

## MRI in patients with pacemakers? First global consensus recommendations from radiologists and cardiologists



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### Bibliography

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Under the title “MR Imaging in Patients with Cardiac Pacemakers and Implantable Cardioverter Defibrillators”, this issue of *Röfo* – simultaneously with the journal of the German Cardiac Society “Der Kardiologe” – presents a consensus paper of the German Roentgen Society and the German Cardiac Society [1, 2] that was jointly written by the authors in radiology and cardiology but does not exclusively address cardiac MRI. This publication relates to MR imaging of all regions of the body.

In Germany and internationally the number of MRI examinations is increasing: 1,008,944 examinations were performed on patients receiving inpatient treatment in 2005 while 1,767,005 examinations were performed in 2013 (DRG hospitals). This development can be attributed to our aging population as well as to new indications for MRI including: Analyses of tissue composition and function, for example in the liver [3, 4] and the heart [5, 6]; multiparametric analyses of MR perfusion, e. g. in treated brain tumors [7]; new organs such as the lung [8]; dedicated examinations for intervention planning and operation monitoring [9–11]; as well as MRI-guided interventions [12–16].

Implants must always be considered in all of these MRI examinations even if the reason for the examination request is not related to an implant. The involvement of cardiology in this case is not based on the medical issue but rather on the type of implant. Expertise in cardiology is required when dealing with cardiac pacemakers (PM) and implantable cardioverter defibrillators (ICD).

## Background

MR imaging is fundamentally seen as safe because interactions between the electromagnetic fields needed for MR imaging (static field, high-frequency field and gradient field in the audio frequency range) and body tissue do not have a lasting effect on the person being examined. However, if other materials are in the body, e. g. in the case of implants, interactions affecting patient safety can occur. Safety concerns regarding these interactions resulted in the presence of an implant being considered an absolute contraindication for MR imaging. Manufacturers of MRI units therefore stated in their instructions for use that examination of patients with implants is fundamentally not allowed. This satisfies the requirements of an international standard for manufacturers of MRI units regarding safe operation of their devices. According to the (German) Medical Devices Operator Ordinance [17], operators of MRI units are required to observe (safety) information in the operating instructions.

The realization that it is ultimately not feasible to exclude all patients with implants from MR imaging due to developments in medicine prompted manufacturers of implants and MRI units to examine the possible risks posed by implants more closely. As a result, conditions under which MR imaging can be performed without harm to the patient were defined for suitable implants. These implants are labeled as “MR conditional”. The conditions, i. e., the requirements regarding MR imaging and possibly implant

settings, are included in the labeling [18, 19]. These requirements can be extensive and complicated so that examinations involving implants often cannot be performed in the daily routine even when the implants are labeled as “MR conditional”.

Knowledge of the exact conditions of use and the guarantee that these conditions will be strictly observed during MR imaging are essential for patient safety in the case of such “MR conditional” implants.

At the same time, manufacturer standards, which contain specifications regarding the content of operating instructions, have been updated to state that patients with “MR conditional” implants can be examined, provided that the specified conditions are met [20].

## Current situation

There is still great uncertainty about implants so that even patients with “MR conditional” implants are sometimes barred from a permissible MRI examination.

This is particularly true for patients with “MR conditional” cardiac implants. The conditions to be met are complicated and involve radiology as well as cardiology even if the examination request is made by a completely different department. Radiologists and cardiologists must work in close collaboration when preparing for an MRI examination involving a cardiac pacemaker or ICD. Therefore, this joint statement by radiologists and cardiologists presenting guidelines regarding the conditions and necessary procedures for examining patients with pacemakers and ICDs represents an important step forward for these patients.

The revised standards initially affect patients with implants explicitly labeled as “MR conditional”. The situation for patients with implants without this labeling is more complicated. This doesn't just apply to patients with older implants. Implants that were not specifically designed or tested for safe operation during MR imaging are still used today because implants that are designed to withstand the fields of MRI scanners are more expensive.

However, the in-depth investigation of possible interactions between PMs or ICDs and MR fields allows better assessment of the possible risks that can occur during MR imaging in patients with conventional, not “MR conditional”, implants. It was shown that the risks can be significant. However, in some cases the benefits of an MRI examination can be so great that examination is justified despite the risks. In such a case, the referring department, cardiology, and radiology (and possibly additional departments that can evaluate therapeutic consequences) must perform a joint risk-benefit analysis so that the patient can make a decision regarding a proposed off-label examination. The paper presented here also describes the decision criteria and processes for examinations in patients with PMs and ICDs that are not approved for MR imaging.

Cardiology and radiology are responsible for the settings and monitoring of their respective devices for both in-label and off-label examinations. The radiologist or the specialized physician with MR expertise conducting the MRI examination is ultimately responsible for the examination procedure.

It must be noted that “MR conditional” only means that the MRI examination does not pose an immediate danger to patients

and personnel. Whether image artifacts can affect the diagnostic value of imaging (thus making an examination obsolete) or whether the implant will resume full functionality after the examination is explicitly omitted here. The most recent documentation of the implant manufacturer should always be closely reviewed in this regard. Some manufacturers provide this documentation on their websites.

This consensus paper is based on the current state of the art. It would appear that newer developments may be able to simplify examinations in patients with implants: Manufacturers of implants and MRI units have agreed on a set of measurement parameters to be implemented initially at 1.5 T for MRI scanners as “fixed parameter option: basic” (FPO:B) [21]. When this option is (hopefully easily) selected, all relevant measurement parameters of the MRI system will be limited to values that prevent harmful interactions with appropriately designed or prepared implants. Moreover, there are software options that can be used to limit a series of parameters beyond basic parameters like SAR that are otherwise inaccessible and are specified as critical by implant manufacturers in the list of conditions for MR imaging. Additional settings (besides limitation of the SAR value) that, for example, reduce the risk of voltage induction in systems and leads can be made even in conventional PMs and ICDs.

This consensus paper clearly defines procedures for MR imaging in the case of active cardiac implants. The requirements are high. Such examinations should only be performed if the necessary radiology and cardiology expertise can be ensured. An attempt should be made to develop or further develop similar procedures for MR imaging for additional implant types in order to ensure maximum patient safety.

## Interessenkonflikt

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