

Prometra® and Prometra® II Programmable Pumps Magnetic Resonance Imaging (MRI) Safety Information

GENERAL



MR Conditional



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.



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



Warning: EMPTY ALL DRUG SOLUTION FROM BOTH PROMETRA AND PROMETRA II PUMPS PRIOR TO ENTERING THE MRI ENVIRONMENT. If a patient with a Prometra II Pump requires an emergent MRI, please see page 5 of these instructions for more details on the potential risks involved.

Strong magnetic fields, such as those created in MRI scanners, may cause the Inlet and Outlet Valves to open, resulting in the immediate discharge of the contents of the Drug Reservoir and Catheter into the patient. This could result in drug overdose that could lead to serious patient injury or death.

Prior to initiating the MRI procedure, the physician must determine if the patient can 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.

Note: Pre-MRI, Post-MRI, and Medical Emergency Use instructions are provided in this document.

SCANNING PARAMETERS

Non-clinical testing has demonstrated that the Prometra and Prometra II Programmable Pumps are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

1. Static magnetic field of 1.5 T
2. Maximum spatial field gradient of 1,900 gauss/cm (19 T/m)



Warning: Exceeding the 1,900 gauss/cm (19T/m) at 1.5T limit could result in excessive force or torque which could lead to patient injury.

3. Maximum MR System reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) using body coil transmission.
4. Scan duration should be limited to 10 minutes per pulse sequence.
5. All Pre-MRI Instructions must be completed.



NOTE: The MRI conditions for safe scanning detailed in this document only pertain to the Prometra Pumps 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 Adjacent to Implant during MR Scans

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.



Warning: Static Magnetic Field

In a 1.5 Tesla 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 a tugging and/or vibration sensation at the implant site when placed within the magnetic field. An elastic garment or wrap will help restrict movement and reduce these sensations while the patient is in the magnetic field.

Image Artifacts

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

In non-clinical testing, the image artifact caused by Flowonix Medical's Prometra II 20 mL Pumps extends approximately 18.5 cm from the device when imaged with a spin-echo or gradient-echo pulse sequence in a 1.5 T MRI system. Image artifacts may be reduced when sequences are 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.

SPECIFIC PRE-MRI INSTRUCTIONS



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Prometra® (REF 11827) and Prometra® II (REF 13827) Programmable Pumps

Protocol for Prometra® (REF 11827) and Prometra® II (REF 13827) Programmable Pumps *Pre-MRI Procedure*



Warning: EMPTY ALL DRUG SOLUTION FROM BOTH PROMETRA AND PROMETRA II PUMPS PRIOR TO ENTERING THE MRI ENVIRONMENT. If a patient with a Prometra II Pump requires an emergent MRI, please see page 5 of these instructions for more details on the potential risks involved.

Strong magnetic fields, such as those created in MRI scanners, may cause the Inlet and Outlet valves to open, resulting in the immediate discharge of the contents of the Drug Reservoir and Catheter into the patient. This could result in drug overdose that could lead to serious patient injury or death.

The physician must determine if the patient can safely be deprived of medication during the MRI procedure. If medication is needed then alternative means of drug delivery (such as I.V. administration or analgesic patch) should be employed.

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.

PERFORM THE FOLLOWING STEPS PRIOR TO ENTERING THE MRI ENVIRONMENT.

1. Pump Inquiry

Inquire the pump with the programmer to verify pump model, the pump is operational and without errors. Print inquiry page.



WARNING: IF PUMP STATUS CANNOT BE PROPERLY CONFIRMED, DO NOT PROCEED SINCE THE PUMP MAY NOT BE OPERATING PROPERLY, PLEASE CONTACT FLOWONIX TECHNICAL SOLUTIONS FOR ASSISTANCE AT: 855-356-9665.

2. Pump Programming

Set the flow mode to a constant flow rate of 0.0 mg/day. Re-inquire the pump and print inquiry page to confirm a constant flow rate of 0.0 mg/day.

3. Empty Drug Reservoir

Follow the procedures for emptying the Drug Reservoir in the Refill Kit Instructions for Use.

