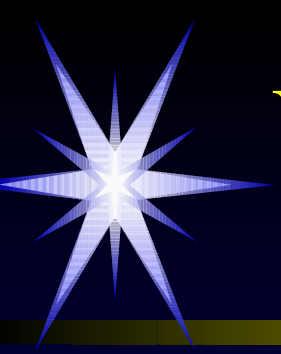


Current Clinical Issues for MRI Scanning of Pacemaker and Defibrillator Patients





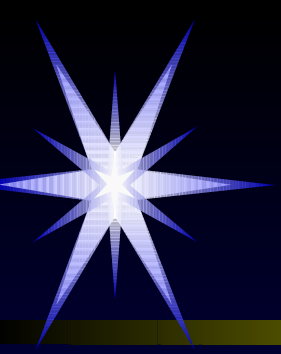
Why MRI Scans are Important to Clinical Medicine

- Fastest Growing Standard of Care in Diagnostic Imaging¹
- Superior Soft Tissue Imaging²
 - Primary method to evaluate:
 - Central Nervous System
 - Musculoskeletal System
 - Oncological Conditions
 - Some Cardiovascular Disorders
- MRI complements CT (which excels when imaging bony structures)
- No radiation risk to patient or healthcare provider



1. Kaiser CP. Soaring MRI use draws scrutiny. Diagnostic Imaging Online January 4, 2002. CMP United Business Media: A CMP Healthcare Media Web Site. Available at: <http://www.diagnosticimaging.com/dinews/2002010401.shtml>. Accessed October 19, 2004.

2. Duru F, Luechinger R, Scheidegger MB, et al. Pacing in magnetic resonance imaging environment: Clinical and technical considerations on compatibility. *Eur Heart J*. January 2001;22(2):113-124.



