVOS™ system is operating in Case archive function, the data is output in case history format. To capture and store the data:

1. On the PC, open the HyperTerminal™* program via the INVOS™ system terminal icon.
2. Select TRANSFER and CAPTURE TEXT. In the CAPTURE TEXT window, enter the file name and directory to save the file.
3. Select START.
4. On the INVOS™ system, select operating mode and data output format (see below).
5. On the PC, when monitoring is complete, select CALL, DISCONNECT, and close HyperTerminal™*.

In Run Function—Real-Time Data Output

Once the INVOS™ system components and the PC are connected, the INVOS™ Monitor is on and rSO₂ data is trending, press the HOME  key to display the Main screen and perform the following navigation bar options to begin interfacing:

BASILINE MENU	EVENT MARK	ALARM AUDIO ON/OFF	NEXT MENU
OUTPUT SELECT	USER CONFIGURATION	TIME SCALE	NEXT MENU
USB	DIGITAL OUTPUT		PREVIOUS MENU
PC LINK	VUELINK	PREVIOUS MENU	MAIN MENU
CASE HISTORY	OUTPUT FORMAT	PREVIOUS MENU	MAIN MENU

Select **MAIN MENU** to return to the Main screen. The INVOS™ system will begin to communicate with the PC via HyperTerminal™* in real-time format. This setting will be retained until changed by selecting a different output format.

In Run Function—Case History Data Output

Once the INVOS™ system components and the PC are connected, the INVOS™ monitor is on and rSO₂ data is trending, press the HOME  key to display the Main screen and perform the following navigation bar options to begin interfacing:

BASILINE MENU	EVENT MARK	ALARM AUDIO ON/OFF	NEXT MENU
OUTPUT SELECT	USER CONFIGURATION	TIME SCALE	PREVIOUS MENU
USB	DIGITAL OUTPUT		PREVIOUS MENU
PC LINK	VUELINK	PREVIOUS MENU	MAIN MENU
CASE HISTORY	OUTPUT FORMAT	PREVIOUS MENU	MAIN MENU

The INVOS™ system will begin to communicate with the PC via HyperTerminal™*. This setting will be retained until changed by selecting a different output format.

The case history data will output until complete. The time required is short; there is no cancel option. While outputting case history data, monitoring will cease and the INVOS™ system will display the last rSO₂ value measured before the output started. Monitoring will resume when the outputting function is complete. Up to 24 hours of data may be stored per case history file.

In Case Archive Function—Case History Data Output

To access Case archive function and download a case, press the ON/OFF  key to display the Start screen, then perform the following navigation bar options:

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

Select **DIGITAL OUTPUT** to download the case history data. The INVOS™ system will begin to communicate with the PC via HyperTerminal™*.

When capturing a case, a message in yellow may be displayed in the upper area to alert for "COM PORT UNAVAILABLE." This message will appear until the error is corrected and the screen is refreshed.

When downloading is complete, perform the following navigation bar options to select another case or return to the Start screen:

USB STORAGE	DIGITAL OUTPUT		PREVIOUS MENU
TABULAR TRENDS	DOWNLOAD	PREVIOUS MENU	NEXT MENU
NEXT FILE	PREVIOUS FILE	SELECT FILE	START SCREEN

7.5 Data Output Formats

The INVOS™ system data can be outputted via the USB and digital output ports in real-time and case history formats. It can be accessed and graphed on a personal computer using a common spreadsheet program like Microsoft Excel (see section [7.5.1 Graph Data Files—rSO₂ versus Time with Microsoft Excel](#)).

Stored 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 function, 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 September 13, 2009 in Normal run function would have a filename of 090913N.H1. An asterisk (*) indicates a desaturation of $\geq 20\%$ from baseline or < 40 rSO₂ values occurred during the case.

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.

It is necessary to parse the data when entering it into a spreadsheet before charting. Follow the spreadsheet software supplier's directions to proceed.

The USB output data formats are the same for two-channel and four-channel software versions. When two-channel data is being displayed, the data for channels 3 and 4 will be zeros.

The digital output data format 1 and 2 are the same for two-channel and four-channel software versions. For two-channel software versions, format 1 and 2 include zeros for the fields that correspond to channels 3 and 4. The digital output data format 3 (two-channel only) outputs data for channels 1 and 2.

For additional information about connectivity and data formats, contact Technical Services:

1.800.255.6774, option 1

or

HQTSWEB@covidien.com

7.5.1 Graph Data Files—rSO₂ versus Time with Microsoft Excel

In Microsoft Excel, a macro can be written that automates graphing rSO₂ data versus time and places event marks on a chart. Versions of Microsoft Excel may be different, but the general steps to chart without a macro include the following:

1. Turn on the PC and open the Microsoft Excel program. Under File>Open, select the file name and directory where the data file is stored (make sure "all files" or "text files" is selected). Excel will display the Text Import Wizard dialog box. Stored 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 function, C = control, I = intervention) and a file extension consisting of a letter (H = history, or R = real-time) and a sequence number.
2. Under Original Data Type, select Delimited, remove Tab, and select Space. The data should now be parsed into individual cells. Select Finish.
3. Insert an empty row at the top of the data by selecting Row from the Insert menu. Enter the column headings in row 1.
4. Select CTRL (PC) or Command (Mac™*) on the keyboard and select or highlight the time column starting from row 1 to the end of the data. Without releasing the CTRL key, select or highlight the rSO₂ data columns from row 1 to the end of the data.
5. Select the Chart icon from the Chart tool bar or select Chart from the Insert menu. The Chart Wizard will appear.
6. Choose chart type by selecting XY Scatter as the Chart type and Scatter with data points connected by smooth lines as the chart subtype. Other chart subtypes may be chosen for different graph line formats. Select Next.



Note:

Using the XY Scatter instead of Line will yield a true x-axis time scale.

7. Chart source data with the data range and columns previously selected in step 4. Select Next.
8. Enter chart options, such as Chart title, Value (X) axis, and Value (Y) axis. Other parameters may also be entered, if desired. After completing all of the chart options, select Next.
9. Select Finish and save the file as an Excel Workbook.
10. To further format the graph, double click on either axis and a dialog box will appear to allow changes to other attributes.

8 Database Operational Mode and Area Under the Curve

8.1 Overview

Effective January 1, 2008, the Society of Thoracic Surgeons (STS) has added cerebral oximetry as a new metric to be collected in its adult cardiac surgery database. This chapter describes the metrics, as well as how to capture and download the metric data with the INVOS™ regional saturation patient monitoring system. Importantly, this will allow all users access to area under the curve calculations.



WARNING:

For area under the curve (AUC) to calculate you must set left and right baselines prior to induction in real-time or accept the auto-baseline value when prompted by the device (approximately 5 minutes after monitoring begins). Baselines should not be reentered at any other time or the integrity of AUC will be compromised. Similarly, entering skin closure will cease calculation of AUC.



Note:

Database software is not compatible with cases collected using previous software versions. Therefore, previous cases stored on the INVOS™ system should be downloaded and saved elsewhere prior to loading the database software.

8.1.1 INVOS™ System Database Application Software

To inquire about the Database operational mode versions of application software and Database operational mode access, contact Covidien's customer service department at 800 635 5267, Customer.Service-RMS@covidien.com, www.covidien.com, or via your local representative.

8.2 Database Variable and Fields

8.2.1 Field Name: Preinduction Baseline Regional Oxygen Saturation—Left

Format: Integer

Valid Data: 1-99

Definition: Indicates the percent baseline left cerebral regional oxygen saturation (rSO_2) values at the beginning of the operation, when the patient is awake and functional. Patient can be sedated or on supplemental oxygen at the time measurement is taken. In the absence of a user-specified baseline, the cerebral oximeter will automatically select a baseline value from the first few minutes of the case.

8.2.2 Field Name: Preinduction Baseline Regional Oxygen Saturation—Right

Format: Integer

Valid Data: 1–99

Definition: Indicates the percent baseline right cerebral regional oxygen saturation (rSO_2) values at the beginning of the operation, when the patient is awake and functional. Patient can be sedated or on supplemental oxygen at the time measurement is taken. In the absence of a user-specified baseline, the cerebral oximeter will automatically select a baseline value from the first few minutes of the case.

8.2.3 Field Name: Cumulative Saturation Below Threshold—Left

Format: Integer

Valid Data: 0–9999

Definition: Indicates the cumulative integral of time and depth of desaturation events below the threshold of 75% of the baseline rSO_2 value (relative decline of 25% below baseline) for the left rSO_2 . Calculated by the cerebral oximeter by multiplying the difference between the threshold and current rSO_2 values times the duration that rSO_2 is below the threshold. Values are accumulated throughout the operation. Units are minute-percent. This is also called area under the curve (AUC).

8.2.4 Field Name: Cumulative Saturation Below Threshold—Right

Format: Integer

Valid Data: 0–9999

Definition: Indicates the cumulative integral of time and depth of desaturation events below the threshold of 75% of the baseline rSO_2 value (relative decline of 25% below baseline) for the right rSO_2 . Calculated by the cerebral oximeter by multiplying the difference between the threshold and current rSO_2 values times the duration that rSO_2 is below the threshold. Values are accumulated throughout the operation. Units are minute-percent. This is also called area under the curve (AUC).

8.2.5 Field Name: Cerebral Oximeter Provided the First Indication

Format: Yes/No

Valid Data: Yes; No

Definition: Indicates whether the cerebral oximeter provided the first indication of a technical problem or physiological change in the patient that could potentially lead to an adverse patient outcome.

8.2.6 Field Name: Skin Closure Regional Oxygen Saturation—Left

Format: Integer

Valid Data: 1–99

Definition: Indicates the left cerebral regional oxygen saturation of blood (rSO_2) value at the time of skin closure at the end of the operation. Units are percent.

8.2.7 Field Name: Skin Closure Regional Oxygen Saturation—Right

Format: Integer

Valid Data: 1–99

Definition: Indicates the right cerebral regional oxygen saturation of blood (rSO_2) value at the time of skin closure at the end of the operation. Units are percent.

8.3 Database Operational Mode Screens

When the INVOS™ system is in Database operational mode, there are screens that differ or are additional from Normal mode. Those different or additional screens include the following:

- Start screen in Database operational mode
- Main screen in Database operational mode displaying AUC
- Tabular trends for entering Induction time screen
- Tabular trends for entering Skin closure time screen

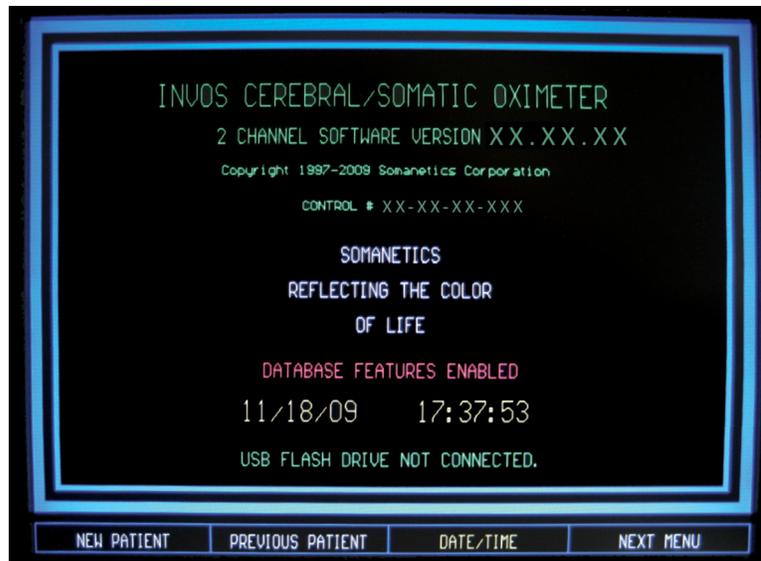
- Database summary screen—real-time review
- Database summary screen—case archive review

8.3.1 Start Screen in Database Operational Mode

The Start screen displays the software version, date, time, and operator-selectable navigation bar. The INVOS™ system software version appears where XX.XX.XX is shown in *Figure 8-1.* and *Figure 8-2.*

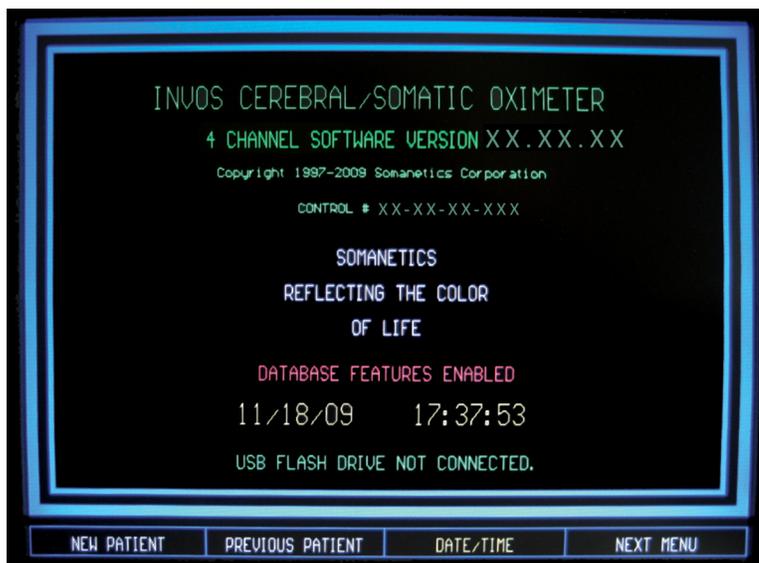
The message “DATABASE FEATURES ENABLED” will appear in red on the Start screen if the Database operational mode is enabled.

