Computer-Assisted Personalized Sedation System

Clinical User Guide/Operator's Manual

Document Part Number EES0001446 Revision B

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.

COPYRIGHT INFORMATION

The SEDASYS® System is covered by the following U.S. patents: 7,997,271; 7,992,556; 7,970,631; 7,935,081; 7,837,651; 7,727,194; 7,565,905; 7,527,052; 7,308,894, 7,299,981, 7,229,430; 7,201,734; 7,198,605; 7,152,604; 6,986,347; 6,807,965; 6,745,764; 6,186,977; D621,722; D613,184; 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	Oxygen Delivery Adapter
SEDWXP01	Wireless External Printer
SEDE3AMI	ECG Leads AAMI Color Std
SEDECAMI	ECG Cable AAMI 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, IEC 60601-1-1, 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
Hummelsbuetteler 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:

- Pulse Oximeter Probe and Cable: One (1) Year, Replacement.
- NIBP Cuff and Extension: One (1) Year, Replacement.

- Oxygen Delivery Adapter: One (1) Year, Replacement.
- ECG Leads and Cable: One (1) Year, Replacement.
- Printer: 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.

Ethicon Endo-Surgery, Inc. neither assumes nor authorizes any other person to assume for it any other liability in connection with the sale or use of any of Ethicon Endo-Surgery, Inc. products. There are no warranties that extend beyond the terms hereof.

Ethicon Endo-Surgery, Inc. reserves the right to make changes to products built and/or sold by them at any time without incurring any obligation to make the same or similar changes on products previously built and/or sold by them.

SERVICE AND SUPPORT INFORMATION

Within the USA contact:
EES Customer Support Center, 1-800-SEDASYS, 1-800-733-2797 (English speaking only)

Outside of USA contact:
Local Johnson & Johnson Affiliate office or closest Authorized Service Center

Authorized Service Centers locations:
USA
Ethicon Endo-Surgery, Inc.
4480 Lake Forest Drive Suite 318
Cincinnati, OH 45242
1-800-SEDASYS (U.S.), 1-800-733-2797
Phone: 1-513-337-8901 (International calls - English speaking only)
Email: sedasystechsupport@its.jnj.com

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.

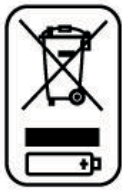
Contraindication: Medical situations in which the device should not be used because the risk of use clearly outweighs any possible benefit.

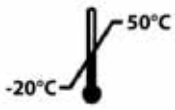
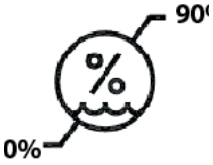
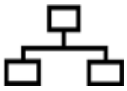
SYMBOLS

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

Symbol	Description
	See Instructions for Use.
	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_2) 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.
	Non-Pyrogenic Fluid Pathway

Symbol	Description
	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.
	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).
	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 a bag mask device.
	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
	Caution: Federal (U.S.A) law restricts this device to sale by or on the order of a physician.
	Sterilized by irradiation. Sterility Guaranteed Unless Package Opened or Damaged. Do Not Resterilize.
	Lot Number

Symbol	Description
	Use Until Date
	Non-Sterile
	Date of Manufacture
	Manufacturer
	Attention, consult accompanying documents
	Laser Radiation. Laser Light - Do not stare into beam. Class 2 laser product.
	Catalog Number
	Authorized Representative
	Electrical and electronic equipment containing batteries. Return waste to a collection system or treatment and recycling facilities. Applicable in the EU.
	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).

Symbol	Description
	Serial Number
	Allowable storage conditions, temperature.
	Allowable storage conditions, humidity.
	Device port to be used for Ethernet connection.
	Device contains a wireless transmitter that complies with the following regulatory directives: FCC, R&TTE, Industry Canada & C-Tick.

This page is intentionally left blank.

Contents

Chapter 1 Introduction

SEDASYS® System Overview

The SEDASYS® Computer-Assisted Personalized Sedation System is an integrated physiological monitoring and drug delivery system intended to provide physician-led teams with a means of administering 1% propofol (10 mg/mL) injectable emulsion to sedate patients ≥ 18 (ASA I-II) undergoing esophagogastroduodenoscopy (EGD) and colonoscopy procedures.

The SEDASYS® System should be used by a physician-led team trained in administering moderate sedation and the management of under and over sedation. At a minimum, the member of the physician-led team who is administering sedation must have training in the management of the cardiorespiratory effects of propofol when administered using computer-assisted personalized sedation systems. It should be noted that the EES-approved device training program does not replace formalized training in moderate sedation. This training must be completed before users administer propofol with the SEDASYS® System

The System is designed to continuously monitor the patient in the pre-procedure area, procedure room, and post-procedure 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 standalone 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 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.

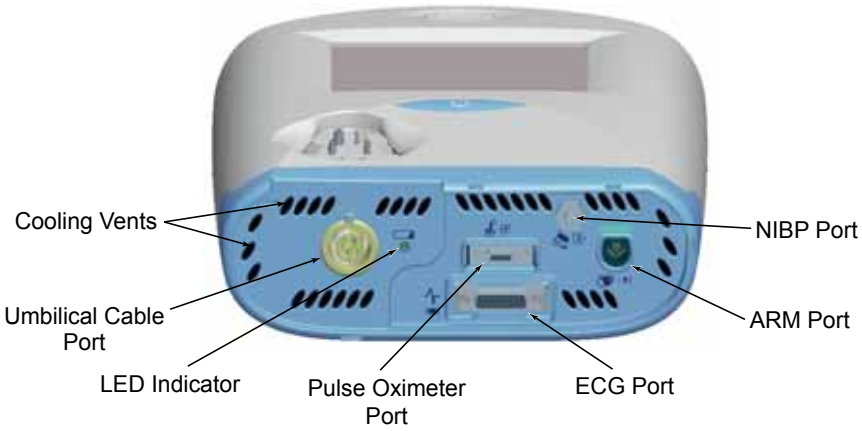


Figure 1-2 Bottom View of BMU

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.

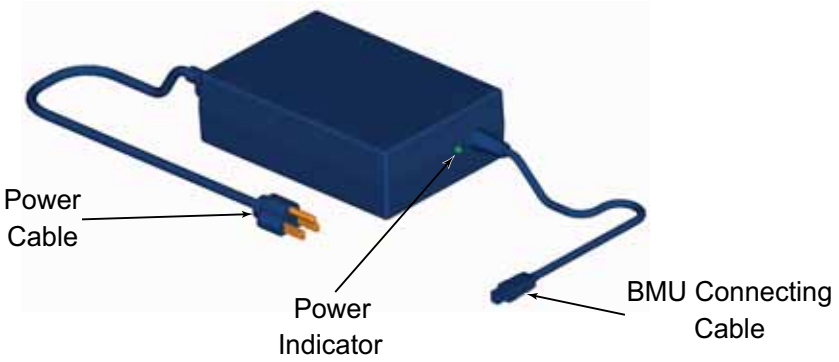


Figure 1-3 BMU Power Adapter

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.

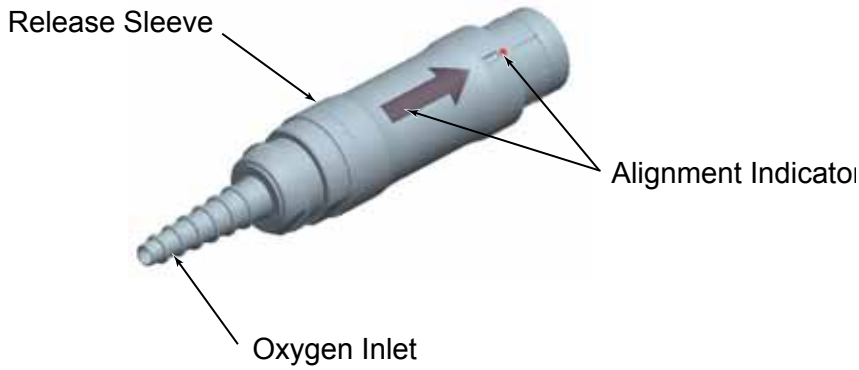


Figure 1-4 Oxygen Delivery Adapter

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

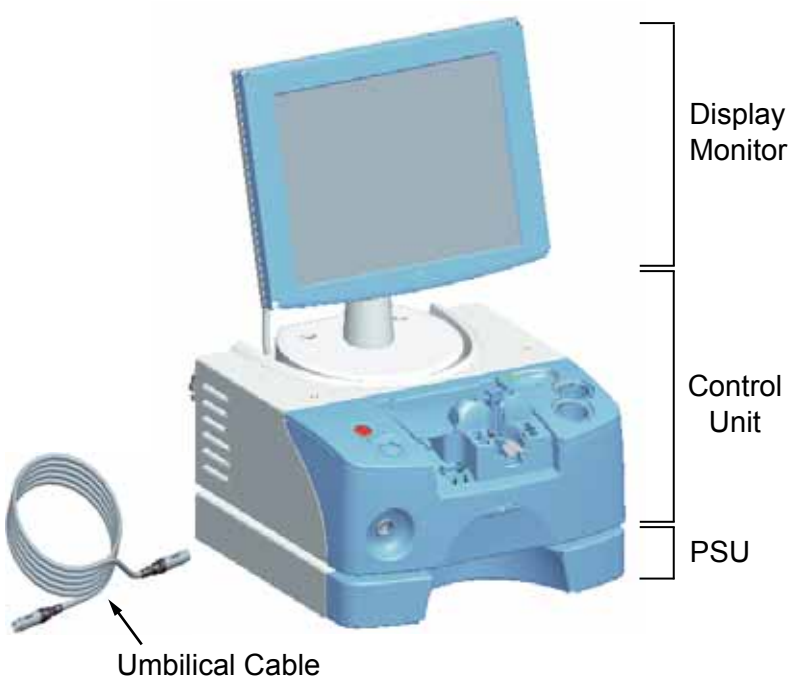


Figure 1-5 Front View of Procedure Room Unit

Control Unit

The Control Unit includes the infusion pump and drug delivery algorithms that allow the administration of propofol; capnometry to monitor the patient's respiratory rate and end-tidal CO_2 ($EtCO_2$); 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.

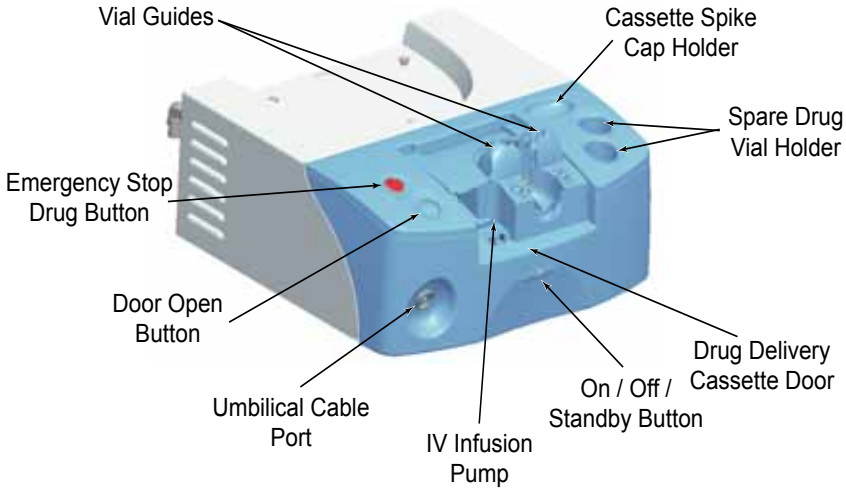


Figure 1-6 Front View of PRU Control Unit

Emergency Stop Drug Button: Immediately stops delivery of 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 propofol.

IV Infusion Pump: Integrates intravenous infusion pump located beneath the Drug Delivery Cassette door for delivering 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 vials.

Cassette Spike Cap Holder: Recess to hold the cassette Spike Cap when cassette is in use.

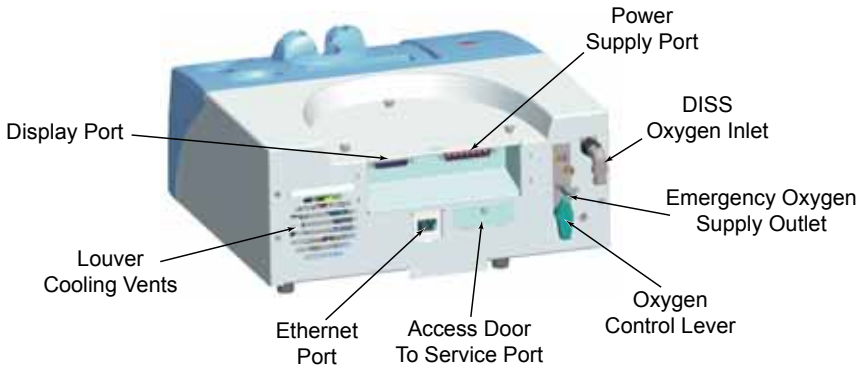


Figure 1-7 Back View of PRU Control Unit

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 Control Unit.

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.

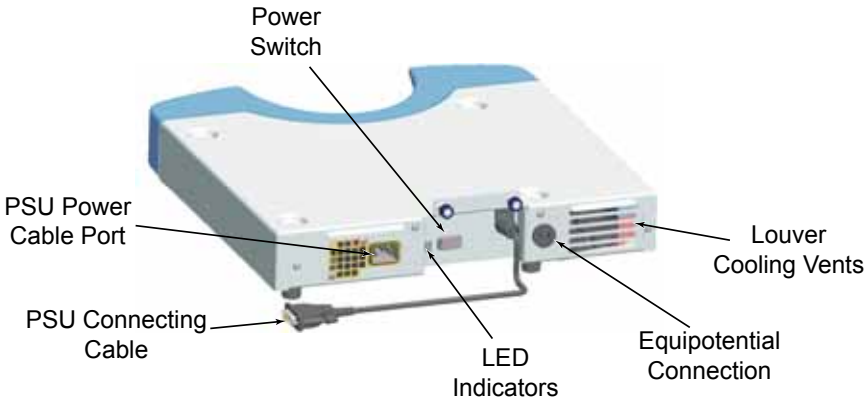


Figure 1-8 Back View of PRU Power Supply Unit

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 Control Unit while the Control Unit 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.

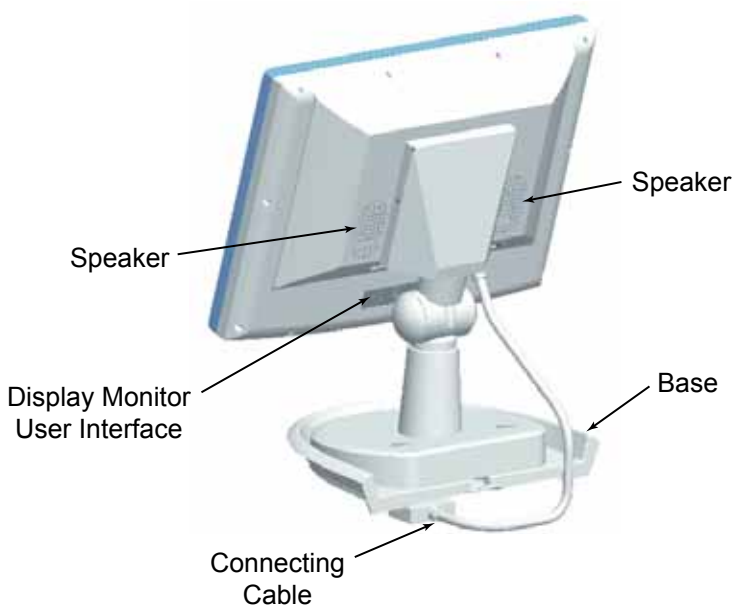


Figure 1-9 Back View of PRU Display Monitor

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.

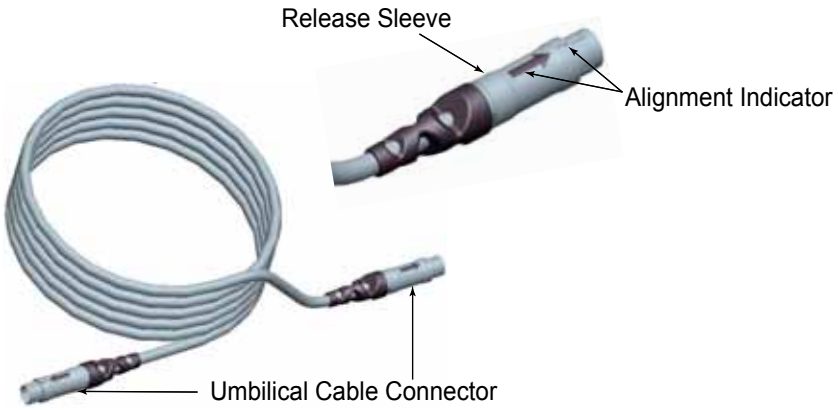


Figure 1-10 Umbilical Cable

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 1% propofol 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 propofol to the patient directly from the 1% propofol vial.

WARNING

1. Use only the approved Drug Delivery Cassette supplied with the SEDASYS® System. The use of infusion tubing not approved for use with the System may result in inaccurate delivery of propofol.
2. Purging and/or priming the Cassette's IV Tubing while the T-site is connected to the patient may result in an air embolism or inappropriate drug delivery. Prior to connecting the Drug Delivery Cassette T-site to the patient and delivering propofol, examine the Cassette's IV Tubing for residual air and manually purge any residual air.
3. The Drug Delivery Cassette is packaged sterile for single-patient use only. Do not re-use or re-sterilize. Re-use of the cassette may result in the transmission of infectious disease(s) from one patient to another, leading to injury, illness, or death. Re-sterilization may compromise structural integrity and/or lead to cassette failure that in turn 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 set to administer additional fluids (i.e., saline drip) to the patient, make sure it contains an integrated back-check valve to prevent inaccurate dosing of propofol.

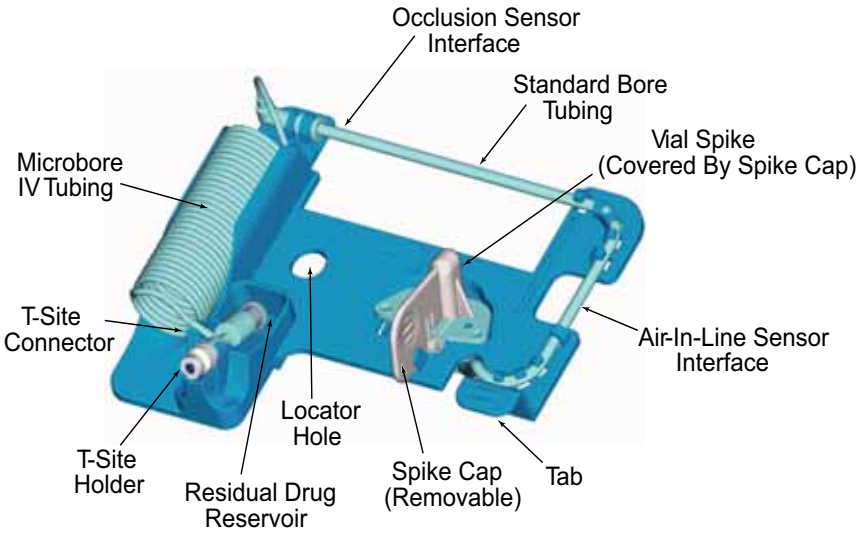


Figure 1-11 Drug Delivery Cassette

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

T-site Connector: Is removed from the Drug Delivery Cassette and attaches to the stopcock on the patient's IV catheter.

WARNING

The Drug Delivery Cassette's 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 propofol that may occur during the autopriming 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 Automated Responsiveness Monitor (ARM). The earpiece is fitted into the patient's ear and is used to communicate the audio ARM request.

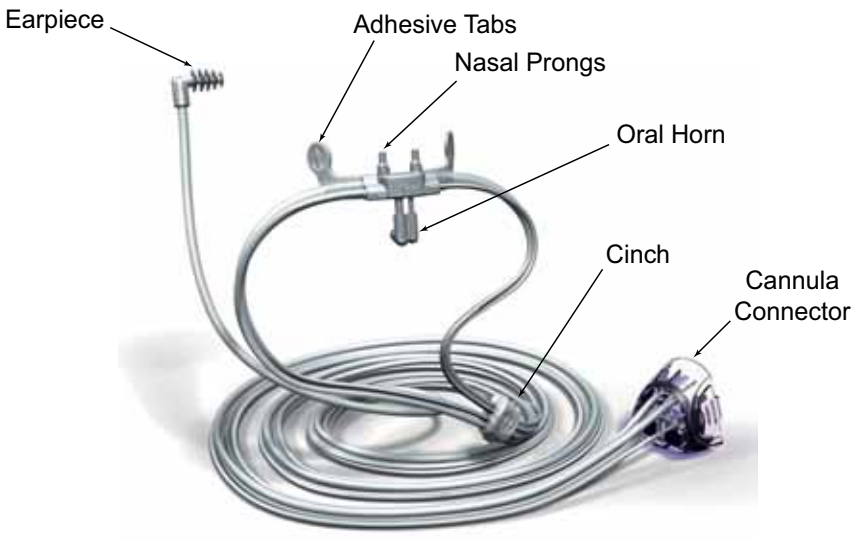


Figure 1-12 Oral/Nasal Cannula

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 on the Oral/Nasal Cannula 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 SEDASYS® 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.

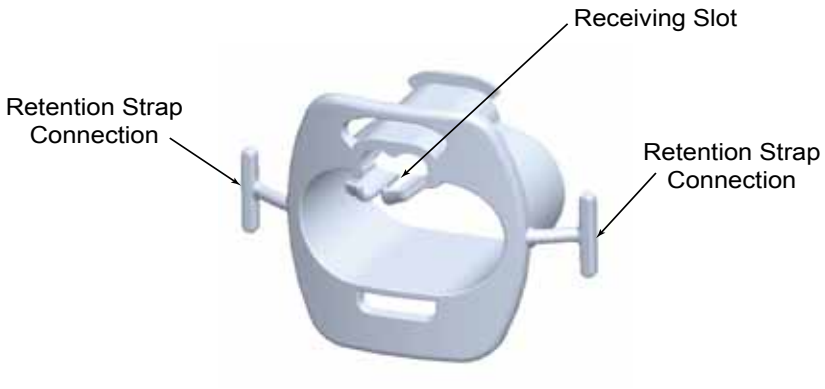


Figure 1-13 Bite Block

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 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.

Pulse Oximetry (SpO_2) Probe

The System utilizes a finger probe sensor, compatible with the BMU SpO_2 module, for measuring the patient's $\%SpO_2$ and heart rate. This finger probe connects into the System through the BMU.

Non-Invasive Blood Pressure (NIBP) Cuff

The System utilizes a 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.

Electrocardiogram (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.

Automated Responsiveness Monitor 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

Work Surface: Slides out from both sides of Cart.

Transport Handles: Features include handles on front and back of Cart, dock for Umbilical Cable, and a cord wrap for main power cord.

Storage Bin: Removes for easy handling.

Locking Drawer: Slides out from both sides of Cart with a front positioned Key Lock that locks Drawer in closed position.

BMU Docking Bracket: For docking the BMU during transport, if desired. Located on back side of Cart (not shown).

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 and drug delivery information can be printed via a Stat Print request or an end-of-case summary (refer to *Appendix F: Printing*). 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 in order to achieve and maintain a desired sedation effect. It enables the physician-led team to adjust the patient's sedation level by 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 achieve the sedation effect for the entered dose rate.

Note

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, Non-Invasive 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 to aid the physician-led team in assessing the patient's level of sedation.

All five monitors and drug delivery are integrated together through a proprietary software module. It monitors the patient's condition, keeps the physician-led team informed of the patient's status, and stops the delivery of propofol within 1 second of detecting apnea (defined by 30 seconds of no respiratory activity) or an oxygen saturation less than 92%. 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-led 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-led team to assess the status of the patient. It has also been designed to give the physician-led 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_2 through the capnometer and assesses patient responsiveness through ARM. This information is displayed to the physician-led team. As soon as the System detects ventilation 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-led 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 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 propofol injectable emulsion with the SEDASYS® System.

Note

Before administering propofol injectable emulsion with the System, each member of the physician-led team should review and be completely familiar with the specific dosage and administration information detailed in both this document and in the propofol injectable emulsion product labeling.

The SEDASYS® System is designed to be used with a **single** pre-medication dose of fentanyl (25 to 100 mcg) given approximately 3 minutes before the start of propofol infusion. The fentanyl is given because propofol does not have analgesic properties.

WARNING

Use of fentanyl and propofol concurrently has a synergistic effect that results in an increased sedative effect as well as an increased risk for respiratory depression. Use only the recommended dose of fentanyl (refer Administering Fentanyl in *Chapter 6: Procedural Use*).

Initiating Propofol Sedation

The SEDASYS® System automatically calculates an appropriate loading dose with which to initiate sedation with propofol injectable emulsion. The calculation is based on patient weight and the maintenance dose rate entered by the clinician. The loading dose is administered over 3 minutes. After the loading dose is complete, the System automatically starts delivering propofol at the dose rate entered.

The formula for calculating the loading dose is based on the recommended dosing guideline in the 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 75 mcg/kg/min. The maintenance dose rate may need to be titrated to achieve and maintain an adequate level of sedation.

To avoid sedative administration of 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.

ARM Responsiveness Tests

During 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 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.

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.

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, the System records the patient as non-responsive.

Guarding Against Risks of Over-Sedation

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

The first element of the integration consists of dosing lockouts and limits. To ensure that the physician-led team observes the full effect of a dosing decision before increasing the dose, the System provides the following lockouts:

- 3-minute lockout that prevents a maintenance dose rate increase during a loading dose.
- 90-second lockout that prevents stacking of PRN doses.

To reduce the risk of accidental overdose, the SEDASYS® System provides the following dosing limits:

- Initial maintenance rate is limited to 75 mcg/kg/min, or less.
- Maintenance dose rate increases are limited to 50 mcg/kg/min, or less, if the patient's ARM response time is less than or equal to 5 seconds.
- Maintenance dose rate increases are limited to 25 mcg/kg/min, or less, if the patient's ARM response time is less than or equal to 14 seconds.
- Maintenance dose rate increases are limited to 10 mcg/kg/min, or less, if the patient is non-responsive to ARM.

The second element of the integration consists of alarms and automatic adjustments to the propofol maintenance dose rate based on patient physiology. Since integration relies on availability of monitoring data, all patient monitors must be connected and functioning properly before the System will allow propofol delivery. These adjustments include:

- Maintenance dose rate is reduced if the patient becomes non-responsive to ARM during the 3-minute loading dose.
- Maintenance dose rate is reduced if the patient is non-responsive to ARM for 6 consecutive minutes.
- Maintenance dose rate is reduced for low respiratory rate/apnea or low SpO_2 (see *Chapter 7: Patient Alarms*, Yellow Alarms).
- Maintenance dose rate is stopped in the event of prolonged apnea or very low SpO_2 (see *Chapter 7: Patient Alarms*, Red Alarms That Stop Drug Delivery).

In addition to the above, the System has alarms for bradycardia, tachycardia, hypotension, hypertension and high respiratory rate (see *Chapter 7: Patient Alarms*, Red Alarms That Do Not Stop Drug Delivery).

The third element of the integration automatically adjusts the oxygen delivery rate based on patient physiology. Since the integration relies on the presence of oxygen, an oxygen source must be connected to the SEDASYS® System before the System will allow propofol delivery. The adjustments include:

- Oxygen delivery rate is increased if the patient's oxygen saturation decreases

Training on the Use of the SEDASYS® System

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

WARNING

The SEDASYS® System should be used by physician-led team trained in administering moderate sedation and the management of under and over sedation. At a minimum, the member of the physician-led team who is administering sedation must have training in the management of the cardiorespiratory effects of propofol when administered using computer-assisted personalized sedation systems. It should be noted that the EES-approved device training program does not replace formalized training in moderate sedation. This training must be completed before users administer propofol with the SEDASYS® System.

Chapter 2 Indications, Contraindications, Warnings and Precautions

Indications

The SEDASYS® 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 (ASA) Continuum of Depth of Sedation, in ASA physical status I and II patients ≥ 18 years old undergoing colonoscopy and esophagogastroduodenoscopy (EGD) procedures.

Note

1. The SEDASYS® System must only be used in hospitals and/or healthcare facilities where an anesthesia professional is immediately available for assistance or consultation as needed. The definition of 'immediate availability of an anesthesia professional' will be determined by each individual facility.
2. The user is ultimately responsible for clinical care of the patient. The SEDASYS® System is an adjunct to assist in the administration of propofol infusion.
3. To achieve analgesia, a **single** bolus dose of fentanyl should be administered 3 minutes prior to the start of propofol infusion by the System.
4. 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.

Contraindications

The SEDASYS® System is contraindicated in the following:

Patients with a known hypersensitivity to 1% propofol injectableThe SEDASYS® 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

WARNING

1 In the pivotal trial, administration of propofol using the SEDASYS® System was associated with non-sustained, unintended episodes of deep sedation and/or complete unresponsiveness or non-purposeful response to painful stimulation. The SEDASYS® System should be used by a physician-led team trained in administering moderate sedation and trained in the management of under and over sedation.
At a minimum, the member of the physician-led team who is administering sedation must have training in the management of the cardiorespiratory effects of propofol when administered using computer-assisted personalized sedation systems. The training must include:

- Pharmacology of propofol.
- Identification of high risk patients.
- Recognition of progression of levels of sedation, and actions necessary to return a patient to intended levels of sedation.
- Use of capnometry and the determination of adequate ventilation.
- Management of airway obstruction and hypoventilation.

The identified team member responsible for monitoring the patient and managing sedation should not be involved in the conduct of the procedure.

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

3 Immediate availability of narcotic reversal agents and equipment for maintenance of the patient's airway, positive pressure ventilation, oxygen enrichment, and circulatory resuscitation and personnel trained in their use should be assured.

4 An anesthesia professional should be consulted 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 classification III or IV).

5 Do not supplement propofol administered by the SEDASYS® System with additional manual bolus doses of any other sedative (e.g., midazolam) as this may result in overdosing and respiratory depression.

6 Do not use the SEDASYS® System in combination with flammable or other inhalation anesthetic agents or with external breathing systems.

7 The SEDASYS® System should not be used for the induction and/or maintenance of deep sedation or general anesthesia.

8 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 improper dosing of propofol.

WARNING

9 Purging and/or priming the Cassette's IV Tubing while the T-site is connected to the patient may result in an air embolism or inappropriate drug delivery. Prior to connecting the Drug Delivery Cassette T-site to the patient and delivering propofol, examine the Cassette's IV Tubing for residual air and manually purge any residual air.

10 When using a standard IV set to administer additional fluids (i.e., saline drip) to the patient, make sure it contains an integrated back-check valve to prevent inaccurate dosing of propofol.

11 Use only the approved Drug Delivery Cassette supplied with the SEDASYS® System. The use of infusion tubing not approved for use with the System may result in inaccurate delivery of propofol.

12 Do not connect another active infusion pump to the Drug Delivery Cassette's IV Tubing. Connection of another may result in inaccurate dosing of propofol.

13 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 propofol.

14 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.

Propofol

WARNING

1 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.

2 Do not supplement propofol administered by the SEDASYS® System with additional manual bolus doses of propofol as this may result in overdosing and respiratory depression.

3 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 non-asthmatic people.

4 Further guidance on the administration of 1% (10 mg/ml) propofol injectable emulsion for sedation, overdose and associated adverse reactions can be found in the propofol package insert.

Note

The SEDASYS® System will not deliver propofol unless the cardiorespiratory monitors, automated responsiveness monitor, and supplemental oxygen are working properly.

Fentanyl

WARNING

1. Only a single pre-procedure dose of fentanyl should be administered. Administration of fentanyl beyond the start of the procedure increases the risk of severe respiratory depression.
2. Do not administer fentanyl until all of the patient monitors are connected.
3. Do not supplement the single pre-procedure doses of fentanyl with additional doses of any other analgesic (e.g., meperidine) as this may result in overdosing and respiratory depression.
4. Further guidance on the administration of fentanyl during sedation, overdose and associated adverse reactions can be found in the fentanyl package insert.

Supplemental Oxygen Delivery

WARNING

Do not attach the PRU DISS Oxygen Inlet to anything other than a breathable, 100% oxygen source with regulated inlet pressure (40 to 60 psi).

Electrocardiogram

WARNING

1. The SEDASYS® System provides electrocardiogram (ECG) monitoring. The System does not provide an ECG waveform with diagnostic resolution.
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 in 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 or sterilize. Re-use of the cannula may result in the transmission of infectious disease(s) from one patient to another, which could lead to injury or illness. Sterilization may compromise structural integrity and/or lead to device failure of the cannula.
2. Do not use the Drug Delivery Cassette if its sterile package is damaged or if past the labeled expiration date.
3. The Drug Delivery Cassette is packaged sterile for single-patient use only. Do not re-use or re-sterilize. Re-use of the cassette may result in the transmission of infectious disease(s) from one patient to another, which could lead to injury, illness, or death. Re-sterilization may compromise structural integrity and/or lead to cassette failure that in turn my result in patient injury.
4. Do not use the System if any component has been dropped or severely abused.

Electrical Hazards

WARNING

1 To help protect against electric shock due to leakage current, use only power cords supplied with the System.

2 Do not simultaneously make contact with the patient and any exposed metal from any electrical connectors on the System.

3 Only an authorized service technician should service the SEDASYS® System. Risk of electrical shock or other hazards may occur if high voltage internal components are touched.

4 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.

5 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.

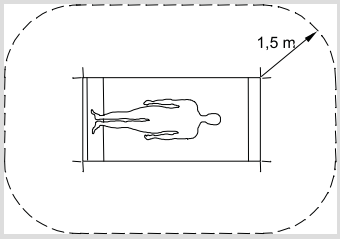
6 Do not use the System if the integrity of the protective earth conductors is in doubt.

7 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.

8 Using items not approved for use with the SEDASYS® 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® System must be verified if used adjacent to or stacked with other electrical equipment.

10 Risk of Electrical Shock Hazard: Accessory equipment connected to the monitor's data interface Ethernet port must be certified according to the respective standards, i.e., EN (IEC) 60950-1 for data processing equipment or EN (IEC) 60601-1 for electromedical equipment. All combinations of equipment must be in compliance with EN (IEC) 60601-1-1 system requirements. Anyone connecting additional equipment to the signal input port or the signal output port configures a medical system, and therefore is responsible that the System complies with the requirements of the System standard EN (IEC) 60601-1-1. EN (IEC) 60950-1 approved Information Technology Equipment (e.g., printer, computer, etc.) must be placed outside the "patient environment." The patient environment is defined as an area 1.5 m (4.92 feet) from the patient. Additionally, IT equipment such as printers and computers, as well as other non-medical electrical equipment, must not have a pathway or connection to the patient (including indirect connection through another person).



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 cooling vents 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. The diameter of the IV pole should be between 1.27cm and 3.18cm (0.5 inches and 1.25 inches) to accept the pole clamp adapter. The BMU should be attached no higher than 1.4m (55 inches) 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. Secure the placement of all components of the SEDASYS® System during transport to prevent injury to the clinician or patient.
6. 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.
7. The adhesive pad on the Oral/Nasal Cannula is manufactured from a hypoallergenic, pressure sensitive, acrylate adhesive. Some patients may be sensitive or allergic to adhesive.
8. The SEDASYS® System 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.
9. 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.
10. The System may not meet performance specifications if operated outside the specified temperature and humidity ranges.
11. Use of the SEDASYS® System with analgesics other than fentanyl has not been studied and is thus not recommended.

Note

For proper use, care, and installation of the printer, refer to the documentation from the printer manufacturer.

Special Populations

Precaution

1 The SEDASYS® System has not been sufficiently studied in patients classified as ASA physical status III, and is thus not recommended.

2 In the following patients the SEDASYS® System has not been studied and should not be used:
- Patient's <18 years old.
- ASA physical status IV and V.
- Patients using a fentanyl patch.
- Patients with abnormal airway or diagnosed sleep apnea.
- Patients with gastroparesis.
- Patients with Body Mass Index ≥ 35.
- Patients undergoing both colonoscopy and esophagogastroduodenoscopy during the same procedure visit.
- Patients undergoing emergent colonoscopy or esophagogastroduodenoscopy.

An anesthesia professional should administer propofol in these patient populations.

Propofol

Precaution

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

2 Care should be exercised when considering sedation of patients who are 70 years old or older because safety and effectiveness data in this age group are limited.

Fentanyl

Precaution

To reduce the risk of transient apnea or hypoxemia at the start of the procedure, the single dose of fentanyl should be administered approximately 3 minutes before initiating propofol delivery with the SEDASYS® 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, fingernail polish, and artificial fingernails may affect the accuracy of the SpO_2 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 of the SEDASYS® 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 result in limb ischemia and associated clinical sequelae.

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. 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.
4. 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.
5. 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.
6. 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.

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 external power adapter and the IEC320 hospital-grade power cords 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® 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.

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.

This page is intentionally left blank.

Chapter 3 Clinical Safety and Effectiveness

This section describes the results of a 1,000 patient, non-blinded, multi-center, randomized, comparative trial of the SEDASYS® System versus the current standard of care (Control) for sedation in subjects undergoing colonoscopy or esophagogastroduodenoscopy (EGD) procedures. A total of 721 colonoscopy and 279 EGD patients were enrolled across eight centers. The objective of the study was to assess the ability of physician-led teams, using the SEDASYS® System, to safely and effectively provide minimal-to-moderate sedation to patients undergoing routine colonoscopy and EGD procedures.

In the SEDASYS® 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 3 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 Control 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® System.

Patient vital signs and Automated Responsiveness Monitoring (the SEDASYS® 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 5. 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% for > 15 seconds). AUC_{Desat} integrates incidence, duration and depth of desaturation. It is an objective and sensitive surrogate measure of a patient's risk for major over-sedation related adverse events. The concept of AUC_{Desat} is illustrated in Figure 3-1.

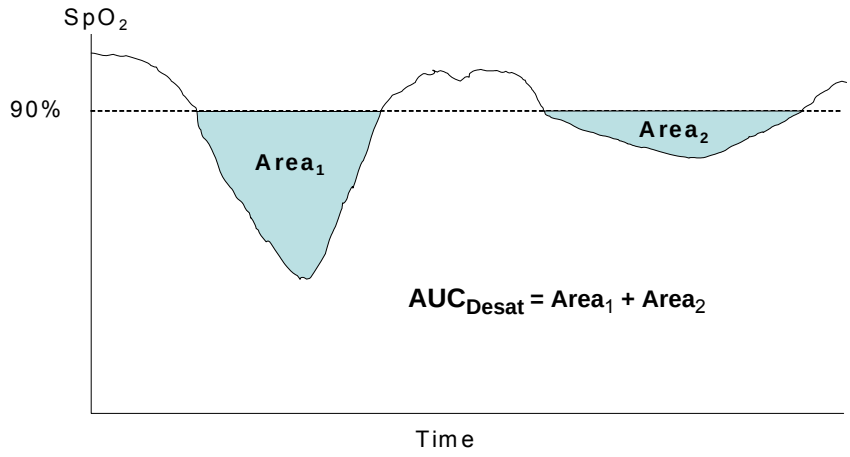


Figure 3-1 Area-Under-The-Curve of Oxygen Desaturation

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 measures of 5 have been reached.
- Duration of deep sedation and/or non-purposeful response to painful stimulation (i.e., trapezius squeeze) measured by the occurrences of all MOAA/S scores of 1 or 0 during a procedure.

In addition to the above measures, all adverse events (AEs) 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 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^2 or greater. If the investigator anticipated the procedure time to exceed 45 minutes due to anatomical difficulty, subjects were excluded.

Results

Primary and Secondary Endpoints

A tabulation of the results from the primary and secondary endpoints for colonoscopy and EGD are provided in Tables 3-1 and 3-2.

Table 3-1: Primary and Secondary Endpoints for Colonoscopy[a] [b]

	SEDASYS® System (N = 358)	**Control** (N = 363)	**p-value[c]**
Primary Endpoint			
AUC_{Desat} (seconds•%)	17.8 ± 124.59 [0 - 1741]	98.8 ± 510.32 [0 - 7040]	0.004
Secondary Endpoints			
CSSI	92.4 ± 10.32 [27.1 - 100]	75.8 ± 17.18 [25.0 - 100]	< 0.001
PSSI	92.5 ± 12.09 [0 - 100]	90.5 ± 12.44 [35.4 - 100]	0.052
Recovery Time (minutes)	2.7 ± 2.37 [0 - 15]	6.3 ± 6.78 [0 - 37]	< 0.001
Duration of Deep Sedation and/or Non-Purposeful Response to Trapezius Squeeze (minutes)	0.1 ± 1.16 [0 - 16]	0.1 ± 1.23 [0 - 22]	0.573

a. All data for intent-to-treat population.
b. Plus-minus values are means ± SD; values in brackets are the range.
c. Values were analyzed using an ANOVA, except Recovery Time which used a Cox Proportional Hazards Regression Analysis.

Table 3-2: Primary and Secondary Endpoints for EGD[a] [b]

	SEDASYS® System (N = 138)	Control (N = 141)	p-value[c]
Primary Endpoint			
AUC_{Desat} (seconds•%)	38.6 ± 181.87 [0 - 1771]	60.2 ± 179.92 [0 - 996]	0.315
Secondary Endpoints			
CSSI	92.1 ± 11.30 [35.4 - 100]	77.0 ± 15.84 [42.7 - 100]	< 0.001
PSSI	91.0 ± 12.68 [24.0 - 100]	87.9 ± 12.59 [39.6 - 100]	0.067
Recovery Time (minutes)	3.5 ± 2.53 [0 - 12]	7.0 ± 7.43 [0 - 36]	< 0.001
Duration of Deep Sedation and/or Non-Purposeful Response to Trapezius Squeeze (minutes)	0.0 ± 0.38 [0 - 4]	0.1 ± 0.85 [0 - 10]	0.731

a. All data for intent-to-treat population.
b. Plus-minus values are means ± SD; values in brackets are the range.
c. Values were analyzed using an ANOVA, except Recovery Time which used a Cox Proportional Hazards Regression Analysis.

AUC_{Desat}: Patients in the SEDASYS® System group experienced less oxygen desaturation, a major risk of oversedation. Patients in the SEDASYS® System group experienced a total of 52 oxygen desaturation events compared to the Control group of 183. There were 82 ASA I and II patients 70 years of age or older in the clinical trial. In this age group the primary endpoint, AUC_{Desat}, for colonoscopy and EGD combined was 22 ± 84 (seconds•%) for the SEDASYS® System group compared to 341 ±1,119 (seconds•%) for the Control Group.

CSSI: Physicians in the SEDASYS® System group were significantly more satisfied with the sedation achieved during the study. Satisfaction was measured using a validated tool, the Clinician Satisfaction with Sedation Index (CSSI). This tool evaluated sedation administration and recovery/post-operative procedures.

PSSI: Patients in the SEDASYS® System group were satisfied with the sedation achieved during the study. Satisfaction was measured using a validated tool, the Patient Satisfaction with Sedation Index (PSSI). This tool evaluated sedation delivery, procedure recall and sedation side effects.

Recovery Time: Patients in the SEDASYS® System group recovered significantly faster than patients in the CSC group. Ten minutes after

completion of the procedure, less than 1% of the SEDASYS® System patients had not recovered from sedation while approximately 25% of the Control patients had yet to recover. Several subjects in the Control group took greater than 35 minutes to recover.

Level of Sedation: Patients in both the SEDASYS® System and Control 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% were deep sedation and/or non-purposeful response to painful stimulation (i.e., trapezius squeeze).

Cardiorespiratory Measures

A tabulation of the cardiorespiratory measures for colonoscopy is provided in Table 3-3. These measures were defined as:

- **Oxygen Desaturation:** Oxygen saturation less than 90% for more than 15 seconds.
- **Apnea:** Absence of ventilatory activity for 30 seconds or more.
- **Bradycardia:** Heart rate less than 50 beats per minute, or 80% of baseline (whichever is lower) for 30 seconds or more.
- **Hypotension:** Two or more consecutive systolic blood pressure measurements less than 80 mmHg, or 80% of baseline (whichever is lower).

Table 3-3: Cardiorespiratory Measures for Colonoscopy

	SEDASYS® System (N = 358)	**Control** (N = 363)
Oxygen Desaturation		
n (%)	18 (5%)	56 (15%)
Magnitude range (%)	72 - 88	39 - 89
Duration range (sec)	20 - 133	17 - 335
Apnea		
n (%)	127 (35%)	119 (33%)
Duration Range (sec)	30 - 124	30 - 175
Bradycardia		
n (%)	10 (3%)	4 (1%)
Magnitude range (bpm)	36 - 47	37 - 45
Duration range (sec)	36 - 143	66 - 253
Hypotension		
n (%)	8 (2%)	5 (1%)
Magnitude range (mmHg)	55 - 78	65 - 76
Duration range (sec)	208 - 678	80 - 335

A tabulation of the cardiorespiratory measures for EGD is provided in Table 3-4.

Table 3-4: Cardiorespiratory Measures for EGD

	SEDASYS® System (N = 138)	Control (N = 141)
Oxygen Desaturation n (%) Magnitude range (%) Duration range (sec)	 17 (12%) 53 - 88 16 - 97	 24 (17%) 68 - 89 16 - 199
Apnea n (%) Duration Range (sec)	 52 (38%) 30 - 109	 57 (40%) 30 - 121
Bradycardia n (%) Magnitude range (bpm) Duration range (sec)	 2 (1%) 37 - 43 132 - 144	 0 0 0
Hypotension n (%) Magnitude range (mmHg) Duration range (sec)	 0 0 0	 0 0 0

Over-Sedation

The SEDASYS® System was associated with deeper-than-intended sedation, including non-responsiveness to a painful trapezius squeeze. In the study, 17 (1.7%) of the 1,000 patients had at least one episode of deeper-than-intended sedation. Of these 17 patients, 12 (2.4% of 496) were sedated using the System and 5 (1.0% of 504) were Control.

Adverse Events

A tabulation of the Adverse Events (AEs) occurring in the study possibly related to the study drug is provided in Table 3-5. The table presents combined data for colonoscopy and EGD.

Table 3-5: Causal Adverse Events

	SEDASYS® System (N = 496)	Control (N = 504)
Body Trembling	3 (0.6%)	0
IV Site Discomfort	2 (0.4%)	0
Oxygen Desaturation	1 (0.2%)	27 (5.4%)
Nausea or Vomitting	1 (0.2%)	2 (0.4%)
Hypertension	1 (0.2%)	0
Apnea	1 (0.2%)	0

	SEDASYS® System (N = 496)	Control (N = 504)
Dizziness	1 (0.2%)	0
Rash on Chest/Back	1 (0.2%)	0

A tabulation of the Adverse Events occurring in the study not related to the study drug or device is provided in Table 3-6. The table presents combined data for colonoscopy and EGD.

Table 3-6: Non-Causal Adverse Events

	SEDASYS® System (N = 496)	Control (N = 504)
Nausea or Vomitting	7 (1.4%)	4 (0.8%)
Abdominal Pain/Bloating/ Cramping	5[a] (1.0%)	1 (0.2%)
Esophageal Pain/Hoarse Voice	2 (0.4%)	3 (0.6%)
Flatulence	1 (0.2%)	1 (0.2%)
Hypertension	1 (0.2%)	0
Hypotension	1 (0.2%)	0
Anxiety	1 (0.2%)	0
Fever	1 (0.2%)	0
Headache	1 (0.2%)	0
Sinus Headache	1 (0.2%)	0
Stiff Neck	1 (0.2%)	0
Dizziness	1 (0.2%)	0
Diarrhea	0	2 (0.4%)
IV Site Swelling/Pain	0	2 (0.4%)
Partial Small Bowel Obstruction	0	1[b] (0.2%)
Oxygen Desaturation	0	1 (0.2%)
GI Related Chest Pain	0	1 (0.2%)
Blood with Bowel Movement	0	1 (0.2%)
Crohn's/Ileitis	0	1 (0.2%)
Hemorrhoid	0	1 (0.2%)

a. One (1) of these events was recorded as a severe Adverse Event. The event was neither study drug nor device related.

b. This event was recorded as both a severe Adverse Event as well as a Serious Adverse Event. The event was neither study drug nor device related.

There were no device related AEs occurring in this study. There were no Serious AEs in the SEDASYS® System group, and one Serious AE in the Control group. There were no deaths in the study.

Conclusions

This study of 1,000 patients provided both clinically and statistically significant results. Clinically, the SEDASYS® System group was comparable or better than the Control group in regards to the primary and secondary endpoints. Statistically, the SEDASYS® System was superior in the primary endpoint (AUC_{Desat}) for colonoscopy procedures and two secondary endpoints (physician satisfaction and recovery time) for both procedures. These data demonstrate that physician-led teams, using the SEDASYS® System, safely and effectively provide minimal-to-moderate sedation to patients undergoing routine colonoscopy and EGD procedures.

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.

Note

Refer to *Appendix H: Functional and Performance Verification Testing* for BMU Functional Testing to assist service personnel.

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.

