Programmable Infusion Pump and Catheter: Evaluation Using 3-Tesla Magnetic Resonance Imaging

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ABSTRACT

Objective. This study assessed 3-Tesla magnetic resonance imaging (MRI) issues for a programmable infusion pump and associated catheters. Methods. A programmable infusion pump and associated catheters (MedStream Programmable Infusion Pump, 40 mL; SureStream TI Coil-Reinforced Intraspinal Catheter; SureStream TI Connector; and SureStream Silicone Catheter; Codman and Shurtleff Inc., a Johnson & Johnson Company, Raynham, MA, USA) underwent evaluation for magnetic field interactions (deflection angle and torque), heating (transmit/receive body radiofrequency coil; whole-body averaged specific absorption rate, 3 W/kg for 15 min), functional changes (before and after MRI using eight different MRI conditions), and artifacts (T1-weighted spin-echo and gradient-echo pulse sequences) at 3-Tesla. Results. The programmable infusion pump and associated catheters exhibited minor magnetic field interactions. Heating was not excessive (≤1.9°), especially considering the experimental conditions used for this evaluation (ie, relatively high radiofrequency power/specifc absorption rate level and use of a nonperfused phantom). The function of three of six pumps was temporarily altered by exposures to 3-Tesla MRI conditions. Reset was achieved in each case. Artifacts were relatively large for the pump and minor for the catheter. Conclusions. The programmable infusion pump and catheters will not pose increased risk to a patient examined using 3-Tesla MRI as long as specific safety guidelines are followed, which includes interrogation of the pump post-MRI to ensure proper settings. Artifacts for the programmable infusion pump may impact the diagnostic use of MRI if the area of interest is in the same area or near the device.

KEY WORDS: Artifacts, catheter, heating, implants, magnetic resonance imaging (MRI), MRI safety, pump.

Introduction

Implanted, programmable infusion pumps and associated catheters are used for intrathecal or intravascular administration of medications such as morphine, baclofen, cisplatin, clindamycin, methotrexate, and others. The use of these devices for “targeted” drug delivery has several advantages including significantly decreasing the dosages used, which appears to reduce drug-related adverse events, and increasing patient mobility (1–6).

Programmable infusion pumps and catheters typically contain metallic components and, thus, have certain features that may be impacted by magnetic resonance imaging...
(MRI) (7), particularly if the procedure is performed at 3-Tesla (8,9). For example, MRI-related electromagnetic fields (static, gradient magnetic, and radiofrequency fields) may displace this implant, generate excessive heating, alter the programmed settings, damage the device, or create substantial artifacts (7–9). To our knowledge, no other programmable infusion pump has undergone evaluated at 3-Tesla. As such, the information provided by this study is particularly timely as there is increased clinical use of 3-Tesla MRI. Therefore, this investigation assessed magnetic field interactions, heating, function, and artifacts for a programmable infusion pump and associated catheters to identify safety issues or other problems in relation to the use of a 3-Tesla scanner.

Materials and Methods

Programmable Infusion Pump and Catheter

The programmable infusion pump (MedStream Programmable Infusion Pump, 40 mL; diameter, 76-mm; overall height, 38.7 mm [Note: there also is a smaller 20-mL version of this pump, accordingly, testing version of the pump represents a worst case with regard to the MRI evaluation]; Codman and Shurtleff Inc., a Johnson & Johnson Company, Raynham, MA, USA) is an implantable, battery-powered device that stores and dispenses drugs according to instructions received from an externally applied programmer/control unit (Fig. 1). The programmer/control unit was not assessed relative to the utilization of MRI because it is not intended for use in the MRI environment. The primary material used for this pump is titanium. Notably, this programmable infusion pump has suture loops that are used to anchor it as it is implanted in a subcutaneous pocket, typically located in the lower abdomen. The catheter (SureStream Coil-Reinforced Intraspinal Catheter, SureStream Connector, and SureStream Silicone Catheter; Codman and Shurtleff Inc., a Johnson & Johnson Company) is part of the infusion system used with the pump to deliver drugs to the intrathecal space (Fig. 1). The programmable infusion pump and associated catheter are indicated for long-term continuous or intermittent drug administration via intrathecal infusion of morphine sulfate in the treatment of chronic intractable pain (benign or malignant) and the intrathecal infusion of baclofen in the treatment of severe spasticity.