Figure 8-1. Two-Channel Start Screen in Database Operational Mode



ROS_10107_A

Figure 8-2. Four-Channel Start Screen in Database Operational Mode

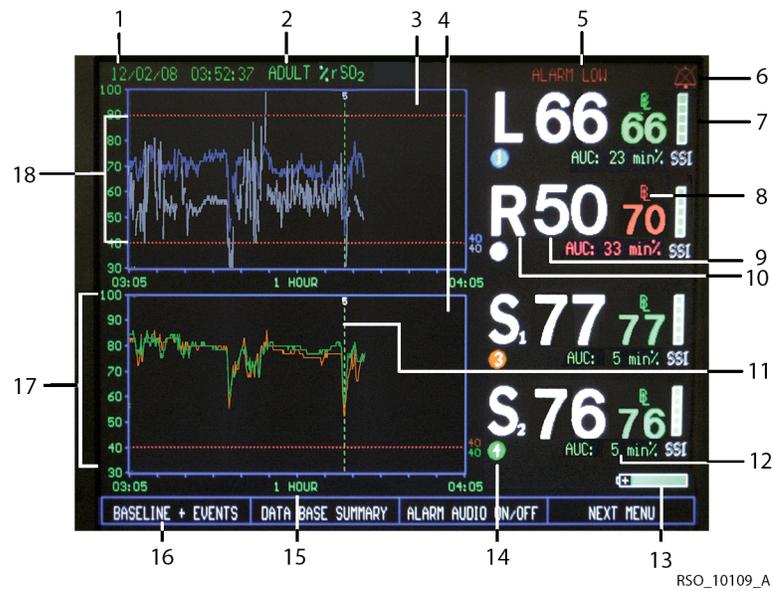


ROS_10108_A

8.3.2 Main Screen in Database Operational Mode

The Main screen is composed of several elements. These include real-time rSO₂ values, trend data, system status, alarm limits and messages, rSO₂ limits, date, and time. It also displays navigation bar options for the baseline parameter, event marking, audible alarm, and other default parameters.

Figure 8-3. Main Screen (Four-Channel Monitoring) Database Operational Mode



1	Date and time	10	Data channel label (for example, L: left cerebral, R: right cerebral, S: somatic)
2	Adult, pediatric, or neonatal indication for sensor model	11	Event mark line and numerical code
3	Trend data graph (for data channels 1 and 2)	12	Cumulative saturation below threshold (AUC)
4	Trend data graph (for data channels 3 and 4)	13	Battery power status
5	Alarm status message	14	Channel indicator 
6	Alarm symbol	15	Time scale, in hours; selectable up to 24 hours
7	Signal strength indicator	16	Menu options (navigation bar)
8	rSO ₂ baseline and symbol	17	rSO ₂ trend (high and low) scale
9	Real-time rSO ₂ (index) values, updated continuously while monitoring	18	Upper and lower alarm limits

8.3.3 Tabular Trends for Entering Induction Time Screen

The Tabular trends for entering induction time screen displays stored data in a numerical, tabular format (see [Figure 8-4](#), section [8.6.1 Marking the Induction Time](#), and [Table 5-1](#)). Alarm messages, channel identification, and rSO₂ area elements will continue to be displayed.

Figure 8-4. Tabular Trends for Entering Induction Time Screen

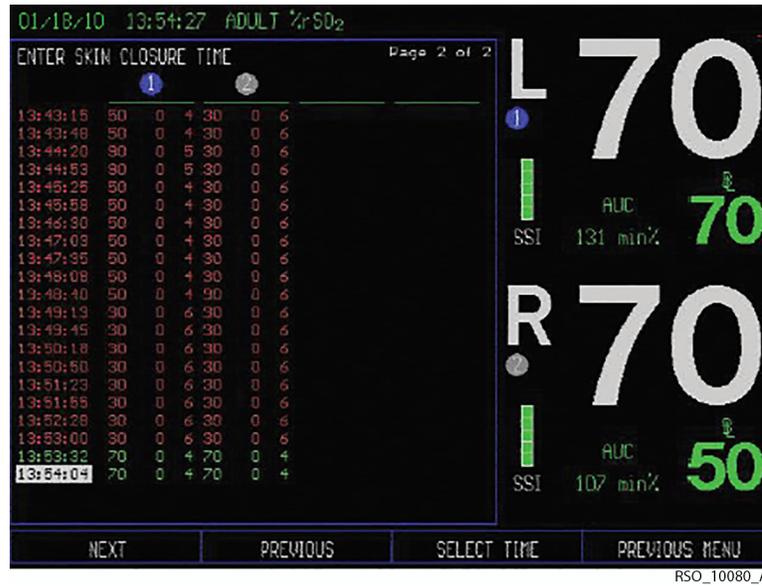


RSO_10079_A

8.3.4 Tabular Trends for Entering Skin Closure Time Screen

The Tabular trends for entering skin closure time screen displays stored data in a numerical, tabular format (see [Figure 8-5](#), section [8.6.2 Marking the Skin Closure Time](#), and [Table 5-1](#)). Alarm messages, channel identification, and rSO₂ area elements will continue to be displayed.

Figure 8-5. Tabular Trends for Entering Skin Closure Time Screen



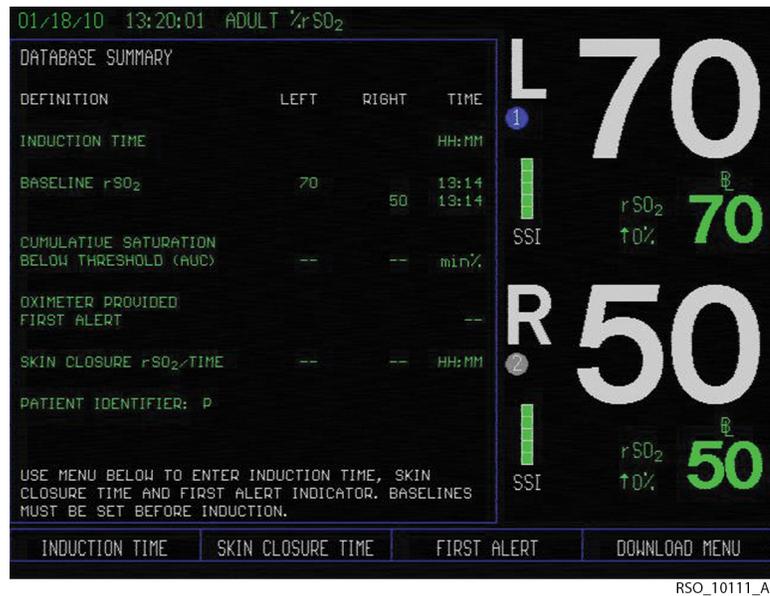
8.3.5 Database Summary Screen

The Database summary screen displays the database metrics in a summary menu format (see *Figure 8-6.* , *Figure 8-7.* , *Figure 8-8.* , *Figure 8-9.* , and section 8.6 *Collecting Metrics in Database Operational Mode*). Alarm messages, channel identification, and rSO₂ area elements will continue to be displayed when operating in Run function.

Figure 8-6. Database Summary Screen—Auto Set Baseline



Figure 8-7. Database Summary Screen—Real-Time Review Before Skin Closure



RSO_10111_A

Figure 8-8. Database Summary Screen—Real-Time Review After Skin Closure



RSO_10112_A

Figure 8-9. Database Summary Screen—Case Archive Review

DEFINITION	LEFT	RIGHT	TIME
INDUCTION TIME			14:05
BASELINE rSO ₂	70	50	14:03
CUMULATIVE SATURATION BELOW THRESHOLD (AUC)	22	20	min%
OXIMETER PROVIDED FIRST ALERT			--
SKIN CLOSURE rSO ₂ /TIME	30	30	14:12
PATIENT IDENTIFIER: 54545455555555555555555555555555			

REGRAPH CASE ARCHIVE TO PRINTER TO USB

RSO_10113_A

8.4 Features

Database operational mode is for patient monitoring, and collecting and downloading cerebral oximetry metrics for the STS adult cardiac surgery database. This mode is similar to the Normal mode and, in addition, permits the calculation and display of area under the curve. It also enables other features related to the database, such as time entries and display of rSO₂ data for induction and skin closure, and data entry if monitor provided a first alert.

- Area under the curve (AUC) represents the cumulative saturation below threshold and is expressed in min.-percent. A baseline must be set to autocalculate the area of the curve below 75% of baseline and continuously update the AUC as a cumulative variable in the memory. For AUC to also display on the screen, an induction time must be set after the baselines are set. The AUC is calculated for left (L) and right (R) channels only. The user will be able to set high and low alarm limits and variance for the auto low alarm.
- The baselines or baselines are a moment defined in time as the normative reference for the case. After the baseline is selected, the system starts calculating the cumulative saturation depth and time below the threshold (75% of baseline) but it is not displayed on the monitor until the induction time is entered.

The baseline can be set the following ways:

- From the Baseline + events screen and the Set baselines menu
- As an event from the Event list screen (see code 2 on [Table 6-1.](#)) (current time only)
- Automatically 5–6 minutes after NEW PATIENT is selected and an rSO₂ value is obtained.

Induction time is defined as the beginning of the intubation process, immediately prior to preoxygenation or heavy sedation. An induction time must be set after the baseline is set for AUC to display on-screen.

Induction time can be set the following ways:

- As an event (see code 3 on [Table 6-1.](#)) from the OR event list screen (current time only)
- From the Database summary screen and the Induction time screen

Skin closure time represents the end of the procedure, immediately prior to the patient's exit from the operating room. It is important to enter the skin closure time because it triggers AUC to stop calculating.

Skin closure time can be set the following ways:

- As an event (see code 13 on [Table 6-1.](#)) from the OR event list screen (current time only)
- From the Database summary screen and the Skin closure time screen



WARNING:

For area under the curve (AUC) to calculate you must set left and right baselines prior to induction in real-time or accept the auto-baseline value when prompted by the device (approximately 5 minutes after monitoring begins). Baselines should not be reentered at any other time or the integrity of AUC will be compromised. Similarly, entering skin closure will cease calculation of AUC.

First alert (yes/no) indicates whether the INVOS™ system provided the first indication of a technical problem or physiological change in the patient that could potentially lead to an adverse patient outcome. FIRST ALERT can be selected from the Database summary screen. When the FIRST ALERT key is pressed, choose YES/NO using the navigation menu options.

