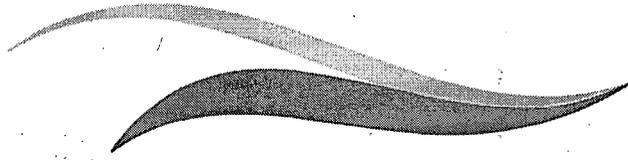


2009-4438b1-04

**Clinical User Guide / Operator's Manual**



sedasys™

Computer-Assisted Personalized Sedation System

**Clinical User Guide / Operator's Manual**

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ETHICON ENDO-SURGERY, INC.  
a Johnson & Johnson company

**WARNING**

The SEDASYS® System must only be used as described in this manual. Failure to do so may result in serious injury and/or inadequate device performance.

***The Food & Drug Administration (FDA) has approved the use of the SEDASYS® System, a Computer-Assisted Personalized Sedation device, for the administration of propofol by a physician/nurse team. This team must be trained in the administration of minimal-to-moderate sedation (sometimes referred to as conscious sedation) to use the SEDASYS® System. This team does not need to be trained in the administration of general anesthesia. The FDA reached this determination based upon the review of clinical data provided by Ethicon Endo-Surgery and understands this is a departure from the approved labeling of Diprivan® and other generic forms of propofol. Administration of propofol sedation by a physician/nurse team not trained in the administration of general anesthesia, by any means other than with the SEDASYS® System, has not been approved by the FDA. For more information about propofol, including warnings and precautions, consult the approved package insert of this drug.***

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The SEDASYS® System is covered by the following U.S. patents: 7,338,470; 7,308,894; 7,299,981; 7,229,430; 7,201,734; 7,198,605; 7,152,604; 7,034,692; 6,807,965; 6,745,764; 6,186,977; D559,383; D546,947.

## PRODUCT INFORMATION

Product Code	Product
SEDPRU01	Procedure Room Unit (PRU)
SEDPSU01	Power Supply Unit (PSU) with Power Cord
SED15LCD	PRU 15" LCD Display
SEDCRT01	Cart
SEDBMU01	Bedside Monitoring Unit (BMU)
SED8UC	Umbilical Cable
SEDARM01	Automated Responsiveness Monitor (ARM) Handset
SEDO2ADT	O2 Adapter
SEDWXP01	Wireless External Printer
SEDE3AMI	ECG Leads AAMI Color Std
SEDE3IEC	ECG Leads IEC Color Std
SEDECAMI	ECG Cable AAMI Color Std
SEDECIEC	ECG Cable IEC Color Std
SEDOXFP	Pulse Oximeter Sensor - Finger Probe
SEDOXEC	Pulse Oximeter Sensor - Extension Cable
SEDBPSM	NIBP Cuff - Adult Small
SEDBPA	NIBP Cuff - Adult
SEDBPAL	NIBP Cuff - Adult Large
SEDBPAP	NIBP Cuff - Thigh
SEDBP6EC	NIBP Extension - 6' length
SEDCAN01	Cannula
SEDCAS01	Cassette
SEDBBSM	Bite Block - Small
SEDBBLG	Bite Block - Large

**MANUFACTURED BY:**

ETHICON ENDO-SURGERY, INC.  
4545 Creek Road  
Cincinnati, Ohio 45242-2839 USA



MEDICAL EQUIPMENT

WITH RESPECT TO ELECTRIC SHOCK,  
FIRE AND MECHANICAL HAZARDS ONLY  
IN ACCORDANCE WITH UL 60601-1,  
IEC/EN 60601-1, CAN/CSA C22.2 No. 601.1, IEC 60601-1-4,  
IEC 60601-2-24, IEC 60601-2-27, IEC 60601-2-30



Ethicon Endo-Surgery (Europe) GmbH  
Hummelsbueteler Steindamm 71  
DE-22851 Norderstedt  
GERMANY

**WARRANTY INFORMATION**

Ethicon Endo-Surgery, Inc. warrants this product to be free from defects in material and workmanship under normal use and maintenance for the respective warranty period shown below. Ethicon Endo-Surgery Inc.'s obligation under this warranty is limited to the repair or replacement, at its option, of any product, or part thereof, which has been returned to Ethicon Endo-Surgery, Inc. or its Authorized Affiliate Service Centers within the applicable time period shown below and which examination disclosed, to Ethicon Endo-Surgery, Inc.'s satisfaction, to be defective. This warranty does not apply to any product, or part thereof, that has been:

1. Adversely affected due to use with devices manufactured or distributed by parties not authorized by Ethicon Endo-Surgery, Inc.
2. Repaired or altered outside Ethicon Endo-Surgery, Inc.'s approved processes so as to, in Ethicon Endo-Surgery, Inc.'s judgment, affect its stability or reliability.
3. Subjected to improper use, negligence, or accident, or
4. Used other than in accordance with the design and use parameters, instructions and guidelines for the product or with functional, operational, or environmental standards for similar products generally accepted in the industry.

Warranty Service does not include calibration or routine maintenance that should be performed by qualified service personnel according to the schedule provided in this manual or any other normal maintenance required of facility personnel.

Ethicon Endo-Surgery, Inc.'s products are warranted for the following periods after delivery to the original purchaser:

- PRU: One (1) Year, Parts and Labor.
- PSU: One (1) Year, Parts and Labor.

- 
- LCD/Touchscreen Monitor: One (1) Year, Replacement.
  - Cart: One (1) Year, Parts and Labor.
  - BMU: One (1) Year, Parts and Labor.
  - BMU AC Adapter: One (1) Year, Replacement.
  - Umbilical Cable: One (1) Year, Replacement.
  - ARM Handset: One (1) Year, Replacement.
  - Pulse Oximeter Probe and Cable: One (1) Year, Replacement.
  - NIBP Cuff and Extension: One (1) Year, Replacement.

**UNLESS SUPERCEDED BY APPLICABLE LOCAL LAW, THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON THE PART OF ETHICON ENDO-SURGERY, INC. AND IS A PURCHASER'S EXCLUSIVE REMEDY. IN NO EVENT SHALL ETHICON ENDO-SURGERY, INC. BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES INCLUDING, WITHOUT LIMITATION, DAMAGES RESULTING FROM LOSS OF USE, PROFITS, BUSINESS OR GOODWILL OTHER THAN AS EXPRESSLY PROVIDED BY A SPECIFIC LAW.**

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### **Within the USA contact:**

**EES Customer Care Center, 1-800-USE-ENDO, 800-873-3636 (English speaking only)**

### **Outside of USA contact:**

**Local Johnson & Johnson Affiliate office or closest Authorized Service Center**

### **Authorized Service Centers locations:**

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##### **Ethicon Endo-Surgery, Inc.**

4480 Lake Forest Drive Suite 318

Cincinnati, OH 45242

1-800-USE-ENDO (U.S.), 800-873-3636

**Phone:** 1-513-337-8901 (International calls - English speaking only)

**Email:** techsupport@eesus.jnj.com

#### **Australia**

##### **Medifix Pty Ltd**

7 Conder Street

Burwood NSW 2134

**Phone:** 02 9744 7410

**Email:** support@medifix.com.au

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## DOCUMENT CONVENTIONS

The following conventions are used throughout this manual:



### WARNING

Describes serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. Warnings alert the clinician to the possibility of serious injury, death, or other serious adverse reactions associated with the use or misuse of the system.



### Precaution

Pertains to information regarding any special care to be exercised by the practitioner and/or patient for the safe and effective use of the device. Precautions alert the clinician to the possibility of minor or moderate injury to the clinician or patient, or damage to the device associated with the use or misuse of the system.



### Note

Notes emphasize important details.

**Intended Use:** Refers to the objective intent of the persons legally responsible for the labeling of the device.

**Indication:** Identifies the target population in of which sufficient valid scientific evidence has demonstrated that the device as labeled will provide clinically significant results and at the same time does not present an unreasonable risk of illness or injury associated with the use of the device.

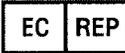
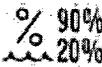
**Contraindication:** Medical situations in which the device should not be used because the risk of use clearly outweighs any possible benefit.

## SYMBOLS

The following symbols will be physically located on one or more components of the system.

Symbol	Description
	Consult the accompanying documentation before operating the equipment.
	Device requires a direct supply current.
	Device requires an alternating supply current.
	Button is to be used to turn the device on or off, or place in Standby mode.
	Switch position applies DC power to the PRU Control Unit.
	Switch position removes DC power from the PRU Control Unit.
	Device port is to be used for the Electrocardiogram (ECG) connection.
	Device port is to be used for the Pulse Oximeter (SpO <sub>2</sub> ) connection.
	Device port is to be used for the Non-Invasive Blood Pressure (NIBP) connection.
	Device port is to be used for the Automated Responsiveness Monitor (ARM) connection.
	Type BF Applied Part provides protection against electrical shock as defined in standard EN60601.
	Type CF Applied Part is defibrillation-proof and provides protection against electrical shock as defined in standard EN60601.

Symbol	Description
	Position of oxygen control lever for normal oxygen delivery through the Oral/Nasal Cannula.
	Device port is to be used as an equipotential connection (if required by the facility).
<b>O<sub>2</sub></b>	Device port is to be used for connection to the oxygen supply source.
	Position of oxygen control lever for oxygen delivery through the Emergency Oxygen Supply outlet for connection to an Ambu bag.
	Button is to be used to open the infusion pump door.
	Button is to be used for emergency stopping of drug delivery.
	Single Patient Use
<b>Rx Only</b>	Caution: Federal (U.S.A) law restricts this device to sale by or on the order of a physician
<b>STERILE R</b>	Sterilized by irradiation.
<b>STERILITY GUARANTEED UNLESS PACKAGE OPENED OR DAMAGED. DO NOT RESTERILIZE.</b>	
<b>LOT</b>	Lot Number
	Use Until Date
<b>NON-STERILE</b>	Non-Sterile
	Date of Manufacture

Symbol	Description
	Protective Earth (ground) connection
	Laser Radiation
	Catalog Number
	Authorized Representative
	Electrical and electronic equipment. Return waste to a collection system or treatment and recycling facilities. Applicable in the EU. Follow decontamination instructions before returning waste.
	Un-insulated voltage within the unit may have sufficient magnitude to cause electrical shock. Therefore, it is dangerous to make contact with any part inside the unit. To reduce the risk of electric shock, DO NOT remove cover (or back)
	Serial Number
	Allowable shipping conditions, temperature.
	Allowable shipping conditions, humidity.

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## Chapter 1 Introduction

### SEDASYS® System Overview

The SEDASYS® System is an integrated physiological monitoring and drug delivery system intended to provide physician/nurse teams with a means of administering 1% propofol (10 mg/mL) injectable emulsion to sedate adult patients (ASA I and II) undergoing esophagogastroduodenoscopy (EGD) and colonoscopy procedures.

The system is designed to continuously monitor the patient in the pre-procedure area, procedure room, and postprocedure area.

The SEDASYS® System consists of four main components:

- The Bedside Monitoring Unit (BMU)
- The Procedure Room Unit (PRU)
- Single Patient Use (SPU) Devices
- Multiple Patient Use (MPU) Devices

An optional Cart is also available to facilitate mounting, storage and transport of system components.

The BMU monitors the patient's blood pressure, heart rate, and oxygen saturation. It is connected to the patient in the pre-procedure area and stays with the patient through recovery. In the pre-procedure and post-procedure areas, the BMU is used as a stand-alone monitoring unit.

When the patient is moved into the procedure room, the BMU is connected to the PRU through an Umbilical Cable. The Umbilical Cable provides communication, power, and pneumatic connection between the BMU and the PRU.

When the PRU and the BMU are connected, the PRU adds capnometry and automated responsiveness monitoring, oxygen delivery, and the ability to deliver 1% propofol.

### Device Description

Each component of the SEDASYS® system provides a function that together meet the intended use of the system. The following is a functional description of these components.

#### Bedside Monitoring Unit

The BMU monitors the patient's oxygen saturation, blood pressure, and heart rate during all phases of a procedure. The BMU stays with the

patient from the pre-procedure area to the procedure room, and finally to the post-procedure area.

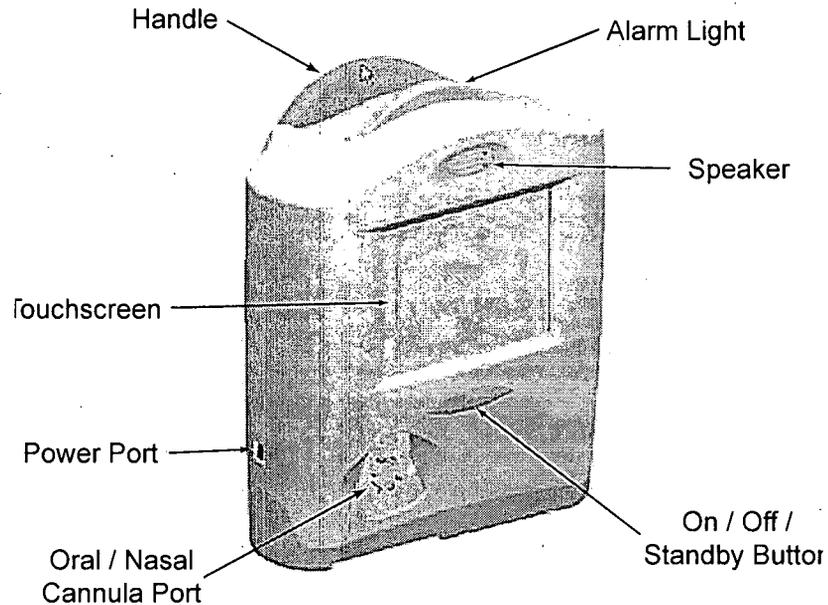


Figure 1-1 Front View of BMU

**Handle:** Enables the clinician to hold the BMU.

**Touchscreen:** Displays patient physiology when the BMU is used as a standalone unit. Displays drug delivery control functions when the BMU is connected to the PRU. Provides interface for clinician input.

**Power Port:** Provides Connection port for power adapter when the BMU is used as a standalone unit and for recharging the BMU batteries.

**Oral/Nasal Cannula Port:** Provides Connection port for the Oral/Nasal Cannula.

**On/Off/Standby Button:** Allows the clinician to turn the BMU on or off, or to place the unit in Standby mode.

**Speaker:** Emits the system sounds from the BMU when the BMU is used as a standalone unit.

**Alarm Light:** Flashes blue light during Alarms and Advisories.

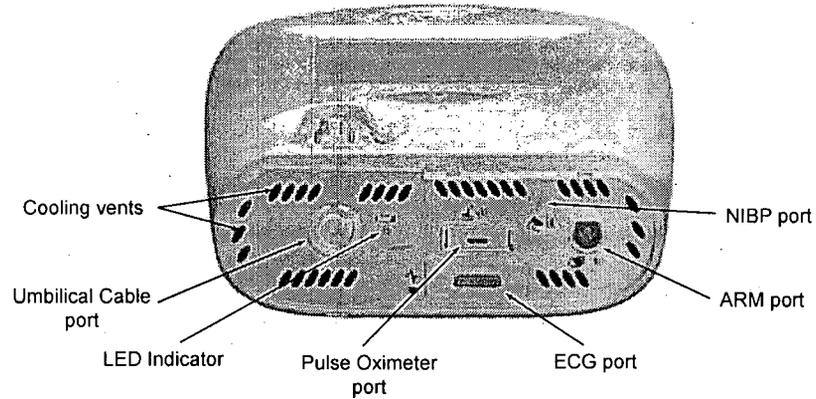


Figure 1-2 Bottom View of BMU

**Cooling vents:** Openings on the bottom of the BMU that provide air flow to the cooling fan.



**Precaution**

To prevent overheating during use, do not block the cooling vents of the BMU.

**Umbilical Cable port:** Provides Connection for the Umbilical Cable when connecting the BMU to the PRU. This port is also used for the optional Oxygen Adapter if oxygen delivery is necessary when the BMU is used as a standalone unit.

**LED Indicator:** Indicates power status of the BMU.

**Pulse Oximeter port:** Provides Connection for the Pulse Oximeter cable.

**Electrocardiogram (ECG) port:** Provides Connection for the 3-lead ECG cable.

**Automated Responsiveness Monitor (ARM) port:** Provides Connection for the ARM handset cable.

**Non-Invasive Blood Pressure (NIBP) port:** Provides Connection for the NIBP extension tubing.

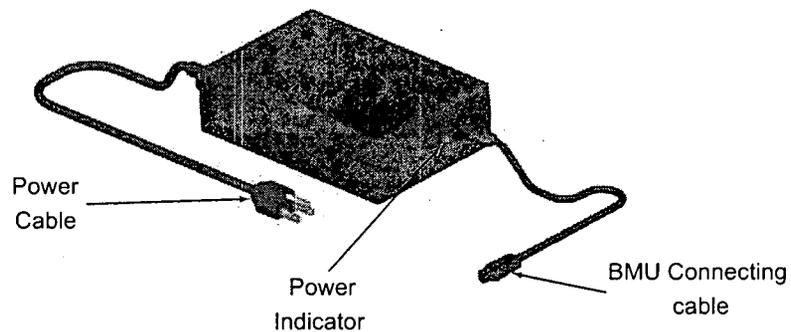
**BMU Power Adapter**

The BMU Power Adapter provides DC power to the BMU when it is not connected to the PRU and allows charging of the BMU internal batteries.



**Note**

When used as a standalone unit, the power adapter should be connected to the BMU whenever possible to ensure full battery capacity.



**Figure 1-3 BMU Power Adapter**

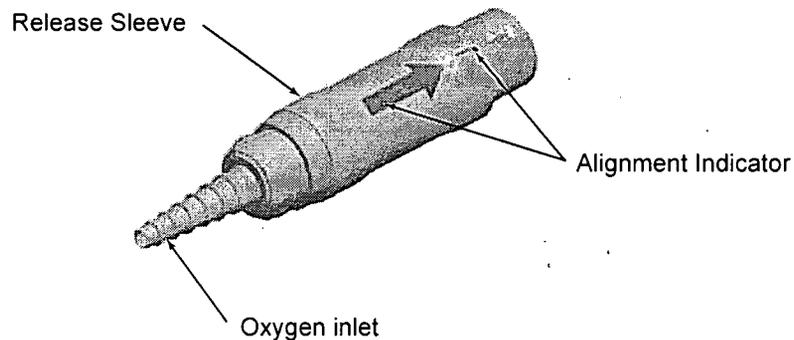
**BMU Connecting cable:** Connects the BMU Power Adapter to the BMU. This cable is permanently attached to the Power Adapter.

**Power Cable:** Attaches the BMU Power Adapter to the AC outlet.

**Power Indicator:** Illuminates when the Power Adapter is connected to an active AC power source.

### Oxygen Delivery Adapter

When the BMU is used as a standalone unit, the Oxygen Delivery Adapter allows connection of the BMU to an externally regulated oxygen source so that oxygen can be delivered to the patient through the Oral/ Nasal Cannula. The Oxygen Delivery Adapter is connected to the Umbilical Cable port of the BMU.



**Figure 1-4 Oxygen Delivery Adapter**

**Alignment Indicator:** Red dot and arrow illustrates alignment location to a corresponding red alignment indicator on the Umbilical Cable port on the BMU.

**Release Sleeve:** Facilitates disconnection of the Oxygen Delivery Adapter from the BMU by pulling downward away from the BMU.

**Oxygen Inlet:** Accepts standard oxygen delivery tubing from a regulated oxygen supply source.

## Procedure Room Unit

The PRU provides for monitoring and display of patient physiologic parameters, user input of patient data, user input of dose rate, and hardware and software for delivery of propofol and oxygen during the procedure. The PRU is designed to stay in the procedure room and is the mechanism for drug delivery.

The PRU consists of four components:

- Control Unit
- Power Supply Unit (PSU)
- Display Monitor
- Umbilical Cable

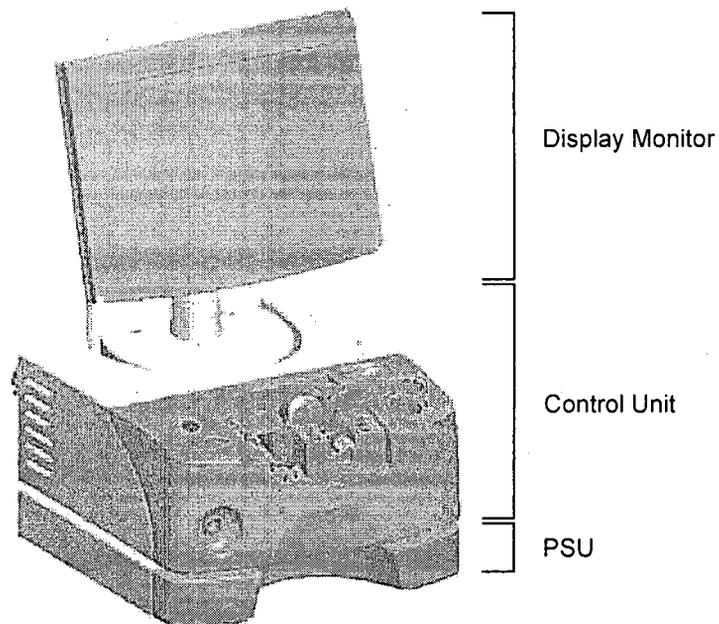
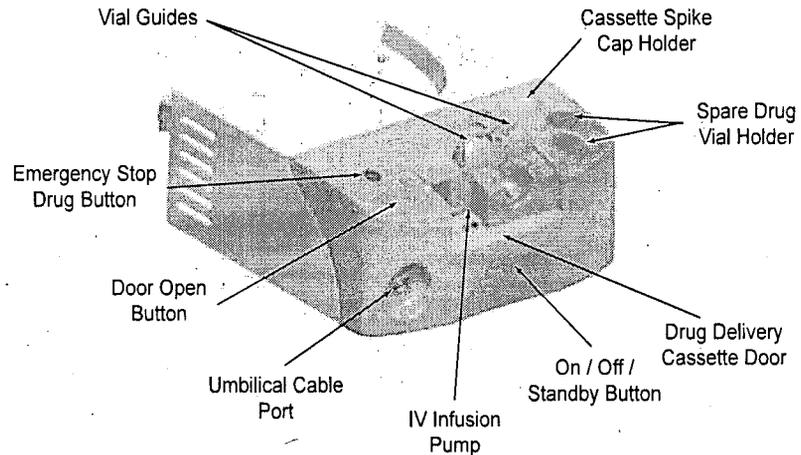


Figure 1-5 Front View of Procedure Room Unit

### Control Unit

The Control Unit includes the infusion pump and drug delivery algorithms that allow the administration of 1% propofol; capnometry to monitor the patient's respiratory rate and end-tidal CO<sub>2</sub> (EtCO<sub>2</sub>); automated responsiveness monitoring to monitor the patient's responsiveness to mild verbal and tactile stimulus; and a regulator to provide oxygen delivery during the procedure.



