

**IMAGEREADY™**  
MR-Conditional Systems

# Programming Manual for MRI Protection Mode

**Transvenous Pacing System MRI Protection Mode Programming:**

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**Transvenous Defibrillation System MRI Protection Mode Programming:**

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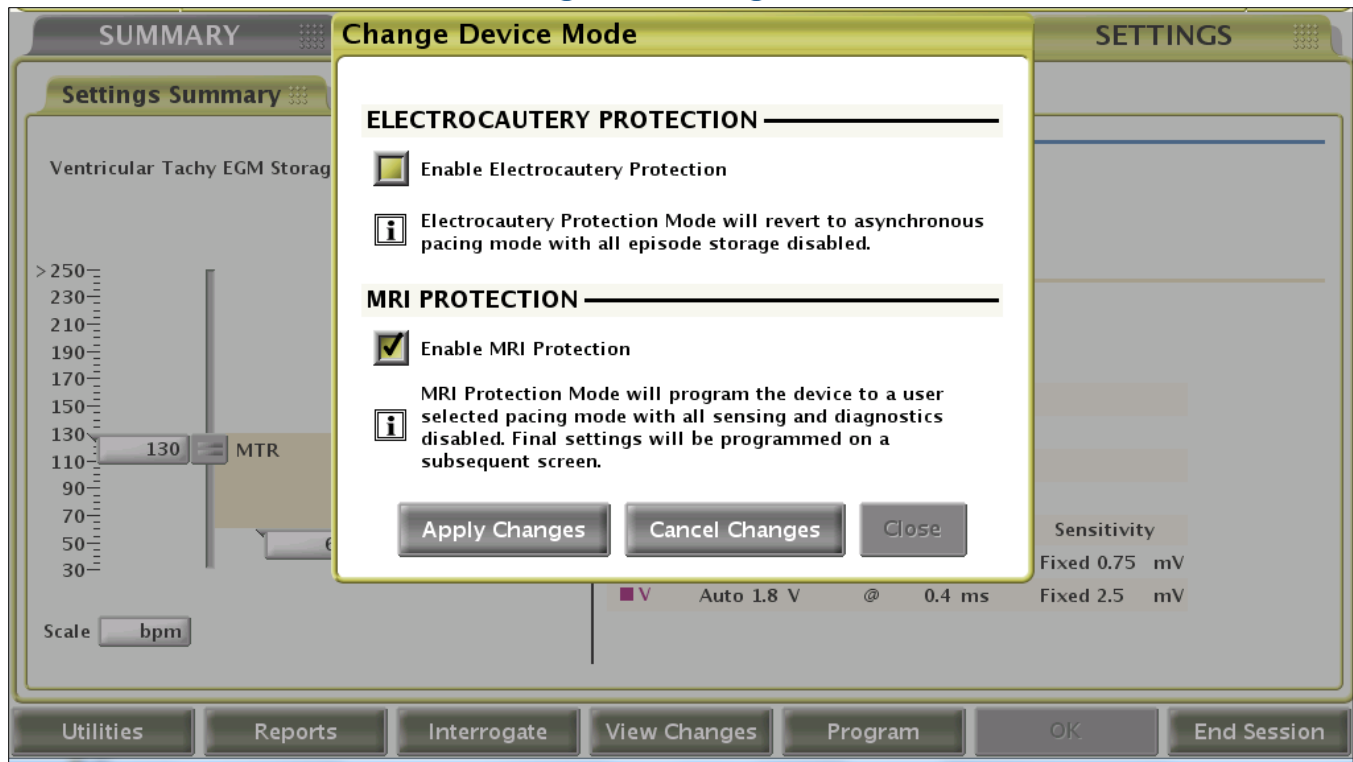
The following are additional references:

- *Boston Scientific MRI Technical Guide: ImageReady™ MR Conditional Pacing System*
- *Boston Scientific MRI Technical Guide: ImageReady™ MR Conditional Defibrillation System*
- [www.bostonscientific.com/imageready](http://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](http://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 screenshot displays the ImageReady MR-Conditional Pacing System interface. The main window is divided into several sections: SUMMARY, EVENTS, TESTS, and SETTINGS. The SUMMARY section is active, showing patient information, lead status (Leads OK), and battery status (Battery OK). A dialog box titled "ATTENTION" is overlaid on the screen, indicating that RA, RV, and LV lead impedances are out of range. The dialog box contains the following text:

**ATTENTION**

RA, RV, and LV lead impedances are out of range.

Check for evidence of a fractured lead or compromised pulse generator-lead system integrity. (Refer to the Pacing System MRI Technical Guide for risks of MRI scans under this condition.)

Press Continue only after evaluating leads and ruling out possibility of a fractured lead or compromised pulse generator-lead system integrity.

Continue with MRI Protection    Cancel

The background interface shows the following data:

Parameter	Value	Unit
Paced AV Delay	180	ms
Sensed AV Delay	120	ms
LV Offset	0	ms

Additional interface elements include a "Percent Paced" section with A (0%), RV (0%), and LV (0%) leads, and a "Battery" section showing an approximate time to explant of > 7 years.

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

**ATTENTION**

It is less than six weeks since the implant of this device. The system is not designated as MR Conditional for MRI scans conducted in the first six weeks after implant.

Press Continue only after review of the risks of MRI scans under this condition in the Pacing System MRI Technical Guide.

Continue with MRI Protection Cancel

2017 3

Percent Paced

- A 1 %
- RV 1 %
- LV 1 %

AT/AF: N/R %

Leads **OK** Daily lead me range.

POST in progress. Complete session and reinterrogate in 30 minutes.

Battery **OK**

Approximate time to explant: > 7 years

LRL-MTR	45	-	130	min <sup>-1</sup>
Paced AV Delay	180	-	180	ms
Sensed AV Delay	120	-	120	ms
LV Offset			0	ms

Utilities Reports Interrogate View Changes Program OK End Session

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

**ATTENTION**

The most recent RA and RV pace threshold measurements are greater than 2.0 volts.

Use caution for pacing-dependent patients. Maximum pacing amplitude during MRI Protection Mode is 5.0 V. Failure to maintain sufficient pacing amplitude safety margin may result in loss of capture.

Press Continue with MRI Protection to program MRI Protection Mode.

Continue with MRI Protection    Cancel

**SYSTEM SUMMARY**

Patient Info

Last Follow Up

Implant Date

Device Model

Leads **OK**

Battery **OK**

Approximate time to explant: > 7 years

LRL-MTR	45	-	130	ppm
Paced AV Delay	180	-	180	ms
Sensed AV Delay	120	-	120	ms
LV Offset			0	ms

Utilities    Reports    Interrogate    View Changes    Program    OK    End Session

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

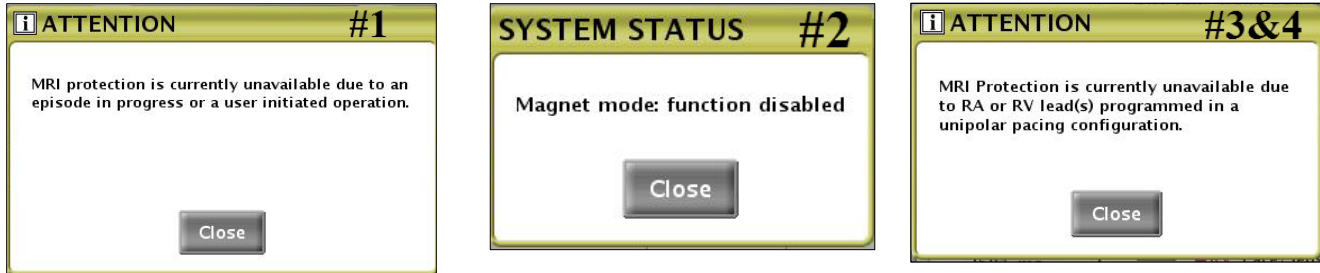
If the recorded threshold was > 2.0 V, an ATTENTION message appears on the screen advising the user to review risks of proceeding.

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.

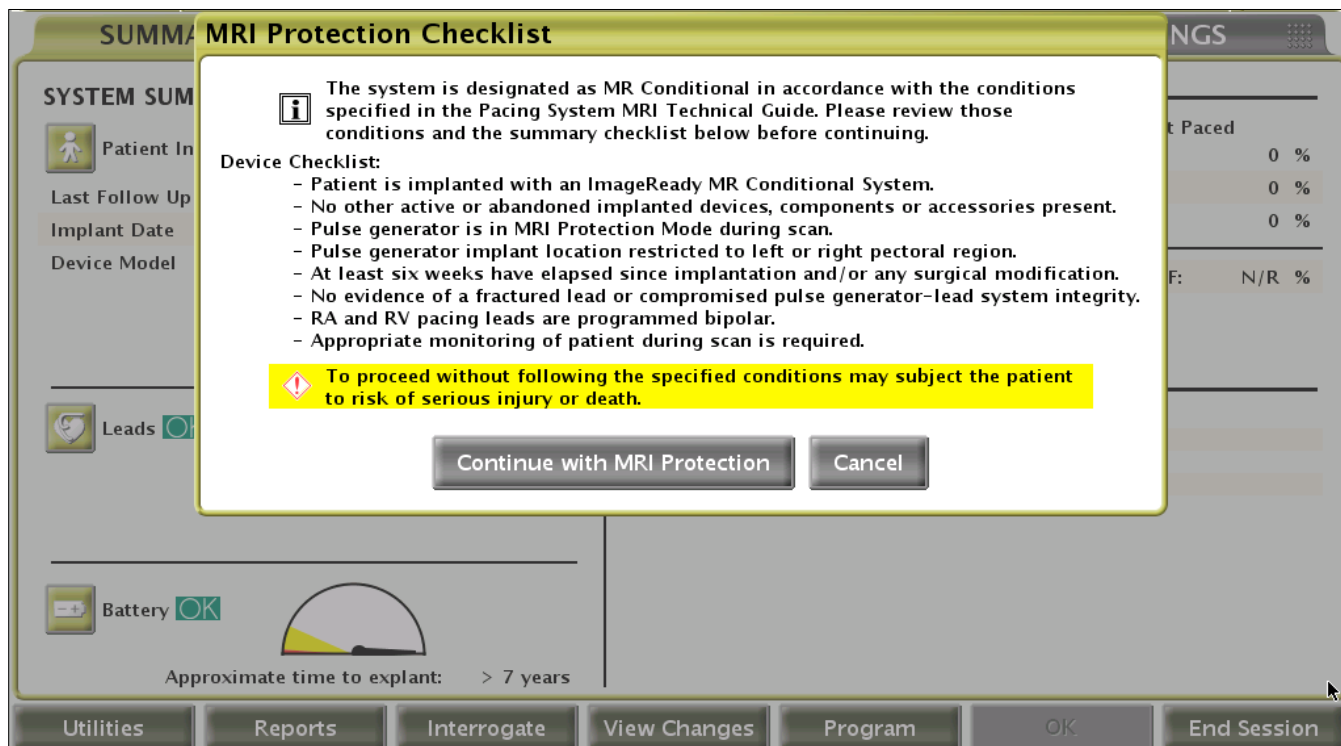
NOTE: The LV Lead can be programmed to unipolar pacing in MRI Protection Mode.

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.

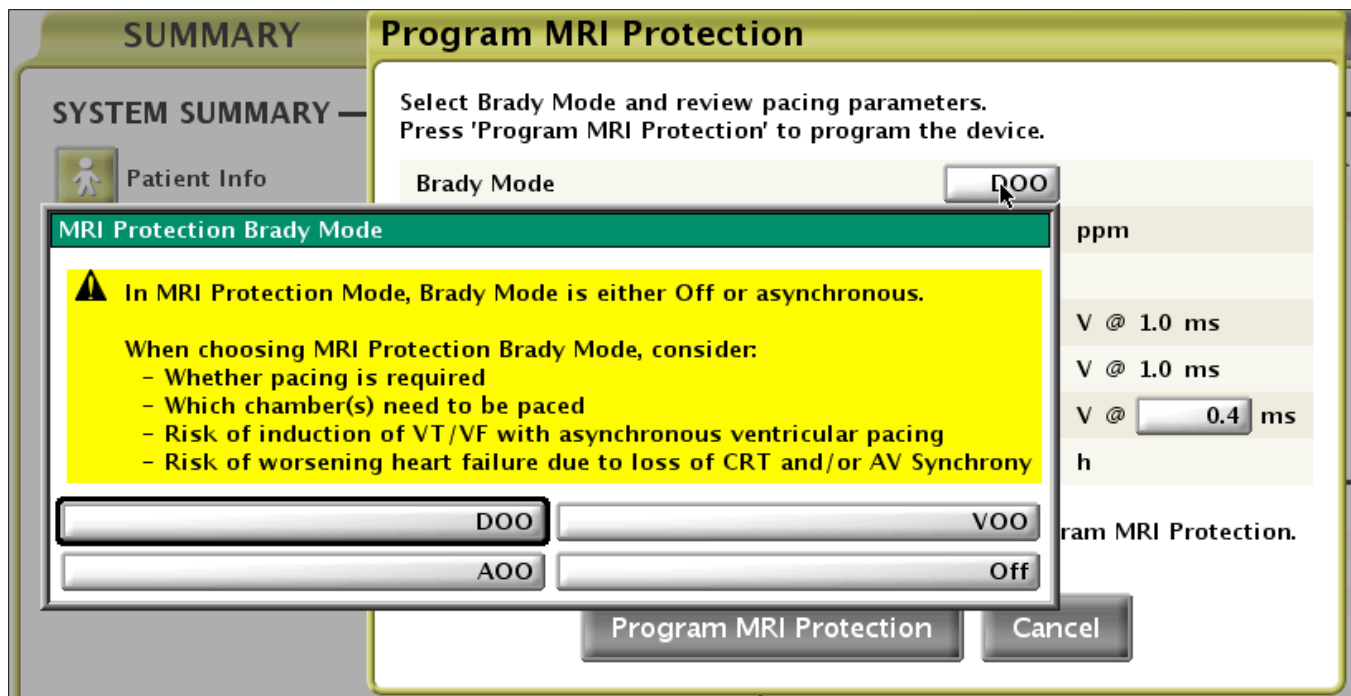
If the Conditions of Use are not met, the Cancel button is selected to return to normal system operation, and the patient does not undergo an MRI scan.