8.5 Operating in the Database Operational Mode

When the INVOS™ system is in Database operational mode, the system will indicate that on the Start screen (see [Figure 8-1.](#) and [Figure 8-2.](#)). Contact your representative or Covidien's customer service department for database activation instructions.



Note:

The Database operational mode setting is retained after the monitor is turned off and is restored when the monitor is turned on. Database operational mode is set separately for two-channel and four-channel operation.

8.5.1 Baseline Set and Status Database Operational Mode



WARNING:

For area under the curve (AUC) to calculate you must set left and right baselines prior to induction in real-time or accept the auto-baseline value when prompted by the device (approximately 5 minutes after first rSO₂ data is received). Baselines should not be reentered at any other time or the integrity of AUC will be compromised. Similarly, entering skin closure will cease calculation of AUC.

An rSO₂ baseline should be set so subsequent cerebral oximetry metrics and rSO₂ changes from baseline can be measured. The rSO₂ numbers will turn red if rSO₂ is above or below set alarm thresholds. A red baseline status indicates a desaturation $\geq 20\%$ or ≤ 40 rSO₂ value.

As soon as rSO₂ trend data begins to be gathered and patient condition is stable, an awake baseline reading should be obtained (for example, for surgical patients, prior to induction). Baseline or baselines may be set for all channels in use at once, individually for the selected channel or channels or automatically to an rSO₂ value 5–6 minutes after an rSO₂ value is obtained.

Set Current rSO₂ as Baseline for All Channels

To set a baseline, press the HOME  key to display the Main screen, then perform the following navigation bar options:

BASELINE + EVENTS	DATABASE SUMMARY	ALARM AUDIO ON/OFF	NEXT MENU
SET BASELINES	SET CHANNEL	EVENT MARK	PREVIOUS MENU

The baseline value or values will be set at the current rSO₂ value or values, and the menu will return to the Main screen. This will display an event mark line and code on the screen in the graph of each channel.

Set Individual Channels to Current rSO₂ Baseline in 2-Channel Monitoring

To set an individual channel baseline, press the HOME  key to display the Main screen, then perform the following navigation bar options:

BASELINE + EVENTS	DATABASE SUMMARY	ALARM AUDIO ON/OFF	NEXT MENU
SET BASELINES	SET CHANNEL	EVENT MARK	PREVIOUS MENU
CHANNEL 1 SET	CHANNEL 2 SET	PREVIOUS MENU	

Select the channel or channels to set the baseline at the current rSO₂ value. This will display an event mark line and code on the screen in the graph area for the individual channel only.

When finished, press the HOME  key to exit the Baseline menu and return to the Main screen.

Set Individual Channels to Current rSO₂ Baseline in Four-Channel Monitoring

To set an individual channel baseline, press the HOME  key to display the Main screen, then perform the following navigation bar options:

BASELINE + EVENTS	DATABASE SUMMARY	ALARM AUDIO ON/OFF	NEXT MENU
SET BASELINES	SET CHANNEL	EVENT MARK	PREVIOUS MENU
CHANNEL 1 SET	CHANNEL 2 SET	CHANNEL 3 SET	CHANNEL 4 SET

Select the channel or channels to set the baseline at the current rSO₂ value. This will display an event mark line and code on the screen in the graph area for the individual channel only.

When finished, press the HOME  key to exit the Baseline menu and return to the Main screen.

Auto Baseline Set

If a baseline is not set for all channels within 5 minutes of first rSO₂ data displayed, the system will automatically identify baselines and notify the user with an audio tone and the visual message “AUTO BASELINE SET” displayed in yellow on the upper right corner of the screen. The alarm notification will last for 5–10 seconds. The Database summary screen will display with the “AUTO BASELINE SET—PLEASE ACCEPT OR SET NEW BASELINES” message in yellow (see [Figure 8-6](#)). Perform the following navigation bar options:

ACCEPT AUDIO BL	SET CURRENT VALUES		PREVIOUS MENU
------------------------	---------------------------	--	---------------

Select **ACCEPT AUTO BASELINES** if the automatic baseline time is appropriate for the procedure or select **SET CURRENT VALUES** to select current rSO₂ value or values as the baseline or baselines.

On the Main screen, the auto set baselines will be displayed in the graph area of each channel, and status code 21 (AUTO BASELINE SET) will appear in the tabular data and case history outputs.

8.5.2 Patient Identifier in Database Operational Mode

The Patient identifier allows for storing in memory the unique individual patient number. The identifier allows the operator to locate the stored files. The Patient identifier can be entered at different times during the case when operating in Database operational mode (see [Figure 5-3](#), and sections [Entering Patient Identifier after Start Screen](#), [Entering or Editing Patient Identifier through Main Screen](#), and [Entering or Editing Patient Identifier through Database Summary](#)).

Entering or Editing Patient Identifier through Main Screen

To enter or edit a Patient identifier, press the HOME  key to display the Main screen, then perform the following navigation bar options:

BASELINE + EVENTS	DATABASE SUMMARY	ALARM AUDIO ON/OFF	NEXT MENU
OUTPUT SELECT	USER CONFIGURATION	TIME SCALE	NEXT MENU
REVIEW	PATIENT ID	PREVIOUS MENU	MAIN MENU
<---	--->	NEXT ROW	SELECT
<---	--->	NEXT ROW	SELECT

Select <---, ---> and **NEXT ROW** to scroll through the characters and **SELECT** to input the high-lighted character. When entry is complete, select **DONE** in the Patient identifier entry screen to save the unique alphanumeric identification and return to the Main screen.

Up to 24 alphanumeric characters may be entered.

Entering or Editing Patient Identifier through Database Summary

To enter or edit a patient identifier, press the HOME  key to display the Main screen, then perform the following navigation bar options:

BASELINE + EVENTS	DATABASE SUMMARY	ALARM AUDIO ON/OFF	NEXT MENU
PATIENT I.D.	FIRST ALERT	TO PRINTER	TO USB
<---	--->	NEXT ROW	SELECT
<---	--->	NEXT ROW	SELECT

Select <---, ---> and **NEXT ROW** to scroll through the characters and **SELECT** to input the high-lighted character. When entry is complete, select **DONE** in the Patient identifier entry screen to save the unique alphanumeric identification and return to the Main screen.

Up to 24 alphanumeric characters may be entered.

8.6 Collecting Metrics in Database Operational Mode

In Database operational mode, metrics can be collected in the Database summary screen or entered using the OR event mark lists. The metrics are displayed on the screen and 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 appear at that time in the line of Tabular trends screen or stored and outputted data.

**WARNING:**

For area under the curve (AUC) to calculate you must set left and right baselines prior to induction in real-time or accept the auto-baseline value when prompted by the device (approximately 5 minutes after first valid rSO₂ data is received). Baselines should not be reentered at any other time or the integrity of AUC will be compromised. Similarly, entering skin closure will cease calculation of AUC.

**Note:**

For capturing cerebral oximetry metrics, the OR event list should be set (see section [6.5.8 Event Mark List](#)).

8.6.1 Marking the Induction Time

Baselines must be set before the induction time. Induction time is defined as the beginning of the intubation process, prior to preoxygenation or heavy sedation. To select the current time as induction time, use the OR event list (see section [Marking the Current Time as Induction Time in the OR Event List](#)). To select an earlier time, use the Database summary screen (see section [Marking the Induction Time Using Tabular Data](#)).

Marking the Induction Time Using Tabular Data

To mark the induction event, press the HOME  key to display the Main screen, then perform the following navigation bar options:

BASELINE + EVENTS	DATABASE SUMMARY	ALARM AUDIO ON/OFF	NEXT MENU
INDUCTION TIME	SKIN CLOSURE TIME	FIRST ALERT	DOWNLOAD MENU

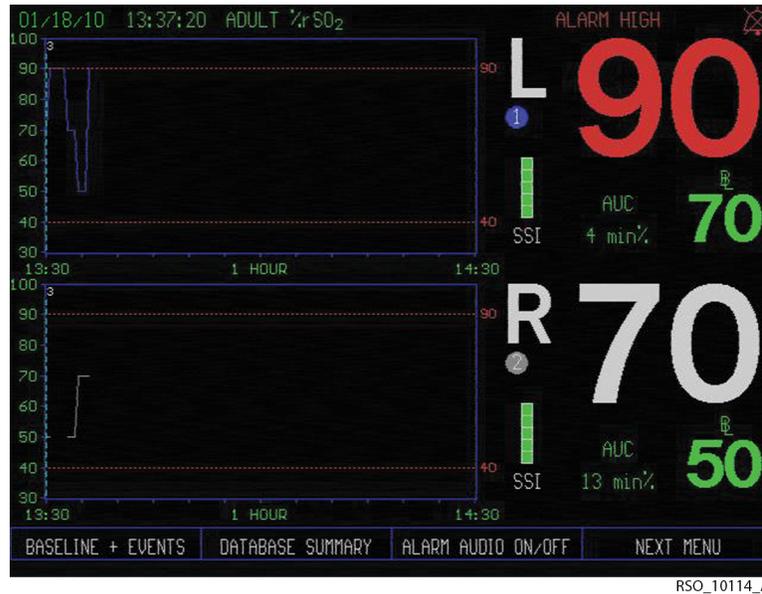
The Enter induction time menu will be displayed, then perform the following navigation bar options:

NEXT PAGE	PREVIOUS PAGE	LAST PAGE	SCROLL MENU
NEXT	PREVIOUS	SELECT TIME	PREVIOUS MENU

Use the **NEXT PAGE/PREVIOUS PAGE** menu options to scroll to the appropriate page and select **SCROLL MENU**. Scroll to the time/rSO₂ value for induction time using the **NEXT/PREVIOUS** menu options. Then, select **SELECT TIME** to enter the appropriate induction time (see [Figure 8-4](#)).

A vertical dashed line and event code will appear on the Main screen at the induction time and the AUC value in the data channel area will be displayed. The AUC value will be displayed as min-percent (see [Figure 8-10](#)).

Figure 8-10. Events Marked on Main Screen During Database Operational Mode



Marking the Current Time as Induction Time in the OR Event List

To mark the induction event, press the HOME  key to display the Main screen, then perform the following navigation bar options:

BASELINE + EVENTS	DATABASE SUMMARY	ALARM AUDIO ON/OFF	NEXT MENU
SET BASELINES	SET CHANNEL	EVENT MARK	PREVIOUS MENU
<--- --->	NEXT EVENT	PREVIOUS EVENT	SELECT EVENT
<--- --->	NEXT EVENT	PREVIOUS EVENT	SELECT EVENT

From the event mark list, select **NEXT EVENT** to highlight the event 3 induction. Select **SELECT EVENT** to choose the highlighted event code and return to the trend data graph.

A vertical dashed line and event code will appear on the Main screen at the induction time and the AUC value in the data channel area will be displayed. The AUC value will be displayed as min-percent (see *Figure 8-10.*).

8.6.2 Marking the Skin Closure Time

Entering the skin closure time is used to cease calculation of AUC.

Marking the Skin Closure Time in the Database Summary Menu Using Tabular Data

To mark the skin closure event, press the HOME  key to display the Main screen, perform the following navigation bar options:

BASELINE + EVENTS	DATABASE SUMMARY	ALARM AUDIO ON/OFF	NEXT MENU
INDUCTION TIME	SKIN CLOSURE TIME	FIRST ALERT	DOWNLOAD MENU

The Enter skin closure time menu will be displayed, then perform the following navigation bar options:

NEXT PAGE	PREVIOUS PAGE	LAST PAGE	SCROLL MENU
NEXT	PREVIOUS	SELECT TIME	PREVIOUS MENU

Use the **NEXT PAGE/PREVIOUS PAGE** menu options to scroll to the appropriate page and press **SCROLL MENU**. Scroll to the time/rSO₂ value for induction time using the **NEXT/PREVIOUS** menu options. Then, select **SELECT TIME** to enter the appropriate skin closure time.