**Figure 1-6 Front View of PRU Control Unit**

**Emergency Stop Drug Button:** Immediately stops delivery of 1% propofol when pressed. This button should only be used in the event that the touchscreen display of the PRU and BMU cannot be used to control drug delivery.

**Door Open Button:** Opens the Drug Delivery Cassette door for installation and removal of the Drug Delivery Cassette.

**On/Off/Standby Button:** Allows the clinician to turn the PRU on or off, or to place the unit in Standby mode.

**Umbilical Cable Port:** Provides Connection for the Umbilical Cable.

**Bar Code scanner (not shown in figure):** Scans the bar code on the Drug Delivery Cassette package. The scanner is located on the bottom of the Control Unit below the On/Off/Standby button.

**Drug Delivery Cassette Door:** Locks the Drug Delivery Cassette in place and prevents free flow of 1% propofol.

**IV Infusion Pump:** Integrates intravenous infusion pump located beneath the Drug Delivery Cassette door for delivering 1% propofol.

**Vial Guides:** Aligns the 1% propofol vial for proper placement on the Vial spike of the Drug Delivery Cassette.

**Spare Drug Vial Holder:** Recesses to hold spare 10 mL or 20 mL 1% propofol drug vials.

**Cassette Spike Cap Holder:** Recesses to hold the cassette spike cap when cassette is in use.

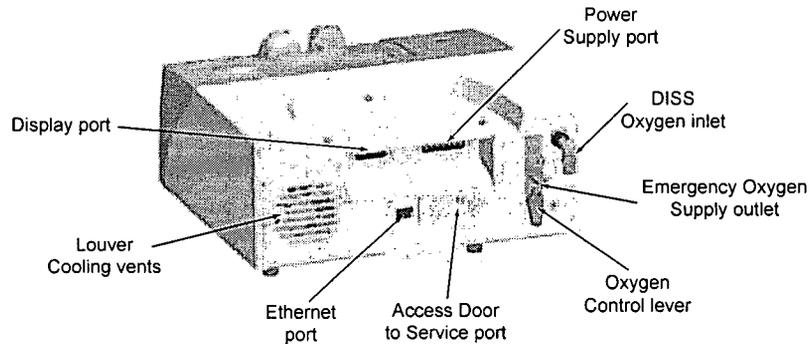


Figure 1-7 Back View of PRU Control Unit

**Power Supply Port:** Provides Connection port for the PSU connecting cable that provides DC power from the PSU to the Control Unit.

**Louver Cooling Vents:** Slotted openings on the back of the Control Unit that provide airflow to the cooling fan.



**Precaution**

To prevent overheating during use, do not block the cooling vents of the PRU.

**Ethernet Port:** Allows data communication with an external source.

**Access Door to Service Port:** For authorized service personnel only. Do not open.

**DISS Oxygen Inlet:** Provides Standard oxygen inlet to connect the oxygen supply tubing with a male DISS connector.

**Oxygen Control Lever:** Can be turned to divert oxygen flow from the DISS oxygen inlet to the Emergency Oxygen Supply outlet (for example, you can connect a bag mask to the Emergency Oxygen Supply outlet).

**Emergency Oxygen Supply Outlet:** Allows the oxygen supply to be diverted to the Emergency Oxygen Supply outlet (for connection to a bag mask).

**Display Port:** Provides Connection port to attach the LCD cable from the Display Monitor to the Control Unit.

### Power Supply Unit

The Control Unit receives continuous DC power from the PSU when the PSU is plugged into an AC power source (a grounded outlet). In the event that power is lost or the PSU is disconnected from the power source, a battery-powered backup system in the PSU provides temporary DC power. Sufficient temporary power is provided to allow up to 10 minutes

of use to complete or terminate the procedure should AC power be interrupted.

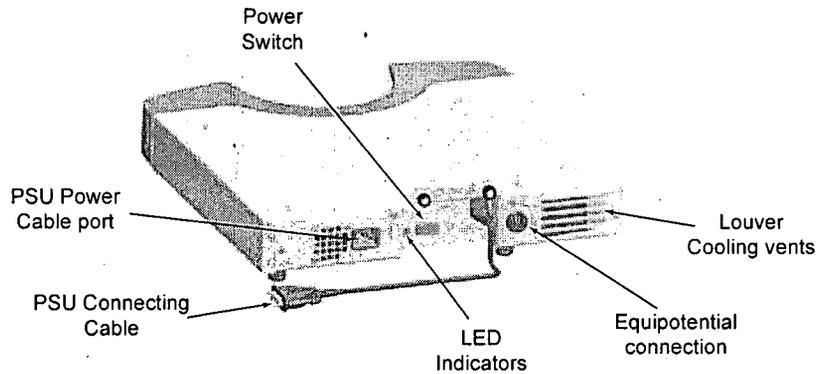


Figure 1-8 Back View of PRU Power Supply Unit

**Equipotential Connection:** Additional grounding connection that meets certain facility-specific requirements.

**Louver Cooling Vents:** Slotted openings on the back of the PSU that provide airflow to the cooling fans.



**Precaution**

To prevent overheating during use, do not block the cooling vents of the PSU.

**PSU Connecting Cable:** Connects the PSU to the Control Unit to provide DC power. This cable is permanently attached to the PSU.

**Power Switch:** Turns power from the PSU to the Control Unit on or off. The switch does NOT turn off AC power to the PSU. To turn off AC power to the PSU, you must unplug the PSU power cable from the AC power source.



**Precaution**

Do not use the PSU Power switch to power off the PRU while the PRU is operating. This action could result in loss of data.

**PSU Power Cable Port:** Provides Connection to attach the PSU power cable. The PSU power cable is connected to an AC source.

**LED Indicators:** Provides indicator of Control Unit and PSU power status.

## Display Monitor

The Display Monitor has a touchscreen that displays patient data and allows the clinician to interact with the PRU.

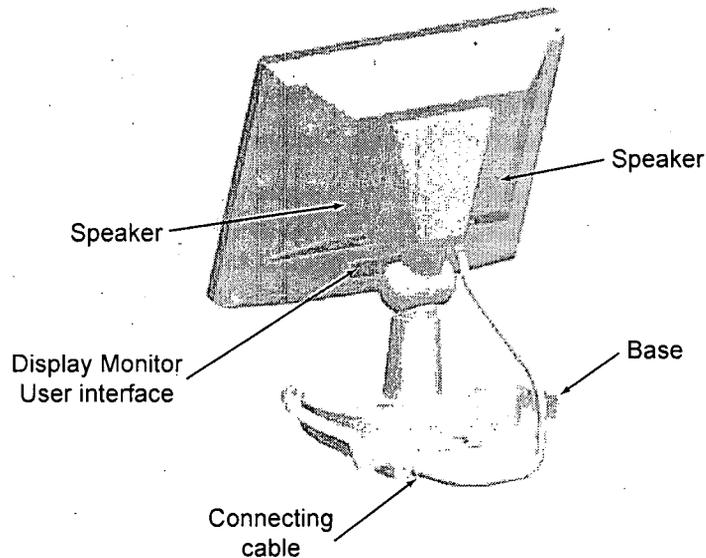


Figure 1-9 Back View of PRU Display Monitor

**Speakers:** Emits the PRU system sounds.

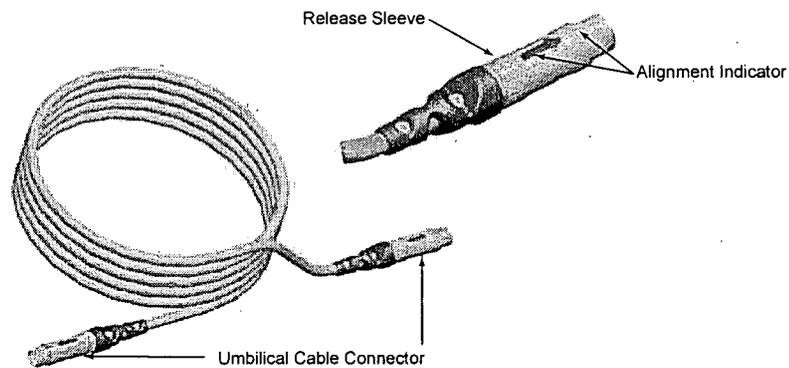
**Display Monitor User Interface:** Buttons located on the back of the Display Monitor that allow the clinician to adjust brightness and contrast of the PRU display.

**Base:** Bottom portion of the Display Monitor that fits into the recessed portion of the Control Unit top.

**Connecting Cable:** Connects the Display Monitor to the Control Unit. Provides power, display, touchscreen control, and audio to the Display Monitor. This cable is permanently attached to the Display Monitor.

## Umbilical Cable

The Umbilical Cable provides communication, power and pneumatic connection between the PRU and the BMU. The connectors on either end of the Umbilical Cable are identical. Therefore, either end of the cable can be connected to the BMU or the PRU. The Umbilical Cable is connected to the PRU at all times.



**Figure 1-10 Umbilical Cable**

**Umbilical Cable Connector:** End of Umbilical Cable that connects to the Umbilical Cable ports to allow for gas sampling, oxygen delivery, data communication, and power supply between the BMU and PRU.

**Alignment Indicator:** Red dot and arrow that indicate alignment location to the Umbilical Cable Port on the BMU or PRU.

**Release Sleeve:** Facilitates disconnection of the Umbilical Cable connector from the BMU or PRU by pulling away from the BMU or PRU.

## Single Patient Use Devices

The SEDASYS® System contains three single patient use disposable components.

- The drug delivery cassette is the propofol drug vial/device interface that allows the infusion pump module of the PRU to extract propofol for delivery to the patient.
- The Oral/Nasal cannula is the patient/device interface for oxygen delivery and also serves as the collection unit for the capnometer module of the PRU to assess respiratory activity.
- The bite block is used in EGD procedures to enable proper function of the oral/nasal cannula in the presence of a scope or esophageal dilator.

## Drug Delivery Cassette

The Drug Delivery Cassette is a sterile, single-patient use component of the system for delivering 1% propofol to the patient directly from the drug vial.



### WARNING

- 1 Use only the approved Drug Delivery Cassette. Using infusion tubing not approved for use with the SEDASYS® System may result in inaccurate delivery of 1% propofol.
- 2 Prior to connecting the intravenous (IV) line to the patient and delivering 1% propofol injectable emulsion, examine the IV line for residual air and manually purge any residual air. Purging and/or priming the IV line while the IV administration set is connected to the patient may result in an air embolism or inappropriate drug delivery.
- 3 The Drug Delivery Cassette is packaged sterile for single-patient use only. Do not re-use or re-sterilize. Re-sterilization may compromise the integrity of the device, which may result in patient injury.
- 4 Do not use the Drug Delivery Cassette if its sterile package is damaged or if past the labeled expiration date.
- 5 When using a standard IV administration set, make sure the IV set contains an integrated backcheck valve to prevent inaccurate dosing of 1% propofol.

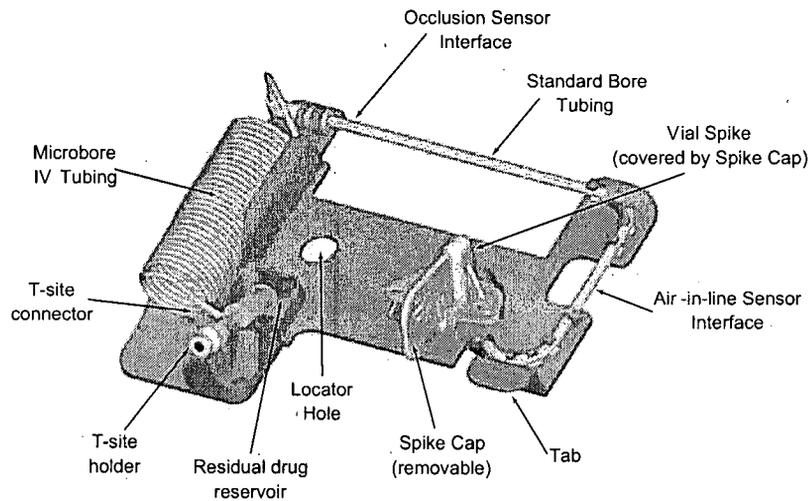


Figure 1-11 Drug Delivery Cassette

**Microbore IV Tubing:** Uncoils to the required length and keeps excess tubing coiled in placeholder.

**WARNING**

**T-site Connector:** Is removed from the Drug Delivery Cassette and attaches to the stopcock on the patient's IV catheter. The T-site connector should be connected to the lure fitting closest to the patient's IV catheter.

- 1 Do not connect the T-site of the Drug Delivery Cassette to the patient's IV administration set before the Drug Delivery Cassette and its IV tubing are completely primed.
- 2 The T-site must not be connected to the patient during manual purge.

**T-site Holder:** Holds the T-site connector to the cassette before and after the case.

**Residual Drug Reservoir:** Holds small amounts of the overflow of 1% propofol that may occur during the autoprimering sequence.

**Locator Hole:** Aligns and ensures proper insertion of the Drug Delivery Cassette with the Locator pin in the PRU.

**Spike Cap:** Protective cap that covers the Vial spike. The Spike Cap must be removed prior to vial insertion.

**Tab:** Facilitates the insertion and removal of the Drug Delivery Cassette from PRU.

**Air-In-Line Sensor Interface:** Interfaces with air-in-line detector to detect air in the IV tubing.

**Vial Spike:** Plastic spike into which the 1% propofol vial is inserted to initiate drug delivery through the Drug Delivery Cassette.

**Standard Bore Tubing:** Interfaces with the peristaltic pumping action to provide continuous drug delivery.

**Occlusion Sensor Interface:** Interfaces with the occlusion sensor to detect an occlusion in the IV tubing.

### Oral/Nasal Cannula

The oral/nasal cannula is a proprietary single patient use component consisting of three gas sampling ports (the right and left nares and the mouth) for assessing respiratory rate. There are outlets on both the nasal and oral side of the cannula for oxygen delivery. In addition, the cannula contains an earpiece for the audible portion of the ARM module. The earpiece is fitted into the patient's ear and is used to communicate the verbal ARM request to respond.

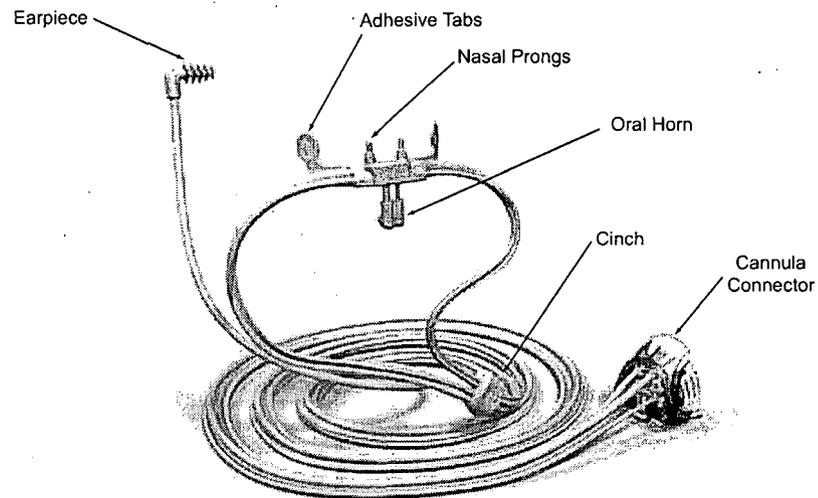


Figure 1-12 Oral / Nasal Cannula

**Earpiece:** Provides audio input to the patient as part of the Automated Responsiveness Monitor.

**Adhesive Tabs:** Allows the cannula to be secured to the patient's face to ensure constant positioning during the procedure.



**Precaution**

The adhesive pad is manufactured from a hypoallergenic, pressure sensitive, acrylate adhesive. Some patients may be sensitive or allergic to adhesive.

**Nasal Prongs:** Gas sampling port for the right and left nares.

**Oral Horn:** Gas sampling port for the mouth. The oral horn should be adjusted to be centered between the patient's lips or to be placed in the receiving slot of a Bite Block (if used).

**Cinch:** Tightens the cannula tubing beneath the patient's chin for a secure fit.

**Cannula Connector:** Provides the connector to the Oral / Nasal Cannula Port on the Bedside Monitoring Unit.

**Bite Block**

The bite block is a proprietary single patient use component used to ensure proper function of the oral/nasal cannula in the presence of a scope or esophageal dilator during EGD procedures.

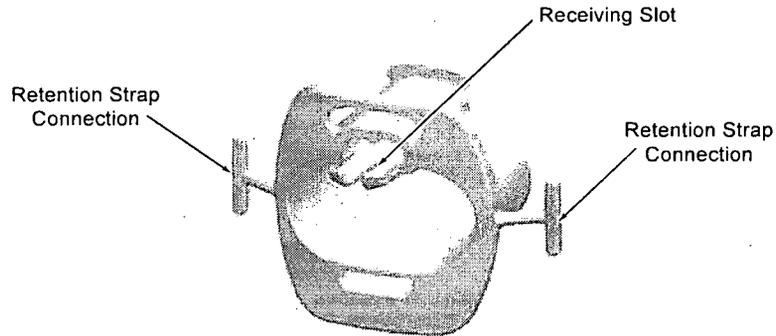


Figure 1-13 Bite Block

**Retention Strap Connection:** Provides the connection points for the retention strap that is positioned around the patient's head to securely hold the bite block in position.

**Receiving Slot:** Interface location for the oral horn of the oral/nasal cannula.

## Multiple Patient Use Devices

The SEDASYS® System utilizes four MPU devices to provide sensory functions for measuring patient physiology or responsiveness. These are reusable components of the system.



### WARNING

Only the SEDASYS® System peripheral devices, parts, components, and accessories should be used. Using items not approved for use with the system may invalidate safety certifications, compromise patient safety, result in increased emissions or decreased immunity, and result in measurement error.

### Pulse Oximetry (SpO<sub>2</sub>) Probe

The system utilizes a finger probe sensor, compatible with the BMU SpO<sub>2</sub> module, for measuring the patient's %SpO<sub>2</sub> and Pulse Rate. This finger probe connects into the system through the BMU.

### Non-Invasive Blood Pressure (NIBP) Cuff

The system utilizes a non-invasive blood pressure cuff, compatible with the BMU NIBP module, for measuring the patient's systolic and diastolic blood pressure. This cuff connects into the system through the BMU.

### Electro-Cardiogram (ECG) Leads

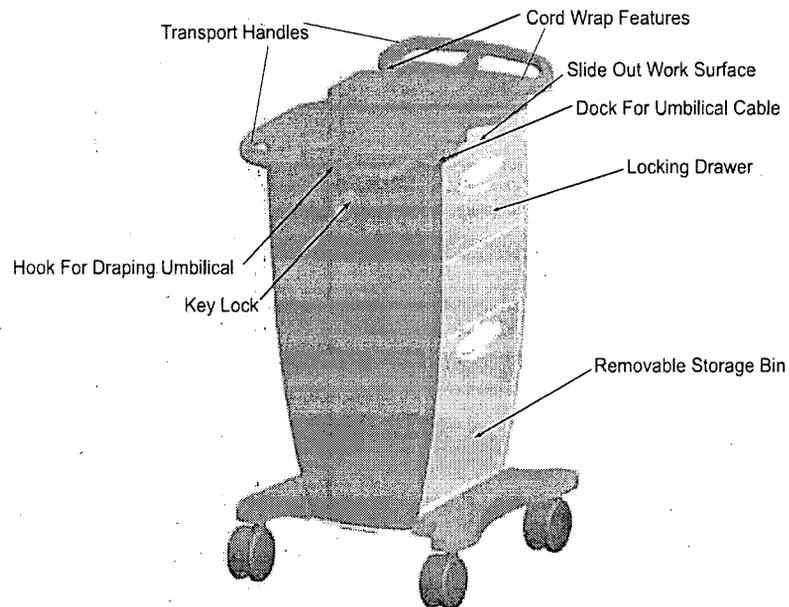
The system utilizes three ECG leads, compatible with the BMU ECG module, for measuring the patient's heart rate and heart waveform. These leads connect into the system through the BMU.

## ARM Handset

The ARM handset is ergonomically designed to fit in the hand of the patient. A strap retains the handset in the palm. Squeezing the handset transmits signals to the BMU ARM module. The handset is made to vibrate at one of three increasing levels depending on the rapidity of the response by the patient.

## Cart (Optional)

The Cart provides a stable mounting surface for the PRU, facilitating easy movement of the PRU within (or between) procedure rooms. The top of the Cart contains recessed indentations to receive and retain the feet of the assembled PRU. Each of the four wheels on the Cart swivel for improved mobility, and lock independently to provide stability.



**Figure 1-14 Cart Front View**

The Cart also provides the following features:

- a "slide-out" work surface
- a locking drawer for propofol vial storage
- a removable bin for storing packaged single-patient use items
- features to retain and dock the umbilical cable
- a cord wrap for the main power cord
- a bracket (not shown, as it is on the back side of the Cart) for docking the BMU during transport, if desired.

The work surface, locking drawer, and storage bin are accessible from either side of the Cart for user convenience.

**WARNING**

To prevent injury, do not lean on the cart.

**Precaution**

To prevent damage, do not pull the Cart by using the Umbilical Cable.

## Wireless Printing

The BMU and the PRU (when connected to the BMU) can send data to an external, wireless printer. Physiological data including those from alarm events, a Stat Print request by the clinician, and an end-of-case summary can be printed. System error messages can also be printed using the wireless printer.

## Principles of Operation

The SEDASYS® System uses a proprietary drug delivery algorithm and an intravenous infusion pump to deliver propofol with a variable rate infusion that rapidly achieves and maintains a desired sedation effect. It enables the physician/nurse team to adjust the patient's sedation level by simply entering the dose rate that they believe will maintain the desired sedation effect. The system calculates the appropriate loading dose, based on the patient's weight and guidelines in the propofol labeling, which will rapidly achieve the sedation effect for the entered dose rate.

**Note**

1% propofol injectable emulsion labeling refers to dose rate as maintenance rate.

The SEDASYS® System is comprised of four routine physiologic monitors. These are a pulse oximeter for monitoring the patient's oxygen saturation, noninvasive blood pressure (NIBP) and electrocardiogram (ECG) for monitoring the patient's cardiodynamics, and a capnometer for measuring the patient's respiratory activity. In addition, the system has an automated responsiveness monitor (ARM) to aid the physician/nurse team in assessing the patient's level of sedation.

All five monitors and drug delivery are integrated together through a proprietary software module. It vigilantly monitors the patient's condition, keeps the physician/nurse team informed of the patient's status, and immediately stops the delivery of propofol if it detects a potential sedation-related adverse condition. Under certain circumstances, the system will re-initiate propofol delivery, but at a reduced dose rate, once the patient's condition returns to normal. If the adverse condition is persistent or severe, the system will not reinitiate infusion. Instead, it requires intervention by the physician/nurse team member to re-initiate propofol delivery following such a condition. An integral part of The SEDASYS® System is a Graphical User Interface (GUI) that displays the monitored

physiologic values in a fashion that enables the physician/nurse team to readily surmise the status of the patient. It has also been designed to give the physician/nurse team an efficient means of adjusting the patient's level of sedation, through changes in the dose rate.

