FLOWONIX

Indications, drug stability, and emergency procedures

Prometra Programmable Infusion Systems

Rx only

Table of contents

Refer to the appropriate Prometra Programmable Pump IFU for device description, package contents, device specifications, and instructions for use.

Indications

Physicians prescribing Prometra Programmable Infusion Systems for use with the drugs listed in Table 1 must be familiar with the indications, contraindications, warnings, precautions, adverse events, dosage and administration information, and screening procedures described in the drug labeling. Each Prometra Programmable Infusion Pump System includes (at a minimum) a pump and a catheter.

Warning: Prometra Programmable Infusion Systems are approved for use with the drugs identified in Table 1. Use of unapproved drugs (e.g., drug cocktails, pharmacy-compounded drugs, morphine with preservatives, etc.) with the Programmable Pump could RESULT IN Pump failure and/or serious adverse events SUCH AS SEVERE UNDERDOSE, OVERDOSE OR DEATH.

Table 1. Flowonix Prometra and Prometra II Programmable Infusion Systems are approved for use with the following:

Infusion System is specifically approved for	Prometra	Prometra II
The chronic intrathecal infusion of Infumorph (preservative-free morphine sulfate sterile solution) in the treatment of chronic intractable pain. The maximum approved concentration is 25 mg/mL.	X	X
The chronic intrathecal infusion of baclofen injection (intrathecal) in the management of severe spasticity. The approved concentrations are 0.5, 1.0, 2.0 mg/mL.	X	X

Drug stability

Testing has indicated that the drugs in Table 2 are stable and compatible with the infusion systems listed in the table. Refer to the appropriate drug labeling for complete prescribing information, including indications, contraindications, warnings, precautions, and adverse events.

Table 2. Stability of drugs approved for use with Flowonix Prometra Programmable Infusion Systems

Drug	Manufacturer	Concentration	Duration of Study
Infumorph Preservative-free Morphine Sulfate Sterile Solution	Baxter Healthcare (Infumorph has been acquired by West-Ward Pharmaceuticals)	25 mg/mL, 10 mg/mL	90 days
Baclofen injection (intrathecal)	FDA Approved manufacturers of baclofen injection (intrathecal)	0.5 mg/mL, 2 mg/mL	60 day refill intervals, 180 days total

Emergency procedures

Morphine intrathecal overdose

Consult the patient's medical record or the patient's physician to confirm the drug or drug concentration within the pump reservoir.

Symptoms

Respiratory depression with or without concomitant central nervous system depression (i.e. dizziness, sedation, euphoria, anxiety, seizures, respiratory arrest).

Actions

See Figure 1 below.