A vertical dashed line and event code will appear on the Main screen at the skin closure time. The AUC value in the data channel area is updated with the skin closure time on the graph (see [Figure 8-10](#)). The monitor stops the AUC calculation.

Marking the Current Time as Skin Closure Time in the OR Event List

To mark the skin closure event, press the HOME  key to display the Main screen, then perform the following navigation bar options:

BASELINE + EVENTS	DATABASE SUMMARY	ALARM AUDIO ON/OFF	NEXT MENU
SET BASELINES	SET CHANNEL	EVENT MARK	PREVIOUS MENU
<--- --->	NEXT EVENT	PREVIOUS EVENT	SELECT EVENT
<--- --->	NEXT EVENT	PREVIOUS EVENT	SELECT EVENT

From the event mark list, select **NEXT EVENT** to highlight the event 13 skin closure. Select **SELECT EVENT** to choose the highlighted event code and return to the trend data graph.

A vertical dashed line and event code will appear on the Main screen at the skin closure time. The last AUC value in the data channel area will be the displayed and no longer updated on the screen (see [Figure 8-10](#)).

8.6.3 Capturing the First Alert Metric

The first alert metric is captured in the Database summary menu.

To capture first alert data, press the HOME  key to display the Main screen, then perform the following navigation bar options:

BASELINE + EVENTS	DATABASE SUMMARY	ALARM AUDIO ON/OFF	NEXT MENU
INDUCTION TIME	SKIN CLOSURE TIME	FIRST ALERT	DOWNLOAD MENU
YES	NO		

Select **YES** or **NO**.

8.6.4 Marking Metrics at the End of a Case

If cerebral oximetry database metrics were not marked during the case, they can be retroactively captured and calculated.



Note:

Retroactive entry of database metrics can only be entered if within 24 hours of case completion and before a new case has begun.



Note:

Induction time chosen must be after the time of baselines set.

Retroactively enter the metrics in the following order. AUC will calculate and display automatically on the Database summary page once the other metrics have been entered.

1. Baseline (see section [Mark a Baseline at the End of a Case](#))
2. Induction time (see section [Marking the Induction Time Using Tabular Data](#))
3. Skin closure (see section [Marking the Skin Closure Time in the Database Summary Menu Using Tabular Data](#))
4. First alert (see section [8.6.3 Capturing the First Alert Metric](#))

Mark a Baseline at the End of a Case

If no baseline was set during the case, it can be marked at the conclusion. To mark the baseline, press the HOME  key to display the Main screen. Or, if the monitor has been turned off, turn it

on by selecting the green ON/OFF  key and pressing **PREVIOUS PATIENT** from the Start screen. Then, perform the following navigation bar options:

BASELINE + EVENTS	DATABASE SUMMARY	ALARM AUDIO ON/OFF	NEXT MENU
SET BASELINES	SET CHANNEL	EVENT MARK	PREVIOUS MENU

The monitor will prompt to use the auto-set baselines. An alert will display with the message “AUTO BASELINE(S) SET—PLEASE ACCEPT AUTO BASELINE(S) OR SET NEW BASELINE(S) WITH CURRENT VALUES” in yellow (see [Figure 8-6](#)). Perform the following navigation bar menu option:



Select **ACCEPT AUTO BL**. The baseline values set approximately 5 minutes after first rSO₂ data is stored will appear in the data channel area.

8.7 Reviewing the Case in Database Operational Mode

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.

Stored case data files can be viewed on screen (real-time review) or downloaded (case archive) in the Database operational mode.

8.7.1 Real-Time Review of Database Information

At any time during a case, press the HOME  key to display the Main screen, then select **DATA-BASE SUMMARY**.



From the Database summary menu, review information about induction time, baselines rSO₂, skin closure rSO₂/time, AUC in [min%], and first alert [yes/no].

Real-Time Review in Database Operational Mode—Graphical Format



Note:

More than 1 hour of data must be stored to activate trend graph review. Data can only be reviewed in 1 hour increments.



Note:

Alarm messages, channel identification, and rSO₂ area elements will continue to be displayed while in real-time review.

To use real-time review in graphical format, press the HOME  key to display the Main screen, then perform the following navigation bar options:

BASELINE + EVENTS	DATABASE SUMMARY	ALARM AUDIO ON/OFF	NEXT MENU
OUTPUT SELECT	USER CONFIGURATION	TIME SCALE	NEXT MENU
REVIEW	PATIENT I.D.	PREVIOUS MENU	MAIN MENU
<--- TREND GRAPH	TREND GRAPH --->	TABULAR TRENDS	MAIN MENU

Select **<--- TREND GRAPH** or **TREND GRAPH --->** options to scroll across the trend lines on the display screen.

When reviewing is complete, press the HOME  key or **MAIN MENU** to exit real-time review and return to the Main screen.

When reviewing in graphical format during a case, a message in yellow may be displayed in the upper area of the graphs to alert for the following cases: "USB STORAGE ERROR", "USB STORAGE FULL", and "COM PORT UNAVAILABLE." This message will appear until the error is corrected and the screen is refreshed.

Real-Time Review in Database Operational Mode—Tabular Format



Note:

Alarm messages, channel identification, and rSO₂ area elements will continue to be displayed while in real-time review.

To use real-time review in Tabular trends screen format, press the HOME  key to display the Main screen, then perform the following navigation bar options:

BASELINE + EVENTS	DATABASE SUMMARY	ALARM AUDIO ON/OFF	NEXT MENU
OUTPUT SELECT	USER CONFIGURATION	TIME SCALE	NEXT MENU
REVIEW	PATIENT I.D.	PREVIOUS MENU	MAIN MENU
<--- TREND GRAPH	TREND GRAPH --->	TABULAR TRENDS	MAIN MENU
NEXT PAGE	PREVIOUS PAGE	LAST PAGE	REGGRAPH

Select **NEXT PAGE**, **PREVIOUS PAGE**, and **LAST PAGE** to scroll through the data (see [Table 5-1](#)).

When reviewing is completed, select **REGGRAPH** to exit Tabular trends and return to the real-time review trend graph.

NEXT PAGE	PREVIOUS PAGE	LAST PAGE	REGGRAPH
-----------	---------------	-----------	-----------------

Press the HOME  key to exit real-time review and return to the Main screen.

8.7.2 Case Archive Function in Database Operational Mode



Note:

Database software is not compatible with cases collected using previous software versions. Therefore, previous cases stored on the INVOS™ system should be downloaded and saved elsewhere prior to loading the database software.

Case archive allows review of up to 28 separate cases of 24-hour duration and two case examples. When run-on data storage exceeds 24 hours, it will be stored as a separate case. Case history data files are selected for review in the Case archive file list. The data may be viewed in graphical or tabular format (see sections [5.1.10 Tabular Trends Screen](#), [5.1.11 Case Archive File List Screen](#), and [5.1.12 Review Screen](#)).

Files with an asterisk (*) next to them indicate rSO₂ desaturations of ≥20% or values ≤40 (see section [Data File Name Format](#)).

Case Archive Function—Database Summary



Note:

More than 1 hour of data must be stored to activate trend graph review. Data can only be reviewed in 1 hour increments.

To access Case archive function in graphical format, press the ON/OFF  key to display the Start screen and perform the following navigation bar options:

NEW PATIENT	PREVIOUS PATIENT	DATE/TIME	NEXT MENU
CASE ARCHIVE	PREVIOUS MENU		
NEXT FILE	PREVIOUS FILE	SELECT FILE	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.

<--- TREND GRAPH	TREND GRAPH --->	FULL GRAPH	NEXT MENU
TABULAR TRENDS	DOWNLOAD	PREVIOUS MENU	NEXT MENU
CASE ARCHIVE	START SCREEN	DATABASE SUMMARY	PREVIOUS MENU

Select **NEXT MENU** twice and **DATABASE SUMMARY** to display the screen containing information about induction time, baselines rSO₂, skin closure rSO₂/time, AUC in [min%], and first alert [yes/no] (see [Figure 8-9](#)).

When reviewing is complete, to return to trend graph select **REGRAPH**. To return to the Case archive list and select a case, select **CASE ARCHIVE**.

REGRAPH	CASE ARCHIVE	TO PRINTER	TO USB
----------------	---------------------	------------	--------



Note:

The Case archive file list will display only the cases with four-channel monitoring when the configuration is for four channels, and only the cases with two-channel monitoring when the configuration is for two channels.

8.8 Outputting the Metrics in Database Operational Mode

All cerebral oximetry metrics appear on the Database summary screen (see sections [8.7 Reviewing the Case in Database Operational Mode](#)). Metrics for each case should be written down or stored to Covidien USB flash drive and then submitted into the database through STS-certified software program (see section [7.3 Using the USB Port](#)).

8.8.1 Outputting Database Summary Screen to USB Flash Drive During a Case or Prior to Next Patient



Note:

USB flash drives not supplied by Covidien may not meet system requirements. Additional drives may be ordered from Covidien (see section [3.12 Accessories](#)).

To capture the Database summary screen as an output to the USB flash drive, make certain the INVOS™ system components, including the USB flash drive, are connected. With the monitor on and Run function operating, press the HOME  key to display the Main screen, then perform the following navigation bar options:

BASILINE + EVENTS	DATABASE SUMMARY	ALARM AUDIO ON/OFF	NEXT MENU
INDUCTION TIME	SKIN CLOSURE TIME	FIRST ALERT	DOWNLOAD MENU
TO PRINTER	TO USB	PREVIOUS MENU	MAIN MENU

Select **TO USB**.

When the download is complete, press the HOME  key or **MAIN MENU** to exit and return to the Main screen.

When outputting during a case, a message in yellow may be displayed in the upper area to alert for the following cases: "USB STORAGE ERROR" and "USB STORAGE FULL." This message will appear until the error is corrected and the screen is refreshed.

The Database summary screen is saved on the USB flash drive as a file with the name format YYM-MDDN.DXX.

8.8.2 Outputting Database Summary to USB Flash Drive in Case Archive Function



Note:

USB flash drives not supplied by Covidien may not meet system requirements. Additional drives may be ordered from Covidien (see section [3.12 Accessories](#)).

To capture the Database summary screen as an output to the USB flash drive, make certain the INVOS™ system components, including the USB flash drive, are connected. To access Case archive function and download a case, press the ON/OFF  key to display the Start screen, then perform the following navigation bar options:

NEW PATIENT	PREVIOUS PATIENT	DATE/TIME	NEXT MENU
CASE ARCHIVE	START SCREEN		
NEXT FILE	PREVIOUS FILE	SELECT FILE	START SCREEN
<--- TREND GRAPH	TREND GRAPH --->	FULL GRAPH	NEXT MENU
TABULAR TRENDS	DOWNLOAD	PREVIOUS MENU	NEXT MENU
CASE ARCHIVE	START SCREEN	DATABASE SUMMARY	PREVIOUS MENU
REGRAPH	CASE ARCHIVE	TO PRINTER	TO USB

Select **TO USB** to download the Database summary screen.

When outputting during a case, a message in yellow may be displayed in the upper area to alert for the following cases: "USB STORAGE ERROR" and "USB STORAGE FULL." This message will appear until the error is corrected and the screen is refreshed.

When outputting is complete, select another case or return to the Start screen by selecting **CASE ARCHIVE**.

The Database summary screen is saved on the USB flash drive as a file with the name format YYM-MDDN.DXX.

Page Left Intentionally Blank

9 Maintenance

9.1 Overview

This chapter defines the product upgrades, repair policy, maintenance and inspections, and troubleshooting techniques for the INVOS™ regional saturation patient monitoring system.



Note:

The INVOS™ system is calibrated during manufacturing and does not require additional adjustments. The sensor also is calibrated during manufacturing. The ID number stored in the sensor's chip allows calibration of the individual sensor to the INVOS™ system. Additional calibration is not required.

