

# TECHNICAL BULLETIN

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## The use of ON-Q\* in the Magnetic Resonance (MR) environment

This technical bulletin is intended to verify the safety profile of the ON-Q\* Pain Management System in the MR environment.

The term "MR safe" as defined by the American Society for Testing and Materials (ASTM), means: "The device, when used in the MR environment, has been demonstrated to present no additional risk to the patient or other individuals, but may affect the quality of the diagnostic information."

### Testing Methods:

Testing for magnetic field interactions was conducted by an outside laboratory according to ASTM guidelines F 2052-02 to determine translational attraction and torque using a 3-Tesla MR system (General Electric Medical Systems, Milwaukee, WI.). Products tested were categorized as MR Conditional, or MR Unsafe.

### MR Safe Devices: ON-Q Elastomeric Pump, ON-Q Elastomeric Pump with Select-a-Flow\* and ON-Q\* Catheters.

This device has a minimal amount of nonferromagnetic metallic material. Through non-clinical testing, the catheter has been shown to be MR safe for patients undergoing examinations using MR systems operating at static magnetic field strengths of 3-Tesla or less. There are no magnetic field interactions ( i.e. magnetically induced displacement force and magnetically induced torque), no MRI-related heating. The artifacts are highly unlikely to present problems if the MR imaging area of interest is in or near the area where this device is located. Testing has not been performed at field strengths higher than 3-Tesla.

### MR Conditional Devices: ON-Q\* Elastomeric pump with ONDEMAND\* Bolus

These devices are used external to the body and the bolus device has a minimal amount of metallic material, which is isolated and insulated from the patient. Through non-clinical testing, these products have been shown to be MR safe for patients undergoing examinations using MR systems operating at static magnetic field strengths of 3-Tesla or less. There are minor magnetic field interactions present at 3-Tesla. Therefore, it is advisable to secure these devices by suitable means (e.g. adhesive tape) while in the 3-Tesla MRI environment. Since these devices are external to the body with minimal metallic material, MR-related heating is not a safety concern. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the device. Testing has not been performed at field strengths higher than 3-Tesla.

### MR Unsafe Devices: E-Clip Accessory and Carry Case.

The E-clip exhibits substantial magnetic field interactions in a 1.5-Tesla MR environment. **Therefore, the E-Clip must be removed from the pump before entering the MR environment.**

Additional Note: The carrying case that is provided as an accessory for the larger volume ON-Q pumps was not tested for MR safety. This pouch contains a metal grip on the zipper, and therefore should be removed prior to MR testing.

Conclusion:

Halyard, ON-Q\* products, excluding the E-Clip accessory and the carrying case, are deemed MR safe or MR conditional up to a 3- Tesla magnetic field. Halyard recommends removing the E-Clip and the Carrying Case, if present, from the pump prior to MR testing.

Note: The function of the pumps before and after exposure to MR was not a part of this safety testing.

 MR SAFE	 MR CONDITIONAL	 MR UNSAFE
An item that poses no known hazards in all MR environments.	An item that has demonstrated to pose no known hazards in a specified MR environment with specified conditions of use.	An item that is known to pose hazards in all MR environments.

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There are inherent risks in all medical devices. Please refer to the product labeling for **Indications, Cautions, Warnings and Contraindications**. Failure to follow the product labeling could directly impact patient safety. Physician is responsible for prescribing and administering medications per instructions provided by the drug manufacturer. Refer to [www.halyardhealth.com](http://www.halyardhealth.com) for additional product safety **Technical Bulletins**.

Please contact the Clinical Services Department at 800-444-2728 or 949-923-2400 if you have any questions regarding this information.