



## **INTRATHECAL CATHETER (REF 91823)**

For use with Prometra® Programmable Pump



## **PROMETRA® PROGRAMMABLE PUMP (REF 91827)**


















For use with Intrathecal Catheter



**MR Conditional**

# Explanation of Symbols

Refer to the package and product labeling to see which symbols apply to this product.

	Catalog number
	Serial number
	Batch code
	Use by date
	Date of manufacture
	Sterilized using ethylene oxide
	Sterilized using steam or dry heat
	Do not re-use
	Caution, consult accompanying documents
	Do not use if package is damaged
	Fragile, handle with care
	Temperature limitations
	Keep away from sunlight
	MR Conditional
	Authorized Representative in the European Community
	Warning
	Information
<b>Nonpyrogenic</b>	Non-pyrogenic
<b>Latex-Free</b>	No patient or fluid contact with latex components
<b>PVC-Free</b>	No patient or fluid contact with polyvinyl chloride components
<b>DEHP-Free</b>	No patient or fluid contact with di(2-ethylhexyl)phthalate components
<b>Rx only</b>	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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## Introduction

The Prometra Programmable Pump is designed to provide controlled delivery of drugs to the intrathecal space via the separately supplied Intrathecal Catheter. The Prometra Programmer is a separately supplied handheld, menu-driven device that enables remote programming of the Prometra Pump.

## Contents

### Catheter Contents

- 1 - Catheter, Radiopaque, 1.3 mm OD (4F) x 110 cm x 0.6 mm ID
- 1 - Catheter Lock
- 1 - Hub, Flushing, 0.6 mm (23G) x 13 mm (0.5 in.)
- 1 - Needle, Tuohy, 1.8 mm (15G) x 89 mm (3.5 in.)
- 1 - Stylet, Hydrophilic, Flush-Through, 0.43 mm (0.017 in.) x 109 cm
- 1 - Syringe, 12 mL, Luer Slip
- 2 - Wings, Suture, 90°, Angled with:
  - 2 – Anchors, Angled
- 1 Wing, Suture, Slit with:
  - 1 – Anchor, Straight
- 1 – Sheet of Catheter Stickers

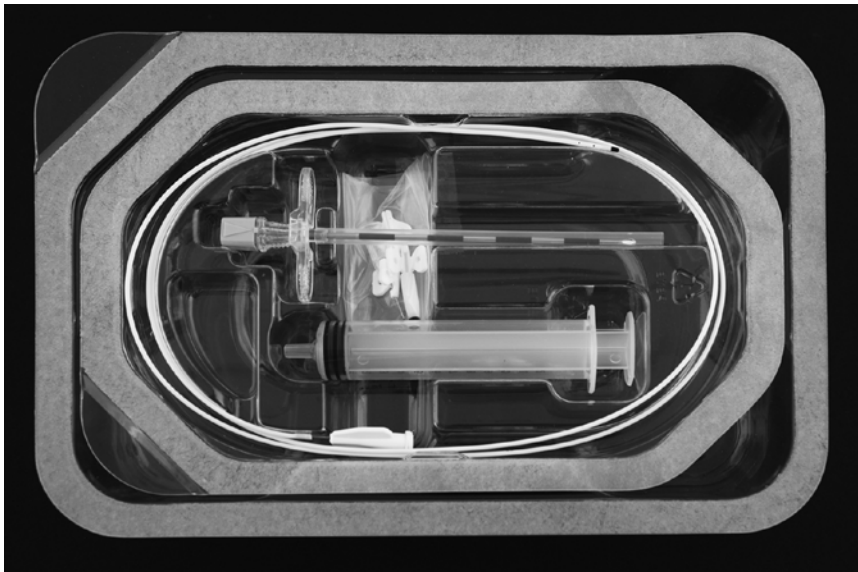
### Pump Contents

- 1 – Prometra Programmable Pump
- 1 – Needle, Non-Coring, 0.7 mm (22G) x 38 mm (1.5 in.)
- 1 – Needle, Catheter Access, 0.9 mm (20G) x 45 mm (1.75 in.)
- 1 – Patient and Physician Information packet, including:
  - 2 – Patient Implant Cards
  - 1 – Patient Guide
  - 1 – Patient Device Tracking Form
  - 1 – Sheet of Pump Stickers

## Description

### Catheter Description

The Intrathecal Catheter is a single-piece, radiopaque, silicone catheter with pre-inserted hydrophilic stiffening stylet that is used to assist in placing the catheter. The catheter has a tungsten-filled tip to enhance radiopacity and side-holes at the tip for dispersion of the infusate into the intrathecal space. The catheter also features depth markings indicated in centimeters starting 5 cm from the distal end of the catheter, extending to a distance 30 cm from its distal end. The intrathecal catheter is provided with accessories to assist in its placement and securement at implant and a radiopaque catheter lock to secure the catheter onto the stem of the Prometra Programmable Pump. The intrathecal catheter and package contents are sterilized using ethylene oxide.



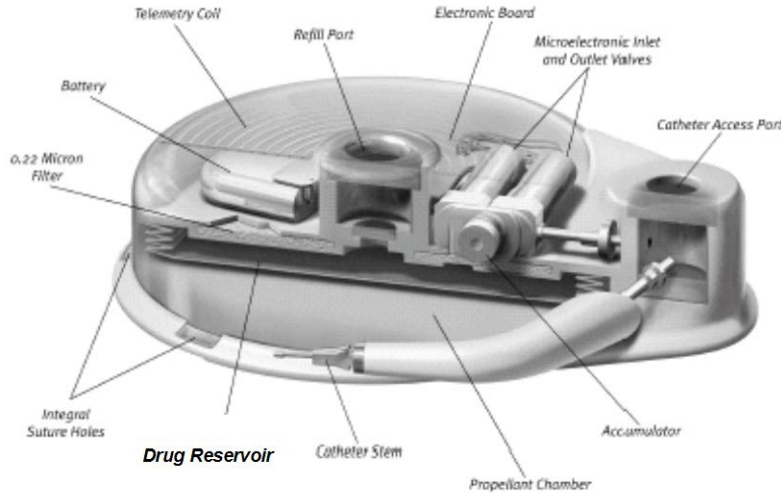
### Pump Description

The Prometra Pump is a battery-powered, teardrop-shaped pump with a rigid titanium housing and a triple redundancy flow controller system.



The triple redundancy flow control system is designed to provide a precise and accurate flow rate. The flow rate accuracy is independent of normal operating environmental conditions such as altitude, temperature and reservoir volume.

Once implanted, the device can be identified by using the programmer to inquire the system. If a programmer is not available, the shape of the pump, tear drop access port and raised refill port provide features distinct to the Prometra pump for easy identification. The programmable pump and package contents are sterilized using steam.

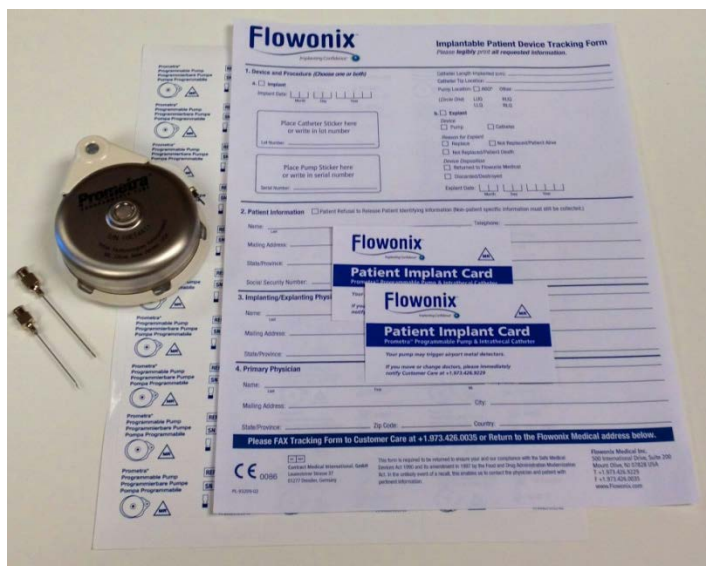


Specifications of the Prometra Programmable Pump are:

