

Title: Establishing the metrological foundation for revised ISO 81060 and IEC 80601-2-30 standards by introducing dynamic verification of sphygmomanometers

Abstract

According to the World Health Organization, about 13 % of all deaths worldwide are due to high blood pressure. Reliable and accurate blood pressure measurements performed using sphygmomanometers are crucial in hypertension diagnostics, but measurement errors can be systematic, random, or, more commonly, a combination of both. Therefore, it is essential to establish and ensure metrological traceability of dynamic blood pressure measurements. Nowadays, the metrological requirements for sphygmomanometers (blood pressure meters) are exclusively defined in terms of static pressure testing which is inadequate for automated sphygmomanometers. To overcome this, dynamic pressure traceability for automated sphygmomanometers should be established by using non-invasive blood pressure simulators as transfer standards and defining appropriate testing methods.

Keywords

Medical metrology, automated sphygmomanometers, blood pressure simulators

Background to the Metrological Challenges

Hypertension is a leading risk factor for overall mortality on a global scale. Persistent high blood pressure can lead to chronic failure of heart, brain, and kidneys. Furthermore, high blood pressure is directly responsible for approximately 25 % of heart attacks in Europe. Several studies have shown that detection of hypertension is very sensitive to systematic errors (including inadequate calibration), which underlines the importance of a clear and accurate validating process for non-invasive blood pressure (NIBP) measurements.

Nowadays, the safety and performance of non-invasive sphygmomanometers is implemented through metrological checks against the ISO 81060-1 and IEC 80601-2-30 standards by verifying the accuracy of static pressure measurements alone. While this approach works well for the manual auscultatory method, it is inadequate for the predominantly used automated sphygmomanometers. This normative gap has been recognised by the ISO/IEC Joint working group ISO/TC121/JWG7 “Non-invasive sphygmo-manometers”, which agreed that the repeatability and the reproducibility of simulators is an important physical property to test the short- and long-time performance of automated sphygmomanometers.

NIBP simulators should be suited for that purpose, but basic performance requirements and appropriate testing methods still need to be defined. A new work item ISO/NP 81060 Part 5: Requirements for the repeatability and reproducibility of NIBP simulators for testing” has been defined but still needs the metrological foundation defining the necessary requirements and test procedures for NIBP simulators to be acceptable as transfer standards for the traceable calibration of automated oscillometric sphygmomanometers.

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 metrology research necessary to support standardisation in dynamic verification of sphygmomanometers.

The specific objectives are

1. To define the necessary requirements and test procedures for non-invasive blood pressure simulators to be acceptable as transfer standards for the traceable calibration of automated oscillometric sphygmomanometers.
2. To develop dynamic metrological checks for automated sphygmomanometers based on NIBP simulators as transfer standards. This will should setting up guidelines (e.g. written standards) for the dynamic testing of automated sphygmomanometers and concordance tables for possible simulator/sphygmomanometers combinations for the blood pressure values to be achieved.
3. To develop standardised requirements for advanced NIBP simulators generating oscillometric blood pressure signals containing external disturbances. This should be used to investigate the potential of using an automated non-invasive sphygmomanometer for measuring accurately under rough environmental conditions, e.g. in ambulatory environment.
4. To contribute to the standards development work of ISO/TC 121/SC 3/JWG 7, to ensure that the outputs of the project are aligned with their needs and will provide input to different standardisation documents being developed e.g. ISO/NP 81060-5, IEC 80601-2-33 and ISO/NP 81060-4 TS. In addition, to facilitate the take up of the measurement capacity developed in the project by other stakeholders e.g. metrological committees, medical experts, professional medical societies, and device manufacturers.

The proposed research shall be justified by clear reference to the measurement needs within strategic documents published by the relevant Regulatory body or Standards Developing Organisation or by a letter signed by the convenor of the respective TC/WG. EURAMET encourages proposals that include representatives from industry, regulators and standardisation bodies actively participating in the projects. The proposal must name a “Chief Stakeholder”, not a member of the consortium, but a representative of the user community that will benefit from the proposed work. The “Chief Stakeholder” should write a letter of support explaining how their organisation will make use of the outcomes from the research, be consulted regularly by the consortium during the project to ensure that the planned outcomes are still relevant, and be prepared to report to EURAMET on the benefits they have gained from the project.

Proposers should establish the current state of the art, and explain how their proposed research goes beyond this.

EURAMET expects the average EU Contribution for the selected JRPs in this TP to be 0.6 M€, and has defined an upper limit of 0.8 M€ for this project.

EURAMET also expects the EU Contribution to the external funded partners to not exceed 30 % of the total EU Contribution across all selected projects in this TP.

Any industrial partners that will receive significant benefit from the results of the proposed project are expected to be unfunded partners.

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,
- Feed into the development of urgent documentary standards through appropriate standards bodies,
- Transfer knowledge to the health sector.

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.