The system is designed to provide continuous hemodynamic monitoring of the patient in the pre-procedure room, the procedure room, and the recovery room. The BMU is connected to the patient in the pre-procedure room and stays with the patient through recovery. The BMU contains the pulse oximeter, NIBP, ECG and ARM modules. Once connected to the patient, it monitors and displays the patient's oxygen saturation, blood pressure, and heart rate. Supplemental oxygen can be delivered in the pre-procedure configuration through the BMU and the proprietary oral/nasal cannula.

When the patient is in the procedure room, the BMU is attached to the PRU via an umbilical cable, containing both pneumatic and electrical lines. The PRU assesses the patient's respiration rate and end-tidal CO<sub>2</sub> through the capnometer and assesses patient responsiveness through ARM. This information is displayed to the physician/nurse team. As soon as the system detects respiration activity (from the capnometer), oxygen delivery is initiated. All propofol delivery is performed by the PRU as it contains the intravenous infusion pump and the proprietary software algorithm. The PRU is the main interface between the physician/nurse team member responsible for administering sedation and the system. It contains the comprehensive GUI that displays the status of the patient and facilitates easy adjustment of the patient's level of sedation.

When the procedure is complete, the BMU is disconnected from the PRU and the patient is wheeled into the recovery room. The BMU continues to monitor and display the patient's arterial saturation, arterial pressure, and heart rate. Supplemental oxygen can be delivered at this time through the BMU and the proprietary oral/nasal cannula.

## Propofol Dosing

Dosing with 1% propofol injectable emulsion should be individualized and titrated to the desired effect, according to clinically relevant factors, including concomitant medications, age, weight, ASA physical classification, and level of debilitation of the patient.

The following sections describe abbreviated dosing information, which is intended as a general guide in the use of 1% propofol injectable emulsion with the SEDASYS® System.



### Note

Before administering 1% propofol injectable emulsion with the system, it is imperative that the physician review and be completely familiar with the specific dosage and administration information detailed in both this document and in the 1% propofol injectable emulsion product labeling.

The SEDASYS® System is designed to be used with a **single** pre-medication dose of fentanyl given approximately 3 minutes before the

start of propofol infusion. The fentanyl is given because propofol has limited analgesic properties. See the following sections:

- Fentanyl from Warnings of *Chapter 2: Indications, Contraindications, Warnings and Precautions*.
- Fentanyl from Precautions of *Chapter 2: Indications, Contraindications, Warnings and Precautions*.
- Administering Fentanyl and Loading the Drug Delivery Cassette from *Chapter 6: Procedural Use* for specific dosing information.

### Initiating Propofol Sedation

The SEDASYS® System automatically calculates an appropriate loading dose with which to initiate sedation with 1% propofol injectable emulsion. The calculation is based on patient weight and the dose rate entered by the clinician.

The formula for calculating the loading dose is based on the recommended dosing guideline in the 1% propofol injectable emulsion labeling. Immediately following delivery of the loading dose, the system will begin delivering the dose rate entered by the clinician.

### Maintaining Propofol Sedation

Patients generally require maintenance dose rates of 25 to 75mcg/kg/min.

To avoid sedative administration of 1% propofol injectable emulsion at rates higher than are clinically necessary, dose rates should always be titrated downward once the desired sedation effect has been achieved.

## Propofol Delivery With The SEDASYS® System

The SEDASYS® System uses a proprietary drug delivery algorithm that enables the clinician to enter a dose rate to attain the desired sedation effect. At the start of drug delivery to the patient, the system automatically calculates the loading dose using the patient weight and dose rate entered by the clinician and begins to deliver the loading dose to the patient. The loading dose is administered over 3 minutes. After the loading dose is complete, the system automatically starts delivering 1% propofol at the dose rate entered. The clinician may need to titrate the dose rate to maintain an adequate level of sedation.

During the 3-minute loading dose, the system does not allow additional increases in the dose rate. This is to ensure that the care team observes the full effect of the current loading dose before deciding to increase the dose rate.

All physiological monitoring and drug delivery are integrated through a proprietary software algorithm. The SEDASYS® System is designed to help guard the patient against over-sedation related adverse physiology. To achieve this, the system:

- Requires that all monitors be connected and functioning properly before initiating 1% propofol delivery.
- Requires oxygen delivery to administer 1% propofol.
- Places limits on both the initial dose rate and maximum dose rate.
- Places limits on the dose rate increases based on patient responsiveness.
- Reduces the dose rate for low respiratory rate/apnea or low SpO<sub>2</sub> as indicated by a visual and audible yellow alarm.
- Stops the dose rate in the event of very low respiratory rate/apnea or very low SpO<sub>2</sub> as indicated by a visual and audible red alarm.
- Adjusts the flow of oxygen as required to maintain patient's oxygen saturation.

## ARM Responsiveness Tests

During 1% propofol delivery, ARM plays a key role in aiding the clinician with maintaining and adjusting the level of sedation. Once drug delivery is initiated, the ARM responsiveness tests are automatically performed at preset intervals throughout the procedure. The ARM responsiveness tests are performed automatically at preset timed intervals, after the initiation of drug delivery and throughout the procedure.

The SEDASYS® System considers the patient responsive if the patient squeezes the handset in response to the audible and tactile stimuli in less than 14 seconds. The amount of time it takes for the patient to respond to ARM stimuli is recorded in seconds by the system and displayed on the ARM graph located on the PRU Monitoring screen.



Note

1. If the patient response time is greater than 5 seconds, the maximum allowable maintenance rate increase is 25 mcg/kg/min.
2. If the patient response time is less than or equal to 5 seconds, the maximum allowable maintenance rate increase is 50 mcg/kg/min.

If the patient does not respond within this 14-second period, the system records the patient as non-responsive and displays NR (Non-Responsive) on the PRU Monitoring screen.



Note

1. If the patient is non-responsive, the maintenance rate can be increased by 10 mcg/kg/min. However, if the Additional Limit for preventing a maintenance rate increase when the patient is not responsive to ARM is active, you cannot increase the maintenance rate.
2. If the patient is non-responsive to ARM for 6 consecutive minutes, the system automatically reduces the maintenance rate.
3. If the patient becomes non-responsive to ARM during the 3 minute loading dose, the system will reduce the selected maintenance rate to one equivalent to the maintenance rate at the time of loss of responsiveness.

During the procedure, if the patient forgets to release the handset and an ARM responsiveness test is about to begin, the system provides the following audio command to the patient: *"Release the handset, then squeeze again."* This is repeated at three levels of intensity. In the event the patient does not respond to the command, at which time the system records the patient as non-responsive.

The system also uses the ARM earpiece to command the patient to *"Take a deep breath"* during a SpO<sub>2</sub> or low respiratory rate / apnea alarm.

## Training

Prospective users of the SEDASYS® System must complete an EES-approved device training program before using the device.



### WARNING

The SEDASYS® System should only be used by physician/nurse teams who have received prior training in the administration of minimal-to-moderate sedation including airway management, provided by their facility or a certified third party, and who have completed an EES-approved device training program. It should be noted that the EES-approved device training program does not replace formalized training in minimal-to-moderate sedation. This training must be completed before users administer propofol with the SEDASYS® System.

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## Chapter 2 Indications, Contraindications, Warnings and Precautions

### Indications

The SEDASYS<sup>®</sup> System is indicated for the intravenous administration of 1% (10 mg/mL) propofol injectable emulsion for the initiation and maintenance of minimal-to-moderate sedation, as defined by the American Society of Anesthesiologists Continuum of Depth of Sedation, in adult patients (American Society of Anesthesiologists physical status I and II) undergoing colonoscopy and esophagogastroduodenoscopy (EGD) procedures.

1. To achieve analgesia, a **single** bolus dose of fentanyl should be administered three minutes prior to the start of propofol infusion by the system.
2. ASA Class Description:
  - I - A normal healthy patient.
  - II - A patient with mild systemic disease with no functional limitations.
  - III - A patient with severe systemic disease with definite functional limitations.
  - IV - A patient with severe systemic disease that is a constant threat to life.
  - V - A moribund patient who is not expected to survive 24 hours with or without the operation.



Note

### Contraindications

The SEDASYS<sup>®</sup> System is contraindicated in the following:

- Patients with a known hypersensitivity to 1% propofol injectable emulsion or its components
- Patients with allergies to eggs, egg products, soybeans or soy products
- Patients with a known hypersensitivity to fentanyl
- Pregnant or lactating women
- Delivery of any drug other than 1% propofol injectable emulsion
- Patients with a full stomach

## Warnings

The following WARNINGS alert the clinician to the possibility of serious injury, death, or other serious adverse reactions associated with the use or misuse of The SEDASYS® System.

### General Use

- 1 The SEDASYS® System should only be used by physician/nurse teams who have received prior training in the administration of minimal-to-moderate sedation including airway management, provided by their facility or a certified third party, and who have completed an EES-approved device training program. It should be noted that the EES-approved device training program does not replace formalized training in minimal-to-moderate sedation. This training must be completed before users administer propofol with the SEDASYS® System.
- 2 As with any medical procedure, the safety of the patient is the responsibility of the physician. The primary role of the physician is to conduct the endoscopic procedure. A nurse, under the direction of the physician, should assist the physician and tend to the patient in accordance with ASA Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists (2002).
- 3 The SEDASYS® System should be operated only by, or under the supervision of, persons trained to rescue patients who enter a state of deep sedation, as defined by the American Society of Anesthesiologists Continuum of Depth of Sedation.
- 4 The SEDASYS® System does not take automatic drug action (i.e. reduce or stop propofol delivery) for bradycardia, tachycardia, hypotension, hypertension, high respiratory rate or high end tidal CO<sub>2</sub>. If any of these conditions occur, it is the clinician's responsibility to assess the patient and take the appropriate drug action.
- 5 Rescue medications (i.e., narcotic reversal agents) and equipment for maintenance of the patient's airway, positive pressure ventilation, oxygen enrichment, and circulatory resuscitation must be immediately available.
- 6 Practitioners should consult an anesthesiologist when the ASA classification is unclear, the patient is medically compromised or unstable, or a difficult airway is anticipated (e.g., sleep apnea or Mallampati airway classification III or IV).
- 7 Only approved peripheral devices, parts, components, and accessories should be used. Using items not approved for use with the system may invalidate safety certifications, compromise patient safety, result in increased emissions or decreased immunity, and result in measurement error.
- 8 Do not use the SEDASYS® System in combination with flammable or other inhalation anesthetic agents or with external breathing systems.



### WARNING

- 9 The safety and effectiveness of the SEDASYS<sup>®</sup> System has not been established in the following patient populations:
- ASA physical status III
  - Patients using a fentanyl patch
  - Patients with abnormal airway or diagnosed sleep apnea
  - Patients with gastroparesis
  - Patients with Body Mass Index  $\geq 35$
  - Patients undergoing both colonoscopy and esophagogastroduodenoscopy during the same procedure visit
  - Patients undergoing emergent colonoscopy or esophagogastroduodenoscopy
- 10 Use of the SEDASYS<sup>®</sup> System with analgesics other than fentanyl has not been studied.
- 11 Do not supplement propofol administered by the SEDASYS<sup>®</sup> System with additional manual bolus doses of any other sedative (e.g., midazolam) as this may result in overdosing and respiratory depression.
- 12 The SEDASYS<sup>®</sup> System should not be used for the induction and/or maintenance of deep sedation or general anesthesia.
- 13 Some generic forms of propofol injectable emulsions contain sodium metabisulfite and may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. While the overall presence of sulfite sensitivity in the general population is low, it is seen more frequently in asthmatic than in nonasthmatic people.

**WARNING**

## Electrical Hazards



### WARNING

- 1 Do not use electrosurgical equipment in close proximity to the Oral/Nasal Cannula. Sparks from the electrosurgical unit's probe could result in combustion during oxygen delivery.
- 2 To help protect against electric shock due to leakage current, use only power cords supplied with the system.
- 3 Do not simultaneously make contact with the patient and any exposed metal from any electrical connectors on the system.
- 4 Only an authorized service technician should service the SEDASYS<sup>®</sup> System. Risk of electrical shock or other hazards may occur if high voltage internal components are touched.
- 5 Make visual checks on cables, sensors, and electrode wires prior to each use. All cables, sensors, and electrode wires must be inspected (no insulation gaps, cracks, or physical damage), properly maintained, and in proper working order to allow the equipment to function properly and ensure patient safety.
- 6 Ensure that the Control Unit Power Switch, located at the rear panel of the PSU, is in the OFF position whenever connecting or disconnecting the PSU cable. If the PSU connecting cable is not securely attached, an electrical shock or arc may occur.
- 7 Do not use the system if the integrity of the protective earth conductors is in doubt.
- 8 Using items not approved for use with the SEDASYS<sup>®</sup> System, including other equipment simultaneously connected to the patient, may invalidate safety certification, increase leakage currents to the user and/or patient and compromise patient safety.
- 9 Performance of the SEDASYS<sup>®</sup> System must be verified if used adjacent to or stacked with other electrical equipment.

## Propofol

- 1 Carefully review all aspects of the propofol package insert, especially the warning and precaution sections, before using the SEDASYS<sup>®</sup> System to administer 1% propofol injectable emulsion.
- 2 Only use 1% (10 mg/mL) propofol injectable emulsion in new 10 or 20 mL vials. Do not use an expired or previously used vial.
- 3 1% propofol injectable emulsion has been associated with both fatal and life-threatening anaphylactic and anaphylactoid reactions.
- 4 Do not supplement propofol administered by the SEDASYS<sup>®</sup> System with additional manual bolus doses of propofol as this may result in overdosing and respiratory depression.
- 5 Use only the approved Drug Delivery Cassette supplied with the SEDASYS<sup>®</sup> System. The use of infusion tubing not approved for use with the system may result in inaccurate delivery of 1% propofol injectable emulsion.
- 6 Purging and/or priming the intravenous (IV) line while the IV administration set is connected to the patient may result in an air embolism or inappropriate drug delivery. Never connect the T-site of the Drug Delivery Cassette to the patient before the Drug Delivery Cassette and its IV tubing are completely primed. Examine the IV line for residual air and manually purge any residual air prior to connecting. When using a standard IV administration set, make sure it contains an integrated back-check valve to prevent inaccurate dosing of 1% propofol injectable emulsion.
- 7 Do not connect another active infusion pump to the IV delivery line. Connection of another pump may result in inaccurate dosing of 1% propofol injectable emulsion.
- 8 At the end of a case, always press the End Case button on the Procedure Room Unit (PRU) and the Bedside Monitoring Unit (BMU) to reset default settings for the next patient. Using past settings may lead to improper dosing of 1% propofol injectable emulsion. Incorrectly entered weights may cause improper dosing of 1% propofol injectable emulsion.
- 9 Always verify patient's weight, including proper unit of measure (lb or kg), when beginning a new case. Failure to do so may result in inaccurate drug dosing.



### WARNING



### Note

The SEDASYS<sup>®</sup> System will not deliver propofol unless the cardio-respiratory monitors, automated responsiveness monitor, and supplemental oxygen are working properly.

## Fentanyl

- 1 Users should carefully review all aspects of the fentanyl package insert, especially the warning and precaution sections, before administering this drug.
- 2 Only a **single** pre-procedure dose of fentanyl should be administered. Administration of additional doses of fentanyl beyond the start of the procedure increases the risk of severe respiratory depression.
- 3 Do not administer fentanyl until all of the patient monitors are connected.



### WARNING

## Supplemental Oxygen Delivery



### WARNING

Do not attach a standard oxygen supply hose to anything other than a breathable, 100% oxygen source with regulated inlet pressure (40 to 60 psi).

## Electrocardiogram



### WARNING

1. The SEDASYS<sup>®</sup> System provides electrocardiogram (ECG) monitoring and does not perform diagnostics.
2. During defibrillation, keep the discharge paddles away from the ECG leads and electrodes, as well as other conductive parts in contact with the patient. Avoid contact with any accessories connected to the system during defibrillation. Failure to isolate the defibrillation current from components of the system may cause burns or electric shock.
3. To ensure patient safety, the conductive parts of the ECG leads (including associated connectors) and other patient-applied parts should not contact other conductive parts, including earth ground, at any time. Failure to prevent contact from the conductive parts may cause the patient to be burned.
4. High-intensity radio frequency (RF) energy from external sources, such as an improperly connected electrosurgical unit, can induce heat into the electrodes and cables that can cause burns on the patient. Reading errors and damage to equipment may also result. This hazard can be reduced by (1) avoiding the use of small ECG electrodes, (2) using electrosurgical return electrodes with the largest practical contact area, and (3) assuring proper application of the electrosurgical return electrode to the patient.
5. PACEMAKER PATIENTS. Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter ALARMS. Keep pacemaker patients under close surveillance.

## Packaging, Sterilization, Transportation, and Storage



### WARNING

1. The Oral/Nasal Cannula is packaged non-sterile for single-patient use only. Do not re-use. Re-use may result in transmission of disease from patient to patient.
2. Do not use the Drug Delivery Cassette if its sterile package is damaged or if past the labeled expiration date. Dispose of the Drug Delivery Cassette per your facilities protocol.
3. The Drug Delivery Cassette is packaged sterile for single-patient use only. Do not re-sterilize as this may compromise the integrity of the cassette and result in patient injury.
4. Do not use the system if any component of the system has been dropped or severely abused.

## Cleaning and Maintenance



### WARNING

Failure to follow the service interval recommendations may cause system measurement inaccuracies, equipment failure, or improper functioning of devices.

## Precautions

The following PRECAUTIONS alert the clinician to the possibility of minor or moderate injury to the clinician or patient, or damage to the device associated with the use or misuse of the SEDASYS® System.

### General Use



#### Precaution

- 1 To avoid damaging the display, use only your fingers or other blunt objects to press the buttons on the touchscreen.
- 2 To prevent overheating during use, do not block the ventilation openings of the system enclosures.
- 3 Care should be exercised in selecting the type of IV pole to be used to mount the BMU. The BMU should not be attached to a freestanding 4-wheel IV stand unless stabilization from the extra weight is added to the wheel base. The diameter of the IV pole should be between 0.5" and 1.25" to accept the pole clamp adapter. The BMU should be attached no higher than 55" from the floor on a freestanding 5 or 6-wheel IV pole. An IV bag should not be positioned over the BMU and should be positioned on a hook opposite the BMU. Do not attach any other devices to the IV stand when the BMU is attached.
- 4 Although the IV pole clamp allows the BMU to be rotated to attach the Multiple Patient Use devices (MPUs) to the BMU, the BMU must remain in an upright, vertical position when in use to ensure consistent operation of the Oral/Nasal Cannula.
- 5 An audio tone is played at each press of the Up or Down Arrow buttons corresponding to the new audio level. Set the audio level such that the tone is clearly heard in the clinical environment.
- 6 Some patient's may be sensitive or allergic to the adhesive strips on the Oral/Nasal Cannula.
- 7 The Bite Block must be used during EGD procedures to ensure proper function of the Oral/Nasal Cannula in the presence of a scope or an esophageal dilator.
- 8 Do not pull directly on the Umbilical Cable without grasping the Release Sleeve. The connector will not be unlocked and damage to the cable or BMU may result.
- 9 The system may not meet performance specifications if operated outside the specified temperature and humidity ranges.

## Electrical Hazards



### Precaution

- 1 Electronic equipment, such as portable and mobile RF communications equipment, can cause electrical interference with the system. Avoid operating the system near equipment that emits strong electromagnetic or radio frequency signals.
- 2 To remove the device from the external power, you must disconnect the power cable from the wall outlet.
- 3 Use only the approved IEC320 hospital-grade power cord that is supplied with the system.
- 4 The PSU should be allowed to charge the internal battery back-up system for 30 minutes prior to installation or following extended storage without connection to external AC power.
- 5 The device must be disconnected from external power when the internal battery pack is replaced.
- 6 The SEDASYS<sup>®</sup> System requires precautions regarding Electromagnetic Compatibility (EMC) and should be installed and put into service according to information provided in this document. EMC compatibility is insured only when the system is used with the provided peripheral devices, parts, components, and accessories.

## Propofol



### Precaution

Care should be exercised to replace the 1% propofol drug vial when initially indicated by the system. Failure to do this may result in air being introduced into the IV tubing requiring purging before continuing the procedure.

## Fentanyl



### Precaution

To reduce the risk of transient apnea or hypoxemia at the start of the procedure, a single dose of fentanyl should be administered approximately three minutes before initiating 1% propofol delivery with the SEDASYS<sup>®</sup> System.

## Pulse Oximeter



### Precaution

- 1 It is recommended that the Pulse Oximeter probe be placed on the right hand, opposite the NIBP cuff on the left arm. Placing the Pulse Oximeter probe on the same arm as the NIBP cuff may disrupt the Pulse Oximeter data when the cuff is inflated, leading to potential false alarms.
- 2 Excessive patient motion, excessive ambient light, electromagnetic interference, dysfunctional hemoglobin, low perfusion, intravascular dyes, finger nail polish, and artificial finger nails may affect the accuracy of the SpO<sub>2</sub> measurement.

## Automated Responsiveness Monitor (ARM)



### Precaution

It is recommended that the ARM handset be placed in the left hand, in the hand opposite the Pulse Oximeter probe. Placing the ARM handset in the same hand as the Pulse Oximeter probe can lead to inaccurate Pulse Oximeter measurements.

## Supplemental Oxygen Delivery



### Precaution

- 1 Do not use any additional sources of oxygen in conjunction with the oral/nasal cannula. Additional sources of oxygen delivery to the patient may impact capnometry accuracy.
- 2 Connection to an oxygen supply source greater than 60 psi may damage the internal oxygen delivery system.

## Electrocardiogram



### Precaution

- 1 Electronic equipment that emits strong electromagnetic or radio frequency signals can cause electrical interference with the ECG monitor operation. This interference may distort the displayed or recorded ECG signal, thereby preventing accurate ECG waveform. Avoid operating the system near equipment of this type.
- 2 The ECG display may be interrupted while using electrosurgical equipment or a defibrillator. This interruption may continue for up to 10 seconds after discontinuing use of the electrosurgical equipment or defibrillator.
- 3 Use only the approved ECG cables and leads. Use of other ECG cables and leads may be subject to large offset potentials due to polarization, and may compromise recovery time after application of defibrillator pulses.
- 4 Do not use ECG electrodes that are beyond the expiration date.
- 5 Improper electrode placement may lead to inaccurate ECG readings.