The programmable infusion pump functions independently, once it has been programmed. This pump contains three separate chambers: a outer chamber, which contains a chemically inert liquid gas mixture used as a propellant to exert a constant force onto a second chamber serving as the drug reservoir, and a third chamber, which contains electronics, a battery, and a flow regulation system. The pump can be refilled, as needed, by accessing the refill septum via a transcutaneous injection.

The mechanism of action for the programmable infusion pump involves a constant force provided by a propellant gas that pushes the drug out of the reservoir, across a filter, through a flow restrictor and into the valve system. The flow restrictor sets the maximum flow rate and the duty cycle of the valve titrates the flow from the minimum to maximum flow rate. The valve system is activated using a ceramic (nonmagnetic) actuator to minimize the influence of external magnetic fields on the actual flow-control mechanism. The drug passes through the flow regulation system to the outlet. The flow restrictor limits the maximum flow rate that will be delivered by the programmable infusion pump. The remaining drug volume within the reservoir is detected by a fill level sensor, which determines the volume of the reservoir chamber and converts the calculation to determine the remaining drug volume. Importantly, prior published work from our laboratory (10), has demonstrated the use of finite element modeling (ANSYS Emag 9, Canonsburg, PA, USA) to limit susceptibility of the pump electronics to induced voltages created by MRI-related electro-magnetic fields.

Magnetic Field Interactions

Magnetic field interactions were determined for the programmable infusion pump (MedStream Programmable Infusion Pump, 40 mL) (deflection angle and torque) and catheter (SureStream Coil-Reinforced Intraspinal Catheter, SureStream Connector, and SureStream Silicone Catheter; deflection angle, only) using an active-shielded, 3-Tesla MR.
system (Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI, USA).

Translational Attraction
Translational attraction was assessed for the programmable infusion pump and catheter using the deflection angle method, as previously described (11–16). The device (ie, the programmable infusion pump with the catheter wound around it to facilitate testing) was attached to a test fixture to measure the deflection angle in the 3-Tesla MR system. The test fixture has a protractor with 1-degree graduated markings mounted to the top and a bubble level to ensure proper orientation in the scanner. The device was suspended from the protractor by a 20-cm length of string (weight, less than 1% of the weight of the test object) that was attached at the 0-degree indicator. Measurements were obtained in the 3-Tesla MR system that produced the greatest magnetically induced deflection angle (11–17). This point was determined using gauss line plots, magnetic field measurements, and visual inspection to identify the location of the highest spatial magnetic gradient. For the 3-Tesla MR system, the maximum magnetic spatial gradient is 720 gauss/cm (11–13). The deflection angle from the vertical direction to the nearest 1 degree was measured three times and a mean value was calculated.

Torque
Torque was evaluated for the programmable infusion pump at the center of the 3-Tesla MR system (Achieva, Philips Medical Systems, Best, The Netherlands) according to the method described by the American Society for Testing and Materials (ASTM) International (18) (torque was not assessed for the catheter due to the relatively small amounts of low magnetic susceptibility materials used in the construction of this device). The programmable infusion pump was secured to a special test fixture (nonmagnetic force gauge incorporated with a turntable platform that was mounted on a near-frictionless shaft which was free to rotate). The fixture was placed in the center of the 3-Tesla scanner, where the effect of torque is the known to be the greatest (18). Torques readings were obtained with the programmable infusion pump placed in three different axes (18). Measurements were recorded three times during rotation of the pump 90 degrees in each orientation (18).

Magnetic Resonance Imaging-Related Heating
In vitro experiments were performed at 3-Tesla/128-MHz to determine MRI-related heating for the programmable infusion pump (MedStream Programmable Infusion Pump, 40 mL) (deflection angle and torque) and catheter (SureStream Coil-Reinforced Catheter, SureStream Connector, and SureStream Silicone Catheter), according to a previously described protocol (11–15,19). The device was placed according to its intended in vivo use but also with regard to a worst-case condition, insofar as it was placed close to the edge of a plastic head/torso phantom (dimensions: head portion – width, 16.5 cm; length, 29.2 cm; height, 16.5 cm; torso portion – width, 43.2 cm; length, 61.0 cm; height, 16.5 cm), positioning it close to the transmit radiofrequency (RF) coil (ie, worst case with regard to MRI-related heating for a metallic object) (8,9). The phantom was filled to a depth of 10 cm with a gelling agent in an aqueous solution (ie, 0.8 g/L NaCl plus 5.85 g/L polyacrylic acid in distilled water) (11–15,19). A plastic frame placed on the bottom of the head/torso phantom had small adjustable posts that were used to position the device and to maintain fluoroptic thermometry probes in place (see below) (11–15,19).

