Publishable Summary for 22HLT02 A^{4}IM
Affordable low-field MRI reference system

Overview

Low-field magnetic resonance imaging (MRI) is 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 workflows in radiology, where MRI comes to the patient rather than the patient to the MRI. These innovations are driven primarily by Artificial Intelligence (AI) combined with low-cost hardware customised to clinical applications. This project will establish the necessary metrological framework for the harmonised development of clinical low-field MRI to facilitate greater access to this technology and ensure reliable and reproducible diagnostic information for patients in the EU and worldwide.

Need

Around 40 million MRI scans are performed in the EU each year. The number of examinations is unevenly distributed among the member states, to such an extent that the number of MR scans per million inhabitants is 26 times smaller in Cyprus compared to Germany, while in many non-EU countries MRI is not available at all.

Low-field MRI offers the potential for greater access to this critical diagnostic technology through more portable scanners opening the possibility of scans in the patients home or in intensive care units. 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 or using these scanners to advance healthcare, science, and technology. Low-field MR scanners based on open-source hardware designs operated by open-source software will change this paradigm. First prototypes demonstrated a truly affordable (< 50 k€ material cost) alternative with image quality comparable to commercially available scanners. A strategy that is fully in-line with the recent resolution of the UN Economic and Social Council asking to "better leverage open-source technologies for sustainable development" and latest EU4Health Programme 2021-2027 which focuses on "*supporting actions to enhance the availability, accessibility and affordability of medicinal products [...]*". By increasing MRI affordability based on greater low field MRI uptake, medical practitioners and their patients will have more portable reliable and robust tools to assess a wide range of different neurological and orthopaedic conditions based on the quantitative T2 and T1, rho methods developed. Mapping of these factors enables primary brain cancer tumour types to be distinguished and supports Europe`s Beating Cancer Plan established in 2021 where "*early detection*" and "*diagnosis*" are one of its four key pillars. These quantitative parameters are also used to successfully identify patients at risk from osteoarthritis which affects more than 40 million people in the EU and is the "*fastest growing cause of disability worldwide*". These quantitative parameters also have potential for use in the detection of the onset of ischemia - a key factor for stroke patient treatment.

To scale these low-field MRI innovations and increase use, a metrological framework to support and boost the development and application of affordable open-source low-field MR systems is needed. This must include metrologically characterised reference systems for benchmarking (objective 1 and 3) and software for scanner control, image reconstruction and data processing (objective 2). Modular strategies to medical device development need to be established including open-source documentation blueprints of hardware and software according to the requirements of the EU's medical device regulation (EU)2017/745 (MDR) (objectives 1 and 4). This will improve access to this essential technology, facilitate adoption by clinical end-users and unleash the vast innovation potential of this technology.

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PU – Public, fully open

Publishable Summary

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European Partnership Co-funded by the European Union

METROLOGY PARTNERSHIP EURAMET

The consortium benefits from a strong participation of companies who can directly utilise the outcomes of this project. Project stakeholders include low-field MR vendors, electronics and RF hardware companies, software companies specialised in cloud-based solutions for MR data acquisition and deep-learning based image reconstructions.

Objectives

The overall goal of this project is to establish affordable open-source low-field MRI systems covering hardware components, data acquisition and image reconstruction within the EURAMET network, which are reproducible, fully documented and metrologically characterised. The specific objectives of the project 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. This includes the full characterisation of these reference systems by metrologically validated methods including B_0, radiofrequency and switched gradient fields. To furthermore 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 and to distribute the complete documentation of the system under open-source licences.
2. To develop accurate and fast image reconstruction techniques for the low-field MRI reference systems from Objective 1, and to enable quantitative imaging of biophysical parameters using these systems based on combining hardware models and MR signal models with physics-informed deep learning approaches. Access to these reconstruction techniques is to be enabled by the implementation of an open cloud-based platform to facilitate reproducibility studies and the benchmarking of commercial low-field systems against the developed low-field MRI reference systems.
3. To evaluate the clinical suitability of the developed low-field MRI reference systems by standardised testing to assess imaging performance across sites involving clinical radiologists. In addition, (i) 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) and (ii) to compare the performance of these reference 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 adoption 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).

