Heart Rhythm Society SM

Summary of Expert Consensus Statement for CLINICIANS

2017 HRS Expert Consensus Statement on Magnetic Resonance Imaging and Radiation Exposure in Patients with Cardiovascular Implantable Electronic Devices

This is a summary of the Heart Rhythm Society Expert Consensus Statement *2017 HRS Expert Consensus Statement on Magnetic Resonance Imaging and Radiation Exposure in Patients with Cardiovascular Implantable Electronic Devices*, which was published in the **Heart**Rhythm journal as article in press on Thursday, May 11, 2017, and appears in the July 2017 issue. Please refer to the full statement for more information.

This document is intended to help cardiologists, radiologists, radiation oncologists, and other health care professionals involved in the care of adult and pediatric patients with cardiac implantable electronic devices (CIEDs) who are to undergo magnetic resonance imaging (MRI), computed tomography, and/or radiation treatment. The document also addresses the safety of employees with CIEDs who might come into an MRI environment.

Recommendations and Protocol for the Management of Patients with an MR Conditional Device Undergoing MRI

MR conditional devices should be considered MR conditional only when the product labeling is adhered to, which includes programming the appropriate "MR mode" and scanning with the prerequisites specified for the device. (COR I; LOE A)
MR imaging in a patient with an MR conditional system should always be performed in the context of a rigorously applied standardized institutional workflow, following the appropriate conditions of use. (COR I; LOE B-R)
It is recommended for patients with an MR conditional system that personnel with the skill to perform advanced cardiac life support, including expertise in the performance of CPR, arrhythmia recognition, defibrillation, and transcutaneous pacing, be in attendance with the patient for the duration of time the patient's device is reprogrammed, until assessed and declared stable to return to unmonitored status. (COR I; LOE B-R)
It is recommended for patients with an MR conditional system that ECG and pulse oximetry monitoring be continued until baseline, or until other clinically appropriate CIED settings are restored. (COR I; LOE A)
It is recommended for patients with an MR conditional system that ECG and pulse oximetry monitoring be continued until baseline, or until other clinically appropriate CIED settings are restored. (COR I; LOE C-EO)
It is recommended for patients with an MR conditional system that personnel with the skill to program the CIED be available as defined by the institutional protocol. (COR I; LOE C-EO)
It is reasonable to perform an MR scan on a patient with an MR conditional system implanted more recently than the exempt period for conditionality of the system, based on assessment of risk and benefit for that patient. (COR IIa; LOE C-EO)

Recommendations for the Decision to Perform an MRI on Patients with an MR Nonconditional CIED

It is reasonable for patients with an MR nonconditional CIED system to undergo MR imaging if there are no fractured, epicardial, or abandoned leads; the MRI is the best test for the condition; and there is an institutional protocol and a designated responsible MR physician and CIED physician. (COR IIa; LOE B-NR)
It is reasonable to perform an MR scan immediately after implantation of a lead or generator of an MR nonconditional CIED system if clinically warranted. (COR IIa; LOE B-NR)
For patients with an MR nonconditional CIED, it is reasonable to perform repeat MRI when required, without restriction regarding the minimum interval between imaging studies or the maximum number of studies performed. (COR IIa; LOE C-LD)

Recommendations for the Management of Patients with an MR Nonconditional CIED Who Are to Have an MRI Scan

