Publishable JRP Summary Report for JRP HLT06 MRI Safety Metrology for next-generation safety standards and equipment in MRI

Background

Magnetic Resonance Imaging (MRI) has become an indispensable medical imaging modality with about 30 million patient exams in the EU every year and an excellent history of safe use. Nevertheless, it is continuously evolving and several recent technological developments such as ultrahigh magnetic fields, parallel transmission, or MRI guided radiotherapy promise to significantly enhance the quality and the range of applicability of MRI. The main reason why these technological developments haven't yet made it to product level and clinical application are their unresolved safety issues for patients and staff. For example an estimated 8 – 10 % of the European population, namely those carrying metallic medical implants, are effectively excluded from MRI scanning because these devices interfere with the MRI related radio-frequency (RF) fields inside the human body which might result in impermissible local "hot spots". The issue is that the associated patient risks cannot currently be quantified in this situation and in the case of such uncertainty a 'safety first' attitude naturally prevails and prohibits the clinical use of MRI for such cases. The overall goal of this JRP is to provide the metrics for the assessment of the associated risks with MRI and to define scan parameters or limiting values for the safe use of MRI.

Need for the project

Aside from conventional X-ray, MRI is the second most important medical imaging modality today. It is an indispensable tool in diagnosis and therapy control of neurologic, oncologic, cardiovascular, or musculoskeletal diseases. Its adjustable contrast capabilities particularly with respect to soft tissue are unmatched and cannot be provided by any other imaging modality. Worldwide, about 100 million MRI scans are performed per year. OECD statistics indicate about 4% of the western and 2.5% of the eastern European population having an MRI scan every year, numbers growing by 10% p.a. in Western and even 20% p.a. in Eastern Europe. Every matter affecting safety, performance or the applicability of MRI has an impact on European society as a whole. According to the manufacturer's organisation COCIR, the market for MRI scanners in the EU is about 900 units per year and growing, corresponding roughly to a 1-billion-Euro, 75 – 80 % of which are covered by European manufacturers.

The future development of MRI, at least in Europe, is severely impeded by two major factors. First, there is the still existing uncertainty about how the EU's new Electromagnetic Fields (EMF) directive will finally be implemented. Second, there is a prevalent uncertainty about how to ensure patient safety if new developments like parallel transmission come into play or carriers of medical implants are to be scanned. Several JRP workpackages have been setup to specifically address these issues. Upon successful completion of this JRP an extended knowledge base for legislators, standardisation bodies, manufacturers and end users should be available to assist them in their decision making with respect to MRI safety.

Another exciting new development is the MRI-accelerator combination, an emerging technology for radiotherapy and for MRI, fusing both modalities and providing precise, soft-tissue based, on-line position verification and treatment monitoring for radiotherapy. This has the potential to revolutionise cancer treatment but up to now a traceable gamma dosimetry inside an MRI scanner is a completely missing, a mandatory prerequisite before any clinical application. One workpackage in this JRP will be exclusively focused on closing this gap.

EMRP European Metrology Research Programme Programme of EURAMET
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Scientific and technical objectives

- To develop a mathematical modelling concept to calculate RF electromagnetic field distributions inside the human body;
- To produce reference instrumentation that can be used to perform traceable measurements of RF electromagnetic fields generated by MRI scanners, in the range 64 MHz to 300 MHz; these measurements will be suitable to validate the modelling results;
- To develop an assessment of the risk to human subjects from moving through the inhomogeneous stray fields of MRI scanners, in the range from zero up to 7 T, which can induce eddy currents at frequencies of the order of 1 Hz inside the human body;
- To develop a validated measurement method for the assessment of Specific Absorption Rate (SAR) hazards associated with emerging new MRI technologies e.g. parallel transmission (pTx) or ultrahigh magnetic fields (≥ 7 T);
- To produce a dosimetry method for the application of MRI guided radiotherapy, comprising a system for traceably measuring the absorbed dose to water for high energy photon beams in an MRI-accelerator combination and assessment of the potential changes in relative biological effectiveness of photon beams due to the magnetic field.
- To develop a method for the assessment of the risks due to the presence of passive, metallic, medical implants inside the patient's body during an MRI scan.