Progress beyond the state of the art and results

Objective 1: Mobile, low-cost and fully replicable low-field MRI reference systems

Current low-field MR systems (B_0 ~50 mT) can be brought directly to patients, but they use iron yoke magnets leading to a weight > 600 kg. In this project a Halbach magnet design will be adopted making the scanner 3-4 times lighter and smaller. The construction does not require specialised machines and is safer, facilitating local production and repair. Investigations of improved RF shielding or novel contactless sensors for patient monitoring will allow for safe, stable and high quality low-field imaging under varying environmental conditions. The system will be fully characterised and all information to rebuild, operate and maintain these scanners will be shared publicly and freely under open-source licences for other metrology institutes, research groups, companies etc. to be reproduced. The estimated total cost over 10 years will be 1/10th of the current cost of low-field systems. Providing open-source documentation fulfilling the requirements of the EU medical device regulation (EU)2017/745 facilitates the approval for similar low-field MR systems by companies and an easier assessment by notified bodies, which culminates in cost savings for public healthcare systems. The fully characterised reference systems will provide excellent and necessary testbeds to investigate safety related aspects of low-field MRI on vendor-neutral transparent systems to improve current standards (IEC 60601-2-33).

Objective 2: Open-source platform with model-based image reconstruction techniques

Image reconstruction for low-field applications is still in its infancy. There are image reconstruction and correction algorithms developed specifically for low-field applications, but these are proprietary products relying on proprietary AI solutions, making it extremely challenging to reproduce results, to innovate and to benchmark inter-vendor performance. This project will provide an open-source platform with model-based image reconstruction approaches optimised for the challenges of low-field low-cost MRI (e.g. low SNR due to the small magnetic field and hardware limitations due to cost-effective design). Deep learning approaches will

be leveraged to enable fast and accurate quantitative imaging of biophysical parameters (e.g. T_2, $T_{1,rho}$). A database with MR raw data acquired from low-field scanners will be created and made publicly available to enable comparisons and foster further developments. Cloud-based solutions to operate and maintain the MR scanners will ensure the utilisation of complex image reconstructions without the need for high-end local computing power.

Objective 3: Evaluation of the clinical suitability and comparison to other low-field systems

For the first time multiple low-field low-cost open-source MR scanners will be built at different sites and evaluated. This will establish a long-lasting framework for metrology in this growing field. The performance of the constructed reference scanner will also be compared to commercially available low-field MR systems of similar (B_0 = 50 mT) and higher (B_0 =0.2 - 0.6 T) field strengths. This will give important results to evaluate signal-to-noise ratio (SNR), contrast-to-noise ratio (CNR) and image quality for clinical use over a variety of low-field strengths. The open-source nature of the project allows the developed hardware, software, pulse sequences and image reconstruction techniques to be easily translated to other low-field MR systems improving their imaging performance.

Outcomes and Impact

Outcomes for industrial and other user communities

The innovative low-cost reference low-field MRI (e.g. novel magnet design, embedded sensor technology, novel pulse sequences and image reconstruction techniques) can be easily benchmarked and translated into novel products by MR vendors decreasing time-to-market drastically. Its open-source user interface and imaging platform is based on transparent interfaces to MR console hardware (Pulseq) and MR image reconstruction (ISMRMrd) making it easily adaptable by MR manufacturers to their products, while the large scientific community can feed into the development of the image processing pipeline. The project's cloud-based user interface and reconstruction platform will create an accessible and secure EU infrastructure for research institutions and other healthcare stakeholders globally and thus supporting the World Health Organisation's 4A (available, accessible, appropriate, affordable) strategy for medical devices. These developments address the current gap in healthcare access to diagnostic MRI for patients across the EU member states in accordance with the EURAMET 2030 Strategy to "*Develop and maintain an appropriate, integrated and cost-effective measurement infrastructure for Europe aligned to the needs of society and industry*".

