Programming Manual for MRI Protection Mode

INGEVITY™ MRI Pacing Lead
ACCOLADE™ MRI Pacemakers
ESSENTIO™ MRI Pacemakers

Please refer to the MRI Technical Guide: ImageReady™ MR-Pacing System as the system is designated as MR-conditional in accordance with specific conditions.
Boston Scientific’s ImageReady™ MR-Conditional Pacing System has been created specifically as a system for use with MRI scans when performed under the Conditions of Use.

The Cardiology an Radiology Checklists are included as references at the end of this manual.

Additionally, an MRI Protection Mode has been created for use during an MRI scan. Use the Boston Scientific Programmer to program the pulse generator entry into MRI Protection Mode.

Select Device Mode, next select Enable MRI Protection and then Apply Changes.

Once “Apply Changes” is selected, 2 checks are automatically performed: a lead impedance test in all chambers and a calculation of the time since implant.
The ImageReady™ MR-Conditional System is designed with several built-in safety reminders, viewable as Attention Screens.

If the impedance value for any of the leads is outside the programmed normal range, a dialog recommending review of the associated risks if the user chooses to proceed is displayed.

The dialog provides the option to either continue with MRI Protection or Cancel.
The programmer calculates the time since implant based on when the device was taken out of storage mode.

If the calculated time is < 6 weeks, a dialog is displayed recommending reviewing the associated risks.

The dialog provides the option to either continue with MRI Protection or Cancel.

**Note:** If the programmer clock is not set to the correct time and date, this determination will not be accurate.
The system will automatically assess the most recent pacing threshold(s). If the threshold is $>2.0\,\text{V}$, an attention message appears on the screen advising the user to review risks of proceeding.

A Condition of Use applicable to pace-dependent patients is pacing thresholds are less than or equal to $2.0\,\text{V}$.

Thresholds greater than $2.0\,\text{V}$ may result in an insufficient safety margin and failure to capture in MRI Protection Mode.

The most recent results of either the ambulatory PaceSafe™ tests or commanded tests are used.
There are certain conditions in the device and/or system that will cause a user request to enter MRI Protection Mode to be rejected. There will be no option to continue with MRI Protection programming. These include:

1. A ventricular episode as detected and recognized by the device is in progress. MRI Protection mode will not be available.

2. Magnet presence is detected by the magnet sensor. The function of enabling MRI Protection mode is disabled until the magnet is removed.

3. A Unipolar pacing configuration is programmed in chamber(s) where pacing will occur in MRI Protection Mode. One of the Conditions for Scanning is a bipolar pacing operation. The device will automatically confirm that the Pacing Lead Configuration is set to bipolar. Unipolar lead configurations increase the risk of induced voltages in the lead system. Additionally, bipolar ventricular pacing operation is required to support Safety Core operation, if Safety Core is entered from MRI Protection Mode.

4. The user will see the same message if the device is in a STAT PACE mode, which uses unipolar pacing. If any one or more of these conditions are present, a dialog box will appear describing the condition, and MRI Protection Mode cannot be entered.

Other device conditions that will preclude the user from having the option to enter MRI Protection Mode include:

- Battery capacity status is depleted
- Device is in Storage Mode
- Device is in Electrocautery Mode
- Device is in Safety Core operation
- A diagnostic test is in progress
- An EP test is in progress
Upon continuing with entry into MRI Protection Mode, the MRI Protection Checklist screen is displayed which 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.

The Device Checklist is specific to the Cardiologist’s assessment of eligibility. Below this list is the Radiology Checklist, specific to the MRI environment, patient positioning, and patient monitoring.

**Note:** Labeling provides additional Conditions and details regarding the Radiology Checklist. Appropriate monitoring of the patient includes an external defibrillator and medical personnel skilled in CPR being present during the MRI scan.

If the Conditions of Use are not met, the Cancel button is selected to return to normal system operation, and the patient does not undergo an MRI scan.