SPECIFIC POST-MRI INSTRUCTIONS

Protocol for Prometra® (REF 11827) and Prometra® II (REF 13827) Programmable Pumps *Post-MRI Procedure*

1. Confirm Pump Operational Status –

- a. Inquire the pump with the programmer to verify pump operation and settings.
- b. Confirm that settings are unchanged from the Pre-MRI settings, e.g., flow rate must be 0.0 mg/day.
- c. If the programmer displays any pump errors, proceed to Step 2 “Clear Pump Errors”.
- d. If no pump errors are displayed, proceed to Step 3 “Inlet and Outlet Valve Closure Confirmation”.



WARNING: IF PUMP STATUS CANNOT BE PROPERLY CONFIRMED, DO NOT PROCEED SINCE THE PUMP MAY NOT BE OPERATING PROPERLY, PLEASE CONTACT FLOWONIX TECHNICAL SOLUTIONS FOR ASSISTANCE AT: 855-356-9665.

2. Clear Pump Errors

- a. If pump errors are displayed from the Inquiry performed in Step 1, perform an Emergency Pump Stop using the programmer, and contact Flowonix Technical Solutions for assistance 855-356-9665.
- b. If pump errors are cleared, proceed to Step 3.

3. Confirm Inlet / Outlet Valve Closure

- a. Attempt to aspirate the Drug Reservoir through the Refill Port. To aspirate, attach the 22G non-coring needle (available in Refill Kit) to a sterile syringe.
- b. Advance needle through center Refill Port Septum until needle tip resides completely inside the Drug Reservoir.
- c. Pull a vacuum with the syringe for approximately 10 to 30 seconds to confirm Inlet / Outlet Valve closure.



Warning: If any significant volume (>1ml) is retrieved, it may be indicative that the pump Inlet / Outlet Valves are open, providing direct access to the catheter/cerebral spinal fluid; If so, DO NOT proceed with the refill since the pump may not be operating properly. The pump may need to be explanted and replaced. For questions, Contact Flowonix Technical Solutions for assistance at: 855-356-9665.

4. Refill The Drug Reservoir

- a. Proceed to refill the Drug Reservoir in accordance with the refill procedure 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 prescribing information of the drug.

IN THE EVENT OF A MEDICAL EMERGENCY REQUIRING AN MRI SCAN:

Prometra® Programmable Pump (REF 11827)

Medication **MUST** be removed from the Prometra® Pump REF 11827. Do not expose patient to MRI magnetic fields with drug in the Prometra Drug Reservoir, even in the event of a medical emergency. Follow instructions above (Pre-MRI) for removing drug from the Prometra Pump.



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.

Prometra® II Programmable Pump (REF 13827)

In the event of a medical emergency requiring a STAT MRI, the treating physician must be aware of the following as inputs to decision making regarding proceeding with an Emergency MRI for the Prometra II Pump (REF 13827):



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.



WARNING: In the event an MRI scan was performed on a patient with a **Prometra® II Pump** where the drug was NOT removed due to a medical emergency situation, the **Prometra® II Pump** contains a Flow Activated Valve (FAV) intended to reduce, but not eliminate, the risk of drug overdose. A physician must evaluate the patient immediately for signs and symptoms of drug overdose and develop a plan for immediate monitoring in a medically supervised and adequately equipped environment. Resuscitative equipment should be available, as should medications to manage drug overdose.

FLOWONIX STRONGLY RECOMMENDS THAT ALL DRUG BE REMOVED FROM THE PROMETRA® II DRUG RESERVOIR PRIOR TO ANY MRI SCAN.

The Prometra® II Pump includes a Flow Activated Valve (FAV) intended to reduce, but not eliminate, the risk of drug over-infusion during an MRI procedure.