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

**Program MRI Protection**

Select Brady Mode and review pacing parameters.  
Press 'Program MRI Protection' to program the device.

Brady Mode	DOO
Lower Rate Limit	80
Ventricular Pacing Chamber	BiV
● A Amplitude	5.0
■ RV Amplitude	5.0
◆ LV Amplitude	3.5
MRI Protection Time-out	24

**MRI Protection Lower Rate Limit**

30	50	70	90
35	55	75	95
40	60	<b>80</b>	100
45	65	85	

**i** Place the telemetry wand over the device to program MRI Protection.

**Program MRI Protection** **Cancel**

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

### Program MRI Protection

Select Brady Mode and review pacing parameters.  
Press 'Program MRI Protection' to program the device.

Brady Mode	<input type="text" value="DOO"/>
Lower Rate Limit	<input type="text" value="65"/> ppm
Ventricular Pacing Chamber	<input type="text" value="BiV"/>
● A Amplitude	<input type="text" value="5.0"/> V @ <input type="text" value="1.0"/> ms
■ RV Amplitude	<input type="text" value="5.0"/> V @ <input type="text" value="1.0"/> ms
◆ LV Amplitude	<input type="text" value="3.5"/> V @ <input type="text" value="0.4"/> ms
MRI Protection Time-out	<input type="text" value="24"/> h

 Place the telemetry wand over the device to program MRI Protection.

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

### Program MRI Protection

Select Brady Mode and review pacing parameters.  
Press 'Program MRI Protection' to program the device.

Brady Mode	<input type="text" value="DOO"/>
Lower Rate Limit	<input type="text" value="65"/> ppm
Ventricular Pacing Chamber	<input type="text" value="BiV"/>
<input checked="" type="radio"/> A Amplitude	<input type="text" value="5.0"/> V @ <input type="text" value="1.0"/> ms
<input type="radio"/> RV Amplitude	<input type="text" value="5.0"/> V @ <input type="text" value="1.0"/> ms
<input checked="" type="radio"/> LV Amplitude	<input type="text" value="3.5"/> V @ <input type="text" value="0.4"/> ms
MRI Protection Time-out	<input type="text" value="24"/> h

 Place the telemetry wand over the device to program MRI Protection.

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

**SUMMARY**

**SYSTEM SUMMARY**

Patient Info

Last Follow Up

Implant Date

Device Model

### Program MRI Protection

Select Brady Mode and review pacing parameters.  
Press 'Program MRI Protection' to program the device.

Brady Mode	DOO	
Lower Rate Limit	65	ppm
Ventricular Pacing Chamber	BiV	
● A Amplitude	5.0	V @ 1.0 ms
■ RV Amplitude	5.0	V @ 1.0 ms
◆ LV Amplitude	3.5	V @ 0.4 ms
	24	h

Press 'Program MRI Protection' to program MRI Protection.

**MRI Protection Time-out**

Select the duration of the MRI Protection period (in hours). Selecting Off leaves the PG in MRI Protection Mode until reprogrammed.

**Attention: If MRI Protection Time-out is programmed Off, and Brady Mode is Off, patient will not receive pacing until reprogrammed.**

Off	9	48
3	12	
6	24	

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

### Program MRI Protection

Select Brady Mode and review pacing parameters.  
Press 'Program MRI Protection' to program the device.

Brady Mode	<input type="text" value="DOO"/>
Lower Rate Limit	<input type="text" value="65"/> ppm
Ventricular Pacing Chamber	<input type="text" value="BiV"/>
● A Amplitude	<input type="text" value="5.0"/> V @ 1.0 ms
■ RV Amplitude	<input type="text" value="5.0"/> V @ 1.0 ms
◆ LV Amplitude	<input type="text" value="3.5"/> V @ <input type="text" value="0.4"/> ms
MRI Protection Time-out	<input type="text" value="24"/> h

 Place the telemetry wand over the device to program MRI Protection.

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

### MRI Protection Mode Programmed

MRI Protection is programmed with the following settings:

Brady Mode	DOO
LRL	65 ppm
AV Delay	100 ms
Ventricular Pacing Chamber	BiV
● A Amplitude	5.0 V @ 1.0 ms
■ RV Amplitude	5.0 V @ 1.0 ms
◆ LV Amplitude	3.5 V @ 0.4 ms
LV Offset	0 ms
MRI Protection Time-out	24 h
Scheduled Expiration Time	23 Sep 2017 13:20

 MRI Protection Time-out is reset on each new session.  
Press End Session to keep the device in MRI Protection Mode.  
Press Exit MRI Protection to program the device out of MRI Protection Mode.

**Exit MRI Protection**   **Print Settings**   **End Session**

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.

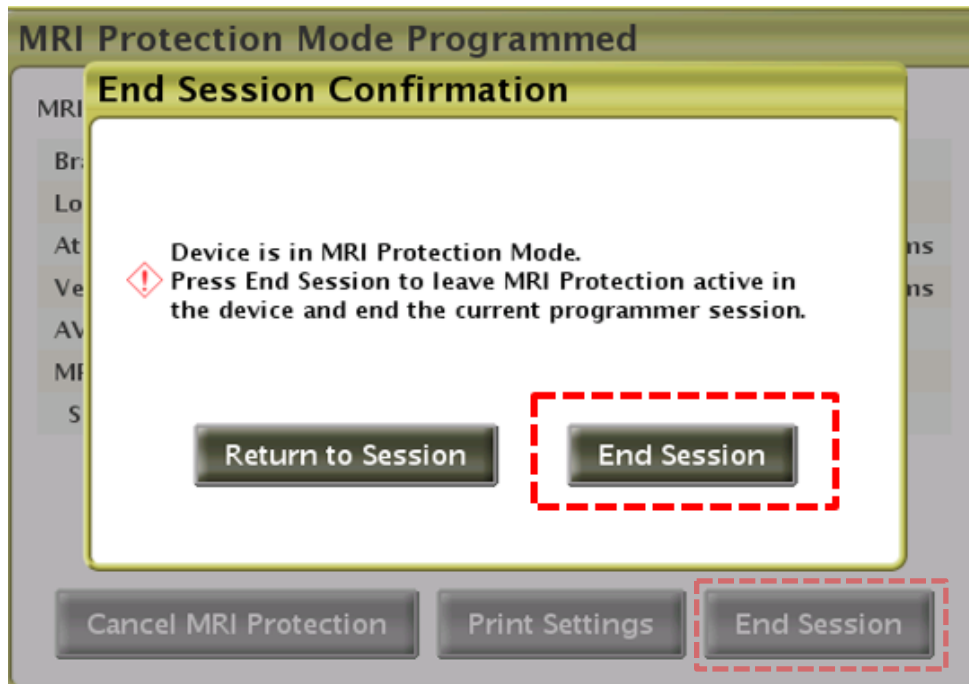
The report lists the settings in operation during MRI Protection Mode, including the time and date MRI Protection Mode will expire, if the Time-out function is used.

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](http://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 programmed 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

### MRI Protection Mode Programmed

MRI Protection is programmed with the following settings:

Brady Mode	DOO
LRL	65 ppm
AV Delay	100 ms
Ventricular Pacing Chamber	BiV
● A Amplitude	5.0 V @ 1.0 ms
■ RV Amplitude	5.0 V @ 1.0 ms
◆ LV Amplitude	3.5 V @ 0.4 ms
LV Offset	0 ms
MRI Protection Time-out	24 h
Scheduled Expiration Time	23 Sep 2017 13:20

 MRI Protection Time-out is reset on each new session.  
Press End Session to keep the device in MRI Protection Mode.  
Press Exit MRI Protection to program the device out of MRI Protection Mode.

**Exit MRI Protection**   **Print Settings**   **End Session**

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.

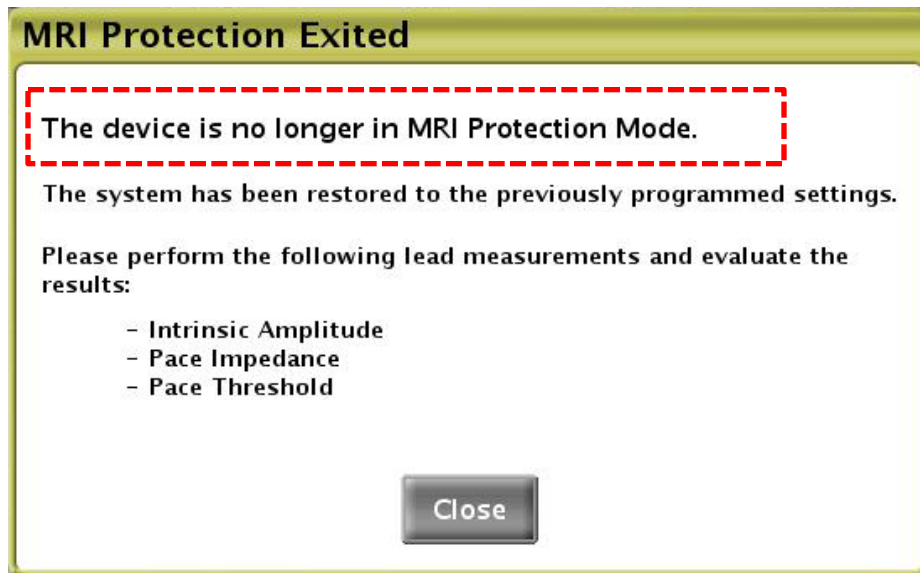
Alternatively, if the Time-out function is not used (is programmed to Off), the device must be interrogated by the wand to exit MRI Protection Mode.

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

The screenshot displays the Boston Scientific ACCOLADE MRI EL programmer interface. At the top, it shows 'Device Mode' with 'Brady Therapy Enabled' and 'ACCOLADE MRI EL Dual Chamber Pacemaker'. The ECG strip shows Lead-I with A and V channels. The 'EVENTS' tab is active, showing an 'Arrhythmia Logbook' for the last 3 months. The logbook table lists several MRI and NonSustV events from March 2015.

Event	Date/Time	Type	Summary	Duration
MRI-2	26 Mar 2015 16:27	MRI	MRI Protection Mode	00:13:03
MRI-1	24 Mar 2015 15:52	MRI	MRI Protection Mode	00:00:49
V-152	26 Mar 2015 14:38	NonSustV	Avg V Rate at Onset: 347 bpm	00:00:16
V-151	26 Mar 2015 14:37	NonSustV	Avg V Rate at Onset: 224 bpm	00:00:24
V-150	26 Mar 2015 14:33	NonSustV	Avg V Rate at Onset: 273 bpm	00:00:16
V-149	26 Mar 2015 14:31	NonSustV	Avg V Rate at Onset: 240 bpm	00:00:16
V-148	24 Mar 2015 11:53	VT (V>A)	Avg V Rate at Onset: 107 bpm	00:00:23

Additional information from the screenshot: 'Last Follow Up: 26 Mar 2015'. The interface includes buttons for 'Utilities', 'Reports', 'Interrogate', 'View Changes', 'Program', 'OK', and 'End Session'.

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  $\leq$ 35%) and QRS duration  $\geq$  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 minute ventilation and/or 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 MV/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;
- Minute ventilation is contraindicated in patients with both unipolar atrial and ventricular leads;
- 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. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, 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. Safety Core pacing may be unipolar, which may interact with an ICD. Safety Core behavior is affected by MRI Protection Mode. 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 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. Automatic Lead Recognition should be programmed to Off before implant with 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. VISIONIST X4 and VALITUDE X4 devices 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. All other devices covered by this statement are not MR conditional. Do not expose patients with non-MR Conditional devices to MRI scanning. For potential adverse events when 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

- Programming minimum PVARP less than retrograde V–A conduction may increase the likelihood of a Pacemaker-mediated tachycardia (PMT).
- The safety and efficacy of the MV Sensor modes have not been clinically established in patients with abdominal implant sites.
- MV Sensor performance may be adversely affected under transient conditions such as pneumothorax, pericardial effusion, or pleural effusion. Consider programming the MV Sensor Off until these conditions are resolved.
- Adaptive-rate modes based completely or in part on MV might be inappropriate for patients who can achieve respiratory cycles shorter than one second (greater than 60 breaths per minute). Higher respiration rates attenuate the impedance signal, which diminishes the MV rate response (i.e., the pacing rate will drop toward the programmed LRL).

