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IMAGEREADY™
MR-Conditional Systems

# Programming Manual for MRI Protection Mode

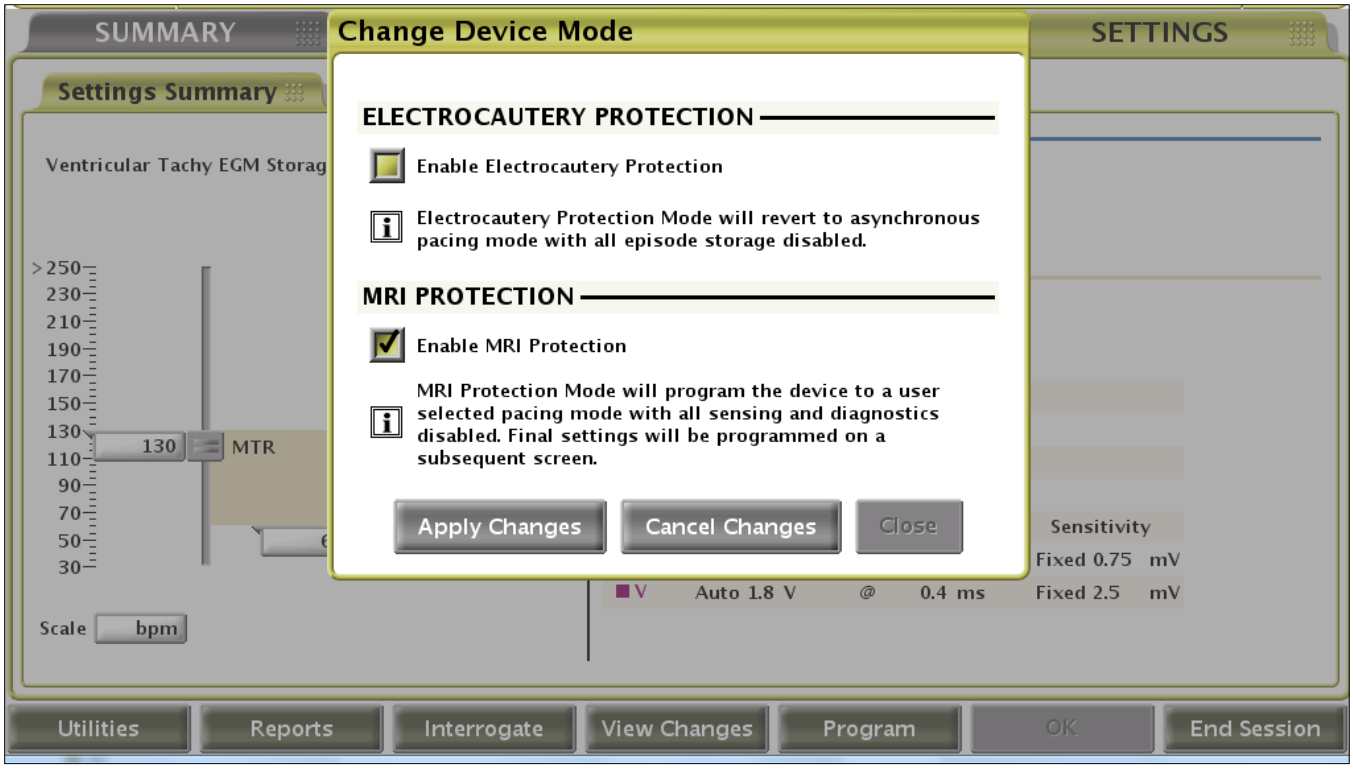


The following are additional references:

- *Boston Scientific MRI Technical Guide: ImageReady™ MR Conditional Pacing System*
- *Boston Scientific MRI Technical Guide: ImageReady™ MR Conditional Defibrillation System*
- *www.bostonscientific.com/imageready*

*Boston Scientific MRI Hotline Number: 1.844.427.2674 (1.844.4.BSC.MRI)*

# ImageReady™ Transvenous Pacing System
# MRI Protection Mode Programming




## MRI Protection Mode General Information

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 and Radiology Checklists describing Conditions of Use are available at www.bostonscientific.com/ImageReady.

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.

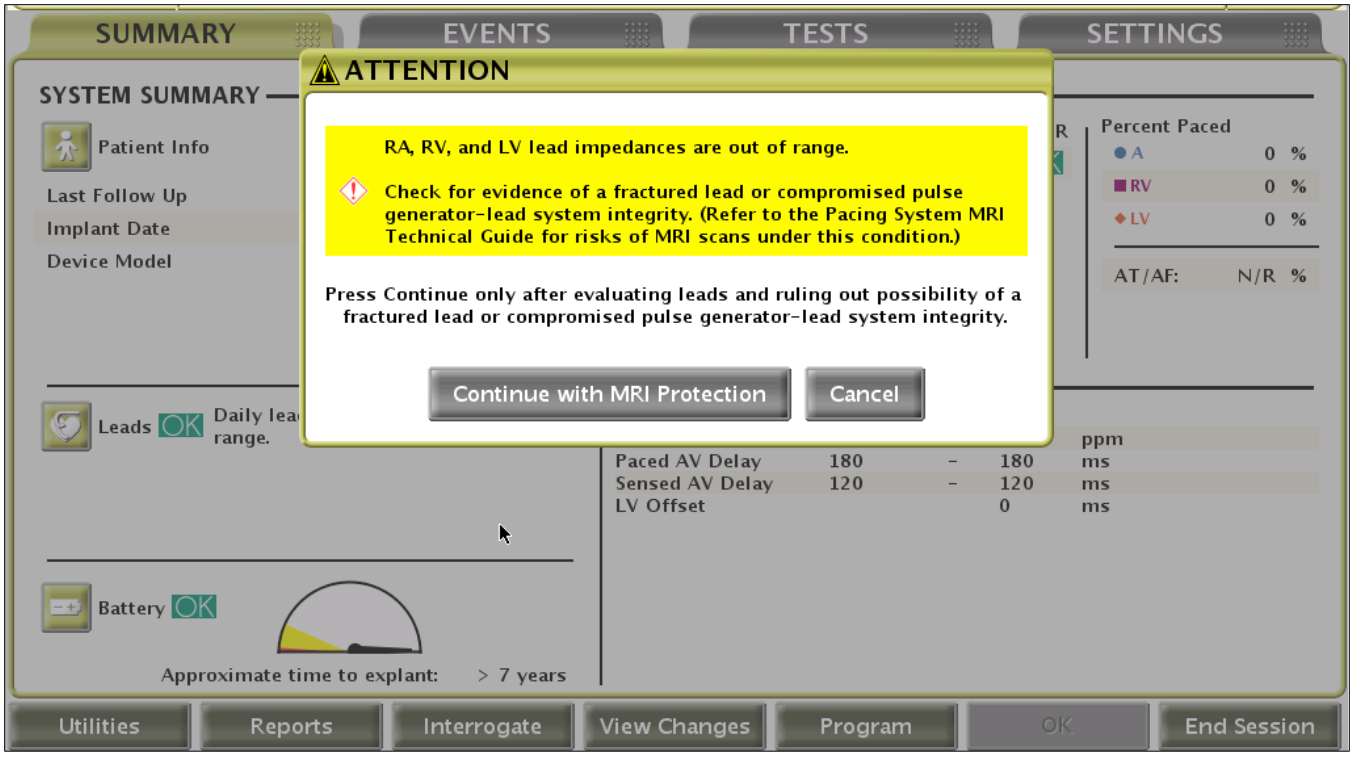
Prior to starting programming, print the Device Settings Report as a reference for selecting Brady settings in MRI Protection Mode.

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

Once "Apply Changes" is selected, three assessments are automatically completed:

- Lead impedance test in all chambers
- Calculation of the time since implant
- Check of the most recently recorded thresholds in the RA and RV

## Lead Impedance Check

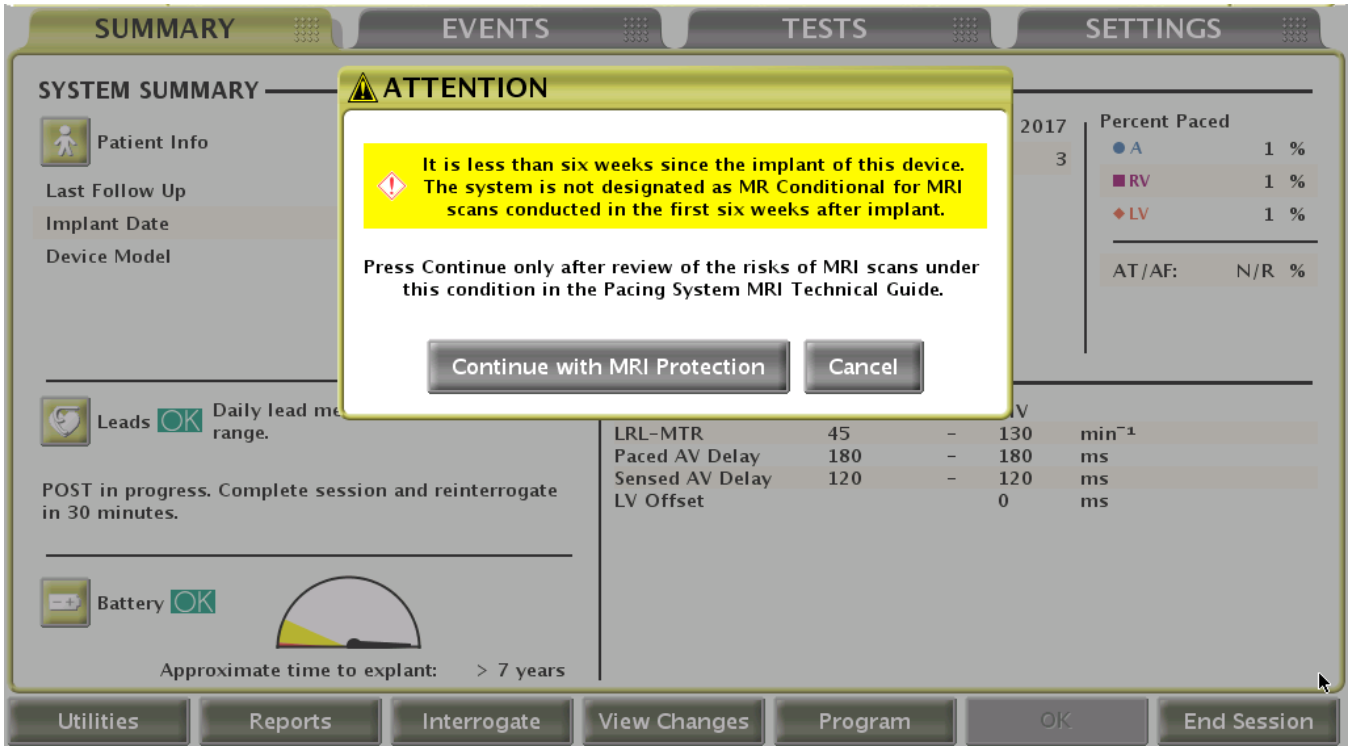



The ImageReady™ MR-Conditional Pacing System is designed with several built-in safety reminders, viewable as ATTENTION Screens.

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.

## Time Since Implant Check



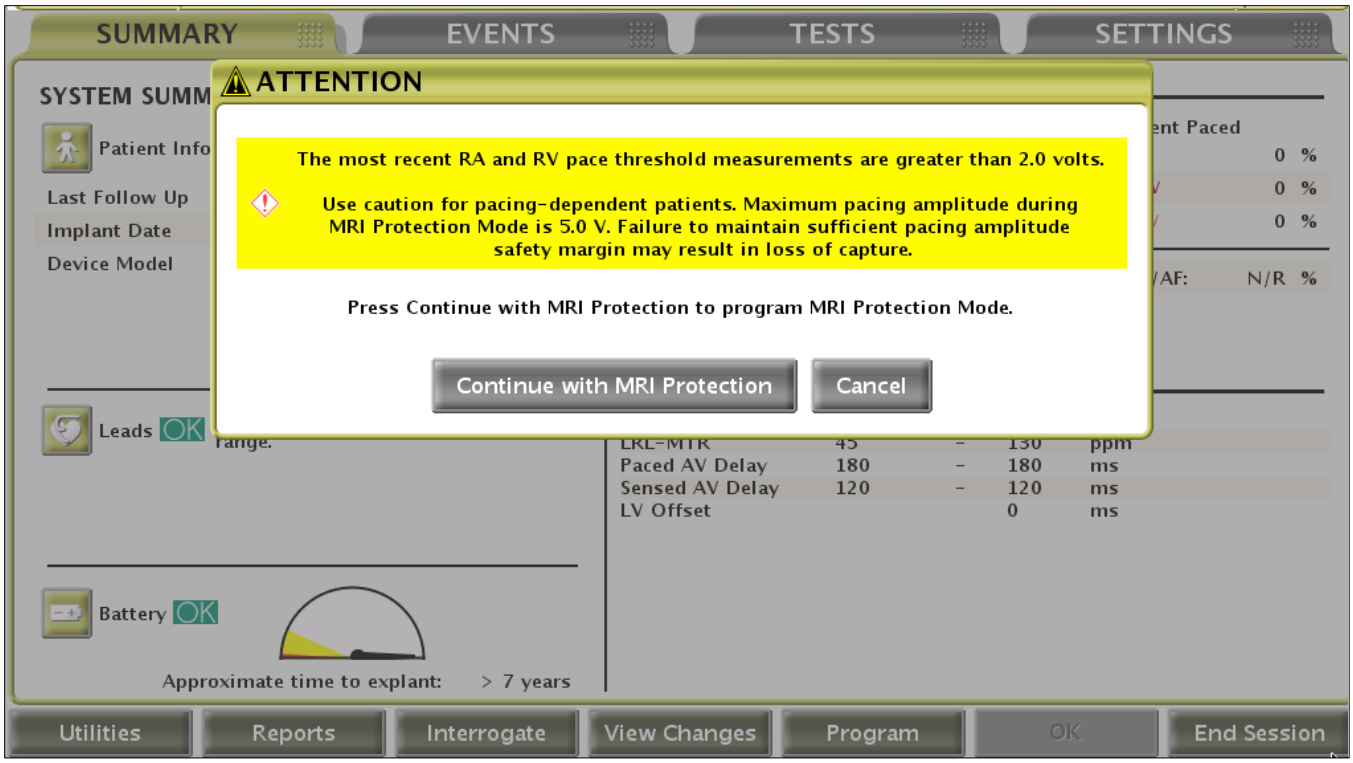

The programmer calculates the time since implant based on when the device was taken out of Storage Mode.

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.

## Recent RA and RV Pace Threshold Check




The system will automatically assess the most recently recorded RA and RV pacing threshold(s).