## Non-Invasive Blood Pressure



### Precaution

- 1 Using the wrong size cuff may result in inaccurate blood pressure readings.
- 2 It is recommended that the NIBP cuff be placed on the patient's left arm, opposite the IV site on the right arm so that inflation of the blood pressure cuff during NIBP measurements will not interfere with drug delivery.
- 3 Accuracy of blood pressure measurements can be affected by patient position or any physical limitation that may impact placement of the cuff. Ensure that the patient does not lie on the NIBP cuff or tubing.
- 4 Periodically monitor the patient's limb with the cuff attached to make sure that circulation is not impaired for a prolonged period of time. Prolonged impairment of circulation due to over-inflation of the cuff or patient position can cause bruising.

## Packaging, Sterilization, Transportation, and Storage



### Precaution

- 1 The SEDASYS® System may not meet its performance specifications if shipped, stored, or operated outside the specified temperature and humidity ranges.
- 2 Do not attempt to use the system if it appears damaged or fails the initial self-check during power-up. The system may have been damaged during shipping and handling.
- 3 Secure the placement of all components during transport to prevent injury to the clinician or patient.
- 4 Before removing the SEDASYS® System and its components from the packaging, inspect the outside packaging for obvious signs of damage that may have occurred during transit and/or storage. Do not use the system or its components if the packaging appears to have been opened or damaged.
- 5 After removing the SEDASYS® System and components from their packaging, check all items for damage, including loose wires, cracks, gaps, breaks, cuts, and tears in the wires or plastic housings. Do not use any damaged components.
- 6 Do not autoclave, steam-sterilize, ETO-sterilize, or gas plasma sterilize any components of the system. This may damage the system or degrade the performance of the system.
- 7 Leaving the system batteries (PRU or BMU) in a discharged state may result in permanent battery damage. The system should be connected to power to maintain charged batteries.

## Cleaning and Maintenance



### Precaution

- 1 Failure to follow cleaning and maintenance instructions provided in this manual may result in damage to the system or degradation of system performance.
- 2 Do not immerse any part of the system or any of its components in liquid.

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## Chapter 3 Clinical Safety and Effectiveness

This section describes the results of a large, non-blinded, multi-center, randomized, comparative trial of the SEDASYS<sup>®</sup> System versus the current standard of care (CSC) for sedation in subjects undergoing colonoscopy or esophagogastroduodenoscopy (EGD) procedures. A total of 1000 subjects (721 colonoscopy and 279 EGD) were enrolled across eight centers. The objective of the study was to demonstrate that the SEDASYS<sup>®</sup> System enabled a physician/nurse team to safely and effectively administer propofol in colonoscopy and EGD procedures.

In the SEDASYS<sup>®</sup> System group, a single IV bolus dose of fentanyl (mean dose of 74.0 mcg for colonoscopy and 65.6 mcg for EGD) was administered three minutes prior to the start of propofol infusion. The physician initiated propofol infusion at a maintenance rate of up to 75 mcg/kg/min. The mean propofol maintenance rate throughout the procedure was 48.1 mcg/kg/min for colonoscopy and 53.7 mcg/kg/min for EGD. Topical analgesics were administered during EGD to facilitate passage of the endoscope.

In the CSC group, a benzodiazepine (midazolam) and opioid (meperidine or fentanyl) was administered according to the physician's normal sedation protocol. Physicians were instructed to use the dosage regimen they are accustomed to when they sedate subjects undergoing colonoscopy and EGD. As above, topical analgesics were administered during EGD to facilitate passage of the endoscope. Supplemental oxygen was administered at 2 liters/minute consistent with the rate automatically delivered by the SEDASYS<sup>®</sup> System.

Patient vital signs, including Automated Responsiveness Monitoring (the SEDASYS<sup>®</sup> System group only), were recorded electronically throughout the procedure. Level of sedation was assessed every two minutes using a Modified Observers Assessment of Alertness/Sedation (MOAA/S) scale, from first drug until recovery. Recovery was defined as a return to two consecutive MOAA/S scores of five. At recovery, the physician completed the Clinician Satisfaction with Sedation Instrument (CSSI). Twenty-four to forty-eight hours after the procedure the patient completed the Patient Satisfaction with Sedation Instrument (PSSI).

### Primary Endpoint

The primary endpoint of the study was area under the curve of oxygen desaturation ( $SpO_2 < 90\%$  saturation for  $> 15$  seconds). The  $AUC_{Desat}$ , by integrating incidence, duration and depth of desaturation, is an objective and sensitive surrogate measure of a patient's risk for major over-sedation-related AEs. Figure 3-1 on page 3-2 illustrates the concept of  $AUC_{Desat}$ .

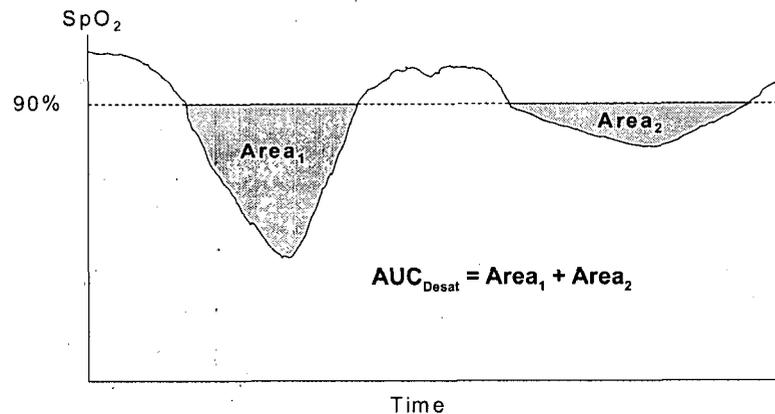


Figure 3-1 Area Under The Curve Of Oxygen Desaturation

## Secondary Endpoints

Four secondary endpoints were selected for this trial as follows:

- Clinician satisfaction evaluated by the Clinician Satisfaction with Sedation Instrument (CSSI) on a 0-100 scale where 100 represents the most satisfied while 0 represents the least satisfied.
- Patient satisfaction evaluated by the Patient Satisfaction with Sedation Instrument (PSSI) on a 0-100 scale where 100 represents the most satisfied while 0 represents the least satisfied.
- Recovery time defined as the time (to the nearest minute) from 'scope-out' until the first of two consecutive MOAA/S scores of five have been reached.
- Duration of deep sedation/general anesthesia measured by the occurrence of all MOAA/S scores of 1 or 0 during a procedure.

In addition to the above measures, all adverse events (AE) occurring during the course of the study were recorded.

## Inclusion Criteria

Subjects were eligible for enrollment into the study after they met certain criteria. Subjects were required to be adults aged 18 years or older, able to comprehend, sign and date the written Informed Consent Form, and they were scheduled to undergo an EGD or colonoscopy. Subjects also were required to have taken nothing by mouth except water and the preparation for colonoscopy for a minimum of 6 hours prior to the study procedure. The subjects were to have been classified by the endoscopists as ASA physical status I, II, or III.

## Exclusion Criteria

Subjects were excluded from the study if they met certain criteria. Subjects were excluded if they had an allergy or an inability to tolerate study medications, were pregnant or nursing, or currently used the fentanyl patch. Subjects were also excluded if they had a diagnosed history of sleep apnea or gastroparesis, had a baseline oxygen saturation of less than 90% on room air, or if they had a BMI of 35 kg/m<sup>2</sup> or greater. If the investigator anticipated the procedure time to exceed 45 minutes, due to anatomical difficulty, subjects were excluded.

## Results

Adverse Events (AEs) that occurred during the trial at an incidence greater than or equal to 1%:

- During colonoscopy, the most frequently reported AEs in the SEDASYS<sup>®</sup> System group were nausea (1.4%) and abdominal pain (1.1%). The most frequently reported AE in the CSC group was oxygen desaturation (4.7%).
- During EGD, there were no AEs reported with a frequency greater than or equal to 1% in the SEDASYS<sup>®</sup> System group. The most frequently reported AEs in the CSC group were oxygen desaturation (7.1%), pharyngolaryngeal pain (2.1%), and nausea (1.4%).
- There were no device related AEs occurring in this study. There were no serious AEs in the SEDASYS<sup>®</sup> System group, and one serious AE in the CSC group (neither device nor drug related).

A tabulation of the results from the primary and secondary endpoints for colonoscopy is provided in Table 3-1: Primary and Secondary Endpoints for Colonoscopy.

Table 3-1: Primary and Secondary Endpoints for Colonoscopy<sup>a b</sup>

	SEDASYS® System (N = 358)	Current Standard of Care (CSC) (N = 363)	p-value <sup>c</sup>
<b>Primary Endpoint</b>			
<b>AUC<sub>Desat</sub>:</b> (seconds · %)	17.8 ± 124.59	98.8 ± 510.32	0.004
<b>Secondary Endpoints</b>			
<b>CSSI:</b>	92.4 ± 10.32	75.8 ± 17.18	<0.001
<b>PSSI:</b>	92.5 ± 12.09	90.5 ± 12.44	0.052
<b>Recovery Time:</b> (minutes)	2.7 ± 2.37	6.3 ± 6.78	<0.001
<b>Duration of Deep Sedation/General Anesthesia:</b> (minutes)	0.1 ± 1.16	0.1 ± 1.23	0.573

a. All data for intent-to-treat population.

b. Plus-minus values are means ± SD.

c. Values were analyzed using an ANOVA, except Recovery Time which used a Cox Proportional Hazards Regression Analysis.

**AUC<sub>Desat</sub>:** Patients in the SEDASYS® System group experienced statistically significantly less oxygen desaturation, a major risk of over-sedation. AUC<sub>Desat</sub> integrates incidence, duration and depth of oxygen desaturation events. Patients in the SEDASYS® System group experienced a total of 32 oxygen desaturation events compared to 140 in the current standard of care group. The longest duration of oxygen desaturation in the SEDASYS® System group was 133 seconds compared to 335 seconds for the current standard of care group.

**CSSI:** Physicians were statistically significantly more satisfied with the sedation achieved in the SEDASYS® System group, compared to the sedation achieved in the current standard of care group. Satisfaction was measured using a validated tool. This tool evaluated sedation administration and recovery/post-operative procedures.

**PSSI:** Patients in the SEDASYS® System group were more satisfied with the sedation they received during the study. Satisfaction was measured using a validated tool. This tool evaluated sedation delivery, procedure recall and sedation side effects.

**Recovery Time:** Patients in the SEDASYS® System group recovered statistically significantly faster than patients in the current standard of care group. Ten minutes after completion of the procedure, less than 1% of SEDASYS® System patients had not recovered from sedation while approximately 25% of the current standard of care patients had yet to recover. Several subjects in the current standard of care group took greater than 30 minutes to recover.

**Level of Sedation:** Patients in both the SEDASYS® System and current standard of care groups were predominantly minimally-to-moderately sedated throughout the procedure. Greater than 99% of all MOAA/S measures were minimal or moderate sedation while less than 1% was deep sedation or general anesthesia.

A tabulation of the results from the primary and secondary endpoints for EGD is provided in Table 3-2: Primary and Secondary Endpoints for EGD.

Table 3-2: Primary and Secondary Endpoints for EGD<sup>a b</sup>

	SEDASYS <sup>®</sup> System (N = 138)	Current Standard of Care (CSC) (N = 141)	p-value <sup>c</sup>
<b>Primary Endpoint</b>			
<b>AUC<sub>Desat</sub>:</b> (seconds · %)	38.6 ± 181.87	60.2 ± 179.92	0.315
<b>Secondary Endpoints</b>			
<b>CSSi:</b>	92.1 ± 11.30	77.0 ± 15.84	<0.001
<b>PSSI:</b>	91.0 ± 12.68	87.9 ± 12.59	0.067
<b>Recovery Time:</b> (minutes)	3.5 ± 2.53	7.0 ± 7.43	<0.001
<b>Duration of Deep Sedation/General Anesthesia:</b> (minutes)	0.0 ± 0.38	0.1 ± 0.85	0.731

a. All data for intent-to-treat population.

b. Plus-minus values are means ± SD.

c. Values were analyzed using an ANOVA, except Recovery Time which used a Cox Proportional Hazards Regression Analysis.

**AUC<sub>Desat</sub>:** Patients in the SEDASYS<sup>®</sup> System group experienced less oxygen desaturation, a major risk of over-sedation. AUC<sub>Desat</sub> integrates incidence, duration, and depth of oxygen desaturation events. Patients in the SEDASYS<sup>®</sup> System group experienced a total of 20 oxygen desaturation events compared to 43 in the current standard of care group. The longest duration of oxygen desaturation in the SEDASYS<sup>®</sup> System group was 97 seconds compared to 199 seconds for the current standard of care group.

**CSSi:** Physicians were more satisfied with the sedation achieved in the SEDASYS<sup>®</sup> System group, compared to the sedation achieved in the current standard of care group. Satisfaction was measured using a validated tool. This tool evaluated sedation administration and recovery/post-operative procedures.

**PSSI:** Patients in the SEDASYS<sup>®</sup> System group were satisfied with the sedation they received during the study. Satisfaction was measured using a validated tool. This tool evaluated sedation delivery, procedure recall and sedation side effects.

**Recovery Time:** Patients in the SEDASYS<sup>®</sup> System group recovered faster than patients in the current standard of care group. Ten minutes after completion of the procedure, less than 1% of SEDASYS<sup>®</sup> System patients had not recovered from sedation while approximately 25% of the current standard of care patients had yet to recover. Several subjects in

the current standard of care group took greater than 35 minutes to recover.

**Level of Sedation:** Patients in both the SEDASYS® System and current standard of care groups were predominantly minimally-to-moderately sedated throughout the procedure. Greater than 99% of all MOAA/S measures were minimal or moderate sedation while less than 1% was deep sedation or general anesthesia.

## Conclusions

This randomized, well controlled study of 1000 patients provided both clinically and statistically significant results. Clinically, the SEDASYS® System performed similarly, or better than, the current standard of care in regards to the primary and secondary endpoints for both colonoscopy and EGD. Statistically, the SEDASYS® System was superior in the primary endpoint ( $AUC_{Desat}$ ) and two secondary endpoints (physician satisfaction and recovery time) for colonoscopy procedures. This demonstrates that the SEDASYS® System enables physician/nurse teams to safely and effectively administer propofol sedation for colonoscopy and EGD procedures.

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## Chapter 4 BMU Installation and Setup



### Precaution

1. Before removing the Bedside Monitoring Unit (BMU) and its components from the packaging, inspect the outside packaging for obvious signs of damage that may have occurred during transit and/or storage. Do not use the BMU or its components if the packaging appears to have been opened or damaged.
2. After removing the BMU and components from their packaging, check all items for damage, including loose wires, cracks, gaps, breaks, cuts, and tears in the wires or plastic housings. Do not use any damaged components.

## Mounting the BMU

The BMU has an integrated pole clamp adapter that allows it to be easily attached to or removed from the included intravenous (IV) pole clamp. The pole clamp attaches to a standard IV pole found on most hospital beds or gurneys. Alternatively, the BMU can be mounted to the bed rail or to a separate IV pole.



### Precaution

1. The diameter of the IV pole should be between 0.5" and 1.25" to accept the pole clamp adapter.
2. An IV bag should not be positioned over the BMU and should be positioned on a hook opposite the BMU.
3. Do not attach any other devices to the IV stand when the BMU is attached.
4. When not in use, the MPU devices should be placed on the Cable Management bracket behind the BMU.
5. The BMU should be attached no higher than 55" from the floor on a freestanding 5 or 6-wheel IV pole.
6. The BMU should not be attached to a freestanding 4-wheel IV stand unless stabilization from extra weight is added to the wheel base.

### To mount the Cable Management bracket

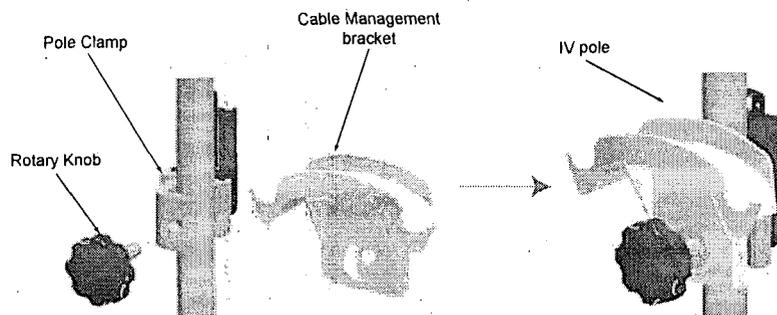


Figure 4-1 Mounting the Cable Management Bracket

A Cable Management bracket is available to facilitate storage of the cables for the Multiple Patient Use devices between cases when not in use. These devices may be draped over the top curved portion of the bracket or placed over the hooks on either side of the bracket. Use of this bracket is optional.

1. The Rotary Knob must be completely removed from the Pole Clamp by rotating the knob counterclockwise.
2. Slide the Cable Management bracket over the Pole Clamp until the holes are aligned for the Rotary Knob.
3. Re-insert the Rotary Knob by rotating clockwise.

### To mount the BMU to the IV pole

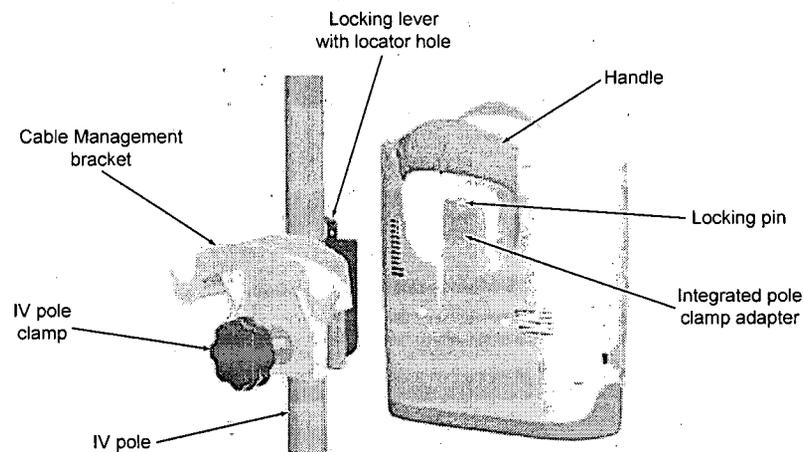


Figure 4-2 Attaching BMU to an IV Pole

1. Attach the included IV pole clamp to the IV pole by turning the clamp rotary knob clockwise for a secure fit to the pole.
2. Align the integrated pole clamp adapter on the back of the BMU with the IV pole clamp and slide the BMU downward onto the IV pole clamp until the clamp adapter locking pin clicks into place with the locator hole on the pole clamp locking lever.
3. Before releasing your grasp on the BMU, ensure the BMU is securely attached to the IV pole clamp and IV pole.

### To disconnect the BMU from the IV pole

1. Pull the IV pole clamp locking lever away from the BMU and hold the locking lever in this retracted position to disengage the locking pin on the BMU clamp adapter from the locator hole on the pole clamp locking lever.
2. Grasping the handle, simultaneously slide the BMU upward to remove it from the IV pole clamp.

## Connecting MPU Devices to the BMU



### WARNING

Use only approved peripheral devices, parts, components, and accessories with the SEDASYS® System. Using items not approved for use with the system may invalidate safety certifications, compromise patient safety, result in increased emissions or decreased immunity, and result in measurement error.



### Precaution

Although the IV pole clamp allows the BMU to be rotated to attach the Multiple Patient Use devices (MPUs) to the BMU, the BMU must remain in an upright, vertical position when in use to ensure consistent operation of the Oral/Nasal Cannula.

All MPUs may remain connected to the BMU between patient uses.

## Connecting the Pulse Oximeter Probe

The SEDASYS® System uses a pulse oximeter to measure the patient's oxygen saturation and pulse rate.

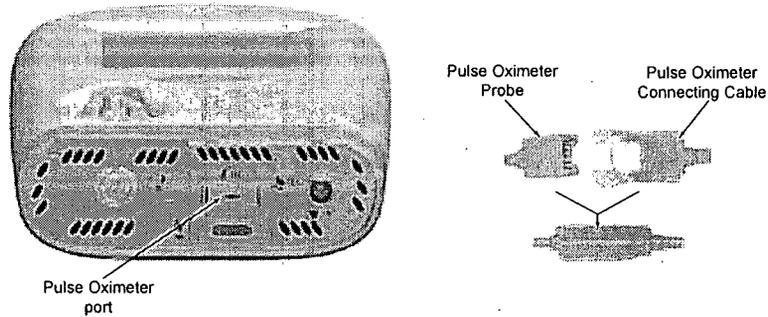


Figure 4-3 Pulse Oximeter Probe Connection to BMU

1. Connect the Pulse Oximeter probe to the appropriate end of the Pulse Oximeter connecting cable. Close the latch on the Pulse Oximeter connecting cable to ensure a secure connection.
2. Connect the other end of the Pulse Oximeter connecting cable to the Pulse Oximeter port on the bottom of the BMU by pushing until the connector snaps into position.

## Connecting the Electrocardiogram Wire Set

The SEDASYS® System uses a 3-lead electrocardiogram (ECG) to capture the patient's ECG waveform and measure heart rate.

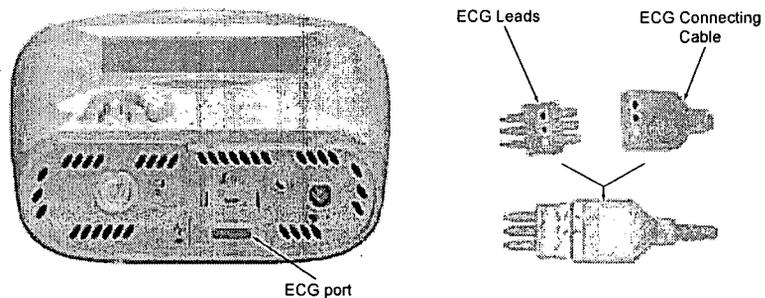


Figure 4-4 3-lead ECG Connection to BMU

1. Connect the 3-lead ECG wire set to the color-coded port of the ECG connecting cable.
2. Connect the other end of the ECG connecting cable to the ECG port located on the bottom of the BMU. The two mounting screws on the cable must be connected to the BMU ECG port and securely tightened using a flat blade screwdriver.

## Connecting the Non-Invasive Blood Pressure Cuff

The SEDASYS® System uses a Non-Invasive Blood Pressure (NIBP) monitor to measure the patient's systolic and diastolic blood pressure.

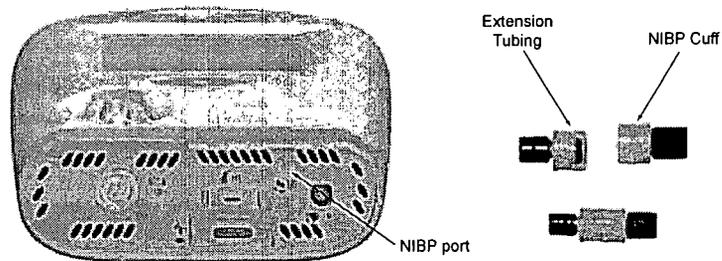


Figure 4-5 NIBP Cuff Connection to BMU

1. Connect the NIBP cuff to the white plastic connector on the end of the extension tubing.
2. Connect the other end of the extension tubing to the NIBP port on the bottom of the BMU by pushing until the connector snaps into position.

