When is Electromagnetic Interference a Clinical Concern?

David Hayes, MD, Chief Medical Officer

BIOTRONIK
excellence for life

1

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

BIOTRONIK
excellence for life

2

Clinically Significant EMI: Class I

- Interference associated with: presyncope, syncope, dizziness, dyspnea
- Transient ventricular inhibition for > 3 secs
- Transi
- 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, et al. NEJM 1997; 336:1473

BIOTRONIK excellence for life

3

Potential Effects of EMI

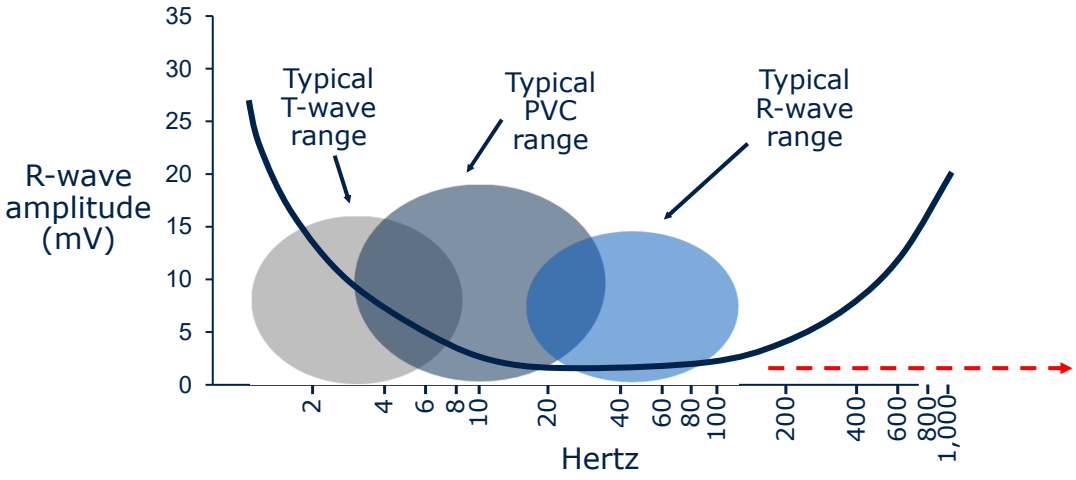
- Failure to deliver antibradycardia pacing or effective CRT therapy
- Inappropriate delivery of antitachycardia therapy
- Resetting of programmed parameters
- Damage to the pulse generator and/or lead/myocardial interface

BIOTRONIK excellence for life

4

Frequency Spectrum For Cardiac Events

'Hospital' vs 'out of hospital'



BIOTRONIK excellence for life

5

Sources of EMI in the Hospital Environment[1]

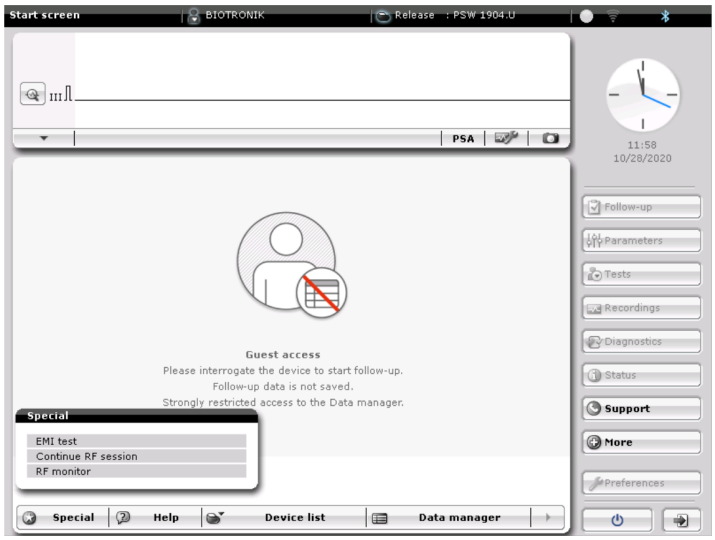
- Electrocautery/cardioversion/defibrillation
- Magnetic resonance imaging (MRI)
- Lithotripsy
- Radiofrequency ablation
- Electroshock therapy
- Transcutaneous nerve stimulators

