

2009-4438b1-04-01

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

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## 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 to the end of the IV catheter. The Drug Delivery Cassette tubing can be connected directly to the 3-way stopcock of an IV catheter.



#### WARNING

When using a standard IV administration set, make sure the IV set contains an integrated backcheck valve to prevent inaccurate dosing of 1% propofol injectable emulsion.



#### 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<sub>2</sub>, 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 4-8 for instructions on accessing this screen):

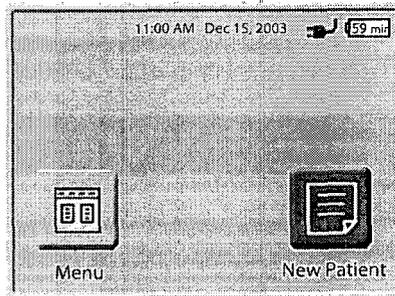


Figure 6-1 BMU Ready Screen

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 4-15), 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.

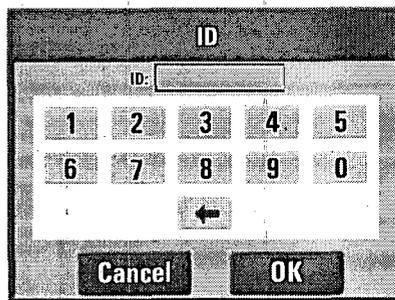


Figure 6-2 ID Entry Screen

**Note**

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

3. Numeric values for SpO<sub>2</sub>, Heart Rate, and NIBP will be automatically displayed as the monitors are connected to the patient. Refer to *Appendix D: The BMU Monitoring Screen* for a description of system functions that can be reached through the BMU Monitoring screen.

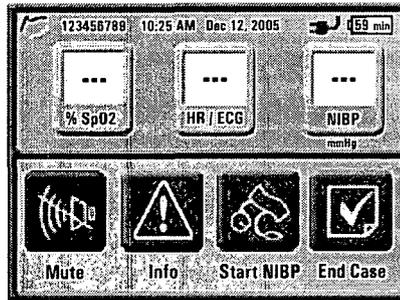


Figure 6-3 BMU Monitoring Screen

## Connecting the Oral/Nasal Cannula



### WARNING

The Oral/Nasal Cannula is packaged non-sterile for single-patient use only. Do not re-use. Re-use may result in transmission of disease from patient to patient.

### 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.

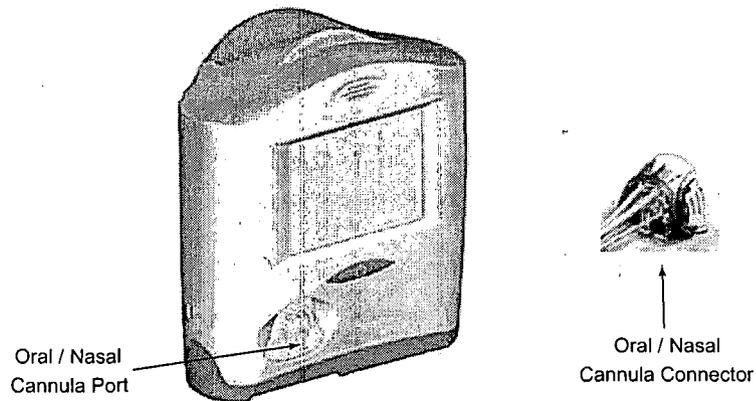


Figure 6-4 Connecting Oral/Nasal Cannula to BMU

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.

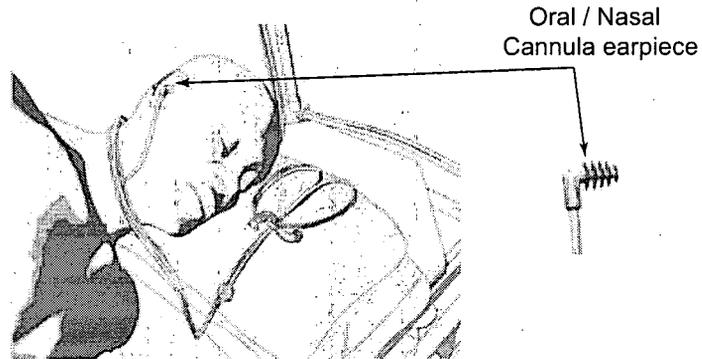


Figure 6-5 Attaching Earpiece Portion of Oral/Nasal Cannula to Patient

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.
- 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 6-14 for instructions).
- 2 After connecting the earpiece to the patient, ensure that the earpiece tubing is not pinched or beneath the patient.



Note

## 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 could lead to inaccurate Pulse Oximeter measurements.

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

## ARM Training

1. Instruct patients to squeeze on the ARM handset with their hand for 3 seconds to initiate ARM training. The following screen appears on the BMU:

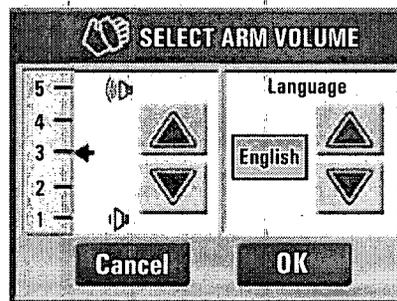


Figure 6-7 Select ARM Volume Screen

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 6-34.

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:

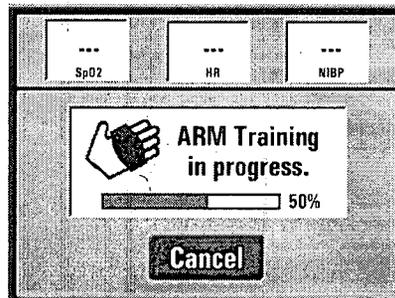


Figure 6-8 ARM Training In Progress Screen

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 one second later.

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

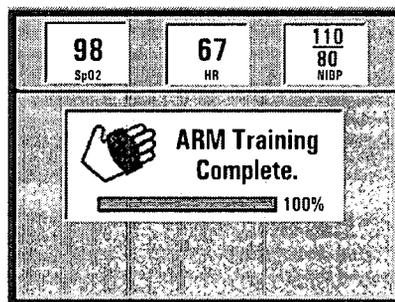


Figure 6-9 ARM Training Complete Screen

### ARM Training Incomplete

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

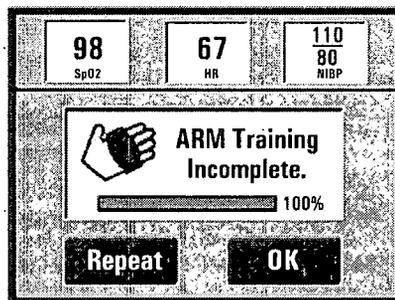


Figure 6-10 ARM Training Incomplete Screen

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 6-34.

## 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.

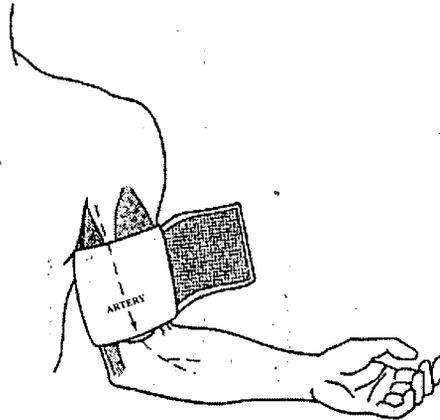


Figure 6-11 Attaching NIBP Cuff to Patient

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 on page 6-8.



Precaution

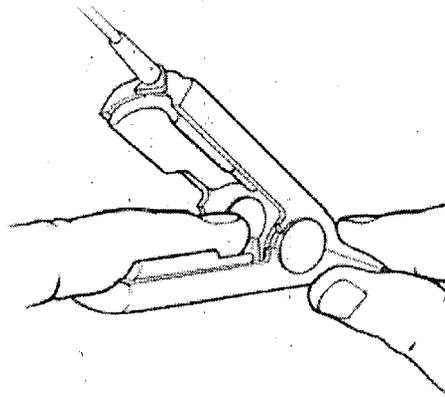
1. It is recommended that the NIBP cuff be placed on the patient's left arm, opposite the IV site on the right arm so that inflation of the blood pressure cuff during NIBP measurements will not interfere with drug delivery.
2. Ensure the patient's skin is intact before applying the cuff.

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 cause bruising.
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 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<sub>2</sub> value and pulse 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. Make sure bright lights are not shining directly on the SpO<sub>2</sub> probe. Excessive light may interfere with the accuracy of the probe 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.

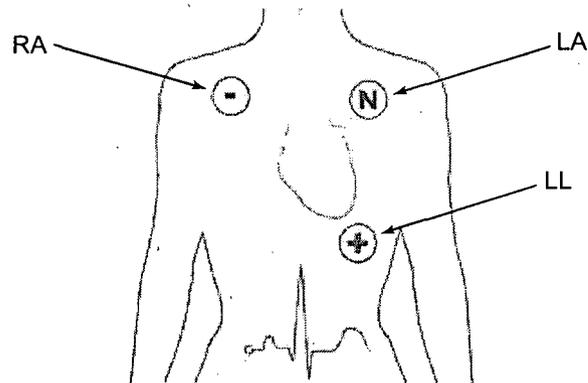


Figure 6-13 Lead II ECG Electrode Placement<sup>a</sup>

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):

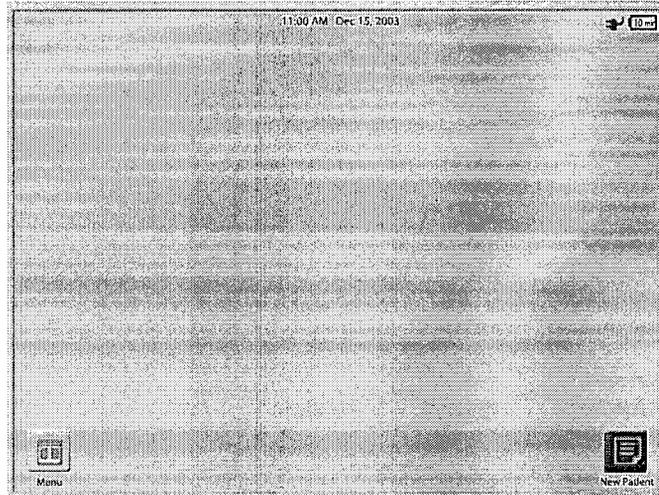


Figure 6-14 PRU Ready Screen



### 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.

1. 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.

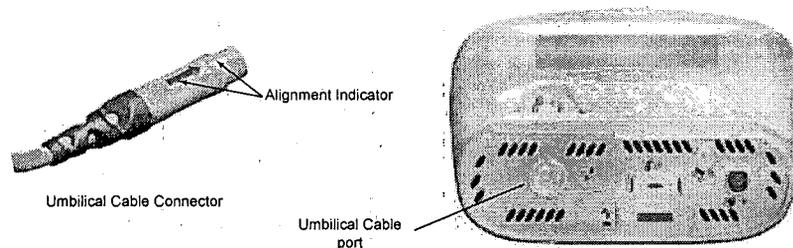


Figure 6-15 Umbilical Cable to BMU



Note

- 1 The Umbilical Cable should already be connected to the PRU (refer to Connecting the Umbilical Cable to the PRU on page 5-32).
- 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 rotate for easier access to the Umbilical Cable port, 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 BMU is connected to the Umbilical Cable, the PRU automatically displays the following screen:

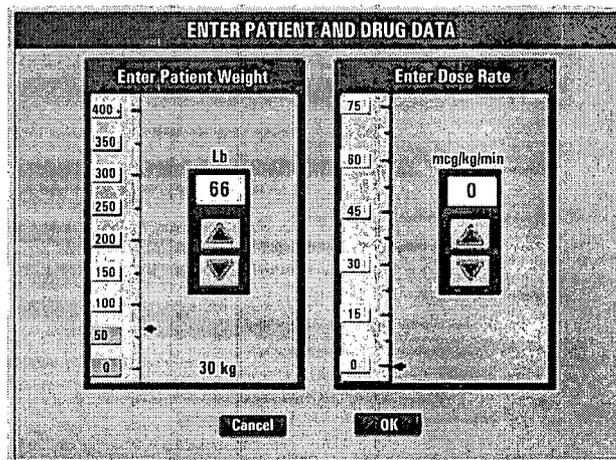


Figure 6-16 Enter Patient and Drug Data Screen

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

Verify the proper unit of measure (lb or kg) for the patient weight entered. Failure to do so may result in inaccurate drug dosing.



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 5-16).
4. Select and press the **Dose Rate** button located on the left side of the screen below Enter Dose Rate (e.g., 15, 30, 45, 60, 75 mcg/kg/min) that most closely corresponds to the desired initial dose rate.

- 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.

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

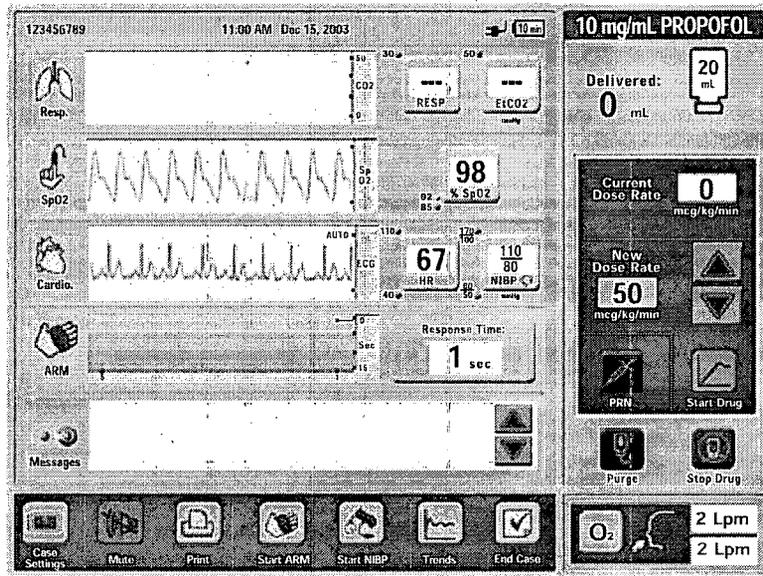


Figure 6-17 PRU Monitoring Screen



Note

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

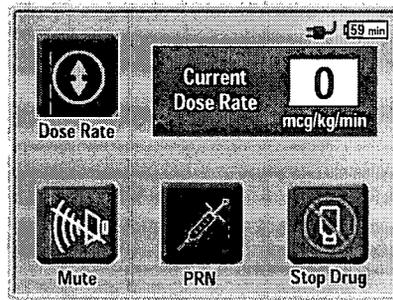


Figure 6-18 BMU Remote Entry Screen



Note

Refer to *Appendix E: The 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<sub>2</sub> or delivering oxygen.

