

PROMETRA MRI REFERENCE GUIDE: MRI CONDITIONS FOR SAFE SCANNING FOR THE PROMETRA INTRATHECAL PUMP

IMPORTANT INFORMATION FOR CLINICIANS, MRI OPERATORS AND PATIENTS

For full instructions, warnings and precautions related to the Prometra Programmable Pump System, please refer to the complete Prometra Pump Instructions for Use.



MR CONDITIONAL

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 by 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 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 a 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 non-clinical testing was performed using the ASTM F2119 GRE and SE sequences in a 1.5T Phillips Medical Systems Intera (Software release 12.6.4.3, 2010-012-02) 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

Confirmation of Pump Operational Status

1. Pump Inquiry

Upon completion of an MRI procedure, inquire the pump with the programmer to verify pump operations 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 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 an 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 Customer Care for assistance: +1 844-229-6729

3. Pump Aspiration

- a. Once the pump status and flow rate are 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.