## Connecting the ARM Handset

The SEDASYS<sup>®</sup> System uses a proprietary Automated Responsiveness Monitor (ARM) which incorporates mild audible and tactile stimulation to assess the patient's responsiveness during procedural sedation.

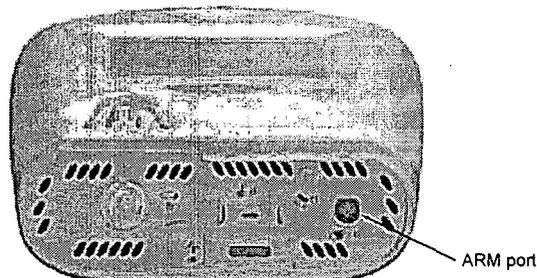


Figure 4-6 ARM Handset Connection to BMU

To connect the ARM handset to the BMU, connect the ARM handset cable to the ARM port on the bottom of the BMU by pushing until the connector snaps into position.

## Powering on the BMU

The BMU receives its power from one of three sources: an external power adapter, the Procedure Room Unit (PRU) when connected via the Umbilical Cable, or internal batteries when disconnected from the external power adapter or PRU.

### External Power Connection

An AC-to-DC power adapter provides power to the BMU when connected to an AC power source (a grounded outlet).



#### WARNING

Do not use the system if the integrity of the protective earth conductors is in doubt. Inspect all cords, cables, plugs, and connectors for fraying or other insulation damage.



#### Precaution

Use only the approved external power adapter and the IEC320 hospital-grade power cord that is supplied with the system.

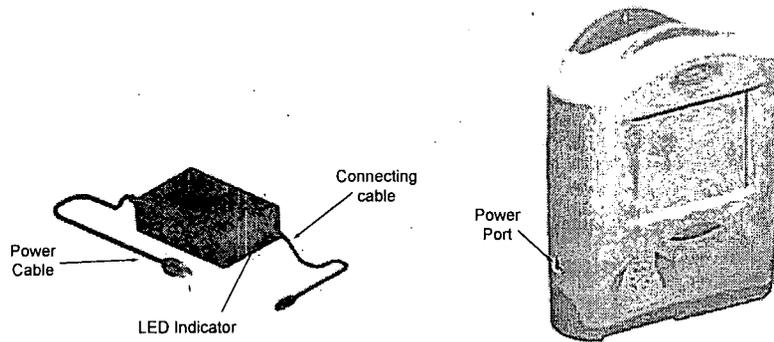


Figure 4-7 Power Adapter Connection to BMU

**To connect and power on the BMU**

1. Connect the power adapter connecting cable to the power port located on the side of the BMU.
2. Connect the power cable to the Power Adapter.
3. Connect the other end of the power cable to an appropriately grounded, hospital-grade only, wall outlet.



**Precaution**

To remove the BMU from external AC power, you must disconnect the BMU power cable from the wall outlet or from the BMU.

4. The LED indicator located adjacent to the Umbilical Cable port indicates power status.

Table 4-1: Indicator Status

Indicator Status	Description
Steady Green Light	DC power is provided to the BMU, the battery is fully charged and the BMU is turned off.
Steady Yellow Light	DC power is provided to the BMU and the battery is charging.
Steady Yellow Light	DC power is provided to the BMU, the battery is fully charged and the BMU is turned on or is in standby mode.  -OR-  DC power is not provided to the BMU.

**Battery Backup System**

The BMU is capable of operating only on battery power (for example, during patient transport). A new, fully charged battery should function continuously for at least 90 minutes before the BMU must be connected to the external power adapter or the PRU.

The BMU always recharges its batteries when connected to the external power adapter or the PRU. The BMU batteries take approximately 120 minutes to fully charge. Charge time is independent of whether the BMU is in use.

When the BMU is on, the battery charge indicator in the upper right corner of the BMU display shows the remaining capacity of the battery.



Figure 4-8 BMU Battery Charge Indicator

When the BMU is on and is connected to the external power adapter or the PRU, the "electrical plug" icon and the remaining minutes of battery life in one-minute increments are displayed. When the BMU is operating off of the battery, only the remaining battery life is displayed.



**Note**

1. The BMU is not intended to be simultaneously connected to the external power adapter and the PRU. Disconnect the BMU from the external power adapter or the PRU prior to connecting to the other power source.
2. The system will provide a prompt for battery calibration when required. To maintain battery health, follow the instructions provided on the screen. Refer to the SEDASYS® Service Manual for the recommended calibration frequency and procedure.

## BMU Operational Modes

Table 4-2: Modes, Mode Indicators, and Changing Modes

Modes	Mode Indicators	Changing Modes
Off	<ul style="list-style-type: none"> <li>Screen is dark (off).</li> <li>The <b>On/Off/Standby</b> button is not lit when external power is not provided.</li> </ul> <p>-OR-</p> <ul style="list-style-type: none"> <li>The <b>On/Off/Standby</b> button is pulsing slowly when external power is provided.</li> </ul>	<p>Press the <b>On/Off/Standby</b> button to get to Ready mode.</p> <p><b>Caution:</b> The system emits sound during start-up. Ensure that this tone is audible before using the system to verify proper function of the alarm speaker.</p>
On: Ready	<ul style="list-style-type: none"> <li>The BMU Ready screen is displayed.</li> <li>The <b>On/Off/Standby</b> button is lit.</li> </ul>	<ul style="list-style-type: none"> <li>Press and release the <b>On/Off/Standby</b> button to get to Standby mode.</li> <li>Press and hold the <b>On/Off/Standby</b> button for at least 3 seconds to get to Off mode.</li> </ul> <p><b>Note:</b> If the BMU sits in <b>Ready</b> mode for 5 minutes, it will go to <b>Standby</b> mode.</p>
On: Standby	<ul style="list-style-type: none"> <li>Screen is dark (off).</li> <li>The <b>On/Off/Standby</b> button is lit.</li> </ul>	<p>To get to Ready mode:</p> <ul style="list-style-type: none"> <li>Press and release the <b>On/Off/Standby</b> button.</li> </ul> <p>- OR -</p> <ul style="list-style-type: none"> <li>Touch the screen.</li> </ul> <p><b>Note:</b> The BMU will require approximately 6 seconds to transition to Ready mode.</p> <p>Press and hold the <b>On/Off/Standby</b> button for at least 3 seconds to get to Off mode.</p> <p><b>Note:</b> The BMU will change to Ready mode if external power is lost.</p>
On: In-Case	<ul style="list-style-type: none"> <li>The BMU standalone monitoring screen is displayed.</li> <li>The <b>On/Off/Standby</b> button is lit.</li> </ul>	<p>The BMU automatically enters this mode when a new patient is selected and exits this mode at the completion of the case.</p>

## Changing BMU Facility Settings

The BMU is shipped with factory-default Facility Settings. The factory-default settings are listed in Table A-1 on page A-1 and Table A-3 on page A-2 of *Appendix A: Factory Default Settings*.

Your facility has the option to change these settings through an access-code-protected process. Once changed, the Facility Settings become the new default settings for all procedures subsequently performed with that specific BMU. Note that if your facility has multiple BMUs, the facility settings on each BMU will need to be independently set. Facility Settings can be restored to the factory-default values.

The touchscreen on the BMU is used to change the following BMU Facility Settings:

- **Volume Settings** (Alarms, system sounds, and ARM audio)
- **Units of Measure** (NIBP)
- **Alarm Settings** (Heart rate, SpO<sub>2</sub>, and blood pressure settings)
- **Timing / Print Options** (Timing intervals for NIBP and data collection, and printer options for enabling printer, printing on alarms, and printout identification)
- **Time and Date**
- **Display Information** (Language, brightness, continuous display of alarm limits, ECG gain, and waveform speed)

The following steps show you how to make changes to your Facility Settings and reset them to factory-default settings. The BMU should be powered on and in Ready mode so that the BMU Ready screen appears on the touchscreen.

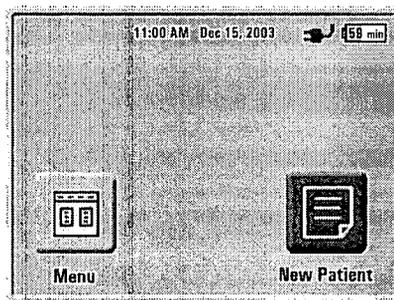


Figure 4-9 BMU Ready Screen

1. Press **Menu** on the BMU Ready screen. The following screen appears:

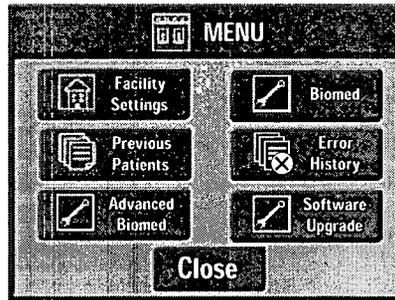


Figure 4-10 BMU Menu Screen



**Note**

- 1 The **Biomed** button is to be used only by an authorized service technician to perform system tests and calibrations. Access to the Biomed functions is permitted only through a four digit access code.
- 2 The **Previous Patients** button provides access and display of stored patient data of the last 100 patients.
- 3 The **Error History** button provides access and display of stored system errors.

2. Press **Facility Settings**. The following screen appears:

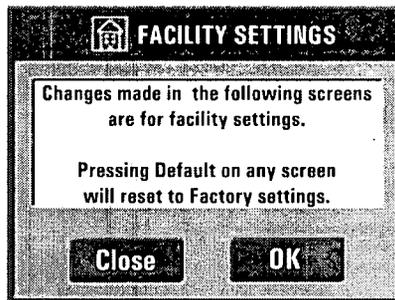


Figure 4-11 BMU Facility Settings Notification Screen

3. Press **OK**. The following screen appears:

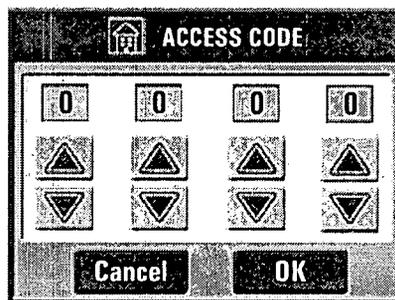


Figure 4-12 BMU Access Code Screen

4. Enter the 4-digit access code (4680), then press **OK**. A Facility Settings menu screen appears. This screen displays all the Facility Settings that you can change for the BMU.

**Note**

The 4-digit access code cannot be changed.

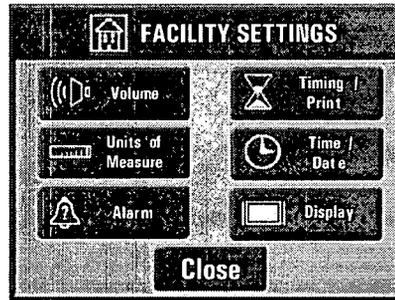


Figure 4-13 BMU Facility Settings Menu Screen

5. Select and press the button for the Facility Setting that you want to change.

A screen appears for your selection:

**Note**

For certain setting selections, an "intermediate" screen appears, which provides you with additional options before you can enter the Facility Setting change.

6. When you have selected the Facility Setting, select one of the following options:
  - Press **OK** to confirm the new Facility Setting changes and return to the previous screen. These changes now become the default settings for all procedures.
  - Press **Cancel** to terminate setting changes entered and to return to the previous screen.
  - Press **Default** to reset the settings to the factory-default settings for all procedures. Press **OK** to confirm the new Facility Setting changes and return to the previous screen. These changes now become the default settings for all procedures.
7. When you have finished changing all your selected Facility Settings, press **Close** from the Facility Settings screen. You will be returned to the Menu screen.
8. Press **Close** on the Menu screen to return to the BMU Ready screen.

## Facility Settings Screens for the BMU

The following are the screens that appear when you select and press a button from the Facility Settings screens:

## Volume Settings

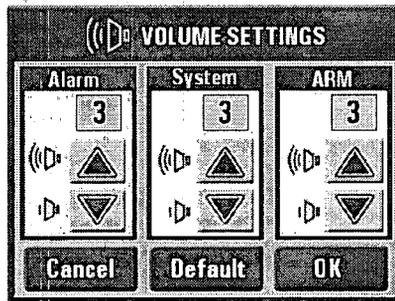


Figure 4-14 BMU Volume Settings Screen

Change each setting by pressing the **Up** or **Down Arrow** buttons, and then press **OK**.

- **Alarm:** The audible alarm levels on the BMU.
- **System:** The pulse/heart rate tone levels and system startup tone.
- **ARM:** The volume level for the ARM audio.



**Note**

The alarm and ARM volume levels cannot be set to zero (0).



**Precaution**

An audio tone is played at each press of the **Up** or **Down Arrow** buttons corresponding to the new audio level. Set the audio level such that the tone is clearly heard in the clinical environment.



**Note**

- 1 Select zero (0) for system volume to continuously mute all non-alarm sounds. However, this does not mute the system start-up audio.
- 2 The ARM audio signal is supplied through the earpiece portion of the Oral/Nasal Cannula, not the system speaker.

## Units of Measure

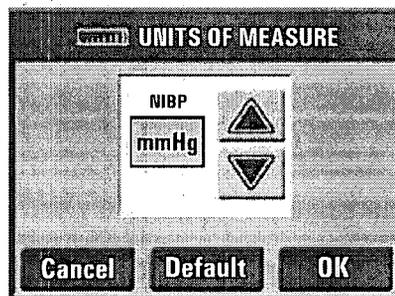


Figure 4-15 BMU Units of Measure Setting Screen

Change the units by pressing the **Up** or **Down Arrow** buttons, and then press **OK**. The alarm setting screens for Systolic and Diastolic NIBP will be automatically displayed if the unit of measure is changed.

### Alarm Settings

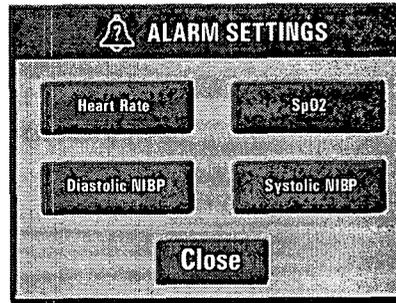


Figure 4-16 BMU Alarm Settings Menu Screen

1. Select and press the button for each setting that you want to change.
  - **Heart Rate:** In beats per minute (minimum and maximum)
  - **SpO<sub>2</sub>:** In % (minimum only)
  - **Diastolic NIBP:** (Minimum and maximum)
  - **Systolic NIBP:** (Minimum and maximum)

For example, if you press **SpO<sub>2</sub>**, the following screen appears:

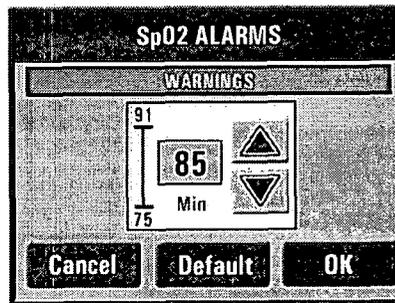


Figure 4-17 BMU SpO<sub>2</sub> Alarms Screen

2. Change each setting by pressing the **Up** or **Down Arrow** buttons, and then press **OK**.

## Timing / Print

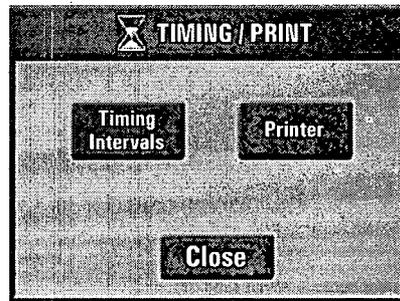


Figure 4-18 BMU Timing Intervals / Printer Menu Screen

1. Press **Timing Intervals** from the Timing / Print Menu screen to select the interval at which the NIBP module takes pressure readings and the interval that patient physiology is recorded for post-procedure printing.

**Note**

The Timing Intervals are effective when the BMU is operating as a standalone unit. When the BMU is connected to the PRU, the Timing Intervals are defined by the settings in the PRU.

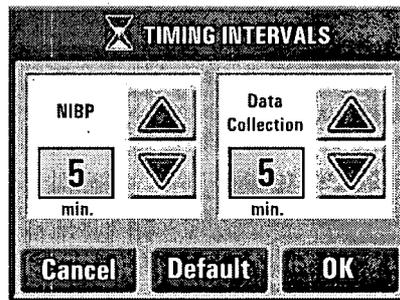


Figure 4-19 BMU Timing Intervals Screen

2. Change each setting by pressing the **Up** or **Down Arrow** buttons, and then press **OK**.

3. Press **Printer** from the Timing / Print Menu screen to select options for wireless printing.

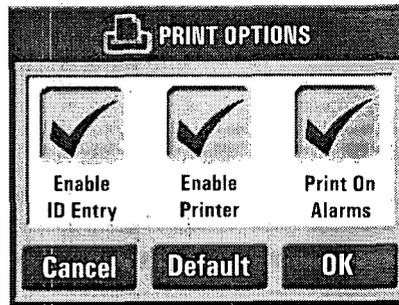


Figure 4-20 BMU Print Options Screen

4. Select the desired print functions by pressing the checkbox above each feature to enable. Press **OK** when complete.
  - “Enable ID Entry” requires the clinician to enter up to a 9-digit numeric patient identifier that will be displayed on the BMU and PRU screens and printed on the hardcopy patient record.
  - “Enable Printer” allows the BMU to print to a wireless printer.
  - “Print On Alarms” enables automatic printing to the wireless printer in the event of a patient physiology alarm condition in pre- and post-procedures.



**Note**

1. If “Enable ID Entry” is not selected, the system will automatically generate a 5-digit identifier that will be displayed on the BMU and PRU screens and printed on the hardcopy patient record.
2. If “Enable Printer” is selected, the wireless printer will need to be configured. Refer to Setting up the BMU Wireless Printer on page 4 - 17.

**Time / Date**

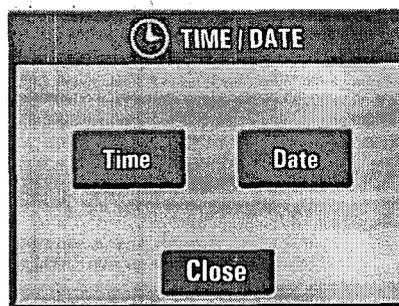


Figure 4-21 BMU Time and Date Menu Screen

1. Select and press the button for each setting that you want to change. For example, if you press **Time**, the following screen appears:

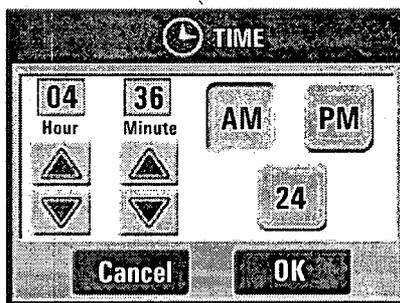


Figure 4-22 BMU Time Screen

2. Select the format for time display by pressing the **AM**, **PM** or **24** button. The number 24 is a setting that represents a 24-hour clock.
3. Change the setting for hour and minute by pressing the **Up** or **Down Arrow** buttons, and then press **OK**.

### Display Settings

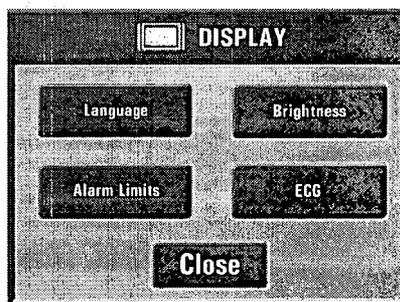


Figure 4-23 BMU Display Settings Menu Screen

1. Select and press the button for each setting that you want to change.
  - **Language:** Select languages for BMU display (English only) and for ARM audio (English, French, and Spanish).
  - **Alarm Limits:** Turn on or off continuous display of alarm limit settings.
  - **Brightness:** Adjust brightness level of BMU display.
  - **ECG:** Adjust ECG waveform display gain and waveform speed.

For example, if you press **Language**, the following screen appears:

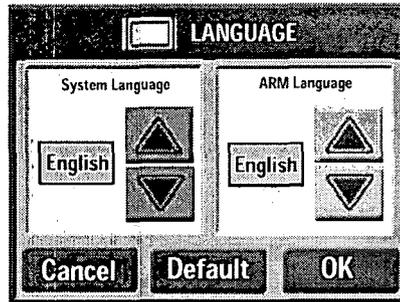


Figure 4-24 BMU Language Settings Screen

2. Select the setting you want to change by pressing the **Up** or **Down Arrow** buttons, and then press **OK**.



**Note**

The System Language cannot be changed. English is the only available language.

## Setting up the BMU Wireless Printer

The first time BMU wireless printing is enabled, the wireless printer and wireless network must be configured. After pressing **OK** from the BMU Print Options Screen in Figure 4-20 on page 4-15, the following screen appears.

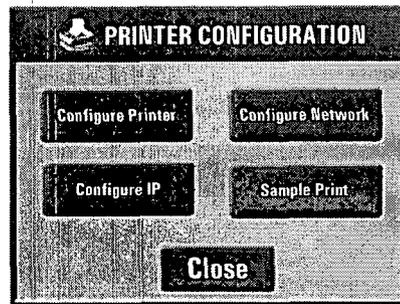


Figure 4-25 BMU Printer Configuration Menu Screen

Select and press the button for the Printer Configuration that you want to change. A screen appears for your selection.

## Configure Printer

Figure 4-26 BMU Printer Configuration Screen

1. Enter the IP Address configuration for the printer using the numeric keypad. The numeric value in each field cannot exceed 255. The value in the first field must be between 1 and 223, and cannot use 127. The value in the fourth field must be between 1 and 254. Press the **Tab** button to switch between fields as needed.
2. Enter the Net Mask configuration using the numeric keypad to 255.255.255.0. Press the **Tab** button to switch between fields as needed.
3. Enter the Default Gateway configuration using the same values as the IP Address. Press **OK**.



### Note

Every wireless printer and every BMU in your facility should be configured with a unique IP address. The first three fields of all Printer IP Addresses and all BMU IP Addresses (refer to Figure 4-29 on page 4-19) should be identical with the fourth field being unique.

## Configure Network

Figure 4-27 Wireless Printer Network Configuration Screens

1. Enter the Service Set Identifier (SSID) of the wireless printer using the keypads. Press the **ABC** or **123** buttons at the bottom of the screen to switch between the number and letter keypads.
2. Press **OK**.



Note

1. An SSID is the network name shared by all devices in a wireless printer network. Your network's SSID should be unique to your network and identical for all devices within the network.
2. The SSID can be up to 15 digits.
3. Every wireless printer must have a unique SSID.