Expected results and potential impact

The aim of this JRP is to provide more complete and robust safety data for MRI patients and medical staff. By supporting the identification and removal of over-conservative safety margins due to insufficient knowledge, better image quality, improved diagnostic value, and shorter MRI scan times shall the achieved. By providing a robust and validated risk assessment for emerging technologies such as ultrahigh magnetic fields, pTx or MRI accelerators, this JRP will help European manufacturers to streamline their developmental targets and eliminate costly delays between product development and market introduction. The JRP also aims to provide results and impact future safety standards and regulatory guidelines, such as EN/IEC 60 601-2-33 and ISO DTS 10974. In short, this JRP aims to support MRI development by providing new guidelines, new standards, and more-over a new scientific state of the art.

Within the work on RF electromagnetic field measurements an MR compatible TEM cell was designed and built. Simulations and in-situ measurements show that this device allows traceable in situ calibrations of RF field probes (for E and B fields) right in the bore of an MR scanner. For the current measurements a body phantom with a phantom liquid characterised at 64 MHz, 128 MHz, and 300 MHz and a gantry for reproducible positioning of field probes is used. Using these developments extensive calibrated RF E- and H-field measurements in and around a body phantom inside a 3T MRI scanner were performed and successfully used to evaluate the accuracy of simulations. While this instrumentation was primarily developed for use within the JRP it has nevertheless already been taken up by end users. Stakeholders from academia who were aware of the JRP-Consortium's new measurement capabilities had actively sought the co-operation with JRP-Partners for an ongoing research project. Meanwhile, this collaboration has already produced the first publishable results.

The sensor-based EM field measurements have been compared to simulations and allow the JRP to verify how detailed a coil model is required to be. A frequency domain hybrid solver, combining aspects of the Finite Element Method (FEM) and the Boundary Elements Method (BEM) was developed and applied to the analysis of sensitivity of external E- and H- fields to internal induced phenomena in phantoms, also considering the presence of metallic object mimicking massive implants. This analysis is presently being extended to anatomical voxel models.

In order to investigate motion induced low-frequency fields, e.g., a human subject moving in the fringe field of an MRI magnet, a green's function based BEM algorithm was implemented. One particular advantage of this approach is its robust behaviour even for body rotations, a type of motion which is now known to need careful inspection with the more widespread potential-based modelling techniques. BEM implementations for modelling RF electromagnetic fields in weakly inhomogeneous structures and for modelling of highly

inhomogeneous structures like voxel data sets (parallelized for GPU) were developed and tested. In addition, it was shown that the BEM approach is intrinsically better adopted to calculate the extremely low-frequency electric fields inside the human body induced by movements in stray magnetic fields compared to alternative methods. The consistency of the BEM approach, which had been questioned in the literature, was convincingly demonstrated. A massively parallelised hybrid code combining elements from both BEM and FEM has been developed and tested for frequency-domain electromagnetic simulations of human model based on voxel data-sets. A new FEM formulation has been developed and implemented in a parallelised computational code that will be used to simulate motion-induced fields in high resolution anatomical models. Such a formulation is suitable to describe the contribution of both conduction and dielectric currents. An extensive inter-comparison of electromagnetic codes has been completed and the results have also been compared to those obtained through experiments on a specific phantom developed to this purpose. The FEM code which was found to be very suitable for studying high resolution anatomical models has been exploited to analyse the effects introduced by the dielectric currents, the dispersion of tissue parameters and, mainly, accelerated/decelerated motion phases on the induced electric field. On the basis of this analysis a set of simulations describing the exposure under realistic conditions could be derived. Stakeholders from an academic research group investigating the feasibility of a new MRI-accelerator design with the patient rotating within the MRI scanner took up these results and asked for co-operation to utilize JRP expertise for their specific application.

