2017 HRS expert consensus statement on magnetic resonance imaging and radiation exposure in patients with cardiovascular implantable electronic devices

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KEYWORDS Magnetic resonance imaging; Computed tomography imaging; Radiation therapy; Cardiac pacemakers; Implantable cardioverter defibrillators

ABBREVIATIONS **CIED** = cardiac implantable electronic device; **COR** = Class of Recommendation; **CRT** = cardiac resynchronization therapy; **CRT-D** = cardiac resynchronization therapy with implantable cardioverter-defibrillator; **CRT-P** = cardiac resynchronization therapy-pacemaker; **CT** = computed tomography; **dB/dt** = time-varying magnetic field; **DFT** = defibrillation threshold test; **ECG** = electrocardiogram; **EMI** = electromagnetic interference; **EO** = expert opinion; **EP** = electrophysiology; **ERI** = elective replacement interval; **FDA** = Food and Drug Administration; **Gy** = Gray, a measurement of absorbed radiation dose; **HR** = heart rate; **ICD** = implantable cardioverter defibrillator; **ILR** = implantable loop recorder; **LD** = limited data; **LINAC** = linear accelerator; **LOE** = Level of Evidence; **MR** = magnetic resonance; **MRI** = magnetic resonance imaging; **ms** = milliseconds; **MV** = megavolt; **mV** = millivolts; **NMR** = nuclear magnetic resonance; **NR** = nonrandomized; **PM** = pacemaker; **POR** = power-on reset; **R** = randomized; **RCT** = randomized controlled trial; **RF** = radiofrequency; **RT** = radiation treatment; **SAR** = specific absorption rate; **T** = Tesla, a measurement of magnetic field strength; **V** = volts; **VT** = ventricular tachycardia (Heart Rhythm 2017;■:e1–e57)

Developed in collaboration with and endorsed by the American College of Cardiology (ACC), American College of Radiology (ACR)*, American Heart Association (AHA), American Society for Radiation Oncology (ASTRO), Asia Pacific Heart Rhythm Society (APHRS), European Heart Rhythm Association (EHRA), Japanese Heart Rhythm Society (JHRS), Pediatric and Congenital Electrophysiology Society (PACES), Brazilian Society of Cardiac Arrhythmias (SOBRAC), and Latin American Society of Cardiac Stimulation and Electrophysiology (SOLAECE) and in collaboration with the Council of Affiliated Regional Radiation Oncology Societies (CARROS). *Endorsement pending. **Address reprint requests and correspondence**: Heart Rhythm Society, 1325 G Street NW, Suite 400, Washington, DC 20005. E-mail address: clinicaldocs@hrsonline.org.

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Section I: Introduction and Methodology

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 (CT), and/or radiation treatment. We also address the safety of employees with CIEDs who might come into an MRI environment. Our objective is to delineate practical recommendations in appropriate detail for health care providers of various backgrounds for the management of patients with CIEDs so they can undergo imaging and treatments in a manner that balances benefit and risk, while recognizing that risk cannot be eliminated.

This international consensus statement was written by experts in the field chosen by the Heart Rhythm Society (HRS) and collaborating societies. Eleven societies collaborated in this effort: American Heart Association (AHA), American College of Cardiology (ACC), American College of Radiology (ACR), Asia Pacific Heart Rhythm Society (APHRS), American Society for Radiation Oncology (ASTRO), Council of Affiliated Regional Radiation Oncology Societies (CARROS), European Heart Rhythm Association (EHRA), Japanese Heart Rhythm Society (JHRS), Pediatric and Congenital Electrophysiology Society (PACES), Brazilian Society of Cardiac Arrhythmias (SOBRAC), and the Latin American Society of Cardiac Stimulation and Electrophysiology (SOLAECE).

Some areas are outside the scope of this document. First, in the health care environment, reimbursement by commercial insurance or Medicare can become integral to the decision

Figure 1 Applying Class of Recommendations and Level of Evidence to clinical strategies, interventions, treatments, or diagnostic testing in patient care.

whether to perform a test. Because this document is solely targeted to the clinical aspects of decision making, it does not address reimbursement issues. Second, although this document is intended to provide useful and practical recommendations, it is not intended to dictate management details that are best left to individual institutions to decide. Many aspects of health care vary by geographic location and resources, and are best prescribed by the individual institution. We stress the importance of each institution developing the protocols that will best serve its patient population, guided by the recommendations provided in this document.

In accordance with the policies of the HRS, disclosure was required of each writing committee member of any relationships with industry as well as from all peer reviewers; this disclosure is provided in Appendices C and D. Of the 27 committee members, 8 are free of any relevant relationships with industry, including the document chair. Sections that contain recommendations were written by committee members who were free of any relevant relationships with industry.

The writing committee reviewed evidence gathered by electronic literature searches (MEDLINE/PubMed,

EMBASE, Cochrane Library). Although no specific year was chosen for the oldest literature, we emphasized studies on patients with devices that would likely still be in clinical use. Search terms included *PM*, *defibrillator*, *cardiovascular electronic implantable device*, *magnetic resonance imaging*, *electromagnetic interference*, *computed tomography*, *radiotherapy*, and *radiation*. The committee considered evidence to support recommendations from randomized controlled trials, nonrandomized observational studies (retrospective or prospective), and case series. Computational modeling studies were also considered to support the recommendations. Modeling studies of the interactions of CIED systems within an MRI are a critical form of evidence that has emerged in recent years and is used by the Food and Drug Administration (FDA) to evaluate CIED systems for magnetic resonance (MR) conditionality. In computational studies, tens of thousands of CIED configurations, including location, generator type, lead type and length, and part of the body imaged, can be explored to identify specific combinations that might pose a higher risk to the patient, which cannot be determined by clinical studies alone. The committee also considered *in vitro* (i.e., phantom) and animal studies, but such evidence was used only as an adjunct to the other types of evidence listed above, to support recommendations. Evidence tables are provided in Appendix B.

The recommendations were formulated using the Class of Recommendation (COR) and Level of Evidence (LOE) system formulated by the ACC and AHA (Figure 1).[1] This provides a transparent mechanism to judge benefit relative to risk using a classification scheme (I, IIa, IIb, and III), supported by evidence quality and quantity using an LOE rating (A, B-R, B-NR, C-LD, C-EO); all the recommendations are listed with a class and LOE rating. Recommendations that are based solely on the opinion of the committee are given an LOE rating of C-EO. For clarity and usefulness, each recommendation contains the specific references from the literature used to justify the LOE rating and is accompanied by explanatory text.

To reach consensus, we conducted surveys of the writing committee, requiring a predefined threshold of 80% for each recommendation. An initial failure to reach consensus was resolved by subsequent discussions, revisions as needed, and re-voting. The mean consensus was 94%.

This document underwent internal review by peers from the HRS, including review by the HRS Scientific and Clinical Documents Committee, as well as external review from the collaborating societies. Public comment on the recommendations was also obtained. Itemized responses to reviewer comments and revisions were provided by the chair.

Section II: Definitions of CIED Systems in Relation to MRI

a. Definition of MR Conditional Systems

The term *MR conditional* refers to any device for which a specified MRI environment with specified conditions of use does not pose a known hazard. Field conditions that define the MRI environment can include the region of imaging, static magnetic field strength, spatial gradient, time-varying magnetic field (dB/dt), radiofrequency (RF) fields, and specific absorption rate (SAR). Additional conditions might be required, including the use of specific leads and generator combinations, as well as MRI mode programming of the CIED system. Furthermore, specified conditions for MRI can vary among manufacturers and specific devices made by individual manufacturers. The designation *MR Safe* requires there be no hazard in any MR environment. For example, plastic objects are MR safe. No CIED has an *MR Safe* designation. The designation *MR Unsafe* refers to an object that is known to pose hazards in all MR environments.

For MR conditional CIED systems, the labeling requires testing sufficient to characterize the system behavior in the MRI environment. Such testing includes measuring magnetically induced force and torque, current induction, and RF heating. Other testing measures involve modeling of potential electromagnetic interference from the MRI environment with the CIED system.

b. Definition of MR Nonconditional Systems

MR nonconditional systems include all CIED systems other than those that meet MR conditional labeling. This includes MR conditional generators that have been combined with nonconditional leads or MR conditional systems implanted in patients that do not meet all specified conditions of use, such as patients with abandoned leads.

Section III: MRI Technology and Relationship to Risk

a. MRI Physics

MRI is the clinical application of the science of nuclear magnetic resonance (NMR) spectroscopy. NMR is based on the physical properties of specific atomic nuclei absorbing and emitting RF energy when placed in an external magnetic field. In clinical MRI, hydrogen nuclei are most often used to generate the images of the anatomy of interest. Hydrogen nuclei exist naturally in the human body in abundance, especially in water and fat; thus, MRI scans essentially map the location of water and fat within the body.

MRI requires a static magnetic field (e.g., 1.5 Tesla) to align the protons with or against the magnetic field, a source of pulsed RF waves to excite the nuclear spin of the proton causing an energy transition, and magnetic field gradients to localize in space the signal that is emitted after the RF signal is turned off. Pulse sequences describe a series of RF pulses applied to the anatomy of interest. By varying the parameters of the pulse sequence, various contrasts can be generated between tissues, based on the relaxation properties of the hydrogen nuclei. These three fields (static magnetic, gradient magnetic, and RF), alone or in combination, can interact with some metallic objects as well as potentially damage the performance of sensitive electronic components.

Table 1 Programmed parameters for PMs during power-on reset mode[11]

Manufacturer	Pacing mode	Pacing output	Pacing polarity	Sensitivity	Magnet response
BIOTRONIK	VVI 70 bpm	4.8 V @ 1.0 ms	Unipolar	2.5 mV	Yes
Boston Scientific*	VVI 65 bpm	5.0 V @1.0 ms	Bipolar	1.5 mV	No
Medtronic	VVI 65 bpm	5.0 V @ 0.4 ms	Bipolar	2.8 mV	Yes
St. Jude Medical	VVI 67.5 bpm	4.0 V @ 0.6 ms†	Unipolar	2.0 mV	No
ELA-Sorin	VVI 70 bpm	5.0 V @ 0.5 ms	Unipolar	2.2 mV	No

bpm = beats per minute; V = volts; ms = milliseconds; mV = millivolts; magnet = device will/will not pace asynchronously in response to a magnet during safety and power-on reset mode. Magnet response varies by manufacturer.

*Boston Scientific CRT-P devices differ in pacing output (5 V @ 0.5 ms) and pacing polarity (right ventricle lead is unipolar and left ventricle lead paces from left ventricle to pulse generator).

†St. Jude Medical Accent/Anthem and Frontier II models deliver 5 V @ 0.6 ms.

MRI scanners use a number of different magnetic field strengths (static magnetic field), typically ranging from 0.2 Tesla to 9 Tesla. Tesla is a measure of strength of the magnetic field. Another unit of measure commonly used with magnets is the gauss (1 Tesla = 10,000 gauss). These magnets are very powerful, ranging from 4000 to 60,000 times greater than the Earth's magnetic field. Due to the risk of injury (such as mechanical injury from moving objects) when certain metal objects and implanted metal devices are brought into these magnetic fields, standards have been accepted to define physical zones within the MRI suite to control this risk.[2] For example, 5 gauss is broadly used as the "safe" magnetic field strength around MRI scanners.

Zone 4 refers to the MRI scanner room and is the physical space with the highest risk to patients and staff, including the potential for flying metal objects. Metal objects, internal and/or external to the patient, should never be brought into Zone 4 without proper screening.[2]

Zone 3 is the space just outside the MRI scanner room (Zone 4), and includes the areas for patient holding and the control room. Because there is a potential for injury in this area related to the MR scanner static and time-varying magnetic fields, access must be restricted by MR safety-trained personnel, under the authority of the MR medical director or an MR-trained designated physician.[2]

Only MR personnel may have free access to Zone 3. Zone 2 includes the patient reception and interview/screening areas, and Zone 1 refers to regions that are accessible to the general public with no restrictions.

b. Hardware and Software Components

MRI generates static and gradient magnetic fields as well as RF energy. The potential interactions between CIEDs and electromagnetic interference from MRI include the following:

1. Magnetic field-induced force and torque due to ferromagnetic materials: CIED generator movement is extremely unlikely due to confinement in the subcutaneous tissues.[3] Leads do not contain any significant ferromagnetic materials to cause movement in a magnetic field.
2. Gradient magnetic field-induced electrical current: Gradient magnetic fields can induce current in conductive wires within the field that could lead to myocardial capture and potentially lead to atrial or ventricular arrhythmias.[4–6]
3. Heating and tissue damage: RF fields can lead to nonconditional CIED component heating and subsequent thermal damage to the surrounding tissue (functional ablation). Changes in sensing or capture thresholds can occur as a result of tissue damage near lead electrodes.[7,8]

Table 2 Programmed parameters for ICDs during power-on reset mode[11]

Manufacturer	Rate cutoff	Detection criteria	Sensitivity	Energy	Pacing mode	Pacing output
BIOTRONIK	150 bpm	8/12	0.8 mV	40 J × 8	VVI 70 bpm	7.5 V @ 1.5 ms*
Boston Scientific	165 bpm	8/10	0.25 mV	41 J × 5	VVI 72.5 bpm	5.0 V @ 1.0 ms
Medtronic	188 bpm	18/24	0.3 mV	35 J × 6	VVI 65 bpm	6.0 V @ 1.5 ms
St. Jude Medical†	146 bpm	12	0.3 mV	36 J × 6‡	VVI 60 bpm	5.0 V @ 0.5 ms
ELA-Sorin	190 bpm	6/8	0.4 mV	42 J × 4§	VVI 60 bpm	5.0 V @ 0.35 ms

All devices will respond to magnet application by temporarily disabling tachyarrhythmia detection. Pacing polarity for all devices is bipolar with the exception of Boston Scientific, which paces in a unipolar configuration. Energy values listed for Medtronic and St. Jude Medical represent energy delivered. The remaining represent energy charged.

bpm = beats per minute; V = volts; ms = milliseconds; mV = millivolts; magnet = device will/will not pace asynchronously in response to a magnet during safety mode/reset mode.

*In CRT devices, left ventricle lead output is 4.8 V @ 0.5 ms.

†The St. Jude Medical Current and Promote family of devices revert to an autosense sensitivity setting, pace at VVI 67.5 bpm with pacing outputs of 5.0 V @ 0.6 ms.

‡The St. Jude Medical Epic and Epic II family of devices delivers 30 J × 6.

§ELA-Sorin LivaNova Ovatio family of devices: 34 J × 4.

Table 3 U.S. Food and Drug Administration (FDA)-approved MR conditional devices

	PMs	ICDs	Leads	Implantable cardiac monitors
BIOTRONIK	Eluna PM series (DR-T and SR-T) Entovis PM series (DR-T and SR-T)	Iforia (DR-T and VR-T DX) Iperia (DR-T and VR-T DX) Inventra (VR-T DX)	Setrox S, 53- or 60-cm length Protego DF-1 S DX (ICD) Linoxsmart S DX (ICD)	Bio Monitor 2 implantable monitor
Boston Scientific	Accolade MRI Essentio MRI	Emblem S-ICD	Ingevity MRI	
Medtronic	Revo MRI™ Model RVDR01 Advisa DR MRI SureScan PM Model A2DR01 Advisa SR MRI SureScan PM Model A3SR01 Micra® Transcatheter Pacing System Model MC1VR01 (TPS)	Evera MRI XT VR (DVMB1D4) Evera MRI XT DR (DDMB1D4) Evera MRI S DR (DDMC3D4) Visia AF MRI VR (DVFB1D4) Amplia MRI CRT-D (DTMB1D4) Amplia MRI Quad CRT-D (DTMB1QQ) Compia MRI Quad CRT-D (DTMC1QQ)	CapSureFix Novus MRI SureScan 5076 lead CapSureFix MRI 5086MRI lead Sprint Quattro Secure MRI™ SureScan 6947M (ICD), 6935M (ICD) Attain Performa (4298, 4398, 4598) LV lead Attain Ability (4196, 4296, 4396) LV lead	Reveal implantable cardiac monitor LINQ implantable cardiac monitor
ELA-Sorin LivaNova	—	—	—	—
St. Jude Medical	Assurity MRI single-chamber Model PM1272 Assurity MRI dual-chamber Model PM2272	—	Tendril MRI Model LPA1200M	Confirm implantable monitor

Table 4 Adaptive and advanced features requiring deactivation prior to MRI of a nonconditional CIED

Rate response mode
Anti-tachycardia therapies (including anti-tachycardia pacing and shocks) — ICD only
LV-triggered pacing (ventricular sense response) — biventricular devices only
Anti-pacemaker–mediated tachycardia pacing (PMT algorithms)
PVC-triggered pacing response
PAC-triggered pacing response
Atrial fibrillation therapies (rate smoothing, overdrive pacing, conducted atrial fibrillation response)
Hysteresis pacing
Magnet response (if the option exists)
Noise response

4. Effects on reed switch activity: The reed switch is a feature that permits programming of the device by placement of a magnet. Magnetic fields might therefore affect the reed switch activity of a nonconditional CIED, leading to asynchronous pacing and inhibition of tachycardia therapies.[9,10]
5. Electrical reset: High-energy electromagnetic interference (EMI) can lead to electrical or *power-on reset*, a backup demand mode, wherein pacing might be inhibited and tachyarrhythmia therapy activated. Power-on reset parameters vary by vendor and type of CIED (see Tables 1 and 2), and can include reset of pacing polarity to unipolar. Inhibition of pacing function due to oversensing of MRI-generated signals or pacing at an output below threshold (bipolar or unipolar) in a pacemaker (PM)-dependent patient might occur in the setting of power-on reset and must be recognized to prevent catastrophic consequences.[12,13] Additionally, battery status can be affected, particularly for CIEDs that are near an elective replacement interval (ERI), which could result in unreliable function.
6. Inappropriate function and therapies: EMI from RF energy pulses or rapidly changing magnetic field gradients might cause oversensing that can lead to inappropriate inhibition of demand pacing and possibly asystole in a pacing-dependent patient, or induction of therapies such as inappropriate shocks in a patient with an implantable cardioverter defibrillator (ICD). Other inappropriate tracking or programming changes can occur.[14]

These effects are influenced by various factors, including magnet field strength, RF power, position of the patient and the CIED within the MRI bore, CIED characteristics, and the size of the patient.[15]

c. Imaging Artifacts

Because of their metal composition, CIEDs cause various types of artifacts within MR images. MRI artifacts are typically image distortions or signal loss within the image slices that contain and neighbor the CIED device. These artifacts are caused by an alteration in the local magnetic field, which causes misreading of the correct localization of the proton signal (phase and frequency) by the MRI scanner.[16]

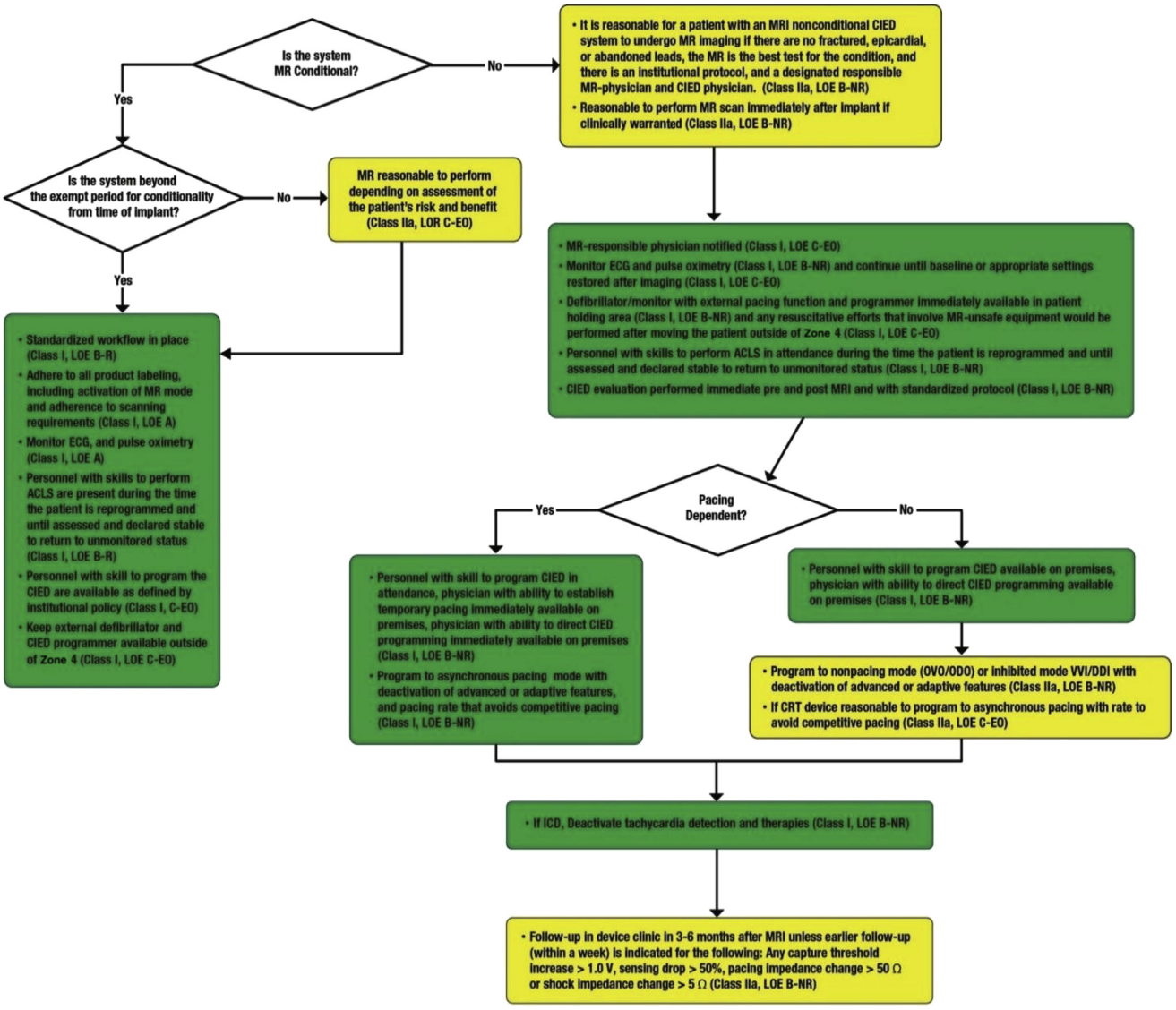

Figure 2 Recommendations and protocol for the management of the patient with an MR nonconditional device undergoing MRI.

