C MRI procedure

C.1 Performing a Magnetic Resonance Imaging (MRI) procedure

It is important to read the information in this chapter before conducting an MRI scan on a patient with an implanted Reveal DX. Contact your Medtronic representative if you have any questions about the information provided.

C.1.1 MRI conditions for use

MR Conditional – The Reveal DX has been demonstrated to pose no known hazards in a specified MR environment with the conditions of use specified in this section.

Non-clinical testing has demonstrated that the Reveal DX is safe for use in the MRI environment when used according to the instructions provided in this section.

The Reveal DX can be safely scanned in patients under the following conditions:

- Closed bore, cylindrical magnet with static magnetic field must be 1.5 Tesla (T) or 3.0 T.
- Whole body gradient systems with gradient slew rate specification must be ≤200 T/m/s.
- Whole body Specific Absorption Rate (SAR) as reported by the MRI equipment must be ≤2.0 W/kg; head SAR as reported by the MRI equipment must be ≤3.2 W/kg.
- The uninterrupted duration of active scanning (when radio frequency (RF) and gradients are on) over the chest during MRI must not exceed 30 min. If additional chest scans beyond 30 min are necessary, a waiting period of at least 10 min is required.

In non-clinical testing, the device produced a temperature rise of less than 4 °C. A maximum whole body average SAR was used for a 30 min scanning period. In the 1.5 T device (manufacturer Philips, model Intera, software version 2.1.3.2, Field strength B1 of 4.5 µT), the maximum SAR level of 4.0 W/kg was used, which was displayed on the MRI scanner console. In the 3 T device (manufacturer Philips, model Achieva, software version 2.1.3.2, Field strength B1 of 1.6 µT) a maximum level of 0.9 W/kg was used, which was displayed on the MRI scanner console.
C.1.2 General information on MRI procedures

C.1.2.1 Types of electromagnetic fields generated by MRI systems

An MRI system produces 3 types of electromagnetic fields that may interact with implanted devices. All 3 of these fields are necessary to produce an MRI image. The 3 fields are defined as follows:

Static magnetic field – This is a steady state, non-varying magnetic field that is normally always on, even when no scan is in progress.

Gradient magnetic fields – These low-frequency, pulsed magnetic fields are present only during a scan. MRI equipment uses 3 orthogonal gradient magnetic fields to form the image. These gradient magnetic fields vary linearly within the bore. In non-clinical testing the 1.5 T machine had a spatial gradient field of 21 mT/m and the 3 T machine had 80 mT/m.

RF field – This is a pulsed RF field that is present only during a scan. The RF field can be produced by a variety of transmission RF coils, such as a whole body transmit coil or an extremity coil (for example, a transmit head coil).

C.1.2.2 Potential interactions for implanted Reveal DX devices in the MRI environment

The Reveal DX design and the conditions for use (see Section 2.1) limit the potential interactions described in this section. The effects described might be experienced by the patient but will not harm the patient or damage the device.

Magnetic and RF field interactions – The magnetic material of an implanted device may exert force, vibration, and torque effects due to the static magnetic field and gradient magnetic fields produced by an MRI scanner.

The gradient magnetic field and modulated RF field may induce currents and voltages in the device. This could lead to tissue heating, nerve stimulation and electrical stress on device components.

The gradient magnetic field and modulated RF field may induce voltages in the sensing circuitry. This may affect sensing and event detection and thus could lead to inappropriate data recorded by the Reveal DX. Pre-MRI and post-MRI operation precautions are described to prevent potentially misleading information.

Image artifacts and distortion – The Reveal DX causes image distortion for areas in the image that surround the implanted device. Image artifacts and distortion resulting from
the presence of the device within the field of view must be considered when selecting the field of view and imaging parameters (see Section C.1.5.3).

C.1.3 MRI contraindications

Although the Reveal DX is considered conditionally safe for use in the MRI environment when used under the specified conditions, other implanted devices or the patient’s individual medical condition might have an impact on safety and might require additional examination. If applicable, user manuals for the other implanted devices, including abandoned leads, should be consulted before conducting the MRI scan.

Patients with a Reveal DX that has been implanted for less than 6 weeks are contraindicated for an MRI procedure. The 6-week post-implant waiting period allows sufficient time for implant pocket and wound healing and minimizes the effects of “tugging” on the device caused by the magnetic fields.