If the Conditions of Use are met, or if the Conditions of Use are not met but the user elects to continue with MRI Protection Mode after reviewing the risks or proceeding, the Continue with MRI Protection button is selected.

As a result, the Program MRI Protection screen is displayed and the user can program the following parameters shown on the next page.
Use the dialog boxes to set the Pacing Mode: DOO, VOO, AOO, or off.
Set the Lower Rate Limit, which is nominally set to 20 beats per minute above the normal mode Lower Rate Limit.

Because MRI Protection Mode pacing is asynchronous, when setting the lower rate limit, the patient’s intrinsic rate should be considered to avoid competitive pacing.
Set the Atrial and Ventricular Amplitudes, programmable in normal increments from 2.0-5.0 V.

The pulse generator nominal amplitudes in MRI Protection Mode are set to 5.0 V, providing a minimum two-fold safety margin for patients with a pacing threshold ≤ 2.0 V plus an additional 1.0 V to counteract gradient-induced pace pulse offsets.
Unique to Boston Scientific, a Time-out feature can be programmed to allow automatic exit from MRI Protection Mode after a set number of hours chosen by the user.

MRI Protection Time-out is nominally set to 24 hours, programmable to Off, 12, 24, and 48 hours. Important to note, if the value is programmed to Off, the device will remain in MRI Protection Mode indefinitely; only a programmer can be used to exit MRI Mode.

If the Time-out feature is set to a value other than Off, the Radiologist verifies that adequate time remains to complete the scan.

After exiting MRI Protection Mode, all parameters are immediately restored to pre-MRI Protection Mode values with two exceptions.

If PaceSafe™ Automatic Capture (RVAC) was programmed on, this feature enters suspension upon entry of the device into MRI Protection Mode.

Upon exit from MRI Protection Mode, the RV pace amplitude is set to 2 times the last capture threshold determined by the RVAC feature before it entered suspension (output is limited to between 3.5 V and 5.0 V).

After the next scheduled autothreshold test runs (within the next 21 hours), and is successful, the RV pace amplitude is set to the new capture threshold plus 0.5 V.

Restoration of function of the Minute Ventilation sensor is also delayed upon exit from MRI Protection Mode.

If MV is programmed to On or Passive at the time of entry into MRI Mode, upon exit from the mode, an automatic six-hour calibration of the sensor will begin.

If MV-driven rate response is desired sooner, a manual calibration can be performed.

Please note that if MRI Protection Time-out is programmed Off, and Brady Mode is off, the patient will not receive pacing until the device is manually programmed out of MRI Protection Mode and back to normal operation.
Once all settings have been determined, the user is now ready to enable MRI Protection.

A reminder on the screen states that all sensing and diagnostics will be disabled. There is an additional message that states programming MRI Protection Mode will force the use of inductive telemetry.

This means that the user must maintain access to the programmer wand, as RF telemetry becomes unavailable during the process of entering MRI Protection Mode.

When the user presses the Program MRI Protection button, the wand must be used from this point forward to complete entry into MRI Protection Mode.
This screen indicates that the device has been successfully programmed into MRI Protection Mode at the settings indicated.

Print a copy of the settings before ending the session.

The report lists the settings in operation during MRI Protection Mode.
In this example, the MRI Protection Time-out is programmed to 12 hours.

If the Time-out feature is used, the report includes the time and date when MRI Protection Mode will expire, returning the pulse generator to the pre-MRI Protection Mode settings.

Most recent lead measurements are also listed.

The printed report can be placed in the patient's file and used by Radiology personnel, for example, to confirm that sufficient time remains to complete the MRI scan.
The third page of the report includes both the Device Checklist for Conditions of Scanning and the Radiology Checklist.
Selecting the End Session button will end the current programmer session with the device remaining in MRI Protection Mode.

