MR Conditional Pacemakers: What to do?

Anshuman Panda, Ph.D.

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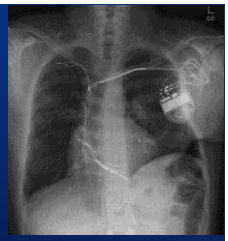
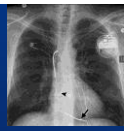
No conflict of interest to declare

Outline

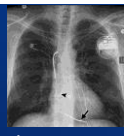


- MR-conditional pacemakers
  - Pacemaker MRI safety
  - FDA approved devices
- Scan guidelines
  - ACR 2013 white paper
  - How we do it
    - Mayo Arizona guidelines
- Look ahead
  - Role of Medical Physicist?
  - Role of AAPM?

Pacemaker MRI: Safety Concerns

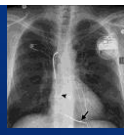


- Static magnetic field
  - Mechanical forces exerted are usually negligible at 1.5 T
    - Exception: older devices pre-1998
  - Magnetic sensor activation and unpredictable reed-switch behavior
    - Causing the device to revert to asynchronous pacing
  - Magnetohydrodynamic effect
    - Simulate life-threatening arrhythmias and produce other electrocardiographic changes



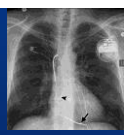
Pacemaker MRI: Safety Concerns

- Gradient magnetic fields
  - Capable of producing gradient magnetic fields of 20–100 mT/m or higher at 1.5 T
    - Repeatedly and rapidly turned on and off
  - Can induce electrical currents in pacemaker lead
    - Cause oversensing or undersensing
    - Life-threatening arrhythmias



Pacemaker MRI: Safety Concerns

- Radiofrequency energy: Pacemaker
  - Pacing at multiples of the radiofrequency pulse and associated rapid ventricular pacing
  - Pacemaker leads can act as “antennae” producing heat and electrical by concentrating RF energy
    - Damage to the pulse generator circuitry
    - Pacemaker reset
    - Battery depletion



Pacemaker MRI: Safety Concerns

- Radiofrequency energy: Lead Wires
  - Produce heat and electrical currents
  - Cause pacemaker reset
  - Cause tissue destruction at the lead tip, myocardial stimulation
  - Damage to the pulse generator circuitry and battery/ battery depletion
  - Adverse effects on sensing, pacing thresholds, and lead impedances
  - Abandoned or fractured leads are more prone to tip heating

Reported Adverse Events

Table: Summary of published literature on MRI in the setting of Implantable Cardiac Devices

Authors	Number of patients	Pacemaker	ICD	MRI field strength	Adverse events
Gimbel et al (24)	5	✓		0.5 Tesla	One pacemaker dep… with dual chambe… DOO mode
Gimbel et al. (25)	7		✓	1.5 Tesla	One pati…
Del Ojo et al (26)	13	✓		2.0 Tesla	
Gimbel et al (21)	15	✓	✓	3 Tesla	
Halshtok et al (27)	18	✓	✓		…m to backup
Naehle et al (28)	18		✓		…was decreased. Over …ds noticed in 2 devices …attempt to deliver therapies
Vahlhaus et al (29)	32	✓			Battery voltage was decreased with recovery three months later; 12 patients had temporary deactivation of reed switch
Buendia et al (30)	33			1.5 Tesla	In 11 leads a change in capture threshold was noted. Over sensing was reported in 2 patients, and one patient had reversion to backup mode
Mollerus et al (31)			✓	1.5 Tesla	
Burke et al (32)			✓	1.5 Tesla	
Sommer et al…		✓		0.5 Tesla	
Naehle…		✓		3 Tesla	
…		✓		1.5 Tesla	Repeat MRI was associated with decreased pacing capture threshold and battery voltage
…	54	✓		1.5 Tesla	In 10 leads changes in measured parameters were noticed. 2 required reprogramming
S…er et al (7)	82	✓		1.5 Tesla	Increased capture threshold was noted. In 4 of 114 examinations an increase of Troponin-I level was noticed
Mollerus et al (36)	103	✓	✓	1.5 Tesla	Decreased in sensing amplitude and impedances
Strach et al (37)	114	✓		0.2 Tesla	