It is recommended for the patient with an MR nonconditional CIED that device evaluation be performed immediately pre- and post-MRI with documentation of pacing threshold(s), P- and R-wave amplitude, and lead impedance using a standardized protocol. (COR I; LOE B-NR)
A defibrillator/monitor (with external pacing function) and a manufacturer-specific device programming system should be immediately available in the holding area adjacent to the MR scanner room while an MR nonconditional CIED is reprogrammed for imaging. (COR I; LOE B-NR)
It is recommended that continuous MR conditional ECG and pulse oximetry monitoring be used while an MR nonconditional CIED is reprogrammed for imaging. (COR I; LOE B-NR)
It is recommended that personnel with the skill to perform advanced cardiac life support, including expertise in the performance of CPR, arrhythmia recognition, defibrillation, and transcutaneous pacing, accompany the patient with an MR nonconditional CIED for the duration of time the patient's device is reprogrammed, until assessed and declared stable to return to unmonitored status. (COR I; LOE B-NR)
For patients with an MR nonconditional CIED who are pacing-dependent (PM or ICD), it is recommended that: a) Personnel with the skill to program the CIED be in attendance during MR scanning. b) A physician with the ability to establish temporary transvenous pacing be immediately available on the premises of the imaging facility. c) A physician with the ability to direct CIED programming be immediately available on the premises of the imaging facility. (COR I; LOE B-NR)
For patients with an MR nonconditional CIED who are not pacing-dependent, it is recommended that: a) Personnel with the skill to program the CIED be available on the premises of the imaging facility. b) A physician with the ability to direct CIED programming be available on the premises of the imaging facility. (COR I; LOE B-NR)
It is recommended that for the patient with an MR nonconditional CIED who is pacing-dependent to program their device to an asynchronous pacing mode with deactivation of advanced or adaptive features during the MRI examination, and the pacing rate should be selected to avoid competitive pacing. (COR I; LOE B-NR)
All tachyarrhythmia detections for patients with an ICD should be disabled prior to MRI. (COR I; LOE B-NR)
The MR-responsible physician who is accountable for overseeing the safety of the MRI environment, including the administration of any medication and/or contrast agents (if applicable), should be made aware of the presence of a patient with an MR nonconditional CIED. (COR I; LOE C-EO)
It is recommended that ECG and pulse oximetry monitoring be continued until baseline or until other clinically appropriate CIED settings are restored for patients with an MR nonconditional CIED. (COR I; LOE C-EO)
All resuscitative efforts and emergency treatments that involve the use of a defibrillator/monitor, device programming system, or any other MRI-unsafe equipment should be performed after moving the patient outside of Zone 4. (COR I; LOE C-EO)
For a patient with an MR nonconditional CIED who is not pacing-dependent, it is reasonable to program their device to either a nonpacing mode (OVO/ODO) or to an inhibited mode (DDI/VVI), with deactivation of advanced or adaptive features during the MRI examination. (COR IIa; LOE B-NR)

It is reasonable to program patients with an MR nonconditional CRT device who are not pacing-dependent to an asynchronous pacing mode (VOO/DOO) with deactivation of advanced or adaptive features during the MRI examination, and with a pacing rate that avoids competitive pacing. (COR IIa; LOE C-EO)
For patients with an MR nonconditional CIED, it is reasonable to schedule a complete follow-up CIED evaluation within 1 week for a pacing lead threshold increase ≥1.0 V, P-wave or R-wave amplitude decrease ≥50%, pacing lead impedance change ≥50 **Ω**, and high-voltage (shock) lead impedance change ≥5 **Ω**, and then as clinically indicated. (COR IIa; LOE C-EO)

Implantable Loop Recorder

It is recommended that prior to MRI scanning patients with an implantable loop recorder (ILR) that the ILR be evaluated and that any desired recorded information be removed/downloaded from the system and cleared after the MRI. (COR I; LOE B-NR)
MR scanning of MR conditional ILRs should be performed within labeled scanning prerequisites specific to each device manufacturer. (COR I; LOE C-LD)

Employee Safety

It is recommended that the MR suite have a clearly delineated 5 gauss boundary and visible signs to advise individuals who have an implantable cardiac device, regardless of MR conditional labeling, to stay outside of the 5 gauss boundary at all times. (COR I; LOE C-EO)

