Potential Risks of MRI in Device Patients

Redha Boubertakh

r.boubertakh@qmul.ac.uk

Barts Health NHS Trust
Queen Mary University

Outline

- MRI and cardiac implantable electronic devices (CIED)
- Components of an MRI scanner
- MRI implant and device safety classification
- Risks associated with scanning CIEDs
  - Main magnetic field
  - Radiofrequency waves
  - Time-varying magnetic field gradients
- Summary & Conclusion

MRI and Cardiac Implantable Electronic Devices

- Number of patients fitted with cardiac implantable electronic devices (CIED) is growing
- Large percentage will require an MRI scan over their lifetime
- In the past, CIEDs have been considered an absolute contraindication to MRI

MRI and Cardiac Implantable Electronic Devices

- However, recent studies have shown that, if strict screening, safety and monitoring procedures are followed, **legacy non MR Conditional** CIEDs can also be scanned with minimal risks to the patient

Assessing the Risks Associated with MRI in Patients with a Pacemaker or Defibrillator
Robert J. Russo, M.D., Ph.D., Heather S. Costa, Ph.D., Patricia D. Silva, M.S., Jeffrey L. Anderson, M.D., Aysha Arshad, M.D., Robert W.W. Biederman, M.D.,
New England Journal of Medicine, 2017

Safety of Magnetic Resonance Imaging in Patients with Cardiac Devices
Saman Nazarian, M.D., Ph.D., Rozann Hansford, R.N., M.P.H., Amir A. Rahsepar, M.D., Valeria Weltin, M.S., Diana McVeigh, B.S.,
New England Journal of Medicine, 2017

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,‡]
Heart Rhythm, 2017

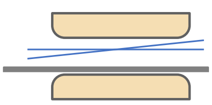
Safe use of MRI in people with cardiac implantable electronic devices
Martin D Lowe,[1] Christopher J Plummer,[2] Charlotte H Manisty,[3] Nicholas J Linker[4]
Heart, 2015

Components of an MRI Scanner

Static main magnetic field B_0

- Magnetic fields ~ 50,000 - 100 000 × stronger than the earth's
- **Always on!**

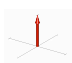
Time-varying magnetic field gradients



- Linear magnetic field gradient are used to encode the MR signal

Radiofrequency (RF) pulses

Transmit coil
Body or T/R local coil



Perturbed net spin magnetisation

Receive coil
Body or local coil

General MRI Safety Risks

Source	Safety risks
Static Magnetic field B_0 field (1T, 1.5T, 3T, …)	- Projectile or "missile" effect - Displacement and torque effects - Device disruption - Bioeffects
Radiofrequency (RF) pulses B_1 field Amplitude~ µT, MHz frequency range	- Tissue heating, Burns - Medical device heating and disruption - Interference with equipment (monitoring systems) and devices
Time varying Gradient Magnetic Field $G_{x,y,z}$ gradients. Strength (mT/m) and slew rate (mT/m/ms) scanner dependent	- Peripheral nerve stimulation (PNS) - Acoustic noise - Interference with equipments and devices
Cryogens Liquid Helium at -269 ºC (4 K)	- Burns - Asphyxia - Hypothermia
Gadolinium Based Contrast Agents	-Nephrogenic Systemic Fibrosis (NFS)

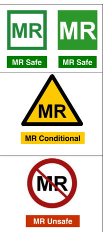
Affect CIEDs (Static Magnetic field, Radiofrequency (RF) pulses, Time varying Gradient Magnetic Field)

MRI Safety Terminology for Implants and Devices

- Any device/implant falls into one of these three categories
- **No** CIED is **MR Safe**
- An **MR Conditional** device can be safely scanned if **conditions** defined by the manufacturer are met

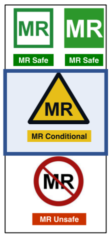
Table 1 Definitions from ASTM international standard F2503-13

MR Safe 'an item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic' *	MR Safe / MR Safe
MR Conditional 'an item with demonstrated safety in the MR environment within defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field and the radiofrequency fields. Additional conditions, including specific configurations of the item, may be required.'	MR Conditional
MR Unsafe 'an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.'	MR Unsafe



MRI Safety Terminology for Implants and Devices

- The development of **MR Conditional CIEDs** (2008) has made MRI scans safe to use
- Condition of use include:
  - **The type of device**
    - **Generator + Leads type**
    - Programming modes and parameters,
    - Time since implantation,…
  - **The MRI environment**
    - Type of magnet, maximum value of field strength
    - Spatial magnetic field gradient
    - Time varying magnetic field gradients
    - Type of imaging sequence, induced heating
    - Imaged body part
    - Type of imaging coils used, …



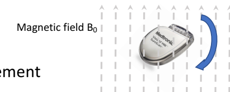
Potential Risks of CIEDs in the MRI Environment

