When is Electromagnetic Interference a Clinical Concern?

David Hayes, MD
Chief Medical Officer

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Which of the following is most concerning in terms of EMI effect on pacemakers is the presence of:

1. Asymptomatic transient ventricular pacing inhibition
2. Presyncope or syncope
3. Palpitations
4. Secondary pacemaker mediated tachycardia

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Clinically Significant EMI: Class I

- Interference associated with: presyncope, syncope, dizziness, dyspnea
- Transient ventricular inhibition for > 3 secs
- Trans
- Persi
- Persi
- Any change in programmed settings
- Secondary events of supraventricular or ventricular arrhythmias

If the patient is symptomatic and/or if the abnormality could lead to potentially life-threatening situation

Hayes D, et al. *N Engl J Med*. 1997;336(21):1473-1479

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Potential Effects of EMI

- Failure to deliver antibradycardia pacing or effective CRT therapy
- Inappropriate delivery of antitachycardia therapy
- Resetting of programmed parameters
- Damage to the pulse generator and/or lead/myocardial interface

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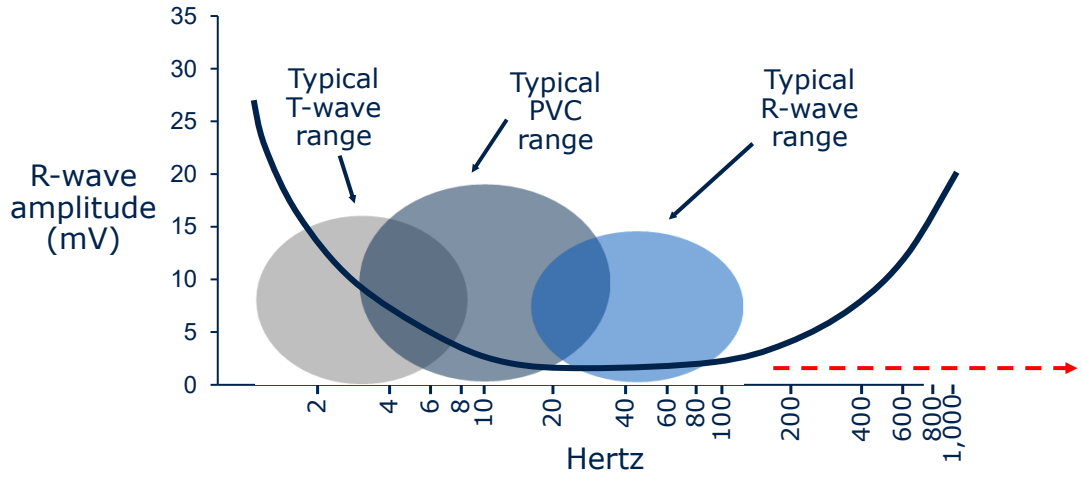
Frequency Spectrum For Cardiac Events



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Major Sources of EMI in the Hospital Environment

- Electrocautery/cardioversion/defibrillation
- Magnetic resonance imaging (MRI)
- Lithotripsy
- Radiofrequency ablation
- Electroshock therapy
- Transcutaneous nerve stimulators

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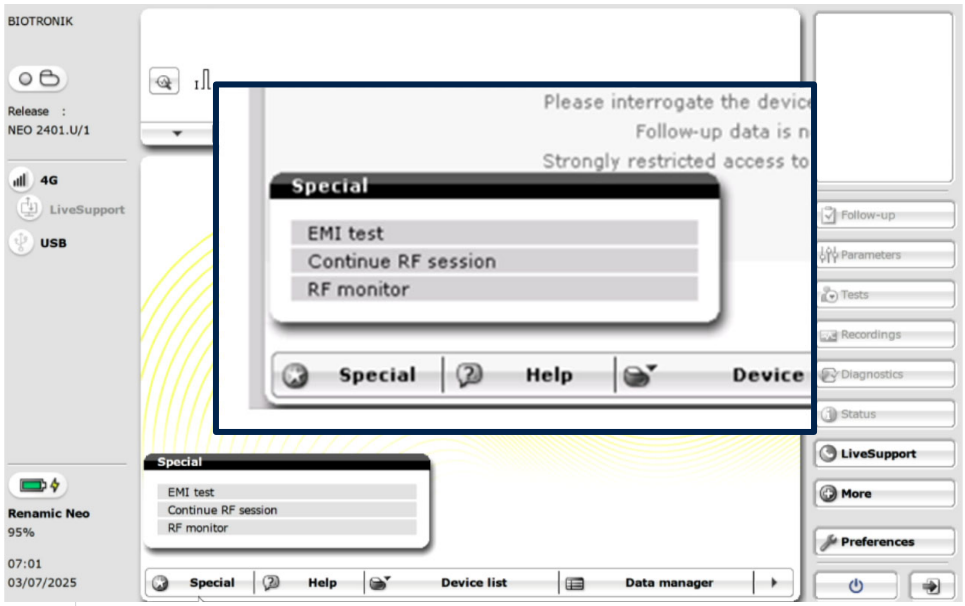
BIOTRONIK EMI Test



