

Radiology Checklist for the ImageReady™ Pacing Systems

Refer to the Boston Scientific ImageReady™ MR Conditional Pacing System MRI Technical Guide or link: www.bostonscientific.com/imageready

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, the cardiologist will 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

- MRI magnet strength of 1.5T or 3T (See the tables on back side).
 - 3T
 - Radio frequency (RF) of approximately 128 MHz.
 - Spatial gradient no greater than 50 T/m (5,000 G/cm) over the pacing system
 - 1.5T
 - Radio frequency (RF) of approximately 64 MHz
 - Spatial gradient no greater than 50 T/m (5,000 G/cm) over the pacing system
- Horizontal, ¹H proton, closed bore scanners only
- Specific Absorption Rate (SAR) limits:
 - For all ImageReady Pacing Systems, SAR limits for Normal Operating Mode¹ must be observed for the entire active scan session as follows:
 - Whole body averaged, ≤2.0 watts/kilogram (W/Kg)
 - Head, ≤3.2 W/Kg
 - For ImageReady Pacing Systems utilizing only **INGEVITY MRI** leads, SAR limits up to First Level Controlled Operating Mode² may be applied for the entire active scan session as follows:
 - Whole body averaged, ≤4.0 W/Kg
 - Head, ≤3.2 W/Kg
- Gradient Field limits: Maximum specified gradient slew rate ≤200 T/m/s per axis
- The use of receive-only coils is not restricted. Local transmit-only coils or local transmit/receive coils may be used, but should not be placed directly over the pacing system.
- Patient in supine or prone position only
- The patient must be monitored during the MRI scan by pulse oximetry and/or electrocardiography (ECG)

Figure 1: Sample MRI Protection Settings Report

ZOOM® View™		Report Created 02 Sep 2014
Boston Scientific		
MRI Protection Settings Report		
Doe John		Last Office Interrogation 02 Sep 2014
Date of Birth	24 Jun 1943	Implant Date
Device	ACCOLADE MRI EL L331/ 417207	1 Jul 2014
MRI Protection is Programmed		
MRI Protection Entry Time	02 Sep 2014 09:58	
MRI Protection Time-out	24 h	
Scheduled Expiration Time	03 Sep 2014 09:58	
▲ Patient must be out of MRI scanner before the scheduled expiration time.		
Parameter	Previous Value	MRI Protection Value
Brady Mode	DDO	DDO
Lower Rate Limit	60 mm ¹	60 mm ¹
AV Delay	80 - 160 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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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	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 VALITUDE™ X4 Pulse Generator		1.5T or 3T scanner allowed Normal Operating Mode only	

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

Component	Model Number(s)	MR Status	3T	1.5T
Pacemaker Pulse Generators				
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		✓
CRT-P Pulse Generators				
VALITUDE™ X4	U128	MR Conditional	✓	✓
VISIONIST™ X4	U228	MR Conditional	✓	✓
Right Atrial and Right Ventricular Leads and Accessories				
INGEVITY™ MRI Leads				
INGEVITY™ MRI Pacing Lead	7731, 7732, 7735, 7736, 7740, 7741, 7742	MR Conditional	✓	✓
Suture Sleeve for INGEVITY™ MRI Pacing Leads	6402	MR Conditional	✓	✓
IS-1 Lead-Port Plug	7145	MR Conditional	✓	✓
FINELINE™ II Sterox / Sterox EZ Leads				
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	✓	✓
Left Ventricular Leads and Accessories				
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	✓	✓
ZOOM™ LATITUDE™ Programmer/Recorder/Monitor (PRM) and PRM Software Application				
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.

For the purposes of this guide, MRI is used as a general term and encompasses all MR-based clinical imaging activities. In addition, information in this guide applies only to 'H MRI (Proton MRI) scanners.

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CRM-271805-AD Printed in Germany by medicalvision.

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