### Place the Oral/Nasal Cannula on the Patient for Colonoscopy

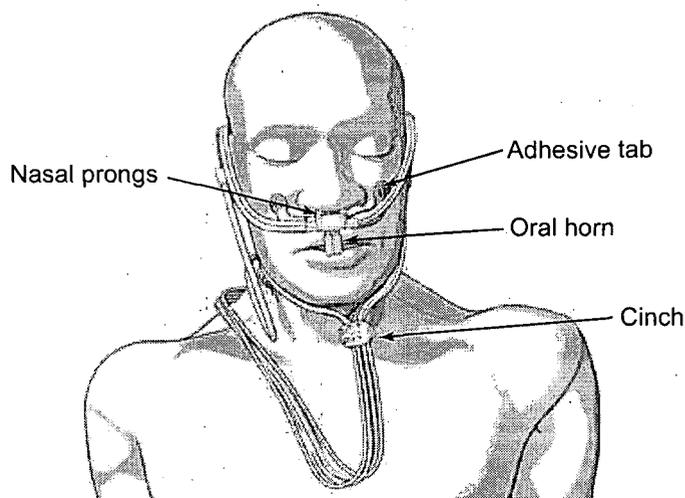


Figure 6-19 Oral/Nasal Cannula on Patient

1. Position the two nasal prongs of the 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 cannula, and attach the wings to the patient's face to provide a more secure fit.



### Precaution

Some patients may be sensitive or allergic to the adhesive strips on the Oral/Nasal Cannula.

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 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.

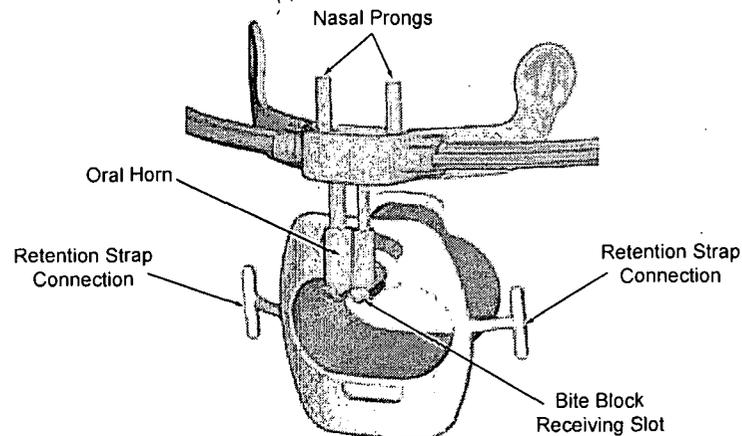
**Note**

If needed, remove the adhesive tab covers from the wings of the 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 three 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:

- 50µg–100µg IV bolus for all healthy subjects ≤ 64 years of age.
- 25µg–50µg IV bolus for all subjects who are frail, debilitated, or ≥ 65 years of age.



**WARNING**

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



**Precaution**

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



**Note**

See the fentanyl package insert for more information.

## Loading the Drug Delivery Cassette

The PRU drug delivery unit allows the delivery of 1% propofol directly from the drug vial.



**WARNING**

- 1 The Drug Delivery Cassette is packaged sterile for single-patient use only. Do not re-use.
- 2 Do not use the Drug Delivery Cassette if its sterile package is damaged or if past the labeled expiration date. Dispose of the Drug Delivery Cassette per your facilities protocol.

## 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.

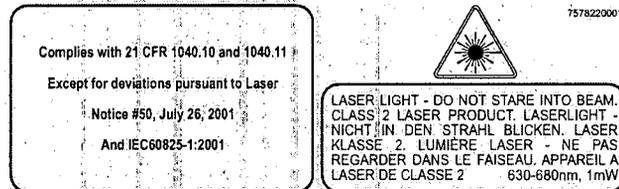


Figure 6-21 Laser Caution Label



### 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.

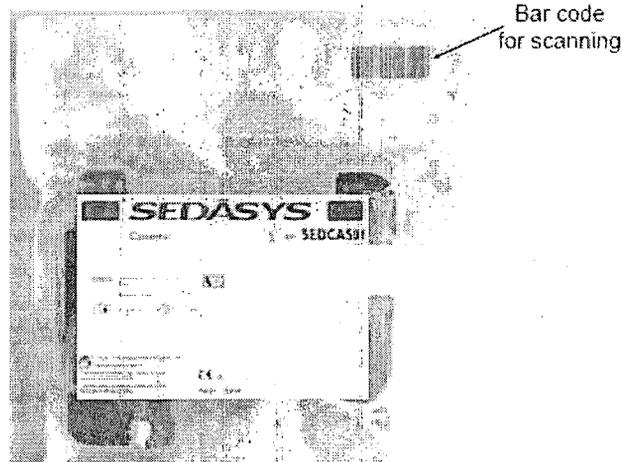


Figure 6-22 Drug Delivery Cassette with Bar Code

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 cassette is accepted, the Drug Delivery Cassette door is closed, and a drug 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 6-18).
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 in the PRU.

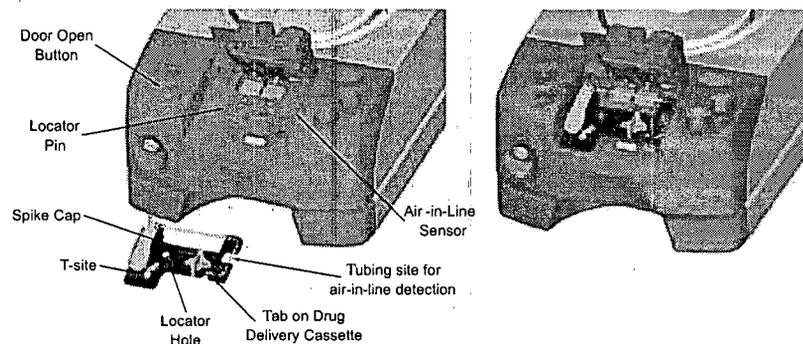


Figure 6-23 Placement of Drug Delivery Cassette into PRU

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 1% 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

Do not use an expired or previously used vial of 1% propofol.

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 1% propofol into the vial guides.

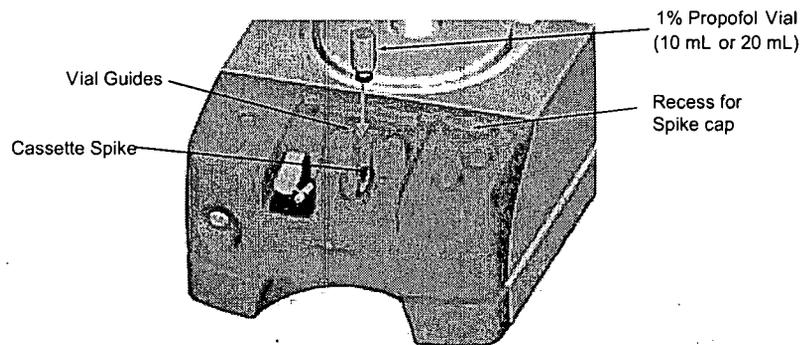


Figure 6-24 Placement of Drug Vial into PRU

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



## Note

Once the 1% propofol vial is fully inserted, the cassette door is locked and cannot be opened again until the vial is removed.

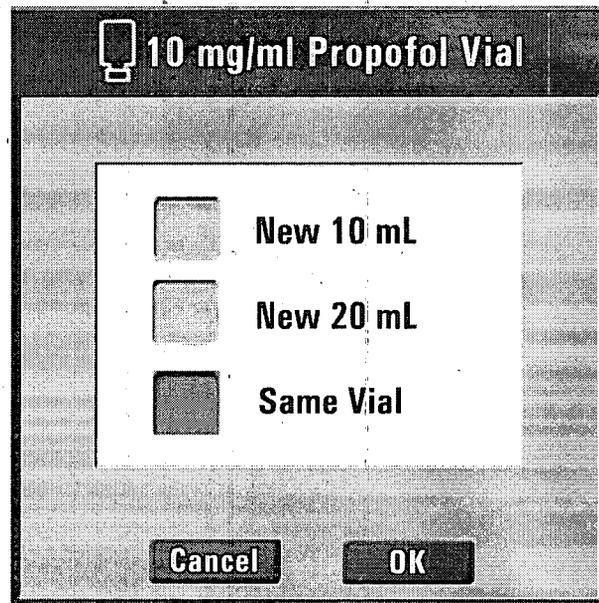


Figure 6-25 PRU Vial Selection Screen

- 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.

- 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.

- 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 1% propofol. If the tubing is not completely full of 1% propofol, you must manually purge the air from the tubing (refer to next section).
- Remove the cap from the luer fitting on the T-site connector.
- Connect the T-site connector to the stopcock attached to the patient's IV catheter.



**WARNING**

Do not connect the T-site of the Drug Delivery Cassette to the patient's IV administration set before the Drug Delivery Cassette and its IV tubing are completely primed.

### 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 T-site must not be connected to the patient during manual purge.

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

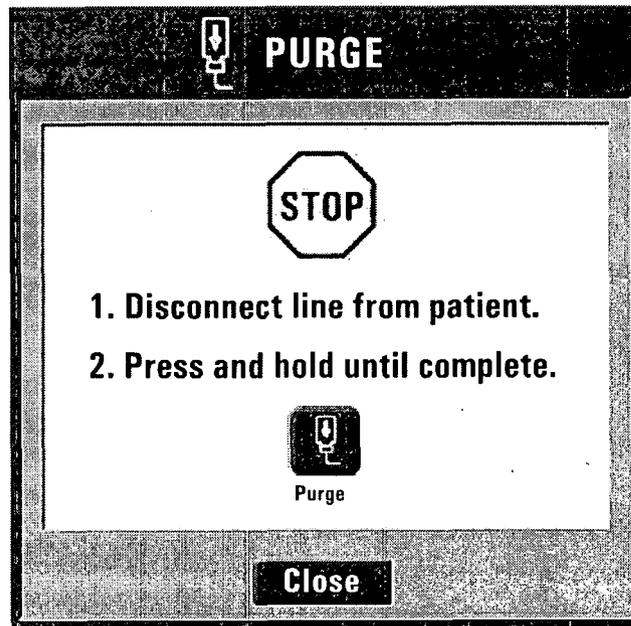


Figure 6-26 PRU Manual Purge Screen

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 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 1% 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.

**Confirm Patient and Drug Data**

Confirm Patient Weight: 150 Lb

Confirm Dose Rate: 50 mcg/kg/min

Check the following items:

- Resuscitation Kit
- Defibrillator
- Additional 10 mg/mL Propofol Vials
- O<sub>2</sub> Delivery on

Cancel    Change    OK

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 6-23, 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.

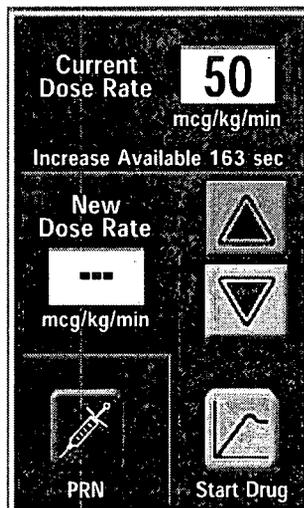


Figure 6-28 Dose Rate Section of PRU Monitoring Screen During Loading Dose

### 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.

### 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.

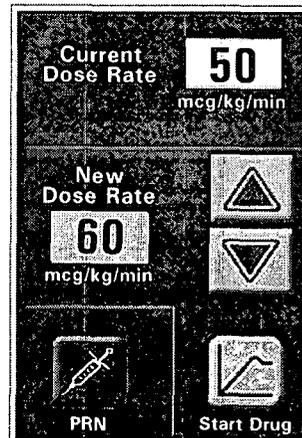


Figure 6-29 Dose Rate Section of PRU Monitoring Screen During Dose Rate Increase



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 6-23). 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 6-13).

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

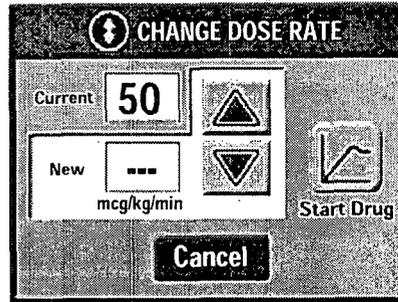


Figure 6-30 BMU Dose Rate Change Screen

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.

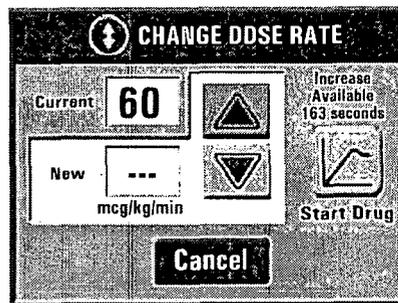


Figure 6-31 BMU Dose Rate Change Screen with Lockout Timer

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 1% 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 1% propofol that will be delivered during the PRN dose:

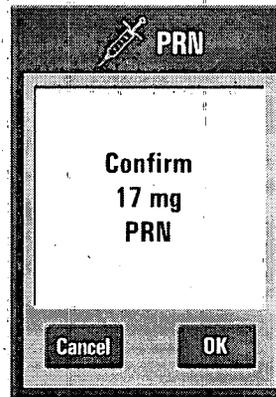


Figure 6-32 PRU PRN Confirmation Screen



#### 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:

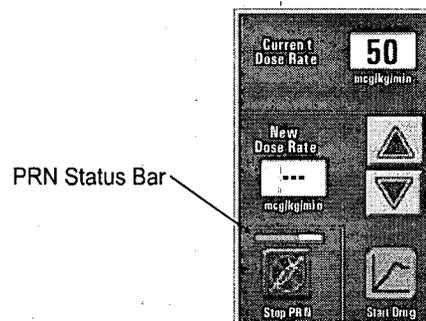
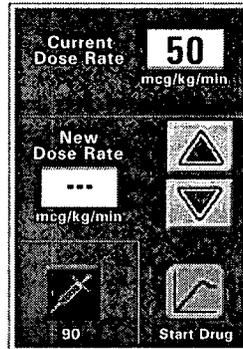


Figure 6-33 Dose Rate Section of PRU Monitoring Screen During PRN Delivery

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.



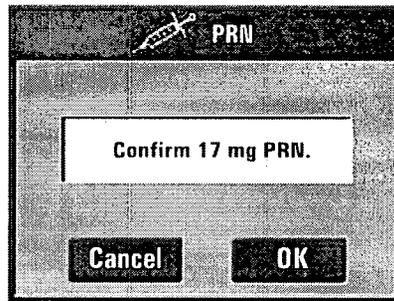
**Note**

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 1% 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:

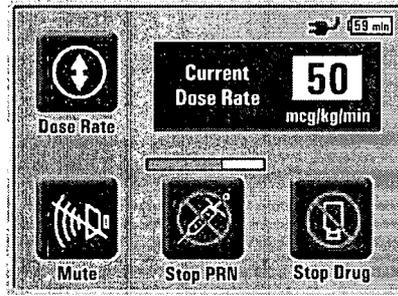


Figure 6-36 BMU Remote Entry Screen During PRN Delivery

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 time 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 1% propofol to complete the case. When the system calculates that approximately 4 mL (for a 20 mL vial) or approximately 3 mL (for a 10 mL vial) of 1% 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 1% propofol is remaining. When initially selecting the number of 1% 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 1% 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. Place a new, inverted vial of 1% 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**.