Adaptive-rate modes based completely or in part on MV should not be used for patients with:

- An ICD
- Unipolar leads – for MV detection, a bipolar lead is required in either the atrium or ventricle
- A lead other than a bipolar transvenous lead-MV measurement has only been tested with a bipolar transvenous lead
- A mechanical ventilator-use of the ventilator might result in an inappropriate MV Sensor-driven rate
- The clinical benefit of Rate Adaptive Pacing in heart failure patients has not been studied. Rate Adaptive Pacing should be used with medical discretion if the patient develops an indication such as chronotropic incompetence. Patients with heart failure may have hemodynamic compromise at rapid sensor-driven rates, and the physician may wish to program less aggressive rate adaptive parameters in accordance with patient condition. Heart failure-related respiratory changes in patient's minute ventilation (MV) may inappropriately increase paced rate to the upper rate (MSR), for instance during heart failure at rest. If this occurs, physicians may consider turning off rate responsive pacing or modifying the Rate Adaptive Pacing settings.
- Implanting a replacement device in a subcutaneous pocket that previously housed a larger device may result in pocket air entrapment, migration, erosion, or insufficient grounding between the device and tissue. Irrigating the pocket with sterile saline solution decreases the possibility of pocket air entrapment and insufficient grounding. Suturing the device in place reduces the possibility of migration and erosion.
- Use only the designated programmer and software application to communicate with this pulse generator.
- The device is intended to provide biventricular pacing therapy. Programming the device to provide RV-only pacing, or programming the RV pace amplitude below the pacing threshold (resulting in LV-only pacing), is not intended for the treatment of heart failure. The clinical effects of RV-only pacing for the treatment of heart failure have not been established.
- If properly functioning leads with stable measured impedance values near the programmed impedance limits are used, consider programming Lead Safety Switch Off or changing the impedance limits to avoid undesirable switching to a Unipolar Lead Configuration.
- If the Lead Configuration is programmed to Bipolar when a unipolar lead is implanted, pacing will not occur.
- Determine if the device and programmable options are appropriate for patients with supraventricular tachyarrhythmias (SVTs) because SVTs can initiate unwanted device therapy.
- To ensure a high percentage of biventricular pacing, the programmed AV Delay setting must be less than the patient's intrinsic PR interval.
- Rate Adaptive Pacing should be used with care in patients who are unable to tolerate increased pacing rates.
- Adaptive-rate pacing is not limited by refractory periods. A long refractory period programmed in combination with a high MSR can result in asynchronous pacing during refractory periods since the combination can cause a very small sensing window or none at all. Use Dynamic AV Delay or Dynamic PVARP to optimize sensing windows. If you are programming a fixed AV Delay, consider the sensing outcomes.
- The pulse generator's MTR and MSR should be programmed to a rate lower than a concomitant S-ICD's lowest tachycardia detection zone.
- Atrial Tachy Response (ATR) should be programmed to On if the patient has a history of atrial tachyarrhythmias. The delivery of CRT is compromised because AV synchrony is disrupted if the ATR mode switch occurs.
- The clinical effect of Left ventricular (LV) pacing alone for heart failure patients has not been studied.
- Sensing high atrial rates may impact device longevity. Therefore, the Atrial Sense lead configuration will be seeded to Off when programming from an atrial sensing mode to a non-atrial sensing mode.
- For maximum sensitivity in detecting and preventing potential signal artifact-generated oversensing, it is recommended that the Signal Artifact Monitor (SAM) is programmed On any time the MV/Respiratory Sensor is programmed to On or Passive. Turning the Signal Artifact Monitor Off may put the patient at increased risk of oversensing, unless the MV/Respiratory Sensor is also programmed Off.

- Turning the Signal Artifact Monitor Off may put the patient at increased risk of oversensing, unless the MV/Respiratory Sensor is also programmed Off.
- When a single pass VDD lead is used with a dual-chamber device, the atrial electrodes may not be in contact with the atrial wall. In this case, the measured depolarization signal has a relatively low Amplitude and could require a more sensitive setting.
- When an LV/Ring4>>RV pacing configuration is programmed with an IS4-LLLL lead, the LV tip may be used as the anode rather than the RV ring. When programming to this configuration, evaluate the pacing threshold and ensure no extracardiac stimulation is present.
- To obtain an accurate MV baseline following any surgical procedure involving the pulse generator or leads, a new, manual calibration should be performed. Lead maturation, air entrapment in the pocket, pulse generator motion due to inadequate suturing, external defibrillation or cardioversion, or other patient complications (e.g., pneumothorax) require a new MV baseline for appropriate MV behavior.
- Following any Sensitivity parameter adjustment or any modification of the sensing lead, always verify appropriate sensing. Programming Sensitivity to the highest value (lowest sensitivity) may result in delayed detection or undersensing of cardiac activity. Likewise, programming to the lowest value (highest sensitivity) may result in oversensing of non-cardiac signals.
- The amplitude and prevalence of myopotential noise is increased in unipolar lead configurations, as compared to bipolar lead configurations. For patients with a unipolar lead configuration and myopotential oversensing during activity involving the pectoral muscles, the programming of Fixed Sensitivity is recommended.
- 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 the magnet rate in the presence of EMI.
  - Moving away from the source of the EMI or turning off the source usually allows the pulse generator to return to normal operation.
- Any medical equipment, treatment, therapy, or diagnostic test that introduces electrical current into the patient has the potential to interfere with pulse generator function.
  - External patient monitors (e.g., respiratory monitors, surface ECG monitors, hemodynamic monitors) may cause:
    - Inappropriate MV Sensor-driven rate (up to maximum sensor-driven rate)
    - Misleading respiration-based trending
- Medical therapies, treatments, and diagnostic tests that use conducted electrical current (e.g., TENS, electrocautery, electrolysis/thermolysis, electrodiagnostic testing, electromyography, or nerve conduction studies) may interfere with or damage the pulse generator. Program the device to Electrocautery Protection Mode prior to the treatment, and monitor device performance during the treatment. After the treatment, verify pulse generator function ("Post-Therapy Pulse Generator Follow Up" in manual).
  - To resolve suspected interactions with MV rate driving and/or MV/Respiratory Sensor-based diagnostics deactivate the MV/Respiratory Sensor by programming it to Off. If a PRM is not available and the pulse generator is pacing at the sensor-driven rate, apply a magnet to the pulse generator to initiate temporary asynchronous, non-rate responsive pacing.
- Extracorporeal shock wave lithotripsy (ESWL) may cause electromagnetic interference with or damage to the pulse generator.
- Therapeutic ultrasound (e.g., lithotripsy) energy may damage the pulse generator. If therapeutic ultrasound energy must be used, avoid focusing near the pulse generator site. Diagnostic ultrasound (e.g., echocardiography) is not known to be harmful to the pulse generator.
- Electrical interference or "noise" from devices such as electrocautery and monitoring equipment may interfere with establishing or maintaining telemetry for interrogating or programming the device. In the presence of such interference, move the programmer away from electrical devices, and ensure that the wand cord and cables are not crossing one another. If telemetry is cancelled as a result of interference, the device should be re-interrogated prior to evaluating information from pulse generator memory.
- Radio frequency (RF) signals from devices that operate at frequencies near that of the pulse generator may interrupt ZIP telemetry while interrogating or programming the pulse generator. This RF interference can be reduced by increasing the distance between the interfering device and the PRM and pulse generator.
- Use caution when inserting guidewires for placement of other types of central venous catheter systems such as PIC lines or Hickman catheters in locations where pulse generator leads may be encountered. Insertion of such guidewires into veins containing leads could result in the leads being damaged or dislodged.

### Minimizing Pacemaker/S-ICD Interaction

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.

A pacemaker can interact with an S-ICD in the following ways:

- If during the tachyarrhythmia the pacemaker is not inhibited and the pacing pulses are detected by the rate-sensing circuit of the S-ICD, the S-ICD could interpret the pacing pulses as a normal rhythm. The S-ICD would not detect the arrhythmia and therefore would not deliver therapy.
- Pacemaker failure to sense or capture could result in two independent signals (intrinsic and pacing pulses) to the S-ICD. This could cause the S-ICD's rate measurement to be faster than the actual heart rate. As a result, the S-ICD could deliver unnecessary therapy.
- If the S-ICD counts both the pacing pulses and the resultant ventricular depolarizations, the S-ICD's rate measurement would be faster than the actual heart rate. This could result in unnecessary S-ICD therapy.

In Safety Mode, these pulse generators use a unipolar pacing and sensing configuration. Safety Mode is compatible for use with an S-ICD because the configured parameters mitigate the potential pacemaker and S-ICD interactions as follows:

- Sensing is AGC at 0.25 mV. The AGC sensing is able to effectively sense an intrinsic rhythm faster than the Safety Mode LRL of 72.5 bpm. As a result, pacing is inhibited and does not interfere with S-ICD tachyarrhythmia detection.
- When pacing is necessary, the evaluated output of 5.0 V and 1.0 ms reduces the risk of not capturing.
- If double detection of the pace pulse and the resulting depolarization were to occur, it would not result in unnecessary S-ICD therapy provided the S-ICD tachy threshold is more than twice the Safety Mode LRL (145 ppm).

To help minimize device-device interaction of a bipolar pacemaker when an S-ICD is already implanted, follow these precautionary measures:

- Use bipolar pacing leads with close electrode spacing in both chambers. Significant spacing between electrodes may increase the likelihood that the S-ICD will detect the pacing pulses.
- Consider programming the pacemaker to (1) the lowest Amplitude allowable for safe capture in the chronic state, (2) the maximum Sensitivity (the lowest programmable level) while maintaining an adequate safety margin, and (3) the minimum cardiac rate acceptable for the patient.

In addition to the above steps, perform the following testing to assess device-device interaction:

- Use the S-ICD features, such as markers, real-time electrograms (EGMs), and/or beeping tones, to help evaluate potential for pacemaker interaction due to oversensing by the S-ICD.

**NOTE:** If a single chamber pacemaker is implanted with an atrial lead, perform testing in both unipolar and bipolar configurations.

**CAUTION:** Transcutaneous Electrical Nerve Stimulation (TENS) involves passing electrical current through the body, and may interfere with pulse generator function. If TENS is medically necessary, evaluate the TENS therapy settings for compatibility with the pulse generator.

**CAUTION:** Elevated pressures due to HBOT or SCUBA diving may damage the pulse generator.

Refer to the MRI Technical Guide at [www.bostonscientific-elabeling.com](http://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 the included devices: Air embolism; Allergic reaction; Bleeding; Bradycardia; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Electrolyte imbalance/dehydration; 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; 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); 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 a device malfunction.

Additionally, potential adverse events associated with the implantation of a coronary venous lead system include: Allergic reaction to contrast media; Breakage/failure of implant instruments; Prolonged exposure to fluoroscopic radiation; Renal failure from contrast media used to visualize coronary veins.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev D) 046774 AG

## **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 nonrecooperable 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**

- Programming minimum PVARP less than retrograde V–A conduction may increase the likelihood of a Pacemaker-mediated tachycardia (PMT).
- Automatic Capture is intended for ventricular use only. Do not program Amplitude to Auto for single-chamber devices implanted in the atrium.
- The safety and efficacy of the MV Sensor modes have not been clinically established in patients with abdominal implant sites.
- MV Sensor performance may be adversely affected under transient conditions such as pneumothorax, pericardial effusion, or pleural effusion. Consider programming the MV Sensor Off until these conditions are resolved.
- Adaptive-rate modes based completely or in part on MV might be inappropriate for patients who can achieve respiratory cycles shorter than one second (greater than 60 breaths per minute). Higher respiration rates attenuate the impedance signal, which diminishes the MV rate response (i.e., the pacing rate will drop toward the programmed LRL).
- Adaptive-rate modes based completely or in part on MV should not be used for patients with:
  - An ICD
  - Unipolar leads – for MV detection, a bipolar lead is required in either the atrium or ventricle
  - A lead other than a bipolar transvenous lead – MV measurement has only been tested with a bipolar transvenous lead
  - A mechanical ventilator – use of the ventilator might result in an inappropriate MV Sensor-driven rate
- Implanting a replacement device in a subcutaneous pocket that previously housed a larger device may result in pocket air entrapment, migration, erosion, or insufficient grounding between the device and tissue. Irrigating the pocket with sterile saline solution decreases the possibility of pocket air entrapment and insufficient grounding. Suturing the device in place reduces the possibility of migration and erosion.
- For patients with respiratory disorders or abnormal breathing patterns, the physician should use medical judgment when programming the MV Sensor to On. To mitigate inappropriate sensor-drive rates, the physician may evaluate the rate response and consider a lower Response Factor.
- Use only the designated programmer and software application to communicate with this pulse generator.
- If properly functioning leads with stable measured impedance values near the programmed impedance limits are used, consider programming Lead Safety Switch Off or changing the impedance limits to avoid undesirable switching to a Unipolar Lead Configuration.
- If the Lead Configuration is programmed to Bipolar when a unipolar lead is implanted, pacing will not occur.
- Determine if the device and programmable options are appropriate for patients with supraventricular tachyarrhythmias (SVTs) because SVTs can initiate unwanted device therapy.
- Rate Adaptive Pacing should be used with care in patients who are unable to tolerate increased pacing rates.
- Adaptive-rate pacing is not limited by refractory periods. A long refractory period programmed in combination with a high MSR can result in asynchronous pacing during refractory periods since the combination can cause a very small sensing window or none at all. Use Dynamic AV Delay or Dynamic P Ventricular refractory periods (VRPs) to optimize sensing windows. If you are programming a fixed AV Delay, consider the sensing outcomes.
- The pulse generator's MTR and MSR should be programmed to a rate lower than a concomitant S-ICD's lowest tachycardia detection zone.
- Take care to ensure that artifacts from the ventricles are not present on the atrial channel, or atrial oversensing may result. If ventricular artifacts are present in the atrial channel, the atrial lead may need to be repositioned to minimize its interaction.
- Sensing high atrial rates may impact device longevity. Therefore, the Atrial Sense lead configuration will be seeded to Off when programming from an atrial sensing mode to non-atrial sensing mode.
- Turning the Signal Artifact Monitor Off may put the patient at increased risk of oversensing, unless the MV/Respiratory Sensor is also programmed to Off.

