ImageReady™ Supported Devices

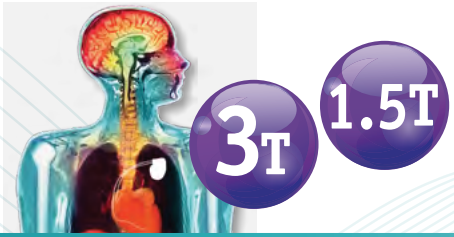
Pacing Systems

Boston Scientific
Advancing science for life™

ImageReady™ MR Conditional Pacing System Components for 1.5T and 3T[1]

Component	Model Number(s)	3T	1.5T
Pulse Generators			
PROPONENT™ MRI	L210, L211, L231	✓	✓
ACCOLADE™ MRI	L310, L311, L331	✓	✓
ADVANTIO™ MRI	K085, K086, K087		✓
INGENIO™ MRI	K185, K186, K187		✓
VITALIO™ MRI	K285, K286, K287		✓
FORMIO™ MRI	K289		✓
Leads and Accessories			
INGEVITY™ MRI Leads			
INGEVITY™ MRI Pacing Leads	7731, 7732, 7735, 7736, 7740, 7741, 7742	✓	✓
Suture Sleeve for INGEVITY™ MRI Pacing Leads	6402	✓	✓
IS-1 Lead-Port Plug	7145	✓	✓
FINELINE™ II Sterox / Sterox EZ Leads			
FINELINE™ II Sterox Pacing Lead	4456, 4457, 4458, 4459, 4479, 4480		✓
FINELINE™ II Sterox EZ Pacing Lead	4469, 4470, 4471, 4472, 4473, 4474		✓
Suture Sleeve for FINELINE™ II Pacing Leads	6220, 6221		✓
IS-1 Lead-Port Plug	7145		✓

1. For conditions of use and scan conditions, refer to ImageReady™ MR Conditional Pacing System Technical Guide 359489-01 EN Australia 2016-12.



ImageReady™ Supported Devices

ICDs and CRT-Ds

Boston Scientific
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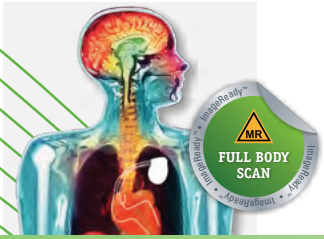
ImageReady™ MR Conditional Defibrillation System Components for 1.5T[1]

Component	Model Number(s)	1.5T
Pulse Generators		
AUTOGEN™, DYNAGEN™, RESONATE™ EL ICD	D150, D152, D174, D176, D432, D433	✓
AUTOGEN™, DYNAGEN™ Mini ICD	D020, D022, D044, D046	✓
AUTOGEN™, DYNAGEN™, RESONATE™ CRT-D	G158, G179, G447	✓
EMBLEM™, EMBLEM™ MRI S-ICD	A209, A219	✓
Leads and Accessories		
FINELINE™ II Sterox Pacing Leads	4479, 4480	✓
FINELINE™ II Sterox EZ Pacing Leads	4469, 4470, 4471, 4472, 4473, 4474	✓
Suture Sleeve for FINELINE™ II Leads	6220, 6221	✓
INGEVITY™ MRI Pacing Leads	7735, 7736, 7740, 7741, 7742	✓
Suture Sleeve	6402, 6403, 4603	✓
Lead Port Plug	7145, 7148	✓
ENDOTAK RELIANCE® (DF4) Defibrillation Leads	0262, 0263, 0265, 0266, 0272, 0273, 0275, 0276, 0282, 0283, 0285, 0286, 0292, 0293, 0295, 0296	✓
RELIANCE 4-FRONT™ Defibrillation Leads	0636, 0650, 0651, 0652, 0653, 0654, 0655, 0657, 0658, 0662, 0663, 0665, 0672, 0673, 0675, 0676, 0682, 0683, 0685, 0686, 0692, 0693, 0695, 0696	✓
ACUITY™ X4 Pacing Leads	4671, 4672, 4674, 4675, 4677, 4678	✓
EMBLEM™ S-ICD Electrode	All Models	✓
Cameron Health Q-TRAK S-ICD Electrode	All Models	✓
S-ICD Electrode Suture Sleeve	All Models	✓