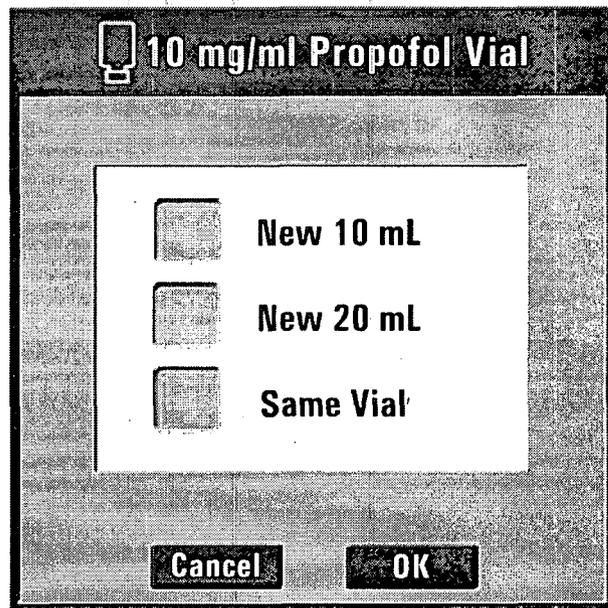


Figure 6-37 PRU Vial Selection Screen Following Vial Change



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

## Ending the Procedure

1. If the delivery of 1% 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.

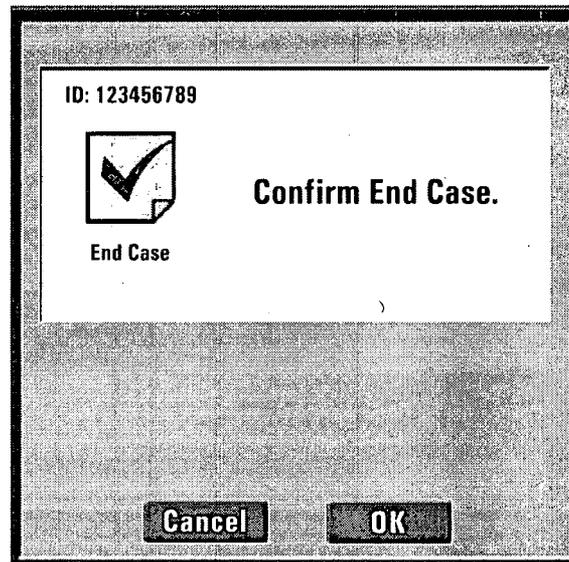


Figure 6-38 PRU End Case Confirmation Screen

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 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<sub>2</sub>, 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 1% propofol vial from the vial guides on the top of the PRU cassette door by firmly grasping the vial and lifting upward.



WARNING

The 1% propofol vials are for single-patient use only. After single-patient use, discard the vial according to your facility's protocol.

2. Press the **Door Open** button on the PRU to open the cassette door.
3. Replace the Spike Gap 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 1% propofol that may have collected in the Residual Drug reservoir (refer to Figure 1-11 on page 1-11).

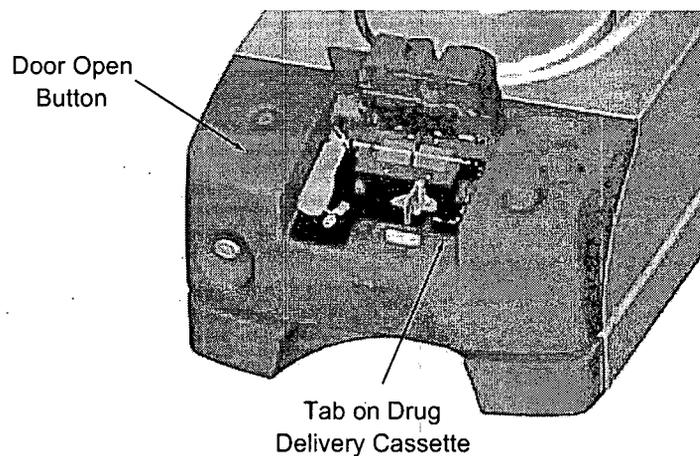


Figure 6-39 Tab on Drug Delivery Cassette



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 of all open Drug Delivery Cassettes (used or unused) and used 1% propofol vials according to your facility's protocol.

6. Carefully clean up any fluid or debris in the cassette bay with a soft cloth or swab dampened with an appropriate cleaner.

### 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, all opened Drug Delivery Cassettes (used or unused), and used 1% propofol vials according to your facility's protocol.

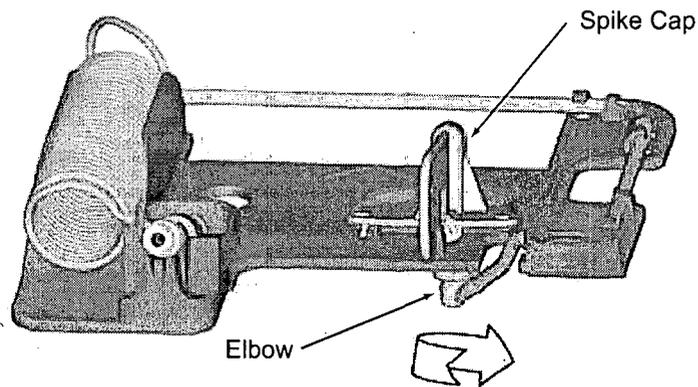


Figure 6-40 Top View of Drug Delivery Cassette and Removal of Vial Spike With Spike Cap

## 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.

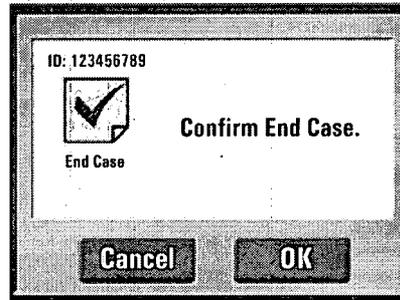


Figure 6-41 BMU End Case Confirmation Screen

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 4-15), a summary of the procedure will be printed. Refer to *Appendix F: Printing* for a sample of the procedure summary.

2. Remove the following from the patient:

- Oral/Nasal Cannula (including the earpiece)
- ARM handset
- ECG wire set and ECG electrodes
- SpO<sub>2</sub> 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<sub>2</sub> 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<sup>®</sup> 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 touch screen if delivery was stopped using the red, emergency **Stop Drug** button.

### Clinician-Response Mode

If the patient is not able to pass ARM training, selecting **Clinician Responds** 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.

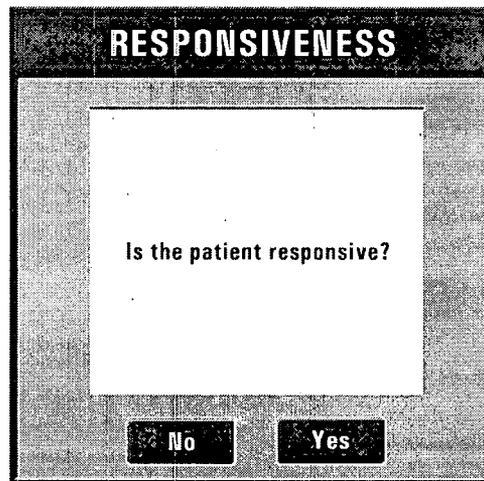


Figure 6-42 PRU Responsiveness Pop-up Window for Clinician Response Mode

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:

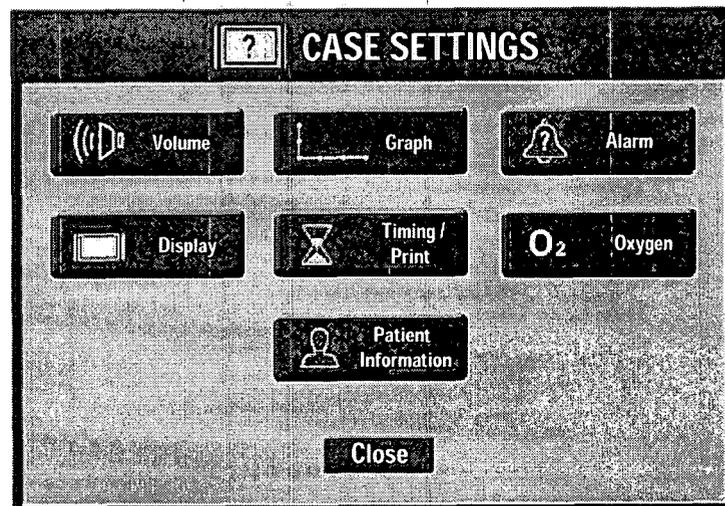


Figure 6-43 PRU Case Settings Screen

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 5-14 for instructions on adjusting the volume level for the Alarm, System, and ARM audio.

### Display Information

Refer to Display Information on page 5-15 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 5-9).

### Graph Settings

Refer to Graph Settings on page 5-17 for instructions on adjusting the waveform speed and scale settings for each displayed graph.

### Timing/Print Options

Refer to Timing/Print Options on page 5-19 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 5-9).

### Alarm Settings

Refer to Alarm Settings on page 5-24 for instructions on adjusting the alarm limits for Heart Rate, Systolic NIBP, Diastolic NIBP, EtCO<sub>2</sub>, SpO<sub>2</sub>, and Respiration Rate.

### Oxygen Delivery

Refer to Oxygen Delivery on page 5-27 for instructions on adjusting the oxygen delivery rate during inhalation and exhalation.

### Patient Information

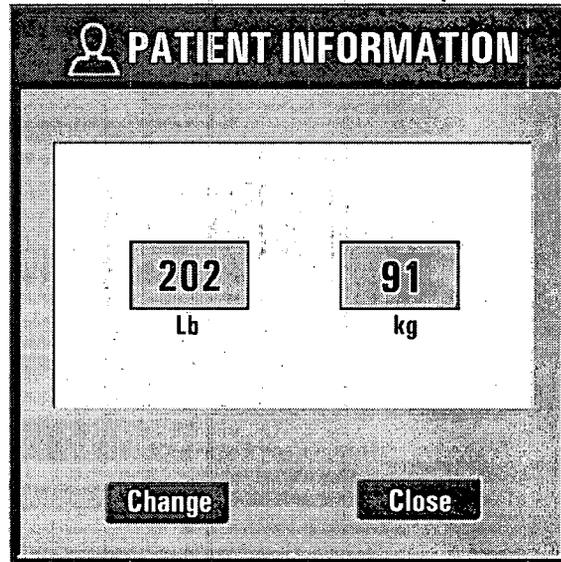


Figure 6-44 Patient Information Screen

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<sub>2</sub>**, **%SpO<sub>2</sub>**, **HR**, or **NIBP**.

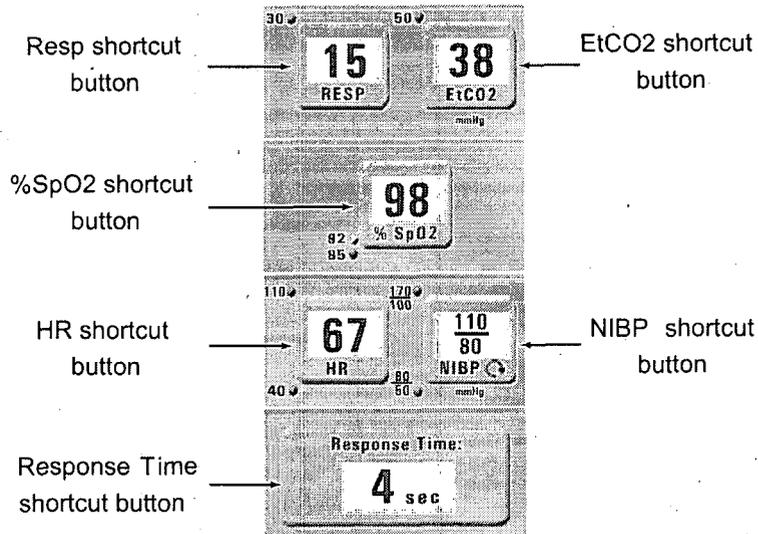


Figure 6-45 Patient Monitoring Shortcut Buttons on PRU Monitoring Screen

For **RESP**, **EtCO<sub>2</sub>**, and **%SpO<sub>2</sub>**:

Pressing the **RESP**, **EtCO<sub>2</sub>**, and **%SpO<sub>2</sub>** 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:

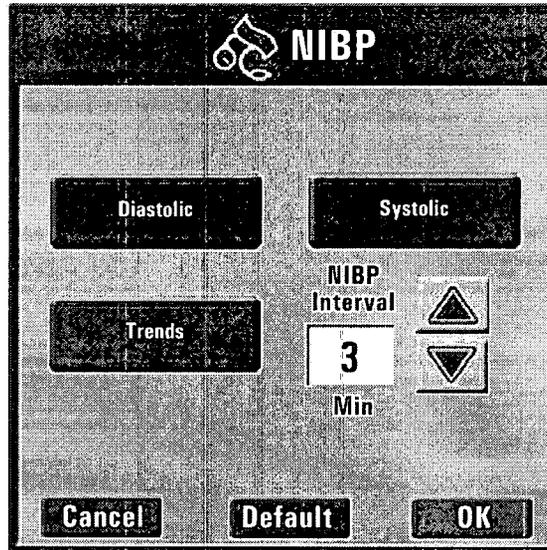


Figure 6-46 PRU NIBP Screen Reached Through NIBP Shortcut Button

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.

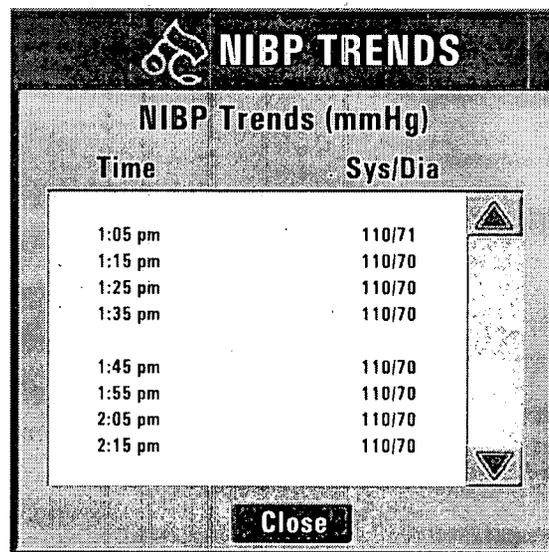


Figure 6-47 PRU NIBP Trends Screen

For HR:

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

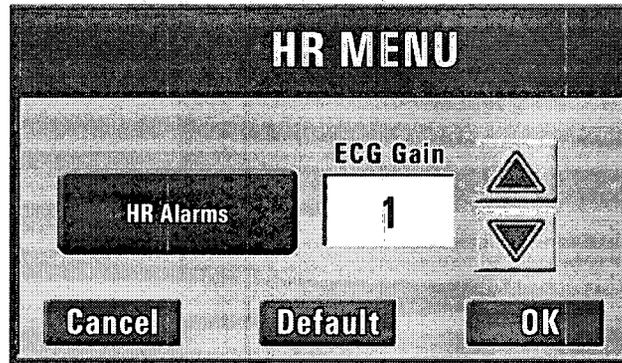


Figure 6-48 PRU HR Menu Screen Reached Through HR Shortcut Button

- 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:

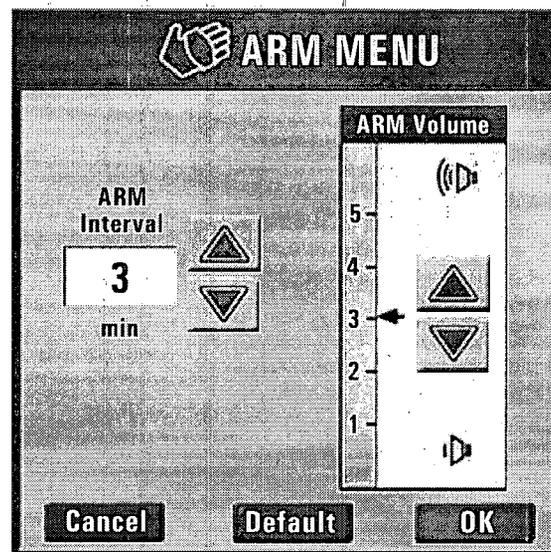


Figure 6-49 PRU ARM Menu Screen Reached Through ARM Shortcut Button

- 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).