At least 17 supposed MRI-associated deaths among patients with pacemakers

Beinart et.al. Magnetic Resonance Imaging in Patients with ICDs and Pacemakers http://crm.cardiosource.org

Which of the following is a primary concern during MR scanning of a pacemaker:

20% 1. Heating at the lead tip and at the lead tissue interface

13% 2. Force and torque on devices

23% 3. Change of programming with potential damage to the pacemaker circuitry

27% 4. Asynchronous pacing or pacing at multiples of the radiofrequency pulse

17% 5. All of the above

Which of the following is a primary concern during MR scanning of a pacemaker:

5. All of the above
   - Heating at the lead tip and at the lead tissue interface
   - Force and torque on devices
   - Change of programming with potential damage to the pacemaker circuitry
   - Asynchronous pacing or pacing at multiples of the radiofrequency pulse

- ACR Guidance Document on MR Safe Practices: 2013 Journal of Mag Res Imag. 2013:37 501-503

MR Conditional Pacemaker: Development Timeline

- 2008: MRI-conditional pacemakers introduced
- 2011: FDA approved the first MR-conditional pacemaker - Medtronic Revo
  - Both lead and pulse generator have to be MR conditional
- 2013: Second Generation Medtronic (Advisa) MR-conditional pacemaker gets FDA approval
- 2014: Biotronik single chamber and dual chamber pacemaker gets FDA approval

MR Conditional Pacemakers: FDA-approved

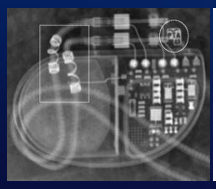
- Medtronic
  - Revo MRI SureScan – Approved 2011
  - Advisa MRI SureScan – Approved 2013 (Both dual chamber only)
  - Leads: CapSure Sense and CapSureFix MRI
- Biotronik
  - Entovis ProMRI single chamber and dual chamber – Approved 2014
  - Leads: Setrox S53/S60

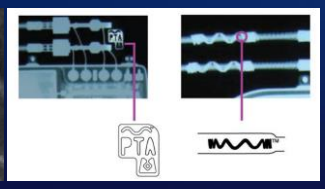
Pacemaker Design Changes: Pulse Generator

- Pulse generator shielding
  - Minimize effect of the electromagnetic environments
- Reducing ferromagnetic content
  - Avoid damage or malfunction of components
  - Reduce magnetic attraction and susceptibility artifacts
- Reed switch changes to a solid-state Hall sensor
  - Allows for predictable behavior in a magnetic field
- Radio-opaque markings
  - Identify the device and components as MR conditional
- Dedicated programming modes - asynchronous pacing
  - Prevent inappropriate pacemaker inhibition
  - Prevent competing rhythms

Radio-Opaque Markings

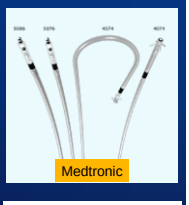
- Visual confirmation through radiograph
  - MR-conditional pulse generator - emblem
  - MR-conditional leads - wavy pattern





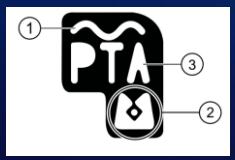
Pacemaker Design Changes: Lead Wire

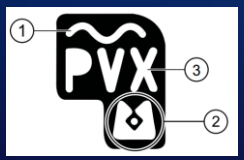
- Design: Higher inductance and reduce lead tip heating
  - Minimize resonant frequency conduction
    - Changing the winding pattern
    - Modifications in lead geometry of the filaments
- Insulation: Filter circuitry
  - Prevent damage to internal power supply
  - Limit transfer of certain frequencies and dissipate energy
- Identification: Radio-opaque indicator*