<b>Device Longevity</b>	
Pump	10 years at 0.25 mL/day
Septum (Refill and CAP)	1000 punctures maximum
<b>External Properties</b>	
Material	Titanium Polyphenylsulfone access ports
Thickness	20 mm nominal
Diameter	71 mm
Average Volume Displacement	100 mL
Weight, unfilled	150 g
Pump to Catheter Connection Strength	1.1 lbs
<b>Drug Reservoir</b>	
Material	Titanium
Usable Capacity	20 mL
<b>Flow Control System</b>	
Accumulator stroke volume	2 mL
Material	Titanium

	MP35N alloy Stainless steel Silicone rubber
<b>Refill Septum</b>	
Septum material	Silicone rubber
Access needle	Huber point, 22G non-coring needle
<b>Catheter Access Septum</b>	
Septum material	Silicone rubber
Access needle	Lancet point with side hole, 20G
<b>Bacterial filter</b>	
Material	Polyvinylidene fluoride
Pore size	0.22 micron
<b>Flow Rate</b>	
Range	0-28 mL/day
Clinical Dose Related Error	97.4 ±3.8%

The pump is supplied with a Catheter Access needle and a non-coring Refill needle for priming the pump at implantation. The Patient Information packet contains a patient guide and two patient implant cards to be completed and given to the patient. Additionally, a federally-mandated patient device tracking form is included.



## Indications

The Intrathecal Catheter is indicated for use in patients receiving a Prometra Programmable Pump. The Intrathecal Catheter is intended to be attached to the Prometra Programmable Pump to provide access to the intrathecal space.

The Prometra Programmable Pump System is indicated for use in the treatment of chronic intractable pain and the management of severe spasticity. In the treatment of chronic intractable pain, it is intended for chronic, intrathecal infusion of preservative-free morphine sulfate solution. For the management of severe spasticity, it is indicated for chronic intrathecal infusion of baclofen injection sterile solution. Sterile preservative-free 0.9% saline solution may be used when therapy is interrupted to maintain catheter patency. When required, infusion of radiopaque contrast media labeled for intrathecal use may be used.

The labeling for the drug will govern the indications, contraindications, dose rates and warnings related to the use of the drug.

## Contraindications

Implantation of this device is contraindicated when:

- The presence of infection is known or suspected.
- The patient's body size or anatomy is insufficient to accommodate the size of the implanted pump or catheter.
- The pump cannot be implanted 2.5 cm (1 in.) or less from the surface of the skin. Deeper implants could interfere with septum access or telemetry.
- The patient is known or is suspected to be allergic to materials contained in the catheter: silicone rubber, acetal resin, or tungsten.
- The patient is known or is suspected to be allergic to materials contained in the pump: silicone rubber, polyphenylsulfone, buna-n rubber, MP35N metal (multiphase quaternary nimonic alloy primarily composed of chromium, cobalt, molybdenum and nickel), titanium, polyvinylidene fluoride, stainless steel, epoxy resin, acetal resin or tungsten.
- The patient has exhibited a prior intolerance to implanted devices.
- The patient has a spinal column anatomy that would obstruct cerebrospinal fluid flow or that would prevent intraspinal drug administration.
- The patient has emotional, psychiatric or substance abuse problems that are deemed to prohibit intrathecal drug administration.
- The patient is under 18 years old. Safety and effectiveness for use in pediatric patients under 18 years old has not been investigated or established
- The patient will require magnetic therapies.
- The patient will require hyperbaric treatments.
- The patient has an occupation where he/she would be exposed to high current industrial equipment, powerful magnets or transmitting towers, such as, electricians, electrical engineers or MRI technicians.
- Contraindications relating to preservative-free morphine sulfate or baclofen sterile injection must be observed and followed per the approved drug labeling.



# Warnings

## General



**WARNING: FAILURE TO EMPTY THE PUMP PRIOR TO EXPOSURE TO MRI ENVIRONMENT COULD RESULT IN DRUG OVERDOSE THAT COULD LEAD TO SERIOUS PATIENT INJURY OR DEATH.**

- Prior to infusion of any substance into the catheter, medical personnel should be familiar with and observe all warnings, cautions, contraindications, and instructions as specified by the manufacturer of the infused substance.
- Only use this device with drugs listed under “Indications.” Use of non-indicated drugs, such as drug cocktails, pharmacy-compounded drugs, or morphine with preservatives with this product may cause pump failure.
- Always select and program drug dosages consistent with the drug labeling to prevent improper drug administration.
- In the event of over-medication, refer to the approved drug labeling for appropriate treatment.
- Clinicians implanting, programming, accessing, or maintaining implanted programmable pumps must comply with the instructions for use. Technical errors may result in a return of underlying symptoms, drug withdrawal symptoms, or clinically significant or fatal overdose.
- The effects of implanting this device in patients with medical devices, other than neurostimulators, are unknown.
- Pain on injection that was not noted during previous injections may be an early sign of infection.
- The Intrathecal Catheter and Prometra Programmable Pump components are supplied sterile and non-pyrogenic. The packages should be examined carefully prior to opening. Do not use the contents if there is any evidence of damage to the package or package seal that could compromise sterility. Do not resterilize contents of any damaged or opened packages.
- After use, this device is a biohazard. Handle and dispose of in accordance with accepted hospital practice and all applicable laws and regulations.
- Do not incinerate or cremate the pump.
- Do not expose the pump to temperatures above 57°C (122°F) or below 2°C (41°F)
- For MRI procedures, always follow the specific instructions detailed below in section, Magnetic Resonance Imaging (MRI) Conditions for Safe Scanning.

## Device Compatibility

- **Pump accessories.** Only use the Prometra Programmable Pump with the accessories listed in these instructions for use. Use of alternate accessories may result in damage to Prometra components, less than adequate therapy, or increased risks to the patient.
- **Pump.** Only use with Prometra Programmer.
- **Alcohol.** Do not use alcohol on any part of the pump or catheter system. Alcohol is neurotoxic.
- **Contrast media.** Do not inject contrast media into the refill reservoir since this may damage the pump or impair pump function.
- **External devices.** Do not connect any external devices or pumps to the Prometra® Pump. Pressures generated by an external pump could damage the implanted pump/catheter system and result in serious patient injury or death.
- **Therapeutic ultrasonics or lithotripsy** - Use of therapeutic ultrasonic devices, such as

electrohydraulic lithotriptors, has not been tested on the Prometra pump. If lithotripsy must be used, do not focus the beam in proximity of the pump.

- **Medical devices.** The Prometra Pump Programmer may affect other medical devices. Use or interference with medical devices, other than neurostimulators, has not been established.
- **Applied electric currents.** Interaction of the Prometra® Pump with electric currents applied to the body such as cardioversion or defibrillation has not been established. Care must be exercised if the patient receives these treatments. Where practical, the pump should be turned off before application of electric currents to the patient's body. Confirmation that the pump programming has not changed must be carried out as soon as possible after the procedure.
- **Radiation.** Do not use radiation therapy in the area of the pump. The effects of ionizing radiation on the Prometra® Pump have not been established, and these therapies may have effects on pump operation that are not immediately apparent.
- **Magnetic fields.** Magnetic fields of 50 gauss or less will generally not affect the pump (e.g. Common therapeutic magnets or theft/security screening devices found in airports, libraries, and some department stores).
- **MRI.** Strong magnetic fields, such as those created in Magnetic Resonance Imaging (MRI) devices may cause the valves of the pump to open, resulting in the immediate discharge of the contents of the drug reservoir into the patient.