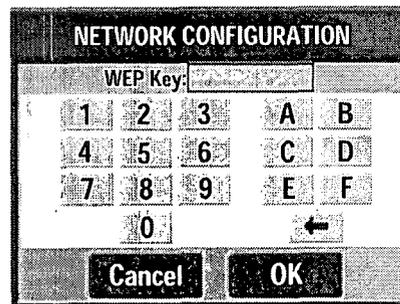


Figure 4-28 BMU WEP Configuration Screens

3. For 64-bit encryption, enter a 10 digit hexadecimal Wired Equivalent Privacy (WEP) Key of the wireless printer using the keypad. Press **OK**.



Note

Following the initial entry of the SSID or whenever the SSID is changed, the BMU must be turned off and restarted for the Network Configuration to be active.

### Configure IP

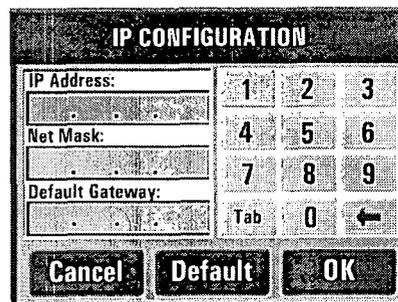


Figure 4-29 BMU IP Configuration Screen

1. Enter the IP Address configuration using the numeric keypad. The numeric value in each field cannot exceed 255. The value in the first field must be between 1 and 223, and cannot use 127. The value in

the fourth field must be between 1 and 254. Press the **Tab** button to switch between fields as needed.

2. Enter the Net Mask configuration using the numeric keypad to 255.255.255.0. Press the **Tab** button to switch between fields as needed.
3. Enter the Default Gateway configuration using the same values as the IP Address
4. Press **OK**.

**Note**

Every wireless printer and every BMU must be configured with a unique IP address. The first three fields of the Printer IP Address (refer to Figure 4-26 on page 4-18) and the BMU IP Address must be identical.

**Configure the Wireless Printer**

The IP Address, Net Mask, Default Gateway, SSID, and WEP Key of the wireless printer must be configured as per the instructions provided in the Print Server or Wireless Printer manual.

*Example of a valid configuration*

	Printer Configuration	BMU #1	BMU #2
IP Address	192.168.10.1	192.168.10.2	192.168.10.3
Net Mask	255.255.255.0	255.255.255.0	255.255.255.0
Default Gateway	192.168.10.1	192.168.10.1	192.168.10.1

**BMU Functional Testing**

Refer to SEDASYS® Service Manual for functional test procedure.

## Chapter 5 PRU Installation and Setup



### Precaution

- 1 Before removing the Procedure Room Unit (PRU) and its components from the packaging, inspect the outside packaging for obvious signs of damage that may have occurred during transit and/or storage. Do not use the PRU or its components if the packaging appears to have been opened or damaged.
- 2 After removing the PRU and its components from their packaging, check all items for damage, including loose wires, cracks, gaps, breaks, cuts, and tears in the wires or plastic housings. Do not use any damaged components.

## Connecting the Control Unit to the PSU

The Control Unit receives DC power from the Power Supply Unit (PSU). For setup, you must connect the Control Unit to the PSU using the PSU connecting cable.



### WARNING

Ensure that the Control Unit Power Switch, located at the rear panel of the PSU, is in the OFF position whenever connecting or disconnecting the PSU cable. If the PSU connecting cable is not securely attached, an electrical shock or arc may occur.

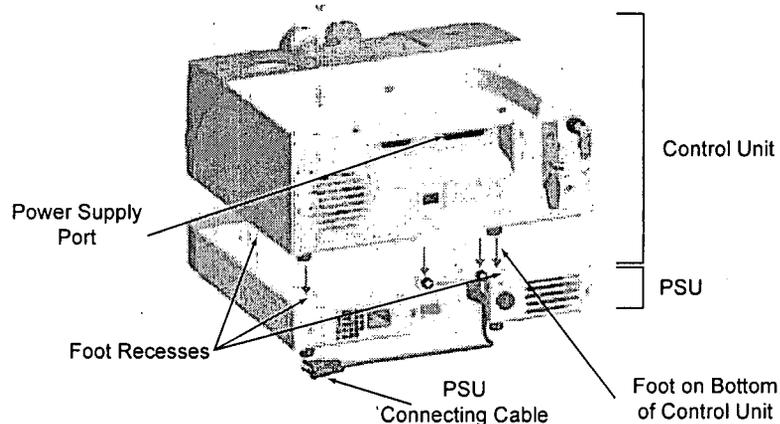


Figure 5-1 Attaching Control Unit to PSU

### To attach the Control Unit to the PSU

1. Place the PSU on a flat, stable surface or on top of the SEDASYS® System Cart.
2. Place the Control Unit on top of the PSU.



### Note

For stability and proper alignment, the four feet on the bottom of the Control Unit should fit into the foot recesses located on top of the PSU.

3. Connect the PSU connecting cable to the Power Supply port on the back of the Control Unit. The two mounting screws must be securely tightened using a flat blade screwdriver.

## Attaching the Display Monitor to the Control Unit

The Display Monitor with touchscreen displays patient data and propofol infusion information, and allows the clinician to interact with the PRU. After the Control Unit is attached to the PSU, attach the Display Monitor to the Control Unit.

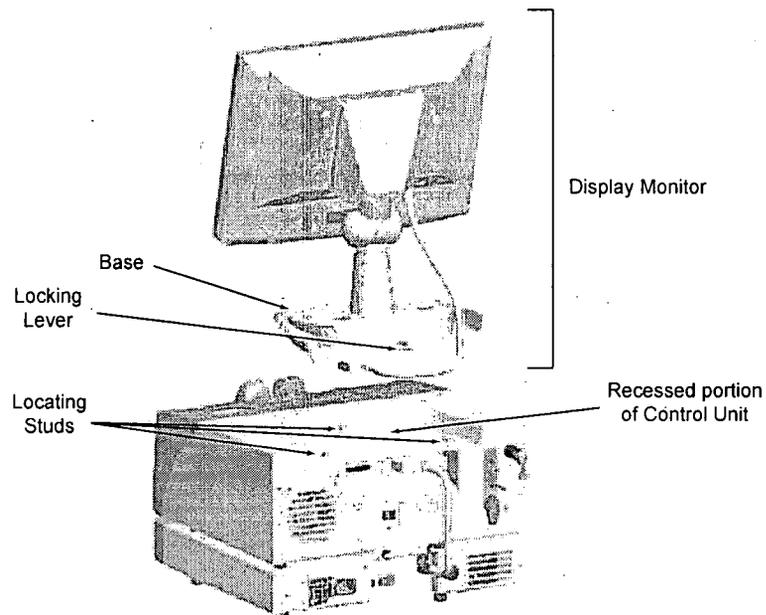


Figure 5-2 Attaching Display Monitor to Control Unit

### To attach the Display Monitor to the Control Unit

1. From the back of the Control Unit, install the Display Monitor by placing the base of the Display Monitor on top of the recessed portion of the Control Unit.
2. Place the three alignment slots located underneath the base of the Display Monitor over the mating locating studs located on the recessed portion on the top of the Control Unit.
3. Slide the base of the Display Monitor forward until the locking lever snaps into place.

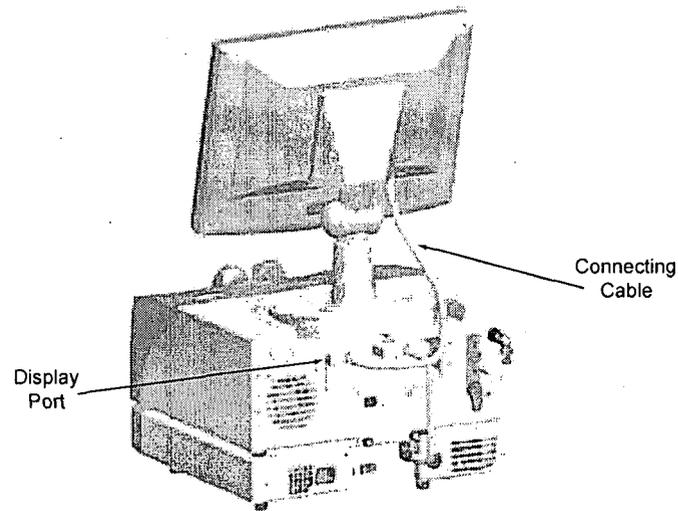


Figure 5-3 Back View of Assembled PRU

4. Attach the Connecting Cable from the Display Monitor to the Display Port on the back of the Control Unit. The two mounting screws must be securely tightened using a flat blade screwdriver.

## Connecting the PRU to Oxygen Source

The SEDASYS<sup>®</sup> System requires that oxygen be delivered to the patient during propofol delivery. The PRU has an internal oxygen flow regulator that controls the delivery of oxygen to the patient during the procedure.



### WARNING

Do not attach the oxygen supply hose to anything other than a breathable, 100% oxygen source with sufficient pressure (40 to 60 psi) and capacity to complete the case.



### Precaution

Connection to an oxygen supply source greater than 60 psi may damage the internal oxygen delivery system.

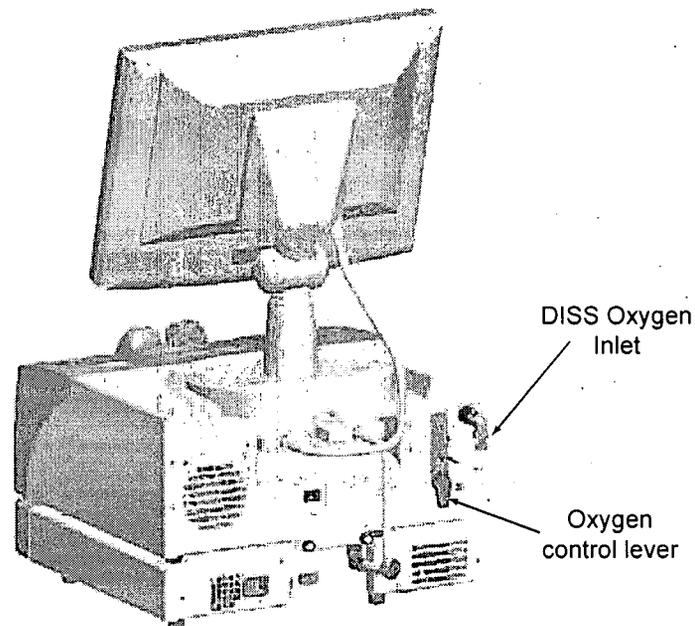


Figure 5-4 PRU Connection to Oxygen Source

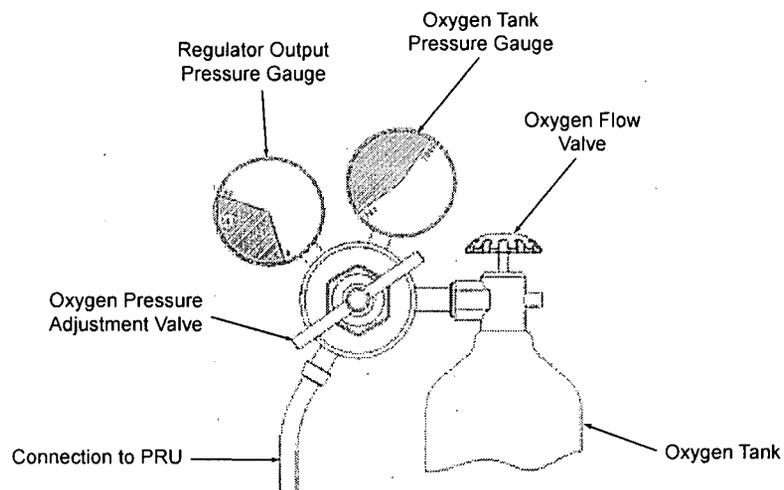


Figure 5-5 Pressure Regulator

### To connect the PRU to the oxygen source

A pressure regulator is required to reduce the pressure typically provided by oxygen tanks from a possible 2000 psi to the required 40 – 60 psi required for the Sedation Delivery System. The regulator will have an Oxygen Tank Pressure Gauge that measures the internal pressure within the tank and an Output Pressure Gauge that measures pressure that will be provided to the system.

**Note**

If an oxygen supply wall outlet is used instead of an oxygen tank in the procedure room and the output pressure is regulated to 40 – 60 psi, steps 1, 5, and 6 should be followed.

1. Connect an oxygen supply hose with a female Diameter Index Safety System (DISS) fitting to the male DISS fitting on the back of the PRU.
2. Follow the instructions provided with your pressure regulator to connect the regulator to the oxygen tank.
3. Completely close the oxygen tank flow valve by rotating the valve clockwise until it stops.
4. On the pressure regulator, rotate the pressure adjustment valve counterclockwise to close the valve.
5. Connect the other end of the oxygen supply hose to the oxygen source.
6. Turn the oxygen control lever on the back of the PRU 90° clockwise so that the lever is placed in a horizontal position. The short end of the lever should be pointing towards the right.
7. Open the Oxygen Flow Valve one-half turn counterclockwise to allow oxygen to flow from the tank.
8. Slowly turn the Oxygen Pressure Adjustment Valve clockwise until the Regulator Output Gauge indicates 40 – 60 psi. If a 40 psi minimum output cannot be reached, the oxygen tank must be changed.

**Note**

- 1 The PRU contains a sensor that detects oxygen concentration levels sufficient for delivering oxygen to the patient. If the oxygen concentration is inadequate, the system does not permit delivery of oxygen through the PRU and displays an advisory.
- 2 The PRU may remain connected to the oxygen source between cases.
- 3 The system displays advisory messages if the oxygen source pressure is out of range.

**To disconnect the PRU from the oxygen source**

1. Turn the Oxygen Flow Valve fully clockwise to close the valve and stop oxygen flow to the Regulator.
2. Turn the Oxygen Control Lever on the back of PRU to the vertical position to release pressure in the oxygen line. A small amount of oxygen will be discharged from the PRU as the pressure is released.
3. Once the pressure has been released, return the Oxygen Control Lever to the horizontal position.
4. Disconnect the Oxygen Hose from the Regulator.

## Powering on the PRU

The PRU, when temporarily disconnected from the AC power source, receives power either from an AC power source or from its internal back-up batteries.



### WARNING

Do not use the system if the integrity of the protective earth conductors is in doubt. Inspect all cords, cables, plugs, and connectors for fraying or other insulation damage.



### Precaution

1. Use only the approved PSU and the IEC320 hospital-grade power cord that is supplied with the PSU.
2. During initial installation or following extended storage without connection to external AC power, the PSU should be allowed to charge the internal battery back-up system prior to use. The PSU should be connected to external AC power for 30 minutes prior to proceeding with installation.
3. To remove the PSU from external AC power, you must disconnect the PSU power cable from the wall outlet or from the PSU.

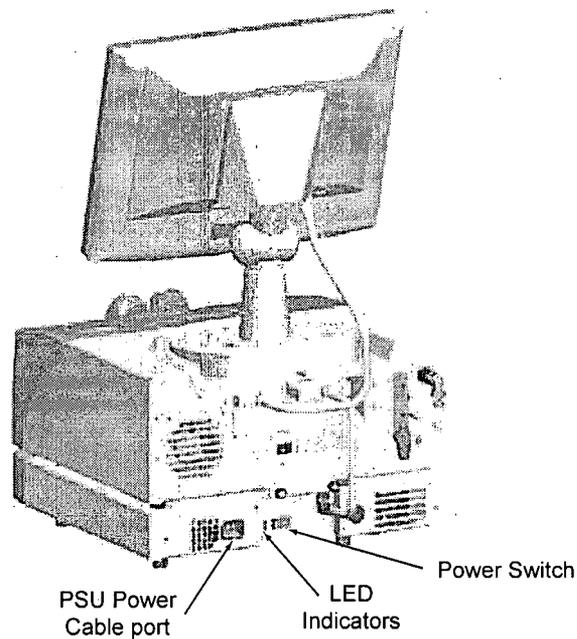


Figure 5-6 Back View of Assembled PRU

### To connect and power on the PRU

1. Connect the PSU Power Cable to the back of the PSU.
2. Connect the PSU Power Cable to an appropriately grounded, hospital-grade only, wall outlet.

3. Turn on the Power Switch located on the back of the PSU to deliver power to the PRU.
4. The LED Indicators located on the back of the PSU indicate power status.

#### Top LED – PSU Power Indicator

Indicator Status	Description
Steady Green Light	PSU is connected to AC power and the battery is fully charged
Steady Yellow Light	PSU is connected to AC power and the battery is charging

#### Bottom LED – Control Unit Power Indicator

Indicator Status	Description
Steady Green Light	PSU is supplying power to the Control Unit
Off	Control Unit is not receiving any power from the PSU

## Battery Backup System

In the event of a power failure, the PRU contains a battery-powered backup system that allows up to 10 minutes of full system use to complete or terminate the procedure.

The PRU will recharge its battery whenever the PSU is connected to an AC power source. The PSU battery takes approximately 60 minutes to fully charge.

The battery charge indicator in the upper right corner of the PRU Main Monitoring Screen shows the remaining capacity of the battery.



Figure 5-7 PRU Battery Charge Indicator

When the PRU is receiving external power, the “electrical plug” icon and the remaining minutes of battery life in one-minute increments are displayed. When the PRU is not receiving external power and is operating off of battery backup, only the remaining minutes of battery life are displayed.



#### Note

The system will provide a prompt for battery calibration when required. To maintain battery health, follow the instructions provided on the screen. Refer to the SEDASYS® Service Manual for the recommended calibration frequency and procedure.

## PRU Operational Modes

Table 5-1: Modes, Mode Indicators, and Changing Modes

Modes	Mode Indicators	Changing Modes
Off	<ul style="list-style-type: none"> <li>Screen is dark (off).</li> <li>The <b>On/Off/Standby</b> button is not lit.</li> </ul>	<p>Press the <b>On/Off/Standby</b> button to get to Ready mode.</p> <p><b>Caution:</b> The system will play an audio tone during start-up. Insure that this tone is audible before using the system to verify proper function of the audio system.</p> <p><b>Caution:</b> Do not touch the display touchscreen during start-up until the Ready Screen is displayed (refer to Figure 5-8 on page 5-10). Contact with the touchscreen may cause the system to lock-up during initialization.</p>
On: Ready	<ul style="list-style-type: none"> <li>The PRU Ready screen is displayed</li> <li>The <b>On/Off/Standby</b> button is lit.</li> </ul>	<ul style="list-style-type: none"> <li>Press and release the <b>On/Off/Standby</b> button to get to Standby mode.</li> <li>Press and hold the <b>On/Off/Standby</b> button for at least 3 seconds to get to Off mode.</li> </ul> <p><b>Note:</b> If the PRU sits in Ready mode for 30 minutes, it will go to Standby mode as long as the PRU is connected to AC power.</p> <p><b>Note:</b> The PRU will shut down from Ready mode within 3 minutes if external AC power is lost.</p>
On: Standby	<ul style="list-style-type: none"> <li>Screen is dark (off).</li> <li>The <b>On/Off/Standby</b> button is lit.</li> </ul>	<p>To get to Ready mode:</p> <ul style="list-style-type: none"> <li>Press the <b>On/Off/Standby</b> button for less than 3 seconds.</li> </ul> <p>- OR -</p> <ul style="list-style-type: none"> <li>Touch the screen.</li> </ul> <p>To get to Off mode:</p> <ul style="list-style-type: none"> <li>Press and hold the <b>On/Off/Standby</b> button for at least 3 seconds.</li> </ul> <p><b>Note:</b> The PRU will change from Standby to the Ready mode if external AC power is lost.</p>
On: In-Case	<ul style="list-style-type: none"> <li>The PRU Main Monitoring screen is displayed.</li> <li>The <b>On/Off/Standby</b> button is lit.</li> </ul>	<p>Press the <b>End Case</b> button to get to Ready mode.</p>

## Changing PRU Facility Settings

The PRU is shipped with factory-default Facility Settings. The factory-default settings are listed in Table A-2 on page A-1 and Table A-4 on page A-3 of *Appendix A: Factory Default Settings*.

Your facility has the option to change these settings through an access code-protected process. Once changed, the Facility Settings become the new default settings for **all** procedures subsequently performed with that specific PRU. Note that if your facility has multiple PRUs, the facility settings on each PRU will need to be independently set. Facility Settings can be restored to the factory-default values.

The touchscreen on the PRU Display Monitor is used to change the following PRU Facility Settings:

- **Volume Settings** (Alarms, system sounds, and ARM audio).
- **Alarm Settings** (Heart rate, SpO<sub>2</sub>, blood pressure, EtCO<sub>2</sub>, and respiratory rate).
- **Timing / Print** [Timing intervals for Non-Invasive Blood Pressure (NIBP), ARM and data collection, and print on alarms].
- **Time and Date**
- **Display Information** (Language, alarm limits, and electrocardiogram (ECG) gain).
- **Graph Settings** (Vertical and horizontal scale and waveform speed).
- **Units of Measure** (for patient weight and EtCO<sub>2</sub>).
- **Additional Limits** (allows clinician to activate additional drug delivery limits).
- **Oxygen Delivery** (rate of oxygen delivery during inhalation and exhalation).
- **HL7 Settings** (electronic communication to an external data management system).

The following steps show you how to make optional changes to your Facility Settings and reset them to factory-default settings. The PRU

should be powered on and in the Ready mode so that the PRU Ready screen appears on the touchscreen.

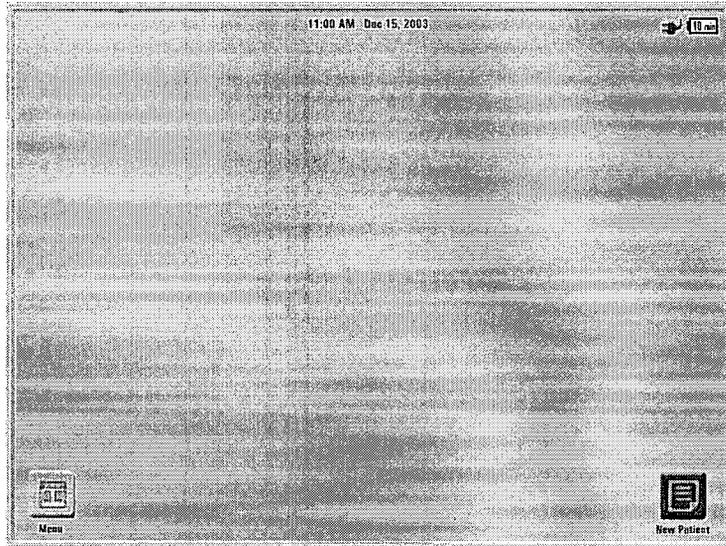


Figure 5-8 PRU Ready Screen

To change Facility Settings for the PRU:

1. Press **Menu** from the PRU Ready screen. The following screen appears:

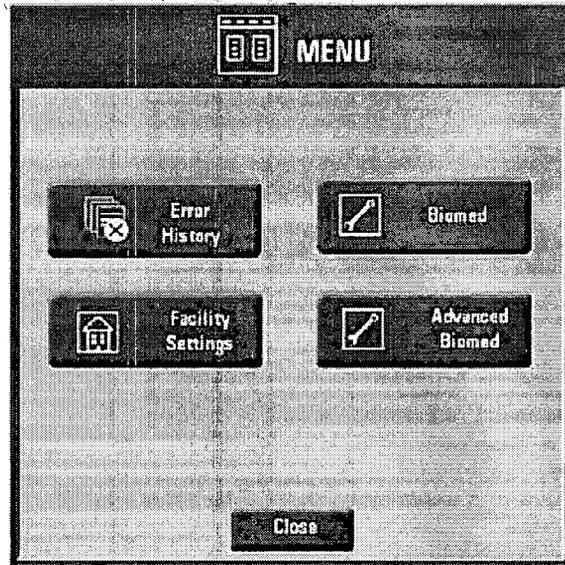


Figure 5-9 PRU Menu Screen



**Note**

1. The **Biomed** button is to be used only by an authorized service technician to perform system tests and calibrations. Access to the biomed functions is permitted only through a 4-digit access code.
2. The **Error History** button displays stored system errors.