Descriptions of the types of artifacts can be found in the literature.[17–21] Artifacts cannot be predicted in advance (when the CIED is within or near the region scanned), due to the many variables within the body; e.g., object size and shape, position in the patient's body, magnetic susceptibility of the CIED, dielectric constant of the body, patient's body size and shape, specific pulse sequence used, and the chosen parameters within the pulse sequence. Through careful consideration of the type of pulse sequence and imaging parameters, the artifacts can be reduced. Wideband filtering algorithms can also enhance image quality in the vicinity of a CIED.[22–24] As a rule of thumb, the best way to reduce imaging artifacts is to image as far away from the metal object as possible and to use pulse sequences that are known to reduce artifacts (i.e., do not use susceptibility-weighted image sequences such as gradient echo sequences because they magnify artifacts from metals). In general, MRI scans in patients with a CIED yield interpretable results.[25,26]

Section IV: MR Conditional CIED Technology

As described in Section III, during MRI, three types of fields are present that can, alone or in combination, adversely affect the CIED, the patient, or both: a static magnetic field, gradient magnetic fields, and RF fields. These forces, in varying combinations, lead to the potential for device movement, excess heating, electric current induction, EMI, abnormal reed switch behavior, power-on reset activity, and battery depletion.

Rendering a CIED system MR conditional entails modifying features of the leads, generators, or the MRI scan itself.[27] The use of computer modeling and clinical testing have led to the design of new CIED systems and, in some cases, the labeling of currently available systems as MR conditional, including certain leads without further modification. Conditional labeling, however, requires the use of leads and generators that were specifically tested together.

<table>
<tr><td colspan="2">SECTION 1 – GENERATOR INFORMATION</td><td colspan="5">SECTION 2 – LEAD INFORMATION</td></tr>
<tr><td>PM</td><td>ICD</td><td>Abandoned/Epicardial Lead(s)</td><td colspan="2">RA</td><td colspan="2">RV</td><td>LV</td></tr>
<tr><td>☐yes ☐no</td><td>☐yes ☐no</td><td>☐yes ☐no</td><td colspan="2">☐yes ☐no</td><td colspan="2">☐yes ☐no</td><td>☐yes ☐no</td></tr>
<tr><td rowspan="2">Manufacturer & Model #</td><td rowspan="2">Manufacturer & Model #</td><td rowspan="2">☐
Note: CXR may identify if abandoned/epicardial leads are present.</td><td colspan="2">Manufacturer & Model #</td><td colspan="2">Manufacturer & Model #</td><td>Manufacturer & Model #</td></tr>
<tr><td colspan="2"></td><td colspan="2"></td><td></td></tr>
<tr><td colspan="3">SECTION 3 – MR CONDITIONAL STATUS AND MANAGEMENT</td><td colspan="6">SECTION 4 – PRE- & POST-MRI DEVICE PARAMETERS</td></tr>
<tr><td colspan="3"></td><td colspan="2">RA</td><td colspan="2">RV</td><td colspan="2">LV</td></tr>
<tr><td colspan="3">MR Conditional System?
Pre-MR imaging pacing/tachycardia mode activated? ☐yes ☐no</td><td></td><td>Pre-MRI</td><td>Post-MRI</td><td>Pre-MRI</td><td>Post-MRI</td><td>Pre-MRI</td><td>Post-MRI</td></tr>
<tr><td colspan="3">☐ 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).</td><td>Sensing (mV)</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="3">☐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</td><td>Capture Threshold (V @ _____ms)</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="3">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</td><td>Impedance (Ω)</td><td></td><td></td><td>Pace
Shock</td><td>Pace
Shock</td><td></td><td></td></tr>
<tr><td colspan="3">Pacing-dependent</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
</table>

Figure 3 Checklist for MRI safety in the setting of implanted devices (PM or ICD).

a. Lead Development

Engineers face two general challenges in designing a lead that is MR conditional: The first is to minimize heating at the tip, which could cause myocardial damage, pain, and changes in pacing and sensing function. The second is to reduce the antenna effect, in which picking up the resonant frequency causes electric current to conduct and possibly induce rapid capture and stimulation of the myocardium, with the potential to induce arrhythmia (see Section III).

Most pacing leads are composed of an inner and outer insulation and an inner and outer coil, arranged in a manner to maximize energy delivery while maintaining flexibility and durability. Inner coils are made of filaments wound three-dimensionally with a certain pitch (or angle). Changing the geometry of these relationships by altering the number of filars or winding turns can change the propensity of the lead to act as an antenna and/or the likelihood of efficient lead tip heating. An alternative is the co-radial design, used in one manufacturer's pacing lead.[28] Other changes to a lead include coating the tip with a substance resistant to polarization and applying a heat-dissipating filter/inductor at the near-distal end to reduce electrode heating within an MR environment.

☐yes	☐no	Battery Voltage (V)						
☐*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).*		**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 on 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).*

Figure 3 (*continued*).

Computer modeling can assess the potential for lead heating, which is influenced by multiple variables, including patient size, anatomy, body composition, lead design, and position. Such variables cannot be completely accounted for in clinical studies. Changes in pacing threshold as a function of RF power can be investigated computationally, using millions of combinations of variables to provide a comprehensive safety evaluation.[29,30]

Lead modifications, together with modeling and clinical studies, have enabled MRI conditional status to be conferred to leads already in clinical use.[31]

b. Generator Development

Compared with the leads, the PM or ICD generator face more challenges from magnetic fields and RF energy from the MRI. Reducing the ferromagnetic content decreases magnetic attraction and imaging artifacts. The reed switch initiates asynchronous operation in the presence of a magnet. The replacement of reed switches with solid-state Hall effect sensors, which behave more predictably in magnetic environments, has led to more reliable behavior in the MRI environment. Shielding with special filters limits the transfer of certain frequencies and dissipates energy, thereby reducing the risk of damage to the circuitry and internal power supply. Finally, MR conditional generators contain a dedicated MRI programming pathway to be turned on and off before and after a scan. "MRI-mode" features include prescan system-integrity checks, asynchronous pacing or nonstimulation modes (nonsensing modes), disabling of tachycardia detection, increased output during the scan, and restoration of prescan program states and values.

MRI protocols and procedures can also be used to reduce the chances of interaction. These include using a lower static magnetic field system, lower gradient slew rates with maximal amplitudes, and limiting RF power as well as slowing its rate of transmission/deposition. Most of the literature on MR conditional systems use 1.5T scans in "normal operating mode,"[29–40] and some systems are FDA-approved for 3T scanning.

Section V: Management of Patients with a CIED Referred for MRI

a. Identification of Patient and CIED Characteristics

The decision to perform MRI on a patient with a CIED is similar to any other medical decision: There are potential benefits and risks. Factors that influence these risks and benefits should be identified.

Patient characteristics that could increase the risk of bradyarrhythmias or tachyarrhythmias should be understood, such as knowledge of the underlying (intrinsic) rhythm, which

will determine the appropriate pacing programming for the MR scan. It must be determined whether the CIED system meets MR conditionality, including a full understanding of the implanted hardware such as the presence of abandoned or fractured leads, epicardial leads, or system components from different vendors, all of which would render the system nonconditional. CIED evaluations are needed to ensure that there will be appropriate CIED performance during the MR scan. Subsequent sections detail the approach to patients with an MR conditional or MR nonconditional CIED.

b. MR Conditional Devices

i. MR Conditional CIEDs Currently Available

In the past few years, due to advances in engineering and manufacturing, a variety of PMs and defibrillators have been released to the market and approved by the FDA as MR conditional (see Section 2a). Many others are awaiting such approval. Table 3 depicts a listing of the devices FDA approved and available on the US market (as of 2016), and this list will likely grow rapidly.

CIED technology continues to evolve, and new devices might be released with conditional status, an example being Medtronic's Micra leadless PM. Others, such as Boston Scientific's EMBLEM subcutaneous defibrillator, are released initially without MR conditional labeling, but later achieve conditional labeling. The Medtronic 5076 pacing lead is also an example of hardware initially released as MR nonconditional but which later gained conditional labeling when used with a Medtronic MR conditional CIED. An MR conditional system refers to both the CIED generator and the attached leads that are approved by the FDA as a combination that is MR conditional. Therefore, combined hardware from various vendors does not meet FDA conditional labeling. For existing CIED systems, conditions of use for MR scanning are specified by the manufacturer. CIED manufacturers are urged to consider MR conditional labeling of new products as they are evaluated for release.

ii. Evidence Review

At least two prospective, multicenter, randomized controlled trials[32,33] and three prospective multicenter cohort studies[35,36,39] have been performed to assess MRI performance safety in patients with MR conditional PMs. Evidence (Table B1) is available in Appendix B.

The two prospective, multicenter randomized controlled trials were performed on patients implanted with the Medtronic EnRhythm SureScan[33] and the Medtronic Advisa,[32] respectively. In the study assessing the EnRhythm,[33] MRI scanner use was specifically limited to well-defined anatomic regions (head and lumbar spine) to avoid placing the isocenter over the PM leads or generator. In the Advisa trial,[32] however, there were no position restrictions. In both studies, the patients were assessed 9–12 weeks after PM implantation using 1.5T whole-body MRI scanners at a prescribed maximum SAR limit of 2 W/kg and followed for up to 1 month. In the EnRhythm study,[33] there were a total of 464 patients, with 258 randomized to MRI and 206 randomized to the no MRI control group. There were 226 undergoing MRI without MRI-related complications (defined as an adverse event resulting in an invasive intervention or termination of significant device function) during or after the imaging examination. The Advisa study[32] had a total of 263 patients, with 177 randomized to MRI and 86 to the no MRI control group, with no MRI-related complications. In the EnRhythm trial,[33] one patient experienced a ventricular pacing capture threshold (PCT) increase. In both studies, a small number of patients reported paresthesia and/or implant warmth. The Medtronic 5076 pacing lead was evaluated with an Advisa dual-chamber PM in 266 patients randomized to undergo MRI scans (177 patients) or to a control group.[31] Both head and chest MRI scans were performed. At the 1-month follow-up, the MRI group was noninferior compared with the control group for lead function, and there were no MRI-related complications.

A prospective, randomized controlled trial has been performed on patients implanted with the Medtronic Evera ICD system.[34] Patients were randomized to undergo MRI at 1.5T of the chest, cervical region, and head at 9–12 weeks after implant of a single- or dual-chamber Evera ICD system, or to a control group. From 42 centers, a total of 275 patients were randomized, with 175 patients undergoing MRI and 88 patients assigned to the control group. There was 100% freedom from a composite endpoint, consisting of sustained ventricular arrhythmia while being programmed for MR scanning, complications related to MRI, or loss of capture within 30 days. Noninferiority was also demonstrated for the efficacy endpoints of changes in pacing threshold or R wave amplitude. Additionally, a small subset (24 patients) underwent defibrillation testing, with no effects on sensing detection or treatment for ventricular fibrillation.

Of the three prospective cohort studies, the two largest were performed on patients implanted with the BIOTRONIK Entovis ProMRI PM. In these two trials, 226[39] and 216[35] patients completed both the MRI examination and the 1-month follow-up. Only one adverse event (pericarditis with pericardial effusion requiring lead repositioning) was determined to be possibly related to both the implanted system and the MRI procedure.

A prospective, multicenter cohort study has been performed assessing 1.5T MRI performance safety in patients implanted with the BIOTRONIK Iforia ICD.[37] Of 170 patients enrolled, 153 patients underwent MRI scanning and were followed for 1 month. There were no serious adverse events. In one patient, a reduced R-wave amplitude was detected one month post-MRI.

Numerous single-center, retrospective cohort studies assessing MR conditional PMs have also been performed.[41–45] The most common MR-related effect has been an increase in PCT; this is rare, however, and when it occurred it was not statistically significant.

There are significant practical and logistical limitations to the conduct of human trials because they cannot address the millions of potential variables present during MR scanning of a patient with a CIED. Computer modeling is valuable and is

an accurate method of assessing millions of combinations in variables affecting PM and ICD lead heating and the probability of PCT change.[29,30] Lead electrode heating can be affected by many factors, including patient size, patient position within the scanner, scan sequence, lead route, and lead design.[29,34] In the studies by Wilkoff et al[29] and Gold et al,[34] the RF power at the lead electrode-tissue interface was simulated using models of human bodies, RF coils, leads, and lead routings; the effect of RF power on PCT was validated through an *in vivo* canine study. PCT is the minimum voltage required for a PM to pace or capture the heart, and changes in PCT can be directly caused by tissue heating at or near the lead electrode. In both studies,[29,34] RF coil models were simulated using computer simulation software, and a library of anatomically correct human models spanning the 2nd to 97th percentile and electromagnetic models of the cardiac leads at 1.5T were developed. One thousand anatomically correct lead routes were developed from PM patient chest X-rays and computed tomographic scans. Together, these components simulated approximately 2.4 million unique cases. The physiologic effect of lead electrode heating was also evaluated in both studies with *in vivo* canine experiments.[29,34] Excellent agreement was found between simulated and measured powers, demonstrating very good accuracy for the model; thus, computer models can be used as one means of determining PM and ICD lead heating probability.

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

See Figure 2 for a flowchart to illustrate these recommendations, and Figure 3 for a practical checklist to facilitate an institutional workflow.

COR	LOE	Recommendations	References
I	A	**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.**	32–36,39,42,44

MR conditionality is approved for specific combinations of CIEDs and leads, and should only apply to those combinations. Table 3 in this document lists the approved systems from various manufacturers. Device systems that combine individual MR conditional lead and device components from various manufacturers should not be regarded as an MR conditional system, because these are not combinations specifically tested for conditional labeling. Patients with MR conditional systems who also have abandoned PM or ICD leads (capped or not), extenders or adaptors, lead remnants, fractured lead(s), or surgically implanted epicardial leads, should be evaluated for scanning as if they have an MR nonconditional system.

In general, most systems have been approved for scanning with 1.5T, gradient slew rate $\leq$200 T/m/s, a maximal SAR $\leq$2 W/kg, and a limited number and length of imaging sequences; however, compatibility of other scanning parameters might also be safe with newer devices. Most systems now allow full-body scanning (including thorax and cardiac structure).

Most device manufacturers provide specific instructions as part of their conditions of use. These instructions include a full evaluation of the CIED and leads. MR program settings are activated manually before the scan, or could in some devices activate automatically within the MRI magnet. Changed settings might impact the patient's rhythm. Settings include disabling advanced pacing algorithms as well as tachyarrhythmia detection and therapies in ICD systems. The choice of pacing mode and rate (asynchronous or inhibited) will depend on the patient's characteristics, including pacing dependence. For patients with a CRT device, there could be the possibility of hemodynamic deterioration during scanning if biventricular pacing is not provided.

I	B-R	**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.**	32–36,39,42,44

An increasing number of PMs and defibrillators from various manufacturers have received approval as "MR conditional" systems (see Table 3). Conditions of use can include the region being scanned, scanning parameter restrictions, and active reprogramming of the device before and after the scan. There is also a potential impact on the rhythm status (i.e., with potential occurrence of untreated tachyarrhythmias or absence of bradycardia pacing) while the CIED is being reprogrammed for scanning. Despite several clinical, animal, and modeling studies, the myriad device and scanning parameter combinations do not allow the evaluation of all possible scenarios. Therefore, vigilance is required even when scanning patients with devices approved for MRI. For these reasons, a standardized institutional workflow should be developed in collaboration between at least institutional experts in MR imaging and a cardiologist with expertise in CIEDs. A suggested institutional protocol can be found in Appendix A of this text. Such workflow should include assessment of the benefits of MR imaging compared with alternative imaging or nonimaging diagnostic methods, pre- and postscan CIED evaluation, and appropriate MR conditional programming during the scan based on device and patient characteristics. The protocol should be practically implemented, including the use of checklists (see Figure 3), preferably embedded in an electronically traceable workflow.

I	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.**	32–36,39,42,44

(*Continued*)

(*Continued*)

COR	LOE	Recommendations	References
		While the CIED is being reprogrammed for scanning, there is a potential for the absence of bradycardia pacing and for untreated tachyarrhythmias, which could lead to harm to the patient. Despite several clinical, animal, and modeling studies, the myriad of device and scanning parameter combinations do not allow evaluation of all possible scenarios. Such scenarios include ventricular pacing inhibition in a previously unrecognized, intermittently pacing-dependent patient, or occurrence of hemodynamically unstable ventricular arrhythmias while tachycardia detection is deactivated in patients with an ICD. Therefore, vigilance is required even when scanning patients with devices approved for MRI. Professional oversight by appropriately trained personnel able to react appropriately in case of an emergency should be performed for the duration of time that the patient's device is reprogrammed for the MR scan, until deemed stable. The institutional protocol should specify whether this is nursing or medical staff (radiologists or other physicians) at the imaging facility, or external staff who are present during scanning and monitoring.	
I	**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.**	32–36,39,42,44
		Because CIEDs are reprogrammed to allow safe scanning, but with a potential impact on rhythm status (i.e., with potential occurrence of untreated tachyarrhythmias or absence of bradycardia pacing), monitoring of the patient should be continued as long as the reprogrammed mode is active. There is commonly live contact with the patient throughout the scan via visual and voice contact (or as clinically appropriate if mental status is altered or the patient is intubated). If an emergency arises, such as ventricular pacing inhibition, in a previously unrecognized, intermittently pacing-dependent patient, or in the unlikely event of a power-on reset to an inhibited mode in a pacing-dependent patient, then appropriate emergency actions can be undertaken as specified in the institutional protocol (see for example, Appendix A). An MR-safe heart rate and rhythm monitor and transcutaneous pulse oximetry are required for patient safety, as well as the ability to directly observe the monitor from the adjacent control room. Although continuous monitoring of the cardiac rhythm is the primary objective, the electrocardiogram (ECG) might not be interpretable during the use of many MR sequences that induce significant electrical artifact. However, transcutaneous pulse oximetry is relatively unaffected during MR sequences, and thus can confirm a change in pulse rate in the absence of a technically adequate ECG signal. Special attention to ECG electrode positioning and skin preparation can optimize ECG monitoring and minimize potential artifacts from monitor lead movement.	
I	**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.**	
		The institutional protocol should specify a zone determined to be magnetically safe, that is close to the scanning location where emergency equipment that is not MRI-safe can be used and emergency treatments can be performed.	
I	**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.**	
		The institutional policy should define how personnel with the skill to program the CIED can be reached for the scan, because it is generally not necessary for such personnel to be present during the scan itself. These skills include the ability to provide age-appropriate programming for pediatric patients.	
IIa	**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.**	
		Most clinical trials that formed the basis for MR conditional approval prespecified that the (nonclinical) scans were performed outside a certain exempt period after CIED implantation. There is no theoretical reason, however, why interactions with the lead (e.g., dislodgement) or device might occur when the patient is scanned earlier after implantation, because leads do not contain any significant amount of ferromagnetic materials (see Section IIIb). Although the requirements for MR conditionality are not strictly met in such a case, it is reasonable to perform an MR scan earlier based on an assessment of risk and benefit for that patient.	

Practical Workflow Details:

Safe and effective MRI of patients with CIEDs requires a concerted workflow between the institutional experts in MRI and the cardiologists with expertise in CIEDs, based on a standardized protocol, with consecutive phases through which the patient is sequentially guided. This requires development of predefined institutional protocols, avoiding ad hoc improvisation, which could result in missed details and potential increased risk to the patient. The reticence of some physicians and institutions to scan patients with MR conditional systems could have more to do with unfamiliarity rather than with concerns about the safety of such scanning. Figure 3 provides a practical checklist based on these recommendations.

Ideally, such workflow is described in an action plan with a dedicated checklist. The latter facilitates the workflow and exchange of information, and allows for immediate referral to external data sources for up-to-date information. The institutional plan should consider addressing the need for emergency MR scanning outside normal staffing hours.

Appendix A describes the important steps in such a workflow and serves as a reference for institutions to devise their specific plans.

Although, in the future, a CIED system might have an "activator" that can program the CIED to an MR conditional mode without the need of a device programmer, or can automatically detect an MR environment and reprogram itself, this does not negate the need for the same workflow for elective scans. It remains important to check the absence of contraindications prescan, the need for special programming and monitoring during the scan, and system integrity evaluation after the scan.

c. MR Nonconditional Devices

i. Overview of Types of Devices

An MR conditional system consists of a designated combination of leads and generator that has been specifically tested to be safe for MR under specific conditions of use (see Section II).

Scanning of any CIED that does not fulfill the criteria for MR conditionality is regarded as non-MR conditional. This includes an MR conditional generator combined with nonconditional components and device systems that combine individual MR conditional lead and device components from various manufacturers (see Section II), given these are not combinations specifically tested together for conditional labeling. Conditional labeling also specifies the location of the CIED generator (such as a pectoral location for a transvenous system). Other examples of nonconditional components include epicardial leads, abandoned leads, fractured leads, or an active noncardiac device.

Programming of the device outside of the MR conditional programming mode would also make the scan MR nonconditional. Other conditions of use require adequate battery longevity. MR conditional scanning specifies the static magnetic field strength and allowed scanning parameters, such as landmark isocenter of the static and gradient magnetic fields, type of imaging coil, patient position, scanner operational mode, and maximum RF energy and SAR.

ii. Evidence Review

The evidence for MRI scans in patients with nonconditional CIEDs arises from retrospective and prospective series and registry studies. Table B2 in Appendix B summarizes the evidence.

Between 1984 and 1996, numerous case reports and small series investigated MRI (both 0.5 and 1.5T) effects in patients with PMs.[7,46–52] In general, these studies found no significant adverse effects to the leads, generator, or patient. However, Fontaine et al[53] reported rapid cardiac pacing during a 1.5T MRI in a patient with a dual-chamber PM. Other adverse events published in case reports include inappropriate shock, power-on reset, and high lead impedance.

Several small CIED patient cohorts ($N<100$ patients) undergoing MR scanning have been reported in the literature.[13,48,54–60] Overall, MR scanning was performed safely. Electrical resets were rarely seen and were successfully reprogrammed.[61] Pacing thresholds were noted to increase,[61] but rarely required a change in programming. In one series,[61] battery voltage was also reported to decrease immediately after the scan, but returned to normal at 3 months.[61] In two case series, troponin values were assessed.[59,61] Troponin was increased in one patient who had an increase in pacing threshold[61] in one case series, whereas no changes in troponin were observed in another case series.[59] Defibrillation thresholds were assessed in a series of 38 patients with an ICD or CRT-D device, with no change seen.[55]

In larger case series, MR scanning has also proceeded without clinical adverse effects. In one series of 103 patients by Mollerus et al,[62] there was a statistically significant (but not clinically significant) decrease in sensing amplitude and pacing impedance. Cohen et al[63] compared lead data from a single-center retrospective review of 109 patients with PMs and ICDs who underwent MRI with data from a prospective cohort of 50 patients with cardiac devices who did not undergo MRI (the control group). In the MRI group, there were no device failures, induced arrhythmias, loss of capture, or electrical reset. A small number of clinically relevant changes in device parameters were noted in the MRI group, but these changes were similar to a control group who did not undergo MRI, raising the possibility that these changes could be due to natural variation.