## MR Conditional

### Magnetic Resonance Imaging (MRI) Conditions for Safe Scanning

#### Warnings



**WARNING: FAILURE TO EMPTY THE PUMP PRIOR TO EXPOSURE TO MRI ENVIRONMENT COULD RESULT IN DRUG OVERDOSE THAT COULD LEAD TO SERIOUS PATIENT INJURY OR DEATH.**



**IF AN MRI PROCEDURE IS NECESSARY, THE PUMP MUST BE EMPTIED of drug solution, not refilled and the pump programmed to 0.0 mg/DAY drug flow rate prior to entering the environment of the MRI. Strong magnetic fields, such as those created in Magnetic Resonance Imaging (MRI) devices, may cause the valves of the pump to open, resulting in the immediate discharge of the contents of the drug reservoir and catheter into the patient.**



**Patients should not be exposed to MRI environments until the surgical site following pump implantation is fully healed.**

**The Prometra Pump can be safely exposed to an MR system when ALL of the following conditions are met:**

1. The pump reservoir is completely emptied of drug by following the procedures for emptying the Drug Reservoir in the Refill Kit Instructions for Use.
2. The Prometra Programmer is used to program the pump to 0.0 mg/day flow rate prior to MRI exposure and throughout the MRI scanning sequence.
3. The MRI device has a static magnetic field of 1.5 Tesla
4. The MRI device has a maximum spatial gradient field of 410 Gauss/cm



**Warning: Exceeding the 410 Gauss/cm limit could result in excessive force or torque which could lead to patient injury.**

5. A maximum whole body average specific absorption rate (SAR) of 2 W/kg for 20 minutes of scanning in the Normal Operating Mode.



**NOTE:** The MRI conditions for safe scanning detailed in this document only pertain to the Prometra Pump implanted in the abdomen. Testing has not been conducted in other implantation locations or in the presence of other implanted active or passive medical devices. Other implanted devices (such as pacemakers, abandoned leads, knee implants, etc.) could have conflicting MR conditions which could lead to patient injury or device malfunction.

## **TISSUE HEATING, MAGNETIC FIELD AND IMAGE ARTIFACTS**

### **Tissue Heating Adjacent to Implant during MR Scans**

In non-clinical testing, the Prometra Pump produced a maximum temperature rise of 1.5°C during 20 minutes of continuous MR scanning in the Normal Operation Mode at a maximum whole-body averaged specific absorption rate (SAR) of 2 W/kg using a transmit body coil.

The local temperature increase produced by the pump is considered to be below level of concern. In the unlikely event that the patient experiences uncomfortable warmth near the pump, the MRI scan should be stopped and the scan parameters adjusted to reduce SAR to comfortable levels.



### **Static Magnetic Field**

In a 1.5 T MR environment, the pump has a significant magnetically induced deflection force and very strong torque. The static and gradient magnetic fields produced by an MRI scanner could potentially interact with the pump and cause vibration. However, when pumps are implanted with proper techniques, the patient may safely be scanned under the conditions listed above. Not following the specific conditions may result in serious patient injury. The patient may experience tugging and/or vibration sensation at the implant site when placed within the magnetic field. An elastic garment or wrap will restrict movement and reduce these sensations while the patient is in the magnetic field.

## Image Artifacts

The Prometra programmable pump contains ferromagnetic components that will cause image distortion and localized voids in large regions of the image around the pump. MR image quality will be compromised if the area of interest is near the pump.

Worst case artifacts measured from the edge of the device in non-clinical tests using a spin echo sequence were found to extend more than 11 cm from the pump. Image artifacts were reduced by up to 36% when sequences were optimized for imaging (e.g. shorter echo time, decreased water fat shift, etc.). Images of the head and lower extremities away from the location of the Prometra Pump should be largely unaffected. The nonclinical testing was performed using the ASTM F2119 GRE and SE sequences in a 1.5T Philips Medical Systems Intera (software release 12.6.4.3, 2010-12-02) MR system with a body coil in transmit and receive mode.

## PRE- MRI PROCEDURE INSTRUCTIONS

- Prior to initiating the MRI procedure, the physician should determine if the patient could safely be deprived of medication for the length of the MRI procedure. If medication is needed, then alternate means of drug delivery (such as I.V. administration) should be employed for the duration of the MRI procedure.
- Prior to scheduling an MRI scan and upon its completion, pump status should be confirmed by inquiring the pump to verify pump operation and settings.
- All drug must be removed from the pump prior to an MRI procedure (see Warnings).

## POST- MRI PROCEDURE INSTRUCTIONS

### 1. Confirmation of Pump Operational Status

#### Pump Inquiry

Upon the completion of an MRI procedure, inquire the pump with the programmer to verify pump operation and settings. If the programmer displays any pump errors, proceed to Step 2), "Clear Pump Errors." If no pump errors are displayed, proceed to Step 3) "Pump Aspiration." Confirm that settings are unchanged from the Pre-MRI settings, e.g., flow rate must be 0.0 mg/day.



**Warning: If pump status cannot be properly confirmed, DO NOT proceed since the pump may not be operating properly. Please contact Flowonix Customer Care for assistance at: +1 844-229-6729.**

### 2. Clear Pump Errors

- a. Inquire the pump with the programmer to determine if any errors have been generated during the MRI procedure.
- b. If pump errors are displayed, perform an Emergency Pump Stop using the programmer.

- c. Program a Demand Bolus of 0mg for 1 minute
- d. Allow 1 minute to elapse to allow all errors to clear.
- e. Inquire the pump with the programmer to confirm errors are cleared, if errors persist please contact Flowonix Customer Care for assistance at: +1 844-229-6729.

### 3. Pump Aspiration

- a. Once the pump status and flow rate is confirmed to be 0.0 mg/day via inquiry, attempt to aspirate the pump reservoir through the Refill Port
- b. To aspirate, attach the 22G non-coring needle (available in Refill Kit) to a sterile syringe.
- c. Advance needle through center refill septum until needle tip resides completely inside the drug refill reservoir.
- d. Pull a vacuum with the syringe for approximately 10 to 30 seconds.



**Warning: If any significant volume (>1ml) is retrieved, it may be indicative that the pump valves are open, providing direct access to the catheter/cerebral spinal fluid; if so, DO NOT proceed with the refill since the pump is not operating properly and should be explanted and replaced.**

### 4. Refill Procedure

- a. After confirming that the pump is operating properly, proceed to refill the pump in accordance with the refill procedures defined in the Refill Kit Instructions for Use.
- b. Confirm the correct prescription is programmed, or program a new prescription.



**Warning: A period of observation should follow the Refill Procedure to closely monitor patients for clinical symptoms of underdose or overdose based upon the drug's prescribing information.**

## Precautions

### General

- Carefully read all instructions prior to use. Follow all instructions.
- Certain equipment may cause electrical noise, which may interfere with programming. If suspected, move the patient from the suspected source of interference to facilitate the programming procedure.
- Do not use accessories that are not referenced in these instructions for use. Only use devices and accessories that are referenced for use with the Prometra® Programmable Pump in these instructions.

### Implant

- Implantation of this device and subsequent use, reprogramming, and refill should only be conducted by qualified medical personnel specifically trained for surgical implantation, use, and maintenance of the device. Use of this device by non-qualified or untrained personnel could lead to serious consequences involving under- or over-medication. In the event of over-medication, refer to the approved drug labeling for appropriate treatment.
- The pump and catheter system should be implanted carefully to avoid any sharp or acute angles, which could compromise the patency of the catheter lumen.

- Over-pressurization can damage the catheter. Small syringes can generate very high pressures and may damage the catheter or catheter connection. Do not use a syringe smaller than 10 mL when accessing the catheter access chamber.
- If therapy is discontinued for an extended period, the pump should be emptied of the drug and filled with a preservative-free sterile saline solution to maintain catheter patency.

## Adverse Events

The use of implanted pumps provides an important means of treating patients with intractable pain or severe spasticity. However, the potential exists for serious complications including the following:

- Bleeding
- Body rejection phenomena
- Catheter breakage
- Catheter disconnection
- Catheter fibrosis
- Catheter migration
- Catheter occlusion or kinking
- Catheter or pump erosion through the skin
- Cerebrospinal fluid (CSF) leak leading to spinal headache, CSF subcutaneous collection, or rare Central Nervous System (CNS) pressure-related problems
- Cessation of therapy due to pump battery depletion or pump failure
- Epidural abscess
- Fever
- Granulomas
- Implant site cellulitis
- Inability to program the device due to Prometra® Pump Programmer failure or loss of telemetry
- Infection of intrathecal space, including meningitis, pocket, or subcutaneous catheter tract
- Inflammation, necrosis, or scarring of skin over implant area
- Malpositioning of catheter
- Neurological impairment, including paralysis.
- Overdose as a result of bolus delivered during MRI procedure (see MR conditions for safe scanning)
- Pain on injection
- Pocket seroma, hematoma, or infection
- Programming or refill errors resulting in under-dosing or over-dosing
- Pump flipped over
- Risks normally associated with use of the prescribed medication for delivery, local and general anesthesia, surgery, and post-operative recovery
- Spinal cord or nerve injury
- Spinal cord pressure leading to paralysis
- Subcutaneous catheter tract infection.