9.2 Software Upgrades

Software upgrades are performed using a USB flash drive supplied by Covidien. To inquire about software upgrades contact Covidien's customer service department. USB flash drives supplied by Covidien are accompanied by software upgrade instructions for use .

9.3 Repair Policy

Have all repairs performed by Covidien's authorized repair representative (see section [1.7 Customer Inquiries](#)).

9.4 Cleaning the INVOS™ System



WARNING:

Electrical shock warning.  Disconnect the INVOS™ system from the AC power before cleaning.



WARNING:

Do not immerse the INVOS™ system in any liquids as they may cause electric shock hazard or damage the device.



Caution:
Do not autoclave the INVOS™ system.



Caution:
Do not gas sterilize the INVOS™ system.

1. Disconnect the AC power from the INVOS™ monitor. Turn the system off by selecting the green ON/OFF  key.
2. Clean the outside surface of the enclosure with a cloth dampened with Isopropyl alcohol–70% or a mild soap and water solution.
3. Clean the faceplate and screen with a clean, soft cloth and isopropyl alcohol or a commercial glass cleaner. Do not use acetone or abrasives.
4. If necessary, the INVOS™ system and cables can be wiped clean with commercial germicidal agents.
5. Allow the INVOS™ system monitor to completely dry before reconnecting the AC power.

9.5 Battery Recharge



WARNING:
The backup battery is not user replaceable.

The battery charges itself while the INVOS™ system is connected to AC power. It acts as a backup for data storage, power outages, and patient transport. The battery has an approximate 20-minute operation capacity. Recharge time from 50% discharge to full charge is approximately 20 hours and 100% discharge to full charge is approximately 24 hours.



Note:
Upon initial unpacking the battery may be partially discharged. Before attempting battery operation, the battery must be charged by connecting the INVOS™ system monitor to AC power in either operational or nonoperational mode. A charge time of 24 hours is required to recharge a fully depleted battery. The blue  LED on the key panel illuminates to indicate the power is connected and the battery is charging.



Note:
The backup battery is not user replaceable. Any attempt to access the battery by the user will void the product warranty.

9.5.1 Check Battery Status

1. Place the monitor on a sturdy, flat surface and plug it in to a power source (mains) by attaching the power cord to the inlet (see *Figure 3-1.*).

**Note:**

Use only hospital-grade AC mains outlets.

2. Turn the mains power switch on. The blue  LED on the key panel illuminates to indicate the power is connected and the battery is charging (see *Figure 3-1.*).
3. Access Run function by pressing the ON/OFF  key to display the Start screen, then select NEW PATIENT or PREVIOUS PATIENT from the navigation bar options.
4. Turn the mains power switch off. A battery symbol/gauge  should appear in the lower right side of the display screen, indicating the battery status. If the symbol shows a full battery, there is no need for battery charging. If the symbol shows a partial or total discharge of the battery, turn the mains power switch on and the battery recharges automatically.

9.5.2 Recharge the Battery

1. Place the monitor on a sturdy, flat surface and plug it in to a power source (mains) by attaching the power cord to inlet (see *Figure 3-1.*).

**Note:**

Use only hospital-grade AC mains outlets.

2. Turn the mains power switch on. The blue  LED on the key panel illuminates to indicate the power is connected and the battery is charging (see *Figure 3-1.*). The monitor can be on or off. The battery recharges as long as the blue LED is on.

9.6 Maintenance Schedule

Table 9-1. Maintenance Schedule

How often?	What to do
Annually	Check the INVOS™ system (see section 9.7 Annual Inspection Procedure).
After 5 years	Replace the backup battery. (The battery is not user replaceable. See section 1.8.8 Who to Contact for Authorized Repair .)
After 5–6 years	Replace the lithium battery on the CPU. (The lithium battery is not user replaceable. See section 1.8.8 Who to Contact for Authorized Repair .)
After 10 years	Replace the disk on the chip module. This replacement is only available at Covidien authorized repair facilities. (See section 1.8.8 Who to Contact for Authorized Repair .)
As needed	LCD lamps (after 50 000 hours of operation) Fan (after 40 000 hours of operation) CPU (after 46 250 hours of operation) These replacements are only available at Covidien authorized repair facilities. (See section 1.8.8 Who to Contact for Authorized Repair .)

9.7 Annual Inspection Procedure



Note:

The INVOS™ system should be inspected at least once every year for safety and normal operation.

9.7.1 Mechanical Inspection Points

Inspect the following for loose screws, cracks, dirt, loose connectors, corroded or bent pins, fluid contamination or stains, or damaged cords.

- Power cord
- Reusable sensor cable or cables
- Preamplifier or preamplifiers with cable or cables
- Battery status (see section [9.5.1 Check Battery Status](#))
- Key panel
- Fan

**Note:**

The air intakes on the side of oximeter and the fan should be inspected and vacuumed if dust or debris is present.

9.7.2 Electrical Inspection Points

Table 9-2. Electrical Inspection Points

Inspection point	Method
Power up/power down	<p>Place the monitor on a sturdy, flat surface and plug it in to a power source. Verify the blue  LED on the key panel is illuminated.</p> <p>Press the ON/OFF  key to display the Start screen, and observe the monitor for proper functioning and display. Verify the green  LED on the key panel is illuminated.</p> <p>Press the ON/OFF  key again. Verify the monitor turns off correctly.</p>
Battery backup	<p>With mains (AC power) switch OFF, turn the INVOS™ system on by pressing the ON/OFF  key to display the Start screen. Select NEW PATIENT or PREVIOUS PATIENT and observe the battery capacity indicator on the Main screen. Turn the mains power switch ON and fully charge the battery.</p> <p>Unplug the line cord (AC power) and observe that the monitor continues to run and that the battery capacity indicator on the screen shows a full charge. The monitor should operate for about 20 minutes on a fully charged battery.</p>
Unit self diagnostics	<p>Observe that the INVOS™ system monitor boots up to the Start screen following power up and Welcome screen.</p>
Sensor operation	<p>Connect preamplifier, sensor cable, and sensor.</p> <p>Turn the INVOS™ system on by pressing the ON/OFF  key to display the Start screen. Select NEW PATIENT or PREVIOUS PATIENT and observe the light emitting diodes (LED) functioning on the sensor.</p> <p>Perform the functional test with optional field test device (see section 9.7.3 Functional Test with Optional Field Test Device).</p>
Video output port	<p>Connect an external VGA monitor. Observe the INVOS™ screen on the external device.</p>
Data output port	<p>Connect an external device to the data output port.</p> <p>Follow the procedure described in section 7.4 Using the Digital Output Port. Verify that the data is correctly transmitted.</p>
USB port	<p>Connect a Covidien USB flash drive to the USB port.</p> <p>Follow the procedure described in section 7.3 Using the USB Port. Verify that the monitor can write data on the USB flash drive.</p>

9.7.3 Functional Test with Optional Field Test Device

**Note:**

Only a Covidien-supplied field test device should be used with the INVOS™ system. No other field test devices should be connected to the system. For additional information on acquiring and using a field test device, contact Covidien's customer service department.

The field test device allows for functional testing of the INVOS™ system. To perform a functional test with the field test device:

1. Place the monitor on a sturdy, flat surface and turn on the monitor from the AC power source (mains) (see *Figure 3-1.*).

**Note:**

Use only hospital-grade AC mains outlets.

2. Connect the preamplifier to the INVOS™ system monitor (see *Figure 3-2.*).
3. Connect the optional field test device to the preamplifier.
4. Turn the mains power switch ON. Observe the illuminated blue  LED on the key panel.
5. Turn the INVOS™ system on by pressing the ON/OFF  key to display the Start screen. Select **NEW PATIENT** or **PREVIOUS PATIENT** to display the Main screen.
6. On the Main screen, data from connected channels should appear. An rSO₂ of 50±1 should be displayed for all connected channels.

9.8 Troubleshooting Techniques

**WARNING:****Electric shock hazard:**

- **Before performing any service, turn off the unit, then disconnect the AC power (see *Figure 3-1.* for location), remove the enclosure, and disconnect the battery from the DIB board.**
- **Electrostatic discharge (ESD) protection also is required before performing any service on the unit.**
- **Make sure all cables are connected and all components are installed correctly before attempting to apply power or turn on the unit.**

**Caution:**

Do not attempt to perform any service or tamper with the warranty seal unless you have been authorized in writing by Covidien. Repairs made by anyone not authorized by Covidien during the warranty period will void the product warranty.

This section provides troubleshooting assistance. The system diagram can be used when attempting to isolate the cause of a problem (see [Figure A-1](#), and sections [9.8.1 Who to Contact for Technical Service](#), [9.8.2 Check Fuses](#), [9.8.3 Troubleshooting Chart](#), and [9.8.4 Troubleshooting the Digital Output](#)).

9.8.1 Who to Contact for Technical Service

For additional assistance troubleshooting, contact Covidien's customer service department at 800 635 5267, Customer.Service-RMS@Covidien.com, www.covidien.com, or via an authorized repair representative (see section [1.8.8 Who to Contact for Authorized Repair](#)).

9.8.2 Check Fuses

Above the mains power switch is the external access fuse compartment. The AC input line is fused with 2.5 A, 250 V fuses.

**WARNING:**

Disconnect the AC power cord before operating fuse compartment door.

1. Remove the fuse holder by inserting a jeweler's size, flat-blade screwdriver into the slot at the top of the holder. Pry the fuse holder out.
2. Remove the fuse holder from the line filter.
3. To replace the fuses, place the new fuse in the side of the holder with one end closest to the four posts at the back of the holder. The other end of the fuse should go to the middle of the fuse holder and latch into the middle fuse holder spot. When both fuses are installed, place the fuse holder back in the line filter and push it in completely.
4. Close the fuse compartment door.
5. Using an ohmmeter, verify the resistance (it should be 0.0 Ω).

9.8.3 Troubleshooting Chart

Table 9-3. provides problems that may be encountered while using the INVOS™ system and a list of the possible causes for each problem.

Table 9-3. INVOS™ System Troubleshooting Chart

Indication	Possible cause	Action
Does not turn on	No AC power or battery power	Plug the INVOS™ system into a hospital-grade electrical outlet. Turn on the back panel AC power switch.
	Blown fuse on line filter	Check the fuses.
	Defective CPU board	Service the INVOS™ system. ¹
	Defective key panel	Service the INVOS™ system. ¹
	Blown fuse on internal module	Service the INVOS™ system. ¹
Locks up/intermittent	Erratic AC power input	Change the electrical outlet.
	Defective CPU board	Service the INVOS™ system. ¹
	No AC power or battery power	Plug the INVOS™ system into a hospital-grade electrical outlet. Turn on the back panel AC power switch.
Monitor turns off	Defective battery	Service the INVOS™ system. ¹
	Blown fuse on internal module	Service the INVOS™ system. ¹
	Defective fan	Service the INVOS™ system. ¹
Key panel does not function	Defective key panel	Service the INVOS™ system. ¹
	INVOS™ system locked up	Reboot the INVOS™ system.
	Defective internal module	Service the INVOS™ system. ¹
No rSO ₂ reading	See error messages in data channel area on the display screen.	Follow the on-screen instructions.
	Preamplifier not connected to the monitor, sensor cable, or sensor	Connect the preamplifier, cable, or sensor.
	Sensor not connected to the patient	Apply the sensor to the patient.
	INVOS™ system monitor locked up	Reboot the INVOS™ system.
	Defective CPU board	Service the INVOS™ system. ¹
	Defective preamplifier cable or connector	Service the INVOS™ system. ¹
	Blown fuse on the internal module	Service the INVOS™ system. ¹
	Defective preamplifier	Service the INVOS™ system. ¹

Table 9-3. INVOS™ System Troubleshooting Chart (Continued)

Indication	Possible cause	Action
No display	Defective CPU board	Service the INVOS™ system. ¹
	Defective monitor	Service the INVOS™ system. ¹
	Defective inverter board	Service the INVOS™ system. ¹

1. For additional troubleshooting assistance, contact Covidien's customer service department at 800 635 5267, Customer.Service-RMS@Covidien.com, www.covidien.com, or via an authorized repair representative.