To mount the Cable Management Bracket

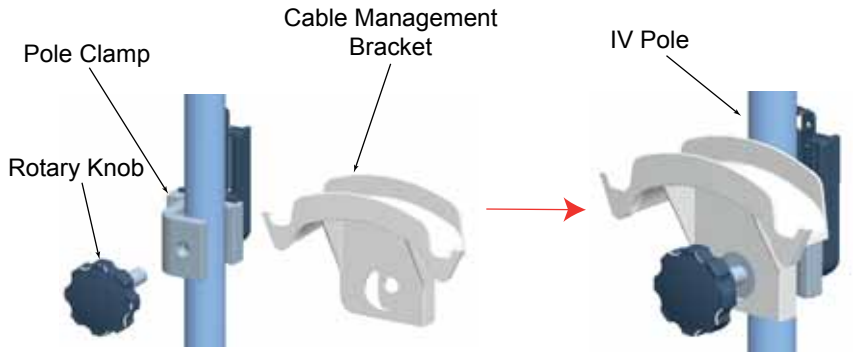


Figure 4-1 Mounting the Cable Management Bracket

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

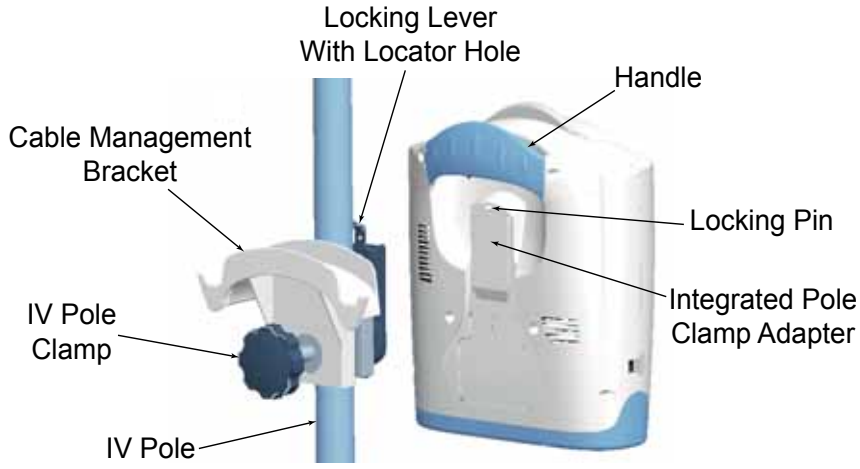


Figure 4-2 Attaching BMU to an IV Pole

1. Attach the included IV Pole Clamp to the IV Pole by turning the clamp's Rotary Knob clockwise for a secure fit to the IV 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 Locking Pin on the Integrated Pole Clamp Adapter

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 and hold the IV Pole Clamp Locking Lever away from the BMU to disengage the Locking Pin on the Integrated Pole 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

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

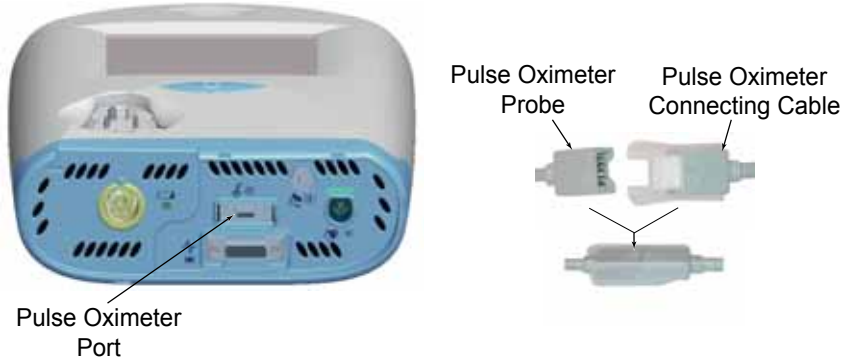


Figure 4-3 Pulse Oximeter Probe Connection to BMU

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.

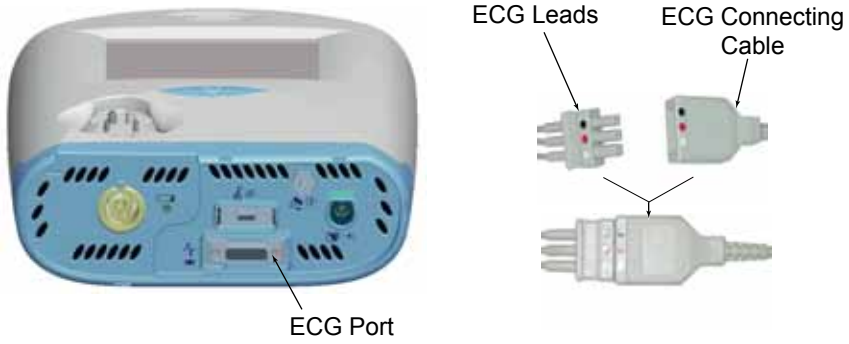


Figure 4-4 3-lead ECG Connection to BMU

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® System uses a proprietary Automated Responsiveness Monitor (ARM) that 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 and 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 such as insulation gaps, cracks, and physical damage.

Precaution

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

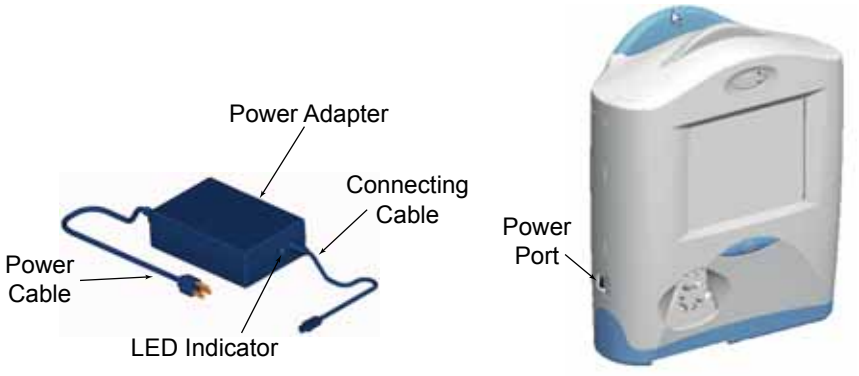


Figure 4-7 Power Adapter Connection to BMU

Powering on 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 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.
No 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 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 battery is recharged when the BMU is connected to the external power adapter or the PRU. The BMU battery takes 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 minutes of battery life in 1-minute increments.

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 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. For assistance, call 1-800-SEDASYS.

BMU Operational Modes

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

Modes	Mode Indicators	Changing Modes
Off	• Screen is dark (off). • The **On/Off/Standby** button is not lit when external power is not provided. **-OR-** • The **On/Off/Standby** button is pulsing slowly when external power is provided.	Press the **On/Off/Standby** button to get to Ready mode. **Caution:** 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.

Table 4-2: Modes, Mode Indicators, and Changing Modes (Continued)

Modes	Mode Indicators	Changing Modes
On: Ready	• The BMU Ready screen is displayed. • The **On/Off/Standby** button is lit.	• Press and release the **On/Off/Standby** button to get to Standby mode. • Press and hold the **On/Off/Standby** button for at least 3 seconds to get to Off mode. **Note:** If the BMU sits in **Ready** mode for 5 minutes, it will go to **Standby** mode.
On: Standby	• Screen is dark (off). • The **On/Off/Standby** button is lit.	To get to Ready mode: • Press and release the **On/Off/Standby** button. **- OR -** • Touch the screen. **Note:** The BMU will require approximately 6 seconds to transition to Ready mode. • Press and hold the **On/Off/Standby** button for at least 3 seconds to get to Off mode. **Note:** The BMU will change to Ready mode if external power is lost.
On: In-Case	• The BMU standalone monitoring screen is displayed. • The **On/Off/Standby** button is lit.	The BMU automatically enters this mode when a new patient is selected and exits this mode at the completion of the case.

Changing BMU Facility Settings

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

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_2, 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.

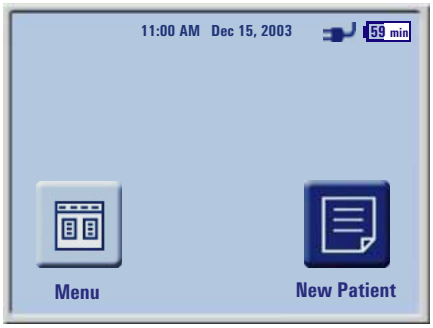


Figure 4-9 BMU Ready Screen

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

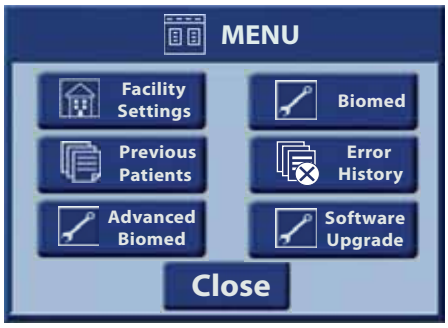


Figure 4-10 BMU Menu Screen

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 displays stored system errors that can be printed.

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

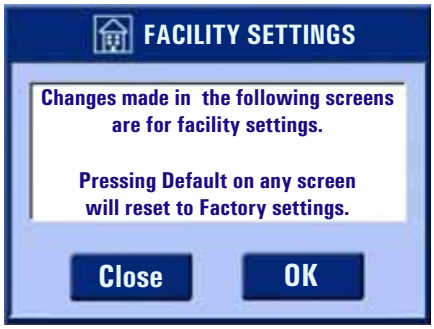


Figure 4-11 BMU Facility Settings Notification Screen

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

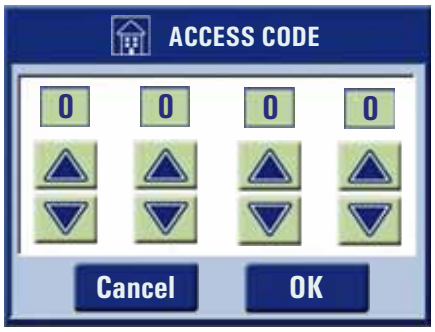


Figure 4-12 BMU Access Code Screen

4. Contact the Facility Administrator for the access code. Enter the 4-digit access code, 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 changed 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

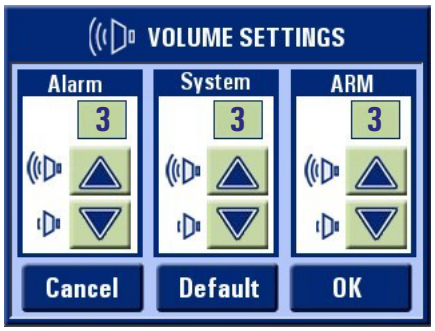


Figure 4-14 BMU Volume Settings Screen

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 SEDASYS® 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

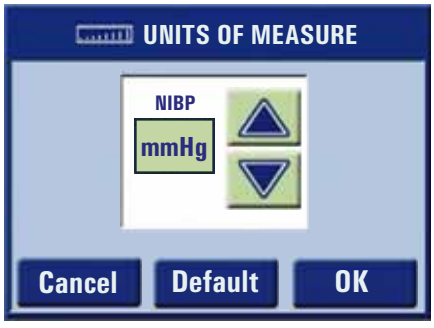


Figure 4-15 BMU Units of Measure Setting Screen

Change the units by pressing the **Up** or **Down Arrow** buttons, 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

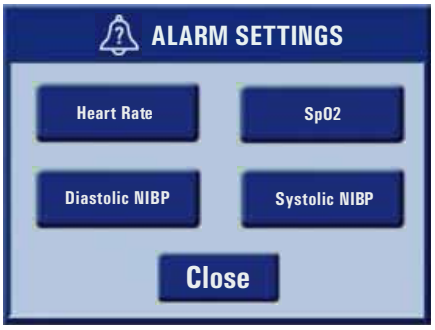


Figure 4-16 BMU Alarm Settings Menu Screen

1. Select and press the button for each setting that you want to change.
   - **Heart Rate:** In beats per minute (minimum and maximum)
   - **SpO_2:** In % (minimum only)
   - **Diastolic NIBP:** (Minimum and maximum)
   - **Systolic NIBP:** (Minimum and maximum)

For example, if you press **SpO_2**, the following screen appears:

Figure 4-17 BMU SpO_2 Alarms Screen

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

Timing/Print

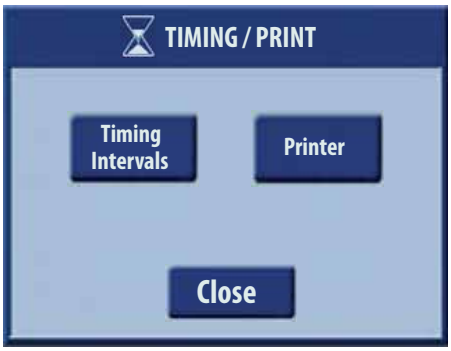


Figure 4-18 BMU Timing Intervals/Printer Menu Screen

1. Press **Timing Intervals** from the Timing/Print Menu screen to select the intervals at which the NIBP module takes pressure readings and at which 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.

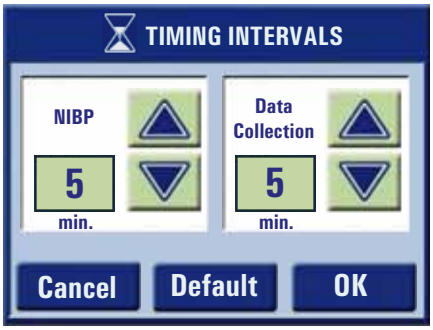


Figure 4-19 BMU Timing Intervals Screen

2. Change each setting by pressing the **Up** or **Down Arrow** buttons, then press **OK**.
3. Press **Printer** from the Timing/Print Menu screen to select options for wireless printing.

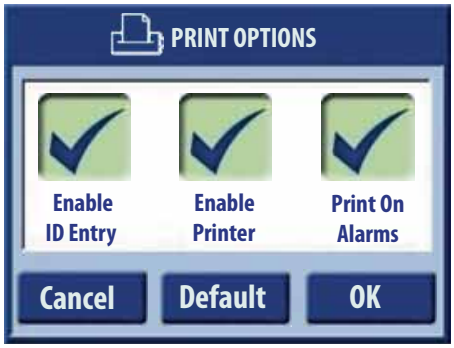


Figure 4-20 BMU Print Options Screen

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 SEDASYS® 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 4-16.

Time/Date

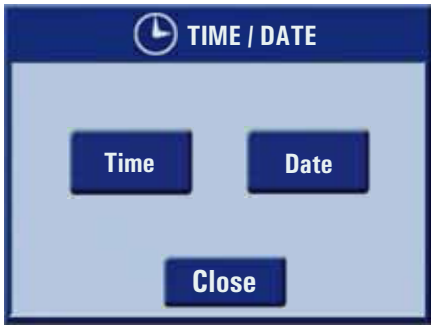


Figure 4-21 BMU Time and Date Menu Screen

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, then press **OK**.

Display Settings

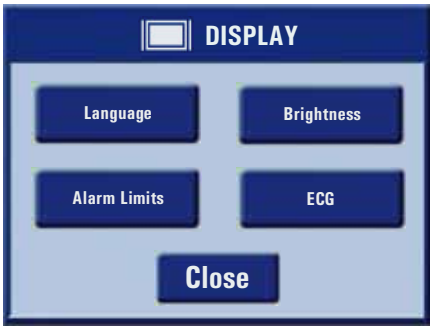


Figure 4-23 BMU Display Settings Menu Screen

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:

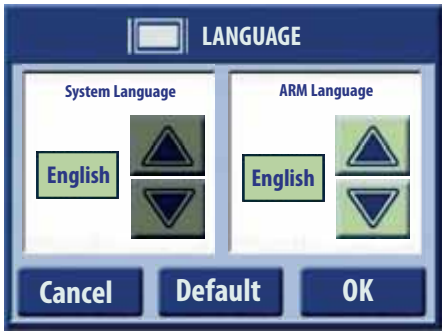


Figure 4-24 BMU Language Settings Screen

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

Note

The SEDASYS® 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 4-14, the following screen appears.

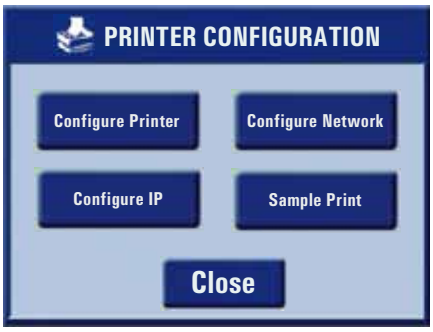


Figure 4-25 BMU Printer Configuration Menu Screen

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

Configure Printer

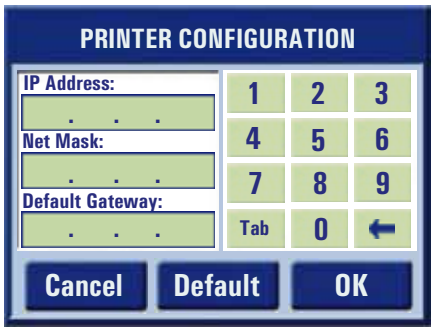


Figure 4-26 BMU Printer Configuration Screen

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

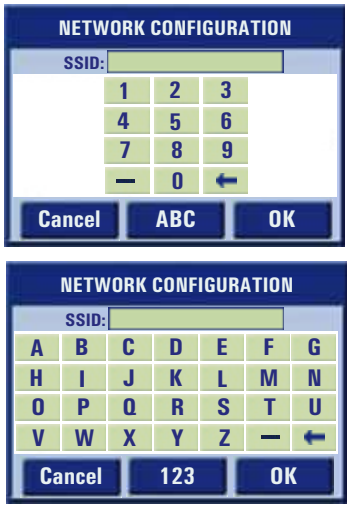


Figure 4-27 BMU Wireless Printer Network Configuration Screens

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.

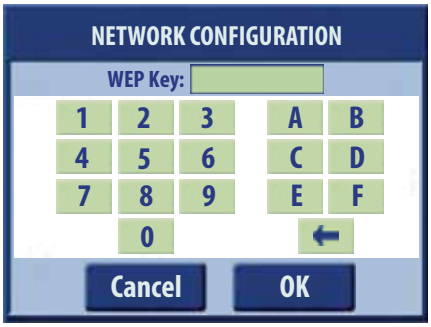


Figure 4-28 BMU WEP Configuration Screens

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

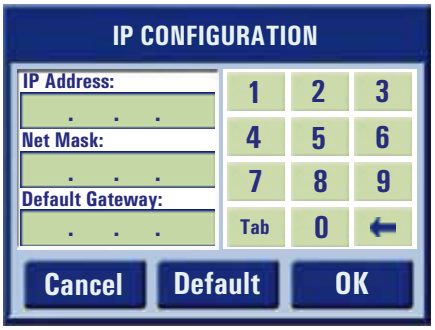


Figure 4-29 BMU IP Configuration Screen

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 4-17) 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.

Valid Network Configuration Example

Table 4-3 provides an example of a valid facility network configuration. Note that the IP address of each component are unique, the Net Mask is the same across components, and the Default Gateway on all components is identical to the printer IP Address.

Table 4-3: Example of Valid Configuration

	Printer Configuration	BMU #1	BMU #2
IP Address	192.168.10.1	192.168.10.2	192.168.10.3

	Printer Configuration	BMU #1	BMU #2
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

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.

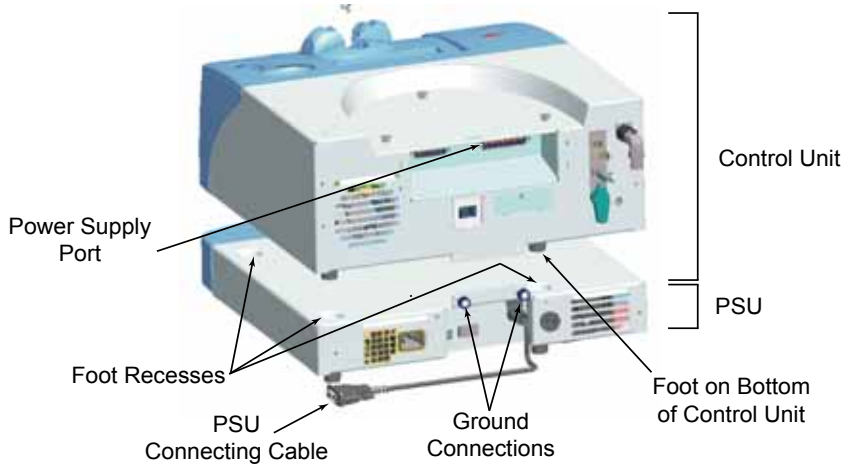


Figure 5-1 Attaching Control Unit to PSU

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.

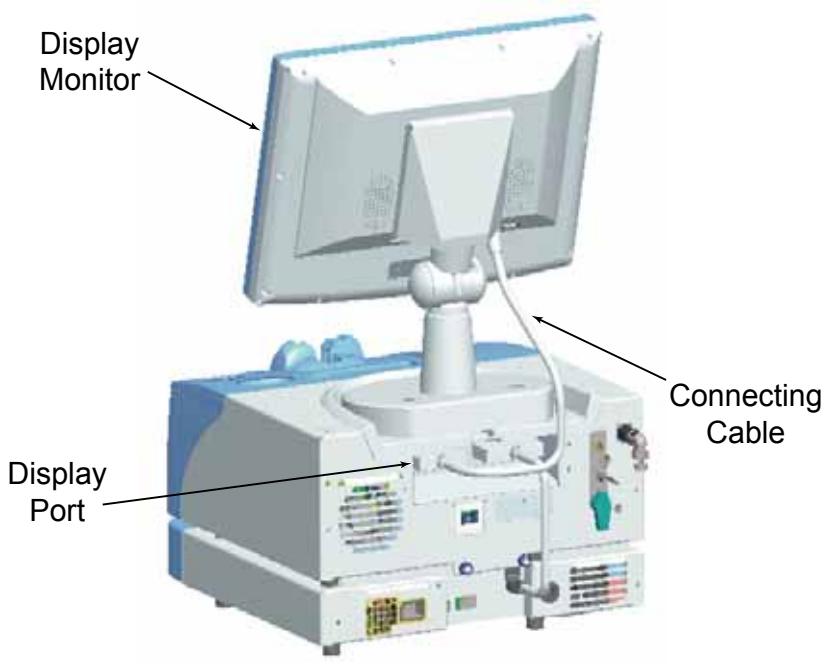


Figure 5-2 Attaching Display Monitor to Control Unit

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.

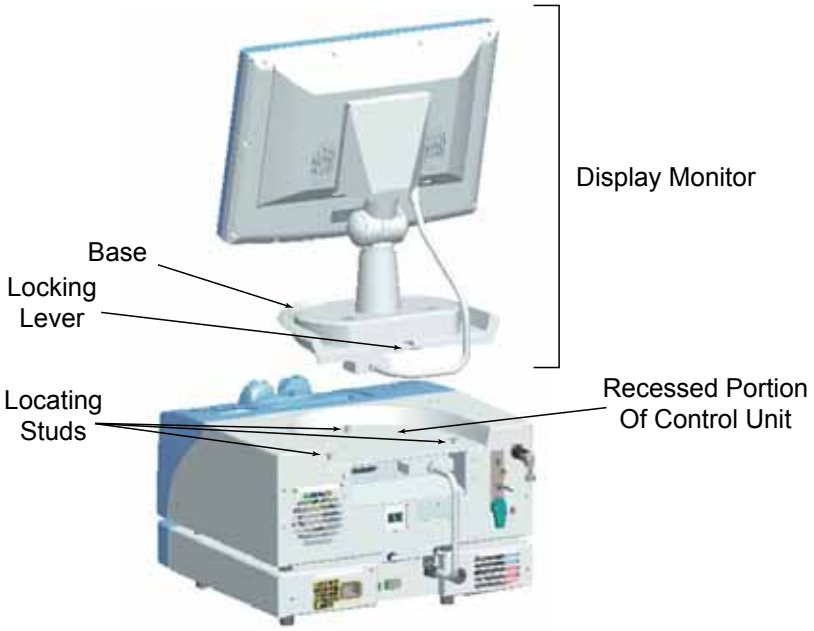


Figure 5-3 Back View of Assembled PRU

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® 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.

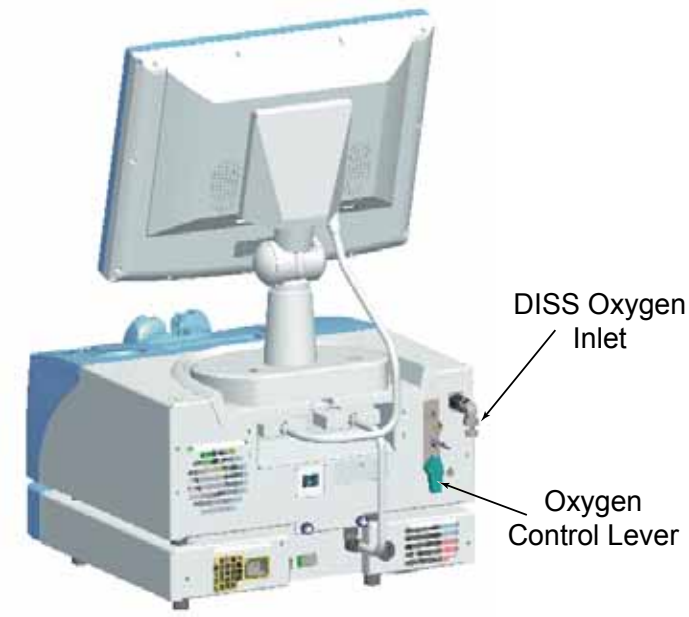


Figure 5-4 PRU Connection to Oxygen Source

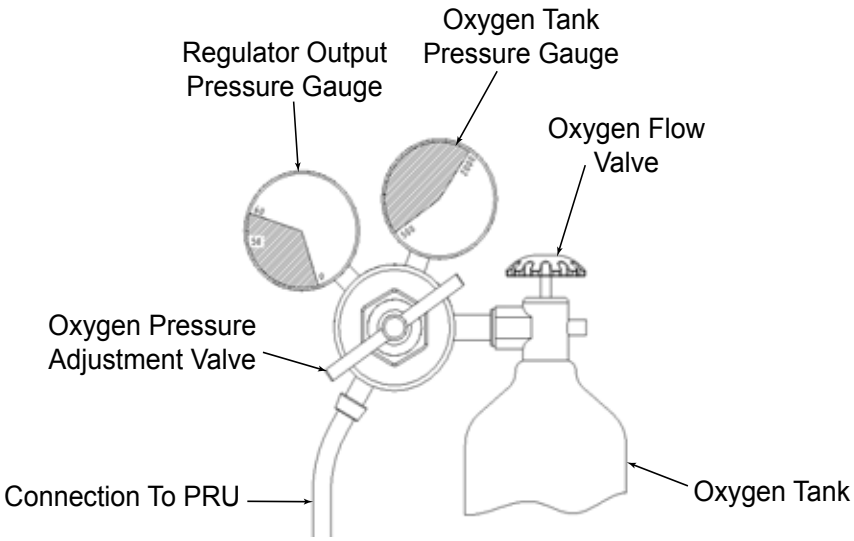


Figure 5-5 Pressure Regulator

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 40–60 psi required by the SEDASYS® System. The Pressure Regulator will have an Oxygen Tank Pressure Gauge that measures the internal pressure within the tank and a Regulator 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. On the Pressure Regulator, rotate the Oxygen Pressure Adjustment Valve counterclockwise to close the valve.
4. Connect the other end of the oxygen supply hose to the Pressure Regulator.
5. 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.
6. Open the Oxygen Flow Valve one-half turn counterclockwise to allow oxygen to flow from the Oxygen Tank.
7. 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 utilizes a sensor to measure oxygen concentration levels in the gas delivered from the oxygen source. If the oxygen concentration from this source is inadequate, the System does not permit oxygen delivery through the PRU and instead 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 Tank Flow Valve fully clockwise to close the valve and stop oxygen flow to the Pressure 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 Pressure Regulator.

PRU Power Management

The PRU, when temporarily disconnected from the AC power source, receives power from its internal backup 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 such as insulation gaps, cracks, and physical damage.

Precaution

1. Use only the approved IEC320 hospital-grade power cord that is supplied with the PSU.
2. 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.
3. To remove the PSU from the external power, you must disconnect the power cable from the wall outlet (Powering Off the PRU/PSU on page 5 - 9).

Figure 5-6 Back View of Assembled PRU

Powering on 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 wall outlet.

3. Turn on the Power Switch located on the back of the PSU to deliver power to the Control Unit.
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 minutes of battery life in 1-minute increments.

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 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. For assistance, call 1-800-SEDASYS.

PRU Operational Modes

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

Modes	Mode Indicators	Changing Modes
Off	• Screen is dark (off). • The **On/Off/Standby** button is not lit.	Press the **On/Off/Standby** button to get to Ready mode. **Caution:** The System will play an audio tone during start-up. Ensure that this tone is audible before using the System to verify proper function of the audio system. **Caution:** Do not touch the display touchscreen during start-up until the Ready Screen is displayed (refer to Figure 5-9 on page 5-11). Contact with the touchscreen may cause the System to lock-up during initialization.
On: Ready	• The PRU Ready screen is displayed • The **On/Off/Standby** button is lit.	• Press and release the **On/Off/Standby** button to get to Standby mode. • Press and hold the **On/Off/Standby** button for at least 3 seconds to get to Off mode. **Note:** 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. **Note:** The PRU will shut down from Ready mode within 3 minutes if external AC power is lost.

Table 5-1: Modes, Mode Indicators, and Changing Modes (Continued)

Modes	Mode Indicators	Changing Modes
On: Standby	• Screen is dark (off). • The **On/Off/Standby** button is lit.	To get to Ready mode: • Press the **On/Off/ Standby** button for less than 3 seconds. **- OR -** • Touch the screen. To get to Off mode: • Press and hold the **On/ Off/Standby** button for at least 3 seconds. **Note:** The PRU will change from Standby to the Ready mode if external AC power is lost.
On: In-Case	• The PRU Main Monitoring screen is displayed. • The **On/Off/Standby** button is lit.	Press the **End Case** button to get to Ready mode.

Powering Off the PRU/PSU

Proper shutdown of the PRU should be performed to prevent the premature discharge of the PSU battery pack. This process is described below.

1. Press and hold the On/Off/Standby Buttons on the front of the Control Unit until shutdown cycle begins (see Figure 5-8).

Figure 5-8 Powering Off PSU

2. After the shutdown cycle is complete, place the Power Switch on the back of the PSU into the Off Position.

3. On the back of the PSU, observe the bottom LED Indicator in the off state, indicating that power to the Control Unit has been shutoff.
4. The PSU Power Cable can now be disconnected from the wall outlet.

Changing PRU Facility Settings

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

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_2, blood pressure, $EtCO_2$, 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 $EtCO_2$).
- **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.

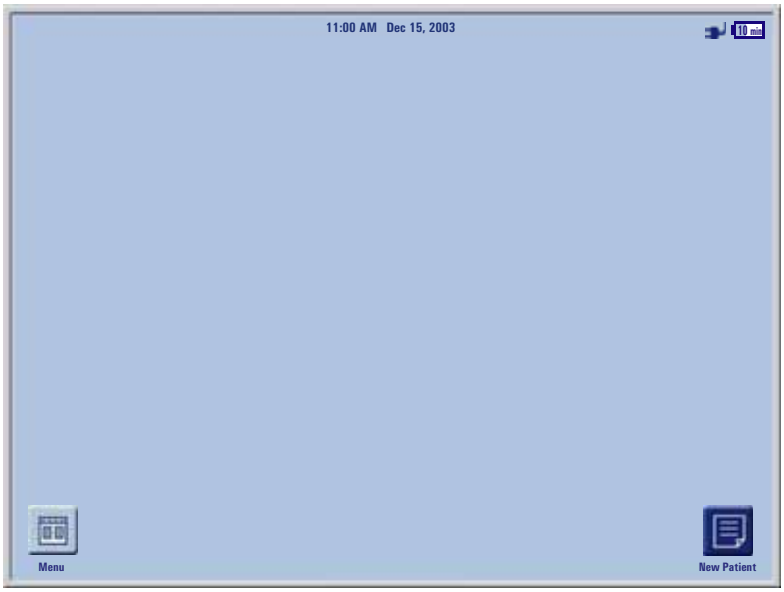


Figure 5-9 PRU Ready Screen

To change Facility Settings for the PRU:

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

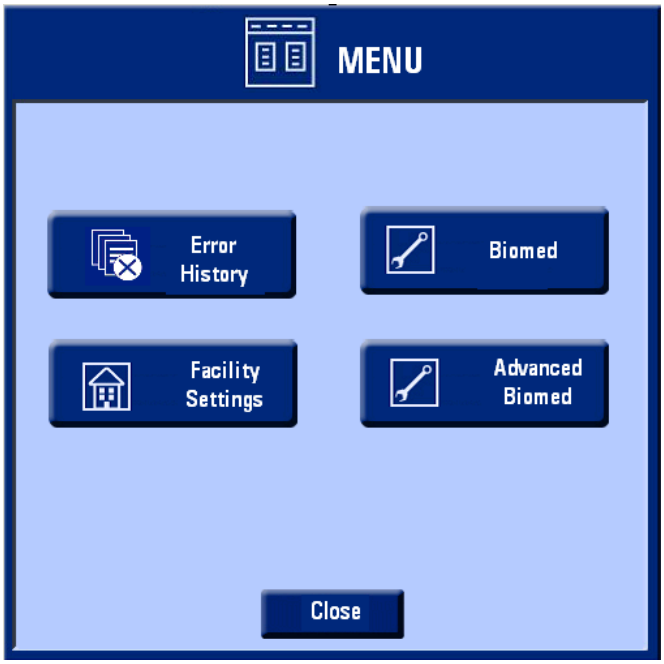


Figure 5-10 PRU Menu Screen

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 that can be printed.

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

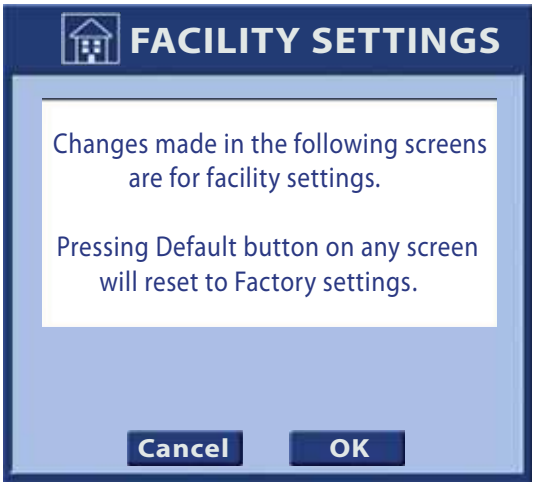


Figure 5-11 PRU Facility Settings Notification Screen

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

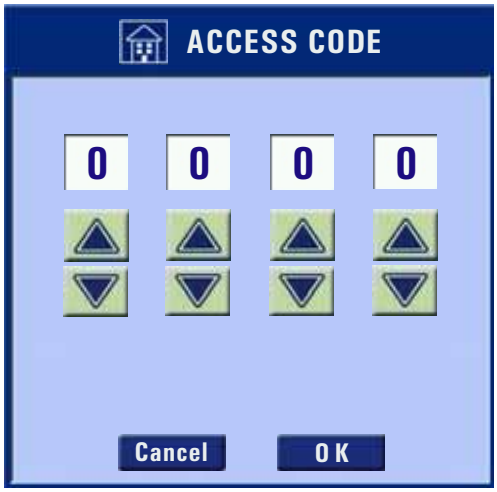


Figure 5-12 PRU Enter Access Code Screen

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

Note

The 4-digit access code cannot be changed.

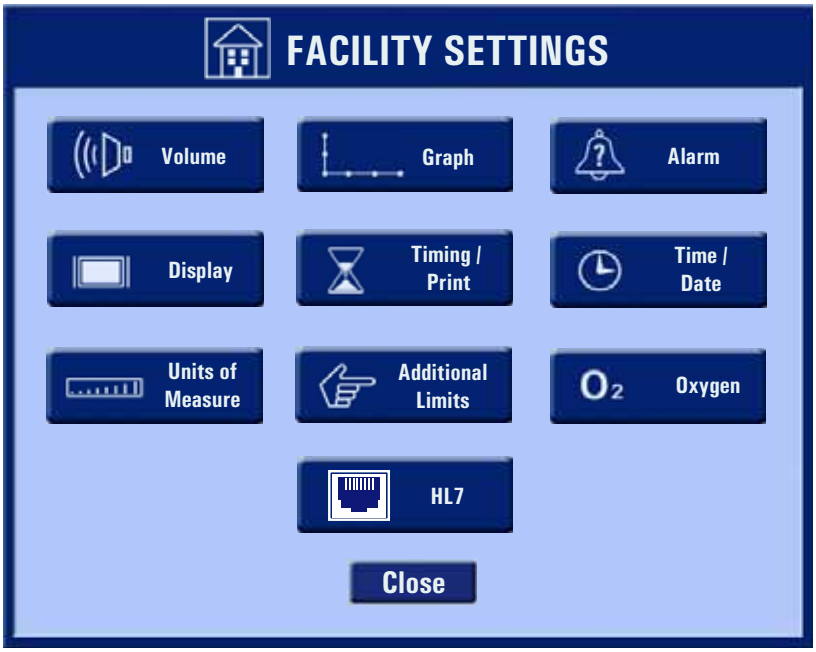


Figure 5-13 PRU Facility Settings Menu Screen

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 5-10 on page 5-12).
8. Press **Close** on the Menu screen to return to the PRU Ready screen (refer to Figure 5-9 on page 5-11).

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 5-13 on page 5-13):

Volume Settings

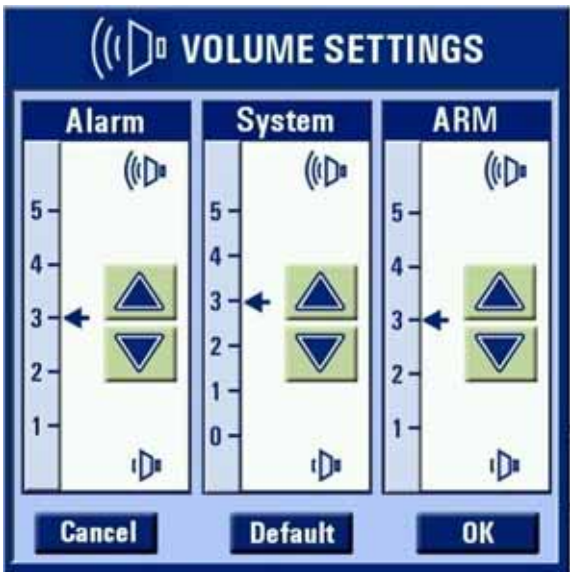


Figure 5-14 Volume Settings Screen

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

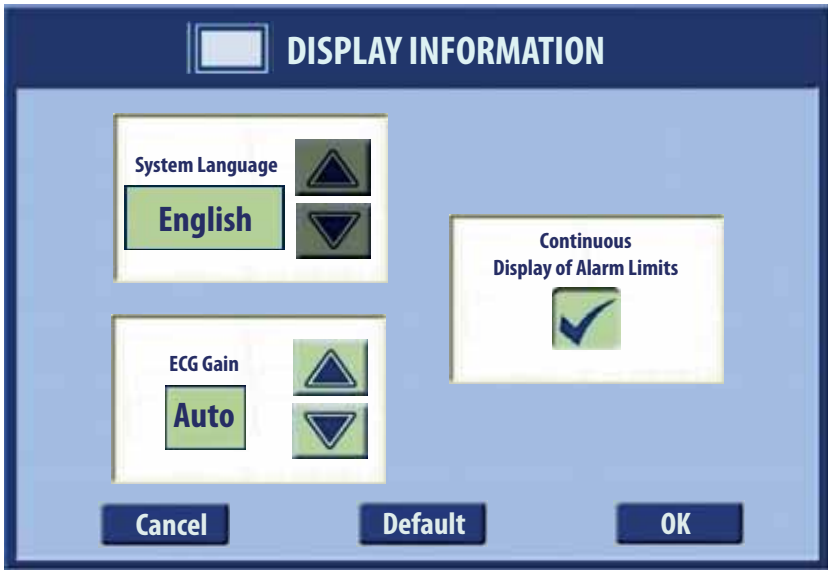


Figure 5-15 PRU Display Information Screen

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.

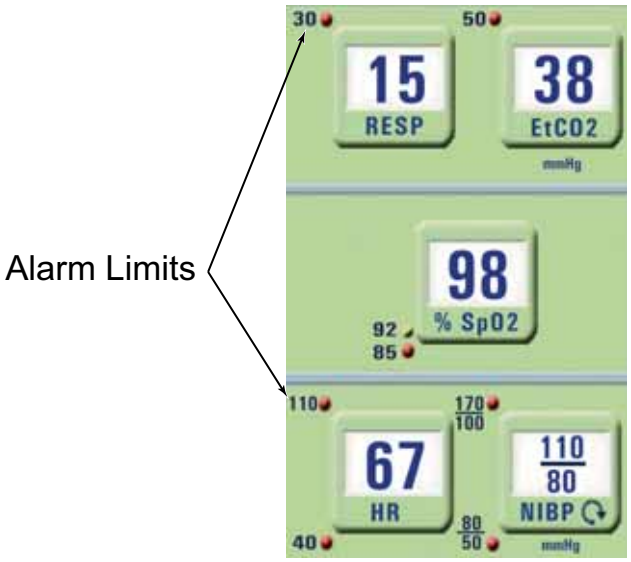


Figure 5-16 PRU Continuous Display of Alarm Limits

Units of Measure

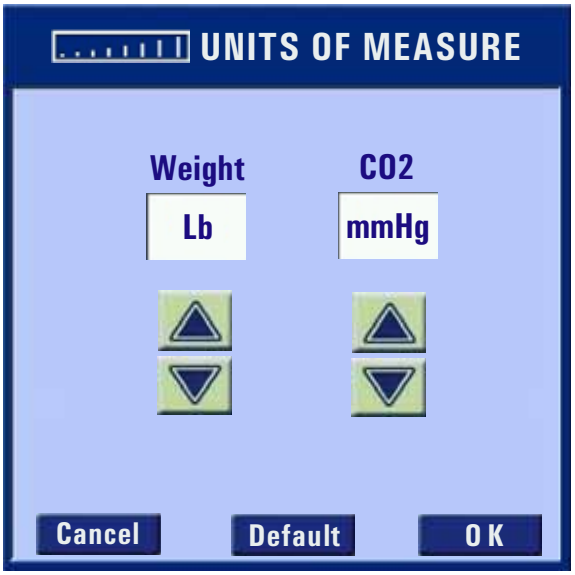


Figure 5-17 PRU Units of Measure Setting Screen

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

Graph Settings

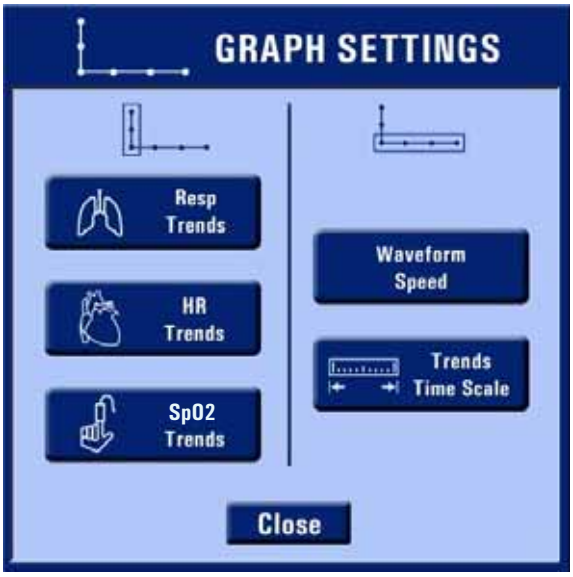


Figure 5-18 PRU Graph Settings Screen

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_2 Trends:** The vertical trend scale range displayed.
   - **Waveform Speed:** The sweep rate of the ECG/SpO_2 waveform and the CO_2 waveform in mm/s.
   - **Trends Time Scale:** The horizontal trend scale in minutes that is displayed in the “Trends” screen.

For example, if you press **SpO_2 Trends** or **Waveform Speed**, the following screens appear:

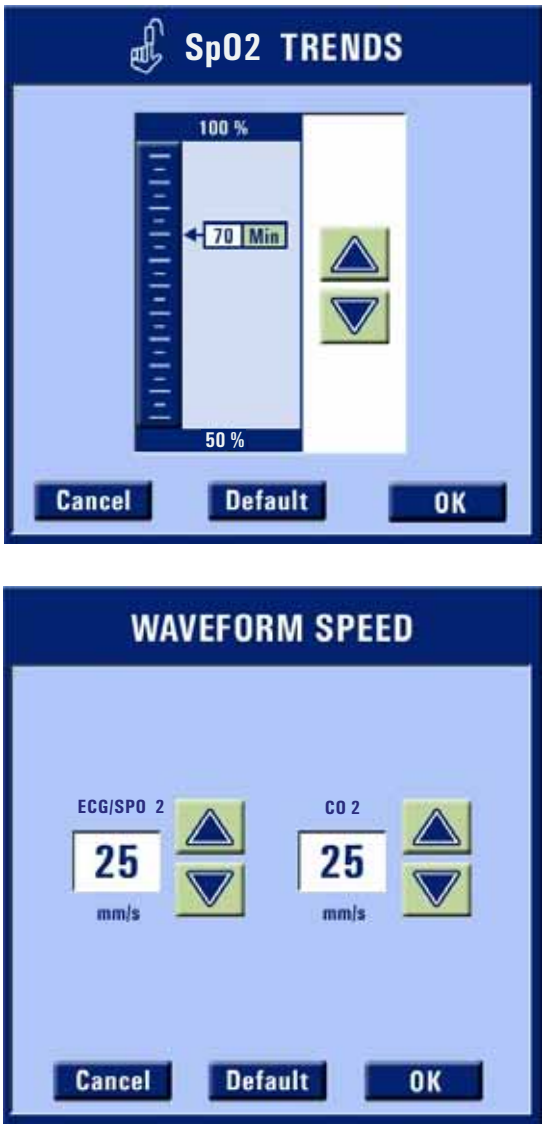


Figure 5-19 PRU SpO_2 Trends and Waveform Speed Screens

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

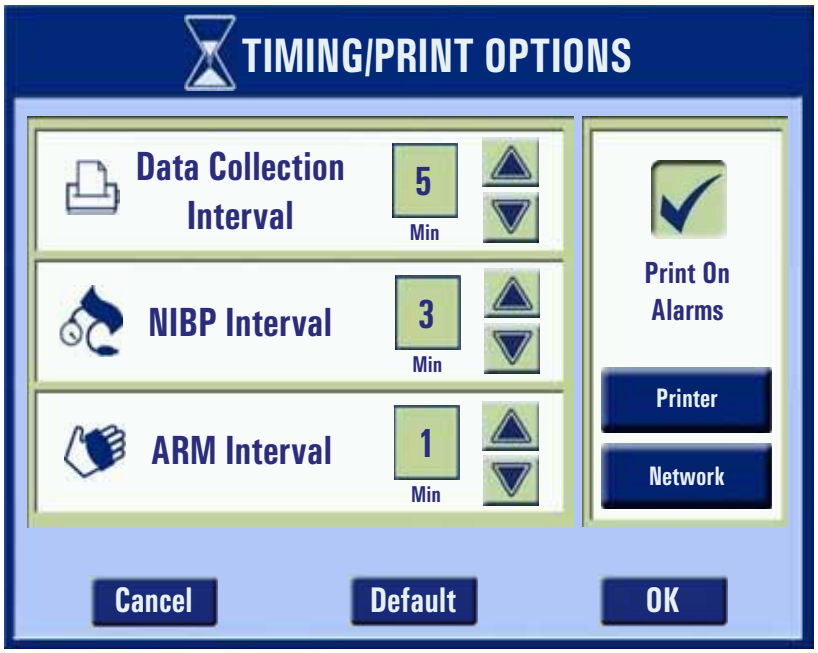


Figure 5-20 PRU Timing/Print Options Screen

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 - 16).

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

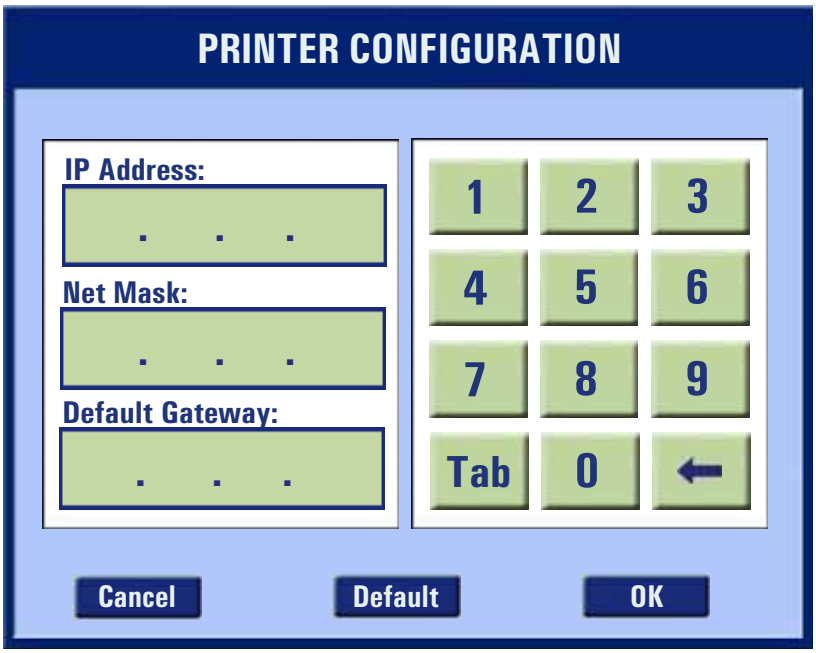


Figure 5-21 PRU Printer Configuration

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 5-20 on page 5-20).

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.

