Herzschrittmacher im MR
- Erfahrungen mit eigentlich kontraindizierten Untersuchungen

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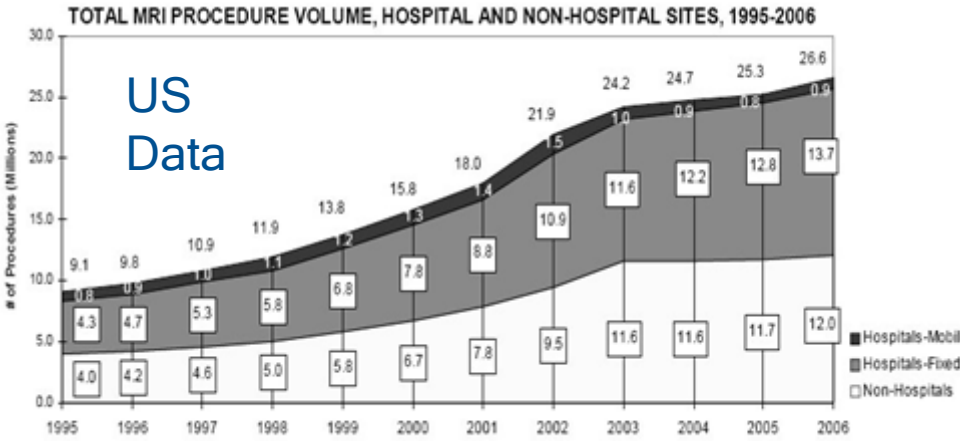
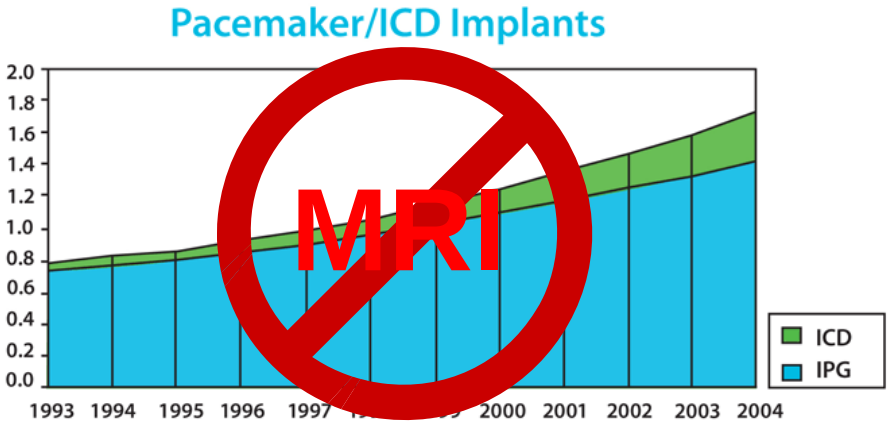
Declaration of conflict

- Roger Luechinger:

  - research grant for Medtronic INC.
  - consultant for Medtronic INC.

MRI and Pacemaker?





Prevalence of Implantable Pulse Generators (IPGs) and Implantable Cardioverter Defibrillators (ICDs) implanted in the US, 1993-2004.*

MRI is one of the fastest growing areas in diagnostic imaging and is considered the standard of care for soft tissue imaging

50-75% of patients with implantable cardiac devices will be indicated for MRI scans over the lifetime of their device

Why are pacemakers excluded from MRI?

6 patients with pacemakers **died** during MRI in Germany (1992-2001)[1]

Heating effects of over 15°C could be found in Animal experiments[2]

The presence of a pacemaker is regarded as a contraindication for MR investigations

[1]Irnich W, et al. Europace 2005;7(4):353-365.
[2]Luechinger R., et al. Eur Heart J 2005; 26, 376-383

Pacemaker Patient Studies

However, in several studies >500 patient had MRI without any severe incidents.

Sommer et al.	6/115 significant (≥1V) threshold changes
	7/115 device resets
Martin et al.	10/63 significant (>0.5V) threshold changes
Nazarian et al.	68 no adverse effects

Other events like induced ventricular tachycardia/fibrillation or inhibition of pacing have been reported.

