EMPIR Call 2017 – Industry, Fundamental, Normative and Research Potential

Selected Research Topic number: **SRT-i19**
Version: 1.0

Title: Procedures allowing medical-implant manufacturers to demonstrate compliance with MRI safety regulations

Abstract

Medical implants represent a 3 billion € market in the EU. Approximately 50 million citizens carry some kind of medical implant and about 50 % of these will need a magnetic resonance imaging (MRI) scan during the lifetime of the implant. Therefore, it is vital that implant manufactures can demonstrate safety compliance in an MRI environment. In order to do this a system level approach for an MRI-safety assessment is required which includes high-resolution modelling and sensor feedback for risk quantification and active mitigation. This will then provide implant manufacturers with trusted procedures for compliance testing, spurring the innovation of new products.

Keywords

Medical implants; compliance testing; device safety; radiofrequency heating; MRI compliance.

Background to the Metrological Challenges

Magnetic Resonance Imaging (MRI) is one of the most important medical imaging techniques used today and it is likely that around 50 % of the 50 million implant carriers in the EU will need an MRI scan during their lifetime. This has resulted in increased pressure on implant manufacturers to demonstrate compliance of their devices for safe use in an MRI environment and as a result well defined, standardised procedures are needed. Currently, the only existing standard for assessing the safety of metallic medical implants during MRI is ASTM F2182-2011. However there are limitations, as although individual metallic implants must be proven to be safe during an MRI scan, the MRI instrument needs only to be proven to be safe in subjects without metallic implants. Hence, a system level approach is now needed that can enhance patient safety.

Numerical modelling of field distributions in human subjects is an established state of the art technique. However, even though this technique has been used to include the presence of metallic implants there were limitations as only generic implants with non-detailed features were modelled and there was limited experimental verification of the results.

Parallel-transmit (pTx) radiofrequency systems can be used in MRI scanners to measure the electromagnetic field as well as temperature distributions in and around the implant. The use of pTx for risk mitigation has enormous potential to ensure safety for a wide range of different implants and boundary conditions, and these systems can be combined with sensor-equipped implants to provide real-time feedback. However, currently such pTx methodology is still in early development and further work is needed to prove its use.

The heating of metallic implants due to switched magnetic-field gradients is an underestimated hazard in MRI, the effects of which were investigated in EMRP project HLT06 MRI safety. Some normative documents ignore this effect completely, whilst others mention the possibility of such effects only in the context of protecting the device rather than the patient. Recently, an experimental investigation of these effects hinted at the possibility that the induced heating effect might not scale with the root-mean-square averaged field changes, which is in contrast to the assumptions of existing standards on this subject. Therefore, more work is needed to investigate the hazards associated with the interaction between bulk metallic implants and switched magnetic fields.

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

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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 the demonstration of compliance with MRI safety regulations.

The specific objectives are:

1. To develop anatomical models of human subjects with realistic medical implants and having millimetre resolution. The models should be sufficiently detailed for use with *in-silico* medicine concepts.
2. To develop validated computational tools for the numerical simulation of electromagnetic fields and temperature distributions in a virtual human subject during MRI exposure. The computational tools should be able to process high-resolution anatomical models.
3. To develop validated methods and sensor-equipped reference implants for quantifying real-time implant-induced hazards during MRI exposure. This should include an assessment of parallel-transmit (pTx) radiofrequency systems in MRI with real-time feedback and the development of appropriate mitigations strategies.
4. To investigate numerically and experimentally the hazards associated with the interaction between bulk metallic implants and switched magnetic fields in the kilohertz regime. In addition, to develop a reference set-up for testing metallic implant heating, using switched magnetic-field gradients of a few mT/m with a target gradient-uncertainty below 5 %.
5. To interact closely with manufactures of implants, MRI and test equipment and with standards developing organisations (e.g. ISO/TS 10974, ISO/TC 121/SC 3 and ASTM Subcommittee F04.15 on Material Test Methods) to align the project and facilitate the take up of the technology and measurement infrastructure developed in the project.

Proposers shall give priority to work that meets documented industrial needs and include measures to support transfer into industry by cooperation and by standardisation. An active involvement of industrial stakeholders is expected in order to align the project with their needs – both through project steering boards and participation in the research activities.

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 the EMRP project HLT06 and how their proposal will build on those.

EURAMET expects the average EU Contribution for the selected JRPs in this TP to be 1.5 M€, and has defined an upper limit of 1.8 M€ for this project.

EURAMET also expects the EU Contribution to the external funded partners to not exceed 30 % of the total EU Contribution to the project.

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 healthcare 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.