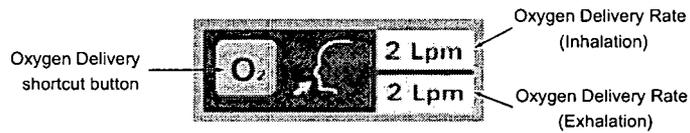


Figure 6-50 Oxygen Delivery Shortcut Buttons on PRU Monitoring Screen

## 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<sub>2</sub>**, **HR/ECG**, or **NIBP**.

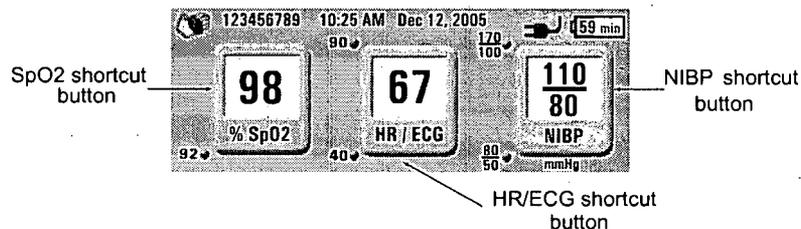


Figure 6-51 Patient Monitoring Shortcut Buttons on BMU Monitoring Screen

### For SpO<sub>2</sub>:

Pressing the **%SpO<sub>2</sub>** 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.

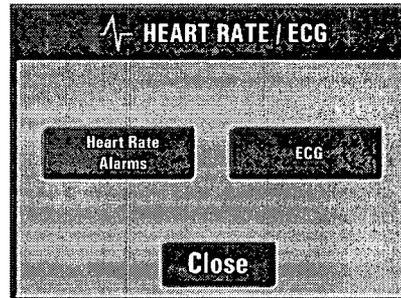


Figure 6-52 BMU Heart Rate / ECG Waveform Screen

- 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:

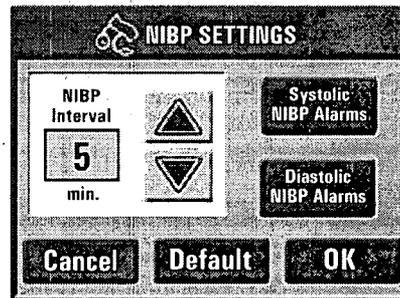


Figure 6-53 BMU NIBP Settings Screen

- 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.

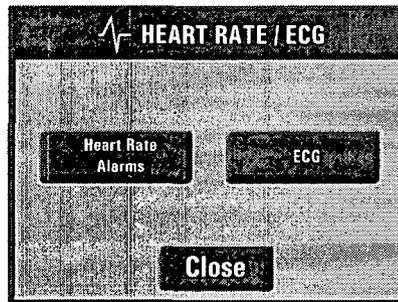


Figure 6-54 BMU Heart Rate / ECG Waveform Screen

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

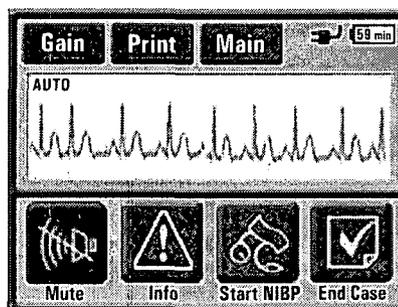


Figure 6-55 BMU ECG Waveform Screen

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**

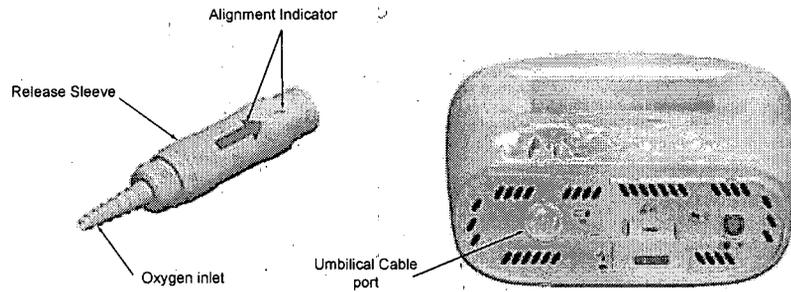
The selected Gain setting is displayed in the upper left corner of the ECG waveform display.

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.

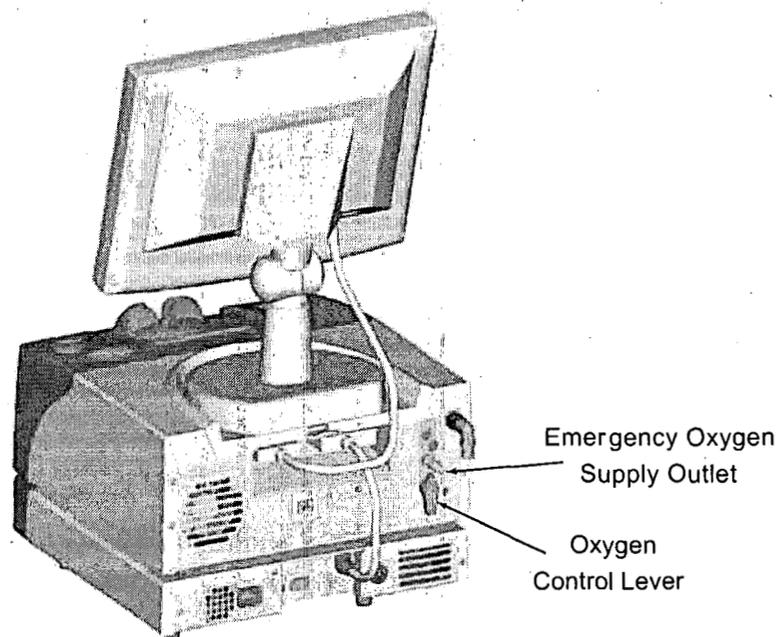


**Note**

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 bag 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 control lever 90° counterclockwise, so that the lever is placed in a vertical position. The lever should be pointing towards the emergency oxygen supply outlet (long medical barb fitting).

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.

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## Chapter 7 Patient Alarms

Physiological monitoring and drug delivery are integrated through a proprietary software algorithm. The SEDASYS<sup>®</sup> System is designed to help guard the patient against over-sedation related adverse physiology. A primary function of the SEDASYS<sup>®</sup> System is monitoring patient physiology and stopping drug delivery and/or providing alarms to the clinician in the event of adverse physiology.

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<sub>2</sub>, 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.

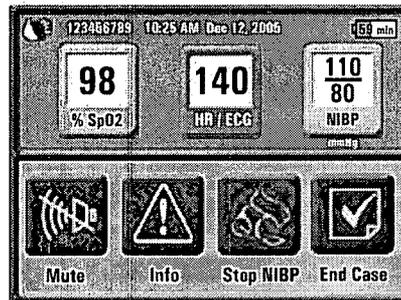


Figure 7-1 BMU Monitoring Screen During Red Alarm

### 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 1% 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<sub>2</sub> and/or low respiratory rate or apnea. These physiological conditions have a high correlation with over-sedation.

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 on page 7-3 below, the example shows the changes for a SpO<sub>2</sub> 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<sub>2</sub> 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.

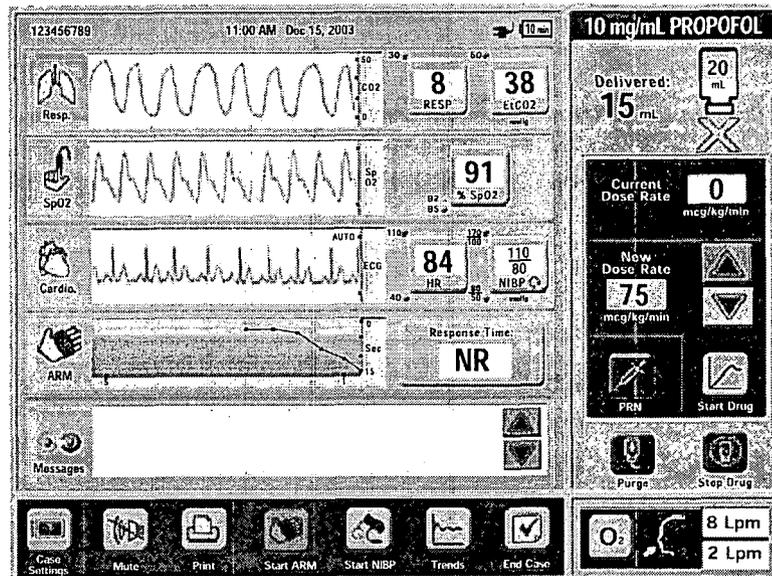


Figure 7-2 PRU Monitoring Screen During Yellow Alarm

### 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.

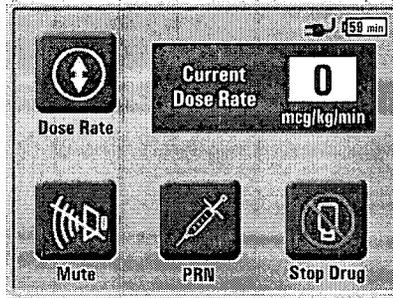


Figure 7-3 BMU Remote Entry Screen During Yellow Alarm

### 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 5-22), you cannot restart drug delivery. The **Start Drug** button will be disabled until the yellow alarm clears.

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.

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

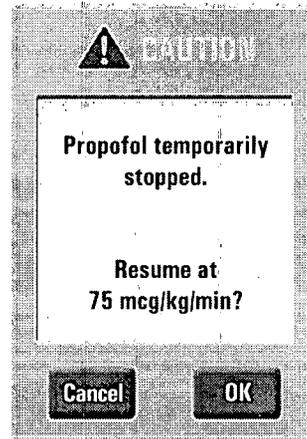


Figure 7-4 PRU Caution Screen - Resume Drug Delivery During Yellow Alarm

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

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

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

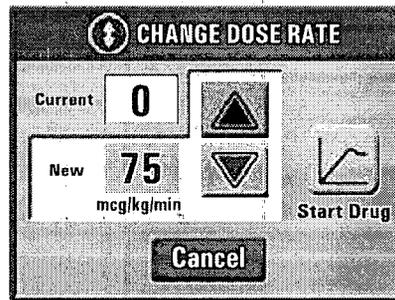


Figure 7-5 BMU Change Dose Rate Screen

- 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.

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

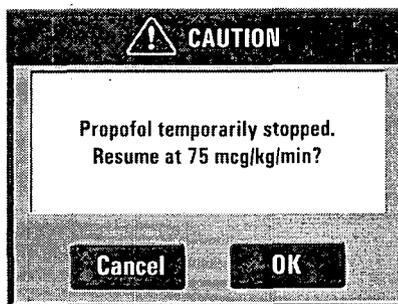


Figure 7-6 BMU Caution Screen - Resume Drug Delivery During Yellow Alarm

- 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 5-22), you cannot provide a PRN dose. The **PRN** button will be disabled until the yellow alarm clears.

To deliver a PRN dose from the PRU:

- Press **PRN**.
- 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 the patient weight (in kg), multiplied by 0.25 (mg/kg).

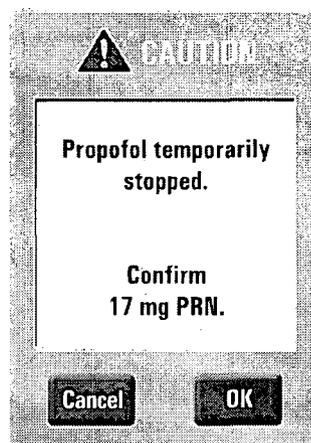


Figure 7-7 PRU Caution Screen - Deliver PRN During Yellow Alarm

- 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).

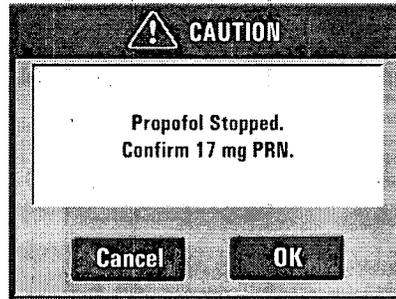


Figure 7-8 BMU Caution Screen - Deliver PRN During Yellow Alarm

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<sub>2</sub> and/or low respiratory rate or apnea. These adverse physiological conditions have a high correlation with over-sedation.

In response to these Red Alarms, the system stops delivery of 1% propofol. During a red alarm, the dose rate cannot be re-initiated. After

the red alarm clears, you must manually restart the delivery of 1% propofol.

### PRU Changes During a Red Alarm

When this type of red alarm is first triggered, the following changes appear on the PRU Main 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 below, the example shows the changes for a SpO<sub>2</sub> 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 a SpO<sub>2</sub> 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 5-19), a hardcopy record of the alarm condition will be printed.

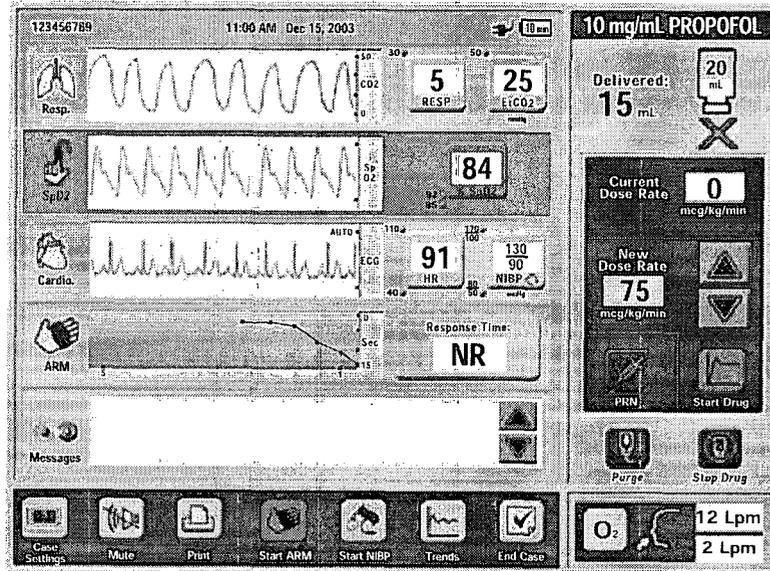


Figure 7-9 PRU Monitoring Screen During Red Alarm That Stop Drug Delivery

### 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 5-22), you cannot provide a PRN dose. The PRN button will be disabled until the red alarm clears.