Friedman et al[64] reported a single-center prospective study of 171 patients who underwent 219 scans, including 8 patients who were recently implanted (7–36 days), with no differences observed between the early and late implanted groups in terms of device function parameters, and no complications in the entire cohort, supporting the feasibility of MRI in patients with recently implanted CIEDs. Muehling et al[65] reported a single-center prospective study of 356 patients with a CIED who underwent cranial MRI at 1.5T. Patients with complete heart block were included and comprised 20% of the cohort. There were no complications or arrhythmias, nor were there significant changes in pacing capture or sensing. Nazarian et al[13] tested a protocol for performing MRI scans at a strength of 1.5T in patients with implanted devices. They performed 555 scans on 438 patients

(54% PMs, 46% ICDs) and included pacing-dependent patients (N = 53) with a PM. No adverse clinical events were observed. A power-on reset occurred in 3 patients without long-term effects. Minor changes in lead parameters were observed but did not require programming changes.

The MagnaSafe Registry[66,67] was a multicenter prospective study to determine the risk of nonthoracic MRI scans at 1.5T in patients with PMs and ICDs. PM-dependent patients with an ICD were excluded. Nonthoracic MRI studies were performed (N = 1000 with PMs and N = 500 with ICDs), and included pacing-dependent patients (N = 284) with a PM. No deaths, device failures, generator/lead replacements, loss of capture, or ventricular arrhythmias occurred during MRI. Episodes of self-terminating atrial fibrillation occurred in 5 patients, and 6 instances of partial electrical reset were observed. One patient with an ICD had not been programmed appropriately for scanning and subsequently required generator replacement. Repeat MRI scanning was not associated with adverse events. Additionally, MRI was performed within 90 days of implantation in 46 patients with PMs and 17 patients with ICDs, with no correlation observed between lead performance (sensing amplitude, pacing threshold, or impedance) and time from lead implantation.

Abandoned Leads:

Radiofrequency heating can induce myocardial heating and raises concern over performing MRI scans in patients with abandoned (endocardial or epicardial) leads.[51,68] It has been suggested from *in vitro* studies, that MRI with abandoned PM leads exhibited greater lead tip heating compared with PM-attached leads using lead lengths of 40–60 cm.[69] In a series of 114 patients (which included an unreported number with abandoned leads) who underwent low-power MRI scans (<0.5T), Strach et al observed that MRI scans were completed safely without significant changes in lead or device parameters.[70] Patients with abandoned leads showed no symptoms or arrhythmias related to the MRI scan, but a limitation is that details of this subgroup are not provided.

Higgins et al examined outcomes of MRI scans performed on 19 patients with a mean of 1.63 abandoned leads, including three ICD leads. This was a protocol prior to 2008, when patients with a CIED who required an MRI had the generator removed for the MRI scan, then were reimplanted with a new generator afterward if deemed clinically appropriate. At that time, it was thought that MRI scanning was safer with abandoned leads than with the generator in place. A generator was reimplanted in 12 of the 19 patients. Most of the scans (31 of 35) were of the central nervous system. In the 7-day follow-up, no adverse clinical events or changes in pacing threshold were noted in the patients in whom a generator was reimplanted.[68]

Epicardial Leads:

Published safety experience with MRI of permanent epicardial surgical leads is limited. Some investigators have noted greater heating in such leads using *in vitro* models, which is possibly explained by the lack of blood flow. In a letter, Kanal cautioned that higher gradient fields and selection of imaging site could lead to cardiac stimulation from an epicardial lead.[71] Small case series have shown successful MRI in pediatric patients with congenital heart disease. Pulver et al performed 1.5T scans, including 4 cardiac, in 11 young patients (mean age 9.2 years [range 1.7–24.5]) with PMs. The series included nine epicardial leads. No inappropriate pacing or significant changes in generator or lead parameters were noted.[72]

Scanning at >1.5T:

Few studies have analyzed outcomes in patients who have undergone scans at greater than 1.5T. Naehle et al evaluated the safety and feasibility of 3T brain imaging in patients with PMs. A transmit-receive head coil was used to measure force and torque. In 41 patients who had 51 MR exams, no safety events, rises in troponin, or changes in lead parameters were recorded. Patients with complete atrioventricular (AV) block were excluded from this study.[73]

Gimbel et al studied 14 patients who underwent 16 MRI scans at 3T without restriction on PM dependency, the region scanned, or the device type. A programming strategy using OOO mode in nondependent patients and asynchronous pacing at highest output in dependent patients was used. All the patients were scanned without clinical incident or change in device parameters.[74]

PM dependence, however, is an important consideration. Gimbel reported asystole during a 3T brain scan in a pacing-dependent patient. In this case, reversion to back-up mode (VVI mode) occurred during the scan, and device inhibition from noise resulted in asystole.[12] It should be noted that reversions to a backup mode due to a power-on reset can occur at any magnetic field strength.

iii. Recommendations and Protocol for the Management of Patients with an MR Nonconditional Device Undergoing MRI

For an estimated 8 million people worldwide, the presence of an MR nonconditional PM or ICD has been considered an absolute or relative contraindication to MRI. This lack of access has created a dilemma because many of these patients might need an MRI examination during their lifetime after a cardiac device has been implanted.[75] When MRI is determined to be the imaging examination of choice without an acceptable alternate modality for a particular patient or disease entity, a discussion regarding risks and benefits is needed in collaboration with a CIED cardiologist and an MR physician before the examination is performed. A standardized institutional policy (Appendix A) should be developed that includes an assessment of the benefits of MR imaging compared with alternative imaging modalities, protocols for prescan and postscan CIED evaluation, appropriate programming during the scan based on device and patient characteristics, and procedures in the event of an adverse clinical event. The protocol should be practically implemented, including the use of checklists (see Figure 3 for one example). A flowchart depicting these recommendations is given in Figure 2.

Recent registry studies examining the risk of MRI for patients with a CIED did not restrict imaging to a specific vendor of MR scanners or field strength. However, the majority of clinical experience of MRI with a CIED has been obtained at 1.5 Tesla with a lesser number of patients imaged at other static magnetic field strengths. In addition, MRI has been primarily performed using Normal Operating Mode of the scanner. This mode restricts the MR technologist from exceeding vendor-determined SAR limits and is intended to promote safety without defining an examination-specific power limit or position of the device or leads within the magnet.

d. Inadvertent Exposure of Patients with a CIED to MRI

Unintended MR Scanning of a Patient with a CIED

There could be scenarios in which a patient is inside the MR scanner or has even undergone (partial) MRI before it becomes apparent that the patient has a CIED. It is appropriate in this situation to interrupt the scan and monitor the patient until a full CIED evaluation is performed. Future scanning should be conducted in line with the recommendations under Section Vb-iii (MR conditional systems) or Vc-iii (MR nonconditional systems).

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

COR	LOE	Recommendations	References
IIa	**B-NR**	**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.**	9,13,49,55,56,58–63,65,67–69,72,77–79

Several recent clinical registries of varying size have examined the risk of clinically indicated MRI for patients with MR nonconditional CIEDs (PMs, ICD, CRT-P, or CRT-D). These studies are reviewed in Section Vc-ii and overall have largely reported successful MRI scanning without clinically significant changes in CIED function or patient harm. A standardized collaborative institutional policy (Appendix A) should be developed to clearly identify inclusion and exclusion criteria as well as personnel responsibilities and workflow. Such workflow should include assessment of the benefits of MR imaging compared with alternatives, protocols for pre- and postscan CIED evaluation, and appropriate programming during the scan based on device and patient characteristics. The protocol should be practically implemented, including the use of checklists (see Figure 3).

Due to the risk of lead heating and in some cases the inability to accurately assess the electrical properties of the leads prior to MRI, fractured leads, epicardial leads, and abandoned leads have been excluded from these registries and most single-center studies. *In vitro* studies suggest that MRI with abandoned PM leads exhibited greater lead heating compared with leads attached to pulse generators using lead lengths of 40–60 cm.[69] In a small clinical study of 19 patients, the use of MRI in patients with abandoned cardiac device leads performed in awake patients under careful monitoring with voice communication with monitoring nurses resulted in no adverse events, and MRI did not affect the function of leads that were subsequently reconnected to a cardiac device.[68] At the present time, however, there are insufficient data to comment on the safety of MRI performance with abandoned, epicardial, or fractured leads. Postsurgical temporary epicardial leads that have been partially removed are not considered to be abandoned pacing leads.[2]

IIa	**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.**	58,63,64,67,80

Limits have previously been placed on the minimum time between lead and generator implantation and MR imaging for patients with MR conditional CIEDs. Because lead dislodgements are more likely to occur in the immediate postimplantation period, a 6-week waiting period was adopted in clinical trials of MR conditional PMs to avoid confusion as to whether a lead dysfunction was related to performance of the MRI scan. In a single-center prospective cohort of 171 patients that included 8 patients with recently implanted systems (7–36 days), there were no differences in device function observed between patients scanned early or late after CIED implantation.[64] In the MagnaSafe registry, there were 63 cases in which MRI was performed within 90 days of implant, 17 cases in which MRI was performed within 30 days of implant, and 5 cases in which MRI was performed within 7 days of implant; there was no correlation between changes in lead performance (sensing, pacing threshold, or impedance) and time from implantation.[67] These data support the feasibility of MRI in patients with recently implanted CIEDs.

IIa	**C-LD**	**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.**	13,57,63,67

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. Studies that included patients with multiple MRI scans have not shown changes in device function related to the number of MRI scans performed or the interval between studies.[13,57,63,66]

Recommendations for the Management of Patients with an MR Nonconditional CIED Who Are to Have an MRI scan			
COR	LOE	Recommendations	References
I	B-NR	**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.**	13,58,63,67

To determine whether changes in generator or lead function have occurred during MRI, a full device interrogation is performed immediately before and immediately after MRI. The interrogation should include a new measurement of pacing thresholds, P- and R-wave amplitudes, and lead impedance. A checklist or standardized device interrogation is presented in Figure 3.

Battery voltage is determined prior to the scan to identify a device at or near ERI or end of life (EOL), given these devices could be more vulnerable to power supply disruption, memory corruption, changes in programmable device variables, and partial or full electrical device reset during MRI. The high-energy challenge presented by the MRI environment and inductive/telemetry device interrogation creates a temporary decrease in measured battery voltage, which in clinical practice requires a re-equilibration period of several weeks.

I	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.**	9,13,63,67,81

A defibrillator/monitor with capacity for external cardiac pacing and a manufacturer-specific device programming system are kept in the patient holding area adjacent to the MR scanner room while the patient with an MR nonconditional CIED is reprogrammed for imaging. However, it should be recognized that all external cardiac defibrillators/monitors and all device programming systems are MRI-unsafe and cannot enter the scanner room (Zone 4) under any circumstance.[2] The manufacturer-specific device programming system must remain immediately available while the device is reprogrammed for imaging, not only to minimize the time between scanning and reprogramming, but also due to the possibility of an unanticipated event, and the need for urgent device reprogramming.

I	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.**	13,63,67

Prior to MR imaging, a CIED can be reprogrammed to an inactivated, inhibited, or asynchronous pacing mode, whereas ICD tachyarrhythmia therapies are always deactivated. During the time that a device has been reprogrammed to accommodate the MRI environment, continuous monitoring is required.[13,63,67] There is also commonly live contact with the patient throughout the scan via visual and voice contact (or as clinically appropriate if mental status is altered or patient is intubated). If an emergency arises, such as ventricular pacing inhibition in a previously unrecognized, intermittently pacing-dependent patient, then appropriate emergency actions can be undertaken as specified in the institutional protocol (see for example, Appendix A).

An MR-safe heart rate and rhythm monitor and transcutaneous pulse oximetry are required for patient safety, as well as the ability to directly observe the monitor from the adjacent control room. Although continuous monitoring of the cardiac rhythm is the primary objective, the ECG might not be interpretable during the use of many MR sequences that induce significant electrical artifact. However, transcutaneous pulse oximetry is relatively unaffected during MR sequences and thus can confirm a change in pulse rate in the absence of a technically adequate ECG signal. Special attention to ECG electrode positioning and skin preparation can optimize ECG monitoring and minimize potential artifacts from monitor lead movement.

I	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.**	13,63,67

With CIED reprogramming to a pacing mode with the potential to create a clinically unstable arrhythmia (VOO/DOO), or inactivation of ICD arrhythmia recognition and therapy, the presence of medical professionals able to acutely recognize and treat a significant change in cardiac rhythm or a change in hemodynamic stability is important. Personnel with the skill to recognize the above, the expertise to perform advanced cardiac life support, and to perform transcutaneous pacing or cardioversion/defibrillation are vital to the safe performance of MRI for the patient with an MR nonconditional CIED.[13,63] These personnel are required to be in attendance with the patient for the duration of time the patient's device is reprogrammed for scanning, until assessed and declared stable to return to an unmonitored status.

I	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.**	13,63,67

(*Continued*)

COR	LOE	Recommendations	References
		For patients who are pacing-dependent with an MR nonconditional CIED, additional personnel are needed. Personnel with the skill to program the CIED should be in attendance during MR scanning, a physician who can establish temporary transvenous pacing should be immediately available on the premises, and a physician who can direct CIED programming should be immediately available on the premises, in accordance with reported clinical study protocols.[13,63] It must be remembered that CIED programming cannot be performed in the MR scanner room (Zone 4), and if necessary, the patient would need to be quickly moved to an area where the device programmer can be used safely.	
I	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.**	13,63,67
		For patients who are not pacing-dependent with an MR nonconditional CIED, it is recommended to have available on the premises personnel with the skills to program the CIED as well as a physician able to direct the CIED programming in accordance with reported clinical study protocols. These skills include the ability to provide age-appropriate programming for pediatric patients.[13,63]	
I	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.**	9,13,63,67,80
		For pacing-dependent patients undergoing MRI, their CIED is placed in a device-appropriate asynchronous pacing mode (D00/V00/A00) with deactivation of advanced adaptive features (Table 4). The asynchronous pacing rate will be determined by the CIED physician to avoid potential competition from an underlying native rhythm and to minimize the risk of pacing-mediated arrhythmia regardless of the patient's underlying rate and rhythm. For pacing-dependent patients with both atrial and ventricular pacing leads, an asynchronous D00 mode will be selected. For patients with a single-chamber device, an appropriate single-lead asynchronous pacing mode (either V00 or A00) will be selected. If the device has only an active atrial lead, and an asynchronous atrial pacing mode (A00) is not available, then the device will either be programmed at the discretion of the CIED physician, or the patient will be determined not to be an acceptable candidate for imaging. It should be remembered that the presence of an intermittent underlying rhythm not suppressed by asynchronous pacing can lead to vulnerable-period ventricular activation and the initiation of a potentially life-threatening ventricular tachyarrhythmia. DDD mode can potentially lead to atrial sensing and ventricular pacing based on RF energy of the MR pulse sequence rather than true atrial depolarization. Thus, for the pacing-dependent patient with both atrial and ventricular leads, a D00 pacing mode is recommended. In addition, patients with a cardiomyopathy of any etiology could have a significant and intermittent burden of ventricular ectopy. Programming the device of such a patient to an asynchronous pacing mode could also increase the potential of vulnerable-period ventricular activation. This requires the input of the CIED physician for the selection of a pacing rate and mode that avoids competitive pacing.	
I	B-NR	**All tachyarrhythmia detections for patients with an ICD should be disabled prior to MRI.**	13,59,62,67
		During MRI for patients with an MR nonconditional ICD, anti-tachyarrhythmia functions (sensing and treatment) are inactivated regardless of pacing-dependent status, and per protocols in published studies.[13,59,62] For patients who are pacing-dependent, some might have an MR nonconditional ICD incapable of an asynchronous pacing mode while anti-tachycardia therapies are disabled; this could preclude the ability to perform an MRI if the appropriate programming cannot be achieved. If ICD tachyarrhythmia sensing and therapy functions remain active during MRI, replacement of the device might be required after the examination if disruption of the pulse generator's functional status occurs.[82] With anti-tachycardia therapy active, the device will sense and misinterpret the MRI pulse-sequence as a tachyarrhythmia and will attempt to deliver therapy for ventricular fibrillation. Repetitive unsuccessful attempts will then be made to charge the capacitor within the magnetic field, although no shocks will be delivered. Then, during post-MRI evaluation, ICD device failure may be documented, requiring generator replacement.	
I	C-EO	**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.**	

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COR	LOE	Recommendations	References
		The MR-responsible physician is accountable for overseeing the safety of the MRI environment, including the administration of any medication and/or contrast agents during the imaging examination. Before MRI, this physician (who may be a radiologist or other nonradiologist physician including a cardiologist), once made aware of a patient with an MR nonconditional CIED, will oversee the examination and will be responsible for managing the appropriate team of medical professionals required. Overall, communications between the ordering physician, the CIED physician, and the MR-responsible physician are important to the performance of MRI for patients with an MR nonconditional CIED.	
I	**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.**	
		Patient monitoring by ECG and pulse oximetry should be continued during the entire time that the patient's device is reprogrammed for imaging. Following the completion of the MRI examination, the CIED is evaluated and reprogrammed to baseline, or other clinically appropriate parameters. After restoration of baseline pacing parameters, ECG and pulse oximetry monitoring can be discontinued.	
I	**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.**	
		There are unique challenges for resuscitative efforts in the MRI environment, and the first concern is to quickly and safely move the patient from the MR scanner room (Zone 4) to an area where resuscitative efforts can be performed safely. The institutional protocol should specify a zone determined to be magnetically safe close to the scanning location, where emergency equipment that is not MRI-safe can be used and emergency treatments can be administered.	
IIa	**B-NR**	**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.**	13,58,61–63,67
		When reprogramming either a PM or ICD in preparation for MRI, the first level of assessment is to determine pacing dependence. The minimum pacing rate is decreased slowly to 40 bpm and the underlying rhythm is documented. If the patient is asymptomatic with a sustained and reliable intrinsic rhythm of >40 bpm with hemodynamic stability, he or she is determined to be not pacing-dependent. If the underlying cardiac rhythm is <40 bpm, or if symptoms of presyncope, lightheadedness, or hemodynamic instability are noted in the upright or supine position with an intrinsic heart rate of <40 bpm, then the patient is determined to be pacing-dependent. Regardless of the underlying rhythm and rate, decisions regarding pacing dependence may be based upon the discretion of the CIED physician. The DDD mode should not be used because it can lead to tachycardia due to ventricular pacing at the maximum tracking rate in response to inappropriate sensed RF-energy of the MR pulse sequence as an apparent atrial depolarization. For patients undergoing MRI who are not pacing-dependent, it is reasonable to program their CIED to either a nonpacing mode (ODO/OVO/OAO) or to an inhibited mode (DDI/VVI/AAI); the latter is reasonable if the underlying rhythm is determined to be stable but slow. For patients with a device that cannot be programmed to an appropriate nonpacing mode (ODO/OVO/OAO), the device can be programmed to either an inhibited mode or an asynchronous (DOO/VOO/AOO) pacing mode, with pacing output and rate set at the lowest allowable values, with confirmation that these are subthreshold to avoid competitive pacing. In addition, advanced or adaptive features are deactivated for scanning (see Table 4).	
IIa	**C-EO**	**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.**	
		For patients with cardiomyopathy benefitting from biventricular pacing therapy for heart failure, the deactivation of pacing functions or temporary reprogramming to a nonbiventricular pacing mode could have significant negative hemodynamic consequences. For these patients, it is reasonable to program the CRT device to an asynchronous pacing mode (VOO/DOO), with deactivation of advanced or adaptive features, including the triggering of a biventricular pace upon sensing a ventricular signal (Table 4), and with a pacing rate that avoids competitive pacing with an underlying rhythm. This process prevents the potential for vulnerable-period ventricular activation and the initiation of a potentially life-threatening ventricular tachyarrhythmia.	

(*Continued*)

COR	LOE	Recommendations	References
IIa	**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.**	

After MRI, before noninvasive monitoring is discontinued, CIED evaluation is performed (Figure 3), including an evaluation of pacing lead thresholds, P-wave and R-wave amplitudes, as well as pacing and shock lead impedance. The CIED is then programmed back to baseline or clinically appropriate settings. Battery voltage may be reassessed after the MRI examination, but the high-energy challenge of the MRI environment and device evaluation can create a temporary decrease in measured battery voltage, which in clinical practice requires a reequilibration period of several weeks. Thus, a change in measured battery voltage should be anticipated after MRI.

A change in programmed device parameters is defined as the Post-MRI – Pre-MRI difference. For patients with an MR nonconditional CIED, if a pacing lead threshold increase ≥1.0 V is noted, P-wave or R-wave amplitude decreases by ≥50%, pacing lead impedance changes (increases or decreases) by ≥50 Ω, or high-voltage (shock) lead impedance changes (increases or decreases) ≥5 Ω, it is reasonable to schedule a complete follow-up CIED evaluation within 1 week. Otherwise, routine CIED follow-up is appropriate.

e. Deciding on the Type of CIED System for a First Implantation or Replacement

How to best determine the initial device remains a matter of debate. More than half the patients having an implanted CIED could be confronted with an indication for MRI later in life.[75] It might seem obvious to choose an MR conditional system at first implantation. However, there are cost considerations that could impact upon the decision whether to implant an MR conditional or nonconditional system. Aside from the hardware cost of an MR conditional system itself, one must consider that an MR nonconditional system could require a more complex workflow to perform the MR scan, which might impose additional costs. Difficulties with patient access to off-label scanning and important, potentially large, out-of-pocket costs to patients who do not have an MR conditional device could also be relevant. Other considerations that can favor the implantation of a nonconditional system include a preference to implant leads and generator from different manufacturers, or to implant the generator in a nonpectoral location. These considerations should be balanced when choosing the CIED system details.[76]

When patients with an MR nonconditional system undergo generator replacement, the existing leads might have gained MR conditional status, which could impact the decision whether to replace with an MR conditional generator. However, if the existing leads are not MR conditional, then implanting an MR conditional device (even when adding an MR conditional lead) will still render the system nonconditional in the presence of the old MR nonconditional leads. Although the option of extracting nonconditional leads to allow implantation has been discussed in the past, given the relative safety of scanning nonconditional systems (see Section Vc), compared with extraction, there are few or no situations in which extraction would be the safer option. Another scenario to consider is whether to maintain a dual-chamber CIED system in patients coming for generator change who no longer need atrial pacing, such as in permanent atrial fibrillation, because downgrading to a single-chamber system would result in an abandoned lead.

f. Implantable Loop Recorder

COR	LOE	Recommendations	References
I	**B-NR**	**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.**	74,81,83–85

Artifacts can be recorded by the ILR during MR scanning, which can mimic asystole, ventricular tachycardia (VT), and supraventricular tachycardia (SVT),[74,81,83–85] and potentially misguide clinicians to recommend the implantation of PMs or ICDs, or cause the performance of unnecessary electrophysiological studies and ablations. These artifactual events can be so numerous as to cause the deletion of previously recorded events. For this reason, it is recommended to evaluate the ILR prior to MR scanning and download and remove any desired previously recorded events; and following MR scanning, to clear artifactual events that occurred during MR scanning.

