EMPIR Call 2019 – Energy, Environment, Normative and Research Potential

Selected Research Topic number: **SRT-r01**
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 ensure the safety of patients who are scanned, diagnosed or treated with ultrasound and to support industry in developing novel products. Additional capabilities therefore need to be established in a coordinated approach 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. This equipment is commonly regulated (e.g., through the Medical Device Directive and by the US Food and Drug Administration) by reference to the harmonised series of IEC60601 safety standards (published by IEC TC62 (Medical Electrical Equipment)) and a range of supporting measurement and specification standards generated by IEC Technical Committee 87 (Ultrasonics). 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, as evidenced by the recently completed key comparisons for ultrasound pressure and ultrasound power which included only two and three European NMIs respectively. There is therefore 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. In a different technique, the ultrasound power is measured by the change in buoyancy due to absorbed acoustic energy by a target suspended in water. This technique is specifically developed for high intensity therapeutic ultrasound, but its sensitivity is approximately a factor of 20 lower compared to the radiation force. Acoustic power of 1 W exerts the equivalent of a change in weight of approximately 69 mg on the suspended target. The acoustic power generated by diagnostic equipment ranges from a few mW to less than 200 mW and for therapeutic equipment it is between 10 W and up to 500 W. However, commercial mass balances are not designed to weigh objects suspended in water. In addition, the evolving technological sophistication and closed architecture of mass balance hardware and software creates limitations, as it is designed to smooth out small, short-timescale changes in mass. Such changes are representative of the momentum changes seen when measuring applied ultrasound, as so these are interpreted as being background noise. This results in increased uncertainty, with uncertainties reaching as high as 20%, depending on the power level and technique employed. To address these challenges, new instrumentation needs to be developed to measure ultrasound power using load-cell technology (primary

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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.

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

The specific objectives are

1. To develop traceable measurement capabilities and expertise in (i) the measurement of ultrasound power and calibration of ultrasound power meters relevant to diagnostic and therapeutic output levels, and (ii) 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 to overcome the technological restrictions associated with closed architecture of commercial mass balances, including the establishment of standard measurement protocols and associated uncertainty budgets.
3. To validate the NMI capabilities related to the measurement of ultrasound power developed within the project via an intercomparison and to identify Calibration and Measurement Capabilities for ultrasound power and pressure based on the validated capabilities that should be developed for future submission to the BIPM Key Comparison Database (KCDB).
4. 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 related to existing IEC standards 61161 and 62555 that could be proposed to IEC Technical Committee 87.
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 including members of relevant the EMNs or JRPs, to ensure that a coordinated and optimised approach to the development of traceability in this field is developed for Europe as a whole. In addition to develop material and appropriate mechanisms to disseminate the project outputs and results to instrument manufacturer's, calibration providers and clinicians.

Joint Research Proposals submitted against this SRT should identify

- the JRP(s) or/and the joint European metrology structure initiative they refer to,
- 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 competitiveness and societal needs of the region,
- how the research capability will be sustained and further developed after the project ends.

In particular, proposers should outline the achievements of the EMRP project HLT03 DUTy and how their proposal will build on those.

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

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 0.5 M€ for the EU Contribution to any project in this TP, and a minimum of 0.1 M€.

EURAMET also expects the EU Contribution to the external funded partners to not exceed 10 % of the total EU Contribution across all selected projects in this TP.

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, including the related JRP or EMN as applicable,
- 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, standardisation developing organisations such as IEC, 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.