If the Drug Reservoir volume is $\leq 1\text{mL}$ or expected to be $\leq 1\text{mL}$ at the time of the Emergency MRI scan, do not proceed with an Emergency MRI scan without first emptying the drug from the Reservoir. If there is $\leq 1\text{mL}$ of drug in **the Reservoir, the drug must be removed prior to the Emergency MRI procedure. When the Reservoir volume is at $< 1\text{ mL}$, the FAV may not close.** Thus, the drug within the Reservoir may be bolused to the patient. This could result in drug overdose that could lead to serious patient injury or death. To determine the volume of drug in the Reservoir, inquire the pump with a Prometra® Programmer. The Reservoir volume is shown on the inquiry screens. **If a Programmer is not available, then all drug must be removed from the Drug Reservoir prior to the Emergency MRI scan.**

The Flow Activated Valve (FAV) of the Prometra® II Pump is intended to shut off drug flow when exposed to strong magnetic fields. When this occurs a small amount of drug, $\leq 10 \mu\text{L}$, will be delivered to the patient. **The physician must determine if the patient can safely receive this 10 μL bolus dose during the Emergency MRI procedure^(1,2).** If not, then all drug must be completely emptied from the Drug Reservoir prior to the Emergency MRI procedure.



NOTE:

1. For a pump containing Infumorph® at a concentration of 25 mg/mL, a bolus dose of < 0.25 mg would be delivered to the patient during an Emergency MRI procedure if the drug was not removed from the Drug Reservoir prior to the MRI.
2. For a pump containing baclofen at a concentration of 0.5 mg/mL, 1 mg/mL and 2 mg/mL, a bolus dose of < 5 μg , 10 μg , and 20 μg , respectively, would be delivered to the patient during an Emergency MRI procedure if the drug was not removed from the Drug Reservoir prior to the MRI.

Following an MRI, the FAV will be closed, and will prevent further drug delivery to occur until the pump is manually reset after the completion of the MRI procedure. **The physician must determine if the patient can safely be deprived of medication until the FAV is reset after the MRI procedure.** If medication is needed, then alternate means of drug delivery (such as I.V. administration or analgesic patch) should be employed keeping in mind that the patient will be receiving up to a 10 μL bolus of drug during the Emergency MRI if drug was not removed from the Reservoir prior to the MRI procedure.

In the event that an Emergency MRI scan was performed on a patient with a Prometra® II pump in which the drug was NOT removed due to a medical emergency situation, the Prometra II FAV must be reset by performing a reset procedure.

¹Per Deer et al., Polyanalgesic Consensus Conference 2012: Recommendation for the Management of Pain by Intrathecal (Intraspinal) Drug Delivery: Report of an Interdisciplinary Expert Panel, bolus doses of 5%-20% of the daily dose are typical, but cautions that doses are additive to baseline infusion and cumulative side effects could occur.

²Lioresal (Baclofen Injection) Instructions for Use. Medtronic, Inc., Minneapolis, MN; Gablofen (Baclofen Injection) Instruction for Use. Mallinckrodt Pharmaceuticals, Inc., Hazelwood, MO.

Emergency Procedure PRE-MRI Steps for Prometra II Pump

1. Pump Inquiry

- a. Inquire the pump with the programmer to verify pump model, the pump is operational and without errors.
- b. Verify that more than 1mL of drug is present in the Drug Reservoir.
- c. Print inquiry page.



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2. Pump Programming

- a. Set the flow mode to a constant flow rate of 0.0 mg/day.
- b. Re-inquire the pump and print inquiry page to confirm a constant flow rate of 0.0 mg/day.

Emergency Procedure POST-MRI Steps for Prometra II Pump

1. Confirm Pump Operational Status –

- a. Inquire the pump with the programmer to verify pump operation and settings.
- b. Confirm that settings are unchanged from the Pre-MRI settings, e.g., flow rate must be 0.0 mg/day.
- c. If the programmer displays any pump errors, proceed to Step 2 “Clear Pump Errors”.
- d. If no pump errors are displayed, proceed to Step 3 “FAV Reset Procedure”.



WARNING: IF PUMP STATUS CANNOT BE PROPERLY CONFIRMED, DO NOT PROCEED SINCE THE PUMP MAY NOT BE OPERATING PROPERLY, PLEASE CONTACT FLOWONIX TECHNICAL SOLUTIONS FOR ASSISTANCE AT: 855-356-9665.