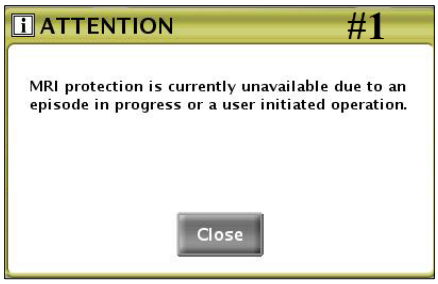
If the recorded threshold was > 2.0 V, an ATTENTION message appears on the screen advising the user to review risks of proceeding.

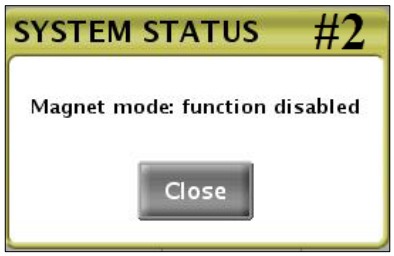
Pacing thresholds greater than 2.0 V may result in an insufficient safety margin and failure to capture in MRI Protection Mode. The maximum pacing amplitude during MRI Protection Mode is 5.0 V.

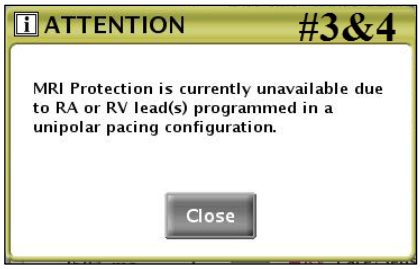
The most recent results of either the ambulatory PaceSafe™ tests or commanded tests are used.

## Additional Status Notifications

There are certain conditions in the device and/or system that will cause a user request to enter MRI Protection Mode to be rejected. 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.




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 an RA and RV bipolar pacing operation. The device will automatically confirm that the Pacing Lead Configuration is set to bipolar.

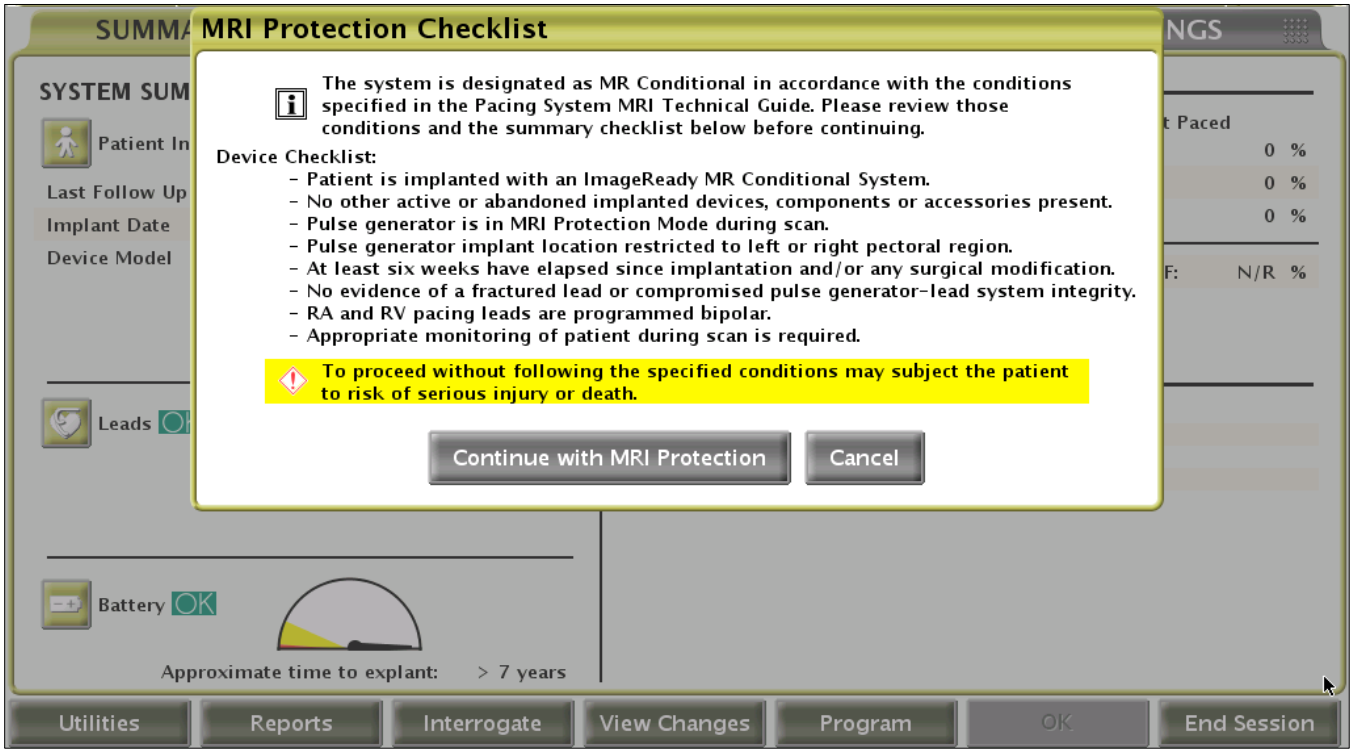
   Unipolar lead configurations increase the risk of induced voltages in the lead system. Additionally, bipolar ventricular pacing operation is required to support Safety Core operation, if Safety Core is entered from MRI Protection Mode.

   NOTE: The LV Lead can be programmed to unipolar pacing in MRI Protection Mode.
4. The user will see the same message if the device is in a STAT PACE mode, which uses unipolar pacing.

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

   a. Battery capacity status is Depleted
   b. Device is in Storage Mode
   c. Device is in Electrocautery Mode
   d. Device is in Safety Core operation (Safety Mode)
   e. A diagnostic test is in progress
   f. An EP test is in progress

## MRI Protection Checklist




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 for a patient to be eligible for an MR Conditional Scan.

Note: Labeling provides additional Conditions of Use 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.

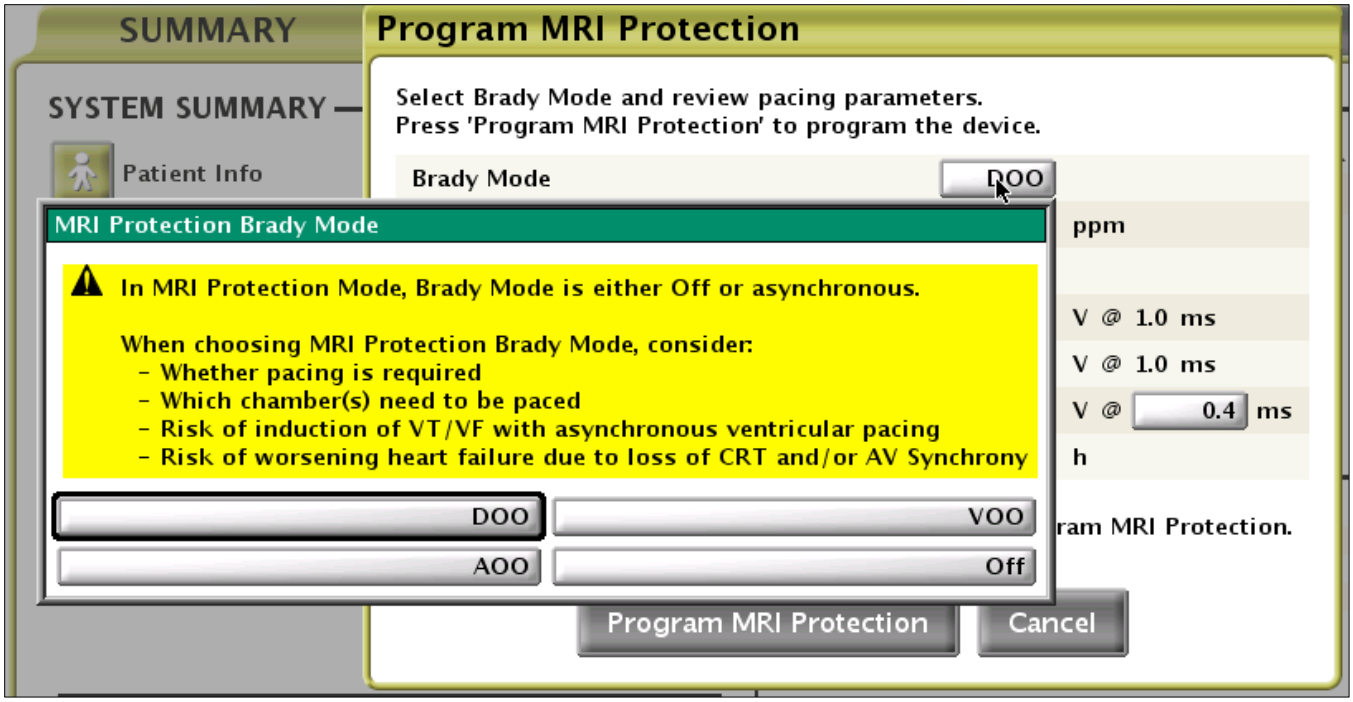
If the Conditions of Use are not met, the Cancel button is selected to return to normal system operation, and the patient does not undergo an MRI scan.

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 for 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.

## Programming Parameters

### Brady Mode

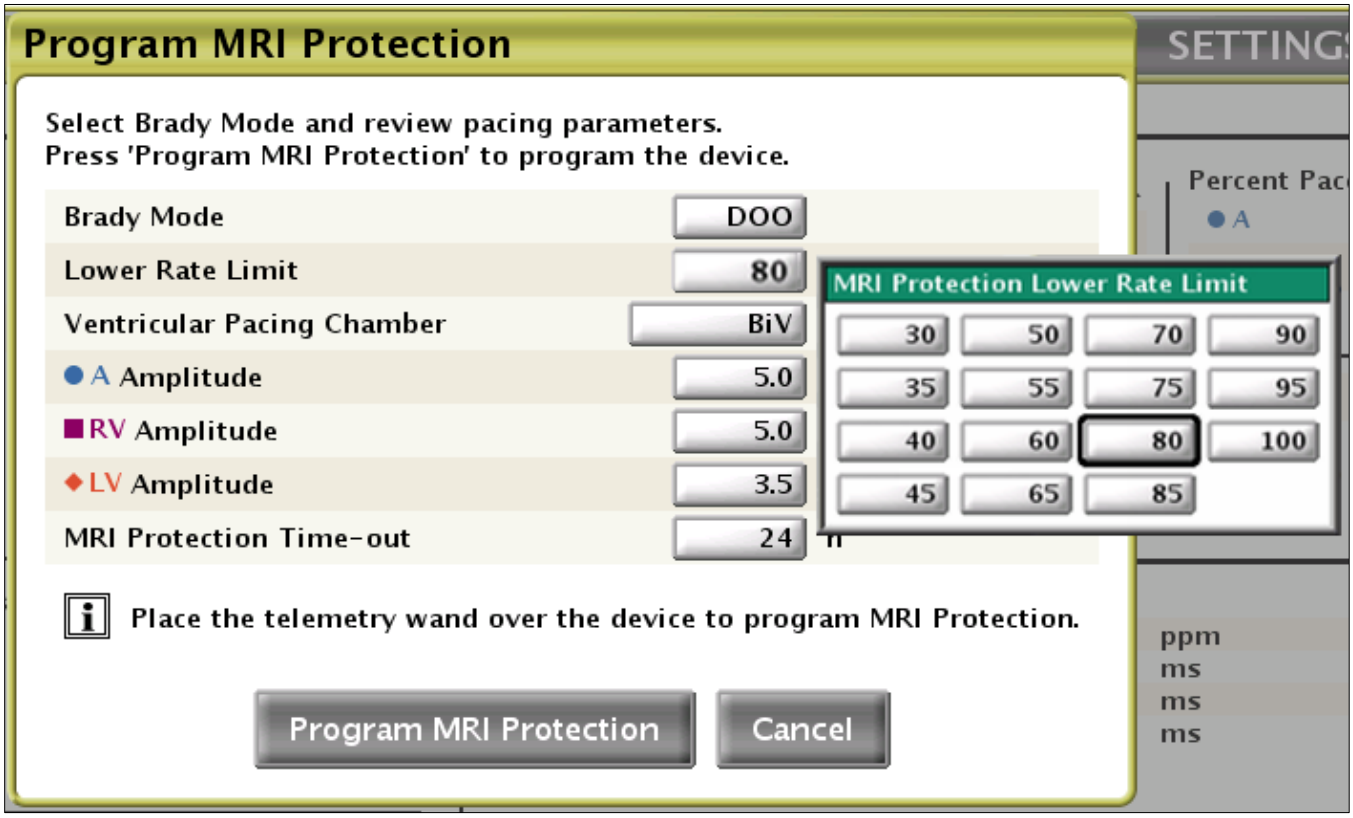



Use the dialog box to set the Brady Mode: DOO, VOO, AOO, or Off. Options in programming Brady mode include points of consideration for the clinician.

Note during MRI Protection Mode, if Brady Mode is programmed to Off, Bradycardia therapy and Cardiac Resynchronization Therapy (CRT) are suspended. The patient will not receive pacing until the pulse generator is programmed back to normal operation. Only program Brady Mode to Off during MRI Protection Mode if the patient is judged to be clinically capable of tolerating no Bradycardia therapy and/or no CRT for the entire duration in which the pulse generator is in MRI Protection Mode.

Per labeling, do not leave the pulse generator in MRI Protection Mode any longer than necessary following the scan.