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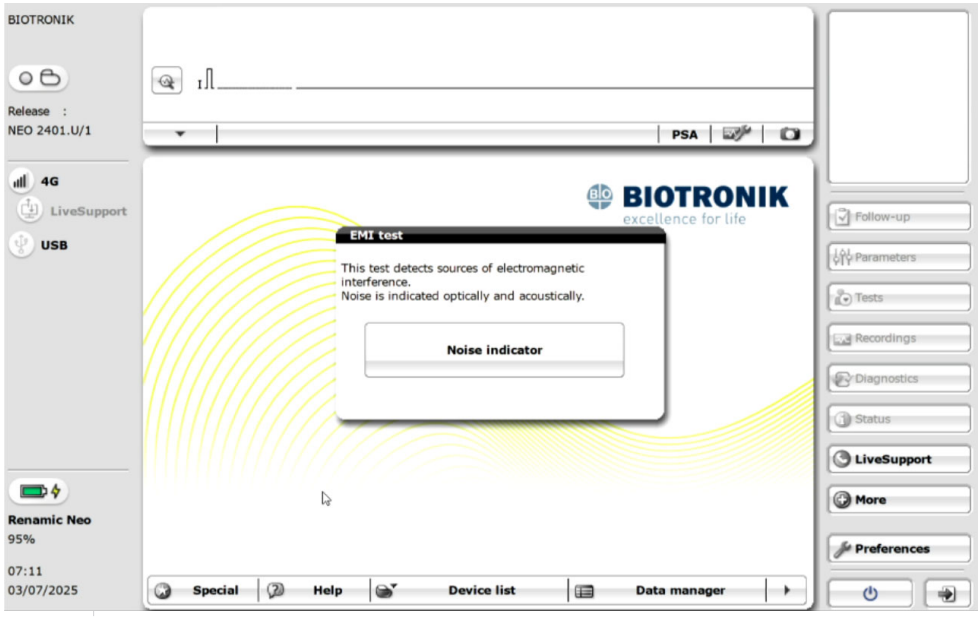
BIOTRONIK EMI Test



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EMI in the Hospital Environment

- Know the potential sources
- Know programmed parameters prior to exposure
- Reprogram ICDs to monitor only; do so after patient placed on monitoring
- Recheck after exposure and reactivate ICD therapy

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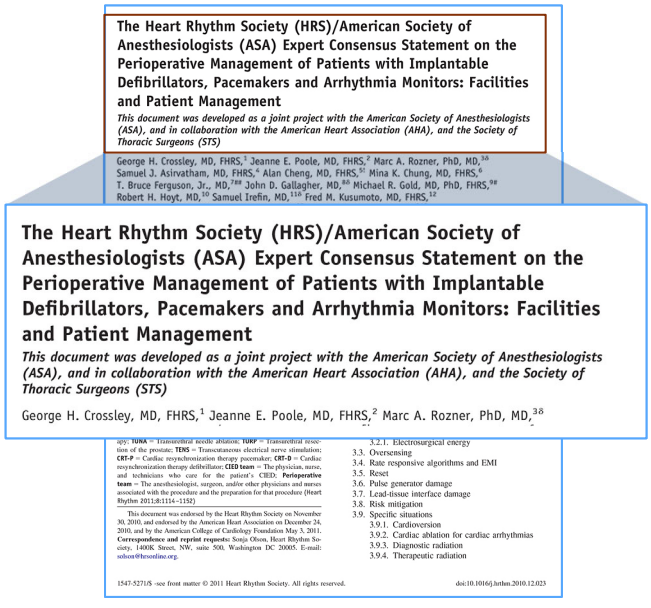

The Heart Rhythm Society (HRS)/American Society of Anesthesiologists (ASA) Expert Consensus Statement on the Perioperative Management of Patients with Implantable Defibrillators, Pacemakers and Arrhythmia Monitors: Facilities and Patient Management

This document was developed as a joint project with the American Society of Anesthesiologists (ASA), and in collaboration with the American Heart Association (AHA), and the Society of Thoracic Surgeons (STS)

George H. Crossley, MD, FHRS,[1] Jeanne E. Poole, MD, FHRS,[2] Marc A. Rozner, PhD, MD,[3&]

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Crossley G, et al. Heart Rhythm. 2011;8(7):1114-1154.

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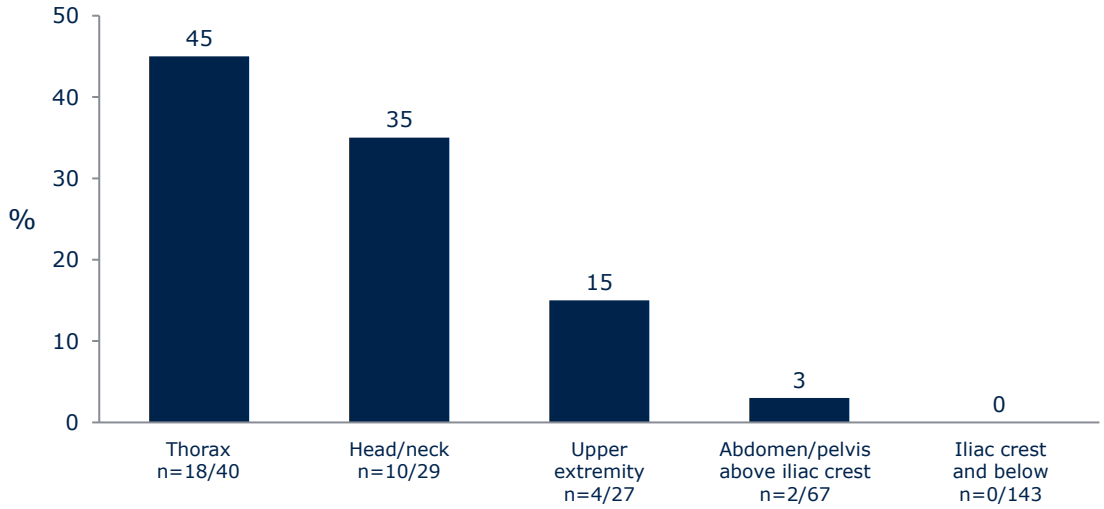
Incidence of EMI Based on Surgical Location