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).

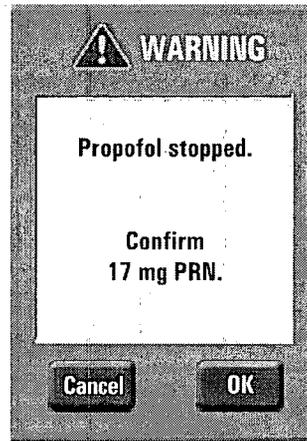


Figure 7-10 PRU Warning Screen - Deliver PRN During Red Alarm

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).

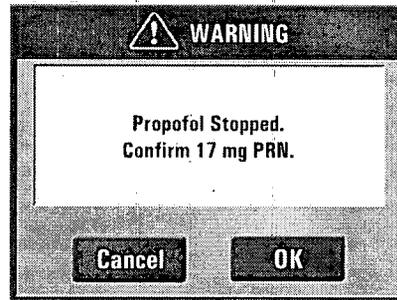


Figure 7-11 BMU Warning Screen - Deliver PRN During Red Alarm

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.
- If the red alarm clears prior to the end of the artifact mitigation period (15 seconds), the Current Dose Rate box displays the previous dose rate and the drug delivery is automatically resumed.
- New Dose Rate box on PRU Monitoring screen displays a reduced dose rate.

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.

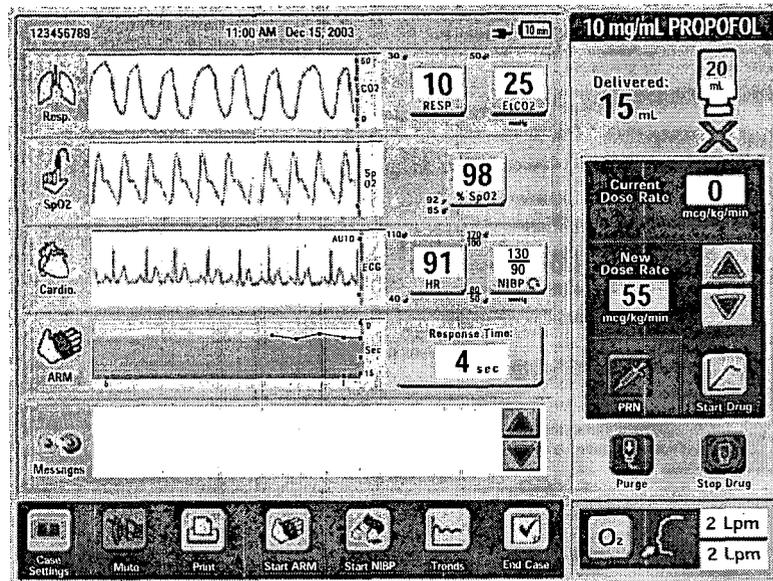


Figure 7-12 PRU Monitoring Screen After Red Alarm Clears to Normal

### 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.

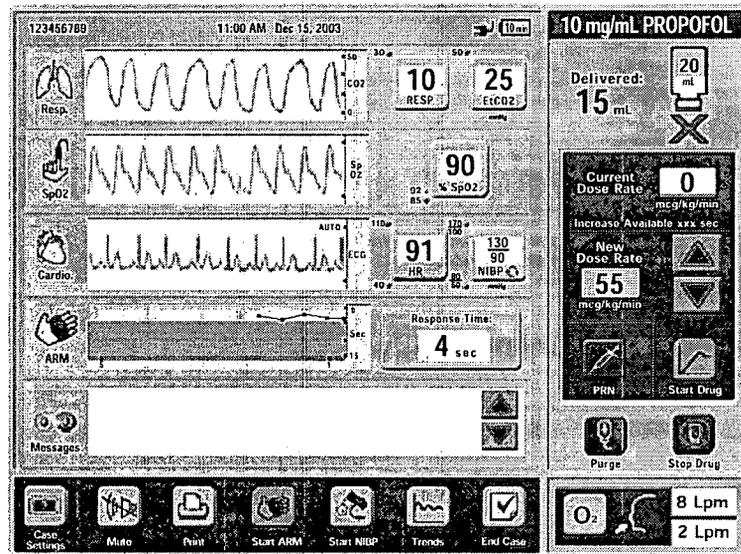


Figure 7-13 PRU Monitoring Screen After Red Alarm Clears to Yellow Alarm



#### 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 Take 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<sub>2</sub>) do not result in automatic drug action. Should any of these red alarms occur, the physician should assess the patient to determine the appropriate course of action.

### 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 7-14 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 5-19), a hardcopy record of the alarm condition will be printed.

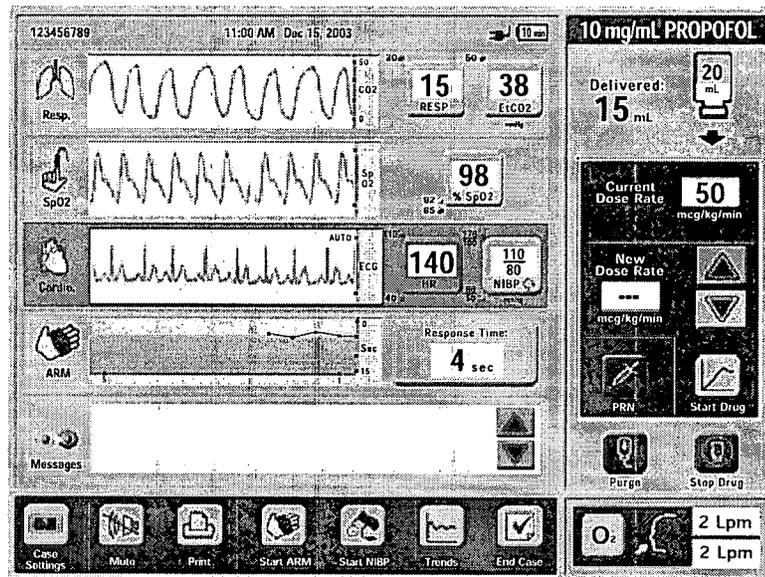


Figure 7-14 PRU Monitoring Screen During Red Alarm That Takes No Drug Action

### 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.

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## 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<sub>2</sub> 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.

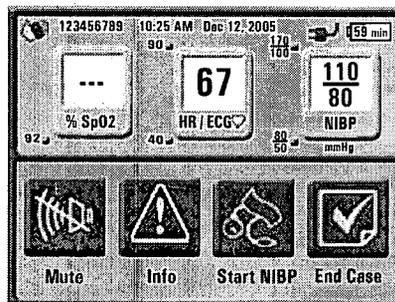


Figure 8-1 BMU Monitoring Screen During Pulse Oximeter Correctable Advisory

- 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.

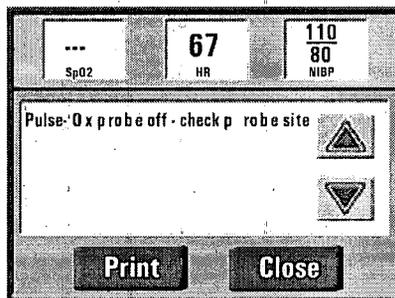


Figure 8-2 BMU Information Screen

## 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 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 of drug delivery, 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 Procedure Room Unit (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

If there is a message in the Messages field, the background of the Messages field changes to orange.

- The PRN button is disabled.



Note

1. For some IV pump advisories, the Up and Down Arrow for dose rate changes and the Start Drug and Purge buttons may be disabled.
2. The Current Dose Rate and New Dose Rate display, PRN, Start Drug and Up and Down Arrow buttons are hidden beneath the Advisory pop-up screen and are not visible until the Advisory window is closed.

- 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.

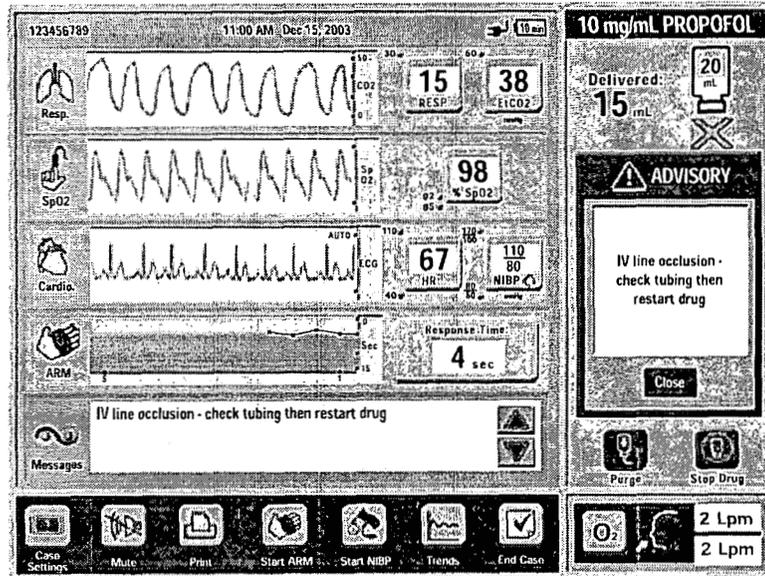


Figure 8-3 PRU Monitoring Screen During IV Pump Correctable Advisory

### 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.

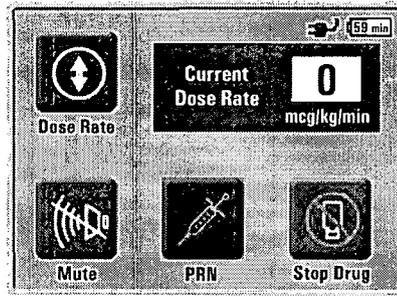


Figure 8-4 BMU Remote Entry Screen During IV Pump Correctable Advisory

### 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<sub>2</sub>, Capnometer, ARM, or Oxygen 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 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<sup>®</sup> System detects a gas with insufficient oxygen concentration, the system will immediately stop delivery of the "gas" and will display the message "O<sub>2</sub> stopped - low O<sub>2</sub> 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 is blank.



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<sub>2</sub> 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 - 38) are disabled.
- An audio signal is sounded.

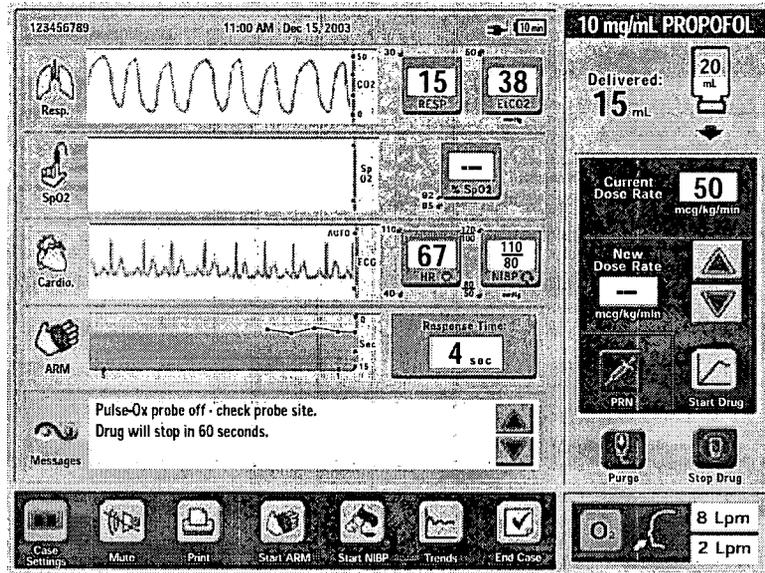


Figure 8-5 PRU Monitoring Screen During Pulse Oximeter Correctable Advisory

### 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.

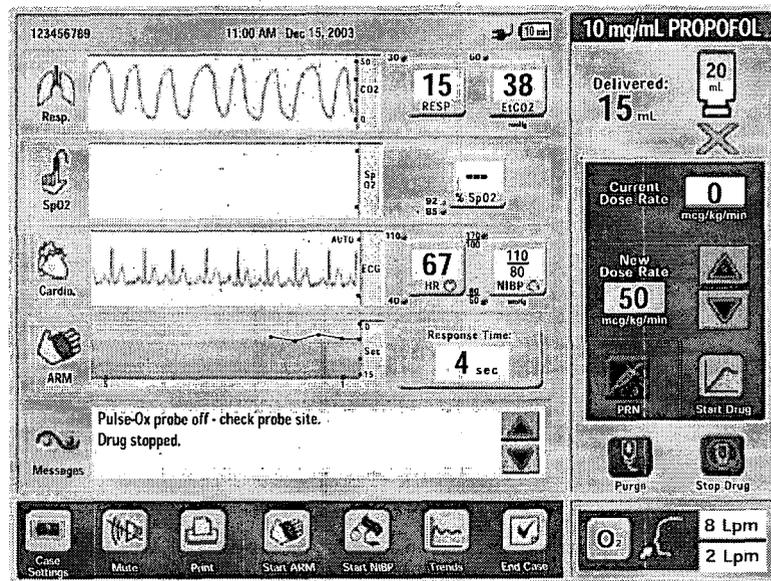


Figure 8-6 PRU Monitoring Screen During Pulse Oximeter Correctable Advisory, After Drug Delivery Has Been Stopped

### 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.

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.

BMU Remote Entry screen returns to normal except:

- Current Dose Rate box still displays "0".

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**.

### 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 ECG failure, a heart rate is still displayed on the HR button because the system receives the pulse 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.

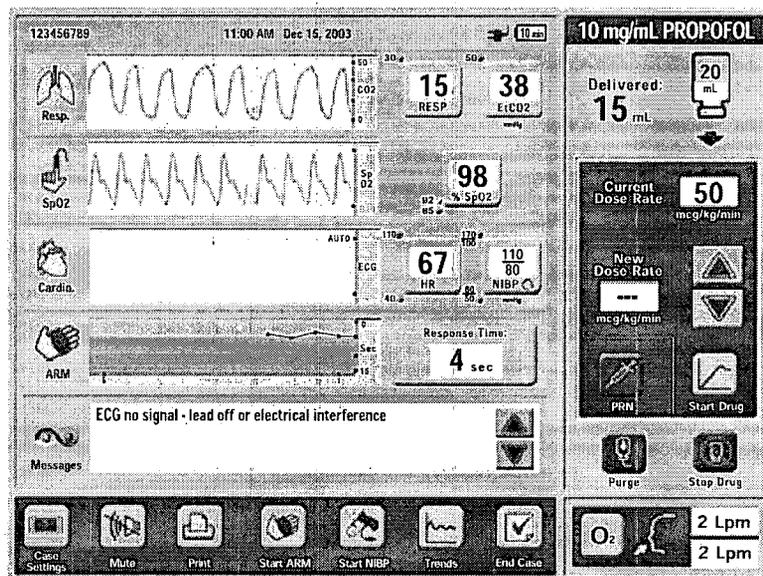


Figure 8-7 PRU Monitoring Screen During ECG Correctable Advisory

### 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<sub>2</sub> 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<sub>2</sub> module is affected, the SpO<sub>2</sub> waveform box is blank and the SpO<sub>2</sub> button displays "---".
- If the Capnometry module is affected, the Capnometry waveform box is blank and the RESP and EtCO<sub>2</sub> buttons display "---".