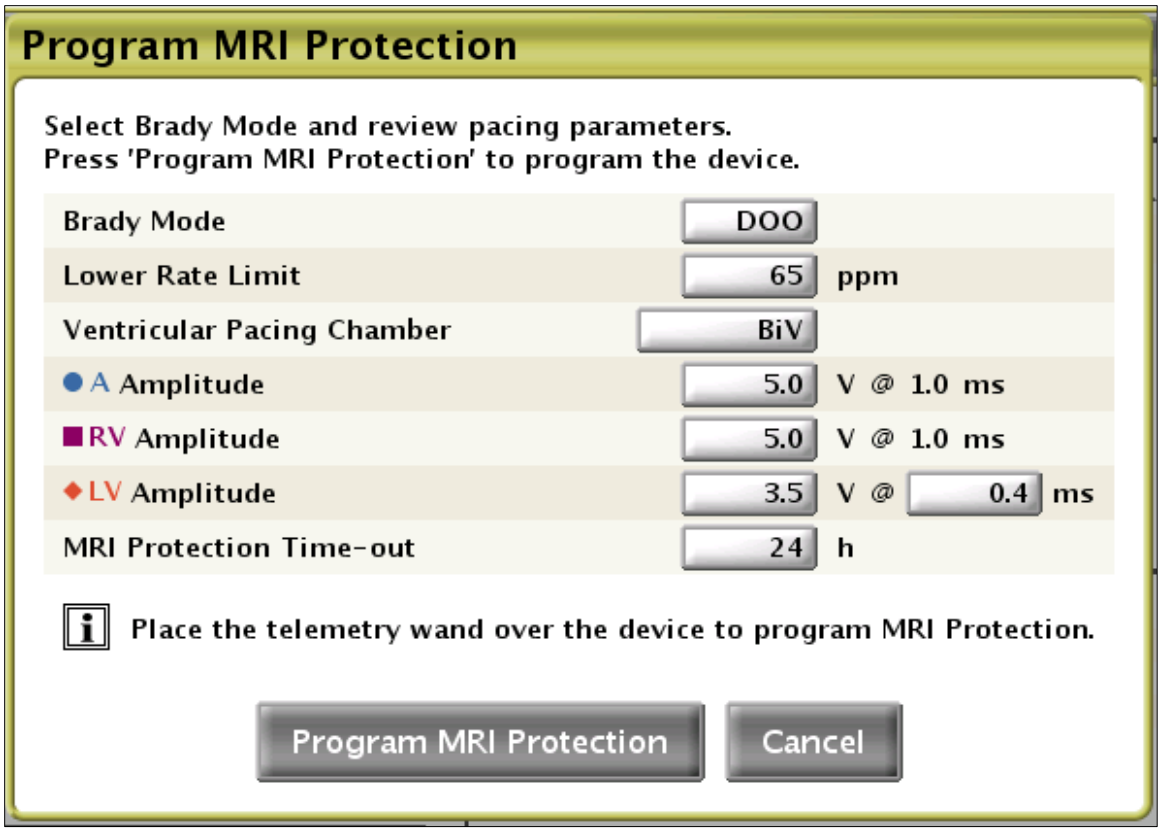
### Lower Rate Limit




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.

**Pacing Amplitude: RA and RV**



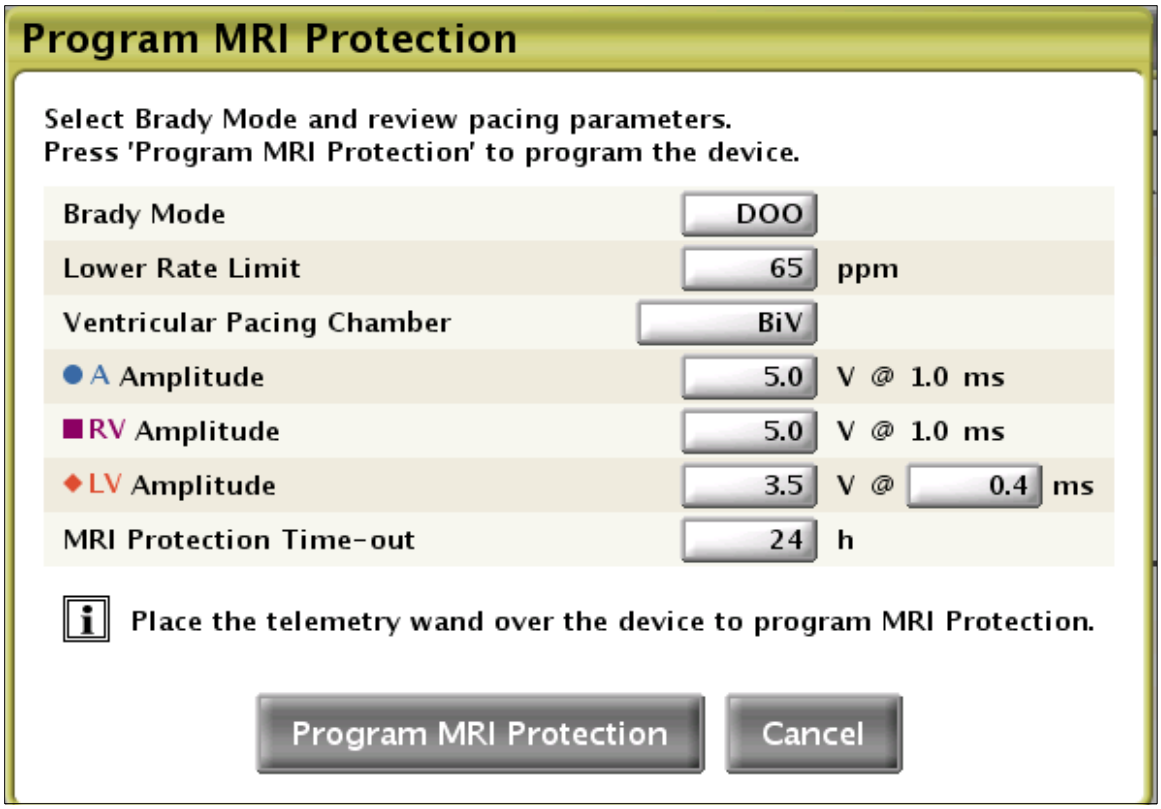

Set the Atrial and Right Ventricular Amplitudes, programmable in normal increments from 2.0 - 5.0 V with a fixed pulse width of 1.0 ms.

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.

Note programming pacing amplitudes below 5.0 V are provided as an option in case of extracardiac stimulation.

In CRT-P devices, the RA pace pulse may decay more rapidly in MRI Protection Mode than in normal mode if all 3 chambers (RA, RV, and LV) are simultaneously paced.  Pacing amplitude of 5.0 V is recommended to ensure RA capture.

**Pacing Amplitude: LV**

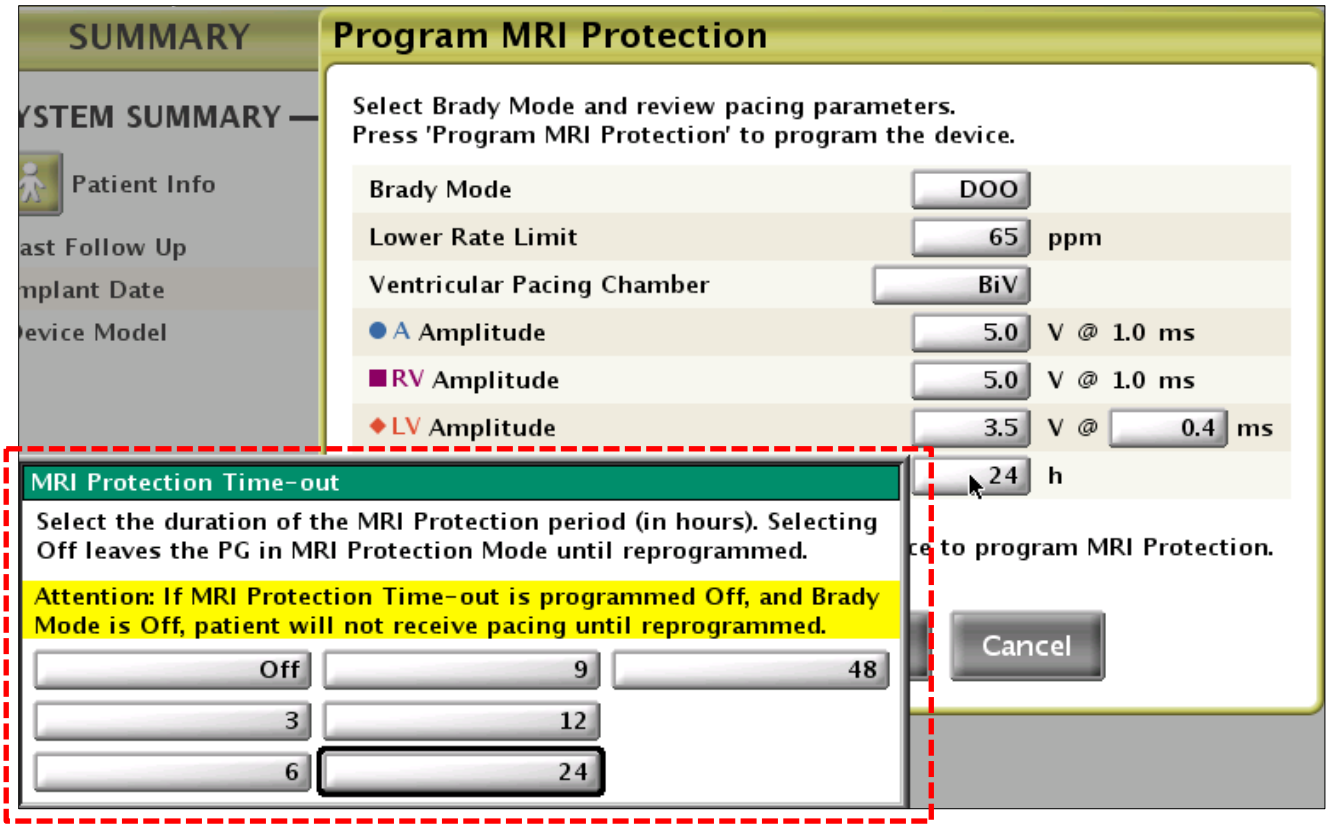



Set the Left Ventricular Amplitude, which defaults to the normal Brady value when within the range of 2.0 V to 5.0 V (inclusive) and is programmable in normal increments from 2.0 to 5.0 V. The pulse width defaults to the normal Brady setting and is programmable in normal increments from 0.1 ms to 2.0 ms.

Note if the normal programmed value is outside the 2.0 V to 5.0 V range, the MRI amplitude value will be set to the nearest end of the value range (i.e., if the LV lead is normally programmed to 1.0 V, the MRI value will be set to 2.0 V).

Note the minimum allowed pacing amplitude for the LV lead is 2.0 V. If extracardiac stimulation is a concern at LV pacing amplitudes programmed to 2.0 V, consider programming the MRI Protection Ventricular Pacing Chamber to RV Only and minimize the time in MRI Protection Mode, if the patient does not require LV pacing.

### Time-out Function




The MRI Protection Time-out function is programmable 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, 3, 6, 9, 12, 24, and 48 hours.

Before enabling the Time-out function, verify the programmer clock is set to the correct time and date to ensure accuracy of the projected expiration time (displayed on the screen and on the printed MRI Protection Settings Report).

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 function is set to a value other than Off, the Radiologist verifies that adequate time remains to complete the scan.

Note that if a subsequent wanded telemetry session is started during the MRI Protection Mode with the Time-out function enabled, the Time-out function will reset to the start of the initially selected time period.

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

### PaceSafe

If PaceSafe™ Automatic Capture (RVAC) was programmed on, this function 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.

### Minute Ventilation

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.

MV-driven rate response is not available during this calibration period.

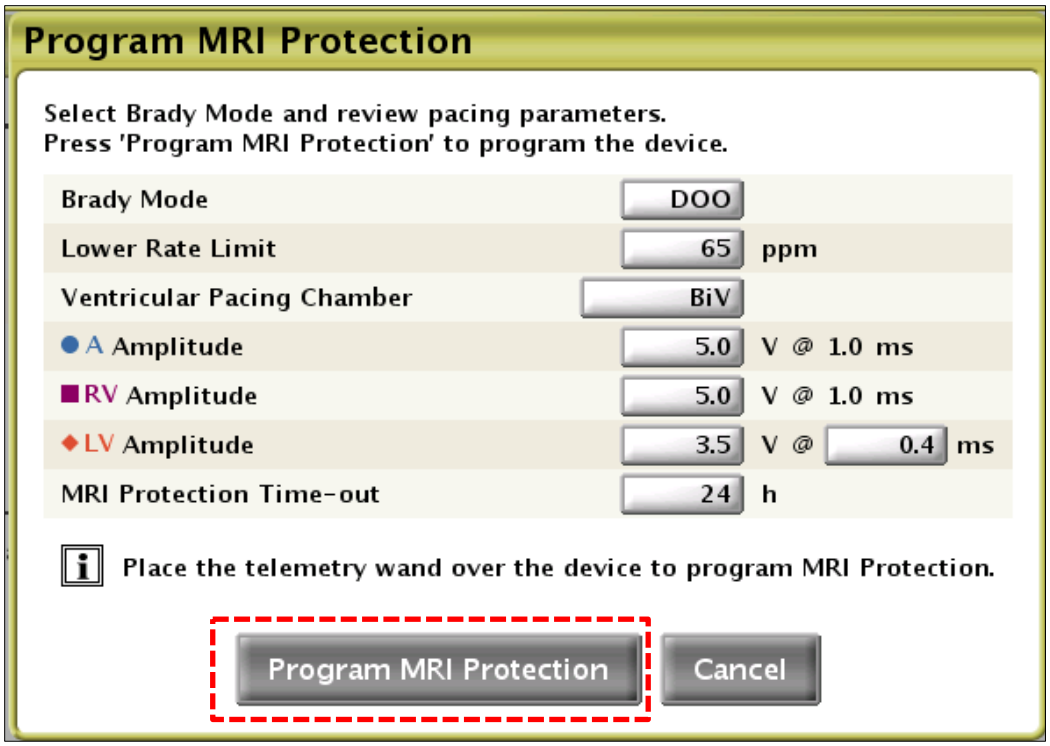
If MV-driven rate response is desired sooner, a manual calibration can be performed.

### Important

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.

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

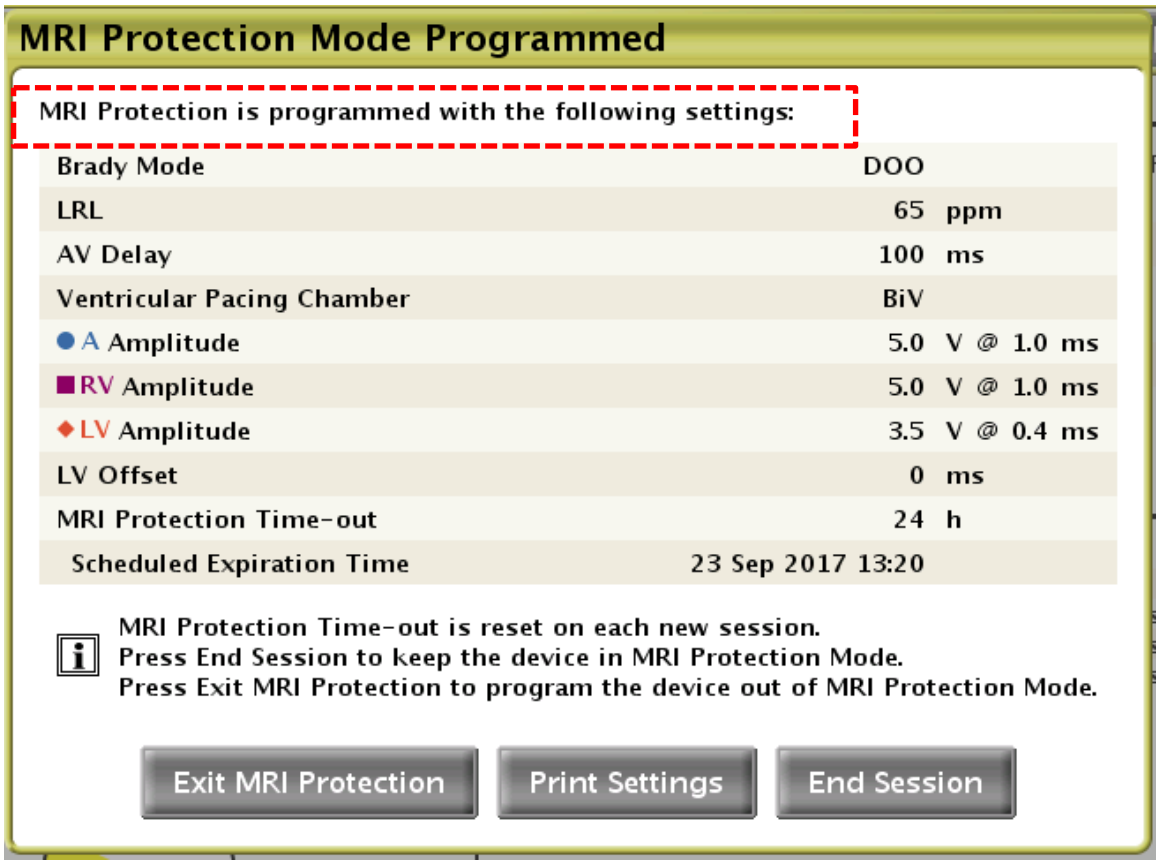
### Program MRI Protection Mode




Once all settings have been determined, the user is now ready to enable MRI Protection.