COR	LOE	Recommendations	References
I	**C-LD**	**MR scanning of MR conditional ILRs should be performed within labeled scanning prerequisites specific to each device manufacturer.**	74,81,83–85

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COR	LOE	Recommendations	References
		The currently available ILRs are classified as MR conditional by their manufacturers for use at both 1.5T and 3.0T field strengths. In addition, several studies have demonstrated that ILRs are safe to scan at 1.5T field strength[81,84,85] and 3.0T.[74,83] The largest study assessed 24 patients with paroxysmal atrial fibrillation wearing the Reveal XT ILR during and after 62 brain MRI scans performed at 3.0T field strength.[83] All the patients were interviewed for potential ILR-associated clinical symptoms, and data from the ILR were transmitted before and after the MRI examination. In this study, all the patients were clinically asymptomatic during the MRI procedure. In one patient, an MRI-induced artifact was recorded by the ILR, mimicking a narrow-complex tachycardia. In all the studies, following MRI scanning, all the patients were asymptomatic, without device movement, or patient-reported heating. In addition, the functionality of all the devices remained unaffected.	

g. Employee Safety

Health care workers who have a PM or ICD could intentionally or unintentionally find themselves in proximity to the MR suite. These workers include physicians, physicists, technologists, nurses, building and maintenance personnel, and security, as well as emergency first responders who do not typically work in the MR suite. These workers with a CIED, regardless of MR conditionality, are a special group that can be at risk within the MR environment.

COR	LOE	Recommendations
I	C-EO	**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.**
		Exposure to both the static magnetic field as well as the time-varying RF and gradient magnetic fields during active scanning can pose a risk to workers with a CIED. Modern CIEDs can be sensitive to field strengths as low as 5 gauss. Electromagnetic interference can result in oversensing, which, depending on the device and patient characteristics, could have detrimental effects, including pacing inhibition, erroneous tachycardia detection, and inappropriate attempts to deliver therapies. Other potential risks include programming changes, reed switch activity, and power-on reset (see Section III). Workers with MR conditional CIEDs are also susceptible to many of these risks because the device would not be specifically programmed for safe exposure to the MR environment. Therefore, it is recommended that the MR suite identify the 5 gauss boundary and to warn individuals to stay outside of this boundary at all times. This recommendation applies regardless of whether or not the CIED is MR conditional.

h. Pediatric and Adult Congenital Heart Disease Populations

The recommendations in this document are intended to apply to all patients with a CIED. However, pediatric patients as well as pediatric and adult patients with congenital heart disease who have a CIED are an important population deserving additional consideration related to the recommendations.

Children are not simply "small adults." Clinical and computer modeling safety studies related to imaging adult patients with a CIED might not be directly translatable to this population, given physiologic and anatomic differences. These patients typically have undergone implantation of a PM or ICD at a young age, ranging from infancy to adolescence. As a result, they will have multiple generator changes and possibly entire system revisions over their lifetime. Patients with complex palliated and repaired heart disease, such as tetralogy of Fallot, transposition of the great arteries, hypoplastic left heart syndrome, and other forms of single ventricle disease, will undergo multiple cardiac operations, typically prior to reaching young adulthood. For these patients, MRI is a preferred tool for evaluating anatomy, cardiac function, and myocardial viability, given the lack of radiation. Although other forms of nonradiation imaging are possible, such as echocardiography, MRI has superior spatial resolution. In addition, in many forms of congenital heart disease, repeated MRI throughout development is indicated to develop appropriate medical and interventional treatment plans. Therefore, decisions related to imaging, as well as CIED implantation, in this population are complex and ongoing, and require careful consideration of the risks and benefits.

CIED implantation in children with or without congenital heart disease and in adults with congenital heart disease can differ significantly from that in adults with normal cardiovascular anatomy. Infants with congenital or surgically acquired complete heart block requiring pacing will undergo implant of an epicardial single- or dual-chamber system with subcutaneous generator placement over the abdomen. By late childhood, depending on size and cardiac anatomy, conversion to a more conventional transvenous system might be performed with usual removal of the generator from the abdominal position. However, the epicardial leads are typically abandoned in place. Therefore, in many pediatric patients who might have placement of a transvenous MR conditional system, the presence of abandoned epicardial leads makes the entire system MR nonconditional.

In patients with complex forms of congenital heart disease, conversion to a transvenous system might be impossible. In these patients, revisions of the lead system can require repeat median sternotomy, thoracotomy, or other forms of invasive access to the epicardium in order to place new leads. Frequently, epicardial pacing leads are placed

and capped in anticipation of future need for use, such as progression of sinus node dysfunction in patients after a Fontan-type operation. Commonly, during placement of epicardial leads in patients with complex congenital heart disease, multiple leads, including bipolar and unipolar types, can be placed in the same operative procedure due to difficulty finding an epicardial location with adequate pacing thresholds. ICD lead placement in infants, children, and those with complex congenital heart disease follows similar nonconventional methods and at times requires on-the-spot creativity to achieve successful implantation.

MR conditional pacing or ICD systems are desirable in this patient population, and the ability to perform repeated MRI could be beneficial in the patient's care. However, in the current era, the predominance of MR nonconditional systems implanted in these patients warrants careful and thoughtful evaluation of imaging needs. There are few studies in pediatric patients related to imaging nonconditional systems and safety. Pulver et al[72] studied MRI in a small set of pediatric patients with congenital heart disease and PMs ranging from 1.7 to 24.5 years of age with *nonconditional* systems. They studied 11 MRI scans in 8 patients, including MRI of the heart, brain, and spine, specifically excluding patients with abandoned leads, but including 9 patients with epicardial lead systems. In this study, there were no detected adverse effects. A more recent study[86] was performed in an adult congenital heart disease population without epicardial or abandoned leads but with an MR *conditional* system, which suggested safety without adverse device or patient effects. Nonetheless, there are a paucity of data to determine level of risk of device or patient effects during MRI of a nonconditional system or of a conditional transvenous system implanted in an unexpected manner in patients with congenital heart disease.

As device manufacturers continue to advance MR conditional technology, it is an expectation and hope that MR conditional epicardial systems will be developed. However, currently, decision making on a patient-by-patient basis must be made related to implantation of an MR conditional generator requiring an epicardial lead system. The current combination of an MR conditional generator and epicardial lead set renders the entire system MR nonconditional, as described previously in this document. Given the paucity of data related to the safety of MRI in this situation, recommendations cannot be made. Careful consideration of patient risk and benefit must therefore be made on a case-by-case basis. In this population, there are multiple other areas of consideration, but without data to support any particular approach, many questions remain unanswered. For example, in a patient with an epicardial lead system who is large enough to transition to a transvenous system, should the epicardial lead sets be surgically removed in order to convert to an MR conditional system if a clinically necessary MRI is anticipated in the future? In a patient with retained epicardial leads undergoing cardiac surgery for other reasons, should the surgeon be encouraged to remove previously abandoned epicardial leads to facilitate future MRI? Again, given lack of data related to risks and safety, these situations require thoughtful, collaborative, clinical decision making with detailed and careful consideration of patient risk and benefit.

It is appropriate that a pediatric patient with a CIED who has normal cardiac anatomy and who meets all criteria for having an MR conditional CIED system (with no abandoned leads or other circumstance to render the system nonconditional) could undergo imaging following the MR conditional recommendations in this document. For all other situations, however, it is appropriate to seek consultation with a pediatric cardiologist or congenital electrophysiologist for pediatric patients and with an adult congenital heart disease specialist for adult patients with congenital heart disease.

Section VI: Management of Patients with a CIED Undergoing CT Imaging

a. Evidence Review and FDA Advisory

Since its introduction for clinical diagnostic imaging in the 1970s, CT has traditionally been considered safe for patients with CIEDs, including ICDs and permanent PMs. A summary of the evidence is available in Table B3 in Appendix B.

However, potential temporary interactions between CT and CIEDs are possible due to the emission of electromagnetic ionizing radiation during CT imaging (electromagnetic energy of very short wavelengths) resulting in electromagnetic interference. Exposure of the metal oxide semiconductor circuitry to ionizing radiation can result in buildup of charge in the silicon dioxide insulators and leakage current within the circuits, thus creating the potential of oversensing, with PM inhibition, tracking, or power-on-reset.[87,88] These changes are temporary, and would occur only when the sensor circuits of the CIED are within the CT beam (i.e., device can, not device leads). Permanent damage is not expected from diagnostic X-ray exposure.[89]

Interaction between the CT beam and the CIED generator is rare, but has been reported in several *in vitro* studies[90–92] as well as in a few clinical case reports,[93–96] confirming the possibility of temporary pacing inhibition. Yamaji et al reported CT-PM (all Medtronic) interaction in 6 of 11 patients using 4-slice spiral CT, resulting in tracking on the atrial channel and oversensing, with 4 seconds of ventricular pacing inhibition as well as temporary asynchronous pacing.[97] In a Medtronic-supported follow-up *in vitro* study using a 16- and 64-slice CT with spiral and dynamic mode, McCollough et al tested 13 PMs and 8 ICDs (all Medtronic) using an anthropomorphic phantom. When the X-ray beam passed directly over the sensing circuit, oversensing with tracking or pacing inhibition and ventricular safety pacing were observed. Partial electrical reset, a safety feature that resets pacing parameters to specific default settings, occurred in 2 devices at maximum CT doses. All the devices were investigated after CT exposure and passed quality assurance testing.[98] These reports, together with a publication of the ECRI Institute[99] and a small number of directly communicated events, prompted the FDA to release a public health warning on July 14, 2008[100] that the exposure to X-ray

radiation during CT scanning could interfere with proper function of some electronic devices, including PMs and ICDs. Reported events included power-on reset, battery depletion, detected noise, changes in device programming (reset to default, shock counter resetting), inappropriate ICD shocks, capacitor charging, corrupted memory, communication or interrogation issues, and oversensing.

A retrospective study evaluated the real-life experience of 516 CT scans on 332 ICDs and 184 PMs at two large centers and failed to identify a single composite endpoint event consisting of death, bradycardia, or tachycardia requiring termination of the CT, or an intervention, unplanned hospital admission, reprogramming of the device, inappropriate ICD shock, or device replacement or revision thought to be due to CT interaction. Device parameter changes (e.g., impedance, thresholds, sensing, battery voltage) occurred at a similar rate as in a non-CT control group.[101]

Although the original 2008 FDA advisory favored a very cautious approach, recommending, for example, device checks after each CT scan that covered the CIED, a recent update (3-31-2016)[102] states that "based on the available evidence, the probability of device malfunction due to CT is not clinically significant."[100]

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

COR	LOE	Recommendations	References
I	B-NR	**It is recommended that patients with a CIED undergo clinical diagnostic CT without any additional device interrogation, programming, or monitoring.**	101
		It is important to underscore the vast clinical experience that, in over 40 years of clinical CT imaging, these interactions have not resulted in direct harm or injury to patients. The retrospective study by Hussein et al evaluated the real-life experience of 516 CT scans on 332 ICD and 184 PM patients and supports the safety of diagnostic CT imaging in patients with a CIED. If the diagnostic CT study is deemed clinically indicated to guide the further care of the patient, the prior implantation of a permanent PM or ICD should not delay or prevent the required imaging study.	
IIa	C-EO	**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.**	
		Although rarely clinically needed, 4D CT (e.g., used for perfusion imaging) or cone-beam CT can result in prolonged CIED generator exposure to ionizing radiation. Alternative imaging planes that avoid the PM or defibrillator generator can frequently provide the same diagnostic yield and minimize the very small risk of CT/CIED interaction.	
IIb	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.**	
		Most CT studies today are performed as spiral (helical) studies with continuous X-ray tube rotation and simultaneous table motion. During this scan mode, the CIED device is only for a very short time in the CT beam, resulting in no clinically significant interactions. For some indications, however, axial scans might be preferred (e.g., angiography or interventional procedures) with stationary CT beam position, during which a prolonged exposure of the CIED generator to the CT beam (>30 s) is possible. In these circumstances, there is the concern for the potential of oversensing and inhibition of pacing or inappropriate detection and therapies in an ICD, although clinical evidence for this is lacking. Therefore, it could 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.	

Section VII: Management of Patients with a CIED Undergoing Radiation Therapy

a. Overview

i. RT Overview

The use of ionizing radiation in the treatment of malignancies and other proliferative disorders spans over a century. The unit of measurement for absorbed radiation dose (i.e., energy deposited) is the Gray (Gy). In general, the total dose to be delivered during the course of radiotherapy is split into daily increments, or *fractions*, to allow for interval recovery of the surrounding normal tissues. A radiation course can range from a single fraction to 8–9 weeks of daily treatment, depending on the condition being treated.

Types of external beam radiation in clinical use include photons, electrons, protons, and more rarely, neutrons and carbon ions. As a general principle for any given modality, higher energies of incident radiation result in deeper penetration within tissue. Higher energies are also associated with the production of contaminating secondary neutrons, which have been implicated in the malfunction of CIEDs.

Photon-based radiation is the most common modality used in clinical practice today, typically generated and delivered by means of a linear accelerator. Multiple beams are typically designed to enter the body at various angles to converge on the target, allowing for differential sparing of nearby normal tissues. The shape and sometimes the fluence of the beam are modified most commonly with motor-driven tungsten leaves. Photon energies are described units of megavolt (MV), which is an approximate measure of the maximum energy of X-rays

produced by the treatment machine. Photon energies emitted from a linear accelerator are typically between 4 MV and 23 MV, with most machines capable of operating at two or more distinct energy levels. To clarify, the Gy measures the energy deposited (absorbed radiation dose), whereas the MV refers to the beam energy (how penetrating the radiation).

In addition to standard photon-based external beam radiation therapy, other common approaches include using radioactive isotopes that emit photons during the natural decay process, such as cobalt-60 sources used in Gamma Knife™, or Iodine-125 seeds implanted for prostate brachytherapy. Electrons are also common, and are generated from the same linear accelerator that is used to deliver photons. Electrons dissipate within tissue over a shorter distance than photons, making them well suited to the treatment of superficial targets in which sparing of deeper tissues is desired. As is the case with photons, a single linear accelerator can generate multiple electron energies (typically 4–20 MeV), with higher energies penetrating deeper into tissue. Finally, proton therapy is an increasingly available modality that uses a cyclotron or synchrotron to accelerate hydrogen ions stripped of their electrons up to an energy of 250 MeV. The energy deposited by protons abruptly dissipates at the end of their range, which spares distal tissues.

For all treatment modalities, the radiation field conforms to the target, and high doses of radiation are largely limited to this volume. However, unavoidably, the entirety of the patient is exposed to low doses of radiation. This "secondary" radiation that deposits dose away from the target originates from scatter of radiation within the patient, scatter of radiation from within the linear accelerator head, and leakage of radiation through the accelerator head shielding. Although the radiation dose decreases sharply with increasing distance from the target, the dose can still be ~1 Gy as far as 10 cm outside the edge of the target.

Under certain conditions, neutron contamination also contributes to the secondary radiation field. Neutrons are important at photon energies above approximately 10 MV. Lower energy sources, such as radioactive sources, do not produce a meaningful number of neutrons. Similarly, neutron production is not a relevant byproduct at most electron energies, although 20 MeV electrons do produce more neutrons than 10 MV photons. However, when high-energy particles or photons interact with the heavy metal within the linear accelerator head or proton gantry (or within the patient for proton therapy), neutrons are generated and scatter throughout the treatment room, forming a relatively uniform bath to which all of the patient is exposed. The amount of secondary neutron production depends predominantly on beam energy (for photon therapy) and the beam energy and delivery modality (for proton therapy). For proton therapy, secondary neutrons are a substantial feature for all energies (although higher for higher energies of proton beams). Neutron production in passively scattered proton therapy is several times more than for 18 MV photon therapy, but use of scanning proton beams can substantially reduce this. With scanning beams, neutron production occurs primarily within the patient (in the treatment field); neutrons are abundant near the treatment field (comparable to 18 MV photon therapy), but far from the treatment field there are very few neutrons (comparable to less than 10 MV photon therapy). For a summary of these modalities, please see Table 5.

ii. Risks to CIED Function

The potentially damaging effects of therapeutic radiation on a CIED can occur as a result of (1) stochastic effects related to interactions with particles of high linear energy transfer (specifically neutrons); (2) transient oversensing as a result of the dose rate employed; or (3) the cumulative dose delivered to the device.

Cumulative dose damage formed the basis of the recommendations in the American Association of Physicists in Medicine (AAPM) 1994 report,[89] which set 2 Gy as a threshold dose above which the device could be at an elevated risk of damage. This assessment was based on device studies performed in the 1980s, which showed output failures with increasing amounts of direct radiation dose and are hypothesized to occur due to the buildup of abnormal charge or current within the circuitry. This 2 Gy threshold has largely been adopted by subsequent recommendations and treatment protocols, although the dose threshold has often been raised to 5 Gy based on recent clinical reports showing limited associations between device failure and exposure to lower doses of radiation.[103–106]

Studies performed on contemporary devices report tremendous variations in the association between incident dose and device failure (Tables B4 and B5, Appendix B).

As CIED technology has evolved and radiation modalities have expanded, the predominant malfunction is the stochastic type, typically seen as recoverable resets to device memory or parameters that are not likely to cause permanent device damage. Unrelated to cumulative incident dose, these reset errors have been found to occur in the setting of radiation with sufficient energy to cause secondary neutron production. Indeed, an association between these "soft" resets and the presence of neutrons has been well described in the field of electrical and aerospace engineering, as a result of alpha particle production when neutrons interact with the boron contained in integrated circuits.[107–111] Clinical and *in vitro* studies have shown a higher likelihood of reset with RT energies capable of higher secondary neutron production,[103,104] showing no correlation with the cumulative dose received by the device or its distance to the treatment field.[112,113]

Another malfunction described in the literature consists of transient signal interference, wherein the device oversenses electromagnetic signals during the time of radiation exposure. Electromagnetic interference from the linear accelerator (LINAC) does not appear to cause clinical effects,[89] although there is the potential for inhibition of pacing or inappropriate detection of a ventricular arrhythmia and ICD therapy.[104] Other clinical malfunctions reported include changes in pacing thresholds[106] and premature battery depletion or device failure in *in vitro* studies.[112–115]

Malfunctions described in *in vitro* studies include software errors resulting in a partial reset with loss of memory

Table 5 Secondary neutron-producing radiation in various commonly used radiation modalities

Radiation modality	No relevant neutron production	Marginal neutron production	Clinically significant neutron production
Photons	<10 MV	10 MV	>10 MV
Electrons	<20 MeV	≥20 MeV	
Protons			All clinically used energies
Radioactive isotopes (cobalt-60, brachytherapy)	All clinically used modalities		

or programming changes; transient signal disturbances intermittently resulting in oversensing; full reset (restoration of factory-programmed settings); and complete device failure.[112,114,116–118] *In vitro* studies vary in methodology, particularly with respect to the placement of devices directly in the beam or outside the radiation field. The aforementioned effects on CIED function relate to consequences to the device generator. There are insufficient data to suggest CIED leads are sensitive to RT effects.

iii. Risks to Patients

Despite these potential mechanisms of interaction between radiation and device, clinical reports of symptomatic malfunctions in humans are rare.[103,104,113,119–124] The clinical consequences of a CIED malfunction depend on the medical comorbidities of the patient and the device type (PM, defibrillator, or biventricular pacing device), because patients will have differing intrinsic tolerance to the inhibition of pacing, to inappropriate pacing at maximum sensor rate, or to a loss of biventricular pacing. Reported clinical consequences have ranged from none (most common), to bradycardia, hypotension, and heart failure (all very rare events).[104] An oversensing event might lead to inappropriate delivery of ICD therapies, although no inappropriate shocks due to oversensing have been reported in the literature.

b. Evidence Review

Eligible studies used to inform the development of recommendations were identified by a search of PubMed and the Cochrane Central Register of Controlled Trials, using a publication date of January 1, 2000, through May 15, 2016. Search terms included *PM*, *defibrillator*, *cardiovascular electronic implantable device*, *radiotherapy*, and *radiation*. References of studies and articles citing the retrieved publications were also reviewed for inclusion. Observational and cohort studies were included, and case reports were excluded. There were no randomized controlled trials identified.