Recommendations for the Management of Patients with a CIED Undergoing CT Imaging

It is recommended that patients with a CIED undergo clinical diagnostic CT without any additional device interrogation, programming, or monitoring. (COR I; LOE B-NR)
It is reasonable to exclude the device from the field of view of 4D CT and cone-beam CT scans if the images are not compromised. (COR IIa; LOE C-EO)
It might be reasonable to monitor patients who have an ICD or who are pacing-dependent by ECG or pulse oximetry if the CIED will undergo prolonged, uninterrupted exposure by CT. (COR IIb; LOE C-EO)

Recommendations and Protocol for the Management of Patients with a CIED Undergoing Radiation Therapy

Prior to the initiation of radiation treatment, a complete CIED evaluation should be performed and the treatment team should be informed of: a) Whether the device is a PM or ICD b) Whether the patient is pacing-dependent c) The minimum programmed pacing rate d) The maximum programmed tracking and sensor rates. (COR I; LOE B-NR)
Non–neutron-producing treatment is preferred over neutron-producing treatment in patients with a CIED to minimize the risk of device reset. (COR I; LOE B-NR)
Perform weekly complete CIED evaluations for patients undergoing neutron-producing treatment. (COR I; LOE B-NR)
A complete CIED evaluation should be performed at the conclusion of the course of radiation therapies. (COR I; LOE B-NR)
Continuous visual and voice contact is recommended during each treatment fraction. (COR I; LOE C-EO)
CIED relocation is recommended if its current location will interfere with adequate tumor treatment. (COR I; LOE C-EO)
It might be reasonable to perform a complete CIED evaluation weekly for patients who are pacing-dependent and undergoing non–neutron-producing treatment. (COR IIb; LOE B-NR)
CIED relocation is not recommended for devices receiving a maximum cumulative incident dose of <5 Gy. (COR III; LOE B-NR)

Checklist for Performance of Radiation Treatment

CIED CLINIC CHECKLIST

1 CIED implantation date:

2 CIED implant indication:

3 Device manufacturer and model:

4 Pacing-dependent *(intrinsic HR <40 bpm)*: Yes [ ] No [ ]

5 Complete weekly CIED evaluation recommended[1]: Yes [ ] No [ ]

6 System features:

Pacemaker/CRT-P [ ] ICD/CRT-D [ ]

Pacing mode: _____

Minimum pacing rate: _____

Maximum tracking rate: _____

Maximum sensor rate: _____

Measurements of the pacing system function and parameters are stable[2]:

Yes [ ] No [ ]

7 CIED evaluation following completion of radiation therapy:

Measurements of the pacing system function and parameters are stable[2]:

Yes [ ] No [ ]

Comments: _____

RADIATION CLINIC CHECKLIST

8 Type of radiation course:

Neutron-producing:[3] Yes [ ] No [ ]