Note

During a SpO<sub>2</sub> 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.

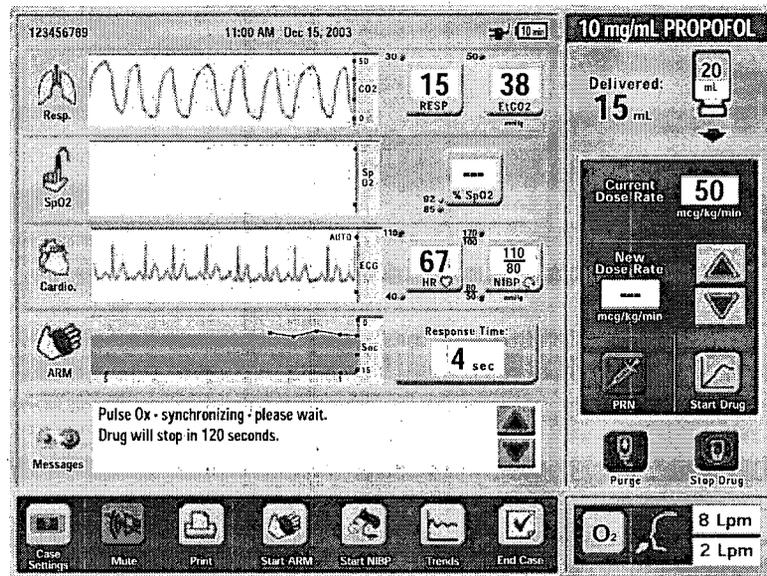


Figure 8-8 PRU Screen During Pulse Oximeter Synchronization Advisory



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 pulse 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.

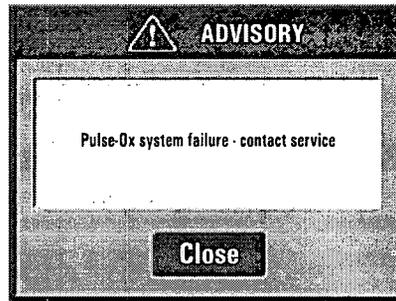


Figure 8-9 BMU Advisory Screen During Pulse Oximeter Failure

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



Note

- 1 For example, if the Pulse Oximeter is the affected module, the %SpO<sub>2</sub> 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.

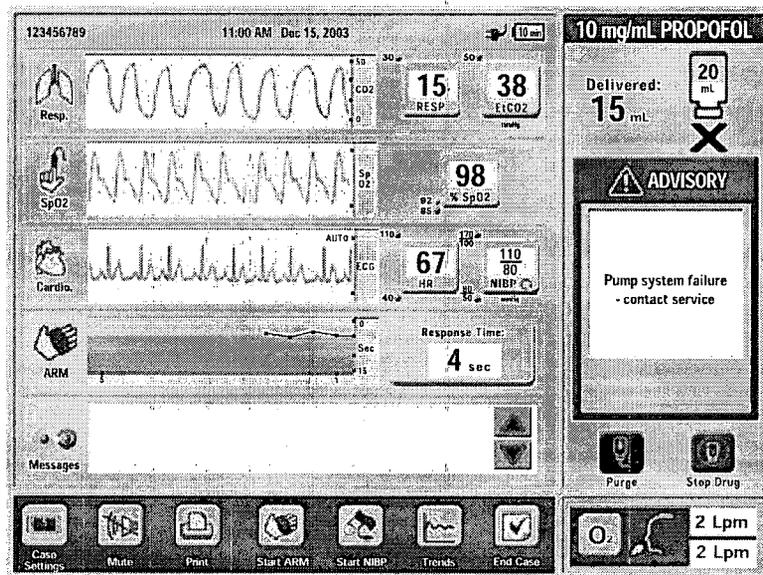


Figure 8-10 PRU Monitoring Screen During IV Pump Failure Advisory

### 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.

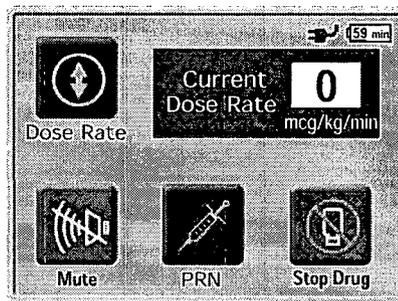


Figure 8-11 BMU Remote Entry Screen During IV Pump Failure Advisory

### Pulse Oximeter or Capnometer Failure Advisory

Since the SEDASYS<sup>®</sup> 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<sub>2</sub> 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 - 38).
- An audio signal is sounded.

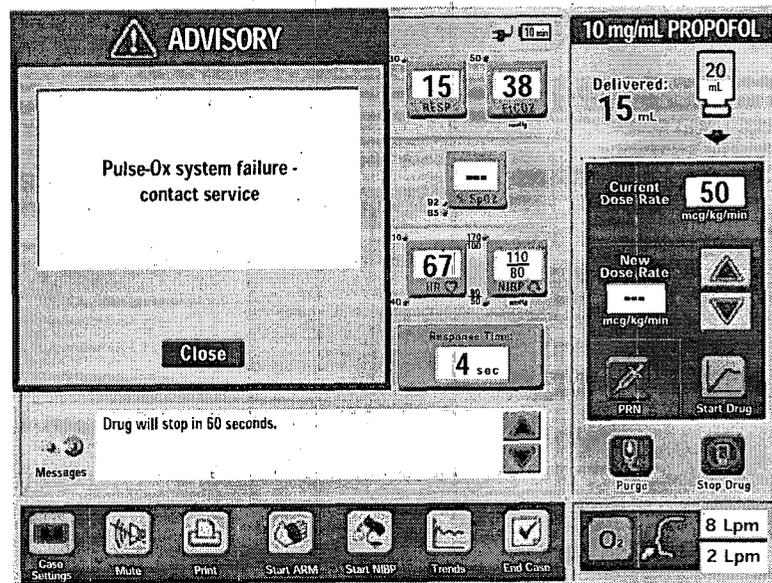


Figure 8-12 PRU Monitoring Screen During Pulse Oximeter Failure Advisory

### 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

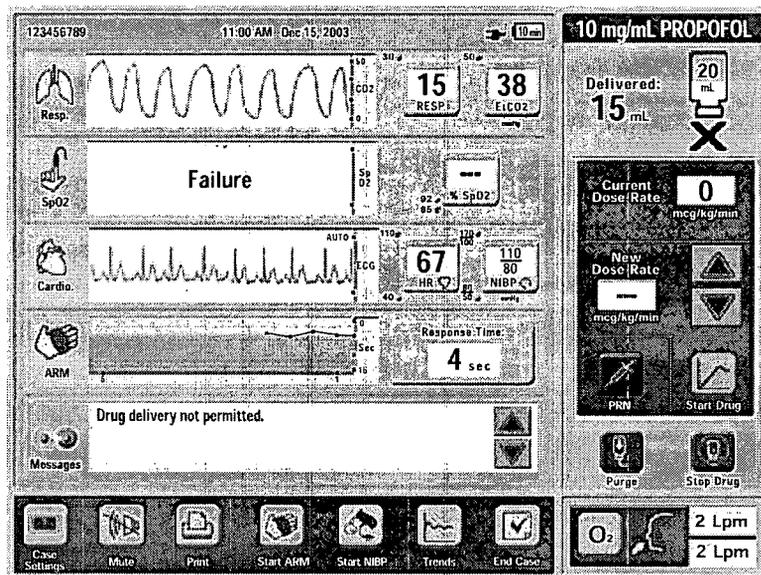


Figure 8-13 PRU Monitoring Screen During Pulse Oximeter Failure Advisory, After Drug Delivery Has Seen Stopped

### 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 - 34.

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 - 38).

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.

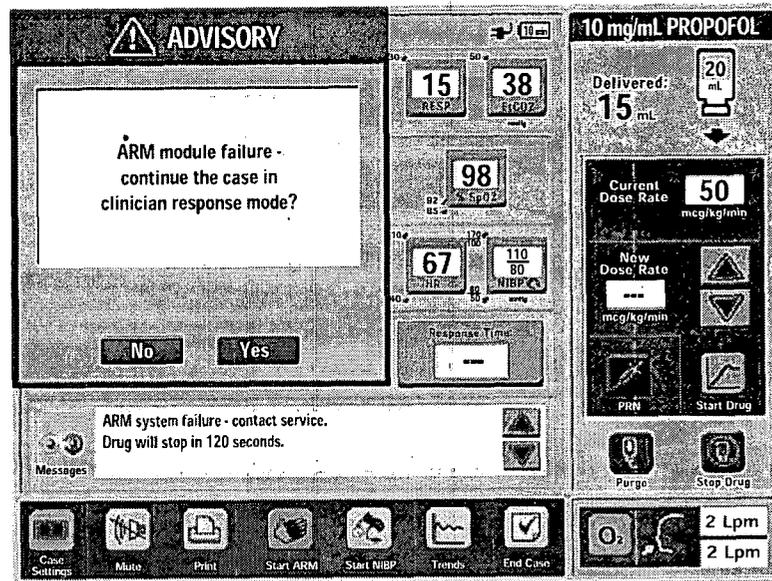


Figure 8-14 PRU Main Monitoring Screen During ARM Failure Advisory

### 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 pulse 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 we also be stopped after 60 seconds.

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

## 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 subsystems 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: The 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.

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## 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 the performance of the system.
- 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 units 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 units 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, 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: Installation and Daily Maintenance Schedule

Required Maintenance	Recommended Maintenance Interval	
	Installation	Daily
Perform CO <sub>2</sub> gain calibration.	+	—
Complete BMU and PRU functional testing.	+	—
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.	+	+
Inspect safety labels for legibility.	+	—



Note

- 1 The internal batteries should be calibrated every 6 months to maintain battery capacity. Refer to the SEDASYS® Service Manual for instructions.
- 2 Refer to the SEDASYS® Service Manual for the complete Maintenance Schedule.

## Recycling

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

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## 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.

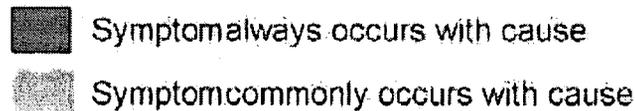


Figure 10-1 Symptom and Possible Causes

### 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 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 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 SEDASYS® System. If this does not resolve the failure, service must be contacted.

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

Symptom always occurs with cause

Symptom commonly occurs with cause

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Symptom		Possible Cause(s)
Initial System Start-up		
Software or screen freezes	<input type="checkbox"/>	Connectors are physically damaged
Cannot enter biomed mode	<input type="checkbox"/>	Unit not plugged in or outlet has no power
Flashing green light on back of PSU	<input type="checkbox"/>	Battery fully depleted; has not been re-charged
Yellow light on back of PSU	<input type="checkbox"/>	PSU Connecting Cable disconnected from PRU
No response to stat request	<input type="checkbox"/>	PSU power switch not turned on
Touch screen response is unpredictable	<input type="checkbox"/>	PRU On/Off/Standby button not fully depressed
Cannot load cassette correctly	<input type="checkbox"/>	PSU internal power supply fuse damaged
Cannot calibrate touch screen	<input type="checkbox"/>	Cooling fans are blocked
Monitor info not available in PRU after Umbilical connection	<input type="checkbox"/>	Environment is too hot
Loud hiss sound after connecting oxygen source	<input type="checkbox"/>	Brightness or Contrast needs adjustment
Oxygen fitting does not connect	<input type="checkbox"/>	Display is damaged
BMU will not clamp to pole	<input type="checkbox"/>	Touchscreen requires calibration
Low or no sound	<input type="checkbox"/>	Touchscreen is damaged
Display is too dim/bright	<input type="checkbox"/>	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

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Symptom		Possible Cause(s)
Start of Day		
Unit takes a long time to start up	<input type="checkbox"/> Symptom always occurs with cause <input type="checkbox"/> Symptom commonly occurs with cause	Connectors are physically damaged
Low battery even though it was plugged in all night		Unit not plugged in or outlet has no power
Screen goes dark after successful start-up		Battery fully depleted; has not been re-charged
System beeps and shuts off		PSU Connecting Cable disconnected from PRU
Unusual noise		PSU power switch not turned on
Facility settings or system (patient) settings lost		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

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Symptom		Possible Cause(s)
Patient Set-up		
<input type="checkbox"/>	BMU is alarming but no patient is hooked up	Connectors are physically damaged
<input type="checkbox"/>	Unit takes a long time to start up	Unit not plugged in or outlet has no power
<input type="checkbox"/>	NIBP begins working without being told	Battery fully depleted; has not been re-charged
<input type="checkbox"/>	Patient monitor alerts when patient is not connected	PSU Connecting Cable disconnected from PRU
<input type="checkbox"/>	Cannula does not fit on face	PSU power switch not turned on
<input type="checkbox"/>	No vital signal(s) after connection	PRU On/Off/Standby button not fully depressed
<input type="checkbox"/>	Patient fails ARM™ training	PSU internal power supply fuse damaged
<input type="checkbox"/>	Unable to deliver oxygen	Cooling fans are blocked
<input type="checkbox"/>	Oxygen line does not fit cannula	Environment is too hot
<input type="checkbox"/>	Oxygen line does not fit BMU	Brightness or Contrast needs adjustment
<input type="checkbox"/>	No resp rate or EtCO2 despite Cannula connection	Display is damaged
<input type="checkbox"/>	ARM™ audio is low	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 always occurs with cause

Symptom commonly occurs with cause

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Symptom		Start of Case - From PRU Connection		Possible Cause(s)
<input type="checkbox"/>	ECG trace looks strange	<input type="checkbox"/>	<input type="checkbox"/>	Connectors are physically damaged
<input type="checkbox"/>	No ECG	<input type="checkbox"/>	<input type="checkbox"/>	Unit not plugged in or outlet has no power
<input type="checkbox"/>	ECG and pulse ox out of synch	<input type="checkbox"/>	<input type="checkbox"/>	Battery fully depleted; has not been re-charged
<input type="checkbox"/>	Inaccurate O2 delivery	<input type="checkbox"/>	<input type="checkbox"/>	PSU Connecting Cable disconnected from PRU
<input type="checkbox"/>	Umbilical won't connect	<input type="checkbox"/>	<input type="checkbox"/>	PSU power switch not turned on
<input type="checkbox"/>	BMU Monitor signals don't appear on PRU	<input type="checkbox"/>	<input type="checkbox"/>	PRU On/Off/Standby button not fully depressed
<input type="checkbox"/>	O2 delivery does not start	<input type="checkbox"/>	<input type="checkbox"/>	PSU internal power supply fuse damaged
<input type="checkbox"/>	PRU does not recognize BMU	<input type="checkbox"/>	<input type="checkbox"/>	Cooling fans are blocked
<input type="checkbox"/>	Required to change date and time	<input type="checkbox"/>	<input type="checkbox"/>	Environment is too hot
<input type="checkbox"/>	Required to verify alarm levels	<input type="checkbox"/>	<input type="checkbox"/>	Brightness or Contrast needs adjustment
<input type="checkbox"/>	BMU patient data disappears	<input type="checkbox"/>	<input type="checkbox"/>	Display is damaged
<input type="checkbox"/>	No response from barcode	<input type="checkbox"/>	<input type="checkbox"/>	Touchscreen requires calibration
<input type="checkbox"/>	Barcode cannot be read	<input type="checkbox"/>	<input type="checkbox"/>	Touchscreen is damaged
<input type="checkbox"/>	Cannot insert a vial (too much force)	<input type="checkbox"/>	<input type="checkbox"/>	LCD connection is loose
<input type="checkbox"/>	Vial ran out too soon (air in line)	<input type="checkbox"/>	<input type="checkbox"/>	CPU failure
<input type="checkbox"/>	Air in line, but no air is visible	<input type="checkbox"/>	<input type="checkbox"/>	Pump door button not completely depressed
<input type="checkbox"/>	Occlusion alarm but no occlusion	<input type="checkbox"/>	<input type="checkbox"/>	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