A message is presented on the screen reminding the user that the telemetry wand must be used for programming the device.

### Confirm MRI Protection Mode Enabled




This screen indicates the device has been successfully programmed into MRI Protection Mode at the settings indicated. The scan should not proceed until this confirmation screen is seen.

Print a copy of the settings before ending the session.

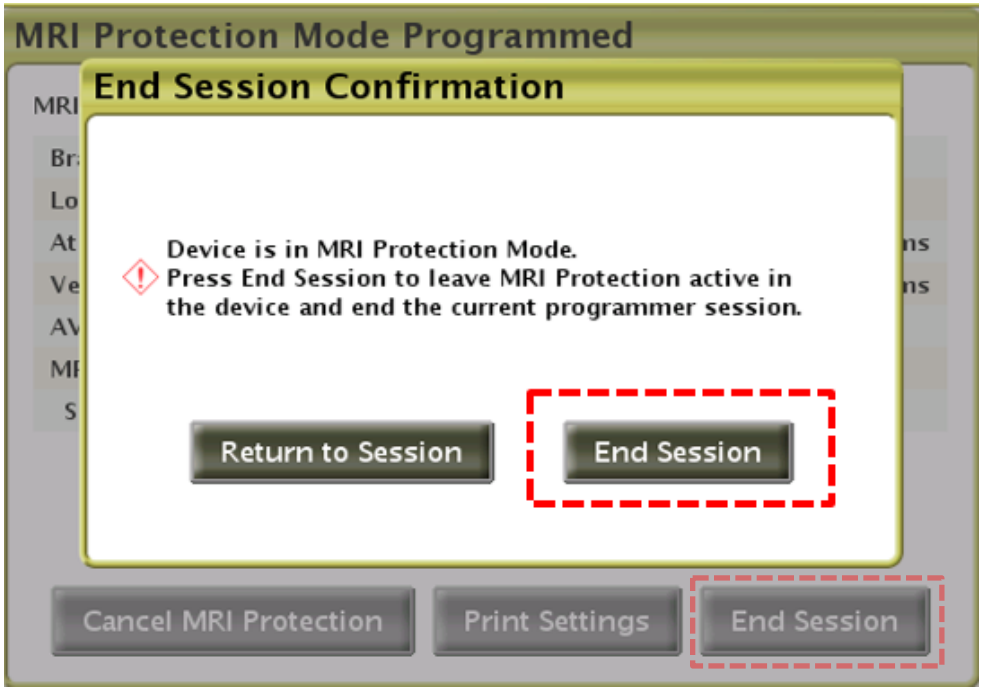
The report lists the settings in operation during MRI Protection Mode, including the time and date MRI Protection Mode will expire, if the Time-out function is used.

The printed report can be placed in the patients' file and used by Radiology personnel to confirm that sufficient time remains to complete the MRI Scan.

### MRI Protection Settings Report

A sample of the MRI Protection Settings Report is available in the MRI Technical Guide: ImageReady™ MR Conditional Pacing System at www.bostonscientific.com/imageready.

### Ending the Telemetry Session




Selecting the End Session button will end the current programmer session with the device remaining in MRI Protection Mode.

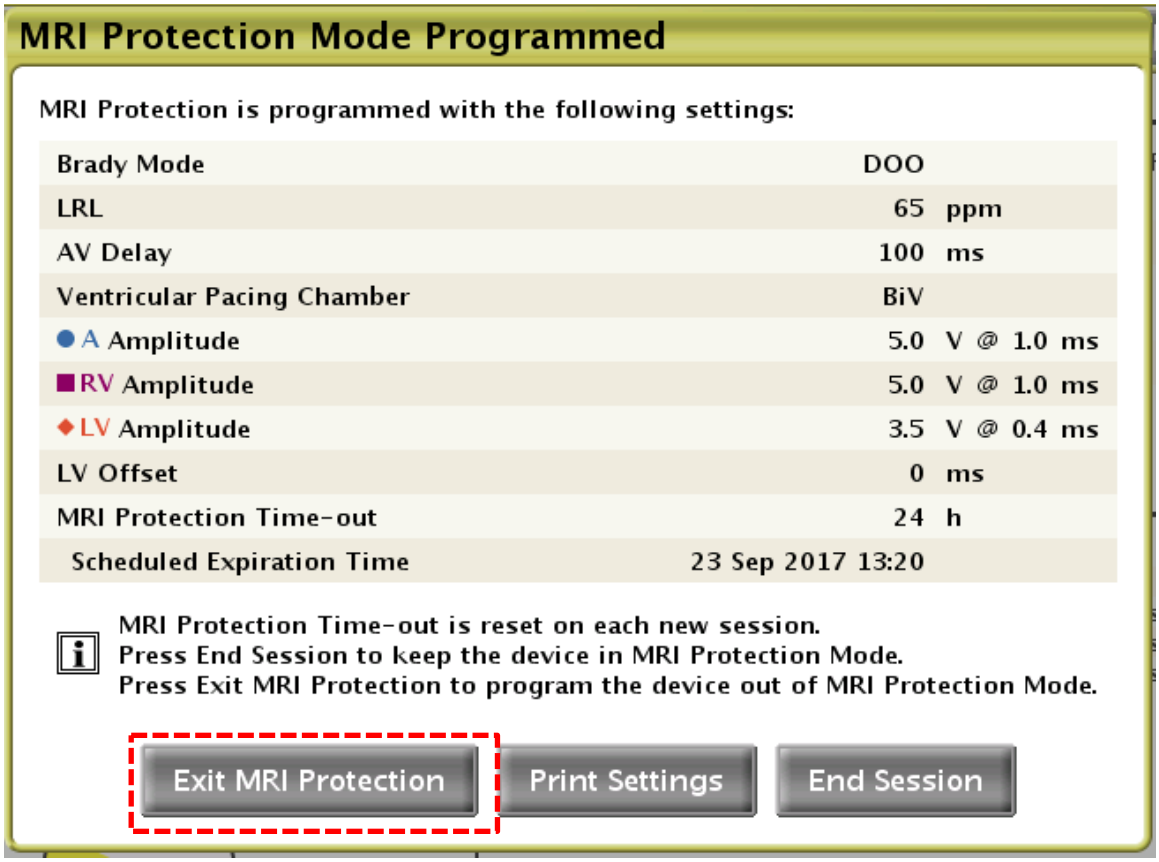
Remember, if Brady Mode is programed to Off, the patient will not receive Bradycardia pacing and CRT.

When Brady Mode is programmed Off, it is recommended to have a Boston Scientific Programmer powered On near the MRI room in case the patient develops the urgent need for pacing.

Most device functions shutdown in MRI Protection Mode, including:

- PaceSafe™
- Cardiac sensing
- Daily diagnostics (lead impedance, intrinsic amplitude, pace threshold)
- Motion and respiratory sensors
- Magnet detection
- RF telemetry
- Battery voltage monitoring

### Exiting MRI Protection Mode




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 value was programmed to a value other than Off, the device will exit MRI Protection Mode automatically after the selected number of hours.

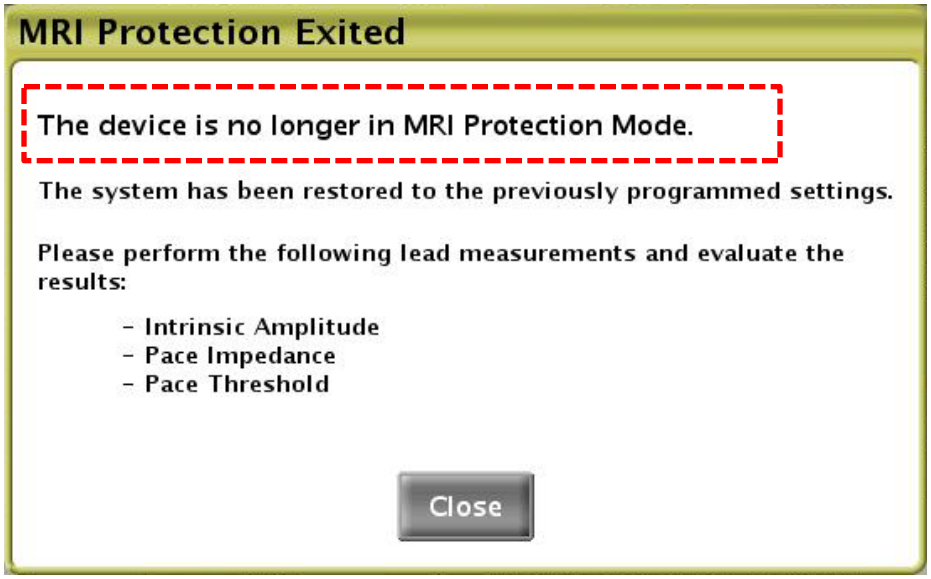
Alternatively, if the Time-out function is not used (is programmed to Off), the device must be interrogated by the wand to exit MRI Protection Mode.

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

Select the Exit MRI Protection button.

Note that if necessary, STAT PACE or DIVERT THERAPY can also be used to exit MRI Protection Mode.

### Evaluate Device

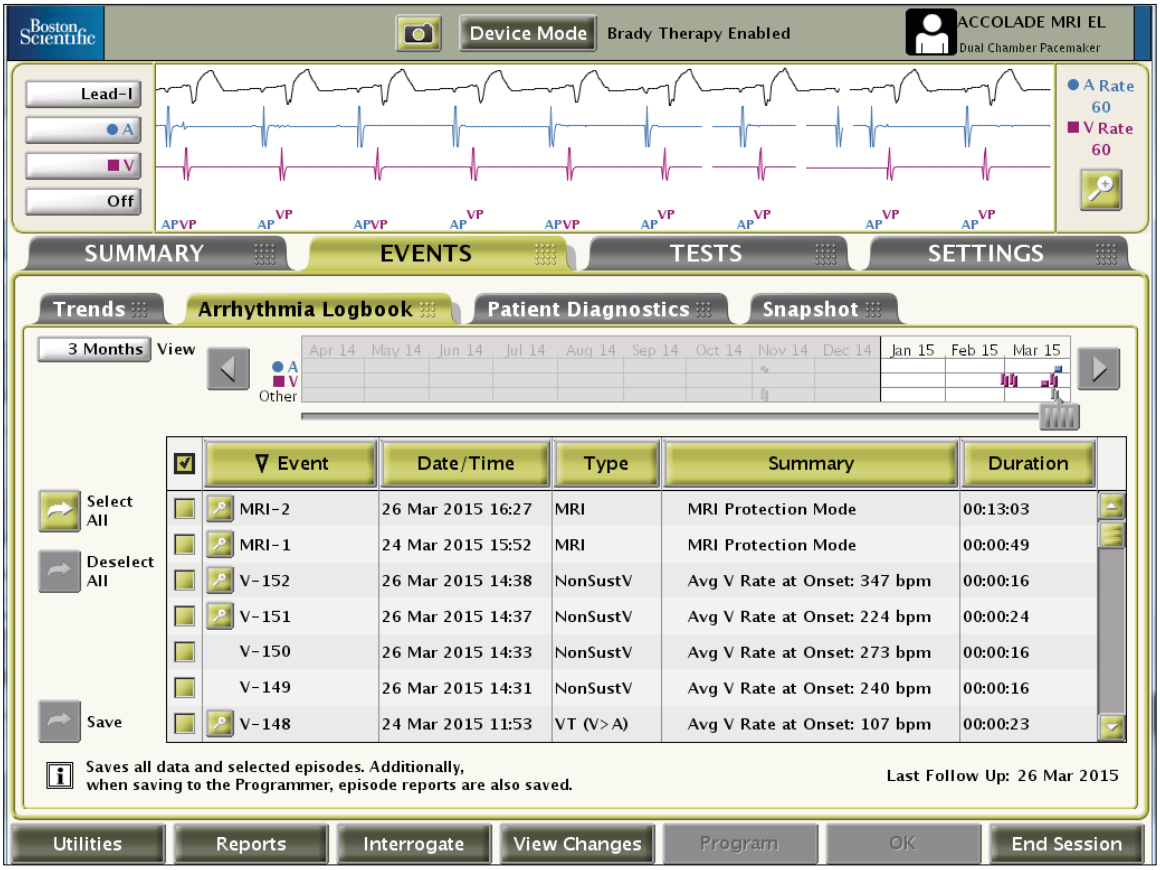



Following user-initiated cancellation of MRI Protection Mode, the programmer will automatically navigate to the Lead Tests screen and prompt the user to perform the following lead tests:

- Intrinsic amplitude
- Pace impedance
- Pacing threshold

When testing is complete, it is recommended that the Programmer be used to save all patient data.

## Event Storage – VITALIO™ MRI, ESSENTIO™ MRI, PROPONENT™ MRI, and ACCOLADE™ MRI




For VITALIO™ MRI, ESSENTIO™ MRI, PROPONENT™ MRI, and ACCOLADE™ MRI devices, upon exiting MRI Protection Mode (either Timer initiated or manually exited), an MRI Episode is stored and can be printed as an episode report.

The MRI episode can also be viewed in the Arrhythmia Logbook via Remote Patient Monitoring (if available).

Note that VALITUDE™ X4, and VISIONIST™ X4 (CRT-P) devices do not store an MRI Episode. The indication that CRT-P devices have been in MRI Protection Mode will be found in the MRI counters in LATITUDE™ and on the device Summary Screen.