9.8.4 Troubleshooting the Digital Output

Table 9-4. provides problems that may be encountered while outputting data and a list of the possible causes and action to correct for each problem (see section 7.4 *Using the Digital Output Port*).

Table 9-4. Digital Output Troubleshooting Chart

Indication	Possible Cause	Action
Selecting CASE HISTORY in the Digital output menu produces the "COM PORT UNAVAILABLE" message on the screen	The digital output port is not connected to the PC with a null modem cable.	Verify the connection of the monitor to the PC with a null modem cable.
	The wrong COM port is specified in the HyperTerminal™** program.	Verify the correct COM port is specified.
No data received or transmission is scrambled.	The HyperTerminal™** settings are not correct.	Verify the HyperTerminal™** settings are correct.

9.8.5 Troubleshooting Signal Strength Indicator (SSI)

The signal strength indicator (SSI) reflects the strength and stability of the signal that is used to make an rSO₂ 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 rSO₂ values from very small signals.

The SSI scale ranges from one to five bars, with five bars being the highest. Generally, the SSI symbol will read five bars. However, rSO₂ values displayed on-screen with one through four stable SSI bars are also reliable. It just means the rSO₂ values are being generated from a signal intensity that is lower than normal.

When only one SSI bar appears, it may be an early warning that rSO₂ values on-screen may soon cease if the signal continues to degrade. Similarly, bars fluctuating rapidly between five through one bar (rather than appearing stable) may also reflect a signal that could soon be lost. In these scenarios, when the signal is lost for one channel, the rSO₂ value is not displayed for that channel

and an alarm message and help notes are displayed (see section [6.5.13 Alarms and Status Messages](#)).

[Table 9-5](#) provides SSI ranges and a list of the possible causes and action to correct for each, if necessary.

Table 9-5. Signal Strength Indicator Troubleshooting Chart

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.
1 through 4 bars—fluctuating and unstable	Signal is weak and unstable	
	Signal interference	Identify any possible sources of interference, such as electrocautery 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, reapply the sensor to the 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 a new sensor to the 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 screen (see Table 6-6 .)	Follow on-screen instructions.

A Specifications

A.1 Overview

This chapter provides product specifications for the INVOS™ regional saturation patient monitoring system.

A.2 Specifications

A.2.1 Physical

Table A-1. Physical Specifications

		Oximeter	Preamplifier
Dimensions	Height	24 cm (9.5 in.)	24 cm (9.5 in.)
	Width	29 cm (11.25 in.)	8 cm (3.13 in.)
	Depth	19 cm (7.5 in.)	4.5 cm (1.75 in.)
Weight		4.95 kg (10.9 lbs)	0.52 kg (1.2 lbs)
Preamplifier cable length	4.5 m (15 ft)		
Reusable sensor cable length (INVOS™ adult regional saturation sensor or pediatric regional saturation sensor)	1.5 m (5 ft)		
INVOS™ OxyAlert NIRSensor cable length	1.5 m (5 ft)		

A.2.2 Operational

Table A-2. Operational Specifications

Range of rSO ₂	15–95 (updated every 5–6 seconds)
Repeatability	Hardware (including sensor) repeatability if within 1 rSO ₂ point from unit to unit (measured in vitro).
Alarm limit range	High: 20–95; Low: 15–90 High and low limits cannot cross
Trend memory	24 hours at two samples per minute

Table A-2. Operational Specifications (Continued)

Diagnostics	Automatic self-test Continuous operation
Safety class	Type BF  Class I
Power	External AC mains or backup battery
Signal strength indicator  SSI	0–5 bars (5 being the highest signal strength) See sections 6.5.14 Signal Strength Indicator (SSI) and 9.8.5 Troubleshooting Signal Strength Indicator (SSI)

A.2.3 Electrical

Table A-3. Electrical Specifications

Input voltage	100–240 VAC
Frequency	50/60 Hz
Current	1.0 A – 0.5 A (maximum at 100 and 240 volts respectively)
Fuse	 F2.5 A 250V
Backup battery	 12 VDC; approximately 20 minutes
Digital output	 RS-232 communications
USP port	 USB 2.0 flash memory (does not support other USB devices)

A.2.4 Environmental Requirements

Table A-4. Environmental Requirements

Operating temperature	+16°C to +32°C (+60°F to +90°F)
Shipping/storage temperature	0°C to +50°C (+32°F to +122°F)
Operating humidity	20% to 80%, non-condensing
Shipping/storage humidity	15% to 95%, non-condensing
Operating altitude and pressure	–380 m to +3000 m (–1247 ft to +9842 ft) Ambient pressure 106 kPa to 70 kPa
Shipping/storage altitude and pressure	–500 m to +4600 m (–1640 ft to +15092 ft) Ambient pressure 109 kPa to 52 kPa

A.2.5 Alarm Conditions

Table A-5. Alarm Conditions

Priority	Rate	Color	Type	Messages
Medium	Sounds every 8 seconds while the alarm condition persists	Yellow Steady message, slow flashing label	Physiological	High rSO ₂
				Low rSO ₂
			Technical	Sensor not connected
				Excessive light
				Poor signal quality
				Preamp not connected
				Replace sensor
				Interference detected
Sensor unusable				
Low	Sounds every 16 seconds while the alarm condition persists	Steady yellow	Technical	Battery low
				COM port unavailable
				Printer unavailable
				USB storage full
				USB storage error
				Auto baseline set



Note:

During multiple-alarm conditions, alarms are presented as follows:

- If two medium-priority alarms occur simultaneously, the alarm status message toggles between the two.
- If a medium-priority and low-priority alarm occur simultaneously, only the medium-priority alarm is displayed and only the medium-priority tone is sounded.
- A medium-priority physiological alarm overrides a low-priority alarm.

A.2.6 Alarm Tone Definitions

Table A-6. Alarm Tone Definitions

Tone category	Description
Medium priority alarm tone	
Volume level	High, medium, and low
Sound pressure	57 dB (high volume), 49 dB (medium volume), 40 dB (low volume)
Pitch (± 5 Hz)	720 Hz
Pulse width (± 20 msec)	146 msec
Number of pulses in burst	3
Repetitions	Continually
Interburst interval	Approximately 8 sec
Low priority alarm tone	
Volume level	High, medium, and low
Sound pressure	51 dB (high volume), 42 dB (medium volume), 34 dB (low volume)
Pitch (± 5 Hz)	720 Hz
Pulse width (± 20 msec)	187 msec
Number of pulses in burst	1
Repetitions	Continually every 16 seconds while visual alarm is presented
Interburst interval	Approximately 16 sec
Alarm reminder tone	
Volume level	High, medium, and low
Sound pressure	50 dB (high volume), 42 dB (medium volume), 33 dB (low volume)
Pitch (± 20 Hz)	720 Hz
Pulse width (± 20 msec)	900 msec
Number of pulses	1
Repetitions	Continually every 3 minutes

A.2.7 Default Settings

Table A-7. Default Settings

	Default	Range
High alarm limit	OFF	20–95
Low alarm limit	40	15–90
Alarm volume	Medium	Low, medium, high
High rSO ₂ scale limit	100	60–100 in increments of 10; 5 above high alarm limit
Low rSO ₂ scale limit	30	0–30 in increments of 10; 5 below low alarm limit

Table A-7. Default Settings (Continued)

	Default	Range
Time (trend) 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, S1, S2	A-Z, S1-S4
Color coded labels	No	Yes, No
Output format (digital output)	1	1-3

A.2.8 Additional

Software	Software version is displayed on the Start screen. The software version for two channel monitoring is 30.XX.XX and for four channel monitoring is 40.XX.XX.
End-of-life management and recycling 	Lifetime is indefinite when used under specified operating conditions and preventive maintenance is performed, subject to component availability. This product is designed to comply with the Waste Electrical and Electronic Equipment (WEEE) Directive, 2002/96/EC. For end-of-life product return and recycling, contact your authorized representative or Covidien customer service at 800 635 5267, Customer.Service-RMS@Covidien.com, or via the internet www.covidien.com.
Certification and compliance	The INVOS™ system complies with the following U.S. and international regulatory standards for medical equipment: UL 60601-1 CSA C22.2.601.1 EN 60601-1
Essential performance	The INVOS™ system has no essential performance characteristics.
Corporate information	Covidien's quality system is registered to the ISO 13485 standard. 



Note:

Specifications subject to change without notice to user.

A.3 **Guidance and Manufacturer's Declaration—Electromagnetic Compatibility (EMC)**



WARNING:

The INVOS™ system is intended for use by healthcare professionals only. The INVOS™ system may cause radio interference or may disrupt the operation of nearby equipment, regardless of whether it is CISPR compliant or not. It may be necessary to take mitigation measures, such as reorienting or relocating the INVOS™ system or shielding the location.



WARNING:

The INVOS™ system should not be used adjacent to or stacked with other equipment, except as may be specified elsewhere in this manual. If adjacent or stacked use is necessary, the INVOS™ system should be observed to verify normal operation in the configurations in which it will be used.



WARNING:

The use of accessories, sensors, and cables other than those specified may result in poor performance of the INVOS™ system and increased electromagnetic emissions or decreased electromagnetic immunity of the INVOS™ system.



Caution:

The INVOS™ system is not intended for use in residential environments and may not provide adequate protection to radio communication services in such environments.

The INVOS™ system is suitable for prescription use only in the specified electromagnetic environments, in accordance with the IEC 60601-1-2:2014 standard. The INVOS™ system requires special precautions during installation and operation for electromagnetic compatibility. In particular, the use of nearby mobile or portable communications equipment may influence system performance.

A.3.1 Guidance and Manufacturer's Declaration—Electromagnetic Emissions

The INVOS™ system is intended for use in the electromagnetic environment specified below. The customer or user of the INVOS™ system should ensure that it is used in such an environment.

Table A-8. Electromagnetic Emissions

Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	The INVOS™ system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The INVOS™ system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/flicker emissions IEC / EN 61000-3-3	N/A	

A.3.2 Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The INVOS™ system is intended for use in the electromagnetic environment specified in [Table A-9](#). The customer or user of the system should ensure that it is used in such an environment.

Table A-9. Electromagnetic Immunity

Immunity test	IEC/EN 60601-1-2 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC/EN 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC/EN 61000-4-4	± 2 kV for power supply lines ±1 kV for input/output lines	± 2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	± 1 kV differential mode ±2 kV common mode	± 1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Table A-9. Electromagnetic Immunity (Continued)

Immunity test	IEC/EN 60601-1-2 test level	Compliance level	Electromagnetic environment guidance
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC/EN 61000-4-11 Note: U_T is the AC mains voltage prior to application of the test level.	$<5\% U_T$ ($>95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $<5\% U_T$ ($>95\%$ dip in U_T) for 5 seconds	$<5\% U_T$ ($>95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $<5\% U_T$ ($>95\%$ dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that the INVOS™ system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC/EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

A.3.3 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the INVOS™ System

The INVOS™ system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the INVOS™ system as recommended in [Table A-10](#). Portable and mobile RF communications equipment should be used no closer to any part of the INVOS™ system, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.



Note:

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.



Note:

At 80 MHz and 800 MHz, the higher frequency range applies.

Table A-10. Electromagnetic Immunity—Conducted and Radiated RF

Immunity test	IEC/EN 60601-1-2 test level	Compliance level	Electromagnetic environment guidance
	Frequency of transmitter		Equation for separation distance (<i>d</i>)
Conducted RF IEC/EN 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	$d = 1.2\sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC/EN 61000-4-3	3 V/m 80 MHz to 800 MHz	3 V/m 80 MHz to 800MHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
	3 V/m 800 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz

P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the separation distance in meters (m).