Gifford J, Larimer K, Thomas C, May P. Pacing Clin Electrophysiol. 2017;40(2):128-134

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CIED Management for Surgical Procedure

- Document preoperative programmed parameters
- Determine whether patient is pacemaker dependent (PMD)
- Not PMD:
    1. PM: ? Need to turn off rate adaptive sensor; place on monitor
    2. High voltage device: place on monitor; turn off tachy Rxs
- Additional for PMD:
    1. PM: Program asynchronous mode [intraoperative magnet application preferred by some – requires magnet mode set to asynchronous response]
    2. High voltage: Program to equivalent of asynchronous mode
- Post-op: Interrogate; restore original programming
- The current path and ground plate should be kept as far away from the pulse generator/ICD and leads as possible (at least 6 inches / 15 cm)
- The bipolar setting on the electrocautery equipment should be used, if available
- The electrocautery ground pad should be placed on the same side of the patient that electrocautery will be performed

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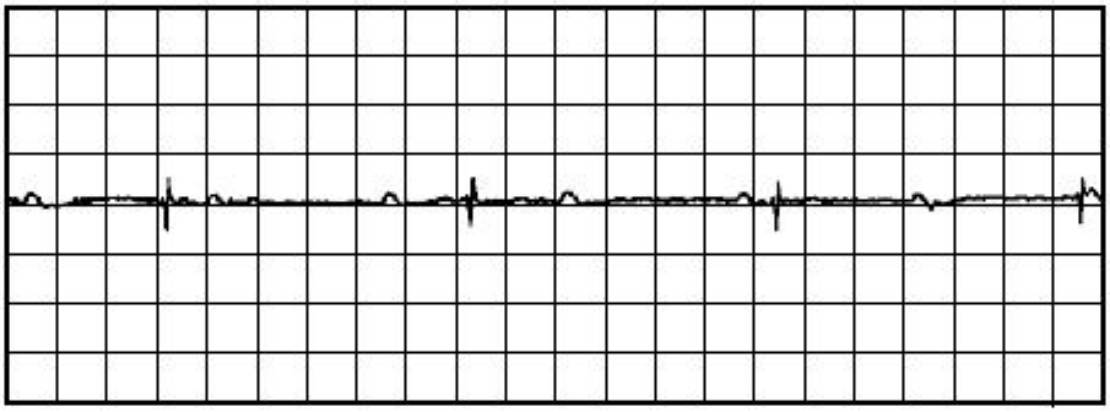
Pt with DC-PM programmed VVI for cardioversion for atrial fib
Tracing obtained post-cardioversion



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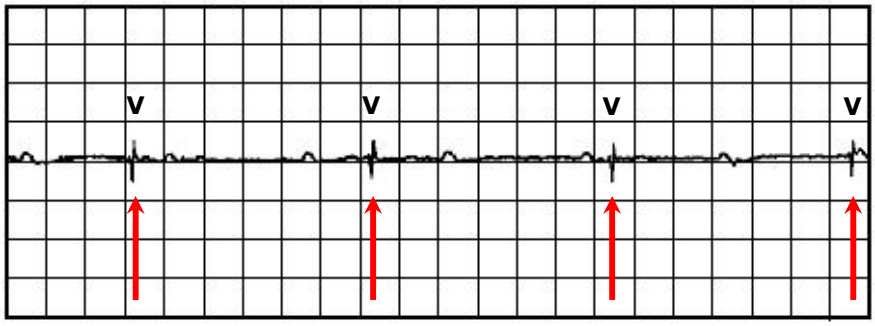
Pt with DC-PM programmed VVI for cardioversion for atrial fib. Tracing obtained post-cardioversion demonstrates?