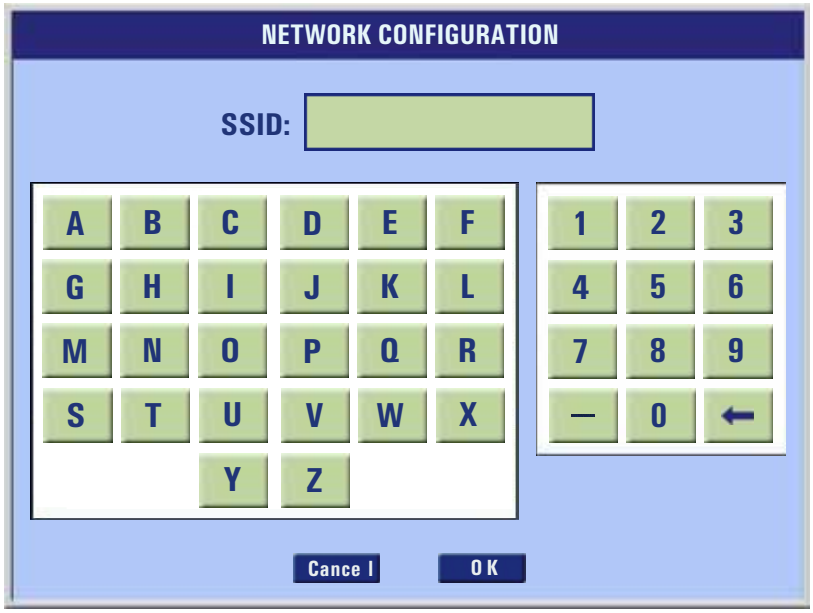


Figure 5-22 PRU Network Configuration

7. Enter the Service Set Identifier (SSID) of the wireless printer using the keypads. 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.

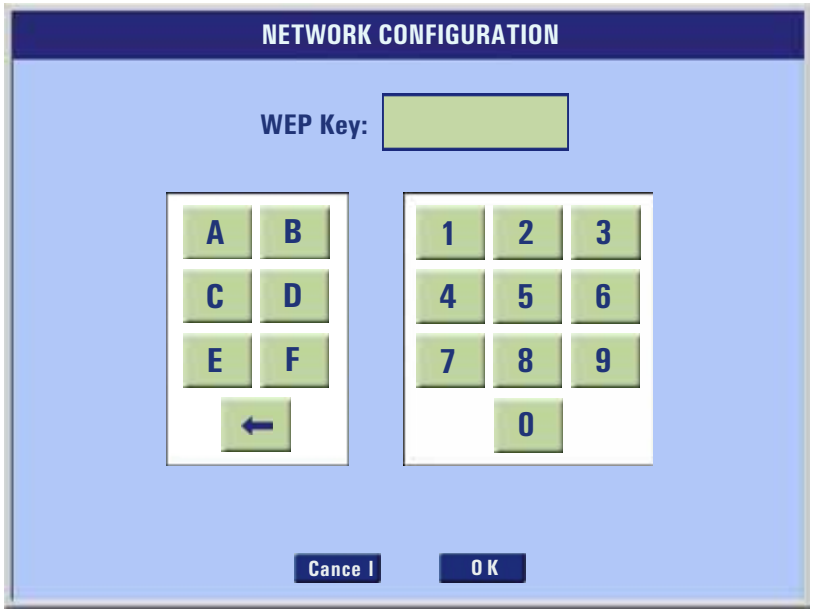


Figure 5-23 PRU Network Configuration

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® System is shipped from the factory with the additional limits disabled. The facility can enable these limits through the access code protected procedure.

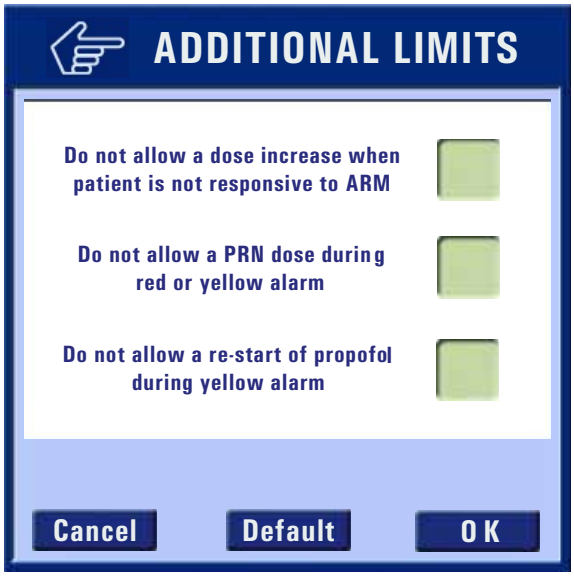


Figure 5-24 PRU Additional Limits Screen

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® 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® 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® 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.

Note

The options to restart drug delivery or deliver a PRN during an alarm are tools to help manage the administration of sedation if an alarm has been triggered by an artifact. As with any patient monitoring system, in response to an alarm you should assess the patient. If the alarm has been triggered by artifact you should take appropriate action to remove the source of the artifact. Otherwise, you should take the appropriate action to restore the patient's condition to normal.

Alarm Settings

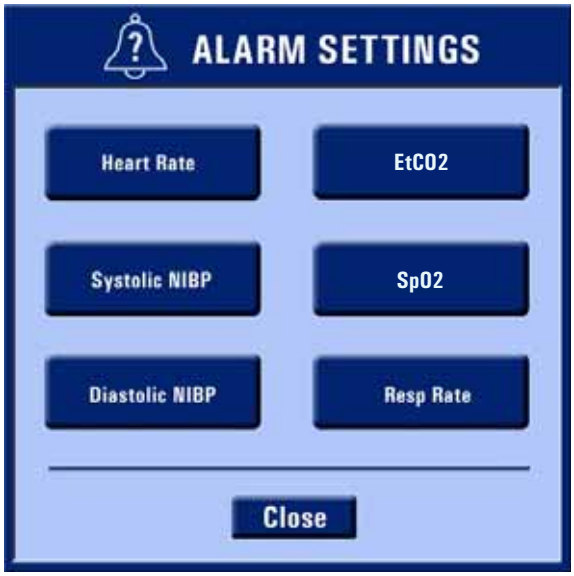


Figure 5-25 PRU Alarm Settings Screen

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)
   – **$EtCO_2$:** (Maximum)
   – **SpO_2:** 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:

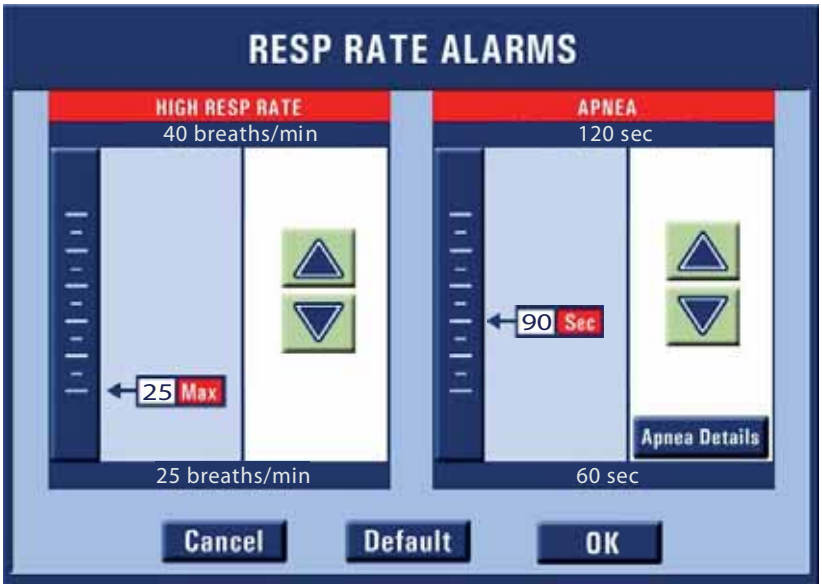


Figure 5-26 PRU Resp Rate Alarms Screen

2. 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_2 values. Changes to Respiration Rate or SpO_2 alarm limits will be shown in this graph. Press **Close** to return to the Resp Rate Alarms screen.

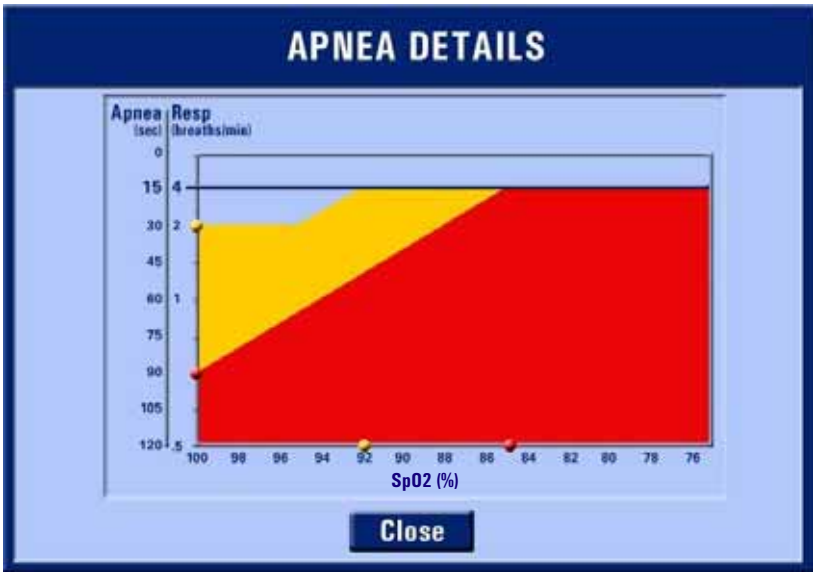


Figure 5-27 PRU Apnea Details Screen

Time/Date

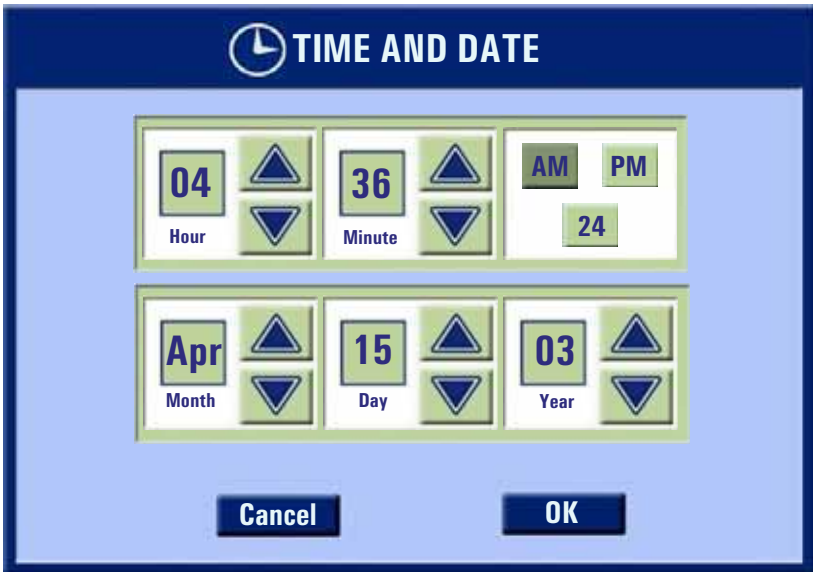


Figure 5-28 PRU Time and Date Screen

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

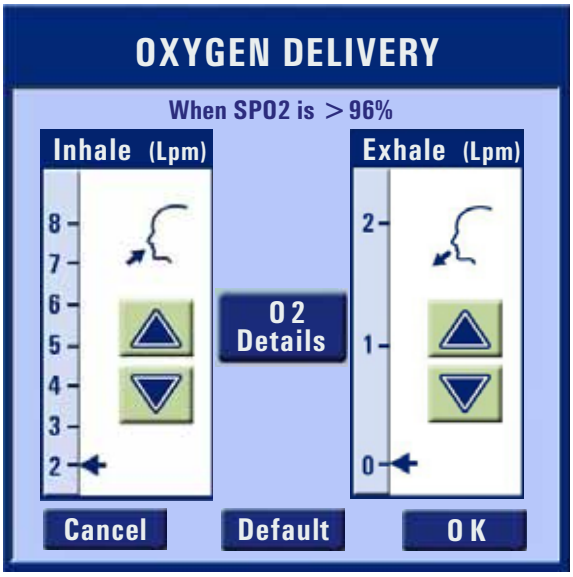


Figure 5-29 PRU Oxygen Delivery Screen

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_2 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_2 value. Press **Close** to return to the Oxygen Delivery screen.

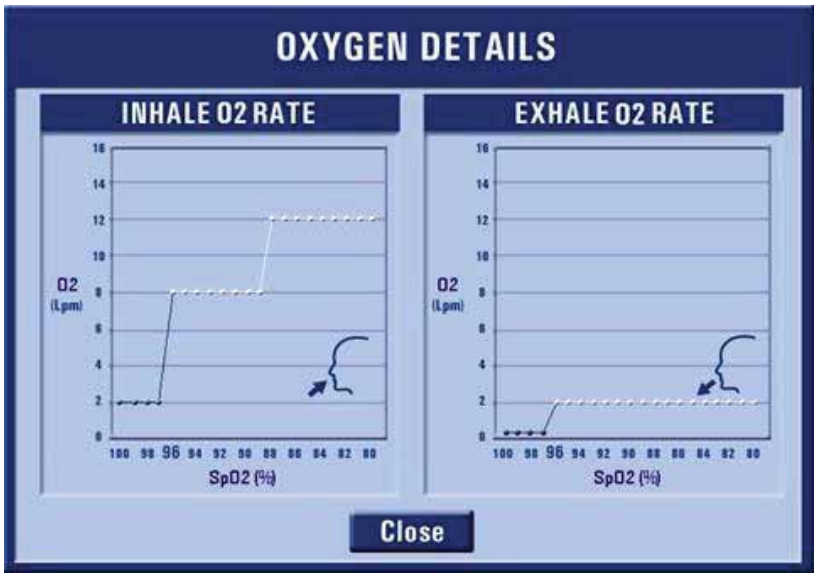


Figure 5-30 PRU Oxygen Details Screen

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_2 reading is greater than 96%.
2. For an SpO_2 reading of less than or equal to 96%, the System controls the oxygen delivery rate.
3. If the System is able to detect the inhalation/exhalation of the patient, the System will switch the oxygen delivery rate. Otherwise, oxygen will be delivered at a constant rate.

For more information about the PRU's default oxygen delivery at all SpO_2 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® System. If a connection to an external information system is not being used, this section can be skipped.

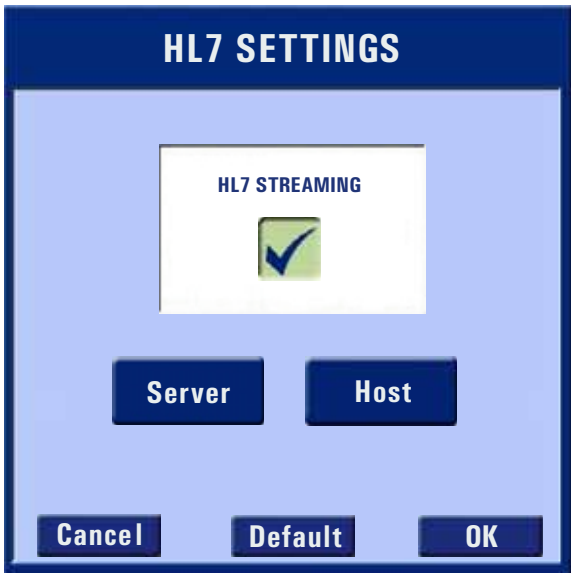


Figure 5-31 PRU HL7 Settings Screen

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.

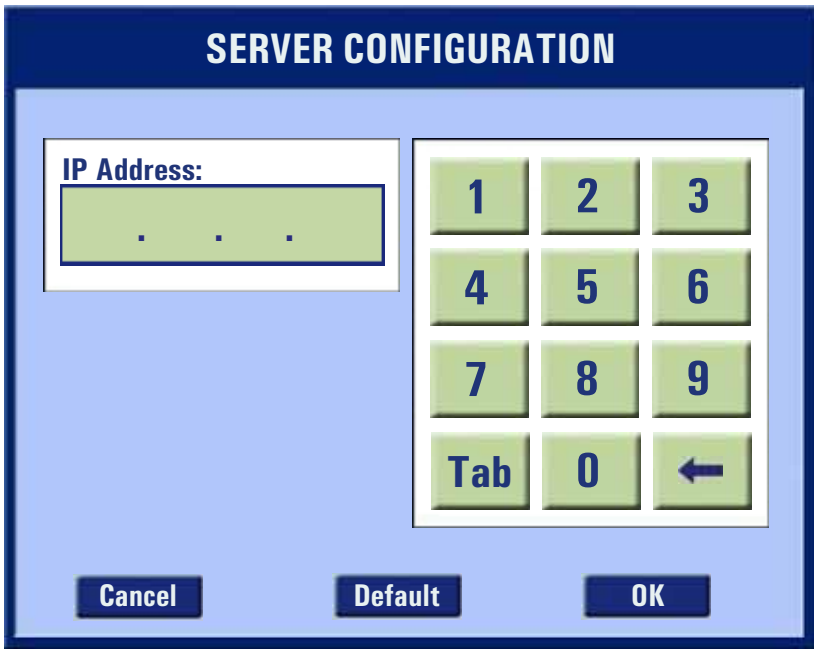


Figure 5-32 PRU HL7 Server Configuration Screen

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 5-31 on page 5-30).
4. Select and press the **Host** button.

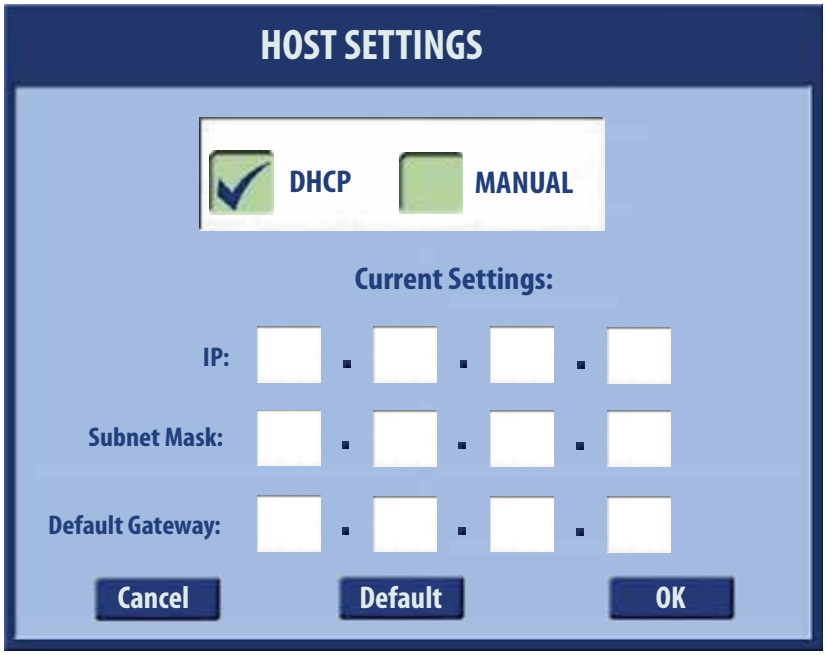


Figure 5-33 PRU HL7 Host Settings Screen

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 time accessed.

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

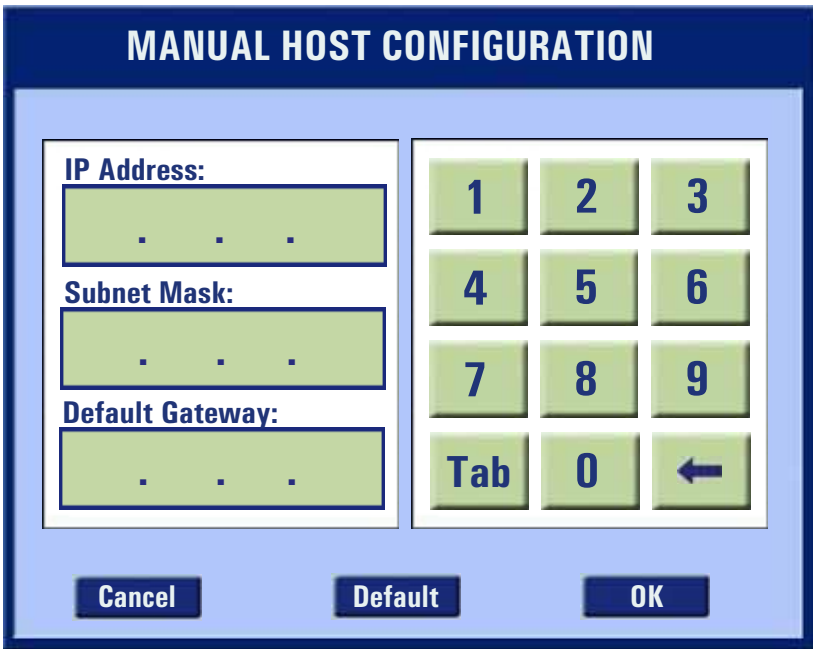


Figure 5-34 PRU HL7 Manual Host Settings Screen

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.

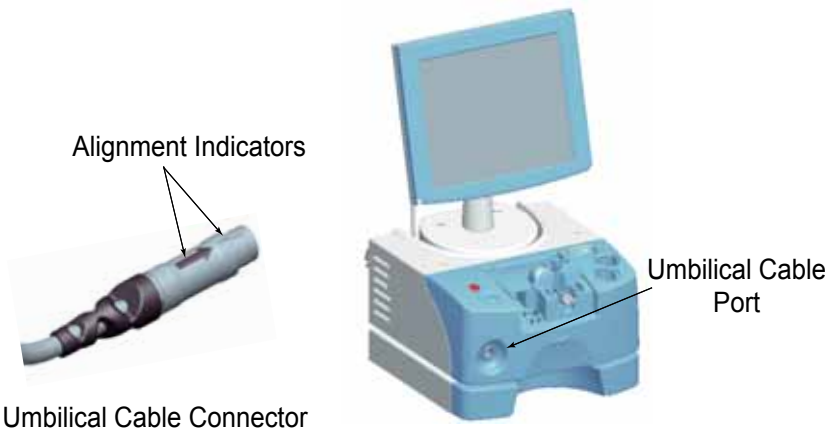


Figure 5-35 Umbilical Cable to PRU

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.

This page is intentionally left blank

Chapter 6 Procedural Use

Preparing the Patient

Insert an intravenous (IV) catheter into the patient per facility protocol. It is recommended to attach a 3-way stopcock or Y-Connector (not to exceed 0.45 ml max volume) to the end of the IV catheter. The Drug Delivery Cassette tubing can be connected directly to the 3-way stopcock or Y-Connector (not to exceed 0.45 ml max volume) of an IV catheter.

WARNING

When using a standard IV set to administer additional fluids (i.e., saline drip) to the patient, make sure it contains an integrated back-check valve to prevent inaccurate dosing of propofol.

Note

1 It is recommended that all IV set components utilize locking luer fittings to maintain a secure connection.

2 It is recommended that the IV catheter be placed into the patient's right arm to facilitate optimal placement of the monitoring devices.

Initiating a New Case on the BMU

A new patient case is typically initiated in the pre-procedure area of your facility. At the end of this section, the steps required for the Bedside Monitoring Unit (BMU) to monitor SpO_2, Heart Rate and Non-Invasive Blood Pressure (NIBP), and patient training for use of the Automated Responsiveness Monitor (ARM) will be complete. The patient and BMU will then be ready for transport to the procedure room and connection to the PRU (refer to Connecting the BMU to the PRU on page 6-11).

Note

If your facility prepares the patient in the procedure room and the BMU is already connected to the PRU, all of the steps in this section should still be followed.

Before starting a new case, the BMU should be powered on with the following Ready screen displayed (refer to Table 4-2 on page 4-7 for instructions on accessing this screen):

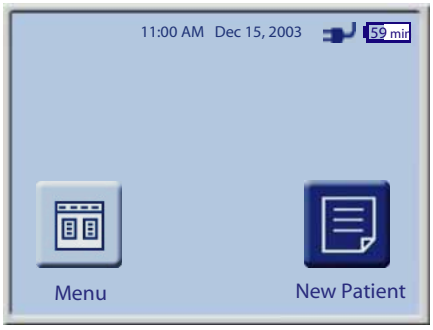


Figure 6-1 BMU Ready Screen

1. Select **New Patient** from the BMU Ready screen.

Note

1 If “Enable ID Entry” has been selected during facility installation (refer to Figure 4-20 on page 4-14), proceed to step 2.

2 If “Enable ID Entry” has not been selected during facility installation, the System will automatically generate a 5-digit patient identifier when New Patient is selected on the Ready screen. This patient identifier will be displayed on the BMU and PRU screens and printed on the hardcopy patient record. Skip step 2 and proceed to step 3.

2. Using the numeric keypad, enter up to a 9-digit patient identifier that will be displayed on the BMU and PRU screens and printed on the hardcopy patient record. Once the identifier is entered, press **OK** to display the BMU Monitoring screen.

Figure 6-2 BMU ID Entry Screen

Note

At least one digit must be entered for the patient identifier.

3. Numeric values for SpO_2, Heart Rate, and NIBP will be automatically displayed as the monitors are connected to the patient. Refer to *Appendix D: BMU Monitoring Screen* for a description of system functions that can be reached through the BMU Monitoring screen.

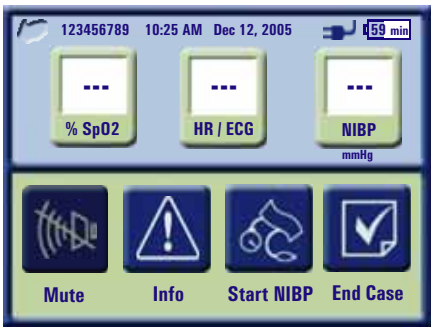


Figure 6-3 BMU Monitoring Screen

Connecting the Oral/Nasal Cannula

WARNING

The Oral/Nasal Cannula is packaged non-sterile for single-patient use only. Do not re-use or sterilize. Re-use of the cannula may result in transmission of infectious disease(s) from one patient to another, which could lead to injury or illness. Sterilization may compromise structural integrity and/or lead to failure of the Oral/Nasal Cannula.

Connect the Oral/Nasal Cannula to the BMU

1. Open a new Oral/Nasal Cannula package by grasping the two small notches on the bottom end of the package and tearing it open.

Figure 6-4 Connecting Oral/Nasal Cannula to BMU

2. Align the triangular-shaped Oral/Nasal Cannula connector with the Oral/Nasal Cannula port on the front of the BMU. Push the connector until it clicks in place.

Attach the Oral/Nasal Cannula Earpiece to the Patient

The Oral/Nasal Cannula includes the earpiece used for the audible stimulus of the ARM responsiveness tests.

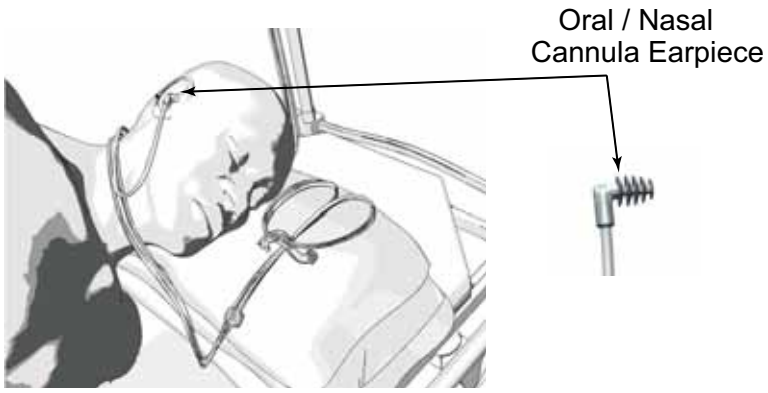


Figure 6-5 Attaching Earpiece Portion of Oral/Nasal Cannula to Patient

1. Remove any hearing aid from the patient's ear into which the earpiece will be inserted.
2. Insert the Oral/Nasal Cannula Earpiece securely into the patient's ear.

Note

1 For continued comfort of the patient, connecting the remainder of the Oral/Nasal Cannula to the patient does not need to be completed at this time. This action, however, must take place prior to initiation of drug delivery (refer to Connecting the Oral/Nasal Cannula on page 6-15 for instructions).

2 After connecting the earpiece to the patient, ensure that the earpiece tubing is not pinched or beneath the patient.

Attaching the ARM Handset

The ARM Handset delivers a tactile stimulus by vibrating within the patient's hand. The patient responds to the stimulus by squeezing the handset.

Figure 6-6 ARM Handset Attached to Patient's Hand

1. Place the ARM Handset in the patient's left hand.

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.

2. Secure the ARM Handset strap around the back of the patient's hand.

ARM Training

1. Instruct patient to squeeze the ARM Handset for 3 seconds to initiate ARM training. The following screen appears on the BMU:

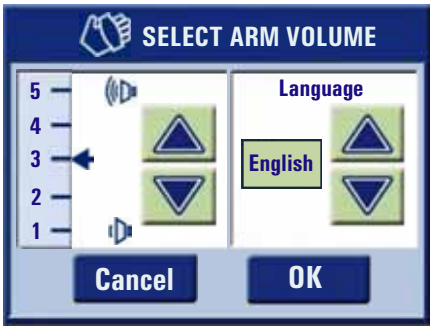


Figure 6-7 BMU Select ARM Volume Screen

2. Select the appropriate ARM Language for the patient by pressing the **Up** or **Down Arrow** buttons.

Note

All communication to the patient, including the audio tutorial, will be in the selected ARM language. If the patient is unable to understand any of the available languages, the clinician may have to respond for the patient.

3. Increase or decrease the ARM volume level (heard through the earpiece portion of the Oral/Nasal Cannula) by pressing the **Up** or **Down Arrow** buttons. Each time the volume level is changed with the **Up** or **Down Arrow** buttons, the audio message "*Can you hear me?*" is played for the patient. Confirm that the patient is able to hear and understand the audible message.

Note

If the patient is unable to hear the audio message at the highest volume level, the clinician may have to respond for the patient. For more information, refer to Clinician-Response Mode on page 6-36.

Press **OK** to confirm the correct language and volume level for the patient. This begins ARM training. The BMU provides a short audio tutorial through the earpiece. The patient hears the following message:

"Hello. During this procedure, you will be sedated and monitored. One of the monitors is the handset placed in your hand. I am going to explain what the handset is for and how it works. Throughout the procedure, I will ask you to squeeze the handset and at the same time, the handset will vibrate. It is important that you squeeze the handset every time it vibrates. Just to practice, we will begin a series of up to 3 vibrations. Remember to squeeze the handset every time it vibrates. We will begin the first vibration now…"

The following screen appears while the BMU conducts ARM training:

Figure 6-8 BMU ARM Training In Progress Screen

After receiving the vibration and audible commands ("*Please squeeze the handset*"), if the patient takes 5 seconds or less to squeeze the handset, the test is recorded as successful. The next test begins 1 second later.

After receiving the vibration and audible commands, if the patient does not respond by squeezing the handset within 5 seconds, the test is recorded as incomplete. The next test begins 1 second later.

The patient must successfully complete two of the three responsiveness tests to demonstrate the patient's ability to use ARM. If the first two tests are successful, the third test is not administered.

If the patient has not successfully completed two of the three responsiveness tests, the patient is not considered to have passed ARM training. The clinician can repeat ARM training or choose to use Clinician Response mode.

ARM Training Complete

If the patient passes two of the three tests, the following screen appears. This screen will automatically close after a few seconds.

Figure 6-9 BMU ARM Training Complete Screen

ARM Training Incomplete

If the patient does not pass two of the three tests, the following screen appears:

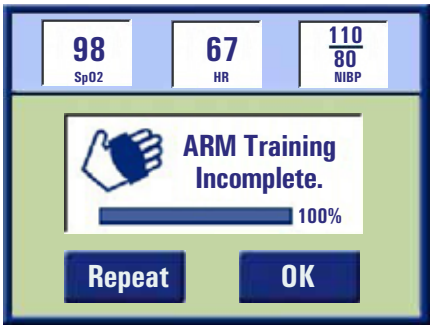


Figure 6-10 BMU ARM Training Incomplete Screen

If the ARM Training Incomplete screen appears, you have the following two options:

- Press **Repeat** to repeat the ARM training.

- OR -

- Press **OK** to accept incomplete ARM training, allowing you to use the Clinician Response mode in the procedure. For more information, refer to Clinician-Response Mode on page 6-36.

Attaching the NIBP Cuff

Note

It is recommended that the NIBP cuff be attached to the patient before attaching the Pulse Oximeter or Electrocardiogram (ECG). This is because the System automatically initiates the NIBP interval measurements within 8 seconds of the initial pulse oximetry reading or ECG heart rate value.

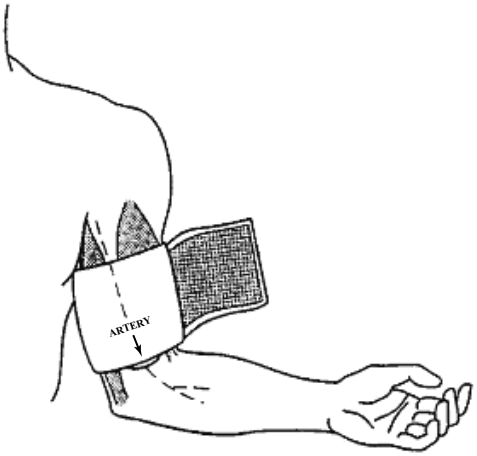


Figure 6-11 Attaching NIBP Cuff to Patient

1. Select the appropriate cuff size that corresponds to the circumference of the patient's arm. Use the *Range Lines* on the inside of the cuff to determine the correct size cuff to use.

Precaution

Using the wrong size cuff may result in inaccurate blood pressure readings.

The available NIBP cuff sizes are:
- Small adult: 170-250 mm
- Adult: 230-330 mm
- Large adult: 310-400 mm
- Thigh: 380-500 mm

2. Attach the NIBP cuff to the patient's arm. When wrapping the cuff around the arm, make sure that the *Artery Marker* is aligned over the brachial artery between the biceps and triceps muscles on the inside of the arm as shown in Figure 6-11.

Precaution

1 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.

2 Ensure the patient's skin is intact before applying the cuff.

3. Make sure that the tubing connecting the BMU to the cuff is not compressed, crimped, or damaged.

Precaution

1 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.

2 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 result in limb ischemia and associated clinical sequelae.

3 Avoid contact with the cuff, other than that of the patient's limb, while the measurement is in process.

Attaching the Pulse Oximeter Probe

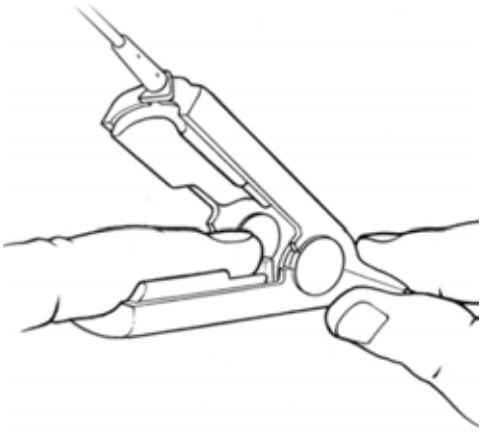


Figure 6-12 Attaching Pulse Oximeter Probe to Patient

Place the Pulse Oximeter probe on the patient's index or middle finger making sure the finger icon on the probe is placed over the patient's fingernail. The sensor cable extends along the top of the patient's hand.

The BMU automatically begins monitoring and displaying the SpO_2 value and heart rate measurements, and automatically initiates the NIBP measurement within 8 seconds of the initial pulse oximetry reading. The systolic and diastolic pressure values will be displayed as soon as the first NIBP measurement is complete.

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, fingernail polish, and artificial fingernails may affect the accuracy of the SpO_2 measurements.

Note

Remove any fingernail polish on the patient's finger before placing the probe.

Attaching the 3-Lead ECG Wire Set

To attach the ECG wire set to the patient, first prepare the patient's skin per facility protocol and then attach the electrodes to the lead wires and place on the patient's chest. The BMU will automatically monitor and display the ECG waveform.

ECG Electrodes

1. Inspect the electrodes to ensure they have adequate gel and are not dry.

Note

The SEDASYS® System is compatible with Ag/AgCl ECG gel electrodes.

2. Attach the electrodes to the three ECG lead wires.
3. Attach the three ECG electrodes to the patient's chest for a Lead II configuration:
   - Place one electrode on the patient in the right arm (RA) position with the white (negative) lead wire.
   - Place one electrode on the patient in the left leg (LL) position with the red (positive) lead wire.
   - Place one electrode on the patient in the left arm (LA) position with the black (neutral) lead wire.

Precaution

Improper electrode placement may lead to inaccurate ECG readings.

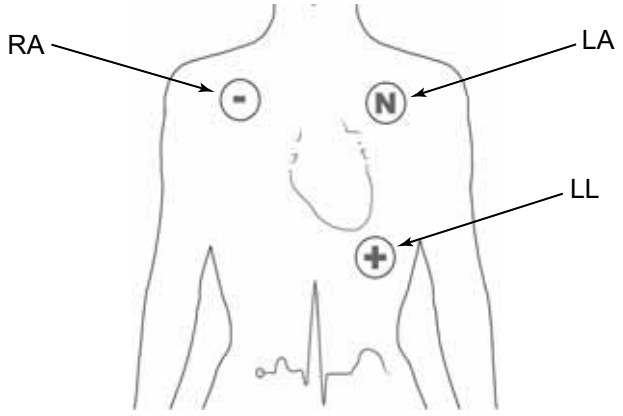


Figure 6-13 Lead II ECG Electrode Placement[a]

a. © 1999, Health Interactive

Connecting the BMU to the PRU

When the patient is brought into the procedure room, the BMU must be connected to the PRU with the Umbilical Cable.

Before connecting the BMU to the PRU, the PRU should be powered on with the following Ready Screen displayed (refer to Table 5-1 on page 5-8 for instructions on accessing this screen):

Figure 6-14 PRU Ready Screen

Note

If the PRU is not previously turned on when the BMU is connected, the PRU will automatically power on when the powered-on BMU is connected.

To insert the Umbilical Cable Connector into the Umbilical Cable Port on the bottom of the BMU, align the Alignment Indicator (red dot) on the

Umbilical Cable Connector with the red dot on the BMU Umbilical Cable Port and push the connector until it clicks into place.

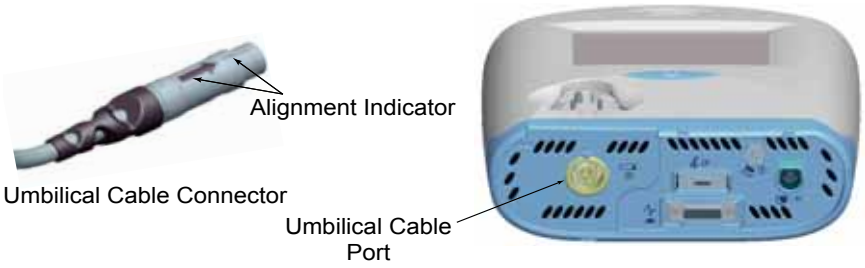


Figure 6-15 Umbilical Cable to BMU

Note

1. The Umbilical Cable should already be connected to the PRU (refer to Connecting the Umbilical Cable to the PRU on page 5-33).
2. The two connectors on either end of the Umbilical Cable are identical. Therefore, either end of the Umbilical Cable can be connected to the BMU.

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.

Entering Patient Weight and Dose Rate

1. After the Umbilical Cable is connected to the BMU, the PRU automatically displays the following screen:

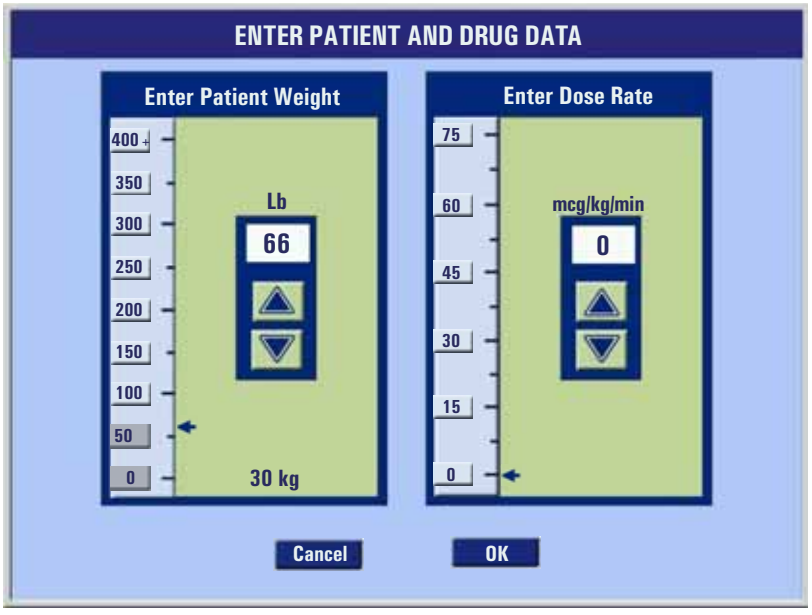


Figure 6-16 PRU Enter Patient and Drug Data Screen

2. Select and press the numeric button located on the left side of the screen below Enter Patient Weight (e.g., 100, 150, 200) that most closely corresponds to the patient's weight.
3. Press the **Up** or **Down Arrow** button to select the patient's weight (in increments of 1 lb or 1 kg).

WARNING

Always verify patients weight, including proper unit of measure (lb or kg), when beginning a new case. Failure to do so may result in improper dosing of propofol.

Note

1 The minimum allowable patient weight is 66 lb (30 kg). The maximum allowable patient weight is 440 lb (200 kg).

2 The unit of measure for the patient weight entry is set during facility installation (refer to Units of Measure on page 5-17).

4. Select and press the **Dose Rate** button located on the left side of the screen (refer to Figure 6-17 on page 6-14). Enter Dose Rate (e.g., 15, 30, 45, 60, 75 mcg/kg/min) that most closely corresponds to the desired initial dose rate.
5. Press the **Up** or **Down Arrow** button to enter the initial dose rate determined by the physician (in increments of 5 mcg/kg/minute).

Note

The maximum allowable dose rate is 75 mcg/kg/minute to initiate sedation.

6. Press **OK** to accept the data entered. The PRU will display the Monitoring Screen and the BMU will display the Remote Entry screen.

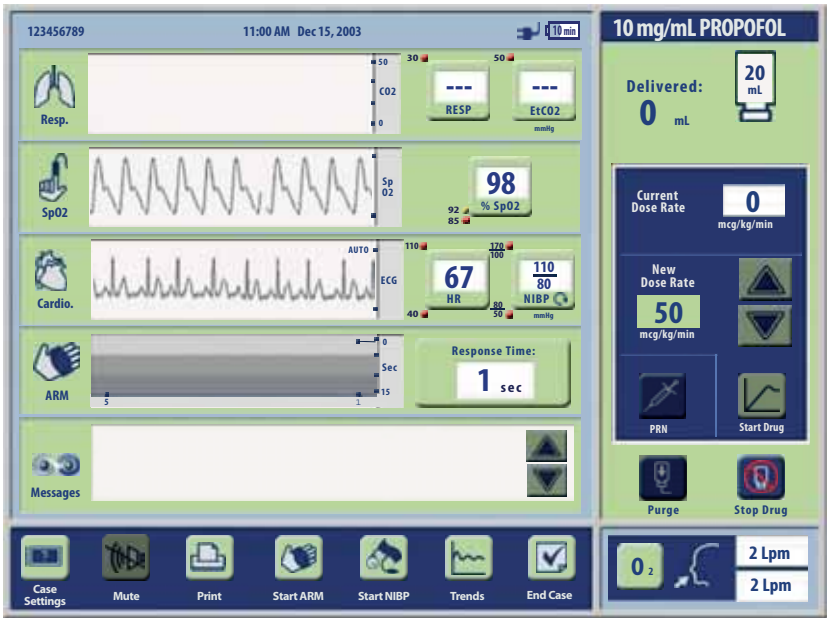


Figure 6-17 PRU Monitoring Screen

Note

Refer to *Appendix C: PRU Monitoring Screen* for a full description of all system functions that can be reached from the PRU Monitoring screen.

Figure 6-18 BMU Remote Entry Screen

Note

Refer to *Appendix E: BMU Remote Entry Screen* for a description of system functions that can be reached from the BMU Remote Entry screen.

Connecting the Oral/Nasal Cannula

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 Do not place a surgical drape over the patient's head while measuring CO_2 or delivering oxygen.

Place the Oral/Nasal Cannula on the Patient for Colonoscopy

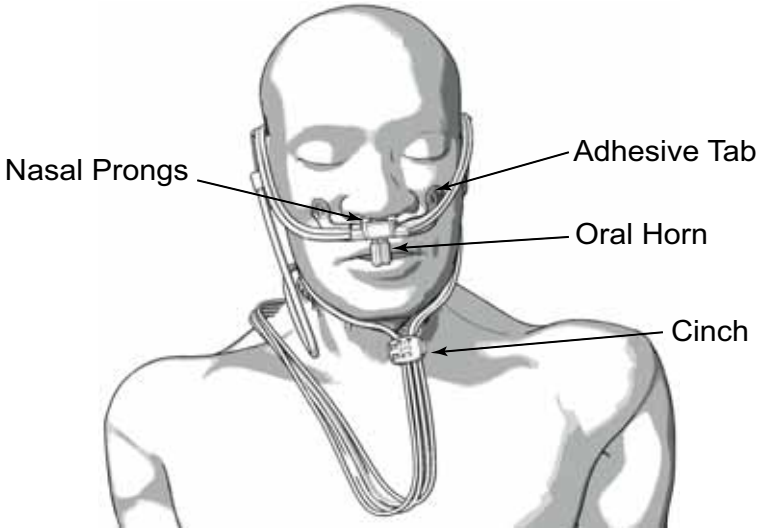


Figure 6-19 Oral/Nasal Cannula on Patient

1. Position the two Nasal Prongs of the Oral/Nasal Cannula into the patient's nares.
2. Slide the extension of the Oral Horn until it is centered between the patient's lips.
3. Wrap the tubing around the patient's ears and Cinch the tubing securely under the patient's chin.

Note

If needed, remove the Adhesive Tab covers from the wings of the Oral/Nasal Cannula and attach the wings to the patient's face to provide a more secure fit.

Precaution

The Adhesive Pad on the Oral/Nasal Cannula is manufactured from hypoallergenic, pressure sensitive, acrylate adhesive. Some patients may be sensitive or allergic to adhesive.

4. Make sure the Earpiece is still securely placed in the patient's ear and the two Nasal Prongs remain positioned within the patient's nares.

Place the Oral/Nasal Cannula on the Patient for EGD

1. Position the two Nasal Prongs of the Oral/Nasal Cannula into the patient's nares.
2. Slide the extension of the Oral Horn until it is centered between the patient's lips.
3. Wrap the tubing around the patient's ears and Cinch the tubing securely under the patient's chin.

Note

If needed, remove the Adhesive Tab covers from the wings of the Oral/Nasal Cannula and attach the wings to the patient's face to provide a more secure fit.

Precaution

The Adhesive Pad on the Oral/Nasal Cannula is manufactured from a hypoallergenic, pressure sensitive, acrylate adhesive. Some patients may be sensitive or allergic to adhesive.

4. Make sure the Earpiece is still securely placed in the patient's ear and the two Nasal Prongs remain positioned within the patient's nares.

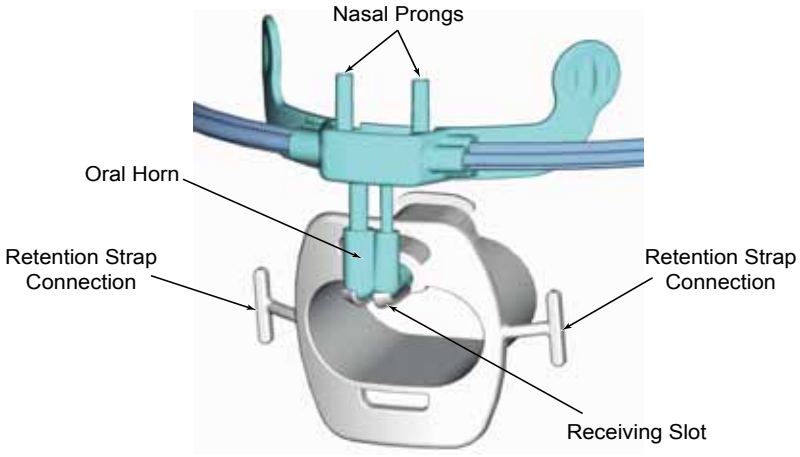


Figure 6-20 Oral/Nasal Cannula with Bite Block

5. When ready to insert the scope or esophageal dilator, place the Bite Block into the patient's mouth. If desired for your facility, connect the Retention Strap to the Bite Block and position the strap around the patient's head.

Precaution

The Bite Block must be used during EGD procedures to enable proper function of the Oral/Nasal Cannula in the presence of a scope or an esophageal dilator.

6. Place the Oral Horn into the receiving slot of the Bite Block.
7. Make sure the Earpiece is still securely placed in the patient's ear, the two Nasal Prongs remain positioned within the patient's nares, and the Oral Horn remains positioned within the Bite Block.

Administering Fentanyl

The SEDASYS® System is designed to be used with a **single** pre-procedure dose of fentanyl given approximately 3 minutes before the start of propofol infusion. The fentanyl is given because propofol has limited analgesic properties.

The following dose of fentanyl should be administered:

- 50–100 µg IV bolus for patients ≤ 64 years of age.
- 25–50 µg IV bolus for patients ≥ 65 years of age.

WARNING

1. Only a single pre-procedure dose of fentanyl should be administered. Administration of fentanyl beyond the start of the procedure increases the risk of severe respiratory depression.
2. Do not administer fentanyl until all of the patient monitors are connected.
3. Do not supplement the single pre-procedure doses of fentanyl with additional doses of any other analgesic (e.g., meperidine) as this may result in overdosing and respiratory depression.
4. Further guidance on the administration of fentanyl during sedation, overdose and associated adverse reactions can be found in the fentanyl package insert.

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 3 minutes before initiating propofol delivery with the SEDASYS® System.

Loading the Drug Delivery Cassette

The PRU drug delivery unit allows the delivery of propofol directly from the propofol vial.