Radio-Opaque Markings: Medtronic

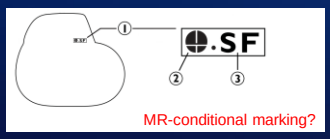
- Gen 1: Revo/EnRhythm
  1. Marker identifying the device as MR conditional
  2. Medtronic identifier
  3. Device specific identifier
- Gen 2: Advisa/Ensura
  1. Marker identifying the device as MR conditional
  2. Medtronic identifier
  3. Device specific identifier





Radio-Opaque Markings: Biotronik

- Entovis Single/Dual Chamber
  1. Radiopaque device maker
  2. Biotronik identifier
  3. Device specific identifier



MR-conditional marking?

- No radiopaque markers are present for MR-conditional lead identification

Needs Standardization

MR-Conditional Pacemakers: FDA Restrictions

	MEDTRONIC	BIOTRONIK
Scan Zone Restrictions	Whole body	Exclusion zone: between C1 and T12 vertebrae
Field Strength	Cylindrical bore magnet, clinical MRI systems with a static magnetic field of 1.5T	
Gradient Slew Rate	≤ 200 T/m/s	≤ 200 T/m/s
SAR – Head	≤ 2.0 W/kg	≤ 2.0 W/kg
SAR – Body	≤ 3.2 W/kg	≤ 3.2 W/kg
Scan Duration	No	Each scan ≤30 min maximum: 10 hours lifetime
Coils	Transmit/Receive	No additional local Transmit
Patient positioning	No Lateral Decubitus	Only supine
Patient height – min	No exclusion	1.4 m
Patient Monitoring	ECG/Blood Ox/BP	ECG/Blood Ox/BP

"MRI-conditional pacemakers: current perspectives"
Medical Devices: Evidence and Research. 2014:7 115–124

Which of the following static magnetic fields and SAR limitations will meet safe scanning conditions of all FDA approved MR-conditional pacemakers:

33% 1. 1.5 T and 2.0 W/kg
10% 2. 3.0 T and 2.0 W/kg
20% 3. 1.5 T and 4.0 W/kg
17% 4. 3.0 T and 4.0 W/kg
20% 5. None of the above. All pacemakers are contraindicated for MRI.

Which of the following static magnetic fields and SAR limitations will meet safe scanning conditions of all FDA approved MR-conditional pacemakers:

1. 1.5 T and 2.0 W/kg

- Evaluating MRI-Compatible Pacemakers: Patient Data Now Paves the Way to Widespread Clinical Application? Pacing Clin Electrophysiol. 2013;36(3):270-278.
- MRI-conditional pacemakers: current perspectives Medical Devices: Evidence and Research. 2014:7 115–124

FDA/CEMARK MR-Cleared Pacemakers

	MEDTRONIC	ST JUDE MED	BIOTRONIK	BOSTON SCI	SORIN
Pacemaker Model	Revo SureScan Ensura SureScan Advisa SureScan	Accent	Evia ProMRI Entovi ProMRI Estella ProMRI Ecuro ProMRI	Ingenio Advantio	KORA 100™
Leads	CapSure™ leads	Tendril™ leads	Safio™and Solia™ leads	FINELINE™ leads	BEFLEX™ leads
MRI machine	Cylindrical bore magnet, clinical MRI systems with a static magnetic field of 1.5T				
SAR – Body	≤ 2.0 W/kg	≤ 4.0 W/kg	≤ 2.0 W/kg	≤ 2.0 W/kg	≤ 2.0 W/kg
SAR – Head	≤ 3.2 W/kg	≤ 3.2 W/kg	≤ 3.2 W/kg	≤ 3.2 W/kg	≤ 3.2 W/kg
Gradient Slew Rate	≤ 200 T/m/s	≤ 200 T/m/s	≤ 200 T/m/s or ≤ 125 T/m/s	≤ 200 T/m/s	≤ 200 T/m/s
Max nr of scans	No	No	Each scan: ≤30 min Lifetime max: 10 hours	No	No
Scan zone restrictions	No	No	Exclusion zone between C1 and T12 vertebrae	No	Exclusion zone between C1 and T12 vertebrae
Patient positioning	No Lateral Decubitus	Supine only	Supine only	Supine only	Supine Only

