

Title: Developing an infrastructure for improved and harmonised metrological checks of blood-pressure measurements in Europe

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 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 blood pressure measurement devices. Research is therefore required to establish traceability for dynamic blood pressure measurements, including developing an appropriate metrological infrastructure via a smart specialisation approach.

Keywords

Blood pressure, blood pressure simulator, medical metrology, traceability of medical devices, sphygmomanometer, smart specialisation

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 measurements are the foundation of hypertension diagnostics. Blood pressure measuring devices, i.e. sphygmomanometers 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 sphygmomanometers to demonstrate adequate accuracy. Clinical trials are also used by sphygmomanometer manufacturers for tuning the internal algorithms to derive systolic and diastolic blood pressure values. This procedure is established and is accepted by all relevant players in the field. However, for each sphygmomanometer 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 sphygmomanometers by static pressure measurements (only) was developed for manual devices and works satisfactorily for those. However, many sphygmomanometer devices utilise automated oscillometric methods and the statically applied reference pressure measurements are inadequate for calibrating those as the clinically relevant quantities, systolic and diastolic blood pressure, 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. Blood pressure simulators are needed to address this challenge. Whilst a number of commercial blood pressure simulators are available on the market, these commercial devices use artificial, strictly periodic signals, which whilst easy to generate do not reflect real-life blood pressure signals. The signals generated by commercial simulator models also vary from type to type and each sphygmomanometer-simulator combination therefore gives different blood pressure readings. These devices were developed for quality assurance purposes, they were not meant to be and are not suited to serve as reference standards. An alternative approach, suitable for use as a reference standard able to provide traceability for dynamic blood pressure measurements, is required to enable the verification of automated sphygmomanometers. 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 blood pressure.

A common factor in Central and South-Eastern Europe is that national laws require periodic metrological 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 blood pressure 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 development of metrological capacity and infrastructure for the traceable dynamic measurement of blood pressure using oscillometric signal generators as a reference.

The specific objectives are

1. To develop an advanced oscillometric signal generator device, including a recording unit, with the capability of accurately reproducing pre-recorded real-life oscillometric blood pressure pulses.
2. To define the necessary requirements and test procedures for such an oscillometric signal generator to be acceptable as a reference standard and hence as a means to establish the traceability for automated sphygmomanometers.
3. To develop a procedure for the periodic recalibrations of such advanced oscillometric signal generators at the NMI level, including defining acceptable uncertainty limits which should be ± 1.5 mmHg or better.
4. To engage closely with regional and European stakeholders, including regulatory and governmental bodies, medical experts, professional medical societies, standards developing organisations, metrological committees and device manufacturers to ensure that all medical, legal and metrological requirements are met.
5. To develop and implement a concept for smart specialisation in the field of traceable blood pressure measurements and to integrate this concept with similar ones for other medical devices. The smart specialisation should aim at the establishment of a single joint research capacity. To develop a strategy for the perpetuation and sustainability of this new capability and a strategy for offering calibration and research services to national or international customers including NMIs/DIs. Additionally for each participant, to develop an individual strategy for the long-term operation and transnational use of this joint research capacity, and access to the calibration and testing services by their own country. The overall and 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 competitiveness 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 across all selected projects in this TP.

EURAMET is aware that SRT-n08 and SRT-r01 are in the same technical area and request that those responding to either SRT coordinate their proposals so that there is no overlap of technical work. If both proposals are funded, they should consider joint dissemination activities.

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 and regulatory sectors 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.