SUMMARY
MRI systems utilize powerful static and pulsed magnetic fields combined with pulsed radio wave energy to visualize detailed internal structures.

Patients with MR-Conditional Pacing Systems manufactured by Boston Scientific may be eligible for MRI scanning.

This article discusses MR-Conditional and MR-Unsafe systems as well as procedure considerations and potential interactions between MRI and implantable devices.

Products Referenced
All Boston Scientific pacing and defibrillation systems (both MR-Conditional and Non-MR-Conditional), and the ZOOM LATITUDE Programmer/Recorder/Monitor

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For comprehensive information on device operation, reference the full instructions for use found at www.bostonscientific.com/imageready. CAUTION: Law restricts this device to sale by or on the order of a physician. Indications, contraindications, precautions and warnings can be found at www.bostonscientific.com/imageready.

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Magnetic Resonance Imaging (MRI) and Implanted Medical Device Systems

Magnetic Resonance Imaging (MRI) uses powerful magnetic waves to produce images of the soft tissue on the interior of the human body. Many patients with implanted heart devices are not eligible to have an MRI scan because their pacing systems are not approved for use during an MRI scan or near MRI scanners. However, patients implanted with a Boston Scientific's ImageReady™ MR-Conditional System may be eligible to undergo a full-body MRI scan. To download or view a copy of the MRI Technical Guide that defines MR-Conditional Pacing Systems, or to determine if a system is MR-Conditional, please visit the website below and refer to the appropriate geography:

www.bostonscientific.com/imageready

This article discusses MRI considerations for all Boston Scientific pacing and defibrillation systems (MR-Conditional or non-MRI Conditional), and the ZOOM LATITUDE Programmer/Recorder/Monitor (PRM).

Definition of “System”
An implant system consists of the pulse generator, lead(s), and a port plug (where applicable). Only patients implanted with a complete system designed, optimized, and tested for the ability to function correctly under specified conditions during an MRI scan are eligible to be scanned. Furthermore, by complying with the MRI Conditions of Use found in the appropriate MRI Technical Guide, patient risks (Table 1) can be significantly mitigated during MRI scans as compared to comparable, non-MR-Conditional, pulse generators and leads.¹

MR-Conditional Systems
Boston Scientific’s ImageReady MR-Conditional Pacing System consists of specific combinations of pulse generator and lead components. Note that system approval is geography-specific. To determine if the system under consideration is approved as MR-Conditional, please refer to the MRI Technical Guide for the specific geography of interest. Guides can be downloaded from www.bostonscientific.com/imageready.

MR-Unsafe Systems
Conditions for Use must be met for a patient to undergo a MRI scan. Use of any other components or combination of components not detailed in the MRI Technical Guide has not been approved as MR-Conditional. If the system in its entirety is not listed in the appropriate MRI Technical Guide, it has not been approved as MR-Conditional.

MRI for patients with MR-Unsafe systems is contraindicated by MRI manufacturers and warned against by medical device manufacturers. If MRI scanning is being considered, a careful and complete risk-benefit analysis should be completed. If MRI cannot be avoided, patients must be closely monitored and appropriate device function should be verified upon cessation of MRI.²

³The American Society for Testing and Materials (ASTM) defines MR-Conditional in F2503:2008a as: “An item with demonstrated safety in the MR environment within defined conditions. At a minimum, address the conditions of the static magnetic field, the switch gradient magnet field and the radiofrequency fields. Additional conditions, including specific configuration to the item, may be required.”

²Many device diagnostics are performed automatically once per hour, therefore, device evaluation should not be concluded until device diagnostics have been updated and reviewed at least one hour after MRI.
Among other information, the guide contains:

- Conditions for Scanning/Use (Cardiology and Radiology)
- Potential adverse events
- Valid combinations of pulse generators and leads by scanner strength
- MRI scan procedure protocol, including details regarding programming the device into MRI Protection Mode.

Additionally, a ZOOM™ LATITUDE™ PRM must be available throughout the MRI procedure and must remain outside MRI Zones III and IV. The PRM is used to program the device into MRI Protection Mode (only available for MR-Conditional devices). If the MRI Protection Time-out value of Off is selected, the PRM will also be necessary following the procedure to program MRI Protection Mode Off. Please note, the MRI Protection Checklist, which will appear on the PRM, summarizes the conditions that must be met at the time of scanning in order for a patient to be eligible for an MR-Conditional Scan.

