German Ultrahigh Field Imaging

Approval of subjects for measurements at ultra-high-field MRI

Current state of science and technology

Since 2005 studies on humans have been performed at 7T MRI or at higher field strengths (ultra-high-field MRI) at nine sites in Germany.

In these studies the exclusion criteria are much more stringent than those usually defined for research purposes at clinical field strengths such as 3T. Because the level of knowledge about interactions between this new technology and implants was significantly lower than at clinical field strengths of 1.5 or 3 Tesla, many subjects had to be excluded.

Meanwhile, thousands of studies at ultra-high-field MRI have been performed with no known critical side effects or injuries. A multicenter study of 8357 subject measurements conducted regarding acceptance and temporary physiological side effects showed that these effects occur only mildly in the form of temporary dizziness, metallic taste sensation, nausea, or light flashes (phosphenes). Such effects were reported by up to 25% of the examined subjects; however, these were considered to be less unpleasant by the subjects than, for example, lying still during the extended investigation [1].

Active implants such as pacemakers and neuro stimulators as well as their implanted electrodes are not covered by the following statements due to their higher risk potential. Active implants are contraindicated at ultra-high field until further notice.

For passive implants, for example dental implants [2,3], stents [4], osteosynthesis plates [5,6], knowledge about interactions and experience in handling such implants in ultra-high-field MRI has significantly increased over the last years. Therefore, some sites now have new procedures when dealing with passive implants (for example, structured decision-making processes at the University of Duisburg-Essen and the DKFZ Heidelberg [7,8]). First and foremost, differentiated consideration of risks to persons to be examined at ultra-high-field MRI should continue to guarantee the safety of the subjects. At the same time, the largest possible number of studies and subjects should benefit from this technology and the advantages of this imaging.

A comparison with safety at the clinical field strength of 3T and the effects of the electromagnetic fields at different frequencies (static field, gradient field, and RF field) served as the basis for these considerations:

- The static magnetic field is higher than at 3T. The main biosensory effects are described above. These are temporary and very well tolerated by the subjects. The mechanical effects on ferromagnetic foreign objects (implants), i.e. the possible attractive forces, are less than twice as high compared to 3T due to the magnetic field geometry of passively-shielded ultra-high-field MR magnets. For the latest generation of actively-shielded 7T magnets, mechanical effects can be about twice as high.[1] Torques can be up to 2.3 times higher. Since for implants certified as "MR safe" or "MR conditional" at 3T the maximum allowed force has to be less than the inherent gravitational force, these implants will not have critical effects at ultra-high field.

- The gradient fields used in 7T MRI are not greater than those used in clinical 3T MRI. Different effects at ultra-high field are not expected for implants certified at 3T as "MR safe" or "MR conditional".

- The radiofrequency (RF) fields in ultra-high-field MRI are limited to the same maximum absorption rate [9], but the frequency of the electromagnetic waves is significantly higher than for clinical 1.5T and 3T MRI devices. This can lead to altered coupling of energy, which may result in locally increased heating. The radiofrequency transmission antenna in approved clinical 3T devices is the so-called body volume coil. This coil excites a large volume in the scanner with radiofrequency fields. Currently, local transmitting coils are used in ultra-high-field MRI (for example, local head or knee coils) that excite smaller volumes.

- The RF power density decreases very quickly outside the coil. A detailed prediction of the heating of an implant with a specific coil is dependent on the body geometry as well as the position of the implant, the body, and the transmitting coil with respect to one another. Passive implants that are further away from the transmitting coil and that are classified as "MR safe" or "MR conditional" at 3T are no longer considered to be an absolute exclusion criterion. This must be examined on a case by case basis. One possible approach [7, 8] is to define a minimum distance for a given transmitting coil and particular passive implants that ensures safe examination. Examinations with implants that are within the excitation field of the coil should only be performed after a validated field simulation for the implant has been carried out showing that all limits [9] are fulfilled.

[1] see the Siemens MR compatibility data sheet

- **The following procedure should apply only to studies with inclusion criteria regarding, for example, specific pathologies.** (For measurements with healthy individuals, the Principle Investigator is responsible for the clarification of contraindications.)

- The Principle Investigator[2] is responsible for the evaluation of the type and exact location of passive implants as well as for the inclusion of persons with passive implants. Therefore, the Principle Investigator should make use of the expertise of a MR Safety Panel.

Based on these considerations, the following procedure is recommended for the inclusion of persons in studies at ultra-high-field MRI as consensus of all participating ultra-high-field sites in the DFG-funded project GUFI. Only the special aspects at ultra-high field that go beyond the usual criteria for MRI are considered here. All other inclusion and exclusion criteria must be observed in accordance with the respective study.

Recommended procedure for inclusion of subjects for measurements at ultra-high-field MRI in suspected case of implants

Examination of contraindications

Should suspicion for the presence of an implant arise when the person to be examined is given information about the study, the Principle Investigator must clarify the situation in a timely manner (usually at least one full working day before the planned MRI measurement).