Main Magnetic Field

- The static magnetic field B_0 (mainly 1.5T or 3T on clinical scanners) is one of the main sources of danger
- Strong attractive force exerted on ferromagnetic objects
  - "Projectile effect"
- Additionally, a device can experience a torque (rotational forces) to align it with the direction of B_0

Associated Risks:

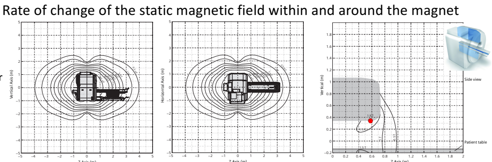
- Device motion, vibration and displacement



Static Field Characteristics

- Attractive forces depend on the ferromagnetic content of the device
  - High ferromagnetic content ➜ higher risk
- An important parameter is the **spatial magnetic field gradient**
  - Rate of change of the static magnetic field within and around the magnet

Siemens scanner



B_0 field - Side view B_0 field - Top view   Spatial field gradient - Side view

Main Magnetic Field

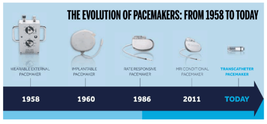
- **Attractive forces** are proportional to the spatial gradient of the static field
  - Force highest at the **bore entrance**
- However, **torque** is proportional to the static field strength
  - Torque largest at the **centre of the magnet bore**
- Both forces depend on the ferromagnetic/paramagnetic content of the device
- **MR conditional** devices are designed with reduced ferromagnetic content
  - Stainless steel and titanium alloys used

Main Magnetic Field

- Even for **non MR Conditional** pacemakers, these risks are less of an issue for device post 2000 due to low ferromagnetic content
  - Subcutaneous tissue fibrosis around the device

Luechinger, R et al, PACE 2001
2017 HRS expert consensus statement, Heart Rhythm

- Reduction in device size throughout the years has sensibly diminished potential risks



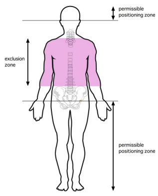
St. Jude Medical

Main Magnetic Field Conditions

- **Field strength** and **spatial magnetic field gradient** are specified in the conditions of use of MR Conditional devices
- Example:
  - **Horizontal cylindrical bore magnet**, clinical MRI systems with a **static magnetic field of 1.5 Tesla** (T) must be used
  - Maximum **spatial magnetic field gradient** of **750 G/cm**

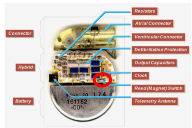
Imaging Exclusion Zones

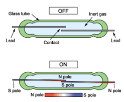
- An MR Conditional CIED does not always allow all body parts to be scanned
- MRI conditions usually also include possible **Exclusion Zones**
- If an exclusion zone of an MR Conditional device is imaged
  - Device is used off-label
  - Follow non MR Conditional safety protocols



Reed Switch Malfunction

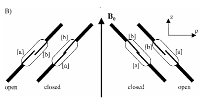
- Strong magnetic fields can result in device malfunction
- For non MR Conditional devices, **reed switches** have been shown to malfunction
- A reed switch is used to program devices
  - A small magnetic field is used to change device mode to asynchronous pacing





Reed Switch Malfunction

- Switch behaviour has been shown to be unpredictable depending on orientation
  - Unexpected switch opening or closure

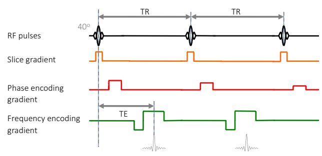


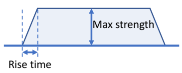
Scheidegger, M et al, PACE 2002

- Electronic solid-state **Hall effect sensors** have improved reliability
  - Behave in a predictable manner

Time-Varying Magnetic Field Gradients

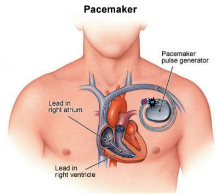
- MRI sequences use magnetic gradients to spatially encode the imaged object
- Important scanner parameters:
  - **Slew rate** (up to 200 T/m/s)
  - **Maximum gradient strength** (such as 45 mT/m)





Time-varying Magnetic Field Gradients

- Rapidly switching gradients can induce Electromagnetic interference (EMI)
- Electrical currents and voltages can be induced in conduction wires
  - Device leads
  - Generator



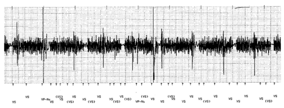
Effects of EMI

- Interferences could be interpreted by a CIED as a real or missing heart rhythm signal (oversensing, undersensing). EMIs can lead to:
- **Therapy inhibition**

  A pacemaker may be withhold pacing
  - Pacing dependent patients
- **Innapropriate shocks**

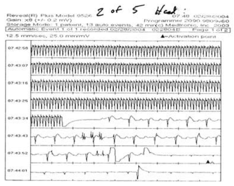
  An ICD may interpret an interference as requiring an unnecessary shock

Effects of EMI



High-frequency noise and noise response ventricular pacing are noted on the bipolar ventricular channel from a single-chamber pacemaker during MRI