- When a single pass VDD lead is used with a dual-chamber device, the atrial electrodes may not be in contact with the atrial wall. In this case, the measured depolarization signal has a relatively low Amplitude and could require a more sensitive setting.
- To obtain an accurate MV baseline following any surgical procedure involving the pulse generator or leads, a new, manual calibration should be performed. Lead maturation, air entrapment in the pocket, pulse generator motion due to inadequate suturing, external defibrillation or cardioversion, or other patient complications (e.g., pneumothorax) require a new MV baseline for appropriate MV behavior.
- The amplitude and prevalence of myopotential noise is increased in unipolar lead configurations, as compared to bipolar lead configurations. For patients with a unipolar lead configuration and myopotential oversensing during activity involving the pectoral muscles, the programming of Fixed Sensitivity is recommended
- Advise patients to avoid sources of electromagnetic interference (EMI). The pulse generator may inhibit pacing due to oversensing, or may switch to asynchronous pacing of the programmed pacing rate or at the magnet rate in the presence of EMI.  
Moving away from the source of the EMI or turning off the source usually allows the pulse generator to return to normal operation.
- Any medical equipment, treatment, therapy, or diagnostic test that introduces electrical current into the patient has the potential to interfere with pulse generator function.
- External patient monitors (e.g., respiratory monitors, surface ECG monitors, hemodynamic monitors) may cause:
  - Inappropriate MV Sensor-driven rate (up to maximum sensor-drive rate)
  - Misleading respiration-based trending
- Medical therapies, treatments, and diagnostic tests that use conducted electrical current (e.g., TENS, electrocautery, electrolysis/thermolysis, electrodiagnostic testing, electromyography, or nerve conduction studies) may interfere with or damage the pulse generator. Program the device to Electrocautery Protection Mode prior to the treatment, and monitor device performance during the treatment. After the treatment, verify pulse generator function ("Post-Therapy Pulse Generator Follow Up" in the manual). To resolve suspected interactions with MV rate driving and/or MV/Respiratory Sensor-based diagnostics, deactivate the MV/Respiratory Sensor by programming it to Off. If a PRM is not available and the pulse generator is pacing at the sensor-driven rate, apply a magnet to the pulse-generator to initiate temporary asynchronous, non-rate responsive pacing.
- Extracorporeal shock wave lithotripsy (ESWL) may cause electromagnetic interference with or damage to the pulse generator. If ESWL is medically necessary, consider the following to minimize the potential for encountering interaction:
  - Focus the ESWL beam at least 15 cm (6 in) away from the pulse generator.
  - Depending on the pacing needs of the patient, program the Brady Mode to Off or a non-rate responsive VVI or VOO mode.
- Therapeutic ultrasound (e.g., lithotripsy) energy may damage the pulse generator. If therapeutic ultrasound energy must be used, avoid focusing near the pulse generator site. Diagnostic ultrasound (e.g., echocardiography) is not known to be harmful to the pulse generator.
- Electrical interference or "noise" from devices such as electrocautery and monitoring equipment may interfere with establishing or maintaining telemetry for interrogating or programming the device. In the presence of such interference, move the programmer away from electrical devices, and ensure that the wand cord and cables are not crossing one another. If telemetry is cancelled as a result of interference, the device should be re-interrogated prior to evaluating information from pulse generator memory.
- Radio frequency (RF) signals from devices that operate at frequencies near that of the pulse generator may interrupt ZIP telemetry while interrogating or programming the pulse generator. This RF interference can be reduced by increasing the distance between the interfering device and the PRM and pulse generator.
- Use caution when inserting guidewires for placement of other types of central venous catheter systems such as PIC lines or Hickman catheters in locations where pulse generator leads may be encountered. Insertion of such guidewires into veins containing leads could result in the leads being damaged or dislodged.

### Minimizing Pacemaker/S-ICD Interaction

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

A pacemaker can interact with an S-ICD in the following ways:

- If during a tachyarrhythmia the pacemaker is not inhibited and the pacing pulses are detected by the rate-sensing circuit of the S-ICD, the S-ICD could interpret the pacing pulses as a normal rhythm. The S-ICD would not detect the arrhythmia and therefore would not deliver therapy.
- Pacemaker failure to sense or to capture could result in two independent signals (intrinsic and pacing pulses) to the S-ICD. This could cause the S-ICD's rate measurement to be faster than the actual heart rate. As a result, the S-ICD could deliver unnecessary therapy.
- If the S-ICD counts both the pacing pulses and the resultant ventricular depolarizations, the S-ICD's rate measurement would be faster than the actual heart rate. This could result in unnecessary S-ICD therapy.

In Safety Mode, these pulse generators use a unipolar pacing and sensing configuration. Safety Mode is compatible for use with an S-ICD because the configured parameters mitigate the potential pacemaker and S-ICD interactions as follows:

- Sensing is AGC at 0.25 mV. The AGC sensing is able to effectively sense an intrinsic rhythm faster than the Safety Mode LRL of 72.5 bpm. As a result, pacing is inhibited and does not interfere with S-ICD tachyarrhythmia detection.
- When pacing is necessary, the elevated output of 5.0V and 1.0 ms reduces the risk of not capturing.
- If double detection of the pace pulse and the resulting depolarization were to occur, it would not result in unnecessary S-ICD therapy provided the S-ICD tach threshold is more than twice the Safety Mode LR (145 ppm).

To help minimize device-device interaction of a bipolar pacemaker when an S-ICD is already implanted, follow these precautionary measures:

- Use bipolar pacing leads with close electrode spacing in both chambers. Significant spacing between electrodes may increase the likelihood that the S-ICD will detect the pacing pulses.
- Consider programming the pacemaker to (1) the lowest Amplitude allowable for safe capture in the chronic state, (2) the maximum Sensitivity (the lowest programmable level) while maintaining an adequate safety margin, and (3) the minimum cardiac rate acceptable for the patient.
- In addition to the steps above, perform the following testing to assess device-device interaction:
- Use the S-ICD features, such as markers, real-time electrograms (EGMs), and/or beeping tones, to help evaluate potential for pacemaker interaction due to oversensing by the S-ICD.

**NOTE:** If a single chamber pacemaker is implanted with an atrial lead, perform testing in both unipolar and bipolar configurations.

- Ventricular fibrillation and all of the patient's ventricular tachycardias should be induced while the S-ICD is activated and the pacemaker is programmed to an asynchronous mode at maximum Amplitude and Pulse Width. This should provide the greatest opportunity for inhibition of arrhythmia detection due to detection of pacemaker pacing pulses. The pacemaker leads might have to be repositioned to eliminate detection of the pacing pulses by the S-ICD.

Temporarily deactivate the patient's S-ICD when (1) evaluating pacing and sensing thresholds, (2) when using an external temporary pacemaker during implant, and (3) when reprogramming an implanted pacemaker.

Following any S-ICD discharge, reinterrogate the pacemaker to ensure that the S-ICD shock did not damage the pacemaker.

If implanting an S-ICD in a patient who has a pacemaker already implanted, refer to the S-ICD manual for implantations considerations.

Refer to the Warnings section for additional information regarding pacemaker and S-ICD interactions.

**CAUTION:** Transcutaneous Electrical Nerve Stimulation (TENS) involves passing electrical current through the body, and may interfere with pulse generator function.

**CAUTION:** Elevated pressures due to HBOT or SCUBA diving may damage the pulse generator.

### 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.

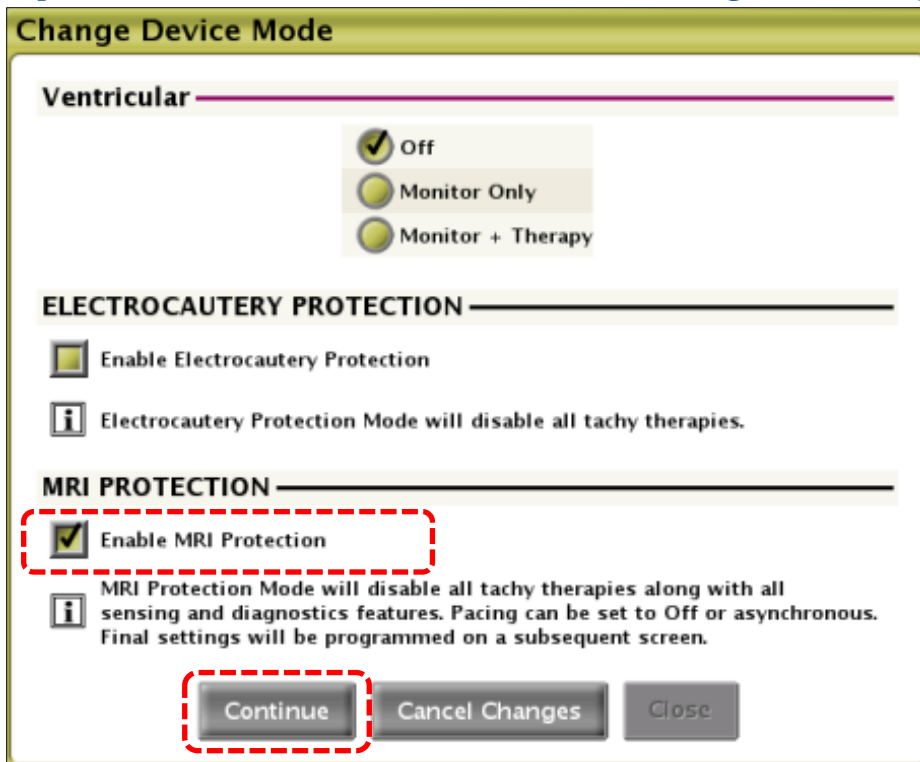
For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide.

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](http://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

**ATTENTION**

It is less than six weeks since the implant of this device. The system is not designated as MR Conditional for MRI scans conducted in the first six weeks after implant.

Press Continue only after review of the risks of MRI scans under this condition in the MRI Technical Guide.

Continue with MRI Protection    Cancel

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

**ATTENTION**

The LV lead impedance is out of range in at least one pace vector.

Check for evidence of a fractured lead or compromised pulse generator-lead system integrity. (Refer to the MRI Technical Guide for risks of MRI scans under this condition.)

Press Continue only after evaluating leads and ruling out possibility of a fractured lead or compromised pulse generator-lead system integrity.

Continue with MRI Protection    Cancel

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.

**ATTENTION**

The Shock lead impedance is out of range.

Check for evidence of a fractured lead or compromised pulse generator-lead system integrity. (Refer to the MRI Technical Guide for risks of MRI scans under this condition.)

Press Continue only after evaluating leads and ruling out possibility of a fractured lead or compromised pulse generator-lead system integrity.

Continue with MRI Protection    Cancel

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

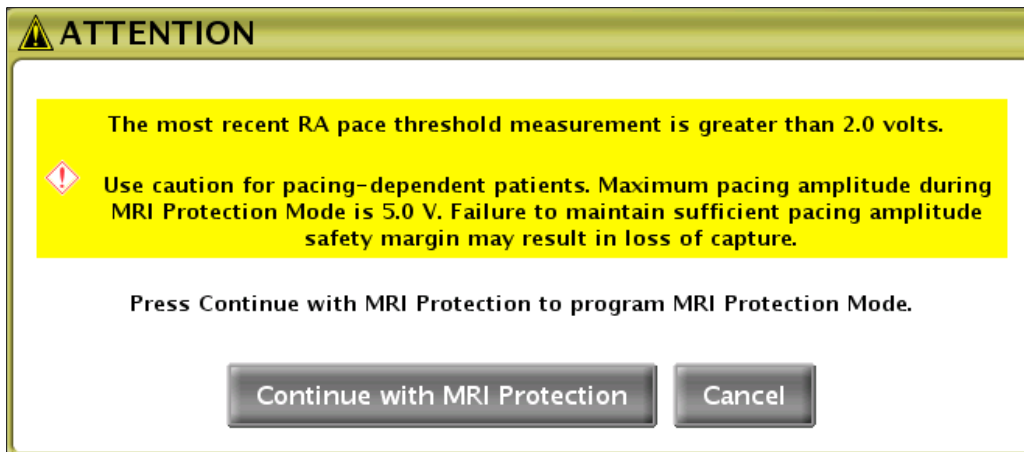
## Recent RA and RV Pace Threshold Check

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.