2. Press **Facility Settings**. The following screen appears:

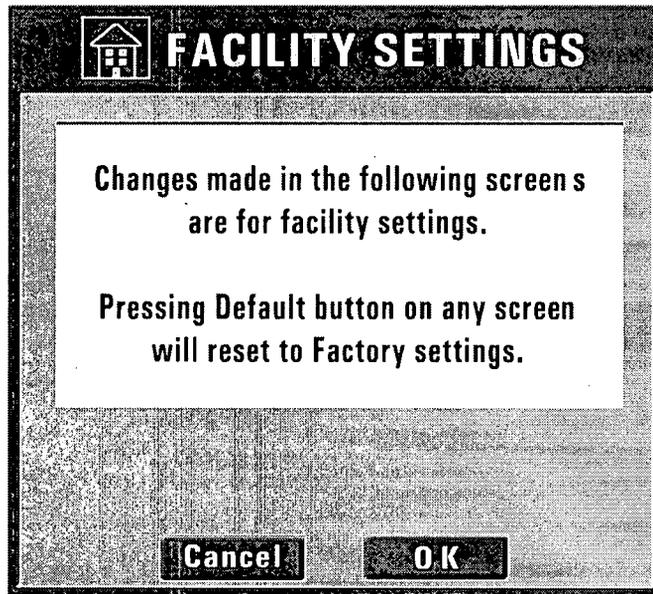


Figure 5-10 PRU Facility Settings Notification Screen

3. Press **OK**. The following screen appears:

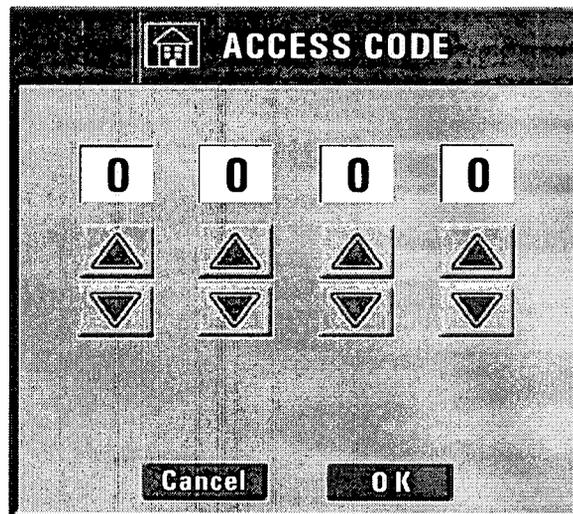


Figure 5-11 PRU Enter Access Code Screen

4. Enter the 4-digit access code (2468), then press **OK**. A Facility Settings menu screen, shown in Figure 5-12 on page 5-13, appears. This screen displays all the Facility Settings that you can change for the PRU.



**Note**

The 4-digit access code cannot be changed.

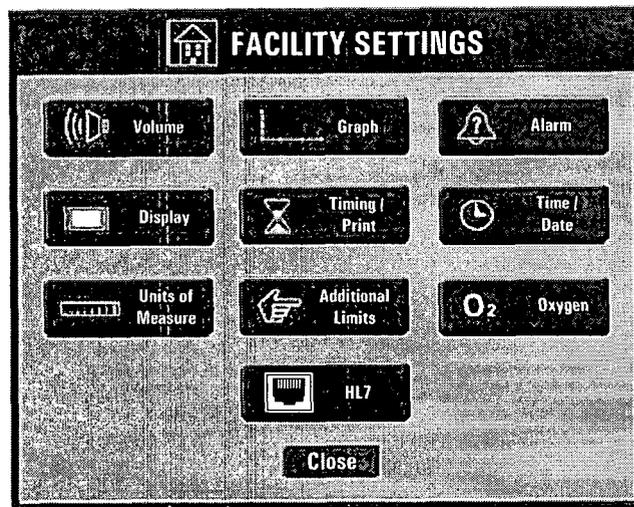


Figure 5-12 PRU Facility Settings Menu Screen

5. Select and press the button for the Facility Setting that you want to change. A screen appears for your selection.



**Note**

For certain setting selections, an "intermediate" screen appears that provides you with additional options before you can enter the Facility Setting change.

6. When you have changed the Facility Setting, choose one of the following options:
  - Press **OK** to confirm the new Facility Setting changes and return to the previous screen. The changes made now become the default settings for all procedures.
  - Press **Cancel** to terminate setting changes entered and to return to the previous screen.
  - Press **Default** to reset the settings to the factory-default settings for all procedures. Press **OK** to confirm the new Facility Setting changes and return to the previous screen. The changes become the default settings for all procedures.
7. When you have finished changing all your selected Facility Settings, press **Close** from the Facility Settings screen. You will be returned to the Menu screen (refer to Figure 5-9 on page 5-11).
8. Press **Close** on the Menu screen to return to the PRU Ready screen (refer to Figure 5-8 on page 5-10).

## Facility Settings Screens for the PRU

The following screens appear when you select and press a button from the Facility Settings Menu screen (refer to Figure 5-12 on page 5-13):

### Volume Settings

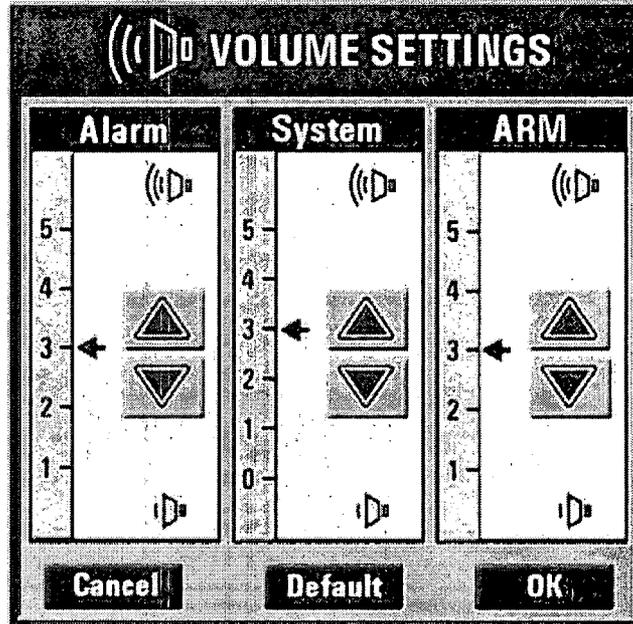


Figure 5-13 Volume Settings Screen

Change each setting by pressing the related **Up** or **Down Arrow** buttons, and then press **OK**.

- **Alarm:** The audible alarm levels on the PRU.
- **System:** The pulse/heart rate tone levels and system startup tone.
- **ARM:** The volume level for the ARM audio.



**Note**

The alarm and ARM audio levels cannot be set to zero (0).



**Precaution**

An audio tone is played at each press of the **Up** or **Down Arrow** buttons corresponding to the new audio level. Set the audio level such that the tone is clearly heard in the clinical environment.



**Note**

- 1 Select zero (0) for System volume to continuously mute all non-alarm sounds. A selection of zero (0) will not mute the audio tone played during system start-up.
- 2 The ARM audio signal is supplied through the earpiece portion of the Oral/ Nasal Cannula from the BMU, not the PRU system speaker.

## Display Information

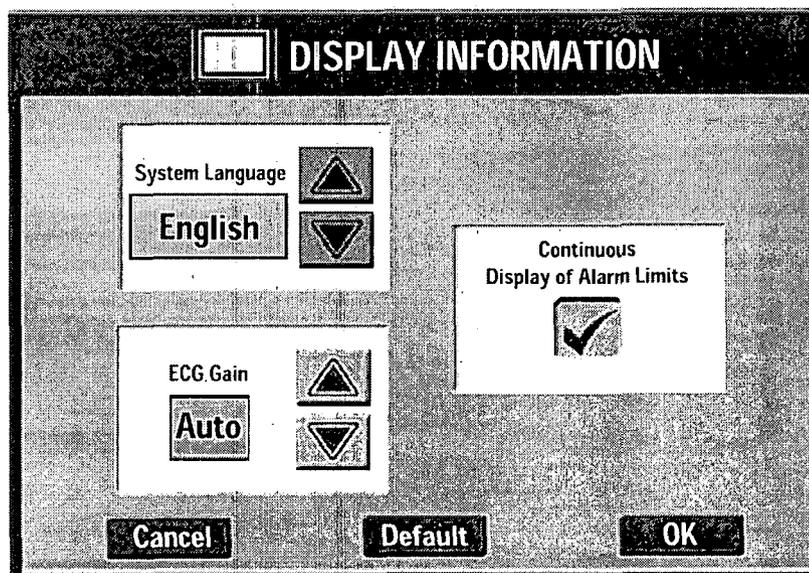


Figure 5-14 Display Information Screen

Change each setting by either pressing the **Up** or **Down Arrow** buttons or by pressing the checkbox, and then press **OK**.

- **System Language:** Languages for PRU display (English only).
- **ECG Gain:** Sets the magnification of the ECG waveform displayed. The higher the number, the more magnified the waveform size becomes.
- **Continuous Display of Alarm Limits:** When the checkbox is checked, the PRU Monitoring screen continuously displays the upper and lower alarm limits. When the checkbox is not checked, the upper and lower alarm limits are not displayed.

**Note**

If an individual alarm limit is changed during a procedure, that alarm limit will be displayed independent of this setting.

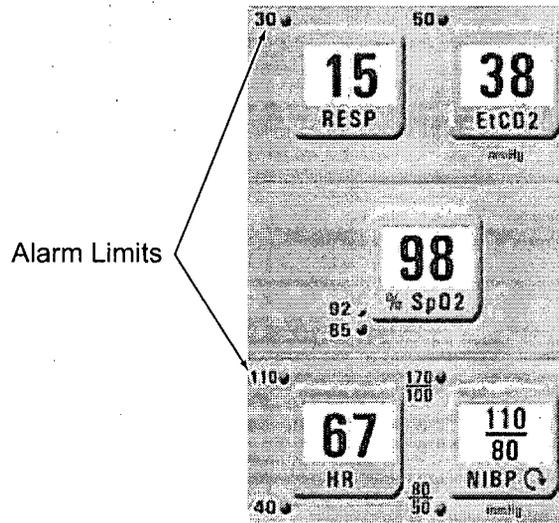


Figure 5-15 Continuous Display of Alarm Limits

### Units of Measure

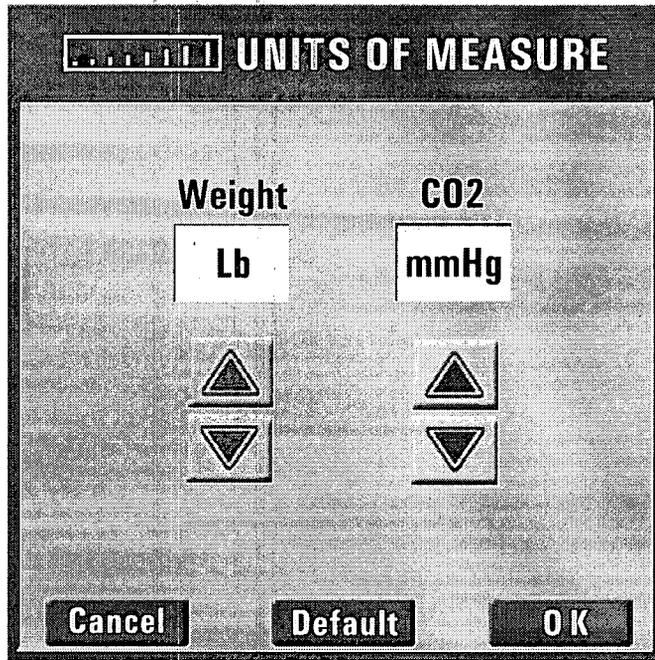


Figure 5-16 Units of Measure Setting Screen

Change each setting by either pressing the related Up or Down Arrow buttons, and then press OK.

## Graph Settings

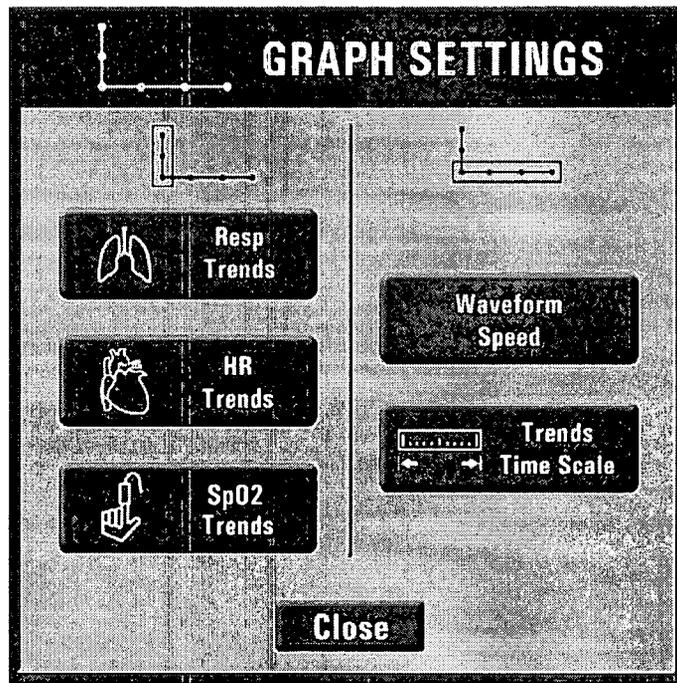


Figure 5-17 Graph Settings Screen

1. Select and press the button for each setting that you want to change.
  - **Resp Trends:** The vertical trend scale range displayed in breaths per minute (minimum and maximum).
  - **HR (Heart Rate) Trends:** The vertical trend scale range displayed in beats per minute (minimum and maximum).
  - **SpO<sub>2</sub> Trends:** The vertical trend scale range displayed.
  - **Waveform Speed:** The sweep rate of the ECG/SpO<sub>2</sub> waveform and the CO<sub>2</sub> waveform in mm/s.
  - **Trends Time Scale:** The horizontal trend scale in minutes that is displayed in the "Trends" screens

For example, if you press **SpO<sub>2</sub> Trends** or **Waveform Speed**, the following screens appear:

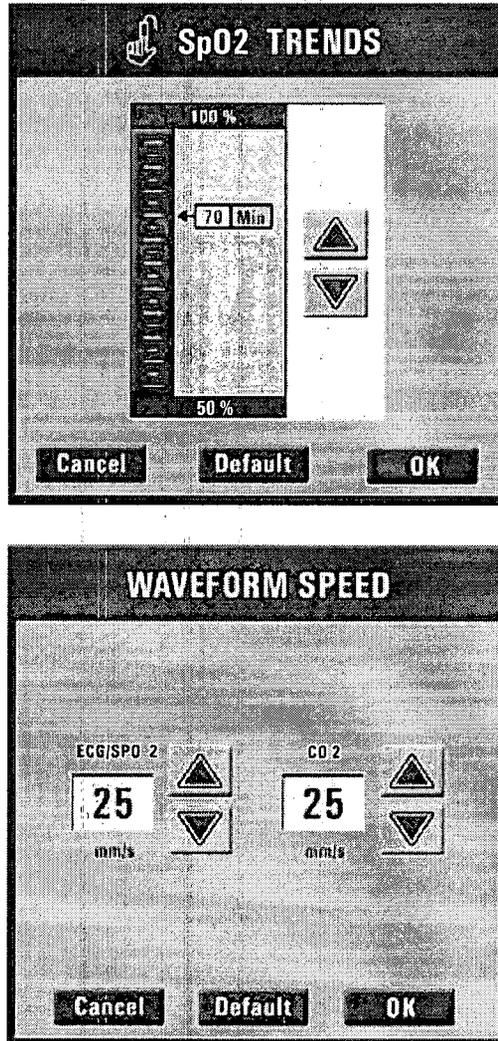


Figure 5-18 PRU SpO<sub>2</sub> Trends and Waveform Speed Screens

2. Change each setting by pressing the related Up or Down Arrow buttons, and then press OK.
3. Press Close on Graph Settings screen to return to Facility Settings screen.

## Timing/Print Options

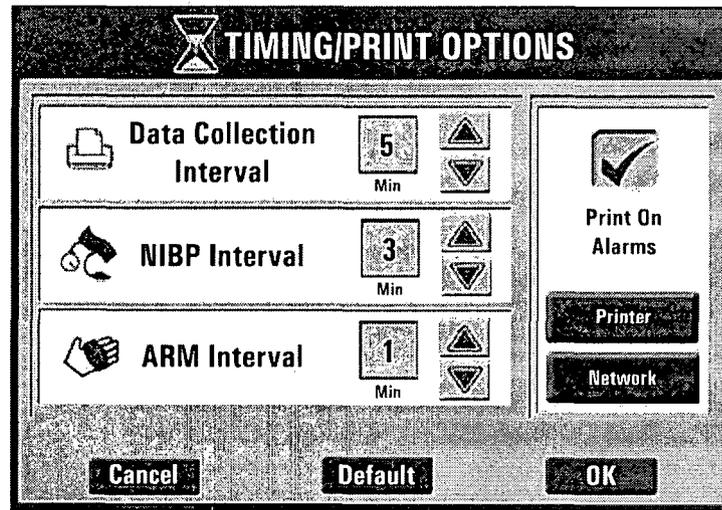


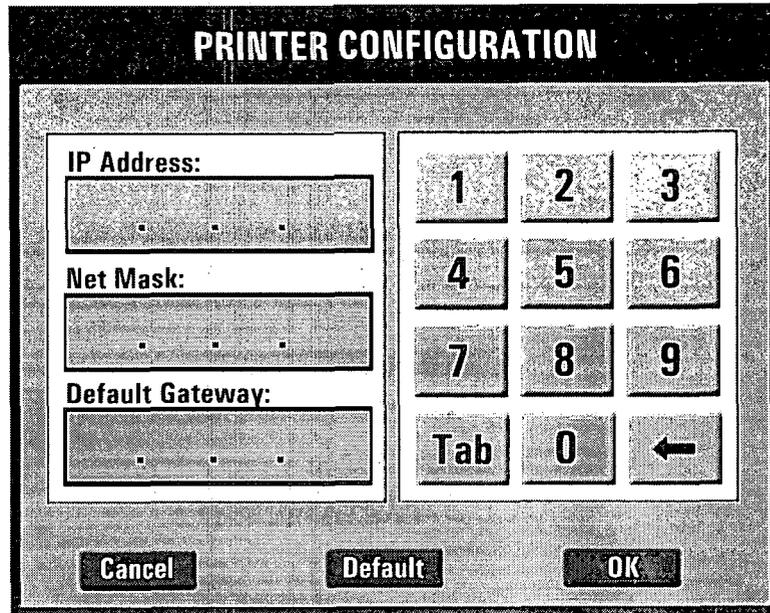
Figure 5-19 PRU Timing/Print Options Screen

1. Change each setting by either pressing the **Up** or **Down Arrow** buttons or by pressing the checkbox, and then press **OK**. All settings are displayed in minutes.
  - **Data Collection Interval:** Interval at which patient physiology is recorded for post-procedure printing.
  - **NIBP Interval:** The time interval for automatic NIBP measurements.
  - **ARM Interval:** The time interval for automatic ARM responsiveness tests.
  - **Print on Alarms:** Enables automatic printing to the wireless printer in the event of a patient physiology alarm condition.

**Note**

'Print on Alarms' is functional only if the printer is enabled on the BMU (refer to Setting up the BMU Wireless Printer on page 4 - 17).

2. Press the **Printer** button to configure the PRU for wireless printing.



The image shows a 'PRINTER CONFIGURATION' screen. It features three input fields for 'IP Address:', 'Net Mask:', and 'Default Gateway:'. To the right of these fields is a numeric keypad with buttons for digits 1-9, 0, a 'Tab' button, and a left-pointing arrow. At the bottom of the screen are three buttons: 'Cancel', 'Default', and 'OK'.

Figure 5-20 Printer Configuration

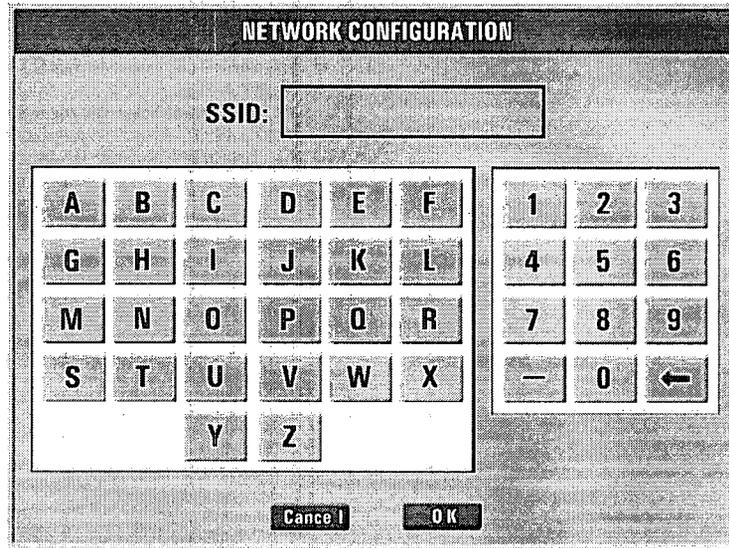
3. Enter the IP Address configuration for the printer using the numeric keypad. The numeric value in each field cannot exceed 255. The value in the first field must be between 1 and 223 and cannot use 127. The value in the fourth field must be between 1 and 254. Press the **Tab** button to switch between fields as needed.
4. Enter the Net Mask configuration using the numeric keypad to 255.255.255.0. Press the **Tab** button to switch between fields as needed.
5. Enter the Default Gateway configuration using the same values as the IP Address previously entered in Step 3. Press **OK** to return to the PRU Timing/Print Options Screen (refer to Figure 5-19 on page 5-19).



**Note**

Every wireless printer and every PRU in your facility must be configured with a unique IP address. The first three fields of all Printer IP Addresses should be identical with the fourth field being unique.