Temperatures were recorded using a fluoroptic thermometry system (model 3100, Luxtron, Santa Clara, CA, USA). Fluoroptic thermometry probes (model SFF, 0.5 mm in diameter) were positioned on the device, as follows (ie, to record sites on this implant that would be associated with the greatest heating during MRI): Probe no. 1, sensor portion of the probe placed in contact with the metallic edge of the pump; Probe no. 2, sensor portion of the probe placed in contact with the middle of the pump; and Probe no. 3, sensor portion of the probe placed inside of the distal tip of the SureStream Catheter. In addition, a thermometry probe was placed in the phantom at a position removed (close to the opposite edge of the phantom) from the pump but within the area of MRI, to record a reference temperature during the heating experiment (Probe no. 4). The thermometry system underwent calibration prior to the MRI-related heating experiment and the fluoroptic thermometry probes were visually inspected immediately before and immediately after the experiment to ensure that they were properly positioned, as stated above.

Magnetic resonance imaging was performed on the gelled saline-filled phantom with the device using a 3-Tesla/128-MHz MR system (Excite, Software G3.0-052B, General Electric Healthcare). The body RF coil was used to transmit and receive RF energy. MRI parameters were applied to generate a relatively high level of RF energy at 3-Tesla, as follows: fast spin-echo pulse sequence; axial plane; repetition time, 425 msec; echo time, 14 msec; echo train length, 4; flip angle, 90 degrees; bandwidth, 16 kHz; field of view, 40 cm; imaging matrix, 256 × 256; section thickness, 10 mm; number of section locations, 20; phase direction, anterior to posterior; transmitter gain, 180; imaging time, 15 min. The land-marking position (ie, the center position or anatomic region for the MRI procedure) and section locations were selected to encompass the entire area of the device. The imaging parameters produced an MR system reported value for the whole-body averaged specific absorption rate (SAR) of 3 W/kg. The room temperature and scanner’s bore temperature were at a constant level
throughout the MRI-related heating experiment. After recording baseline temperatures (5 min), MRI was performed for 15 min with temperatures recorded at 10 second intervals. This basic protocol has been utilized to assess MRI-related heating for other devices including programmable cerebral spinal fluid valves, neurostimulation systems, and cardiac pacemakers (11–15).

Effects of 3-Tesla Magnetic Resonance Imaging on Function
The effects of exposing six different programmable infusion pumps (MedStream Programmable Infusion Pump, 40 mL) and catheters (SureStream Silicone Catheter; wound around each pump) to the 3-Tesla static magnetic field (Part 1) and eight different MRI pulse sequences (Part 2) selected to be representative of typical and “extreme” techniques used for clinical MRI examinations (Table 1) was assessed in order to determine if there was a significant change in function for these devices. This procedure followed a protocol similar to that described in previous publications (11–15). The function of the programmable infusion pumps was thoroughly evaluated before and after Part 1 and Part 2 conditions and involved comprehensive evaluations of alarm function, infusion accuracy, and device damage. Device functionalities were assessed using two discrete procedures: 1) a self-test procedure that documents the status of the pump; this activity is conducted by interrogating the pump with the programming/control unit, and 2) a continuous flow assessment, which documents valve function.

Part 1
Six samples of the programmable infusion pumps and catheters were attached in different orientations to a plastic cylindrical phantom (height, 35 cm; diameter, 20 cm) in the following orientations: 1) front end of phantom, front position, 2) front end of phantom, side position, 3) front end of phantom, top position, 4) back end of phantom, front position, 5) back end of phantom, side position, and 6) back end of phantom, top position. The orientations for the devices were selected to encompass possible clinical placement scenarios for this device implanted in a patient undergoing an MRI procedure. The phantom with the attached devices was placed on the patient table of the 3-Tesla MR system, and inserted in (ie, past isocenter and out the back of the scanner to the farthest point) and out (ie, approximately 0.5 m past the opening of the bore of the MR system) of the scanner 10 times. Total exposure time to the 3-Tesla static magnetic field was 20 min.