1. Persistent atrial fibrillation
2. Ventricular failure to output
3. Ventricular failure to capture



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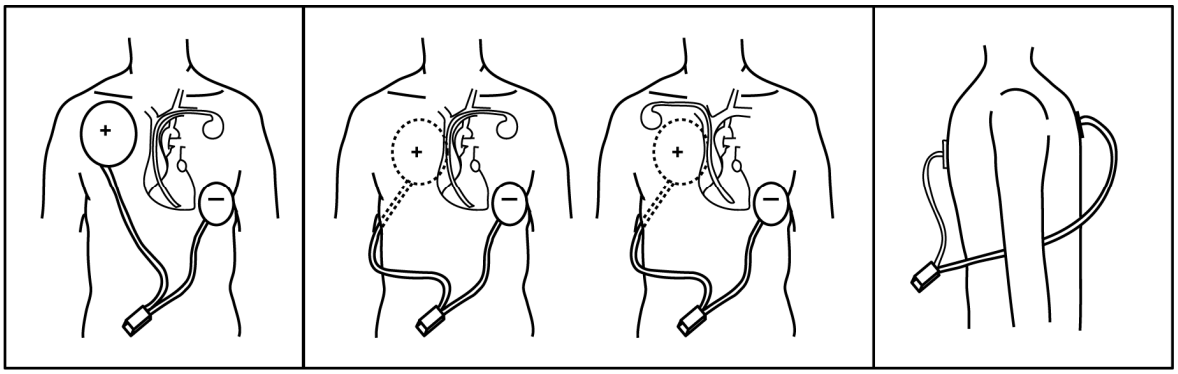
Paddle Placement for Elective Cardioversion

Apex-Anterior Apex-Posterior



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'Conditionally Safe' MRI CIED Systems

- Many leads have been approved as conditionally safe
- For a 'system' to be considered conditionally safe the components must be from the same manufacturer
- MagnaSafe and other registries imaging non-conditionally safe CIED systems have demonstrated that carefully managed MRI can be done safely in many patients[1]*
- Guidelines for imaging standard CIED systems have been published by HRS[2]

*MRI of non-conditionally approved devices would be considered "off-label" and is therefore not recommended

1 Russo RJ, et al. "Assessing the Risks Associated with MRI in Patients with a Pacemaker or Defibrillator". *New England Journal of Medicine*. 2017. 376(8):755-764.

2 Indik J. Heart Rhythm. 2017;14(7):e97-e153. 2017 HRS expert consensus statement on magnetic resonance imaging and radiation exposure in patients with cardiovascular implantable electronic devices. Heart Rhythm. 2017 Jul;14(7):e97-e153. doi: 10.1016/j.hrthm.2017.04.025. Epub 2017 May 11. PMID: 28502708.

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MRI hazard	Static	Gradient	RF
Force and torque Patient discomfort, dislodgement	♦		
Vibration Patient discomfort, device damage	♦	♦	
Image artifact **Diagnostic image quality**	♦	♦	♦
Device interactions Therapy delivery, device reset/damage	♦	♦	♦
Case heating Patient discomfort, necrosis		♦	♦
Unintended cardiac stimulation (UCS)[1] Arrhythmia induction, asystole		♦	♦
Lead-electrode heating Therapy delivery, sensing			♦

1. Hayes D, Holmes D Jr, Gray J. J Am Coll Cardiol. 1987;10(4):782-786

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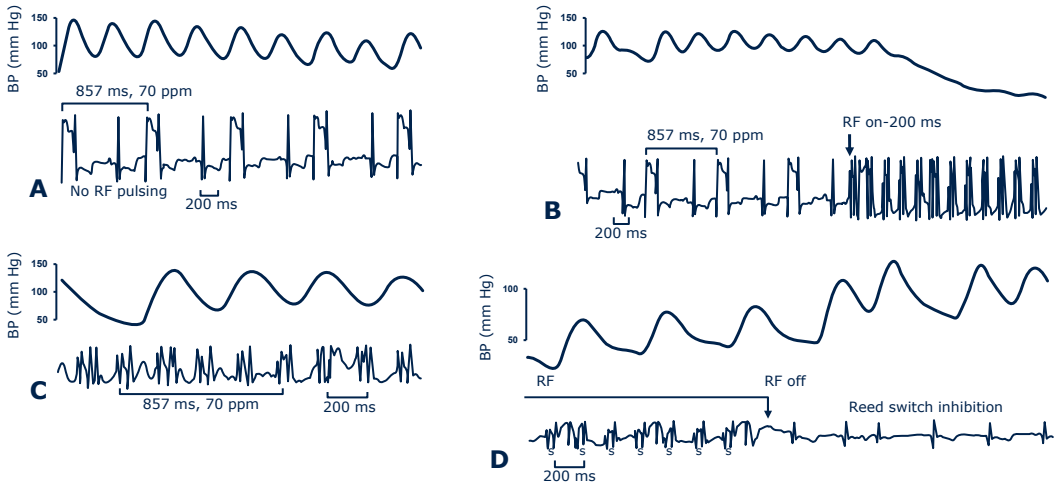
Effect of MRI on Implanted Pacemakers



Hayes D, Holmes D Jr, Gray J. J Am Coll Cardiol. 1987;10(4):782-786

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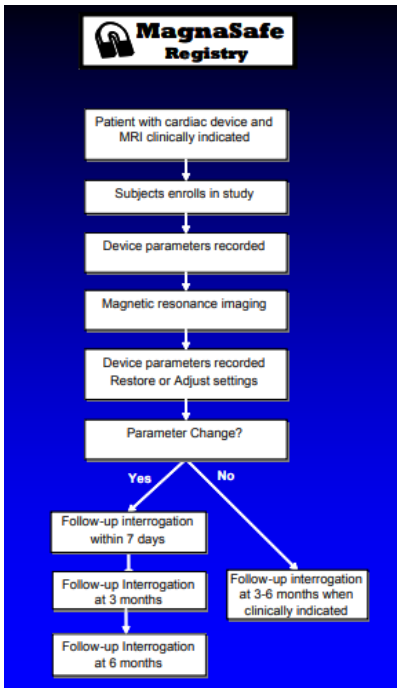
MagnaSafe Registry