1 Other potential sources of EMI are present

BIOTRONIK excellence for life

6

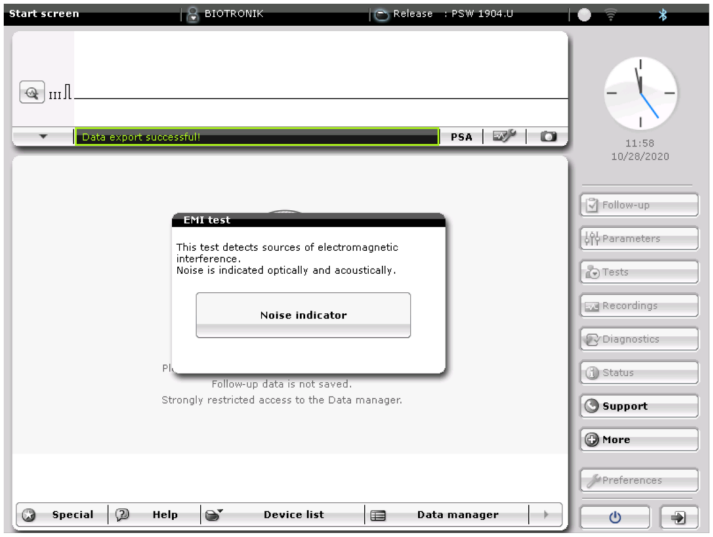
BIOTRONIK EMI Test



BIOTRONIK excellence for life

7

BIOTRONIK EMI Test



BIOTRONIK excellence for life

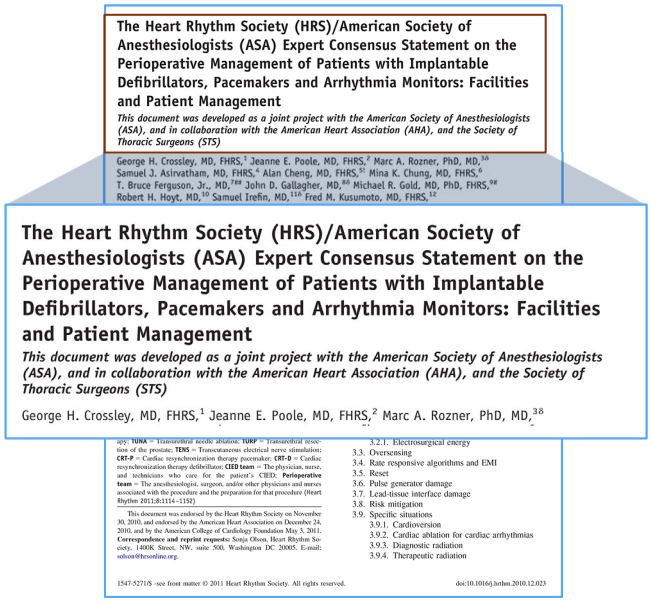
8

EMI in the Hospital Environment

- Know the potential sources
- Know programmed parameters prior to exposure
- Reprogram ICDs to monitor only
- Recheck after exposure and reactivate ICD therapy

BIOTRONIK excellence for life

9


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&]

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)

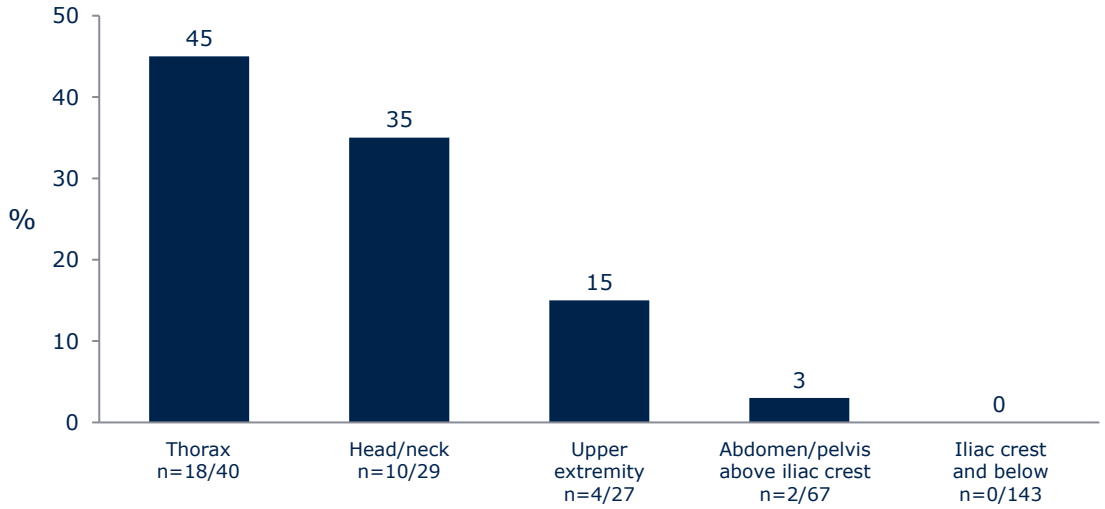
George H. Crossley, MD, FHRS,[1] Jeanne E. Poole, MD, FHRS,[2] Marc A. Rozner, PhD, MD,[3&]

Heart Rhythm. 2011 Jul;8(7):1114-54. doi: 10.1016/j.hrthm.2010.12.023. PMID: 21722856.