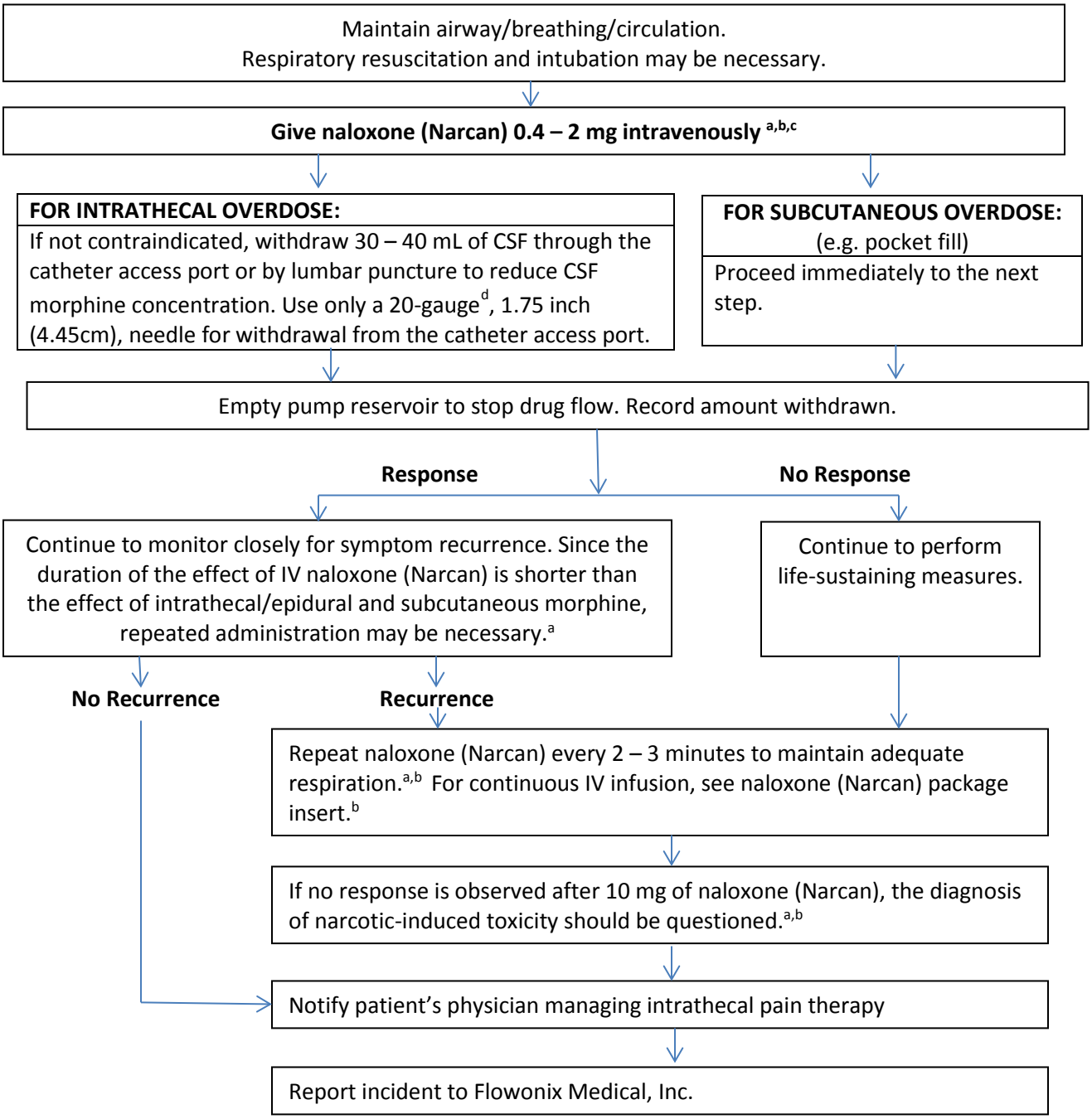

Figure 1. Morphine intrathecal overdose emergency procedures.

[a] Infumorph (Preservative-free morphine sulfate sterile solution) manufacturer's package insert (West- Ward Pharmaceuticals).

[b] Narcan (naloxone hydrochloride) manufacturer's package insert (Adapt Pharma Operations Limited).

[c] Refer to the drug manufacturer's package insert for a complete list of indications, contraindications, warnings, precautions, adverse events, and dosage and administration information.

[d] Use a 20-gauge needle for withdrawal from a Prometra or Prometra II catheter access port.

Baclofen injection (intrathecal) overdose

Consult the patient's medical record or the patient's physician to confirm the drug or drug concentration within the pump reservoir.

Symptoms

Drowsiness, lightheadedness, dizziness, somnolence, respiratory depression, seizures, rostral progression of hypotonia, and loss of consciousness progressing to coma.

There is no specific antidote for treating overdoses of baclofen injection (intrathecal).

Actions

See Table 3 below.

Table 3. Baclofen injection (intrathecal) overdose emergency procedures

Maintain airway/breathing/circulation. Intubation and respiratory support may be necessary.	
⬇	
Empty pump reservoir to stop drug flow. Record Amount withdrawn.	
⬇	
FOR INTRATHECAL OVERDOSE:	**FOR SUBCUTANEOUS OVERDOSE:** (e.g. pocket fill)
⬇	⬇
If not contraindicated, withdraw 30 – 40 mL CSF by lumbar puncture or through the catheter access port to reduce the concentration of baclofen in the CSF. Use only a 20-gauge or smaller, 1.75 inch (4.45 cm), needle for withdrawal from the catheter access port.[a]	Proceed immediately to the next step.
⬇	⬇
Notify patient's physician managing the baclofen injection (intrathecal) therapy.	
⬇	
Continue to monitor closely for symptom recurrence.	
⬇	
Report incident to Flowonix Medical, Inc.	

[a] Use a 20-gauge needle for withdrawal from a Prometra or Prometra II catheter access port.

Baclofen injection (intrathecal) underdose/withdrawal

Consult the patient's medical record or the patient's physician to confirm the drug or drug concentration within the pump reservoir.

Symptoms of underdose

Return to baseline spasticity, pruritis, hypotension and paresthesias.

Symptoms of withdrawal

High fever, altered mental status, exaggerated rebound spasticity and muscle rigidity, rhabdomyolysis, and multiple organ failure. The condition may resemble autonomic dysreflexia, sepsis, malignant hyperthermia, and neuroleptic-malignant syndrome.

Actions

See Table 4 below.