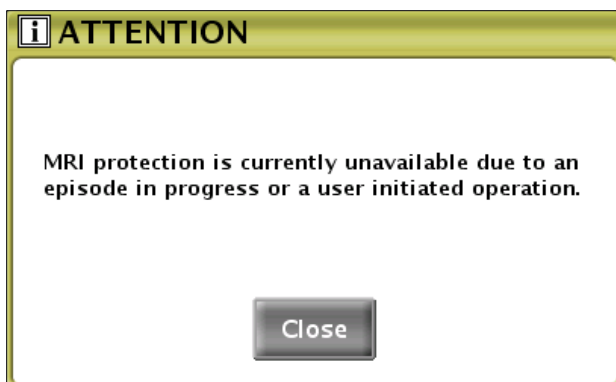
There are certain conditions assessed during programming that will prevent entry into MRI Protection Mode. There will be no option to continue with MRI Protection programming.

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

**MRI Protection Checklist**

**i** The system is designated as MR Conditional in accordance with the conditions specified in the MRI Technical Guide. Please review those conditions and the summary checklist below before continuing.

**Device Checklist:**

- Patient is implanted with an ImageReady MR Conditional System.
- No other active or abandoned implanted devices, components or accessories present.
- Pulse generator is in MRI Protection Mode during scan.
- Patient must be continuously monitored after MRI Protection Mode is programmed.
- Ensure backup therapy is available (external rescue).
- Patient is clinically capable of tolerating no Tachy protection.
- Pulse generator implant location restricted to left or right pectoral region.
- At least six weeks have elapsed since implantation and/or any surgical modification.
- No evidence of a fractured lead or compromised pulse generator-lead system integrity.

**⚠ To proceed without following the specified conditions may subject the patient to risk of serious injury or death.**

Continue with MRI Protection    Cancel

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

### Program MRI Protection

Select Brady Mode and review pacing parameters. Press 'Program MRI Protection' to program the device.

Tachy Mode	Off
Brady Mode	<input type="button" value=""/>
Lower Rate Limit	<input type="text"/> ppm
Ventricular Pacing Chamber	<input type="text"/>
• A Amplitude	<input type="text"/> V @ -- ms
■ RV Amplitude	<input type="text"/> V @ -- ms
◆ LV Amplitude	<input type="text"/> V @ <input type="text"/> ms
MRI Protection Time-out	<input type="text" value="6"/> h

Ensure patient is monitored until MRI Protection Mode is exited:

- Patient should be monitored by pulse oximetry and electrocardiography (ECG).
- Ensure backup therapy is available (external rescue).

In MRI Protection Mode:

- Patient will not receive Tachycardia therapy (i.e., no defibrillation, and no ATP).
- Pacing is Off or asynchronous.

The beeper will no longer be usable following an MRI scan.

Coming in contact with the strong magnetic field of an MRI scanner causes a permanent loss of the beeper volume. This cannot be recovered, even after leaving the MR scan environment and exiting MRI Protection Mode.

Place the telemetry wand over the device to program MRI Protection.

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.

### MRI Protection Brady Mode

In MRI Protection Mode, Brady Mode is either Off or asynchronous.

When choosing MRI Protection Brady Mode, consider:

- Whether pacing is required
- Which chamber(s) need to be paced
- Risk of induction of VT/VF with asynchronous ventricular pacing
- Risk of worsening heart failure due to loss of CRT and/or AV Synchrony

<input type="button" value="DOO"/>	<input type="button" value="VOO"/>
<input type="button" value="AOO"/>	<input type="button" value="Off"/>

## 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.

### Program MRI Protection

Select Brady Mode and review pacing parameters. Press 'Program MRI Protection' to program the device.

Tachy Mode	Off
Brady Mode	DOO
* Lower Rate Limit	65 ppm
* Ventricular Pacing Chamber	BiV
• A Amplitude	5.0 V @ 1.0 ms *
■ RV Amplitude	5.0 V @ 1.0 ms *
◆ LV Amplitude	3.5 V @ 0.4 ms
MRI Protection Time-out	6 h

**Ensure patient is monitored until MRI Protection Mode is exited:**

- Patient should be monitored by pulse oximetry and electrocardiography (ECG).
- Ensure backup therapy is available (external rescue).

**In MRI Protection Mode:**

- Patient will not receive Tachycardia therapy (i.e., no defibrillation, and no ATP).
- Pacing is Off or asynchronous.

The beeper will no longer be usable following an MRI scan.

Coming in contact with the strong magnetic field of an MRI scanner causes a permanent loss of the beeper volume. This cannot be recovered, even after leaving the MR scan environment and exiting MRI Protection Mode.

Place the telemetry wand over the device to program MRI Protection.

## Programmable Options:

### Lower Rate Limit All Chambers

MRI Protection Lower Rate Limit			
30	50	70	90
35	55	75	95
40	60	80	100
45	65	85	

### Pacing Amplitudes All Chambers

MRI Protection LV-Amplitude			
2.0	2.5	3.0	3.5
2.1	2.6	3.1	4.0
2.2	2.7	3.2	4.5
2.3	2.8	3.3	5.0
2.4	2.9	3.4	

### Pulse Width LV Only

MRI Protection LV-Pulse Width			
0.1	0.6	1.1	1.6
0.2	0.7	1.2	1.7
0.3	0.8	1.3	1.8
0.4	0.9	1.4	1.9
0.5	1.0	1.5	2.0

## 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.

Program MRI Protection	
Select Brady Mode and review pacing parameters. Press 'Program MRI Protection' to program the device.	
Tachy Mode	Off
Brady Mode	AOO
Lower Rate Limit	65 ppm
Ventricular Pacing Chamber	
• A Amplitude	5.0 V @ 1.0 ms
■ RV Amplitude	V @ - - ms
◆ LV Amplitude	V @ - - ms
MRI Protection Time-out	6 h

## 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.

Program MRI Protection	
Select Brady Mode and review pacing parameters. Press 'Program MRI Protection' to program the device.	
Tachy Mode	Off
Brady Mode	VOO
Lower Rate Limit	65 ppm
Ventricular Pacing Chamber	BiV
• A Amplitude	V @ - - ms
■ RV Amplitude	5.0 V @ 1.0 ms
◆ LV Amplitude	3.5 V @ 0.4 ms
MRI Protection Time-out	6 h

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.

### Program MRI Protection

Select Brady Mode and review pacing parameters. Press 'Program MRI Protection' to program the device.

Tachy Mode	Off	
Brady Mode	Off	
Lower Rate Limit		ppm
Ventricular Pacing Chamber		
• A Amplitude		V @ -- ms
■ RV Amplitude		V @ -- ms
◆ LV Amplitude		V @ -- ms
MRI Protection Time-out	6	h

Place the telemetry wand over the device to program MRI Protection.

Program MRI Protection
Cancel

**Ensure patient is monitored until MRI Protection Mode is exited:**

- Patient should be monitored by pulse oximetry and electrocardiography (ECG).
- Ensure backup therapy is available (external rescue).

**In MRI Protection Mode:**

- Patient will not receive Tachycardia therapy (i.e., no defibrillation, and no ATP).
- Pacing is Off or asynchronous.

**The beeper will no longer be usable following an MRI scan.**

Coming in contact with the strong magnetic field of an MRI scanner causes a permanent loss of the beeper volume. This cannot be recovered, even after leaving the MR scan environment and exiting MRI Protection Mode.

## Time-out Function

### MRI Protection Time-out

Select the duration of the MRI Protection period (in hours).

**If MRI Protection Time-out is programmed Off, the patient will receive**

- No tachy therapy
- Either no pacing therapy, or asynchronous pacing therapy until MRI Protection is manually exited.

Off	9
3	12
6	

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.

### Program MRI Protection

Select Brady Mode and review pacing parameters. Press 'Program MRI Protection' to program the device.

Tachy Mode	Off
Brady Mode	<input type="button" value="DOO"/>
Lower Rate Limit	<input type="button" value="65"/> ppm
Ventricular Pacing Chamber	<input type="button" value="BiV"/>
• A Amplitude	<input type="button" value="5.0"/> V @ 1.0 ms
■ RV Amplitude	<input type="button" value="5.0"/> V @ 1.0 ms
◆ LV Amplitude	<input type="button" value="3.5"/> V @ <input type="button" value="0.4"/> ms
MRI Protection Time-out	<input type="button" value="6"/> h

Ensure patient is monitored until MRI Protection Mode is exited:


- Patient should be monitored by pulse oximetry and electrocardiography (ECG).
- Ensure backup therapy is available (external rescue).

In MRI Protection Mode:

- Patient will not receive Tachycardia therapy (i.e., no defibrillation, and no ATP).
- Pacing is Off or asynchronous.

The beeper will no longer be usable following an MRI scan.

Coming in contact with the strong magnetic field of an MRI scanner causes a permanent loss of the beeper volume. This cannot be recovered, even after leaving the MR scan environment and exiting MRI Protection Mode.

 Place the telemetry wand over the device to program MRI Protection.

## 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.

### MRI Protection Programmed

**The device is in MRI Protection Mode.**

Ensure patient is monitored until MRI Protection Mode is exited:

- Patient should be monitored by pulse oximetry and electrocardiography (ECG).
- Ensure backup therapy is available (external rescue).

In MRI Protection Mode as programmed:

- Patient will not receive Tachycardia therapy (i.e., no defibrillation, and no ATP).
- Patient will receive asynchronous pacing only.

MRI Protection is programmed with the following settings:

Tachy Mode	Off
Brady Mode	DOO
LRL	65 ppm
AV Delay	100 ms
Ventricular Pacing Chamber	BiV
● A Amplitude	5.0 V @ 1.0 ms
■ RV Amplitude	5.0 V @ 1.0 ms
◆ LV Amplitude	3.5 V @ 0.4 ms
LV Offset	0 ms
MRI Protection Time-out	6 h
Scheduled Expiration Time	06 Sep 2017 19:19

Press End Session to keep the device in MRI Protection Mode.  
Press Exit MRI Protection to program the device out of MRI Protection Mode.

Exit MRI Protection
Print Settings
End Session

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		√	√	√

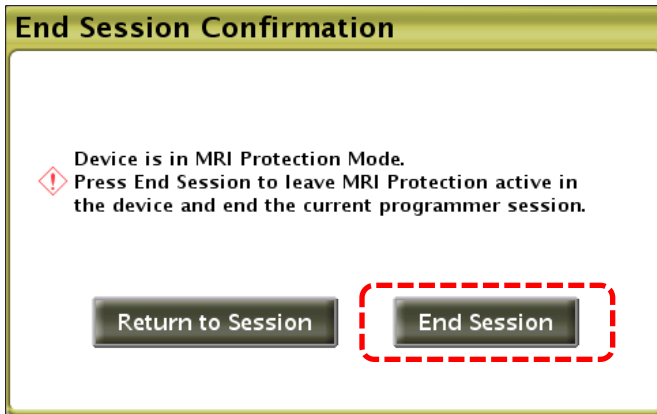
## MRI Protection Settings Report

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](http://www.bostonscientific.com/imageready).

## Ending the Telemetry Session

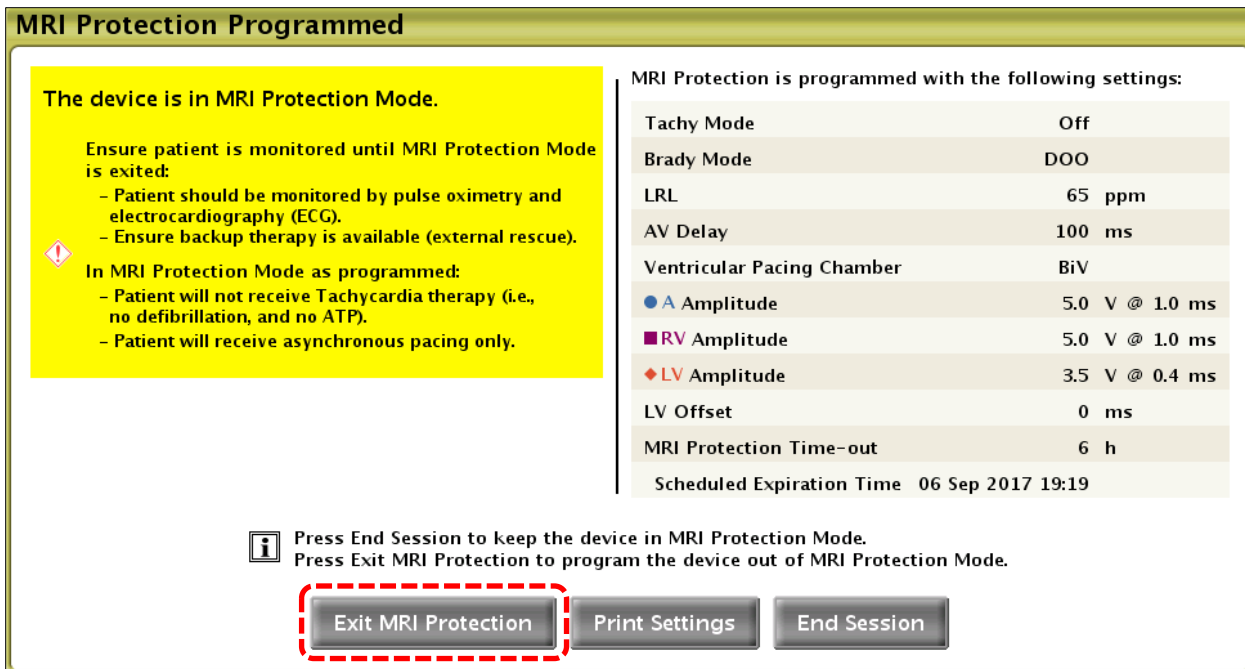


Selecting the End Session button will end the current programmer session with the device remaining in MRI Protection Mode. Remember, the patient will not receive Tachycardia therapy and, if Brady Mode is programmed to Off, will not receive Bradycardia pacing and CRT.