BIOTRONIK excellence for life

10

Incidence of EMI Based on Surgical Location



Gifford J, Larimer K, Thomas C, May P. ICD-ON registry for perioperative management of CIEDs: most require no change. Pacing Clin Electrophysiol 2017; 40: 128-34.

BIOTRONIK excellence for life

11

CIED Management for Surgical Procedure

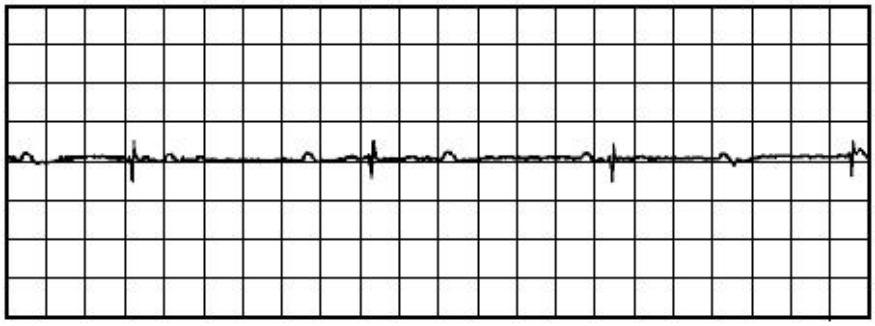
- Document preoperative programmed parameters
- Determine whether patient is pacemaker dependent (PMD)
- Not PMD:
    1. PM: Possible turn off rate adaptive sensor; place on monitor
    2. High voltage CIED: place on monitor; turn off tachy Rxs
- Additional for PMD:
    1. PM: Program asynchronous mode [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

BIOTRONIK excellence for life

12

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

1. Normal function
2. Persistent atrial fibrillation
3. Ventricular failure to capture

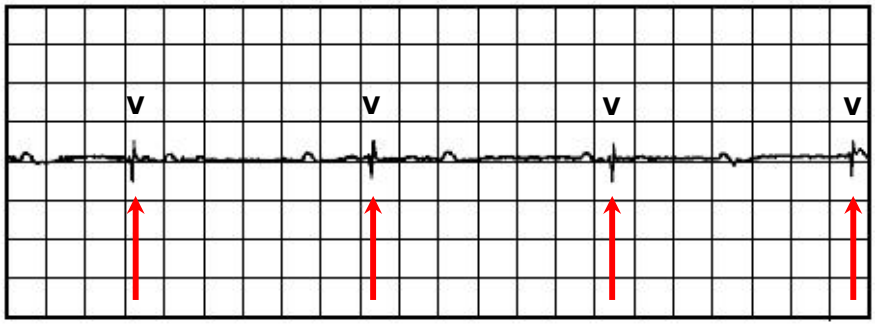


BIOTRONIK excellence for life

13

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

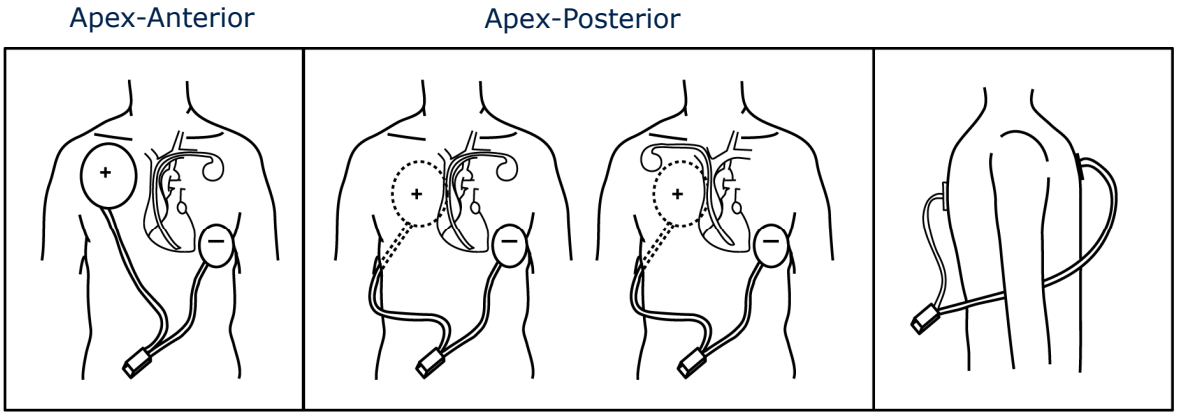
1. Normal function
2. Persistent atrial fibrillation
3. **Ventricular failure to capture**