Patients with a Reveal DX implanted in sites other than the subcutaneous region of the chest are contraindicated for an MRI procedure.

C.1.4 MRI potential adverse events

An implanted Reveal DX may be subject to interactions in the MRI environment. The device design minimizes the potential adverse effects that may result from these interactions to an acceptable level. However, patients may experience minor discomfort, due to tissue heating or “tugging”.

The MRI environment may interfere with the device’s capability to detect irregular heart rhythms, and therefore, diagnostic information collected during the MRI procedure may be corrupted.

C.1.5 Radiology-specific MRI warnings and precautions

C.1.5.1 MRI equipment requirements

The MRI equipment requirements listed in this section must be satisfied during all MRI procedures performed on patients with a Reveal DX. If you are unsure of the capabilities of your MRI machine, contact the MRI manufacturer.
Compatible MRI equipment classifications – The safety and reliability of Reveal DX devices have been evaluated in vitro using MRI equipment that has the following operating characteristics:

- hydrogen proton magnetic resonance imaging equipment with a static magnetic field of 1.5 T and 3.0 T
- RF excitation frequency that is approximately 64 MHz in a 1.5 T static magnetic field and approximately 128 MHz in a 3 T static magnetic field
- closed bore, cylindrical magnet systems
- whole body gradient systems with a gradient slew rate specification of 200 T/m/s or less

C.1.5.2 MRI procedure requirements

MRI RF power – The whole body SAR as reported by the MRI equipment must be \( \leq 2.0 \) W/kg. The head SAR as reported by the MRI equipment must be \( \leq 3.2 \) W/kg.

Local or surface coils – If local or surface coils are needed, adhere to the following requirements:

- Do not use a local, interventional, or surface transmit coil over or near the chest, trunk, or shoulder region of the patient. A local or surface receive-only coil is permissible.
- Extremity volume or surface coils should not be used.

Total scan duration over the chest – The uninterrupted duration of active scanning (when RF and gradients are on) over the chest during MRI must not exceed 30 min. If additional chest scans beyond 30 min are necessary, a waiting period of at least 10 min is required.

\(^1\) The true limitation for gradient magnetic fields necessary to safely scan patients is that the maximum gradient magnetic field time rate of change (dB/dt) the patient is exposed to is in the range of 30-60 T/s. The Reveal DX has been evaluated in vitro using test equipment with a gradient magnetic field time rate of change of 100 T/s. The maximum gradient magnetic field (dB/dt) that the gradient system will produce during a scan may not be reported via the MRI console or MRI equipment specifications. Therefore, the above MRI equipment requirement that restricts scans to whole body gradient systems with a gradient slew rate specification of 200 T/m/s or less is an alternative means of ensuring that the gradient system cannot produce gradient magnetic field levels that could potentially harm the patient. Using a whole body gradient system that exceeds the gradient slew rate specification of 200 T/m/s, or any type of special purpose gradient system, is allowed only if the maximum gradient magnetic field (dB/dt) the device is exposed to can be verified to be 100 T/s or less.
Total scan duration outside of the chest region – There are no scan duration limitations when imaging areas outside of the chest region, provided the Reveal DX is not in the RF field.

⚠️ Caution: Although the instruction to the patient is to carry the Patient Assistant at all times, it is not allowed to take the Patient Assistant into the MRI controlled room (magnet room).

C.1.5.3 Image quality

MRI image quality may be compromised if the area of interest is at or near the implanted Reveal DX. The figures below show the image artifacts (top view) of 2 Reveal DX devices placed on a grid. The device on the right was placed vertically on the grid and the one on the left horizontally. Figure 24 and Figure 25 show the artifacts for the 1.5 T machine (spinEcho and gradientEcho images respectively) and Figure 26 and Figure 27 show the same artifacts for the 3 T machine. The images show worst-case artifacts of about 6 cm around the Reveal DX. For both the 1.5 T closed bore device (manufacturer Philips, model Intera, software version 2.1.3.2), and the 3 T closed bore device (manufacturer Philips, model Achieva, software version 2.1.3.2), the results are summarized in Table 15. The gradient field is expressed as a percentage of the maximum peripheral nerve stimulation (PNS).

