Selected Research Topic number: **SRT-h02**
Version: 1.0

Title: Affordable low-field MRI reference system

Abstract

Low-field magnetic resonance imaging (MRI) is currently experiencing a renaissance: these systems are cheaper, safer, more adaptable to different environments, and easier to use than their high-field counterparts. Compact and mobile scanners are changing the workflow in radiology, where MRI comes to the patient rather than the patient to the MRI. These innovations are driven primarily by artificial intelligence (AI) in combination with low-cost hardware customised to a clinical application. To facilitate access to this technology and ensure reliable and reproducible diagnostic information for a wide range of patients in the EU and worldwide, this project will provide a metrological framework for the harmonised development of clinical low-field MRI.

Keywords

low-field MRI, low-cost healthcare, physics-informed deep learning, image reconstruction, artificial intelligence, clinical radiology, radiofrequency, gradient fields, biophysical parameters

Background to the Metrological Challenges

There are around 40 million MRI scans performed in the EU each year. The number of examinations is unevenly distributed among the member states; while in Germany around 150 000 scans per million inhabitants are performed, the number is 26 times smaller in Cyprus and in many non-EU countries MRI is not available at all due to the high cost of MRI devices and their installation. Affordable (<50 k€ material cost) MRI hardware with design and production documented according to the requirements of the EU's medical device regulation (EU)2017/745 (MDR) and shared non-exclusively by open-source licences, are needed to improve access to this essential technology.

Despite low-field scanners being more affordable than their high-field counterparts, proprietary low-field MRI units are still relatively costly to purchase, operate and maintain. This prevents most hospitals, doctors' offices, research institutions, metrology institutes and companies from purchasing/using these scanners in order to advance healthcare, science and industry. Affordable, fully characterised open-source reference devices will change this paradigm.

Field distortions from inhomogeneous magnets and non-linear gradient systems belong to common challenges even in high-end high-field MRI scanners. For current low-field MRI systems, imaging is carried out in the presence of much stronger field distortions including environmental uncertainties in point-of-care applications. In addition, low-field MRI scanners are developed as integrated hardware packages that rely on very specific hardware configurations such as phased arrays or embedded sensors for noise cancellation and motion detection. Data on the performance and uncertainties of the various correction strategies implemented by the vendors is, however, unavailable. Furthermore, these systems often rely on AI to perform corrections before presenting the final images to a radiologist. Up to now, the robustness and effectiveness of these approaches could not be evaluated objectively, not to mention a systematic investigation of these correction strategies and implications on effective treatment thresholds across various imaging systems. For the robust monitoring of long-term patient conditions and for the patient's safety, it is essential to continuously characterise the scanner performance, evaluating robustness of these systems in point-of-care applications, performing quantitative imaging, comparing the results to other low-field systems and assessing the effectiveness of current image reconstruction methods and improving these.

In order to achieve high image quality using low-field MR systems, a tight integration of data acquisition hardware and image reconstruction software is required. This includes detailed information about the MR system (B_0 inhomogeneities, radiofrequency system, etc.) in model-based image reconstructions either through an a priori characterisation or through on-the-fly measurements from embedded sensors to achieve robust and reproducible MR imaging. These model-based, non-linear reconstructions can become computationally too demanding and hence challenging for potential issues to be solved in clinical routine. In such cases physics-based machine learning approaches are required, ensuring short reconstruction times. A cloud-based solution enables these reconstruction issues to be effectively solved also when the required high performance computing infrastructure is locally not available.

Proprietary products are increasingly relying on proprietary AI and solutions, making it extremely challenging to reproduce results, to innovate and to benchmark inter-vendor performance. At the same time, regulators are facing challenges to evaluate safety and robustness of the diagnostic imaging performance of such devices. Consequently, a fully transparent and fully characterised reference system is needed to test, understand, evaluate and improve machine learning-based methods along the complete imaging pipeline from hardware to post-processing level.

Low-field MRI systems can be adapted for a wide range of different applications and therefore it is expected that many different systems will become available in the next couple of years. A metrologically well assessed open-source reference system, where all the details from data acquisition to image reconstruction are well characterised, is required to enable a harmonisation of low-field MRI systems and pave the way for quantitative results.

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 metrology research necessary to support the development of harmonised low-field magnetic resonance imaging.

The specific objectives are

1. To design, develop and evaluate mobile (<300 kg), low-cost (<50 k€) and fully replicable low-field MRI reference systems (main static field $B_0 \approx 50$ mT), capable of imaging the human head and extremities. To fully characterise these reference systems by metrologically validated methods including B_0, the radiofrequency and the switched gradient fields. To draft the technical documentation for the design and production process of the reference systems in accordance with the requirements of the EU medical device regulation (EU)2017/745.

2. To develop model-based image reconstruction techniques using the reference systems in objective 1. To achieve accurate and fast image reconstruction and to enable quantitative imaging of biophysical parameters by combining hardware models and MR signal models with physics-informed deep learning approaches. To implement an open platform with cloud-based access to these reconstruction techniques, thus facilitating reproducibility studies and the benchmarking of commercial low-field systems against the reference systems.

3. To evaluate the clinical suitability of the developed low-field MRI reference systems by standardised tests involving clinical radiologists to assess imaging performance across sites. To perform multisite reproducibility studies and to evaluate the uncertainties of the constructed low-field MR scanners under different operational conditions (e.g., thermal fluctuations or electromagnetic interferences). To compare the performance of these systems and their uncertainties to commercially available low-field MR systems (B_0 = 0.05 - 0.6 T) in inter-vendor comparisons.

4. To facilitate the take up of the technology and measurement infrastructure developed in the project by the measurement supply chain (e.g. accredited laboratories, instrumentation manufacturers), standards developing organisations (e.g. IEC TC 62/SC 62B), and end users (e.g. clinical community).

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.

EURAMET expects the average EU Contribution for the selected JRPs in this TP to be 1.9 M€ and has defined an upper limit of 2.6 M€ for this project.

EURAMET also expects the EU Contribution to the external funded beneficiaries to not exceed 35 % of the total EU Contribution across all selected projects in this TP.

Any industrial beneficiaries that will receive significant benefit from the results of the proposed project are expected to be beneficiaries without receiving funding or associated 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 the Partnership 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.