

ImageReady™ Checklist for Cardiology Department

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

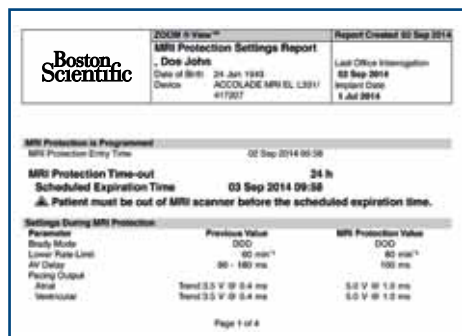
- Ensure patient eligibility for MRI scan (refer to MRI Conditions of Use, see the right column).
- As close to start of the scan as possible, program the pulse generator in MRI Protection Mode.
 - The MRI Protection Settings Report is printed, placed in the patient's file, and provided to radiology 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.
- 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 cardiac-related implanted devices, components, or accessories present other than an ImageReady™ MR Conditional Pacing System.
- Pacing threshold $\leq 2.0V$ in pace-dependent patients.
- No abandoned leads or pulse generators.
- No evidence of a fractured lead or compromised pulse generator-lead system integrity.

Figure 1: Sample MRI Protection Settings Report



MRI Protection is Programmed
MRI Protection Entry Time: 02 Sep 2014 09:58

MRI Protection Time-out
Scheduled Expiration Time: 03 Sep 2014 09:58

24 h

⚠ Patient must be out of MRI scanner before the scheduled expiration time.

Name and signature: _____

Date: _____

ImageReady™ MR Conditional Pacing System

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 only 1.5T scanners and combinations that are valid for use with both 1.5T and 3T scanners.

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

Component	INGEVITY™ MRI Leads	FINELINE™ II Leads
ACCOLADE™ PROPONENT™ ESSENTIO™	3T or 1.5T	1.5T
VITALIO™ MRI FORMIO™ MRI ADVANTIO™ MRI INGENIO™ MRI	1.5T	1.5T
MRI Scanner Operating Mode	Normal Operating Mode or First Level Controlled Operating Mode	Normal Operating Mode

Warnings:

- The combined use of a FINELINE™ II lead and an INGEVITY™ MRI lead with a Boston Scientific MR Conditional pulse generator has not been evaluated and does not constitute an ImageReady™ MR Conditional Pacing System.
- Only the combination of INGEVITY™ MRI lead(s) with an ESSENTIO™ MRI, PROPONENT™ MRI, or ACCOLADE™ MRI pulse generator is valid to use with either 1.5T or 3T scanners. All other allowable combinations of Boston Scientific MR Conditional system components must use only 1.5T scanners.

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

Component	Model Number(s)	MR Status	3T	1.5T
Pulse Generators				
ESSENTIO™ MRI	L110, L111, L131	MR Conditional	✓	✓
PROPONENT™ 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		✓
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		✓
IS-1 Lead-Port Plug	7145	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

**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.

**Boston
Scientific**
Advancing science for life™

www.bostonscientific.eu

All cited trademarks are the property of their respective owners. CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations.

CRM-269403-AA SEP 2014 Printed in Germany by medicalvision.

© 2015 Boston Scientific Corporation or its affiliates. All rights reserved.
DINCRM0856EA