WARNING

1. The Drug Delivery Cassette is packaged sterile for single-patient use only. Do not re-use or re-sterilize. Re-use of the cassette may result in the transmission of infectious disease(s) from one patient to another, leading to injury, illness, or death. Re-sterilization may compromise structural integrity and/or lead to cassette failure that in turn may result in patient injury.
2. Do not use the Drug Delivery Cassette if its sterile package is damaged or if past the labeled expiration date.

Using the Bar Code Scanner

The Bar Code Scanner protects the patient by ensuring that the single-patient use Drug Delivery Cassette has not been previously used.

Figure 6-21 Laser Caution Label

Precaution

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Note

The laser **CAUTION** label is located on the rear of the PRU.

Figure 6-22 Drug Delivery Cassette with Bar Code

1. Make sure the Bar Code on the package (located in upper right-hand corner of the package) is flat and smooth.
2. Position the Bar Code face-up under the Bar Code Scanner that is located on the front of the PRU.
3. Scan the Bar Code on the Drug Delivery Cassette packaging until you hear a confirmation tone and see a pop-up window ("The SEDASYS® System Cassette Accepted") on the PRU display.

4. Press **Close** to close the pop-up window.

Note

The Bar Code Scanner will be automatically disabled after the Drug Delivery Cassette is accepted, the cassette door is closed, and a propofol vial has been inserted.

Placing the Drug Delivery Cassette

1. Open the cassette door by pressing the **Door Open** button on the top of the PRU (refer to Figure 6-23 on page 6-19).
2. Make sure the cassette bay is clean and free from liquids and debris.
3. Using sterile technique, open and remove the cassette from its packaging. ***Do not*** remove the Spike Cap or the T-site Connector from its holder at this time.

Note

Before removing the cassette from the sterile package, verify that the cap is located on the luer fitting of the T-site Connector. If the cap is not located on the luer fitting, remove the cassette and cap from the package and re-install the cap on the luer fitting.

4. Hold the cassette by its tab located on the front right corner and align the Locator Hole on the cassette with the Locator Pin in the cassette bay. Make sure the Tubing Site for Air-In-Line Detection is aligned with the Air-In-Line Sensor on the PRU.

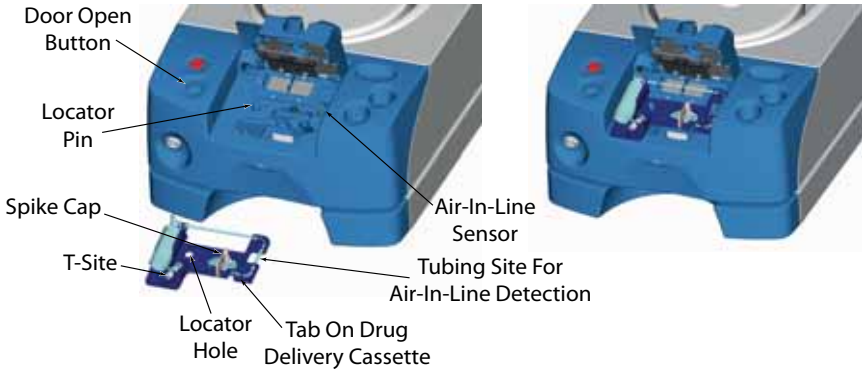


Figure 6-23 Placement of Drug Delivery Cassette into PRU

5. When properly aligned, place the cassette into the cassette bay.

Note

It is not necessary to fully seat the cassette into the cassette bay. Proper seating of the cassette will occur when the Drug Delivery Cassette door is closed.

6. Close the Drug Delivery Cassette door by pushing down until the door clicks securely into place.

Note

1 Another pop-up screen (“Drug vial not detected - check vial placement”) will appear on the PRU. This is a prompt to insert a vial of propofol.

2 If the Drug Delivery Cassette door is opened during a procedure to remove the cassette, do NOT close the door without first re-inserting the cassette. If the door is closed without re-inserting the cassette, the door cannot be re-opened until the case is ended.

Placing the Propofol Vial and Autopriming

WARNING

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.

1. Remove the cassette’s Spike Cap by grasping and lifting the cap wing upward. The Spike Cap may be placed in the recess to the right of the pump until the procedure is complete.

Note

Do not discard the Spike Cap. This cap may be replaced on the Vial Spike just prior to removing the cassette at the end of the procedure depending on your facility’s protocol.

2. Place a new, inverted 10 mL or 20 mL vial of propofol into the Vial Guides.

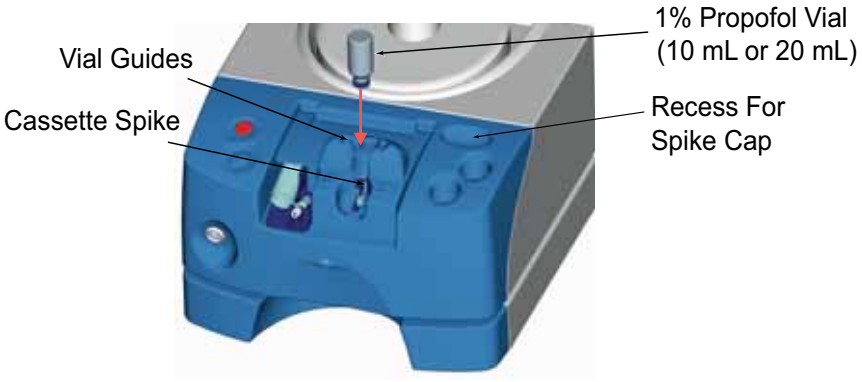


Figure 6-24 Placement of Propofol Vial into PRU

3. Press straight down ***firmly*** on the vial until it is seated into place on the cassette spike. When the vial is seated, the PRU Vial Selection screen appears.

Note

Once the propofol vial is fully inserted, the cassette door is locked and cannot be opened again until the vial is removed.

Figure 6-25 PRU Vial Selection Screen

4. To enter the volume of the vial, select and press the **New 10 mL** or **New 20 mL** checkbox then press **OK**. The PRU automatically begins priming the tubing.

Note

The Same Vial checkbox is disabled when you are initiating a new case.

5. Wait for 10 seconds until the PRU completes the autopriming sequence. The message “Connect T-site to IV” appears in the Message Box on the PRU Monitoring screen when autopriming is complete.

Note

The T-site Connector must remain in its holder on the cassette for autopriming to be completed.

6. Remove the T-site from its holder on the Drug Delivery Cassette and visually inspect the T-site and the cassette’s IV Tubing to verify that the tubing is completely filled with propofol. If the tubing is not completely full of propofol, you must manually purge the air from the tubing (refer to next section).
7. Remove the cap from the luer fitting on the T-site Connector.
8. Connect the T-site Connector to the stopcock or Y-Connector attached to the patient’s IV catheter.

WARNING

Purging and/or priming the Cassette’s IV Tubing while the T-site is connected to the patient may result in an air embolism or inappropriate drug delivery. Prior to connecting the Drug Delivery Cassette T-site to the patient and delivering propofol, examine the cassette’s IV Tubing for residual air and manually purge any residual air.

Purging Air from the Drug Delivery Cassette

If air is detected in the Drug Delivery Cassette during autopriming or at any time during the procedure, you must manually purge the air from the tubing.

WARNING

The Drug Delivery Cassette's T-site must be disconnected from the patient during manual purge.

1. Press **Purge** from the PRU Monitoring screen.

Figure 6-26 PRU Manual Purge Screen

2. Press and hold the **Purge** button until all the air has been removed from the Drug Delivery Cassette. The infusion pump will operate when the **Purge** button is depressed and will immediately stop when the **Purge** button is released.

Note

Hold the T-site Connector over a wastebasket to avoid getting fluid on the floor.

3. Press **Close** when purging is complete.
4. Connect the T-site Connector to the stopcock or Y-Connector attached to the patient's IV catheter.

Delivering Propofol

Initiating Drug Delivery

1. After successfully completing the setup steps described above, press **Start Drug** from the PRU Monitoring screen to begin propofol delivery to the patient. The following confirmation screen appears:

Note

The PRU must be used for initiation of drug delivery. Control of drug delivery after initiation can also occur from the BMU.

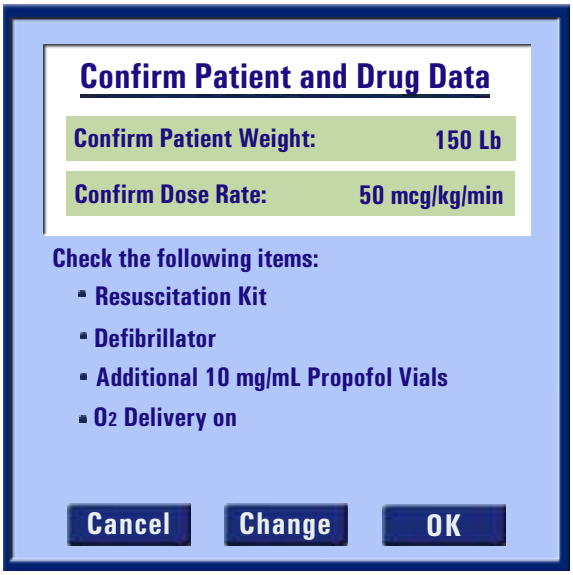


Figure 6-27 PRU Confirm Patient and Drug Data Screen

2. Press **OK** to confirm the patient weight and dose rate.

Note

Press **Change** to return to the Enter Patient and Drug Data screen (refer to Figure 6-16 on page 6-12) to change patient weight and/or dose rate.

The lockout timer will be displayed on the PRU Monitoring screen below the Current Dose Rate box. For example, in Figure 6-28 on page 6-24, the lockout timer displays 163 sec (seconds) remaining before any increase in the dose rate is allowed. The lockout time ensures that the

clinician assesses the full effect of the most recent increase before additional new dosing decisions can be made.

Figure 6-28 Dose Rate Section of PRU Monitoring Screen During Loading Dose

ARM and NIBP Monitoring During Loading Dose

During any loading dose, the System performs ARM responsiveness tests every 15 seconds and performs “continuous” NIBP measurements.

If the patient becomes non-responsive (patient does not respond to ARM within 14 seconds) during a loading dose, the System immediately stops the loading dose and continues drug delivery at an appropriately reduced dose rate.

Maintaining and Adjusting the Sedation Level

Once the dose rate is being delivered to the patient, the System maintains that rate and continuously monitors the patient (including the ARM responsiveness tests). However, when necessary, you can adjust the sedation level by manually changing the dose rate or by giving the patient a PRN dose.

WARNING

Do not supplement propofol administered by the SEDASYS® System with additional manual bolus doses of propofol as this may result in overdosing and respiratory depression.

Adjusting the Dose Rate Using the PRU

At times, you may need to manually adjust the dose rate to achieve the desired sedation level.

1. Press the **Up** or **Down Arrow** buttons to enter the desired dose rate. The dose rate changes in increments of 5 mcg/kg/min with each button press.

Figure 6-29 Dose Rate Section of PRU Monitoring Screen During Dose Rate Increase

Note

If the infusion rate increase limit is reached, the Up Arrow button will be disabled.

2. Press **Start Drug** to confirm the new dose rate and begin delivering the new dose rate to the patient.

Note

If **Start Drug** is not pressed within 10 seconds, the New Dose Rate box will reset to display "---" and the Current Dose Rate will not be changed.

If the dose rate is increased, a 180-second lockout timer is displayed under the Current Dose Rate box and the **Up Arrow** button is disabled (refer to Figure 6-28 on page 6-24). The lockout time ensures that the clinician assess the full effect of the most recent increase before additional new dosing decisions can be made.

The clinician can still ***decrease*** the dose rate at any time during the procedure.

Adjusting the Dose Rate Using the BMU

The Dose Rate may also be adjusted from the BMU Remote Entry screen (refer to Figure 6-18 on page 6-14).

1. Press **Dose Rate** from the BMU Remote Entry screen.

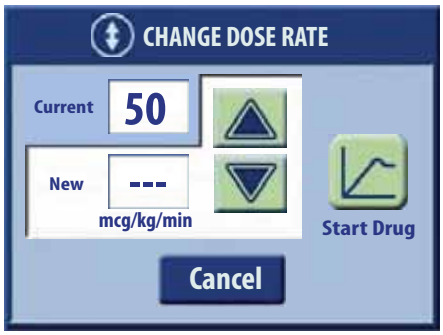


Figure 6-30 BMU Dose Rate Change Screen

2. Press the **Up** or **Down Arrow** buttons to enter the desired dose rate. The dose rate changes in increments of 5 mcg/kg/min.

Note

If the infusion rate increase limit is reached, the Up Arrow button will be disabled.

3. Press **Start Drug** to confirm the new dose rate and begin delivering the new dose rate to the patient.

Note

If **Start Drug** is not pressed within 10 seconds, the New Dose Rate box will reset to display "---" and the Current Dose Rate will not be changed.

If the dose rate is increased, a 180-second lockout timer is displayed above the **Start Drug** button and the **Up Arrow** button is disabled. The lockout time ensures you assess the full effect of the most recent increase before you are allowed to make any new dosing decisions.

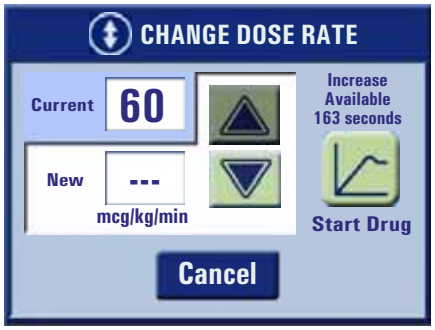


Figure 6-31 BMU Dose Rate Change Screen with Lockout Timer

The clinician can still ***decrease*** the dose rate at any time during the procedure.

Administering a PRN Dose Using the PRU

The SEDASYS® System allows you to treat transient episodes of discomfort with a supplemental dose of propofol that is given at a fixed dose of 0.25 mg/kg.

1. Press **PRN** from the PRU Monitoring screen.

The following pop-up window appears displaying the amount of propofol that will be delivered during the PRN dose:

Figure 6-32 PRU PRN Confirmation Screen

Note

The example shown assumes a patient weight of 68 kg. The actual value displayed will be based on the weight of patient entered in the Enter Patient and Drug Data screen (refer to Figure 6-16 on page 6-12).

2. Press **OK** to confirm and begin delivering the PRN dose.

The following figure shows an example of the PRU Monitoring screen's Drug Delivery Interface while the PRN dose is being delivered:

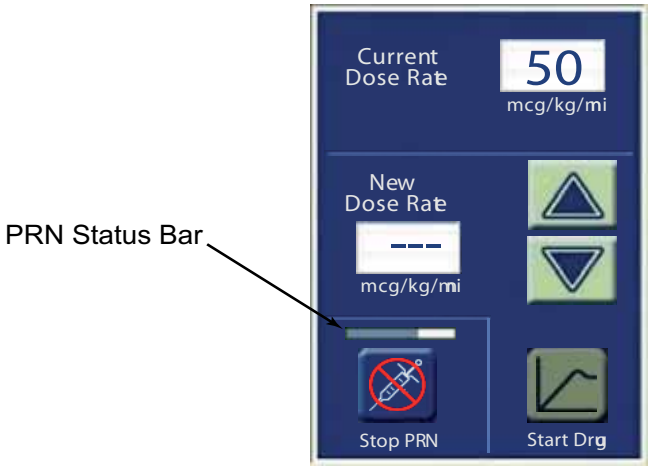


Figure 6-33 Dose Rate Section of PRU Monitoring Screen During PRN Delivery

While the PRN dose is being delivered, the **PRN** button changes to **Stop PRN**. You can press **Stop PRN** at any time to immediately stop the PRN dose delivery.

After the complete PRN dose is administered, you cannot give another PRN dose for 90 seconds. During this lockout period, the 90-second lockout timer appears under the **PRN** button and the **PRN** button is disabled. The lockout time ensures you assess the full effect of the PRN dose before you are allowed to administer a new PRN dose.

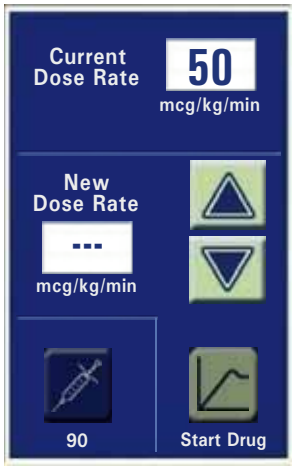


Figure 6-34 Dose Rate Section of PRU Monitoring Screen Following PRN Delivery

Note

The PRN status bar and the 90-second lockout timer appear in both the PRU and BMU, no matter from which display the PRN was initiated.

Note

During the administration of a PRN dose and the 90-second lockout period, the System performs ARM responsiveness tests every 15 seconds and continuous NIBP measurements.

Administering a PRN Dose Using the BMU

1. Press **PRN** from the BMU Remote Entry screen.

The following screen appears displaying the amount of propofol that will be delivered during the PRN dose:

Figure 6-35 BMU PRN Confirmation Screen

Note

The example shown assumed a patient weight of 68 kg. The actual value displayed will be based on the weight of patient entered in the Enter Patient and Drug Data screen (refer to Figure 6-16 on page 6-12).

2. Press **OK** to confirm and begin delivering the PRN dose.

The following shows an example of the BMU Remote Entry screen while the PRN dose is being delivered:

Figure 6-36 BMU Remote Entry Screen During PRN Delivery

While the PRN dose is being delivered, the **PRN** button changes to **Stop PRN**. You can press **Stop PRN** at any time to immediately stop the PRN dose delivery.

After the complete PRN dose is administered, you cannot give another PRN dose for 90 seconds. During this lockout period, the 90-second lockout timer appears under the **PRN** button and the **PRN** button is

disabled. The lockout timer ensures you assess the full effect of the PRN dose before you are allowed to administer a new PRN dose.

Note

1 The PRN status bar and the 90-second lockout timer appear in both the PRU and BMU displays, no matter from which display the PRN was initiated.

2 During the administration of a PRN dose and the 90-second lockout period, the System performs ARM responsiveness tests every 15 seconds and continuous NIBP measurements.

Stopping Drug Delivery Using the PRU or BMU

1. Press **Stop Drug** from the PRU Monitoring screen or BMU Remote Entry screen at any time to immediately stop drug delivery to the patient. The Current Dose Rate box is set to 0 and the New Dose Rate box displays "---".
2. To resume drug delivery, press the **Up Arrow** button from the PRU Monitoring screen or BMU Remote Entry screen to select the desired dose rate. Press the **Start Drug** button.

Replacing the Propofol Vial

Sedation for some procedures may require more than one vial of propofol to complete the case. When the System calculates that approximately 4 mL (for a 20 mL vial) or 3 mL (for a 10 mL vial) of propofol is remaining, the "Drug Vial Low" message appears on the PRU display. The vial should be replaced before the "Drug vial empty – replace vial" message appears and the System stops the drug infusion.

Note

The "Drug vial empty – replace vial" message will appear when approximately 2 mL (for a 20 mL vial) or approximately 1 mL (for a 10 mL vial) of propofol is remaining. When initially selecting the number of propofol vials that are needed for each patient, make sure to allow for this volume of fluid in the vial being unavailable for infusion.

1. Remove the propofol vial from the vial guides on the top of the cassette door by firmly grasping the vial and lifting upward. The "Drug vial not detected – check vial placement" pop-up window appears on the PRU and drug infusion is stopped.
2. Using sterile techniques place a new, inverted vial of propofol into the vial guides.
3. Press straight down *firmly* until the vial is seated in place on the cassette spike.
4. To enter the volume of the vial, select and press the **New 10 mL** or **New 20 mL** checkbox then press **OK**.

Figure 6-37 PRU Vial Selection Screen Following Vial Change

Note

Only select the **Same Vial** checkbox in instances when you are reinserting the same vial that you removed for the same patient.

5. Press **Start Drug** from the PRU Monitoring screen to restart the drug delivery at the previous rate.

Precaution

Care should be exercised to replace the propofol 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.

Ending the Procedure

1. If the delivery of propofol has not been previously stopped, press **Stop Drug** from either the BMU Remote Entry screen or the PRU Monitoring screen.
2. Press **End Case** from the PRU Monitoring screen. The End Case Confirmation pop-up window appears.

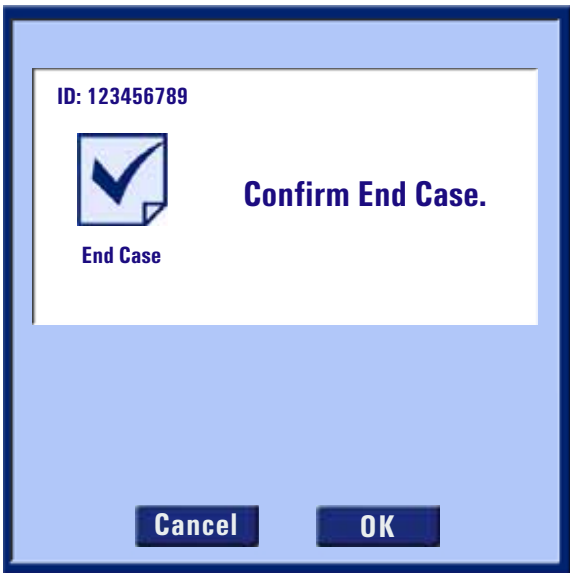


Figure 6-38 PRU End Case Confirmation Screen

3. Press **OK** on the End Case Confirmation pop-up screen to confirm.

Note

The BMU will continue to monitor the patient for oxygen saturation, heart rate, and blood pressure.

4. Disconnect the Drug Delivery Cassette's T-site Connector from the stopcock or Y-Connector at the IV catheter.
5. Replace the T-site Connector on the cassette T-site Holder.

Disconnect the Umbilical Cable from the BMU

Following completion of the procedure and prior to moving the patient to recovery, the BMU must be disconnected from the PRU.

1. Grasp the Release Sleeve of the Umbilical Cable Connector (refer to Figure 1-10 on page 1-10) that is connected to the BMU and pull directly away from the BMU.

Precaution

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.

Note

1 When disconnected from the PRU, the BMU continues to monitor the patient for SpO_2, Heart Rate, and NIBP.

2 The opposite end of the Umbilical Cable should remain connected to the PRU.

2. The patient can now be transported to the recovery room.

Preparing the System for the Next Patient

1. Remove the propofol vial from the vial guides on the top of the PRU cassette door by firmly grasping the vial and lifting upward.
2. Press the **Door Open** button on the PRU to open the cassette door.
3. Replace the Spike Cap by grasping the cap wing and snapping in place over the cassette vial spike.
4. Grasp the tab located on the right front of the cassette to lift and remove the cassette from the PRU.

Note

When lifting the cassette from the cassette bay, use caution not to spill any propofol that may have collected in the Residual Drug Reservoir (refer to Figure 1-11 on page 1-11).

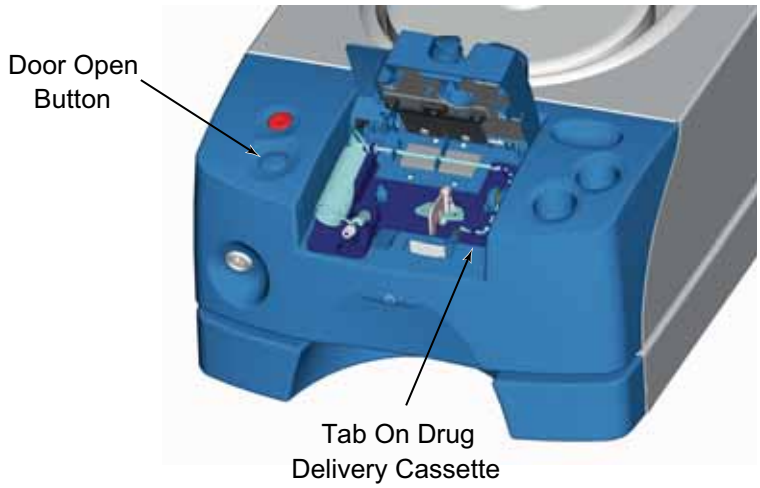


Figure 6-39 Tab on Drug Delivery Cassette

Note

At this time, you have the option to remove the Vial Spike from the cassette prior to disposal of the cassette. For instructions, refer to Optional Removal of the Vial Spike in the following section.

5. Dispose all open Drug Delivery Cassettes (used or unused) and used propofol vials according to your facility's protocol.

WARNING

1 The propofol vials are for single patient use only. Do not re-use.

2 The Drug Delivery Cassette is packaged sterile for single-patient use only. Do not re-use or re-sterilize.

6. Carefully clean up any fluid or debris in the cassette bay with a soft cloth or swab dampened with an appropriate cleaner (refer to Table 9-1 on page 9-3).

Optional Removal of the Vial Spike

The Drug Delivery Cassette is designed so that the Vial Spike can be detached and discarded separately from the rest of the cassette.

WARNING

The Vial Spike is sharp and may cause injury.

1. With the arrow on the cassette pointing away from you, turn the elbow underneath the spike clockwise until the elbow releases.
2. Grasp the wing of the Spike Cap and pull the cap up and away from the cassette. The Vial Spike will remain attached to the Spike Cap.
3. Dispose of the capped spike and remainder of the Drug Delivery Cassette according to your facilities protocol.

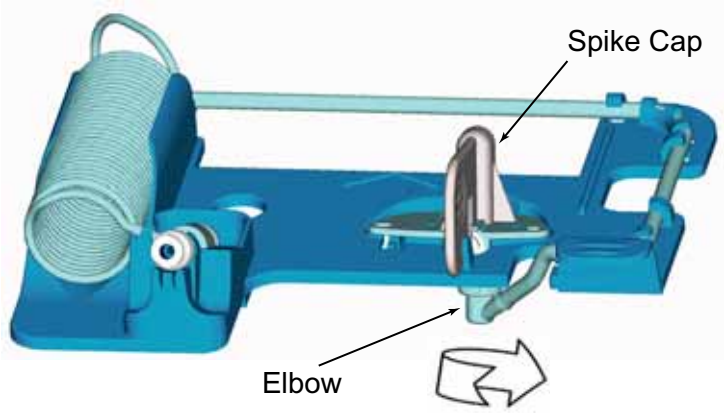


Figure 6-40 Top View of Drug Delivery Cassette and Removal of Vial Spike With Spike Cap

Ending the Case

When the patient is ready for discharge, monitoring from the BMU can be discontinued.

1. Press **End Case** from the BMU Monitoring screen. The End Case Confirmation pop-up window appears.

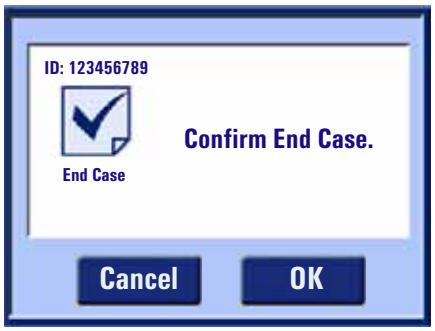


Figure 6-41 BMU End Case Confirmation Screen

Perform one of the following actions:

– Press **OK** on the End Case Confirmation window to confirm.

- OR -

– Press **Cancel** to return to the BMU Monitoring screen.

Note

If **OK** is selected and wireless printing is enabled (refer to Figure 4-20 on page 4-14), a summary of the procedure will be printed. In order to capture ECG data on the procedure summary, do not remove the ECG wire set from the patient before pressing End Case on the BMU. For a sample of the procedure summary, refer to *Appendix F: Printing*.

2. Remove the following from the patient:
   – Oral/Nasal Cannula (including the Earpiece)
   – ARM Handset
   – ECG wire set and ECG electrodes
   – SpO_2 probe
   – NIBP cuff

Note

Dispose of the used Oral/Nasal Cannula according to your facility's protocol.

3. Clean the ECG wire set, Pulse Oximeter probe, ARM Handset, and NIBP cuff prior to each use. For more information, refer to Cleaning on page 9-1.
4. Store the ECG lead wires and cable, SpO_2 probe and cable, NIBP cuff and extension tubing, and the ARM Handset and cable with the BMU.

Note

These items may remain connected to the BMU.

Other System Functions

The SEDASYS® System provides other functions that the clinician may not always perform for each patient using the System.

Emergency Stopping of Drug Delivery

The red emergency **Stop Drug** button should only be used in the event of a touchscreen or display failure. Pressing the emergency **Stop Drug** button located on the top left of the PRU shuts off power to the infusion pump and results in the immediate stopping of drug delivery.

After pressing the emergency **Stop Drug** button, the **Dose Rate** and **PRN** buttons on the BMU are disabled. Drug delivery can only be re-established using the PRU touchscreen.

Clinician-Response Mode

If the patient is not able to pass ARM training, selecting **Clinician Response** enables the clinician to assess the patient's responsiveness for the System. Instead of querying the patient, the System will now prompt the clinician at regular intervals to assess the patient's responsiveness.

The following pop-up window appears on the PRU along with an audible notification at preset intervals. A similar screen simultaneously appears on the BMU.

Figure 6-42 PRU Responsiveness Pop-up Window for Clinician Response Mode

1. Assess the patient's responsiveness.
2. Press one of the two Responsiveness buttons:
   – **Yes** (if the patient is responsive).

- OR -

   – **No** (if the patient is not responsive).

Note

1 If you do not respond within 14 seconds, the System records the patient as non-responsive.

2 In the Clinician Response Mode, dose rate increases are limited to 50 mcg/kg/min if the patient is responsive. However, any increase over 25 mcg/kg/min will generate a warning against such a large increase.

Changing PRU Case Settings

The Case Settings can be changed by the clinician for the specific needs of an individual patient. These settings are ***not*** access code protected. Each time **New Patient** is pressed on the PRU Ready screen to initiate a New Case, the Case Settings will automatically return to the default settings for your facility.

1. Press **Case Settings** from the PRU Monitoring screen. The following screen appears:

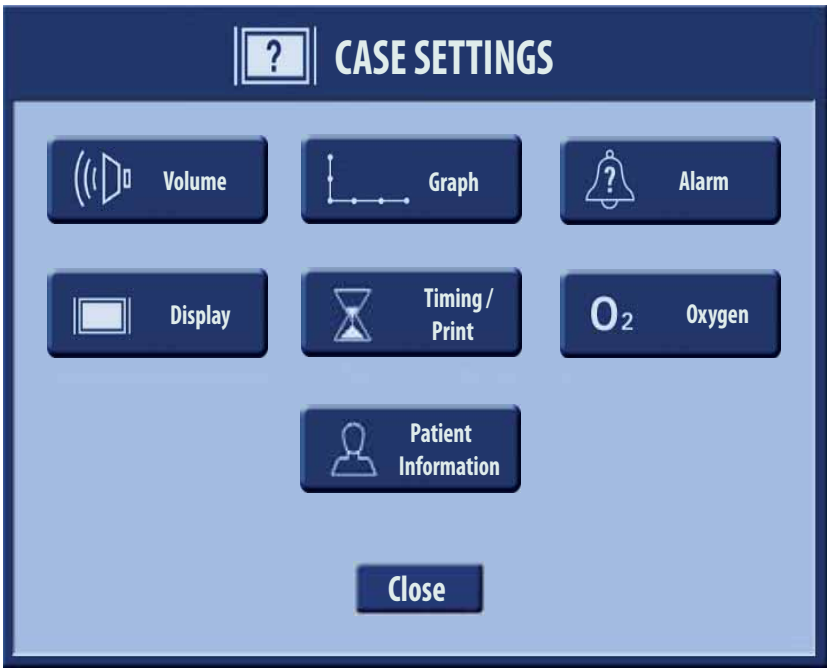


Figure 6-43 PRU Case Settings Screen

2. Select and press the button for the **Case 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 **Case Setting** change.

3. When you have changed the Case Setting, choose one of the following options:
   – Press **OK** to confirm the new Case Setting changes and return to the previous screen.
   – Press **Cancel** to terminate setting changes entered and to return to the previous screen.
   – Press **Default** to return to the pre-set facility default settings for all procedures. Press **OK** to confirm the facility default settings and return to the previous screen.
4. When you have finished changing all your selected Case Settings, press **Close** from the Case Settings screen. You will be returned to the PRU Monitoring screen.

Case Settings Screens for the PRU

The following are the PRU settings that can be adjusted when you select and press a button from the Case Settings screen:

Note

These screens automatically close after 10 seconds if no action is taken.

Volume Settings

Refer to Volume Settings on page 5-15 for instructions on adjusting the volume level for the Alarm, System, and ARM audio.

Display Information

Refer to Display Information on page 5-16 for instructions on adjusting the ECG Gain or enabling//disabling the continuous display of alarm limits.

Note

During a case, the printer settings cannot be changed and this section of the Timing/Print Options screen will be disabled. The Printer Settings can only be changed through Facility Settings (refer to Changing PRU Facility Settings on page 5-10).

Graph Settings

Refer to Graph Settings on page 5-18 for instructions on adjusting the waveform speed and scale settings for each displayed graph.

Timing/Print Options

Refer to Timing/Print Options on page 5-20 for instructions on adjusting data collection interval and ARM and NIBP sampling intervals.

Note

The Printer settings cannot be changed during a case and this section of the Timing/Print Options screen will be disabled. The Printer Settings can only be changed through Facility Settings (refer to Changing PRU Facility Settings on page 5-10).

Alarm Settings

Refer to Alarm Settings on page 5-25 for instructions on adjusting the alarm limits for Heart Rate, Systolic NIBP, Diastolic NIBP, $EtCO_2$, SpO_2, and Respiration Rate.

Oxygen Delivery

Refer to Oxygen Delivery on page 5-28 for instructions on adjusting the oxygen delivery rate during inhalation and exhalation.

Patient Information

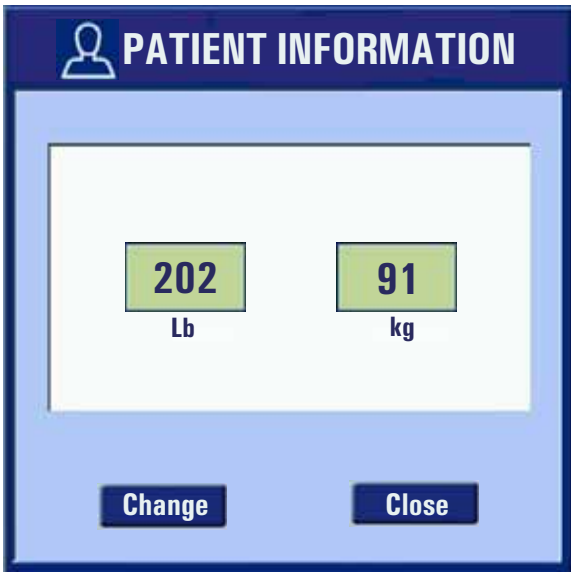


Figure 6-44 PRU Patient Information Screen

1. Press **Change** to return to the Enter Patient and Drug Data screen (refer to Figure 6-16 on page 6-12) to change patient weight.

Note

After drug delivery has been initiated, the patient weight cannot be changed and the **Change** button is disabled.

2. Press **Close** to return to the previous screen.

Shortcuts to Changing Case Settings

Alarm Settings

Shortcuts are provided for changing alarm settings during a procedure. Press one of the following buttons on the PRU Monitoring screen to change alarm settings: **RESP**, **EtCO$_2$**, **%SpO$_2$**, **HR**, or **NIBP**.

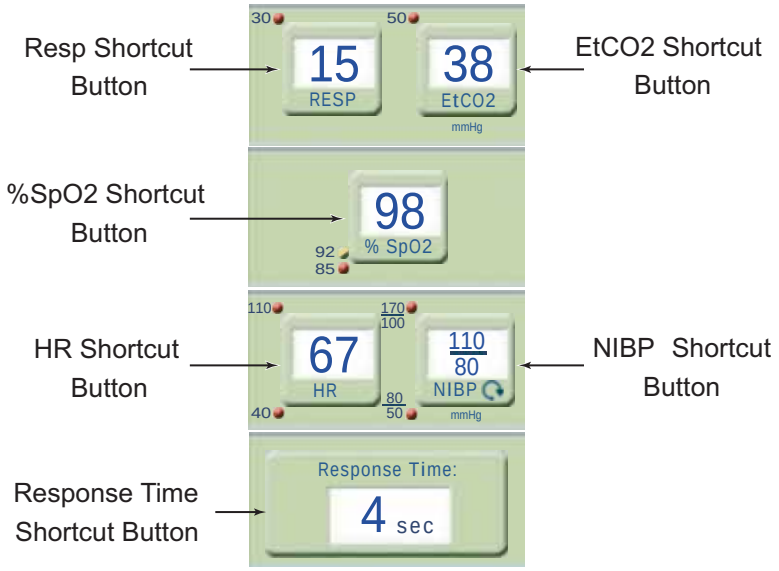


Figure 6-45 Patient Monitoring Shortcut Buttons on PRU Monitoring Screen

For **RESP**, **EtCO$_2$**, and **%SpO$_2$**:

Pressing the **RESP**, **EtCO$_2$**, and **%SpO$_2$** buttons directly from the PRU Monitoring screen are shortcuts to the same parameter pop-up screens that appear when pressing the **Alarm Settings** button from the Case Settings pop-up screen on the PRU Monitoring screen.

For **NIBP**:

Pressing the **NIBP** button on the PRU Monitoring screen displays the following pop-up screen:

Figure 6-46 PRU NIBP Screen Reached Through NIBP Shortcut Button

Pressing **Diastolic** or **Systolic** displays the same pop-up screen that appears through the **Case Settings** button (or the **Facility Settings** button).

- Pressing the **Up** or **Down Arrow** buttons changes the interval of the automatic NIBP measurements (in minutes).
- Pressing **Trends** allows you to view the NIBP Trends and use the **Up** or **Down Arrow** buttons to scroll through Trend data.

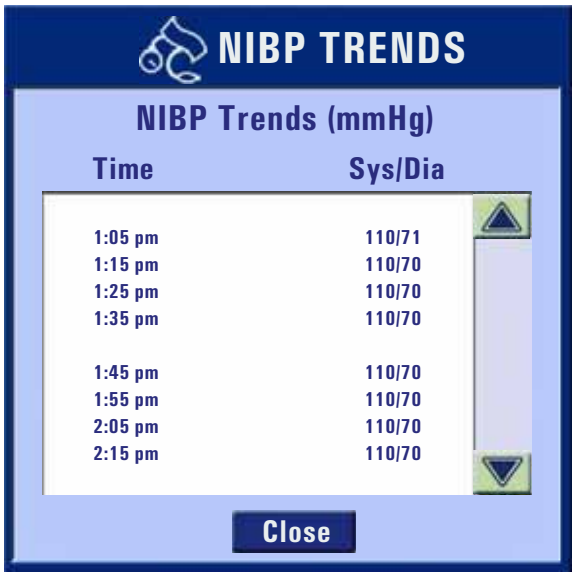


Figure 6-47 PRU NIBP Trends Screen

For **HR**:

Pressing the **HR** button on the PRU Monitoring screen displays the following pop-up screen:

Figure 6-48 PRU HR Menu Screen Reached Through HR Shortcut Button

- Pressing **HR Alarms** displays the same pop-up screen that appears through the **Case Settings** button (or the **Facility Settings** button).
- Pressing the **Up** or **Down Arrow** buttons changes ECG gain.

ARM Interval and ARM Volume

Pressing the **Response Time** button on the PRU Monitoring screen displays the following pop-up screen:

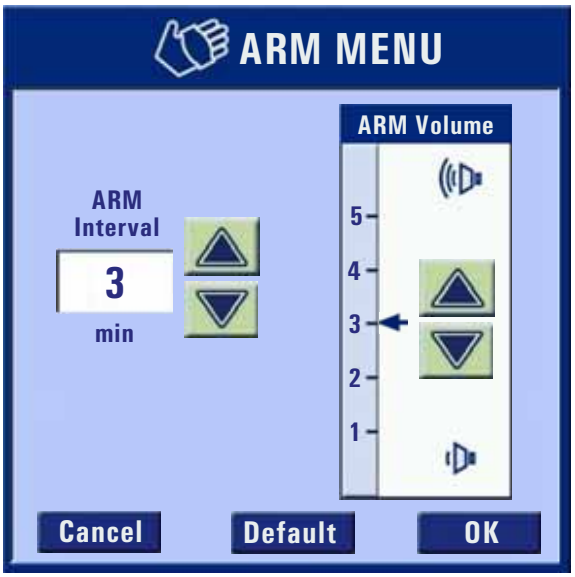


Figure 6-49 PRU ARM Menu Screen Reached Through ARM Shortcut Button

- Pressing the **Up** or **Down Arrow** buttons changes the interval of the ARM responsiveness test or the ARM volume.

Oxygen Delivery Rate:

Pressing the **O_2** button on the PRU Monitoring screen displays the same pop-up screen that appears through the **Case Settings** button (or the **Facility Settings** button).

Figure 6-50 Oxygen Delivery Shortcut Buttons on PRU Monitoring Screen

Changing BMU Alarm Settings

BMU Alarm settings can be changed by the clinician for the specific needs of an individual patient. These settings are ***not*** protected by access code. Each time **New Patient** is pressed on the BMU Ready screen, the System settings will automatically return to the default settings for your facility.

Note

1. The BMU Monitoring screen is only displayed when the BMU is disconnected from the PRU. When the BMU is connected to the PRU, all patient settings must be changed through the PRU.
2. During connection of the BMU to the PRU, any alarms settings that were changed on the BMU for the specific needs of an individual patient will be displayed on the PRU during connection to confirm acceptance for procedure room use.

The method for changing alarm settings during a procedure is to press one of the following buttons on the BMU Monitoring screen: **%SpO_2**, **HR/ECG**, or **NIBP**.

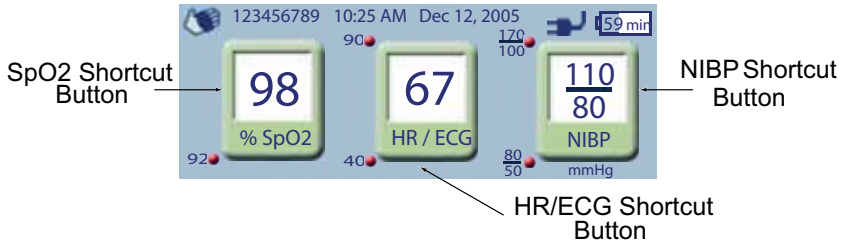


Figure 6-51 Patient Monitoring Shortcut Buttons on BMU Monitoring Screen

For **SpO_2:**

Pressing the **%SpO_2** button from the BMU Monitoring screen displays the same alarm setting screen that appears in Facility Settings (refer to Alarm Settings on page 4-13).

For **HR/ECG:**

Pressing the **HR/ECG** button from the BMU Monitoring screen displays a Heart Rate/ECG menu.

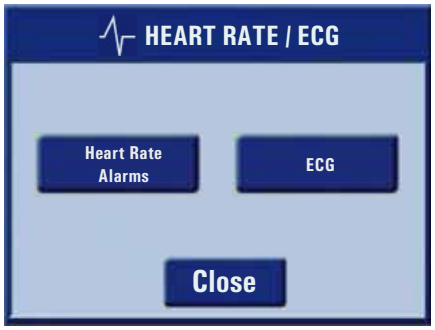


Figure 6-52 BMU Heart Rate/ECG Waveform Screen

- Pressing the **Heart Rate Alarms** button displays the same alarm setting screen that appears in Facility Settings (refer to Alarm Settings on page 4-13).

For **NIBP:**

- Pressing the **NIBP** button on the BMU Monitoring screen displays the following screen:

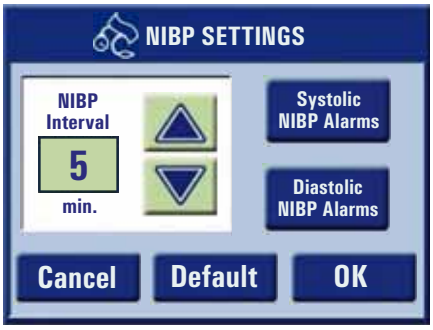


Figure 6-53 BMU NIBP Settings Screen

- Pressing **Systolic NIBP Alarms** or **Diastolic NIBP Alarms** buttons display the same screens that appear through Facility Settings (refer to Alarm Settings on page 4-13).
- Pressing the **Up** or **Down Arrow** buttons changes the interval of the automatic NIBP measurements (in minutes).

Displaying ECG Waveform on the BMU

1. To display the ECG waveform, press the **HR/ECG** button from the BMU Monitoring screen.

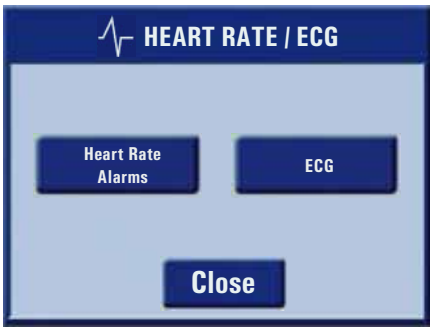


Figure 6-54 BMU Heart Rate/ECG Waveform Screen

2. Press the **ECG** button from the Heart Rate/ECG menu screen. The BMU waveform will be displayed.

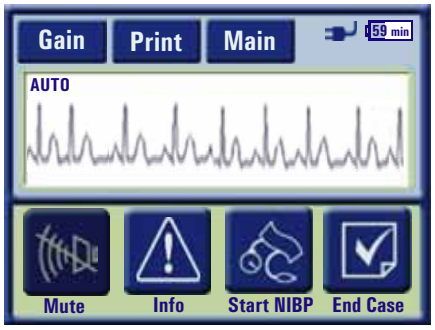


Figure 6-55 BMU ECG Waveform Screen

3. To change the magnification of the ECG waveform, press the **Gain** button. Repeated presses of the **Gain** button will cycle through the levels of magnification.

Note

The selected **Gain** setting is displayed in the upper-left corner of the ECG waveform display.

4. To return to the BMU Monitoring screen, press the **Main** button.

Delivering Oxygen through the BMU

The BMU and Oral/Nasal Cannula can be used to deliver supplemental oxygen to the patient in pre- or post-procedure when the BMU is not connected to the PRU. The Oxygen Delivery Adapter allows connection of the BMU to an externally regulated oxygen source.

1. To insert the Oxygen Delivery Adapter into the Umbilical Cable Port on the bottom of the BMU, align the Alignment Indicator (red dot) on the Oxygen Delivery Adapter with the red dot on the BMU Umbilical Cable Port and push the connector until it clicks into place.

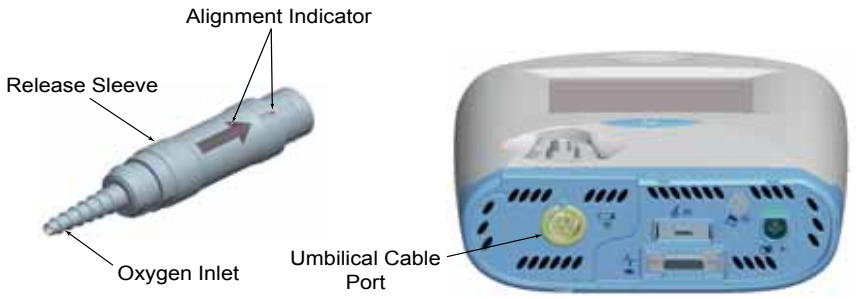


Figure 6-56 Connecting Oxygen Supply To the BMU

2. Connect one end of standard Oxygen Supply Tubing (not supplied) to the ¼ inch hose barb Oxygen Inlet of the Oxygen Delivery Adapter and the other end to the facility-provided oxygen flow meter.
3. If the Oral/Nasal Cannula is not connected to the patient, follow the instructions in Connecting the BMU to the PRU on page 6-11 to connect the Oral/Nasal Cannula to the patient.
4. Adjust the flow meter to the desired oxygen flow rate.

Note

The facility flow meter must be used to adjust the oxygen flow rate to the desired level. The BMU does not provide control of the oxygen flow rate.

5. The Oxygen Delivery Adapter must be disconnected from the BMU prior to connecting the Umbilical Cable to the PRU. To disconnect the Oxygen Delivery Adapter from the BMU, grasp the Release Sleeve of the Oxygen Delivery Adapter and pull directly away from the BMU.

Note

Follow facility protocol for disposal or re-use of the Oxygen Supply Tubing.

Connecting a Bag Mask to the PRU

When manual ventilation is required, a standard bag mask can be connected to the emergency oxygen supply on the back of the PRU.

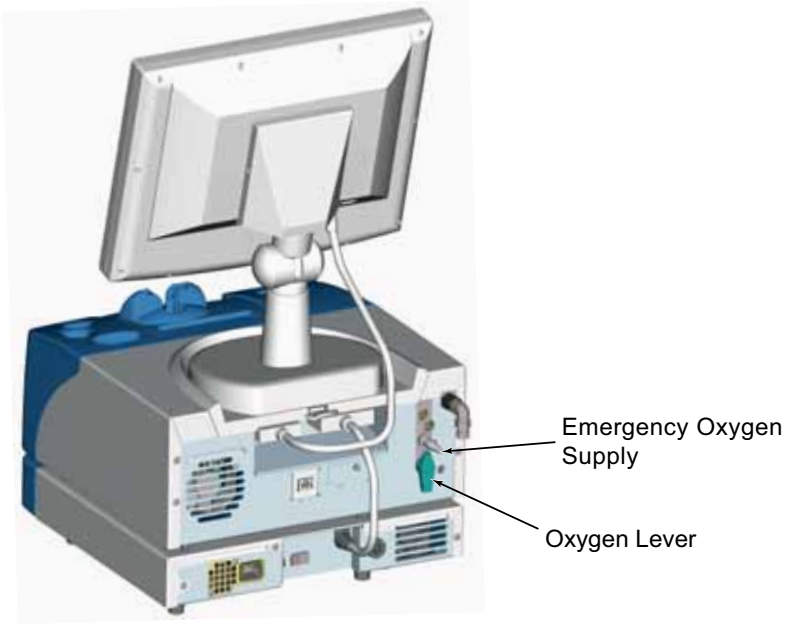


Figure 6-57 Connecting Bag Mask to PRU

1. Connect one end of the standard oxygen supply tubing to the long medical barb fitting on the back of the PRU. This long medical barb fitting is the Emergency Oxygen Supply Outlet.
2. Connect the other end of the standard oxygen supply tubing to the bag mask.
3. Turn the Oxygen Lever 90° counterclockwise so that the lever is placed in a vertical position. The lever should be pointing towards the Emergency Oxygen Supply Outlet.