Absolute exclusion criteria for measurements at ultra-high-field MRI are factors that can result in a health risk to the subject or serious side effects. These include all incorporated materials that themselves generate a static magnetic field or that are strongly attracted by an external magnetic field. Non-ferromagnetic metals (for example copper, silver, titanium) may lead to signal dropouts in the image (artifacts) and possible local heating of tissue if they are in the exposure range of the excitation coil. The resulting absence of image information or presence of distortions may make the data unusable.

For subjects carrying passive implants, application of the following flowchart determines whether a measurement in the ultra-high-field MRI can be safely performed.

[2] The Principle Investigator should have experience in performing MRI studies and be familiar with the method of magnetic resonance imaging. The Principle Investigator is named by a competent authority (in association with a corresponding institution) and confirmed by a User Commission (if any). The Principle Investigator takes part at the regular "safety training for magnetic resonance imaging" (for example, at least once per calendar year).

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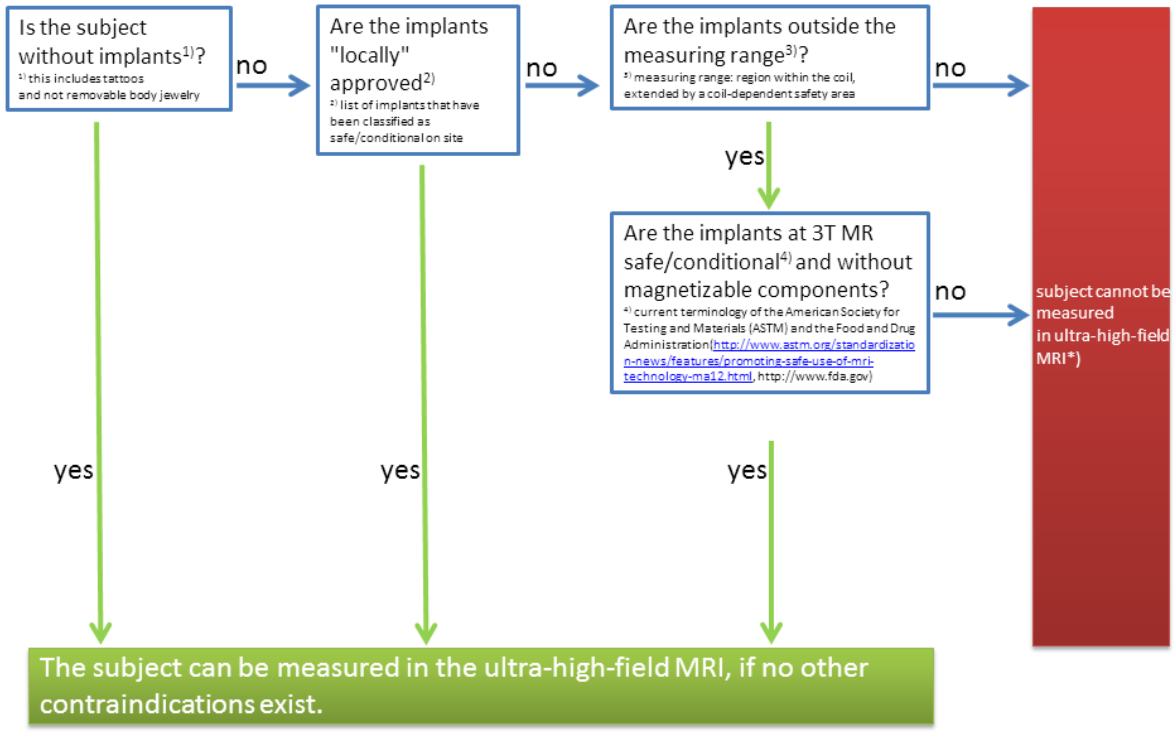
Flow diagram to include subjects for measurements in ultra-high-field MRI



*) If security is not determined by this flowchart, an examination can only be realized if a validated field simulation was performed for the specific passive implant and thereby can be shown that any limit values are kept.

List of GUFI Partners

Physikalisch-Technische Bundesanstalt, Berlin Ultrahigh Field Facility (B.U.F.F.)

Max-Delbrueck Center for Molecular Medicine, Berlin Ultrahigh Field Facility (B.U.F.F.)

German Center for Neurodegenerative Diseases (DZNE), Bonn

Universitätsklinikum Erlangen, Institute of Radiology

Erwin L. Hahn Institute for Magnetic Resonance Imaging, Essen

University Medical Center Freiburg, Department of Radiology, Medical Physics

German Cancer Research Center Heidelberg, Division of Medical Physics in Radiology

Forschungszentrum Jülich, Institute of Neuroscience and Medicine

Max Planck Institute for Human Cognitive and Brain Sciences, Leipzig

European Centre of Excellence in Ultra-High-Field Maastricht, scannexus

Leibniz Institute for Neurobiology Magdeburg, Non-Invasive Brain Imaging

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Max-Planck-Institute for Biological Cybernetics, Tübingen

High Field MR Centre, Medical University of Vienna, Department of Biomedical Imaging and Image-guided Therapy

Universitätsklinikum Würzburg, Comprehensive Heart Failure Center (CHFC)

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