BIOTRONIK excellence for life

14

Paddle Placement for Elective Cardioversion



BIOTRONIK excellence for life

15

'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*
- Guidelines for imaging standard CIED systems have been published by HRS[1]

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

1 Indik JH, Gimbel JR, Abe H, Alkmim-Teixeira R, Birgersdotter-Green U, Clarke GD, Dickfeld TL, Froelich JW, Grant J, Hayes DL, Heidbuchel H, Idriss SF, Kanal E, Lampert R, Machado CE, Mandrola JM, Nazarian S, Patton KK, Rozner MA, Russo RJ, Shen WK, Shinbane JS, Teo WS, Uribe W, Verma A, Wilkoff BL, Woodard PK. 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.

BIOTRONIK excellence for life

16

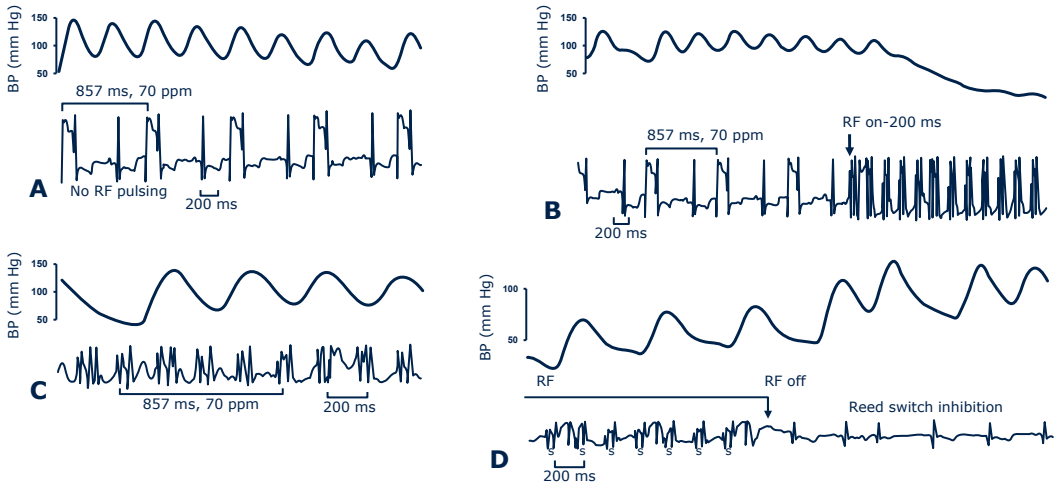
MRI hazard	Static	Gradient	RF
Force and torque Patient discomfort, dislodgement	♦		
Vibration Patient discomfort, device damage	♦	♦	
Image artifact **Diagnostic image quality**	♦	♦	♦
Device interactions Therapy delivery, device reset/damage	♦	♦	♦
Case heating Patient discomfort, necrosis		♦	♦
Unintended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

ISO/TS 10974:2012
Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device

BIOTRONIK excellence for life

17

Effect of MRI on Implanted Pacemakers



Hayes, et al. JACC 1987;10:782

BIOTRONIK excellence for life

18

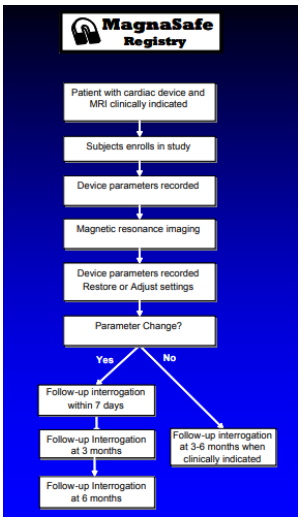
MagnaSafe Registry

Inclusion Criteria

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

Exclusion Criteria

1. Metallic objects that are a 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. Pacemaker or ICD that is labeled as MRI-Conditional (approved by the FDA for exposure to MRI).