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Symptom		Start of Case - From PRU Connection												Possible Cause(s)		
<input checked="" type="checkbox"/>	Symptom always occurs with cause	<input checked="" type="checkbox"/>														Connectors are physically damaged
<input checked="" type="checkbox"/>	Symptom commonly occurs with cause															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

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Symptom		Possible Cause(s)
End of Case		
<input type="checkbox"/>	Cannot disconnect Umbilical	Connectors are physically damaged
<input type="checkbox"/>	Do not get end of case print out	Unit not plugged in or outlet has no power
<input type="checkbox"/>	Cannot stop the case	Battery fully depleted; has not been re-charged
<input type="checkbox"/>	BMU battery advisory after disconnect	PSU Connecting Cable disconnected from PRU
<input type="checkbox"/>	O2 cannot connect directly to BMU (doesn't fit)	PSU power switch not turned on
<input type="checkbox"/>	Unit turned it off but the fan keeps running	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

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## 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 <sub>2</sub>	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 <sub>2</sub> <sup>a</sup>	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 <sub>2</sub>	–	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 <sup>b</sup> )	90 seconds	–	60-120 seconds in increments of 5 <sup>c</sup>	–

a. The Yellow Alarm limit for SpO<sub>2</sub> is 92%. This limit is not adjustable.

b. The Yellow Alarm limit for apnea is a function of the patient's SpO<sub>2</sub> (refer to Figure 5-25 on page 5 - 25).

c. At 100% SpO<sub>2</sub>.

**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 <sup>a</sup>	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 <sup>b</sup>	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 <sub>2</sub> Trends Lower Limit <sup>a</sup> (y-axis scale)	70-100% (minimum/maximum)	50-70% in increments of 5 (for minimum value only)	
ECG/SpO <sub>2</sub> 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 <sup>b</sup>	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 <sup>c</sup>	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
<b>Units of Measure</b>	Weight: kg, EtCO <sub>2</sub> :mmHg	Weight: lb. or kg, EtCO <sub>2</sub> : mmHg, %, kPa, or mbar	
<b>Additional Limits</b>	Inactive (unchecked) <ul style="list-style-type: none"> <li>No dose increase when non-responsive to ARM</li> <li>No PRM during red or yellow alarm</li> <li>No re-start of propofol during yellow alarm</li> </ul>	Inactive (unchecked) or Active (checked) <ul style="list-style-type: none"> <li>No dose increase when non-responsive to ARM</li> <li>No PRM during red or yellow alarm</li> <li>No re-start of propofol during yellow alarm</li> </ul>	

- a. SpO<sub>2</sub> 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 <sub>2</sub> Level	Factory Default	Available Ranges	Factory Default	Available Ranges	Factory Default
SpO <sub>2</sub> > 96%	2 Lpm	2-8 Lpm	0 Lpm	0-2 Lpm	2 Lpm
88% < Sp O <sub>2</sub> <= 96%	8 Lpm	—	2 Lpm	—	5 Lpm
SpO <sub>2</sub> <= 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 $\pm$ 5Hz, 30Hz $\pm$ 5Hz, 35Hz $\pm$ 5Hz, and 40Hz $\pm$ 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 <sub>2</sub>
Measurement accuracy	± 2.0 mmHg @ < 5% CO <sub>2</sub> ATPS (Ambient Temperature and Pressure, Saturated) < 10% of reading @ > 5% CO <sub>2</sub> (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<sup>®</sup> 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 <sub>2</sub> , 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 <sub>2</sub> , NIBP, Respiration Rate, EtCO <sub>2</sub> Physiological alarm events

## Drug Delivery Cassette Specification



### WARNING

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

Table B-9: Drug Delivery Cassette Specifications

Characteristics	Performance
Sterility	Gamma irradiated sterile (SAL 10 <sup>-6</sup> )

Table B-9: Drug Delivery Cassette Specifications

Characteristics	Performance
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 style="list-style-type: none"> <li>• UL 60601-1</li> <li>• IEC 60601-1-2</li> </ul>
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 style="list-style-type: none"> <li>• UL 60601-1</li> <li>• IEC 60601-1-2</li> </ul>
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)
Phase	Single

Table B-11: PRU Electrical Safety Specifications

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

Table B-12: PSU Electrical Safety Specifications

Characteristics	Performance
Electrical safety standards	The SEDASYS® System has been tested to applicable sections of the following standards: <ul style="list-style-type: none"> <li>• UL 60601-1</li> <li>• IEC 60601-1-2</li> </ul>
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)
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)

Table B-14: SPU Electrical Safety Specifications

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

Table B-15: ECG Specifications (Continued)

Characteristics	Performance
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

If the SEDASYS® System is used adjacent to or stacked with other equipment, its performance should be observed to verify normal performance in that configuration.



### Precaution

The SEDASYS® System requires precautions regarding 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 EES-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 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<sup>®</sup> 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 $d = [3.5/\sqrt{1}]P^{1/2}$	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<sup>®</sup> System may not meet performance specifications if 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 10,000 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	$\leq \pm 5\%$	Infusion rate accuracy can be affected by variations in fluid temperature and back pressure. Specified rate accuracy is only valid when using the SEDASYS <sup>®</sup> System Drug Delivery Cassette with propofol temperature between 15°C and 35°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	<ul style="list-style-type: none"> <li>• Drug vial low</li> <li>• Drug vial empty</li> <li>• Drug Vial not present</li> <li>• Air-in-line</li> <li>• Occlusion (patient side)</li> </ul>	

Table B-20: Infusion Pump Specifications (Continued)

Characteristics	Performance	Conditions
Rate Conversion from Dose Rate (mcg/kg/min) to Pump Rate (mL/hr)	$(\text{Dose Rate} \div 166.67) \times \text{Patient Weight (kg)}$	
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 $\mu\text{L}$	Single air bubble
Single air bubble size resulting in infusion stoppage	> 250 $\mu\text{L}$	
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)

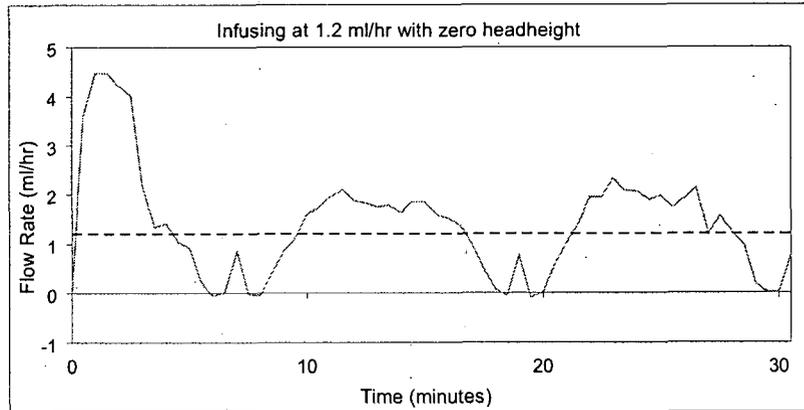


Figure B-1 Infusing at 1.2 ml/hr with zero headheight

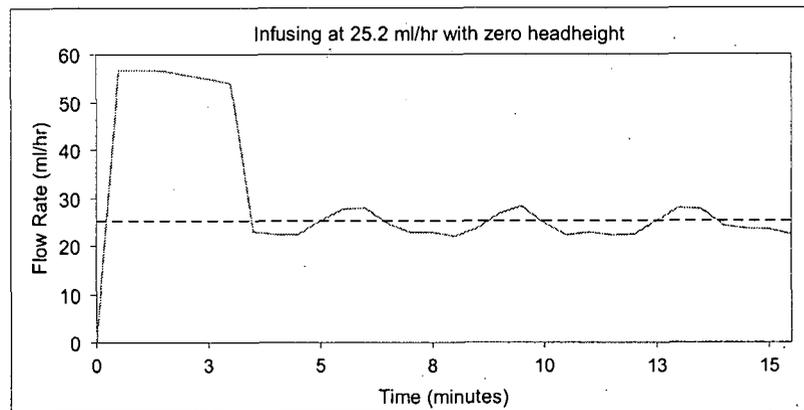


Figure B-2 Infusing at 25.2 ml/hr with zero headheight

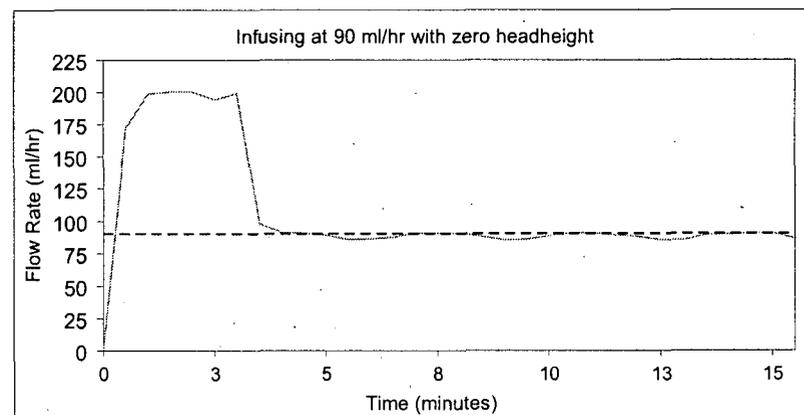


Figure B-3 Infusing at 90 ml/hr with zero headheight

### IV Pump Trumpet Graphs during Second (last) Hour

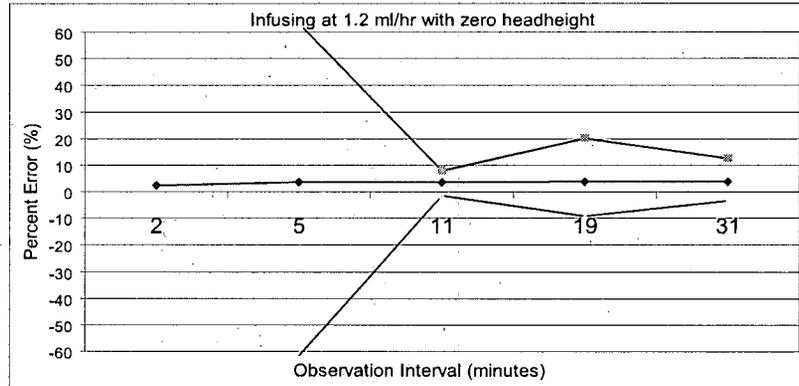


Figure B-4 Infusing at 1.2 ml/hr with zero headheight

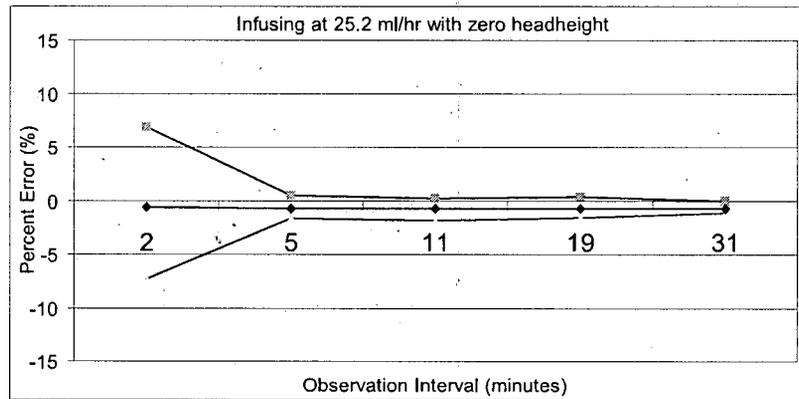


Figure B-5 Infusing at 25.2 ml/hr with zero headheight

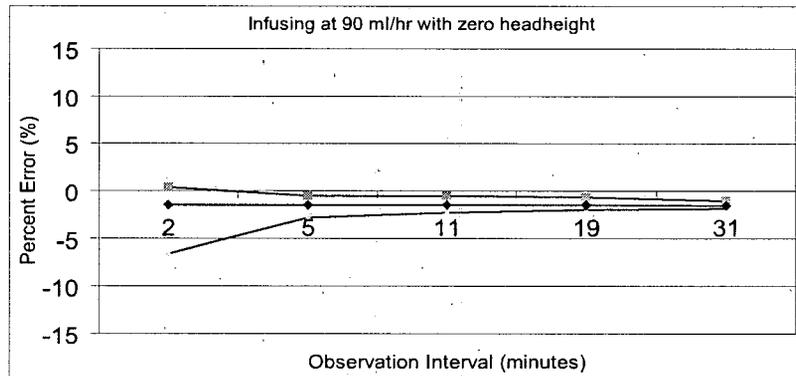


Figure B-6 Infusing at 90 ml/hr with zero headheight

## 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.
Pulse 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 electro-surgery.
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<sub>2</sub>) Specifications

Table B-31: Pulse Oximeter Specifications

Characteristics	Performance
SpO <sub>2</sub> range	70 - 100% hemoglobin saturation (for proper operation)
SpO <sub>2</sub> accuracy	± 2% SpO <sub>2</sub> over the range of 70 - 100%, with no motion and with normal perfusion.
	± 3% SpO <sub>2</sub> over the range of 70 - 100%, with motion or low perfusion.
Pulse 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 <sub>2</sub> resolution	0.1%
Pulse 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<sub>2</sub> 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<sup>®</sup> 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

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## Appendix C The 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