*Photon–*In Vitro *Studies:*

Since January 1, 2000, 12 *in vitro* studies of photon radiation effects on PMs, ICDs, or biventricular devices have been published (Table B4). In a relatively large study published in 2002, Mouton et al delivered 18 MV photons to 96 PMs in a polystyrene phantom at varying dose rates.[117] They described potentially clinically significant changes in signal amplitude >10% in 66%, permanent silence in 50%, rate slowing in 48%, pacing pause >10 s in 41%, and an accelerated pacing rate in 30%, at total doses ranging from as little as 0.05 Gy (inhibition of output >10 s) to as high as 140 Gy (permanent silence). Two studies published in 2005 by Hurkmans et al evaluated the effects of 6MV photons on 19 PMs and 11 ICDs in separate publications.[114,115] Devices were directly irradiated in a water-equivalent phantom with increasing doses delivered in fractions to a total dose of 20 Gy. After evaluation, the devices were irradiated to failure or 120 Gy. PMs showed wide variability in sensitivity to radiation; 5 had no malfunctions, 8 had pacing inhibition during RT delivery, and all but one device withstood a dose of 90 Gy or more before failure (ERI or no output).[115] ICDs appeared to be more sensitive than PMs, yet variability was marked; all ICDs showed malfunctions, 2 at a dose of 0.5 Gy, 3 at 10–20 Gy, and 6 at 80–120 Gy.[114] Mollerus et al described a loss of shock output in 4 older ICDs exposed to 6 MV photon beams, but saw no malfunctions in newer generation devices.[125] Zaremba et al reported a significant influence of beam energy in a study exposing 10 PMs and 2 ICDs directly to either 6 MV or 18 MV photons. In the 18 MV group, memory reset was observed in an ICD at 44 Gy, and all the PMs underwent parameter reset requiring programming; 1 could not be reprogrammed and 1 had battery depletion. No inappropriate oversensing was noted.[113]

The effects of scatter radiation due to neutron production were reported in a study by Kapa et al on 12 ICDs and 8 CRTs using a polystyrene phantom with devices placed outside a radiation field generated by a 6 MV photon beam.[128] No parameter changes, resets, or limitations in programming were observed in any device. Trigano et al irradiated 14 PMs with a high-flux fast neutron beam; 8 PMs functioned normally after irradiation and 6 had an electrical reset that responded to reprogramming.[127] Hashimoto et al reported on the scatter effects of 10 and 18 MV beam energy on 8 ICDs; soft-error malfunctions (transient or permanent memory loss and full reset) were more likely to be observed at a higher beam energy, suggesting the errors were due to secondary neutron generation.[126] A phantom study on 34 PMs and 25 ICDs confirmed an association between device malfunction and neutron generation.[112] After exposure to 15 MV photon beam therapy, 52% of ICDs and 18% of PMs had soft errors including reset, programming changes, and even device failure. Neutron capture was demonstrated to be significantly higher in ICDs than in PMs and was nonsignificantly greater in damaged devices.[112]

*Photon–*In Vivo *Studies:*

With the exception of three recent publications, the majority of the 12 *in vivo* studies published since 2000 on the effects of photon radiotherapy on CIEDs are small, single-center

observational reports and CIED malfunctions were rare (Table B5).[128,129]

Gelblum et al reported on a series of 33 ICD patients undergoing RT.[130] Only one malfunction was detected, and it was due to treatment with a beam energy of 15 MV for prostate cancer.[130] The patient successfully completed RT at a lower beam energy of 6 MV. Two additional patients had ICD relocations to move the device out of the beam. Three devices received >2 Gy of non–neutron-producing RT without malfunction, with a limitation of beam energy to <10 MV, supporting the hypothesis that high linear energy transfer from neutrons is a major source of CIED malfunction during RT.[130] Ferrara et al described a series of 45 patients with 37 PMs and 8 ICDs who underwent RT with 6 or 18 MV beam energy.[119] No CIED experienced a malfunction with total dosages up to 2 Gy in the PM group or up to 1 Gy in the ICD group.[119]

A prospective series of 62 patients from 29 centers in Japan with CIEDs (2 ICDs) found only one patient with a PM reset after therapy with 15 MV photons.[120] Wadasadawala et al reported no PM defects after RT in a series of 8 patients with primary tumors in various locations treated with cobalt or 6 to 18 MV photons with a cumulative dose range of 0.14 to 60 Gy to the device.[124] Precautionary measures included continuous telemetry monitoring of PM-dependent patients during the first day of therapy and weekly device evaluations.[124]

Makkar et al described a prospective evaluation of patients with a CIED undergoing RT using a pre-specified management protocol.[105] Sixty-nine patients (50 with a PM and 19 with an ICD) underwent 6 to 16 MV photon beam therapy with or without electron beams. Device relocations were performed on 5 patients because the generator was directly in the field. No device malfunctions were observed in the PM group, and 2 ICDs had a partial reset with loss of historical data. Both patients with partial reset underwent 16 MV photon beam RT.[105]

In a study of 15 ICD patients undergoing RT with 6 to 18 MV photon beams, Elders et al evaluated ICDs before and after delivery of each fraction.[122] Tachycardia therapies were programmed to monitor only during the delivery, and doses to the devices were calculated at <1 Gy. No clinical events occurred, but a partial reset was noted in 4 devices, 1 inappropriate detection was observed, and one late device data error was found 9 months after RT.[122] All events occurred in patients receiving either 10 or 18 MV photon beams. Because all the devices were located outside of the direct beam, the overall dose was low, and because malfunctions correlated with high beam energies, the authors hypothesized that the defects were due to neutron effects. A phantom model was created that confirmed neutron production at the head of the LINAC at beam energies of >10 MV.[122]

Similar findings were reported in a retrospective review of 69 patients with 50 PMs and 19 ICDs undergoing 6 to 18 MV beam energy RT. The devices received a cumulative dose of 0.01–5.06 Gy; 2 ICDs exposed to 16 MV photons underwent a reset of memory data.[131]

Three important studies, all published in 2015, had substantially larger sample sizes than prior publications. In a prospective study of 34,706 patients undergoing RT from several centers in Canada using from 6 to 18 MV photon beams, 261 were found to have a CIED (207 PMs, 54 ICDs) during screening.[103] A care protocol was used that assigned risk category based on cumulative dose (0–2 Gy, 2–10 Gy, or >20 Gy), PM dependence, and the presence of an ICD. Patients were considered high risk if they had an ICD, were PM dependent, if the device was to receive >20 Gy, or if the field was thoracic.[103] Initially, a magnet was applied to all ICDs during RT delivery, but this part of the protocol was discontinued after one year and was used only in the subgroup of ICD patients in whom the delivery field included the upper chest or neck. Three years later, magnet applications were discontinued in all patients.[103] Device relocations out of the field were performed on 9 patients with a PM. Due to the care protocol, 14.6% of patients had CIED programming, 18.8% had a magnet application prior to the protocol change, and 30.7% underwent weekly CIED evaluations during the course of RT. Nineteen patients received a cumulative dose to the device between 2 and 20 Gy, and 2 patients received a cumulative dose to the device greater than 2 Gy. Device malfunctions were found in 4 patients (1.5%): 3 had ventricular pacing at the maximum sensor rate (the beam energy was not reported), and 1 patient had a full reset of an ICD during therapy with 18 MV photons. One of these patients had a cumulative radiation dose of 3 Gy (measured) and the other 3 patients had an estimated cumulative radiation dose of less than 2 Gy. No patient suffered a clinical CIED complication from RT.[103]

In the largest published series of patients with a CIED undergoing RT, Zaremba et al conducted a review of 560 patients with 462 PMs, 25 biventricular PMs, 54 ICDs, and 19 biventricular ICDs in 4 centers receiving 678 courses of RT.[106] Notably, the rate of RT in the patients with a CIED increased 199% between 2003 and 2012. Although 97% had initial CIED evaluations, follow-up CIED information was available for only 68.8%. Generator relocation was performed on 24 patients, including 20 new lead implantations and 8 lead extractions.[106] Magnet applications were performed in 8 of 74 treatments in patients with an ICD, and reprogramming was performed on only 10 patients with a CIED. In the 453 RT courses with follow-up information, 14 (3.1%) device malfunctions occurred.[106] Transient or partial reset requiring reprogramming was the most frequently observed defect (11 cases), 2 cases required programming help from the manufacturer, and one patient had an increase in atrial pacing threshold.[106] No malfunctions required revision, and only 1 patient had clinical symptoms from programming changes from a reset.[106] In cases with device malfunction, the median cumulative tumor dose was 46.5 Gy and the median beam energy was 16.5 MV (interquartile range 15–18 MV). The cumulative tumor dose was not associated with device errors (cumulative dose to the CIED was not specified).[106] A beam energy >15 MV was the strongest predictor of device malfunction, conferring a 5-fold risk. These findings provide support for limiting beam energy in patients with a CIED and oppose the common

recommendations to limit cumulative exposure to the device to <2 Gy. Similarly, the authors suggest that CIED distance from the field might not be as significant a clinical problem as has been historically believed.[106]

Grant et al reported the outcomes of a retrospective series of 215 patients (123 PMs and 92 ICDs) undergoing 249 courses of RT with 6 to 18 MV photons, electrons, or Gamma Knife™, with a focus on the effects of neutron-producing RT due to high-beam energy.[104] Patients were followed with a protocol that included a device evaluation prior to RT with characterization of PM dependence, biventricular pacing dependence, and anti-tachycardia therapy dependence. Reprogramming of pacing settings to a specific rate was performed for high-risk patients to diagnose a full reset by pulse check. A magnet application was not performed.[104] The devices were evaluated after completion of RT. RT effects were seen in 18 devices. There were 15 cases of neutron-related upsets, including memory resets in 5, parameter resets requiring reprogramming in 8, and unrecoverable resets requiring CIED replacement in 2.[104] Three devices were shown to have undergone transient signal disturbances consistent with oversensing. No high-rate pacing or inappropriate therapies occurred, but one device charged and aborted therapy prior to delivery. Clinical symptoms of hypotension and/or bradycardia (3), abnormal chest ticking (2), and heart failure (1) developed in 6 of 10 patients with device reset.[104] Device malfunctions were dominated by single-event upsets (15 of 18 events), which occurred only with the delivery of neutron-producing therapy.[104] RT delivery to the abdomen/pelvis was also independently associated with CIED defects. Importantly, cumulative dose was not correlated with device malfunction with either non–neutron-producing or neutron-producing RT; 46 devices received at least 2 Gy, 11 received >4 Gy, and 2 received 12 and 30 Gy.[104] Device alterations were observed in follow-up, although whether RT was the cause is unclear. Increases in pacing threshold were observed in 3 patients, and a data error was observed in 1 ICD 1 year after treatment.[104] This study confirms the association between CIED malfunction and neutron production; similar to prior analyses, it provides reassurance regarding the safety of higher cumulative doses up to at least 5 Gy.

Proton Therapy:

Two clinical studies and one *in vitro* study have been published on the effects of proton therapy on CIEDs. Hashimoto et al[126] placed 4 new ICDs outside the treatment field of a passively scattered 200 MeV proton beam. Memory or power resets occurred at a rate of 1 per 15 Gy, with power-on resets occurring approximately every 50 Gy. No unrecoverable damage was sustained by any device.

Oshiro et al[132] published the first clinical experience of 8 patients with implanted PMs treated with proton energies between 155 and 250 MeV with continuous electrocardiogram monitoring during treatment. Two episodes of device malfunction were noted: one reversion to the safety backup program during a liver treatment, and one transient pacing rate change in a lung treatment. The proton doses received by the generators in these instances were negligible, and both patients remained asymptomatic throughout their course.

Gomez et al[133] published the largest clinical series consisting of 42 patients with 28 PMs and 14 ICDs, treated with proton therapy between the years 2009 and 2012. Fifty-five percent of the patients received radiation to the thorax, 36% to the prostate, 7% to the liver, and 2% to the base of the skull. The majority of courses (76%) used a passively scattered technique, with the remaining 24% of cases utilizing a scanning beam, all of which comprised prostate treatment. The median incident proton dose received by the CIEDs was 0.8 Gy. Overall, 5 resets were noted in 4 devices (2 PMs and 2 ICDs), all in patients who received thoracic radiation. All the resets were recoverable, and no adverse clinical outcomes were reported. The incidence of reset was 10% for all patients and 25% for the subset receiving thoracic radiation.

Manufacturer Recommendations:

Boston Scientific, Medtronic, St. Jude, and ELA-Sorin (LivaNova) all recommend moving the CIED generator outside of the field. Manufacturer recommendations regarding the allowable maximum radiation dose vary. Medtronic suggests limitations of 1–5 photon Gy depending on the device, St. Jude and ELA-Sorin (LivaNova) do not state a recommendation, and Boston Scientific and BIOTRONIK state that there is no safe radiation dose.

CIED Relocation:

Data are quite limited on the clinical risks of direct radiation to CIEDs *in vivo*. As described above, many observational series report generator relocation due to concerns, yet they also report no clinical effects in patients who did not have device relocation, despite generator location in the field.[105] There are insufficient data to suggest CIED leads are sensitive to RT effects.

Similarly, multiple studies have reported tolerance of CIED generators far in excess of the commonly recommended 2 Gy threshold.[103,104,106] This tolerance is increasingly important because the high risks of opening a CIED generator pocket are recognized.[134] In a registry of patients with a CIED undergoing generator replacement or lead revision procedures from 72 U.S. centers, major complications occurred in 4% of generator replacements and 15.3% of lead revision procedures.[134] These data underscore the complexity of the decision-making process involved in determining the risks and benefits of relocating a CIED generator, and the importance of an informed discussion with the patient regarding the data. The clinical impact of an infection could be even more deleterious in oncology patients for whom chemotherapy might be planned or recommended.

If the CIED is situated in the path of the planned radiation beam it could interfere with adequate tumor treatment. Dosimetric studies report dose deposition alterations of up to 20% in the immediate vicinity of the generator.[135,136] CIED relocation in this situation is for the purpose of ensuring adequate tumor treatment. An informed discussion between the patient, the radiation oncologist, and the CIED physician is needed to decide whether CIED relocation should be performed.

There are various techniques for relocating the CIED generator; in some cases the generator can simply be moved away from the field if there is enough extra lead length coiled in the pocket; lead extenders can be used to facilitate device relocation; the generator can be removed and a new implant can be placed on the contralateral side; in exceedingly rare instances, the leads can be extracted and the system moved contralaterally or elsewhere if needed. As noted above, CIED leads have not been demonstrated to be sensitive to radiation.

Summary:
Despite the large number of patients with a CIED worldwide undergoing RT, data regarding radiation effects on CIED function are relatively sparse and of low quality. Recognition of the deleterious effects of RT on CIED function is well described. Substantial data now strongly and compellingly implicate the production of secondary neutrons as the strongest predictor of CIED malfunction in contemporary devices. Historically, despite the stochastic nature of device malfunctions, direct exposure and cumulative radiation dosage have been considered primarily from data from older *in vitro* studies.[114,115,117,137] However, recent large observational studies[103,104,106] suggest that CIED malfunction is a rare occurrence, although only a minority of patients receive a cumulative radiation dose to their device over 2 Gy. It should be noted that even when CIED malfunctions occurred, they were well tolerated and correctable with programming and were not reported to require a CIED generator change. Evidence is lacking to define an appropriate CIED evaluation frequency for patients with a cumulative incident device dose of radiation that exceeds 5Gy. Institutions are encouraged to develop protocols that specify a CIED evaluation frequency for such patients, and determine if evaluation should be performed at intervals during the radiation course.

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

The management of patients undergoing radiation therapy requires cooperation between personnel from both radiation

COR	LOE	Recommendations	References
I	B-NR	**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.**	103–105,119,124,133
		The assessment of RT risk to a patient requires an understanding of the patient and device factors that contribute to the risk. Patient factors include bradycardia pacing dependence and biventricular pacing dependence. Device factors include battery status, impedance thresholds, and pacing, tracking, and sensor rates. Understanding device programming helps with the identification of potential device malfunctions during RT.	
I	B-NR	**Non–neutron-producing treatment is preferred over neutron-producing treatment in patients with a CIED to minimize the risk of device reset.**	103–105,120,122,133
		The strongest predictor of RT risk-associated CIED malfunction is exposure to neutron-producing RT. For high-energy photons, this is usually defined as a beam energy of >10 MV. Whether to recommend the avoidance of exactly 10 MV photons is a matter of debate. Neutron production is approximately 20-fold less using 10 MV beam energy compared with 18 MV but has still been associated with device reset. Likewise, electron energies ≥20 MeV produce a similar amount of neutrons as 10 MV photons. Protons produce a higher number of neutrons than photons (Table 5).	
I	B-NR	**Perform weekly complete CIED evaluations for patients undergoing neutron-producing treatment.**	103–106
		Because neutron-producing RT confers a higher risk of CIED malfunction, if it is necessary to treat with >10 MV beam energy, the devices should be carefully monitored, and published studies have specified increased monitoring for patients in this group. Of note, a complete CIED evaluation includes a determination of the pacing threshold, which might not be included in a remote interrogation.	
I	B-NR	**A complete CIED evaluation should be performed at the conclusion of the course of radiation therapies.**	103–106,119,124,133
		Although the overall risk of CIED malfunction due to RT is low, the risk of electrical reset or other failure is frequent enough to warrant device assessments at the conclusion of therapy, and is included in the protocols of several published studies. CIED malfunctions are mostly due to software errors and electrical resets that can be corrected by programming.	
I	C-EO	**Continuous visual and voice contact is recommended during each treatment fraction.**	
		Although the overall risk of CIED malfunction due to RT is low, maintaining continuous visual and voice contact with the patient is important during radiation treatment for patients with a CIED.	

(*Continued*)

(*Continued*)

COR	LOE	Recommendations	References
I	C-EO	**CIED relocation is recommended if its current location will interfere with adequate tumor treatment.**	
		Clinical factors influencing the decision to relocate a CIED situated in the path of the planned radiation beam include the patient's overall prognosis, underlying cardiac function, the ability to tolerate a relocation procedure, and the importance of dose homogeneity in the tissues adjacent to the CIED. Dosimetric studies report dose deposition alterations of up to 20% in the immediate vicinity of the generator head.[135,136] For most patients being treated with definitive intent, the balance of risk and benefits will likely favor relocating a device situated within the beam path. For patients treated with palliative intent or with significant comorbidities, the balance of risks could justify delivering therapeutic doses to the device to avoid relocation. These decisions should be made based on informed discussions between the patient, radiation oncologist, and cardiologist/electrophysiologist.	
IIb	B-NR	**It might be reasonable to perform a complete CIED evaluation weekly for patients who are pacing-dependent and undergoing non–neutron-producing treatment.**	[103,105]
		Because PM-dependent patients are at the highest risk of clinical consequences from electrical reset, published studies have included increased monitoring in their protocols for this group.[103,105]	
III (harm)	B-NR	**CIED relocation is not recommended for devices receiving a maximum cumulative incident dose of <5 Gy.**	[104,106,134]
		CIED relocation imparts significant risk of complications,[134] particularly if a lead revision is required. Considerable published observational (*in vivo*) data suggest that the majority of RT-associated CIED malfunctions are due to neutron exposure, with no evidence of increased risk at cumulative incident doses above the historical limit of 2 Gy up to 5 Gy.[104,106,113,116,125,134,138–141] Data are not sufficient to guide relocation decisions for exposure above 5 Gy. Informed discussions with the patient, radiation oncologist, and cardiologist/electrophysiologist are often necessary to determine the full extent of patient risk and benefits. Evidence is lacking to define an appropriate CIED evaluation frequency for patients with a cumulative incident device dose of radiation that exceeds 5Gy. Institutions are encouraged to develop protocols that specify a CIED evaluation frequency for such patients, and determine if evaluation should be performed at intervals during the radiation course.	

therapy and the CIED clinic. A checklist to document key elements related to the CIED system and planned radiation treatment based on the following recommendations is provided in Table 6 and in a flowchart in Figure 4.

Section VIII: Future Directions

The importance of MRI for patient evaluation cannot be overstated, and the presence of a CIED should not preclude the performance of MR scanning when clinically indicated. The growing range of devices now labeled MR conditional is welcome, and further development of MR conditional devices is encouraged. Nevertheless, improvements could be made, particularly in the area of lessening the service burden to the patient and clinical team before, during, and after the performance of MRI. First and foremost, efforts could be made to incorporate features into CIEDs that automatically modulate the device to facilitate safe MR scanning without the intensive programming, monitoring, and supervision now required. Cross-compatibility of the manufacturer's MR conditional products, giving the clinician options with various devices and leads, would be a very welcome development; clinicians need flexibility in the products they use. The ability to actively program and monitor devices while in the magnet bore might also be helpful, facilitating investigations into both device function and optimal patient response to various programming strategies using MR's powerful imaging capabilities. Further studies to identify strategies and solutions directed toward helping device patients with abandoned hardware (in whatever condition or configuration) who need MR imaging should be developed. A wider range of MR conditional CIEDs are now available, but improvements are hoped for in the areas of service burden, cross-compatibility, feature sets available during MRI, and addressing patients with abandoned hardware. Finally, further registries of patients with MR-nonconditional CIED systems undergoing MRI would be helpful moving forward to identify risks and suggest strategies to reduce those risks.

Table 6 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*: 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†: Yes [ ] No [ ]
7	CIED evaluation following completion of radiation therapy: Measurements of the pacing system function and parameters are stable†: Yes [ ] No [ ] Comments: _____
	RADIATION CLINIC CHECKLIST
8	Type of radiation course: Neutron-producing‡: Yes [ ] No [ ] CIED location might interfere with adequate tumor treatment§: Yes [ ] No [ ] Maximum expected cumulative incident dose <5 Gy‖: Yes [ ] No [ ]

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

*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;

†Device function–pacing output, pacing thresholds, sensing of R and P waves, lead impedance, battery voltage and impedance;

‡Non–neutron-producing radiation is preferred [neutron-producing: >10 mV photons, protons, electrons ≥20 MeV];

§CIED relocation is recommended if it will interfere with adequate tumor treatment;

‖CIED relocation is not recommended for devices receiving a max cumulative incident dose of <5 Gy.

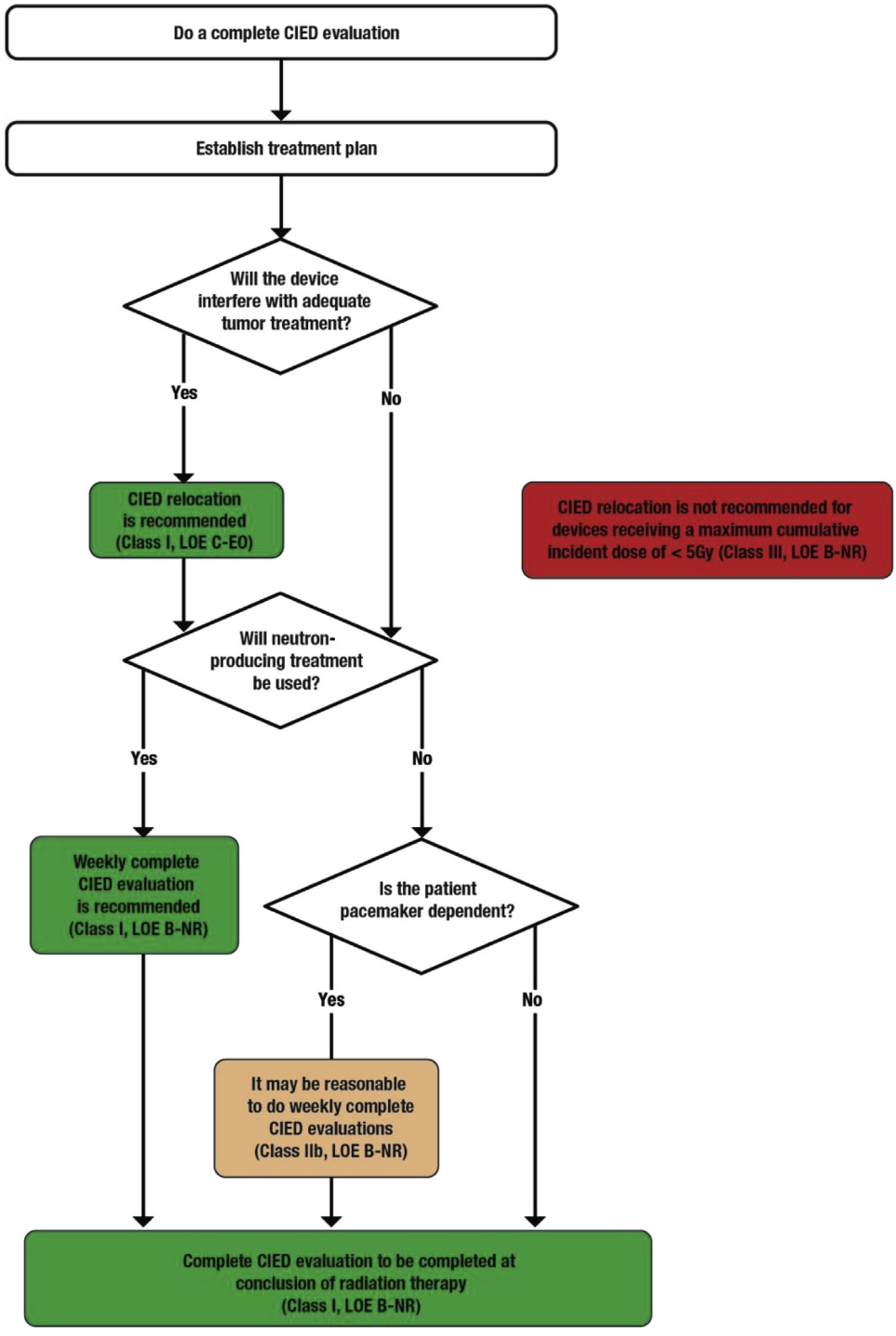

Figure 4 CIED management for radiation therapy.