What is MRI Protection Mode?
In preparation for an MRI scan, the pulse generator in an MR-Conditional system is programmed to MRI Protection Mode using the PRM. Please refer to the MRI Technical Guide for a complete description of MRI Protection Mode. MRI Protection Mode modifies the behavior of the device and has been designed to accommodate the electromagnetic environment of the scanner. Additionally, a time-out feature may be programmed to cancel MRI Protection mode after a specified number of hours. Features disabled or changed when MRI-Protection mode is entered include (where applicable):

- Tachy Therapy
- Brady Therapy (Mode and Output may be programmable)
- Magnet Operation
- MV Sensor (includes Rate Response Pacing, Respiratory Rate Trend, and AP Scan)
- Accelerometer (Rate Responsive Pacing and Activity Level Trend)
- Daily Diagnostics disabled (Pace Impedance, Intrinsic Amplitude and Pace Threshold tests)
- RF Communications
- Beeper Function (not applicable to brady devices)

WARNING: The beeper may be rendered inaudible due to an MRI scan. Coming in contact with the strong magnetic field of an MRI scanner causes permanent loss of the beeper volume. This cannot be recovered, even after leaving the MR scan environment and exiting MRI Protection Mode. Before an MRI procedure is performed, a physician and patient should weigh the benefit of the MR procedure against the risk of losing beeper volume. It is strongly recommended that patients are followed on LATITUDE NXT after an MRI scan if they are not already. Otherwise, an in-clinic follow-up schedule of every three months is strongly recommended to monitor device performance.

During and After Scanning

During the Scan
During MRI Protection Mode, the patient may not receive Bradycardia pacing (including backup pacing), depending on available device features and programming. Also, the patient will not receive Cardiac Resynchronization Therapy, or Tachycardia therapy (including ATP and defibrillation). Therefore, the patient needs to be continuously monitored for the entire time that the system is in MRI Protection Mode, including during the scan. Continuous monitoring includes maintaining normal voice and visual contact, as well as monitoring pulse oximetry and ECG for the entire duration that the pulse generator is in MRI Protection Mode. Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present as long as the pulse generator is in MRI Protection Mode, including during the scan, should the patient require external rescue.

After the Scan
Continue patient monitoring until the pulse generator is returned to pre-MRI operation.

Do not leave the pulse generator in MRI Protection Mode any longer than necessary following the scan. Upon exiting MRI-Protection Mode (either timer-initiated or manually exited) all parameters are immediately restored to pre-MRI Protection Mode values with three exceptions:

- Tachy devices: the beeper remains turned off.
- AUTOGEN™ and Boston Scientific pacers: If Minute Ventilation (MV) was programmed to ON or Passive at the time of entry into MRI Protection Mode, an automatic six-hour calibration of the sensor begins upon exit from the mode. MV-driven rate response is not available during this calibration.
- Pacers: If PaceSafe RV Automatic Capture was programmed to ON the device will remain in suspension until the next scheduled 21 hour ambulatory automatic threshold test.

Changing the beeper setting to ON will remove the MRI warning message and the beeper parameters will be re-set to pre-MRI Mode values and become programmable again. To test if the beeper is audible:

1) Program the beeper On
2) Place a magnet over the device and listen for beeps
3) If beeper is audible, leave the beeper On. If not audible, program the beeper Off.
Following user-initiated cancellation of MRI Protection Mode, the PRM will automatically navigate to the Lead Tests screen and prompt the user to perform the following lead tests:

- Lead impedance
- Pacing threshold
- Intrinsic amplitude

These tests may be performed subsequent to automatic (Time-out) exit from MRI Protection Mode as well.