Inclusion Criteria

1. Male or Female 18 years or older
2. Pacemaker or ICD implanted after 2001
3. Strong clinical indication for MRI
4. Scheduled for non-thoracic MRI

Exclusion Criteria

1. Metallic objects that are contraindication to MRI
2. Claustrophobia unresponsive to oral sedatives
3. Morbid obesity (abdominal diameter >60 cm)
4. Has an ICD and is pacing dependent
5. Pregnancy
6. Battery voltage at ERI
7. Active implanted device (other than pacemaker/ICD)
8. Presence of abandoned leads
9. Cardiac device in abdominal position
10. CIED that is labeled as MRI-Conditional



Russo RJ, et al. "Assessing the Risks Associated with MRI in Patients with a Pacemaker or Defibrillator". *New England Journal of Medicine*. 2017. 376(8):755-764.

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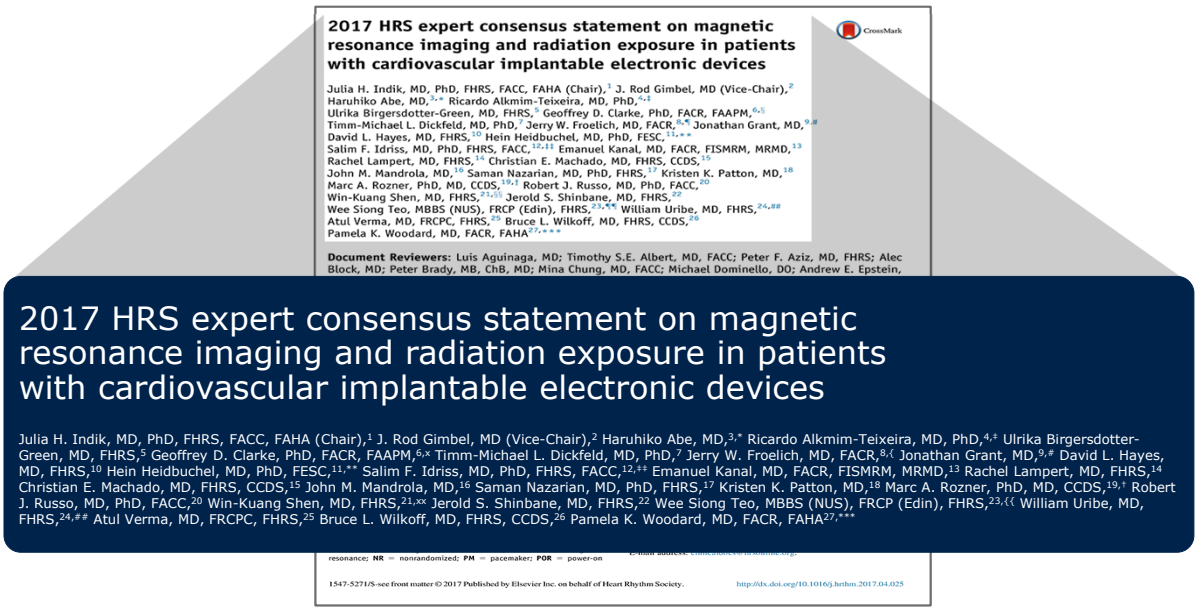

2017 HRS expert consensus statement on magnetic resonance imaging and radiation exposure in patients with cardiovascular implantable electronic devices

Julia H. Indik, MD, PhD, FHRS, FACC, FAHA (Chair),[1] J. Rod Gimbel, MD (Vice-Chair),[2] Haruhiko Abe, MD,[3,*] Ricardo Alkmim-Teixeira, MD, PhD,[4,‡] Ulrika Birgersdotter-Green, MD, FHRS,[5] Geoffrey D. Clarke, PhD, FACR, FAAPM,[6,§] Timm-Michael L. Dickfeld, MD, PhD,[7] Jerry W. Froelich, MD, FACR,[8,¶] Jonathan Grant, MD,[9,#] David L. Hayes, MD, FHRS,[10] Hein Heidbuchel, MD, PhD, FESC,[11,**] Salim F. Idriss, MD, PhD, FHRS, FACC,[12,‡‡] Emanuel Kanal, MD, FACR, FISMRM, MRMD,[13] Rachel Lampert, MD, FHRS,[14] Christian E. Machado, MD, FHRS, CCDS,[15] John M. Mandrola, MD,[16] Saman Nazarian, MD, PhD, FHRS,[17] Kristen K. Patton, MD,[18] Marc A. Rozner, PhD, MD, CCDS,[19,†] Robert J. Russo, MD, PhD, FACC,[20] Win-Kuang Shen, MD, FHRS,[21,xx] Jerold S. Shinbane, MD, FHRS,[22] Wee Siong Teo, MBBS (NUS), FRCP (Edin), FHRS,[23,{{] William Uribe, MD, FHRS,[24,##] Atul Verma, MD, FRCPC, FHRS,[25] Bruce L. Wilkoff, MD, FHRS, CCDS,[26] Pamela K. Woodard, MD, FACR, FAHA[27,***]

Indik J. Heart Rhythm. 2017;14(7):e97-e153.

