

## Devices and Safety

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### Conflicting Epidemiology of MRI and Devices

MRI has been proven to be the superior imaging modality in many medical applications, e.g. neurology, cardiology, gastroenterology and orthopaedics which explains an almost 240% increase of MRI procedures during the last 10 years. However MRI up to now has the limitation that it cannot be used in patients with implanted pacemakers due to safety reasons. On the other hand device based electrotherapy plays an important and increasing role in cardiology and also neurology. Cardiac pacemakers are not only used to counteract a slow heart rhythm, but also to improve symptoms and to reduce mortality in heart failure patients by left ventricular stimulation, which resynchronizes cardiac contraction. Special pacemakers with the ability to terminate a malignant, potentially fatal fast heartbeat, so-called ICDs (= implantable cardioverter-defibrillator), reduce sudden cardiac death, which is the leading cause of death in patients with reduced left ventricular function. This implies that the number of pacemaker/ICD implantations dramatically increased during the last years, and extrapolations predict that demography and improved medical treatment will sustain this trend.

So the increasing number of patients with pacemaker and the increasing number of indications for MRI are two conflicting developments. It is estimated that in 75% of these patients MRI will be denied during the lifetime of the device [1].

### Interaction of the pacemaker and electrode with the Magnetic Fields

The safety issues arise from the interaction of the pacemaker plus electrode with the static magnetic field (B<sub>0</sub>), the gradient and the radiofrequency field (RF). Whereas the force and torque the static field exerts on ferromagnetic material plays only a role in older devices, effects of the gradient and RF field may have serious consequences. The latter may induce malignant cardiac arrhythmias [2]. Especially the RF field, the wavelength of which is ~ 50 cm in the body, may induce resonance in the pacemaker electrode, the length of which is in the same range. This may result in heating at the tip which may damage tissue or induce arrhythmias [2,3].

### Clinical Observations and Recommendations of Societies

MRI may be harmful in patients, and a significant number of fatal events have been reported [4]. On the other hand it has been shown that MRI may be *rather* safely performed in pacemaker/ICD patients [5, 6], though irritations of myocardium and the device were demonstrated in some cases. The rather small number of patients in these studies and the fact that the risk factors still have to be determined induced the American Heart Association to state that it is not justified to perform MRI routinely in patients with cardiovascular devices [7]. The position paper of the European Society of Cardiology recommends that the risk and diagnostic benefit should be outweighed and they recommend a strategy for MRI imaging [8].

### Technical Solutions

The fact that MRI may be harmful to patients with cardiovascular devices implies the need to find technical solutions, even when the risk is rather low. Some approaches depend on

decoupling of the RF-field, some on the bad antenna principle, i.e. the absorbed RF-energy is not transmitted solely to the tip, but is dissipated along the electrode to the surrounding blood. These approaches must not only reduce the MR-related risk, but their implementation in electrodes must not affect their mechanical stability and long-life cycle.

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