The oxygen supply flow should now be directed from the Diameter Index Safety System (DISS) oxygen inlet on the back of the PRU to the Emergency Oxygen Supply Outlet.

This page is intentionally left blank.

Chapter 7 Patient Alarms

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. A primary function of the SEDASYS® System is monitoring patient physiology and stopping drug delivery and/or providing alarms to the clinician when it detects adverse physiology.

Note

The SEDASYS® System patient alarms are a tool to help manage the administration of sedation. They are not intended to replace your clinical judgment, nor can they take physical action to restore a patient's airway. As with any patient monitoring system, in response to a patient alarm you should assess the patient and take the appropriate action to restore the patient's condition to normal.

The factory-default alarm threshold settings can be found in *Appendix A: Factory Default Settings*.

Patient Alarms for BMU Only

When the Bedside Monitoring Unit (BMU) is not connected to the Procedure Room Unit (PRU) and is operating as a standalone monitoring unit, red alarms may be triggered for low SpO_2, low and high heart rate, low and high systolic blood pressure, and low and high diastolic blood pressure.

BMU Changes During a Red Alarm

When a red alarm is first triggered, the following changes appear on the BMU Monitoring screen:

- The general background field and the shortcut button for the patient physiological parameter that is causing the alarm change to red. In Figure 7-1 on page 7-2, the example shows the changes for a heart rate alarm.
- Displayed digital value of the alarming parameter flashes.
- Light Bar on the top of the BMU flashes.
- An audio alarm is sounded.

Note

To mitigate the impact of false alarms, the System immediately displays the visual alarm indication but waits for the alarm condition to persist for 15 seconds prior to emitting the audio alarm. The audio alarm consists of a continuous series of high pitched tones.

- If "Print On Alarms" has been enabled in Facility Settings (refer to Timing/Print on page 4-14), a hardcopy record of the alarm condition will be printed.

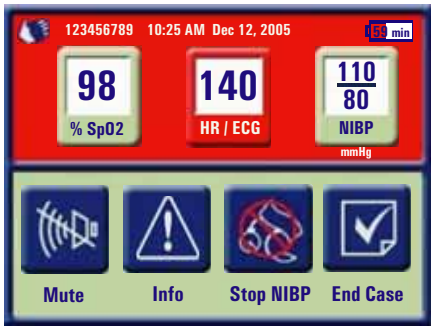


Figure 7-1 BMU Monitoring Screen During Red Alarm

BMU Changes When a Red Alarm Clears

When the red alarm condition clears, the following BMU changes occur:

- Audible alarm ceases.
- BMU Monitoring screen returns to the pre-alarm condition.
- Displayed digital value of the alarming parameter stops flashing.
- Light Bar on BMU stops flashing.

Patient Alarms for PRU/BMU Combination

When the BMU is connected to the PRU with the Umbilical Cable, the System is able to deliver propofol to the patient. In this configuration, the System may produce both yellow alarms and red alarms. Depending on patient physiology and system status, these yellow alarms and red alarms may or may not cause the System to take drug delivery action (reducing or stopping drug delivery).

Yellow Alarms

Yellow alarms inform the clinician of potential over-sedation as indicated by low SpO_2 and/or low respiratory rate or apnea. These physiological conditions have a high correlation with over-sedation.

Note

The SEDASYS® System yellow alarms are a tool to help manage the administration of sedation. They are not intended to replace your clinical judgment, nor can they take physical action to restore a patient's airway. As with any patient monitoring system, in response to a yellow alarm you should assess the patient and take the appropriate action to the patient's condition to normal.

In response to a yellow alarm, the System reduces the dose rate. The first step in reducing the dose rate is stopping the infusion. When the yellow alarm condition clears, the System re-initiates the infusion at an appropriately reduced dose rate.

PRU Changes During a Yellow Alarm

When a yellow alarm is first triggered, the following changes appear on the PRU Monitoring screen:

- The general background field and the shortcut button for the patient physiological parameter that is causing the alarm change to yellow. In Figure 7-2 below, the example shows the changes for a SpO_2 alarm.
- Displayed digital value of alarming parameter flashes.
- Flashing yellow "X" appears under the vial icon to indicate that drug delivery has been stopped.
- Current Dose Rate box displays "0" and New Dose Rate box displays the dose rate prior to the alarm.
- The System uses the ARM earpiece to command the patient to "*Take a deep breath*" during a SpO_2 or low respiratory rate/apnea alarm.
- The **Start ARM** button is disabled.
- An audio alarm is sounded.

Note

To mitigate the impact of false alarms, the System immediately displays the visual alarm indication but waits for the alarm condition to persist for 15 seconds prior to emitting the audio alarm. This audio alarm consists of a continuous series of low-pitched tones.

- If "Print On Alarms" has been enabled in Facility Settings (refer to Timing/Print on page 4-14), a hardcopy record of the alarm condition will be printed.

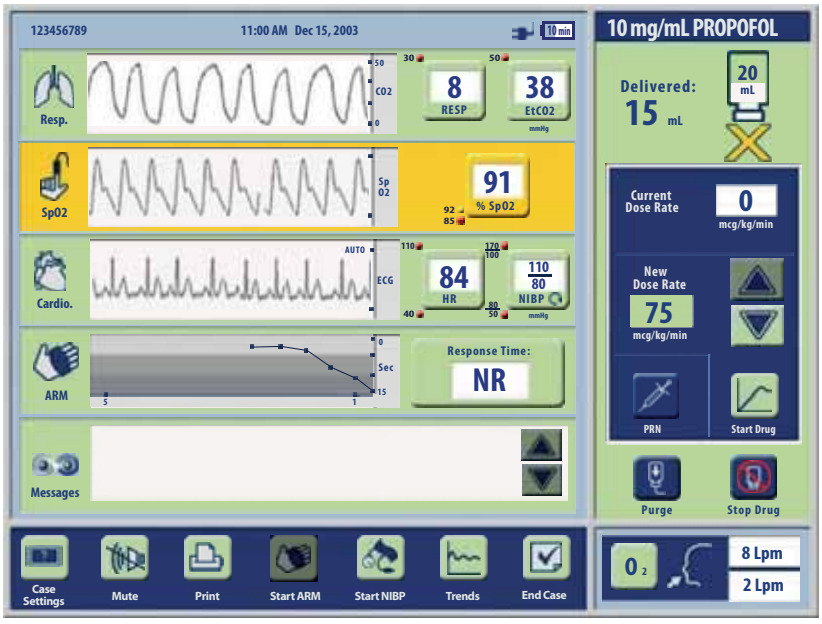


Figure 7-2 PRU Monitoring Screen During Yellow Alarm

BMU Changes During a Yellow Alarm

When a yellow alarm is first triggered, the following changes appear on the BMU Remote Entry screen.

- Current Dose Rate box displays flashing "0".
- Light Bar on the top of the BMU flashes.

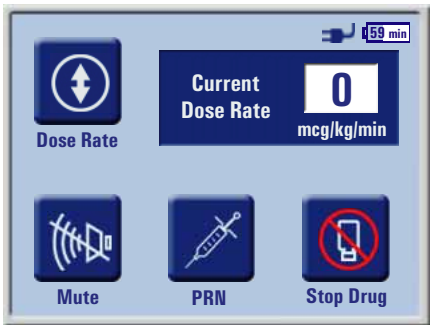


Figure 7-3 BMU Remote Entry Screen During Yellow Alarm

Restarting Drug Delivery During a Yellow Alarm

You can restart drug delivery during a yellow alarm. However, if the Additional Limit that prevents re-starting drug delivery during a yellow alarm is enabled (refer to Additional Limits on page 5-23), you cannot restart drug delivery. The **Start Drug** button will be disabled until the yellow alarm clears.

Note

The option to restart drug delivery during a yellow alarm is a tool to help manage the administration of sedation if an alarm has been triggered by artifact. As with any patient monitoring system, in response to a yellow alarm you should assess the patient. If the alarm has been triggered by artifact you should take the appropriate action to remove the source of the artifact. Otherwise, you should take the appropriate action to restore the patient's condition to normal.

To restart drug delivery from the PRU during a Yellow Alarm:

1. Press **Start Drug** to accept the dose rate displayed in the New Dose Rate box.

Note

This is the dose rate prior to the alarm, not a suggested reduced rate.

- OR -

Use the **Down Arrow** button to reduce the dose rate, and then press **Start Drug**.

Note

The **Up Arrow** button is disabled. You cannot increase the dose rate during a yellow alarm.

2. The following pop-up screen appears showing the dose rate that you selected in re-initiating drug delivery during a yellow alarm:

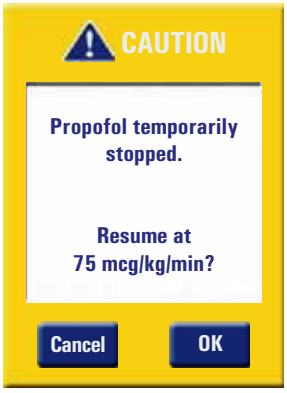


Figure 7-4 PRU Caution Screen - Resume Drug Delivery During Yellow Alarm

3. Press **OK** to restart the drug delivery.

To restart drug delivery from the BMU during a yellow alarm:

1. Press **Dose Rate** to display the Change Dose Rate screen.

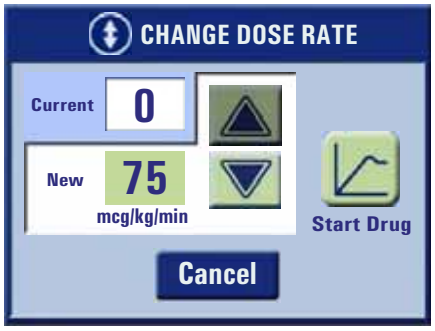


Figure 7-5 BMU Change Dose Rate Screen

2. Press **Start Drug** to accept the dose rate displayed in the New (Dose Rate) box.

Note

This is the dose rate prior to the alarm, not a suggested reduced rate

- OR -

Use the **Down Arrow** button to reduce the dose rate, and then press **Start Drug**.

Note

The **Up Arrow** button is disabled. You cannot increase the dose rate.

3. The following screen appears showing the dose rate that you selected in re-initiating drug delivery during a yellow alarm:

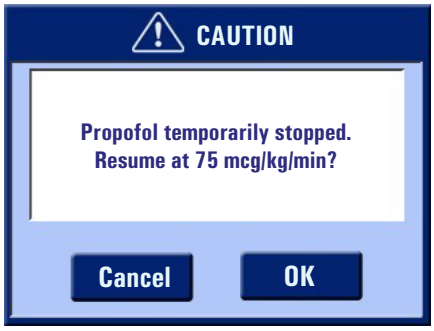


Figure 7-6 BMU Caution Screen - Resume Drug Delivery During Yellow Alarm

4. Press **OK** to restart the drug delivery.

Providing a PRN Dose During a Yellow Alarm

You can provide a PRN dose during a yellow alarm. However, if the Additional Limit that prevents allowing a PRN dose during a yellow alarm is enabled (refer to Additional Limits on page 5-23), you cannot provide a PRN dose. The **PRN** button will be disabled until the yellow alarm clears.

Note

The option to deliver a PRN during a yellow alarm is a tool to help manage the administration of sedation if an alarm has been triggered by artifact. As with any patient monitoring system, in response to a yellow alarm you should assess the patient. If the alarm has been triggered by artifact you should take the appropriate action to remove the source of the artifact. Otherwise, you should take the appropriate action to restore the patient's condition to normal.

To deliver a PRN dose from the PRU:

1. Press **PRN**.

2. The following pop-up screen appears on the PRU for a yellow alarm.

Note

This screen displays the PRN dose (in mg). This dose is equal to the patient weight (in kg), multiplied by 0.25 (mg/kg).

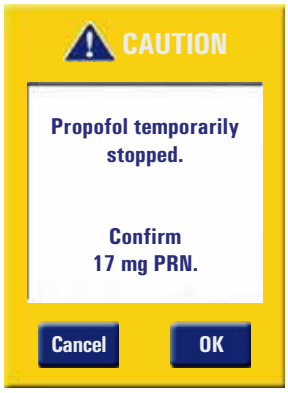


Figure 7-7 PRU Caution Screen - Deliver PRN During Yellow Alarm

3. Press **OK** to deliver the PRN dose.

To deliver a PRN dose from the BMU:

1. Press **PRN**.
2. The following screen appears on the BMU for a yellow alarm.

Note

This screen displays the PRN dose (in mg). This dose is equal to the patient weight (in kg), multiplied by 0.25 (mg/kg).

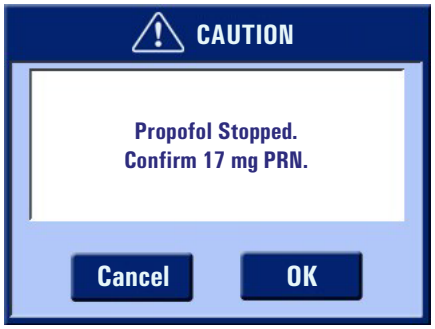


Figure 7-8 BMU Caution Screen - Deliver PRN During Yellow Alarm

3. Press **OK** to deliver the PRN dose.

BMU and PRU Changes When a Yellow Alarm Clears

When the yellow alarm condition clears, drug delivery is automatically resumed at a reduced dose rate. The following changes occur for the PRU and BMU:

- Audible alarm ceases.
- PRU Monitoring screen returns to pre-alarm condition.
- Light Bar on BMU stops flashing.

- Digital value of the alarming parameter stops flashing.
- Current Dose Rate box displays the new reduced dose rate.

Note

To mitigate the impact of false alarms, the System immediately displays the visual alarm indication but waits for the alarm condition to persist for 15 seconds prior to emitting the audio alarm. If the yellow alarm clears prior to the end of this 15-second period, the Current Dose Rate box displays the previous dose rate rather than a reduced dose rate.

Red Alarms That Stop Drug Delivery

Red alarms that stop drug inform the clinician of adverse physiology related to low SpO_2 and/or low respiratory rate or apnea. These adverse physiological conditions have a high correlation with over-sedation.

Note

The SEDASYS® System red alarms are a tool to help manage the administration of sedation. They are not intended to replace your clinical judgment, nor can they take physical action to restore a patient's airway. As with any patient monitoring system, in response to a red alarm you should assess the patient and take the appropriate action to restore the patient's condition to normal.

In response to this type of red alarm, the System stops delivery of propofol. During these red alarms, the dose rate cannot be re-initiated. After this red alarm clears, you must manually restart the delivery of propofol.

PRU Changes During a Red Alarm

When this type of red alarm is first triggered, the following changes appear on the PRU Monitoring screen:

- The general background field and the shortcut button for the patient physiologic parameter that is causing the alarm change to red. In Figure 7-9 on page 7-9, the example shows the changes for a SpO_2 alarm.
- Displayed digital value of alarming parameter flashes.
- Flashing red "X" is displayed below the drug vial, which indicates that drug delivery has been stopped.
- Current Dose Rate box displays "0" and New Dose Rate box displays the dose rate prior to the alarm.
- **Start Drug**, **Up** or **Down Arrow** and **Start ARM** buttons are disabled during the red alarm state.
- The System uses the ARM earpiece to command the patient to "*Take a deep breath*" during an SpO_2 or low respiratory rate/apnea alarm.

- An audio alarm is sounded.

Note

To mitigate the impact of false alarms, the System immediately displays the visual alarm indication but waits for the alarm condition to persist for 15 seconds prior to emitting the audio alarm. This audio alarm consists of a continuous series of high-pitched tones.

- If "Print On Alarms" has been enabled in Facility Settings (refer to Timing/Print Options on page 5-20), a hardcopy record of the alarm condition will be printed.

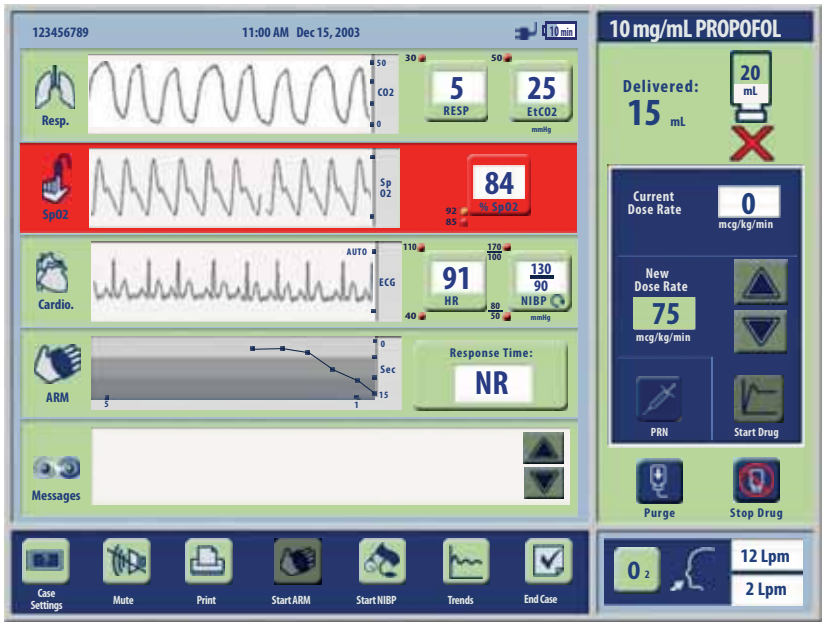


Figure 7-9 PRU Monitoring Screen During Red Alarm That Stop Drug Delivery

BMU Changes During a Red Alarm

When this type of red alarm is first triggered, the following changes appear on the BMU Remote Entry screen:

- Current Dose Rate box displays flashing "0".
- Light Bar on the top of the BMU flashes.
- **Dose Rate** button is disabled during the red alarm state.

Providing a PRN Dose During a Red Alarm

You can provide a PRN dose during a red alarm. However, if the Additional Limit that prevents allowing a PRN dose during a red alarm is

enabled (refer to Additional Limits on page 5-23), you cannot provide a PRN dose. The **PRN** button will be disabled until the red alarm clears.

Note

The option to deliver a PRN during a red alarm is a tool to help manage the administration of sedation if an alarm has been triggered by artifact. As with any patient monitoring system, in response to a red alarm you should assess the patient. If the alarm has been triggered by artifact you should take the appropriate action to remove the source of the artifact. Otherwise, you should take the appropriate action to restore the patient's condition to normal.

To deliver a PRN dose from the PRU:

1. Press **PRN**.
2. The following pop-up screen appears on the PRU.

Note

This screen displays the PRN dose (in mg). This dose is equal to the patient weight (in kg), multiplied by 0.25 (mg/kg).

Figure 7-10 PRU Warning Screen - Deliver PRN During Red Alarm

3. Press **OK** to deliver the PRN dose.

To deliver a PRN dose from the BMU:

1. Press **PRN**.
2. The following screen appears on the BMU.

Note

This screen displays the PRN dose (in mg). This dose is equal to the patient weight (in kg), multiplied by 0.25 (mg/kg).

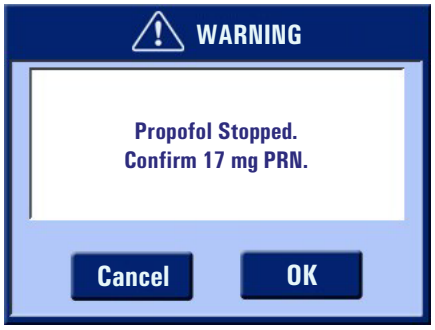


Figure 7-11 BMU Warning Screen - Deliver PRN During Red Alarm

3. Press **OK** to deliver the PRN dose.

BMU and PRU Changes When a Red Alarm Clears

If this type of red alarm condition clears to a "normal" state, the following changes occur with the PRU:

- Audible signal ceases.
- Entire PRU background box and shortcut button of alarming parameter return to the pre-alarm condition.
- Displayed digital value of alarming parameter stops flashing.
- Light Bar on BMU stops flashing.
- New Dose Rate box on PRU Monitoring screen displays a reduced dose rate.

Note

To mitigate the impact of false alarms, the System immediately displays the visual alarm indication but waits for the alarm condition to persist for 15 seconds prior to emitting the audio alarm. If the red alarm clears prior to the end of this 15 second period, the Current Dose Rate box displays the previous dose rate and the drug delivery is automatically resumed.

To indicate that you must manually restart drug delivery after a Red Alarm clears, the following screen displays are unchanged:

- Current Dose Rate box continues to display "0".

- Red "X" continues to display below the vial icon on PRU Monitoring screen.

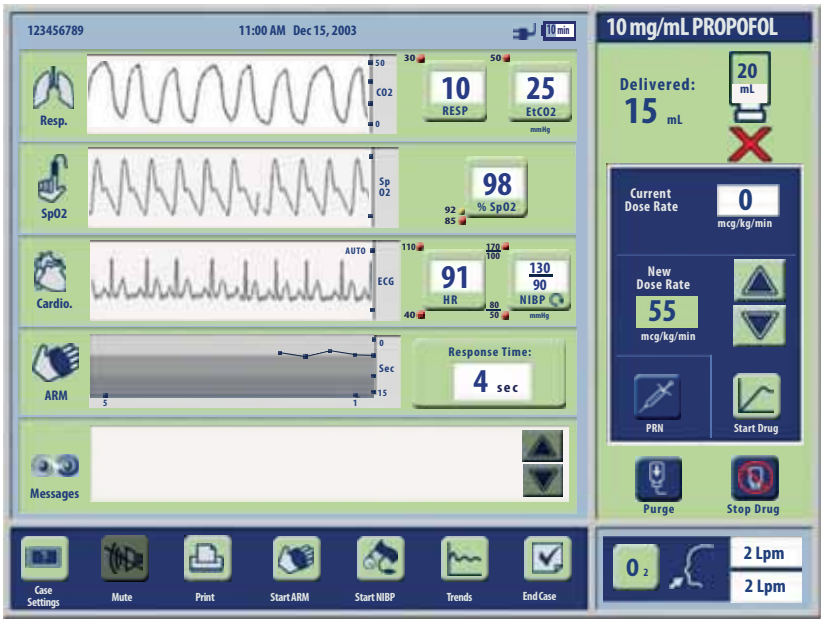


Figure 7-12 PRU Monitoring Screen After Red Alarm Clears to Normal

Restarting Drug Delivery After a Red Alarm Clears

After this type of red alarm has cleared, the user is responsible for restarting drug delivery. This can be done from either the PRU or BMU.

To restart drug delivery from the PRU:

1. Press **Start Drug** to accept the suggested dose rate displayed in the New Dose Rate box.

- OR -

Use the **Up** or **Down** Arrow buttons to select the dose rate, and then press **Start Drug**.

To restart drug delivery from the BMU:

1. Press **Dose Rate** to display the Change Dose Rate screen.

2. Press **Start Drug** to accept the suggested dose rate displayed in the New (Dose Rate) box.

- OR -

Use **Up** or **Down Arrow** buttons to select the dose rate, and then press **Start Drug**.

PRU Changes When a Red Alarm Clears to a Yellow Alarm

If this type of red alarm condition clears to a yellow alarm condition (prior to clearing to "normal"), the following PRU changes occur:

- Audible alarm signal changes to the audio signal for yellow alarm (low pitched tones).
- Entire background field and shortcut button of alarming parameter changes to yellow.
- New Dose Rate box on PRU Monitoring screen displays reduced dose rate.

Even though the red alarm has cleared to a yellow alarm, you must manually re-start drug delivery. The following screen displays remain unchanged:

- Current Dose Rate box continues to display "0".
- Red "X" continues to display below the vial icon.

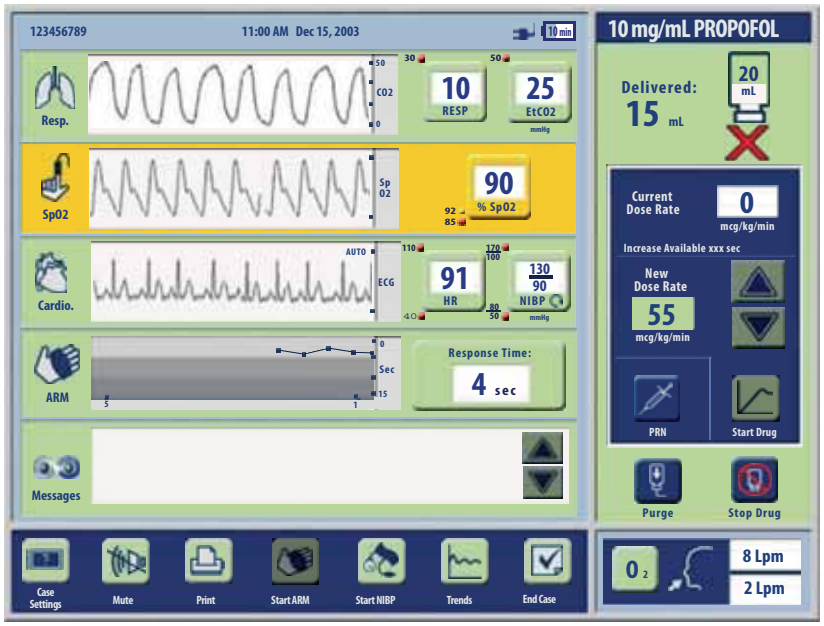


Figure 7-13 PRU Monitoring Screen After Red Alarm Clears to Yellow Alarm

Note

When the alarming parameter clears to "normal" from a yellow alarm state, the screen looks like a red alarm clearing to "normal" (refer to Figure 7-13 on page 7-13). The clinician will need to restart drug delivery.

Red Alarms That Do Not Stop Drug Delivery

Red alarms triggered by physiological parameters that do not have a high correlation with over-sedation (e.g., low and high heart rate, high respiratory rate, low and high systolic pressure, low and high diastolic pressure, and high $EtCO_2$) do not result in automatic drug action. For example, should a low systolic/diastolic pressure (hypotension) red alarm occur, the etiology of this alarm may be a vasovagal reaction where

reducing the drug delivery may not be a clinically appropriate action. Should any of these red alarms occur, the physician should assess the patient to determine the appropriate course of action, including whether it is clinically appropriate to stop drug delivery.

Note

The SEDASYS® System red alarms are a tool to help manage the administration of sedation. They are not intended to replace your clinical judgment, nor can they take physical action to restore a patient's airway. As with any patient monitoring system, in response to a red alarm you should assess the patient and take the appropriate action to the patient's condition to normal

Stat NIBP Following a Red Alarm

A "Stat" NIBP measurement will be initiated immediately after a red alarm has been triggered for low or high blood pressure (systolic or diastolic) or low or high heart rate.

PRU Changes During a Red Alarm

When this type of red alarm is first triggered, the following changes appear on the PRU Monitoring screen:

- The general background field and the shortcut button for the patient physiologic parameter that is causing the alarm change to red. In Figure 7-14 on page 7-15 below, the example shows the changes for a heart rate alarm.
- Displayed digital value of the alarming parameter flashes.
- An audio alarm is sounded.

Note

To mitigate the impact of false alarms, the System immediately displays the visual alarm indication but waits for the alarm condition to persist for 15 seconds prior to emitting the audio alarm. This audio alarm consists of a continuous series of high-pitched tones.

- If "Print On Alarms" has been enabled in Facility Settings (refer to Timing/Print Options on page 5-20), a hardcopy record of the alarm condition will be printed.

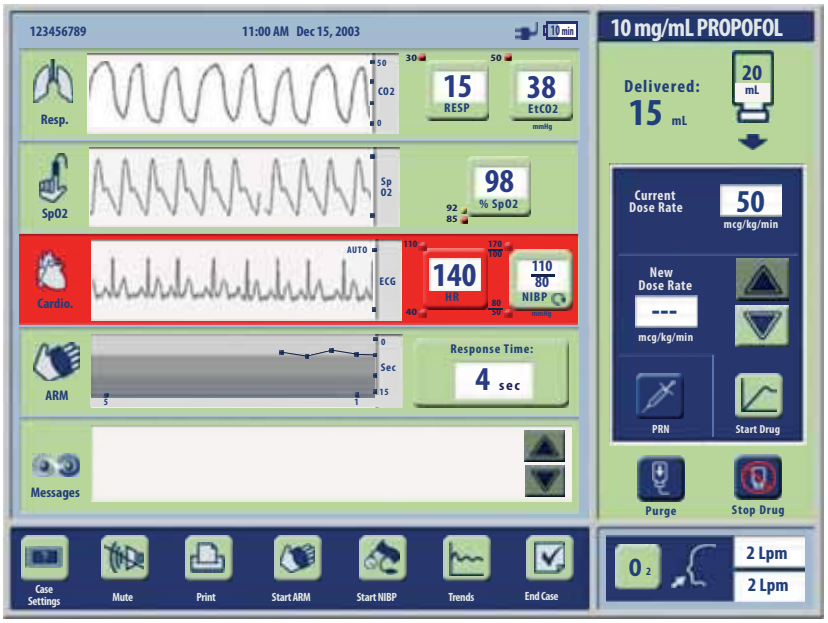


Figure 7-14 PRU Monitoring Screen During Red Alarm That Takes No Drug Action

BMU Changes During a Red Alarm

When this type of red alarm is triggered, the following change appears on the BMU:

- Light Bar on the top of the BMU flashes.

PRU and BMU Changes When a Red Alarm Clears

When this type of red alarm condition clears, the following changes occur for the PRU and BMU:

- Audible alarm signal ceases.
- PRU Monitoring screen returns to "normal".
- Displayed digital value of the alarming parameter stops flashing.
- Light Bar on BMU stops flashing.

Muting Alarms

The **Mute** button temporarily silences all audible alarms. Press it once to mute the alarm for 60 seconds; press it again to mute for an additional 60 seconds; and press it a third time (maximum) for an added 60 seconds (maximum total time: 180 seconds). The alarms remain muted for the period selected and cannot be unmuted.

When **Mute** is pressed, the label identifying the Mute button is replaced with a countdown timer that displays the time remaining until the alarms are audible again.

When an alarm is muted, any new alarm and/or advisory that occurs will trigger a new audible signal. However, the highest existing priority alarm and/or advisory will be heard, regardless of whether it was previously muted or not.

Muting the alarms does not change the visual indications on the PRU or BMU Monitoring screens, nor does it impact drug delivery.

Chapter 8 System Advisories

Correctable Advisories for Standalone BMU

A Correctable Advisory communicates a problem of identifiable cause that can be corrected by the clinician during the procedure. An example of a Correctable Advisory is the Pulse Oximeter probe being dislodged from the patient's finger.

BMU Changes During a Correctable Advisory

When the SEDASYS® System detects a problem with the Pulse Oximeter, Non-Invasive Blood Pressure (NIBP), or Electrocardiogram (ECG) modules, the following changes appear on the Bedside Monitoring Unit (BMU):

- Background of the lower half of the display changes to orange.
- The numeric display of the affected module will display "---".

Note

1. For example, if the Pulse Oximeter is the affected module, the %SpO_2 button displays "---".
2. If the Pulse Oximeter is the affected module, the System will obtain the Heart Rate from the ECG. The ♡ icon is displayed on the **HR/ECG** button to indicate that the Heart Rate source is from the ECG module.

- Light Bar on top of the BMU flashes.
- An audio signal is sounded.

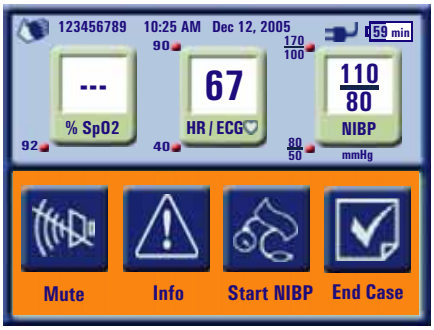


Figure 8-1 BMU Monitoring Screen During Pulse Oximeter Correctable Advisory

- A descriptive message of the problem appears in the Information screen. This message provides guidance for the clinician to correct the problem. To access the Information screen, press the **Info** button.

Note

When the problem first appears, the **Info** button will flash indicating a new message has been posted in the Information screen.

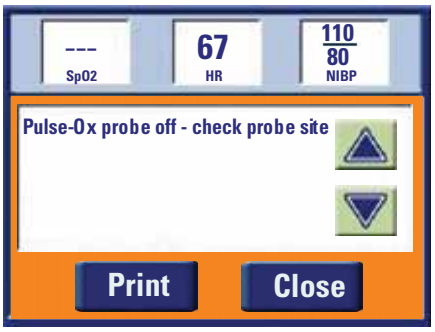


Figure 8-2 BMU Information Screen

Correctable Advisories for PRU/BMU Combination

A Correctable Advisory communicates a problem of identifiable cause that can be corrected by the clinician during the procedure. The response of the System to Correctable Advisories depends on which module of the System is affected. Some responses are different when the BMU is connected to the Procedure Room Unit (PRU) than when the BMU is used as a standalone unit. Examples of this type of advisory and system response are:

- A problem with the intravenous (IV) pump module immediately disables drug delivery.
- A problem with the Pulse Oximeter, Capnometer, Automated Responsiveness Monitor (ARM) or Oxygen Delivery modules, or with communication between the BMU and PRU, will disable drug delivery after 60 seconds (if the problem is not corrected within this timeframe).
- A problem with the NIBP or ECG modules that occurs after initiation of drug delivery does not affect drug delivery. However, if the problem occurs prior to the initiation, drug delivery will be prevented.

Complete information about these advisories is provided below.

IV Pump Correctable Advisory

When detecting a problem with the IV pump module, the System immediately stops drug delivery. Once the clinician has corrected the problem, drug delivery must be manually re-started.

Procedure Room Unit Changes During a Correctable Advisory

When the System detects a problem with the IV pump module, the following changes appear on the PRU:

- Descriptive message of the problem appears in the Messages field and/or an Advisory pop-up screen. This message provides guidance for the clinician to correct the problem.

Note

1. If there is a message in the Messages field, the background of the Messages field changes to orange.
2. If there is an Advisory pop-up screen, the Current Dose Rate and New Dose Rate display, **PRN**, **Start Drug** and **Up** and **Down Arrow** buttons will be hidden beneath the pop-up screen and are not visible until the screen is closed.

- The PRN button is disabled.

Note

For some IV pump advisories, the **Up** and **Down Arrow** for dose rate changes and the **Start Drug** and **Purge** buttons may also be disabled.

- Current Dose Rate box displays a flashing "0".
- New Dose Rate box displays the previous dose rate.
- A flashing orange "X" appears under vial icon that indicates that drug delivery has been stopped.
- An audio signal is sounded.

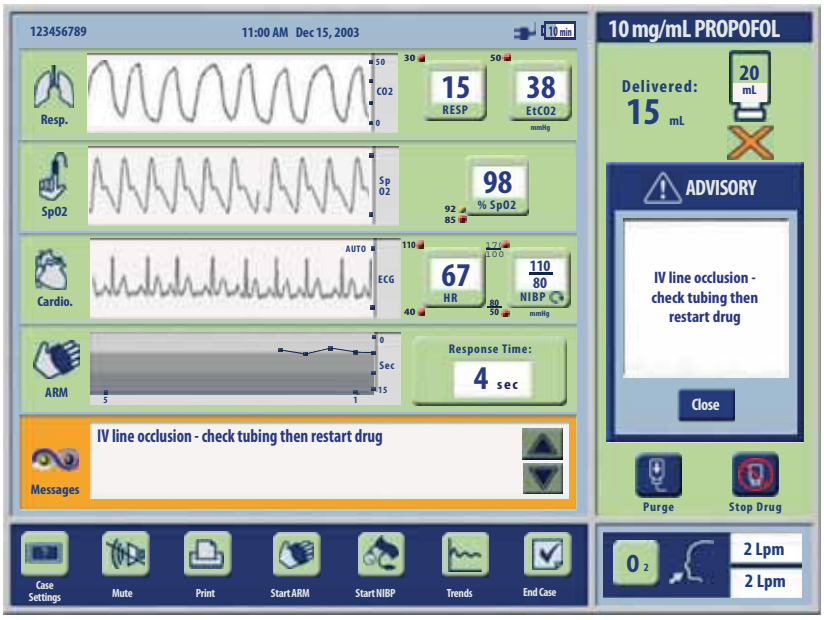


Figure 8-3 PRU Monitoring Screen During IV Pump Correctable Advisory

BMU Changes During a Correctable Advisory

When the System detects a problem with the IV pump module, the following changes appear on the BMU:

- Current Dose Rate box displays a flashing "0".
- Light Bar on top of the BMU flashes.

- PRN button is disabled.

Note

For some IV pump advisories, the **Dose Rate** button may be disabled.

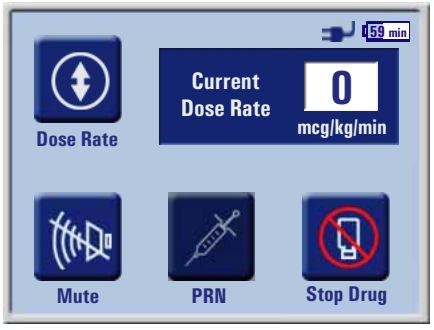


Figure 8-4 BMU Remote Entry Screen During IV Pump Correctable Advisory

Restarting Drug Delivery After Advisory Corrected

Before restarting drug delivery, the clinician must first fix the problem causing the Correctable Advisory for the IV pump module.

To restart drug delivery from the PRU:

1. From the Advisory pop-up screen, press **Close** to access the Drug Delivery Interface of the PRU Monitoring screen.

Note

The Advisory pop-up screen may need to be closed prior to correcting the problem. Also, some Advisory pop-up screens will automatically close upon correction of the problem.

2. Press **Start Drug** to accept the previous dose rate displayed in the New Dose Rate box.

- OR -

Use the **Up** or **Down Arrow** buttons to select a different dose rate, and then press **Start Drug**.

Note

If the Correctable Advisory condition still exists, the System will immediately stop drug delivery. If the condition no longer exists, the PRU Monitoring and BMU Remote Entry screens return to "normal" and the audio signals are discontinued.

To restart drug delivery from the BMU:

The problem with the IV pump module must be corrected from the PRU. After the problem is corrected, drug delivery may be restarted from the BMU.

1. Press **Dose Rate** from the BMU Remote Entry Screen.
2. Press **Start Drug** to accept the previous dose rate displayed in the New Dose Rate box.

- OR -

Use the **Up** or **Down Arrow** buttons to select a different dose rate, and then press **Start Drug**.

Note

If the Correctable Advisory condition still exists, the System will immediately stop drug delivery. If the condition no longer exists, the PRU Monitoring and BMU Remote Entry screens return to "normal" and the audio signals are discontinued.

SpO_2, Capnometer, ARM, or Oxygen Delivery Correctable Advisory

The inputs to the System may be compromised if the Pulse Oximeter, Capnometer, ARM, or Oxygen Delivery modules are not functioning properly. Therefore, when responding to a problem with any of these modules, the System automatically disables drug delivery after 60 seconds if the problem has not been corrected.

PRU Changes During a Correctable Advisory

When the System detects a problem with the Pulse Oximeter, Capnometer, ARM, or Oxygen Delivery modules, the following changes appear on the PRU:

- Background of Messages field changes to orange.
- Descriptive message of problem appears in Messages field. This message provides guidance for the clinician to correct the problem.

Note

1 For example, if the Pulse Oximeter probe is dislocated from the patient's finger, the message "Pulse-Ox probe off - check probe site" is displayed.

2 If the SEDASYS® System detects a gas with insufficient oxygen concentration, the System will immediately stop delivery of the "gas" and will display the message "O_2 stopped - low O_2 content - change supply".

- The Messages field also displays "Drug will stop in 60 seconds."

Note

The number of seconds (60) in the message acts as a countdown timer. The number will decrement until it reaches 0 (zero) seconds and drug delivery will automatically stop.

- Waveform box of the affected module will have no signal displayed.

Note

For example, if the Pulse Oximeter is the affected module, the plethysmogram is absent.

- The numeric display of the affected module will display "---".

Note

1. For example, if the Pulse Oximeter is the affected module, the **%SpO$_2$** button displays "---".
2. If the Pulse Oximeter is the affected module, the System will obtain the Heart Rate from the ECG. The ♡ icon is displayed on the **HR** button to indicate that the Heart Rate source is from the ECG module.

- Shortcut buttons (refer to Shortcuts to Changing Case Settings on page 6-40) are disabled.
- An audio signal is sounded.

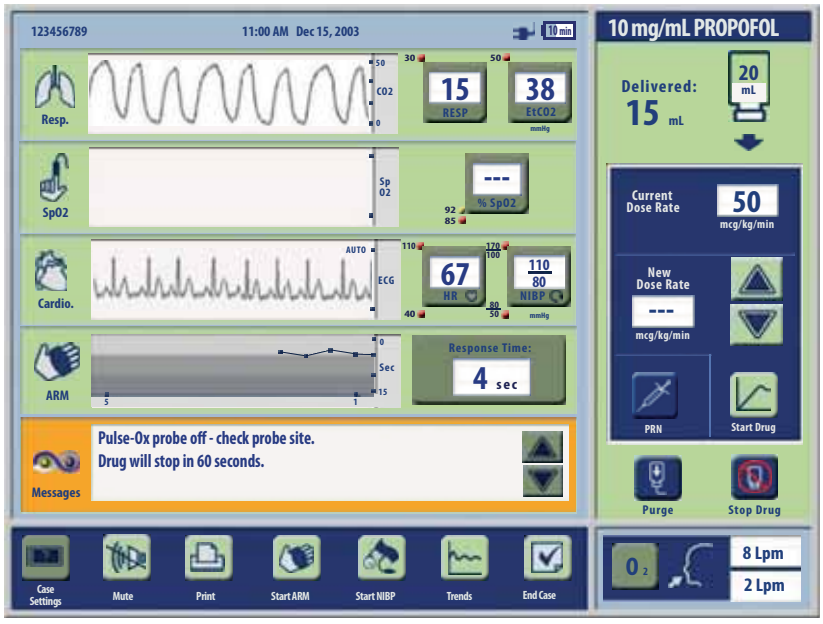


Figure 8-5 PRU Monitoring Screen During Pulse Oximeter Correctable Advisory

BMU Changes During a Correctable Advisory

When the System initially detects a problem with the Pulse Oximeter, Capnometer, ARM, or Oxygen Delivery modules, the only change to the BMU is the flashing of the Light Bar. Detailed information on the Correctable Advisory can be found on the PRU display.

PRU Changes When Countdown Timer Has Expired

If the problem causing the Correctable Advisory for the Pulse Oximeter, Capnometer, ARM, or Oxygen Delivery module is fixed within

60 seconds, the PRU Monitoring and BMU Remote Entry screens return to "normal" and the audio signal is discontinued.

However, if the problem causing the Correctable Advisory for these modules is not fixed within 60 seconds, the System automatically stops drug delivery and the following changes appear on the PRU:

- Messages field displays "Drug stopped".
- Current Dose Rate box displays a flashing "0".
- New Dose Rate box displays the previous dose rate.
- Flashing orange "X" appears under vial icon that indicates that drug delivery has been stopped.
- **Up** and **Down Arrow**, **PRN**, and **Start Drug** buttons are disabled.

Note

The shortcut buttons are no longer disabled and are active.

- The frequency of the audio signal changes.

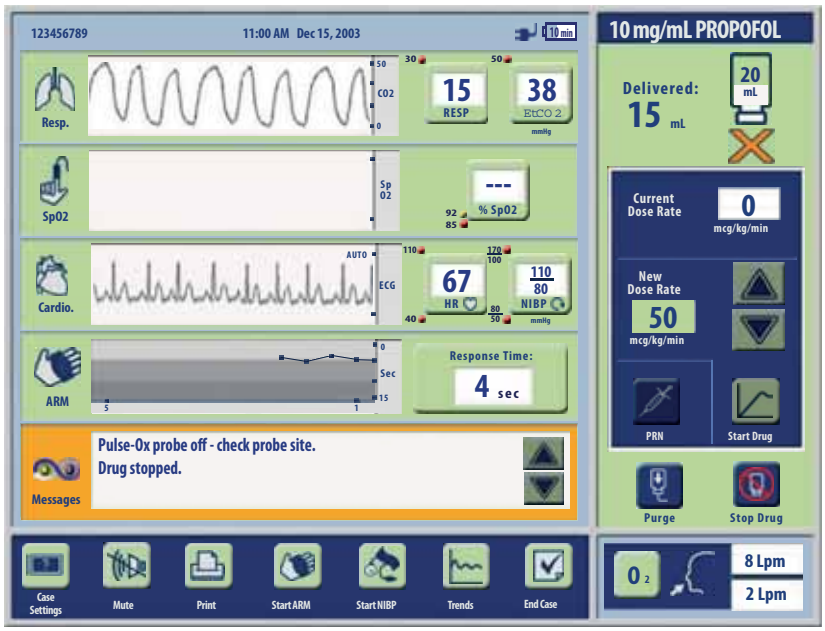


Figure 8-6 PRU Monitoring Screen During Pulse Oximeter Correctable Advisory, After Drug Delivery Has Been Stopped

BMU Changes When Countdown Timer Has Expired

When the 60-second countdown expires for a Correctable Advisory of the Pulse Oximeter, Capnometer, ARM, or Oxygen Delivery modules, the System will automatically stop drug delivery and the following changes appear on the BMU:

- Current Dose Rate box displays "0".
- **Dose Rate** and **PRN** buttons are disabled.

Restarting Drug Delivery After Countdown Timer Has Expired

Before restarting drug delivery, you must first fix the problem causing the Correctable Advisory for the Pulse Oximeter, Capnometer, ARM, or Oxygen Delivery modules. The System will automatically detect the correction of the problem and discontinue the audio signal.

To restart drug delivery from the PRU:

1. Press **Start Drug** to accept the previous dose rate displayed in the New Dose Rate box.

- OR -

Use the **Up** or **Down Arrow** buttons to select a different dose rate, and then press **Start Drug**.

To restart drug delivery from the BMU:

1. Press **Dose Rate** from the BMU Remote Entry Screen.
2. Press **Start Drug** to accept the previous dose rate displayed in the New Dose Rate box.

- OR -

Use the **Up** or **Down Arrow** buttons to select a different dose rate, and then press **Start Drug**.

After restarting drug delivery, the PRU Monitoring screen returns to "normal" except:

- Current Dose Rate box still displays "0".
- New Dose Rate box still displays the previous dose rate.
- Flashing orange "X" remains under vial icon.

Similarly, the BMU Remote Entry screen returns to normal except:

- Current Dose Rate box still displays "0".

NIBP or ECG Correctable Advisory

The System does not take any drug action when responding to a problem with the NIBP or ECG modules.

PRU Changes During a Correctable Advisory

When the System detects a problem with the NIBP or ECG modules, the following changes appear on the PRU:

- Background of Messages field changes to orange.
- Descriptive message of the problem appears in Messages field. This message provides guidance for the clinician to correct the problem.

- If the affected module is the ECG, the waveform box is blank.

Note

For failure of the ECG module, a heart rate is still displayed on the HR button because the System receives the heart rate from the Pulse Oximeter.

- If the affected module is the NIBP, the NIBP button displays "---".

Note

The Start NIBP button is NOT disabled. The only way to clear an NIBP advisory (after fixing the problem causing the Correctable Advisory) is to manually initiate a NIBP measurement by pressing the Start NIBP button. The PRU Monitoring and BMU Remote Entry screens return to "normal" after a successful NIBP reading.

- An audio signal is sounded.

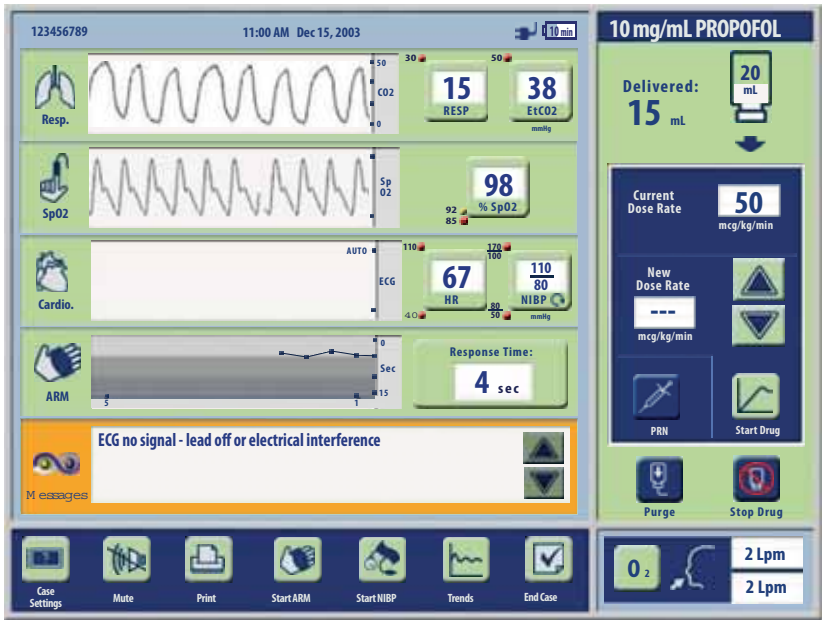


Figure 8-7 PRU Monitoring Screen During ECG Correctable Advisory

BMU Changes During a Correctable Advisory

When the System detects a problem with the NIBP or ECG modules, the only change to the BMU is the flashing of the Light Bar. Detailed information on the Correctable Advisory can be found on the PRU display.

Umbilical Cable Correctable Advisory

During the procedure, if the Umbilical Cable becomes disconnected from either the BMU or PRU, the PRU no longer receives valid data from the Pulse Oximeter, NIBP, ECG, Capnometry or ARM modules. Therefore, the System will trigger a Correctable Advisory that is only displayed on the PRU.