**Post-Therapy Pulse Generator Follow-Up**

Following any surgery or medical procedure with the potential to affect pulse generator function, you should perform a thorough follow-up, which may include the following:

- Interrogating the pulse generator with a programmer
- Reviewing clinical events and fault codes
- Reviewing the Arrhythmia Logbook, including stored electrograms (EGMs)
- Reviewing real-time EGMs
- Testing the leads (threshold, amplitude, and impedance) – see above
- Performing a manual capacitor re-formation
- Reviewing MV sensor-based diagnostics, MV sensor performance, and performing a manual MV sensor calibration if desired
- Verifying battery status
- Programming any permanent brady parameter to a new value and then reprogramming it back to the desired value
- Saving all patient data
- Verifying the appropriate final programming prior to allowing the patient to leave the clinic

**Potential Interactions between MRI Scanners and implanted medical device systems**

**MR-Conditional System**

Boston Scientific MR-Conditional pulse generators and leads, when used together under the Conditions of Use outlined in the MRI Technical Guide, were designed to significantly reduce the device interactions traditionally associated with MRI scans (Table 1). However, both radiologist and cardiologist should be familiar with the potential interactions listed in Table 1, since it is possible that interactions may not be fully mitigated when an MR-Conditional system is exposed to atypical conditions.

**MR-Unsafe Systems**

Unless a patient’s implanted Boston Scientific system is approved as MR-Conditional and all of the MRI Conditions of Use detailed in the appropriate MRI Technical Guide are met, MRI scanning of the patient is not recommended. Potential interactions are listed in Table 1.
Table 1. Potential interactions between MRI scanners and implanted medical device systems. Note that implantation of an MR-Conditional system and compliance with the MRI Conditions of Use found in the appropriate MRI Technical Guide, can successfully mitigate many of the potential interactions (listed in this Table) during MRI scans.

*Requires reprogramming to restore.

<table>
<thead>
<tr>
<th>Potential interaction(s)</th>
<th>ICDs &amp; CRT-Ds</th>
<th>S-ICD</th>
<th>Pacemakers &amp; CRT-Ps</th>
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</thead>
<tbody>
<tr>
<td>Loss of beeper function</td>
<td></td>
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<td>No beeper</td>
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<tr>
<td>Side effects of MRI Protection Mode Pacing at elevated fixed rate and increased output including:</td>
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<td>reduced exercise capacity, acceleration of heart failure, arrhythmia induction</td>
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<tr>
<td>Induced arrhythmias</td>
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<td>Slight movement or heating of the device</td>
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<tr>
<td>Side effects of pacing at a fixed high rate such as competition with intrinsic rhythms and arrhythmias. Competitive pacing may increase the rate of pacing-induced arrhythmia until the device is reprogrammed.</td>
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<tr>
<td>Physical movement of device and/or leads</td>
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<tr>
<td>Damage to pulse generator and/or leads</td>
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<tr>
<td>Lead heating, which may cause tissue damage and/or pacing threshold changes</td>
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<tr>
<td>Inhibition of pacing (pacing therapy not provided when needed, including post-shock therapy)</td>
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<tr>
<td>Asynchronous pacing (pacing therapy provided independent of intrinsic cardiac activity)</td>
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<tr>
<td>Inappropriate pacing</td>
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<tr>
<td>Increased rate of lead dislodgment prior to six weeks of implant</td>
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<tr>
<td>Inhibition of tachyarrhythmia therapy (ATP/shock therapy not provided when needed)</td>
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<tr>
<td>Inappropriate tachyarrhythmia therapy (ATP/shock therapy provided when not needed)</td>
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<tr>
<td>Sensing changes</td>
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<tr>
<td>Pacing threshold changes</td>
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<tr>
<td>Irregular or intermittent capture or pacing</td>
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<tr>
<td>Deactivation of tachyarrhythmia therapy*</td>
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<tr>
<td>Erratic device behavior</td>
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<tr>
<td>Triggered ventricular pacing up to the Maximum Tracking Rate (MTR)</td>
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<td>Erroneous episodes stored in pulse generator EGM and counter memory</td>
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<tr>
<td>Apparent drop in battery voltage or appearance of replacement indicator†</td>
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<td>Pulse generator pulling or twisting at implant site</td>
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<td>Pulse generator vibration</td>
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<tr>
<td>Unintended stimulation (gradient-field induced current incident on lead causing a short pulse)</td>
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</table>

*In most instances, the indicator can be reset/cleared in defibrillators with a manual capacitor reformation.

For additional information and considerations, please refer to the American Heart Association’s Scientific Statement on the safety of MRI in patients with cardiovascular devices.

Common identified medical risks associated with an MRI procedure for patients who do not have an implanted medical device also apply to MRI scans with a MR-Conditional Pacing System. Consult MRI scanner documentation for a complete list of risks associated with MRI scanning.

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