MRI Utilization

Scan Volume in Europe significant and is growing at $> 10\%$ per year³

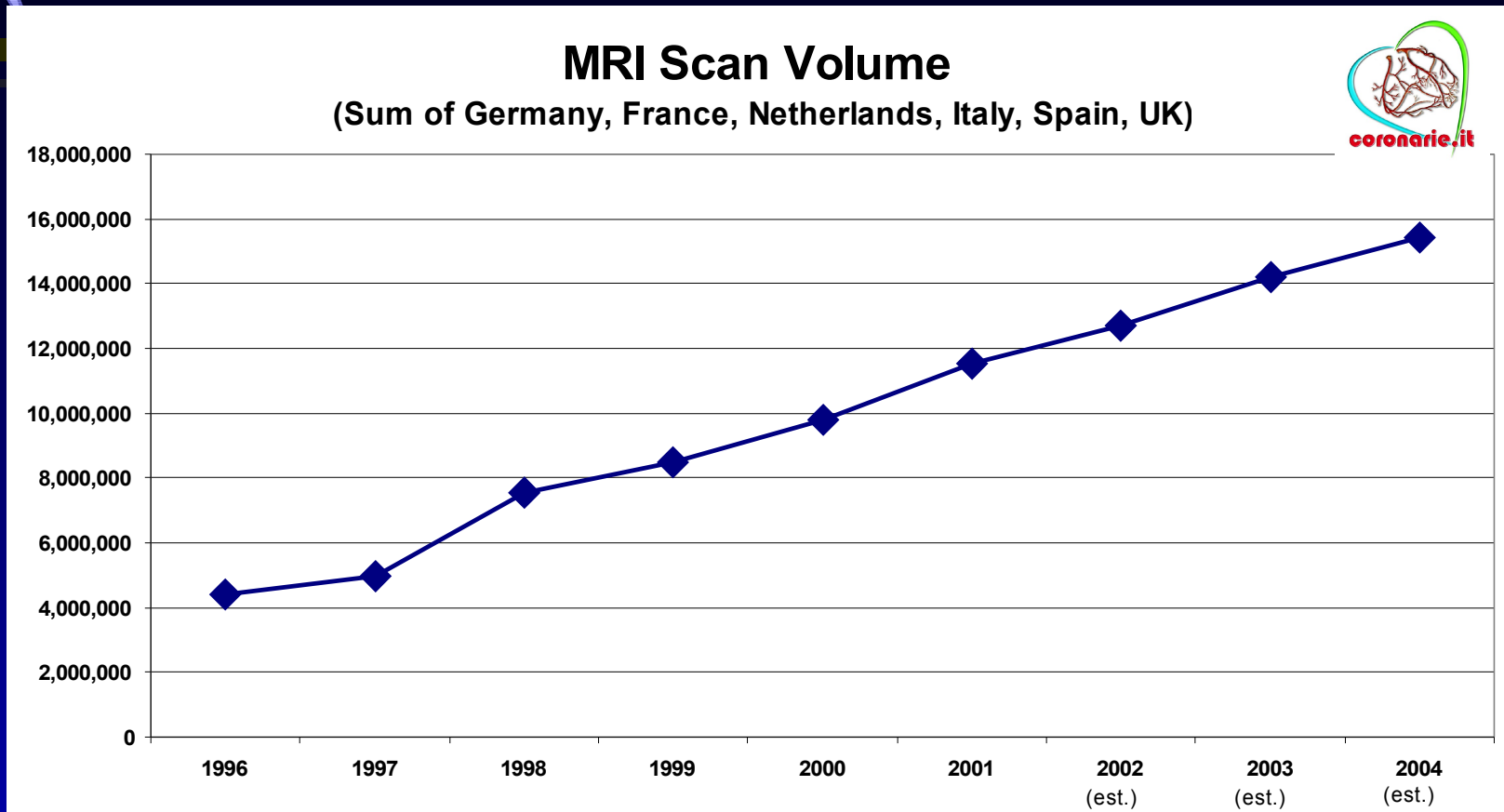


MRI Scan Volumes (2001)

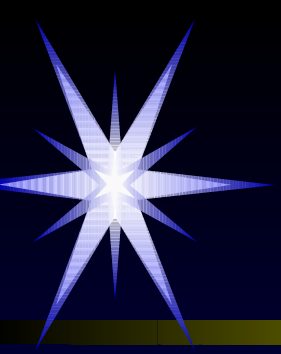
	Scans	Population	MRIs per 1,000:
Germany	6,494,000	83,000,000	78
US	15,900,000	283,000,000	56
Netherlands	756,000	16,000,000	47
Italy	1,295,000	58,000,000	22
France	1,297,000	59,000,000	22
Spain	753,000	40,000,000	19
UK	958,178	60,000,000	16

³ Frost and Sullivan Market Research, 2003.

MRI Utilization in Europe³



Current estimates show a 40-50% probability of any device-aged patient needing an MRI over the service life of their device.^{3,4}



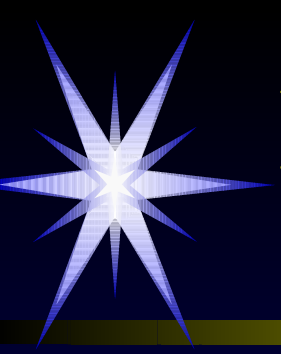
MRI Utilization

MRI Procedures by Anatomy³

MRI Procedure Categories	% of All MRI Procedures
Brain	27%
Spine	26%
Lower Extremities	10%
Upper Extremities	9%
Head & Neck	8%
Pelvic and Abdominal	6%
Vascular	9%
Chest	3%
Cardiac	1%
Interventional	*
Miscellaneous	*
Total 2002 MRI Procedures	100%

*Less than 1%





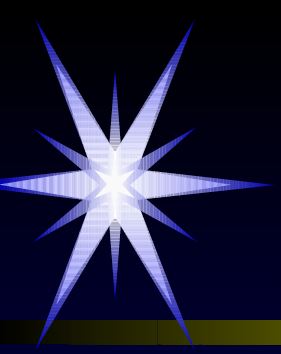
MRI is not Currently Considered Safe For Device Patients

- Long standing manufacturer contraindications



WARNING: Certain implants, devices, or objects may be hazardous to you and/or may interfere with the MR procedure (i.e., MRI, MR angiography, functional MRI, MR spectroscopy). Do not enter the MR system room or MR environment if you have any question or concern regarding an implant, device, or object. Consult the MRI Technologist or Radiologist **BEFORE** entering the MR system room. The MR system magnet is **ALWAYS** on.