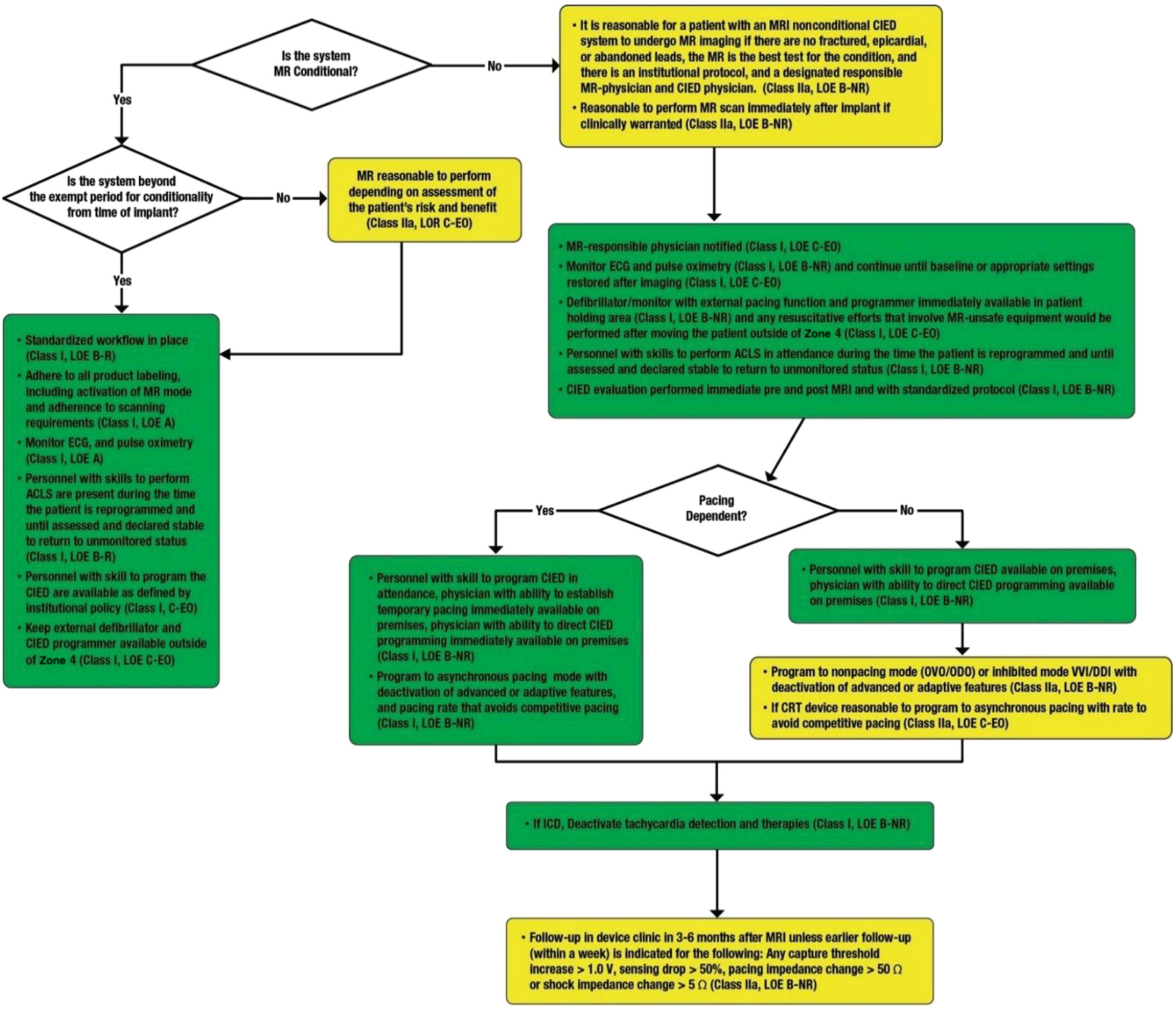
CIED location might interfere with adequate tumor treatment[4]: Yes [ ] No [ ]

Maximum expected cumulative incident dose <5 Gy[5]: Yes [ ] No [ ]