In rare instances, the development of an inflammatory mass at the tip of the implanted catheter may occur, which can result in serious neurological impairment. Patients should be monitored carefully at each visit for any new neurological signs or symptoms, including:

- progressive change in the character, quality, or intensity of pain or spasticity
- an increase in the level and degree of pain or spasticity despite dose escalation

- sensory changes (i.e., numbness, tingling, burning)
- hyperesthesia and/or hyperalgesia

Presentations that require immediate diagnosis include

- bowel and/or bladder dysfunction
- myelopathy
- conus syndrome
- gait disturbances or difficulty ambulating
- paraparesis or paralysis

If the presence of an inflammatory mass is suspected, recommended evaluation should include a review of the patient history and neurological evaluation, radiological diagnostic procedures (such as an MRI with contrast) and appropriate clinical consultation.



**Warning: Pump MUST be emptied prior to MRI procedures. MRI procedures could cause the entire contents of the reservoir to be expelled into the intrathecal space.**

### **Possible Risks Associated with baclofen Intrathecal Infusion**

Prevention of abrupt discontinuation of intrathecal baclofen requires careful attention to programming and monitoring of the infusion. Early symptoms of under dosing include: return to baseline spasticity, pruritis, hypotension and paresthesias.

Abrupt withdrawal of baclofen may be life-threatening. Symptoms include: high fever, altered mental status, exaggerated rebound spasticity and muscle rigidity. Withdrawal left untreated may result in: rhabdomyolysis, multiple organ failure and death.

Overdosing signs and symptoms include: drowsiness, lightheadedness, dizziness, somnolence, respiratory depression, seizures, rostral progression of hypotonia, loss of consciousness progressing to coma.

## **Equipment**

- Prometra Programmable Pump
- Intrathecal Catheter
- Tunneler
- Prometra Pump Programmer (Not Sterile)

The following items may be needed and are **not** provided:

- Sterile Programmer Sleeve
- Sterile preservative-free 0.9% saline
- Drug solution (infusate) for refill, not to exceed 20 mL

# Pump Operation

## Programmable Features

The Prometra Pump Programmer uses telemetry to exchange information with the pump. This information includes the following:

- Date and Time
- Current Prescription
- Patient Identification
- Drug Name and Concentration
- Flow Mode, Drug Dose and Delivery Rate
- Pump Model and Serial Number
- Low Reservoir Setting and Alarm
- Low Battery Alarm
- Next Refill Date

The Prometra Pump Programmer allows clinicians convenient, non-invasive access for interrogating and programming the implanted Prometra Pump. Refer to the Prometra Pump Programmer Technical Manual for further information regarding pump programming.

## Programming Medication Regimens

The Prometra Programmable Pump can be programmed to deliver a precise flow of medication at a constant or variable rate, or it can be set to periodically deliver a drug dosage at distinct intervals of time (i.e. Periodic Flow Mode). There is also an option to interrupt the pump's current medication regimen and deliver an immediate infusion of medication (Demand Bolus). Refer to the Prometra Pump Programmer Technical Manual for further information regarding pump programming.



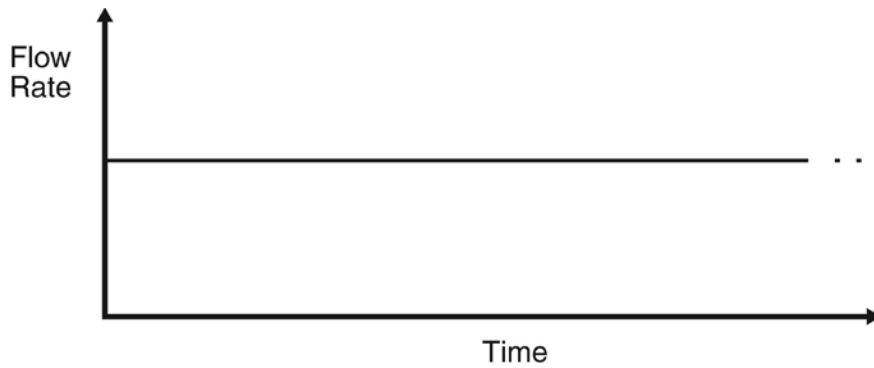
**Warning: Implantation of the Prometra Programmable Pump System and subsequent use, reprogramming and refill should only be conducted by qualified medical personnel specifically trained for surgical implantation, use and maintenance of the device. Prescription of pump infusion regimens may only be conducted by physicians with a full understanding of the relationships between concentration, dose, and infusion rate. Use of this device by non-qualified or untrained personnel could lead to serious consequences involving under or over-medication. In the event of over-medication, refer to the approved drug labeling for appropriate treatment.**

The following illustrations describe the four basic medication regimens:

### **Constant Flow**

The Constant Flow regimen delivers a specific daily dose, e.g. mg/24 hr, of drug at a constant flow rate dependent on the drug concentration.

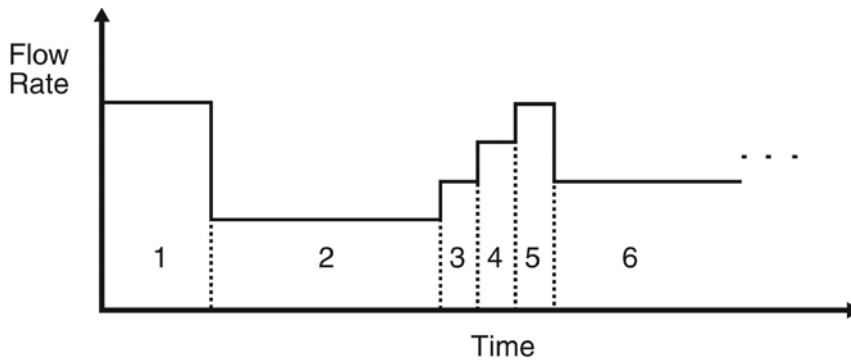




**Constant Flow Regimen**

**Multiple Rates**

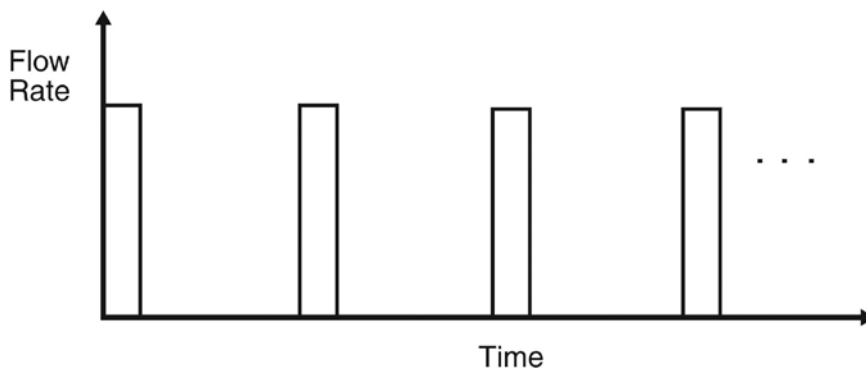
The Multiple Rates regimen delivers medication using one to eight user-programmed rates that repeat daily. For each prescribed rate, the specific medication dose and time period is programmed.