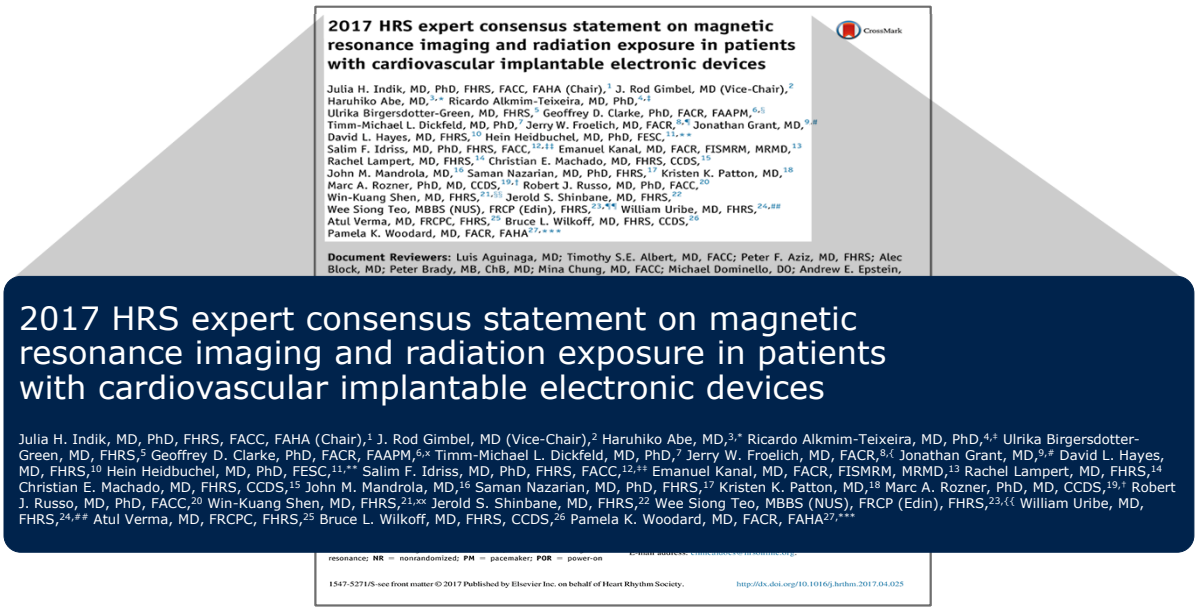


Mayo Clinic

- 2008 – 2019
- > 1500 patients with standard pacemakers/ICDs underwent MRI under approved protocol
- Majority were non-pacemaker dependent
- Majority were pacemakers and majority were non-thoracic scans
- CK and troponin done pre- and 24 hours post MRI while under IRB status
- No significant abnormalities or clinical issues occurred

BIOTRONIK excellence for life

19



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

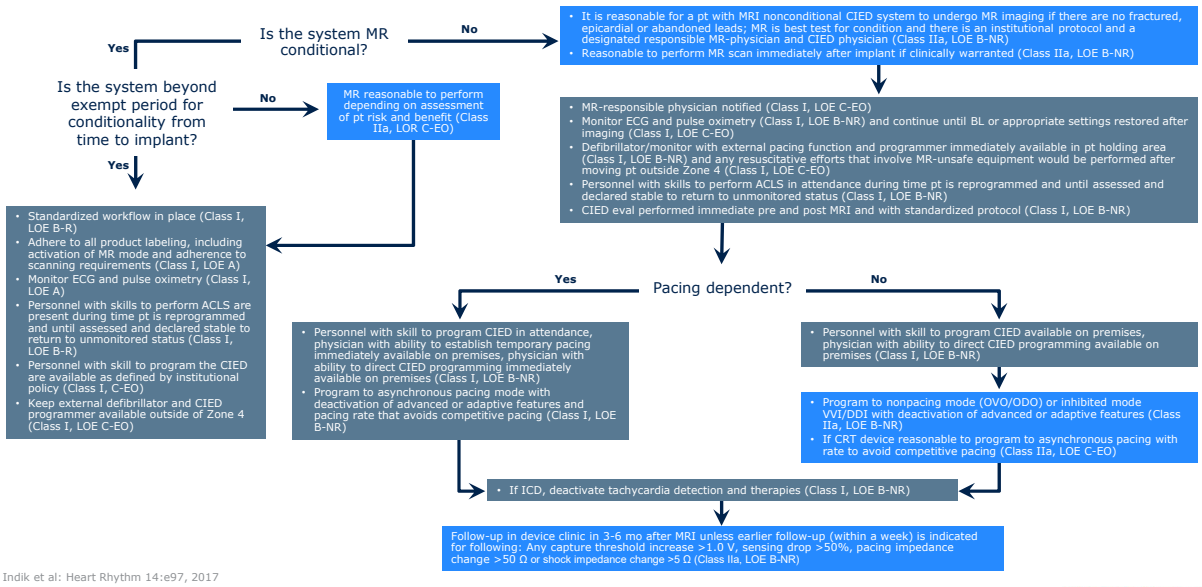
Julia H. Indik, MD, PhD, FHRS, FACC, FAHA (Chair),[1] J. Rod Gimbel, MD (Vice-Chair),[2] Haruhiko Abe, MD,[3,*] Ricardo Alkmim-Teixeira, MD, PhD,[4,‡] Ulrika Birgersdotter-Green, MD, FHRS,[5] Geoffrey D. Clarke, PhD, FACR, FAAPM,[6,§] Timm-Michael L. Dickfeld, MD, PhD,[7] Jerry W. Froelich, MD, FACR,[8,¶] 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,‡‡] 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 et al: Heart Rhythm; 14:e97-e153, 2017