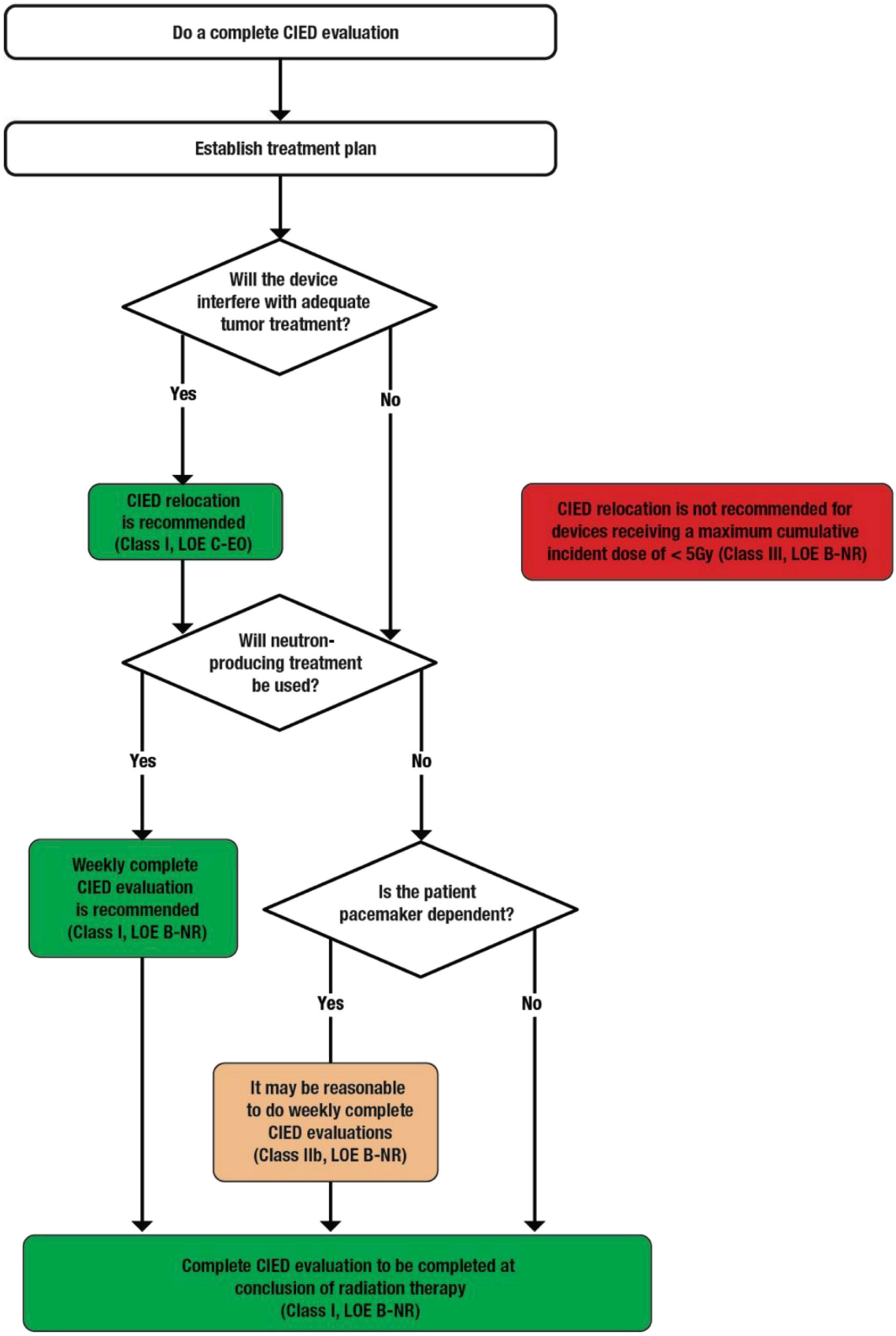
1) It is recommended to perform a weekly CIED evaluation for patients undergoing neutron-producing treatment and might be reasonable for pacing-dependent patients undergoing non–neutron-producing treatment.
2) Device function — pacing output, pacing thresholds, sensing of R and P waves, lead impedance, battery voltage, and impedance.
3) Non–neutron-producing radiation is preferred [neutron-producing: >10 mV photons, protons, electrons ≥20 MeV].
4) CIED relocation is recommended if it will interfere with adequate tumor treatment.
5) CIED relocation is not recommended for devices receiving a max cumulative incident dose of <5 Gy.

HR: heart rate; CRT-P: cardiac resynchronization therapy-pacemaker; CRT-D cardiac resynchronization therapy with implantable cardioverter defibrillator; CIED: cardiac implantable electronic device.