**Multiple Rates Regimen**

**Periodic Flow**

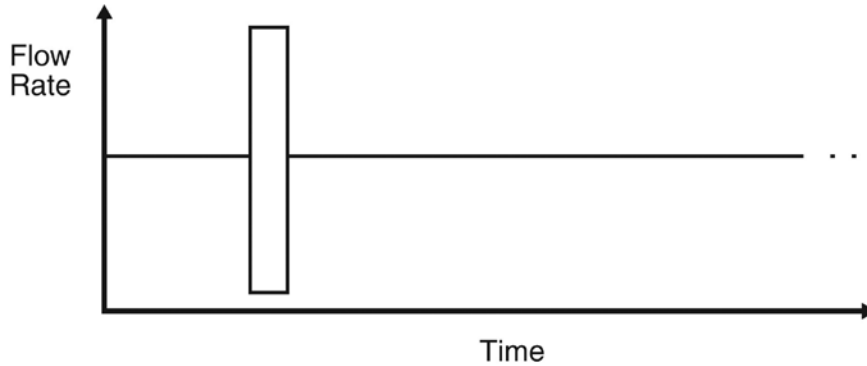
The Periodic Flow regimen delivers medication in a sequence of periodic infusions. The medication dose, the time over which the dose is delivered, and the interval at which the dose is repeated are programmed.



**Periodic Flow Regimen**

## Demand Bolus

The Demand Bolus regimen temporarily replaces the current dose regimen to deliver an immediate, one-time infusion of medication. The medication dose and the time over which the dosage is delivered are programmed. Once the Demand Bolus is complete, the pump resumes its previously programmed regimen.



**Demand Bolus Regimen**

## Pre-Programmed Pump Settings

When the Prometra Pump Programmer inquires the Prometra Pump for the first time, the pump status screens display the pre-programmed pump settings. The clinician can change these presets using the programmer.

Parameter	Description	Data Preset
Patient	Name or code	No
Pump Model	Model of Pump	Yes, Prometra
Pump SN	Serial Number of Pump (e.g., 36DA4A77)	Yes, pump specific
Pump Ver.	Current control software version (e.g. 1.02)	Yes, pump specific
Drug	Drug contained in pump	No, specified by user
Conc	Concentration of drug in pump	Yes, preset to 1.000 mg/mL
Accum	Accumulator Volume Constant (e.g. 2.010 µL)	Yes, pump specific
Reservoir Volume	Current estimated volume contained in reservoir	Yes, 00.0 mL
Low Res. Alarm	Alarm to indicate reservoir volume is low	Yes, to OFF
Low Res. Volume	Setting to actuate Low Reservoir Alarm	Yes, 2.0 mL
Battery	Pump battery charge status	No, reports condition, e.g. OK or Low
Flow Mode	Constant Flow, Multiple Rates, Periodic Flow or Demand Bolus	Yes, to Constant Flow
Next Refill	Date: month/day/year (mo/da/yr)	No

Parameter	Description	Data Preset
	Calculated by programmer, appears after refill is programmed	
Daily Dose	Programmed daily dose (e.g. 2.005 mg)	Yes, to 0.000 mg

## Pump Alarms

The Prometra Pump has two audible alarms that alert patients and clinicians to low reservoir volume and critical errors that cause the drug delivery to stop. All alarms use the same tone but can be distinguished from each other by the number of “beeps” in a group and the length of each beep.

### Low Reservoir Alarm

The Low Reservoir Alarm warns patients when the medication in the pump reservoir gets below a certain volume. The pump signals a low volume condition by sounding two short (1/4 second) beeps every 30 minutes. The alarm continues to sound until turned off by telemetry using the Prometra Pump Programmer or until a new volume of drug is programmed into the pump.



**Warning: The Low Reservoir Alarm must be turned “On” and the threshold volume programmed using the Prometra Pump Programmer. When pumps are shipped from the factory, the Low Reservoir Alarm is set to “Off”. For information on setting the low reservoir volume and enabling the alarm, refer to the Prometra Pump Programmer Instructions.**

### Critical Error Alarm

The Critical Error Alarm alerts patients and clinicians that the pump has stopped delivering medication. The pump signals an error condition by sounding three long (1/2 second) beeps every 30 minutes. This alarm occurs for any detected condition that results in the pump not delivering medication, including a low pump battery.

If due to a low battery, the alarm will continue to sound until the pump is explanted or until the battery power is depleted to a point that the pump can no longer communicate with the programmer. As the battery is further depleted, the alarm signal may convert to a continuous tone. If due to another error condition, the alarm continues to sound until a drug delivery schedule is programmed using the Prometra Pump Programmer.

Each time the pump is inquired, the Prometra Pump Programmer reads and displays the condition(s) causing the alarm to sound. The Prometra Pump Programmer clears the error and attempts to restart the pump. If the error condition remains, the pump will restart the error alarm.

# Implantation Instructions

The implanting physician is responsible for choosing the surgical procedure, techniques, and the intended therapy for the patient. These instructions are provided as a guide.

## Pre-Implant Pump Preparation



**Warning: Examine all packages carefully. If any package has been damaged or opened prior to use, do not use package contents. If the pump has been dropped onto a hard surface or shows signs of damage, do not implant. Do not resterilize any pump system components.**



**Warning: Make sure the Programmer is sealed in a Sterile Sleeve before approaching the sterile field.**

1. Open the outer pump box and verify that the pump serial number on the pump matches that on the Patient Implant Card.
2. Place one of the pump labels on the patient implant card
3. While the pump is still in the packaging and facing upward, turn the programmer on, press inquire and place the programmer over the pump
4. From the Main Menu select Setup, Pump Setup, and then Patient Name
5. Enter the patient's name using the select and navigation keys
6. Transfer patient's name by placing the programmer over the pump
7. Under Pump Setup, select low reservoir alarm and program the low reservoir alarm to the "ON" position at a level of 2.0 mL
8. Verify that the daily dose limit is NOT enabled
9. Program by placing the programmer over the pump while still in the inner box
10. From the main menu select refill
11. Enter the appropriate information (drug, concentration, refill volume) into each field and then program the pump
12. Again, from the main menu select constant flow and continue to program in the physician's prescribed daily dose
13. Pass the pump, catheter, and tunneler to the scrub nurse in sterile fashion
14. Attach a sterile syringe filled with 5 mL of sterile preservative-free 0.9% saline solution to the 22G non-coring needle provided in the Prometra Pump tray.
15. Advance needle through center refill septum until needle tip resides completely inside the drug refill reservoir.



**Caution: Do not force the needle. Excessive force on the needle may damage the needle tip. Do not rock the needle sideways as this could damage the septum or cause drug to leak from the reservoir.**

16. Inject the 5 mL of sterile preservative-free 0.9% saline solution into the drug reservoir.
17. Allow the saline solution to return from the pump reservoir into the empty syringe barrel.
18. Note: Return volume may be more or less than the infused volume. If air is noted, repeat the priming procedure with another 5 mL of the sterile saline solution.
19. Remove the syringe from the needle.
20. Verify that the volume of infusate in the syringe does not exceed 20 mL, the maximum volume of the pump reservoir. Attach the syringe filled with the infusate to the 22G non-coring needle provided with the pump. **Caution: When first filled, the Prometra Pump has a small amount (2-3ml) of sterile water in the pump. As a result, there is an approximate 13% reduction in concentration of morphine sulfate or baclofen as a result of dilution in the initial filling of the 20mL drug reservoir.**
21. Prior to using the syringe to fill the Prometra Pump reservoir, ensure that air is purged from the syringe and needle using customary medical procedure.
22. Inject the infusate into the pump reservoir. Remove the needle and syringe assembly from the refill septum.
23. Remove and discard the knotted silicone rubber tubing from the pump stem.

24. Attach a syringe filled with 5 mL of sterile preservative free 0.9% saline to the 20G Catheter Access needle. Advance needle through the Catheter Access septum until needle tip resides completely inside the Catheter Access chamber.



25. Flush approximately 5 mL through the Catheter Access septum to remove air from the fluid pathway. Fluid will emerge from the pump stem. Remove the needle and syringe assembly from the Catheter Access chamber and discard.