Appendix A:

Suggested Provisions for Institutional Protocols for MR Scanning of Patients with a CIED

The performance of an MR scan for a patient with a CIED requires institutional protocols to detail the management of the patient that go beyond the recommendations in this document. Institutions should provide detail in these protocols to best serve their patient populations. The sections below offer guidance for the creation of such protocols and are not recommendations. For simplicity, this text refers to departments of Radiology and Cardiology, although in some institutions MRI is performed by nonradiologist experts and/or personnel outside of Radiology.

A-1. Radiology Department: Reception of the MR Imaging Request

For all patients with an MR imaging request, the presence or absence of any implanted foreign material, including CIEDs and/or leads, is noted on the request form. If the patient has a history of CIED implantation, regardless of whether the device is still present or not, a chest radiograph is helpful to assess for (residual) leads or device components and prompts the need for further CIED physician evaluation. On the reception of an MR imaging request, the radiology department also evaluates its diagnostic need and potential alternatives. The radiologist can contact the physician requesting the scan to discuss the indication and alternatives to assess the potential clinical benefit to the patient from scanning.

Depending on the urgency of the MRI, the patient can be sent for an elective CIED clinic visit or an urgent CIED evaluation (which could even be performed bedside for critically ill patients). It is helpful to have the patient bring all relevant information about prior device and lead implantations to the CIED clinic, especially if some of those implants were not performed at the local cardiology department.

A-2. Cardiology Department: Evaluation of the type of CIED, Leads, and MR Conditionality

Eligibility evaluation requires the following information:

a) Type of currently implanted leads and device

MR conditionality is based on the implanted system as a whole. Current MR conditional systems are listed under Section Vb-i and can be found in Table 3. Implanted systems based on a combination of components from various MR conditional systems should not be considered MR conditional and requires evaluation according to Section Vc.

For up-to-date information on MR conditionality, one can consult Table 3 or company-specific databases, because new leads and devices enter the market and sometimes older legacy leads receive MR conditional approval in combination with certain devices after their initial market release. Moreover, MR conditional CIED systems might require prespecified scanning parameters or limitations that might not only be manufacturer but also device specific. Other web-based data sources are www.mrisafety.com (manufacturer independent) in general, or http://wwwp.medtronic.com/mrc for Medtronic devices, https://www.promricheck.com/ for BIOTRONIK devices, and https://www.bostonscientific.com/imageready/en-EU/home.html for Boston Scientific devices (in the EU).

CIED evaluations include checking whether there are any product advisories or performance alerts about the leads or device.

b) Exclusion of abandoned and fractured leads

If a medical history is not available and/or there is any suspicion of the presence of abandoned leads (intracardiac, intravascular, in the pericardial space or subcutaneous), a chest X-ray can clarify whether such hardware is present. CIED evaluations will also identify whether any (suspected) fractured leads are present. The presence of any such lead or lead fragment (capped or not) makes an otherwise MR conditional system MR nonconditional and requires evaluation according to Section Vc.

c) Full evaluation of the device and leads

A full CIED evaluation includes impedance, pacing, and sensing thresholds for all leads, a determination of battery status, and evaluation of the pacing dependency of the patient (i.e., no intrinsic ventricular complexes or bradycardia with symptomatic hypotension in the absence of pacing). In ICD recipients, any recent arrhythmia and/or device interventions (appropriate or inappropriate) could warrant the need for tailored monitoring during the scan.

d) Report

The CIED evaluation report describes all current or abandoned components (leads and device type), their implant dates, their location, lead performance data, and any recently detected arrhythmia episodes. The MR eligibility of the system is described, as is the pacing dependency of the patient.

e) Consent

The institution can determine whether specific written or verbal consent is needed and if documentation of the discussion with the patient should be performed.

A-3. Radiology Department: Scheduling the Scan

Once it has been determined that the patient can proceed with an MR scan, appointments for the actual scan as well as immediate pre- and postscan device programming can be arranged. Depending on the institutional protocol and patient, reprogramming may be done at the cardiology unit or by a CIED technician/nurse/physician who comes to the imaging suite.

A-4. Cardiology Department: Prescan Programming on the Day of MRI

Immediately before the scan, the current programming settings are noted, and the appropriate MR programming is performed (see Sections Vb-iii and Vc-iii). The transfer note can include details on contacting personnel who are not present during the scan. For patients with an MR nonconditional CIED, a physician with the ability to direct CIED programming should be alerted that a scan is to be performed.

A-5. Radiology Department: Actual scanning

a) Scan settings/imaging protocols

Imaging is performed with scanning parameters appropriate for the CIED system with the minimum number and length of imaging sequences, still allowing for accurate diagnostic imaging. MR conditional systems allowing imaging of CIED patients in 3T systems are entering the market. Most approvals so far are for 1.5T scanning. The websites mentioned in Appendix A, A-2 might provide up-to-date information.

b) Actions to take in the event of bradycardia in a PM-dependent patient

Abort the scan if (even transient) pacing inhibition is observed in a PM-dependent patient.

Move the patient to Zone 3 as quickly as possible and, if pacing has not resumed, either apply an external magnet in case of a PM (under continuous monitoring of the patient; this approach will not work with an ICD) and/or (re)program to asynchronous pacing and call for Electrophysiology (EP) support.

If rapid programming is not possible or reactivation of pacing is not observed, apply external defibrillation patches and proceed with transcutaneous pacing, in accordance with advanced cardiovascular life support.

c) Actions to take in the event of ventricular arrhythmia

Abort the scan if sustained ventricular arrhythmia or in the event of otherwise unexpected or hemodynamically compromising ventricular tachycardia (which can be discussed prescan between the imaging physician and the CIED/EP physician).

If sustained symptomatic VT is observed, move the patient to Zone 3 as quickly as possible and reactivate ICD therapies; call for EP support.

If the patient collapses and rapid reactivation of ICD therapies is impossible, or if ICD therapies are not delivered, apply external defibrillation patches and proceed with external defibrillation.

d) Postscan planning

After the scan, staff members with the skills to program perform the reprogramming.

A-6. Cardiology Department: Postscan evaluation and reprogramming

The device is reprogrammed to its prescan settings. Lead function and battery status are reevaluated in full. A note is made to confirm the reevaluation and reprogramming to the original settings.

In Memoriam

Sadly, one of the members of the writing committee, Marc A. Rozner, PhD, MD, passed away before the publication of this document. At the University of Texas, MD Anderson Center, Marc held an appointment as Professor in the Department of Anesthesiology and Peri-Operative Medicine. Notably, he was the first anesthesiologist in the world to earn CCDS (Certified Cardiac Device Specialist) status from the International Board of Heart Rhythm Examiners. Those who knew or met him were often struck by his keen mind ("brilliant" said many), devotion to patient care, and attention to detail. While at MD Anderson, Marc started and ran the CIED MRI program scanning over 500 patients safely. Marc was a tremendous individual, clinician, and investigator, and despite his illness and while undergoing treatment, he participated fully in the development of this document, contributing his wisdom and experience. Like Paul Levine, who Marc credited as a mentor, he will be sorely missed.

Appendix B: Evidence tables

Table B1 Evidence for the management of patients with an MR conditional device who are undergoing MRI

RETROSPECTIVE/PROSPECTIVE ANALYSES MRI conditional multiple-center studies Study name or author	Year	PubMed PMID	Study type	Study size	Inclusion criteria	Endpoints	Findings	Outcomes result*	Statistical values†	Limitations	Comments
Wilkoff et al[33] Magnetic resonance imaging in patients with a pacemaker system designed for the magnetic resonance environment	2011	20933098	Prospective, RCT, MCT	464 with PM (258 MRI group; 206 no MRI as control)	9–12 weeks post-PM implant	Complication during MRI or within 1 month after (complication = adverse event that resulted in an invasive intervention or the termination of significant device function) (patients underwent 14 nonclinically indicated brain and lumbar MRI sequences)	Pacing capture threshold and sensed electrogram amplitude changes were minimal and similar between study groups	No MRI-related complications occurred during 226/226 (100%) or after MRI 211/211 (100%)	One-sided 97.5% CI of 98.3%. When analyzed against the comparison rate of 90%, $P < .001$	Use of MRI scanners on PM patients was specifically limited to well-defined anatomic regions	EnRhythm SureScan Medtronic; 1.5T MRI; max SAR 2 W/kg; brain/lumbar MRI
Gimbel et al[32] Randomized trial of pacemaker and lead system for safe scanning at 1.5T	2013	23333721	Prospective, RCT, MCT	263 (177 MRI and 86 no MRI)	9–12 weeks post implant	Primary: MRI-related complication-free rate Secondary: change in atrial or ventricular PCT	No patients saw an increase of 40.5 V in their atrial PCT; thus, the success rate for atrial PCT was 100% (141 of 141) in the MRI group and 100% (75 of 75) in the control group With both rates at 100%, a P value could not be established	No MRI-related complications (100% success) (1-sided lower 97.5% confidence bound 97.5%); $P < .0001$	Safety objective: 1-sided, 1-proportion binomial exact test was used, and the corresponding 1-sided 97.5% lower confidence bound was calculated Effectiveness objective: A Farrington-Manning test of 2 independent proportions was performed, and the 1-sided P value was used to evaluate the test	Only 1.5T evaluated	Advisa, Medtronic, 1.5T MRI, max SAR 2 W/kg, first study, no positioning restrictions
Gold et al[34] Full-body MRI in patients with an implantable cardioverter defibrillator	2015	25982014	Prospective, RCT, MCT	275 (42 centers)	Patients who received an Evera MRI ICD, single- or dual-chamber Evaluations at 2 months, 9–12 weeks and 1 week and 1 month post MR/waiting periods Evaluations also at 6 months post implant and every 6 months thereafter	Primary safety objective: >90% freedom from MRI-related events (sustained ventricular tachycardia or ventricular fibrillation during SureScan mode, complication within 30 days related to MRI, loss of capture within 30 days of MRI) Primary efficacy endpoints: Ventricular pacing capture change >0.5 V and ventricular sensing amplitude >50% decrease (or >25% decrease if <3 mV) seen from MRI to 1 month post MRI	Noninferiority met for changes in pacing threshold ($P < .0001$) or R wave amplitude ($P = .0001$)	Safety endpoint met ($P < .0001$) N = 24 patients underwent defibrillation threshold testing with no effect on sensing, detection, or treatment of ventricular fibrillation	Safety endpoint assessed with 1-proportion binomial exact test Primary efficacy endpoints assessed by Farrington-Manning test of 2 independent proportions Mean change assessed with Student t test	Evera ICD, two DF4 lead models of limited lengths tested at 1.5 T Endpoints are for 1 month post-MRI/waiting period	Evera, Medtronic, 1.5 T MRI, max SAR 2 W/kg Small subset underwent defibrillation threshold testing

(*Continued*)

Table B1 (*Continued*)

RETROSPECTIVE/PROSPECTIVE ANALYSES MRI conditional multiple-center studies Study name or author	Year	PubMed PMID	Study type	Study size	Inclusion criteria	Endpoints	Findings	Outcomes result*	Statistical values†	Limitations	Comments
Bailey et al[35] ProMRI Trial Clinical safety of the ProMRI pacemaker system in patients subjected to thoracic spine and cardiac 1.5-T magnetic resonance imaging scanning conditions	2015	26409098	Prospective, cohort, MCT	245; 32 centers (216 patients completed the MRI and 1-month post-MRI follow-up)	(1) age ≥18 years, informed consent, and ability to complete the MRI studies and required follow-up, including ability to be followed remotely by Cardio Messenger Home Monitoring; (2) stable lead position and PM indices for 5 weeks before the study; (3) pacing threshold(s) ≤2.0 V at 0.4 ms; (4) pacing impedance(s) between 200 and 1500 Ω; (5) spontaneous rhythm allowing measurement of atrial and ventricular sensing indices; (6) battery capacity >30%; and (7) absence of phrenic nerve stimulation at 4.8 V at 1.0 ms	Serious adverse device effect (SADE) free rate; atrial and ventricular pacing threshold increase between pre-MRI and 1 month post-MRI; either a P-wave amplitude decrease >50% or a P-wave amplitude at 1-month follow-up of <1.5 mV; R-wave amplitude decrease >50% or an R-wave amplitude at 1-month follow-up of <5.0 mV	Freedom from atrial and ventricular pacing threshold increase was 100% (194/194, P <.001) and 100% (206/206, P <.001), respectively Freedom from P- and R-wave amplitude attenuation was 98.2% (167/170, P <.001) and 100% (188/188, P <.001), respectively	Primary endpoint: One adverse event possibly related to the implanted system and the MRI procedure occurred, resulting in a serious adverse device effect-free rate of 99.6% (220/221); P <.0001	The analysis of primary endpoints was based on the proportion of leads or patients satisfying endpoint criteria using exact binomial tests Two-sided 95% confidence intervals (CIs) for the parameters involved in the evaluation of primary endpoints were also given Primary endpoint 1 was evaluated on a per-patient basis Primary endpoints 2 through 5 were evaluated on a per-lead basis. P <.05 was considered significant for any of the primary endpoints	The number of cardiac MRI compared to thoracic spine MRI was lower and could underestimate the risk of cardiac MRI; patients not PM dependent	Entovis ProMRI BIOTRONIK; max SAR 2 W/kg
Bailey et al[39] ProMRI/ProMRI AFFIRM	2015	25680307	Prospective, cohort, MCT	226; 37 centers	(1) age ≥18 years, informed consent, and ability to complete the MRI studies and required follow-up, including the ability to be followed remotely by Cardio Messenger Home Monitoring; (2) stable lead position and PM indices for 5 weeks before the study; (3) pacing threshold(s) ≤2.0 V at 0.4	Increase between pre-MRI and 1 month post-MRI; either a P-wave amplitude decrease >50% or a P-wave amplitude at 1-month follow-up of <1.5 mV; R-wave amplitude decrease >50% or an R-wave amplitude at 1-month follow-up of <5.0 mV	The freedom from atrial pacing threshold increase was 99.0% [189/191; P = .003, 95% CI: (96.3%, 99.9%)] The freedom from ventricular pacing threshold increase was 100% [217/217; P<.001, 95% CI: (98.3%, 100%)] The freedom from P-wave amplitude attenuation was 99.4% [167/168; P<.001, 95% CI: (96.7%, 100%)] The freedom from R-wave amplitude attenuation was	Primary endpoint: SADE-free rate of 100.0% [229/229; P<.001, 95% CI (98.4%, 100.0%)] No deaths occurred during the trial	Primary endpoint 1 was evaluated on a per-patient basis Primary endpoints 2 through 5 were evaluated on a per-lead basis. P <.05 was considered significant for any of the primary endpoints.	MRI limited to specific anatomic locations, head and lower lumbar scans; included patients with detectable rhythms and therefore were not technically "PM dependent"	Entovis ProMRI BIOTRONIK

					ms; (4) pacing impedance(s) between 200 and 1500 Ω; (5) spontaneous rhythm allowing measurement of atrial and ventricular sensing indices; (6) battery capacity >30%; and (7) absence of phrenic nerve stimulation at 4.8 V @ 1.0 ms		99.5% [193/194; P <.001, 95% CI: (97.2%, 100%)]				
Savoure et al[36] The Kora pacemaker is safe and effective for magnetic resonance imaging	2015	26327785	Prospective, cohort, MCT	33	Patients previously implanted with the devices	Primary endpoint: To demonstrate a less than 0.75-V change in atrial and ventricular PCTs from the pre-MRI visit to the 1-month post-MRI visit Secondary objectives were (1) to demonstrate the stability of atrial and ventricular PCTs at 0.35 ms from pre-MRI visit to post-MRI visit and the stability of atrial and ventricular sensing thresholds at 0.35 ms from pre-MRI visit to post-MRI visit and from pre-MRI visit to 1-month follow-up visit and (2) to report serious adverse events (SAEs), including relation to the MRI examination	The mean absolute difference for both chambers was statistically significantly lower than 0.75 V (*P* value <.001),	No SAEs experienced during the study were considered by the investigators to be MRI related Minimal mean absolute variation in atrial and ventricular PCTs from pre-MRI visit to post-MRI visit and in atrial and ventricular sensing amplitudes from pre-MRI visit to post-MRI visit and from pre-MRI to 1-month follow-up visit	Sample size was calculated based on the co-primary criteria of the absolute value of the differences between atrial and ventricular thresholds compared to 0.75 V The endpoints were tested using a one-sided *t* test with an alpha risk of 0.025; a Bonferroni adjustment was applied to correct multiplicity and the alpha risk was set to 0.0125.	Sample size	Kora; 2.0 W kg−1 or less (3.2 W kg−1 or less for head scanning) 1.5T Kora automatically switches from programmed to asynchronous mode when detecting a strong magnetic field
Awad et al[37] Clinical safety of the Iforia implantable cardioverter defibrillator system in patients subjected to thoracic spine and cardiac 1.5-T magnetic resonance imaging scanning conditions	2015	26049048	Prospective, MCT, cohort	170 (153 underwent MRI); 39 centers	(1) age >18 years; (2) ability to provide informed consent and to complete the MRI study and required follow-up, including the Cardio Messenger Home Monitoring system; (3) stable lead parameters and position for 5 weeks before the study; (4) pacing threshold(s) ≤2.0 V at 0.4 ms; (5) pacing	SADE-free rate Freedom from ventricular capture threshold increase by >0.5 V at 1 month post-MRI compared to the pre-MRI value Freedom from decrease in R-wave sensing >50% compared to the pre-MRI value	Ventricular pacing threshold did not increase >0.5 V in any patient [153/153, *P* <.001, CI (97.6%, 100.0%)]	SADE-free rate of 100% [153/153, *P* <.001, 95% CI (97.6%, 100.0%)]	All primary endpoints were evaluated on a per-lead (ventricular leads only, primary endpoints 2 and 3) or per-subject basis (primary endpoint 1) using exact binomial tests *P* <.05 was considered significant for any of the primary endpoints Freedom from R-wave sensing attenuation was observed in 99.3% of patients [151/152, *P* <.001, CI (96.4%, 100.0%)]	A larger sample size or longer duration of follow-up would allow for detection of rare SADEs A detectable underlying rhythm was required for enrollment in this study, thus excluding patients who are pacing-dependent, in contrast to other trials Patients with reduced R-wave sensing or poor capture threshold at baseline were excluded from the study; thus, the outcome of MRI is unknown in those patients	Iforia - CardioDefibrillator

(*Continued*)

Table B1 (*Continued*)

RETROSPECTIVE/PROSPECTIVE ANALYSES MRI conditional multiple-center studies Study name or author	Year	PubMed PMID	Study type	Study size	Inclusion criteria	Endpoints	Findings	Outcomes result*	Statistical values†	Limitations	Comments
					impedance(s) between 200 and 1500 Ω; (6) any spontaneous rhythm allowing measurement of atrial and ventricular sensing indices; (7) R-wave amplitude >6.5 mV; (8) shock impedance between 30 and 90 Ω; (9) battery capacity >30%; and (10) absence of phrenic nerve stimulation at 5 V @ 1.0 ms					Patients did not all undergo capacitor formation or defibrillation threshold testing at follow-up Although the study demonstrated safety for a single thoracic scan in a 1.5-T scanner, results might not apply to other scanning conditions	
Shenthar et al[31]	2015		Prospective, RCT, MCT Patients randomized 2:1 to undergo MRI (MRI group) at 9–12 weeks postimplant of a Medtronic 5076 lead with an MR conditional PM (Medtronic Advisa) or control (no MRI after implant)	266 patients involving 36 sites	Class I or II indication for a dual-chamber PM Excluded any previously implanted non-MR conditional materials, abandoned leads or other implantable active medical device	Primary endpoint: MRI-related complication-free rate, and noninferiority of MRI group compared to control for atrial and ventricular threshold change ≤0.5 V at 1-month post-MRI compared to pre-MRI Secondary endpoints: a) noninferiority of MRI group to control for ≤50% decrease in sensing at 1-month post-MRI compared to pre-MRI b) lead impedance changes c) freedom from sustained ventricular arrhythmia or asystole during MRI scan >90%	No MRI-related complications Minimal differences in proportion of patients with ≤05 V threshold change at 1 month post-MRI Sensing amplitude changes similar between groups No arrhythmias occurred during MRI	MRI scans performed safely without positioning restrictions using the Medtronic 5076 lead connected to an MR-conditional PM	Differences in proportions of patients with ≤0.5 V: atrial lead P not calculable, and ventricular leads noninferiority test $P < .0001$ Sensing changes similar, meeting noninferiority $P < .001$ for atrial leads, $P = .004$ for ventricular leads	Only Advisa studied as the generator, thus cannot be generalized to other MR-conditional generators Only the dual-chamber system tested	Both chest and head MRI scans performed

RETROSPECTIVE/PROSPECTIVE ANALYSES MRI conditional – single center studies Study name or author	Year	PubMed PMID	Study type	Study size	Inclusion criteria	Endpoints	Findings	Outcomes result*	Statistical values†	Limitations	Comments
Gold et al[30] Preclinical evaluation of implantable cardioverter defibrillator developed for magnetic resonance imaging use	2015	25496984	Single center, modeling study, animal study, bench testing	66 canine; 1 swine	1.5 T scanner testing; ICD system (leads and can)	Estimated incidence of increased pacing thresholds; unintended cardiac stimulation; incidence of delays or reduction in VF detection/therapy	Incidence of threshold increase >0.5 is 1/160,000 and >1.0 is 1/1,000,000; unintended cardiac stimulation <1/1,000,000; no delay in VF detection or therapy	Very low incidence of increase in thresholds for pacing or VF detection	No comparative statistics	Animal, modeling and bench testing; no patients	Evera MRI SureScan ICD system is composed of an Evera MRI dual-chamber (DR) or single-chamber (VR) SureScan ICD, Sprint Quattro model 6935M (single-coil) or 6947M (dual-coil) DF-4 right ventricular (RV) defibrillation leads, and any SureScan atrial lead