1. For conditions of use and scan conditions, refer to MRI Technical Guide ImageReady™ MR Conditional Defibrillation System 92138524-001 EN Australia 2018-02 and ImageReady MR Conditional S-ICD System 359475-001 EN Europe 2015-11



Cardiology Order Form

IMAGEREADY™

Boston Scientific
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MR-Conditional Systems

PATIENT NAME | D.O.B.

PG MODEL # | ATRIAL LEAD | RV LEAD | LV LEAD | ELECTRODE

According to Boston Scientific's device labeling, the following Conditions of Use **MUST BE MET** for a patient with an ImageReady™ Pacing System, Transvenous Defibrillation System, or EMBLEM™ S-ICD System to undergo an MR-Conditional scan. Adherence to the Conditions of Use **MUST BE VERIFIED** prior to each scan to ensure that the most up-to-date information has been used to assess the patient's eligibility and readiness for an MR-Conditional scan.

RESOURCES

Confirm that patient has a complete ImageReady™ MR-Conditional System by referring to the below resources:

- Boston Scientific MRI Technical Guide www.bostonscientific.com/manuals/
- Boston Scientific ImageReady™ Website www.BostonScientific.com/imageready
- Boston Scientific Technical Services Hotline 1800 245 559 (Australia), 0800 742 678 (New Zealand)

OFF-LABEL MRI SCAN

☐ My patient **DOES NOT HAVE** a complete ImageReady™ MR-Conditional System and/or **DOES NOT MEET** the Conditions of Use listed below. Because not all Conditions of Use have been met, the scan is off-label. Boston Scientific labeling warns of potential risks for off-label MRI scans and does not promote nor encourage this use. Use the Cardiology Order Form *Off-Label MRI Scan* to specify programming parameters during off-label MRI scans.

CONDITIONS OF USE

☐ Patient is implanted with an ImageReady™ MR-Conditional System with all ports occupied by a lead or port plug.

☐ Pulse generator in MRI Protection Mode during scan.

☐ Bipolar pacing operation or pacing off.

☐ No other active or abandoned implanted devices, components, or accessories present, such as lead adapters, extenders, leads, or pulse generators.

☐ As soon as MRI Protection Mode is programmed, the patient must be continuously monitored by pulse oximetry and/or electrocardiography (ECG). Ensure backup therapy is available (external rescue).

☐ Patient does not have elevated body temperature or compromised thermoregulation at time of scan.

☐ Patient is judged to be clinically capable of tolerating no Tachycardia protection for the entire duration in which the pulse generator is in MRI Protection Mode.

☐ (Transvenous Systems only) Pulse generator implant location restricted to left or right pectoral region.

☐ At least six (6) weeks have elapsed since implantation and/or any electrode revision or surgical modification of the ImageReady™ MR-Conditional System.

☐ No evidence of a fractured electrode or compromised pulse generator-electrode system integrity.

☐ Pacing threshold ≤ 2.0 V in pace-dependent patients.

MRI PROTECTION MODE PARAMETERS

Defibrillation therapy will be disabled while in MRI Protection Mode. Program MRI Protection Mode during scan with these parameters.

☐ Pacing OFF

☐ DOO Pacing Rate _____ BPM or _____ BPM above average intrinsic rate to a max of _____BPM

☐ VOO Pacing Rate _____ BPM or _____ BPM above average intrinsic rate to a max of _____BPM

☐ AOO Pacing Rate _____ BPM or _____ BPM above average intrinsic rate to a max of _____BPM

Ventricular Pacing Chamber ☐ RV ☐ BiV

Atrial Amplitude _____V@ 1.0 ms PW RV Amplitude _____V@ 1.0 ms PW

LV Amplitude _____V@ _____ ms PW

MRI Protection Timeout ☐3H ☐6H (Defib nominal) ☐9H ☐12H ☐24H (Pacer nominal) ☐Time-out OFF

NOTE

Do not leave the pulse generator in MRI Protection Mode any longer than necessary following the scan. Beeper may no longer be usable following MRI scan.