MR Conditional Pacemakers: FDA/CEMARK cleared

- Medtronic Advisa® SR MRI(TM) - CEMARK
- Medtronic Ensura SR MRI(TM) SureScan® - CEMARK
- Medtronic Ensura MRI™ SureScan - CEMARK
- Boston Scientific ADVA… FDA
- Boston Scien… IO™MRI - FDA
- Boston… VITALIO™ MRI - FDA
- …entific FORMIO™MRI - FDA
- …onik Entovis SR/DR - FDA
- Biotronik Evia SR/DR – FDA
- Biotronik Es… - FDA
- Biotro… FDA
- …cent RF - FDA
- …ude Assurity™ - FDA
- St Jude Endurity™ - FDA
- Sorin KORA 100™ - CEMARK

Need for Uniform Baseline Standards

MR-Conditional Pacemaker Scanning: Current Guidelines

- American Heart Association (AHA) - 2007
- American College of Radiology (ACR) - 2013
- Mayo Arizona - How we do it?

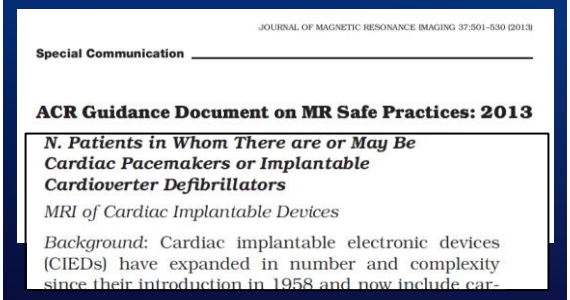
MR-Conditional Pacemaker Scanning Guidelines: AHA 2007

- American Heart Association Committee on Diagnostic and Interventional Cardiac Catheterization; American Heart Association Council on Clinical Cardiology; American Heart Association Council on Cardiovascular Radiology and Intervention
- Safety of magnetic resonance imaging in patients with cardiovascular devices: an American Heart Association scientific statement from the Committee on Diagnostic and Interventional Cardiac Catheterization, Council on Clinical Cardiology, and the Council on Cardiovascular Radiology and Intervention: endorsed by the American College of Cardiology Foundation, the North American Society for Cardiac Imaging, and the Society for Cardiovascular Magnetic Resonance. Circulation 2007; 116:2878–2891

AHA Guidelines: 2007

- MRI examination of nonpacemaker-dependent patients is discouraged
- Should only be considered in cases in which there is a strong clinical indication and in which the benefits clearly outweigh the risks
- MRI examination of pacemaker-dependent patients should not be performed unless there are highly compelling circumstances and when the benefits clearly outweigh the risks
- In every single case the physician should assess the risk-benefit ratio and take the final decision

MR-Conditional Pacemaker Scanning Guidelines: ACR 2013



JOURNAL OF MAGNETIC RESONANCE IMAGING 37:501–530 (2013)

Special Communication

ACR Guidance Document on MR Safe Practices: 2013

N. Patients in Whom There are or May Be Cardiac Pacemakers or Implantable Cardioverter Defibrillators

MRI of Cardiac Implantable Devices

Background: Cardiac implantable electronic devices (CIEDs) have expanded in number and complexity since their introduction in 1958 and now include car-