Most device functions shutdown in MRI Protection Mode, such as:

- PaceSafe™ RV automatic capture
- PaceSafe RA automatic threshold
- Cardiac sensing
- Daily diagnostics (lead impedance, intrinsic amplitude, pace threshold)
- Motion and respiratory sensors
- Magnet detection
- RF telemetry and Remote Monitoring
- Battery voltage monitoring
Following the scan and after interrogating the device with the wand, the user will again be presented with this message on the screen.

If the Time-out parameter was programmed to a value other than Off, the device will exit MRI Protection Mode automatically after the selected number of hours, and the system will return to previously programmed settings.

Alternatively, if the Time-out feature is not used (is programmed to Off), the device must be interrogated by the wand to exit MRI Protection Mode.

Labeling states: Do not leave the device in MRI Protection Mode any longer than necessary following the scan.

Select the Cancel MRI Protection button.
Following user-initiated cancellation of MRI Protection Mode, the programmer will automatically navigate to the Lead Tests screen and prompt the user to perform the following lead tests:

- Intrinsic amplitude
- Lead impedance
- Pacing threshold
Upon exiting MRI Protection Mode (either timer initiated or manually exited), an Event is stored as an MRI episode and can be printed or saved as an episode report. The MRI episode can also be viewed in the Arrhythmia Logbook via Remote Patient Monitoring (if available).

The following are additional references:

www.bostonscientific.com/imageready

Boston Scientific MRI Hotline Number: 1.844.427.2674 (1.844.4.BSC.MRI)
Cardiology/Radiology Checklists

Use the following checklists to ensure that patients who have a Boston Scientific pacing system labeled MR-conditional can receive an MR scan safely. Prior to the procedure, please see the full instructions (including warnings/precautions and potential adverse events) in the Boston Scientific ImageReady MR-Conditional Pacing System MRI Technical Guide, or www.BostonScientific.com/imageready or Boston Scientific MRI Hotline 1.844.4.BSC.MRI (1.844.427.2674).

Patient Name: _________________________________________ Date of Birth: ______________________________________
Pacemaker Model: ______________________RV Lead Model: __________________Atrial Lead Model: __________________

The following conditions must be met in order for a patient with a Boston Scientific ImageReady MR-Conditional Pacing System to undergo an MRI scan:

**For Cardiologists ~ MRI Conditions for Use**¹

- Patient is implanted with an ImageReady MR-Conditional Pacing System
- At least six weeks have elapsed since implantation and/or any lead revision or surgical modification of the MR-conditional pacing system
- Pulse-generator implant location restricted to left or right pectoral region
- No cardiac-related implanted devices, components, or accessories present (such as lead adapters or extenders) other than an ImageReady MR-Conditional Pacing System
- No abandoned leads or pulse generators
- No evidence of fractured lead or compromised pulse-generator-lead integrity (impedance out of normal range, or evidence or record of damage to generator seal plug or sealing rings)
- Pacing threshold ≤2.0V in pace-dependent patients
- Bipolar pacing operation or pacing Off
- Patient does not have elevated body temperature or compromised thermoregulation at time of scan
- Pulse generator in MRI Protection Mode during scan

**For Radiologists ~ MRI Conditions for Use**¹

- MRI magnet strength of 1.5 T
  - Radio frequency of approximately 64 MHz
  - Spatial gradient no greater than 50 T/m (5,000 G/cm) over the pacing system
- Horizontal, H proton, closed bore scanners only
- Specific Absorption Rate (SAR) limits:
  - INGEVITY™ MRI Pacing Leads: SAR limits for Normal Operating Mode or for First Level Controlled Operating Mode must be observed for the entire active scan session as follows:
    - Whole body averaged, ≤4.0 W/Kg
    - Head, ≤3.2 W/Kg
- Gradient Field limits: Maximum specified gradient slew rate ≤ 200 T/m/s per axis
- No local transmit-only coils or local transmit/receive coils placed directly over the pacing system; the use of receive-only coils is not restricted
- Patient in supine or prone position only
- Patient must be monitored during the MRI scan by pulse oximetry and/or electrocardiography (ECG)

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