Klein-Wiele et al[41] Feasibility and safety of adenosine cardiovascular magnetic resonance in patients with MR conditional pacemaker systems at 1.5 Tesla.	2015	26695427	Retrospective, single center	24	Conditional PMs; adenosine stress CMR	Occurrence of arrhythmia or competitive pacing interfering with adenosine stress CMR	Optimal PPM programming avoiding competitive pacing and adenosine still led to increase in heart rate; no asystole or pauses	Adenosine stress CMR is feasible and safe in patients with MRI conditional PPM	No stats	Single center, adenosine stress CMR only	
Mattei et al[77] Impact of capped and uncapped abandoned leads on the heating of an MR conditional PM implant	2015	24436030	Human trunk simulation study	4 leads tested	4 commercially available leads tested next to MRI compatible system; whole body SAR 1 W/kg, 64 MHz body bird cage coil	Effect of abandoned lead tip heating on compatible lead tip heating	Abandoned leads showed heating behavior directly related to termination condition (capped, saline exposed) and on lead path (left- or right-sided). Max temperature rise of 17.6 C observed Presence of abandoned lead modified RF heating profile of compatible lead tip from −63% to 69%	Presence of abandoned leads can modify heating at compatible lead tip depending on relative position of the 2 leads	No comparative stats	Modeling, no patients	Limit the MRI compatibility of a system to a system without abandoned hardware
Raphael et al[42] Clinical value of cardiovascular magnetic resonance in patients with MR conditional PMs	2015	26588986	Consecutive, retrospective cohort study	72 CMR scans in 69 patients	MR conditional PMs; 1.5 T imaging; Siemens system; quality of scan reviewed by blinded reviewer	Change in lead thresholds or pacing parameters; quality of MR scan; incidence of management changing info provided by MR scan	All scans completed with no significant change in lead thresholds or pacing parameters; frequency of nondiagnostic imaging was 22% with steady-state free precession cine imaging vs. gradient echo sequences	Management changing info provided by 63% of scans; use of GRE sequences can improve yield; right-sided implant might improve yield	No comparative stats	Single center	MR compatible PPM only
Van der Graaf et al[43] Noninvasive focus localization, right ventricular epicardial potential mapping in patients with an MRI conditional pacemaker system—a pilot study	2015	26369330	Consecutive, prospective cohort study	10	MR conditional PPM systems; combined MRI imaging with body surface potential mapping	Whether combined inverse potential mapping with MRI can successfully be performed in patients with MR compatible PPM systems	Earliest site of ventricular activation successfully localized with the system; distance between lead position and epicardial breakthrough was 6.0 mm	Combined inverse potential mapping with MRI registration can be successfully performed with MR compatible PPM	No comparative stats	Single center	MR compatible PPM only
Wollmann et al[45] A detailed view on pacemaker lead parameters remotely transmitted after magnetic resonance	2015	25787901	Retrospective	2428 data sets	Data remotely transmitted immediately before (baseline FU) and immediately after MR	Lead function	Mean values for the various lead parameters were (RA/RV) 3.3 ± 2.0/14.4 ± 6.9 mV for sensing, 0.65 ± 0.17/0.78 ± 0.23 V/0.4 ms for PCT, and 516 ± 60/607 ± 47 Ω for pacing impedance No significant differences were found compared with pre-MR measurements. No atrial PCT increases ≥0.5 V compared with pre-MR were observed	See results	Mean values for the various lead parameters were (RA/RV) 3.3 ± 2.0/14.4 ± 6.9 mV for sensing, 0.65 ± 0.17/0.78 ± 0.23 V/0.4 ms for PCT, and 516 ± 60/607 ± 47 Ω for pacing impedance No significant differences were found compared with pre-MR measurements. No atrial PCT increases ≥0.5 V compared with pre-MR were observed	Retrospective	BIOTRONIK Evia

(*Continued*)

Table B1 (*Continued*)

RETROSPECTIVE/PROSPECTIVE ANALYSES MRI conditional – single center studies Study name or author	Year	PubMed PMID	Study type	Study size	Inclusion criteria	Endpoints	Findings	Outcomes result*	Statistical values†	Limitations	Comments
Wollmann et al[44] Monocenter feasibility study of the MRI compatibility of the Evia PM in combination with Safio S PM lead	2012	23009683	Prospective, nonrandomized	31	Standard pacing indications; Evia PM Safio S leads; brain and lower lumbar imaging 1.5 T	RA and RV lead parameters immediately after MR and at 1 and 3 months; SADE rate	1 patient excluded for enrollment violation; 50% DDD PPM; no MR-related SADE; lead measurements not statistically different from baseline to post; MR imaging artifacts seen on DW brain sequences but not others	Use of Evia and Safio systems is feasible with no MR-related SADEs	*t* tests	Single center	BIOTRONIK Evia and Safio system

*e.g., mortality or morbidity %

†e.g., *P* value, hazard ratio, odds ratio, confidence intervals

Table B2 Evidence for the management of patients with an MR nonconditional device who are undergoing MRI

Study name or author	Year	PubMed PMID	Study type	Study size	Inclusion criteria	Endpoints	Findings	Outcomes result*	Statistical values†	Limitations	Comments
Martin et al[58]	2004	15063447	Single center, prospective cohort	N = 54 patients, 62 MR scans	Included cardiac, vascular and general MR studies, no restrictions on PM type but PM-dependent excluded	Pacing threshold post-MRI evaluated for "any change" or "any significant change" Any significant change defined as change >1 voltage or pulse width increment/decrement	A total of 9.4% of leads had significant changes, with 1.9% requiring change in programmed output, but unrelated to cardiac chamber, anatomic location, peak SAR, or time from implant to MR scan	No adverse outcomes, patient symptoms and ECG changes minor and did not require cessation of MRI	Logistic regression for peak SAR, chi-squared or Fisher exact for 2×2 contingency testing	Single center, only immediate post-MRI PM evaluation performed	
Sommer et al[61]	2006	16966587	Single center, prospective cohort	N = 82 patients, 115 MR scans	PM patients who were not dependent, MR scans not of thoracic region, urgent need for MR scan, Medtronic PMs manufactured 1993–2004, with stable device parameters	Change in pacing threshold clinically significant if ^{3} 1V	Pacing threshold increased pre- to post-MRI (P = .017), and clinically significant in 3.1% of leads (95% CI 1.1–6.6%), and in 2 leads increase in threshold detected at follow-up at 3 months Electrical reset occurred after 7 scans Troponin increased in 4 of 114 scans, and in one case rise of troponin associated	No inhibition of pacing or arrhythmia observed and scans performed safely PMs with electrical reset all programmed back to prescan parameters No leads required change in output to maintain function	Mixed repeated-measures regression analysis of threshold and impedance data, with covariates for cardiac chamber, timing of evaluation (pre, post, 3-month follow-up)	Single center Medtronic only	Included measurement of troponin Medtronic PMs manufactured from 1993–2004 Electrical reset observed in 3 Thera and 4 Sigma PMs

							with significant change in threshold, but overall no significant increase in troponin ($P = .0693$)				
Nazarian et al[9]	2006	16966586	Single center, prospective cohort	N = 55 patients, 31 PM 24 ICD, 68 MR scans	Patients included if no imaging alternative and could be pacing-dependent Excluded if <6 weeks from implant, nontransvenous leads, abandoned leads	Change in PM parameters from pre- to immediate post- and long-term follow-up	N = 12 pacing-dependent No inappropriate inhibition or pacing	No significant differences in amplitude, impedance, threshold from prescan to immediate postscan or to long term f/u (median 99 days)	Paired Student *t* test to compare immediate and long term parameters	Single center	N = 10 with reed switch activation and transient asynchronous pacing but expected as had no magnet-mode programming
Pulver et al[72]	2009	19335853	Single center, prospective case series of adult and pediatric patients with congenital heart disease	N = 8 patients, with N = 11 MR scans	Could have epicardial leads Not pacing-dependent and no abandoned leads	Safety Lead parameters	Average age 16.5 ± 9.2 years, and 5 under age 16 No inappropriate pacing or significant change in parameters noted pre- to post-MR scan	9 epicardial leads included Exams performed safely Long-term follow-up data available on 6 patients with no clinically important changes seen	Paired *t* tests to compare pacing parameters pre- and post-MR	Small case series	Congenital heart disease with 9 epicardial leads Included children 1.5 Tesla
Burke et al[55]	2010	20111895	Single center, prospective cohort	N = 38 patients, with N = 92 MR scans	Indication for MR would result in significant clinical impact	Device parameters including DFTs immediate post MR and at 3-month follow up	N = 13 PM-dependent, N = 11 not PM-dependent, N = 10 ICD patients, N = 4 CRT patients	No device circuitry damage, programming alterations, no electrical resets, inappropriate shocks, failure to pace or changes in sensing, pacing, or defibrillation threshold, including patients with multiple MR scans No change in device parameters at 3-month follow-up	Paired *t* test and Wilcoxon rank sum test	Single center	Defibrillation testing performed
Buendia et al[54]	2010	20515632	Single center, prospective cohort	N = 33 patients PPM 28 ICD 5	MR clinically essential	Safety Lead parameters	N = 28 with PMs, N = 5 with ICDT Noted: temporary communication failure in two patients; Sensing errors during imaging in two patients Safety signal generated in one PM at the maximum magnetic resonance frequency and output level	No technical restrictions on imaging or any permanent change in CIED performance, no clinical complications		Small case series	
Cohen et al[63]	2012	22921995	Single center, retrospective cohort that underwent MR and prospective (control) cohort that did not undergo MR	Retrospective cohort: N = 109 patients, with N = 125 clinically indicated MR scans Prospective cohort: N = 50 patients with CIED	All patients with permanent CIEDs who underwent clinically necessary MR scans from 2006–2009 Control group recruited from 2008–2009 Underwent two interrogations one hour apart	Primary endpoints: death during MR, device or lead failure requiring immediate replacement, induced atrial or ventricular arrhythmias during MR, loss of PM capture, electrical reset Secondary endpoints: battery voltage decrease of ^{3} 0.4 V, pacing lead threshold increase of ^{3} 0.5 V at	Pacer dependence: 27% in MR group, 16% in control group No significant change between MR and control groups for battery voltage, P-wave amplitude, R-wave amplitude, or high voltage impedance Small mean decrease in LV threshold in MR group and small mean increase in control group noted	No deaths, device failures, generator/lead replacements, loss of capture, or electrical reset	Linear mixed model analyses to compare MR and control groups for CIED parameters, adjusting for type of device and PM dependence	Retrospective MR cohort, single center	Included PMs, ICD, and CRT-P and CRT-D

(*Continued*)

Table B2 (*Continued*)

Study name or author	Year	PubMed PMID	Study type	Study size	Inclusion criteria	Endpoints	Findings	Outcomes result*	Statistical values†	Limitations	Comments
						0.4 ms pulse width, P-wave amplitude decrease ^{3} 50%, R-wave amplitude decrease ^{3} 25%, lead impedance change ^{3} 50 W, high voltage lead impedance change ^{3} 3W	Significant difference seen in MR group vs. control for lead impedance ($P = .01$), but not clinically important				
Strach et al[70]	2010	20356915	Single center, prospective cohort	N = 114 patients with scans performed at 0.2 Tesla, including PM-dependent and abandoned leads	Urgent clinical need for MR scan Implants at least 3 months prior to scan with stable pacing parameters Excluded ICD	Evaluation pre- and post-MR	No induction of arrhythmias or inhibition of pacing, and no statistically significant changes in lead impedance, pacing threshold, or battery voltage. In no patient was a pacing threshold over 0.5 V observed	No adverse effects; MR at low field strength appeared to be safe and feasible	Wilcoxon signed rank test to compare pre- and post-MR parameters	Number of patients with abandoned leads or details not provided	Low-strength magnetic field
Nazarian et al[13]	2011	21969340	Single center, prospective cohort	N = 438 patients, with N = 555 MR scans	Consecutively enrolled from 2003–2010 Included PM-dependent patients implanted >6 weeks prior to MR scan ICDs excluded abandoned or epicardial leads Excluded ICD patients who were pacing-dependent	Device function at immediate and long-term follow up, safety	Power-on reset occurred in 0.7%thoracic imaging, associated with decreased (compared to nonthoracic) acute RV ($P = .005$) and long-term RV R-wave amplitude ($P = .009$) Small decreases in device parameters seen but not clinically important immediate post-MR: RV amplitude ($P < .001$), atrial impedance ($P < .001$), RV impedance ($P < .001$), LV impedance ($P = .002$), battery voltage ($P < .001$) Small decreases in device parameters but not clinically important in long-term follow-up: RV amplitude ($P = .004$), RV impedance ($P = .044$), RV threshold ($P = .12$), battery voltage ($P < .001$)	MR performed safely Changes in device variables did not require device revision or reprogramming	Wilcoxon signed rank test	Single center	Note: first 55 patients previously reported in Nazarian et al 2006 (see above in this table)
Muehling et al[65]	2014	24903354	Single center prospective	N = 356 patients, cranial MRI	PM patients needing urgent cranial MRI, included pacing-dependent patients, PMs implanted at least 2 months prior to scan; excluded epicardial or fractured lead; enrolled from 2004–2012	Evaluation of pacing parameters pre-, immediate, post-MR scan and follow-up at 2 weeks, and 2,6, and 12 months after scan Measurement of troponin 12 hours postscan	No immediate or late PM dysfunction, no increase in troponin within 12 hours Programmed parameters unchanged, data for threshold, sensing, impedance did not change significantly, with 19 patients having a maximum increase of 0.4 V in threshold seen	No significant changes in device parameters (sensing, impedance or pacing capture threshold) up to 12 months	Paired Wilcoxon rank sum test for continuous variables, Kruskal-Wallis for categorical variables Pre- and postscans compared by ANOVA	Single center, Cranial MRI only PM patients only	Long-term follow-up to 12 months completed for 338 patients

Russo RJ[67]	2017		Multicenter prospective registry	N = 1000 PM (848 patients), and N = 500 (428 patients) ICD cases	Nonthoracic MR scans at 1.5 T Excluded patients with CIEDs implanted before 2002 Excluded ICD patients that are pacing-dependent	Primary outcomes: death, generator or lead failure that required immediate replacement, loss of capture, new onset arrhythmia during scan, partial or full electrical reset Secondary outcomes: decrease in battery voltage ^{3}0.4 V, increase in pacing threshold ^{3} 0.5 V at 0.4 ms, decrease in P-wave ^{3}50%, decrease in R-wave ^{3} 25%, increase/decrease in lead impedance ^{3}50 Ω, increase/decrease in shock impedance ^{3}3 Ω	P wave: ≥50% decrease in .9% of PMs, 0.3% of ICDs R wave: ≥50% decrease in no PMs and 0.2% of ICDs Pacing threshold: ≥0.5 V in 0.7% of PMs, 0.8% of ICDs Lead impedance: ≥50 Ω in 3% of PMs, 4% of ICDs Repeat scanning performed in 22.6% of PMs and 18% of ICDs, with median interval between scans of 153 days for PM patients, 91 days for ICD patients	No deaths, lead failures, losses of capture or ventricular arrhythmias during MRI 5 patients had atrial fibrillation and one atrial flutter during MRI One ICD generator required replacement because it had not been programmed appropriately for scanning 6 partial electrical resets	95% CIs calculated for observed proportions of binary outcomes	Thoracic MRI excluded, also only small number of CRT devices	Large prospective registry, multicenter
Junttila et al[57]	2011	21873440	Single center, prospective case series	N = 10 ICD patients who underwent 3 serial cardiac MR scans	Excluded pacing-dependent patients	Evaluation of device parameters pre- and post-MR and at follow-up and 3, 6, and 12 months	Median follow-up 370 days	No adverse effects with serial MR scans No differences in pacing capture threshold, lead or high voltage lead impedance, or battery voltage, and no ICD dysfunction	Student *t* test and Mann-Whitney test	Small series, single center; troponin/cardiac biomarkers not measured	Serial MR scans and long-term follow-up completed.
Boilson et al[82]	2012	21938517	Single center, prospective cohort	N = 32 patients with 46 MR scans	Not pacing-dependent, with PM (excluded ICD), implanted at least 90 days prior to scan	Safety, lead parameters, cardiac enzymes	No significant change in battery voltage, sensed P/R waves, pacing thresholds, impedance immediately after MR or at 1 month follow-up No increase in cardiac enzymes PVCs noted in one patient	Power-on reset occurred in 5 scans (5 patients), more frequent with Medtronic Kappa No adverse clinical events	Fisher exact test, Pearson chi-squared tests for categorical values ANOVA for continuous variables	MR scan of head (N = 35) and spine (12 cervical, 7 thoracic, 5 lumbar)	PMs programmed to asynchronous pacing at 20 bpm above intrinsic heart rate and to monitor only (OAO, OVO, ODO) if heart rate >90 bpm
Del Ojo[56] et al	2005	15826258	Prospective, single center, case series	N = 13 patients, undergoing MR scan at 2 Tesla 1999–2001	Not pacing-dependent	Safety Lead parameters	No significant differences in sensing, stimulation, threshold, or impedance pre- and post-MR scan	No PM inhibition, asynchronous pacing, or inappropriate rapid pacing occurred	Student *t* test	Small case series, St. Jude PM only	2 Tesla scan
Gimbel et al[80]	2005	16221260	Prospective cohort with substudy of PM-dependent patients	N = 10 patients with 11 MR scans from 1994–2004	PM-dependent No chest or abdominal MR scans	Safety Lead Parameters pre-, post-MR scan, and at 3 months	No PM malfunction, pauses, or rapid pacing No power-on resets No clinically important change in pacing parameters	One patient with a Y adaptor in system	Not provided	Small series	Head and neck only Modification of protocol; programming prescans transmit-receive coil was used
Mollerus et al[59]	2008	18811802	Single center, prospective cohort	N = 37 patients with 40 MR scans	Not pacing-dependent PM, ICD, or CRT Any body region and no peak specific absorption rate (SAR) limit	Device evaluation pre- and post-MR scan; troponin and myoglobin levels pre- and 6–12 hours post-MR scan	Troponin unchanged post-MR scan No significant change in pacing threshold Median SAR 2.4 W/kg	MR scan performed safely and no change in cardiac biomarkers	Wilcoxon rank sum test	Single center, small cohort Excluded pacing-dependent patients No long-term follow-up	No significant change in biomarkers or thresholds in either truncal or nontruncal scans
Mollerus et al[62]	2010	20353963	Single center, prospective cohort	N = 103 patients, with 127 MR scans	Not pacing-dependent PM, ICD, or CRT, implanted at least 6 weeks prior to scan No restriction on SAR	Device evaluation pre- and post-MR scan and followed for at least 3 months	Median peak SAR 2.5 W/kg Pre- and postscan pacing thresholds unchanged Sensed RV amplitudes (P <.00001) and lead impedances (RA, RV) (P <.0001) decreased	One patient with device reset One ICD had arrhythmia log erased during scan No significant study-related events seen at 3-month follow-up	Paired Wilcoxon rank sum test for continuous variables, Kruskal-Wallis test for categorical values	Single center; excluded pacing-dependent	Large series with exposure to high-SAR environment

(*Continued*)

Table B2 (*Continued*)

Study name or author	Year	PubMed PMID	Study type	Study size	Inclusion criteria	Endpoints	Findings	Outcomes result*	Statistical values†	Limitations	Comments
Friedman et al[64]	2013	23826621	Prospectively collected single-center cohort with retrospective analysis of patients with or without recently implanted leads	N = 171 patients with 219 scans, of which 8 had recently implanted leads	Not pacing-dependent	Device evaluation pre- and post-MR scan and with comparison of patients with recently implanted (<42 days) leads	8 patients with recently implanted leads (7–36 days) No complications in either the early or late group and no difference in parameters One patient imaged 79 days after implant had frequent PVCs during scan with no action needed Overall, statistically significant but not clinically significant changes seen pre- to post-MR scan in R-wave amplitude (P = .003), ventricular threshold (P = .009), atrial impedance (P = .001)	MR imaging feasible in patients with recently implanted PMs No clinically significant changes in function or on follow-up (average 104 days post-MRI) Regression analysis of all 171 patients did not predict any change in pacing variables according to implant duration at time of scan	Regression analyses with generalized estimating equation models to compare pre- and post-MR scans, and to account for multiple scans in the same patient	Small number of patients in the recently implanted group	
Higgins et al[49]	2015	25460173	Prospective, single-center cohort	N = 198 patients with 256 MR scans	Not pacing-dependent	Incidence of POR in relation to device characteristics and patient characteristics	PORs occurred in 9 MRI scans in 8 patients and more frequently in Medtronic devices (P = .005) and devices released before 2002 POR caused decrease in heart rate (n = 4) and transient anomalous battery life indication in 1	POR infrequent and occurred in older generators (released prior to 2002)	Pearson chi-squared for categorical variables, Wilcoxon rank sum or t test for continuous variables	Retrospective analysis of a small number of events and majority of patients in the entire database had Medtronic devices Pacing-dependent patients excluded, for which clinical effects of a POR could have been more important	POR infrequent and appeared limited to devices released prior to 2002
Naehle et al[60]	2009	19643318	Prospective, single-center cohort	N = 18 patients, with 18 MR scans	ICD-only Not pacing-dependent At least 3 months from implantation	Safety Lead parameters pre-, post- and at 3 months after MR scan Serum troponin 1 hour before and 12 hours after MR scan	No significant changes in pacing threshold, impedance seen No significant change in troponin observed	Battery voltage decreased from pre- to post-MR (P = .042) In 2 scans oversensing as VF occurred but no attempt at therapy delivery was made	Troponin levels compared with Student t test, other comparisons with a Wilcoxon signed rank test	Small case series	In 3 of 16 scans a persistent decrease in battery voltage of at least 0.05 V was observed
Higgins et al[68]	2014	24809591	Retrospective, single-center cohort	N = 19 patients with abandoned leads (no generator) with N = 35 MR scans	Abandoned leads (no CIED generator) Not pacing-dependent	Safety Lead parameters	Mean of 1.63 abandoned leads per patient. 3 ICD leads, with 2 being dual coil 9 patients had long-term follow-up with no negative sequelae	No adverse events within 7 days of scan When generator reimplanted (12 of 19 patients) there were no lead malfunctions or clinically significant changes in pacing threshold, but one patient had ventricular lead threshold that rose from 1.9 V to 2.6 V at 0.5 ms	Not provided	Small single center, retrospective Unknown whether presence of a generator with functional leads could have affected results No cardiac biomarkers analyzed	Most (31/35) of the scans performed were of the central nervous system, including head and spinal imaging Cohort from prior to 2008 when CIED generator was removed for MR scan and new generator implanted afterward if clinically appropriate

CIED = cardiac implantable electronic device; ICD = implantable cardioverter defibrillator; VF = ventricular fibrillation; POR = power-on reset; CRT = cardiac resynchronization therapy; SAR = specific absorption rate; DFT = defibrillation threshold test.