A setup for in-situ measurements of complete S-parameter matrices for parallel transmission systems in MRI has been designed and assembled. The completed device was successfully tested and has already been used for the in-situ measurement of S-parameter matrices of an 8 channel coil under different loading conditions. These S-parameter measurements allowed the JRP-Consortium to determine the absorbed RF power of the system coil/object for all steering conditions. The new hardware was developed without industrial input and is specifically designed to work with any pTx-capable MRI scanner, independently of vendor specific hardware or software independent. The data acquisition system was primarily built to enhance the JRP-Consortium's measurement capabilities and not with end users in mind. It has nonetheless already applied to answer a real-life question from outside the JRP about the fidelity of RF pulses in a given pTx application.

At the end of 2012 Elekta AB, leading European manufacturer of radiation therapy accelerators, and Royal Philips Electronics, leading Dutch manufacturer of MRI systems, announced that they would take their MRI-accelerator project to the next level and expand the existing research collaboration with University Medical Center (UMC) Utrecht to a worldwide collaboration network. Representatives from Elekta AB confirmed that the traceable dosimetry provided by this JRP was one indispensable prerequisite to make this strategic decision. This referred to a new water calorimeter suitable for operation in high magnetic fields which was successfully designed and built by JRP-Partner VSL. Simulations demonstrated its capability to achieve the required thermal stability and the device is currently being commissioned.

This highly versatile calorimeter will be used as a new primary standard for absorbed dose to water in high-energy photon beams (^{60}Co and MV-photons: 1.25 - 23 MV) and medium-energy x-rays (100 - 320 kV). Considerable effort was taken to build the device as compact as possible and to make it transportable. It will be brought directly to the end users at UMC Utrecht, and later possibly to other sites, as well, and will be used in the high magnetic field of their MRI-accelerator system. Because of the constructional design and materials choices, the calorimeter is anticipated to be applicable in a wide variety of beam modalities such as photons, electrons, protons and heavy ion-beams. The conservation of radiation in the calorimeter was studied by simulations. The calculation of the triple differential cross sections (TDCS) of water for electron scattering showed that the TDCS data in condensed history simulation codes for radiation transport do not need to be modified while simulating macroscopic dose distributions in presence of magnetic fields. On a nanoscopic scale, in contrast, the variation of the TDCS with the orientation of the water molecules may affect the particle track structure and thus needs to be accounted for.

New mathematical and numerical tools were developed for advanced RF electro-magnetic field simulations and detailed human voxel models containing a hip prosthesis were constructed. They enable JRP–Consortium to assess MRI safety issues related to implants. SAR distributions around implanted hip prostheses were investigated for a variety of subject positions within the MRI scanner and a worst-case position was identified. This approach was then extended to include both EM and *thermal* simulations of anatomical models in presence of orthopaedic metallic implants, also in view of possible external field monitoring. First activities were also started regarding the investigation on wire implants, beginning with an

analysis of the modelling issues caused by the presence of thin and long metallic structures within anatomical human models.

Every six months the JRP-Partners attend a project meeting as well as stakeholders and collaborators who have made valuable contributions and given good advice. The number of stakeholders and collaborators is growing, throughout the lifetime of the project, as more research groups in the scientific community become aware of it and express their interest in collaboration or an exchange of knowledge. After 24 months into the project, a total of 50 presentations on JRP related results were given at international conferences, workshops or meetings, eleven papers have been published, and five workshops or symposia have been co-organised; all ensuring that the JRP-Consortium stays in touch with its stakeholders. In addition, efforts have been made to spread the knowledge about HLT06 to the general public by organising a special INRIM seminar with two distinguished speakers from the JRP-Consortium.

JRP start date and duration:	1st April 2012, 36 months
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