Outcomes for the metrology and scientific communities

Current low-field systems are highly integrated commercial devices using deep-learning based image reconstruction algorithms tightly bound to proprietary hardware modules. These are commonly too expensive to purchase and operate for most NMIs. The affordable low-field MR scanners developed in this project will enable more European NMIs to operate and offer services for MRI scanning and will establish a metrological network enabling further collaboration and development. This will strengthen the competitiveness of European NMIs and broaden their portfolio of services in the emerging field of low-field MRI. The developed reference low field MR system will provide a workhorse for innovations, ensure best possible comparability between different systems, foster the translation of novel hardware and imaging techniques into clinical products and facilitate the evaluation of AI algorithms. The project's MRI system will help promote qualitative and quantitative MRI by addressing the need to evaluate the robustness and explicability of deep-learning based approaches, as well as assessing portable low-field MRI uncertainties under varying conditions. The project developed MR hardware will enable benchmarking against commercially available MR systems improving the scientific and clinical evaluation of MR techniques and spurring innovation through improved reproducibility.

Outcomes for relevant standards

Open-source hardware can be reproduced for 1/10th of the price of commercially available products and the availability of a modular technical documentation according to MDR (EU)2017/745 will allow for a much easier transition towards certified products. This project, by offering open-source and modular hardware documentation and technical documentation for the low-field MR reference system to MDR (EU)2017/745 requirements will facilitate increased reproducibility of MR systems and improve their safe operation. This novel approach will provide a blueprint for meeting MDR (EU)2017/745 requirements as an aid to future developments of open-source MR scanners by industry and academia. It will also be adaptable to other medical imaging modalities, e.g. by the echoOpen Foundation developing open-source ultrasound systems. Fully characterised and transparent imaging systems are important for the implementation of the EU Artificial

Intelligence Act. The EU trustworthy AI paradigm requires AI to be technically robust and reliable in its outcomes. This project will generate important results to support industry in demonstrating, and regulatory bodies in evaluating the safety of novel and implemented AI algorithms.

Even though low-field MR scanners might be considered to be safer than higher field (B_0 > 1.0 T) systems in many aspects such as stray magnetic field, acoustic noise, peripheral nerve stimulation or SAR, the most important MR safety standard, the IEC 60601-2-33:2022 “Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis”, currently does not take this into consideration, making regulatory approval unnecessarily complicated. The project results will provide a major contribution to future editions of the IEC standard (e.g. edition 4.1 of IEC 60601-2-33), simplifying current procedures for safety evaluation of low-field MRI. This will improve the innovation potential of this technology, reducing costs and improving global accessibility. The developed reference hardware will furthermore enable investigations into the safety of low-field MR systems (B_0 < 0.1T) for patients with passive and active implants, providing important results to ASTM F2182 and ISO/TS 10974.

Longer-term economic, social and environmental impacts

The economic and social impact of this project is well aligned with the goals of the United Nations Economic and Social Council, who passed E/RES/2021/30, and invited to find “...ways to better leverage open-source technologies for sustainable development…”. The market value of medical imaging was estimated as more than 28 billion USD in 2021 and expectations for 5 % growth over the next 10 years. MRI is growing even faster at a rate of 6.5 %. This project will create a MDR (EU)2017/745 blueprint for new innovations in low field MRI systems helping to keep Europe at the forefront of the medical imaging market.

This project’s affordable low-field MR system has potential to initiate other systems that will be a game changer for radiology. MRI will no longer be an expensive imaging modality, mostly restricted to hospitals and used only for a limited number of conditions, but it will be able to move into the local doctors’ surgery and even to the patient’s bedside, with similar portability to that of ultrasound scanners. This will open new possibilities in healthcare such as: monitoring critically ill patients in intensive care units without needing to transport them through the hospital, monitoring stroke and expanding acute stroke care, screening patients with mild traumatic brain injury using less high-field MRI and/or reduced radiation exposure with Computed Tomography. This will transform MRI from a specialists’ tool to an easy-to-use first choice for many clinical applications worldwide.

The project’s open-source modular MR scanner is built from low-cost materials and uses readily available production facilities, with all necessary documentation provided so that repairs can be easily carried out by users without special training at low cost. This will increase the systems lifetime and offers CO_2 manufacturing reductions as fewer replacement scanners will be needed, addressing the expectations of the European Sustainable Products Initiative which will build on the Ecodesign Directive 2009/125/EC. By providing all the necessary documentation and ensuring a hardware design that can be easily replicated, the project’s open-source low-field MR system is fully aligned with these developments within the European Green Deal programme.

List of publications

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This list is also available here: https://www.euramet.org/repository/research-publications-repository-link/

Project start date and duration:	01 September 2023, 36 months	
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