6. Press the **Network** button.



The screenshot shows a screen titled "NETWORK CONFIGURATION". At the top, there is a header bar with the title. Below the header, there is a label "SSID:" followed by an empty rectangular input field. Below the input field is a keypad. The keypad is divided into two sections: a letter keypad on the left and a numeric keypad on the right. The letter keypad has buttons for letters A through Z, arranged in four rows: Row 1: A, B, C, D, E, F; Row 2: G, H, I, J, K, L; Row 3: M, N, O, P, Q, R; Row 4: S, T, U, V, W, X; Row 5: Y, Z. The numeric keypad has buttons for digits 1 through 9, a hyphen/underscore key, a 0 key, and a left-pointing arrow key. At the bottom of the screen, there are two buttons: "Cancel" and "OK".

Figure 5-21 Network Configuration

7. Enter the Service Set Identifier (SSID) of the wireless printer using the keypad. Press **OK**.



**Note**

1. An SSID is the network name shared by all devices in a wireless printer network. Your network's SSID should be unique to your network and identical for all devices within the network.
2. The SSID can be up to 15 digits.
3. Every wireless printer must have a unique SSID.

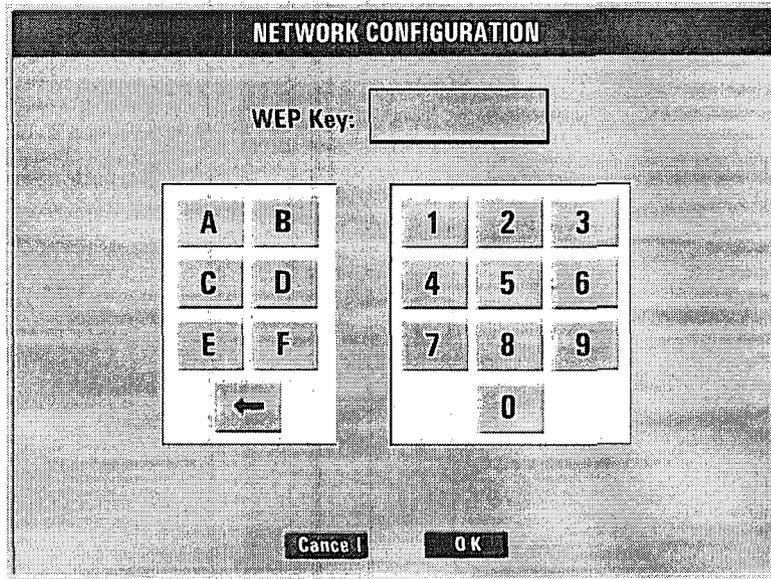


Figure 5-22 Network Configuration

8. For 64-bit encryption, enter the 10 digit hexadecimal Wired Equivalent Privacy (WEP) Key of the wireless printer using the keypad. Press **OK**.
9. The IP Address, Net Mask, Default Gateway, SSID and WEP Key of the wireless printer must be configured per the instructions provided in the Print Server or Wireless Printer manual.

#### Additional Limits

Additional limits are provided to allow the facility to include further restrictions on drug delivery. The SEDASYS<sup>®</sup> System is shipped from the factory with the additional limits disabled. The facility can enable these limits through the access code protected procedure.

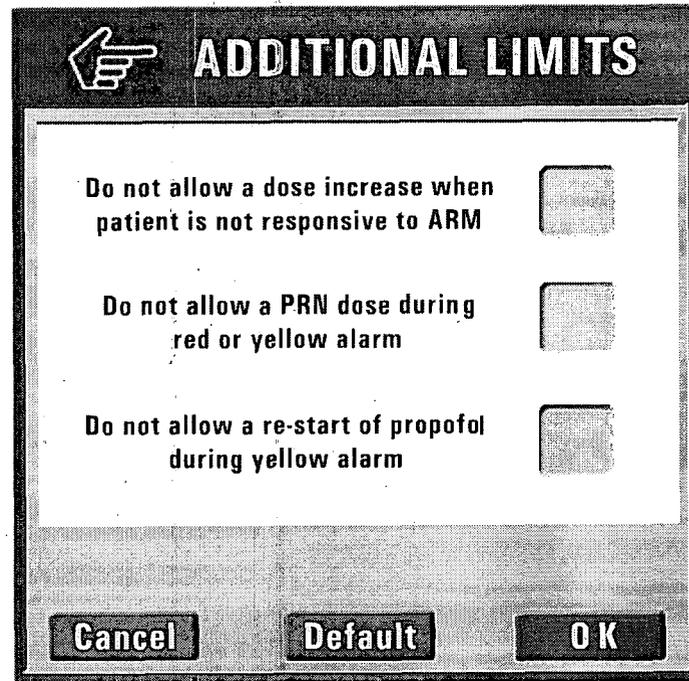


Figure 5-23 PRU Additional Limits Screen

Change each setting by pressing the checkboxes, and then press **OK**.

**Note**

When an additional limit is enabled, the checkbox is checked; when disabled, the checkbox is unchecked.

The following three Additional Limits can be enabled:

- Do not allow a dose increase when patient is not responsive to ARM.
  - Normally, the SEDASYS<sup>®</sup> System allows an increase of up to 10 mcg/kg/min in the dose rate if a patient is non-responsive.
  - If this limit is enabled, the system does not allow any increase in the dose rate if the patient is non-responsive.
- Do not allow a PRN dose during red or yellow alarm.
  - Normally, the SEDASYS<sup>®</sup> System allows a PRN dose during a low oxygen saturation or low respiration rate yellow or red alarm.
  - If this limit is enabled, the system does not allow a PRN dose during a low oxygen saturation or low respiration rate yellow or red alarm.
- Do not allow a re-start of propofol during yellow alarm.
  - Normally, the SEDASYS<sup>®</sup> System allows a continuation of drug delivery by pressing **Start Drug** during the yellow alarm. The system does not, however, allow an increase in the dose rate during the yellow alarm.

- If this limit is enabled, the system does not allow the restarting of drug delivery during a yellow alarm.

### Alarm Settings

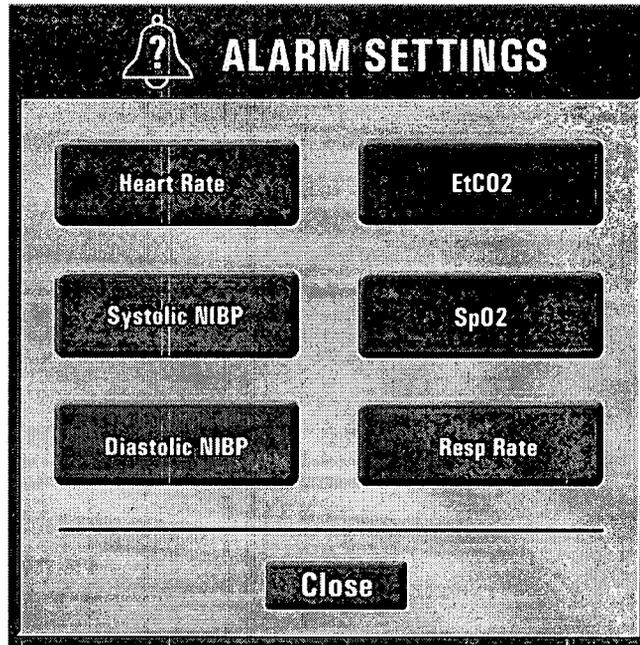


Figure 5-24 PRU Alarm Settings Screen

1. Select and press the button for each setting that you want to change.
  - **Heart Rate:** In beats per minute (minimum and maximum)
  - **Systolic NIBP:** (Minimum and maximum)
  - **Diastolic NIBP:** (Minimum and maximum)
  - **EtCO<sub>2</sub>:** (Maximum)
  - **SpO<sub>2</sub>:** In% (Minimum)
  - **Resp Rate:** Both the high respiratory rate (maximum) and apnea (number of seconds between breaths).

For example, if you press **Resp Rate**, the following screen appears:

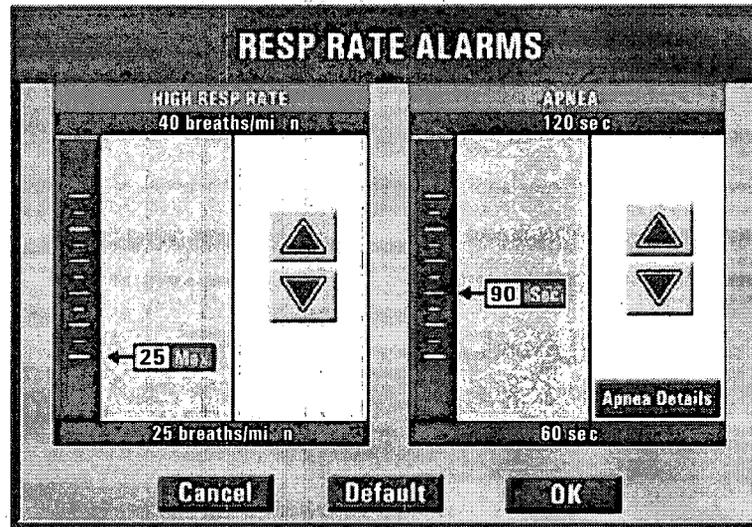


Figure 5-25 PRU Resp Rate Alarms Screen

- Change each setting by pressing the related **Up** or **Down Arrow** buttons, and then press **OK** to confirm alarm settings.



**Note**

To view apnea details, press **Apnea Details** from the Resp Rate Alarms screen. The following screen appears, which displays a graph showing the correlation between respiratory rate alarms and SpO<sub>2</sub> values. Changes to Respiration Rate or SpO<sub>2</sub> alarm limits will be shown in this graph. Press **Close** to return to the Resp Rate Alarms screen.

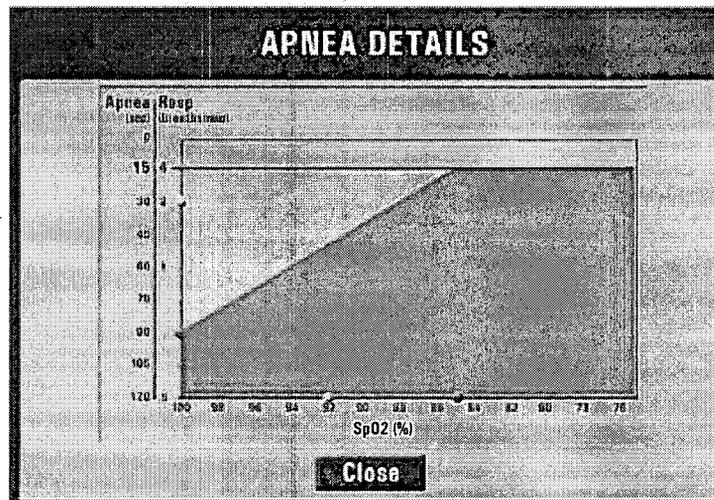


Figure 5-26 PRU Apnea Details Screen

## Time / Date

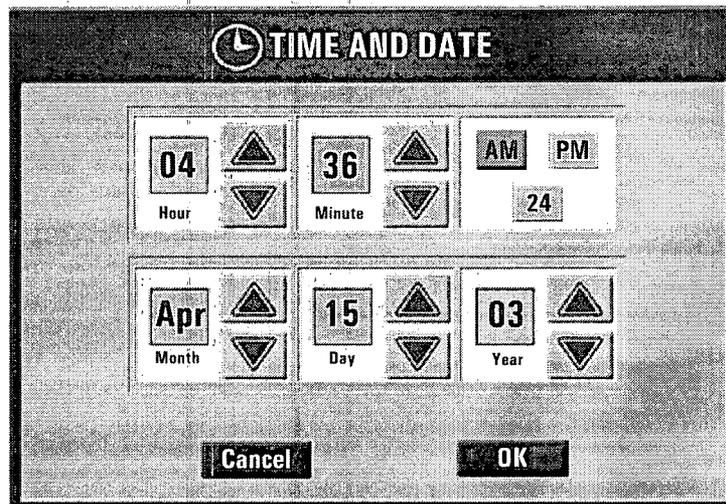


Figure 5-27 PRU Time and Date Screen

1. Select **AM**, **PM**, or **24** for time format. The number **24** is a setting that represents a 24-hour clock.
2. Change the settings by pressing the related **Up** or **Down Arrow** buttons, and then press **OK**.

**Note**

The time setting on the PRU will automatically be adjusted when connected to a BMU to match the time setting on the BMU.

## Oxygen Delivery

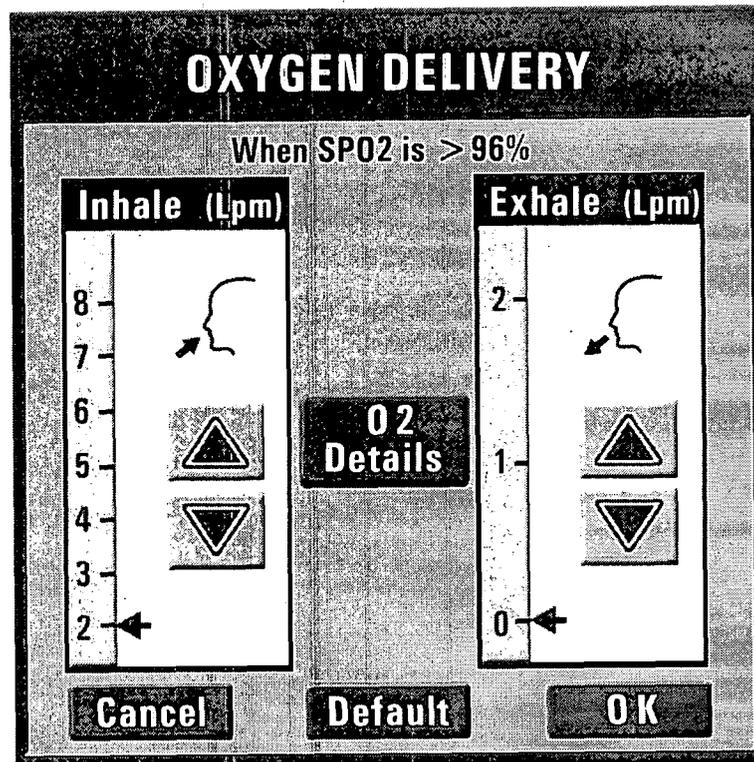


Figure 5-28 PRU Oxygen Delivery Screen

Change each setting by pressing the related **Up** or **Down Arrow** buttons, and then press **OK**.

- Inhale: The oxygen flow rate delivered during patient inhalation.
- Exhale: The oxygen flow rate delivered during patient exhalation.

**Note**

To view oxygen details, press **O<sub>2</sub> Details** from the Oxygen Delivery screen. The following screen appears, which displays a graph showing the correlation between oxygen delivery rate (liters per minute) and the patient's SpO<sub>2</sub> value. Press **Close** to return to the Oxygen Delivery screen.

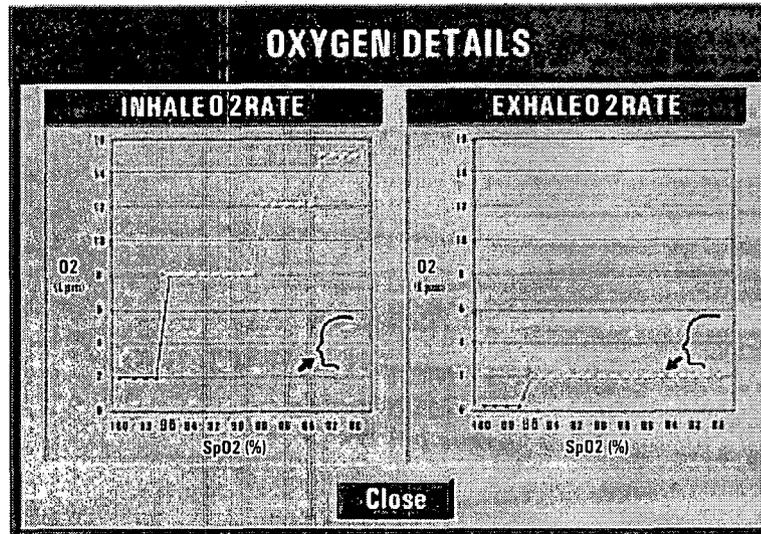


Figure 5-29 PRU Oxygen Details Screen



**Note**

- 1 The oxygen delivery rate can be changed anytime before, during, or after the procedure. However, this rate will only impact oxygen delivery when the SpO<sub>2</sub> reading is greater than 96%.
- 2 For an SpO<sub>2</sub> reading of less than or equal to 96%, the system controls the oxygen delivery rate.
- 3 When the patient is nasal breathing, the system will switch the oxygen delivery rate for inhalation and exhalation. When the patient is oral breathing, oxygen will be delivered at a constant rate.

For more information about the PRU's default oxygen delivery at all SpO<sub>2</sub> levels, refer to Table A-5 on page A-4.

### HL7 Settings

The system can be configured to export patient physiological data to an external hospital information system. HL7 is the communication protocol used by the SEDASYS<sup>®</sup> System. If a connection to an external information system is not being used, this section can be skipped.

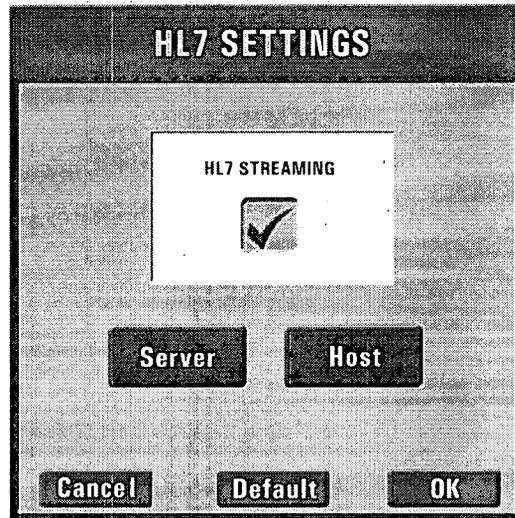


Figure 5-30 PRU HL7 Settings Screen

1. Enable streaming of PRU data through the HL7 communication port by selecting the checkbox.

**Note**

1. When the checkbox is checked, HL7 Streaming is enabled; when the checkbox is disabled, the HL7 streaming is disabled.
2. The **Server** button is disabled until HL7 Streaming is enabled.

2. Press the **Server** button.

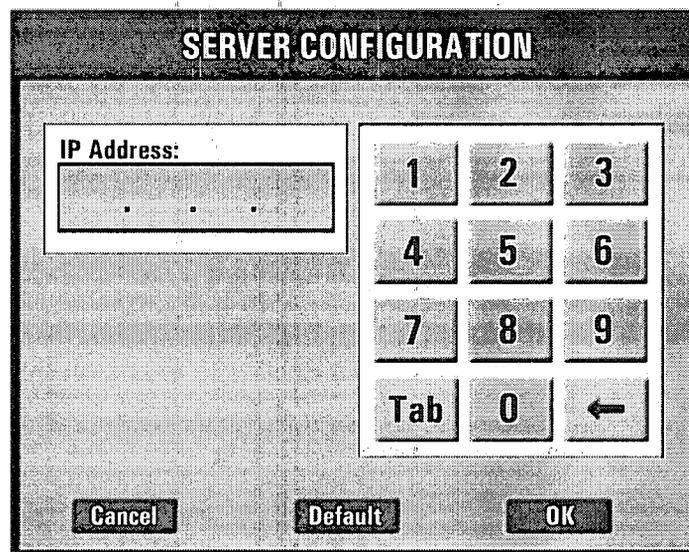


Figure 5-31 PRU HL7 Server Configuration Screen

3. Enter the IP Address configuration using the numeric keypad. The numeric value in each field cannot exceed 255. The value in the first

field must be between 1 and 223 and cannot use 127. The value in the fourth field must be between 1 and 254. Press the **Tab** button to switch between fields as needed. Press **OK** to return to the HL7 Settings screen (refer to Figure 5-30 on page 5-29).

4. Select and press the **Host** button.

Figure 5-32 PRU HL7 Host Settings Screen

5. Select DHCP or MANUAL by selecting the desired checkbox. Press **OK**.



**Note**

- 1 If connecting to an existing network, select DHCP. If connecting one-to-one between the server and the PRU, select MANUAL.
- 2 The Current Settings are blank the first accessed.

6. If MANUAL is selected, the following screen appears.

**MANUAL HOST CONFIGURATION**

**IP Address:**  
[ . . . . ]

**Subnet Mask:**  
[ . . . . ]

**Default Gateway:**  
[ . . . . ]

1 2 3  
4 5 6  
7 8 9  
Tab 0 ←

Cancel Default OK

Figure 5-33 PRU HL7 Manual Host Settings Screen

7. Enter the IP Address configuration for the host using the numeric keypad. The numeric value in each field cannot exceed 255. The value in the first field must be between 1 and 223 and cannot use 127. The value in the fourth field must be between 1 and 254. Press the **Tab** button to switch between fields as needed.
8. Enter the Subnet Mask configuration using the numeric keypad to 255.255.255.0. Press the **Tab** button to switch between fields as needed.
9. Enter the Default Gateway configuration using the same values as the host IP Address. Press **OK**.



**Note**

The first three fields of the Host IP and Server IP should be identical with the fourth field being unique.

## Connecting the Umbilical Cable to the PRU

To connect the Umbilical Cable to the PRU, line up the Alignment Indicator (red dot and the arrow) on the Umbilical Cable connector with the red dot on the PRU Umbilical Cable Port and push the connector until it clicks into place.

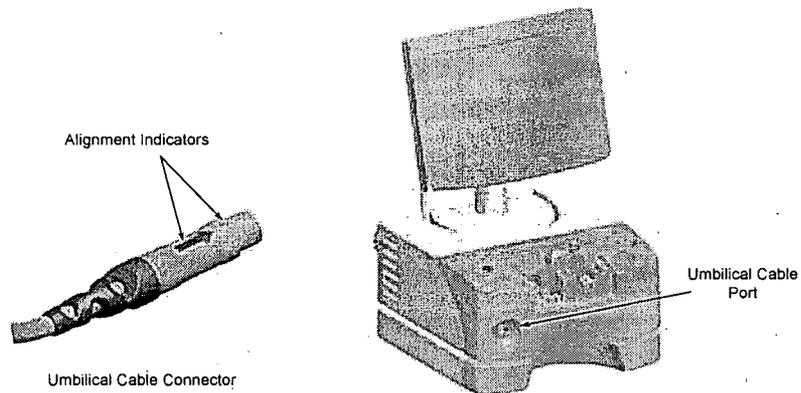


Figure 5-34 Umbilical Cable to PRU



### Note

- 1 The two connectors on either end of the Umbilical Cable are identical. Therefore, either end of the Umbilical Cable can be connected to the PRU.
- 2 The Umbilical Cable may remain connected to the PRU after each case.

## Capnometry Gain Calibration

Refer to SEDASYS® Service Manual for Calibration procedure.

## Functional Testing

Refer to SEDASYS® Service Manual for the functional procedure.