ACR Guidelines: 2013

- All device hardware should be included in the practitioner's assessment of the patient's suitability for MR scanning
- Coordination with the physician managing the device (cardiologist/electrophysiologist) and a representative from the device manufacturer
- Ensure the entire system (pulse generator and leads) must be labeled "MR Conditional" for a system to in fact be considered MR conditionally safe
- MR Conditional system is only considered safe if all of the MR conditions for safe use are followed
- The presence of abandoned leads from previous nonlabeled systems or "mix-and-match" systems (combined MR Conditional labeled and nonlabeled hardware) renders the system as a whole MR Unsafe or at best "MR unknown"

ACR Guidelines: 2013

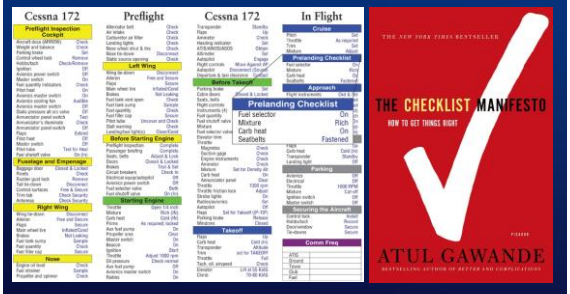
- Each MR conditional device is unique, there are no "universal" labeling guidelines that are applicable for all
- Radiologists and cardiovascular specialists must be familiar with restrictions for each device
- Failure to follow the product labeling is "off-label" and could result in an adverse event.
- The patient's attestations as to their device MR compatibility is not sufficient to establish MR safety
- Recommends development of institutional policies, protocols and care pathways irrespective of device labeling

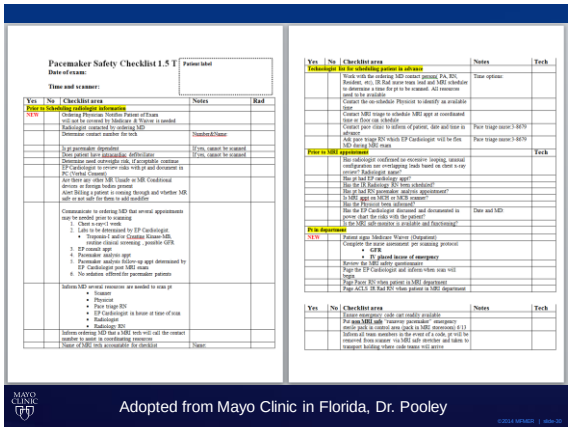
How we do it? Mayo Arizona Guidelines

Medical Physicist is an integral part of the patient care team

Medical Physicist is responsible for safe MR scan execution and has the authority to stop the exam at any point

Use Checklist





Adopted from Mayo Clinic in Florida, Dr. Pooley

Mayo Arizona Scan Guidelines: Scheduling

- Physics pre-scheduling consultation needed
  - Pacemaker dependent – can't sustain 30-35 bpm without pacing*
  - Pacemaker outside of right or left pectoral implant (prepectoral or submuscular)
  - Within 6 weeks after implantation
  - MRI scan under sedation
  - Cardiac or thoracic exams
  - Anticipated scan time longer than 30 mins

Pre-MRI Checklist

- Physicist, Pacer RN, Rad RN, and MRI technologist are present
- EP Cardiologist consult completed
- The risks are documented in Pacemaker Checklist
- Cardiologist called and informed - MRI exam to begin
- Code cart availability check
- Pacemaker model reviewed by Pacer RN and Physicist
- Lead Model (device and leads can be different models) reviewed by Pacer RN and Physicist

During Scan Checklist: Physicist

Patient Name:			**Pacemaker:**	
Patient ID			**Model/Serial**	
MR region scanned			**MR Compatibility:**	
Coil used T/R				
Protocol Used:				
Date:				
Physicist on-Site:				
Normal Mode Engaged:			*Yes/No*	
Normal SAR mode Enganged:			*Yes/No*	
Patient can communicate:			*Yes/No*	
Pacemaker Screening form Verified:			*Yes/No*	
ECG Monitor Hooked and Functioing Verified:			*Yes/No*	
Blood pressure Monitor Hooked and Functioing Verified:			*Yes/No*	
Secondary Monitoring Used:			*PO- Pulse Oximeter*	*Peripl*
			ECG monitor	
Ear Plug + headphone + squeeze ball			*Yes/No*	
IV line connected:			*Yes/No*	
RF On time <30 min:			*Yes/No*	
Cardiologist Oncall check by Pacer Nurse			*Yes/No*	
Time start t	**9:05 AM**		End Time	