2. Clear Pump Errors

- a. If pump errors are displayed from the Inquiry performed in Step 1, perform an Emergency Pump Stop using the programmer, and contact Flowonix Technical Solutions for assistance 855-356-9665.
- b. If pump errors are cleared, proceed to Step 3.

3. FAV Reset Procedure

- a. Remove drug from Drug Reservoir by aspirating through the Refill Port.
- b. To aspirate, attach the 22G non-coring needle to a syringe barrel (available in Refill Kit).
- c. Advance needle through the center Refill Port Septum until needle tip resides completely inside the Drug Reservoir.

- d. Empty the Drug Reservoir until there is no more fluid returning to the syringe barrel. (Refer to Refill Kit Instructions for Use for further details on emptying the pump).
- e. After ensuring the Drug Reservoir is fully empty, program a Demand Bolus to deliver (0.03 mL x concentration) over 2 minutes (this will not dispense drug since the Drug Reservoir is empty).
- f. Wait for the 2-minute Demand Bolus to complete before proceeding.

4. Confirm Inlet / Outlet Valve Closure

- a. Attempt to aspirate the Drug Reservoir through the Refill Port. To aspirate, attach a sterile syringe to the 22G non-coring needle used in Step 3c above.
- b. Pull a vacuum with the syringe for approximately 10 to 30 seconds to confirm Inlet / Outlet Valve closure.



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

For questions, Contact Flowonix Technical Solutions for assistance at: 855-356-9665.

5. Refill The Drug Reservoir

- a. Proceed to refill the Drug Reservoir in accordance with the refill procedure 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 prescribing information of the drug.

Pump Model Determination

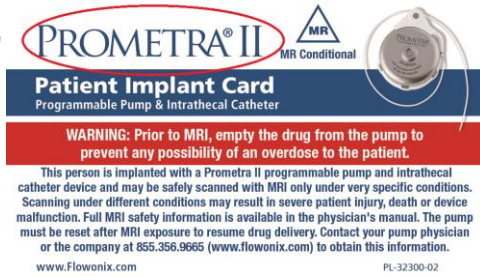
To identify the pump model prior to an Emergency MRI scan use the following methods:

- **Inquiry by programmer:** Identifies model either as **Prometra®** or **Prometra® II** on the Programmer's Inquiry Screen. Contact Flowonix Technical Solutions at 855-356-9665 if you require access to a Flowonix Programmer.
- **Patient ID Card:** Identifies the pump model either as **Prometra® II** (Model # **13827**) or **Prometra®** (Model # **11827**) as noted in the examples on the following page.

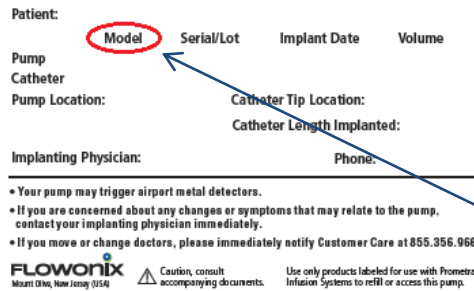


- **Note:** Patients with **Prometra®** and **Prometra® II Pumps** also have Medical Alert bracelets that indicate that the pump must be emptied prior to an MRI.
- **Contact patient's pump management physician:** The patient's medical records indicate the pump model and serial number implanted. **Flowonix provides medical chart labels to facilitate patient record documentation.**
- **Pump serial number:** There is a distinct difference in the serial numbers for the Prometra® Pump versus the Prometra® II Pump. The Prometra® II pump's serial number ends with an X, while the Prometra® Pump's serial number ends with a number.
- **Contact Flowonix Technical Solutions at 855-356-9665:** Pump information may be determined from our patient registration system. **This number is staffed 24 hours a day.**
- **Perform an X-ray of the pump:** The Prometra® II pump can be differentiated from the Prometra® Pump via X-rays as shown on the following page. The image of the Prometra® II Pump shows the addition of the flow-activated valve (FAV) within the Catheter Access Port.