## CRT-P Systems – VISIONIST™, VISIONIST™ X4, VALITUDE™, VALITUDE™ X4, INTUA™, INVIVE™

**Indications and Usage**

Boston Scientific cardiac resynchronization therapy pacemakers (CRT-Ps) are indicated for patients with moderate to severe heart failure (NYHA Class III/IV) including left ventricular dysfunction (EF <=35%) and QRS duration >= 120 ms and remain symptomatic despite stable optimal pharmacological therapy (OPT) for heart failure.
Atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony.
Adaptive-rate pacing is indicated for patients exhibiting chronotropic incompetence and who would benefit from increased pacing rates concurrent with increases in physical activity.

**Contraindications**

These Boston Scientific pulse generators have the following contraindications:

- In patients who have a separate implanted cardioverter defibrillator (ICD) with transvenous leads;
- Unipolar pacing or use of the Respiratory Sensor with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) is contraindicated because it may cause inappropriate therapy or inhibition of appropriate S-ICD therapy;
- Single-chamber atrial pacing is contraindicated in patients with impaired AV nodal conduction;
- Atrial tracking modes are contraindicated in patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing;
- And asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms.

**Warnings**

Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only**.** Do not reuse, reprocess, or resterilize. Such damage may result in patient injury, illness, or death. Always have external defibrillation equipment available during implant and electrophysiologic testing. Using multiple pulse generators could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. In response to applicable nonrecoverable or repeat fault conditions, the pulse generator will switch irreversibly to Safety Core operation. Do not kink, twist, or braid the lead with other leads. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not contact any other portion of the IS4–LLLL lead terminal, other than the terminal pin, even when the lead cap is in place. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. Lead Safety Switch should be programmed Off for patients with an ICD. Unipolar pacing due to Lead Safety Switch is contraindicated for patients with an ICD. Unipolar pacing due to RAAT is contraindicated and should be programmed off for patients with an ICD. Left ventricular lead dislodgement to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition. If programmed to a fixed atrial Sensitivity value of 0.15 mV, or a fixed sensitivity value of 2.0 mV or less in a unipolar lead configuration in any chamber, the pulse generator may be more susceptible to electromagnetic interference. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy.

**Precautions**

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage; implantation; device programming; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments; follow-up testing; explant and disposal; supplemental precautionary information
These pulse generators are compatible for use with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) when implanted with bipolar leads and programmed to a bipolar pacing configuration.

**Potential Adverse Events**

Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of s hocking, fear of device failure, or imagined s hocking. In rare cases severe complications or device failures can occur.
*Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev C)*

## Pacing Systems - ACCOLADE™, ACCOLADE™MRI, PROPONENT™, PROPONENT™ MRI, ESSENTIO™, ESSENTIO™MRI, ALTRUA™ 2, FORMIO™, FORMIO™ MRI, VITALIO™, VITALIO™MRI, INGENIO™, INGENIO™MRI, ADVANTIO™

**INDICATIONS AND USAGE**

Boston Scientific pacemakers are indicated for treatment of the following conditions:

- Symptomatic paroxysmal or permanent second- or third-degree AV block
- Symptomatic bilateral bundle branch block
- Symptomatic paroxysmal or transient sinus node dysfunction with or without associated AV conduction disorders (i.e., sinus bradycardia, sinus arrest, sinoatrial [SA] block)
- Bradycardia-tachycardia syndrome, to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias
- Neurovascular (vaso-vagal) syndromes or hypersensitive carotid sinus syndromes

Adaptive-rate pacing is indicated for patients exhibiting chronotropic incompetence and who may benefit from increased pacing rates concurrent with increases in minute ventilation and/or level of physical activity.

Dual-chamber and atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony.

Dual chamber modes are specifically indicated for treatment of the following:

- Conduction disorders that require restoration of AV synchrony, including varying degrees of AV block
- VVI intolerance (i.e., pacemaker syndrome) in the presence of persistent sinus rhythm
- Low cardiac output or congestive heart failure secondary to bradycardia

**CONTRAINDICATIONS**

These Boston Scientific pacemakers are contraindicated in patients who have a separate implanted cardioverter defibrillator (ICD) with transvenous leads.

Use of certain pacing modes and/or features available in these Boston Scientific pacemakers is contraindicated for the following patients under the circumstances listed:

- Unipolar pacing or use of the MV Sensor with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) because it may cause inappropriate therapy or inhibition of appropriate S-ICD therapy.
- Minute Ventilation in patients with both unipolar atrial and ventricular leads
- Single-chamber atrial pacing in patients with impaired AV nodal conduction
- Atrial tracking modes for patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing
- Dual-chamber and single-chamber atrial pacing in patients with chronic refractory atrial tachyarrhythmias
- Asynchronous pacing in the presence (or likelihood) of competition between paced and intrinsic rhythms

**WARNINGS**

Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. Such damage can result in patient injury or death. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Using multiple pulse generators could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. In response to applicable nonrecoverable or repeat fault conditions, the pulse generator will switch irreversibly to Safety Core operation. Do not kink, twist, or braid the lead with other leads. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Lead Safety Switch should be programmed Off for patients with an ICD. Unipolar pacing due to Lead Safety Switch is contraindicated for patients with an ICD. Automatic Lead Recognition should be programmed to Off before implant for patients with an ICD. Unipolar pacing due to RAAT is contraindicated and should be programmed off for patients with an ICD. If programmed to a fixed atrial Sensitivity value of 0.15 mV, or a fixed sensitivity value of 2.0 mV or less in a unipolar lead configuration in any chamber, the pulse generator may be more susceptible to electromagnetic interference. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device. ACCOLADE MRI, PROPONENT MRI, ESSENTIO MRI, FORMIO MRI, VITALIO MRI and INGENIO MRI devices are considered MRI Conditional. For these devices, unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system. Significant harm to or death of the patient and/or damage to the implanted system may result. All other devices covered by this statement are not MR conditional. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to diathermy.

**PRECAUTIONS**

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage; implantation; device programming; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments; follow-up testing; explant and disposal; supplemental precautionary information. Advise patients to avoid sources of EMI. The pulse generator may inhibit pacing due to oversensing, or may switch to asynchronous pacing at the programmed pacing rate or at the magnet rate in the presence of EMI.

Refer to the MRI Technical Guide at www.bostonscientific-elabeling.com for a comprehensive list of Warnings and Precautions, and Conditions of Use that are applicable to MRI scanning of patients implanted with an ImageReady MR Conditional Pacing System.

These pulse generators are compatible for use with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) when implanted with bipolar leads and programmed to a bipolar pacing configuration.

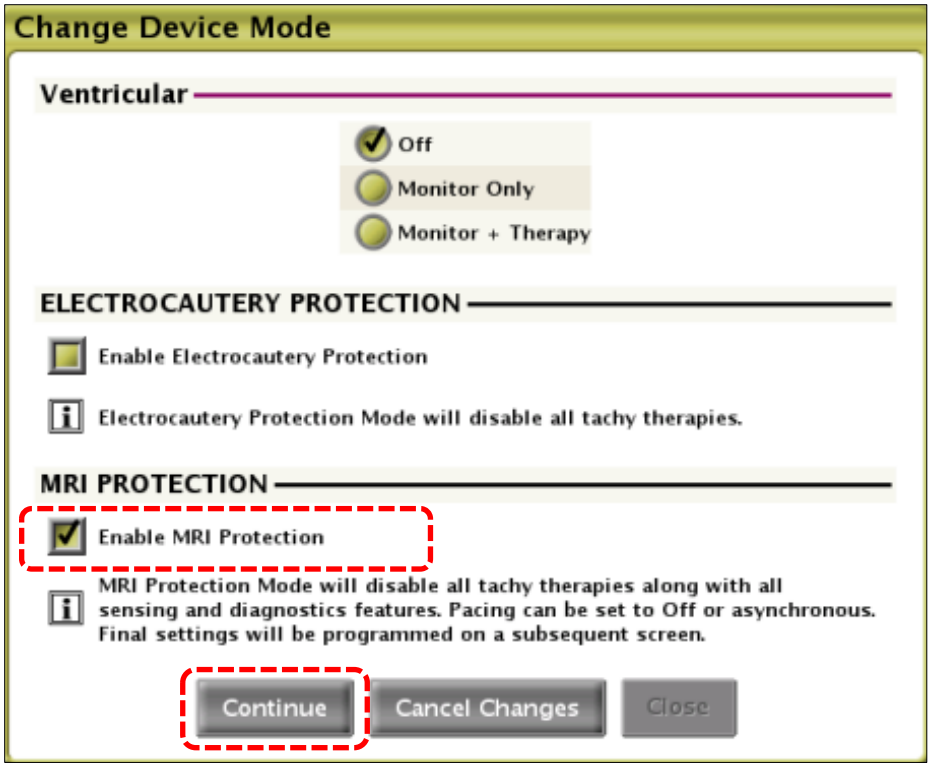
**POTENTIAL ADVERSE EVENTS**

Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse events associated with implantation of the included devices: Air embolism; Allergic reaction; Bleeding; Bradycardia; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Heart failure following chronic RV apical pacing; Inability to pace; Inappropriate pacing; Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Lead dislodgement; Lead fracture; Lead insulation breakage or abrasion; Lead perforation; Lead tip deformation and/or breakage; Local tissue reaction; Loss of capture; Myocardial infarction (MI); Myocardial necrosis; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential sensing; Oversensing/undersensing; Pacemaker-mediated tachycardia (PMT) (applies to dual-chamber devices only); Pericardial rub, effusion; Pneumothorax; Pulse generator migration; Shunting current during defibrillation with internal or external paddles; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Vasovagal response; Venous occlusion; Venous trauma (e.g., perforation; dissection, erosion); Worsening heart failure.

For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide.

Patients may develop psychological intolerance to a pulse generator system and may experience the following: Dependency; Depression; Fear of premature battery depletion; Fear of device malfunction. Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev. D) 046774 AG

# ImageReady™ MR-Conditional Transvenous Defibrillation System MRI Protection Mode Programming




## MRI Protection Mode General Information

Boston Scientific's ImageReady™ MR-Conditional Transvenous Defibrillation System has been created specifically as a system for use with MRI scans when performed under the Conditions of Use.

The Cardiology and Radiology Checklists describing Conditions of Use are available at www.bostonscientific.com/ImageReady

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.

Prior to starting programming, print the Device Settings Report as a reference for choosing Brady settings in MRI Protection Mode.

Use the Tachy Mode button to enable MRI Protection Mode.

Select the Enable MRI Protection button and then choose Continue.

The ImageReady™ MR-Conditional Transvenous Defibrillation System is designed with several built-in safety reminders, viewable as ATTENTION Screens.

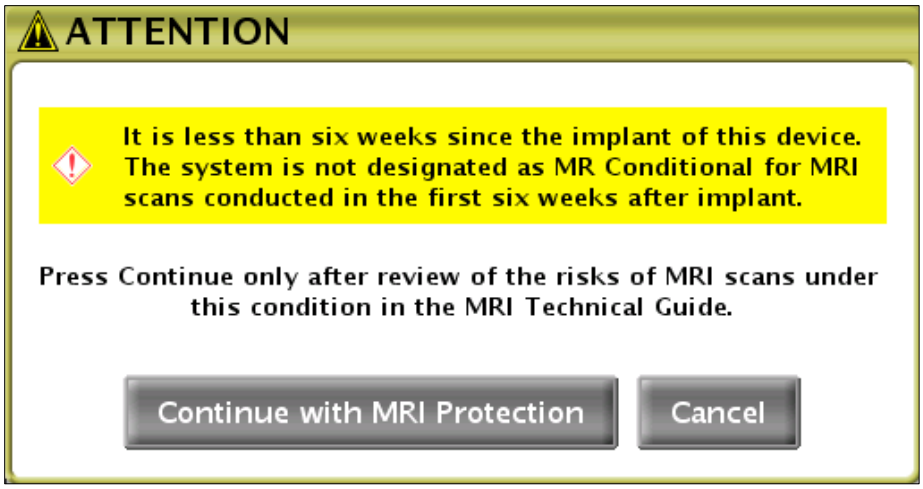
The Programmer determines the time since implant, based on the date and time when the pulse generator was taken out of Storage Mode.

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.

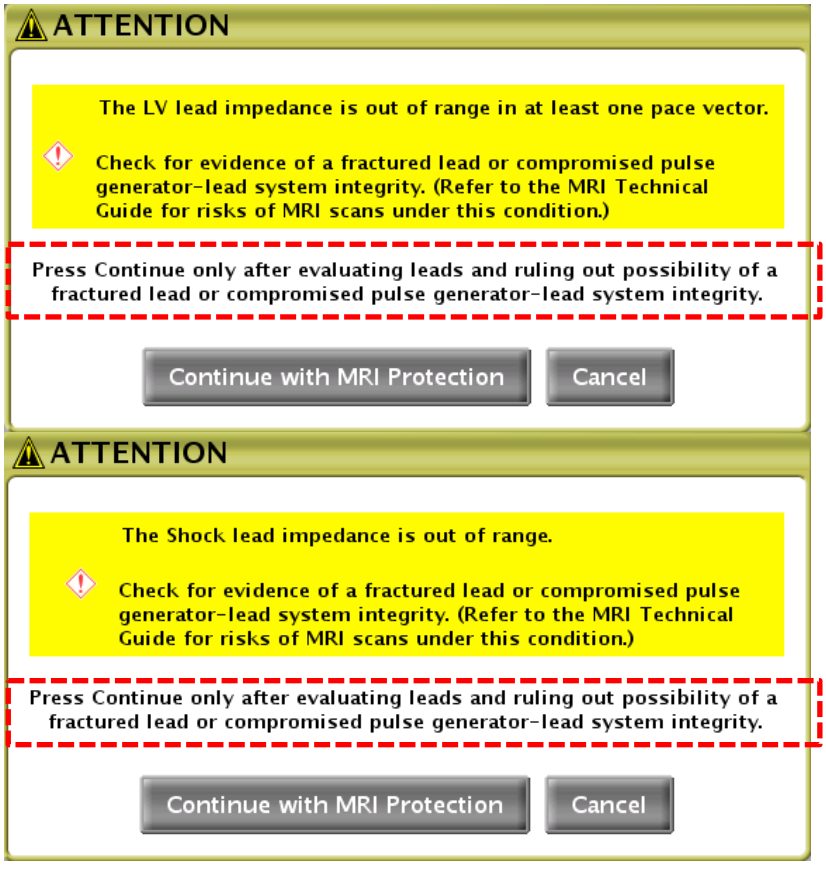
### Time Since Implant Check




A user request to enter MRI Protection Mode triggers a lead impedance test in all chambers. If the impedance value for any of the leads, including shock impedance, 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. Below are two examples:

### Lead Impedance Check




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

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

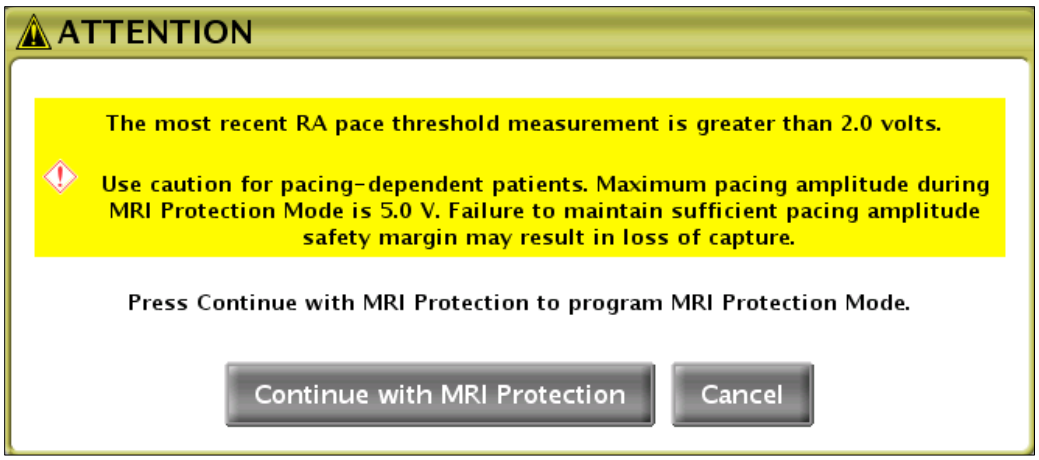
### Recent RA and RV Pace Threshold Check

The system will automatically assess the most recently recorded RA and RV pacing threshold(s). The LV threshold is not checked.

