

Title: Metrology for therapeutic ultrasound

Abstract

Ultrasound is a proven diagnostic tool, used in most healthcare fields, with recent applications beginning to exploit its therapeutic potential. To further improve healthcare, modalities such as the early, routine screening for osteoporosis, high-intensity focused ultrasound (for cancer treatments) and microbubble-based drug/gene delivery vehicles for cancer and Alzheimer therapies promise paradigm shifts in treatment. But the absence of proven methods for specifying the radiation quality, the energy and angular dependence of the detectors' responses, detector specific properties like fading of the radiation induced (latent) signal has made this technique problematic. The objectives are to conduct research for definition and metrological underpinning of a dose concept in therapeutic ultrasound and to develop dose modelling and measurement methods for proper treatment planning and risk assessment. This will finally enable the verification of treatment planning systems on a solid metrological basis and will contribute to the benefit of the patients.

Conformity with the Work Programme

This Call for JRP's conforms to the EMRP Outline 2008, section on "Grand Challenges" related to Health, New Technologies & Fundamental Metrology on pages 2, 22 and 49.

Keywords

Ultrasound therapy, cancer therapy, ultrasound treatment, individually optimised therapy, treatment planning, treatment verification

Background to the Metrological Challenges

Medical applications of ultrasound continue to proliferate, covering diagnosis and treatments like lithotripsy, pain relief, physiotherapy, enhanced bone repair, wound healing, fat removal, and various cosmetic purposes. Ultrasonic imaging now accounts for 1 in 4 of all imaging procedures worldwide. New imaging developments continue at an accelerated rate, driven by a fusion of transducer developments, technological innovations and improved processing power, reflecting an inexorable, safety-related, shift away from the use of ionising radiation.

The metrology for therapeutic ultrasound fields under free-field conditions in water has advanced during the last years, but still requires substantial development. This holds true especially for the metrology of low-frequency ultrasound fields used in physiotherapy, for fat removal or cosmetic purposes.

Commercially available high intensity focused ultrasound (HIFU) systems use different approaches for planning and monitoring of the therapeutic outcome, which are not assessed by any kind of quality testing. Planning systems serve only for aiming and guidance and the treatment is based on intensity data measured in free-field conditions in water, not in tissue. In comparison to the situation for ionising radiation, therapeutic ultrasound applications do not incorporate a standardised, comparable dose concept. Consequently treatment is essentially empirical and it is impossible to compare the effectiveness of different HIFU systems or the susceptibility of different conditions to treatment. This impedes a uniform treatment of patients and is hindering the clinical acceptance of the therapy method.

Scientific and Technological 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 JRP-Protocol.

The JRP shall focus on the traceable measurements required for dosimetry in therapeutic ultrasound. Furthermore, dose modelling and measurement methods for proper treatment planning and risk assessment shall be developed.

The specific objectives are:

1. Development of a dose concept in therapeutic ultrasound on the basis of determined field quantities and related effects
2. Development of a tissue phantom with measurement techniques for testing of dose concept including the characterisation of measurement methods and treatment planning software
3. Development of test methods on the basis of a multimodal phantom for assessment of commercial machines and comparison of treatment effects and efficiency
4. Modelling and validation of non-linear ultrasound propagation through multi-phase phantoms and anatomical structures (tissue and tissue mimicking materials)
5. Usage of multi-modal imaging for acquisition of anatomical data as basis for further improvement and accuracy of the individual treatment planning.

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, this JRP will require a close cooperation with experts from the relevant medical area.

Proposers should establish the current state of the art, and explain how their proposed project goes beyond the EURAMET funded Joint Research Project "T2.J07: EBCT / External Beam Cancer Therapy" in particular on High Intensity Therapeutic Ultrasound (HITU).

The total eligible cost of any proposal received for this SRT is expected to be around the 2.7 M€ guideline for proposals in this call.

Potential Impact

Proposals must demonstrate adequate and appropriate participation/links to the "end user" community. This may be through the inclusion of unfunded JRP partners or collaborators, or by including links to industrial/policy advisory committees, standards committees or other bodies. Evidence of support from the "end user" community (eg letters of support) is encouraged.

You should detail other impacts of your proposed JRP as detailed in the document "Guide 4: Writing a Joint Research Project"

You should detail how your JRP results are going to:

- feed into the development of urgent documentary standards through appropriate standards bodies
- transfer knowledge to the Medical sector.

You should also detail how your approach to realising the objectives will further the aim of the EMRP to develop a coherent approach at the European level in the field of metrology. 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 Member States and countries associated with the Seventh Framework Programme whose metrology programmes are at an early stage of development to be increased
- outside researchers & research organisations other than NMI and DI to be involved in the work

Time-scale

The project should be of up to 3 years duration.