BIOTRONIK excellence for life

20

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



Indik et al: Heart Rhythm 14:e97, 2017

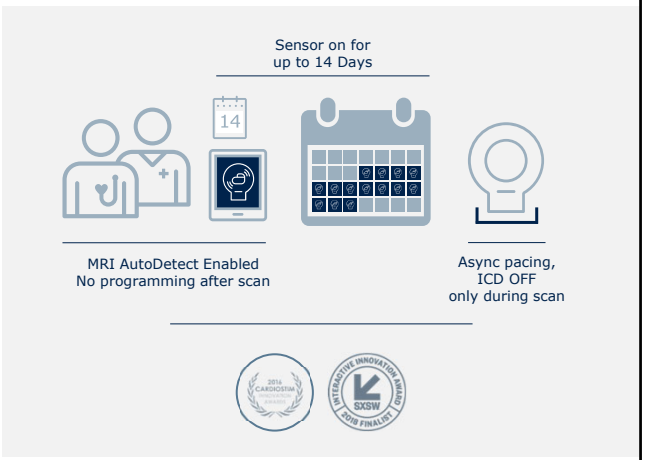
BIOTRONIK excellence for life

21

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



BIOTRONIK excellence for life

22

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

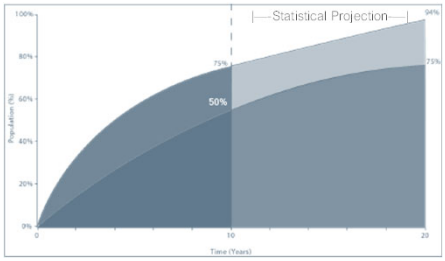


Figure 1: MRI/MRA use by matched ICD-likely patients and forecasted need projected to 20 years.[1,2,3]

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]

1. Gimbel JR, et al. PACE. 2015, 38(12).
2. Kalin R, et al. PACE. 2005, 28(4).
3. Nazarian S, et al. JACC. 2015, 65.
4. Roguin A, et al. Europace. 2008, 10(3).
5. Osborn R, et al. Health Affairs. 2014, 33(12).

BIOTRONIK excellence for life

Why Offer MRI AutoDetect/MRGuard 24/7?

Designed to:

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

BIOTRONIK excellence for life

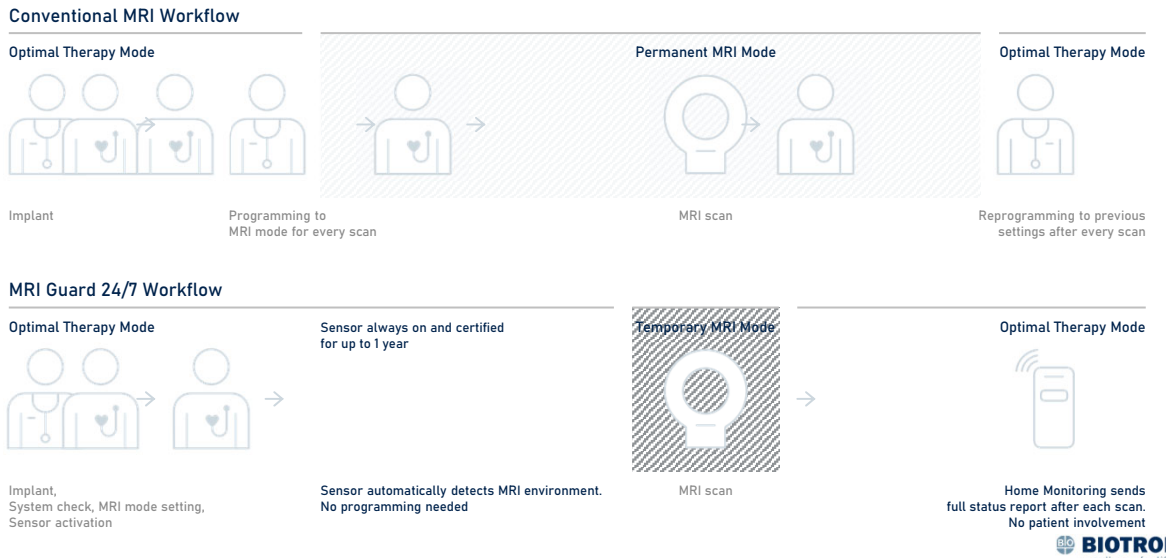
How Is MRI AutoDetect/MRI Guard 24/7 Different from First-Generation MRI Systems?