If the RA or RV threshold is greater than 2.0 V, an ATTENTION message appears on the screen recommending the use of caution for pacing-dependent patients.

Pacing thresholds greater than 2.0 V may result in an insufficient safety margin and loss of capture in MRI Protection Mode.

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



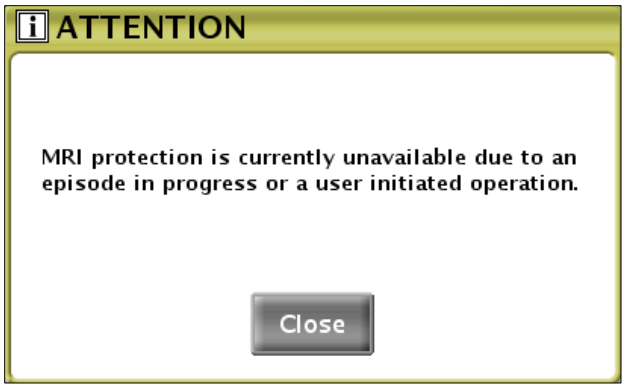

There are certain conditions assessed during programming that will prevent entry into MRI Protection Mode. There will be no option to continue with MRI Protection programming.

These include:

1. A ventricular episode as detected and recognized by the device is in progress.
2. Magnet presence is detected by the magnet sensor.
3. The Pulse generator is in STAT PACE or STAT SHOCK mode.

If one or more of these conditions are present, a dialog box will appear describing the condition, and MRI Protection Mode cannot be entered.

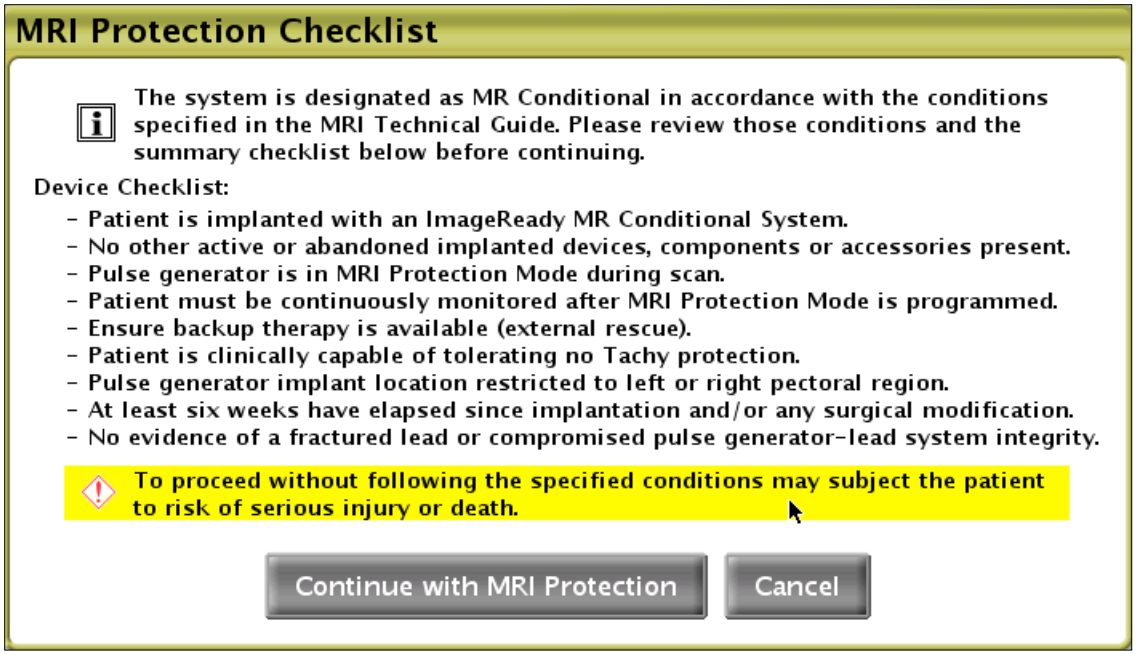
The example below is an 'episode in progress' ATTENTION message:



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

- Battery status is Depleted
- Pulse generator is in Storage Mode
- Pulse generator is in Electrocautery Mode
- Pulse generator is in Safety Core operation (Safety Mode)
- Diagnostic test is in progress
- EP test is in progress

### MRI Protection Checklist




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.

**Note:** Labeling provides additional Conditions of Use and details regarding the Radiology Checklist.

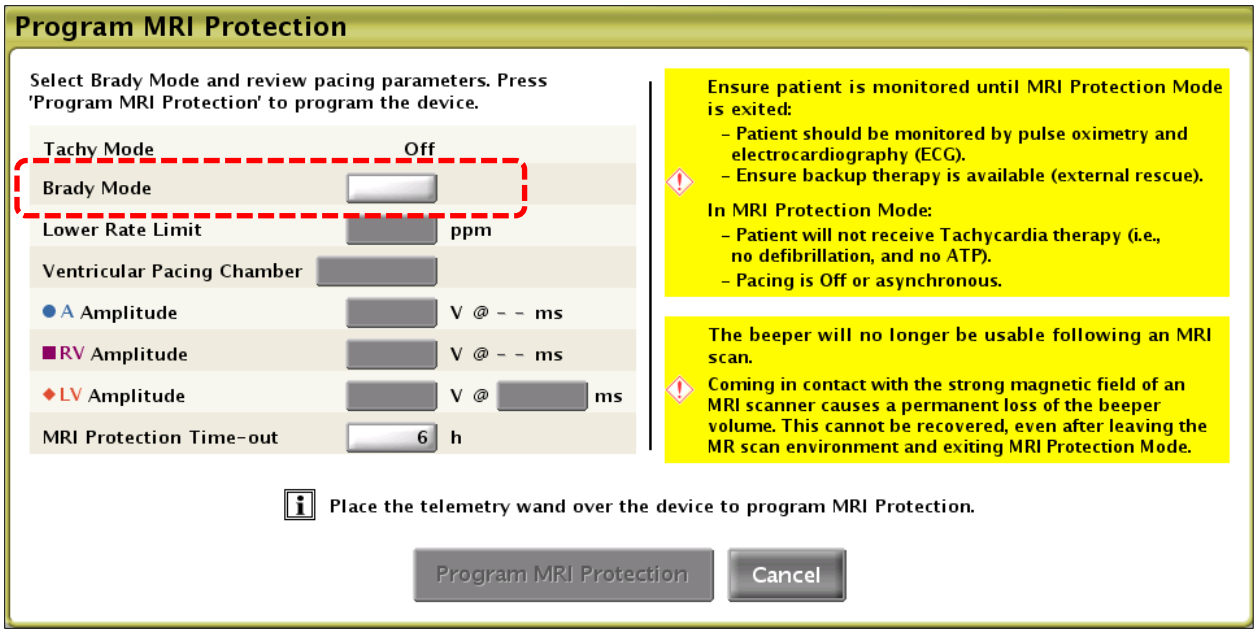
Appropriate monitoring of the patient includes continuous monitoring of the patient's pulse oximetry and ECG for the entire duration in which the pulse generator is in MRI Protection Mode. Backup therapy must be available for external rescue.

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 of 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 parameters shown on the next page.

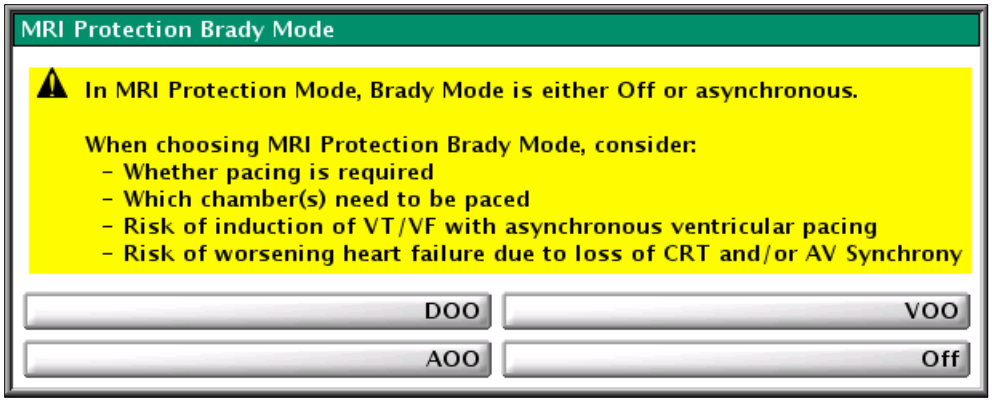
## Programming Parameters

### Brady Mode




Options in programming Brady mode include points of consideration for the clinician.

Use the dialog box to select the Brady Mode. Asynchronous pacing should only be used if the patient is pacing-dependent.



## Nominal Settings for DOO Mode in CRT-D

If asynchronous pacing is required, program the additional pacing parameters. Below are the nominal settings when DOO Brady Mode is selected in a CRT-D pulse generator.

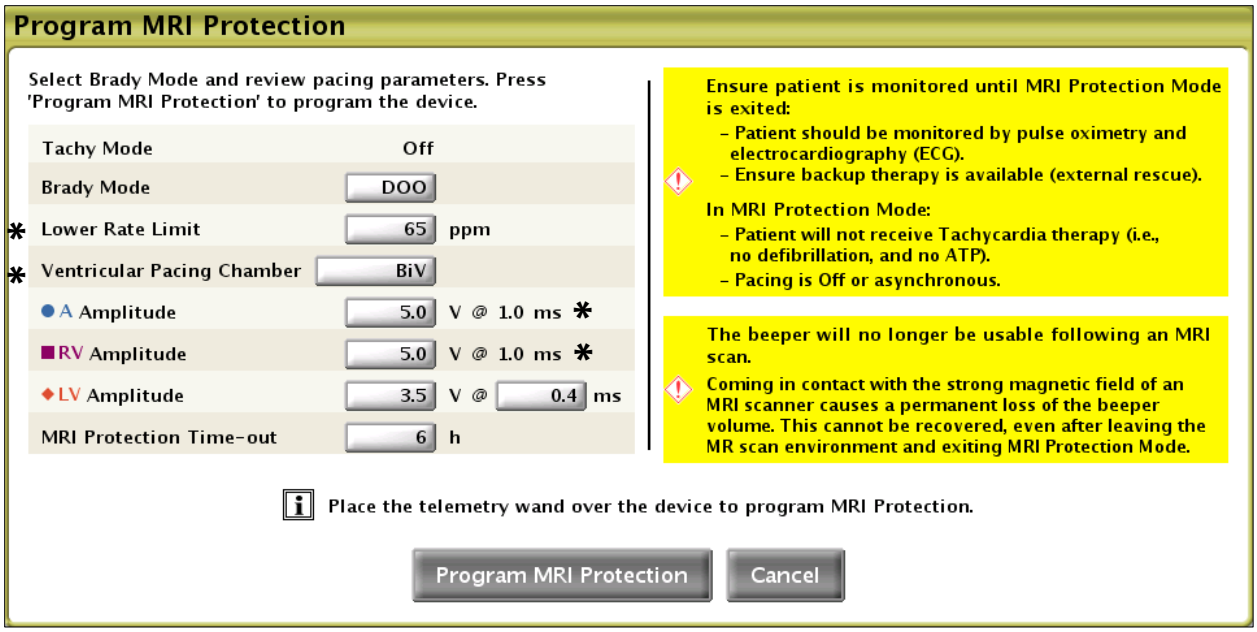
***Note:** Lower Rate Limit defaults to 20 ppm above normal mode LRL.

***Note:** AV Delay is fixed to 100ms.

***Note:** Ventricular Pacing Chamber is limited to BiV or RV Only (no LV Only)

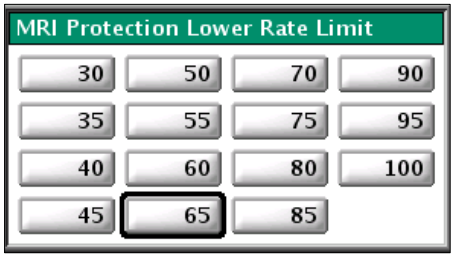
***Note:** Atrial and Right ventricular pulse width is fixed at 1.0ms.

***Note:** Left ventricular amplitude defaults to the normal Brady value when within the range of 2.0 V-5.0 V and pulse width defaults to the normal Brady setting. If the normal Brady value is outside of the 2.0 V - 5.0 V range, the MRI amplitude value will be set to the nearest end of the value range.

