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

Selected Research Topic number: **SRT-r09**
Version: 1.0

Title: Introducing simulators as a means to establish traceability in dynamic blood pressure measurements

Abstract

Globally, one out of eight deaths is caused by hypertension (high blood pressure), an easily treatable disease if properly diagnosed. However, underestimating true blood-pressure (BP) values by merely 5 mmHg would leave one third of 150 million EU hypertension patients falsely undiagnosed and with a 25 % increased risk of stroke and myocardial infarction. Existing recalibration requirements using static measurements are inadequate for the majority of automated BP measurement devices and research is required to establish true traceability for dynamic BP measurements, by utilising commercially available BP simulators as transfer standards.

Keywords

Smart specialisation, medical metrology, traceability of medical devices, sphygmomanometer, blood pressure, blood pressure simulator, ISO/TC 121/SC 3/JWG 7

Background to the Metrological Challenges

Hypertension affects one in three adults worldwide and causes 13 % of all deaths globally. Hypertension increases the probability of stroke, heart attack and kidney disease, causing over 22 % of all heart attacks in Europe. Effective treatment of hypertension is possible but, as it rarely causes symptoms, the key to successful treatment is early detection. Reliable and accurate blood-pressure (BP) measurements are the foundation of hypertension diagnostics. BP measuring devices, i.e. sphygmomanometers (SMs) must be calibrated or verified regularly, and relevant normative documents ISO 81060-1&2 and IEC-60601-2-30 as well as guidelines from medical societies, require extensive and costly clinical trials for SMs to demonstrate adequate accuracy. Clinical trials are also used by SM manufacturers for tuning the internal algorithms to derive systolic and diastolic BP values. This procedure is established and is accepted by all relevant players in the field. However, for each SM type and make it refers to just one single device, often called the 'golden unit', in the safe of the manufacturer, and it allows no conclusion about the status of the instruments in the field.

The current practice of recalibrating SMs by static pressure measurements (only) was developed for manual devices and works satisfactorily for those. However, many SM devices use automated oscillometric methods and the statically applied reference pressure measurements are inadequate for calibrating those as the clinically relevant quantities, systolic and diastolic BP, cannot directly be read from an oscillometric pressure curve; they occur "somewhere" on this curve, not at marked positions like the beginning or the peak or the end of the oscillations. BP simulators are needed to address this challenge. They produce artificial oscillometric signals and thus have the potential to be used as transfer standards to compare an SM in the field to the clinically tested 'golden unit'. Such devices exist and a number of different types are commercially available at reasonable cost, but so far they are only used for quality control purposes. These commercial devices use artificial, strictly periodic signals, which are easy to generate, but do not reflect real-life BP signals. The signals generated by commercial simulator models also vary from type to type and each SM-simulator combination therefore gives different BP readings. A full investigation is required to ascertain which of these devices are actually suitable to serve as transfer standards, including the repeatability and reproducibility of a given simulator. Reference values have to be established for the blood pressure readings to be achieved for different simulator-sphygmomanometer combinations and different set-points, together with a validated and proven procedure for the use of certified simulators in the verification of automated SMs in the field. The above developments should aim, in the long term, at improved and rewritten standards under the auspices of ISO/TC 121/SC 3/JWG 7, together with a metrological framework for the traceable dynamic measurement of BP. A common factor in Central and South-Eastern Europe is that national laws require periodic metrological

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checks for measuring medical devices, and many of the NMIs/DIs in these countries lack either the resources, or the research know-how, or both to cope with the new technical developments in the field of measuring medical devices in general and BP measurements in particular. This makes this region a good starting point for developing a 'smart specialisation' solution addressing this challenge.

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 traceable dynamic measurement of blood pressure using simulators as transfer standards.

The specific objectives are

1. To define the necessary requirements and test procedures for conventional blood-pressure (BP) simulators to be acceptable as transfer standards for the traceable calibration of automated oscillometric sphygmomanometers (SMs); to develop a procedure and define acceptable uncertainty limits of $\pm$ 1 mmHg or better for periodic recalibrations of such simulator-based transfer standards at NMI level.
2. To develop a procedure and define acceptable uncertainty limits for dynamic tests of SMs in the field using a certified BP simulator as a transfer standard.
3. To develop a new oscillometric BP simulator, including a recording unit, with the capability to accurately reproduce pre-recorded real-life oscillometric BP pulses.
4. To engage closely with regional and European stakeholders, including regulatory and governmental bodies, medical experts, professional medical societies, standards developing organisations e.g. ISO/TC 121/SC 3/JWG 7, metrological committees and device manufacturers to ensure that all medical, legal and metrological requirements for a transition from static to dynamic SM testing are met, that the stakeholders' needs are known and considered, and to facilitate the take up of the measurement capacity developed in the project.
5. To develop and implement a concept for smart specialisation in the field of traceable BP measurements and to integrate this concept with similar such concepts for other medical devices. The smart specialisation should aim at the establishment of a single joint research capacity. Additionally for each participant, to develop an individual strategy for the long-term operation and transnational use of this joint research capacity, including regulatory support, research collaborations, quality schemes, accreditation and the offer of calibration and testing services 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 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.