Part 2
Six samples of the programmable infusion pumps and catheters were attached in different orientations to a plastic

<table>
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<tr>
<th>Pulse sequence</th>
<th>TR (msec)</th>
<th>TE (msec)</th>
<th>Flip angle</th>
<th>Field of view</th>
<th>Matrix size</th>
<th>Section thickness</th>
<th>Section gap</th>
<th>Imaging plane</th>
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<th>Pulse sequence</th>
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<th>TE (msec)</th>
<th>Field of view</th>
<th>Matrix size</th>
<th>Section thickness</th>
<th>Section gap</th>
<th>Imaging plane</th>
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<td></td>
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<td>1 mm</td>
<td>Axial</td>
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<tr>
<td>No. 8 EPI</td>
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<td></td>
<td>48 cm</td>
<td>256 × 256</td>
<td>10 mm</td>
<td>1 mm</td>
<td>Axial</td>
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T1-SE, T1-weighted spin echo; T2-SE, T2-weighted spin echo; T1-FSE, T1-weighted fast spin echo; T2-FSE, T2-weighted fast spin echo; 3D, three-dimensional; FGRE, fast gradient echo; MTC, magnetization transfer contrast; EPI, echo planar imaging; N/A, not applicable; GRE, gradient echo; SE, spin echo; TR, repetition time; TE, echo time.
cylindrical phantom, similar to the procedure used for the 3-Tesla static magnetic field exposure. The cylindrical phantom with the devices was placed into a large container (55 cm, length; 35 cm, width; 30 cm, height), which was filled to a depth of 28 cm with normal saline. MRI was performed as cumulative exposures to the eight different MRI pulse sequences (Table 1). The section locations were selected to encompass all programmable infusion pumps to ensure thorough exposures to the MRI conditions, as previously described (11-15).

**Artifacts**

Artifacts were assessed for the programmable infusion pump (MedStream Programmable Infusion Pump, 40 mL) and catheter (SureStream Coil-reinforced Catheter, SureStream Connector, and SureStream Silicone Catheter) by performing MRI at 3-Tesla (Excite, Software G3.0-052B, General Electric Healthcare) with the device placed inside of a gadolinium-doped, saline fluid-filled phantom, as previously described (11,12,14,15). The device was attached to a plastic frame to facilitate positioning and MRI within the phantom. MRI was conducted using a transmit/receive RF body coil and the following pulse sequence parameters (11,12,14,15): T1-weighted, spin-echo pulse sequence; repetition time, 500 msec; echo time, 20 msec; matrix size, 256 x 256; section thickness, 10 mm; field of view, 40 cm; number of excitations, 2; and gradient echo pulse sequence; repetition time, 100 msec; echo time, 15 msec; flip angle, 30 degrees; matrix size, 256 x 256; section thickness, 10 mm; field of view, 40 cm; number of excitations, 2. The imaging planes were oriented to encompass the long axis and short axis of the device and the frequency encoding direction was parallel to the plane of imaging. Section locations were selected through the device from multiple “scout” MR images to represent the largest- or worst-case artifacts, as previously described (11,12,14,15). Image display parameters (ie, window and level settings, magnification) were used in a consistent manner to facilitate valid measurements of artifact size. Planimetry software was used to measure (accuracy and resolution ± 10%) the cross-sectional area of the largest artifact size, for each pulse sequence and each orientation of the section location (11,12,14,15).

**Results**

The mean deflection angle for the programmable infusion pump and catheter was 29 degrees. The maximum measured torque (ie, taking into consideration all axes of orientations) for the programmable infusion pump was 7 mNm. For the MRI-related heating experiment, the highest temperature changes measured by probe numbers 1, 2, and 3 were 1.9°, 1.2°, and 0.8°, respectively.

Findings for the pre- and post-MRI exposures, functional assessment indicated that three of the six programmable infusion pumps went into a “Stopped Infusion” mode due to a reset event experienced by one of the pump's microprocessors. The transition of the programmable infusion pumps into this mode also was indicated by an audible alarm (ie, beeping) from the pump. The other three pumps continued to function in the infusion mode during and after the MRI exposures. Findings for the flow rate evaluation used to assess the valve opening time information (ie, measuring the pump flow rate by weighing the drug delivered by the pump) indicated that function of the valves of the programmable infusion pumps was not altered by the MRI exposures.

Artifact test results are summarized in Table 2. The artifacts were seen as signal voids that were much larger than the size and shape of the programmable infusion pump and catheter, with the gradient-echo pulse sequence showing larger artifacts than the T1-weighted, spin-echo pulse sequence. An example of the artifact associated with the programmable infusion pump and catheter is shown in Fig. 2.

