

Title: Metrology for personalised MRI safety concepts suitable for patients with metallic implants

Abstract

With approximately 100 million magnetic resonance imaging (MRI) scans a year worldwide, any MRI safety-related issue is a major concern. A recent paradigm shift has brought numerical modelling into MRI safety concepts, opening the perspective of subject-specific assessments including previously inaccessible subpopulations (e.g. metallic implant carriers). Utilising new MRI scanner technology to adapt to the presence of metallic implants, a system level safety framework is aimed for by characterising local and systemic thermal effects. With the scientific community moving ahead in these areas, metrological underpinning is needed to fully assess and translate this approach into clinical practice.

Keywords

MRI safety, radio frequency heating, gradient heating, metallic implants, thermal dose

Background to the Metrological Challenges

The World Health Organisation (WHO) has stated that during MRI scans, state-of-the-art assessments "may not be appropriate for estimating temperature rises close to metallic medical implants" and for extremely low frequency electromagnetic fields (EMFs) (up to 100 kHz) more information is needed on such exposures within, or near, the MRI magnet bore. WHO has also identified EMF dosimetry as a priority research area, which also requires metrological assessment of these EMF induced thermal effects. Quantification of such exposure levels is now a necessary requirement to close these gaps.

The only existing standard for assessing the safety of metallic medical implants during MRI is ASTM F2182-2011, but there are limitations – although individual metallic implants must be proven to be safe during an MRI scan, the MRI instrument is currently only proven to be safe in subjects without metallic implants. Hence, a system level approach is now needed to produce an intelligent scanner and device synergy that together can enhance patient safety. A Technical Specification ISO/TS 10974 on MRI scanning of patients with implants has been proposed to define the future of implant testing, but is still lacking key procedures. By providing the underpinning, proposals in response to this SRT should aim for the Technical Specification to become a full standard.

EMRP JRP HLT06 'MRI safety' focussed on EMFs in native tissue and showed how sensitive parallel transmission (pTx) settings can affect the local electric fields (E-fields). E-field steering by pTx has a high potential to ensure patient safety for a wide range of different implants, but further investigation, in particular E-field induced thermal effects, is now needed.

The medical need for MRI scanning of patients carrying implants is already a reality. All major software packages for EMF calculations in tissue offer thermal simulation techniques, but a metrological assessment to check and validate these results is so far missing, preventing these concepts making it into routine clinical use. Much sensor-based thermometry after radiofrequency (RF) heating has been performed on animal carcasses or phantoms, but often suffers from insufficiencies like excessive RF heating to produce measurable effects. Spatially resolved and traceable temperature measurements inside humans are now required.

Advanced thermal and electrical voxel models of humans are readily available, but there is a lack of validation of physical quantities to input into these models (thermal and electrical) and for some implant materials this data is not available. To date, gradient coil heating effects are largely unquantified and experimental validation of simulation results is now required. A new metrological research project on MRI

safety is now required to provide confidence in diagnostic technologies adapted for patients with metallic implants.

Objectives

Proposers should address the objectives stated below, which are based on the PRT submissions. Proposers may identify amendments to the objectives or choose to address a subset of them in order to maximise the overall impact, or address budgetary or scientific / technical constraints, but the reasons for this should be clearly stated in the protocol.

The JRP shall focus on the development of metrological capacity for new system level safety concepts in MRI.

The specific objectives are

1. To develop and validate a methodology for assessing RF-heating related hazards in MRI patients with metallic implants. This should include traceably determining MRI RF induced electric fields and currents in and near metallic implants, electrical properties of tissues and implant materials; and developing methods to mitigate these effects.
2. To develop and validate a methodology for quantitatively assessing the effects of MRI switched gradient fields in terms of induced currents and thermal effects in tissue containing implants.
3. To metrologically underpin numerical simulations of RF or gradient heating of implants and adjacent tissue and evaluate the suitability of 'thermal dose' concepts as a substitute for existing MRI safety standards based on specific absorption rate
4. To determine MRI induced electromagnetic field quantities inside the human body. This should take into consideration individual anatomy and should target the provision of personalised MRI safety concepts.
5. To facilitate the take up of the methodology for providing personalised MRI safety in patients with metallic implants by clinicians, standardisation bodies and industry in order to support the development of new and innovative products for patient safety by MRI equipment and medical implant manufacturers.

These objectives will require large-scale approaches that are beyond the capabilities of single National Metrology Institutes and Designated Institutes, and it is expected that multidisciplinary teams will be required. To enhance the impact of the research, the involvement of the appropriate user community such as medical practitioners, medical (academic) hospitals and industry is strongly recommended, both prior to and during methodology development.

Proposers should establish the current state of the art, and explain how their proposed project goes beyond this. In particular, proposers should outline the achievements of EMRP JRP HLT06 (MRI safety) 'Metrology for next-generation safety standards and equipment in MRI' and how their proposal will build on this.

EURAMET expects the average EU Contribution for the selected JRPs in this TP to be 1.8 M€, and has defined an upper limit of 2.1 M€ for this project.

EURAMET also expects the EU Contribution to the external funded partners to not exceed 35 % of the total EU Contribution to the project. Any deviation from this must be justified.

Any industrial partners that will receive significant benefit from the results of the proposed project are expected to be unfunded partners.

Potential Impact

Proposals must demonstrate adequate and appropriate participation/links to the "end user" community, describing how the project partners will engage with relevant communities during the project to facilitate knowledge transfer and accelerate the uptake of project outputs. Evidence of support from the "end user" community (e.g. letters of support) is also encouraged.

You should detail how your JRP results are going to:

- Address the SRT objectives and deliver solutions to the documented needs,
- Feed into the development of urgent documentary standards through appropriate standards bodies,
- Transfer knowledge to the MRI safety sector.

You should detail other impacts of your proposed JRP as specified in the document "Guide 4: Writing Joint Research Projects (JRPs)".

You should also detail how your approach to realising the objectives will further the aim of EMPIR to develop a coherent approach at the European level in the field of metrology and include the best available contributions from across the metrology community. Specifically the opportunities for:

- improvement of the efficiency of use of available resources to better meet metrological needs and to assure the traceability of national standards
- the metrology capacity of EURAMET Member States whose metrology programmes are at an early stage of development to be increased
- organisations other than NMIs and DIs to be involved in the work

Time-scale

The project should be of up to 3 years duration.