*e.g., mortality or morbidity %

†e.g., P value, hazard ratio, odds ratio, confidence intervals

Table B3 Evidence for the management of patients with a CIED undergoing CT imaging

Study name or author	Year	Study type	Study size	Inclusion criteria	Endpoints	Findings	Outcomes result*	Statistical values†	Limitations	Comments
Yamaji et al[97] Does high-power computed tomography scanning equipment affect the operation of PMs?	2006	Prospective study	11 PM patients	Chest CT scanning using SOMATOM multislice spiral CT system	N/A	Oversensing was transiently observed during CT scan	Oversensing was observed in 6 of 11 patients	N/A	The study was limited to Medtronic PM	The authors recommend ECG monitoring during chest CT scan
Hussein et al[101] Safety of computed tomography in patients with cardiac rhythm management devices	2014	Retrospective study	516 patients (332 ICDs and 184 PMs) and 129 controls (83 ICDs and 46 PMs) in 2 medical centers	Philips 4,16,64-slice multidetector CT, and SOMATOM sensation 16, 64	Primary outcomes: death, bradycardia or tachycardia, termination of CT scan or an immediate intervention, unplanned hospital admission, reprogramming of the device, inappropriate defibrillator shock, or device replacement/ revision due to CT scan Secondary outcomes: significant changes in device parameters		None of the CTs were associated with primary outcome No differences in battery voltage or lead parameters between CT and control groups	None of the primary outcomes	Due to retrospective study design, radiation doses not recorded	None of the CTs were associated with primary outcomes and no differences or significant changes in device parameters and clinical consequences

*e.g., mortality or morbidity %

†e.g., *P* value, hazard ratio, odds ratio, confidence intervals

Table B4 Evidence for the management of the CIED patient undergoing radiation therapy—*in vitro* studies. Effects of radiation therapy on CIEDs: *in vitro* studies

Author	Year	Study	PM device	ICD device	Beam energy	Beam exposure	CIED findings
Hoecht et al[137]	2002	*In Vitro*		5	N/A	Direct and scatter	1 reset with scatter, other malfunctions at >50 Gy direct radiation
Mouton et al[117]	2002	*In Vitro*	96		18 MV	Direct	Amplitude change >10%: 38 PMs at 2–130 Gy; silence >10 s: 35 PMs at 0.15–74 Gy; permanent silence: 12 PMs at 0.5–170 Gy
Hurkmans et al[114]	2005	*In Vitro*		11	6 MV	Direct	Sensing interference; device failure at 0.5–120 Gy
Hurkmans et al[115]	2005	*In Vitro*	19		6 MV	Direct	No malfunction in 5 devices; 7 with either output at high dose, no communication, or inhibition
Uiterwaal et al[142]	2006	*In Vitro*		11	6 MV	Direct and indirect	EMI only when ICD directly in field
Kapa et al[128]	2008	*In Vitro*		20 (12 ICD, 8 CRT)	6 MV	Scatter	No defects noted
Trigano et al[127]	2012	*In Vitro*	14		>10 MV		Reset in 6
Hashii et al[143]	2013	*In Vitro*		10	10–18 MV	Scatter	No hard errors, severe, moderate, or soft errors at 10 and 18 MV
Mollerus et al[125]	2014	*In Vitro*		8	6 MV	Direct	No errors in 4 contemporary devices to 130 Gy, 4 legacy devices with failure
Zaremba et al[113]	2014	*In Vitro*	10	2	6–18 MV	Scatter	Reset at 6 MV at 150 Gy; 14 resets in 18 MV PM group
Zecchin et al[112]	2016	*In Vitro*	34	25	15 MV	Direct	Software malfunction in 52% ICD and 18% PM ranging from reset to programming changes to failure
Augustynek et al[116]	2016	*In Vitro*		2 (CRT)	6 MV	Direct	No malfunctions seen at 10 Gy

Table B5 Evidence for the management of CIED patients undergoing radiation therapy—*in vivo*

Study name or author	Year	PubMed PMID	Study type	Study size	Inclusion criteria	Endpoints	Findings	Outcomes result*	Statistical values†	Limitations	Comments
Brambatti et al[103]	2015	26049049	Single center, prospective cohort	N = 261 patients (54 ICD, 207 PM)	Patients treated with linear accelerator (6, 10, and 18 MV) and managed according to a care-path algorithm with high risk if had ICD, was PM-dependent, or estimated cumulative radiation exposure >20 Gy, or to the thorax	Device malfunction	Site of RT: head and neck (27.4%), chest (30.0%), abdomen/pelvis (32.6%) Continuous cardiac monitoring performed on 63.2%, 14.6% with device reprogramming, 18.8% magnet applied during RT, 3.4% underwent device relocation	Four patients had inappropriate device function, 3 with hemodynamically tolerated ventricular pacing at maximum sensor rate, occurring at <2 Gy One patient had a power-on reset No deaths or permanent device failures	N/A	Observational study, single center, not designed to test different care strategies because all patients managed according to a single algorithm	Large prospective cohort, device malfunction rare and not related to higher radiation cumulative dose
Ferrara et al[119]	2010	20437862	Single center, prospective cohort	N = 45 patients (37 PM, 8 ICD)	Patients undergoing RT at 6, 18 MV	Device function after therapy	No malfunction in any devices Patients treated in regions close to devices had average maximum dose of 2.5 Gy (head/neck) and 1.8 Gy for thorax	No morbidity/mortality reported due to PM/ICD dysfunction	N/A	Small, single center	No specific reprogramming done before RT
Gomez et al[133]	2013	24074931	Single center, prospective cohort	N = 42 patients (28 PM, 14 ICD)	Patients undergoing proton beam therapy, median dose 74 Gy Excluded patients with thoracic tumors and pacing dependence	Device malfunction	Six CIED malfunctions occurred in 5 patients (2 PMs and 3 defibrillators) Five malfunctions were CIED resets, and 1 patient with a defibrillator (in a patient with a liver tumor) had an elective replacement indicator after therapy that was not influenced by radiation Median peak proton dose in all patients was 0.8 Gy (0.13–21 Gy), median neutron dose 346 Sv (11–1100 mSv) Mean max neutron dose in CIED with reset was 655 mSv (range 330–1100 mSv) Mean distance from the proton beam to the CIED among devices with reset was 7.0 cm (range 0.9 cm–8 cm) Median distance for all patients was 10 cm (0.8–40 cm)	CIED resets were 20% among patients receiving proton beam therapy to the thorax Device resets all corrected No reported morbidity or mortality	N/A	Single center	Median peak proton dose in all patients was 0.8 Gy (0.13–21 Gy), median neutron dose 346 Sv (11–1100 mSv) Mean max neutron dose in CIED with reset was 655 mSv (range 330–1100 mSv) Mean distance from the proton beam to the CIED among devices with reset was 7.0 cm (range 0.9 cm–8 cm) Median distance for all pts was 10 cm (0.8–40 cm) No specific reprogramming done before RT
Grant et al[104]	2015	26181143	Single center, retrospective analysis	N = 215 patients (123 PM, 92 ICD) underwent 249 courses of photon and electron-based RT	Patients undergoing RT with photons or electron-based therapy	CIED malfunction (single event upset) and delayed effects, including signal interference, pacing threshold change, and battery depletion	Substantial neutron production in 71 courses (15 or 18 MV photons) 21% single event upsets with neutron producing RT and none at 6 MV Abdomen and pelvis treatments associated with higher malfunction rates	Six patients developed clinical symptoms; hypotension, bradycardia, CHF Three episodes of signal interference No morbidity/mortality reported due to PM/ICD dysfunction	Fisher exact and Wilcoxon rank sum tests Univariate and multivariate logistic regression to predict single event upset	Retrospective	Reset seen in the setting on notable neutron production with none seen in non–neutron-producing RT

(*Continued*)

Table B5 (*Continued*)

Study name or author	Year	PubMed PMID	Study type	Study size	Inclusion criteria	Endpoints	Findings	Outcomes result*	Statistical values†	Limitations	Comments
Makkar et al[105]	2012	23102626	Single center	N = 69 patients (50 PM, 19 ICD) underwent RT (616 MV)	CIED patients undergoing RT	Device malfunction, device-related clinical events, inappropriate ICD therapies	No device failures in PM, no clinical events PMs were exposed to 84.4/–99.7 cGy of radiation and the ICDs 92.1/–72.6 cGy 5 patients underwent device relocation Two patients with ICDs experienced a partial reset of the ICD, with the loss of historic diagnostic data after receiving 123 and 4 cGy, respectively	No morbidity/mortality reported due to PM/ICD dysfunction No device malfunction or premature battery depletion was observed at 6-month follow-up from RT completion	N/A	Single center	Institutional protocol in place but without specific device recommendations
Soejima et al[120]	2011	21905310	Multiple centers in Japan, retrospective	N = 62 patients (60 PM, 2 ICD)	CIED patients undergoing RT	Overall assessment of management practices in Japan	10 patients (16%) did not have any device checks before, during, or after RT Full device checks before and after RT in only 47% of patients One device malfunction noted for RT using 15 MV—PM found to be "initialized" (MDT) and treated for prostate cancer, and device reprogrammed without any cardiac events In one patient maximum dose was 2069 cGy and in other patients dose was <478 cGy	There were no clinical events related to device malfunctions	N/A	Retrospective survey, incomplete data set	
Wadasadawala et al[124]	2011	21041071	Single center	N = 8 patients (PM)	Underwent CT-based treatment planning and RT	Device function directly after RT and at follow-up	Three men with head and neck primaries, 2 men and 3 women with breast primaries Daily dose of 1.8–2.0 Gy with prescribed cumulative dose of 45–70 G6 in 25–35 fractions Four patients with PM on same side as target Dose to PM: mean 0.07–20.6, minimum 0.06–2.0, and maximum 0.14–60 Gy Dose to PM calculated to max 20.6 Gy (opposite side) and 60 Gy (same side) No specific reprogramming done before RT All devices were St. Jude	RT delivered safely with no untoward effects and no PM malfunction	NA	Small series	Included follow-up with cardiologist to 6 months

Zaremba et al[106]	2015	25601489	Four centers in Denmark, retrospective review of registry	N = 560 patients (462 PM, 54 ICD) undergoing RT	CIED patients undergoing RT	CIED malfunction	Relocation of CIED in 3.5%, supplementary evaluation of CIED in 38.3%, reprogramming in 1.5%, and magnet applied to ICDs in 10.8% Out of 453 device evaluations after RT, malfunction seen in 10 PMs (2.5%) and 4 ICDs (6.8%) Electrical reset occurred in 11 of the malfunctions but no failures were life-threatening or required removal of CIED and all reprogrammed successfully One patient had an increase in pacing threshold	Predictors of CIED malfunction: beam energy ≥15 MV (OR 5.73) and tumor below diaphragm (OR 4.31), but this effect was less after adjusting for beam energy There was no correlation between device malfunction and cumulative tumor dose or fraction dose	Logistic regression to determine predictors of CIED malfunction; comparisons with Wilcoxon rank sum test	Retrospective Neither radiation dose to device or distance of RT field to the CIED generally available	High beam energy strongest predictor of device malfunction Large retrospective cohort
Oshiro et al[132]	2008	18538490	Single center, prospective	N = 8 (PM)	PM patients undergoing proton beat therapy Phantom study first performed	CIED malfunction	Change in heart rate occurred in 3 of 127 sessions in 2 patients but asymptomatic One patient who was PM-dependent had a reset to VVI 65 bpm		N/A	Small case series	Phantom study had not predicted an effect of neutron scatter on generators
Kapa et al[128]	2008	18507546	Single center, retrospective review (additional *in vitro* study of ICDs and CRT-ICDs)	N = 13 patients that underwent radiotherapy (7 PM; 5 ICD; 1 CRT-P)	PM patients undergoing radiotherapy (6 MV) where device located outside radiation field	CIED malfunction	5 patients with irradiation of head and neck; 7 for thorax; 1 for abdomen 4 patients had device relocation 12 patients interrogated prior to and after radiation No reset or malfunction during or after radiation	No device resets, no inappropriate sensing or therapy or changes in programming	N/A	Small retrospective series, no detail on cumulative dose	Four of 13 patients had device relocation
Gelblum and Amols[130]	2009	18977096	Single center, retrospective review	N = 33 patients with ICDs undergoing radiation therapy (6 MV)	ICD patients undergoing radiation therapy (6 MV)	CIED malfunction	One patient had initially been treated with 15 MV for rectal cancer and had a device reset, successfully reprogrammed After this, treated with 6 MV and no further events	Device reset in one patient treated with 15 MV photons, device located out of radiation portal	N/A	Small, retrospective	Highlights that it is neutron scatter, relevant to device reset
Elders et al[122]	2013	22848077	Single center, retrospective review	N = 15 ICD patients (6 MV and 18 MV) that underwent 17 radiation treatments	ICD patients undergoing radiation therapy (6 and 18 MV) ICD programmed to monitor only for all sessions	CIED malfunction	Dose at ICD site <1 Gy and all devices outside radiation field 6 ICD malfunctions in 4 patients (35%) correlated to beam energy above 10 MV	Malfunctions consisted of: Reset (2 patients, 18 MV treatment, both reprogrammed successfully) Invalid data retrieval (2 patients)	N/A	Small, retrospective	CIED malfunctions related to neutron scatter for high beam energies All ICDs had been programmed to

(*Continued*)

Table B5 (*Continued*)

Study name or author	Year	PubMed PMID	Study type	Study size	Inclusion criteria	Endpoints	Findings	Outcomes result*	Statistical values†	Limitations	Comments
								Another patient had a second data error 9 months after and had had a reset during RT One patient had inappropriate sensing due to noise (10 MV)			monitor only for each session
Croshaw et al[121]	2011	21607774	Single center, review of prospective data	N = 8	CIED patients who underwent 3D conformal external beam irradiation (3D-CRT using 6 MV) or high-dose balloon brachytherapy (HDRBB) for treatment of breast cancer	CIED malfunction	Maximum radiation dose delivered to any device was 1.03 Gy, with mean PM distance to lumpectomy cavity of 9.1 cm	No adverse device events seen	N/A	Small series	Number of PM and ICD patients not given
Poole et al[134] REPLACE Registry	2010	20921437	Multicenter, prospective registry	72 centers N = 1031 patients in cohort 1, N = 713 patients in cohort 2	Patients undergoing CIED generator replacement either without (cohort 1) or with the addition of a lead	Procedure-related complications	Major complications in 4% (95% CI 2.9–5.4) of cohort 1 patients and 15.3% of cohort 2 patients Complications higher in ICD patients and CRT patients	No periprocedural deaths, but 8 later procedure-related deaths in cohort 2 6-month infection rate was 1.4%, with 5 requiring extraction in cohort 1 and 1.1% with 5 requiring extraction in cohort 2 Hematoma requiring evacuation in 7 cohort 1 patients and 11 cohort 2 patients	Designed as a fixed-sample-size trial requiring 1750 patients to achieve predetermined precision levels in the 2 cohorts	Registry; did not investigate beyond 6 months Did not investigate individual patient risk factors in relation to complications seen	Complication rate includes risks of infection and late deaths, especially with lead additions

RT = radiation treatment; PM = pacemaker; ICD = implantable cardioverter defibrillator; CIED = cardiac implantable electronic device; EP = electrophysiology.

*e.g., mortality or morbidity %

†e.g., *P* value, hazard ratio, odds ratio, confidence intervals

Appendix C: Author disclosure table

Writing group	Employment	Consultant/Advisory board/Honoraria	Speakers' bureau	Research grant	Fellowship support	Equity interests/ Stock options	Others
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Haruhiko Abe, MD, JHRS; Representative	University of Occupational and Environment Health, Kitakyushu, Japan	None	None	None	None	None	None
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Writing group	Employment	Consultant/Advisory board/Honoraria	Speakers' bureau	Research grant	Fellowship support	Equity interests/ Stock options	Others
Hein Heidbuchel, MD, PhD, FESC; EHRA Representative	Antwerp University, Antwerp, Belgium	1: Boehringer Ingelheim, Daiichi-Sankyo, Bayer, BMS, Pfizer	1: Boehringer Ingelheim, Daiichi-Sankyo, Bayer, BMS, Pfizer, Cardiome, WebMD, Remedica Correvio International	1: Bayer	None	None	Other 1: BIOTRONIK—Travel
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Robert J. Russo, MD, PhD, FACC	The Scripps Research Institute (TSRI) La Jolla Cardiovascular Research Institute, La Jolla, CA	None	1: St. Jude Medical	4: BIOTRONIK 5: St. Jude Medical, Boston Scientific, Corp.	None	None	None
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Jerold S. Shinbane, MD, FHRS	USC Keck School of Medicine, Div of Cardiovascular Medicine, Los Angeles, CA	None	None	None	None	None	None
Ricardo Alkmim Teixeira, MD, PhD SOBRAC Representative	Hospital Renascentista, Cardiology, Pouso Alegre, Brazil	None	1: Medtronic	1: BIOTRONIK	None	None	Officer, trustee, director, or any other fiduciary role: 0; SOBRAC
Wee Siong Teo, MBBS, FRCP, FHRS; APHRS Representative	National Heart Center Singapore, Singapore	1: Bayer, Boston Scientific Corp, Biosense Webster, St. Jude Medical	None	None	None	None	None
William Uribe, MD, FHRS; SOLAECE Representative	Clinica CES, Medellin, Colombia	1: St. Jude Medical, Medtronic, Inc., Boehringer Ingelheim	None	None	1: Boston Scientific Corp, St. Jude Medical	None	None
Atul Verma, MD, FRCPC, FHRS	Southlake Regional Health Centre, Toronto, ON, Canada	1: Boehringer Ingelheim, Bayer HealthCare LLC, Biosense Webster, Daiichi-Sankyo	None	4: Medtronic, Inc. 5: Bayer HealthCare LLC, BIOTRONIK, Bristol-Myers Squibb	None	None	None
Bruce Wilkoff, MD, FHRS, CCDS	Cleveland Clinic, Cleveland, OH	1: St. Jude Medical, Boston Scientific Corp. 2: Spectranetics Corporations, Medtronic, Inc.	None	None	None	None	Royalty Income: 2: Medtronic Inc.

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Writing group	Employment	Consultant/Advisory board/Honoraria	Speakers' bureau	Research grant	Fellowship support	Equity interests/ Stock options	Others
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Number Value: 0 = $0; 1 = <$10,000; 2 = >$10,000 to <$25,000; 3 = >$25,000 to <$50,000; 4 = >$50,000 to <$100,000; 5 = >$100,000

Appendix D: Peer reviewer disclosure table

Peer reviewer	Employment	Consultant/Advisory board/Honoraria	Speakers' bureau	Research grant	Fellowship support	Equity interests/ Stock options	Others
Timothy S.E. Albert, MD, FACC	Central Coast Cardiology, Salinas, CA	2: Circle Cardiovascular Imaging, Inc. 1: Medtronic	None	None	None	2: Circle Cardiovascular Imaging Inc.	None
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Alec Block, MD	Department of Radiation Oncology, Stritch School of Medicine, Loyola University Chicago, Maywood, IL	None	None	None	None	None	None
Peter F. Aziz, MD, FHRS	Division of Pediatric Cardiology, Cleveland Clinic Children's, Cleveland, OH	None	None	None	None	None	None
Peter Brady, MB, ChB, MD	Mayo Clinic, Rochester, MN	None	None	None	None	None	None
Mina Chung, MD, FACC	Cleveland Clinic, Cleveland, OH	None	None	3: NIH	None	None	None

Michael Dominello, DO	Division of Radiation Oncology, Department of Oncology, Karmanos Cancer Center, Wayne State University School of Medicine, Detroit, MI	None	None	None	None	None	None
Andrew E. Epstein, MD, FACC	Department of Medicine, Cardiovascular Division, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA	3: Boston Scientific 3: St. Jude Medical 1: Medtronic	None	3: BIOTRONIK 3: Boston Scientific 3: Medtronic 3: St. Jude Medical	3: BIOTRONIK, 3: Boston Scientific, 3: St. Jude Medical, 3: Medtronic	None	None
Susan P. Etheridge, MD, FHRS	Children's Hospital, Department of Pediatrics, University of Utah School of Medicine, Salt Lake City, UT VP SADs	None	None	0: Fischerkeller WPW grant	None	None	Royalties: 1: UpToDate G: VP SADs
Paul A. Friedman, MD	Mayo Clinic, Rochester, MN	1: Boston Scientific 2: Medtronic		1: St. Jude Medical			Intellectual Property Rights: Aegis Medical 2: Sorin Group
Thomas C. Gerber, MD, PhD, FAHA	Paul Scherrer Institute, 5232 Villigen, Switzerland	None	None	None	None	None	None
Robert H. Helm, MD	Boston Medical Center, Boston, MA	None	None	None	None	None	1: Boston Scientific
Ricardo Kuniyoshi, MD, PhD	Centrocor Cardiologia, Vitória, Espírito Santo, Brazil	None	None	None	None	None	None
Martin J. LaPage, MD, MS, FHRS	Division of Pediatric Cardiology, University of Michigan, C.S. Mott Children's Hospital, Ann Arbor, MI	None	None	None	None	None	None
C.P. Lau, MD	Cardiology Division, Department of Medicine, Queen Mary Hospital, University of Hong Kong, Hong Kong SAR, China	None	None	None	None	None	None
Harold Litt, MD	Department of Radiology, Perelman School of Medicine of the University of Pennsylvania, Philadelphia, PA	None	None	5: Siemens Healthineers	None	None	None
Lluis Mont, MD	Hospital Clinic, Universitat de Barcelona, Barcelona, Spain	1: St. Jude; 1: Medtronic; 1: Livanova; 1: Biotronik; 1: Boston Scientific; 1: Johnson & Johnson; 1: Boehringer Ingelheim	1: Medtronic	1: St. Jude; 1: Medtronic; 1: BIOTRONIK; 1: Boston Scientific	1: Medtronic	None	None
Takashi Nitta, MD	Nippon Medical School, Tokyo, Japan	1: Boston Scientific Japan 1: Medtronic Japan 1: Century Medical Inc.	None	None	None	None	None
Jack Rickard, MD, MPH	Cleveland Clinic, Cleveland, Ohio	1: St. Jude Medical, 1: Medtronic	None	None	None	None	None

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(*Continued*)

Peer reviewer	Employment	Consultant/Advisory board/Honoraria	Speakers' bureau	Research grant	Fellowship support	Equity interests/ Stock options	Others
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Wenyin Shi, MD, PhD	Associate Professor Thomas Jefferson University, Philadelphia, PA	None	None	None	None	None	None
Christian Sticherling, MD	Cardiology Division, Department of Medicine, University Hospital Basel, Basel, Switzerland, Cardiovascular Research Institute Basel, University Hospital Basel, Basel, Switzerland	2: BIOTRONIK 1: Boston Scientific 1: Liva Nova 1: St. Jude Medical 0: Medtronic	None	2: Biotronik	None	None	None
Andrew Taylor, MD	Department of Cardiovascular Medicine, Alfred Hospital, Melbourne, Australia	None	None	5: PI of Australian National Health and Medical Research Council Project Grant 5: PI of industry-funded research grant (Vudbenk)	None	None	0: National Heart Foundation Director (nonprofit charity)
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Paul J. Wang, MD, FHRS	Stanford University School of Medicine, Standford, CA	None	None	SIEMENS, CardioFocus, Inc., Medtronic, Inc., ARCA Biopharma, Inc.	Biosense Webster, Boston Scientific, Medtronic, Inc., St. Jude Medical	VytronUS, Inc.	AHA
L. Samuel Wann, MD, MACC	Columbia St. Mary's Cardiovascular Physicians—Clinical Cardiologist, Milwaukee, WI	None	None	None	None	None	None
Ying Xiao, PhD	Department of Pathophysiology, Guizhou Medical University, Guiyang 550025, China	None	None	None	None	None	None

Number Value: 0 = $0; 1 = < $10,000; 2 = > $10,000 to < $25,000; 3 = > $25,000 to < $50,000; 4 = > $50,000 to < $100,000; 5 = > $100,000.

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