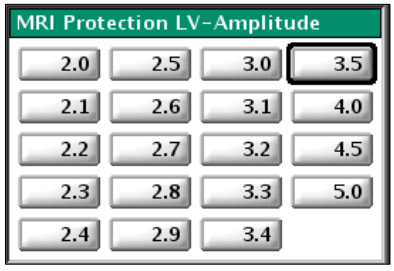



## Programmable Options:

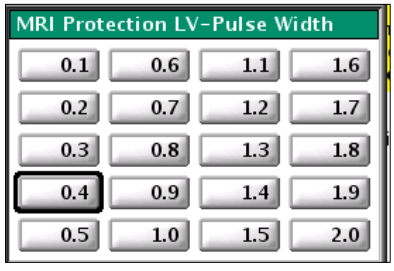
### Lower Rate Limit All Chambers




### Pacing Amplitudes All Chambers

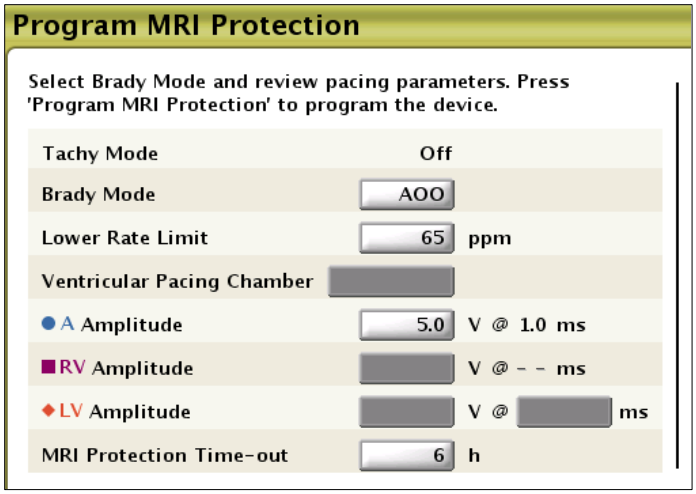



### Pulse Width LV Only



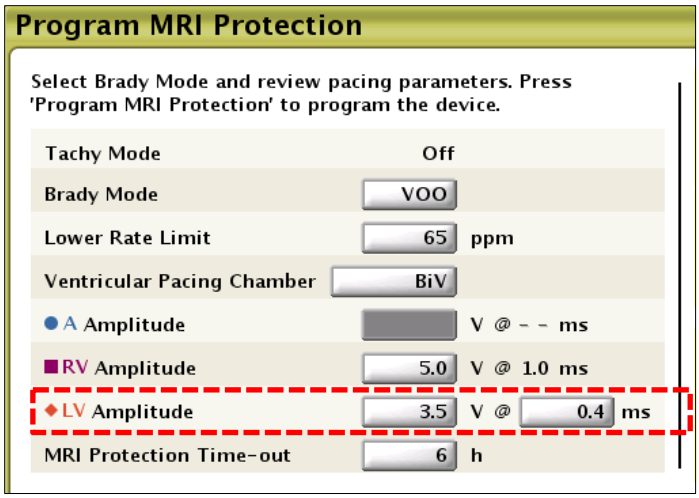
## Nominal Settings for AOO Mode in CRT-D

Below are the nominal settings when AOO Brady Mode is selected in a CRT-D pulse generator.




## Nominal Settings for VOO Mode in CRT-D

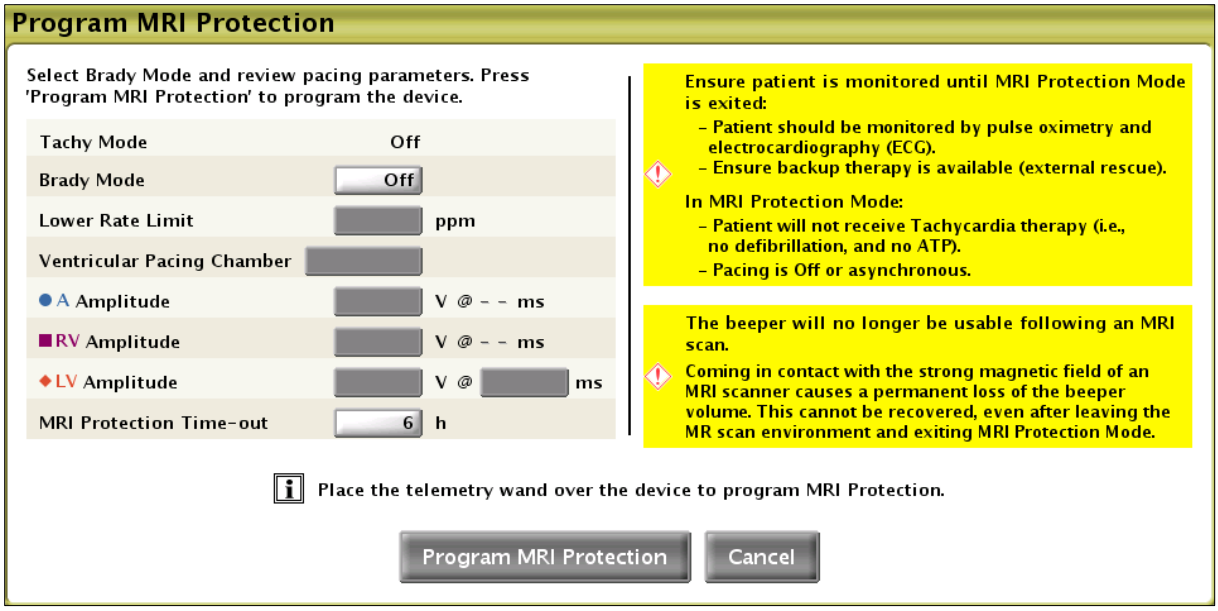
Below are the nominal settings when VOO Brady Mode is selected in a CRT-D pulse generator.



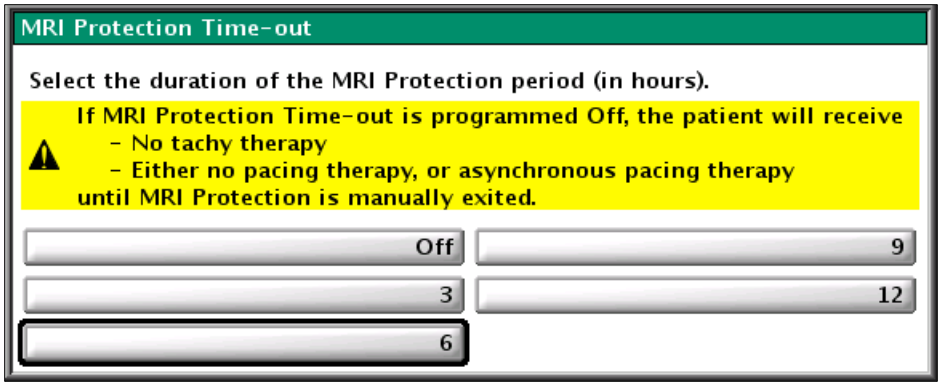

**Left ventricular amplitude defaults to the normal Brady value when within the range of 2.0 V-5.0 V and pulse width defaults to the normal Brady setting. If the normal Brady value is outside of the 2.0 V - 5.0 V range, the MRI amplitude value will be set to the nearest end of the value range.**

## Nominal Settings for Brady Mode Off in CRT-D

Below are the nominal settings when Brady Mode Off is selected.




## Time-out Function




The MRI Protection Time-out function allows the user to choose the length of time the pulse generator remains in MRI Protection Mode.

Programmable values (in hours) of MRI Protection Time-out, chosen by the user, are Off, 3, 6, 9, and 12.

Before enabling the Time-out function, verify the programmer clock is set to the correct time and date to ensure accuracy of the projected expiration time (displayed on the screen and on the printed MRI Protection Settings Report).

When the programmed time has elapsed, the pulse generator automatically exits MRI Protection Mode and all parameters (except for the Beeper) return to the previously programmed settings. Important to note, if the Time-out value is programmed to Off, the device will remain in MRI Protection Mode indefinitely; only a programmer can be used to exit MRI Mode. The patient cannot receive automatic tachy therapy, and either no pacing therapy or asynchronous pacing therapy until MRI Protection is manually exited.

## Program MRI Protection Mode

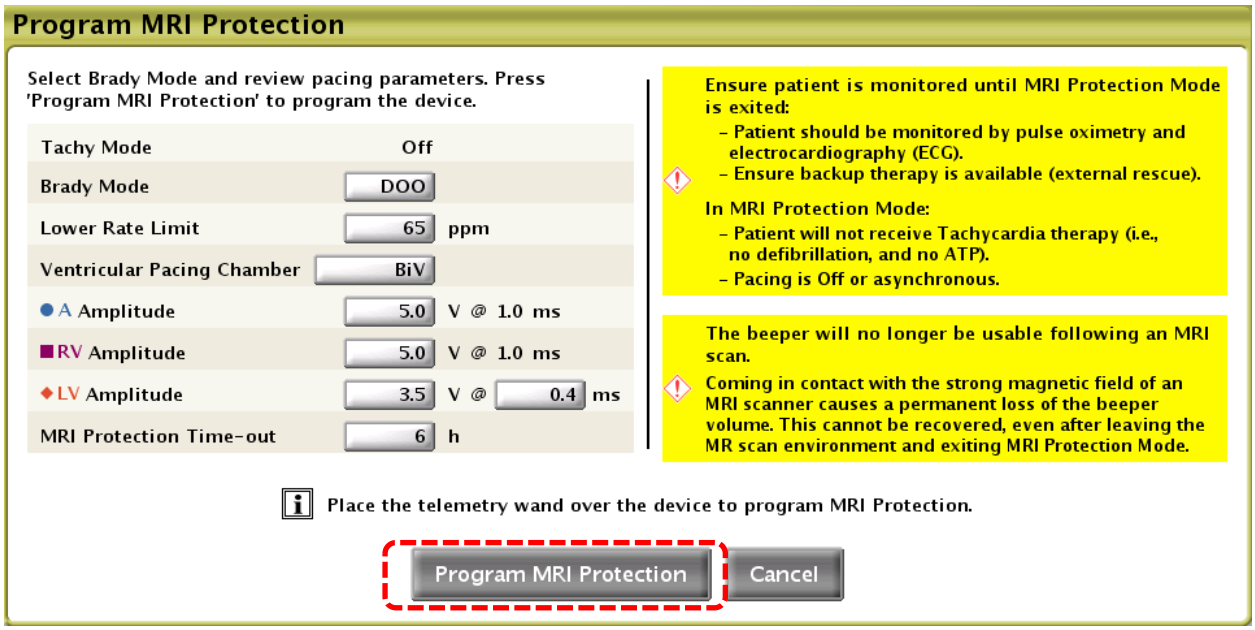
Once all settings have been determined, the user is now ready to enable MRI Protection.

A message is presented on the screen reminding the user that the telemetry wand must be used for programming the device.

Programming will force the use of inductive telemetry.

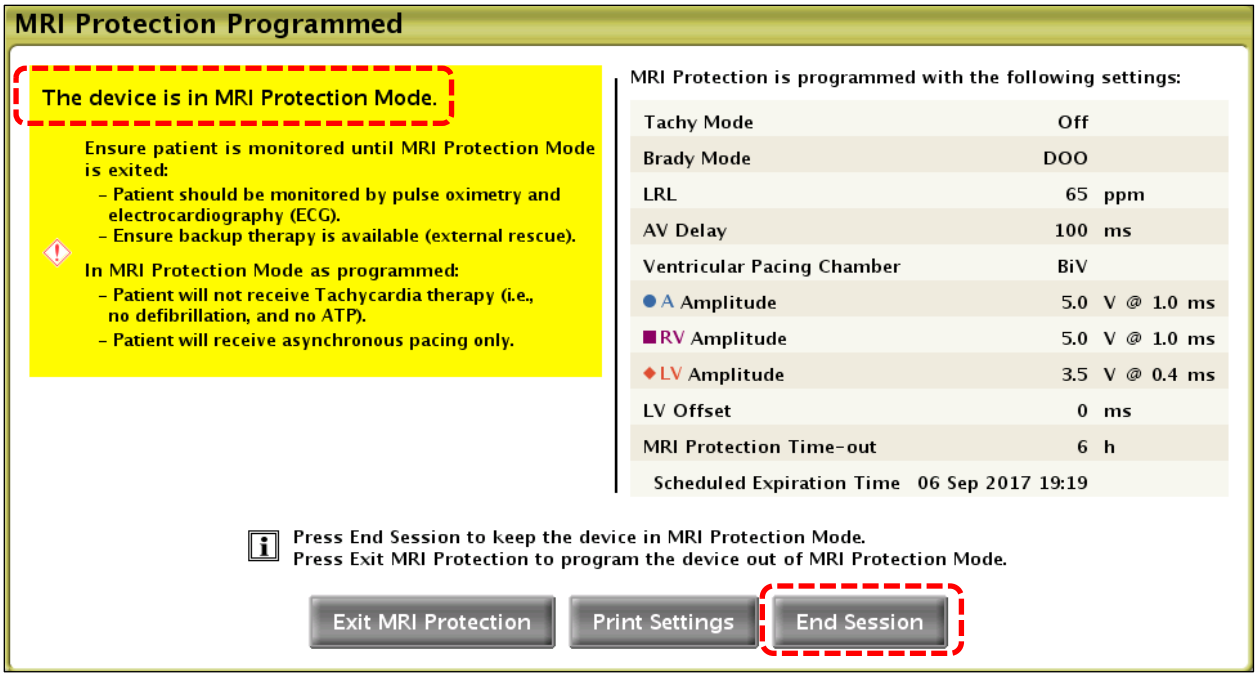
The user must maintain access to the programmer wand, as RF telemetry becomes unavailable during the process of entering MRI Protection Mode.

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.



## Confirm MRI Protection Mode Enabled

This screen indicates that the device has been successfully programmed into MRI Protection Mode at the settings indicated. The scan should not proceed until this confirmation screen is seen.




Print a copy of the current settings before ending the session.

| | 'Print Settings' runs Settings Report via real-time Strip Recorder | 'Print Settings' automatically saves Report to Hard Drive of Programmer | Can send to External Printer via connected USB printer | Can send to External Printer via Bluetooth® |
|---|---|---|---|---|
| LATITUDE™ Model 3120 Programmer | √ | √ | | |
| LATITUDE™ Model 3300 Programmer | | √ | √ | √ |

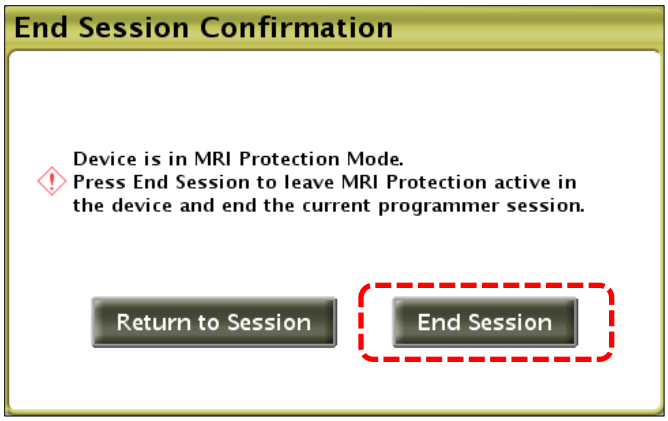
## MRI Protection Settings Report

The report lists the settings in operation during MRI Protection Mode, including the time and date MRI Protection Mode will expire, if the Time-out function is used.

The printed report can be placed in the patients' file and used by Radiology personnel to confirm that sufficient time remains to complete the MRI Scan.

A sample of the MRI Protection Settings Report is available in the MRI Technical Guide: ImageReady™ MR Conditional Defibrillation System at www.bostonscientific.com/imageready.