Sommer et. al. Circulation 2007; Martin et al. J Am Coll Cardiol 2004; Nazarian et. al. Circulation 2006

ICD Patient Studies

Only small studies (total ~150 patients[1]) are available for ICD's.
In a few cases battery voltage drops and in 2 cases communication was no longer possible.
In two cases delivery of therapy was no longer possible (after POR)

Nazarian et al.[2]	24 no adverse effects
Coman et al.[3]	11 patient; 1 ICD has to be replace do to lost of communication
Gimbel et al.[4]	7 patient; 1 Power on reset (brain and lumbar spine)

[1] Gimbel et. al. J Interv Card Electrophys 2010; [2] Nazarian et. al. Circulation 2006;
[3] Coman et al. J Am Coll Cardiol 2004; [4] Gimbel et. al. PACE 2005

Potential Risks for Patients:

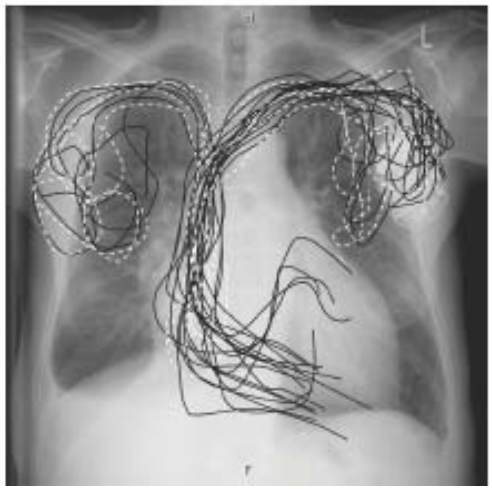
Interaction	Main Magnetic Field	Gradient Field	RF Field
Magnetic forces / torque	√		
Interaction with reed-switch?	√		
Vibration	√	√	
Wrong sensing and triggering		√	√
Stimulation of heart due to induced voltages		√	√
Device component damage	√	√	√
Heating of the tissue around the lead tip			√
Device reset	√	√	√

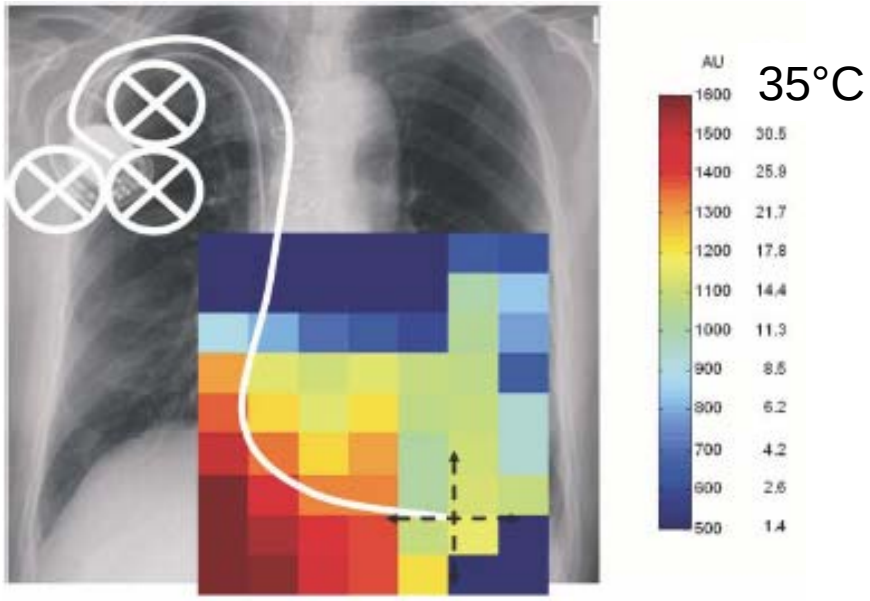
Duru F, et al. Eur Heart J 2001;22(2):113-124

RF-heating?

In vitro tests show large differences in heating effects from different leads and different configurations.

720 lead configurations
ΔT_{max}>60°C (wbSAR=2.8W/kg)





Nordbeck et. al. Magn Reson Med. 2009

„Clinical relevance“ of the effects

Interference, fast pacing, fibrillation:

→ monitoring (ECG and preferable pulse oxymetry)
crash cart + ACLS-certified cardiologist

Device damage:

→ device replacement

RF-Heating:

→ no monitoring
lead replacement

Conventional pacemakers

Waste majority of the pacemakers have not been tested for MR related interaction
→ it is unknown whether there is a safety risk or not.

A few safe scans in patients are not a proof for safety.