- 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

BIOTRONIK excellence for life

25

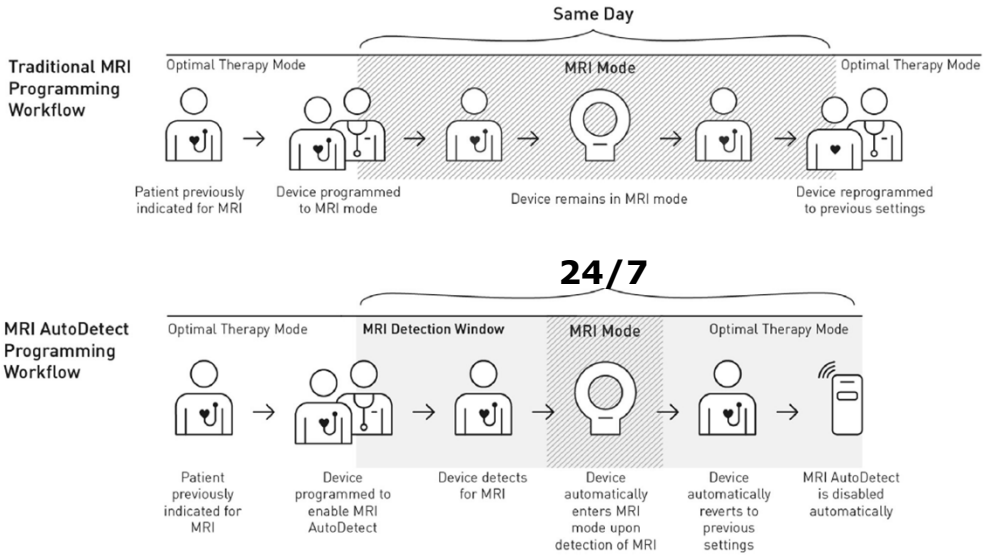
What is typical workflow for device patient requiring MRI?



BIOTRONIK excellence for life

26

What is typical workflow for device patient requiring MRI?



BIOTRONIK excellence for life

27

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.

BIOTRONIK excellence for life

28

Summary: MR and CT Imaging in the CIED Patient

- MR imaging of 'conditional' and 'nonconditional' CIED has been performed safely
- 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

BIOTRONIK excellence for life

29

All but which of the following have been demonstrated to "have the potential" to interfere with device function?

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

BIOTRONIK excellence for life

30

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

BIOTRONIK excellence for life

31

Which of the following is FALSE 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. Normally functioning household appliances are of no concern
4. Therapeutic radiation can damage a device

BIOTRONIK excellence for life

32

Cellular Phones and Implantable Devices

- No significant risk with commercially available phones
- Activated phone should not be held or worn over the pulse generator, within 6 inches
- Phone should ideally be used at the ear contralateral to the pulse generator

BIOTRONIK excellence for life

33

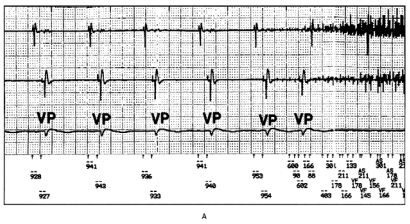
Regarding anti-theft equipment, patients with CIED should be instructed to:

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

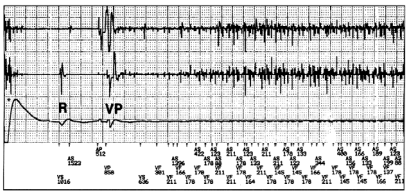
BIOTRONIK excellence for life

34

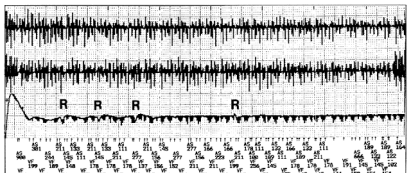
Pacemaker dependent with ventricular pacing (VP); last VP due to atrial tracking of EMI



ICD discharge followed by redetection and Pacemaker inhibition with syncope



Second ICD discharge and redetection



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

BIOTRONIK excellence for life

35

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)