**Discussion**

Implanted, programmable infusion pumps may present safety issues for patients undergoing MRI (7-9). For example, an advanced search of the Food and Drug Administration’s Manufacturer and User Facility Database database for a commonly used programmable infusion pump (SynchroMed, Medtronic Inc., Minneapolis, MN, USA) was conducted for the years January 1, 2001, through December 31, 2005, to determine the types of device malfunctions reported to the Food and Drug Administration (20). There were 30 reports of device malfunction for this programmable infusion pump. “True” pump malfunction, most often related to motor stall, was the most common complaint (16/30, 53.3%). Of these 16, four (25%) were associated with the patient having been exposed to an MRI procedure or other electromagnetic diagnostic modality. Of note is that this particular pump (SynchroMed, Medtronic Inc.) contains an electromagnetic peristaltic

**Table 2.** Artifacts Sizes for the Programmable Infusion Pump and Catheter (MedStream Programmable Infusion Pump, 40 mL; SureStream Coil-Reinforced Intraspinal Catheter, SureStream Connector, and SureStream Silicone Catheter) Associated With MRI at 3-Tesla

<table>
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<tr>
<th>Pulse sequence</th>
<th>Plane orientation</th>
<th>Signal void size</th>
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<tbody>
<tr>
<td>T1-SE</td>
<td>Long axis</td>
<td>28,570 mm²</td>
</tr>
<tr>
<td>T1-SE</td>
<td>Short axis</td>
<td>27,649 mm²</td>
</tr>
<tr>
<td>GRE</td>
<td>Long axis</td>
<td>39,079 mm²</td>
</tr>
<tr>
<td>GRE</td>
<td>Short axis</td>
<td>40,842 mm³</td>
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</table>

(Plane orientation, imaging plane relative to the device; T1-SE, T1-weighted spine echo; GRE, gradient echo).
motor for the pump mechanism, which may be responsible for the problems associated with MRI. Ideally, from an MRI consideration, the flow-control mechanism for an implanted, programmable infusion pump should not be comprised of components that may be susceptible to the electromagnetic fields used for MRI. The programmable infusion pump (MedStream) evaluated in the present investigation has a flow-control mechanism designed primarily from nonmagnetic materials and, as such, it should operate in an acceptable manner in the MRI environment.

**Magnetic Field Interactions**

The programmable infusion pump and catheter displayed a deflection angle of 29 degrees and torque of 7 mN·m. The deflection angle should be considered in view of the deflection angle measurement recommendation provided by the ASTM International (17), which states: “If the implant deflects less than 45°, then the magnetically induced deflection force is less than the force on the implant due to gravity (its weight). For this condition, it is assumed that any risk imposed by the application of the magnetically induced force is no greater than any risk imposed by normal daily activity in the Earth’s gravitational field.” Therefore, the programmable infusion pump and catheter passed the ASTM International acceptance criteria for deflection angle (less than 45 degrees) with respect to exposure to the 3-Tesla MR system. The torque associated with the programmable infusion pump when compared to that imposed by the normal daily activity in the earth’s gravitational field (calculated to be 146 mN·m) (18) is approximately 21 times greater than the maximum magnetically induced torque on the device (i.e., obtained for the different orientations of the programmable infusion pump), thus, satisfying the specification identified by the ASTM International standard (18). Therefore, the programmable infusion pump and catheter will not present an additional risk or hazard to a patient with regard to translational attraction or rotation. Importantly, stabilization of the programmable infusion pump in situ is typically facilitated by means of sutures applied to holes on the sides of this implant (Fig. 1), providing additional means to prevent magnetic field-related movement from occurring. Notably, because of the lack of substantial magnetic field interactions, patients with this device may be examined by MRI performed at 3-Tesla immediately following implantation.

**Magnetic Resonance Imaging-Related Heating**

The highest temperature change measured for the programmable infusion pump during MRI performed at the 3-Tesla, MR system reported whole body averaged SAR of 3 W/kg for 15 min was 1.9° and 0.8° for the catheter. Notably, these temperature increases were generated in a gelled saline-filled, head/torso phantom that lacked blood flow and, as such, represent an extreme heating condition for this device. During the intended in vivo use of the programmable infusion pump and catheter, this amount of heating will not create adverse physiologic consequences for the patient. Importantly, MRI procedures that involve regions above (e.g., cervical spine, brain) or below (e.g., lower extremities) the site of the programmable infusion pump and catheter will inherently result in considerably less heating (16,21). This maximum value of 1.9° also is lower than the limit of “2° above the normal surrounding body temperature of 37° when implanted” identified by section 17 of International Standards Organization 14708-1:2000 (22).

