

# Cardiology Checklist for the ImageReady™ Pacing Systems

Refer to the Boston Scientific ImageReady™ MR Conditional Pacing System MRI Technical Guide or link:  
[www.bostonscientific.com/imagerready](http://www.bostonscientific.com/imagerready)

Patient Name: \_\_\_\_\_

Pacemaker Model: \_\_\_\_\_

Lead Model(s): \_\_\_\_\_

## Patient Flow

- ☐ Ensure patient eligibility for MRI scan (refer to MRI Conditions of Use, see the right column).
- ☐ As close to start of the scan as possible, program the pulse generator in MRI Protection Mode.
  - The MRI Protection Settings Report is printed, placed in the patient's file, and provided to radiology personnel.
  - The report documents MRI Mode settings and details. If the Time-out feature is used, the report includes the exact time and date when MRI Protection Mode will expire. (Figure 1).
  - Each lead implanted in the patient is identified, and this information is communicated to the health care professionals involved in performing the MRI scan.
- ☐ The radiologist checks the patient file and/or printed report. If the Time-out feature is used, the radiologist verifies that adequate time remains to complete the scan.
- ☐ Patient undergoes scan according to the MRI scan procedure protocol outlined in Technical Guide.
- ☐ The pulse generator is returned to pre-MRI operation, either using the programmer, or automatically if the Time-out parameter was set. Follow-up testing of the pacing system may be performed.

## MRI Conditions of Use

The following Conditions of Use must be met in order for a patient with an ImageReady™ Pacing System to undergo an MRI scan.

- ☐ Patient is implanted with an ImageReady™ MR Conditional Pacing System (see reverse.)
- ☐ Pulse generator in MRI Protection Mode during scan.
- ☐ RA and RV leads programmed to bipolar pacing operation or pacing off
- ☐ Patient does not have elevated body temperature or compromised thermoregulation at time of scan.
- ☐ Pulse generator implant location restricted to left or right pectoral region.
- ☐ At least six (6) weeks have elapsed since implantation and/or any lead revision or surgical modification of the MR Conditional Pacing System.
- ☐ No other active or abandoned implanted devices, components, or accessories present than an ImageReady™ MR Conditional Pacing System
- ☐ RA and RV pacing threshold  $\leq 2.0$  V in pace-dependent patients
- ☐ No evidence of a fractured lead or compromised pulse generator-lead system integrity.

Figure 1: Sample MRI Protection Settings Report

<b>Boston Scientific</b>		<b>ZOOM® View™</b>	<b>Report Created 02 Sep 2014</b>
<b>MRI Protection Settings Report</b>		<b>Last Office Interrogation</b>	
<b>Do John</b> Date of Birth 24 Jun 1943 Device ACCOLADE MRI EL L331/ 417207		<b>02 Sep 2014</b> Implant Date 1 Jul 2014	
<b>MRI Protection is Programmed</b>			
MRI Protection Entry Time		02 Sep 2014 09:58	
<b>MRI Protection Time-out</b>		<b>24 h</b>	
<b>Scheduled Expiration Time</b>		<b>03 Sep 2014 09:58</b>	
<b>⚠ Patient must be out of MRI scanner before the scheduled expiration time.</b>			
<b>Parameter</b>	<b>Previous Value</b>	<b>MRI Protection Value</b>	
Brady Mode	DDO	DDO	
Lower Rate Limit	60 mm <sup>-1</sup>	60 mm <sup>-1</sup>	
AV Delay	80 - 180 ms	100 ms	
Pacing Output			
Atrial	Trend 3.5 V @ 0.4 ms	5.0 V @ 1.0 ms	
Ventricular	Trend 3.5 V @ 0.4 ms	5.0 V @ 1.0 ms	
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<b>MRI Protection is Programmed</b>	
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<b>Scheduled Expiration Time</b>	<b>03 Sep 2014 09:58</b>
<b>⚠ Patient must be out of MRI scanner before the scheduled expiration time.</b>	

Name and signature: \_\_\_\_\_

Date: \_\_\_\_\_

# ImageReady™ MR Conditional Pacing Systems Quick Reference Guide

Only specific combinations of pulse generators and leads constitute an ImageReady Pacing System. Consult the following tables to distinguish between combinations that are valid for use with **1.5T** or **3T** scanners.