DATE | **PHYSICIAN NAME** | **PHYSICIAN SIGNATURE**

Cardiology and Radiology Checklists

IMAGEREADY™

MR-Conditional Pacing Systems

PATIENT NAME **D.O.B.**

PG MODEL # **ATRIAL LEAD** **RV LEAD**

Use the following checklists to ensure that patients who have a Boston Scientific Pacing System labeled MR-Conditional can receive a MR-Conditional scan. Only specific combinations of Boston Scientific MR-Conditional pulse generators and MR-Conditional leads/electrodes constitute a valid ImageReady™ MR-Conditional Pacing System for use in 1.5 Tesla or 3 Tesla environments.

RESOURCES

Confirm that patient has a complete ImageReady™ MR-Conditional System by referring to the below resources:

- Boston Scientific MRI Technical Guide www.bostonscientific.com/manuals/
- Boston Scientific ImageReady™ Website www.BostonScientific.com/imageready
- Boston Scientific Technical Services Hotline 1800 245 559 (Australia), 0800 742 678 (New Zealand)

OFF-LABEL MRI SCAN

☐ My patient **DOES NOT HAVE** a complete ImageReady™ MR-Conditional Pacing System and/or **DOES NOT MEET** the Conditions of Use listed below. Because not all Conditions of Use have been met, the scan is off-label. Boston Scientific labeling warns of potential risks for off-label MRI scans and does not promote nor encourage this use. Use the Cardiology Order Form *Off-Label MRI Scan* to specify programming parameters during off-label MRI scans.

CARDIOLOGY CONDITIONS OF USE

- ☐ Patient is implanted with an ImageReady™ MR-Conditional Pacing System with all ports occupied by a lead or port plug.
- ☐ Pulse generator in MRI Protection Mode during scan.
- ☐ Bipolar pacing operation or pacing off.
- ☐ No other active or abandoned implanted devices, components, or accessories present, such as lead adapters, extenders, leads, or pulse generators.
- ☐ As soon as MRI Protection Mode is programmed, the patient must be continuously monitored by pulse oximetry and/or electrocardiography (ECG). Ensure backup therapy is available (external rescue).
- ☐ Patient does not have elevated body temperature or compromised thermoregulation at time of scan.
- ☐ At least six (6) weeks have elapsed since implantation and/or any electrode revision or surgical modification of the ImageReady™ MR-Conditional Pacing System.
- ☐ No evidence of a fractured electrode or compromised pulse generator-electrode system integrity.
- ☐ Pacing threshold ≤ 2.0 V in pace-dependent patients.

RADIOLOGY CONDITIONS OF USE

- ☐ MRI magnet strength
  - · 64 MHz for 1.5T
  - · 128 MHz for 3T
  - · Spatial gradient no greater than 50 T/m (5,000 G/cm) over the pacing system for 1.5T or 3T
- ☐ Horizontal, ^{1}H proton, closed bore scanners only.
- ☐ Specific Absorption Rate (SAR) limits for the entire active scan – Normal Operating Mode[1]
  - · 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.
- ☐ There are no restrictions for positioning the pacing system within the integrated body coil of the MRI scanner. The use of receive-only coils is not restricted; local transmit coils may be used but should not be placed directly over the pacing system.
- ☐ Patient in supine or prone position only.
- ☐ Patient must be continuously monitored during the MRI scan by pulse oximetry and/or electrocardiography.

NOTE Ensure that external defibrillator and medical personnel skilled in CPR are present during the MRI scan should the patient require external rescue.