**Effects of Magnetic Resonance Imaging on Function**

Findings from tests conducted to assess the programmable infusion pumps and catheters demonstrated that three of the six devices went into a “Stopped Infusion” mode, which was indicated by an audible alarm (i.e., the pump beeps every 30 sec and can be heard if near this device). However, the valve function was not altered by the MRI conditions. In response to this situation, a healthcare...
professional has to use the programmer/control unit to interrogate the beeping pump (audible alarm) and to acknowledge the reset event, which then synchronizes the real-time clock. The pump will allow the healthcare professional to restart the infusion only on successful completion of this acknowledgment activity, as synchronizing the clock is essential for delivering a complex infusion profile. Thus, it is necessary to confirm pump status using the programmer/control unit for all pumps after MRI exposure and to reinitiate infusion therapy if it has stopped. Importantly, the programmable infusion pumps did not incur permanent damage in association with MRI at 3-Tesla.

Artifacts
At 3-Tesla, the extent of the signal void associated with the programmable infusion pump and catheter was relatively large in relation to its size and shape. Therefore, if the imaging area of interest is close to or in the same area of this device, the associated artifact may impact the diagnostic use of MRI. Fortunately, careful selection and optimization of imaging parameters applied to 3-Tesla scanning can greatly reduce artifact size for metallic objects and mitigate possible image quality issues (9, 23, 24).

Labeling Information
Over the years, manufacturers have generally used the terms MR Safe and MR Compatible to label both active and passive medical devices. However, it has become clear that these terms are confusing and often used interchangeably or incorrectly (25). Therefore, the ASTM International developed a new set of terms to be used for labeling purposes; the new terms are MR Safe, MR Conditional, and MR Unsafe (26). While the appropriate choice of nonmagnetic materials for the mechanical parts can minimize the ferromagnetic or material composition-based effects of MR electro-magnetic field exposure, it should be noted that the MR susceptibility of the controlling electronic parts and battery included within the implantable device depends on the nature and magnitude of the electro-magnetic fields generated by a MR system. It can therefore be concluded that an active implantable device cannot be MR Safe, because the MR environment is conditionally defined by the MRI sequence parameters and by the MR system specifications; all of which are not controllable at present. As such, the correct term applied to this pump and associated with catheters is MR Conditional with the conditions specified.

Magnetic Resonance Imaging Recommendations
In consideration of the results of the tests conducted to assess the pump (MedStream Programmable Infusion Pump, 40 mL) and associated catheters (SureStream Coil-Reinforced Intraspinal Catheter, SureStream Connector, and SureStream Silicone Catheter) with regard to MRI at 3-Tesla and to take proper precautions to ensure patient safety, the following guidelines are recommended:

1. Patients may undergo MRI exams at 3-Tesla or less immediately after implantation of this pump and catheter after confirmation that cessation of therapy will not negatively impact on the patient. If the cessation of drug therapy will negatively impact the patient but the MRI procedure is still necessary, an alternate means of temporary drug delivery with clinical monitoring should be implemented.

2. Based on the information from this study, while it is not necessary to check the pre-MRI settings for the pump, the need for such a step is left to the discretion of the healthcare professional responsible for the patient. As such, the programmable infusion pump setting would be determined by appropriate personnel using the programming/control unit.

3. The exposure to RF energy should be limited to an MR system-reported, whole-body averaged SAR of 3 W/kg for 15 min for a given pulse sequence applied to the patient.

4. On completion of the MRI examination, the pump parameters should be confirmed and reset, as needed.

5. Exposure to the MR system may cause the programmable pump to alarm. Thus, it is necessary to confirm pump status using the programmer/control unit for all pumps after MRI exposure and to reinitiate infusion therapy if it has stopped. This should be taken into consideration by healthcare professionals with regard to patient management.

Summary and Conclusions
The MedStream programmable infusion pump and associated catheters (SureStream) underwent evaluation for magnetic field interactions, heating, functional changes, and artifacts at 3-Tesla. These devices will not pose increased risk to a patient examined using 3-Tesla MRI as long as specific safety guidelines are followed, which include interrogation of the pump post-MRI to ensure proper settings. Artifacts for the programmable infusion pump may impact the diagnostic use of MRI if the area of interest is in the same area or near the device. Notably, the findings pertain to this programmable infusion pump and catheter, only, and are relative to the MRI conditions used for this evaluation.

Conflict of Interest
The authors reported no conflict of interest.

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22. International Standards Organization (ISO) 14708-1. Implants for surgery—Active implantable medical devices—Part 1: general requirements for safety, marking and for information to be provided by the manufacturer, 2000.