Figure 24. Image artifacts at 1.5 T (spinEcho)

![Image artifacts at 1.5 T (spinEcho)](image_url)

Figure 25. Image artifacts at 1.5 T (gradientEcho)

![Image artifacts at 1.5 T (gradientEcho)](image_url)
Figure 26. Image artifacts at 3 T (spinEcho)

![Image artifacts at 3 T (spinEcho)](image)

Figure 27. Image artifacts at 3 T (gradientEcho)

![Image artifacts at 3 T (gradientEcho)](image)

Table 15. MRI scan, effects on image quality

<table>
<thead>
<tr>
<th>Figure</th>
<th>B0 (T)</th>
<th>Scan type</th>
<th>Flip angle (°)</th>
<th>B1 (μT)</th>
<th>Percentile of max PNS (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Figure 24</td>
<td>1.5</td>
<td>spinEcho</td>
<td>70</td>
<td>2.28 (25%)</td>
<td>8</td>
</tr>
<tr>
<td>Figure 25</td>
<td>1.5</td>
<td>gradientEcho</td>
<td>30</td>
<td>0.49 (1%)</td>
<td>15</td>
</tr>
<tr>
<td>Figure 26</td>
<td>3.0</td>
<td>spinEcho</td>
<td>70</td>
<td>1.57 (94%)</td>
<td>23</td>
</tr>
<tr>
<td>Figure 27</td>
<td>3.0</td>
<td>gradientEcho</td>
<td>30</td>
<td>0.77 (23%)</td>
<td>54</td>
</tr>
</tbody>
</table>

C.1.6 Cardiology-specific MRI warnings and precautions

System information and patient records – All pertinent information about the implanted Reveal DX, such as model name, model number, and serial number, should be recorded in the patient record. This will help communicate to referring physicians that a patient has a Reveal DX.

Patient identification (ID) card requirements – Reference materials, such as a Device Identification Card, should be provided to all patients with an implanted Reveal DX. These materials indicate that the patient may have an MRI procedure, and help to communicate to referring physicians that a patient has a Reveal DX.
C.1.7 Pre-MRI operation

Identifying the Reveal DX – There are 2 ways to verify that a patient has a Reveal DX:

- There is a radiopaque symbol on all implanted Reveal DX devices. An x-ray of the implanted system will verify whether the device is a Reveal DX. The radiopaque symbol (RAB) is located in the header of the device. See Figure 28 for the device radiopaque symbol and its location. An x-ray will also indicate whether the patient has any additional implanted devices.
- The patient records or device identification cards, if applicable, must be complete and accurate if they are to be used to verify that the patient has a Reveal DX or that the patient has no additional implanted devices.

Figure 28. Location of the radiopaque symbol

Preparing a Reveal DX for an MRI procedure – The following tasks must be completed before performing an MRI procedure on a patient with a Reveal DX:

1. Check that the system has been implanted for more than 6 weeks. The 6-week post-implant waiting period allows sufficient time for implant pocket and wound healing and minimizes the effects of “tugging” on the device caused by the magnetic fields.
2. Check that additional implantable devices are not present. Interactions with all other implanted devices have not been tested by Medtronic.
3. Check that abandoned leads are not present. Interactions with abandoned leads have not been tested by Medtronic.
4. Check that the data has been saved. Before the MRI procedure is started, the data stored in the Reveal DX must be read out and saved to diskette using the programmer. The MRI procedure might corrupt the recorded data in the Reveal DX.

5. Make sure that the patient does not bring the Patient Assistant into the MRI controlled room (magnet room).

△ **Caution:** Do not bring the Medtronic CareLink Model 2090 programmer into the MRI controlled room (magnet room). It is not MRI safe.

### C.1.8 During MRI operation

**Radiology considerations during the MRI scan: image artifact and distortion** – The Reveal DX causes image distortion for areas in the image that surround the implanted device (see Section C.1.5.3, “Image Artifacts”). Artifacts and distortion resulting from the presence of the device within the field of view must be considered when selecting the field of view and imaging parameters. These factors must also be considered when interpreting the MRI images.

### C.1.9 Post-MRI operation

After the MRI procedure is complete, check the programmed parameters of the Reveal DX using the programmer. Clear the data collected during the MRI procedure because the MRI procedure might temporarily have affected the event detection and recording of the Reveal DX.