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

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

BIOTRONIK excellence for life

36

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

BIOTRONIK excellence for life

37

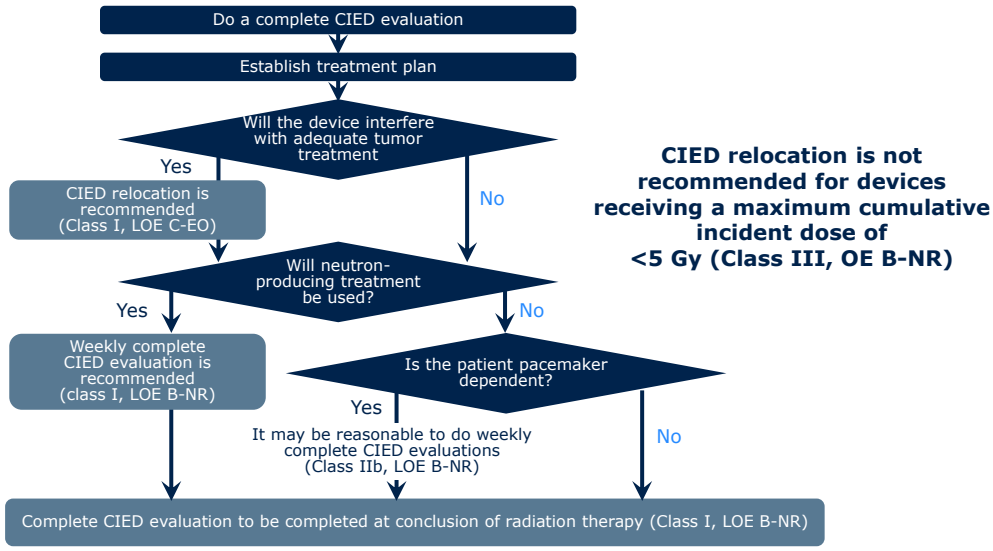
When is Electromagnetic Interference a Clinical Concern?

David Hayes, MD

BIOTRONIK excellence for life

38

CIED Management for Radiation Therapy



CIED relocation is not recommended for devices receiving a maximum cumulative incident dose of <5 Gy (Class III, OE B-NR)

Indik et al: Heart Rhythm, Vol 14, No 7, July 2017

BIOTRONIK excellence for life

39

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: _____

Indik et al: Heart Rhythm 14:e97, 2017

BIOTRONIK excellence for life

40

Manufacturer Recommendations Regarding Safe Radiotherapy in PM/ICD Patients

Recommendation	BIOTRONIK	Boston Scientific
Device checks		
Before RT course	Yes	Specific to each patient
During RT course	Not stated	Specific to each patient
After RT course	Yes, including a supplementary follow-up shortly after RT	Yes, including subsequent close monitoring of the device function
Maximal PM dose	2 Gy	No safe dose (2 Gy as a reference)
Maximal ICD dose	2 Gy	No safe dose (2 Gy as a reference)
Maximal beam energy	<10 MV	Not stated
Inactivation of antitachycardia therapies	Yes	Yes
Lead shielding of the device	Yes	All available shielding options, including both internal shielding within the LA and external shielding of the patient
Heart rhythm monitoring during RT	Yes	As determined most appropriate by the physician team

Zeremba, et al. PACE 2015;35:343-356

BIOTRONIK excellence for life

41

Manufacturer Recommendations Regarding Safe Radiotherapy in PM/ICD Patients

Recommendation	Medtronic	St. Jude Medical
Device checks		
Before RT course	Not stated	Not stated
During RT course	Yes (if recommended safe dose is exceeded	Yes (a detailed evaluation once or twice during the RT course in PM-dependent patients)
After RT course	Yes	Yes
Maximal PM dose	5 Gy	No safe dose
Maximal ICD dose	1-5 Gy depending on model	No safe dose
Maximal beam energy	≥10 MV	Not stated
Inactivation of antitachycardia therapies	Yes	Yes
Lead shielding of the device	No (ineffective against neutrons)	Not stated (reduction in the device dose is recommended
Heart rhythm monitoring during RT	Not stated	Yes

Zeremba, et al. PACE 2015;35:343-356

BIOTRONIK excellence for life

42

Summary: Radiation Therapy in the CIED Patient

- Determine maximum cumulative incident radiation dose the CIED will receive, if < 5 Gy, do not move
- Consider relocating the CIED if cumulative dose will be > 5 Gy and/or the device will impede effective Rx of tumor
- Frequency of CIED evaluation dependent on whether radiation treatment is neutron-producing

In the event the patient is pacemaker dependent, and the site of the radiation is at or within 10 cm of the pacemaker site, it is recommended that the pacemaker or ICD be moved to another site.

BIOTRONIK excellence for life