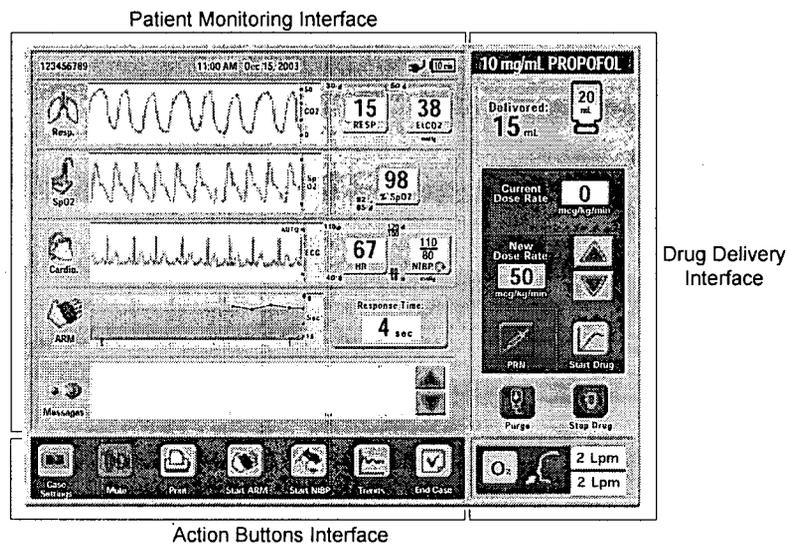


Figure C-1 PRU Monitoring Screen

### 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.

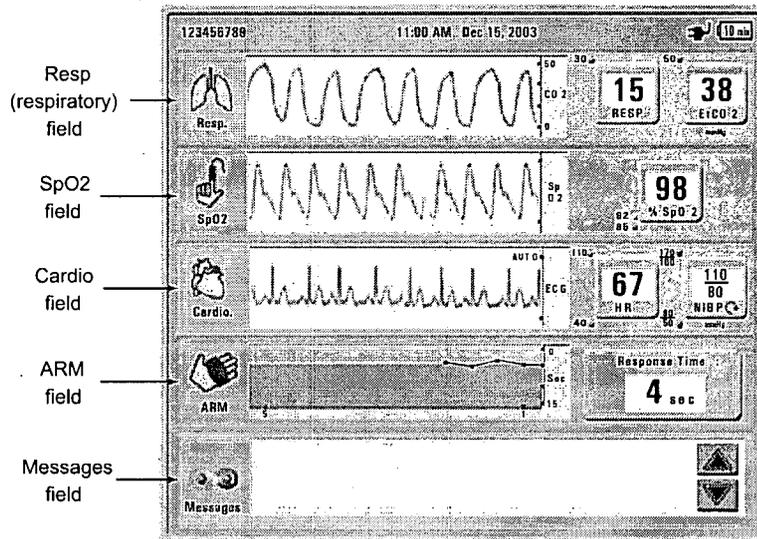


Figure C-2 PRU Patient Monitoring Interface

The PRU Patient Monitoring interface consists of the following four fields:

- *Resp* field, which displays:
  - Capnogram.
  - Respiratory rate in breaths/minute.
  - EtCO<sub>2</sub>.
- *SpO<sub>2</sub>* field, which displays:
  - Plethysmogram.
  - SpO<sub>2</sub>%.
- *Cardio* field, which displays:
  - ECG waveform.
  - Pulse rate or heart rate in beats per minute.
  - Systolic and diastolic blood pressure that was last measured.

1 The default setting is the pulse 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



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<sub>2</sub>, % SpO<sub>2</sub>, HR, and NIBP.

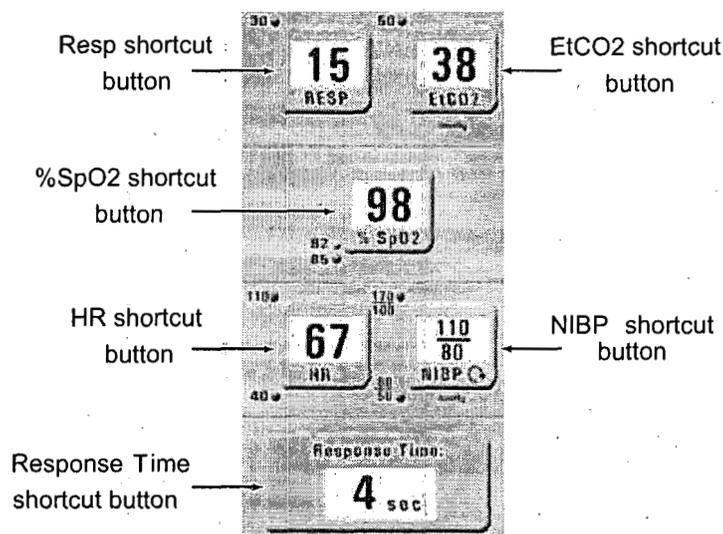


Figure C-3 Patient Monitoring Shortcut Buttons on PRU Monitoring Screen

## 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.

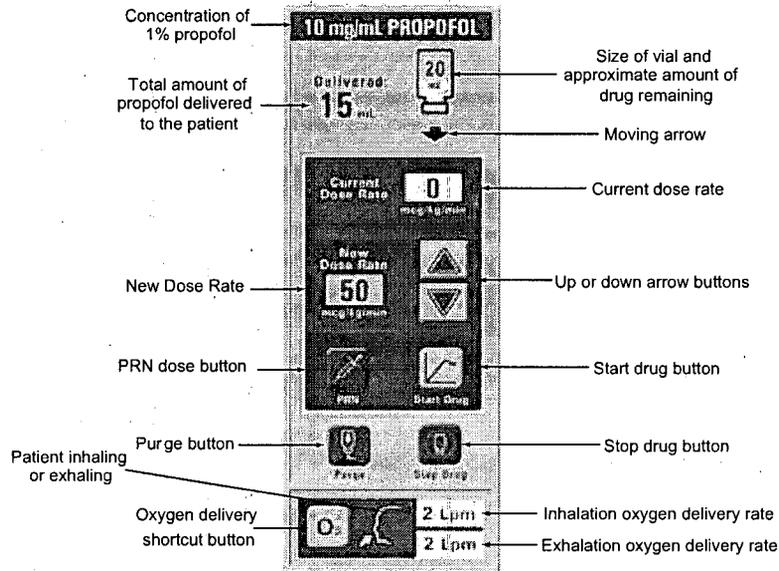


Figure C-4 PRU Drug Delivery Interface

The drug delivery interface consists of the following:

- **Current Dose Rate** box: Displays the dose rate at which 1% 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<sub>2</sub> reading greater than or equal to 96%.
- **Size of propofol vial and approximate amount of drug remaining** graphic: Displays the size of the 1% propofol vial that was entered.

The white filler in the vial graphic (representing the amount of remaining propofol) decreases as the 1% 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 1% propofol to the patient.
- **Stop Drug button:** Immediately stops delivery of 1% 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 the waveforms for respiration, SpO<sub>2</sub>, cardio, and ARM.
- **End Case** button: Stops data collection and resets all settings to default settings.

## Appendix D The 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. This screen allows the clinician to interact with the BMU.

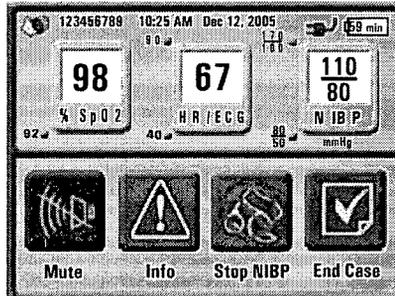


Figure D-1. BMU Monitoring Screen

The BMU Monitoring screen consists of the following:

- **SpO<sub>2</sub>** button: Displays % SpO<sub>2</sub> and provides access to adjust the SpO<sub>2</sub> 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<sub>2</sub>, 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<sub>2</sub>, and HR can be sent to printer port from the Info display window.

---

## Appendix E The 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.

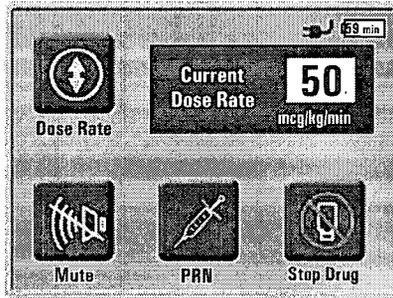


Figure E-1 BMU Remote Entry Screen

- **Current Dose Rate** box: Displays the dose rate at which 1% 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.

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# 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 - 19 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 - 19 for the PRU.

### STAT Print - BMU

ID: 693439	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 (l/min)	Response	Dose Rate (mcg/kg/min)	PRN (mg)	Total Prepopol (mg)
96	60	120	80	---	---	---	---	---	---	---
[**] Alarm Event		[---] Data Not Available		[D] Drug Change Event		[H] HR from ECG				

### ECG Waveform (25mm/sec)

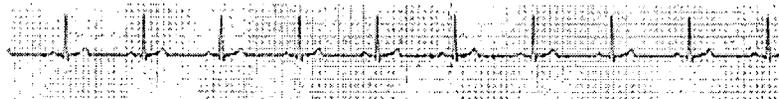


Figure F-1 Sample BMU Printout During A Procedure

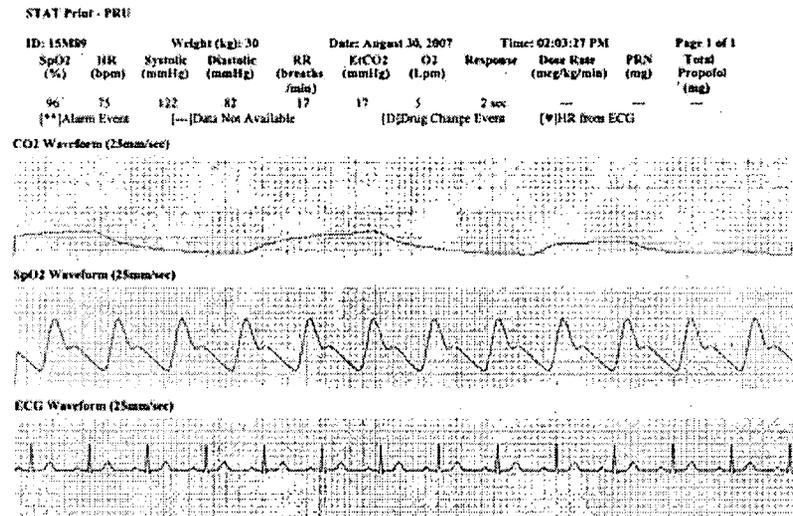


Figure F-2 Sample PRU Printout During A Procedure

## 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 - 19 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 - 19 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 (L/min)	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	---	---	---
23:10:30	95	100	120	80	12	38	5	Yes	---	---	---
Post-procedure											
23:11:07	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)

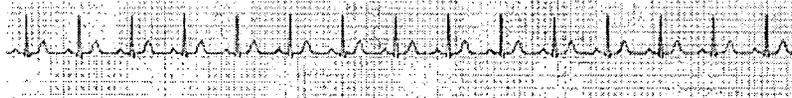


Figure F-3 Sample End Case Summary Printout

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## 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 Menu (OSM) system.

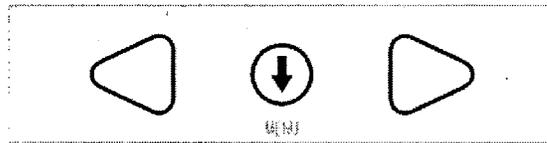


Figure G-1 On Screen Menu

### Menu Systems 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.

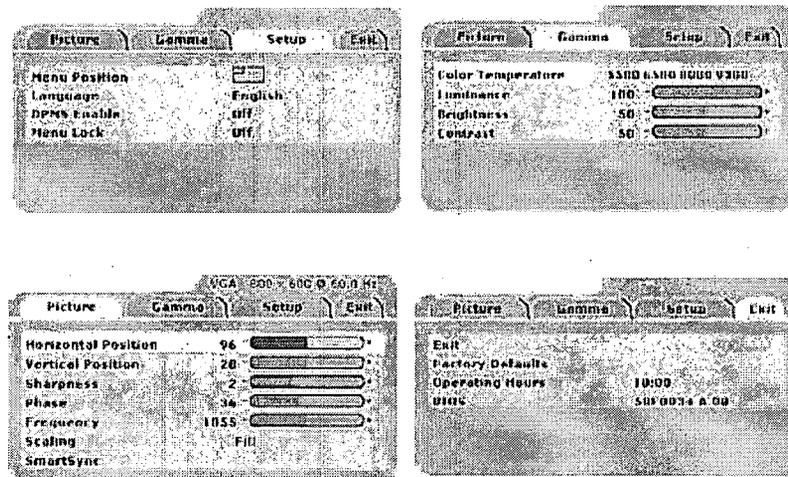


Figure G-2 Menu System

## Language List:

- English
- Deutsch
- Dutch
- Espanol
- Francais
- Italiano
- Scandinavia

## Setting Up the Display

### VGA Picture Menu

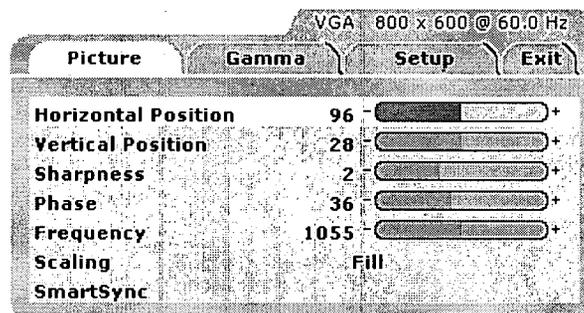


Figure G-3 VGA Picture Menu

### 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.

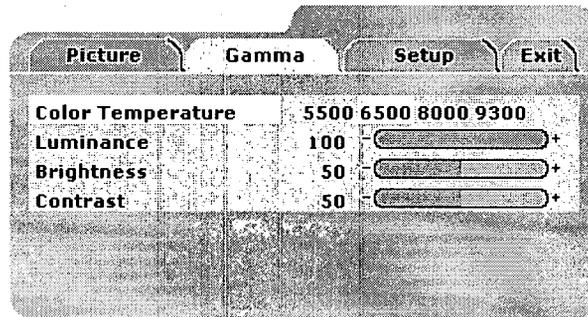


Figure G-4 Gamma Menu

### 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

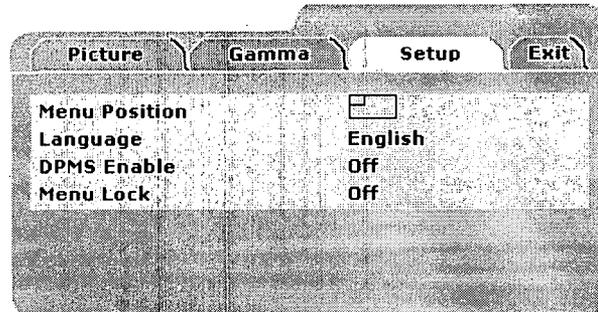


Figure G-5 Setup Menu

### 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

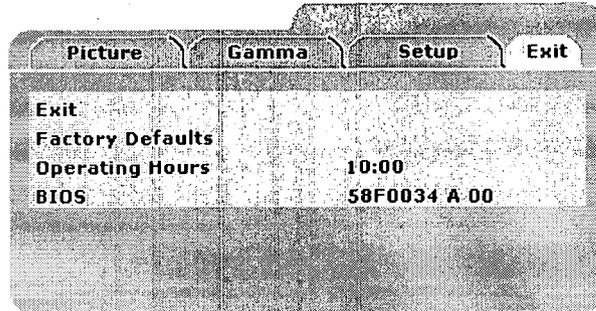


Figure G-6 Exit Menu

### 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. See: 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.

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