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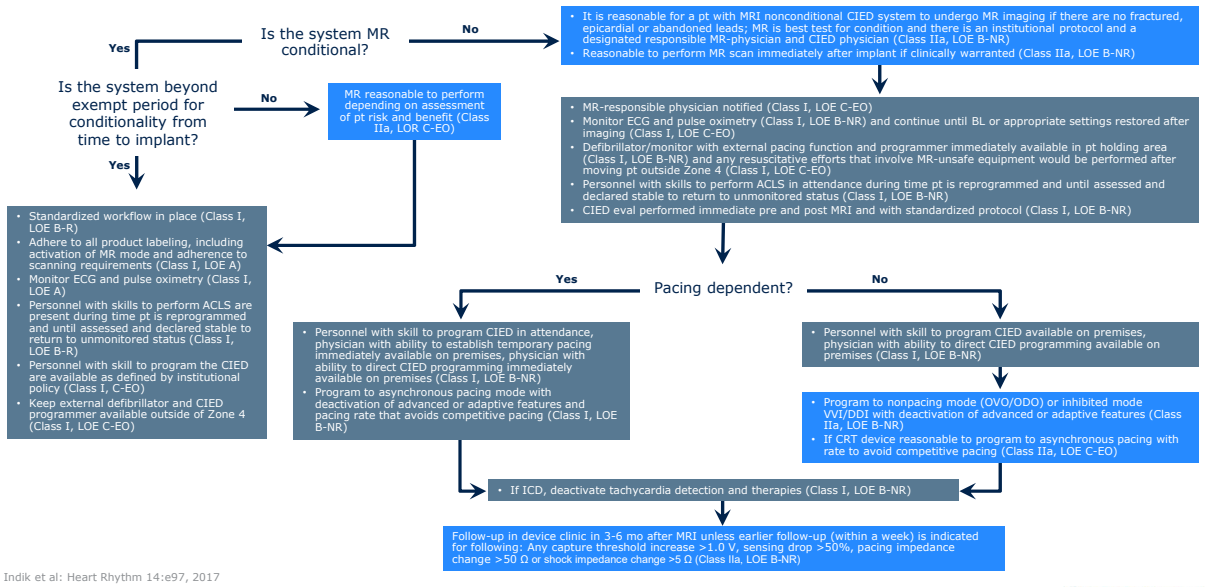
Recommendations and Protocol for Management of Patient With an MR Nonconditional Device Undergoing MRI



Indik et al: Heart Rhythm 14:e97, 2017

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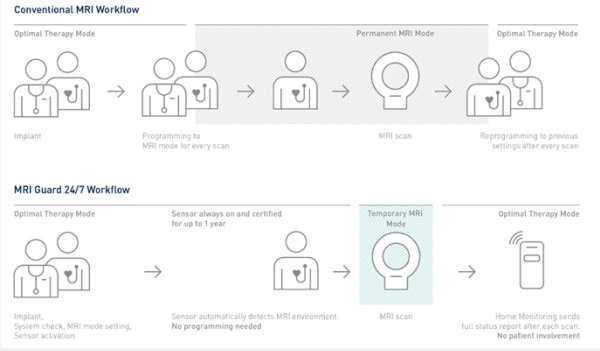
Efficient, Automated MRI Access

MRI Guard 24/7

Always-on sensors that automatically switch device into MRI mode during and following scan

- Eliminates need for pre- and post-scan programming requirements[1,2]
- Increases efficiency and flexibility for providers
- Optimizes work-flow and reduces administrative burden on clinic and healthcare system
- Improves flexibility and access to MRI environment



NOTE: Devices that include MRI Guard 24/7: Amvia Edge Family of devices

1. Data on file at BIOTRONIK.
2. Mullane S, et al. Heart Rhythm O2. 2021;2(2):132-137. Utilization and programming of an automatic MRI recognition feature for cardiac rhythm management devices.

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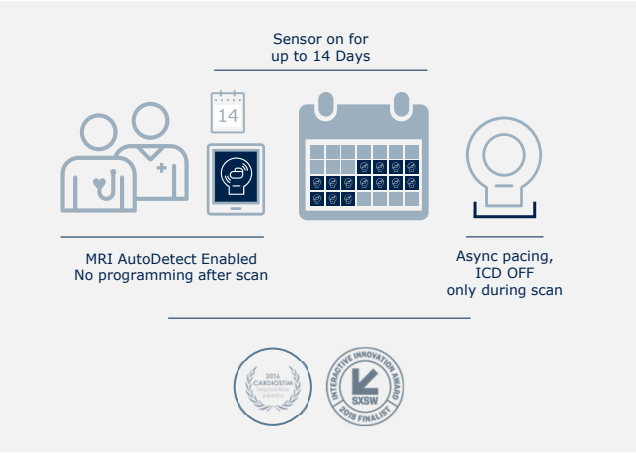
ProPatient. ProMRI.