1 As defined in IEC 60601-2-33, 201.3.244, 3rd Edition.

Cardiology and Radiology Checklists

IMAGEREADY™

MR-Conditional Defibrillation Systems

PATIENT NAME				D.O.B.
PG MODEL #	ATRIAL LEAD	RV LEAD	LV LEAD	ELECTRODE

Use the following checklists to ensure that patients who have a Boston Scientific Transvenous Defibrillation System, or EMBLEM™ MRI S-ICD System labeled MR-Conditional can receive a MR-Conditional scan. Only specific combinations of Boston Scientific MR-Conditional pulse generators and MR-Conditional leads/electrodes constitute a valid ImageReady™ MR-Conditional System for use in 1.5 Tesla environment.

RESOURCES

Confirm that patient has a complete ImageReady™ MR-Conditional System by referring to the below resources:

- Boston Scientific MRI Technical Guide www.bostonscientific.com/manuals/
- Boston Scientific ImageReady™ Website www.BostonScientific.com/imageready
- Boston Scientific Technical Services Hotline 1800 245 559 (Australia), 0800 742 678 (New Zealand)

OFF-LABEL MRI SCAN

☐ My patient **DOES NOT HAVE** a complete ImageReady™ MR-Conditional Pacing System and/or **DOES NOT MEET** the Conditions of Use listed below. Because not all Conditions of Use have been met, the scan is off-label. Boston Scientific labeling warns of potential risks for off-label MRI scans and does not promote nor encourage this use. Use the Cardiology Order Form *Off-Label MRI Scan* to specify programming parameters during off-label MRI scans.

CARDIOLOGY CONDITIONS OF USE

☐ Patient is implanted with an ImageReady™ Transvenous Defibrillation System, or EMBLEM™ MRI S-ICD System with all ports occupied by a lead or port plug.

☐ Pulse generator in MRI Protection Mode during scan.

☐ Bipolar pacing operation or pacing off.

☐ No other active or abandoned implanted devices, components, or accessories present, such as lead adapters, extenders, leads, or pulse generators.

☐ As soon as MRI Protection Mode is programmed, the patient must be continuously monitored by pulse oximetry and/or electrocardiography (ECG). Ensure backup therapy is available (external rescue).

☐ Patient does not have elevated body temperature or compromised thermoregulation at time of scan.

☐ Patient is judged to be clinically capable of tolerating no Tachycardia protection for the entire duration in which the pulse generator is in MRI Protection Mode.

☐ Pulse generator implant location restricted to left or right pectoral region.

☐ At least six (6) weeks have elapsed since implantation and/or any electrode revision or surgical modification of the ImageReady™ MR-Conditional System.

☐ No evidence of a fractured electrode or compromised pulse generator-electrode system integrity.

☐ Pacing threshold ≤ 2.0 V in pace-dependent patients.

RADIOLOGY CONDITIONS OF USE

☐ MRI magnet strength of 1.5T only.

☐ Radio Frequency (RF) field of approximately 64 MHz.

☐ Maximum spatial gradient 20 T/m (2,000 G/cm).

☐ Horizontal, ^{1}H proton, closed bore scanners only.

☐ Specific Absorption Rate (SAR) limits for the entire active scan – Normal Operating Mode[1]
· Whole body averaged, ≤ 2.0 W/Kg · Head, ≤ 3.2 W/Kg

☐ Gradient Field limits – Maximum specified gradient slew rate ≤ 200 T/m/s per axis.

☐ There are no restrictions for positioning the Transvenous Defibrillation System, or EMBLEM™ MRI S-ICD System within the integrated body coil of the MRI scanner. The use of receive-only coils is not restricted; local transmit coils may be used but should not be placed directly over the System.

☐ Patient in supine or prone position only.

☐ Patient must be continuously monitored by pulse oximetry and/or electrocardiography (ECG) for the entire duration in which the pulse generator is in MRI Protection Mode. Ensure backup therapy is available (external rescue).

1 As defined in IEC 60601-2-33, 201.3.244, 3rd Edition.
2 Refer to the MRI Technical Guide: ImageReady™ MRI Defibrillation System as the system is designated as MR-Conditional in accordance with specific conditions.