Recommendations and Protocol for the Management of the Patient with an MR Nonconditional Device Undergoing MRI



CIED Management for Radiation Therapy



Checklist for MRI Safety in the Setting of Implanted Devices (PM or ICD)

SECTION 1 – GENERATOR INFORMATION	
PM	ICD
☐yes ☐no	☐yes ☐no
Manufacturer & Model #	Manufacturer & Model #

SECTION 2 – LEAD INFORMATION			
Abandoned/Epicardial Lead(s)	**RA**	**RV**	**LV**
☐yes ☐no	☐yes ☐no	☐yes ☐no	☐yes ☐no
☐ *Note: CXR may identify if abandoned/epicardial leads are present.*	Manufacturer & Model #	Manufacturer & Model #	Manufacturer & Model #

SECTION 3 – MR CONDITIONAL STATUS AND MANAGEMENT
MR Conditional System?
Pre-MR imaging pacing/tachycardia mode activated? ☐yes ☐no
☐ *Monitor ECG and pulse oximetry by ACLS-trained personnel during the time the patient's device is reprogrammed and until assessed and declared stable to return to unmonitored status.*
☐ *Keep external defibrillator and CIED programmer available (outside of Zone 4).*
☐ *Conform to CIED manufacturer MRI recommendations including field strength, maximum estimated SAR, gradient slew rate, and transmit/receive coil.*
If the MR Conditional System was implanted less than the exempt period for conditionality (e.g., 6 weeks), is the MRI scan considered clinically useful based on assessment of risk and benefit for that patient? ☐yes ☐no

SECTION 4 – PRE- & POST- MRI DEVICE PARAMETERS						
	RA		**RV**		**LV**	
	Pre-MRI	**Post-MRI**	**Pre-MRI**	**Post-MRI**	**Pre-MRI**	**Post-MRI**
Sensing (mV)						
Capture Threshold (V @ _____ms)						

MR Nonconditional System:

It is reasonable to perform MRI if the following conditions are met:

No fractured, epicardial, or abandoned leads

MR is the best test for condition

Institutional protocol in place

Designated responsible MR-physician and CIED physicians

Pacing-dependent

☐ yes	☐ no
☐ *If yes, CIED must have asynchronous (VOO/DOO) pacing capability.* ☐ *Program pacing to VOO/DOO.* *Deactivate tachycardia detection and therapies.*	*Program pacing to OVO/ODO or VVI/DDI.* *Deactivate tachycardia detection and therapies.*

☐ *If programming VOO/DOO and there is an underlying rhythm, program the pacing rate faster than the underlying rate to avoid competitive pacing.*

☐ *Deactivate magnet, rate & noise response, and all advanced features*.*

☐ *Monitor ECG and pulse oximetry by ACLS-trained personnel during the time the patient's device is reprogrammed and until assessed and declared stable to return to unmonitored status.*

☐ *Keep external defibrillator and CIED programmer available (outside of Zone 4).*

Impedance (Ω)			Pace Shock	Pace Shock		
Battery Voltage (V)						

SECTION 5 – MANAGEMENT FOLLOWING MRI

☐ *Keep on ECG monitor after MRI until initial device programming has been restored and patient is assessed and declared stable to return to unmonitored status.*

☐ *Restore all original programming unless pacing output or sensing needs to be adjusted based upon post-MRI CIED evaluation.*

☐ *Advise follow-up in device clinic in 3-6 months after MRI unless earlier follow-up (within a week) is indicated for the following: Any capture threshold increase >1.0 V, sensing drop >50%, pacing impedance change >50 Ω, or shock impedance change >5 Ω.*

**All nonessential features that do not support fundamental backup pacing support if necessary during MRI should be disabled. These include: PMT algorithms, PVC- and PAC-triggered pacing response, hysteresis, rate smoothing, overdrive pacing, and conducted AF response. For CRT patients, deactivate LV-triggered pacing (ventricular sense response).*

This consensus statement was developed in collaboration with and endorsed by the American College of Cardiology, American College of Radiology, American Heart Association, American Society for Radiation Oncology, Asia Pacific Heart Rhythm Society, European Heart Rhythm Association, Japanese Heart Rhythm Society, Pediatric and Congenital Electrophysiology Society, Brazilian Society of Cardiac Arrhythmias, and Latin American Society of Cardiac Stimulation and Electrophysiology and in collaboration with the Council of Affiliated Regional Radiation Oncology Societies.