Available at: <http://www.mrisafety.com/home.asp> Accessed October 22, 2004.



Source of MRI Electromagnetic Interference

1. Static Magnetic Field: 1.5 & 3.0-Tesla
 - 1-Tesla = 10,000 Gauss
 - 1-Gauss = Earth's Gravitational Pull
1. Modulated Radio Frequency Field
(42.57 MHz/Tesla)
2. AC (Gradient) Magnetic Fields
(X, Y, and Z directions)

Three Major MRI Manufacturers:
GE, Philips and Siemens



Hazards of using MRI with Current Pacemakers and Defibrillators

1. Static Magnetic Field

- Mechanical forces on ferromagnetic components
- Unpredictable magnetic sensor activation

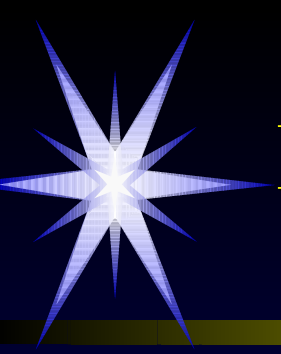
2. Modulated Radio Frequency (RF) Field

- Heating of cardiac tissue adjacent to lead electrodes
- Possible induction of life-threatening arrhythmias
- RF interactions with the device (over- and under-sensing)

3. Gradient Magnetic Field

- Possible induction of life-threatening arrhythmias
- Induced voltages on leads cause over- and under-sensing

(continued)



Hazards of using MRI with Current Pacemakers and Defibrillators

4. Combined Field Effects

- Alteration of device function due to EMI
- Mechanical forces (vibration)
- Electronic reset of device



Variables Affecting Magnitude of Risks

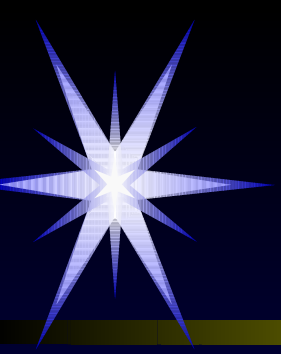
- Length/position of pacing leads
- Patient and device position within machine
- Patient factors / medical history
- MRI scan duration
- Blood flow at lead/tissue interface
- Strength of RF field
- Target anatomy of scan
- Type of imaging MRI sequence
- Pacemaker and Lead Design



Why is MRI Safety Currently a Controversial Topic for Device Patients?

Three recent papers in prominent journals have debated this topic:

- Martin ET, Coman JA, Shellock FG, et al. Magnetic Resonance Imaging and Cardiac Pacemaker Safety at 1.5-Tesla. *J Am Coll Cardiol.* 2004; 43:1315-1324.
- Gimbel JR, Kanal E. Can Patients with Implantable Pacemakers Safely Undergo Magnetic Resonance Imaging? *J Am Coll Cardiol.* 2004;43:1325-1327.
- Roguin A, Zviman MM, Meininger GR, et al. Modern Pacemaker and Implantable Cardioverter/Defibrillator Systems Can be Magnetic Resonance Imaging Safe. *Circulation.* 2004; 110(5): 475-482.



MRI and Device Study Summaries

Modern Pacemaker and Implantable Cardioverter/Defibrillator Systems Can Be Magnetic Resonance Imaging Safe⁵

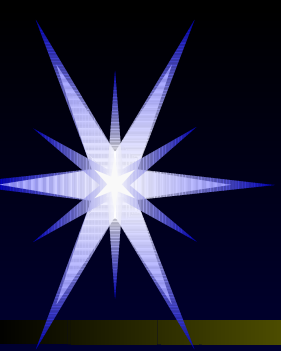
Publicized Results:

- Lead heating *in vivo* (canine) found to rise $< 0.5^{\circ}\text{C}$ during MRI.
- Newer ICDs and most pacemakers were not damaged during scans.

Authors' Conclusions:

- “These data suggest that certain modern pacemaker and ICD systems may indeed be MRI safe. This may have major clinical implications for current imaging practices.