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.

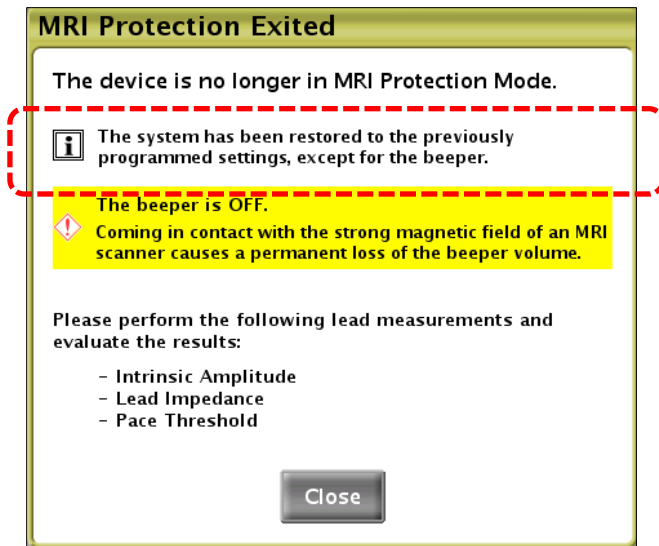


Exiting MRI Protection can be done automatically using the Time-out function or manually using the Programmer. Labeling states: Do not leave the device in MRI Protection Mode any longer than necessary following the scan.

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

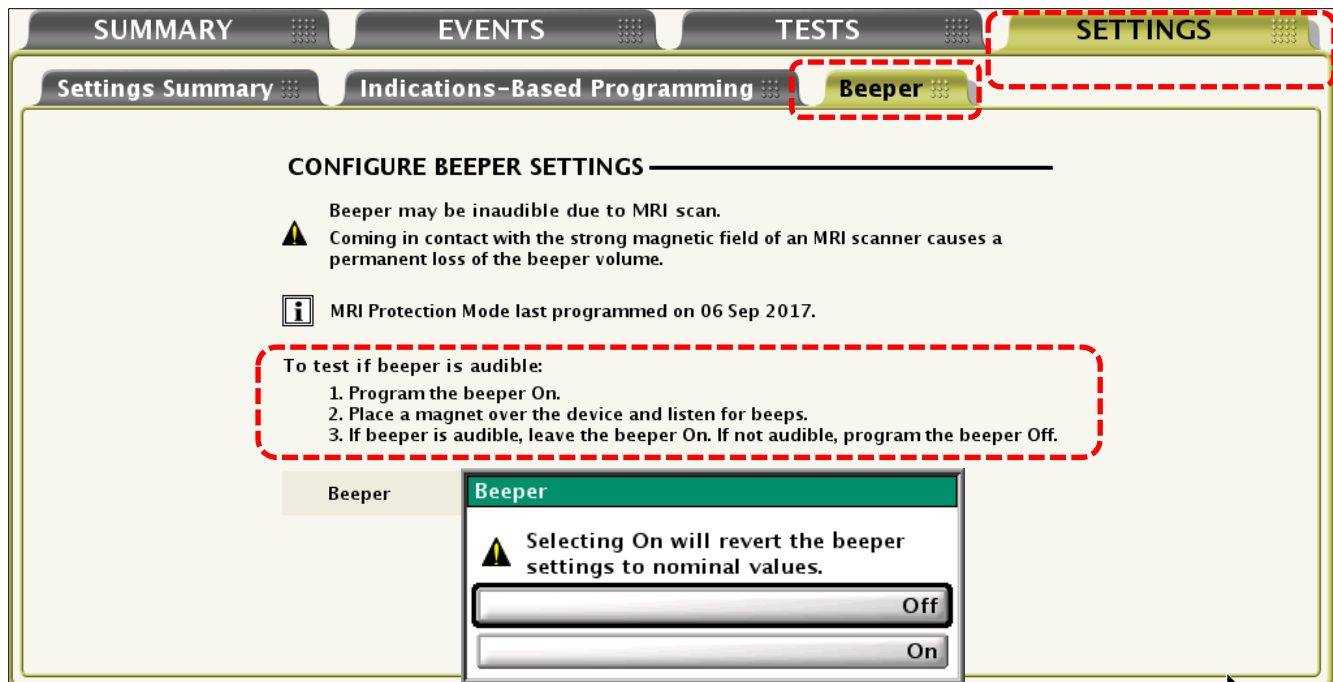
Upon exit from MRI Protection Mode, all parameters are immediately restored to pre-MRI Protection Mode values except for the Beeper.

## 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 –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  $\leq$  35% and QRS duration  $\geq$  120 ms; or left bundle branch block (LBBB) with QRS duration  $\geq$  130 ms, EF  $\leq$  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**

- Programming minimum PVARP less than retrograde V–A conduction may increase the likelihood of a PMT.
- The clinical benefit of Rate Adaptive Pacing in heart failure patients has not been studied. Rate Adaptive Pacing should be used with medical discretion if the patient develops an indication such as chronotropic incompetence. Patients with heart failure may have hemodynamic compromise at rapid sensor-driven rates, and the physician may wish to program less aggressive rate adaptive parameters in accordance with patient condition. It is not recommended for patients who exhibit only heart failure-induced chronotropic incompetency.
- Implanting a replacement device in a subcutaneous pocket that previously housed a larger device may result in pocket air entrapment, migration, erosion, or insufficient grounding between the device and tissue. Irrigating the pocket with sterile saline solution decreases the possibility of pocket air entrapment and insufficient grounding. Suturing the device in place reduces the possibility of migration and erosion.
- Use only the designated programmer and software application to communicate with this pulse generator.
- Programming the device to provide RV-only pacing is not intended for the treatment of heart failure. The clinical effects of RV-only pacing for the treatment of heart failure have not been established.
- If the Lead Configuration is programmed to Bipolar when a unipolar lead is implanted, pacing will not occur.
- If the Shock Vector is programmed to RVcoil>>RAcoil and the lead does not have an RA coil, shocking will not occur.
- Determine if the device and programmable options are appropriate for patients with supraventricular tachyarrhythmias (SVTs) because SVTs can initiate unwanted device therapy.
- To ensure a high percentage of biventricular pacing, the programmed AV Delay setting must be less than the patient's intrinsic PR interval.
- Rate Adaptive Pacing should be used with care in patients who are unable to tolerate increased pacing rates.
- Adaptive-rate pacing is not limited by refractory periods. A long refractory period programmed in combination with a high MSR can result in asynchronous pacing during refractory periods since the combination can cause a very small sensing window or none at all. Use Dynamic AV Delay or Dynamic PVARP to optimize sensing windows. If you are programming a fixed AV Delay, consider the sensing outcomes.
- Atrial Tachy Response (ATR) should be programmed to On if the patient has a history of atrial tachyarrhythmias. The delivery of CRT is compromised because AV synchrony is disrupted if the ATR mode switch occurs.
- Ensure the patient is clinically capable of tolerating low rate RV Backup Pacing and lack of LV pacing during an RVS-LVS Delay test.
- Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Moving away from the source of the EMI or turning off the source usually allows the pulse generator to return to normal operation.
- Any medical equipment, treatment, therapy, or diagnostic test that introduces electrical current into the patient has the potential to interfere with pulse generator function.
  - External patient monitors (e.g., respiratory monitors, surface ECG monitors, hemodynamic monitors) may interfere with the pulse generator's impedance-based diagnostics (e.g., shock lead impedance measurements, Respiratory Rate trend). To resolve suspected interactions with Respiratory Sensorbased diagnostics, deactivate the pulse generator's Respiratory Sensor by programming it to Off.
  - Medical therapies, treatments, and diagnostic tests that use conducted electrical current (e.g., TENS, electrocautery, electrolysis/thermolysis, electrodiagnostic testing, electromyography, or nerve conduction studies) may interfere with or damage the pulse generator. Program the device to Electrocautery Protection Mode prior to the treatment, and monitor device performance during the treatment. After the treatment, verify pulse generator function ("Post-Therapy Pulse Generator Follow Up" in manual).
- Extracorporeal shock wave lithotripsy (ESWL) may cause electromagnetic interference with or damage to the pulse generator.
- Therapeutic ultrasound (e.g., lithotripsy) energy may damage the pulse generator. If therapeutic ultrasound energy must be used, avoid focusing near the pulse generator site. Diagnostic ultrasound (e.g., echocardiography) is not known to be harmful to the pulse generator.
- Electrical interference or "noise" from devices such as electrocautery and monitoring equipment may interfere with establishing or maintaining telemetry for interrogating or programming the device. In the presence of such interference, move the programmer away from electrical devices, and ensure that the wand cord and cables are not crossing one another. If telemetry is cancelled as a result of interference, the device should be re-interrogated prior to evaluating information from pulse generator memory.
- RF signals from devices that operate at frequencies near that of the pulse generator may interrupt ZIP telemetry while interrogating or programming the pulse generator. This RF interference can be reduced by increasing the distance between the interfering device and the PRM and pulse generator.
- Use caution when inserting guidewires for placement of other types of central venous catheter systems such as PIC lines or Hickman catheters in locations where pulse generator leads may be encountered. Insertion of such guidewires into veins containing leads could result in the leads being damaged or dislodged.

**CAUTION:** Transcutaneous Electrical Nerve Stimulation (TENS) involves passing electrical current through the body, and may interfere with pulse generator function. If TENS is medically necessary, evaluate the TENS therapy settings for compatibility with the pulse generator.

**CAUTION:** Elevated pressures due to HBOT or SCUBA diving may damage the pulse generator.

### **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 the included devices: Air embolism; Allergic reaction; Bleeding; Bradycardia; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Electrolyte imbalance/dehydration; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Failure to convert an induced arrhythmia; Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Inability to defibrillate or pace; Inappropriate therapy (e.g., shocks and antitachycardia pacing (ATP) where applicable, pacing); Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Insulating myocardium during defibrillation with internal or external paddles; 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); Pericardial rub, effusion; Pneumothorax; Pulse generator migration; Shunting current during defibrillation with internal or external paddles; Syncop; 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 a device malfunction.

Additionally, potential adverse events associated with the implantation of a coronary venous lead system include: Allergic reaction to contrast media; Breakage/failure of implant instruments; Prolonged exposure to fluoroscopic radiation; Renal failure from contrast media used to visualize coronary veins.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev C) 046774 AG

# ICD Systems – AUTOGEN™ EL, DYNAGEN™ EL, DYNAGEN™ MINI, INOGEN™ EL, INOGEN™ MINI, ORIGEN™ EL, ORIGEN™ MINI, INCEPTA™, ENERGEN™, PUNCTUA™, TELIGEN™100

## 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

- Programming minimum PVARP less than retrograde V–A conduction may increase the likelihood of a Pacemaker-mediated tachycardia (PMT).
- Implanting a replacement device in a subcutaneous pocket that previously housed a larger device may result in pocket air entrapment, migration, erosion, or insufficient grounding between the device and tissue. Irrigating the pocket with sterile saline solution decreases the possibility of pocket air entrapment and insufficient grounding. Suturing the device in place reduces the possibility of migration and erosion.
- Use only the designated programmer and software application to communicate with this pulse generator.
- If the Shock Vector is programmed to RVcoil>>RAcoil and the lead does not have an RA coil, shocking will not occur.
- Determine if the device and programmable options are appropriate for patients with supraventricular tachyarrhythmias (SVTs) because SVTs can initiate unwanted device therapy.
- Rate Adaptive Pacing should be used with care in patients who are unable to tolerate increased pacing rates.
- Adaptive-rate pacing is not limited by refractory periods. A long refractory period programmed in combination with a high MSR can result in asynchronous pacing during refractory periods since the combination can cause a very small sensing window or none at all. Use Dynamic AV Delay or Dynamic P Ventricular refractory periods (VRPs) to optimize sensing windows. If you are programming a fixed AV Delay, consider the sensing outcomes.
- Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Moving away from the source of the EMI or turning off the source usually allows the pulse generator to return to normal operation.
- Any medical equipment, treatment, therapy, or diagnostic test that introduces electrical current into the patient has the potential to interfere with pulse generator function.
- External patient monitors (e.g., respiratory monitors, surface ECG monitors, hemodynamic monitors) may interfere with the pulse generator's impedance-based diagnostics (e.g., shock lead impedance measurements, Respiratory Rate trend). To resolve suspected interactions with Respiratory Sensorbased diagnostics, deactivate the pulse generator's Respiratory Sensor by programming it to Off.
- Medical therapies, treatments, and diagnostic tests that use conducted electrical current (e.g., TENS, electrocautery, electrolysis/thermolysis, electrodiagnostic testing, electromyography, or nerve conduction studies) may interfere with or damage the pulse generator. Program the device to Electrocautery Protection Mode prior to the treatment, and monitor device performance during the treatment. After the treatment, verify pulse generator function ("Post-Therapy Pulse Generator Follow Up" in the manual).
- Do not use internal defibrillation paddles or catheters unless the pulse generator is
- Extracorporeal shock wave lithotripsy (ESWL) may cause electromagnetic interference with or damage to the pulse generator.
- Therapeutic ultrasound (e.g., lithotripsy) energy may damage the pulse generator. If therapeutic ultrasound energy must be used, avoid focusing near the pulse generator site. Diagnostic ultrasound (e.g., echocardiography) is not known to be harmful to the pulse generator.
- Electrical interference or "noise" from devices such as electrocautery and monitoring equipment may interfere with establishing or maintaining telemetry for interrogating or programming the device. In the presence of such interference, move the programmer away from electrical devices, and ensure that the wand cord and cables are not crossing one another. If telemetry is cancelled as a result of interference, the device should be re-interrogated prior to evaluating information from pulse generator memory.
- Radio frequency (RF) signals from devices that operate at frequencies near that of the pulse generator may interrupt ZIP telemetry while interrogating or programming the pulse generator. This RF interference can be reduced by increasing the distance between the interfering device and the PRM and pulse generator.
- Use caution when inserting guidewires for placement of other types of central venous catheter systems such as PIC lines or Hickman catheters in locations where pulse generator leads may be encountered. Insertion of such guidewires into veins containing leads could result in the leads being damaged or dislodged.