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the INVOS™ system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the INVOS™ system.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Interference may occur in the vicinity of equipment marked with the following symbol:



Table A-11. Recommended Separation Distances

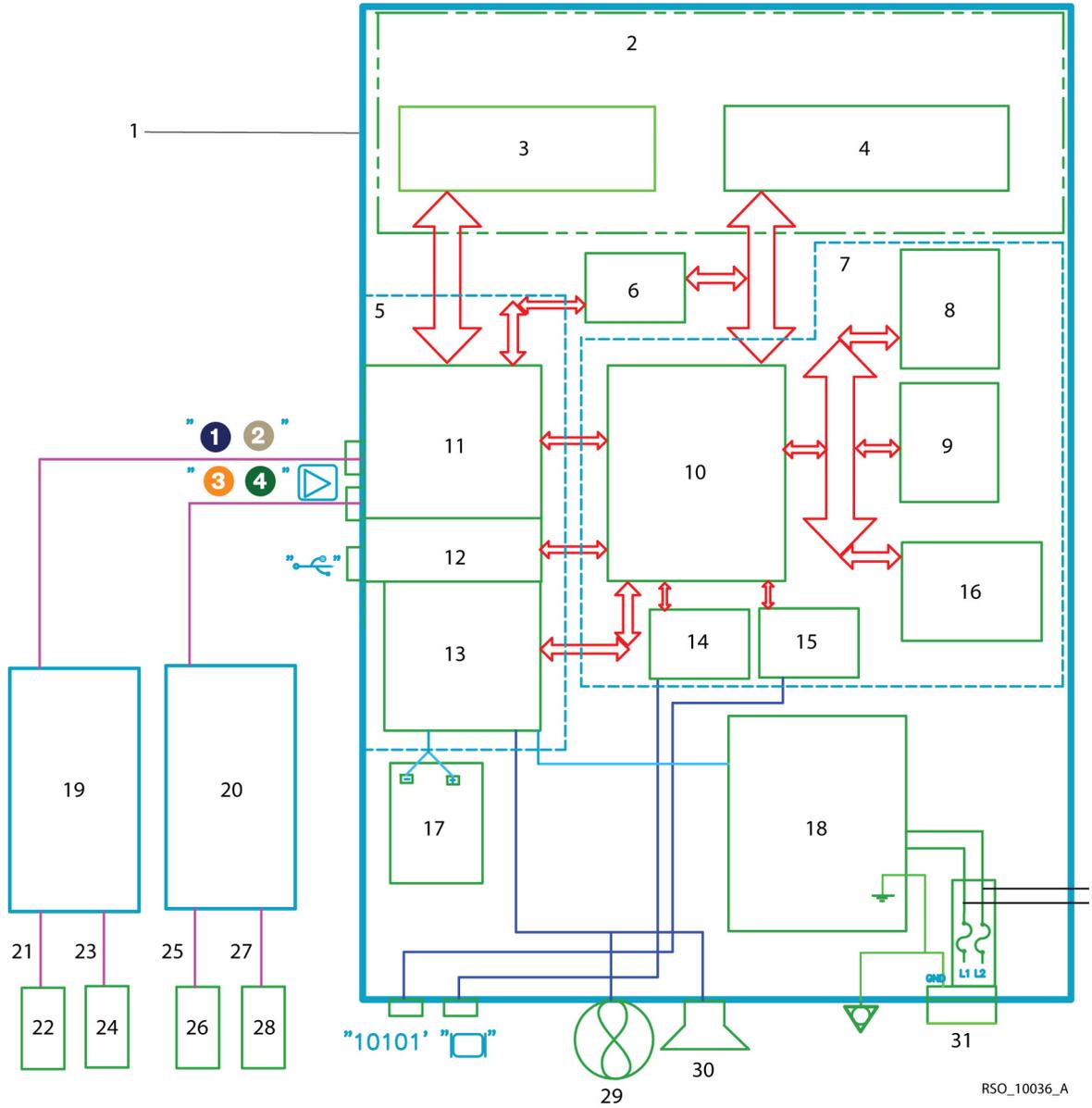
Rated maximum output power (<i>P</i>) of transmitter in watts (W)	Separation distance (<i>d</i>) in meters		
	$d = 1.2\sqrt{P}$ 150 kHz to 80 MHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz	$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1.00	1.20	1.20	2.30
10.00	3.80	3.80	7.30
100.00	12.00	12.00	23.00

For transmitters rated at a maximum output power not listed above, estimate the separation distance (*d*) using the equation in the corresponding column, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

A.4 System Diagram

Figure A-1. shows a diagram of the INVOS™ system. This diagram can also be used when troubleshooting (see section 9.8 *Troubleshooting Techniques*).

Figure A-1. Diagram of INVOS™ System (Model 5100C)



- | | | | |
|---|-----------------|----|----------------------------|
| 1 | Monitor | 18 | Main power supply |
| 2 | Human interface | 19 | Pre-amplifier A |
| 3 | Keypad | 20 | Pre-amplifier B (optional) |

4	Liquid crystal display (LCD)	21	Reusable sensor cable (RSC) 1 blue "1"
5	Digital interface board (DIB)	22	Sensor 1
6	LCD inverter	23	RSC2 taupe "2"
7	Computer processing unit (CPU)	24	Sensor 2
8	Data memory	25	RSC3 orange "3"
9	Program memory	26	Sensor 3
10	Data processing module	27	RSC4 green "4"
11	Data acquisition module and digital interface	28	Sensor 4
12	USB interface	29	Fan
13	Alarming and power control functions	30	Speaker
14	Video out interface	31	AC line in (120 V/60 HZ) (mains voltage)
15	Serial out interface	32	Fuse 1 (2.5 A)
16	Configuration memory	33	Fuse 2 (2.5 A)
17	Battery		

Page Left Intentionally Blank

B Clinical Studies

B.1 Overview

This chapter provides information on two clinical studies using the INVOS™ regional saturation patient monitoring system. A reference bibliography containing additional clinical studies is available on Covidien's website (www.covidien.com) or by contacting Covidien's customer service department.

An adult volunteer study was performed comparing the regional oxygen saturation (rSO₂) from the INVOS™ system to blood sample analysis in 20 volunteers (hypoxia study). No adverse events attributable to the INVOS™ system were reported during the study. A second study also compared the rSO₂ from the INVOS™ system to blood sample analysis in 22 patients with congenital malformations of the heart and great vessels in the pediatric cath lab (pediatric study). No adverse events attributable to the INVOS™ system were reported during the study.

B.2 Hypoxia Study

The hypoxia study compared the rSO₂ as reported by the INVOS™ system to the "field" saturation (fSO₂) calculated from arterial and jugular venous blood oxygen saturation measurements at five levels of oxygen saturation and two levels of inspired CO₂. Based on the assumption that cerebral tissue contains arterial and venous blood in a 1:3 ratio, fSO₂ was calculated as:

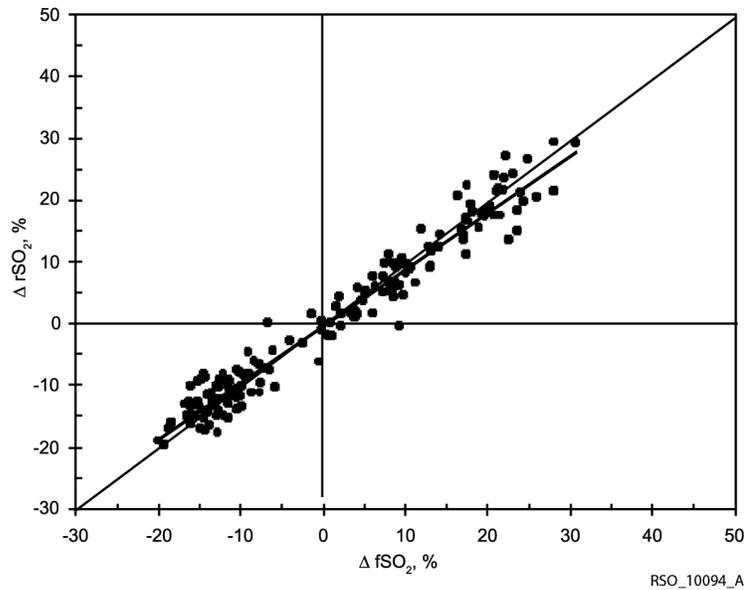
$$fSO_2 = (0.25 \times S_{\text{arterial}O_2}) + (0.75 \times S_{\text{jugular vein}O_2})$$

The 20 volunteers included: 19 with light and 1 with dark skin; 12 males and 8 females; age 20 to 36 years, with a median of 25 years. One data point was excluded from analysis due to delays in blood sampling caused by catheter problems.

Methods: Blood samples were obtained from the right internal jugular bulb and the radial artery. An INVOS™ adult regional saturation sensor was placed on the right forehead. Subjects breathed controlled gas mixtures in a predefined sequence of 4- and 5- minute intervals to attain five levels of arterial O₂ saturation (74% to 100%). This sequence was performed twice at two different CO₂ levels (4-7 mmHg increase) intended to raise cerebral blood flow and evaluate the ability of the INVOS™ system to reject noncerebral data.

Results:

Figure B-1. rSO₂ and fSO₂, 20 Subjects



Transitions 96 and 97 data; last 20 subjects; 179 data points. $y=0.9133x-0.1755$; $R^2=0.9575$; bias=0.26; standard deviation=2.9.

Table B-1. Bias, Error, and Correlation for rSO₂ and fSO₂

	Individual subjects (N=20) mean	Range	Pooled (N=180) transi- tions
Difference ¹ (Bias)%	2.49	-6.47 to +11.78	0.26
Error (standard deviation)%	2.13	0.85 to 4.22	2.90
Correlation (r2)	0.947	0.823 to 0.990	0.958

1. Less subject 206

One subject had a bias value of 37.2%, which corresponded with a very low signal quality index number (SQI=1). The remaining 41 subjects had SQIs that started at 10 and remained greater than four throughout the study.

Subject 206's absolute bias data was excluded from the analysis due to the low signal quality, but the trend data was left in as trending is not dependent on SQI.

B.3 Pediatric Clinical Study

A prospective clinical study was performed to validate the performance of the INVOS™ system in the pediatric cath lab. The study compared the regional oxygen saturation index (rSO₂) from the INVOS™ system to estimates of actual cerebral oxygen saturation derived from blood sample analysis in 22 patients. No adverse events were reported during the study.

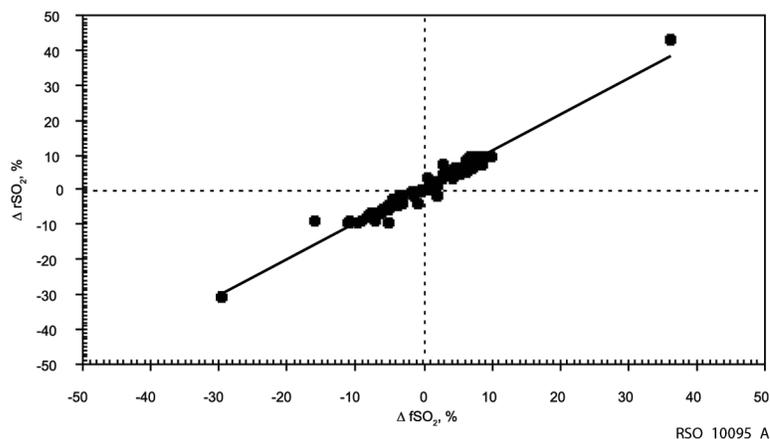
Regional cerebral oxygen saturation was estimated by field saturation (fSO₂) calculated from arterial and jugular venous blood oxygen saturation measurements combined in a 1:3 ratio. Based on the assumption that cerebral tissue contains arterial and venous blood in a 1:3 ratio, fSO₂ was calculated as:

$$fSO_2 = (0.25 \times S_{arterialO_2}) + (0.75 \times S_{jugular\ veinO_2})$$

Twenty-six patients with congenital malformations of the heart and great vessels were recruited for the study. Data from 22 patients was successfully collected and used in the study. Of these subjects, 14 were male and all had light skin. Mean age was 103 months, range 15 months to 34 years.