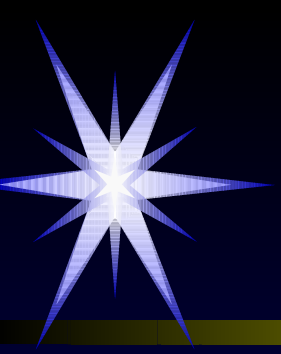
MRI and Device Study Summaries

Results that are Cause for Concern:

- 1 animal, after MRI, had *pacing capture failure* for 12 hours.
- Small sample size: Only 9 different pacemaker models were tested in a single 1.5-Tesla MR scanner.
- At deeper (worst case) positioning of the leads in the test gel, “substantial heating (increase of 35°C) was noted.”
- Three pacemakers experienced an “electrical reset” and nine ICD models experienced post scan interrogation problems or battery changes.

Notable Quotes from the Authors:

- “There are no cardiac devices that currently have achieved Food and Drug Administration (FDA) clearance for MR Compatibility.”
- “Routine imaging of (pacemaker) patients by MR centers would not be appropriate.”



MRI and Device Study Summaries

Magnetic Resonance Imaging and Cardiac Pacemaker Safety at 1.5-Tesla⁶

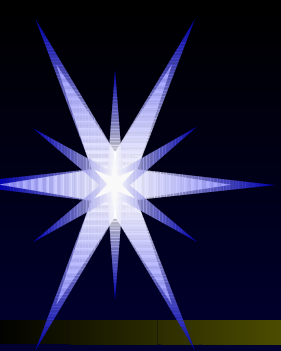


Publicized Results:

- Fifty-four patients underwent a total of 62 MRI examinations at 1.5-Tesla
- MRI examinations included cardiac, vascular, and general MRI studies
- Device interrogations were done before and after MRI. Pacing and sensing thresholds, as well as lead impedances, were measured
- A total of 107 leads and 61 pulse generators were evaluated
- No adverse events occurred

Authors' Conclusions:

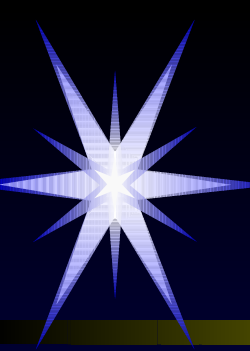
- “Safety was demonstrated in this series of patients with pacemakers at 1.5-Tesla.”



MRI and Device Study Summaries

Results that are Cause for Concern:

- Pacing Thresholds changed in 40 (37%) of the leads
- Ten (9.4%) leads underwent a “*significant*” change in thresholds
- No intermediate or long-term follow-up of the post-MRI pacing thresholds
 - Especially a concern for those who demonstrated an initial rise in thresholds
- Pacemaker-dependent patients were excluded from this study
- All studies were performed using a single 1.5-Tesla MR system



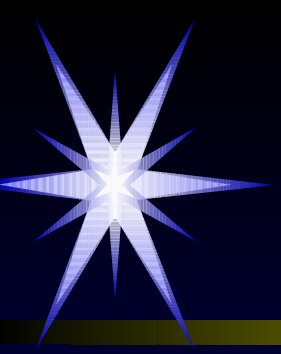
MRI-Safety Expert Response

Can Patients with Implantable Pacemakers Safely Undergo Magnetic Resonance Imaging?⁷

Notable Quotes from the Authors:

- “Failing to identify an adverse event is not equivalent to demonstrating safety [with existing products] – especially when only a limited number of patients are studied.”
- “Patients and the implanting community should expect nothing less than devices that are MR-safe by design, not by chance.”
- “MRI scans will not be considered safe until these devices and leads are specifically designed for use with MRI technology and until they receive the necessary approvals from regulatory authorities.”
- “We do not believe this controversy is settled simply because a handful of device patients have successfully undergone MRI.”





Looking to the Future

- MRI safety for this patient segment is not a matter to be taken lightly, nor does it have a “quick-fix” solution available
- The device industry is on the verge of seeing the world’s first pacing system *designed* to allow MR imaging of pacemaker patients
- To truly affect current clinical practice, it will be of the utmost importance for device manufacturers to secure regulatory approvals to confirm their products’ safety in 1.5-Tesla MRI machines (or higher) for Normal Operating Mode