**CAUTION:** Transcutaneous Electrical Nerve Stimulation (TENS) involves passing electrical current through the body, and may interfere with pulse generator function. If TENS is medically necessary, evaluate the TENS therapy settings for compatibility with the pulse generator.

**CAUTION:** Elevated pressures due to HBOT or SCUBA diving may damage the pulse generator.

Refer to the MRI Technical Guide at [www.bostonscientific-labeling.com](http://www.bostonscientific-labeling.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.

## 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 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); Failure to convert an induced arrhythmia; Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Heart failure following chronic RV apical pacing; Inability to defibrillate or pace; Inappropriate therapy (e.g., shocks and antitachycardia pacing (ATP) where applicable, 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 ImageReady MR Conditional Defibrillation System 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 shocking while conscious; Fear that shocking capability may be lost; Imagined shocking; Fear of a device malfunction.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev D) 046774 AG

# 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. All other devices covered by this manual are not MR conditional. Do not expose patients 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 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

- Programming minimum PVARP less than retrograde V–A conduction may increase the likelihood of a Pacemaker-mediated tachycardia (PMT).
- Implanting a replacement device in a subcutaneous pocket that previously housed a larger device may result in pocket air entrapment, migration, erosion, or insufficient grounding between the device and tissue. Irrigating the pocket with sterile saline solution decreases the possibility of pocket air entrapment and insufficient grounding. Suturing the device in place reduces the possibility of migration and erosion.
- Use only the designated programmer and software application to communicate with this pulse generator.
- If the Shock Vector is programmed to RVcoil>>RAcoil and the lead does not have an RA coil, shocking will not occur.
- Determine if the device and programmable options are appropriate for patients with supraventricular tachyarrhythmias (SVTs), because SVTs can initiate unwanted device therapy.
- Rate Adaptive Pacing should be used with care in patients who are unable to tolerate increased pacing rates.
- Adaptive-rate pacing is not limited by refractory periods. A long refractory period programmed in combination with a high MSR can result in asynchronous pacing during refractory periods since the combination can cause a very small sensing window or none at all. Use Dynamic AV Delay or Dynamic PVARP to optimize sensing windows. If you are programming a fixed AV Delay, consider the sensing outcomes.
- Advise patients to avoid sources of electromagnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Moving away from the source of the EMI or turning off the source usually allows the pulse generator to return to normal operation.
- Any medical equipment, treatment, therapy, or diagnostic test that introduces electrical current into the patient has the potential to interfere with pulse generator function.
- External patient monitors (e.g., respiratory monitors, surface ECG monitors, hemodynamic monitors) may interfere with the pulse generator's impedance-based diagnostics (e.g., shock lead impedance measurements, Respiratory Rate trend). To resolve suspected interactions with Respiratory Sensorbased diagnostics, deactivate the pulse generator's Respiratory Sensor by programming it to Off.
- Medical therapies, treatments, and diagnostic tests that use conducted electrical current (e.g., TENS, electrocautery, electrolysis/thermolysis, electrodiagnostic testing, electromyography, or nerve conduction studies) may interfere with or damage the pulse generator. Program the device to Electrocautery Protection Mode prior to the treatment, and monitor device performance during the treatment. After the treatment, verify pulse generator function ("Post-Therapy Pulse Generator Follow Up" in the manual).
- Extracorporeal shock wave lithotripsy (ESWL) may cause electromagnetic interference with or damage to the pulse generator.
- Therapeutic ultrasound (e.g., lithotripsy) energy may damage the pulse generator. If therapeutic ultrasound energy must be used, avoid focusing near the pulse generator site. Diagnostic ultrasound (e.g., echocardiography) is not known to be harmful to the pulse generator.
- Electrical interference or "noise" from devices such as electrocautery and monitoring equipment may interfere with establishing or maintaining telemetry for interrogating or programming the device. In the presence of such interference, move the programmer away from electrical devices, and ensure that the wand cord and cables are not crossing one another. If telemetry is cancelled as a result of interference, the device should be re-interrogated prior to evaluating information from pulse generator memory.
- Radio frequency (RF) signals from devices that operate at frequencies near that of the pulse generator may interrupt ZIP telemetry while interrogating or programming the pulse generator. This RF interference can be reduced by increasing the distance between the interfering device and the PRM and pulse generator.
- Use caution when inserting guidewires for placement of other types of central venous catheter systems such as PIC lines or Hickman catheters in locations where pulse generator leads may be encountered. Insertion of such guidewires into veins containing leads could result in the leads being damaged or dislodged.

**CAUTION:** Transcutaneous Electrical Nerve Stimulation (TENS) involves passing electrical current through the body, and may interfere with pulse generator function. If TENS is medically necessary, evaluate the TENS therapy settings for compatibility with the pulse generator.

**CAUTION:** Elevated pressures due to HBOT or SCUBA diving may damage the pulse generator.

## 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 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); Failure to convert an induced arrhythmia; Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Heart failure following chronic RV apical pacing; Inability to defibrillate or pace; Inappropriate therapy (e.g., shocks and antitachycardia pacing (ATP) where applicable, pacing; Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Insulating myocardium during defibrillation with internal or external paddles; 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); 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 a device malfunction.

Additionally, potential adverse events associated with the implantation of a coronary venous lead system include: Allergic reaction to contrast media; Breakage/failure of implant instruments; Prolonged exposure to fluoroscopic radiation; Renal failure from contrast media used to visualize coronary veins.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev C) 046774 AG

## **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  $\leq$  35% and QRS duration  $\geq$  120 ms; or left bundle branch block (LBBB) with QRS duration  $\geq$  130 ms, EF  $\leq$  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. AUTOGEN, DYNAGEN, INOGEN, and ORIGEN devices with an IS-1/DF4/IS4 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. 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 by the magnet and an EGM has been stored, the patient should not reapply the magnet.

### **PRECAUTIONS**

- Programming minimum PVARP less than retrograde V–A conduction may increase the likelihood of a PMT.
- The clinical benefit of Rate Adaptive Pacing in heart failure patients has not been studied. Rate Adaptive Pacing should be used with medical discretion if the patient develops an indication such as chronotropic incompetence. Patients with heart failure may have hemodynamic compromise at rapid sensor-driven rates, and the physician may wish to program less aggressive rate adaptive parameters in accordance with patient condition. It is not recommended for patients who exhibit only heart failure-induced chronotropic incompetency.
- Implanting a replacement device in a subcutaneous pocket that previously housed a larger device may result in pocket air entrapment, migration, erosion, or insufficient grounding between the device and tissue. Irrigating the pocket with sterile saline solution decreases the possibility of pocket air entrapment and insufficient grounding. Suturing the device in place reduces the possibility of migration and erosion.
- Use only the designated programmer and software application to communicate with this pulse generator.
- Programming the device to provide RV-only pacing is not intended for the treatment of heart failure. The clinical effects of RV-only pacing for the treatment of heart failure have not been established.
- If the Lead Configuration is programmed to Bipolar when a unipolar lead is implanted, pacing will not occur.
- If the Shock Vector is programmed to RVcoil>>RAcoil and the lead does not have an RA coil, shocking will not occur.
- Determine if the device and programmable options are appropriate for patients with supraventricular tachyarrhythmias (SVTs) because SVTs can initiate unwanted device therapy.
- To ensure a high percentage of biventricular pacing, the programmed AV Delay setting must be less than the patient's intrinsic PR interval.
- Rate Adaptive Pacing should be used with care in patients who are unable to tolerate increased pacing rates.
- Adaptive-rate pacing is not limited by refractory periods. A long refractory period programmed in combination with a high MSR can result in asynchronous pacing during refractory periods since the combination can cause a very small sensing window or none at all. Use Dynamic AV Delay or Dynamic PVARP to optimize sensing windows. If you are programming a fixed AV Delay, consider the sensing outcomes.
- ATR should be programmed to On if the patient has a history of atrial tachyarrhythmias. The delivery of CRT is compromised because AV synchrony is disrupted if the ATR mode switch occurs.
- Ensure the patient is clinically capable of tolerating low rate RV Backup Pacing and lack of LV pacing during an RVS-LVS Delay test.
- Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Moving away from the source of the EMI or turning off the source usually allows the pulse generator to return to normal operation.
- Any medical equipment, treatment, therapy, or diagnostic test that introduces electrical current into the patient has the potential to interfere with pulse generator function.
  - External patient monitors (e.g., respiratory monitors, surface ECG monitors, hemodynamic monitors) may interfere with the pulse generator's impedance-based diagnostics (e.g., shock lead impedance measurements, Respiratory Rate trend). To resolve suspected interactions with Respiratory Sensorbased diagnostics, deactivate the pulse generator's Respiratory Sensor by programming it to Off.
  - Medical therapies, treatments, and diagnostic tests that use conducted electrical current (e.g., TENS, electrocautery, electrolysis/thermolysis, electrodiagnostic testing, electromyography, or nerve conduction studies) may interfere with or damage the pulse generator. Program the device to Electrocautery Protection Mode prior to the treatment, and monitor device performance during the treatment. After the treatment, verify pulse generator function ("Post-Therapy Pulse Generator Follow Up" in the manual).
- Extracorporeal shock wave lithotripsy (ESWL) may cause electromagnetic interference with or damage to the pulse generator.
- Therapeutic ultrasound (e.g., lithotripsy) energy may damage the pulse generator. If therapeutic ultrasound energy must be used, avoid focusing near the pulse generator site. Diagnostic ultrasound (e.g., echocardiography) is not known to be harmful to the pulse generator.
- Electrical interference or "noise" from devices such as electrocautery and monitoring equipment may interfere with establishing or maintaining telemetry for interrogating or programming the device. In the presence of such interference, move the programmer away from electrical devices, and ensure that the wand cord and cables are not crossing one another. If telemetry is cancelled as a result of interference, the device should be re-interrogated prior to evaluating information from pulse generator memory.
- RF signals from devices that operate at frequencies near that of the pulse generator may interrupt ZIP telemetry while interrogating or programming the pulse generator. This RF interference can be reduced by increasing the distance between the interfering device and the PRM and pulse generator.
- Use caution when inserting guidewires for placement of other types of central venous catheter systems such as PIC lines or Hickman catheters in locations where pulse generator leads may be encountered. Insertion of such guidewires into veins containing leads could result in the leads being damaged or dislodged.

**CAUTION:** Transcutaneous Electrical Nerve Stimulation (TENS) involves passing electrical current through the body, and may interfere with pulse generator function. If TENS is medically necessary, evaluate the TENS therapy settings for compatibility with the pulse generator.

**CAUTION:** Elevated pressures due to HBOT or SCUBA diving may damage the pulse generator.

### **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 the included devices: Air embolism; Allergic reaction; Bleeding; Bradycardia; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Electrolyte imbalance/dehydration; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Failure to convert an induced arrhythmia; Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Inability to defibrillate or pace; Inappropriate therapy (e.g., shocks and antitachycardia pacing (ATP) where applicable, pacing); Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Insulating myocardium during defibrillation with internal or external paddles; 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); 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 a device malfunction.

Additionally, potential adverse events associated with the implantation of a coronary venous lead system include: Allergic reaction to contrast media; Breakage/failure of implant instruments; Prolonged exposure to fluoroscopic radiation; Renal failure from contrast media used to visualize coronary veins.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev E) 046774 AG



## ZOOM™ LATITUDE™ Programming System

### INTENDED USE

The Programmer/Recorder/Monitor (PRM) is intended to be used as part of the ZOOM™ LATITUDE™ Programming System to communicate with Boston Scientific implantable pulse generators. The software in use controls all communication functions for the pulse generator. For detailed software application instructions, refer to the associated product literature for the pulse generator being interrogated.

### CONTRAINDICATIONS

The PRM is contraindicated for use with any pulse generator other than a Boston Scientific pulse generator. For contraindications for use related to the pulse generator, refer to the associated product literature for the pulse generator being interrogated.