## Pump Priming Preparation

1. Upon completion of the Pump Programming Setup, in a sterile manner, program the pump for a Demand Bolus of 0.2 mg in 15 minutes using the preset concentration of 1 mg/mL, again following the prompts presented on the Prometra Pump Programmer.
2. Verify that fluid beads form at the tip of the pump stem.



**Warning: Do not implant pump if fluid beads are not observed forming at the tip of the pump stem.**

3. The pump is now ready for implantation.

## Implantation of the Intrathecal Catheter and Prometra Programmable Pump

1. **USE STERILE TECHNIQUE.** Always inspect and aseptically prepare the site according to standard practice.
2. Position the patient and mark the pump implant location and catheter entry location for tunneling.
3. Access the intrathecal space according to standard practice using the 15G Tuohy needle. Proper entry into the intrathecal space is confirmed by observation of clear cerebrospinal fluid (CSF) forming at the hub of the Tuohy needle.

**Caution: Only use smooth-edged atraumatic instruments to handle the catheter to avoid mechanical damage. Do not use the catheter if there is any evidence of mechanical damage or leakage.**

4. Flush catheter with saline through flush-through hub of stylet. This activates the hydrophilic stylet coating to increase lubricity.



**Warning: Do not flush stylet with IPA or drugs. Flushing with solutions other than saline may result in difficulty withdrawing the stylet.**

5. Immediately withdraw the needle stylet from the Tuohy needle.

**Caution: Always flush saline through the catheter hub immediately prior to withdrawing the stylet to facilitate stylet withdrawal.**



**Warning: Do not allow unnecessary CSF backflow during the implant procedure. Replace the needle stylet if catheter insertion is delayed.**

6. Insert the intrathecal catheter with the preloaded stylet in place through the needle and into the desired location within the intrathecal space. Confirm proper placement radiographically.




7. **Warning: Always carefully advance the catheter with stylet to avoid perforation of the spinal cord.**



8. **Warning: Always position catheter with at least 3 vertebral spaces in the intrathecal space. Failure to advance the catheter sufficiently may result in subcutaneous migration of the catheter or retrograde flow of infusate.**

9. Carefully withdraw the Tuohy needle while maintaining catheter position. Disconnect the stylet from the catheter. Firmly hold the catheter near the insertion site and slowly remove the stylet with constant tension.

10.  **Warning: Do not withdraw the catheter back through the Tuohy needle. Doing so may damage the catheter or result in part of the catheter being dislodged in the intrathecal space. If necessary, withdraw the needle and catheter from the tissue as a unit before attempting to reposition the catheter.**

11. If flushing the catheter is necessary after the stylet has been removed, use the flushing hub included in the Catheter Kit. Do not reinsert stylet.

12. Select the angled or the slit suture wings from the tray and position over the catheter.


**Caution: Always position the suture wings over the catheter carefully to avoid mechanical damage to the suture wings or the catheter.**

13. Secure the catheter in place.

**Caution: Always make sure the catheter is straight as it comes out of the spinal entry location to avoid catheter kinking.**


13.1.1. For angled suture wings, fold the wings together with the slit on the inside and suture the wings to the spinous ligaments.



13.1.2.  **Warning: Always fold the angled suture wings together, with the slit on the inside, to assure proper tension on the catheter and minimize catheter migration.**

13.1.3. For the slit suture wing, keep the suture wing in a flat position while suturing to the spinous ligaments. Place sutures around the tubular ends of the suture wing, making sure the sutures do not directly contact the catheter.



13.1.4.  **Warning: Always ensure the flat suture wings remain in a flat position when being sutured to minimize catheter migration.**





**Warning:** Always place sutures around tubular ends of the flat suture wings to minimize catheter migration.

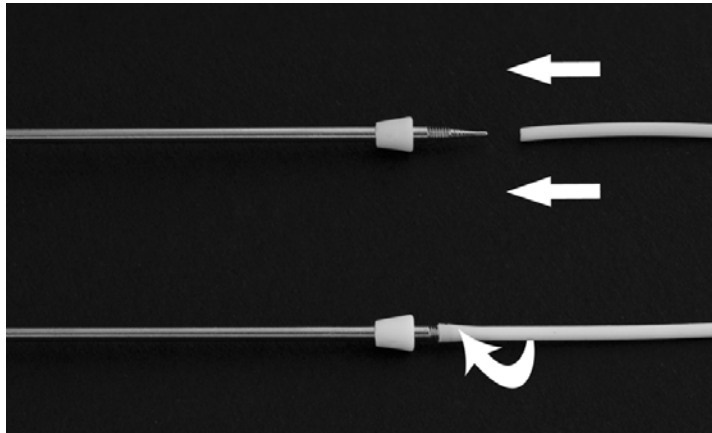
**Caution:** Do not let sutures come in direct contact with the catheter. Sutures in direct contact with the catheter may result in catheter occlusion or damage.

14. Form a subcutaneous pocket using standard technique ensuring snug fit for the pump. Do a trial placement to verify that the pocket is large enough to accommodate the pump and that the pump does not lie beneath the incision.



**Warning:** Implant the pump 2.5 cm (1 in.) or less under the skin. Deeper implants could interfere with septum access or programming.

15. Create a subcutaneous tunnel using the Tunneler.
  - 15.1.1. Push the catheter onto the tunneler until it stops, then turn catheter clockwise until it is fully threaded onto the tunneler.



- 15.1.2. Insert the tunneler at the paravertebral incision site and advance the tunneler tip to the pump pocket site. If necessary, use a second tunneling procedure with a temporary exit in the plane of the midaxillary line.



**Warning:** Do not puncture the skin or thoracic wall with the tip of the tunneler.

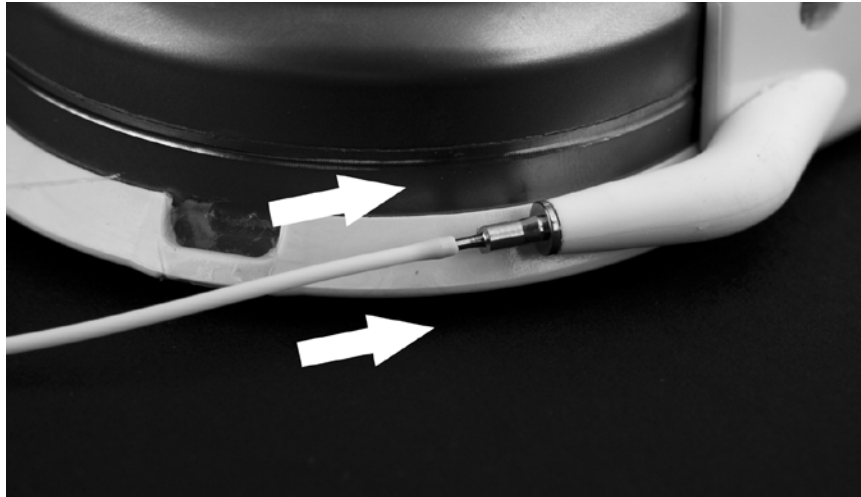
- 15.1.3. Trim the catheter to length at a 90° angle allowing sufficient slack for body movement, pump connection, and an additional 2-3 cm in case a pump reconnection is required. Always trim at least 5 cm from the proximal end of the catheter. Assure that the cut is straight and no catheter fragments are produced. Save the trimmed portion of the catheter – the measurement of this piece will be used to calculate the catheter implant volume.


**Caution:** Always trim excess catheter length. Failure to trim excess length may result in catheter occlusion or kinking.



