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

Selected Research Topic number: **SRT-r03**
Version: 1.0

Title: Development of expanded metrological capability for medical ultrasound

Abstract

Despite the ubiquitous and increasing use of ultrasound in healthcare, there are only a few European NMIs active in this field and work is required to establish a wider base across more countries in order to support industry in developing novel products and to ensure the safety of patients who are scanned, diagnosed or treated with ultrasound. Additional capabilities need to be established that will extend the measurement and calibration capacity across Europe.

Keywords

Ultrasound, ultrasound diagnostic equipment, ultrasound therapeutic equipment, radiation force balance, hydrophone

Background to the Metrological Challenges

Ultrasound for both diagnosis and therapy is a major pillar of modern healthcare. The global ultrasound market is expected to reach $6.2 billion by 2019 at a growth rate of 5.1 %; Europe accounts for the largest share of the market with ultrasonic imaging now accounting for more than 25 % of all imaging procedures worldwide. Medical applications of ultrasound are continually evolving with new imaging methods (e.g., elastography, acoustic radiation force imaging) and potentially important therapeutic techniques emerging (e.g., High Intensity Focused Ultrasound (HIFU), targeted drug delivery). According to EU legislation (Medical Devices Directive 93/42/EEC), medical ultrasound equipment must be tested and CE marked before being placed on the market. At the end-user level, devices also require periodic re-testing and calibration. It is essential therefore that EU regulators, standardisation bodies, end-users and stakeholders have access to a wide range of reliable ultrasound calibration expertise in order to ensure that access to market and ongoing quality assurance are managed and updated appropriately. The number of European NMIs currently offering calibration services in this area is very limited and there is a need to increase the European metrology base, especially as the technologies in use continue to develop.

Future medical ultrasonic equipment development will be limited by the traceability of ultrasound power, which is measured by the radiation force it exerts on a stationary target suspended in water, and can be conveniently measured using a commercial mass balance. However, commercial mass balances are not designed to weigh objects suspended in water and suffer from technical problems and uncertainties as high as 20 %. To address these challenges, new instrumentation needs to be developed to measure ultrasound power using load-cell technology (primary component of mass balance) for which custom electronics and data processing must be built. New measurement protocols need to be developed, with key comparisons undertaken to gain confidence in the results and outcomes. Existing IEC standards (61161 and 62555) need to be assessed to ascertain where appropriate updates are required.

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.

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The JRP shall focus on the development of metrological capacity in the field of medical ultrasound.

The specific objectives are

1. To develop traceable measurement capabilities and expertise in the measurement of ultrasound power and the calibration of ultrasound power meters relevant to diagnostic and therapeutic output levels, and in the calibration of hydrophones and the testing of acoustic output from medical ultrasound equipment.
2. To develop and validate new instrumentation for the measurement of ultrasound power using load-cell technology, including the establishment of standard measurement protocols and associated uncertainty budgets.
3. To compare the results obtained using the new instrumentation for the measurement of ultrasound power using load-cell technology to those obtained with existing commercial mass balances and to identify any amendments that could be proposed related to existing IEC standards 61161 and 62555.
4. To validate the NMI capabilities developed within the project via an intercomparison and to develop draft Calibration and Measurement Capabilities for ultrasound power and pressure, for future submission to the BIPM Key Comparison Database (KCDB).
5. For each participant, to develop an individual strategy for the long-term operation of the capacity developed, including regulatory support, research collaborations, quality schemes and accreditation. They should also develop a strategy for offering calibration services from the established facilities to their own country and neighbouring countries. The individual strategies should be discussed within the consortium and with other EURAMET NMIs/DIs, to ensure that a coordinated and optimised approach to the development of traceability in this field is developed for Europe as a whole.

Joint Research Proposals submitted against this SRT should identify

- The European and national regulatory needs in this field,
- the particular metrology needs of stakeholders in the region,
- the research capabilities that should be developed (as clear technical objectives),
- the impact this will have on the industrial competiveness and societal needs of the region,
- how the research capability will be sustained and further developed after the project ends.

The development of the research potential should be to a level that would enable participation in other TPs.

Proposers should note that the programme funds the activity of researchers to develop the capability, not the required infrastructure and capital equipment, which must be provided from other sources.

EURAMET has defined an upper limit of 500 k€ for the EU Contribution to any project in this TP, and a minimum of 100 k€.

EURAMET also expects the EU Contribution to the external funded partners to not exceed 10 % of the total EU Contribution to the project.

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,
- Provide a lasting improvement in the European metrological capability and infrastructure beyond the lifetime of the project,
- Facilitate improved industrial capability or improved quality of life for European citizens in terms of personal health or protection of the environment,
- Transfer knowledge to the healthcare sector and the metrology community.

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.