Study from Sommer et.al.[1] showed 7 pacemaker resets:

Sigma: 4 (out of 19) market release: 1999
Kappa: 0 (out of 31) market release: 1998

But:
a recent study by Boilson et al. found also several resets in Kappa devices!

[1] Sommer T et. al. Circulation 2007; [2] Boilson, et al. HRS 2010

The way up to now…

Different organizations have published guidelines to examine pacemaker in MRI[1-3]

- in absence of an alternative imaging modality
- after a benefit to risk evaluation
- patient has to be informed on the risks (incl. death)
- under special conditions

(incl. careful monitoring during MRI, reprogramming of the devices, crash cart + ACLS-certified physician present)

- in experienced centers

[1] Kanal E, Barkovich AJ, Bell C, et al. AJR Am J Roentgenol 2007;
[2] Levine GN, Gomes AS, Arai AE, et al. Circulation 2007;
[3] Roguin A, Schwitter J, Vahlhaus C, et al. Europace 2008.

With conventional devices…

The major problem of non MRI conditional pacemakers are:

- not evaluated for potential risks of MRI
- huge number of combinations of devices and leads

Different devices and leads will pose different risks

However, this devices will stay common over the next years

MR conditional pacemakers

A limit number of MRI procedures with “no adverse effects” is no proof of safe scanning of pacemaker patient.

Need: Pacing systems which are safe in MRI by design!

Clear understanding of the hazards and the risks of pacing in MR environment → Design changes based on that understanding → Rigorous testing → Regulatory review

MR conditional pacemakers

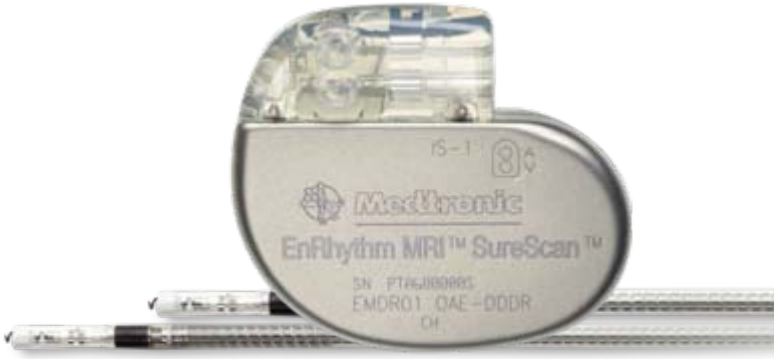
In the meantime two manufacturer sell MR conditional devices with CE approval in Europe. (FDA approval pending):

Medtronic Inc:

- EnRhythm MRI™ or Advisa MRI™ SureScan™ pacemaker
- Model 5086 CapSureFix MRI™ SureScan™ leads

Biotronik:

- Evia™ ProMRI pacemakers
- Safio S™ ProMRI leads



MR conditional

Conditions under which MRI may be performed:

- No other leads, devices, adaptors, etc. in place
- Restrictions for MRI
  - 1.5 Tesla closed bore MRI in Normal Operating Mode
  - Whole body SAR ≤ 2 W/kg
- Monitoring required
- Reprogramming to the a special mode may be required!
- Restriction on the location allowed to be scanned may be possible. (e.g. Exclusion of thorax)

Clinical Study

Safety of the EnRhythm MRI pacemaker has been evaluated in a prospective, randomized controlled, multi-center study[1]

1:1 randomized to receive MRI scans or no MRI scans
Analysis of 464 patients followed-up for 4 months

Scope:

41 centers in the US, Europe, Middle East, and Canada

Purpose:

Evaluate safety
(System-, Implant- and MRI- procedure related complication free rate)
To compare pacing capture thresholds and sensing amplitude endpoints between the MRI and control group for clinical equivalence

[1]First results of the performance of a new pacemaker system desined for use in the MR environment. Wilkoff BL, et al., presented at Heart Rhytm on 05/09

Clinical Study

Safety:

- No evidence of clinical (bradycardia or tachycardia) adverse events (n=0/244)
- No evidence of subclinical (pacemaker performance) adverse events (n=0/244)
- No evidence of technical (pacemaker or lead damage, or interference) adverse events (n=0/244)