Table 4. Baclofen injection (intrathecal) underdose/withdrawal emergency procedures

Initiate life-sustaining measures if indicated.
⬇
If a patient receiving Baclofen injection (intrathecal) presents with the signs and symptoms suggestive of withdrawal (see previous page), the following is consistent with that suggested by a panel of therapy-experienced clinicians convened to explore this issue.[a,b] 1. Immediately contact a physician experienced in Baclofen Injection (intrathecal), preferably the physician managing the therapy for the patient in question; follow the recommendations of this physician. This step is important even if the patient's signs and symptoms seem mild. 2. If a physician experienced in Baclofen injection (intrathecal) is unavailable, consider instituting one or more of the following options, unless otherwise contraindicated: • high-dose oral* or enteral baclofen • restoration of Baclofen injection (intrathecal) infusion • intravenous benzodiazepines by continuous or intermittent infusion, titrating the dosage until the desired therapeutic effect is achieved * Note: Oral baclofen should not be relied upon as the sole treatment for Baclofen injection (intrathecal) withdrawal syndrome.
⬇
Report incident to Flowonix Medical, Inc.

a Refer to the drug manufacturer's package insert for a complete list of indications, contraindications, warnings, precautions, adverse events, and dosage and administration information.

b Coffey RJ, Edgar TS, Francisco GE, et al. Abrupt withdrawal from the intrathecal baclofen: recognition and management of a potentially life- threatening syndrome. *Arch Phys Med Rehabil. 2002;83:735-741.*

Emergency procedure to empty Prometra pump reservoir

Equipment

- Prometra Programmer (not sterile)
- 22-gauge noncoring needle
- 20-mL syringe (if pump reservoir capacity is 40 mL, 2 syringes are required)
- Stopcock
- Extension Tubing, 20 cm (8 in.), with Clamp

WARNING: DETERMINE THE PUMP NAME, MODEL NUMBER, AND MAXIMUM PUMP VOLUME PRIOR TO EMPTYING AND/OR REFILLING THE DRUG REFILL/RESERVOIR.

WARNING: IF SUSPENDING INTRATHECAL DRUG THERAPY, ALTERNATIVE DRUG THERAPY ADMINISTRATION ROUTES (E.G., ORAL OR INTRAVENOUS) MAY BE NECESSARY. AN ALTERNATIVE ORAL OR PARENTERAL DOSE "EQUIVALENT" TO THE INTRATHECAL DOSE MAY RESULT IN SIDE EFFECTS THAT WARRANT TEMPORARY MONITORING IN AN EMERGENCY DEPARTMENT OR INPATIENT FACILITY.

Emptying the Drug Refill/Reservoir

1. Turn the Programmer ON and select Inquiry. Place the Prometra Programmer over the pump. An audible tone sounds during inquiry of the pump. Check the **Inquiry** screen and note the **Reservoir Volume**. The Reservoir Volume is the expected volume of fluid remaining in the pump.

   Note: Prometra® II 40 mL (Model # 16827) Programmable Pumps are not compatible with Prometra Programmers (Model #12828 and Model # 13828) with software versions prior to 2.01.5. If a user attempts to inquire the 40 mL pump, the programmer will display a "Communication Failed. Please try again" message. Contact Flowonix Technical Solutions at 855-356-9665 if you require access to a Flowonix Programmer.

2. **USE STERILE TECHNIQUE.** Always inspect and aseptically prepare the site according to standard practice.

3. Locate the drug refill/reservoir septum with palpation and by placing the refill access template over the pump and aligning the edges of the template with the edges of the pump. You may use a sterile pen to mark the site for needle entry and set template aside.

   Warning: Always use the Prometra Refill Access Template to ensure proper access to the drug refill/reservoir septum. Using the incorrect template may result in drug overdose or infusate delivery into the pump pocket. If you are unsure of the proper access, use image guidance to verify proper needle placement.

4. Attach one of the 22G non-coring needles to the extension tubing.
   Warning: Use only the 22G non-coring needle supplied in the Refill Kit to access the drug refill/reservoir septum.

5. Slide the extension tubing clamp as far as possible toward the loose end of the tubing and close the clamp.

6. Attach the stopcock to the extension tubing. Turn the stopcock to the OFF position, perpendicular to the extension tubing.

7. Attach the syringe barrel to the stopcock. Place the syringe cap on the open end of the syringe barrel.
   Warning: Use only the calibrated syringe barrel supplied in the Refill Kit to collect infusate from the drug reservoir.
   Caution: Always make sure all connections are secure before addressing needle to skin. This will prevent leaks.