MRI AutoDetect

A dedicated sensor that automatically detects the MR environment

- Minimum time in MRI mode intended to improve patient experience
- Increases efficiency and flexibility for providers
- Optimizes work-flow and reduces administrative burden on clinic and healthcare system
- Improves flexibility and access to MRI environment



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ProMRI

MRI diagnostics are growing in importance

- Number of MRI diagnostic scans continues to increase
- Medical applications involving MRI are growing

Device patients are more prone to require MRI diagnostics

- Age and comorbidities contribute to this need
- Trend likely to continue into future

Up to **75%** of patients with a cardiac implantable electronic device will need an MRI during their lifetime.[4]

More than 3 out of 4 adults aged 65 years or older **have two more chronic conditions**.[5]

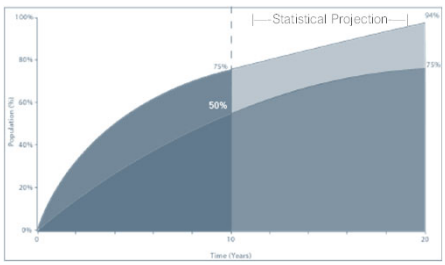

Figure 1: MRI/MRA use by matched ICD-likely patients and forecasted need projected to 20 years.[1,2,3]

1. Gimbel JR, et al. PACE. 2015, 38(12).
2. Kalin R, et al. PACE. 2005, 28(4).
3. Nazarian S, et al. J Magn Reson Imaging. 2016;43(1):115-127.
4. Roguin A, et al. Europace. 2008, 10(3).
5. Osborn R, et al. Health Affairs. 2014, 33(12).

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Design Rationale for MRI Guard 24/7

- Improve patient safety
- Increase provider efficiency
- Expand scheduling flexibility
- Reduce administrative burden on the healthcare system

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How Is MRI AutoDetect/MRI Guard 24/7 Different from First-Generation MRI Systems?

- One programming step (no post-scan programming required)
- Automatic programming change when in MRI field to reduce time in asynchronous pacing and time without therapy for ICDs
- Geographic flexibility for patient and provider
- Programmed up to 14 days (AutoDetect) or certified for up to a year (MRI Guard 24/7)
- Expected to reduce administrative burden on imaging staff
- May allow for more patients to be scanned

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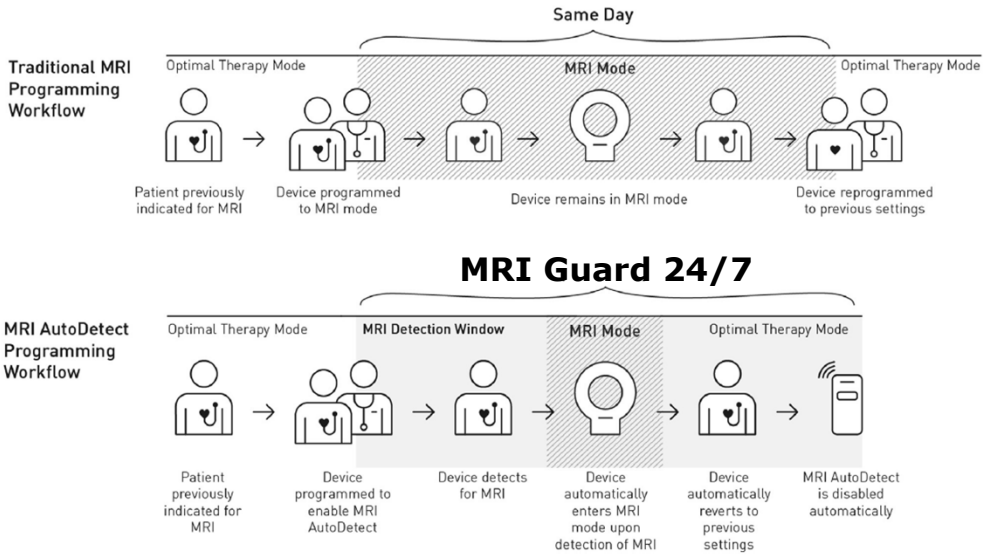
What is typical workflow for device patient requiring MRI?



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How Does the Sensor Technology Work?

Previous-generation devices only had magnet mode. That sensor was designed to respond to a magnetic field strength of 1.5 mT (millitesla).

Devices equipped with MRI AutoDetect have a second sensor that responds to a magnetic field strength of 10 mT. Once the 10 mT criterion is met, the devices switch to MRI mode. Within one minute of removal from the 10 mT field, original programming is restored.

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Summary: MR and CT Imaging in the CIED Patient

- MR imaging of 'conditional' and 'nonconditional' CIED has been performed safely but scanning of 'nonconditionally approved devices is 'off-label''
- Strict adherence to protocol must be followed.
- Pacemaker dependent patients can undergo MR imaging if clinically indicated
- Interpretation of thoracic MR images of a CIED patient may be impacted by artifact from the CIED
- Diagnostic CT in a patient with a CIED is fine; CIED should be excluded from field of view of 4D CT and cone-beam CT scans if possible

NOTE: Please refer to the BIOTRONIK ProMRI System Technical Manual

Indik et al: Heart Rhythm 14:e97, 2017

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Which of the following has not been shown to have the potential to interfere with device function?

1. Industrial welding equipment
2. Anti-theft devices (electronic article surveillance equipment)
3. Traditional telephone land-line
4. Laptop computer

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EMI: Potential Non-Hospital Sources

- Electronic article surveillance (anti-theft) equipment
- Specific work environments
    - Welding equipment
    - Degaussing equipment
    - Industrial combustion equipment
- Miscellaneous sources capable of 1-beat inhibition

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Which of the following is true regarding a variety of "common" sources of EMI and miscellaneous issues?