	Sequence Name	Time (min:sec:milisec)	Mintues	Seconds	Est S
1			0.00	0	

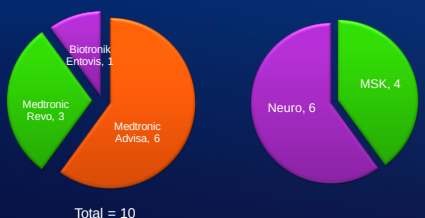
SAR Reduction Strategies

- Set RF Type to “Low SAR”
- Turn gradient mode to Whisper or Normal Scan mode
- Decrease # of slices (for 2D scans)
- Decrease # of averages
- Eliminate SAT bands and Fat Sat
- Increase TR
- Decrease flip angle
- Gradient echo scans provide less SAR than spin echo
- Spin echo scans provide less SAR than fast (turbo) spin echo
- Reduce echo-train-length for FSE

Post-MRI Checklist

- Radiologist review before exam completion
- EP Cardiologist informed MRI has concluded
- Pacer clinic nurse evaluates patient
  - Pacemaker programming restored
- Checklist completed and singed off
  - MR physicist checklist
  - MR technologist checklist
  - Cardiology nurse checklist
- Safety review for root cause analysis is filed
  - Near misses, adverse outcomes, guideline deviation

MR-Conditional Distribution of Cases: Mayo Arizona



Total = 10

Future Growth and Challenges

- Pacemaker scanning at 3T
- Relaxation of Exclusion Zone criteria
  - Newest generations have no limitation on the part of the body to be scanned
- Single-chamber pacemakers (Biotronik and St. Jude)
  - Used in permanent atrial fibrillation patients
  - Significant increase in the number of patients with MR-conditional pacemakers
- New Lead design - Reduced lead performance issues
- Devices getting better - Miniaturization

Future Pacemaker

Role of Medical Physicist?

- Ideally available on site to supervise each scan
  - Integral part of the patient care team
  - Maintains safety checklist during scan
  - On the spot protocol modification
- Out-patient imaging centers - assist to develop
  - MR pacemaker policy
  - Patient scan checklist
  - Pacemaker protocol optimization
  - Annual pacemaker protocol review

Role of AAPM?

- Medical physics practice guidelines
  - Annual review of pacemaker protocols
  - Pacemaker safety checklist
  - Advocate for uniform baseline standards for MR-conditional pacemakers
- SAR report guidelines
  - Similar to CT structured dose report
  - Engage DICOM

- Medtronic Advisa MRI™ SureScan dual chamber – FDA-approved
- Medtronic Revo MRI SureScan dual chamber – FDA-approved
- Medtronic EnRythem MRI SureScan – CEMARK (Revo old)
- Medtronic Advisa® SR MRI(TM) - CEMARK
- Medtronic Ensura SR MRI(TM) SureScan® - CEMARK
- Medtronic Ensura MR… – CEMARK
- Boston Sci… …NTIO™MRI - FDA
- …ntific INGENIO™MRI - FDA
- …on Scientific VITALIO™ MRI - FDA
- Boston Scientific FORMIO™MRI - FDA
- Biotronik Entovis SR/DR - FDA
- Biotronik Evia SR/DR – F…
- Biotronik Estella S…
- Biotronik F…
- Biot…
- …ccent RF - FDA
- …Jude Assurity™ - FDA
- St Jude Endurity™ - FDA

Uncertainty = Compromised Patient Safety

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Antelope Canyon
Page, Arizona