Emptying Setup

8. Insert the needle through the center of the drug refill/reservoir access septum, perpendicular to the skin and the pump. Advance the needle until the needle tip resides completely inside the refill chamber.
   Caution: Do not force the needle. Excessive force on the needle may damage the needle tip. Do not rock the needle sideways as this may damage the septum or cause drug to leak into the pump pocket.

Emptying Setup in Pump

9. Always carefully measure and record empty volume. The measurement of this volume is important to ensure that the pump is working properly.

10. If the **Reservoir Volume** is less than 10 mL, open the clamp on the extension tubing. Slowly turn the stopcock from perpendicular to inline with the extension tubing to open the stopcock. Allow the internal pump pressure to push the contents of the pump into the syringe barrel. This is the **Empty Volume**. Close the clamp on the extension tubing and disconnect the stopcock with its attached capped syringe barrel from the extension tubing. Set the stopcock aside and discard the syringe barrel.

11. If the **Reservoir Volume** is greater than 10 mL, then the Empty Volume must be collected in two to four steps (depending on the **Reservoir Volume**) using the same emptying setup.

Collection of infusate:

11.1 Open the clamp on the extension tubing. Slowly turn the stopcock from perpendicular to inline with the extension tubing to open the stopcock. Allow the internal pump pressure to push the contents of the pump into the syringe barrel.

11.2 Using the stopcock valve as a volume control device, collect up to 10 mL in the syringe barrel. Turn the stopcock valve to the OFF position and close the clamp on the extension tubing.

11.3 Disconnect the stopcock with its attached syringe barrel from the extension tubing. Holding the syringe barrel vertical and at eye level, read the bottom of the meniscus formed by the fluid to the nearest 0.2 mL. Record the syringe barrel volume.

11.4 Place the stopcock-syringe barrel assembly over the sterile Refill Kit Tray.

11.5 Turn the stopcock valve to the ON position to discard the Step One Empty Volume. When the syringe barrel and stopcock are empty, turn the stopcock valve to the OFF position.

If Infusate remains in the reservoir:

11.6 Reattach the stopcock-syringe barrel assembly to the extension tubing. Repeat steps 11.1 – 11.5 until the reservoir is empty.

12. Once the reservoir is empty, close the clamp on the extension tubing and disconnect the stopcock with its attached capped syringe barrel from the extension tubing. Set the stopcock aside and discard the syringe barrel.

Calculating Empty Volume

13. If multiple syringe barrel volumes were collected, the Empty Volume is the sum of the syringe volume(s) minus the correction factor as shown in Table 1.
    Note: The syringe barrel takes into account the 0.3mL stopcock volume and the 0.3mL tubing volume. By design, the markings on the Flowonix Refill Kit syringe barrel are offset and include the volume of infusate in the stopcock and tubing as well as the volume in the syringe barrel. There is no need to adjust the volume measured on the syringe barrel for the first emptying, because the syringe barrel already takes this volume into account. However, upon each additional emptying, the tubing volume must be subtracted because the extension tubing is not emptied between steps.

Table 1. Calculating Empty Volume				
-	***< 10 mL***	***10mL to 20 mL***	***20 mL to 30 mL***	***> 30 mL***
1st Syringe	All volume	Up to 10 mL	Up to 10mL	Up to 10 mL
2nd Syringe		Remaining Volume	Up to 10mL	Up to 10mL
3rd Syringe			Remaining Volume	Up to 10mL
4th Syringe				Remaining Volume
Correction Factor (Tubing Volume)	0.0 mL	0.3 mL	0.6 mL	0.9 mL
EMPTY VOLUME = TOTAL SYRINGE VOLUME(S) - CORRECTION FACTOR				

Example 1. Two syringe barrel volumes collected

Syringe Barrel Volume 1: 10 mL

Syringe Barrel Volume 2: 3.6 mL

Empty Volume = 10 mL + 3.6mL – 0.3 mL = 13.3 mL

Example 2. Three syringe barrel volumes collected

Syringe Barrel Volume 1: 10 mL

Syringe Barrel Volume 2: 10 mL

Syringe Barrel Volume 3: 5.2 mL

Empty Volume = 10 mL + 10 mL + 5.2 mL – 0.6 mL = 24.6 mL

14. Compare the **Empty Volume** to the **Reservoir Volume** to confirm that the pump is flowing properly.

Technical Solutions

For additional information, contact Flowonix Technical Solutions at 855-356-9665.

Manufactured by:
Flowonix Medical, Inc.
500 International Drive, Suite 200
Mount Olive, NJ 07828 USA
T 973.426.9229
F 973.426.0035
www.flowonix.com

FLOWONIX

Issue Date: January 2020
PL-39701-02