Beinart R et al, Circulation 2013



Artefact mimicking narrow complex tachycardia

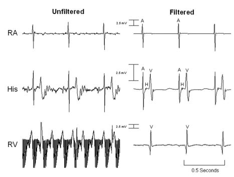
Gimbel J et al, Annals of Noninvasive Electrocardiology 2005

Effects of EMI

- EMI can cause a **power-on-reset**
- The device programming parameters go back to the factory default
  - Pacing could be inhibited
  - Activation of antitachycardia therapy
- Device battery status and longevity affected
- Battery drain may also occur

Preventing EMI

- Electromagnetic interference can be reduced by filtering the ECG signal
- In MR Conditional devices, generators and circuitry are shielded to minimize the effects of interferences
- Better protection of the power supply

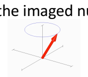


Intracardiac ECG signals in a canine model inside an MR scanner

Nazarian S et al, Circulation 2008

Radiofrequency (RF) Pulses

- Very short RF pulses are used to disturb/tip the net spin magnetization within a tissue
- RF pulse frequency is matched to the imaged nuclei (^{1}H) at a given static magnetic field
  - ~ 64 MHz at 1.5T
  - ~ 128 MHz at 3T



- The body will absorb some of this energy ➜ Resistive heating
- Heating generated by a sequence is measured by the **Specific Absorption Rate** (SAR) in Watt/kg

SAR MODE for CIEDs

Table 8 IEC 2010 patient and volunteer SAR limits (Wkg^{-1}) for RF field exposure

	Whole body	Partial body Head	Partial body Not head [a]	Local Head [b]	Local Trunk	Local Extremities
NORMAL MODE	2	3.2	2–10	10	10	20
CONTROLLED MODE	4	3.2	4–10	20	20	40
RESEARCH / EXPERIMENTAL MODE	>4	>3.2	>(4–10)	>20	>20	>40

a Partial-body SAR scales dynamically with the ratio r between the patient mass exposed and the total patient mass:
– normal operating mode: SAR = (10-8×r) Wkg^{-1}
– controlled operating mode: SAR = (10-6×r) Wkg^{-1}
b In cases where the eye is in the field of a small local coil used for RF transmission, care should be taken to ensure that the temperature rise is limited to 1°C.
Averaging time = 6 min.

Normal Mode (≤ 2 W/kg) for all CIEDs

MHRA, Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use, March 2015

Leads Heating Effects

- Leads can act as antennae and concentrate RF energy
  - Lead lengths (40 – 60 cm) comparable to MRI RF wavelengths
- Effect strongly associated to ratio of lead length to RF wavelength and presence of loops and lead geometry
- High electrical currents can be induced ➜ heating
  - Resistive effect

Leads Heating Effects

- Potential risk of thermal injury by ohmic loss in myocardial tissue around the tip
- Generated currents may lead to:
  - Myocardial stimulation
  - Temporary or permanent changes in impedance and thresholds
  - Device malfunction and damage
- Abandoned and fractured leads, broken lead tips and lead loop configurations may increase heating effects
  - Epicardial lead tips not cooled by blood flow

Leads Heating Effects

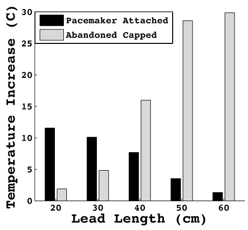


Figure 1. *For pacemaker leads 20–60 cm in length the RF-induced pacemaker lead tip heating is shown for pacemaker-attached and abandoned capped pacemaker leads. Pacemaker leads that are abandoned and capped heat significantly more than pacemaker-attached leads for clinically relevant lead lengths (40–60 cm).*

Langman D et al, PACE 2011

Reducing Lead Heating Effects

- Limit the RF power used during imaging
  - Reduce SAR level

Changes in lead design:

- Improvements to lead inner- and outer-coils structure
- Lead tip coating with polarization resistant material
- Use of heat-dissipating filters

Summary of Potential Risks

	Static Magnetic field B0	Time-varying gradients	RF pulses
Force, Torque Patient discomfort, surrounding tissue damage, device malfunction	✓		
Vibration Patient discomfort, device malfunction		✓	
Induced currents/voltages Induced VT, arrhythmia, pacing inhibition		✓	✓
Heating Tissue damage, impedance and threshold changes, loss of sensing and/or pacing capture			✓
Device malfunction Device reset, mode changes, loss of therapy, patient shocks	✓	✓	✓

Conclusion

- Scanning of **MR Conditional** cardiac devices is safe if specified conditions are followed
  - Relatively straightforward
  - Can be done at any MRI general imaging unit
  - No reason to deny a patient an MRI examination
- Strong evidence from registries and clinical studies show that **non MR Conditional** CIEDs can be scanned safely if strict clinical and scanning protocols are observed
  - Specialized centres

Conclusion

- There still exists a confusion about the used terminology and determining scanning conditions
  - Spatial static field gradient not always easy to check
  - MR safety labelling