## Ending the Telemetry Session

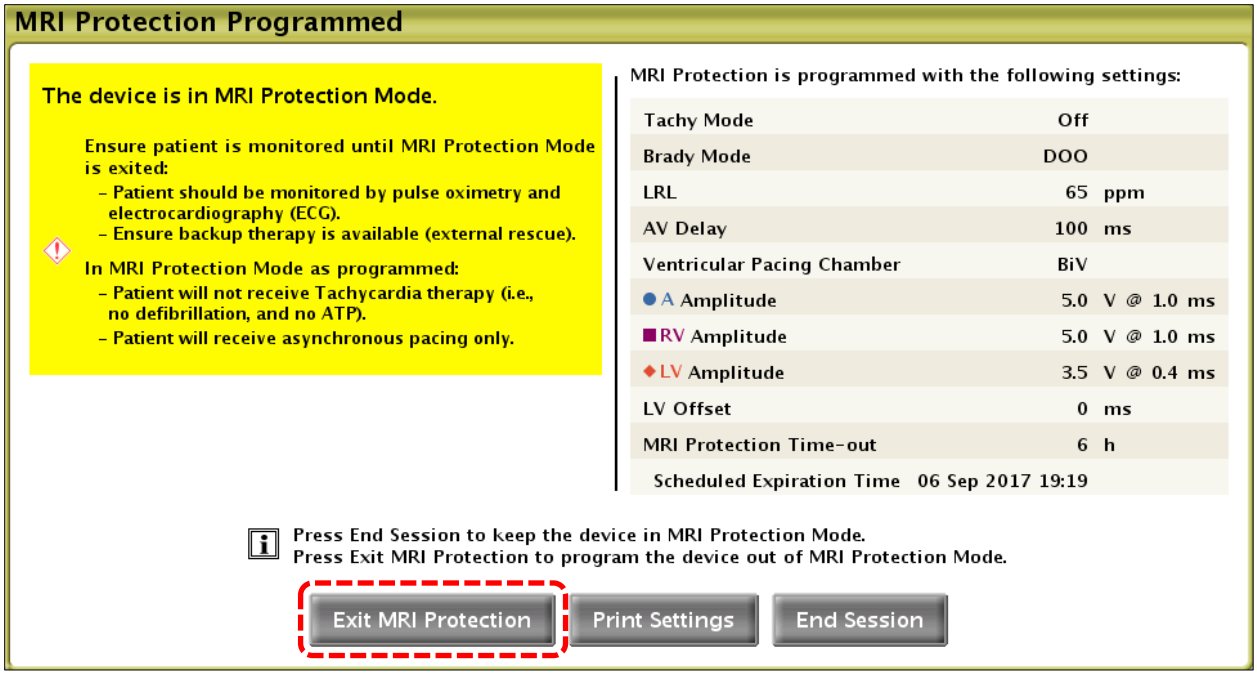



Selecting the End Session button will end the current programmer session with the device remaining in MRI Protection Mode. Remember, the patient will not receive Tachycardia therapy and, if Brady Mode is programed to Off, will not receive Bradycardia pacing and CRT.

If Brady Mode is programmed Off, it is recommended to have a Boston Scientific Programmer powered On near the MRI room in case the patient develops the urgent need for pacing.

## Exiting MRI Protection Mode

Following the scan and after interrogating the device with the wand, the user will again be presented with this message on the screen.

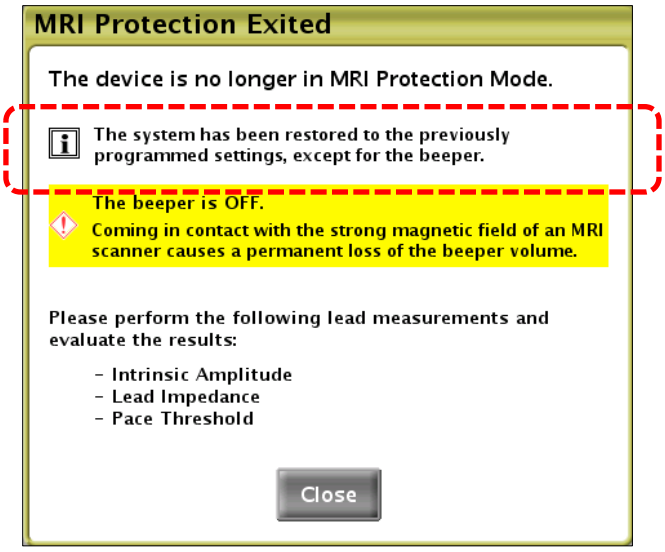



Exiting MRI Protection can be done automatically using the Time-out function or manually using the Programmer. Labeling states: Do not leave the device in MRI Protection Mode any longer than necessary following the scan.

Select the Exit MRI Protection button to manually cancel MRI Protection.

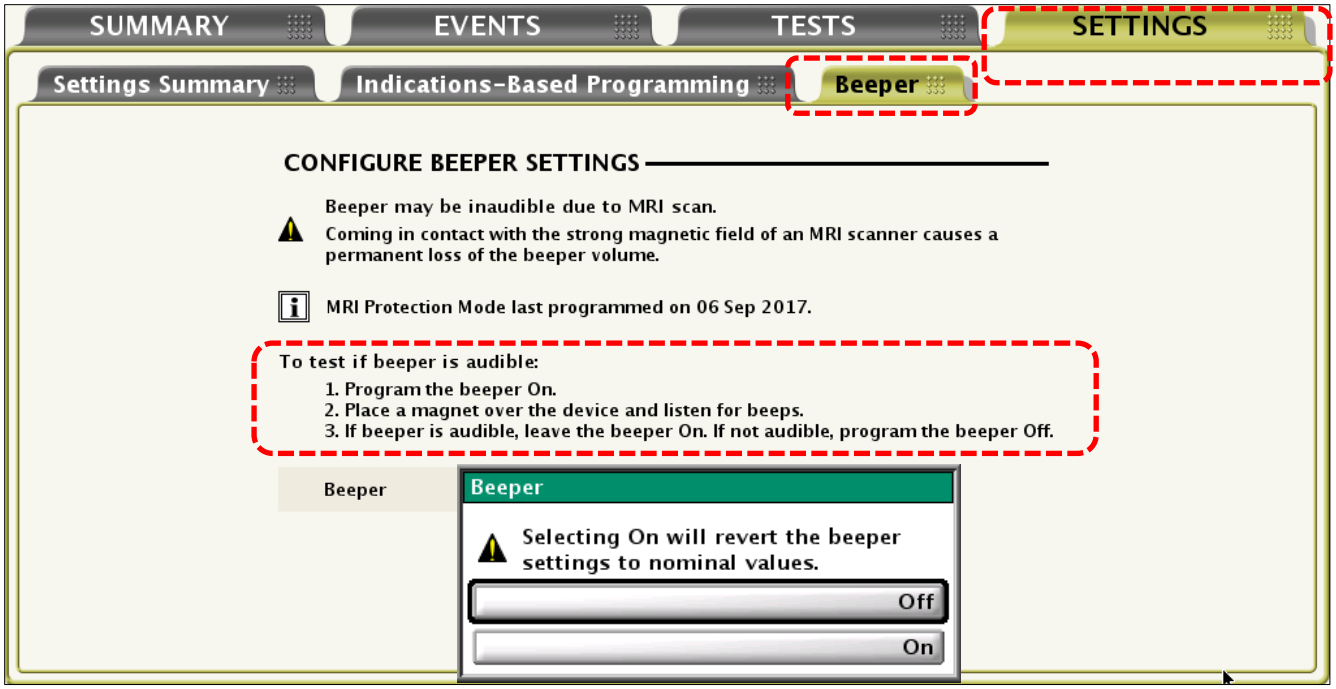
Upon exit from MRI Protection Mode, all parameters are immediately restored to pre-MRI Protection Mode values except for the Beeper.

### Beeper




The Beeper will remain off upon exiting MRI Protection Mode.

If desired, the user can manually attempt to re-enable the Beeper.




### Evaluate Device Header

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
- Pace impedance
- Pacing threshold

For certain transvenous defibrillation devices, on exit from MRI Protection Mode, a summary report of the MRI is stored as an MRI episode and can be printed as an Episode Report.

## CRT-D Systems from Boston Scientific–RESONATE™HF, RESONATE™, RESONATE™X4, VIGILANT™, VIGILANT™X4, MOMENTUM™, MOMENTUM™ X4

**INDICATIONS AND USAGE**

These Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications: Moderate to severe heart failure (NYHA Class III-IV) with EF ≤ 35% and QRS duration ≥ 120 ms; or left bundle branch block (LBBB) with QRS duration ≥ 130 ms, EF ≤ 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure

**CONTRAINDICATIONS**

There are no contraindications for this device.

**WARNINGS**

Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Do not use defibrillation patch leads with the pulse generator system. Do not use this pulse generator with another pulse generator. Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures. Do not kink, twist, or braid the lead with other leads. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4–LLHH or DF4–LLHO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not contact any other portion of the IS4–LLLL lead terminal, other than the terminal pin, even when the lead cap is in place. When implant a system that uses both a DF4–LLHH or DF4–LLHO and IS4–LLLL lead, ensure that the leads are inserted and secured in the appropriate ports. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. Left ventricular lead dislodgement to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. RESONATE HF, RESONATE, and VIGILANT devices with an IS-1/DF4/IS4 lead connection are considered MR Conditional. For these devices, unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. If desired, ensure that Patient Triggered Monitor (PTM) is enabled prior to sending the patient home by confirming the magnet response is programmed to Store EGM. Once the PTM feature has been triggered and the magnet response set to Inhibit therapy the patient should not reapply the magnet.

**PRECAUTIONS**

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information. Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

**POTENTIAL ADVERSE EVENTS**

Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks /pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev. B)

## ICD Systems from Boston Scientific – AUTOGEN™ EL DYNAGEN™ EL, DYNAGEN™ MINI, INOGEN™ EL, INOGEN™ MINI, ORIGEN™ EL, ORIGEN™ MINI

**INDICATIONS AND USAGE**

Boston Scientific implantable cardioverter defibrillators (ICDs) are intended to provide ventricular antitachycardia pacing (ATP) and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

**CONTRAINDICATIONS**

Use of these Boston Scientific pulse generators are contraindicated for the following: patients whose ventricular tachyarrhythmias may have reversible cause, such as: digitalis intoxication, electrolyte imbalance, hypoxia, sepsis; or patients whose ventricular tachyarrhythmias have a transient cause, such as: acute myocardial infarction (MI), electrocution, drowning; or patients who have a unipolar pacemaker.

**WARNINGS**

Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Do not use this pulse generator with another pulse generator. Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4–LLHH or DF4–LLHO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in ventricular tachyarrhythmias. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. AUTOGEN, DYNAGEN, INOGEN, and ORIGEN devices with a DF4 right ventricular lead connection are considered MR Conditional. For these devices, unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system. Significant harm to or death of the patient and/or damage to the implanted system may result. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. All other devices covered by this statement are not MR conditional. Do not expose a patient with non-MR conditional devices to MRI scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. If desired, ensure that Patient Triggered Monitor is enabled prior to sending the patient home. Once the Patient Triggered Monitor feature has been triggered by the magnet and an EGM has been stored, or after 60 days have elapsed from the day that Store EGM was enabled, the patient should not apply the magnet.

**PRECAUTIONS**

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information

**POTENTIAL ADVERSE EVENTS**

Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks /pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.(Rev C)

## CRT-D Systems –AUTOGEN™, AUTOGEN™X4, DYNAGEN™, DYNAGEN™X4, INOGEN™, INOGEN™ X4, ORIGEN™, ORIGEN™X4, INCEPTA™, ENERGEN™, PUNCTUA™. COGNIS™ 100-D CRT-D

**INDICATIONS AND USAGE**

These Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications: Moderate to severe heart failure (NYHA Class III-IV) with EF ≤ 35% and QRS duration ≥ 120 ms; or left bundle branch block (LBBB) with QRS duration ≥ 130 ms, EF ≤ 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure

**CONTRAINDICATIONS**

There are no contraindications for this device.

**WARNINGS**

Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Do not use defibrillation patch leads with the pulse generator system. Do not use this pulse generator with another pulse generator. Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures. Do not kink, twist, or braid the lead with other leads. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4–LLHH or DF4–LLHO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not contact any other portion of the IS4–LLLL lead terminal, other than the terminal pin, even when the lead cap is in place. When implanting a system that uses both a DF4–LLHH or DF4–LLHO and IS4–LLLL lead, ensure that the leads are inserted and secured in the appropriate ports. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. Left ventricular lead dislodgement to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. DYNAGEN, INOGEN, and ORIGEN devices with an IS-1/DF4/IS4 right ventricular lead connection are considered MR Conditional. For these devices, unless all the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system. Significant harm to or death of the patient and/or damage to the implanted system may result. All other devices covered by this statement are not MR conditional. Do not expose a patient with non-MR Conditional devices to MRI scanning. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the ImageReady MR Conditional Defibrillation System MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. If desired, ensure that Patient Triggered Monitor (PTM) is enabled prior to sending the patient home by confirming the magnet response is programmed to Store EGM. Once the PTM feature has been triggered and the magnet response set to Inhibit therapy the patient should not reapply the magnet.

**PRECAUTIONS**

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information. Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

**POTENTIAL ADVERSE EVENTS**

Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks /pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.(Rev D)

## ICD Systems – RESONATE™ HF, RESONATE™ EL, PERCIVA™ HF, PERCIVA™, VIGILANT™ EL, MOMENTUM™ EL

**INDICATIONS AND USAGE**

Boston Scientific implantable cardioverter defibrillators (ICDs) are intended to provide ventricular antitachycardia pacing (ATP) and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

**CONTRAINDICATIONS**

Use of these Boston Scientific pulse generators are contraindicated for the following: patients whose ventricular tachyarrhythmias may have reversible cause, such as: digitalis intoxication, electrolyte imbalance, hypoxia, sepsis; or patients whose ventricular tachyarrhythmias have a transient cause, such as: acute myocardial infarction (MI), electrocution, drowning; or patients who have a unipolar pacemaker.

**WARNINGS**

Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Do not use this pulse generator with another pulse generator. Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4–LLHH or DF4–LLHO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in ventricular tachyarrhythmias. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. RESONATE HF, RESONATE, PERCIVA HF, PERCIVA, and VIGILANT devices with a DF4 right ventricular lead connection are considered MR Conditional. For these devices, unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. If desired, ensure that Patient Triggered Monitor is enabled prior to sending the patient home. Once the Patient Triggered Monitor feature has been triggered by the magnet and an EGM has been stored, or after 60 days have elapsed from the day that Store EGM was enabled, the patient should not apply the magnet.

**PRECAUTIONS**

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, and supplemental precautionary information.

**POTENTIAL ADVERSE EVENTS**

Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks /pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.(Rev B)

Boston Scientific
Advancing science for life™

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