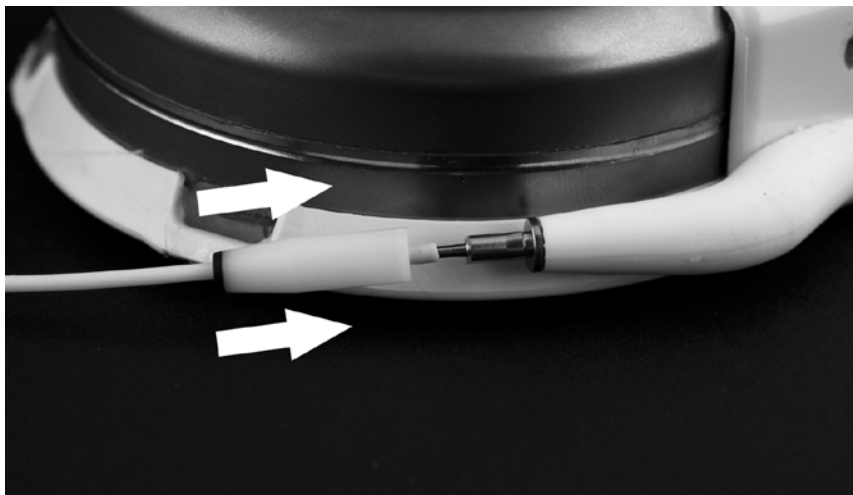
**Warning:** Always save trimmed portion of catheter to measure length and calculate implanted catheter volume. This calculation is required to prevent under- or over-medication.

16. Slide catheter lock on to catheter with larger end towards the pump. Align pump stem with catheter lumen. Advance catheter over barb on pump stem to midway point.



16.1.1.  **Warning:** Prior to advancing the catheter lock, ensure that the catheter is properly positioned on the pump stem. The catheter must be straight with no sign of kinking prior to advancing the catheter lock. A slight pull on the catheter is sufficient to straighten it. Advancing the catheter lock over a kinked catheter may damage the catheter.

17. Advance the catheter lock until it clicks into place, ensuring that the radiopaque band is distal to the pump.



18. Once the catheter and lock are connected, if disconnection and reconnection are required, trim 2-3 cm of the catheter end to ensure a secure connection.

**Caution:** Always cut the catheter as close to the pump stem as possible to avoid excessive stretching. Excessive stretching may damage the catheter.

19. Place the pump in the subcutaneous pocket away from the incision line about 2.5 cm (1 in.) beneath the skin surface. The pump should be positioned so that the Catheter Access septum is medial. This allows the catheter a direct line to the spine and keeps this area away from the ribs.
20. Secure to the underlying fascia using one non-absorbable, monofilament suture per pump suture hole. This will reduce the risk of pump migration and the possibility of the pump rotating or flipping over.
21. Verify that the catheter is not kinked or constrained by the pump sutures.
22. After suturing the pump in the pocket, flush the wound with an appropriate antibiotic solution.
23. Close the incision site so that the pump does not lie beneath the incision.
24. Flush the paravertebral site with an appropriate antibiotic solution.
25. Close the entry site making sure the catheter remains straight.
26. Measure and record in the patient's records the length of intrathecal catheter that was trimmed off. This measurement is required to determine the volume of the implanted catheter.
27. Calculate and record the implanted catheter length and volume:

Implanted Catheter Length (cm) = 110 cm – Trimmed Catheter Length (cm)

Implanted Catheter Volume (mL) = Implanted Catheter Length (cm) x 0.0026 mL/cm



**Warning: Always measure and record the length of the trimmed portion of the catheter, and calculate and record the implanted catheter length and volume. These calculations are required to prevent under- or over-medication.**

### Patient Implant Card and Registration

Included with each Prometra Programmable Pump package is a Patient Implant Tracking/Registration Form. This pre-addressed form should be completed and returned to Flowonix Medical, Inc. Flowonix Medical will use this information to create a record of the implant in their database. A copy should also be placed in the patient's implant records.

A patient guide and two patient implant cards are also provided for the patient. The patient implant card contains information pertinent to the implanted Intrathecal Catheter and Prometra Programmable Pump. The implant card should be carried by the patient at all times. A second card is provided for placement in their glovebox, to be given to a caregiver, or other easily accessible location.

### **Catheter and Pump Explantation**

The Intrathecal Catheter and Prometra Programmable Pump should only be explanted in accordance with the hospital procedures. Explanted product is to be treated as a biohazard.



**Warning: Prior to cremation, the pump should always be explanted. The pump will explode at high temperatures.**

### **Calculations**

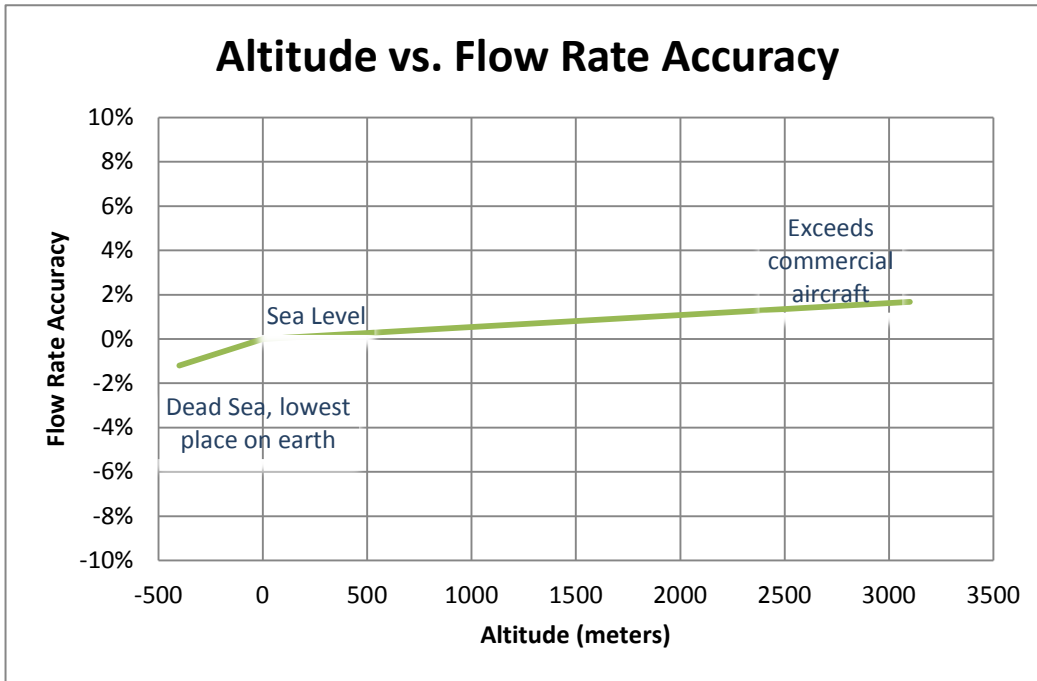
Please refer to supplementary **Calculations Guide**.

## Patient-Related Variables and Flow Rate Accuracy

The Prometra Pump was designed such that changes in pressure or temperature in normal operating environments do not affect the pump's operation.

### Geographical Elevation

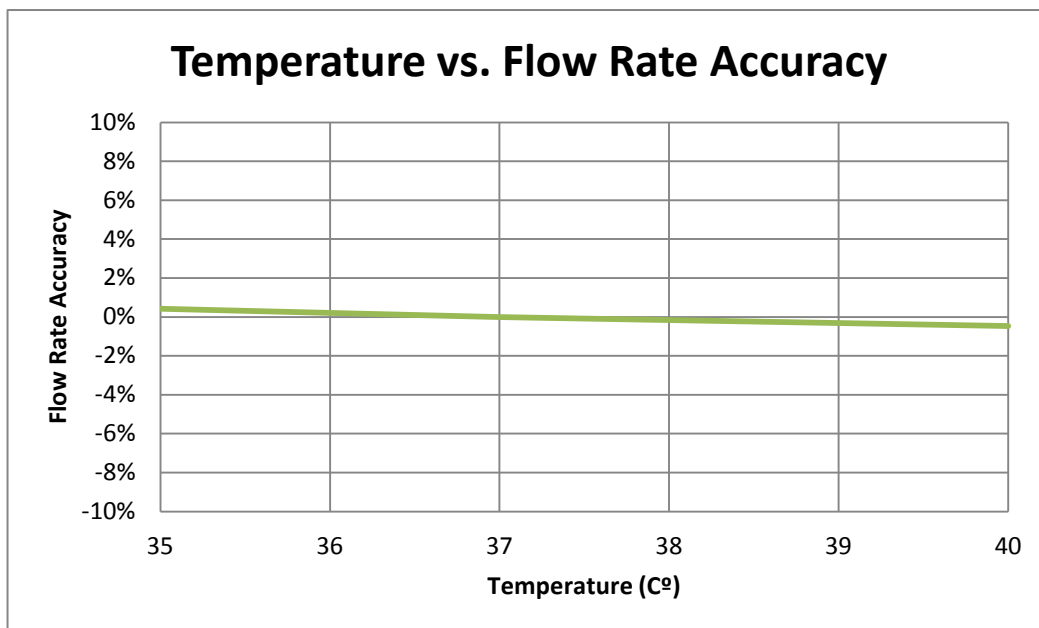
Activities that involve temperature or elevation changes such as skiing, flying, hot-tubbing, or saunas will not affect the operation of the pump.