### WARNINGS

The use of any cables or accessories with the PRM or Zoom Wireless Transmitter (ZWT) other than those specified by Boston Scientific in this manual may result in increased emissions or decreased immunity of the PRM or ZWT. Do not simultaneously touch the patient and any accessible connector contacts on the PRM (e.g., USB, parallel port, external VGA monitor, stimulation input, analog output, and expansion port). Other equipment may interfere with the PRM and ZWT, even if that equipment complies with the International Special Committee on Radio Interference (CISPR) emission requirements. To avoid the risk of electric shock, only connect the PRM to a grounded/earthed power source. Do not use the PRM or ZWT adjacent to or stacked with other equipment. PRM and ZWT must remain outside sterile field. Operation of the PRM with physiological signals that are lower than the minimum detectable amplitude may cause inaccurate results. Do not simultaneously touch the patient and the parts inside the printer door. The PRM and ZWT are MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices1. No modification of this equipment is allowed unless approved by Boston Scientific.

### PRECAUTIONS

- Use only the appropriate Boston Scientific PRMs equipped with the appropriate software to program Boston Scientific pulse generators.
- Use only the Model 6577 Sterilizable Telemetry Wand with the PRM.
- Use the stylus supplied with the PRM; the use of any other object could damage the touchscreen. Using the stylus may also improve accuracy.
- Although optional external equipment connected to the PRM meets leakage-current requirements for commercial products, it may not meet the more stringent leakage requirements for medical products. Consequently, all external equipment must be kept outside the patient environment (at least 1.5m [4.9ft] away from the patient).
- The Model 6577 Telemetry Wand is shipped nonsterile. If the telemetry wand is to be used in a sterile field, it must be actively sterilized before use or enclosed in a disposable sterile surgical sheath during use.
- Remove the telemetry wand from all packaging material before sterilizing it.
- Avoid establishing telemetry communication between the PRM and the pulse generator when the PRM or ZWT are in close proximity to monitors, high-frequency electrosurgical equipment, or strong magnetic fields. The telemetry link may be impaired.
- Do not use an abrasive cloth or volatile solvents to clean any portion of the PRM or ZWT.
- Keep disks away from magnets and magnetized objects, including telephones, power-supply adapters, and monitors.
- Do not place a magnet on the PRM or ZWT.
- The PRM and ZWT are not waterproof or explosion-proof and cannot be sterilized. Do not use them in the presence of flammable gas mixtures including anesthetics, oxygen, or nitrous oxide.
- To completely disconnect the unit from the power source, first use the On/Off button to turn the system off. Then disconnect the power cord from the back of the unit.
- Ensure the back of the unit is accessible at all times so that the power cord can be disconnected.

### ADVERSE EFFECTS

None known.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse effects. Rx only. (Rev G) 046774 AG

## LATITUDE™ Programming System (3300)

### INTENDED USE

The LATITUDE Programming System is intended for use in hospital and clinical environments to communicate with Boston Scientific implantable systems. The software in use controls all communication functions for the PG. For detailed software application instructions, refer to the associated product literature for the PG being interrogated.

### CONTRAINDICATIONS

The LATITUDE Programming System is contraindicated for use with any PG other than a Boston Scientific PG. For contraindications for use related to the PG, refer to the associated product literature for the PG being interrogated. The PSA application is contraindicated for use with any programming system other than the Boston Scientific Model 3300 LATITUDE Programming System.

The following uses of the PSA are contraindicated:

- With AV conduction disorders; atrial single-chamber pacing
- With competing intrinsic rhythms; asynchronous modes
- With chronic atrial tachycardia as well as chronic atrial fibrillation or flutter; modes with atrial control (DDD, VDD)
- With poor tolerance of high ventricular rates (e.g., with angina pectoris); tracking modes (i.e., atrial control modes) and propensity for atrial tachycardia
- Use as an external pacemaker

### WARNINGS

The use of any cables or accessories with the LATITUDE Programming System other than those specified by Boston Scientific could result in increased electromagnetic emissions, decreased electromagnetic immunity, or electrical shock of the LATITUDE Programming System. Keep all RF communications equipment at least 30 cm (12 in) away from the Model 3300 Programmer. Do not simultaneously touch the patient and any accessible LATITUDE Programming System connector or exposed conductor. To avoid the risk of electric shock, only connect the Programmer's Model 6689 Power Adapter to a grounded/earthed power source. When accessing the battery, ensure that power to the Programmer is turned off. Do not touch the metal clips on the patient cable or the pacing lead. Discharge any electrical static charge on your person by touching a grounded metal surface before touching the patient, the patient cables, or the device. Unused PSA cable connections contacting conductive surfaces can induce electrical currents into the patient's heart. Electrocautery can induce electrical currents in the PSA cables that can be conducted into the patient's heart. Never stack the Programmer on top of an electrocautery system or associated components. Do not drape electrocautery components or cables on or near the Programmer or associated cables and components. Whenever possible disconnect the PSA cables from the pacing leads when performing an electrocautery procedure. If the Programmer is connected to the patient during an electrocautery procedure, check its operation afterwards. If the Programmer experiences an issue that causes an error condition, the Programmer will need to be power cycled. Use of the Model 3300 Programmer adjacent or stacked with other equipment should be avoided because it could result in improper operation. The Programmer is non-sterile and cannot be sterilized. Operation of the LATITUDE Programming System with physiological signals that are lower than the minimum detectable amplitude may cause inaccurate results. The LATITUDE Programming System is MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices. When activating PSA Burst Pacing, which may cause unpredictable arrhythmias, always have cardiac emergency equipment in an operational status available for immediate life support. The LATITUDE Programming System is tested and tested to be defibrillation safe. The PSA cable must be disconnected from the lead(s) before using external defibrillation. If the patient is pacer dependent and the Programmer encounters a fault condition, pacing operation continues unless the fault was in the PSA component itself. For this reason, always have external pacing equipment available for patient back-up. Operating the Programmer with a depleted internal battery or no battery can suspend Programmer function if AC power is temporarily interrupted. Always have external cardiac pacing equipment in an operational status available for immediate life support. Single chamber atrial modes are contraindicated for patients with impaired AV conduction. Abruptly terminating pacing may result in extended periods of asystole in some patients. Pacing threshold testing implies loss of capture. Incorrect positioning of the protective silicone rubber sleeves over the PSA cable clip(s) can cause unintended electrical connections that can impair cable function endanger the patient. Moisture or wet cables can impair cable function and endanger the patient. Before cleaning and disinfecting the Programmer surfaces, power down the device and disconnect the external power supply. If this equipment is used in a residential environment, the equipment might not offer adequate protection to radio-frequency communication services. The Model 6753 Battery is a Lithium-ion battery and as such, is deemed a Dangerous Good in regards to shipping.

### PRECAUTIONS

- Use only the appropriate LATITUDE Programming System equipped with the appropriate software to program specific Boston Scientific PGs.
- For transvenous PG telemetry, use only the Model 6395 Telemetry Wand with the LATITUDE Programming System.
- If you want to use a stylus, ensure that it is a projected capacitance stylus. The use of any other object could damage the touchscreen.
- Keep all electrocautery cables at least 30 cm (12 in) away from the LATITUDE Programming System to avoid false signals due to electrocautery energy.
- Although optional external equipment connected to the Model 3300 Programmer must meet the applicable leakage-current requirements for commercial products, it may not meet the more stringent leakage requirements for medical products. Consequently, all external equipment must be kept outside the patient environment.
  - Never touch the electrical contacts on the side panels of the Model 3300 Programmer and the patient, a telemetry wand, or any cable at the same time.
- Telemetry procedures exceeding 8 hours may require a thermal insulator between the Model 6395 Telemetry Wand head and the patient's skin as the wand head temperature can range from 33-41°C (88-106°F).
- Ensure leads are connected appropriately for desired use; incorrect setup can result in pacing/sensing events, which display under a different chamber on the screen. The PSA application user interface associates specific lead connections with the RA, RV, and LV chambers on screen to support testing all three chambers with minimal change of physical connections. Saved PSA measurements are also labeled automatically based upon the chamber in use on the screen. These labels can later be adjusted by the user if the decision is made to use one physical connection to test other chambers (for example, using only the RV connection to test RA, RV, and LV leads).
- Do not clip any PSA connector directly to the skin, pocket, or other tissue of the patient.
- During a PSA session, ventricular sensing behavior is driven by the most recently selected ventricular pacing configuration: RV-only, LV-only, or Bi-V.
  - At system startup, the PSA mode is set to ODO (non-pacing) and the effective ventricular pacing configuration is Bi-V.
  - When a non-pacing mode (ODO or OVO) is selected from the mode palette, sensing is set to Bi-V to ensure sensing is enabled on both leads regardless of any prior configuration.
- Loss of the ECG signal in case of an ECG cable open/short can affect diagnosis and screening by prolonging the procedure or preventing the procedure from completing.
  - Check cables first and replace if cracked or worn.
  - If cable is not functioning properly, replace it.
- The power adapter normally gets warm when it is in use or charging. Do not place the power adapter in the storage pocket of the stand while it is in use or charging as the confined space will not allow

the heat to dissipate adequately.

- If desired for use, connect the Ethernet cable only to the RJ45 Ethernet port connector on the Model 3300 Programmer. Insertion or removal of the Ethernet cable during operation may affect networking functions. The RJ45 Ethernet connection on the Model 3300 Programmer is for Local Area Networking (LAN) use only. It is not to be used for a telephone connection.
- Using the Programmer on battery power only may reduce the telemetry distance (from wand to implanted device). If needed, use AC power to improve inductive telemetry.
- Remove batter to prevent discharging when storing the Programmer for long periods (e.g., months).
- Inability to access a remote time server could lead to discrepancies in the Programmer time. As a backup, the Boston Scientific representative can set the time and date manually.
- Patient data may be stored on the Programmer up to 14 days and appropriate precautions should be taken to secure the programmer from unauthorized access.
  - Delete all patient data from the Programmer (refer to the Patient Data Management Operator's Manual (Model 3931) for delete instructions) before shipping the Programmer or at any time when the Programmer leaves your direct control.
  - Only connect to known Bluetooth devices to reduce the potential of transmitting patient data to inappropriate printers or devices.
- USB devices connected to the Programmer should be controlled to limit the potential introduction of malware.
- Using external devices (USB, display monitor) will deplete the battery. To extend Programmer performance, refrain from using external devices when on battery power only and the battery level indicator shows 25% or less remaining.
- Ensure that you have the latest software versions installed (see "Software Update Tab" in the manual). As a backup, your local Boston Scientific representative can provide software updates using a USB pen drive.
- The Model 6395 Telemetry Wand is shipped non-sterile. Remove the wand from all packaging material before sterilizing it. If the wand is to be used in a sterile field, it must be actively sterilized before use or enclosed in a disposable sterile surgical sheath (Model 3320) during use. Refer to "Cleaning the Programmer and Accessories" in the manual for sterilization and cleaning information.
- The Model 3203 S-ICD Telemetry Wand is shipped non-sterile. Remove the wand from all packaging material before sterilizing it. If the wand is to be used in a sterile field, it must be actively sterilized before use or enclosed in a sterile intraoperative probe cover (Model 3320) during use. Refer to "Cleaning the Programmer and Accessories" in the manual for sterilization and cleaning information.
- Avoid establishing telemetry communication between the Programmer and the PG when the Programmer is in close proximity to monitors, high-frequency electrocautery equipment, or strong magnetic fields. The telemetry link may be impaired.
- The Model 3203 S-ICD Telemetry Wand may be used as an additional antenna to improve the Programmer's RF telemetry performance. If the wand is placed in a sterile field, it must be enclosed in a disposable, sterile surgical sheath (Model 3320) during use. When the Model 3203 S-ICD Telemetry wand is not used for RF telemetry, be sure to disconnect the Model 3203 S-ICD Telemetry Wand from the Programmer to prevent telemetry dropouts.
- No modification of this equipment is allowed unless approved by Boston Scientific. Changes or modifications not expressly approved by Boston Scientific could void the user's authority to operate the equipment.
- Do not use an abrasive cloth or volatile solvents to clean any portion of the device. See "Cleaning the Programmer and Accessories" in the manual for recommended cleaning.
- Do not place a magnet on the Programmer.
- The LATITUDE Programming System is not waterproof or explosion-proof and cannot be sterilized. Do not use it in the presence of flammable gas mixtures including anesthetics, oxygen, or nitrous oxide.
- To completely disconnect the Programmer from the power source, first press and release the power button to turn the system off. Then disconnect the power cord from the side of the Programmer.
- Ensure that the sides of the Programmer are accessible at all times so that the power adapter cord can be disconnected.
- The Model 6753 Lithium-ion battery contains highly flammable chemicals and should be handled with caution. Abuse of this batter can result in fire or explosion. Read the following prior to using this battery:
  - Do not expose the battery to temperatures above 140°F (60°C).
  - Do not puncture the battery as it can lead to a fire or explosion. If the battery housing is punctured, or otherwise visibly damaged, do not attempt to use it.
  - Do not strike the battery or otherwise subject it to strong impacts.
  - Do not submerge the battery in any fluids.
  - Do not connect the + and – terminals with wire or any conductive objects.
  - Do not disassemble, modify, or repair the battery.
  - Only use the Model 3300 Programmer to charge the battery. Use of any other battery charger can permanently damage the battery or even cause a fire or explosion.
- Boston Scientific recommends attaching all necessary cables and devices before turning on the Model 3300 Programmer.

#### **ADVERSE EFFECTS**

None known.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev B) 046774 AG

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#### **Rhythm Management**

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