1. Use of welding equipment < 200 amps is of no clinical concern
2. Microwave ovens are of no concern
3. Household appliances that are non 'grounded' can damage CIED
4. Therapeutic radiation does not pose risk to a CIED

Asirvatham S, Friedman P, Hayes D. Cardiac Pacing, Defibrillation and Resynchronization: A Clinical Approach (4th Edition). Chapter12: Electromagnetic Interference: Sources, Recognition, and Management. pp 551-577

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EMI Sources Noted in Recent Literature

- Pulsed Field Ablation
- Consumer electronics with magnets
- Ab stimulators
- Electronic body fat scales
- CPAP masks with magnetic clips

Liu X. Pulsed field ablation can be a source of electromagnetic interference with cardiac implantable electronic devices. Heart Rhythm Case Reports. 2024; 10:858

Wang D, et al. Device–device interference triggered by an abandoned pacemaker: a case report. European Heart Journal - Case Reports, 2024; 8(1). https://doi.org/10.1093/ehjcr/ytae595

Devices That May Interfere With ICDs and Pacemakers. Heart.org. https://www.heart.org/en/health-topics/arrhythmia/prevention--treatment-of-arrhythmia/devices-that-may-interfere-with-icds-and-pacemakers?utm_source=chatgpt.com

CIEDs and The Impact of Electromagnetic Interference (EMI). Cardiac RMS; May 24, 2023: https://cardiacrms.com/2023/05/24/cieds-and-the-impact-of-electromagnetic-interference-emi/?utm_source=chatgpt.com

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Cellular Phones and CIEDs

- No significant risk with commercially available phones
- Activated phone should not be carried directly over the pulse generator
- Some sources continue to recommend that cell phones be kept at least 6 inches from a CIED.[1] However, clinicians and patients realize the difficulty adhering to this distance and the true lack of evidence base to support it.

1 Devices That May Interfere With ICDs and Pacemakers. Heart.org. https://www.heart.org/en/health-topics/arrhythmia/prevention--treatment-of-arrhythmia/devices-that-may-interfere-with-icds-and-pacemakers?utm_source=chatgpt.com

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Regarding anti-theft equipment, patients with CIED should be instructed to:

1. Stay at least 3 feet away
2. Walk directly through equipment
3. Completely avoid with high-voltage CIED
4. Present CIED ID to management before entering and exiting facility to disable equipment

McIvor, CVR&R, Jan '99:11; Groh, et al. Circ 1999;100:387

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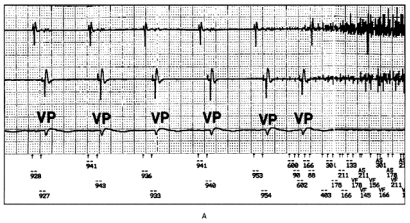
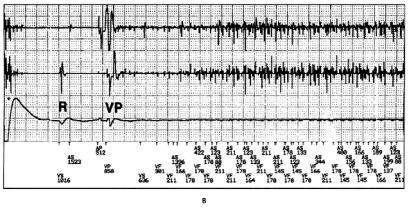
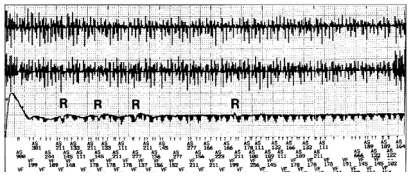
Pacemaker dependent with ventricular pacing (VP); last VP due to atrial tracking of EMI



ICD discharge followed by redetection and Pacemaker inhibition with syncope



Second ICD discharge and redetection



Santucci, et al. NEJM 1998;339:1371-1374

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Response to Anti-theft Equipment

Possible Device Response

- Asynchronous pacing
- Atrial oversensing
- Ventricular oversensing
- Extrasystoles (EAS induced secondary to direct induction of current by the magnetic field)
- Inappropriate therapy from oversensing

Clinicians should advise

- Any risk from EAS systems is negligible when walking through normally
- Do not lean over or against EAS gates
- Do not linger in store doorways
- Move away from EAS if symptomatic

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EMI and Implantable Devices

- Patient education is key
- Pulse generator shielding continues to improve allowing a greater level of comfort
- New sources of EMI must be evaluated specifically for device interference

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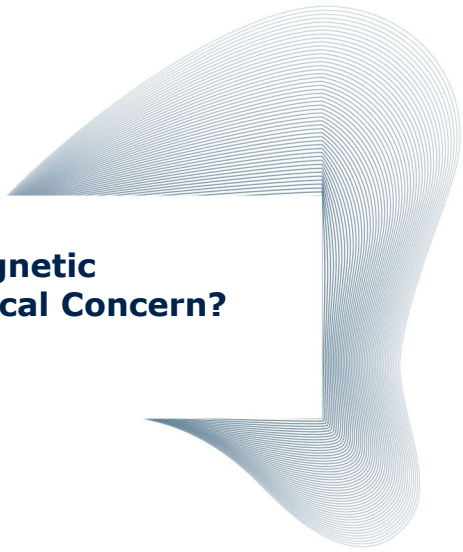

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