Prometra® II Pump Patient ID Card



Card Front

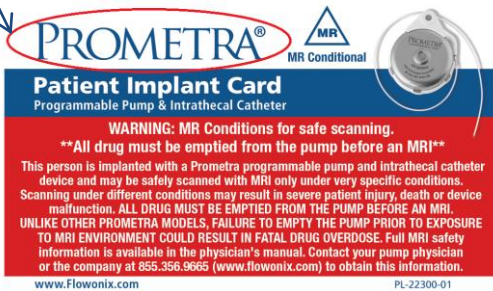


Card Back

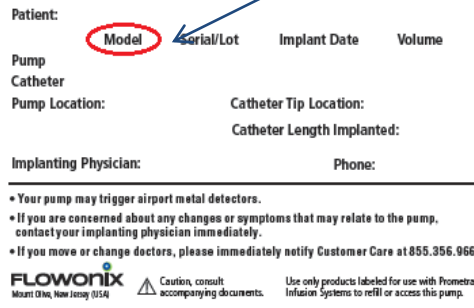
Pump Model Identification

Pump Model Identification

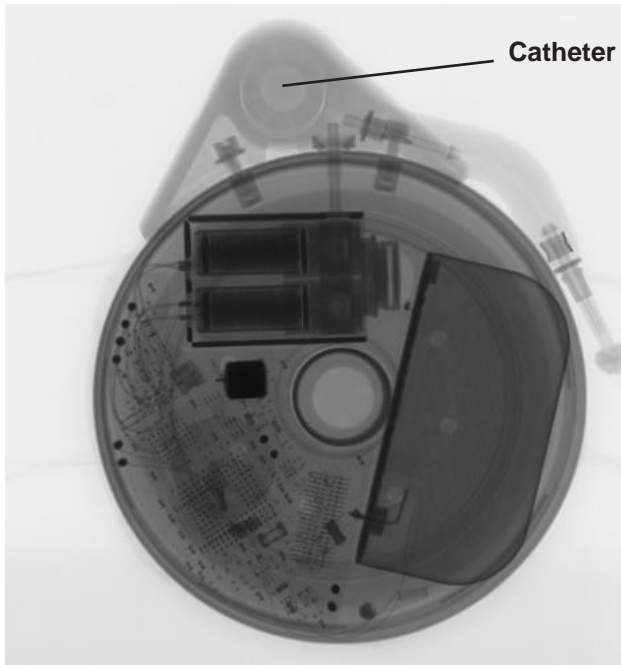
Prometra® Pump Patient ID Card



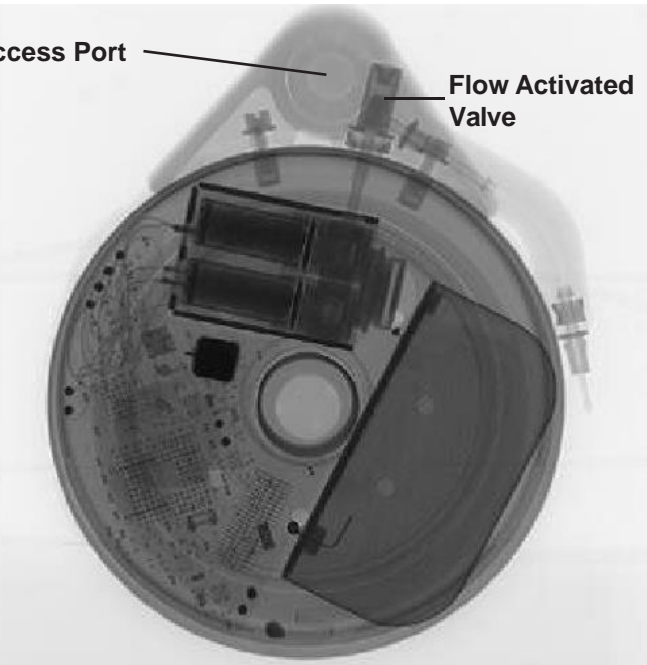
Card Front



Card Back



Prometra® Pump X-ray



Prometra® II Pump X-ray