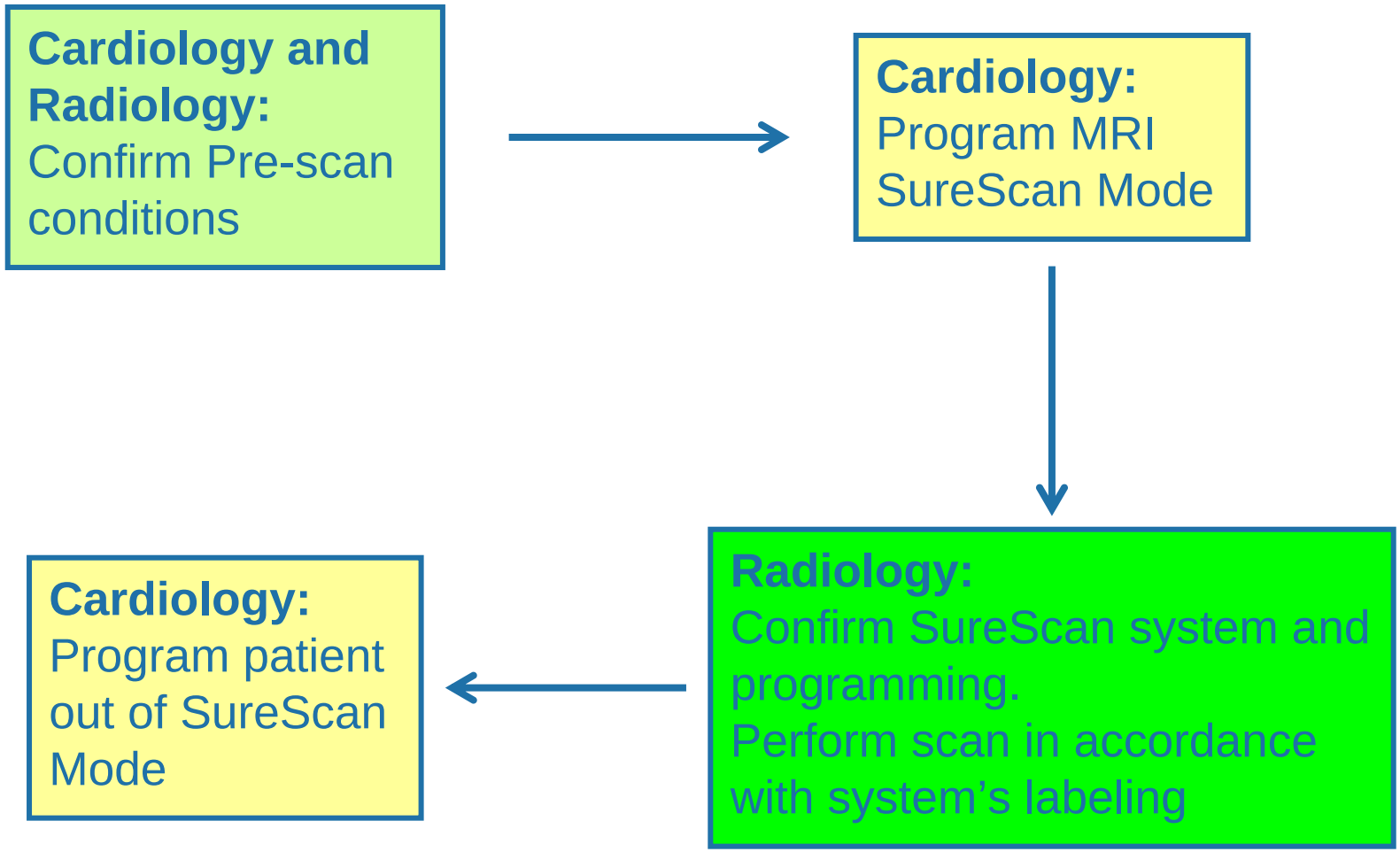
Pacing Capture Thresholds Equivalence:

The 95% CI of the difference in capture thresholds between the MRI group and the control group from pre-MRI/No-MRI to one-month post-MRI/No-MRI was:

For atrial pacing capture thresholds: (-0.01 ± 0.23V) ($p<0.0001$)

For ventricular pacing capture thresholds: (-0.0V±0.21V) ($p<0.0001$)

Patient Flow



Conclusion

MR conditional pacemaker allow safe MRI scanning not only by highly experienced centers.

But, still most of the implanted pacemaker are not tested with respect of MRI safety and safe scanning can not be guaranteed.

However,

under specific conditions (see position papers) MRI may be possible on a case-by-case basis with acceptable benefit to risk ratio in highly experienced centers.