When the System triggers a Correctable Advisory for the Umbilical Cable, the changes appearing on the PRU Main Monitoring screen are a

combination of the same changes that appear when the System detects a Correctable Advisory for the Pulse Oximeter, NIBP, ECG, Capnometry and ARM modules. The only screen difference that occurs for an Umbilical Cable Correctable Advisory is the message "BMU disconnected from PRU - connect BMU to PRU" appears in an advisory pop-up screen.

The BMU displays the BMU Monitoring screen until the connection is re-established. When the connection is re-established, the BMU display returns to the BMU Remote Entry screen.

If the Umbilical Cable connection is not re-established within 60 seconds, drug delivery will automatically stop. If the Umbilical Cable connection is not re-established within 180 seconds, the procedure will be terminated on the PRU. The BMU will remain at the Monitoring screen.

Synchronization Advisories for Standalone BMU

A Synchronization Advisory is an internal problem of identifiable cause that cannot be corrected by the clinician. When the BMU detects an internal problem with the Pulse Oximeter, NIBP, or ECG modules, the BMU will attempt to self-correct the problem for up to 60 seconds. A Synchronization Advisory will be initiated to indicate the System actions during this time. If the problem cannot be self-corrected within 60 seconds, the BMU will display a Failure Advisory (refer to Failure Advisories for Standalone BMU on page 8-12).

BMU Changes During a Synchronization Advisory

When the BMU initially detects a problem with the Pulse Oximeter, NIBP, or ECG modules, the following changes appear on the BMU:

- The numeric display of the affected module will display "---".

Note

If the Pulse Oximeter is the affected module, the System will obtain the Heart Rate from the ECG. The icon is displayed on the **HR/ECG** button to indicate that the Heart Rate source is from the ECG module.

- Light bar on top of the BMU flashes.
- A descriptive message of the problem appears in the Information screen. To access the Information screen, press the **Info** button.

Note

1 For example, if the Pulse Oximeter is the affected module, the message "Pulse Ox - synchronizing - please wait" will be displayed.

2 When the problem first appears, the **Info** button will flash indicating a new message has been posted in the Information screen.

Synchronization Advisories for PRU/BMU Combination

When the System detects an internal problem with the Pulse Oximeter, NIBP, ECG, Capnometry, Barcode or Internal Communication modules that cannot be corrected by the clinician, the System will attempt to self-correct the problem for up to 60 seconds. A Synchronization Advisory will be initiated to indicate the System actions during this time. If the problem cannot be self-corrected within 60 seconds, the System will display a Failure Advisory (refer to Failure Advisories for PRU/BMU Combination on page 8-13).

The response of the System to Synchronization Advisories depends on which module of the System is affected. For example:

- A problem with the Pulse Oximeter or Capnometry modules will initiate a countdown timer to indicate when drug delivery will be terminated if the problem is not corrected.
- A problem with the NIBP or ECG modules will not affect drug delivery.

SpO_2 or Capnometry Synchronization Advisories

When the System detects a problem with the Pulse Oximeter or Capnometry modules, the following changes appear on the PRU:

- Messages field displays "[module name] - synchronizing - please wait".
- Messages field displays "Drug will stop in 120 seconds".

Note

The number of seconds (120) in the message acts as a countdown timer. The number will decrement until it reaches 0 (zero) seconds and drug delivery will stop unless the problem is corrected before the countdown timer expires.

- If the SpO_2 module is affected, the SpO_2 waveform box is blank and the SpO_2 button displays “---“.
- If the Capnometry module is affected, the Capnometry waveform box is blank and the RESP and $EtCO_2$ buttons display “---“.

Note

During a SpO_2 Synchronization Advisory, the System will obtain the Heart Rate from the ECG. The  icon is displayed on the HR button to indicate that the Heart Rate source is from the ECG module.

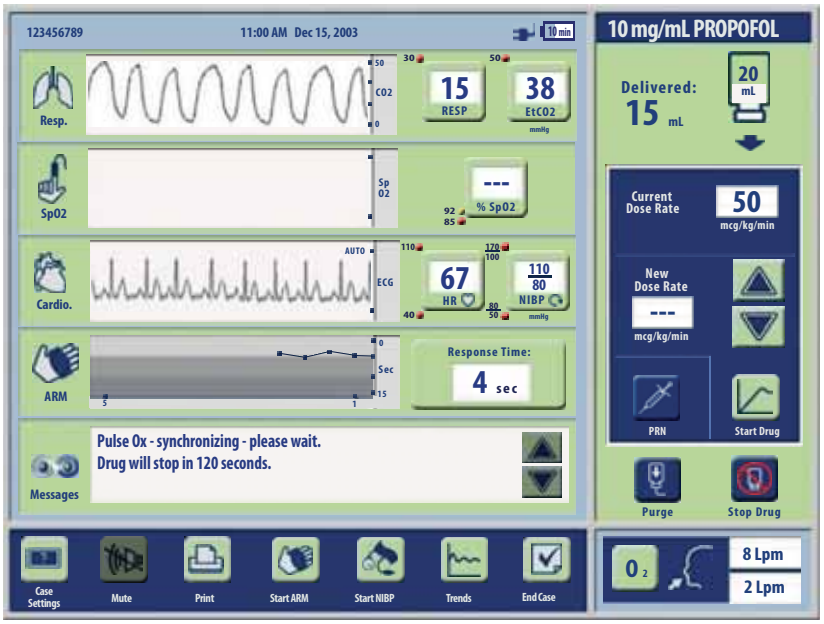


Figure 8-8 PRU Screen During Pulse Oximeter Synchronization Advisory

Note

If a PRN dose is in progress, delivery of the PRN dose will be stopped.

NIBP/ECG Synchronization Advisory

When the System detects a problem with the NIBP or Electrocardiogram modules, the following changes appear on the PRU:

- Message field displays "[module name] - synchronizing - please wait".
- If the ECG module is affected, the ECG waveform box is blank.

Note

For an ECG failure, the heart rate is still displayed on the **HR** button because the default is the heart rate from the Pulse Oximeter.

- If the NIBP module is affected, the NIBP button displays "---".

Failure Advisories for Standalone BMU

A Failure Advisory is a hardware or software problem of identifiable cause that cannot be corrected by the clinician or by the BMU itself. For all Failure Advisories, contact the authorized service representative.

Note

You will not be able to initiate a new case if any module has failed.

BMU Changes During a Failure Advisory

When the System detects a failure with the Pulse Oximeter, NIBP, ECG, ARM, Communication, Battery, Audio, Printer, or Data Storage modules, the following changes appear on the BMU:

- Advisory screen displays "[module name] system failure - contact service" and remains until you close it acknowledging that you have seen the message.

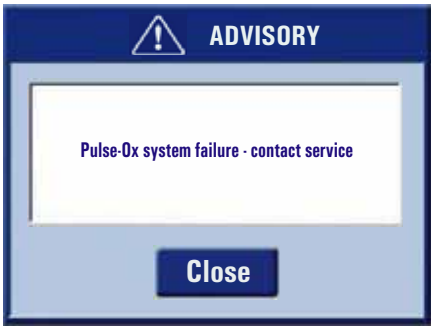


Figure 8-9 BMU Advisory Screen During Pulse Oximeter Failure

- The numeric display of the affected module will display "---".

Note

1. For example, if the Pulse Oximeter is the affected module, the **%SpO$_2$** button displays "---".
2. If the Pulse Oximeter is the affected module, the System will obtain the Heart Rate from the ECG. The icon is displayed on the **HR/EEG** button to indicate that the Heart Rate source is from the ECG module.

- Light bar on top of the BMU flashes.
- An audio signal is sounded.

Failure Advisories for PRU/BMU Combination

A Failure Advisory is a hardware or software problem of identifiable cause that cannot be corrected by the clinician or by the System itself. For any Failure Advisory, contact the authorized service representative.

The response of the System to Failure Advisories depends on which module is affected. For example:

- A failure of the IV pump module immediately disables drug delivery.
- A failure of the Pulse Oximeter, Capnometer or Oxygen Delivery modules stops drug delivery after 120 seconds.
- A failure of the ARM module stops drug delivery after 120 seconds, but only if you decide not to continue the case in the Clinician Response mode.

- A failure of the NIBP or ECG modules during a case does not affect drug delivery.

Note

You will not be able to initiate a new case if any module has failed.

IV Pump Failure Advisory

When responding to a Failure Advisory of the IV pump module, the System immediately terminates drug delivery. Although drug infusion cannot be restarted, you can continue to monitor the patient until the patient has recovered from the effects of sedation.

PRU Changes During a Failure Advisory

When the System detects a failure with the IV pump module that cannot be corrected, the following changes appear on the PRU:

- Advisory pop-up screen displays "Pump system failure - contact service".

Note

Advisory pop-up screen appears on top of Drug Delivery Interface.

- The **Purge** button is disabled.
- Black "X" appears under vial icon that indicates that drug delivery has been stopped.
- An audio signal is sounded.

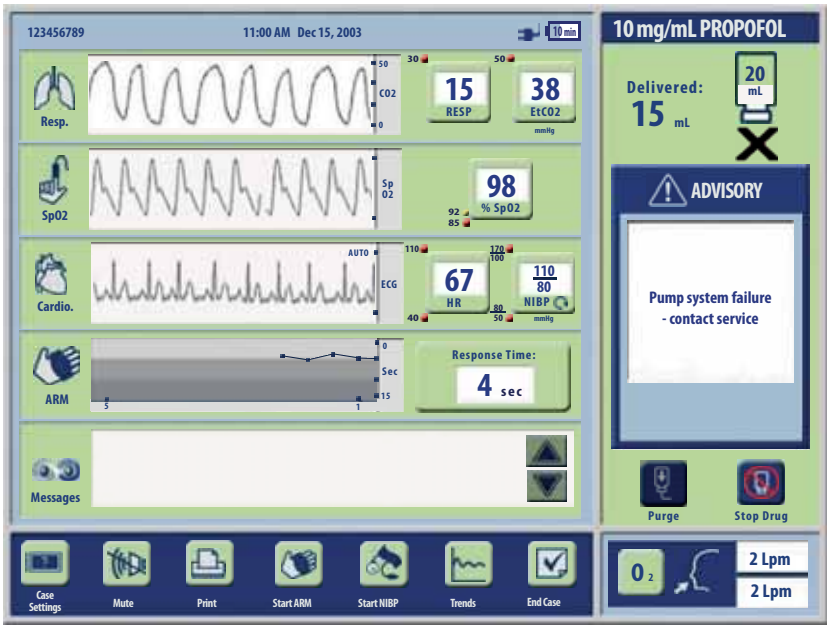


Figure 8-10 PRU Monitoring Screen During IV Pump Failure Advisory

BMU Changes During a Failure Advisory

When the System detects a failure with the IV pump module, the following changes appear on the BMU:

- Current Dose Rate box displays a flashing "0".
- Light Bar on top of the BMU flashes.
- **PRN** and **Dose Rate** buttons are disabled.

Figure 8-11 BMU Remote Entry Screen During IV Pump Failure Advisory

Pulse Oximeter or Capnometer Failure Advisory

Since the SEDASYS® System reduces and/or stops drug delivery in response to alarms generated by the Pulse Oximeter or Capnometer modules, the inputs to the proprietary software may be compromised if either module fails. Therefore, when responding to a Failure Advisory for the Pulse Oximeter or Capnometer modules, the System automatically disables drug delivery after 120 seconds. An active PRN dose will be immediately stopped.

Drug delivery will continue during the 120-second period allowing time for the termination of the procedure with minimal patient discomfort. Although drug delivery cannot be restarted, you can continue to monitor the patient with the remaining monitors.

PRU Changes During a Failure Advisory

When the System detects a failure with the Pulse Oximeter or Capnometer modules, the following changes appear on the PRU:

- Messages field displays "Drug will stop in xxx seconds". The countdown timer starts at 120 seconds. However, if the failure is displayed after a Synchronization Advisory that could not be self-corrected, the countdown timer starts at 60 seconds.

Note

The number of seconds (xxx) in the message acts as a countdown timer. The number will decrement until it reaches 0 (zero) seconds and drug delivery will stop.

- Advisory pop-up screen displays "[module name] system failure - contact service" and remains on the screen until the countdown timer

expires, or until you close it (acknowledging that you have seen the message).

- The word "Failure" appears in the waveform box of the module that failed and is hidden underneath the Advisory pop-up screen.

Note

When a module has failed, no waveform is displayed.

- The failed module's parameter button(s) display "---".

Note

1 For example, if the Pulse Oximeter is the affected module, the **%SpO$_2$** button displays "---".

2 If the Pulse Oximeter is the affected module, the System obtains the heart rate from the ECG and the icon is displayed on the **HR** button.

- Shortcut buttons are disabled (refer to Shortcuts to Changing Case Settings on page 6-40).
- An audio signal is sounded.

Figure 8-12 PRU Monitoring Screen During Pulse Oximeter Failure Advisory

BMU Changes During a Failure Advisory

When the System detects a failure with the Pulse Oximeter or Capnometer modules, the only change to the BMU is the flashing of the Light Bar. Detailed information on the failure can be found on the PRU display.

PRU Changes When Timer Countdown Has Expired

When the countdown expires for a Failure Advisory of the Pulse Oximeter or Capnometer modules, the System automatically stops drug delivery and the following changes appear on the PRU:

- Messages field displays "Drug delivery not permitted."
- Current Dose Rate box displays a flashing "0". The New Dose Rate box displays "---".
- Black "X" appears under vial icon.
- **Up** and **Down Arrow**, **PRN**, and **Start Drug** buttons are disabled.

Note

Shortcut buttons no longer disabled and are active.

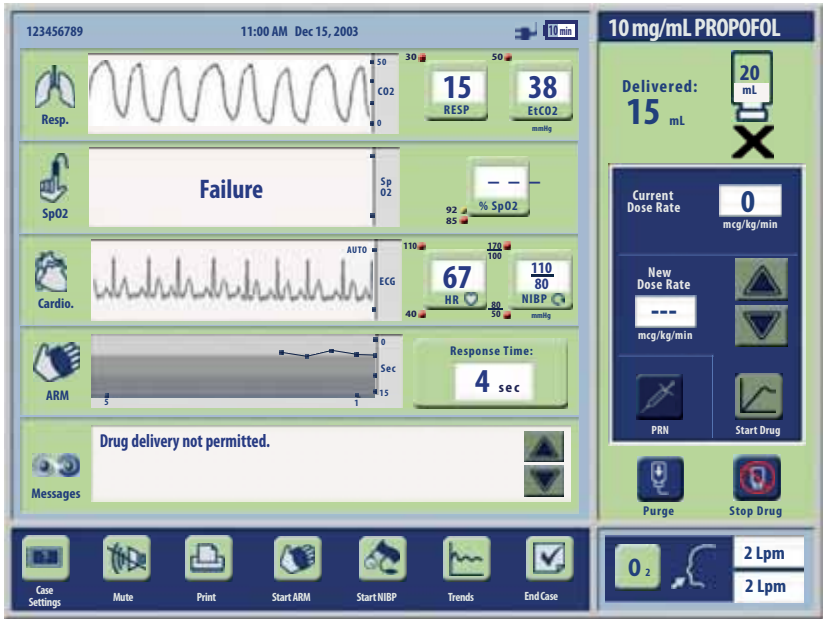


Figure 8-13 PRU Monitoring Screen During Pulse Oximeter Failure Advisory, After Drug Delivery Has Seen Stopped

BMU Changes When Countdown Timer Has Expired

When the countdown expires for a Failure Advisory of the Pulse Oximeter or Capnometer modules, the System automatically stops drug delivery and the following changes appear on the BMU Remote Entry screen.

- Current Dose Rate box displays a flashing "0".
- PRN and Dose Rate buttons are disabled.

ARM Failure Advisory

ARM response plays a key role in guiding drug titration, so the System performance could be compromised if drug infusion were allowed without

monitoring the patient's responsiveness. Therefore, when responding to a Failure Advisory of the ARM module, the System provides an option to continue the case in the Clinician Response Mode. For information about the Clinician Response mode, refer to Clinician-Response Mode on page 6-36.

If you choose not to use the Clinician Response Mode option, the System handles the advisory in the same manner as a Failure Advisory of the Pulse Oximeter or Capnometer and automatically disables drug delivery after 120 seconds. An active PRN dose will be immediately stopped.

PRU Changes During a Failure Advisory

When the System detects a failure with the ARM module, the following changes appear on the PRU:

- Messages field displays "Drug will stop in 120 seconds".

Note

The number of seconds (120) in the message acts as a countdown timer. The number will decrement until it reaches zero (0) seconds and drug delivery will stop.

- **Response Time** button displays "---".
- An audio signal is sounded.
- Advisory pop-up screen displays "ARM module failure. Continue the case in clinician response mode?" and provides options for selecting **YES** or **NO**.
- **Start ARM**, **Up** and **Down Arrow**, **PRN**, **Start Drug** and shortcut buttons are disabled for the duration of the advisory (refer to Shortcuts to Changing Case Settings on page 6-40).

If the clinician selects **YES**, the case will be continued in the Clinician Response Mode. The 120-second timer message is removed from the Messages field and the audible signal is stopped.

If the clinician selects **NO**, the System handles the advisory like a Failure Advisory of the Pulse Oximeter. After 120 seconds, drug delivery stops and the PRU Monitoring and BMU Remote Entry screens change accordingly.

Note

If the clinician does not make a choice within 120 seconds, drug delivery will be automatically disabled.

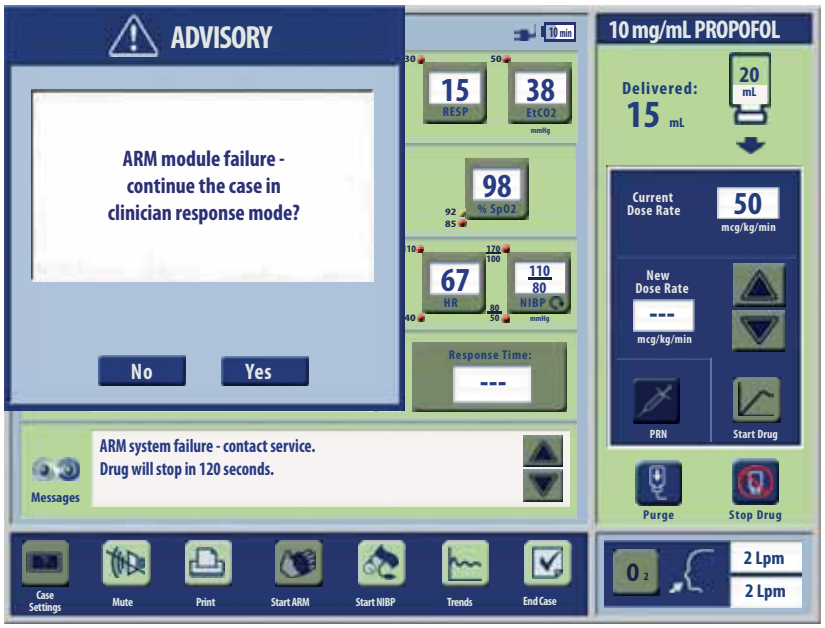


Figure 8-14 PRU Monitoring Screen During ARM Failure Advisory

BMU Changes During a Failure Advisory

When the System detects a failure with the ARM module, the only change to the BMU is the flashing of the Light Bar. Detailed information on the failure can be found on the PRU display.

NIBP or ECG Failure Advisory

Alarms triggered from the NIBP or ECG modules do not affect drug delivery. Therefore, the System does not terminate drug delivery when responding to a Failure Advisory of the NIBP or ECG modules.

Note

Although drug delivery is not terminated for the current case, you will not be able to initiate a new case if the NIBP and ECG modules have failed.

PRU Changes During a Failure Advisory

When the System detects a failure with the NIBP or ECG modules, the following changes appear on the PRU:

- Advisory pop-up screen displays "[module name] system failure - contact service" and remains on the screen for 60 seconds, or until you close it (acknowledging that you have seen the message).
- If the ECG module fails, "Failure" appears in the ECG waveform box.

Note

For an ECG failure, the heart rate is still displayed on the **HR** button because the default is the heart rate from the Pulse Oximeter.

- If the NIBP module fails, the **NIBP** button displays "---" and "NIBP Failure" is displayed in the Messages field.

Note

Start NIBP button is disabled.

- An audio signal is sounded.

BMU Changes During a Failure Advisory

When the System detects a failure with the NIBP or ECG module, the only change to the BMU is the flashing of the Light Bar. Detailed information on the failure can be found on the PRU display.

BMU Communication Failure Advisory

If a problem exists in the communication between the PRU and BMU, the System no longer receives data from the Pulse Oximeter, NIBP, ECG, or ARM modules. When the System triggers a BMU Communication Failure Advisory, the changes appearing on the PRU Monitoring screen are the same changes that appear when the System detects a Failure Advisory for the Pulse Oximeter, NIBP, ECG, and ARM modules.

In addition, the Messages field displays "BMU communication failure," and drug infusion is automatically stopped after 60 seconds. An active PRN dose will also be stopped after 60 seconds.

The BMU displays the BMU Monitoring screen. Refer to *Appendix D: BMU Monitoring Screen* for more information.

Precaution

Care should be exercised in continuing to administer propofol during a BMU Communication Failure. Although you will still be able to monitor the patient's heart rate, blood pressure and oxygen saturation and the BMU will alarm if any of these parameters fall below alarm thresholds, the System will not take automatic action to stop propofol delivery in event of an oxygen desaturation.

System Fault Advisory

A System Fault Advisory is a serious hardware or software problem where the cause cannot be identified by the System and prevents proper functioning of the System. Each time the BMU or PRU is powered up, a system self-check is run to make sure the hardware and software subsystem are functioning correctly.

Note

For any System Fault Advisory, contact an authorized service representative.

System Fault of PRU

If a System Fault in the PRU occurs during a procedure:

- PRU immediately shuts down. Drug delivery and oxygen delivery are stopped.
- PRU will attempt to provide an audible and visual advisory of the System Fault.
- BMU displays the BMU Monitoring screen.

Refer to *Appendix D: BMU Monitoring Screen* for more information.

System Fault of BMU

If a System Fault in the BMU occurs during a procedure:

- BMU immediately shuts down.
- PRU will behave as if there was a Failure Advisory for the Pulse Oximeter, NIBP, ECG, and ARM modules.

Muting Correctable and Failure Advisories

The **Mute** button temporarily silences all audible advisories. Press it once to mute the advisories for 60 seconds; press it again to mute for an additional 60 seconds; and press it a third time (maximum) for an added 60 seconds (maximum total time: 180 seconds). The advisories remain muted for the period selected and cannot be unmuted.

When **Mute** is pressed, the label identifying the Mute button is replaced with a countdown timer that displays the time remaining until the alarms are audible again.

When advisories are muted, any new alarm and/or advisory that occurs will trigger a new audible signal. However, the highest existing priority alarm and/or advisory will be heard, regardless of whether it was previously muted or not.

Muting advisories does not change the visual indications on the PRU or BMU Monitoring screens, nor does it impact drug delivery.

This page is intentionally left blank.

Chapter 9 Cleaning and Maintenance

This chapter includes detailed cleaning, disinfection, and preventative maintenance instructions.

Users in North America should also refer to appropriate sections of AORN Standards & Recommended Practices for additional guidance on cleaning and sterilization. All other localities should refer to appropriate guidelines.

The user must qualify cleaning and sterilization effectiveness.

Precaution

Failure to follow cleaning and maintenance instructions provided in this manual may result in damage to the System or degradation of system performance.

Cleaning

Before cleaning, thoroughly inspect the System for any signs of damage, cracks, or improper mechanical function. While gently bending and flexing cables and tubing, inspect for damage, cracks, cuts, abrasions, and exposed or bent connectors. Report damage or improper function to an authorized service representative.

Precaution

1 Do not autoclave, steam-sterilize, EO-sterilize, or gas plasma sterilize the System or any of its components. This may damage the System or degrade its performance.

2 Do not immerse any part of the System or any of its components in liquid.

Cleaning of the Bedside Monitoring Unit (BMU), the Procedure Room Unit (PRU), Cart, and Umbilical Cable should be performed periodically. All Multiple Patient Use (MPUs) items (ARM Handset, Pulse-Oximetry probe, NIBP cuff, and ECG leads) must be cleaned prior to each patient use.

BMU, PRU, and Cart

1. Clean the unit's surfaces with a neutral pH detergent, prepared according to the manufacturer's instructions.
2. Use a soft clean cloth to manually clean the device with the cleaning solution.
3. Rinse/wipe off detergent thoroughly using a soft clean cloth soaked with lukewarm tap water.
4. Repeat as necessary to remove all detergent.
5. Dry the device with a clean absorbent cloth.

MPU Devices

Includes ARM Handset, Umbilical Cable, Pulse Oximetry probe, NIBP cuffs, and ECG leads.

1. Clean the unit's surfaces with a neutral pH detergent, prepared according to the manufacturer's instructions.
2. Use a soft bristle brush or soft clean cloth to manually clean the device with the cleaning solution.
3. Rinse/wipe off detergent thoroughly using a soft clean cloth soaked with lukewarm tap water.
4. Repeat as necessary to remove all detergent.
5. Dry the device with a clean absorbent cloth.

Precaution

1 Before cleaning, be sure to turn off the power to the BMU, PRU Control Unit, and PSU, and disconnect the AC power from the BMU and PSU.

2 Do not spray cleaner into the connector ends. Do not get cleaning solution inside the pneumatic ports or electrical contacts.

Disinfection

If system components become contaminated with blood or bodily fluid, a disinfection step must follow the cleaning of the device. Sodium hypochlorite solution (10% bleach) is approved for use with SEDASYS® System components, and should be prepared and used according to the manufacturer's recommendation for use and contact time.

WARNING

Do not mix bleach-based cleaners with ammonia-based cleaners (i.e., glass cleaners) because this can produce toxic fumes.

Maintenance

WARNING

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

Precaution

The device must be disconnected from external power when the internal battery pack is replaced.

Table 9-1: Daily Maintenance Schedule

Required Maintenance	Recommended Maintenance Interval
	Daily
Inspect System for obvious physical damage and replace damaged items.	√
Inspect all cords/cables for fraying or other insulation damage. Repair or replace damaged items.	√
Inspect all plugs and connectors for bent prongs or pins. Repair or replace damaged items.	√

Preventative maintenance/calibration schedules should be performed as follows: PRU/PSU every 6 months; BMU every year. These activities should only be performed by an authorized service supplier. For assistance, call 1-800-SEDASYS.

Recycling

When the internal batteries reaches the end of its life, recycle the battery locally according to national, state and local regulations.

This page is intentionally left blank.

Chapter 10 Troubleshooting

Initial troubleshooting of the SEDASYS® System can be accomplished using the Symptom and Possible Cause(s) table shown below.

The horizontal rows represent the System symptoms and are categorized in the following common procedural steps:

- Initial System Start-up
- Start of Day
- Patient Set-up
- Start of Case from PRU Connection
- End Case

The vertical columns represent the possible causes for each symptom. If a symptom always occurs with the cause, there will be a dark blue box at the intersection of the symptom and cause. If a symptom commonly occurs with the cause, there will be a light blue box at the intersection of the symptom and cause.

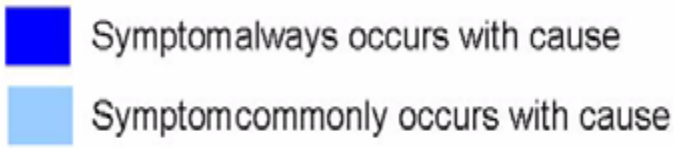
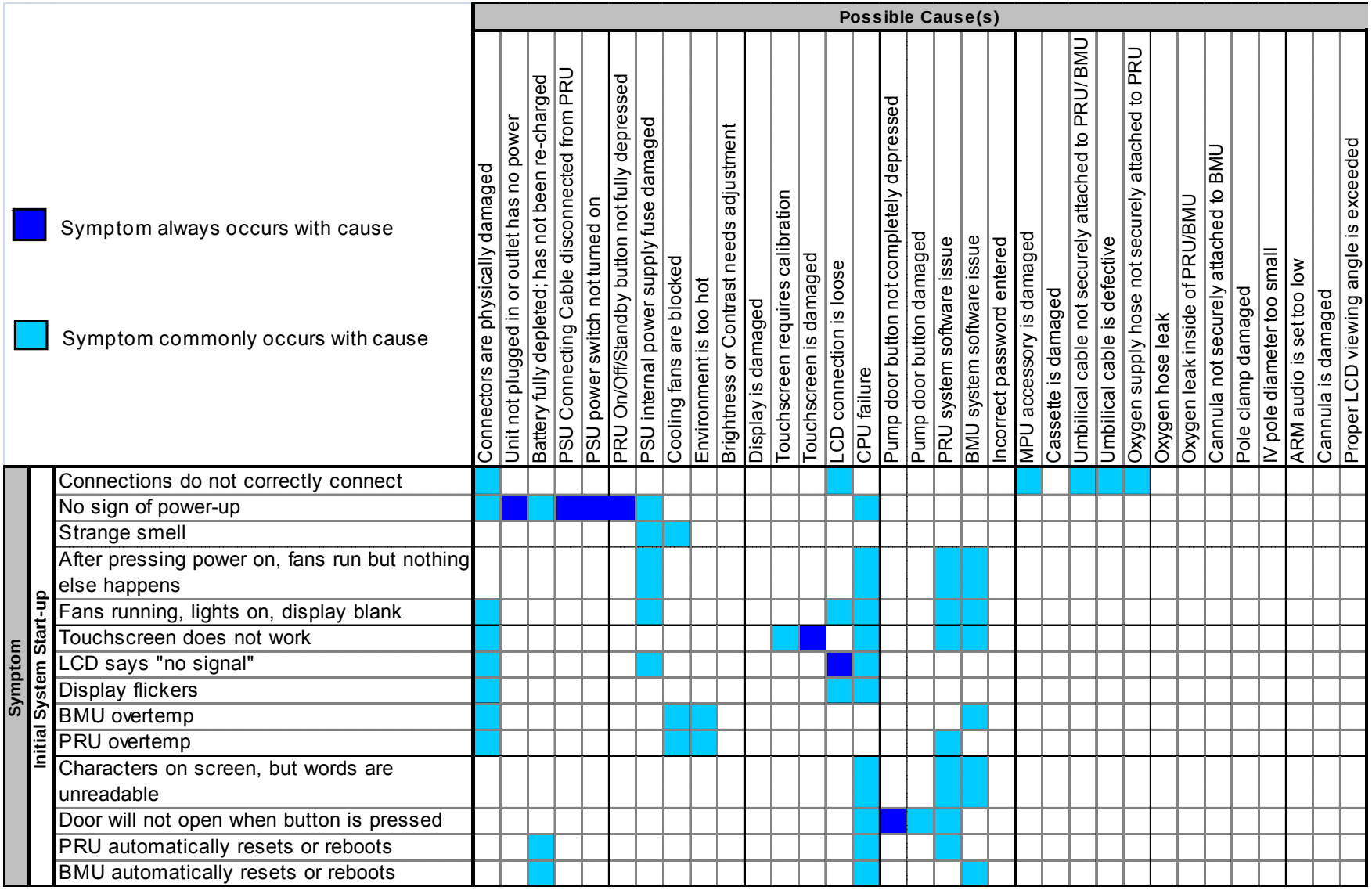


Figure 10-1 Symptom and Possible Causes

Printer Advisories/Failure

The BMU and the PRU (when connected to the BMU) can send data to an external, wireless printer. In the event that wireless communication to the printer is interrupted, one of the following messages will be displayed.

- "*Printer system configuration failure - contact service.*" If this message is displayed, try to power cycle the SEDASYS®System to correct the failure. If this does not resolve the failure, service must be contacted.
- "*Printer not detected - check power and proximity.*" If this message is displayed, the SEDASYS® System will try to self-correct the problem. If the System cannot self-correct the problem, try to power cycle the System to correct the failure or move the printer closer to the System. If this does not resolve the failure, service must be contacted.


Symptom always occurs with cause
Symptom commonly occurs with cause
Possible Cause(s)
Connectors are physically damaged
Unit not plugged in or outlet has no power
Battery fully depleted; has not been re-charged
PSU Connecting Cable disconnected from PRU
PSU power switch not turned on
PRU On/Off/Standby button not fully depressed
PSU internal power supply fuse damaged
Cooling fans are blocked
Environment is too hot
Brightness or Contrast needs adjustment
Display is damaged
Touchscreen requires calibration
Touchscreen is damaged
LCD connection is loose
CPU failure
Pump door button not completely depressed
Pump door button damaged
PRU system software issue
BMU system software issue
Incorrect password entered
MPU accessory is damaged
Cassette is damaged
Umbilical cable not securely attached to PRU/BMU
Umbilical cable is defective
Oxygen supply hose not securely attached to PRU
Oxygen hose leak
Oxygen leak inside of PRU/BMU
Cannula not securely attached to BMU
Pole clamp damaged
IV pole diameter too small
ARM audio is set too low
Cannula is damaged
Proper LCD viewing angle is exceeded
Symptom
Initial System Start-up
Connections do not correctly connect
No sign of power-up
Strange smell
After pressing power on, fans run but nothing else happens
Fans running, lights on, display blank
Touchscreen does not work
LCD says "no signal"
Display flickers
BMU overtemp
PRU overtemp
Characters on screen, but words are unreadable
Door will not open when button is pressed
PRU automatically resets or reboots
BMU automatically resets or reboots

Symptom always occurs with cause

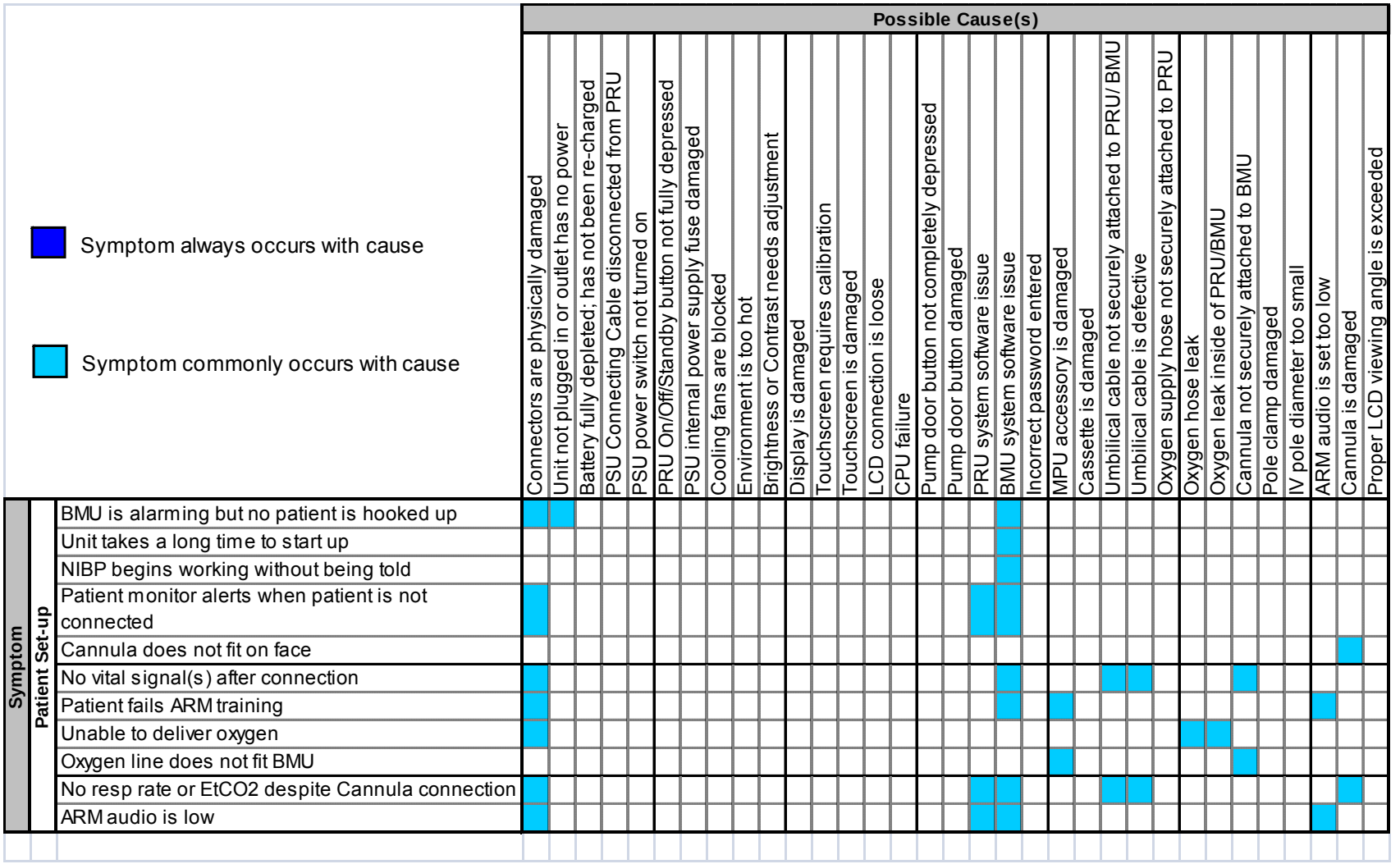
Symptom commonly occurs with cause

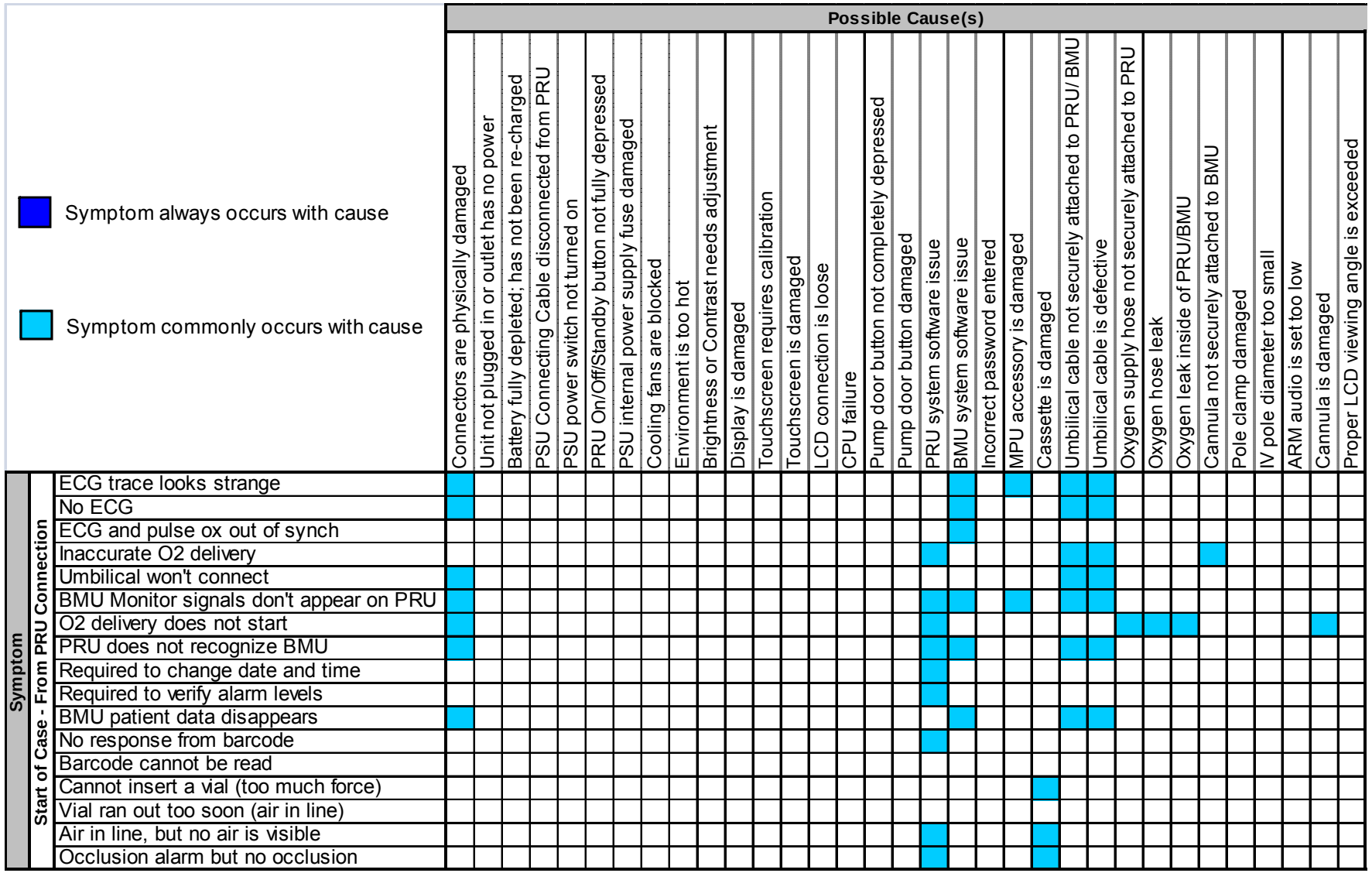
Symptom	Initial System Start-up	Possible Cause(s)																																				
		Connectors are physically damaged	Unit not plugged in or outlet has no power	Battery fully depleted; has not been re-charged	PSU Connecting Cable disconnected from PRU	PSU power switch not turned on	PRU On/Off/Standby button not fully depressed	PSU internal power supply fuse damaged	Cooling fans are blocked	Environment is too hot	Brightness or Contrast needs adjustment	Display is damaged	Touchscreen requires calibration	Touchscreen is damaged	LCD connection is loose	CPU failure	Pump door button not completely depressed	Pump door button damaged	PRU system software issue	BMU system software issue	Incorrect password entered	MPU accessory is damaged	Cassette is damaged	Umbilical cable not securely attached to PRU/ BMU	Umbilical cable is defective	Oxygen supply hose not securely attached to PRU	Oxygen hose leak	Oxygen leak inside of PRU/BMU	Cannula not securely attached to BMU	Pole clamp damaged	IV pole diameter too small	ARM audio is set too low	Cannula is damaged	Proper LCD viewing angle is exceeded
	Software or screen freezes															■			■	■																		
	Cannot enter biomed mode													■					■		■																	
	Flashing green light on back of PSU																																				
	Yellow light on back of PSU		■	■																																	
	Touchscreen response is unpredictable												■	■					■	■																	
	Cannot load cassette correctly																■	■					■														
	Cannot calibrate touchscreen													■					■	■																	
	Monitor info not available in PRU after Umbilical connection	■																	■	■		■		■	■												
	Loud hiss sound after connecting oxygen source	■																				■		■	■	■	■	■									
	Oxygen fitting does not connect	■																				■				■											
	BMU will not clamp to pole																														■	■					
	Low or no sound															■			■	■																	
	Display is too dim/bright										■	■			■																						

Symptom always occurs with cause

Symptom commonly occurs with cause

Symptom	Start of Day	Possible Cause(s)																																				
		Connectors are physically damaged	Unit not plugged in or outlet has no power	Battery fully depleted; has not been re-charged	PSU Connecting Cable disconnected from PRU	PSU power switch not turned on	PRU On/Off/Standby button not fully depressed	PSU internal power supply fuse damaged	Cooling fans are blocked	Environment is too hot	Brightness or Contrast needs adjustment	Display is damaged	Touchscreen requires calibration	Touchscreen is damaged	LCD connection is loose	CPU failure	Pump door button not completely depressed	Pump door button damaged	PRU system software issue	BMU system software issue	Incorrect password entered	MPU accessory is damaged	Cassette is damaged	Umbilical cable not securely attached to PRU/ BMU	Umbilical cable is defective	Oxygen supply hose not securely attached to PRU	Oxygen hose leak	Oxygen leak inside of PRU/BMU	Cannula not securely attached to BMU	Pole clamp damaged	IV pole diameter too small	ARM audio is set too low	Cannula is damaged	Proper LCD viewing angle is exceeded
	Unit takes a long time to start up																		■	■																		
	Low battery even though it was plugged in all night	■	■					■																														
	Screen goes dark after successful start-up		■									■			■	■			■	■																		
	System beeps and shuts off	■	■	■												■			■	■																		
	Unusual noise																											■	■									
	Facility settings or system (patient) settings lost															■			■	■																		

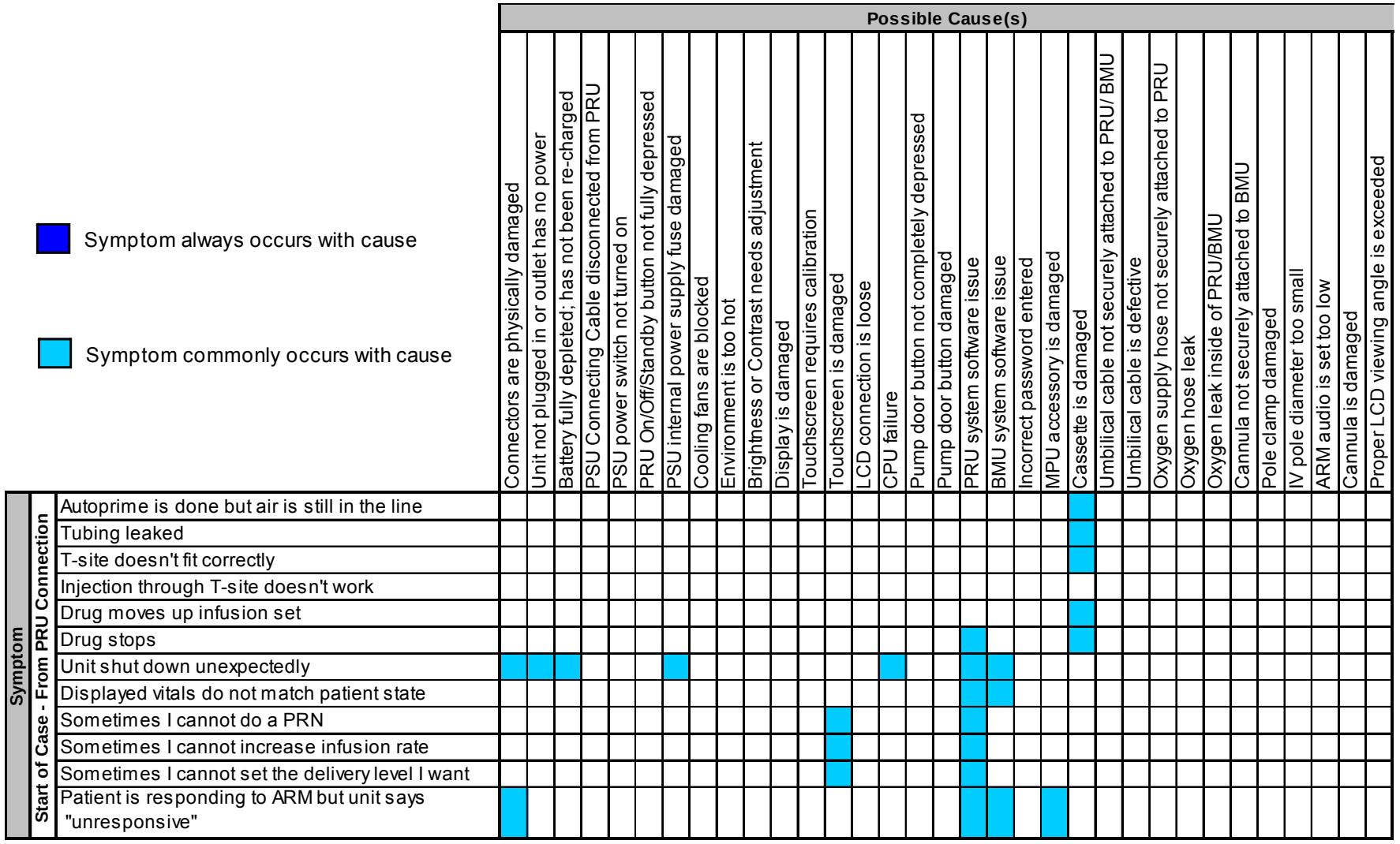

Symptom always occurs with cause
Symptom commonly occurs with cause
Possible Cause(s)
Connectors are physically damaged
Unit not plugged in or outlet has no power
Battery fully depleted; has not been re-charged
PSU Connecting Cable disconnected from PRU
PSU power switch not turned on
PRU On/Off/Standby button not fully depressed
PSU internal power supply fuse damaged
Cooling fans are blocked
Environment is too hot
Brightness or Contrast needs adjustment
Display is damaged
Touchscreen requires calibration
Touchscreen is damaged
LCD connection is loose
CPU failure
Pump door button not completely depressed
Pump door button damaged
PRU system software issue
BMU system software issue
Incorrect password entered
MPU accessory is damaged
Cassette is damaged
Umbilical cable not securely attached to PRU/ BMU
Umbilical cable is defective
Oxygen supply hose not securely attached to PRU
Oxygen hose leak
Oxygen leak inside of PRU/BMU
Cannula not securely attached to BMU
Pole clamp damaged
IV pole diameter too small
ARM audio is set too low
Cannula is damaged
Proper LCD viewing angle is exceeded
Symptom
Patient Set-up
BMU is alarming but no patient is hooked up
Unit takes a long time to start up
NIBP begins working without being told
Patient monitor alerts when patient is not connected
Cannula does not fit on face
No vital signal(s) after connection
Patient fails ARM training
Unable to deliver oxygen
Oxygen line does not fit BMU
No resp rate or EtCO2 despite Cannula connection
ARM audio is low


