Prometra® II Programmable Pump
Magnetic Resonance Imaging (MRI) Conditions for Safe Scanning

MR Conditional

Prior to performing an MRI on a patient with a Flowonix pump implanted, the **exact PUMP MODEL** must be identified, since the pre-MRI and post-MRI procedures differ significantly for each pump model.

If the pump model **CANNOT** be determined **OR** it is identified as a Prometra Pump, then the **PUMP MUST BE EMPTIED** of drug solution prior to entering the MRI environment. Strong magnetic fields, such as those created in MRI scanners, may cause the Prometra Pump 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.

Pump Model Determination

The pump model can be identified by one of the following methods:

- **Inquiry by programmer**: Identifies model either as Prometra or Prometra II on the Programmer’s Inquiry Screen. Contact Flowonix Customer Care 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 below:

**Note**: Patients with Prometra Pumps also have Medical Alert bracelets that indicate they have a Prometra Pump and 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 Customer Care at 855-356-9665: Pump information may be determined from our patient registration system. This number is manned 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 in Figures 1 and 2. The image of the Prometra II Pump, Figure 2, shows the addition of the flow-activated valve within the Catheter Access Port.

If the model is positively identified as a Prometra II, then proceed with the following MRI instructions:

Pre MRI Procedures

During an MRI, the FAV of the Prometra II Pump will shut off drug flow. When this occurs a small amount, \( \leq 10 \mu l \), is delivered. The physician should determine if the patient can safely receive this bolus dose during the MRI procedure.\(^1\) If not, then the drug should be completely emptied from the pump’s drug reservoir prior to the MRI procedure.

**Note:** For a pump containing Infumorph at the highest available concentration of 25 mg/ml, a bolus dose of \( \leq 0.25 \text{ mg} \) would be delivered to the patient during the MRI procedure.

Additionally, the FAV safety valve will prevent further drug delivery to occur until the pump is manually reset after the completion of the MRI procedure. The physician should determine if the patient can safely be deprived of pain medication until the pump is reset after the MRI procedure. If pain 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 during the MRI.

\(^1\) Per Deer et al., Polyanalygesic 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.
Do not proceed with an MRI scan if the reservoir volume is expected to be ≤1ml at the time of the MRI scan. If there is ≤1ml of drug in the reservoir, it should be removed prior to the procedure. When the reservoir volume is at < 1 ml, the safety valve 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.

**MRI Scanning Parameters**

The Prometra II Programmable Pumps are MR Conditional. They can be scanned safely under the following conditions:

- A static magnetic field of 1.5 Tesla
- A maximum spatial gradient field of 410 Gauss/cm
- A maximum whole body averaged specific absorption rate (SAR) of 2W/kg for 20 minutes of scanning in the Normal Operating Mode.

In non-clinical testing, the Prometra\(^2\) 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, therefore the Prometra II will experience a similar maximum temperature rise under the same MR scanning conditions.

**Static Magnetic Field**

In a 1.5 T MR environment, the pump has a significant magnetically induced deflection force and very strong torque; 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 slight tugging sensation at the implant site when placed within the magnetic field. An elastic garment or wrap will help restrict movement and reduce the sensation the patient may experience while 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.

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 II 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.

\(^2\) There are no changes between the Prometra pump and Prometra II pump that would significantly affect the ASTM MRI testing and MRI Scanning Parameters.
Post MRI Procedures

1. Confirmation of Pump Operational Status
   a) 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 Reset”.

   **Warning:** If pump status cannot be properly confirmed, **DO NOT** proceed since the pump may not be operating properly, please contact customer care for assistance: 855-356-9665.

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: 855-356-9665.

3. Pump Reset
   a) Aspirate the pump reservoir 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 center refill septum until needle tip resides completely inside the drug refill reservoir.
   d) Empty the pump 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) Once the pump is fully empty, program a demand bolus to deliver (0.03ml * concentration) over 2 minutes (this will not displace drug since the reservoir is empty)
   f) Wait for the 2 minute Demand Bolus to complete before proceeding to refill.

4. Refill Procedure
   a) Proceed to refill the pump 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 Infumorph’s prescribing information.