Activities that involve an increase in environmental pressure of approximately 1 atmosphere or greater, such as scuba diving or hyperbaric therapy may cause the pump to temporarily stop delivering drug. When normal atmospheric pressure is returned, the pump will resume its programmed delivery rate.

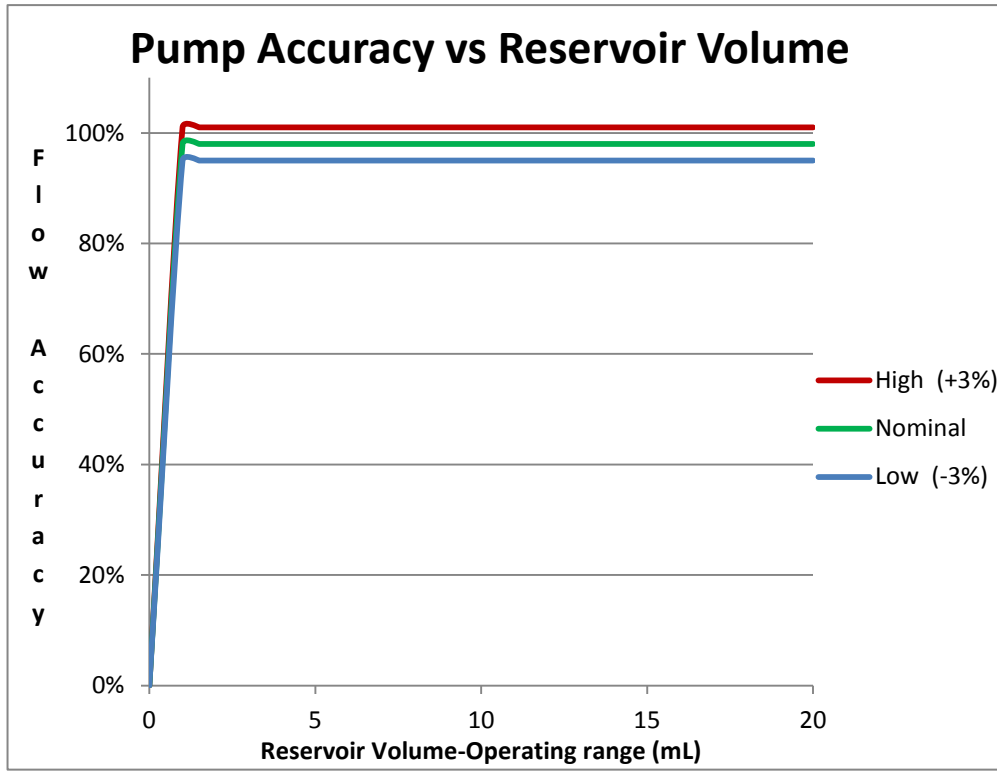
## Temperature Variation

Activities that involve temperature or elevation changes such as skiing, flying, hot-tubbing, or saunas will not affect the operation of the pump. Temperature related therapies such as deep heat therapy, e.g. diathermy, will not affect the operation of the pump.



### Flow Rate Accuracy to 1 mL Refill Volume

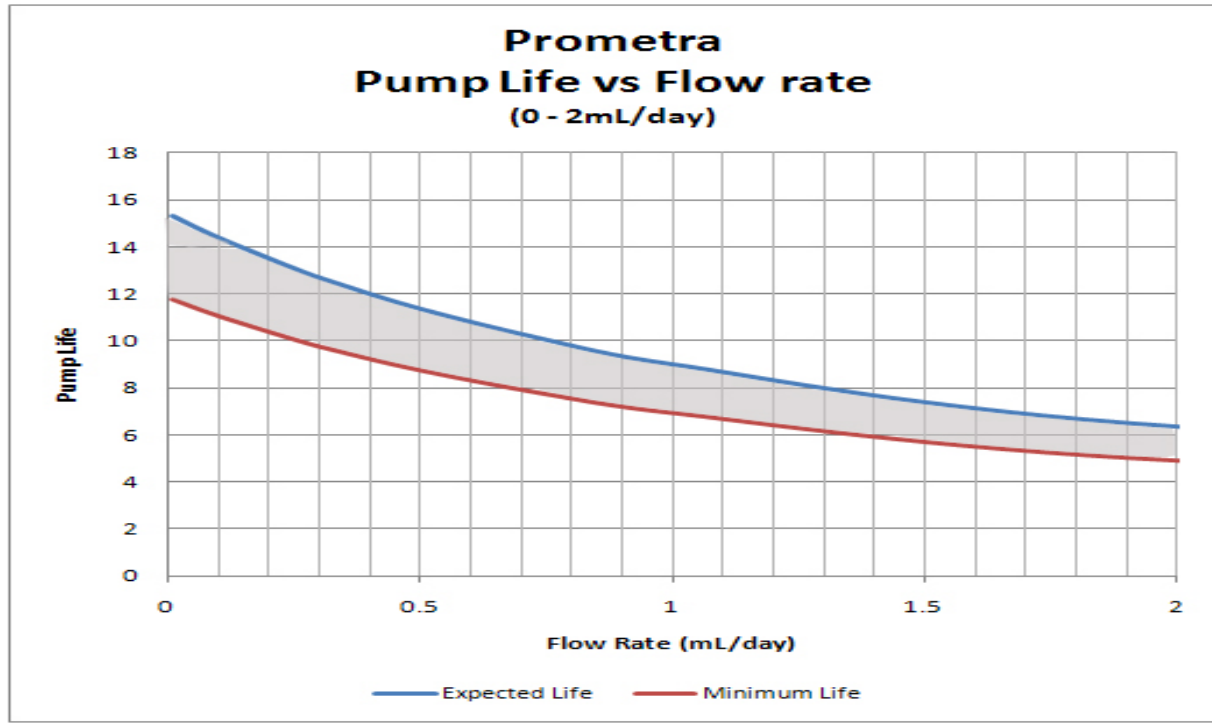
Although it is strongly recommended to program the low reservoir volume alarm to 2 mL, it is important to know that reservoir volume down to 1 mL will not affect the operation of the pump. This margin of safety was designed to offer your patients an additional measure of comfort and safety.



Pump flow rate accuracy was evaluated at multiple infusion rates ( $\approx 0.05\text{mL/day} - 28.8\text{mL/day}$ ), at  $37^\circ\text{C}$  body temperature, utilizing both constant flow and variable flow regimes.

## Device Longevity

The useful life of the Prometra Programmable Pump is dependent on the drug delivery rate. The Prometra pump utilizes an accumulator and dual-gated valve system to regulate the flow rate in order to conserve energy required for pump operation. The life of the pump is a minimum of 10 years at a drug delivery rate of 0.25mL/day.



## IMPLANTABLES WARRANTY

An issued or revision date for these instructions is included for the user's information. In the event two years have elapsed between this date and product use, the user should contact Flowonix Medical, Inc. to see if additional product information is available.

Flowonix Medical, Inc. ("Flowonix") warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase, and liability under this limited product warranty will be limited to repairing or replacing the defective product, at Flowonix's sole discretion, or refunding the net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

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Manufactured by:  
Flowonix Medical Inc.  
500 International Drive, Suite 200  
Mount Olive, NJ 07828 USA  
T +1.973.426.9229  
F +1.973.426.0035  
flowonix.com



EMERGO EUROPE  
Prinsessegracht 20  
2514 AP The Hague  
The Netherlands



Year of Authorization: 2010

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