Methods: A minimum of five blood samples was obtained from the right internal jugular bulb and femoral artery at random times at the discretion of the investigator. One or two samples were drawn at times when inspired oxygen was augmented. INVOS™ data was recorded on disk and compared to the fSO₂ at the time of the blood sample off line. Differences between estimated actual and INVOS™ readings were determined and bias, standard deviation, and regression were calculated.

Results: An initial 26-patient pilot study evaluated system performance. Modifications were made to the hardware and software and an additional 22 patients were studied prospectively, as reported here. Agreement between INVOS™ data and calculated field saturation was very good in individuals and when pooled. It was determined that the pediatric sensor worked optimally in patients with weight between 4 kg and 40 kg. In this study, 7 of 22 patients weighed >40 kg and used the adult sensor.

Figure B-2. Trend Data, 22 Subjects, 90 Points

22 patients, 90 points. $y = 1.0372x - 0.0062$, $R^2 = 0.9609$, bias = -0.02, standard deviation = 1.63.

B.4 Interventional Studies

In controlled studies of carotid endarterectomy (references 1-3), changes in the rSO₂ of 12-20 points (absolute) or 20% to 30% (relative) correlated with changes in the patient's neurological status. In these studies, as well as in other interventional studies of general and cardiac surgery patients (references 4-10), rSO₂ values less than 50 were associated with higher probabilities of a poor outcome.

1. Cho H, Nemoto EM, Yonas H, Balzer J: Cerebral monitoring by oximetry And Somatosensory Evoked Potentials (SSEP) during Carotid Endarterectomy. *J Neurosurg*, 89:533-38, 1998.
2. Roberts KW, Crnkowic AP, Linneman LJ: Near infrared spectroscopy detects critical cerebral hypoxia during carotid endarterectomy in awake patients. *Anesthesiology* 1998;89(3A):A934.
3. Samra S, Dy E, Welch K, Dorje P, Zelenock G, Stanley J: Evaluation of a cerebral oximeter as a monitor of cerebral ischemia during carotid endarterectomy. *Anesthesiology* 2000;93:964-70.
4. Murkin JM, Adams SJ, Novick RJ, Quantz M, Bainbridge D, Iglesias I, Cleland A, Schaefer B, Irwin B, Fox S. Monitoring brain oxygen saturation during coronary bypass surgery: a randomized, prospective study. *Anesth Analg*. 2007 Jan;104(1):51-8.
5. Casati A, Fanelli G, Pietropaoli P, Proietti R, Tufano R, Montanini S. Monitoring cerebral oxygen saturation in elderly patients undergoing general abdominal surgery: a prospective cohort study. *Eur J Anaesthesiol*. 2006 Jul 7;:1-7 [Epub ahead of print].
6. Casati A, Fanelli G, Pietropaoli P, Proietti R, Tufano R, Danelli G, Fierro G, De Cosmo G, Servillo G. Continuous monitoring of cerebral oxygen saturation in elderly patients undergoing major abdominal surgery minimizes brain exposure to potential hypoxia. *Anesth Analg*. 2005 Sep;101(3):740-7.

7. Edmonds HL Jr, Ganzel BL, Austin EH 3rd. Cerebral oximetry for cardiac and vascular surgery. *Semin Cardiothorac Vasc Anesth*. 2004;8:147-66.
8. Goldman S, Sutter F, Ferdinand F, Trace C. Optimizing intraoperative cerebral oxygen delivery using noninvasive cerebral oximetry decreases the incidence of stroke for cardiac surgical patients. *Heart Surgery Forum* 2004;7(5):#2004-1062.
9. Murkin JM, Iglesias I, Bainbridge D, Adams S, Schaefer B, Irwin B, Fox S. Monitoring cerebral oxygen saturation significantly decreases major organ morbidity in CABG patients: A randomized blinded study. *The Heart Surgery Forum* 2004;7(6):515.
10. Yao FSF, Tseng CCA, Ho CYA, Levin SK, Illner P. Cerebral oxygen desaturation is associated with early postoperative neuropsychological dysfunction in patients undergoing cardiac surgery. *J Cardiothorac Vasc Anesth* 2004;18(5):552-558.

B.5 Validation Studies

Validation studies for the INVOS™ system include, but are not limited to the following references:

1. Kim MB, Ward DS, Cartwright CR, Kolano J, Chlebowski S, Henson LC. Estimation of jugular venous O₂ saturation from cerebral oximetry or arterial O₂ saturation during isocapnic hypoxia. *J Clin Monit Comput*. 2000;16(3):191-9.
2. Kolb JC, Ainslie PN, Ide K, Poulin MJ. Effects of five consecutive nocturnal hypoxic exposures on the cerebrovascular responses to acute hypoxia and hypercapnia in humans. *J Appl Physiol*. 2004 May;96(5):1745-54. Epub 2004 Jan 16.

Page Left Intentionally Blank

C Glossary

A

AC power

Alternating electric current.

Alarm limits

Preset and adjustable limits for alarm messages. Alarm tones and a bell symbol will activate if the limits are exceeded.

Area under the curve (AUC)

Area under the curve (AUC) is a metric in the STS adult cardiac surgery database. The AUC indicates the cumulative integral of time and depth of desaturation events below the threshold of 75% of the baseline rSO₂ value (relative decline of 25% below baseline) for rSO₂.

It is calculated by the cerebral oximeter by multiplying the difference between the threshold and current rSO₂ values times the duration that rSO₂ is below the threshold. Values are accumulated throughout the operation. Units are minute-percent.

Authorized repair representative

Those trained individuals authorized by Covidien to service the INVOS™ system.

B

Battery operation

The battery has an approximate 20-30 minutes of operation capacity. Recharge time from 50% discharge to full charge is approximately 20 hours and 100% discharge to full charge is approximately 24 hours.

Type BF

Type BF equipment provides a particular degree of protection against electric shock, particularly regarding allowable leakage current and reliability of the protective earth connection. It has F-type applied part—isolated from all other parts of the equipment to such a degree that the patient leakage current is kept at a very low level (see IEC 601601-1).

C**Case history**

Refers to data relating to oxygen saturation levels and status that can be downloaded at the end of a case.

Connection port

Any of the various inputs or outputs on or relating to the sensor and the INVOS™ system monitor.

CPU board

Central processing unit board. Uses application software to control sequencing of the unit and perform diagnostic functions.

CT scan

A diagnostic procedure employing a computerized axial tomography (CT) scanner to obtain sectional images of the internal structure of the body. Used for greater sensitivity in showing the relationship of various internal structures.

D**Default**

Indicates the automatically preset parameters (field entries) relating to the INVOS™ system monitor. The parameters are adjustable within established limits.

DIB board

The digital interface board (DIB) controls communication between the preamplifier connection and the CPU board. Distributes power to components and provides voltage to charge the battery.

Distributor

Any of the various persons (companies) authorized to distribute the INVOS™ system in conjunction with agreements between the manufacturer and the distributor.

E**ESD**

Electrostatic discharge (ESD) is momentary unwanted current that flows when an excess of electric charge occurs. It can damage the electronic equipment if this current exceeds the allowable limit.

Event and event mark

A relatively important occurrence relating to medical operations (such as meds administration, cross clamp, etc.) that can be marked on the INVOS™ system.

A built-in feature of the INVOS™ system monitor allowing time marking of various events (on a graph or screen) that may occur during patient monitoring.

I

Infrared light

Light waves just beyond the red end of the visible spectrum.

INVOS™

In vivo optical spectroscopy (INVOS™) is the name of the patented technology that a Covidien company uses in the operation of the INVOS™ system.

The noninvasive INVOS™ system is intended for use as an adjunct trend monitor of regional hemoglobin oxygen saturation of blood in the brain or in other tissue beneath the sensor. It is intended for use in any individual at risk for reduced-flow or no-flow ischemic states.

INVOS™ adult regional saturation sensor

The INVOS™ adult regional saturation sensor is a disposable, nonsterile device applied to adult patients and used for transmitting and receiving light.

INVOS™ OxyAlert NIRSensor

A disposable, nonsterile sensor with cable applied to patients and used for transmitting and receiving light.

INVOS™ pediatric regional saturation sensor

The INVOS™ pediatric regional saturation sensor is a disposable, nonsterile device applied to pediatric patients and used for transmitting and receiving light.

K

Key

Any of the control push buttons on the INVOS™ system monitor (front panel).

Key panel

The group of keys on the front of the INVOS™ system monitor.

L

LED

Light emitting diode. A semiconductor diode that emits light when voltage is applied.

M

Menu

Detailed lists of options available to the operator. Menus are found within the INVOS™ system monitor to assist the operator in functions that can be adjusted.

MRI

Magnetic resonance imaging (MRI). A noninvasive diagnostic procedure employing an MR scanner to obtain detailed sectional images of the internal structure of the body using nonionizing means.

O**Optical spectroscopy**

Study of the spectra (series of colors). Relates to the theories behind the INVOS™ system and the interactions between matter and light.

P**Power supply board**

Board that accepts incoming AC power from 100-240 volts and converts it to correct DC levels.

Preamplifier and external preamplifier cable

Preamplifier provides connection of sensor cable and initial amplification of patient signal.

External preamplifier cable connects the preamplifier port or ports to the preamplifier.

R**Real-time**

Refers to data collection and information displayed immediately on the monitor relating to oxygen saturation levels and status.

Representative

Any of various persons (companies) authorized to represent the INVOS™ system in conjunction with agreements between the manufacturer and the representative.

Reusable sensor cable

The shielded, reusable cable that connects SAFB- SM (adult) and SPFB (pediatric) sensors to the preamplifier.

rSO₂

Regional oxygen saturation of blood. Indicates approximate saturation of oxygen within the region being monitored by the INVOS™ system.

rSO₂ (plotting) scale

Refers to rSO₂ values axis (y-scale) plotted on the trend graph.

Run

The operation function. The INVOS™ system is able to monitor and store data in this patient monitoring mode.

S**Signal strength indicator**

The signal strength indicator (SSI) is a displayed parameter that indicates the strength and stability of the signal that is used to make an rSO₂ measurement.

Status codes

Condition or state as relating to operations of the INVOS™ system monitor. Status codes are numbers displayed on the Tabular trends screen and outputted in lines of INVOS™ system data notifying the operator of status messages (for example, REPLACE SENSOR, SSI at full strength).

Status messages

Condition or state as relating to operations of the INVOS™ system monitor. The status message continually updates and displays the status of the INVOS™ system monitor. Status messages notify the operator of an error (for example, REPLACE SENSOR).

T

Tabular trends

Data generated by the INVOS™ system and displayed chronologically; this data may be printed out for further review.

Time (plotting) scale

Refers to hours viewed (x-axis) plotted on the trend graph of rSO₂ values over time.

Trend data

A series of rSO₂ data generated by the INVOS™ system monitor and displayed chronologically, usually in a graphic format.

V

VAC

Voltage alternating current.

VDC

Voltage direct current.

W

Wavelength

The distance within the progression of a wave from one point to its corresponding point in the next wave.

X

X-ray

A diagnostic procedure employing an apparatus to obtain x-ray images; a form of electromagnetic radiation used for their penetrating power in radiography, radiology, radiotherapy, and scientific research.

Page Left Intentionally Blank

Rx
ONLY

CE
0123

 **COVIDIEN**

Part No. PT00055043 Rev C 2018-11

COVIDIEN, COVIDIEN with logo, and Covidien logo and Positive Results for Life are U.S. and internationally registered trademarks of Covidien AG. [™]^{*} brands are trademarks of their respective owners. Other brands are trademarks of a Covidien company.

© 2013 Covidien. All rights reserved.

 Covidien Inc
15 Hampshire Street, Mansfield, MA 02048 USA.

 Covidien Ireland Limited, IDA Business & Technology Park, Tullamore, Ireland.

www.covidien.com

[T] 1 800 635 5267