Symptom always occurs with cause
Symptom commonly occurs with cause
Possible Cause(s)
Symptom
Start of Case - From PRU Connection
Connectors are physically damaged
Unit not plugged in or outlet has no power
Battery fully depleted; has not been re-charged
PSU Connecting Cable disconnected from PRU
PSU power switch not turned on
PRU On/Off/Standby button not fully depressed
PSU internal power supply fuse damaged
Cooling fans are blocked
Environment is too hot
Brightness or Contrast needs adjustment
Display is damaged
Touchscreen requires calibration
Touchscreen is damaged
LCD connection is loose
CPU failure
Pump door button not completely depressed
Pump door button damaged
PRU system software issue
BMU system software issue
Incorrect password entered
MPU accessory is damaged
Cassette is damaged
Umbilical cable not securely attached to PRU/ BMU
Umbilical cable is defective
Oxygen supply hose not securely attached to PRU
Oxygen hose leak
Oxygen leak inside of PRU/BMU
Cannula not securely attached to BMU
Pole clamp damaged
IV pole diameter too small
ARM audio is set too low
Cannula is damaged
Proper LCD viewing angle is exceeded
ECG trace looks strange
No ECG
ECG and pulse ox out of synch
Inaccurate O2 delivery
Umbilical won't connect
BMU Monitor signals don't appear on PRU
O2 delivery does not start
PRU does not recognize BMU
Required to change date and time
Required to verify alarm levels
BMU patient data disappears
No response from barcode
Barcode cannot be read
Cannot insert a vial (too much force)
Vial ran out too soon (air in line)
Air in line, but no air is visible
Occlusion alarm but no occlusion

Symptom always occurs with cause

Symptom commonly occurs with cause

Symptom		Possible Cause(s)																																				
		Connectors are physically damaged	Unit not plugged in or outlet has no power	Battery fully depleted; has not been re-charged	PSU Connecting Cable disconnected from PRU	PSU power switch not turned on	PRU On/Off/Standby button not fully depressed	PSU internal power supply fuse damaged	Cooling fans are blocked	Environment is too hot	Brightness or Contrast needs adjustment	Display is damaged	Touchscreen requires calibration	Touchscreen is damaged	LCD connection is loose	CPU failure	Pump door button not completely depressed	Pump door button damaged	PRU system software issue	BMU system software issue	Incorrect password entered	MPU accessory is damaged	Cassette is damaged	Umbilical cable not securely attached to PRU/ BMU	Umbilical cable is defective	Oxygen supply hose not securely attached to PRU	Oxygen hose leak	Oxygen leak inside of PRU/BMU	Cannula not securely attached to BMU	Pole clamp damaged	IV pole diameter too small	ARM audio is set too low	Cannula is damaged	Proper LCD viewing angle is exceeded
Start of Case - From PRU Connection	Cannot open cassette door																■	■	■				■															
	Cassette door won't stay locked closed																	■	■				■															
	Cassette won't fit properly																						■															
	Tubing is loose in cassette																						■															
	Tubing is kinked																						■															
	Door won't close on cassette																	■					■															
	System thinks it does not have a cassette (T-site)																		■				■															
	System does not recognize loaded vial																		■				■															
	Vial will not seat fully																						■															
	Fluid on system (drug)																						■															
	Vial leaked																						■															
	Autoprime did not start																		■				■															
	Autoprime did not stop																		■				■															
	Earbud will not stay in patient's ear																																■					
	Cannula will not stay on patient																																■					
	Weak ARM vibration																					■																


Symptom always occurs with cause
Symptom commonly occurs with cause
Possible Cause(s)
Connectors are physically damaged
Unit not plugged in or outlet has no power
Battery fully depleted; has not been re-charged
PSU Connecting Cable disconnected from PRU
PSU power switch not turned on
PRU On/Off/Standby button not fully depressed
PSU internal power supply fuse damaged
Cooling fans are blocked
Environment is too hot
Brightness or Contrast needs adjustment
Display is damaged
Touchscreen requires calibration
Touchscreen is damaged
LCD connection is loose
CPU failure
Pump door button not completely depressed
Pump door button damaged
PRU system software issue
BMU system software issue
Incorrect password entered
MPU accessory is damaged
Cassette is damaged
Umbilical cable not securely attached to PRU/ BMU
Umbilical cable is defective
Oxygen supply hose not securely attached to PRU
Oxygen hose leak
Oxygen leak inside of PRU/BMU
Cannula not securely attached to BMU
Pole clamp damaged
IV pole diameter too small
ARM audio is set too low
Cannula is damaged
Proper LCD viewing angle is exceeded
Symptom
Start of Case - From PRU Connection
Autoprime is done but air is still in the line
Tubing leaked
T-site doesn't fit correctly
Injection through T-site doesn't work
Drug moves up infusion set
Drug stops
Unit shut down unexpectedly
Displayed vitals do not match patient state
Sometimes I cannot do a PRN
Sometimes I cannot increase infusion rate
Sometimes I cannot set the delivery level I want
Patient is responding to ARM but unit says "unresponsive"

Symptom always occurs with cause

Symptom commonly occurs with cause

Symptom	Possible Cause(s)																																				
Start of Case - From PRU Connection	Connectors are physically damaged	Unit not plugged in or outlet has no power	Battery fully depleted; has not been re-charged	PSU Connecting Cable disconnected from PRU	PSU power switch not turned on	PRU On/Off/Standby button not fully depressed	PSU internal power supply fuse damaged	Cooling fans are blocked	Environment is too hot	Brightness or Contrast needs adjustment	Display is damaged	Touchscreen requires calibration	Touchscreen is damaged	LCD connection is loose	CPU failure	Pump door button not completely depressed	Pump door button damaged	PRU system software issue	BMU system software issue	Incorrect password entered	MPU accessory is damaged	Cassette is damaged	Umbilical cable not securely attached to PRU/ BMU	Umbilical cable is defective	Oxygen supply hose not securely attached to PRU	Oxygen hose leak	Oxygen leak inside of PRU/BMU	Cannula not securely attached to BMU	Pole clamp damaged	IV pole diameter too small	ARM audio is set too low	Cannula is damaged	Proper LCD viewing angle is exceeded
Patient appears responsive but unit says he's unresponsive	■																	■	■																		
O2 appears to be on all the time (continuous vs pulse)																		■											■					■		
Unit delivers drug at a lower rate than I set																		■																		
No audible alarms when alarm is triggered																		■																		
No print out on alarm																			■																		
Rate on screen is different than rate I set																		■																		
Drug kept flowing after alarm																		■																		
BMU battery issue even though umbilical is connected	■	■	■	■	■		■												■				■	■												
Battery life is short	■	■	■				■																														
Drug did not automatically restart after alarm is resolved																		■																		
Drug remained in vial but it made me change																																				
Unit did not recognize new vial																						■														

■ Symptom always occurs with cause

■ Symptom commonly occurs with cause

Symptom		Possible Cause(s)																																		
		Connectors are physically damaged	Unit not plugged in or outlet has no power	Battery fully depleted; has not been re-charged	PSU Connecting Cable disconnected from PRU	PSU power switch not turned on	PRU On/Off/Standby button not fully depressed	PSU internal power supply fuse damaged	Cooling fans are blocked	Environment is too hot	Brightness or Contrast needs adjustment	Display is damaged	Touchscreen requires calibration	Touchscreen is damaged	LCD connection is loose	CPU failure	Pump door button not completely depressed	Pump door button damaged	PRU system software issue	BMU system software issue	Incorrect password entered	MPU accessory is damaged	Cassette is damaged	Umbilical cable not securely attached to PRU/ BMU	Umbilical cable is defective	Oxygen supply hose not securely attached to PRU	Oxygen hose leak	Oxygen leak inside of PRU/BMU	Cannula not securely attached to BMU	Pole clamp damaged	IV pole diameter too small	ARM audio is set too low	Cannula is damaged	Proper LCD viewing angle is exceeded
End of Case	Cannot disconnect Umbilical	■																				■			■											
	Do not get end of case print out																		■	■																
	Cannot stop the case													■					■																	
	BMU battery advisory after disconnect																			■																
	O2 cannot connect directly to BMU (doesn't fit)	■																				■														
	Unit turned it off but the fan keeps running																																			

Appendix A Factory Default Settings

Table A-1: BMU Factory Default Alarm Limits

	Factory Default		Available Range	
	Minimum	**Maximum**	**Minimum**	**Maximum**
Heart Rate (HR)	50 beats/min.	120 beats/min.	35-60 beats/min. in increments of 5	110-150 beats/ min. in increments of 5
SpO_2	85%	–	80-91%	–
Diastolic NIBP	35 mmHg	110 mmHg	20-40 mmHg in increments of 5	105-130 mmHg in increments of 5
Systolic NIBP	80 mmHg	200 mmHg	65-85 mmHg in increments of 5	180-220 mmHg in increments of 5

Table A-2: PRU Factory Default Alarm Limits

	Factory Default		Available Range	
	Minimum	**Maximum**	**Minimum**	**Maximum**
Heart Rate (HR)	50 beats/min.	120 beats/min.	35-60 beats/min. in increments of 5	110-150 beats/ min. in increments of 5
SpO_2[a]	85%	–	75-91%	–
Diastolic NIBP	35 mmHg	110 mmHg	20-40 mmHg in increments of 5	105-130 mmHg in increments of 5
Systolic NIBP	80 mmHg	200 mmHg	65-85 mmHg in increments of 5	180-220 mmHg in increments of 5
$EtCO_2$	–	50 mmHg	–	50-70 mmHg in increments of 5
Respiratory Rate (RR)	–	30 breaths/min.	–	25-40 breaths/ min. in increments of 5
Apnea (low respiration rate[b])	90 seconds	–	60-120 seconds in increments of 5[c]	–

a. The Yellow Alarm limit for SpO_2 is 92%. This limit is not adjustable.

b. The Yellow Alarm limit for apnea is a function of the patient's SpO_2 (refer to Figure 5-27 on page 5 - 26).

c. At 100% SpO_2.

Note The “User Settings” column in the following table may be used to capture any custom settings for your facility.

Table A-3: Other BMU Factory Defaults

	Factory Defaults	Available Ranges/ Options	User Settings
Alarm volume	3	1-5	
System volume	3	0-5	
System language	English	English only	
Earpiece volume	3	1-5	
ARM language	English	English, Spanish, and French	
ECG Waveform Speed	25 mm/second	12.5 or 25 mm/second	
ECG Gain	Auto[a]	0.2, 0.5, 0.7, 1, 2, 4, or Auto	
Continuous Display of Alarm Limits	Off (unchecked)	Off (unchecked) or On (checked)	
Data Collection Interval[b]	5 minutes	1, 3, 5, 10, or 30 minutes	
NIBP Interval	3 minutes	2, 2.5, 3, 5, 10 or 20 minutes	
Printer Enabled	On (checked)	Off (unchecked) or On (checked)	
Print On Alarms	Off (unchecked)	Off (unchecked) or On (checked)	
Patient ID Entry	Off (unchecked)	Off (unchecked) or On (checked)	
Time Display	24	AM, PM or 24	
Time	This will be set at the factory (Eastern Time, GMT-05:00).	Hour: 1-12 (if AM or PM); 0-23 (if 24) Minute: 00-59	
Date	This will be set at the factory	Up to December 31, 2037	
Units of Measure: NIBP	mmHg	mmHg or kPa	

a. The System will automatically choose the appropriate gain.
b. This is the interval at which the current data is collected and stored.

Note The “User Settings” column in the following table may be used to capture any custom settings for your facility.

Table A-4: Other PRU Factory Defaults

	Factory Defaults	Available Ranges/ Options	User Settings
Alarm volume	3	1-5	
System volume	3	0-5	
System language	English	English only	
Earpiece volume	3	1-5	
Resp Trends (y-axis scale)	0-35 breaths/minute (minimum/maximum)	0-35 breaths/minute in increments of 5 (minimum/maximum)	
HR Trends (y-axis scale)	30-110 beats/ minute (minimum/maximum)	0-110 beats/minute in increments of 5 (minimum/maximum)	
SpO_2 Trends Lower Limit[a] (y-axis scale)	70-100% (minimum/ maximum)	50-70% in increments of 5 (for minimum value only)	
ECG/SpO_2 Waveform Speed	25 mm/second	12.5 or 25 mm/second	
Capnogram Waveform Speed	25 mm/second	6.25, 12.5 or 25 mm/ second	
Trends Time Scale (x-axis scale)	60 minutes	10-90 minutes in increments of 5	
ECG Gain	Auto[b]	0.2, 0.5, 0.7, 1, 2, 4, or Auto	
Continuous Display of Alarm Limits	Off (unchecked)	Off (unchecked) or On (checked)	
Data Storage Interval[c]	5 minutes	1, 3, 5, 10, or 30 minutes	
NIBP Interval	3 minutes	2, 2.5, 3, 5, or 10 minutes	
ARM Interval	1 minute	1, 2, or 3 minutes	
Print On Alarms	Off (unchecked)	Off (unchecked) or On (checked)	
Time	This will be set at the factory (Eastern Time, GMT-05:00).	Hour: 1-12 (if AM or PM); 0-23 (if 24) Minute: 00-59	
Date	This will be set at the factory	Up to December 31, 2037	

Table A-4: Other PRU Factory Defaults (Continued)

	Factory Defaults	**Available Ranges/ Options**	**User Settings**
Units of Measure	Weight: kg, $EtCO_2$:mmHg	Weight: lb. or kg, $EtCO_2$: mmHg, %, kPa, or mbar	
Additional Limits	Inactive (unchecked) • No dose increase when non-responsive to ARM • No PRN during red or yellow alarm • No re-start of propofol during yellow alarm	Inactive (unchecked) or Active (checked) • No dose increase when non-responsive to ARM • No PRN during red or yellow alarm • No re-start of propofol during yellow alarm	

a. SpO_2 Trends Upper Limit fixed at 100%.
b. The System will automatically choose the appropriate gain.
c. This is the interval at which the current data is collected and stored.

Table A-5: PRU Factory Default Oxygen Delivery

	Nasal				**Oral**
	Inhalation		**Exhalation**		**Steady Rate**
SpO_2 Level	Factory Default	Available Ranges	Factory Default	Available Ranges	Factory Default
SpO_2 > 96%	2 Lpm	2-8 Lpm	0 Lpm	0-2 Lpm	2 Lpm
88% < SpO_2 <= 96%	8 Lpm	–	2 Lpm	–	5 Lpm
SpO_2 <= 88%	12 Lpm	–	2 Lpm	–	7 Lpm

Appendix B Technical Information

Note This equipment is suitable for use in the presence of electrosurgery.

Table B-1: Automated Responsiveness Monitor Specifications

Characteristic	Performance
Stimulus Type	Mechanical vibration
Stimulus Frequency Range	20Hz ± 5Hz, 30Hz ± 5Hz, 35Hz ± 5Hz, and 40Hz ± 5Hz
Audio Volume	55 - 85 dBA

Table B-2: Alarm Indicators (Standalone Device BMU)

Characteristics	Priority	Visual Indication	Audible Indication
Patient in Red Alarm Condition	Medium	Red background and flashing numeric on display for alarming parameter. Light bar flashes blue.	One low pitch tone (800 milliseconds on, 100 milliseconds off) followed by 4 high pitch tones (200 milliseconds on, 100 milliseconds off). Repeats continuously.
Equipment Advisories - Correctable	Low	Orange background on lower half of display. Light bar flashes blue.	One tone (200 milliseconds on, 150 milliseconds off). Repeats every 3 seconds.
Equipment Failure Advisories	Low	Advisory pop-up message is displayed. Light bar flashes blue.	One tone (200 milliseconds on, 150 milliseconds off). Repeats every 7 seconds.

Table B-3: Alarm Indicators (PRU connected to BMU)

Characteristics	Priority	Visual Indication	Audible Indication
Patient in Red Alarm Condition	Medium	PRU: Red background and flashing numeric on display for alarming parameter. BMU: Light bar flashes blue.	PRU: One low pitch tone (800 milliseconds on, 100 milliseconds off) followed by 4 high pitch tones (200 milliseconds on, 100 milliseconds off). Repeats continuously. BMU: No audio.

Table B-3: Alarm Indicators (PRU connected to BMU) (Continued)

Characteristics	Priority	Visual Indication	Audible Indication
Patient in Yellow Alarm Condition	Low	PRU: Yellow background and flashing numeric on display for alarming parameter. BMU: Light bar flashes blue.	PRU: Three tones (800 milliseconds on, 700 milliseconds off). Repeats every 10 seconds. BMU: No audio.
Equipment Advisories - Correctable	Low	PRU: Orange background on display message box. BMU: Light bar flashes blue.	PRU: One tone (200 milliseconds on, 150 milliseconds off). Repeats every 3 seconds for automatic drug delivery action, every 7 seconds for no drug delivery action. BMU: No audio.
Equipment Failure Advisories	Low	PRU: Advisory pop-up message is displayed.	PRU: One tone (200 milliseconds on, 150 milliseconds off). Repeats every 3 seconds for automatic drug delivery action, every 7 seconds for no drug delivery action. BMU: No audio.

Table B-4: Barcode Scanner

Characteristics	Performance
Laser Classification	CDRH Class II, IEC Class 2
Light Source	Visible Laser Diode 650nm, 1.0 mW

Biocompatibility

All components of the System that the patient or user may contact in normal use are biocompatible.

Capnometry Specifications

Precaution

The accuracy of the capnometry system may be affected if operated outside of the specified environmental conditions.

Table B-5: Capnometry Specifications

Characteristics	Performance
Measurement method	Sidestream
Measurement range	0 - 13% CO_2
Measurement accuracy	± 2.0 mmHg @ < 5% CO_2 ATPS (Ambient Temperature and Pressure, Saturated) < 10% of reading @ > 5% CO_2 (ATPS)
Breath rate range	2 - 150 breaths per minute
Display units	Clinician selectable - mmHg (millimeters of Mercury), kPa (kilopascal), % (percentage), or mbar (millibar)
Display sweep speed	6.25, 12.5, or 25 mm/second
Standard conditions	Automatic compensation to comply with ATPS

Cart Specifications

WARNING To prevent injury, do not lean on the cart.

Table B-6: Cart Specifications

Characteristics	Performance
Cart drawer – minimum weight carrying capacity (4 X Safety Factor)	18.2 kg (40 lb)
Cart bin – minimum weight carrying capacity (4 X Safety Factor)	18.2 kg (40 lb)
Cart top surface – minimum weight carrying capacity (4 X Safety Factor)	100 kg (220 lb)
Cart bracket for mounting BMU – minimum weight carrying capacity (4 X Safety Factor)	9.1 kg (20 lb)
Cart work surface – minimum weight carrying capacity (4 X Safety Factor)	5.5 kg (12 lb)

Data Storage Specifications

The SEDASYS® System stores case data for a minimum of 90 days in non-volatile memory.

Table B-7: BMU Data Logs

Data Logs	Content
Print Log	Case start time and date Patient Identification Number (clinician input or System generated) Patient Data: Heart Rate, SpO_2, NIBP Physiological alarm events
Error/Event Log	User actions and System advisories
Patient Case Log	System configuration settings and content of print log

Table B-8: PRU Data Logs

Data Logs	Content
Error/Event Log	User actions and System advisories
Patient Case Log	System configuration settings Case start time and date Patient Identification Numbers (clinician input or System generated) Drug Delivery Information: Dose Rate, PRN Dose, Total Drug delivered Oxygen Delivery Flow Rate Patient Responsiveness Time Patient Data: Weight, Heart Rate, SpO_2, NIBP, Respiration Rate, $EtCO_2$ Physiological alarm events

Drug Delivery Cassette Specification

WARNING

The Drug Delivery Cassette is packaged sterile for single-patient use only. Do not re-use or re-sterilize. Re-use of the cassette may result in the transmission of infectious disease(s) from one patient to another, leading to injury, illness, or death. Re-sterilization may compromise structural integrity and/or lead to cassette failure that in turn may result in patient injury.

Table B-9: Drug Delivery Cassette Specifications

Characteristics	Performance
Sterility	Gamma irradiated sterile (SAL 10-6)
Pyrogenicity	Pyrogen free

Electrical Safety Specifications

WARNING

Stated leakage currents are applicable only when approved components of the System are interconnected. Using items not approved for use with the System may invalidate safety certification, increase leakage currents to the user and/or patient and compromise patient safety.

Table B-10: BMU Electrical Safety Specifications

Characteristics	Performance
Electrical safety standards	The SEDASYS® System has been tested to applicable sections of the following standards: • UL 60601-1 • IEC 60601-1-2
AC leakage current	1000 microamperes maximum RMS, 240 volts AC
Protection against electrical shock	Class I; the BMU is internally powered
Protection against water ingress	IPX1 – protected against vertical dripping (pole mount position only; orientation in the upright position)
Phase	Single

Table B-11: PRU Electrical Safety Specifications

Characteristics	Performance
Electrical safety standards	The SEDASYS® System has been tested to applicable sections of the following standards: • UL 60601-1 • UL 60601-1-1 • IEC 60601-1-2
AC leakage current	1000 microamperes maximum RMS, 240 volts AC
Protection against electrical shock	Class I
Protection against water ingress	IPX1 - protected against vertical dripping (counter top or Cart configuration)

Table B-11: PRU Electrical Safety Specifications

Characteristics	Performance
Phase	Single
Drug infusion system	Protection against electrical shock - Type BF

Table B-12: PSU Electrical Safety Specifications

Characteristics	Performance
Electrical safety standards	The System has been tested to applicable sections of the following standards: • UL 60601-1 • IEC 60601-1-2
Protection against water ingress	IPX1 - protected against vertical dripping (counter top or Cart configuration)
Protection against electrical shock	Class I

Table B-13: MPU Electrical Safety Specifications

Device	Performance
ECG wire set and cable	Type CF Applied Part (when used in conjunction with the SEDASYS® System)
ARM Handpiece	Type BF Applied Part (when used in conjunction with the SEDASYS® System) Protection against water ingress: IPX2 - Protected against vertically falling water drops when enclosure is tilted up 15 degrees
Blood Pressure Cuff	Type BF Applied Part (when used in conjunction with the SEDASYS® System)
Pulse Oximeter probe	Type BF (when used in conjunction with the SEDASYS® System) Protection against water ingress: IPX7 - Protected against the effects of continuous immersion in water

Table B-14: SPU Electrical Safety Specifications

Device	Performance
Oral/Nasal Cannula	Type BF Applied Part (when used in conjunction with the SEDASYS® System)

Table B-14: SPU Electrical Safety Specifications

Device	Performance
Drug Delivery Cassette	Type BF Applied Part (when used in conjunction with the SEDASYS® System)

Electrocardiogram Specifications

Precaution

The ECG waveform is provided for reference only. The ECG waveform has not been evaluated against 60601-2-27 Clause 50 for accuracy as it is not intended to be used as the primary means to diagnose patient cardiac function.

Note

The display of heart rate and related alarms are provided through pulse oximetry measurement whenever available. The display of heart rate and related alarms are provided from ECG monitoring only when the pulse oximeter information is not available.

Table B-15: ECG Specifications

Characteristics	Performance
Heart rate range and accuracy	30 - 240 beats/minute (bpm)
Heart Rate Accuracy	± 3 bpm
Time to Alarm for Tachycardia	Waveform B1 Amplitude: Average time to alarm: 0.5 mV - 20 seconds 1.0 mV - 20 seconds 2.0 mV - 20 seconds Waveform B2 Amplitude: Average time to alarm: 1.0 mV - 20 seconds 2.0 mV - 20 seconds 4.0 mV - 20 seconds
Leads	3-wire, provided in AHA colors
Connector	AAMI 15-pin
Electrodes	Disposable snap electrodes Compatible with Gel Ag/AgCl electrodes
Display sweep speeds	12.5, 25 mm/sec
Gain	0.2, 0.5, 0.7, 1, 2, 4, or auto

Table B-15: ECG Specifications (Continued)

Characteristics	Performance
Scale reference bar	A fixed 1 mV reference bar is displayed with the top ECG waveform for scaling of the waveform. This is provided in place of a standardizing voltage.
Lead display	II
Heart rate display	Numeric
Waveform display	One ECG waveform
Leads off condition	Detected and displayed
Input protection	Defibrillator and electrosurgery interference protection when used with provided ECG cables.
Tall T-wave rejection	Heart rate indication is within the error limits for 1.2 mV maximum T-wave amplitude (aT)
Defibrillator recovery	< 10 seconds
Heart rate meter accuracy and response to irregular rhythm	Waveform: Heart Rate reading (bpm): Ventricular Bigeminy - 80 Slow alternating Ventricular Bigeminy - 60 Rapid alternating Ventricular Bigeminy - 120 Bidirectional Systoles - 90
Response to change in heart rate	Increasing from 80 to 120 bpm: 6.96 - 7.48 seconds, Average = 7.08 seconds Decreasing from 80 to 40 bpm: 8.53 - 10.21 seconds, Average = 9.52 seconds
Heart Rate Averaging	Calculated on the basis of the mean RR-interval of the previous 16 beats unless the heart rate calculated using the previous 4 beats is less than or equal to 48, then this rate is used.
Input Lead Impedance	Patient cables intended for use with this device include series resistance (7 Kohm minimum) in each lead for defibrillation protection. Patient cables should be checked for cracks or breakage prior to use.
Pacemaker Pulse Rejection	Not Capable

Electromagnetic Compatibility

WARNING

Performance of the SEDASYS® System must be verified if used adjacent to or stacked with other electrical equipment.

Precaution

The SEDASYS® System requires precautions regarding Electromagnetic Compatibilty (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.

The SEDASYS® System was tested with the following peripheral devices, parts, components and accessories:

- Procedure Room Unit (including Power Supply Unit, Control Unit, and Display Monitor)
- Bedside Monitoring Unit
- ARM Handpiece
- Pulse Oximeter Probe and Cable
- ECG Leads and Cable
- NIBP Cuff and Tube
- Oral/Nasal Cannula
- Drug Delivery Cassette

The SEDASYS® System is intended for use in the electromagnetic environment listed below. The user of this equipment should assure that the System is used in such an environment.

Table B-16: Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions - CISPR 11	Group 1 Class B	The SEDASYS® System is suitable for use in all establishments other than domestic and those directly connected to the public low-wattage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions - IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions - IEC 6100-3-3	Complies	

Table B-17: Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) - IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst - IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge - IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field - IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital setting.
Voltage dips, short interruptions and voltage variations on power supply input lines - IEC 61000-4-11	< 5% UT (> 95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (> 95% dip in UT) for 5 sec	< 5% UT (> 95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (> 95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment.

Table B-17: Electromagnetic Immunity (Continued)

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment - Guidance
Radiated RF - IEC 61000-4-3	3 V/m 80 MHz - 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = [3.5/V1] P 1/2 d = [3.5/E1] P 1/2 80 MHZ to 800 MHz d = [7/E1] P 1/2 800 MHZ to 2.5 GHz where P is the maximum output power rating in watts according to the transmitter manufacturer and d is the recommended separation distance in meters. Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.
Conducted RF - IEC 61000-4-6	3 Vrms 150 kHz - 80 MHz	3 Vrms	

The SEDASYS® System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System as recommended below, according to the maximum power output of the communications equipment.

Table B-18: Recommended Separation Distances

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz d = [3.5/V1]P1/2	80 MHz to 800 MHz d = [3.5/E1] P 1/2	800 MHz to 2.5 GHz d = [7/E1] P 1/2
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.3	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum power output not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Environmental Specifications

Precaution

The SEDASYS® System may not meet performance specifications if shipped, stored, or operated outside the specified temperature and humidity ranges.

Table B-19: Environmental Conditions

Characteristics	Performance
Operating Temperature	10 to 40°C (50 to 104°F)
Operating Relative Humidity	30% to 75%, noncondensing
Operating Altitude	0 to 6,600 feet
Transport and Storage Temperature	0 to 40°C (32 to 104°F)
Transport and Storage Relative Humidity	20% to 90%, noncondensing
Transport and Storage Pressure	500 - 1060 hPa

Note

1. If stored outside the PSU for more than 6 months, the PSU batteries must be run through one calibration cycle. Authorized service technicians should perform the battery calibration to ensure proper performance of the System.
2. If stored outside the BMU for more than 6 months, the BMU batteries must be run through at least one calibration cycle. Authorized service technicians should perform the battery calibration to ensure proper performance of the System.
3. If the BMU and PSU are stored with batteries inside of them for more than 6 months, perform at least one battery calibration cycle. Authorized service technicians should perform the battery calibration to ensure proper performance of the System.

Infusion Pump Specifications

Table B-20: Infusion Pump Specifications

Characteristics	Performance	Conditions
Infusion rate range	1 to 999 mL/hr	Based on selected maintenance rate and patient weight
Infusion rate accuracy	<± 5%	Infusion rate accuracy can be affected by variations in fluid temperature and back pressure. Specified rate accuracy is only valid when using the System Drug Delivery Cassette with propofol temperature between 15^{o}C and 35^{o}C.
PRN Function	Automatic	
PRN Rate	450 mL/hr	
PRN Volume	0.25 mg/kg	Fixed volume based on patient weight
Bolus volume generated after release of occlusion	0.18 mL @ 1.2 mL/hr 0.15 mL @ 25.2 mL/hr	1000 mbar occlusion pressure
Flow rate during priming	1150 mL/hr	Autoprime
Flow rate during purge	1150 mL/hr	
Prevention of overinfusion	Secondary pump speed monitor	
Alarms/Advisories	• Drug vial low • Drug vial empty • Drug Vial not present • Air-in-line • Occlusion (patient side)	

Table B-20: Infusion Pump Specifications (Continued)

Characteristics	Performance	Conditions
Rate Conversion from Dose Rate (mcg/kg/min) to Pump Rate (mL/hr)	(Dose Rate ÷ 166.67) × Patient Weight (kg)	
Volume delivered under single fault condition	0.5 mL maximum	

Table B-21: Air-In-Line Sensor Specifications

Characteristics	Performance	Conditions
Air bubble size detection	> 50 µL	Single air bubble
Single air bubble size resulting in infusion stoppage	> 250 µL	
Air bubble accumulation resulting in infusion stoppage	> 1 mL	Over 15 minute period

Table B-22: Downstream Occlusion Sensor Specifications

Characteristics	Performance	Conditions
Occlusion Alarm	800 - 1200 mbar	
Time to alarm @ minimum pump rate	< 670 seconds	1.2 mL/hr
Time to alarm @ intermediate pump rate	< 13 seconds	25.2 mL/hr

IV Pump Start-up Graphs (including 3 min Loading Dose)

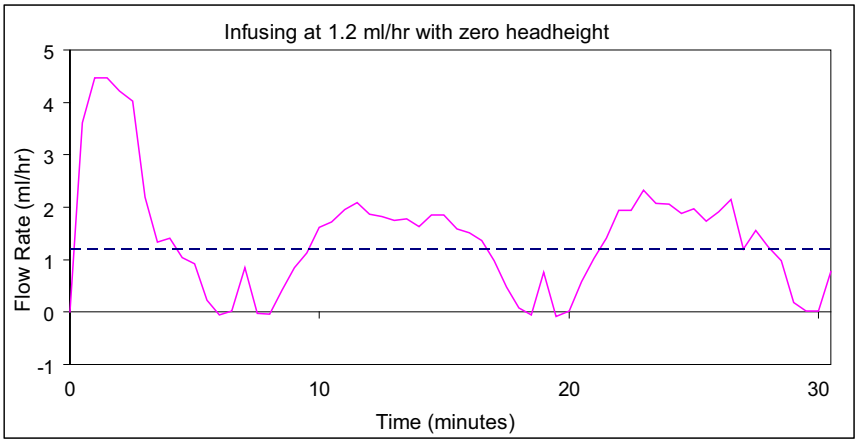


Figure B-1 Infusing at 1.2 ml/hr with zero headheight

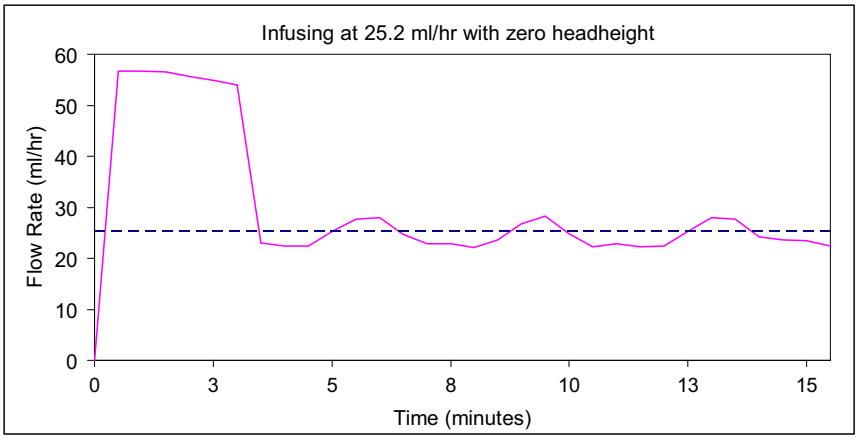


Figure B-2 Infusing at 25.2 ml/hr with zero headheight

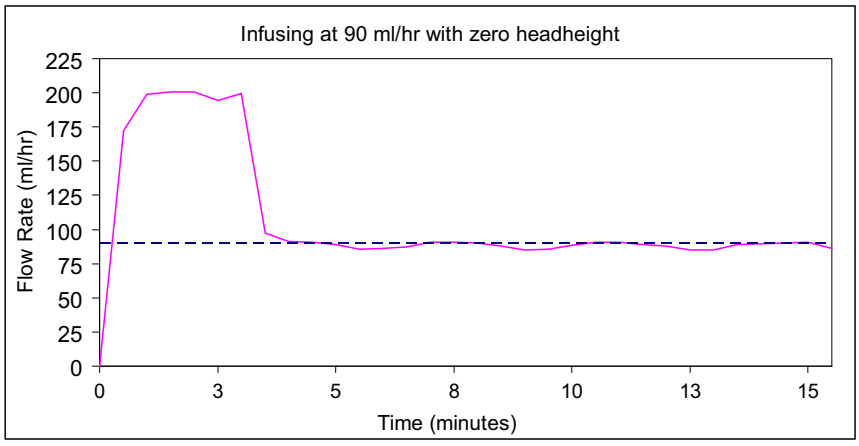


Figure B-3 Infusing at 90 ml/hr with zero headheight

IV Pump Trumpet Graphs during Second (last) Hour

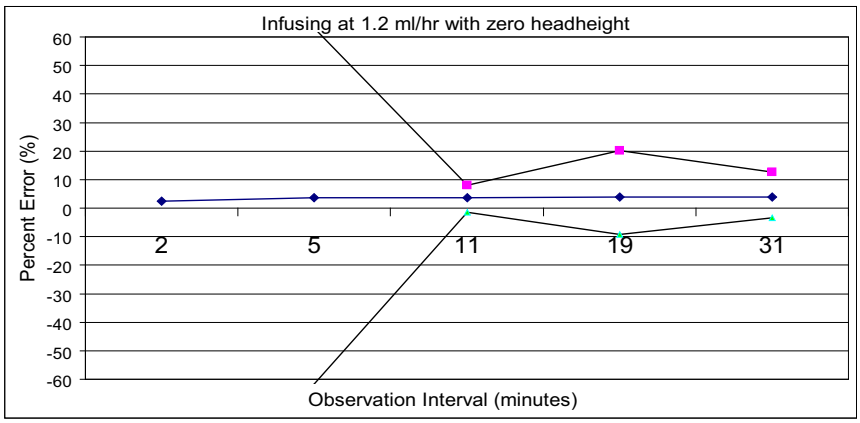


Figure B-4 Infusing at 1.2 ml/hr with zero headheight

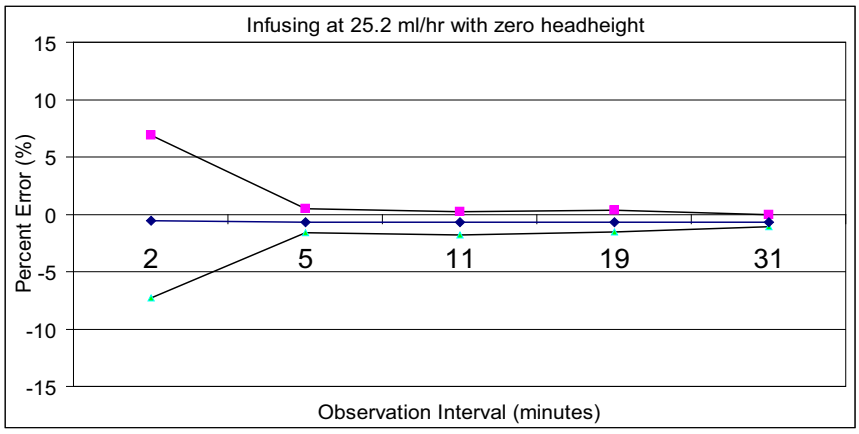


Figure B-5 Infusing at 25.2 ml/hr with zero headheight

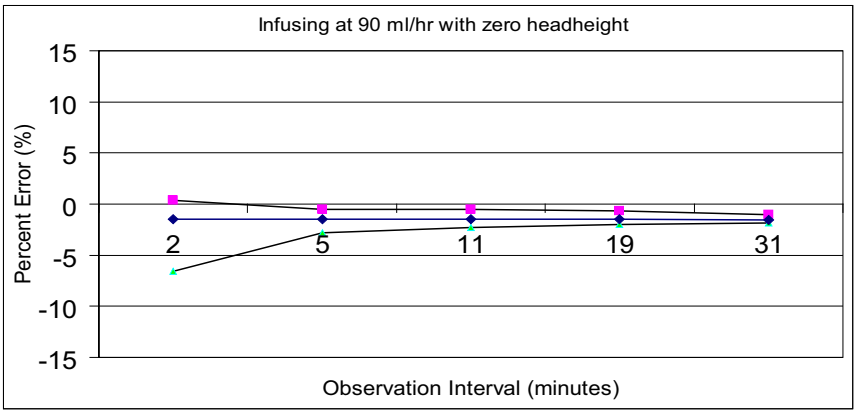


Figure B-6 Infusing at 90 ml/hr with zero headheight

Non-Invasive Blood Pressure (NIBP) Specifications

Table B-23: NIBP Specifications

Characteristic	Performance
Measurement range	20 - 260 mmHg
Blood pressure accuracy	Per AAMI SP10-1992 Clause 4.4.2: Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method, within the limits prescribed by the American National Standard, Electronic or automated sphygmomanometers.
Heart Rate range	40 - 200 bpm
Method of Measurement	Oscillometric with step deflation. Diastolic values correspond to Phase 5 Korotkoff sounds.
Initial cuff pressure	160 mmHg (first reading), last Systolic Pressure + 30 mmHg subsequent readings
Maximum cuff inflation time	180 seconds
Maximum cuff pressure	300 mmHg
Minimum time between automatic measurements	30 seconds
Performance	Functions according to specifications in the presence of common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, and is suitable for use in the presence of electrosurgery.
Recommended Frequency of Pressure Transducer Calibration	The Pressure Transducer calibration should be verified on a yearly interval.

Oxygen Delivery Specifications

Table B-24: Oxygen Delivery Specifications

Characteristics	Performance
Delivery Range	1 - 12 liters/minute
Accuracy	1 liter/minute - OR - 15% of the target flow rate, whichever is greater

Physical Specifications

Table B-25: Bedside Monitoring Unit Physical Specifications

Characteristics	Performance
Weight	2.3 kg (5.1 lb)
Physical Dimensions	Height: 26.7 cm (10.5 inches) Width: 22.9 cm (9.0 inches) Depth: 11.4 cm (4.5 inches)
Display Type	LCD
Equipment Type	Class I

Table B-26: Procedure Room Unit Physical Specifications

Characteristics	Performance
Weight (including Monitor)	17.9 kg (39.5 lb)
Physical Dimensions	Height: 63.5 cm (25 inches) Width: 39.4 cm (15.5 inches) Depth: 40.9 cm (16 inches)
Display Type	LCD
Equipment Type	Class I

Table B-27: Power Supply Unit Physical Specifications

Characteristics	Performance
Weight	6.3 kg (14.0 lb)
Physical Dimensions	Height: 7.6 cm (3 inches) Width: 39.4 cm (15.5 inches) Depth: 40.6 cm (16 inches)
Equipment Type	Class I (internally powered)

Power Specifications

Table B-28: BMU Power Specifications

Characteristics	Performance
Mode of Operation	Continuous

Table B-28: BMU Power Specifications (Continued)

Characteristics	Performance
DC Input Power Required	28 V, 70 W
Internal battery pack type	Lithium Ion
Internal battery pack capacity	50 Watt-hour
Battery Recharge Time	Up to 3 hours
Low battery voltage indication	An Advisory Message is provided when the remaining capacity is < 20, 10, and 2 minutes.
Model Number	MSP1820

Table B-29: BMU Power Adapter Specifications

Characteristics	Performance
Mode of Operation	Continuous
Input line voltage	100 - 240 volts AC
Input line frequency	50/60 Hz
Input line current	1.25 - 0.7 A
Phase	Single
Output voltage	28 volts DC
Output current	2.8 A

Table B-30: PSU Power Specifications

Characteristics	Performance
Mode of Operation	Continuous
Input line voltage	100 - 240 volts AC
Input line frequency	50/60 Hz
Input line current	5 A
Phase	Single
Internal battery pack type	Lithium Polymer
Internal battery pack capacity	70 Watt-hour
Battery Recharge Time	Up to 1 hour
Low battery voltage indication	An Advisory Message is provided when the remaining capacity is < 5 and 2 minutes.

Pulse Oximeter (SpO_2) Specifications

Table B-31: Pulse Oximeter Specifications

Characteristics	Performance
SpO_2 range	70 - 100% hemoglobin saturation (for proper operation)
SpO_2 accuracy	± 2% SpO_2 over the range of 70 - 100%, with no motion and with normal perfusion. ± 3% SpO_2 over the range of 70 - 100%, with motion or low perfusion.
Heart rate accuracy	± 3 beats per minute over a range of 30 - 240 beats per minute, with no motion and with normal perfusion. ± 5 beats per minute over a range of 30 - 240 beats per minute, with motion or low perfusion.
SpO_2 resolution	0.1%
Heart rate resolution	0.1 beats per minute
Measurement Method	Transmittance, Functional saturation
Plethysmograph	Not proportional to pulse volume
Update frequency	Once per second
Sensor LEDs/Energies	Red: 658 - 662 nm operating at 1.9mW Infrared: 895 - 915 nm operating at 2.0mW
Pulse tone	Frequency varies with perfusion
Waveform	Normalized

Note

1. Information regarding the wavelength range of the Pulse Oximeter probe can be especially useful to clinicians.
2. The Pulse Oximeter is calibrated to display functional saturation.
3. Excessive light, motion and low perfusion may impact the accuracy and function of the Pulse Oximeter module.
4. Averaging of the displayed SpO_2 and heart rate can result in a delayed signal.
5. The Pulse Oximeter probe and extension cable have been validated and tested with the SEDASYS® System.

Wireless Printing

Table B-32: Wireless Printing Requirements

Characteristics	Specifications
Print Server Communication	802.11b/g
Printer Control Language	PCL 5 or PCL 6
Printer Communication Protocol	SNMP 1.0 or 1.2
Print Speed	16 pages per minute minimum (Black and White)
Buffer/Memory Size	12 Megabytes minimum
Resolution	300 x 300 dpi minimum

This page is intentionally left blank.

Appendix C PRU Monitoring Screen

The Procedure Room Unit (PRU) Monitoring screen displays the monitored patient data, provides the primary interface for controlling drug delivery and allows the clinician to perform specific actions.

The PRU Monitoring screen consists of three sections that allow the clinician to interact with the PRU.

- Patient Monitoring Interface
- Drug Delivery Interface
- Action Buttons Interface

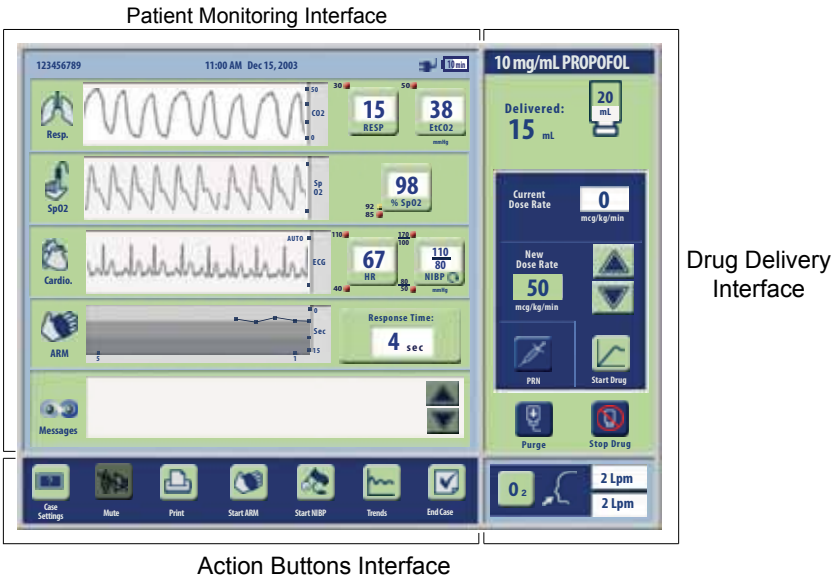


Figure C-1 PRU Monitoring Screen

Patient Monitoring Interface

The patient monitoring interface displays four fields that show the waveforms and values of the patient's monitored physiological parameters. Below these four fields is the Messages field that displays text advisories.

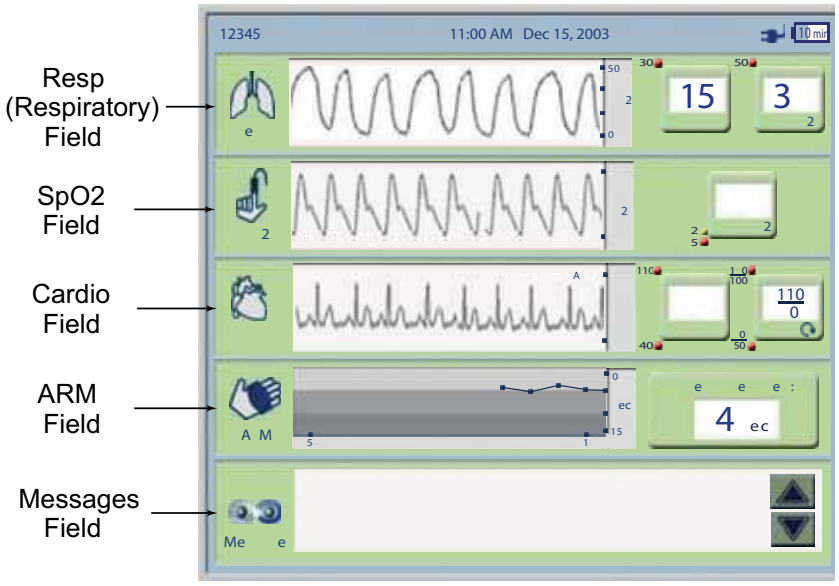


Figure C-2 PRU Patient Monitoring Interface

The PRU Patient Monitoring interface consists of the following four fields:

- *Resp* field, which displays:
  - Capnogram.
  - Respiratory rate in breaths/minute.
  - $EtCO_2$.
- *SpO_2* field, which displays:
  - Plethysmogram.
  - SpO_2%.
- *Cardio* field, which displays:
  - ECG waveform.
  - Pulse rate or heart rate in beats per minute.
  - Systolic and diastolic blood pressure that was last measured.

Note

1 The default setting is the heart rate from the Pulse Oximeter. If the Pulse Oximeter signal is lost, the heart rate will come from the ECG and a heart icon will be displayed next to "HR" on the **HR** button.

2 When the blood pressure reading is being taken, the symbol will appear below the value displayed on the NIBP button. When an NIBP measurement is not being taken, the time in minutes from the last NIBP reading is shown.

- *ARM* field, which displays:
  - Trend graph displaying recorded responsiveness tests in seconds

Note

When in Clinician Response Mode, the graph displays a Y (Yes) or N (No) for the responsiveness, rather than time in seconds.

– Responsiveness time in seconds.

Note

NR will be displayed if the patient is not responsive.

- Messages field, which displays:
  – Text advisories.

Shortcuts to Changing Case Settings

Shortcuts are provided for changing alarm settings during a procedure. The following buttons on the PRU Monitoring screen access alarm setting screens: RESP, $EtCO_2$, % SpO_2, HR, and NIBP.

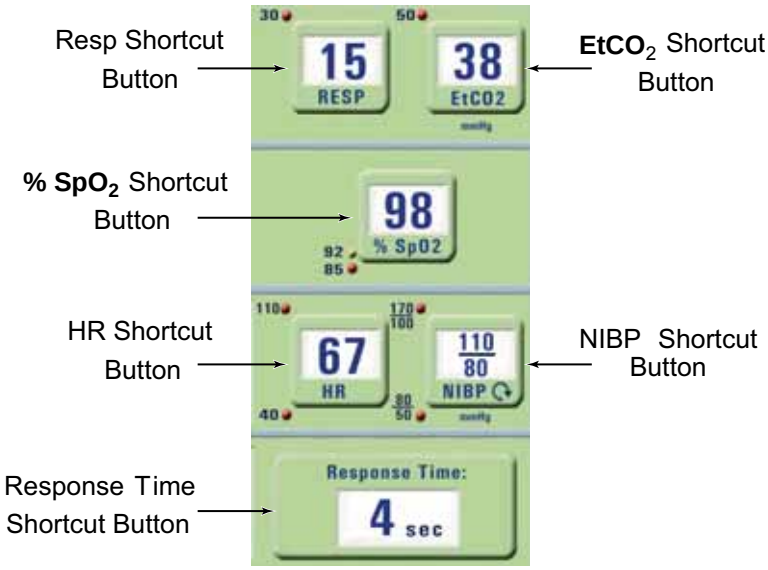


Figure C-3 Patient Monitoring Shortcut Buttons on PRU Monitoring Screen

Drug Delivery Interface

The Drug Delivery interface allows the clinician to start/stop drug delivery, adjust dose rate, deliver a PRN dose, adjust oxygen delivery, and purge the Drug Delivery Cassette.