## Valid Combinations of Pacemaker Pulse Generators and Leads to Use in 1.5T and 3T Environments\*

Component	INGEVITY™ MRI Leads	FINELINE™ II Leads	Combination of one INGEVITY MRI Lead and one FINELINE II Lead
ACCOLADE™ PROONENT™ ESSENTIO™	3T or 1.5T	1.5T or 3T	3T or 1.5T
VITALIO™ MRI** FORMIO™ MRI** ADVANTIO™ MRI** INGENIO™ MRI**	1.5T	1.5T or 3T	1.5T
MRI Scanner Operating Mode	Normal Operating Mode or First Level Controlled Operating Mode	Normal Operating Mode	Normal Operating Mode only

## Valid Combinations of CRT-P Pulse Generators and Leads to Use in 1.5T and 3T Environments\*

Component	Combination of an ACUITY X4 Lead with INGEVITY MRI Lead(s)	Combination of an ACUITY X4 Lead with FINELINE II Lead(s)	Combination of an ACUITY X4 Lead with one INGEVITY MRI Lead and one FINELINE II Lead
VISIONIST™ X4 Pulse Generator		1.5T or 3T scanner allowed	
VALITUDE™ X4 Pulse Generator		Normal Operating Mode only	

## ImageReady™ MR Conditional Pacing System Components for 1.5T and 3T

Component	Model Number(s)	MR Status	3T	1.5T
<b>Pacemaker Pulse Generators</b>				
ESSENTIO™ MRI	L110, L111, L131	MR Conditional	✓	✓
PROONENT™ MRI	L210, L211, L231	MR Conditional	✓	✓
ACCOLADE™ MRI	L310, L311, L331	MR Conditional	✓	✓
ADVANTIO™ MRI**	J065, J066, J067	MR Conditional		✓
INGENIO™ MRI**	J175, J176, J177	MR Conditional		✓
VITALIO™ MRI**	J275, J276, J277	MR Conditional		✓
FORMIO™ MRI**	J279	MR Conditional		✓
<b>CRT-P Pulse Generators</b>				
VALITUDE™ X4	U128	MR Conditional	✓	✓
VISIONIST™ X4	U228	MR Conditional	✓	✓
<b>Right Atrial and Right Ventricular Leads and Accessories</b>				
<b>INGEVITY™ Leads</b>				
INGEVITY™ + MRI Pacing Lead	7840, 7841, 7842	MR Conditional	✓	✓
Suture Sleeve for INGEVITY™ MRI Pacing Leads	6402	MR Conditional	✓	✓
IS-1 Lead-Port Plug	7145	MR Conditional	✓	✓
<b>FINELINE™ II Sterox / Sterox EZ Leads</b>				
FINELINE™ II Sterox Pacing Lead	4456, 4457, 4458, 4459, 4479, 4480	MR Conditional	✓	✓
FINELINE™ II Sterox EZ Pacing Lead	4469, 4470, 4471, 4472, 4473, 4474	MR Conditional	✓	✓
Suture Sleeve for FINELINE™ II Pacing Leads	6220, 6221	MR Conditional	✓	✓
<b>Left Ventricular Leads and Accessories</b>				
ACUITY™ X4 (IS4) Pacing leads	4671, 4672, 4674, 4675, 4677, 4678	MR Conditional	✓	✓
Suture Sleeve for ACUITY X4 leads	4603	MR Conditional	✓	✓
IS4 Lead Port Plug	7148	MR Conditional	✓	✓
<b>ZOOM™ LATITUDE™ Programmer/Recorder/Monitor (PRM) and PRM Software Application</b>				
ZOOM™ LATITUDE™ PRM	3120	MR Unsafe***		
ZOOM™ LATITUDE™ PRM Software App.	2869	Not Applicable		

\*Product availability may vary, please contact your local sales representative for additional information

\*\*FORMIO MRI, VITALIO MRI, INGENIO MRI, and ADVANTIO MRI are no longer available for sale but are still supported Boston Scientific technologies.

\*\*\*The Programmer/Recorder/Monitor (PRM) is MR Unsafe and must remain outside the MRI site Zone III (and higher).

Under no circumstances should the PRM be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

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