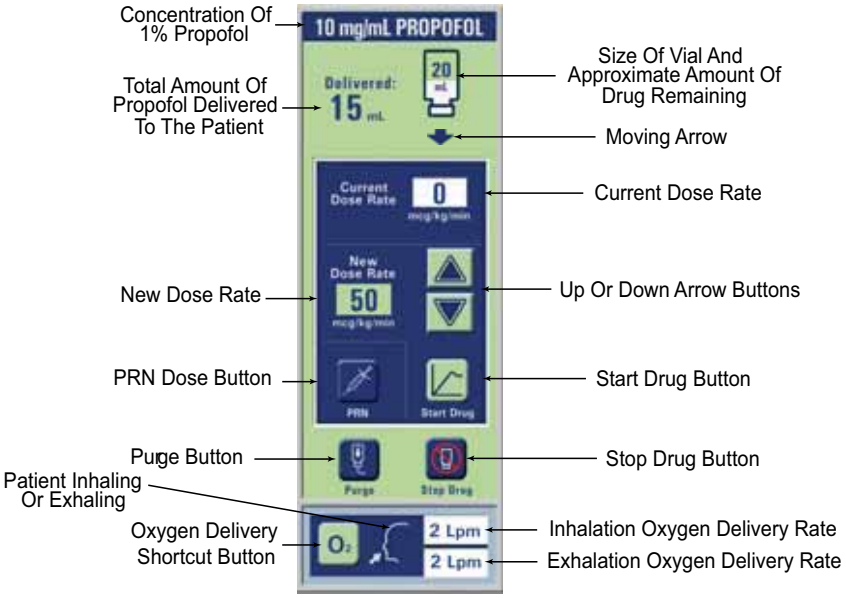


Figure C-4 PRU Drug Delivery Interface

The drug delivery interface consists of the following:

- **Current Dose Rate** box: Displays the dose rate at which propofol is currently being delivered in mcg/kg/min. If **Stop Drug** is pressed, the Current Dose Rate box displays 0 (zero).
- **New Dose Rate** box: Allows a new dose rate to be entered using the **Up** or **Down** Arrow buttons. Press **Start Drug** to deliver the new dose rate to the patient. At this time, the dose rate displayed in the Current Dose Rate box changes to the rate that was entered in the New Dose Rate box. The New Dose Rate box then displays "---".

Note

The background of the New Dose Rate box is green when a value other than "---" is shown. The background of the New Dose Rate box reverts to white when the **Start Drug** button is pressed.

- **Purge** button: Allows purging of air from the Drug Delivery Cassette. The Purge button also allows the purging of drug from the vial and cassette at the end of a case.
- **PRN** button: Delivers a one-time, fixed dose of propofol.
- **Patient inhaling/exhaling** graphic: Active graphic showing patient inhaling when arrow is pointing toward the mouth and exhaling when arrow is pointing away from the mouth.
- **Oxygen delivery** shortcut button: Allows changes in oxygen delivery rate at any time, for an SpO_2 reading greater than or equal to 96%.
- **Size of propofol vial and approximate amount of drug remaining** graphic: Displays the size of the propofol vial that was entered. The white filler in the vial graphic (representing the amount of remaining propofol) decreases as the propofol is being delivered.

- **Moving** arrow: When the arrow is moving, this indicates that drug is being delivered to the patient. When the arrow is replaced by an "X" this indicates that the System has stopped drug delivery.
- **Up or Down Arrow** buttons: Allow the clinician to increase (Up Arrow button) or decrease (Down Arrow button) the new dose rate.
- **Start Drug** button: Confirms the new dose rate entered and begins delivering propofol to the patient.
- **Stop Drug** button: Immediately stops delivery of propofol. This results in 0 (zero) being displayed in the Current Dose Rate box.
- **Inhalation oxygen delivery rate**: Displays the amount of oxygen being delivered during inhalation.
- **Exhalation oxygen delivery rate**: Displays the amount of oxygen being delivered during exhalation.

Action Buttons Interface

The Action Buttons interface allows the clinician to initiate various system actions.

Figure C-5 PRU Action Buttons Interface

- **Case Settings** button: Allows the clinician to make patient-specific setting changes. These changes are not access code protected.
- **Mute** button: Temporarily silences all alarms and/or advisories for up to 180 seconds.

Note

If a new alarm occurs while a previous alarm is muted, the mute will be cancelled and highest priority active alarm will be audible.

- **Print** button: Sends a record of the current patient physiology to the wireless printer.
- **Start ARM** button: Initiates an immediate patient responsiveness test in addition to the scheduled ARM responsiveness test intervals.
- **Start NIBP** button: Initiates an immediate blood pressure measurement in addition to the scheduled NIBP measurement intervals.

Note

During a blood pressure measurement, this button changes to a Stop NIBP button. Press **Stop NIBP** to immediately stop the blood pressure measurement and rapidly deflate the NIBP cuff.

- **Trends** button: Displays trend data along with capnogram, plethysmogram, electrocardiogram and the ARM response time.
- **End Case** button: Stops data collection and resets all settings to default settings.

Appendix D BMU Monitoring Screen

The Bedside Monitoring Unit (BMU) Monitoring screen displays the monitored patient data when the BMU is not connected to the Procedure Room Unit (PRU). This screen allows the clinician to interact with the BMU.

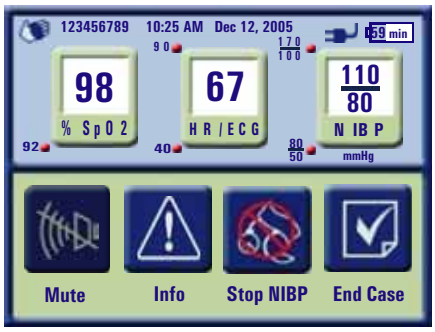


Figure D-1 BMU Monitoring Screen

The BMU Monitoring screen consists of the following:

- **SpO_2** button: Displays % SpO_2 and provides access to adjust the SpO_2 alarm limit.
- **HR/ECG** button: Displays pulse rate or heart rate in beats per minute, provides access to view the ECG waveform and adjust the alarm limits and ECG gain.

Note

The ECG Waveform and current measurements for NIBP, SpO_2, and HR can be sent to printer port from the ECG display window.

- **NIBP** button: Displays systolic and diastolic blood pressure and provides access to adjust alarm limits and the NIBP measurement interval.
- **Mute** button: Temporarily silence all alarms and/or advisories for up to 180 seconds.

Note

If a new alarm occurs while a previous alarm is muted, the mute will be cancelled and the highest priority active alarm will be audible.

- **Start NIBP** button: Initiates an immediate blood pressure measurement in addition to the scheduled NIBP measurement intervals.

Note

During a blood pressure measurement, this button changes to a **Stop NIBP** button. Press **Stop NIBP** to immediately stop the blood pressure measurement and rapidly deflate the NIBP cuff.

- **End Case** button: Stops data collection and resets all settings to default settings.
- **Info** button: Displays system messages and advisories.

Note

The ECG Waveform and current measurements for NIBP, SpO_2, and HR can be sent to printer port from the **Info** display window.

Appendix E BMU Remote Entry Screen

The Bedside Monitoring Unit (BMU) Monitoring screen becomes a BMU Remote Entry screen when the BMU is connected to the Procedure Room Unit (PRU).

Figure E-1 BMU Remote Entry Screen

- **Current Dose Rate** box: Displays the dose rate at which propofol is currently being delivered in mcg/kg/min. If the **Stop Drug** button is pressed, the Current Dose Rate box displays 0 (zero).
- **Dose Rate** button: Displays the Change Dose Rate screen where a new dose rate can be entered.
- **Mute** button: Temporarily silences all alarms and/or advisories for up to 180 seconds.
- **PRN** button: Delivers a one-time, fixed dose of propofol.
- **Stop Drug** button: Immediately stops drug delivery. This results in 0 (zero) being displayed in the Current Dose Rate box.

This page is intentionally left blank.

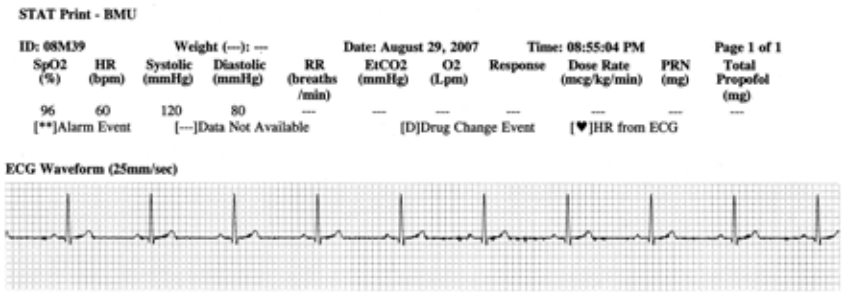
Appendix F Printing

Print During Procedure

A printed record of current patient physiology can be obtained at any time from the wireless printer during a procedure by pressing the **Print** button. When the BMU is used prior to connection to the PRU, the **Print** button is accessed through the BMU Information screen (press the **Info** button from the BMU Monitoring screen to access the Information screen). When the BMU is connected to the PRU, the **Print** button is accessed from the lower portion of the PRU Monitoring screen.

Note

1. For instructions on enabling print functionality, refer to Timing/Print on page 4 - 14 for the BMU and Timing/Print Options on page 5 - 20 for the PRU.
2. If "Print on Alarms" is enabled, a printed record of current patient physiology is automatically sent to the wireless printer at the time of the physiological alarm event. For information on enabling "Print on Alarms", refer to Timing/Print on page 4 - 14 for the BMU in standalone mode and Timing/Print Options on page 5 - 20 for the PRU.


STAT Print - BMU

ID: 08M39 Weight (---): --- Date: August 29, 2007 Time: 08:55:04 PM Page 1 of 1

SpO2 (%)	HR (bpm)	Systolic (mmHg)	Diastolic (mmHg)	RR (breaths /min)	EtCO2 (mmHg)	O2 (Lpm)	Response	Dose Rate (mcg/kg/min)	PRN (mg)	Total Propofol (mg)
96	60	120	80	---	---	---	---	---	---	---

[**]Alarm Event [---]Data Not Available [D]Drug Change Event [♥]HR from ECG

ECG Waveform (25mm/sec)

Figure F-1 Sample BMU Printout During A Procedure

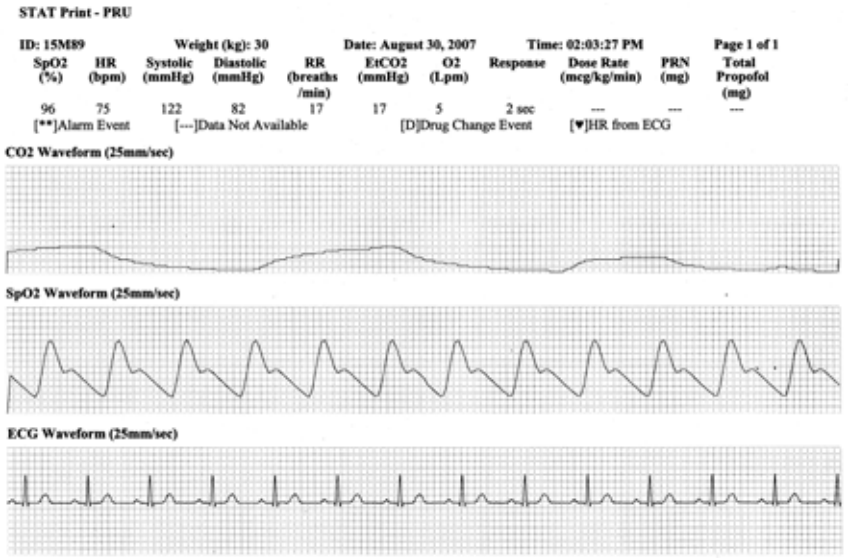


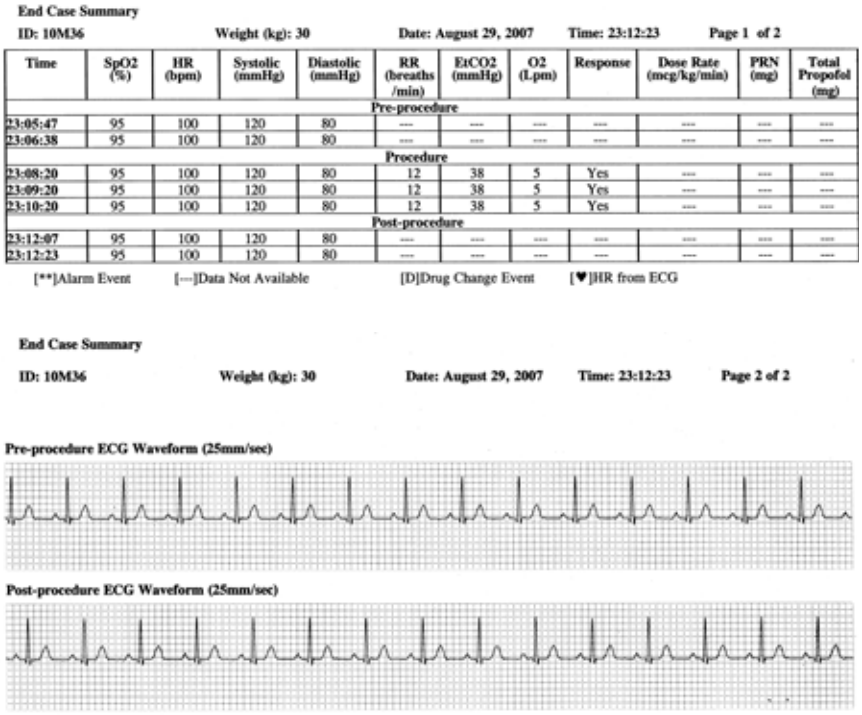
Figure F-2 Sample PRU Printout During A Procedure

End Case Summary

At the completion of a case, a printed summary of the procedure is automatically sent to the wireless printer. This printed record contains patient physiology information collected throughout the procedure at the selected data collection interval. Changes in dose rate, PRN doses, oxygen delivery rate, and alarm events are also captured independent of the selected data collection interval.

Note

1. Data collected at all stages of the procedure are stored and printed at the completion of the case. Data is automatically transferred from the BMU to the PRU when connected with umbilical cable, and from the PRU to the BMU when **End Case** is pressed on the PRU.
2. For information on setting the data collection intervals, refer to Timing/Print on page 4 - 14 for the BMU in standalone mode and Timing/Print Options on page 5 - 20 for the PRU.
3. For instructions on enabling print functionality, refer to Timing/Print on page 4 - 14 for the BMU and Timing/Print Options on page 5 - 20 for the PRU.



End Case Summary

ID: 10M36 **Weight (kg): 30** **Date: August 29, 2007** **Time: 23:12:23** **Page 1 of 2**

Time	SpO2 (%)	HR (bpm)	Systolic (mmHg)	Diastolic (mmHg)	RR (breaths /min)	EtCO2 (mmHg)	O2 (Lpm)	Response	Dose Rate (mcg/kg/min)	PRN (mg)	Total Propofol (mg)
Pre-procedure											
23:05:47	95	100	120	80	---	---	---	---	---	---	---
23:06:38	95	100	120	80	---	---	---	---	---	---	---
Procedure											
23:08:20	95	100	120	80	12	38	5	Yes	---	---	---
23:09:20	95	100	120	80	12	38	5	Yes	---	---	---
23:10:20	95	100	120	80	12	38	5	Yes	---	---	---
Post-procedure											
23:12:07	95	100	120	80	---	---	---	---	---	---	---
23:12:23	95	100	120	80	---	---	---	---	---	---	---

[**]Alarm Event [---]Data Not Available [D]Drug Change Event [♥]HR from ECG

End Case Summary

ID: 10M36 **Weight (kg): 30** **Date: August 29, 2007** **Time: 23:12:23** **Page 2 of 2**

Pre-procedure ECG Waveform (25mm/sec)

Post-procedure ECG Waveform (25mm/sec)

Figure F-3 Sample End Case Summary Printout

This page is intentionally left blank.

Appendix G PRU Display Monitor

Control

The PRU Display Monitor is controlled via a three (3) button keypad. The keypad, located on the back of the display, allows the user to make adjustments to various display parameters using the On Screen Menus (OSM) system.

Figure G-1 On Screen Menu

Menu System Overview

Press the **MENU** button once to open the Menu System. The current video input is shown in the Display Mode tab on the top right of the menu. The Menu System opens with Picture menu displayed. Press the ◀ or ▶ button to select the menu you want to work with, then press the **MENU** button to select the parameter. Press the ◀ or ▶ button to set the parameter to the desired value. Press the **MENU** button until the cursor returns to the menu tabs, then press the ◀ or ▶ button until the Exit tab is illuminated. Press the **MENU** button to select the Exit parameter, then press the ▶ button to save your changes and close the Menu System.

If not explicitly closed, the OSM will automatically close 60 seconds after the most recent button press.

Note

All parameter names change to the language selected in the Setup Menu.

Figure G-2 Menu System

Language List:

- English
- Deutsch
- Nederlands
- Español
- Français
- Italiano
- Svensk

Setting Up the Display

VGA Picture Menu

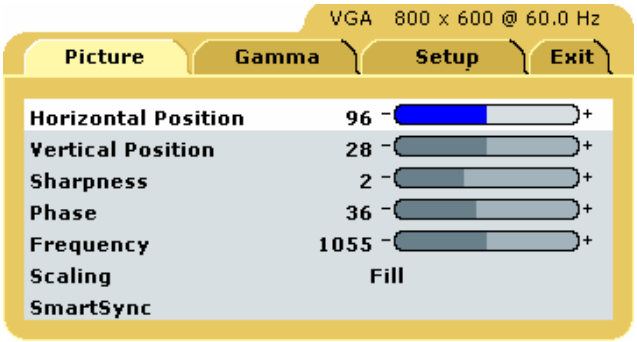


Figure G-3 VGA Picture Menu

Horizontal Position

Moves the image to the left or right. Press ◀ or ▶ to horizontally center the image.

Note

This parameter is not accessible when the data source is DVI - digital.

Vertical Position

Moves the image up or down. Press ◀ or ▶ to vertically center the image.

Note

This parameter is not accessible when the data source is DVI - digital.

Sharpness

Press ◀ or ▶ to adjust the sharpness (focus) of the displayed image.

Note

The Sharpness control is not visible when the display is operating at native resolution.

Phase

Press ◀ or ▶ to adjust the phase of the display's pixel clock. The phase adjustment further refines the pixel clock (frequency) adjustment.

Note

This parameter is not accessible when the data source is DVI - digital.

Frequency

Adjusts the frequency of the display's pixel clock to insure that all pixels of a given scan line are displayed in the appropriate column. With Scaling set to **Fill** adjust until image just fills the screen horizontally. Press ◀ or ▶ to adjust the frequency of the display's pixel clock.

Note

This parameter is not accessible when the data source is DVI - digital.

Scaling

Fill = Expands the video image to fill the entire screen. The aspect ratio may not be accurately displayed. **Aspect** = Expands the video image until

its largest dimension fills the screen. Image may be displayed with black bars. Select using ◀ or ▶ buttons.

SmartSync™

On initialization, NDS' proprietary SmartSync™ technology examines the incoming signal and automatically displays the video image in its proper format. To run, select SmartSync™ and press the ▶ button.

Gamma Menu

Press the **MENU** button once to open the OSM. Press the ▶ button to select the Gamma menu, then press the MENU button to select the parameter to be adjusted. Finally, press the ◀ or ▶ button to set the parameter to the desired value.

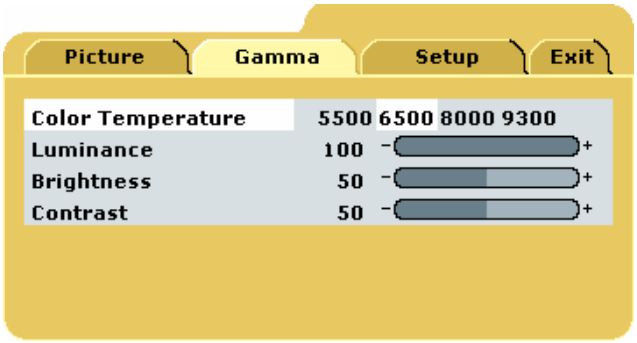


Figure G-4 Gamma Menu

Color Temperature

Press the ◀ or ▶ button to select one of the four preset color temperatures. The selected color temperature will be highlighted in white.

Luminance

Press the ◀ or ▶ button to set the backlighting. Note: Lowering the backlight level will increase the backlight lifetime.

Brightness

Press the ◀ or ▶ button to increase or decrease brightness. Setting the brightness too high or too low will decrease the amount of visible grayscales.

Contrast

Press ◀ or ▶ button to adjust the contrast. Contrast set too high or too low causes loss of some grayscales. Color saturation may appear incorrect.

Setup Menu

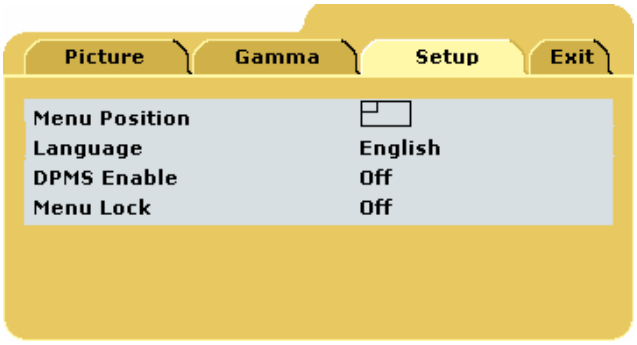


Figure G-5 Setup Menu

Menu Position

Places the menu in 1 of 9 predefined screen positions. Press the ◀ or ▶ button to select any of the 9 screen positions.

Language

Selects 1 of 7 languages: English, Deutsch, Français, Italiano, Svensk, Español or Nederlands. Press the ◀ or ▶ button to select any of the 7 languages.

DPMS Enable

Display Power Management System. When DPMS is enabled (on), and no input signal is present, an “No Input Detected” message is displayed for ~ 20 seconds, after which the display enters its low power state. This prolongs the life of the backlight tubes in the display. The display turns on when the input signal is restored. Press the ▶ button to enable DPMS, press the ◀ button to disable DPMS.

Menu Lock

Disables access to Menu System. This prevents inadvertent changes to the display’s settings. To enable Menu Lock, press the ▶ button. MENU LOCKED is displayed when the ▶ button is pressed. To unlock, press and hold the ◀ or ▶ buttons simultaneously until MENU UNLOCKED is displayed.

Exit Menu

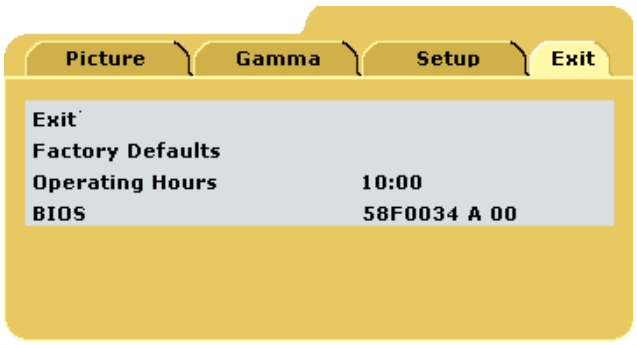


Figure G-6 Exit Menu

Exit

Exits Menu System. Select Exit, then press the ▶ button.

Factory Defaults

Displays “Restoring Factory Defaults” message and returns all settings to their factory preset values. Select Factory Defaults, then press the ▶ button.

Operating Hours

Backlight hours of operation.

BIOS

Version of the display’s BIOS firmware.

Troubleshooting

Image Size Is Very Large for the Screen

If the computer data does not appear to be the correct format, then SmartSync™ must be run. To run SmartSync™, press the Menu button. Select the Setup menu. Press SCROLL to highlight SmartSync™, then press the ▶ button. SmartSync™ will run and size the image properly.

Ghosting in Characters

Ghosting in characters is usually attributed to reflections in the video cable or source. Use a high quality video cable and, if possible, lower the vertical refresh rate. Lower scan rates can help eliminate reflections. Unlike a CRT, a flat-panel will not flicker at lower refresh rates (60 Hz is optimal) and data update will be the same at all refresh rates.

Text is Too Small

Since the monitor accepts and displays computer data with a higher resolution than the display's native resolution, this may produce small text. In the Menu check the Display Mode tab. Verify that the computer data resolution does not exceed the Native Resolution specification.

Character Jitter

If text characters seem to be "shaky" or bold, then Sharpness, Frequency and/or Phase may require adjusting. Refer to Setting Frequency, Phase and Sharpness below.

Character Noise and Vertical Distortion

The Frequency adjustment expands or contracts the horizontal size of the displayed image. The displayed image may be too wide or too narrow and vertical banding and pixel jitter may appear in grays and light colors. Adjust the Frequency until the image just fits the screen. Horizontal position adjustment can be used to verify that Frequency is set correctly. Line up the image on the left edge of the screen and then shift by one "click" to the right. The image should have one column off the screen on the right side if the Frequency is set correctly.

Black Screen

Power the display Off and On. If the NDS logo appears then the display is working properly. Check if the power management feature (DPMS) is enabled. An "Out of Range" message appears in the upper left-hand corner when an input source is out of the display's resolution range. A "Searching" message appears in the lower right-hand corner when the video source is not present.

This page is intentionally left blank.

Appendix H Functional and Performance Verification Testing

BMU Functional Testing

Record all test results on the BMU Functional Test forms.

1. Plug in the AC power adapter and press the **Power Switch** on the BMU and verify the following:
   – Startup audio plays.
   – Light bar LED's illuminate (blue).
   – Both fans are blowing out of the handle shroud vent ports.
   – Power Switch illuminates.
   – AC plug symbol is present.

Once the System boots up, verify that the following BMU Ready screen displays and record the test results:

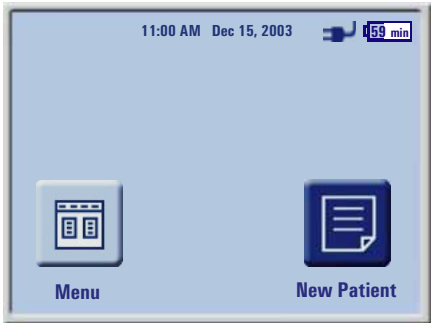


Figure H-1 BMU Ready Screen

2. Attach the Pulse Oximeter probe, NIBP cuff, and ARM Handset to yourself.

Note

SpO_2 and NIBP simulators may also be used. Ensure that they are turned on.

3. Attach the ECG leads to the ECG simulator and ensure that the unit is turned on.
4. Press the **New Patient** button on the BMU screen.

5. Select New Patient from the BMU Ready screen. The BMU Monitoring screen displays after all simulator measurements are obtained.

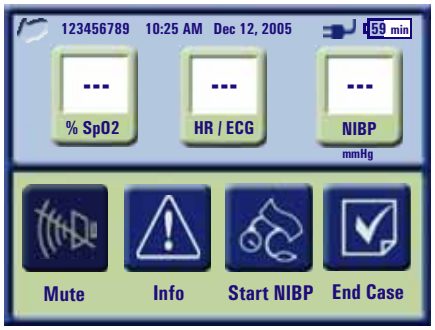


Figure H-2 BMU Monitoring Screen

6. Verify that SpO_2, HR, and NIBP readings display and record the results.
7. Press the **ECG** button on the BMU Monitoring screen. Verify that the ECG waveform displays and record the results.
8. Attach the ARM Handset to yourself.
9. Start ARM training by squeezing the ARM Handset for 3 seconds. Select **OK** from the Select ARM Volume screen, follow the ARM Training instructions, and record the results.
10. Verify wireless print functionality by following the steps in Setting up the BMU Wireless Printer on page 4-16 to configure the wireless printer and network.
11. Press **Sample Print** from the Printer Configuration menu and record the results.
12. Press **End Case** from the BMU monitoring screen and press **OK** from the Confirm End Case pop-up screen.

PRU Functional Testing

Record all test results on the PRU Functional Test forms.

1. To turn on the PSU Switch, press the **Switch** on the front of the PRU, and verify the following:
   – Start-up wave file audio plays.
   – Switch illuminates.
   – Fans are blowing air out of the PRU and PSU chassis.

Once the System boots up, verify that the Ready screen displays on the PRU:

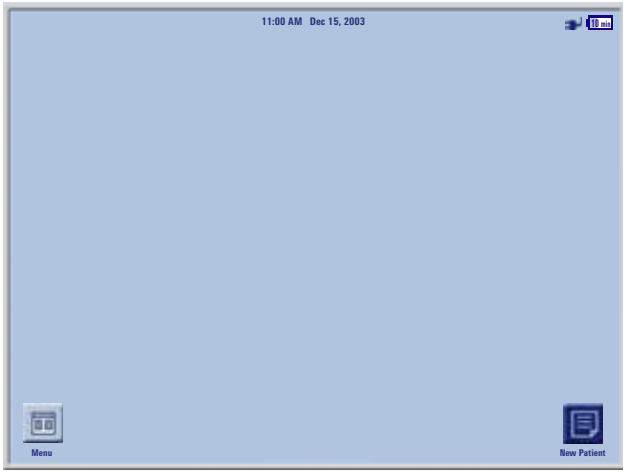


Figure H-3 PRU Ready Screen

2. Connect the BMU to the PRU with the Umbilical Cable.
3. Connect an Oral/Nasal Cannula to the BMU and place the Earpiece in your left or right ear.
4. Select **New Patient** from the PRU Ready screen.
5. Select **OK** from the Enter Patient and Drug Data screen.

6. Verify the PRU Monitoring screen displays along with the SpO_2, HR, and NIBP values and record the results.

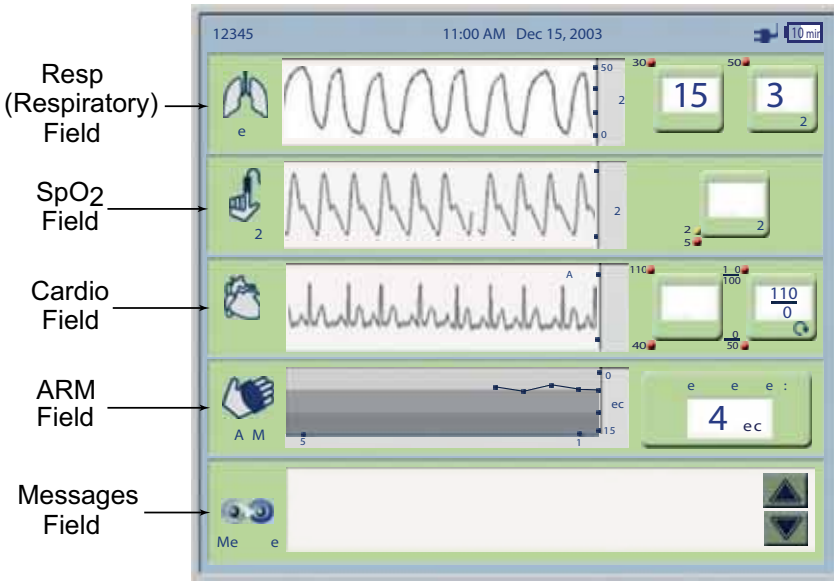


Figure H-4 PRU Monitoring Screen

7. Connect the Oral/Nasal Cannula to yourself. Refer to *Chapter 6: Procedural Use* as needed.
8. Establish the capnometry signals by breathing normally. Verify that a capnometry waveform and respiration rate display on the PRU screen.
9. Verify that the inhalation and exhalation arrows switch as you breathe through your nose into the Oral/Nasal Cannula and record the results.

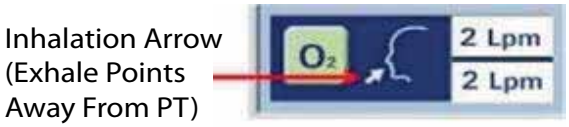


Figure H-5 Inhale and Exhale

10. Verify oxygen is being delivered and record the results.
11. Verify wireless printing. Follow the steps in Timing/Print on page 4-14 to configure the PRU. Press **PRINT** button on the PRU Monitoring screen and record the results.
12. Place Cassette Bar Code under the Bar Code Scanner area and scan the Bar Code and record the results.
13. Press the **Door** button on the PRU to open the Pump Door.
14. Load a new cassette onto the PRU and close the Pump Door. Remove the cassette's Spike Cover.
15. Insert a 20 mL vial containing water and select the 20 mL vial size on the touchscreen.

16. Hold the vial down to ensure seating. The Auto Prime Cycle should start automatically and you should notice bubbles rise in the test vial. Verify that cassette is primed with water and record the results.
17. Press **End Case** from the PRU Monitoring screen and press **OK** from the Confirm End Case pop-up screen.
18. Press **End Case** from the BMU Monitoring screen.
19. Press **OK** from the Confirm End Case pop-up screen. Verify that the Ready screen displays on both the PRU and BMU and record the results.

Performance Verification Testing

BMU Testing

Battery Charging Tests

1. With the BMU connected to the power supply assembly, verify that the electrical plug is displayed on the screen.

Figure H-6 Electrical plug

2. Disconnect the power supply assembly connecting cable from the power port on the BMU. Connect an Umbilical Cable from the PRU to the BMU under test and verify that the electrical plug and remaining minutes of battery life icons are displayed on the screen. Record the results on the test form.

Wireless Printer Test

1. Press **Sample Print** from the Printer Configuration screen and verify that a test page is printed out successfully.
2. Record the results on the test form.

If test page does not print out successfully, refer to for possible causes and suggested actions.

Visual Inspection Checks

1. Verify the following:
   - Two (2) handle shroud screws are installed securely
   - Four (4) rear shroud screws are installed securely
   - Light Bar is present and fully seated
   - Front, rear, and connector shrouds are securely attached and fully seated together
   - No cracks are present in the front, rear, or connector shrouds
   - BMU Information and Serial Number Labels are present and legible at the rear shroud
   - Power switch is properly aligned in the front shroud
   - Pole clamp adapter securely locks into place at rear shroud
2. Record the results on the test form.

Electrical Safety Testing

Ground Bond Tests

The ground bond test provides a method to test the ground circuit in the UUT (Unit Under Test) by applying a high current and checking the ability of the ground circuit to safely handle the fault current. This test is required whenever electrical or mechanical parts in the ground circuit are removed

or replaced. Examples of parts in the ground circuit are: a cable carrying earth ground, a metal cover or chassis, or the AC/DC converter.

Peform the following test steps for the PSU:

1. Connect the Ground Integrity tester to AC power and turn the unit on.
2. Ensure that the power switch on the back of the PSU is OFF.
3. Connect the Red test lead from the Ground Integrity tester to the PCB fan grill on the rear right side of the PSU.
4. Connect the Black test lead from the tester to the center ground terminal of the AC input module on the rear of the PSU.
5. Program the tester as follows:
   – Test current = 25A
   – Test time = 10 sec
   – Max resistance limit = 0.1 ohms
   – Frequency = 60 Hz
6. Perform the PSU Ground Bond test and record the results on PRU/ PSU Electrical Safety Testing Form in *Appendix H: Functional and Performance Verification Testing*.

Peform the following test steps for the Control Unit:

1. Connect the Ground Integrity tester to AC power and turn the unit on.
2. Ensure that the monitor cable is securely connected to the back of the Control Unit.
3. Ensure that the PSU DC Out cable is securely connected to the back of the Control Unit.
4. Ensure that the power switch on the back of the PSU is OFF.
5. Connect the Red test lead and connect it to the PCB fan grill on the back side of the Control Unit.
6. Connect the Black test lead from the tester to the center ground terminal of the AC input module on the rear of the PSU.
7. Program the tester as follows:
   – Test current = 25A
   – Test time = 10 sec
   – Max resistance limit = 0.1 ohms
   – Frequency = 60 Hz
8. Perform the Control Unit Ground Bond test and record the results on the test form.

Current Leakage Testing

Leakage current tests provide a method to test the patient isolation circuit and insulation in the UUT by applying a normal line voltage under both normal and single fault conditions. These tests are required whenever electrical or mechanical parts in the patient isolation circuit are removed or replaced. Examples of the parts in isolation circuit are: the isolation

transformer, any isolated OEM board (SpO_2, ECG) and all external connections.

Required equipment:

- Ground Integrity Tester
- Universal Electrical Safety Tester

Peform the following steps for PSU Earth Leakage Test:

1. Connect the IEC601 Universal Electrical Safety tester to AC power and turn the unit on.
2. Connect the AC power cord from the PSU to the tester.
3. Turn the PSU ON using the switch in the back of the PSU.
4. Set tester to measure Earth Leakage under the following test conditions and record the actual readings on the test form:
   – Normal Polarity, Leakage Current = < 200uA
   – Reverse Polarity, Leakage Current = < 200uA
   – Normal Polarity, Open Neutral, Leakage Current = < 400uA
   – Reverse Polarity, Open Neutral, Leakage Current = < 400uA

Peform the following steps for the Control Unit Earth Leakage Test:

1. Connect the IEC601 Universal Electrical Safety tester to AC power and turn the unit on.
2. Connect the AC Power Cord from the PSU to the tester.
3. Ensure that the monitor cable is securely connected to the back of the Control Unit.
4. Ensure that the PSU DC Out cable is securely connected to the back of the Control Unit.
5. Turn the PSU ON using the switch in the back of the PSU.
6. Press and hold the power switch on the front of the Control Unit until the monitor turns on.

Note

Allow the PRU to boot completely before completing any of the tests.

7. Set tester to measure Earth Leakage under the following test conditions and record the actual readings on the test form:
   – Normal Polarity, Leakage Current = < 275uA
   – Reverse Polarity, Leakage Current = < 275uA
   – Normal Polarity, Open Neutral, Leakage Current = < 550uA
   – Reverse Polarity, Open Neutral, Leakage Current = < 550uA

Peform the following steps for the Control Unit Enclosure Leakage Test:

Note

This test is required when the front bezel, top bezel, or pump housing is replaced.

1. Connect the IEC601 Universal Electrical Safety tester to AC power and turn the unit on.
2. Connect the AC Power Cord from the PSU to the tester.
3. Ensure that the monitor cable is securely connected to the back of the PRU.
4. Ensure that the PSU DC Out cable is securely connected to the back of the PRU.
5. Turn the PSU ON using the switch in the back of the PSU.
6. Press and hold the power switch on the front of the PRU until the monitor turns on.

Note

Allow the PRU to boot completely before completing any of the tests.

7. Open the pump door on the PRU and install a piece of aluminum foil in the pump bed.
8. Close the pump door enough to engage the foil on all exposed metal parts of the pump.
9. Open the pump door on the PRU and install a piece of aluminum foil in the pump bed.
10. Close the pump door enough to engage the foil on all exposed metal parts of the pump.
11. Set the Universal Electrical Safety tester to measure Enclosure (or Case Leakage) under the following test conditions and record the actual readings on the test form:

Note

Hold the test probe from the tester in contact with the foil while taking each leakage measurement.

- Normal Polarity, Closed Ground, Leakage Current = < 100uA
- Reverse Polarity, Closed Ground, Leakage Current = < 100uA
- Normal Polarity, Open Neutral, Closed Ground, Leakage Current = < 500uA
- Reverse Polarity, Open Neutral, Closed Ground, Leakage Current = < 500uA
- Normal Polarity, Open Ground, Leakage Current = < 500uA
- Reverse Polarity, Open Ground, Leakage Current = < 500uA

Peform the following steps for the BMU Earth Leakage Test:

1. Connect the IEC601 Universal Electrical Safety tester to AC power and turn the unit on.
2. Connect the external power adapter from the BMU to IEC601 Universal Electrical Safety Tester.

3. Press and hold the power switch on the front of the BMU until the unit turns on.

Note

Allow the BMU to boot completely before completing any of the test.

4. Connect the following cables to the BMU:
   – ECG Trunk cable and Leads (3 Lead Harness)
   – Pulse Oximeter cable and probe
   – ARM Handset assembly
5. Connect the cables to the tester as follows:
   – Three (3) Lead Harness to RA, LA, LL terminals
   – Wrap aluminum foil around Pulse Oximeter probe and connect a test lead from foil to RL terminal
   – Wrap foil around ARM Handset and connect a test lead from foil to V1 terminal
6. Set tester to measure Earth Leakage under the following test conditions and record the actual readings on the BMU Electrical Safety Test Form in *Appendix H: Functional and Performance Verification Testing*:
   – Normal Polarity, Leakage Current = < 500uA
   – Normal Polarity, All Leads to Ground, Leakage Current = < 500uA
   – Reverse Polarity, Leakage Current = < 500uA
   – Reverse Polarity, All Leads to Ground, Leakage Current = < 500uA
   – Normal Polarity, Open Neutral, Leakage Current = < 1000uA
   – Reverse Polarity, Open Neutral, Leakage Current = < 1000uA
   – Normal Polarity, Open Neutral, All Leads to Ground, Leakage Current = < 1000uA
   – Reverse Polarity, Open Neutral, All Leads to Ground, Leakage Current = < 1000uA

Peform the following steps for the BMU Patient Leakage Test (External Brick or SEDASYS® System):

1. Connect the IEC601 Universal Electrical Safety tester to AC power and turn the unit on.
2. Connect the external power adapter from the BMU or PSU power cord to IEC601 Universal Electrical Safety Tester.
3. Press and hold the power switch on the front of the BMU until the unit turns on.

Note

Allow the BMU to boot completely before completing any of the tests.

4. Connect the following cables to the BMU:
   – ECG Trunk cable and Leads (3 Lead Harness)
   – Pulse Oximeter cable and probe
   – ARM Handset assembly

5. Connect the cables to the tester as follows:
   – Three (3) Lead Harness to RA, LA, LL terminals
   – Wrap aluminum foil around Pulse Oximeter probe and connect a test lead from foil to RL terminal
   – Wrap foil around ARM Handset and connect a test lead from foil to V1 terminal
6. Set tester to measure Patient Leakage as “Patient Lead Each to GND” under the following test conditions and record the actual readings on the test form:

Note

Hold the test probe from the tester in contact with the foil while taking each leakage measurement.

   – Normal Polarity, Leakage Current = < 10uA
   – Reverse Polarity, Leakage Current = < 10uA
   – Normal Polarity, Open Ground, Leakage Current = < 50uA
   – Reverse Polarity, Open Ground, Leakage Current = < 50uA
   – Normal Polarity, Open Neutral, Leakage Current = < 50uA
   – Reverse Polarity, Open Neutral, Leakage Current = < 50uA
7. Set tester to measure Patient Leakage as “Patient Lead All to GND” under the following test conditions and record the actual readings on the test form:

Note

Hold the test probe from the tester in contact with the foil while taking each leakage measurement.

   – Normal Polarity, Leakage Current = < 10uA
   – Reverse Polarity, Leakage Current = < 10uA
   – Normal Polarity, Open Ground, Leakage Current = < 50uA
   – Reverse Polarity, Open Ground, Leakage Current = < 50uA
   – Normal Polarity, Open Neutral, Leakage Current = < 50uA
   – Reverse Polarity, Open Neutral, Leakage Current = < 50uA

BMU Functional Test Form

Test Step	Description	Result
1. Power-up Test	Start-up audio plays, light bar LED's illuminates, fans blowing out of the handle shroud vent ports, power switch illuminates.	Pass / Fail
	Ready screen displays with AC plug symbol.	Pass / Fail
2. Pulse Oximeter and NIBP Tests	A reading displays for SpO2, HR, and NIBP	Pass / Fail
3. ECG Test	ECG waveform displays*	Pass / Fail / NA
4. ARM Test	ARM Training Test completed (audio heard through earpiece, ARM Handset vibrates, ARM Handset squeeze detected)	Pass / Fail
5. Wireless Printing	Test page prints out	Pass / Fail
6. End Case	PRU and BMU Ready screens display after confirming End Case	Pass / Fail

*Optional if patient simulator or patient sinus heart rhythm source is available.

Completed by:

Name (Print): _____

Signature: _____

Date: _____

BMU Serial Number: _____

BMU Electrical Safety Test Form

Test Step	Test Range	Measured Value	Result
BMU Earth Leakage Current (Normal Polarity, Closed Ground)	< 500 uA		Pass/Fail
BMU Earth Leakage Current (Normal Polarity, All leads to Ground, Closed Ground)	< 500 uA		Pass/Fail
BMU Earth Leakage Current (Reverse Polarity, Closed Ground)	< 500 uA		Pass/Fail
BMU Earth Leakage Current (Reverse Polarity, All leads to Ground, Closed Ground)	< 500 uA		Pass/Fail
BMU Earth Leakage Current (Normal Polarity, Open Neutral, Closed Ground)	< 1000 uA		Pass/Fail
BMU Earth Leakage Current (Reverse Polarity, Open Neutral, Closed Ground)	< 1000 uA		Pass/Fail
BMU Earth Leakage Current (Normal Polarity, Open Neutral, All leads to Ground, Closed Ground)	< 1000 uA		Pass/Fail
BMU Earth Leakage Current (Reverse Polarity, Open Neutral, All leads to Ground, Closed Ground)	< 1000 uA		Pass/Fail
BMU Patient Leakage Current (Normal Polarity, Patient Leads Each to Ground)	< 10 uA		Pass/Fail
BMU Patient Leakage Current (Reverse Polarity, Patient Leads Each to Ground)	< 10 uA		Pass/Fail
BMU Patient Leakage Current (Normal Polarity, Open Ground, Patient Leads Each to Ground)	< 50 uA		Pass/Fail
BMU Patient Leakage Current (Reverse Polarity, Open Ground, Patient Leads Each to Ground)	< 50 uA		Pass/Fail
BMU Patient Leakage Current (Normal Polarity, Open Ground, Patient Leads Each to Ground)	< 50 uA		Pass/Fail
BMU Patient Leakage Current (Reverse Polarity, Open Ground, Patient Leads Each to Ground)	< 50 uA		Pass/Fail
BMU Patient Leakage Current (Normal Polarity, Patient Leads All to Ground)	< 10 uA		Pass/Fail
BMU Patient Leakage Current (Reverse Polarity, Patient Leads All to Ground)	< 10 uA		Pass/Fail
BMU Patient Leakage Current (Normal Polarity, Open Ground, Patient Leads All to Ground)	< 50 uA		Pass/Fail
BMU Patient Leakage Current (Reverse Polarity, Open Ground, Patient Leads All to Ground)	< 50 uA		Pass/Fail
BMU Patient Leakage Current (Normal Polarity, Open Ground, Patient Leads All to Ground)	< 50 uA		Pass/Fail

BMU Patient Leakage Current (Reverse Polarity, Open Ground, Patient Leads All to Ground)	< 50 uA		Pass/Fail

Completed by:

Name (Print): _____

Signature: _____

Date: _____

BMU Serial Number: _____

PRU Functional Test Form

Test Step	Description	Result
1. Power-up Test	Start-up audio plays, power switch illuminates, fans are blowing air out of the PRU and PSU chassis.	Pass / Fail
	Ready screen displays	Pass / Fail
2. Communication Test	BMU Connection Test	Pass / Fail
3. Physiologic Monitoring Test	PRU displays SpO_2, HR, NIBP values, and SpO_2, ECG waveforms	Pass / Fail
4. Capnometer Tests	PRU displays capnometry waveform and respiration rate values	Pass / Fail
	Inhalation and Exhalation arrows switch	Pass / Fail
5. Oxygen Test	Oxygen is delivered	Pass / Fail
6. Wireless Printing Test	Test page prints out	Pass / Fail
7. Bar Code Test	Bar code scans	Pass / Fail
8. Infusion Pump Autoprime Test	Autoprime completes	Pass / Fail
9. End-Case	PRU and BMU Ready screens display after confirming End Case	Pass / Fail

Completed by:

Name (Print): _____

Signature: _____

Date: _____

PRU Serial Number: _____

PSU Serial Number: _____

PRU/PSU Electrical Safety Testing Form

Test Step	Test Range	Measured Value	Result
PSU Ground Bond Test	< 0.1 ohms		Pass/Fail
PRU Ground Bond Test	< 0.1 ohms		Pass/Fail
PSU Earth Leakage Current (Normal Polarity, Closed Ground)	< 200 uA		Pass/Fail
PSU Earth Leakage Current (Reverse Polarity, Closed Ground)	< 200 uA		Pass/Fail
PSU Earth Leakage Current (Normal Polarity, Open Neutral, Closed Ground)	< 400 uA		Pass/Fail
PSU Earth Leakage Current (Reverse Polarity, Open Neutral, Closed Ground)	< 400 uA		Pass/Fail
PRU Earth Leakage Current (Normal Polarity, Closed Ground)	< 200 uA		Pass/Fail
PRU Earth Leakage Current (Reverse Polarity, Closed Ground)	< 200 uA		Pass/Fail
PRU Earth Leakage Current (Normal Polarity, Open Neutral, Closed Ground)	< 400 uA		Pass/Fail
PRU Earth Leakage Current (Reverse Polarity, Open Neutral, Closed Ground)	< 400 uA		Pass/Fail
PRU Enclosure Leakage Current (Normal Polarity, Closed Ground)	< 100 uA		Pass/Fail
PRU Enclosure Leakage Current (Reverse Polarity, Closed Ground)	< 100 uA		Pass/Fail
PRU Enclosure Leakage Current (Normal Polarity, Open Neutral, Closed Ground)	< 500 uA		Pass/Fail
PRU Enclosure Leakage Current (Reverse Polarity, Open Neutral, Closed Ground)	< 500 uA		Pass/Fail
PRU Enclosure Leakage Current (Normal Polarity, Open Ground)	< 500 uA		Pass/Fail
PRU Enclosure Leakage Current (Reverse Polarity, Open Ground)	< 500 uA		Pass/Fail

Completed by:

Name (Print): _____

Signature: _____

Date: _____

PRU Serial Number: _____

PSU Serial Number: _____

Index

U

V

W